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Editors: I.V. Kolesnikova, A.V. Kuznetsova *Technical editor:* S.V. Gavrilova

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Dear readers!

A quarter of a century ago, in 1993, the first issue of "Traumatology and Orthopaedics of Russia" journal came out. Its appearance owes to the information gap in our specialty after the Soviet Union collapsed. The only dedicated journal in the USSR was published in Kharkov and after 1991 became a foreign edition. Thus, the "Traumatology and Orthopaedics of Russia" was intended to be a platform for the Russian researchers and practicing surgeons to share scientific accomplishments, hands-on experience, publish information on past and forthcoming forums. However, over time the journal extended the geography of publications by including papers from near and far countries outside the former Soviet Union.

The first editorial board was composed of directors of research and scientific institutes for trauma and orthopaedics, heads of specialized departments and leading specialists. Prof. N.V. Kornilov, director of the Vreden Russian Research Institute of Traumatology and Orthopedics (RNIITO), became the chief editor. The journal has immediately became popular among trauma and orthopaedic surgeons and truly the national edition where authors from all over the country published their articles. In 2001 the journal was enlisted into the register of editions recommended by the Russian State Commission for Academic Degrees and Titles for publishing of dissertation materials. However, there were hard times with lack of funding for composing and printing the journal, so some issues at the end of 1990s and in early 2000s were not released.

A new era of the journal started in 2004 after the decision was made not only to recover a due frequency of issues, but to enhance the quality of publications. We developed quality criteria for scientific papers which correspond to international requirements and to the principles of evidence based medicine. The editorial board was reinforced by internationally acknowledged specialists from the leading world clinics. Primary consideration was given to the selection of reviewers whose expertise, professionalism and efforts provided for boosting the journal's rating.

As of 2007 the journal is available at the national scientific electronic library eLIBRARY and included into the Russian Science Citation Index (RSCI) where it is the leader among editions in "traumatology and orthopaedics" specialty. During past 5 years our journal is among the 15% of the best country medical journals. Biennial impact factor of the journal in RSCI for 2017 was 1.026 including citations from all sources. Five-year impact factor keeps steadily growing and increased more than fivefold, from 0.164 to 0.826, as compared to 2008.

Constant efforts dedicated to improvement of the journal resulted in including of "Traumatology and Orthopaedics of Russia" into the Web of Science platform. This became possible through the work of a large team of reviewers and members of the editorial board each of whom contributed their share of efforts and pursuit to perfect the journal. And certainly the board is grateful to all authors who submit the outcomes of their research to the editorial office and do the meticulous work together with editors for improvement of the manuscripts.

The electronic version of the journal contains all articles fully translated into the English language.

Quarter of a century is both a big and a small period of time for the scientific edition. Nevertheless, we set the task to enter the European and world elite of orthopaedic publications, to gradually achieve the frequency of 6 issues per year, to enter all world databases to make the works of the Russian researchers available to our colleagues in all countries. In working on this task we hope for and rely on further support and contribution of the leading national specialists in trauma and othopaedic surgery to our journal.

Yours respectfully,
Editor-in-Chief of the Journal "Traumatology and Orthopedics of Russia"
professor Rashid Tikhilov

Photo courtesy of the magazine «Opinion Leader»

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Analysis of Publications of the Russian Trauma and Orthopaedic Surgeons in Foreign Top-Rated Journals

A.P. Sereda, M.A. Andrianova

Federal Medical Biological Agency, Moscow, Russian Federation

Abstract

The present paper is dedicated to the publications analysis by Russian authors in top-rated foreign journals. The aim of the research to define the avant-garde status of the national trauma and orthopaedics science. The authors of the present paper analyzed the publications in the first thirty journals under the heading «Orthopaedics and sports medicine» from Scimago Journal & Country Rank rating. The search was conducted from the moment of the first issue of each journal. Total number of publications was calculated, total number of publications from each author, number of publications per institution, citations of each publication in PubMed Central и Google Scholar. The subject, chronologic characteristics and relation of the year of publication with number of citations were analyzed.

Keywords: orthopaedics, traumatology, scientific papers.

Competing interests: the authors declare that they have no competing interests.

Funding: the authors have no support or funding to report.

Background

The third issue of the journal "Traumatology and Orthopedics of Russia" for 2018 contains article by I.V. Reshetov et al, "Scientific specialty "Traumatology and Orthopedics " in 2017: the analysis of the dissertations" [1]. In the same issue, the editors kindly published our comment, in which we criticized the authors for the fact that the defended dissertations were not exactly identical to the actual trends of the national trauma and orthopedic science due to a number of reasons. [2]. Since then, we have felt remorse for having been critical without offering anything in return. Indeed, there is nothing better than to do the work about which it was said. In this regard, we decided to carry out this work.

The objective — to clarify the status of the pioneering work in domestic orthopedics and traumatology by analyzing the number and topics of articles of domesticsorthopaedic surgeons, as well as their institutions, in the top-rated foreign scientific periodicals, based on the number of citations.

Materials and Methods

Our search for articles in foreign journals involved two steps. First, we identified a list of top-rated journals, and then we located articles of compatriots.

To determine the list of top-rated journals, we used the Scimago Journal & Country Rank*, in which the journals are ranked not just by impact factor, which is debatable, but by SJR index (Scimago journal rank).

* https://www.scimagojr.com/journalrank.php?category=2732

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Andrey P. Sereda; e-mail: drsereda@gmail.com

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The SJR index is a ranking which also considers the journal's prestige and influence, and it is measured as the average number of notable citations per year of those works published in the ranked journal over the past three years. Thus, the SJR index is always less than the common impact factor and does not allow those journals that published highly cited works a decades ago to be ranked high.

Scimago Journal & Country Rank indexes all scientific journals in all scientific fields. Orthopedic journals are included in the "Orthopedics and Sports Medicine" heading. There are a total of 266 journals in this category but only the 30 with the highest SJR index were analyzed (Table 1).

Table 1

Thirty journals with the highest SJR values in 2017 that were included in the study

Rank	Title of Journal	SJR Index	Country	Publisher
1	American Journal of Sports Medicine	3,949	USA	SAGE Publications
2	Sports Medicine	3,367	UK	Adis International Ltd.
3	British Journal of Sports Medicine	3,232	UK	BMJ Publishing Group
4	Journal of Bone and Mineral Research	2,808	USA	Wiley-Blackwell
5	Journal of Bone and Joint Surgery — Series A	2,722	USA	LWW Ltd.
6	Osteoarthritis and Cartilage	2,497	UK	W. B. Saunders Co., Ltd.
7	Journal of Arthroplasty	2,373	USA	Churchill Livingstone
8	Journal of Shoulder and Elbow Surgery	2,327	USA	Mosby Inc.
9	Skeletal Muscle	2,32	UK	BioMed Central
10	Medicine and Science in Sports and Exercise	2,073	USA	LWW Ltd.
11	Bone and Joint Journal	2,043	UK	British Editorial Society of Bone and Joint Surgery
12	Exercise and Sport Sciences Reviews	1,943	USA	LWW Ltd.
13	Clinical Orthopaedics and Related Research	1,908	USA	Springer New York LLC
14	Acta Orthopaedica	1,87	UK	Taylor & Francis
15	Knee Surgery, Sports Traumatology, Arthroscopy	1,845	Germany	Springer Verlag
16	International Journal of Sports Physiology and Performance	1,749	USA	Human Kinetics Publishers Inc.
17	Spine	1,736	USA	LWW Ltd.
18	Journal of Science and Medicine in Sport	1,714	Netherlands	Elsevier BV
19	Foot and Ankle International	1,626	USA	SAGE Publications Inc.
20	Scandinavian Journal of Medicine and Science in Sports	1,541	UK	Blackwell Publishing Inc.
21	European Spine Journal	1,535	Germany	Springer Verlag
22	International Orthopaedics	1,502	Germany	Springer Verlag
23	Arthroscopy — Journal of Arthroscopic and Related Surgery	1,459	UK	W. B. Saunders Co., Ltd.
24	Journal of Orthopaedic Trauma	1,451	USA	LWW Ltd.
25	Journal of Athletic Training	1,442	USA	National Athletic Trainers Association, Inc.
26	Journal of Cachexia, Sarcopenia and Muscle	1,432	USA	Wiley-Blackwell

End of Table 1

Rank	Title of Journal	SJR Index	Country	Publisher
27	Journal of Clinical Densitometry	1,423	USA	Elsevier Inc.
28	The Journal of the American Academy of Orthopaedic Surgeons	1,41	USA	Lippincott Williams & Wilkins Ltd.
29	Journal of Strength and Conditioning Research	1,366	USA	National Strength and Conditioning Association
30	Orthopedic Clinics of North America	1,294	UK	W. B. Saunders Co., Ltd.

To find articles of compatriots in the selected 30 top-rated journals, we used the PubMed database, generating for each journal a separate search query of the following type: (Russia [Affiliation]) AND "Journal Name" [Journal].

Thus, in the search within a particular journal, we included only those articles whose authors were listed in column "Russia". The search results were checked manually, because the information about the authors sometimes mentioned them mistakenly as authors from "Russia", despite the fact that the authors were not our compatriots. For example, the search query (Russia [Affiliation]) AND "The American journal of sports medicine" [Journal] identified an article of Kim SH et al. [3], wherein the place of work of one of the co-authors (Jung M) was indicated as follows: «Russia Science Seoul Center» in the Seoul ElectrotechnologyResearch Institute. Of course, we did not take such works into account.

In addition, we did not take into account those articles in which the author indicated two institutions as his place of work, the first of which was a foreign one. For example, when requesting ((Russia [Affiliation])) AND "Sports Med" [Journal], the work of Wilhelm EN, Mourot L and Rakobowchuk M [4] was identified. As the place of work of the second author (Mourot L), two institutions were indicated: the University of Bourgogne and Tomsk Polytechnic University. We did not take into account such works either.

To include in our analysis the scientific heritage of the USSR, in addition to the search options (Russia [Affiliation]), we generated queries of the type: (Soviet [Affiliation]) AND "Journal Title" [Journal] and (USSR [Affiliation]) AND "Journal Title" [Journal].

In cases where the title of the journal has changed, we conducted a separate search for the old name of the journal. For example, the British edition of The Journal of Bone & Joint Surgery in 2013 was renamed The Bone & Joint Journal (the eleventh place in the SJR rating). In such cases, search results are considered to be only for the successor journal (in this particular case, they were counted as publications in The Bone & Joint Journal).

The analysis was conducted as of October 17, 2018. Thus, it is likely that those works that, although they were published at this time (in the September and October issues) but were not yet indexed by PubMed, could not be taken into account.

Results

It turned out that the works of our compatriots were published in 13 of 30 top-rated journals. In total, we found 79 articles (Table 2). Of those, 19 explored exclusively sports medicine (the functional status of athletes, issues of the training process, etc.) and were not related to traumatology and orthopedics at al. The remaining 60 articles were published in 8 journals:

- Journal of Bone and Joint Surgery. Series A — 1 article [5];
- Journal of Bone and Joint Surgery. Series B (Bone and Joint Journal) — 1 [6];
- Clinical Orthopaedics and Related Research — 19 [7, 8, 9, 10, 11, 12, 13, 14, 15,

16, 17, 18, 19, 20, 21, 22, 23, 24, 25];

• Knee Surgery, Sports Traumatology, Arthroscopy — 1 [26];

• Spine — 7 работ [27, 28, 29, 30, 31, 32, 33];

• European Spine Journal — 4 [34, 35, 36, 37];

• International Orthopaedics — 24 [38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61];

• Foot and Ankle International — 3 [62, 63, 64].

Table 2

The number of articles of domestic authors in selected journals

Rank	Title of Journal	Year*	Number of Articles				Total
			Search options				
			Russia	Russian	Soviet	USSR	
1	American Journal of Sports Medicine	1976	0	0	0	0	0
2	Sports Medicine	1984	0	0	0	0	0
3	British Journal of Sports Medicine	1969	4	1	0	0	5
4	Journal of Bone and Mineral Research	1986	2	1**	0	0	2
5	Journal of Bone and Joint Surgery — Series A	1948	1	0	0	0	1
6	Osteoarthritis and Cartilage	1993	0	0	–	–	0
7	Journal of Arthroplasty	1986	0	0	0	0	0
8	Journal of Shoulder and Elbow Surgery	1992	0	0	–	–	0
9	Skeletal Muscle	2011	0	0	–	–	0
10	Medicine and Science in Sports and Exercise	1980	0	0	0	0	0
11	Bone and Joint Journal	1948	1	1**	0	0	1
12	Exercise and Sport Sciences Reviews	1973	0	0	0	0	0
13	Clinical Orthopaedics and Related Research	1963	8	1**	0	11	19
14	Acta Orthopaedica	2005	0	0	–	–	0
15	Knee Surgery, Sports Traumatology, Arthroscopy	1993	1	1**	–	–	1
16	International Journal of Sports Physiology and Performance	2006	1	0	–	–	1
17	Spine	1976	5	2**	0	1	7
18	Journal of Science and Medicine in Sport	1998	1	0	–	–	1
19	Foot and Ankle International	1994	2	3**	–	–	3
20	Scandinavian Journal of Medicine and Science in Sports	1991	3	1**	0	0	3
21	European Spine Journal	1992	3	2**	–	–	4
22	International Orthopaedics	1977	10	20**	0	1	24
23	Arthroscopy — Journal of Arthroscopic and Related Surgery	1985	0	0	0	0	0
24	Journal of Orthopaedic Trauma	1987	0	0	0	0	0
25	Journal of Athletic Training	1992	0	0	–	–	0
26	Journal of Cachexia, Sarcopenia and Muscle	2010	0	0	–	–	0
27	Journal of Clinical Densitometry	1998	0	0	–	–	0
28	The Journal of the American Academy of Orthopaedic Surgeons	1993	0	0	–	–	0
29	Journal of Strength and Conditioning Research	1993	7	1**	–	–	7
30	Orthopedic Clinics of North America	1970	0	0	0	0	0
Total			49	34	0	13	79

* — the year in which the issues of the journal began according to the NLM Catalog; ** — an article or some articles are categorized by two Affiliation keys, so the total number of articles is less.

Further analysis was carried out exclusively among these 60 works. The primary themes of publications were works on the use of external fixators (20 articles), vertebrology and spinal surgery (14 articles), pediatric orthopaedics including vertebrology (10 articles), and reconstruction of bone defects (9 articles) (Fig. 1).

These 60 works of a traumatologic-orthopedic profile were written by 158 authors. Of these, 136 (86.0%) authored only one work, 16 (10.1%) authors have two publications in their portfolio, 3 (1.9%) authors — three publications, 2 (1.3 %) authors — four works, and one author (0.6%) – five works (Table 3).

When analyzing the distribution of the number of articles by year, it turned out that there are four "waves". The first "wave" of 13 articles, including two papers of Ilizarov G.A. [11, 12], began in 1989 and ended in 1991. Undoubtedly, that surge was generated by studies of Soviet period. In 1992 and 1993, not a single article was published. The second "wave" (11 works) came in 1994–1999. Probably, these publications can be also regarded as a continuation or development of research initiated in the USSR, or as their results. From 2000 to 2005, there was a second lull without a single publication. In the third "wave" from 2006 to 2009, there was one publication a year (a total of 4 papers). These are of Sokolovsky VA, Voloshin VP et al. [56], Gorodetsky IG, Gorodnichenko AI et al. [6], Shevtsov VI et al. [55], Gubin AV et al. [29]. We would characterize this as a period of scientific enthusiasm. From 2010 to 2011, there was again a pause. In 2012, the fourth "wave" began which already includes 32 works, nine of which are dated 2018. At the same time, we hope that the year 2018 that has not ended will please us with an even greater number of works (the analysis was carried out as of October 17, 2018). According to the number of works, this fourth period became the most productive — 53.3% of all publications (Fig. 2).

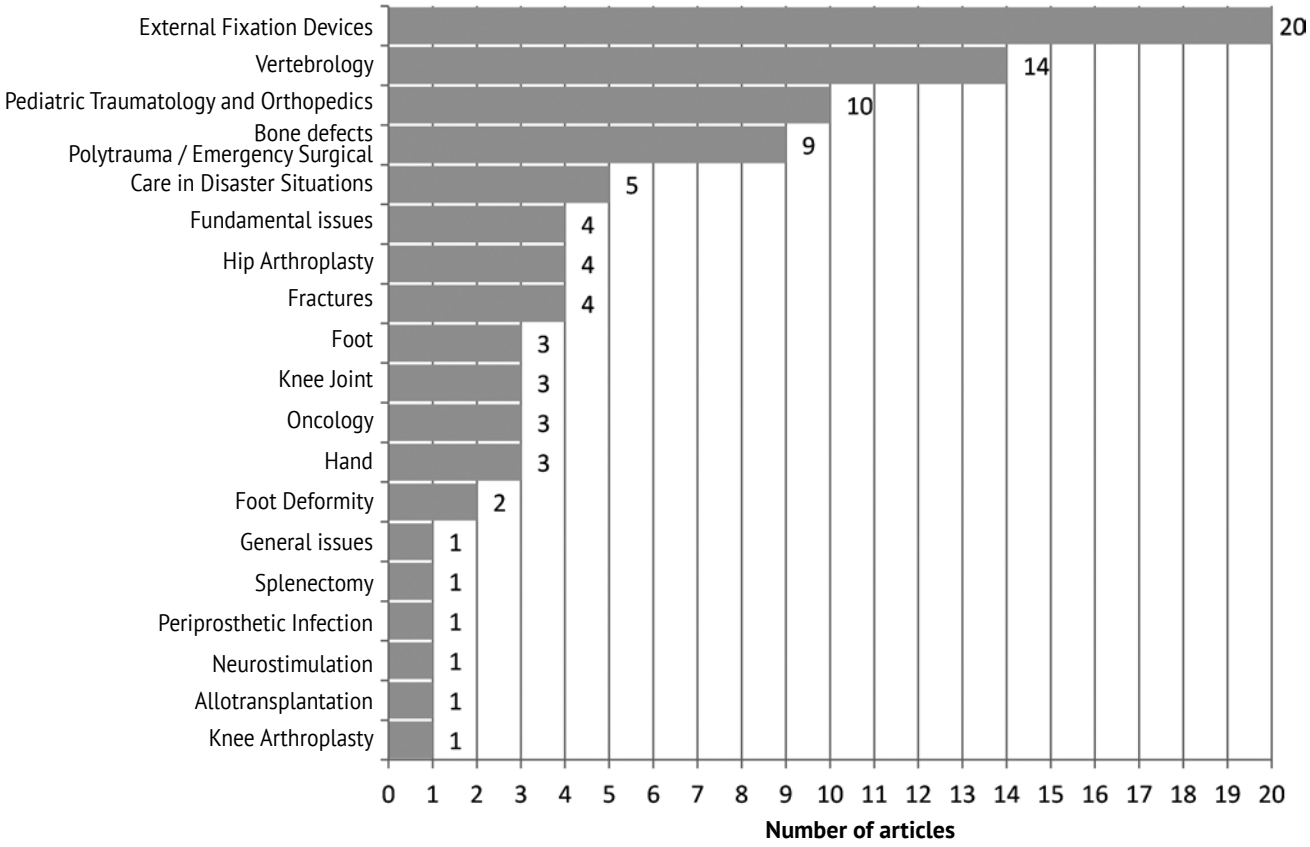


Fig. 1. Distribution of articles by subject (one article could have two or more subjects)

Table 3

Authors with two or more published articles (in descending order of the number of works and alphabetically)

Author	Author's professional institute	City	Articles
Dmitry Yu. Borzunov	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	38, 39, 40, 41, 43
Alexander V. Gubin	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	29, 34, 36, 43
Dmitry A. Popkov	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	50, 51, 52, 62
Gabriel A. Ilizarov	Kurgan All-Union Center for Restorative Traumatology and Orthopaedics	Kurgan	10, 12
	Author indicated "member of the Academy of Sciences" as his professional institute	–	11
Arnold V. Popkov	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	50, 51, 52
Oksana G. Prudnikova	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	34, 53, 54
Anna M. Aranovich	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	50, 51
Irina S. Istomina	N.N.Priorov National Medical Research Center of Traumatology and Orthopaedics	Moscow	5, 17
Razmik A. Keshishyan	Emergency Children's Surgery and Traumatology Research Institute	Moscow	13, 20
Nikolay M. Klyushin	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	45, 64
Marina M. Lipina	I.M.Sechenov First Moscow State Medical University	Moscow	47
	V.A.Nasonova Research Institute of Rheumatology	Moscow	46
Maksim A. Makarov	V.A.Nasonova Research Institute of Rheumatology	Moscow	46, 47
Tatiana A. Malkova	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	43, 45
Alexander Yu. Mushkin	St.Petersburg Research Institute of Phthisiopulmonology	St. Petersburg	37, 49
Oganes V. Oganesyan	N.N.Priorov National Medical Research Center of Traumatology and Orthopaedics	Moscow	5, 17
Vladimir M. Rozinov	Emergency Children's Surgery and Traumatology Research Institute	Moscow	13, 20
Leonid N. Solomin	R.R.Vreden Russian Research Institute of Traumatology and Orthopedics	St. Petersburg	57, 63
Rashid M. Tikhilov	R.R.Vreden Russian Research Institute of Traumatology and Orthopedics	St. Petersburg	59, 60
Eduard V. Ul'rikh	St. Petersburg State Pediatric Medical University	St. Petersburg	29, 36
Alexander Yu. Chevardin	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	38, 39
Igor I. Shubnyakov	R.R.Vreden Russian Research Institute of Traumatology and Orthopedics	St. Petersburg	59, 60
Elena N. Schurova	Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics	Kurgan	53, 54

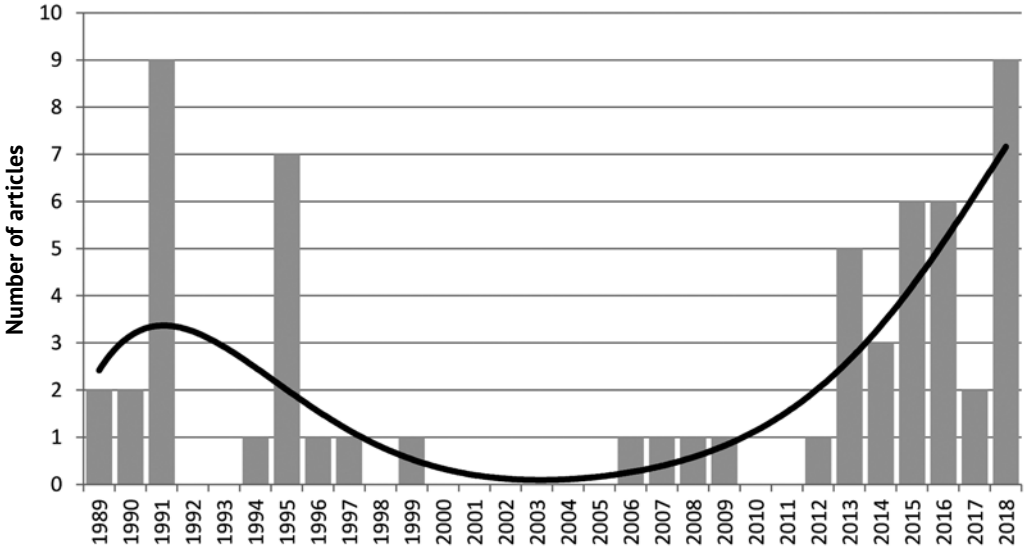


Fig. 2. The distribution of the number of articles by year with a polynomial trend line (sixth degree)

To some extent, perhaps, the increase in the number of publications was also influenced by the introduced system of scientometric results, when colleagues were simply required to have publications. It is gratifying that our colleagues do not follow the path of publications in less rated journals, but set a really high level, sending work to top-rated journals. The fourth wave can be called the renaissance of Russian orthopedic science.

An important indicator of any scientific work is its citation. A total of 60 works of our compatriots have 499 citations in PubMed Central and 6.613 citations in Google Scholar.

In PubMed Central, 30 (50%) of 60 articles were cited, and 30 papers were never cited (Table 4). Some of the uncited articles were published in the fourth "wave", in particular, in 2018. However, many papers published in 1990–2009 still do not have a single citation in PubMed Central.

On the other hand, many articles from the fourth "wave", on the contrary, have a good start of citing which means a real interest to our work on the international scene. Obviously, the proportion of citing recent articles is small and significantly lags behind the works by Ilizarov GA, but their publication has not been published 30 years ago.

46 (76.7%) of 60 works were cited on Google Scholar. All papers that had at least one citation in PubMed Central had citations at Google Scholar. Those works that had at least one citation in PubMed Central had 6499 citations in Google Scholar. Thus, there were 16 works that were not cited in PubMed Central, but had citations in Google Scholar (114 citations).

To date, three works by Ilizarov GA [10, 11, 12] provide 82.2% of all citations of compatriots' articles. When plotting the correlation of the year of publication and number of citations in PubMedCentral, the prevalence of citations of works by Ilizarov GA significantly distorts the mathematical picture (Figure 3).

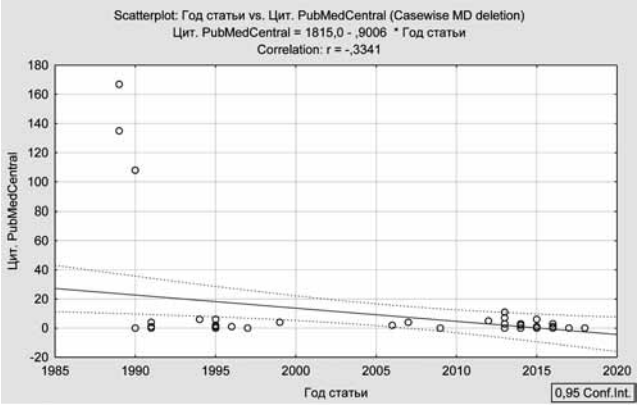
For clarity of analysis, we have excluded, however blasphemous it may sound, the three works by Ilizarov GA [10, 11, 12].

It turned out that the fourth "wave" of publications, which began in 2013, is characterized by respectable citation indicators. These indicators are already better than those of the first, second and third "waves". So far, the advantages of the fourth "wave" citation index over the previous ones (Pearson's 0.4513 coefficient, positive) are unreliable (p = 0.739, Fig. 4). However, so little time has passed that we can confidently hope that the works of our colleagues will continue to find considerable citation numbers.

Table 4

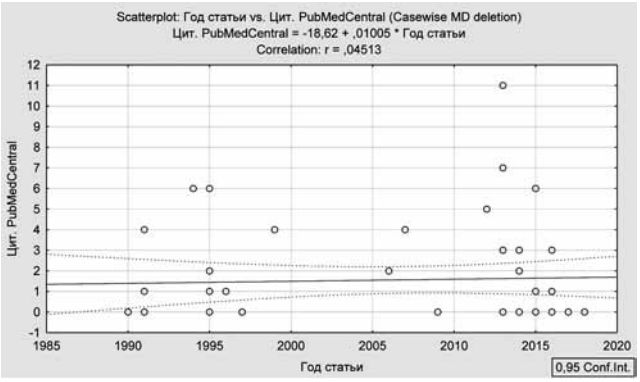
Scientific publications with one or more citations in PubMedCentral in descending order of the number of citations

Authors (including foreign co-authorship)	Year	Number in the List of References	Number of Citations	
			Pubmed Central	Google Scholar
Ilizarov G.A.	1989	[12]	167	2525
Ilizarov G.A.	1989	[11]	135	1965
Ilizarov G.A.	1990	[10]	108	1289
Ryzhkov I.I., Borzilov E.E., Churnosov M.I., Ataman A.V., Dedkov A.A., Polonikov A.V.	2013	[31]	11	31
Ezhevskaya A.A., Mlyavykh S.G., Anderson D.G.	2013	[28]	7	50
Gubin A.V., Borzunov D.Y., Malkova T.A.	2013	[43]	7	47
Keshishyan R.A., Rozinov V.M., Malakhov O.A., Kuznetsov L.E., Strunin E.G., Chogovadze G.A., Tsukanov V.E.	1995	[13]	6	61
Zatsepin S.T., Burdygin V.N.	1994	[24]	6	45
Popkov A., Aranovich A., Popkov D.	2015	[51]	6	21
Borzunov D.Y.	2012	[41]	5	36
Gerasimov A.M., Toporova S.M., Furtseva L.N., Berezhnoy A.P., Vilensky E.V., Alekseeva R.I.	1991	[9]	4	39
Mushkin A.Y., Kovalenko K.N.	1999	[49]	4	37
Gorodetskyi I.G., Gorodnichenko A.I., Tursin P.S., Reshetnyak V.K., Uskov O.N.	2007	[6]	4	34
Shevtsov V.I., Danilkin M.Y.	2008	[55]	4	31
Novikov K.I., Subramanyam K.N., Muradisinov S.O., Novikova O.S., Kolesnikova E.S.	2014	[16]	3	24
Borzunov D.Y., Chevardin A.V.	2013	[38]	3	15
Borzunov D.Y., Chevardin A.Y., Mitrofanov A.I.	2016	[39]	3	10
Toroptsova N.V., Benevolenskaya L.I., Karyakin A.N., Sergeev I.L., Erdesz S.	1995	[32]	2	101
Solomin L.N., Paley D., Shchepkina E.A., Vilensky V.A., Skomoroshko P.V.	2014	[57]	2	19
Sokolovski V.A., Voloshin V.P., Aliev M.D., Zubikov V.S., Saravanan S.A., Martynenko D.V., Nisichenko D.V., Strelnikov K.N.	2006	[56]	2	17
Oganesyan O.V., Istomina I.S., Kuzmin V.I.	1996	[5]	1	46
Bakhtadze M.A., Vernon H., Zakharova O.B., Kuzminov K.O., Bolotov D.A.	2015	[27]	1	14
Azolov V.V., Aleinikov A., Keilmann V.K., Kaiumov Y.	1995	[7]	1	9
Gudushauri O.H., Tvaliashvili L.A.	1991	[44]	1	7
Tikhilov R., Shubnyakov I., Burns S., Shabrov N., Kuzin A., Mazurenko A., Denisov A.	2016	[60]	1	3
Tikhilov R., Bozhkova S., Denisov A., Labutin D., Shubnyakov I., Razorenov V., Artyukh V., Klitsenko O.	2016	[59]	1	10
Barbier D., Neretin A., Journeau P., Popkov D.	2015	[62]	1	6
Popkov A., Aranovich A., Popkov D.	2015	[50]	1	4
Prudnikova O.G., Shchurova E.N.	2016	[53]	1	2
Popkov D., Popkov. A.	2016	[52]	1	1
Total			499	6499



Year of publication

Fig. 3. Correlation of the number of citations and year of publication



Year of publication

Fig. 4. Correlation of the number of citations and year of publication omitting the three articles of G.A. Ilizarov [10–12]

Conclusion

The Scimago Journal & Country Rank that we used, on the one hand, allowed us to select truly modern top-rated journals, but, on the other hand, the rating included mostly "young" journals, which startedkin 1980-90. This probably excluded the possible publications of compatriots, if they were made in the foreign periodicals before 1989 in those journals that were popular at that time.

Another factor that we cannot control is a common rubric for journals, combining the themes of "orthopedics" and "sports medicine". Sports medicine journals often publish purely orthopedic articles. Abroad, the boundaries between these two specialties are not so obvious. However, the filter applied by us excluded a number of orthopedic journals (Knee — 31st place in the ranking, Injury — 53rd place, Foot and Ankle Surgery — 101st place, etc.).

As expected, the proportion of publications from our country in the foreign periodicals is very small, although we did not carry out a specific analysis of this issue. There are a number of reasons for this, ranging from difficulties with the English language to some shortcomings of the design of research.

We found out that there were four "waves" of publications. Moreover, the current fourth "wave" is very productive both in terms of the number of publications and their citation frequency. Our papers are really interesting! On the other hand, the number of publications is still small, and we want this situation to be improved not only due to the introduction of scientometric reporting indicators, but also to scientific enthusiasm.

The leaders among the institutions were: Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics, R.R. Vreden Russian Research Institute of Traumatology and Orthopedics, N.N. Priorov National Medical Research Center of Traumatology and Orthopaedics, Emergency Children's Surgery and Traumatology Research Institute. The fourth wave of publications presents works from only the first two institutions.

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INFORMATION ABOUT AUTHORS:

Andrey P. Sereda — Dr. Sci. (Med.), deputy head of Federal Medical and Biological Agency, Moscow, Russian Federation

Marina A. Andrianova — Cand. Sci. (Eng.), consultant, Department of Health and Industrial Medicine, Federal Medical and Biological Agency, Moscow, Russian Federation

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Adverse Trends in the Etiology of Orthopedic Infection: Results of 6-Year Monitoring of the Structure and Resistance of Leading Pathogens

S.A. Bozhkova [1], A.R. Kasimova [1, 2], R.M. Tikhilov [1,3], E.M. Polyakova [1], A.N. Rukina [1], V.V. Shabanova [1], V.N. Liventsov [1]

[1] *Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation*

[2] *Pavlov First Saint Petersburg State Medical University, St. Petersburg, Russian Federation*

[3] *Mechnikov North-Western State Medical University, St. Petersburg, Russian Federation*

Abstract

Osteomyelitis remains one of the most intractable diseases. The nature of the pathogen and its resistance to antibiotics significantly affect the outcome and cost of treatment. ***The aim of the study:*** to analyze the dynamics of the spectrum and antibiotic resistance of the leading pathogens of orthopedic infection for the period 2012–2017. ***Material and Methods.*** The structure of pathogens isolated from the focus of infection from 2774 patients with periprosthetic infection and chronic osteomyelitis was retrospectively analyzed. Antibiotic resistance of the leading pathogens that occupied more than 4% in the species structure was studied. Comparative analysis of changes in the spectrum of pathogens and antibiotic resistance was carried out for the periods 2012-2013, 2014–2015 and 2016-2017. Epidemiological analysis was performed in the program „microbiological monitoring system" Microbe-2. Statistical processing of the obtained data was carried out using the Z-criterion. ***Results.*** From 2774 patients with orthopedic infection have been isolated 4359 strains, in the structure of which about 73.5% were occupied by *S. aureus, S. epidermidis, E. faecalis, E. faecium, P. aeruginosa, Acinetobacter sp.* representatives of the family Enterobacteriacea. In 27% of the cases, microorganisms of other species were identified. Microbial associations were identified in 19.4% of cases. In the structure of the leading gram-positive (Gram (+)) pathogens, a significant decrease in the incidence of *S. aureus* was detected, while the share of *S. epidermidis* increased significantly. Among the leading gram-negative (Gram (-)) microorganisms, a significant increase in the proportion of representatives of the fam. Enterobacteriacea was found, against the background of a decrease in the share *of Acinetobacter* sp. and *P. aeruginosa*. The level of resistance of MSSA to the studied antibiotics ranged from 0.1 to 8.8%, for MSSE the spread was from 1.9 to 16.7%. Negative dynamics of growth of resistance of non-fermenting bacteria is established. The strains of *Acinetobacter* sp. demonstrated greater resistance to tested antibiotics in comparison with *P. aeruginosa*. ***Conclusion.*** An increase in the role of *S. epidermidis* and *K. pneumoniae* in the etiology of orthopedic infection was established. The revealed increase in the resistance of microbial pathogens to most tested and used antibiotics should be taken into account in the appointment of empirical antibiotic therapy. The extremely high frequency of resistance of gram-negative bacteria to cephalosporins and fluoroquinolones excludes the possibility of their empirical use, which requires the management of carbapenems in the starting treatment regimens. High resistance to fluoroquinolones limits the ability of oral antibiotic therapy in patients with periprosthetic infection.

Keywords: periprosthetic infection, osteomyelitis, leading pathogens, antibiotic resistance.

Competing interests: the authors declare that they have no competing interests.

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Alina R. Kasimova; e-mail: arkasimova@rniito.ru

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Background

Despite the fact that the first description of bone infection was given in the era of Hippocrates, osteomyelitis still remains one of the most intractable diseases. The increasing medical and social significance of this pathology is largely determined by the increase in the number of orthopedic surgeries using implants due to expansion in the number of high-energy injuries associated with open fractures due to road accidents and military injuries [1–3]. Primary total hip and knee endoprosthetics (EP) are among the most common operations in orthopedic surgery. It is predicted that the demand for these interventions will increase significantly in the next two decades [4, 5]. One of the most devastating complications of endoprosthetics is a deep infection of the surgical area — a periprosthetic infection (PI), which is a special case of an implant-associated infection (IAI). The development of this complication significantly increases the period of hospitalization, leads to additional financial costs for treatment, in some cases ends with the chronicity of the infectious process and the development of osteomyelitis. Currently, researchers note that the infection accounts for 15% in the spectrum of causes of revision arthroplasty of large joints [6], and in the structure of early revisions of the hip joint, this measure reaches 64% [7]. While the incidence of periprosthetic infection after primary operations is less than 2%.

Staphylococcus aureus and coagulase-negative staphylococcus (CNS) in more than half of cases are the causes of IAI; gram-negative bacteria are responsible for 5–23% of cases of orthopedic infection, especially among the elderly [8–10]. The pathogenesis of infection caused by gram-negative (Gram (-)) and gram-positive (Gram (+)) pathogens is associated with the formation of biofilms on the components of the endoprosthesis that protect bacteria from antimicrobial agents and the host immune system [11]. It is known that the clinical outcomes of the prosthetic joint infections caused by Gram (-) bacteria are less favorable [12, 13, 14]. The isolation of antibiotic resistant strains of Gram (-) bacteria from patients with periprosthetic infection also cause serious concern. For example, acute PPI, caused by a pathogen resistant to fluoroquinolones, is associated with failure of rehabilitation and the need to remove the endoprosthesis [15].

Monitoring of infectious agents and their antibiotic sensitivity is one of the main tools that allow timely correction of empirical antibiotic therapy schemes, develop means of control of resistance and monitor their effectiveness.

The purpose of this study was to analyze the dynamics of the spectrum and antibiotic resistance of the leading causative agents of orthopedic implant-associated infection for the period 2012–2017.

Materials and Methods

A retrospective analysis of the etiological structure of IAI was performed in 2,774 patients due to periprosthetic infection (73.5%) and chronic postoperative and post-traumatic osteomyelitis (26.5%) from January 1, 2012 to December 31, 2017. As a result the spectrum of the leading causative agents of IAI was determined. Positive growth of microorganisms was obtained in 68.7% of cases.

The leading pathogens were microorganisms, whose share in the species structure was more than 4%. The antibioticograms of the strains of the leading causative agents of IAI isolated from tissue biopsies, aspirates and remote metal structures (endoprostheses, screws, plates, cement spacers, etc.) were analyzed. The strains with identical sensitivity to antibiotics, isolated from different biological materials from one patient were counted only once.

Identification of pathogens was carried out in accordance with standard manual laboratory techniques and also the automatic identification was performed by Microlatest panels (Erba Lachema) using the iEMS

Reader MF. Determination of antibiotic sensitivity was performed by disco-diffusion method using Mueller-Hinton agar (Oxoid, United Kingdom) and disks with antibiotics (Oxoid, United Kingdom), and also by the method of minimum inhibitory concentrations using E-tests (Oxoid, United Kingdom) and automatic analyzer VITEK 2 Compact (BioMerieux, France). Evaluation of sensitivity to antibiotics was performed in accordance with the criteria of EUCAST (2012-2017). A comparative analysis of changes in the spectrum of pathogens and antibiotic resistance was carried out for the periods of 2012–2013, 2014–2015 and 2016–2017. Epidemiological analysis of the results of the study was performed using the program "Microbiological monitoring system "Microbe-2" (©2002–2016 MedProject-3).

Statistical analysis

Statistical analysis of the data obtained was carried out with MS Office Excel 2007 (Microsoft, USA) and the Z-criterion of the standard normal distribution to estimate the difference between the portions.

Results

4359 strains were isolated from 2774 patients with orthopedic infection during the studied period. About 73.5% (n = 3205) of these strains consist of *S. aureus, S. epidermidis, E. faecalis, E. faecium, P. aeruginosa, Acinetobacter sp.* and different species of Enterobacteriacea (*K. pneumoniae, E. coli and E. cloacae*), which have been classified as the leading pathogens. In 27% of cases, microorganisms of other species were identified, whose percent was less than 4% and which were not included in the further analysis. Microbial associations (combination of 2 to 4 pathogens) were founded in 19.4% of cases of these diseases.

In the structure of the leading Gram (+) causative agents of IAI, a significant (p<0.01) decrease in the frequency of *S. aureus* isolation from 34.5% in 2012–2013 up to 28.6% in 2016–2017 was detected, including methicillin-resistant strains (MRSA) (p<0.05) (Fig. 1).

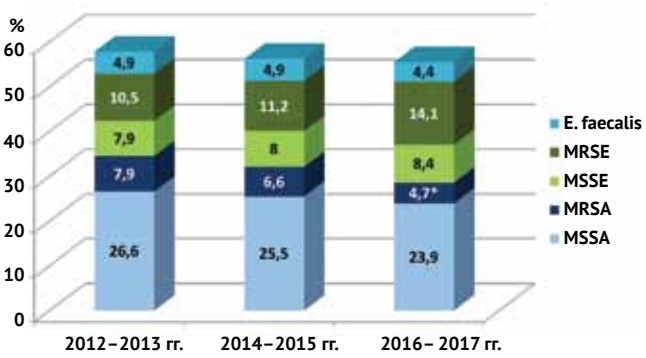


Fig. 1. Spectrum of the leading Gram(+) causative agents of IAI in the analyzed periods of time
* — p<0.05 compared with the period of 2012–2013

At the same time, the proportion of *S. epidermidis* increased significantly (p<0.01) from 18.4% to 22.5%, however, the increase in the frequency of methicillin-resistant isolates (MRSE) was insignificant. In the period 2016-2017 methicillin-resistant (MR) strains accounted for 16.4 and 62.7% of *S. aureus* and *S. epidermidis*, respectively. Significant changes in the dynamics of the percent of enterococci were not founded; this measure was 4.9–4.4% for *E. faecalis* during the entire observation period.

The analysis of the structure of leading Gram (-) pathogens revealed a significant (p<0.05) percent increase of enterobacterial strains from 6.6% in 2012–2013 to 8.7% in 2016–2017, at the same time the significant percent decrease of *Acinetobacter sp.* strains and the trend to reduce of *P. aeruginosa* percentage (Fig. 2).

The species analysis revealed a statistically significant increase (p<0.01) in the proportion of K. pneumoniae from 46.9 to 63.8% and a decrease in the proportion of *E. cloacae* from 36.7 to 12.6% in the spectrum of the leading representatives of fam. Enterobacteriaceae (Table 1).

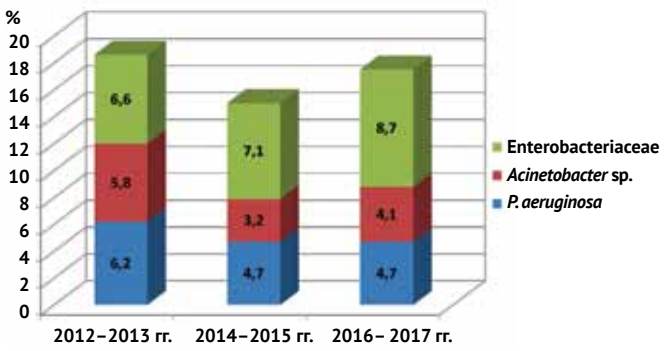


Fig. 2. Spectrum of the leading Gram(-) causative agents of bacteria IAI in the analyzed periods of time
* — p <0.05 compared with the period of 2012–2013
** — p <0.01 in comparison with the period of 2012–2013

A comparative analysis of antibiotico-grams of staphylococcal isolates that are sensitive and resistant to methicillin showed that the latter, regardless of species, are characterized by high cross-resistance to most of the tested antibiotics (Table 2). The level of resistance of the MSSA strains to the antibiotics under study was generally low and ranged from 0.1 to 8.8%; for MSSE isolates, the spread of this indicator ranged from 1.9 to 16.7%. Regardless of sensitivity to methicillin the isolates resistant to gentamicin, fluoroquinolones, co-trimoxazole, erythromycin, clindamycin, and fusidic acid were significantly more common (p<0.05) among *S. epidermidis* compared with *S. aureus*. In addition, MSSE isolates showed resistance to rifampicin and tetracycline significantly (p<0.05) more often, than MSSA.

Vancomycin- and linezolid-resistant staphylococci strains were not detected during the observation period. In addition to these antibiotics, the most active antibiotics for MR strains were fusidic acid and fosfomycin.

Analysis of the dynamics of the resistance level of staphylococcal strains showed that the frequency of MRSA isolation significantly decreased from 22.9 to 16.5% (p<0.05) over the observation period, while for MRSE a trend to increase this indicator from 56.6 up to 63.3% (p>0.05) was detected. Generally, the resistance level of MRSA changed statistically insignificantly, however, the increase of rifampicin resistance from 29.8% to 39% is noteworthy. With respect to all tested antibiotics, the resistance of MSSA strains did not exceed 4% (Table 3), with the exception of tetracycline and erythromycin, for which this indicator ranged from 7.2 to 10.4% and 6.7–7.8%, respectively.

From 2012-2013 to the end of the observation period, the resistance of MSSE to gentamycin decreased significantly (18.3% to 10%) (Table 4) (p<0.05). A similar, but not so significant trend was identified for the MRSE: from 83.8 to 72.1 (p>0.05). The resistance of MSSE to moxifloxacin (from 2.5 to 10%) and fosfomycin (from 3.8 to 15.2%) increased significantly (p<0.05), moreover activity of fosfomycin against MRSE isolates was significantly reduced (p<0.05).

Table 1

The dynamics of the share of leading pathogens from fam. Enterobacteriaceae

Species	2012–2013	2014–2015	2016–2017
Klebsiella pneumoniae	46 (46,9%)	46 (44,7%)	81 (63,8%)$^{1*, 2*}$
Escherichia coli	16 (16,4%)	24 (23,3%)	30 (23,6)%
Enterobacter cloacae	36 (36,7%)	33 (32,0%)	16 (12,6%)$^{1*, 2}$
Total	98 (100%)	103 (100%)	127 (100%)

1* — p<0,01 in comparison with the period of 2012–2013; 2 — p<0,05 in comparison with the period of 2014–2015; 2* — p<0,01 in comparison with the period of 2014–2015.

Table 2

Level of resistance of *S. aureus* and *S. epidermidis* depending on their sensitivity to methicillin

Antimicrobial agent	MSSA, n = 1102	MRSA, n = 283	MSSE, n = 341	MRSE, n = 507
Cefoxitin	0	100	0	100
Oxacilline	0	100	0	100
Gentamycine	2.5	74.1[s*]	15.7[a]	77 [s*]
Moxifloxacin	1.1	81.1[s*]	5.8[a]	44 [s*.a*]
Levofloxacin	1.6	80.0 [s*]	16.7[a]	59.3 [s*.a]
Ciprofloxacin	2.6	86.9 [s*]	10.3[a]	61.2 [s*.a*]
Co-trimoxazole	0.0	5.0 [s*]	14[a*]	39.1 [s*.a*]
Rifampicin	2.5	31.9 [s*]	4.2	19.2 [s*.a*]
Tetracycline	8.8	45.0 [s*]	12.5	35.7 [s*.a]
Erythromycin	6.4	50.0 [s*]	35[a*]	62.5 [s*.a*]
Clindamycin	2.0	48.9 [s*]	5.2[a*]	29.3 [s*.a*]
Fusidic acid	0.0	0.0	1.9[a]	15 [s.a*]
Fosfomicin	0.1	10.5 [s*]	11.5	11.6
Linezolid	0.0	0.0	0	0
Vancomycin	0.0	0.0	0	0

s — p <0.05 compared with methicillin-sensitive (MS) strains of this species; s* — p<0.01 compared with methicillin-sensitive (MS) strains of this species; a — p<0,05 compared with *S. aureus*; a* — p<0,01 compared with *S. aureus*.

Table 3

Dynamics of the resistance level of *S. aureus* depending on the sensitivity to methicillin, %

Antimicrobial agent	MSSA			MRSA		
	2012–2013, n = 390	2014–2015, n = 374	2016–2017, n = 338	2012–2013, n = 116	2014–2015, n = 100	2016–2017, n = 67
Gentamycine	1.5	3.2	3	77.6	75.8	65.7
Co-trimoxazole	0	0	0	5.4	6.1	3
Tetracycline	7.2	9.1	10.4	45.1	41	50.7
Erythromycin	6.7	4.8	7.8	48.2	49.5	53.7
Clindamycin	0.8	1.8	3.6	51.4	47.4	47
Ciprofloxacin	3.3	1.9	2.7	87.5	87.6	84.8
Moxifloxacin	1	0.8	1.5	77.7	85.6	80.3
Levofloxacin	NA	NA	1.6	NA	NA	79.1
Fosfomicin	0.3	0	0	8.3	13.4	9.4
Rifampicin	2.6	1.6	3.6	29.8	29.9	39
Fusidic acid	NA	NA	0	NA	NA	0

NA — no data available.

Table 4

Dynamics of the resistance level of (%) *S. epidermidis* depending on the sensitivity to methicillin

Antimicrobial agent	MSSE			MRSE		
	2012–2013, n = 114	2014–2015, n = 114	2016–2017, n = 113	2012–2013, n = 148	2014–2015, n = 164	2016–2017, n = 195
Gentamycine	18.3	18.3	10*	83.8	76.4	72.1
Co-trimoxazole	17.6	11	13	41.4	37	39.1
Tetracycline	18.2	8.9	9.9	38.8	34.6	34.2
Erythromycin	33.3	34	38	61.1	61.1	64.9
Clindamycin	4.6	3.9	7	29.7	24.4	33.2
Ciprofloxacin	10.9	6.9	13	60.7	57.7	64.6
Moxifloxacin	2.8	5	10*	38.5	47	45.6
Levofloxacin	NA	NA	16.7	NA	NA	60
Fosfomicin	3.8	17.8*	15.2*	5.7	15.5*	12.9*
Rifampicin	4.6	3.9	4	23.5	18.6	16.3
Fusidic acid	NA	NA	1.9	NA	NA	14.5

* — p<0,05 compared with the period 2012–2013; NA — no data available.

All the *E. faecalis* strains (n = 102) isolated during the observation period were sensitive to ampicillin, imipenem, linezolid, and tigecycline. In the period 2016–2017, only one vancomycin-resistant *E. faecalis* strain was isolated. Additional testing showed that the MIC of vancomycin for this strain was more than 256 μg/ml. There was a statistically insignificant increase in resistance to co-trimoxazole from 32.4% to 51.7% and a decrease in resistance to ciprofloxacin from 64.5% to 49.2%.

The most active antibiotic against representatives of non-fermenting bacteria was colistin. All isolates of *P. aeruginosa* and Acinetobacter sp., included in the study, were sensitive to this antibiotic. Negative growth dynamics of the resistance of *P. aeruginosa* strains to all tested antibiotics was detected with the exception of colistin (Fig. 3).

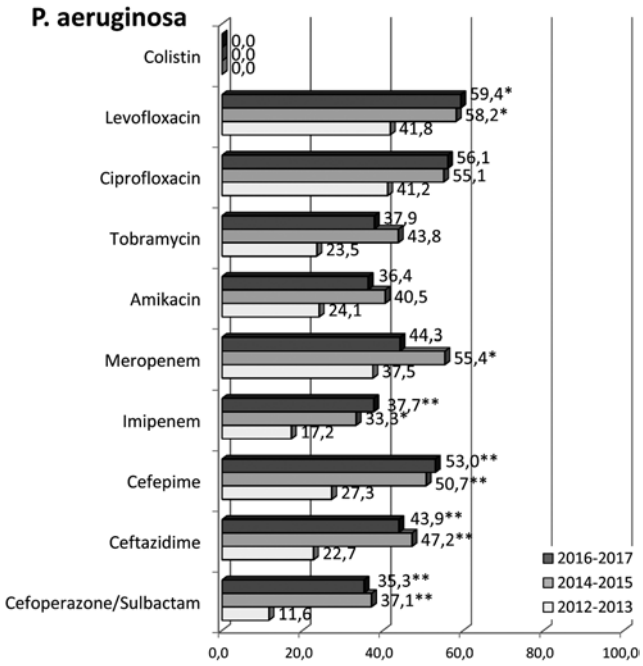
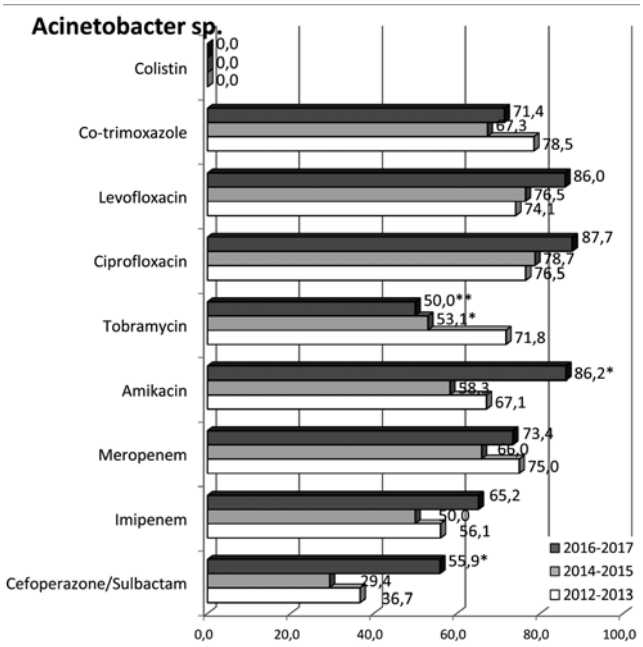


Fig. 3. The dynamics of the level of resistance *P. aeruginosa*
[1] — *p*<0,05 in comparison with the period 2012–2013
[1*] — *p*<0,01 in comparison with the period 2012–2013

An increase in the proportion of resistant isolates to cephalosporins of 3–4 generations, imipenem, meropenem, levofloxacin was statistically significant (p<0.05). By the end of the study, about 63–65% of *P. aureginosa* strains remained sensitive to cefoperazone/sulbactam, imipenem, amikacin and tobramycin, 56–57% to ceftazidime, meropenem, and only about 40–45% to fluoroquinolones and cefipime.

The most active antibiotic (after colistin) against strains of *Acinetobacter* sp. was cefoperazone/sulbactam. However, resistance to cefoperazone/sulbactam significantly increased (p<0.05) compared with 2012–2013 and 2014–2015, and amounted to 55.9%. A similar dynamics was detected for resistance to amikacin, which had reached 86.2% by the end of the study. In general, representatives o*f Acinetobacter sp.* showed greater resistance to tested antibiotics compared to *P. aeruginosa.* Cefoperazone/sulbactam and tobramycin were active against 45–50% isolates of *Acinetobacter sp.* Less than 30% of the strains were sensitive to co-trimoxazole, meropenem, less than 20% were sensitive to fluoroquinolones and amikacin (Fig. 4).



Analysis of the dynamics of intraspecific resistance of representatives of fam. Enterobacteriaceae showed that the main problem is *K. pneumoniae* isolates, whose resistance significantly (p<0.01) increased even to reserve antibiotics: to cefoperazone/sulbactam from 30.4 to 54.1%, to imipenem from 6.5 to 29.6%, to Meropenem from 4.3 to 27.2% (Table 5). More than 90% of isolates isolated at the end of the observation period were resistant to ampicillin/sulbactam, fluoroquinolones, co-trimoxazole and tobramycin. Fosfomycin and colistin, sensitivity to which was additionally determined in 2017, showed activity against 63.3% (19 of 30) and 80% (16 of 20) of *K. pneumoniae* strains, respectively. At the same time, the proportion of amikacin-resistant strains decreased insignificantly from 51.1 to 35.5%. A similar trend was detected for *E. coli,* and all 16 *E. cloacae* isolates isolated in 2016–2017 were sensitive to this antibiotic.

A decrease in the activity of unprotected cephalosporins included in the study was founded with respect to *E. coli,* especially for cefepime (from 72.5 to 38.5%, p<0.05). By the end of the study period, carbapenems, cefoperazone/sulbactam and amikacin were most active against *E. coli* and *E. cloacae.* From 2017, the minimum inhibitory concentration of fosfomycin was determined for all multiresistant strains of enterobacteria (E-test, Oxoid, UK). According to the results of this study, 11 out of 30 (36.7%) K. pneumoniae isolates showed resistance to fosfomycin. All 5 strains of tested *E. cloacae* were sensitive to this antibiotic.

Fig. 4. The dynamics of the resistance level of *Acinetobacter* sp.
[1] — p<0,05 in comparison with the period 2012–2013
[2] — p<0,05 in comparison with the period 2014–2015
[1*] — p<0,01 in comparison with the period 2012–2013
[2*] — p<0,01 in comparison with the period 2014–2015

Table 5

The dynamics of the resistance level (%) of representatives of fam. Enterobacteriaceae

Antimicrobial agent	*Escherichia coli*			*Klebsiella pneumoniae*			*Enterobacter cloacae*		
	2012–2013, *n* = 16	2014–2015, *n* = 24	2016–2017, *n* = 30	2012–2013, *n* = 46	2014–2015, *n* = 46	2016–2017, *n* = 81	2012–2013, *n* = 36	2014–2015, *n* = 33	2016–2017, *n* = 16
Ampicillin/sulbactam	66.7	43.5[1*]	80.8[2*]	95.5	81.8	95.7	72.7	83.9	87.5
Cefoperazone/sulbactam	0.0	4.2	3.6	30.4	50.0	54.1[1*]	28.1	15.2	12.5
Ceftazidime	43.8	37.5	61.5	88.9	79.5	86.1	60.0	71.0	62.5
Ceftriaxone	46.7	34.8	61.5	90.9	81.8	85.5	61.8	71.0	62.5
Cefepime	37.5	33.3	61.5[2]	91.1	79.5	84.7	50.0	71.0	56.3
Imipenem	0.0	0.0	0.0	6.5	21.7[1]	29.6[1*]	2.9	0.0	6.3
Meropenem	0.0	4.2	0.0	4.3	21.7[1]	27.2[1*]	2.9	0.0	0.0
Ertapenem	NA	NA	0.0	NA	NA	46.9	NA	NA	0.0
Amikacin	6.3	16.7	3.3	51.1	37.0	35.5	33.3	29.0	0.0[1*.2]
Tobramycin	33.3	37.5	53.6	89.1	77.3	91.3[2]	47.1	74.2	56.3
Ciprofloxacin	43.8	41.7	69.2	87.0	73.9	93.1[2]	37.1	61.3[1]	37.5
Moxifloxacin	46.7	39.1	75.02	91.1	75.6	92.8[1.2*]	43.8	62.5	37.5
Co-trimoxazole	37.5	33.3	53.8	75.6	63.6[1*]	91.81[*.2*]	52.8	60.0	40.0

1 — p<0,05 in comparison with the period 2012–2013; 2 — p<0,05 in comparison with the period 2014–2015; 1* — p<0,01 in comparison with the period 2012–2013; 2* — p<0,01 in comparison with the period 2014–2015; NA — no data available.

Discussion

The study revealed several trends in the dynamics of the spectrum of leading pathogens and their antibiotic resistance. In the etiological structure of orthopedic infections, the proportion of *S. aureus* decreased in comparison with earlier periods of observation. In 2010–2012, the share of this species was 33.1%, 23.9% of them were MRSA strains [8], whereas in this study in the period 2016–2017 these indicators were respectively — 28.6 and 16.5%. At the same time, insignificant fluctuations or preservation of the level of MRSA resistance to the studied antibiotics were founded. The obtained results are consistent with the changes in the epidemiology of MRSA not only in Russia [16], but also in Europe and North America [17]. An increase in the frequency of *S. epidermidis* isolation from patients with orthopedic infection was revealed at the same time with a decrease in the etiological role of *S. aureus*. In 2010–2012, *S. epidermidis* was isolated in 16.8% of cases of implant-associated infection [8], and by 2016–2017 this measure reached 22.5%, while the share of MRSE was 56.6 and 63.3% respectively. Similar data were obtained in the study of Triffault-Fillit C with co-authors (2018). In an investigation of the etiology of 567 cases of PIP, they revealed that among staphylococci the frequencies of MRSA and MRSE were16.1% and 59.1% respectively [10]. Regardless of the sensitivity of staphylococcal strains to methicillin, *S. epidermidis* isolates were significantly more often resistant to most of the antibiotics studied. The vancomycin and linezolid retain high

activity against staphylococci (no resistant strains). Also the high activity of fusidic acid and fosfomycin was founded. With respect to *E. faecalis*, vancomycin, linezolid, imipenem, and tigecycline remain highly active. However, it is alarming to isolate the first vancomycin-resistant strain in our hospital.

Despite the fact that the most frequent causative agents of nosocomial infections in Russia are representatives of fam. Enterobacteriaceae, *P. aeruginosa* and *Acinetobacter* sp., which account for 43.1, 19.6 and 14.4% of all isolated bacterial pathogens of nosocomial infections [18, 19, 20], their participation in the etiology of orthopedic implant-associated infections does not exceed as a whole 10–35% according to the data of various authors, [9, 10, 21, 22]. In this study, a decrease in the frequency of isolation of Acinetobacter sp. by 29.3% ($p<0.05$) and P. aeruginosa by 24.2% ($p>0.05$) was shown by 2016-2017 compared with the initial period of the study (2012-2013). In this case, the share of fam. Enterobacteriaceae as a whole increased by 31.8% ($p>0.05$) by increasing the frequency of isolation of K. pneumoniae ($p<0.01$). In Western European countries, a significant increase in the number of cases of periprosthetic infection ($p = 0.024$) caused by aerobic Gram (-) rods is also noted: from 25% in 2003–2004. to 33.3% in 2011–2012 and reducing ($p<0.02$) the proportion of Gram (+) cocci from 80.3% to 74.3% [9].

In our opinion, this is an extremely dangerous tendency, since, despite the fact that Gram (-) bacteria share 17% in the etiological structure of IAI, the results of the analysis of the dynamics of antibiotic resistance indicate the growing resistance of *K. pneumoniae* and non-fermentative pathogens to most of the tested drugs. The most clinically significant problem is the resistance of Gram (-) causative agents of IAI to current cephalosporins, carbapenems and fluoroquinolones. At present, the strains of *P. aeruginosa, Acinetobacter* sp., and *K. pneumoniae* resistant to carbapenems are becoming an acute problem in the treatment of infectious diseases due to high mortality [18, 20, 23, 24]. Few existing publications indicate a significant decrease in the effectiveness of treatment of orthopedic IAI caused not only by carbapenem-resistant strains, but also Gram (-) bacteria in general [17, 25, 26].

A contemporary view the list of antibiotics with activity against bacteria in the composition of biofilms is limited to rifampicin (staphylococcal IAI), fluoroquinolones (Gram (-) pathogens) and fosfomycin, that highly active against enterococci [27]. In this regard, pathogens resistant to these antibiotics are referred to as the so-called difficult-to-treat DTT (Difficult-To-Treat) pathogens. Among all strains included in our study, 8.5% (112/1310) of *S. aureus* strains and 13.5% (109/810) *S. epidermidis* were resistant to rifampicin; 50% (110/220) *P. aeruginosa,* 78.9% (112/142) *Acinetobacter sp.* and 81.5% (141/173) *K. pneumoniae* were resistant to ciprofloxacin. Moreover, in 2016-2017, about 85–90% of isolates of *Acinetobacter sp.*, *K. pneumoniae* and *E. coli* showed resistance to fluoroquinolones. The colistin demonstrated the highest activity against Gram (-) bacteria among all the tested antibiotics. All isolates of *P. aeruginosa* and *Acinetobacter sp.* and 80% of *K. pneumoniae* strains were sensitive to this antibiotic. However, the prolongation of the course of antibiotic therapy (at least 4–6 weeks after release from the hospital) at the outpatient stage is almost impossible due to the high cost and the lack of an oral form of colistin, as well as carbapenems. Therefore the isolation of Gram (-) pathogens extremely unfavorable prognostic sign in the treatment of orthopedic IAI.

According to existing recommendations, the main risk factors for isolating multiresistant pathogens, regardless of the source of infection, are elderly age (over 65 years), comorbidity (including multiple), courses of

antibiotic therapy (in the previous 90 days) and previous hospitalizations in history [28]. In our opinion, for patients with IAI, risk factors are also a long period of infection with repeated attempts of conservative antibiotic therapy and previously performed non-radical surgical interventions with preservation of an infected implant [29]. However, this assumption requires further investigation.

Conclusion

Thus, the obtained results indicate an increase in the role of S. epidermidis and *K. pneumoniae* in the etiology of orthopedic infection. The detected increase in the resistance of microbial pathogens to the most of used antibiotics should be considered when it is necessary to prescribe antibiotic therapy before obtaining the results of bacterial studies. With respect to gram-positive pathogens, there remains a high activity of vancomycin, linezolid, fosfomycin, which can be used for empirical therapy of patients with IAI.

The extremely high frequency of resistance of Gram-negative bacteria to modern cephalosporins and fluoroquinolones eliminates the possibility of their empirical use, which requires maintaining carbapenems in starting treatment regimens. In addition, high resistance to fluoroquinolones significantly limits the possibilities of prolonged oral antibiotic therapy in patients with periprosthetic infection and chronic osteomyelitis, which must be considered when choosing the tactics of surgical treatment.

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INFORMATION ABOUT AUTHORS:

Svetlana A. Bozhkova — Dr. Sci. (Med.), head of the Research Department of Prevention and Treatment of Wound Infection and Department of Clinical Pharmacology, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Alina R. Kasimova — clinical pharmacologist, Department of Clinical Pharmacology, Vreden Russian Research Institute of Traumatology and Orthopedics; Assistant, Department of Clinical Pharmacology and Evidence-Based Medicine, Pavlov First Saint Petersburg State Medical University, St. Petersburg, Russian Federation

Rashid M. Tikhilov — Dr. Sci. (Med.), professor, director of Vreden Russian Research Institute of Traumatology and Orthopedics; professor of Traumatology and Orthopedics Department, Mechnikov North-Western State Medical University, St. Petersburg, Russian Federation

Ekaterina M. Polyakova — Cand. Sci. (Biol.), senior researcher, Research Department of Prevention and Treatment of Wound Infection, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Anna N. Rukina — bacteriologist, Central Clinical Diagnostic Laboratory; researcher assistant, Scientific Department of Treatment and Prevention of Wound Infection, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Valentina V. Shabanova — bacteriologist, Central Clinical Diagnostic Laboratory; researcher assistant, Scientific Department of Treatment and Prevention of Wound Infection, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Vitaly N. Liventsov — orthopedic surgeon, Department of Purulent Surgery, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

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Correction of Foot Deformities Using Triple Arthrodesis and Its Effect on Soft Tissue Blood Supply at Surgical Site in Patients with Cerebral Palsy

S.S. Leonchuk, E.N. Shchurova, D.A. Popkov, G.M. Chibirov, R.R. Bidiamshin, O.I. Gatamov

Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Abstract

The aim of the study is to evaluate the efficiency of triple arthrodesis of foot and its effect on soft tissues blood supply at the surgical site during simultaneous correction of segment deformity in patients with cerebral palsy. ***Materials and Methods.*** The present study reflects the authors' experience of triple arthrodesis for correction and stabilization of foot multicomponent deformities of varying severity in 75 patients (136 feet) with cerebral palsy (II-IV level by Gross Motor Function Classification System (GMFCS)) treated in the Ilizarov center in the period from April 2012 to December 2016. The average age of the patients was 16.4±4.3 years (from 11 years 8 months to 43 years 3 months). All patients included into the study had severe arthrosis of hind and midfoot. The main option of foot fixation in this group of patients was internal fixation (elastic threaded wires, compression screws) together with plaster cast immobilization for 6–8 weeks. All patients underwent average of 4.59 surgical elements during a procedure as part of simultaneous multilevel interventions. The blood supply at the surgical site was evaluated by laser and high-frequency Doppler flowmetry before and after all stages of the surgery. ***Results.*** Long-term outcomes were evaluated at the average of 19 months after the surgery in 56 (74.7%) patients. 37 patients (66.1%) demonstrated good treatment outcomes and 19 patients (33.9%) — satisfactory outcomes. No unsatisfactory outcomes were observed. The clinical outcome of foot surgery was evaluated using the Angus-Cowell criteria. The obtained significant x-ray enhancement was maintained at the control stages of the follow up. Despite large simultaneous correction of foot deformity, there was no decrease in the parameters of microcirculatory blood supply of the skin, muscles and subcutaneous fat of the foot. The authors observed a stabilized or an increased perfusion of soft tissues. ***Conclusion.*** Triple arthrodesis for correction of foot deformities in patients with cerebral palsy and severe arthrosis in hind and midfoot is an efficient method which allows to correct and stabilize gained position of segments. The data of physiological research testify the sparing approach of such procedure and a possibility of an earlier weight-bearing on operated limb.

Keywords: foot deformity, triple arthrodesis, internal fixation, cerebral palsy, soft tissue blood supply.

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Sergei S. Leonchuk; e-mail: leon4yk@mail.ru

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Introduction

Foot deformities are the most common orthopaedic pathology in patients with neurological diseases. In preschool children with cerebral palsy (CP), the equinus component of deformity prevails [1]. However, in older children, adolescents and adults with this disease, flat-valgus foot deformity is more common, which is one of the main causes of instability in verticalization [2-7].

Deformities of feet in adolescents and adults manifest by pain, changes in soft tissues (hyperkeratosis) at the pressure site of bone elements (for example. the head of the talus) and are one of the reasons for loss of active independent movement. Patients often experience difficulties in the selection of shoes, orthosis. Flat-valgus foot deformity is an important element in the formation and preservation of pathological crouch gait [8].

Older children and adults with deformities of the feet are recommended to undergo corrective osteotomies of the foot bones, arthroeresis, stabilizing operations [2-4, 9-13]. However, reconstructive intervention on the foot using osteotomy in severe bone deformities and changes in articular cartilage (osteoarthritis 2-3 degree) is doubtful. Irrational interventions and osteosynthesis on the foot without taking into account the age characteristics of the segment skeleton, neurological disease of the patient often do not give the desired result; there are cases of relapse of deformity, non-union of the bones, pain [10, 13-17]. Positive reports on the use of triple arthrodesis for correction of foot deformity and stabilization of the result are described in many works [3, 6, 9, 10, 18].

Undoubtedly, with acute correction of complex deformities of the foot, it is important to control the soft tissue trophic in the postoperative wound and the segment. Methods of laser and high-frequency Doppler flowmetry make it possible to determine early signs of circulatory disorders in various types of anesthesia [19], to study and control changes in tissue microcirculation during combined reconstructive plastic surgeries [20].

The aim of the study was to assess the clinical and radiological results of the use of triple arthrodesis of the foot and to determine its effect on the blood supply of soft tissues in the surgical site with simultaneous correction of segment deformity in patients with cerebral palsy.

Materials and methods

From January 2012 to December 2016, 75 patients (136 feet) with foot deformities were treated in our clinic using triple arthrodesis, in the framework of acute multilevel orthopaedic interventions. Patients belonged to II-IV functional level according to Gross Motor Function Classification System (GMFCS) [21]. The average age of patients was 16.4±4.3 years (from 11 years 8 months to 43 years 3 months.). There were 61 children in the study and 14 adults; there were 46 male patients and 29 — female patients. All patients had severe degenerative changes in the middle and posterior parts of the feet. Patients with spastic diplegia prevailed — 61 (81.3%), there were 14 (18.7%) patients with spastic hemiplegia. Foot deformities with valgus deviation 119 (87.5 %) prevailed. The structure of foot deformities in patients before treatment is presented in table 1.

Patients underwent radiography of the feet in lateral and AP views with loading.

Table 1

Structure of foot deformities before treatment

Type of deformity	Quantity
Equino-cavo-varus	14 (10.3%)
Cavo-varus	3 (2.2%)
Plano-valgus	62 (45.6%)
Equino-plano-valgus	43 (31.6%)
Calcaneal valgus	14 (10.3%)

In addition to clinical and radiological methods of study, quantitative assessment of some parameters of walking using the Edinburgh Gait Score was made [22]. The classification of gait types in patients capable of independent vertical movement was carried out using the scale of J. Rodda et al [8]. The level of motor activity was assessed by GMFCS and FMS (Functional Mobility Scale).

All patients underwent simultaneous multilevel interventions on the operated limb in combination with corrective and stabilizing foot surgery in the amount of triple arthrodesis. Multilevel orthopaedic interventions were performed in accordance with the algorithm adopted in our clinic [23. 24]. In this series, an average of 4.6 surgical elements were performed per operation. Variants of interventions on the tendon-muscular apparatus of the tibia and foot with triple arthrodesis are presented in table 2.

Triple arthrodesis was performed through classical lateral approach in the posterior foot [25]. However, in our work, soft tissue dissection was performed in a special way to reduce its tension during the subsequent suturing of the wound after acute correction of severe foot deformity (Fig. 1):

1) the skin incision was not straight, but arched;

2) *retinaculum mm. extensorum inferius* is mobilized from a short extensor of the toes and dissected not H-shaped, but U-shaped with the base facing posteriorly (a non-free displaced flap with a wide base is formed);

3) *m. extensor digitorum brevis* is also U-shaped mobilized and separated from the surface of the calcaneus, with the base of this muscle flap being distal. Both of these flaps are easily approximated and connected edge-to-edge with no tension, filling the space of the surgical wound.

After cutting the articular cartilage, subchondral bone elements were shaped taking into account the deformity of the foot (Fig. 2).

Table 2

Surgeries on the tendon-muscular apparatus of the tibia and foot with triple arthrodesis

Procedure	Number of feet
Aponeurotomy of gastrocnemius muscles. Achilles tendon plasty, plantotomy	48
Release, lengthening of peroneal tendons	22
Release of posterior tibial muscle, capsulotomy of talus-navicular joint	10
Lengthening of tendons of flexors or extensors of toes	42
Transfer of the short peroneal muscle to the calcaneus	14

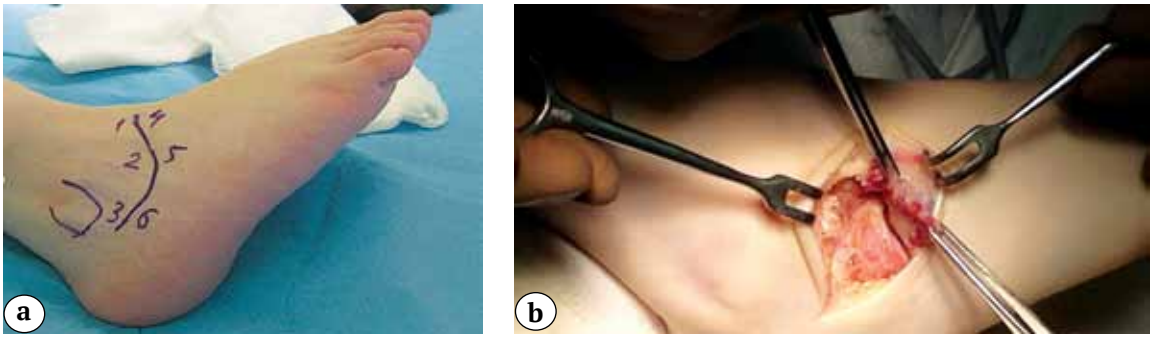

Fig. 1. Approach and dissection of soft tissues during triple arthrodesis in patients with CP: a — incision, marking of the measurement area; b — wound during dissection

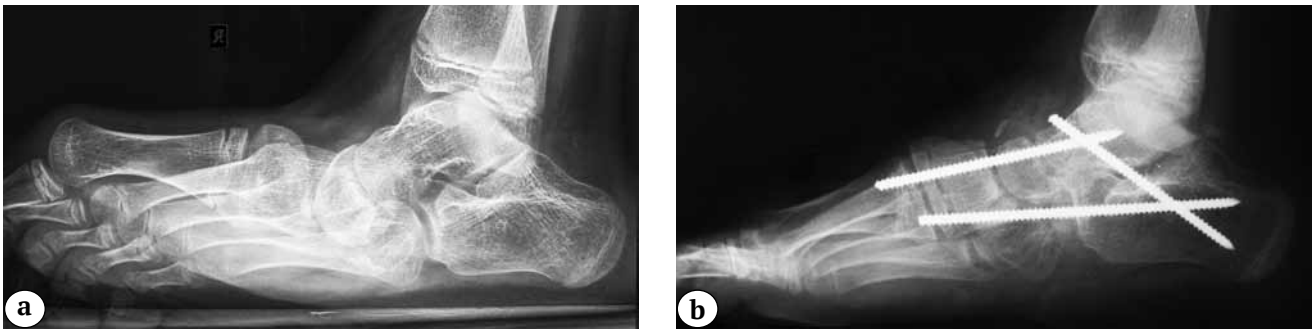

Fig. 2. X-ray images of patient 13 y.o.:
a — before treatment (complex foot deformity with talus verticalization);
b — thrifty resection of bones and creation of contact between bone fragments

The main option for fixation of the foot bones in question was internal fixation: elastic threaded wires with a diameter of 3.0 and 4.0 mm, compression screws 4.0 and 6.5 mm in diameter, the material of osteosynthesis was titanium. Threaded wires, fixing the middle part of the foot, were placed through open approaches in the first and fourth interdigital spaces.

To assess the possible negative impact of these manipulations on the soft tissues of the foot, a study of blood supply of the soft tissues at the surgical site using laser and high-frequency Doppler flowmetry was performed before and after all stages of the surgery.

In the operating room, microcirculation of foot tissues was studied: skin, subcutaneous tissue, muscle tissue in 21 patients with CP with foot deformity at the age of 13 to 23 years (15.4±1.0 years). Capillary skin blood flow (ml/min 100 g of tissue) was assessed by laser Doppler flowmetry (BLF-21, transonic Systems, USA) using a skin sensor. Blood flow registration (three measurements at each point) was performed before the operation, after marking the measurement areas (1-6 points) (see Fig. 1a) and after all stages of the operation, removal of the tourniquet and suturing (in 15.3±1.7 min, 8 to 25 minutes after removal of the tourniquet).

In addition, the study area included subcutaneous tissue, retinaculum mm. extensorum inferior, m. extensor digitorum brevis. Registration of microcirculatory blood flow of these structures was performed using high-frequency Doppler ultrasound (Doppler «Minimax-Doppler-K» (Minimax, St. Petersburg) using an intraoperative sensor 20 mHz in the mode of study of microcirculation and perfusion of small blood vessels.

After the surgery for 2-3 days the operated limb was fixed with a semi-circular plaster cast, change of bandages and wound examination were performed. Then circular plaster cast immobilization of the limb was performed from the middle third of the femur to the toes for 6-8 weeks depending on the amount of the entire multi-level intervention. Gradually increasing weightbearing on the operated limb was allowed in 2 weeks after the surgery. Surgeries on each limb were performed with an interval of 3-4 weeks (on average 25.4±3.1 days).

Efficacy of the treatment was determined by results of orthopaedic and neurological examinations of the patient. The ability to move was evaluated using Gillette questionnaire [26]. Evaluation of clinical outcome of the intervention on the foot was performed using the criteria proposed by P.D. Angus and H.R. Cowell [27].

Statistical analysis

Statistical processing was performed in Microsoft Office Excel (2010) with the AtteStat and SPSS 18.0 add-in. To assess the significance of mean differences, we used paired Student and Mann — Whitney criteria.

Results

Long-term results of treatment were evaluated after an average of 19 months (from 15 to 42 months) in 57 patients (76.0%). According to the criteria of P. D. Angus and H.R. Cowell (1986), long-term follow-up evaluation showed good results of treatment in 38 patients (66.7%), satisfactory — in 19 patients (33.3%) who regularly complained of moderate pain in the feet after a long walk. There were no poor results. The analysis of gait at the long-term follow-up showed improvement of the majority of parameters of the supporting and non-supporting step phases in patients who used and did not use assistive devices to walk. The dynamics of x-ray parameters of multi-component foot deformity with supination component is shown in table 3.

Changes of radiographic parameters in valgus foot deformity are presented in table 4.

Table 3

Dynamics of radiological changes of feet with varus component (*n* = 17)

Studied angle between foot bones	Before treatment, degrees	After treatment, degrees	Changes		Norm. degrees
			Abs., degrees	rel. %	
AP view					
Talus-calcaneus	34.5	15.9	18.6	53.9	15–25
Total adduction	66.74	15.3	51.44	77.1	28–30
Angle between I and V metatarsals	31.76	20.4	11.36	35.8	28–30
Metatarsophalangeal	10.9	3.9	7.0	64.2	10–15
Lateral view					
Tibia-talus	116.55	103.5	13.05	11.2	100–105
Tibia-calcaneus	67.41	76.7	9.29	12.1	75–80
Talus-calcaneus	35.49	30.5	4.99	14.1	20–30
Foot arch angle	119.2	125.78	6.58	5.2	125–130
Meary angle (between talus and the I metatarsal)	33.58	4.33	29.25	87.11	0–5

Table 4

Dynamics of radiological parameters of foot with valgus component of foot deformity (*n* = 119)

Studied angle between axis of shadows of foot bones	Before treatment, degrees	After treatment, degrees	Changes		Norm. degrees
			Abs., degrees	rel. %	
AP view					
Talus-calcaneus	27.6	17.3	10.3	37.32	15–25
Total adduction	15.3	5.1	10.2	66.7	0–7
Angle between I and V metatarsals	24.6	25.19	0.59	2.34	28–30
Metatarsophalangeal	33.4	11.02	22.38	66.5	10–15
Lateral view					
Tibia-talus	122.9	106.71	16.19	13.17	100–105
Tibia-calcaneus	67.17	73.1	5.93	8.11	75–80
Talus-calcaneus	56.52	28.96	27.56	48.76	20–30
Foot arch angle	168.4	136.47	31.93	18.96	125–130
Meary angle (between talus and the I metatarsal)	38.59	2.43	36.16	93.7	0–5

According to Gillette questionnaire, the functional abilities improved by one level in 29 patients (50.9%), by 2 levels — in 2 patients (3.5%), there was no increase of functional abilities — in 26 patients (45.6%).

Clinical case

The patient is 15 years old, GMFCS III, MACS I, FMS 5,2,2, IV type of gait by Rodda. A multi-level surgical intervention was performed, including lengthening of the hamstring group, lowering of the patella and the triple arthrodesis of the feet using elastic threaded wires (Fig. 3). In 20 months at the control outpatient examination, the patient did not complain; the range of motions in the knees and ankles was complete; the presence of foreign bodies in the feet did not cause discomfort. During prolonged walking, the patient observed minor pain in the feet, tension in the gastrocnemius muscles. According to Gillette's questionnaire, the patient's functional abilities increased by one level.

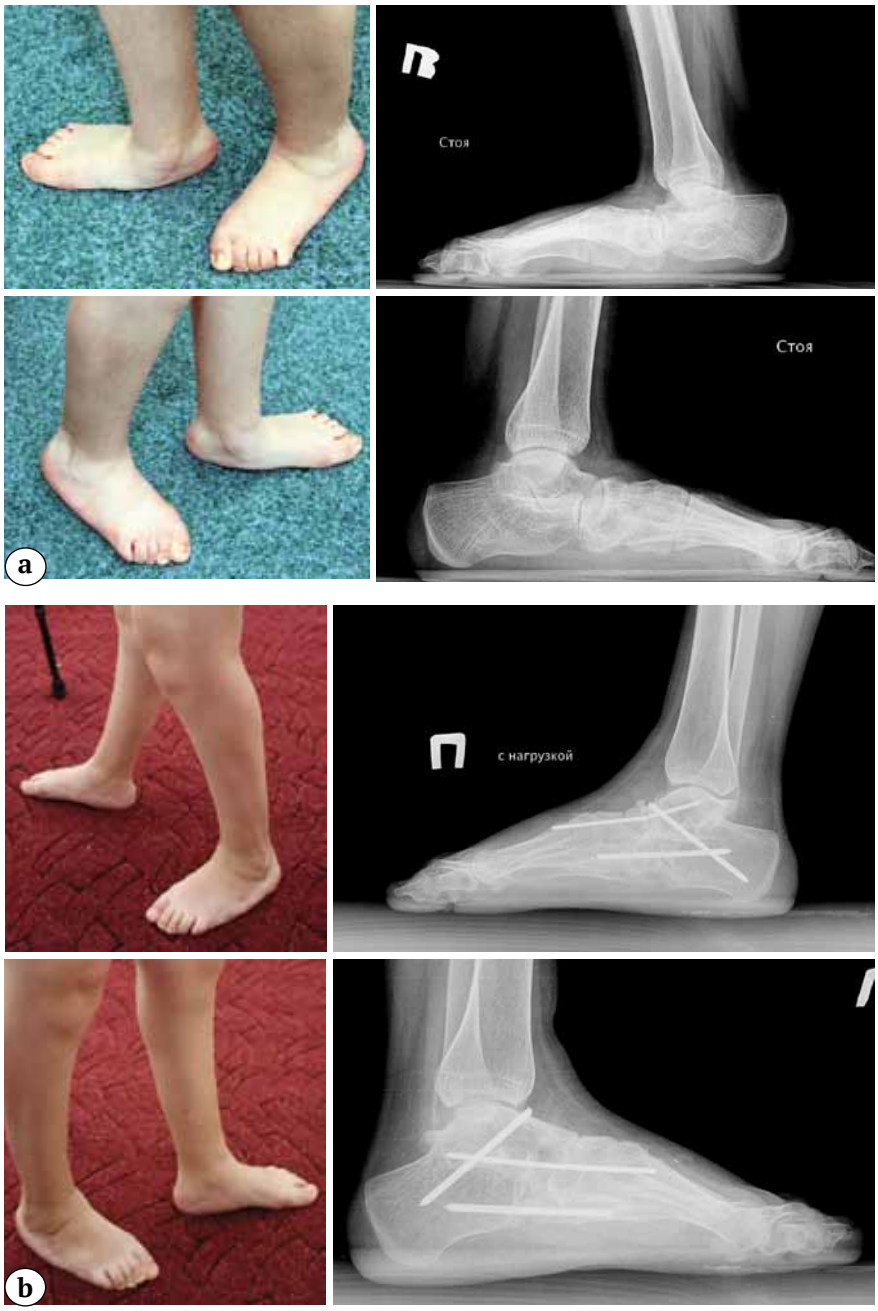

Fig. 3. Image and X-ray of patient of 15 y.o.:
a — planovalgus feet deformity before treatment;
b — follow-up in 20 months after surgery (normal feet position, contact between bones of subtalar and Chopart joint, internal fixation with threaded wires)

Postoperative complications were observed in 15 patients (20%). 5 patients had a poorly granulating wound. It was 6.7% of the total number of patients in this group. This complication was eliminated during treatment (appropriate change of dressings) and did not affect the final result. In 10 patients (13.3%) breakage of threaded wires was observed.

Outpatient examination was performed in 6 months. Consolidation and remodeling of the relevant bones was observed in all the patients. There were no cases of non-union. Removal of threaded wires and screws was performed as planned in 48 (64%) patients. This was done due to both the desire of the patient (or the child's parents) to remove the hardware and pain at the site of the threaded wire as a result of breakage and mobility of its distal fragment outside the area of arthrodesis in 10 (13.3%) patients, which we also attributed to complications of the primary intervention. In case of wire breakage, only its distal fragment was removed. Signs of osteoarthritis (especially in adult patients) of the adjacent joints of the foot in this series of patients remained at the initial level, and we did not observe its progression in the observation period.

The study of soft tissue microcirculation at the surgical site before the surgery showed no statistically significant difference of the indicators of skin capillary blood flow in various measuring points. After performing all stages of the surgery, removing the tourniquet and suturing the skin capillary blood flow tended to increase in all measuring zones (table 5).

Individual approach to analysis of blood flow reactions showed that in various measuring points there was a significant increase of blood flow in 45.5-72.7% of cases. In points 1, 4 and 5 the blood flow increased 4-6 times (p<0.05).

Study of microcirculatory blood flow of the subcutaneous tissue and muscular tissue determined absence of directed dynamics or tendency (table 6).

There was no significant difference from preoperative level in indicators of blood flow after performing all stages of the surgery and removing the tourniquet.

Individual approach to analysis of results of study of microcirculatory blood flow of these structures showed that in different points of measurement there was increase of blood flow in 18-55% of cases. Significant growth by 40-80% (p<0.05) was observed in points 1, 5 and 6 (table 7).

Table 5

Indicators of skin capillary blood flow of the foot before and after all stages of the surgery (M±m, *n* = 21)

Area of study	Capillary skin blood flow (ml/min 100g)					
	before surgery			after performing all stages of the surgery, removing the tourniquet and suturing		
	measurement 1	measurement 2	measurement 3	measurement 1	measurement 2	measurement 3
Point 1	7.7±2.9	7.7±2.9	7.7±3.1	11.9±2.7	11.8±2.7	11.6±2.6
Point 2	6.3±1.5	6.1±1.4	6.3±1.5	8.1±2.7	7.7±2.4	8.2±2.7
Point 3	7.4±2.5	7.3±2.5	7.4±2.5	10.1±4.9	10.3±5.0	10.3±5.1
Point 4	7.4±3.2	7.4±3.2	6.8±2.5	12.2±3.7	12.1±3.9	11.6±3.4
Point 5	7.0±1.9	6.9±1.9	6.9±1.9	11.2±3.4	11.6±3.5	11.2±3.4
Point 6	9.0±1.9	9.1±2.0	9.1±2.0	14.0±4.0	14.4±4.0	13.7±3.7

Table 6

Indicators of microcirculatory blood flow of the foot tissues before and after all stages of the surgery (M±m, *n* = 21)

Area of study	Indicators of blood flow							
	before all stages of the surgery				after performing all stages of the surgery and removing the tourniquet			
	Vs (cm/sec)	Vm (cm/sec)	Vd (cm/sec)	Qs (ml/min)	Vs (cm/sec)	Vm (cm/sec)	Vd (cm/sec)	Qs (ml/min)
Point 1 (subcutaneous tissue)	8.8±0.7	4.5±0.4	1.8±0.3	4.2±0.3	9.5±0.9	4.6±0.6	1.9±0.3	4.2±0.3
Point 2 (subcutaneous tissue)	9.5±0.9	5.0±0.6	1.7±0.2	4.1±0.5	8.1±0.8	3.7±0.4	1.4±0.3	3.8±0.4
Point 2 (subcutaneous tissue)	8.2±0.9	3.9±0.5	1.4±0.2	3.9±0.4	7.7±0.8	3.6±0.6	1.6±0.5	3.6±0.4
Point 4 (muscular tissue)	8.0±0.6	4.4±0.4	1.9±0.3	4.0±0.3	8.4±0.7	4.7±0.4	2.1±0.4	4.1±0.3
Point 5 (muscular tissue)	8.7±1.0	4.8±0.7	2.1±0.5	4.2±0.5	9.0±0.8	4.4±0.6	1.9±0.3	4.3±0.4
Point 6 (muscular tissue)	7.6±0.9	4.0±0.7	1.8±0.5	3.6±0.5	8.0±0.8	3.3±0.6	1.4±0.4	3.8±0.3

Vs — maximum systolic velocity; Qs — volume velocity; Vm — average velocity); PI — pulsatility index); RI — resistivity index.

Table 7

Indicators of microcirculatory blood flow of the foot tissues in positive dynamics (M±m)

Area of study	Indicators of blood flow							
	before all stages of the surgery				after performing all stages of the surgery and removing the tourniquet			
	Vs (cm/sec)	Vm (cm/sec)	Vd (cm/sec)	Qs (ml/min)	Vs (cm/sec)	Vm (cm/sec)	Vd (cm/sec)	Qs (ml/min)
Point 1 (subcutaneous tissue)	7.6±0.7	4.1±0.5	1.3±0.2	3.6±0.3	10.6±1.2*	6.9±0.7*	2.8±0.5*	4.5±0.5
Point 2 (subcutaneous tissue)	6.4±1.0	3.1±0.5	1.2±0.3	2.5±0.6	8.0±0.5	4.1±0.6	2.4±0.3	4.1±0.3
Point 2 (subcutaneous tissue)	6.7±0.5	3.2±1.0	–	2.7±0.3	6.8±0.8	4.9±1.1	–	3.3±0.8
Point 4 (muscular tissue)	6.7±0.8	3.3±0.6	1.2±0.2	3.3±0.5	9.1±1.1	5.1±0.8	2.8±0.8	4.5±0.6
Point 5 (muscular tissue)	6.7±1.2	3.2±0.4	1.2±0.3	3.4±0.6	9.6±0.7*	4.6 ±1.1	1.96±0.4	4.7±0.4
Point 6 (muscular tissue)	5.0±0.4	2.7±0.6	0.9±0.2	2.4±0.2	7.1±0.9*	3.7±0.8	1.5±0.7	3.6±0.5*

* — statistical significance of difference from the initial level, $p<0,05$.

Discussion

The approach to surgical treatment of orthopedic complications of CP is to perform multi-level single-stage surgical interventions [1, 8, 14, 23, 24, 29, 30]. In our series 119 (87.5%) feet had valgus deviation.

In the literature there are known publications that describe the long-term results (over 25 years) of various methods of correction of valgus and flat-valgus foot deformity [4, 5, 13, 31-34]. Some authors describe recurrences of deformity up to 25% after the surgery [13,14]. We believe that in patients older than 12 years with CP and rigid painful multi-component foot deformities and osteoarthrosis of 2-3 degree it is more rational to perform triple arthrodesis. Some of our colleagues believe the same and their patients are satisfied with the result of treatment in 79-95% of cases [6, 9-11, 18, 28 35].

Deformities of the feet in adolescents and adults manifest in pain, changes in soft tissues in the sites of pressure of bone elements and are one of the reasons for the loss of active independent motion. Undoubtedly, with the acute correction of complex deformities of the foot there is a risk of trophic disorders in the soft tissues of the postoperative wound and the segment in general. In our work, we conducted a study of the microcirculation of soft tissues at the surgical site (skin, subcutaneous tissue, muscle tissue) before and after all stages of the operation and removal of the tourniquet and suturing (the skin). Analysis of results showed that, despite a sufficiently large amount of acute correction of foot deformity, there is no decrease in the microcirculatory blood flow of the skin, muscles and subcutaneous tissues of the foot. There is either stabilization or increase in perfusion of these structures. This fact indicates the sparing nature of the surgical influence and presence of conditions for earlier weightbearing than described by other researchers (2 weeks after surgery with assistive devices) [2, 9, 15].

According to some authors, triple arthrodesis of the foot is especially indicated in neuromuscular imbalance [36]. Arthrodesis operations can be performed after the end of active growth of the foot bones [10, 11, 28]. We performed bilateral corrective triple arthrodesis in a patient with open growth zones (11 years 8 months), but did not receive negative consequences. The surgery in this patient was performed due to the need for correction and stabilization of multicomponent foot deformity.

In comparison with the work of our colleagues, who do not recommend weightbearing on the operated foot with triple arthrodesis for 1.5-2 months [2, 9, 15], which brings a number of inconveniences and limitations, including psychological ones, we recommend verticalization with a gradually increasing weight-bearing on the operated segment with assistive devices in 2 weeks after the surgery. With this approach we did not observe any cases of loss of results, nonunions in the study group of patients.

When performing triple arthrodesis of the foot, the most common complication is absence of union in the site of one or more joints after this operation. Thus, in children, the frequency of non-union occurs in up to 23% [6, 10, 12, 15, 25, 29], in adults — up to 46% [16, 29, 34, 37]. And it manifests in pain in the foot in almost 40% of patients [15]. For example, according to the study of I.B. de Groot et al there were 19% of nonunions, which required subsequent revision [36]. Outpatient examination 6 months later showed consolidation and remodeling of the bones in all cases, both in children and adults. We didn't leave diastasis between the bones. If necessary, we took out a bone fragment from the surgical site on the foot in order to create good contact.

In the study of M. Vlachou *и* D. Dimitriadis there was a deep infection of the foot after the triple arthrodesis in 2 (3,85%) patients. No infectious complications were noted. However, in acute correction of severe deformities in 5 patients we observed poorly granulating wound of the foot that did not

affect the final result of treatment. This fact is associated with some tension of soft tissues during acute correction of severe foot deformity [15].

According to the literature, pain in the postoperative period was observed in 20-57% of cases [6, 15, 17, 28]. In our long-term follow-up study, moderate pain in the feet after walking was observed in 19 (33.3%) patients.

C.L. Salzman and co-authors observed arthrosis of the ankle joint at the long-term follow-up (more than 25 years) in 45% of patients after triple arthrodesis [34], S.K. Trehan — in 11.5% of cases [6], P.D. Angus — in more than 50% [27].

We observed no progress of degenerative processes in the ankle joint in the patients included into this study at the time of the last outpatient examination (42 months).

Conclusion

We believe that the rational approach is to use triple arthrodesis of the foot as a part of multi-level orthopedic treatment of patients with CP, taking into account the age, severity of the main condition of the patient, deformity and degenerative changes of the segment; and it does not cause trophic disorders of soft tissues of the segment. The method of triple arthrodesis of the foot allows for restoration and stabilization of the correct interrelations between the bone elements, restoration the limb supportability, which in combination allows for improvement of functionality and minimization of the risk of deformity recurrence. We recommend this operation to patients older than 12 years with osteoarthritis of the foot 2-3 degree, using our proposed method of soft tissue dissection. Despite the rather large amount of acute correction of foot deformity, there is no decrease in the microcirculatory blood flow of soft tissues in the surgical site (skin, muscles and subcutaneous tissues of the foot) after all stages of the operation.

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INFORMATION ABOUT AUTHORS:

Sergei S. Leonchuk — Cand. Sci. (Med.), head of the 6th Orthopedic Department, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Elena N. Shchurova — Dr. Sci. (Biol.), leading researcher, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Dmitrii A. Popkov — Dr. Sci. (Med.), professor of Russian Academy of Science, chief of Neuroorthopedic Division, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Georgii M. Chibirov — Cand. Sci. (Med.), researcher, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Ramil' R. Bidiamshin — postgraduate student, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

Orkhan I. Gatamov — resident, Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics, Kurgan, Russian Federation

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Surgical Treatment of Spine Deformations after Neonatal Sepsis (Analysis of Clinical Series)

V.I. Zorin [1,2], D.G. Naumov [1], A.Yu. Mushkin [1,2], V.A. Evseev [1]

[1] *St. Petersburg State Research Institute of Phthisiopulmonology, St. Petersburg, Russian Federation*

[2] *Mechnikov North-Western State Medical University, St. Petersburg, Russian Federation*

Abstract

Background. Neonatal sepsis presents one of the current issues in modern pediatrics. The orthopedic outcomes of such a state and the possibility of treatment, in particular by surgical spinal reconstruction, are rarely analyzed. ***The purpose*** — to analyze pathology features and treatment outcomes in infants with vertebral complications resulted from neonatal sepsis. ***Materials and Methods.*** The analysis of observation and treatment of 15 infants, who have undergone neonatal sepsis which led to vertebral lesion with subsequent gross kyphotic deformity formation, is presented. ***Results.*** Average age of infants was 2.5 months when spinal pathology was diagnosed. In 7 of the 15 observations, a local angular kyphosis was revealed when the acute phase of disease was already passed („cured"). The thoracic vertebrae were most often affected, mainly Th 7-8 vertebral bodies. Average kyphosis was 53°. All infants were operated on during the period from 2006 to 2017. Each had two-stage spinal reconstruction including the anterior spinal fusion using a titanium mesh cage filled with bone autografts, or an autogenous bone graft only. At the second stage, the instrumental correction and fixation of the spine with a multi-support laminar structure were performed. Average age of patients at the time of surgery was 14 months. Average value of kyphosis correction was 27°. Further correction and anterior spinal fusion were achieved when performing the incorporation of a titanium mesh cage with bone autografts. The histological and bacteriological examination of the surgical material did not reveal any signs of infection or inflammation. Correction of deformity and restoration of the supporting strength of anterior vertebral column as a result of surgery were achieved in all cases. Various complications in the early and late follow-up period were reported in a total of 7 cases. Repeated interventions were required in two patients: in one case in the early period (dislocation of the structure supporting hook) and in one case in the long-term period (graft resorption and kyphotic deformity relapse). ***Conclusion.*** One of the complications of neonatal sepsis is severe multilevel thoracic spondylitis, the outcome of which is the formation of severe kyphosis against the background of subtotal bone vertebral destruction. The principal possibility of radical spine reconstruction in infants with achievement of good anatomical and functional results is shown.

Keywords: neonatal sepsis, spondylitis in infants, kyphosis, spinal reconstruction.

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✉ *Vyacheslav I. Zorin*; e-mail: zoringlu@yandex.ru

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Background

Neonatal sepsis remains a live issue of today's pediatrics: among all infant mortality cases, it ranks 2nd or 3rd with a mortality rate running up to 50% [1, 2]. At this point, a number of risk factors for developing neonatal sepsis (prematurity, pregnancy with prolonged gestosis, complex obstetric and gynecological case history, intrauterine infections), as well as its clinical and laboratory diagnostic criteria, have been identified. Concurrently, attention has been focused on the fact that the bacteriologic verification of the pathogen did not exceed 45% [3, 4, 5, 6]. A significant place is given to the differentiation of early-onset and late-onset sepsis in newborns, which is based on the age at onset of the disease. Despite the fact that the 72-hour interval is considered generally accepted, in literature there are indications on a 48-hour and 7-day time-based delineation as well as the opinion that such a division doesn't influence essentially the choice of therapy [7–10].

The most frequent neonatal sepsis local manifestations include the following: pneumonia, enterocolitis, meningitis, inflammation of soft tissues and osteomyelitis [1, 3, 4, 10]. Descriptions of clinical cases reporting spinal lesions [11, 12, 13] are limited.The outcomes of such states and the possibilities of treatment, in particular surgical reconstruction of the spine, are rarely analyzed [14]. However, along with the optimization of treatment strategies and increased survival rate of the infants who had sepsis in the neonatal period, the relevance of the issue will likely increase.

Objective: Analysis of pathology features and treatment results ininfants with spinal lesions occurring of neonatal sepsis.

Materials and Methods

Study design: retrospective mono-center series of clinical cases. The data of 15 infants who had neonatal sepsis and developed gross deformity of the spine as a result of destructive lesion of the vertebral bodies were analyzed. The data for this study were selected on the basis of the following criteria:

– retrospection time — 2017 back to 2006;

– age of primary manifestationof an infectious somatic disease corresponding to neonatal sepsis i.e. up to 90 days after birth;

– presence of destruction of vertebral bodies and kyphotic deformity which was an indication for referral to the clinic for surgical treatment;

– exclusion of specific etiology (tuberculosis, including post-vaccination form) of spondylitis through morphological and bacteriological examination, including molecular genetic studies of material from the affected area.

During the study the following data were analyzed:

– data of pre-, peri- and postnatal case history and obstetric-gynecological risk factors;

– clinical symptoms of sepsis onset state, local manifestations of infectious-inflammatory process;

– clinical symptoms of vertebral lesions, including the neurological status features;

– radiological semiotics of spinal lesions in neonatal sepsis at various stages from the initial diagnosis until the formation of spinal fusion after surgical treatment;

– results of the bacteriological and histological surgical material examination.

Average term of observation of the patient was 2±0.2 years afterthe main intervention.

The small number of selected data and long duration of retrospective dataselection (12 years) did not suppose the possibility of a complete statistical analysis.

Results

The main clinical features of the studied cohort of patients are shown in the Table below.

Due to the lack of complete radiological follow-up of the patients No. 6, 11, 13, their data were not taken into account when analyzing the relevant indicators in the group.

Table

Main clinical features of the studied cohort of patients

No	Sex	Sepsis local manifestations	Age			Spinal location of lesions before intervention	Neurological status before intervention (Frankel type) after intervention	Angle of kyphosis			Anterior spinal fusion technique	Follow-up period
			when sepsis onset occured	when vertebral lesions started	when patient unde went spinal surgery			before surgery	after surgery	at the end of the follow-up period		
1	M	Pneumonia, otitis	1 m.	4 m.	14 m.	Th 7-10	D	72°	32°	32°	TMC+ AutoB	1 year
2	M	Pneumonia	10 days	1 m.	7 m.	Th 7-10	E	62°	25°	25°	AutoB	2.5 years
3	F	Pneumonia	20 days	2 m.	8 m.	Th 7-10	E	50°	39°	63°	AutoB	2 years
4	M	Chestwall abscess	14 days	1 m.	7 m.	Th 5-8	E	47°	34°	34°	AutoB	1.5 year
5	M	Suppuration of an operational wound, pneumonia	1 m.	7 m.	21 m.	C 5-7, Th 4-7, Th 12-L1	E	80°	32°	32°	TMC+ AutoB	3 years
6	M	Colitis	2 weeks	2.5 m.	11 m.	C 3-4	D	40°	–	–	AlloB	2 years
7	M	Pneumonia, coxitis	1 m.	1.5 m.	14 m.	Th 5-8	E	40°	14°	14°	TMC+ AutoB	2 years
8	M	Pneumonia, chest wall abscess, phlegmon of the hand	3 m.	4 m.	13 m.	Th 5-8	E	45°	25°	25°	TMC+ AutoB	3 years
9	F	Pneumonia	1.5 m.	5 m.	7 m.	Th 8-10	D	54°	40°	40°	TMC+ AutoB	4 years
10	M	Meningitis, enterocolitis	9 days	12 m.	35 m.	Th 3-8	E	37°	18°	34°	TMC+ AutoB	2 years
11	M	None	1 m.	1.5 m.	9 m.	Th 9	E	–	–	–	AutoB	1.5 year
12	M	Pneumonia	3 days	3 m.	13 m.	Th 5-8	E	65°	31°	31°	AutoB	3 years
13	M	Pneumonia	1 day	4 m.	8 m.	C 4-7, Th 9-11	E	57°	–	–	AutoB	1 year
14	M	Pneumonia	2 weeks	2 m.	8 m.	Th 2-5	E	64°	33°	33°	AutoB	1.5 year
15	M	None	1 m.	2 m.	12 m.	Th 5-7	E	52°	22°	22°	TMC+ AutoB	1 year

TMCs — titanium mesh cages); AutoB — bone autografts; AlloB — bone allografts; m. — months.

Anamnesis study showed the presence of obstetric-gynecological and perinatal risk factors in 14 of 15 children: prematurity, severe forms of gestosis, infection of the mother, IVF. In one child, a septic state developed as a complication of cardiac surgery that he underwent when he was one month old (see No.5 in the Table).

Two infants developed illness in the first 72 hours (early-onset neonatal sepsis); in 13 cases, the sepsis onset developed from 3 days to 3 months after birth (average 28 days), which corresponds to the late-onsetneonatal sepsis. In all cases, the onset of disease manifested itself by hyperthermic syndrome (temperature rise above 38°C) and symptoms of intoxication. In 10 cases (67%) pneumonia was diagnosed. Six children had coxitis, gonarthritis, otitis, chest wall abscess, meningitis, enterocolitis.

Spinal lesions have never manifested themselves in the onset of disease. They were often identified accidentally during radiological examinations (CT scan, MRI) which were performedfor diagnosing pneumonia or controlling its dynamics. In 7 of 15 cases, the spinal column pathology as a local deformity was detected by the parents when the acute phase of disease was already passed ("cured"). The minimum period from the sepsis clinical manifestation onset to the diagnosis of vertebral lesions was 21 days, with an average of 2.5 months. Note that in three patients the identified changes were initially interpreted as a tumor process. Thus children were examined for a long time, consultations given and in one case a biopsy was carried out.

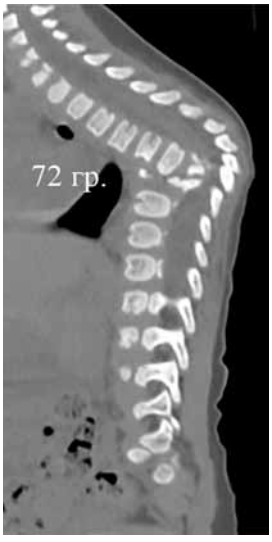

Fig. 1. Outcome of neonatal sepsis: severe kyphotic deformity — CT scan, sagittal view: subtotal destruction of Th7-Th10 vertebrae, kyphos 72°, spinal stenosis

During the active inflammatory process, all infants received near their homes an intensive medical, antibacterial therapy given to reverse the septic state. According to archival radiological data (CT scans and MRI), initially in all cases the scenario of pathology included destruction of vertebral bodies, edema of paravertebral tissues, often with an exudative component, regarded as "abscesses". Along with the soft-tissue component regression, phenomena of vertebral lesions increased up to complete destruction of the vertebrae causing a severe progressive kyphotic deformity (Fig.1).

The topography of vertebral lesions is specific: lesions of the thoracic vertebrae occurred in 14 cases, of cervical vertebrae in 3 patients, the most typical being the destruction of Th 7–8 vertebrae reported in 73% (Fig. 2).

Two-level lesions were reported in two infants, multiple (polysegmental) lesions of three or more vertebrae in 13 cases. A discrete lesion of the cervical spine was reported in one infant.

In all children, when admitted to the clinic, the symptoms appearedas a local, rigid, painless kyphotic deformity. According to imaging studies (X-ray films, CT scans, MRI), average kyphosis was 53° (min 37°; max 80°). Along with the destruction of vertebral bodies, the deformity was associated with dorsal migration of their fragments with stenosis of the spinal canal at the apex. However, only three patients had neurological disorders (Frankel type D). Soft tissue paravertebral changes were characterized by indolent edema and induration.

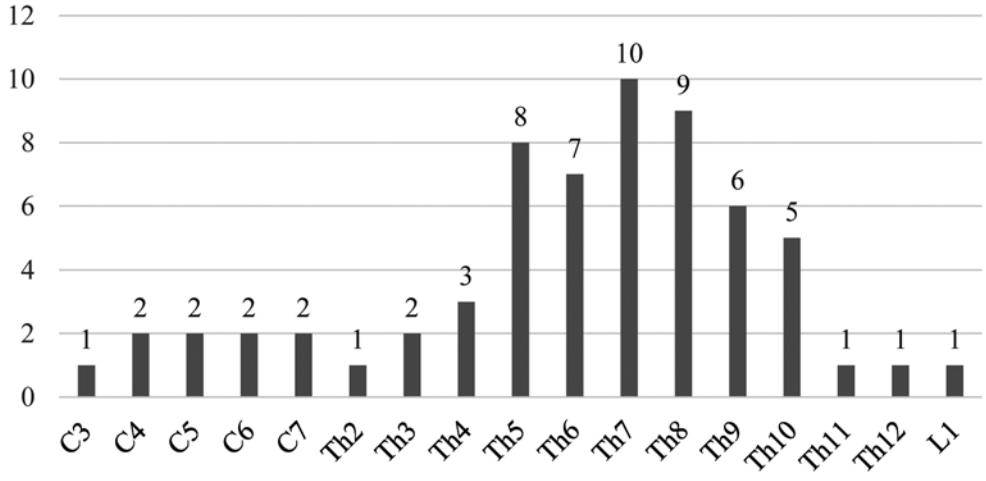

Fig. 2. Incidence of vertebral lesions in neonatal sepsis

Clinical and radiological data — progressive spinal deformity with a defect in the anterior column, in most cases involving two or more segments. This is interpreted, in terms of modern vertebrology, as a progressive kyphosis combined with destructive instabilityand failure of supporting strength of the spine. It is an absolute indication for surgical treatment, considering an unfavorable prognosis of the natural history of disease. All patients underwent reconstructive interventions aimed at restoring the spinal profile and its physiological function of support. The conditional restriction for reconstructive intervention was a baby's body weight exceeding 8 kg, which is due to the technical features of modern spinal surgery instruments used for young children. The patients' average age at the time of surgery was 14 months (min 7 months; max 3 years).

In 13 infants, the two-stage operation (anterior reconstruction and posterior instrumental correction and fixation) was performed with in one surgical session. In one infant, the treatment was separated into two operations (the anterior spinal fusion was carried out at first; the posterior instrumental fixation was performed 7 days later). This was due to severe kyphosis (80°), complexity of the first stage and hemodynamic instability. In aninfant with cervical spine destruction at the C2-5 vertebra level, the operation was limited to anterior reconstruction only (№. 6, Table).

When planning operations, we initially refused to perform a shortening vertebrotomy most commonly performed in the cases of kyphosis in adults (type VCR surgeries). It is associated with a significant shortening of the length of spine, which would negatively affect a growing child.

In 12 patients, access to the thoracic vertebral bodies was performed through right-sided thoracotomy with a rib resection. In two of them, the full extent of surgical intervention was performed from a posterior approach. In case of radical removal of pathological tissues represented by a conglomerate of bone, cartilage and scar tissue fragments, anterior decompression of the spinal canal was also performed. In no case the macroscopic signs of an active inflammatory process were detected. Post-resectional defect of the anterior column of the spine, with a length of two to five segments, was reconstructed under the circumstances of manual or temporary anterior instrumental reclination, by implanting rib fragments (7 patients) or titanium mesh cage (TMC) filled with boneautografts (8 patients). The application of TMC in infants started in the clinic in 2013.

In 14 children, the second stage was the installation of a posterior structure with laminar supports on both sides, with the formation of upper and lower "claw"-type constructs (Fig. 3). The additional correction of the deformity was carried out with the tension of the structure. The presence of residual kyphotic deformity, which was usually predicted at an initial kyphosis of more than 60°, was an indication for a monosegmental apical laminectomy. At the final stage, the posterior osteoplastic spinal fusion was performed using autograft rib fragments, which were placed onthe vertebral archesto the length corresponding to the anterior reconstruction of the spine.

In one infant with cervical spine deformity, reconstruction using an anterior-only approach ensured completing all tasks of intervention.

Average duration of the operation was 3 h 30±52 min, average volume of blood loss was 15.6±5.8% of the total circulating blood volume (TCBV). In 3 cases, despite the fact that the signs of myelopathy were present prior to the operation, the neurological symptoms fully regressed in the postoperative period. Average correction of kyphosis was 27°. In addition to that, when a titanium implant filled with bone autografts was used for anterior spinal fusion, the effectiveness was 7° higher than after interventions performed with the use of autograft ribs only.

In 7 patients (47%), various complications were reported, as follows:

– intraoperative bleeding from epidural vessels (one observation) which was treated with local hemostatic agents, hemotransfusion was performed;

– postoperative radicular syndrome (one case) was stopped by a non-operative method using a neurotropic therapy;

– complications of the early postoperative period — instability of the structure due to the dislocation of the supporting hook on the fourth day after the operation (1) and necrosis of the wound edges in the area of posterior access (1) were stopped by repositioning of the metal structure and necrectomy by stitching the wound, respectively.

In two of three cases of late-onset complications (occurred more than 1 year after surgery), a fracture (pseudarthrosis) of the anterior rib autograft was reported. In one

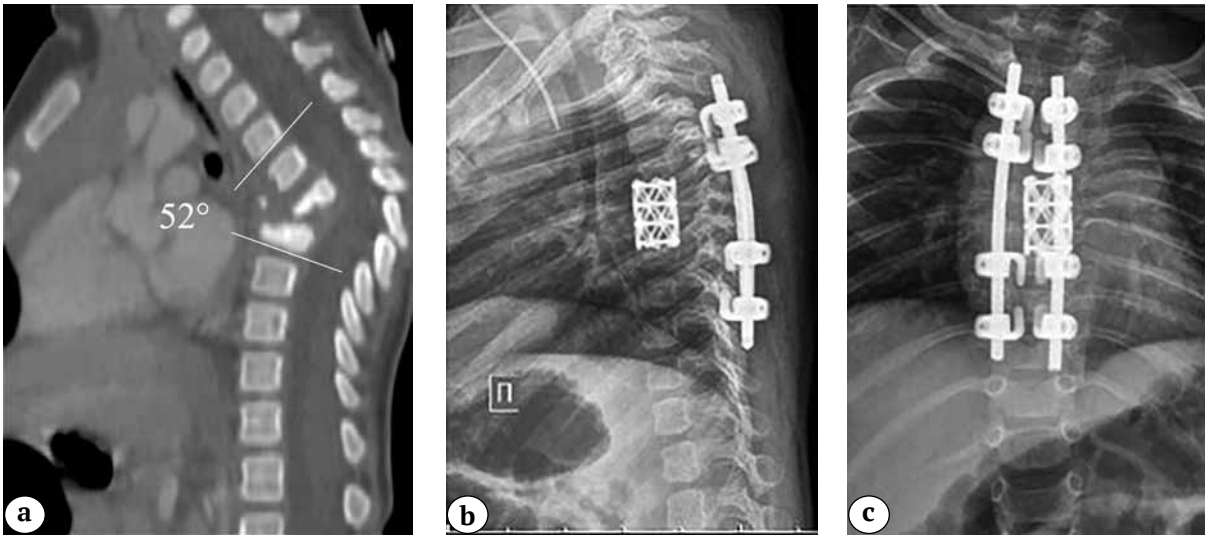

Fig. 3. Infant, 8 months old, the effects of neonatal sepsis with lesion of Th5-Th7 vertebrae:
a — CT scan, sagittal view, kyphosis is 52° combined with subtotal destruction of Th5-Th7 vertebrae;
b, c — postoperation X-rays

observation, the correction achieved during surgery was maintained by posterior stabilization and spinal fusion. In the second, there was a loss of correction by 25° (kyphosis was 63°) one year after removal of the posterior construction (2 years after the spinal reconstruction), which required repeated reconstructive intervention. In the third case, a patient underwent the anterior spinal fusion using a titanium mesh cage filled with bone autografts. After removal of the posterior construction, the loss of correction in this patient was 14°, while a total kyphosis was 34°, which does not exceed the physiological limit. This pediatric patient is followed up to the present.

In all other cases, the achieved correction is preserved. In 6 patients, the posterior metal structure has not been removed (the indication for its removal isthe anterior spinal fusion confirmed by a CT scan). These operations were performed in the last 2 years.

The histological and bacteriological study of the surgical material in all of the cases no signs of the infectious-inflammatory process activity were revealed. In addition, in all observations, there were no infectious complications recorded after surgery.

Conclusion

Severe multilevel spondylitis of the thoracic spine, the outcome of which is the formation of gross kyphosis with subtotal destruction of vertebral bodies, in our opinion, is a relatively rare but not casuistic complication of sepsis in the newborn. The analysis of case history and archival radiological data indicates quite typical characteristics of this process. The difficulties in interpreting existing semiotics, late and occasional diagnostics, incorrect treatment tactics are probably due to the rarity of pathology, as well as the scarcity of information on this problem not only in Russia but in foreign literature also.

A characteristic of the series of observations presented in the publication is a rather early age of interventions performed in the cases of a combination of gross kyphotic deformity and an extensive multilevel defect of the anterior spine. This can probably partially explain the rarity of publications on this topic. This pathology is found in pediatric vertebrology but usually in older children, particularly in specific spondylitis and tumor processes, and extremely rarely in vertebral anomalies.

The surgical tactics we used are based on the principles of modern pediatric orthopedics and traumatology — an early reconstruction of the defect with the restoration of the anatomy and function of the affected segment, taking into account the perspective of the child's growth and development.

The growth and development of the spine in children under the conditions of a multisegment anterior reconstruction necessary for treating of vertebral lesions, particularly in neonatal sepsis, is an unanswered question of modern vertebrology. A total understanding can be obtained only after 10-15 years, when the patients reach puberty. However, this aspect of the problem is still beyond the scope of this publication.

Spondylitis, as one of the neonatal sepsis, is usually diagnosed when an acute inflammatory process was already stopped. Typical radiolological manifestations of spondylitis — pronounced destruction, often polysegmental, paravertebral soft tissue component, angular kyphotic deformity — with good somatic condition of the infant allow refraining from emergency invasive diagnosis or treatment tactics. Exceptions are cases of pronounced neurological manifestations of spinal cord compression. Several of these patients were consulted by us in absentia. According to urgent indications, decompressive neurosurgical interventions were performed near their homes.

Post-destructive defect of the anterior column, causing multilevel instability of the spine, is an indication for surgery, the purpose of which is to correct the deformity and restore its supporting strength. The

extent of reconstruction as presented herein seems to us optimal because it allows avoiding the drawbacks of VCR* type shortening vertebrotomy.

The early age of pediatric patients does not preclude effective spinal reconstruction(anterior and posterior spinal fusion in combination with posterior instrumental correction and fixation). It is relatively safe due to the recession of the active process and gives the infantthe opportunity for developing fully.

To date, weight limits (body weight up to 8 kg) are not fundamental and are most likely due to the technical conformity of the spinal surgicalinstruments to the anatomical and functional state of the pediatric patient. Certainly, such operations belong to a high level of risk and should be performed in specialized clinical centers only.

The authors state that the article does not contain information that is prohibited to be published in public sources, has not been previously reported in its present form and is not being considered for publication in other periodicals.

The study partially includes data from a clinical series previously studied as part of a publication [14]. In the present study, the material is supplemented with new patients, advanced pathology analysis and modern literature.

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INFORMATION ABOUT AUTHORS:

Vyacheslav I. Zorin — Cand. Sci. (Med.), orthopedic surgeon, Pediatric Surgery Clinic, Saint-Petersburg State Research Institute of Phthisiopulmonology; assistant of Pediatric Surgery Department, Mechnikov North-Western State Medical University, St. Petersburg, Russian Federation

Denis G. Naumov — resident physician, St. Petersburg State Research Institute of Phthisiopulmonology, St. Petersburg, Russian Federation

Alexander Yu. Mushkin — Dr. Sci. (Med.), professor, head of Extrapulmonary Tuberculosis Department, head of Pediatric Surgery Clinic, St. Petersburg State Research Institute of Phthisiopulmonology; professor of Department of Pediatric Orthopedics, Mechnikov North-Western State Medical University, St. Petersburg, Russian Federation

Valerii A. Evseev — head of the Department of Pediatric Surgery and Orthopedics, St. Petersburg State Research Institute of Phthisiopulmonology, St. Petersburg, Russian Federation

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Comparative Analysis of Pedicle Screw Placement in Children with Congenital Scoliosis: Freehand Technique (*in vivo*) and Guide Templates (*in vitro*)

D.N. Kokushin, S.V. Vissarionov, A.G. Baindurashvili, A.V. Ovechkina, M.S. Poznovich

Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

Abstract

Objective — to evaluate accuracy between pedicle screw placement in vertebral bodies achieved in vivo with freehand techniques versus their placement in vertebrae plastic models achieved in vitro with the use of guide templates, in toddlers and preschool children with congenital kyphoscoliosis of the thoracolumbar transition and lumbar spine amid the vertebral malformation. ***Materials and Methods.*** The research is based on a retrospective analysis of the results of treatment of 10 patients with congenital kyphoscoliosis of the thoracolumbar transition and lumbar spine amid the vertebral malformation. Age – from 2 years 2 months to 6 years 8 months old (mean 3 years 8 months old), gender – 6 boys, 4 girls. Based on the postoperative multi-slice spiral computed tomography (MSCT) of the spine, the pedicle screws placement accuracy of the correcting multi-support metalwork was evaluated. These patients constituted the 1st research group (in vivo group). The 2nd research group (in vitro group) was formed from 27 vertebrae plastic models with pedicle screws inserted in them with the use of guide templates. The placement accuracy of the installed pedicle support elements was assessed based on the S.D. Gertzbein et al. scale (1990). ***Results.*** In the 1st group, there were 52 pedicle screws placed. The screw placement accuracy according to the rate of misplacement, as follows: 53.8% in Grade 0, 25% in Grade I, 11.6% in Grade II, 9.6% in Grade III. The number of screws with the rate of misplacement in Grade 0 + Grade I was 41 (78.8%). In the 2nd group, there were 54 screws placed and slightly larger than the 1st group. The screw placement accuracy according to the rate of misplacement was 94.4% in Grade 0, 1.9% in Grade I, 3.7% in Grade II, respectively. The number of screws with the rate of misplacement in Grade 0 + Grade I was 52 (96.3%). ***Conclusion.*** Comparative analysis showed that the number of pedicle screws successfully placed in vertebrae plastic models in children with congenital deformities of the thoracolumbar transition and lumbar spine achieved with the use of guide templates was significantly higher than the number of screws successfully placed with freehand techniques (96.3% versus 80.8%, $p = 0.011$). The results obtained with method of navigation templates in vitro showed high precision and accuracy of pedicle screw placement which gives the prospect for using this type of navigation in clinical practice in toddlers with congenital scoliosis.

Keywords: congenital scoliosis, hemivertebra, transpedicular fixation, guide templates, 3D-printing of prototypes, children.

Competing interests: the authors declare that they have no competing interests.

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Publishing ethics: legal representatives of children given the informed consent to clinical cases publication.

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Dmitriy N. Kokushin; e-mail: partgerm@yandex.ru

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Introduction

Hemivertebrae extirpation with subsequent radical correction of deformity and spine fixation by a local metal system at the early age [1–5] has become widely spread as the method of surgical correction of congenital deformities amid vertebral malformation in children. Surgical procedures in congenital scoliosis in children of older children do not allows to obtain radical deformity correction [6]. Transpedicular fixation versus laminar fixation from biomechanical point of view is advantageous, however, bears a risk of screws malposition due to structural vertebrae alterations amid scoliotic process and vertebral column malformation [7]. For that reasons it's important to ensure correct placement of transpedicular support fixators during treatment of patients with congenital scoliosis.

The prevalent method of transpedicular screws (TS) insertion in the spine surgery in general and in children with congenital deformities in particular is the free-hand method with subsequent fluoroscopic control of placement accuracy of support elements in vertebral bodies [8]. There are sporadic publications in foreign literature which present the analysis of TF placement accuracy in children with congenital spine deformities using intraoperative computer tomography (O-arm) and system of active optical navigation [9].

Recently, guiding templates (GT) have been used more often for TS insertion in cases of various diseases and deformities of spinal column (spine injury, degenerative and dystrophic diseases, inflammatory diseases, craniovertebral pathologies, idiopathic scoliosis, etc.). Such publications report rather high precision and accuracy of TS positioning in bony structures of vertebrae in various anatomical areas [10–13].

However, when analyzing national and world literature the authors of the present research did not find any publications dedicated to use of guiding templates for TS insertion in children of preschool age with congenital scoliosis.

Aim of the study — to conduct a comparative evaluation of accuracy of TS position inserted into vertebral bodies in toddlers and children of preschool age with congenital kyphoscoliosis of the thoracolumbar transition and lumbar spine amid the vertebral malformation by a free-hand technique *in vivo* and into vertebrae plastic models with the use of guiding templates (GT) *in vitro*.

Materials and Methods

The research in based on the retrospective analysis of examination and treatment outcomes in the randomized cohort comprised of 10 patients (6 males and 4 females) aging from 2 years and 2 months old to 6 years 8 months old (mean of 3 years 8 months) with congenital kyphoscoliosis with underlying vertebral malformation (posterolateral hemivertebrae in the thoracolumbar transition and lumber spine). All children underwent examination and surgical treatment during 2016 and 2017.

Standard preoperative and postoperative examination included multi-slice spiral computed tomography (MSCT) of thoracic and lumbosacral spine. Extirpation of affected hemivertebra with adjacent intervertebral disks was performed in all children as well as the correction of congenital spine deformity by a multi-supporting transpedicular implant system, anterior interbody fusion and posterior spine fusion by auto bone graft to create a bone block between removed hemivertebra and adjacent intact vertebrae.

Multi-slice spiral computed tomography (MSCT) examination was used in 10 patients with congenital spine deformities was used for 3D modeling as well as surgery planning software PME Planner (Polygon Medical Engineering) which allows to identify dimensions and optimal positioning of TS inserted into the vertebrae. 3D models of guiding templates (GT) were created given the virtually planned screws in specified positioning

and feature of dorsal bone structures of involved vertebrae (Fig.1).

3D printer Formlabs Form 2 (SLA technology) was used for printing of guiding templates for insertion of TS into the vertebrae (Fig. 2).

3D printer PICASO DESINGER PRO250 (FDM technology) was used for prototyping of vertebrae in the fixation zone. Then guiding templates were placed on dorsal surface of the printed plastic model of the vertebra, 2,5mm drill bit was used for forming the holes at specified direction through pedicle into the vertebral body. Standard transpedicular support implants of 3.5 mm in diameter were inserted into the holes and then accuracy of TS positioning was visually checked (Fig. 3).

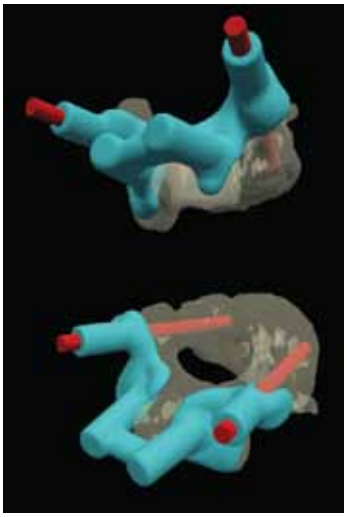

Fig. 1. Virtual screws and navigation templates planning within the PME Planner software environment

Fig. 2. Navigation templates for pedicle screws placement in vertebrae plastic models

Fig. 3. Vertebra plastic model with pedicle screws placed with the use of navigation templates

MSCT examination in postoperative period was used to assess the positioning accuracy of inserted TS in patients of group 1 (*in vivo*).

MSCT was also used to assess accuracy of positioning of support elements in group 2 (*in vitro*) which consisted of 27 plastic vertebra models with TS inserted using navigation templates.

Accuracy of insertion of transpedicular support implants was assessed by the scale suggested by S.D. Gertzbein et al, wherein:

– Grade 0 (full correct) — screw is placed fully intrapedicularly without any contacts with adjacent soft tissues;

– Grade I — < 2 mm implant displacement in relation to pedicle cortex;

– Grade II — 2-4 mm implant displacement;

– Grade III — > 4 mm implant displacement [14].

SLIM+V pattern was used for comparative analysis of accuracy of TS insertion into the vertebrae by free-hand technique *in vivo* and into plastic models of vertebrae using guiding templates *in vitro*. SLIM+V reads as follows: SLIM — identifies screw placement in relation to the pedicle walls: S (superior) - cranial pedicle wall, L (lateral) — outer pedicle wall, I (inferior) — caudal pedicle wall, M (medial) — inner pedicle wall. Second part of the abbreviation, V (vertebral body), represents the evaluation of TS placement in relation to anterolateral surface of the vertebral body [15].

Statistical analysis

Statistical analysis was made in the STATISTICA 10 software. Normalcy of distribution of obtained values was verified by descriptive statistics (histogrammic analysis), the data was described as Me (mi-max). Significance level of differences was evaluated by non-parametrical Mann Whitney U-test (results were considered statistically significant with $p<0.05$).

Results

Results of MSCT research of anatomical and anthropometrical features of vertebrae in thoracolumbar transition and in lumbar spine in children with congenital kyphoscoliosis along with vertebral malformation are demonstrated in table 1.

Obtained anatomical and anthropometrical data on vertebrae in thoracolumbar transition and lumbar spine in children with congenital kyphoscoliosis and vertebral malformation were taken into account during planning of guiding templates for insertion of TS into plastic models of vertebrae. It should be noted that parameters of lumbar vertebrae in children with isolated lumbar hemivertebrae in general were similar to parameters of lumbar vertebrae in toddlers and children of younger age without any spine pathologies [16].

Evaluation data of accuracy of TS positioning by free-hand technique in group 1 are presented in table 2.

Table 1

Anatomical and anthropometric parameters of vertebrae in thoracolumar transition and in lumbar spine

Vert.	Right				Left			
	W	H	L	A	W	H	L	A
Th10	6,0 (5,7; 6,3)	10,3 (10,1; 10,5)	31,6 (29,9; 33,2)	11,5 (10,3; 12,7)	5,9 (5,7; 6,0)	9,8 (9,2; 10,4)	30,5 (30,0; 31,0)	12,9 (10,5; 15,3)
Th11	5,6 (4,5; 6,6)	10,0 (8,6; 10,9)	31,4 (29,7; 34,9)	11,6 (5,7; 17,6)	5,6 (4,0; 6,5)	9,8 (9,0; 11,4)	32,8 (31,2; 35,2)	13,2 (10,2; 16,5)
Th12	5,3 (4,9; 7,9)	9,8 (9,4; 11,0)	31,9 (30,5; 35,4)	12,1 (7,7; 18,1)	5,6 (3,7; 8,3)	10,0 (8,7; 11,4)	32,9 (30,2; 35,1)	12,3 (8,8; 15,7)
Th13	6,0 (5,7; 6,9)	10,4 (9,1; 11,4)	33,1 (30,5; 33,3)	10,7 (10,5; 11,6)	6,2 (5,8; 6,5)	9,7 (9,6; 10,1)	34,1 (32,1; 34,7)	12,7 (11,4; 15,0)
L1	5,7 (4,6; 8,9)	9,9 (7,2; 10,8)	32,7 (31,3; 36,8)	12,0 (8,2; 13,6)	5,3 (3,9; 6,1)	9,5 (7,8; 10,6)	32,6 (26,2; 36,2)	12,1 (4,6; 16,3)
L2	5,8 (4,1; 7,7)	8,7 (7,1; 11,0)	34,0 (30,0; 36,2)	11,5 (9,7; 23,0)	5,8 (4,5; 7,4)	9,2 (7,4; 10,6)	34,0 (31,8; 39,8)	16,2 (13,2; 20,2)
L3	6,5 (4,3; 7,9)	9,4 (6,8; 10,8)	33,0 (28,6; 39,5)	14,7 (11,8; 25,4)	5,7 (3,7; 7,6)	9,4 (0,1; 11,6)	33,6 (31,9; 40,4)	15,2 (11,5; 24,2)
L4	6,8 (5,4; 12,4)	9,0 (6,0; 9,7)	34,5 (28,4; 37,9)	17,0 (7,8; 26,0)	7,0 (4,1; 9,8)	9,3 (6,8; 10,3)	35,0 (32,2; 39,3)	15,8 (14,4; 23,1)
L5	9,1 (7,2; 11,9)	7,7 (6,0; 9,1)	32,8 (29,3; 35,3)	23,7 (13,5; 41,2)	7,8 (5,5; 10,4)	8,4 (7,0; 10,5)	33,7 (32,5; 37,8)	18,5 (12,2; 28,7)
L6	11,1 (9,5; 13,7)	6,9 (5,3; 10,0)	34,2 (30,3; 35,5)	31,2 (19,6; 41,5)	8,4 (7,0; 11,9)	7,4 (4,2; 7,8)	34,0 (27,2; 35,7)	29,8 (19,4; 40,7)
L7	10,3	6,9	31,1	36,0	13,3	7,1	33,4	32,1

V — vertebra; W — width of pedicle base; H — height of pedicle base; L — length of screw hole; A — pedicle angle in axial plane. Data is presented as median, Me (min-max).

Table 2

TS positioning accuracy in group I (*in vivo*)

UO	Vert.	Th10	Th11	Th12	Th13	L1	L2	L3	L4	L5	L6	L7
1	Dex	–	–	V2	N	V3	HV	V3	–	–	–	–
	Sin	–	–	0	N	0		0	–	–	–	–
2	Dex	–	–	–	–	–	0	HV	V1	–	–	–
	Sin	–	–	–	–	–	L2, V3		0	–	–	–
3	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		V1	–	–	–
4	Dex	–	–	0	V2	HV	0	–	–	–	–	–
	Sin	–	–	V1	V1		0	–	–	–	–	–
5	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	V2	N	NS		NS	–	–	–	–
6	Dex	–	–	–	–	–	–	–	–	V3	HV	V3
	Sin	–	–	–	–	–	–	–	–	I2		0
7	Dex	–	–	–	0	0	HV	M1	–	–	–	–
	Sin	–	–	–	V2	V1		0	–	–	–	–
8	Dex	0	0	HV	0	–	–	–	–	–	–	–
	Sin	V1	L1, V1		V1	–	–	–	–	–	–	–
9	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
10	Dex	–	L1	L1	N	HV	0	–	–	–	–	–
	Sin	–	L1	L1, V2	N		0	–	–	–	–	–
TScrew		2	4	10	8	5	10	5	4	2	0	2
Mal		1	3	5	5	2	1	2	2	2	0	1

UO — case; Vert. — vertebra; Dex — screws inserted on the right side; Sin — screws inserted on the left side; T screw — total number of screws inserted into vertebra; Mal — malpositioned screws; HV — hemivertebra; N — vertebra at reported order number is absent; "-" — vertebrae no included into interbody fusion; NS — no screws in the zone of interbody fusion. SLIM+V: S — superior, L — lateral, I — inferior, M — medial walls of pedicle; V — vertebral body (0, 1, 2, 3 — screw malposition by grade of displacement).

The total number of transpedicular support implants inserted in the group 1 was 52 screws. Correct placement of screws in relation to bony structure of fixed vertebrae generally was observed in 53.8% of cases (28 screws), screws malpositioning was observed in 46.2% of cases (24 transpedicular support implants) during analysis of postoperative spine MSCT. Grade I screws displacement was reported in 25% of cases (13 screws), Grade II — in 11.6% of cases (6 screws), Grade III — in 9.6% of cases (5 screws). V type displacement prevailed — 69.2% (18 cases), L type displacement — 23.1% (6 cases), I and M type displacements — 3.85% (one case of each). Screws displacement of Grade 0 + Grade I was 78.8% (41 screws) (Fig. 4).

Evaluation data on positioning accuracy of TS inserted by guiding templates is presented in table 3.

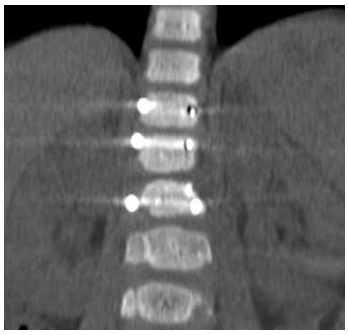

Fig. 4. MSCT of the spine of a patient with congenital kyphoscoliosis following the posterolateral L2 hemivertebra resection, pedicle screw malposition: Th12 vertebra — V2 (vertebral body, Grade II), L1 and L3 vertebrae — V3 (vertebral body, Grade III)

Table 3

TS positioning accuracy in group 2 (*in vitro*)

UO	Vert.	Th10	Th11	Th12	Th13	L1	L2	L3	L4	L5	L6	L7
1	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	V2	N	0		0	–	–	–	–
2	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		0	–	–	–
3	Dex	–	–	–	–	–	0	HV	0	–	–	–
	Sin	–	–	–	–	–	0		0	–	–	–
4	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
5	Dex	–	–	0	N	0	HV	0	–	–	–	–
	Sin	–	–	0	N	0**		0**	–	–	–	–
6	Dex	–	–	–	–	–	–	–	–	0	HV	0
	Sin	–	–	–	–	–	–	–	–	0		0
7	Dex	–	–	–	0	0	HV	0	–	–	–	–
	Sin	–	–	–	V2	0		0	–	–	–	–
8	Dex	0	0	HV	0	–	–	–	–	–	–	–
	Sin	0	L1		0	–	–	–	–	–	–	–
9	Dex	–	–	0	0	HV	0	–	–	–	–	–
	Sin	–	–	0	0		0	–	–	–	–	–
10	Dex	–	0	0	N	HV	0	–	–	–	–	–
	Sin	–	0	0	N		0	–	–	–	–	–
TScrew		2	4	10	8	6**	10	6**	4	2	0	2
Mal		0	1	1	1	0	0	0	0	0	0	0

UO — case; Vert. — vertebra; Dex — screws inserted on the right side; Sin — screws inserted on the left side; Tscrew — total number of screws inserted into vertebra; Mal — malpositioned screws; HV — hemivertebra; N — vertebra at reported order number is absent; "-" — vertebrae no included into interbody fusion; ** — additional screws inserted in the group 2. SLIM+V: S — superior, L — lateral, I — inferior, M — medial walls of pedicle; V — vertebral body (0, 1, 2, 3 — screw malposition by grade of displacement).

Total number of TS placed in the group 2 was 54 screws. Accurate screw positioning in relation to the structure of plastic vertebral models generally was reported in 94.4% of cases (51 screws), malpositioning was observed in 5.6% of cases (3 screws) during the analysis of MSCT examination. Grade II displacement was reported in 2 out of 3 malpositioned screws (3.7%), and Grade I — in one screw (1.9%). L type displacement was reported in 1 case, type V — in other two cases. Number of screws with displacement of Grade 0 + Grade 1 amounted to 52 (96.3%) (Fig. 5).

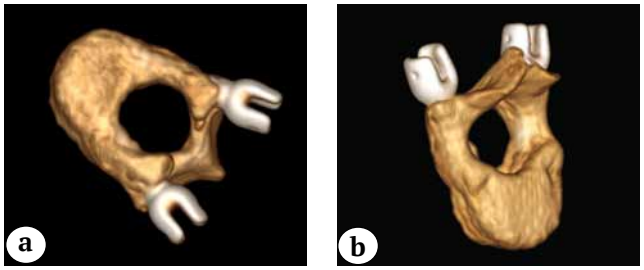

Fig. 5. 3D MSCT scan of the vertebra plastic model of a patient with congenital kyphoscoliosis with pedicle screws placed with the use of navigation templates, the position of the screws is completely successful:
a — top view;
b — bottom view

Thus, comparative analysis demonstrated that in group 2 the number of malpositioned TS inserted by guiding templates was significantly less (5.6%) vs the number of malpositioned TS inserted by free-hand technique in group 2 (46.2%, p = 0,011).

Discussion

While analyzing the current literature on guiding templates use for holes formation and insertion of TS *in vitro* it was observed that there are studies where authors evaluate the efficiency of guiding templates for TS insertion into cervical spine [17–20], thoracic spine [21, 22] and lumbar spine [23-26]. There are also publications with analysis of positioning accuracy for TS inserted by guiding templates in thoracic as well as in lumbar spine [18, 27, 28].

Some authors conducted cadaveric research including MSCT examination of vertebrae specimen with computer processing of obtained data and further 3D printing of guiding templates and their testing on cadavers [17–19, 22–24, 27]. There are research wherein transpedicular screws were inserted by guiding templates into plastic vertebra models obtained during MSCT examination of patients with intact spine [25]. Authors of some publication first created a plastic vertebra model based on MSCT data of cadaveric specimen, tested the method and guiding templates design and then inserted TS into vertebrae of study material [20, 21].

According to the data of conducted research, in general, from 4 to 240 screws (646 screws in total) were inserted by guiding templates *in vitro* [17–28].

TS positioning accuracy per grade of displacement, according to literature, was: Grade 0 — from 58.3% up to 97.6%, Grade I — from 2.4% to 39.5%, Grade II — 8.7%, Grade 0 + Grade I — from 91.3% to 100%. Screws malpositioning of Grade III displacement was not observed [17, 21, 27, 28]. Authors of research without TS malpositioning analysis by displacement grade report placement accuracy from 71.7% to 100% (mean of 96%) [18–20, 22–26].

Authors of some research conducted a comparative analysis of positioning accuracy for TS inserted by free-hand technique and using guiding templates. Placement accuracy after use of guiding templates was from 97.9 up to 100%, by free-hand technique — from 81.3 to 89.2% (p<0,05) [21, 26, 28].

Material of the most research was vertebra specimen of cadavers over 18 years [17–25, 27, 28]. The authors of the present paper identified only one cadaveric study with analysis of guiding templates use in lumbar spine in children from 6 to 13 years old. In that study 10 guiding templates were produced and used for insertion of 20 screws into lumbar

spine; no malpositioning of transpedicular screws was reported [26].

When analyzing publications on guiding templates use for TS insertion *in vivo* the authors of the present paper noted that the majority of papers cover issues of screw fixation in cervical spine [10, 29–36]. Such focus on cervical spine is conditioned by its anatomical features (small dimensions of pedicle, vicinity of spinal arteries) that require high precision and accuracy in screws insertion. Some authors analyzed the use of guiding templates in cervical spine in general including both atlantoaxial segment and subaxial cervical spine [10, 29, 30]. Other authors elaborated on such technique for insertion of screws with different fixation methods only in atlantoaxial segment [31–35]. There are some papers covering the use of guiding templates in subaxial cervical spine [36].

There is some research in literature specifically dedicated to the aspect of guiding templates use for TS insertion in thoracic [11, 37—40] and lumbar spine [12, 41, 42]. Some authors reported studies where positioning accuracy is analyzed by TS inserted by guiding templates both in thoracic and in lumbar spine [13, 43] (table 5).

Majority of publications reflect that research design consisted of preliminary testing of constructive features of guiding template form and insertion of TS into plastic vertebra models obtained by prototyping based on MSCT spine data of the patients, and further evaluation of screws positioning accuracy in prototyped spine segments. The second stage included surgical procedure where screws were inserted by guiding templates *in vivo* and positioning accuracy in relation to vertebral bony structure was evaluated [10, 11, 13, 29, 30, 32, 33, 35–38, 42]. In some research prototypes of plaster cast were used instead of plastic models [39]. Some authors tested the insertion technique and constructive features of guiding templates during cadaveric studies prior to surgical interventions [12, 31]. Some authors inserted TS by guiding templates directly *in vivo* during surgery without a prior stage of prototyping of operated spine segment [34, 40, 41, 43].

According to literature, guiding templates were used for insertion overall from 6 to 582 screws in conducted *in vivo* research (2323 screws in total) [10–13, 29–43].

Analysis of distribution of TS positioning accuracy according to displacement grade provided the following results: TS positioning of Grade 0 constituted from 80.7% to 98.4% (mean 92.2%), Grade I — from 1.4% to 15.9% (mean — 6.8%), Grade II — from 0.2% to 4.0% (mean — 2.7%), Grade 0 + Grade I — from 96.1% to 100% (mean — 98.8%). Grade III screws malpositioning was not reported [10, 13, 29, 34, 36, 37, 39–41, 43]. The papers where authors analyzed TS malpositioning only by its presence without evaluation of displacement grade, accurate screws positioning constituted from 96.1% up to 100% (mean — 99,4%) [11, 12, 30–33, 35, 38, 42].

Some research reported comparative analysis of positioning accuracy for TS inserted by free-hand technique and by guiding templates. The correct TS positioning (Grade 0) inserted by guiding templates was observed in 92.6% to 96% of cases, by free-hand technique — from 75% to 88.8% of cases. Cumulative percentage of TS with displacement of Grade 0 + Grade I in group of guiding templates was from 96,7% to 100% and was significantly higher ($p<0.05$) than the cumulative percentage of TS inserted by free-hand technique with displacement of Grade 0 + Grade I in the range of 86.9% to 98.1% [34, 40, 41, 43].

The greater part of studies on the guiding templates use in the clinical practice concerns the patients of older age (mean of 51.5 years) suffering such spine pathologies as degenerative and dystrophic diseases, rheumatoid arthritis, atlantoaxial instability along craniovertebral malformation, injuries and metastases in the spine [10–12, 29, 31–36, 38, 41, 42].

Significantly less publications are dedicated to the use of guiding templates in children. Majority of those provide data on the guiding templates use for surgical treatment of spine deformities in cases of idiopathic scoliosis, systemic and congenital scoliosis in children of older age [13, 30, 37, 39, 40, 43].

The authors of the present paper note that during analysis of literature no papers were found which would be dedicated to the use of guiding templates for TS insertion in toddlers with congenital scoliosis.

Thus, when collating literature data with own research the authors of the present paper observed a rather high accuracy of TS positioning using guiding templates both *in vitro* (Grade 0+I — 91.3–100%) and *in vivo* (Grade 0+I — 96.1–100%) which conforms with obtained value of TS positioning accuracy in group 2 (*in vitro*) of the present study — Grade 0+I — 96.3%. Accuracy of TS positioning by free-hand technique in group 1 (Grade 0+I — 78,8%) was similar to the literature data on comparative analysis of positioning accuracy of TS inserted by guiding templates and by free-hand technique (Grade 0+I: 96.7% — 100% against 86.9% — 98.1%).

The authors did not find any papers of the same research design which is presented in the current paper. The advantage of this design is the possibility to conduct a comparative analysis of positioning accuracy of already inserted TS in patients by free-hand technique with the potential of guiding templates use and their impact on TS positioning accuracy in plastic models of vertebrae of the same patients. Thus, apart from significantly higher accuracy of TS positioning in group 2 (*in vitro*) of the current study in comparison with group 1 (*in vitro*) the authors also managed to insert a bigger number of TS by guiding templates.

Obtained results look promising and allow to consider the option on further research dedicated to the use of guiding templates for TS insertion in surgical treatment of congenital spine deformities in patients of younger age.

Conclusion

The number of correctly placed TS into the plastic vertebral models of children with congenital deformities of thoracolumbar and lumbar spine using guiding templates was significantly higher than the number of correctly placed screws by free-hand technique (96.3% vs 78.8%, p = 0,011).

The results of guiding templates use in vitro demonstrated a high accuracy for TS placement which opens perspectives for use of such navigation in clinical practice in children of young age with congenital scoliosis.

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INFORMATION ABOUT AUTHORS:

Dmitriy N. Kokushin — Cand. Sci. (Med.), senior research associate, Department of Spinal Pathology and Neurosurgery, Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

Sergei V. Vissarionov — Dr. Sci. (Med.), professor, deputy director, Research and Academic Affairs, head of the Department of Spinal Pathology and Neurosurgery, Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

Alexei G. Baindurashvili — Dr. Sci. (Med.), professor, member of RAS, director of Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

Alla V. Ovechkina — Cand. Sci. (Med.), associate professor, scientific secretary, Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

Makhmud S. Poznovich — research associate, Genetic Laboratory of the Center for Rare and Hereditary Diseases in Children, Turner Scientific and Research Institute for Children's Orthopedics, St. Petersburg, Russian Federation

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Surgical Hip Dislocation Technique in Treatment of Patients with Slipped Capital Femoral Epiphysis

P.S. Vvedenskiy, N.A. Tenilin, M.V. Vlasov, A.B. Bogosyan, A.V. Novikov

Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Abstract

Purpose: to evaluate the efficiency of modified Dunn procedure for treatment of severe slipped capital femoral epiphysis. ***Materials and Methods.*** The authors used the modified Dunn procedure for treatment of 6 patients with SCFE aged from 10 to 13 years and displacement degree over 55°. Chronic disease form was reported in one patient, acute displacement along the chronic process was reported in 5 patients. All patients had a stable form of SCFE by Loder classification. Surgical procedure was performed within 6 to 12 months from the onset of disease. ***Results.*** Normal anatomical relations in the hip joint were restored in all patients. During follow up from 18 until 48 months the patients did not demonstrate aseptic femoral head necrosis or chondrolysis. Adolescents did not complain on pain or hip motion limitations. Treatment outcomes assessment by Harris hip score was 97 points. ***Conclusion.*** Based on outcomes of the modified Dunn procedure the authors conclude that the method provides for complete restoration of the anatomical relations between femoral neck and epiphysis and, thus, the hip joint biomechanics. Femur dislocation allows to form an extended flap to ensure epiphysis perfusion which improves overall blood supply in the femoral head and consequently decreases the risk of aseptic necrosis and chondrolysis.

Keywords: juvenile slipped capital femoral epiphysis, surgical hip dislocation, open reduction of epiphysis, femoral head necrosis.

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Introduction

The choice of surgical technique for treatment of patients with juvenile slipped capital femoral epiphysis (SCFE) with significant degree of epiphysis displacement remains a pressing issue. Advocates of extra-articular correction, namely, intertrochanteric and higher corrective osteotomies speak for avoidance of intervention into the deformity area not to aggravate the critical level of epiphysis perfusion [1–4]. However, performance of extra-articular osteotomies with three-plane reorientation of proximal femur does not always provide for achievement of correct placement of epiphysis in acetabulum [5]. Impingement syndrome developing at this stage leads to early coxarthrosis and later to a complicated hip arthroplasty due to significant alterations in proximal femur anatomy [6].

Advocates of intra-articular correction — open alignment of epiphysis or corrective osteotomy of femoral neck — speak for maximally possible restoration of anatomy and

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✉ *Petr S. Vvedenskiy*; e-mail: petr_v@mail.ru

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biomechanics of the hip joint. However, intra-articular procedure poses a high risk of damaging the epiphysis perfusion with further development of aseptic head necrosis and chondrolysis.

In the last century the open reduction of epiphysis or corrective osteotomy of the femoral neck resulted in aseptic necrosis of femoral neck or chondrolysis in up to 100% of cases [7-19]. A significant breakthrough in this area was achieved by a technique of an open epiphysis reduction proposed by English surgeon Dunn in 1964 who described 63 cases of its application [20, 21].

The key aspect of Dunn procedure is formation of a feeding flap from periosteum of femoral neck by its accurate detachment from the bone. Periosteum of femoral neck on the posteromedial surface contains ascending branches of medial circumflex femoral artery which mainly ensure perfusion of femoral epiphysis. Dunn reported that aseptic necrosis and chondrolysis rate was decreased up to 10% in cases of chronical epiphyseolysis and up to 30% in acute epiphyseolysis along the chronical disease [21].

Russian surgeons A.R. Pulatov and V.V. Mineev in 2010 proposed a method of intra-articular correction of femoral epiphysis positioning in cases of juvenile SCFE (patent of Russian Federation 2405489). The method consists of a wedge resection of femoral neck along anterolateral surface with preservation of ascending branches of the medial circumflex femoral artery on the posterior surface. The authors of this method used the technique in 18 patients and reported that aseptic necrosis of the femoral head developed in 16% [22]. A disadvantage of proposed technique is the failure to gain full correction of deformity.

M. Leunig et al in 2007 proposed a modified Dunn technique of open reduction for femoral epiphysis and described treatment outcomes obtained in 30 clinical cases [23]. The key distinction of proposed procedure is the use of surgical femur dislocation which ensures free access to epiphysis, to femoral neck and allows to form an extended perfusion flap from periosteum of femoral neck and distally from periosteum, posterior capsule elements, piriformis muscle. This allows to prevent critical damage to perfusion of femoral epiphysis. The clinic at Bern University which originated the technique reported 2% rate of above mentioned complications [24].

Purpose of the study — to evaluate the efficiency of modified Dunn procedure for treatment of severe juvenile slipped capital femoral epiphysis.

Materials and Methods

The authors used the modified Dunn procedure for treatment of 6 patients with SCFE, aged from 10 to 13 years and displacement degree over 55°. Chronic disease form was reported in one patient, acute displacement along the chronic process was reported in 5 patients. All patients had a stable form of SCFE by Loder classification.

Procedure was performed within 6 to 12 months from the onset of disease in accordance with technique described by M. Leunig et al [23]. With patient in a lateral positioning the authors made a linear incision on lateral femur, dissected *tractus iliotibialis*, detached the greater trochanter with its mobilization and anterior abduction together with attached *m. vastus lateralis, m. gluteus medius* and *m. gluteus minimus*. Hip joint capsule was approached in the interval between *m. gluteus minimus* and *m. piriformis* through a Z-form capsulotomy. Lig. teres was detached and femoral head was dislocated. A control hole of 2 mm in diameter was made in anterior lateral quadrant of epiphysis to visualize epiphysis perfusion. Then femoral head was reduced into the acetabulum, and synovial flap was formed. Synovium was dissected on femoral neck and detached along anterior and posterior surfaces with detachment of posterior fragment of the greater trochanter and detachment of rotator tendons from their attach-

ment to the femur. After secondary femur dislocation epiphysis was separated from femoral neck with periosteum detachment along its posterior and medial surfaces. The newly formed callus was removed from the posterior surface of femoral neck (Fig.1).

After reduction the epiphysis was fixed by threaded wires of 2,5mm in diameter. Special attention was given to avoid strain and twisting of the flap after reduction and fixation of epiphysis. Status of perfusion was controlled through a preliminary formed hole in femoral epiphysis. When procedure technique is observed blood loss from control hole in the femoral head continues during the whole surgery or is resumed after reduction and fixation of epiphysis to the femoral neck.

Upon completion of procedure the authors performed suturing of periosteum, capsule, screw fixation of the greater trochanter, suturing of *tractus iliotibialis* and skin.

Rehabilitation was started next day after surgery including passive motions in hip joint on Artromot system under prolonged epidural anesthesia. Weight load on the operated limb was allowed 6 months postoperatively.

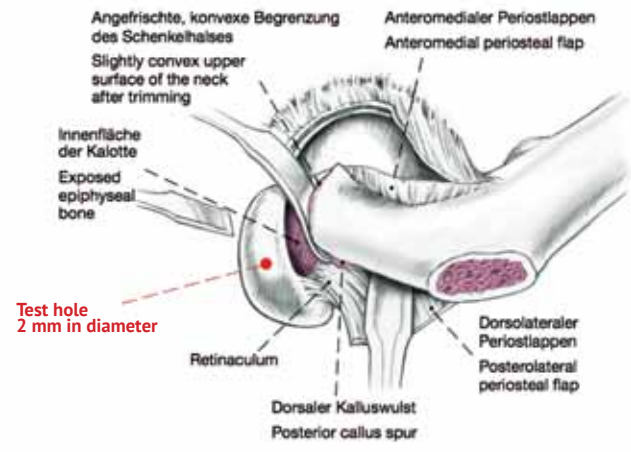

Fig. 1. Separation of femoral epiphysis, formation of the flap – detachment of periosteum from posterior and medial surfaces of femoral neck (Figure from article of M. Leunig et al (2007), was modified upon consent of the authors)

Results

Evaluation of treatment outcomes was made in the period from 18 months to 4 years after the surgery (Table).

Active motion in hip joints was restored in terms from 2 to 3 weeks after the surgery and continued almost with full range during the whole follow up period. During examination of patients a barely noticeable limping was observed. Shortening of affected limb was up to 1 cm. The patients did not complain of pain or hip motion limitations. No aseptic necrosis or chondrolysis of the femoral head was observed. X-rays of three patients at follow up of 3 and 4 years demonstrated dystrophic changes corresponding to coxarthrosis of grade 1 manifesting by irregular joint gap and subchondral sclerosis of acetabulum. Harris hip score was 97 points in patients with and without roentgenological signs of dystrophy.

The clinical case is presented below. Female patient of 10 year old. Hip joint pain and limping manifested in July 2014. Outpatient clinic diagnosed osteochondropathy of the femoral head. The authors diagnosed a chronic juvenile slipped capital femoral epiphysis of the left femur. Roentgenography and computer tomography (Fig. 2) were used to confirm epiphysis displacement at 90°.

The patient underwent an open reduction of epiphysis according to modified Dunn procedure 11 months after the onset of disease, in August of 2015 (Fig. 3).

Table

Treatment outcomes

Patient, age, gender	Form of SCFE	Displacement degree of epiphysis, °	Follow up after the surgery, months	Pain syndrome	Range of motion in hip joint, °	Dystrophic changes	Harris Hip Score
13 y.o., m	O+X	87	48	No	S — 10/0/135, F — 40/0/30, H — 45/0/20	Moderate	97
10 y.o., f	O+X	90	30	No	S — 10/0/135, F — 50/0/30, H — 45/0/35	No	97
13 y.o., f	O+X	65	18	No	S — 5/0/120, F — 30/0/20, H — 25/0/20	Moderate	97
12 y.o., f	X	55	32	No	S — 10/0/140, F — 50/0/30, H — 45/0/30	No	97
13 y.o., f	O+X	60	27	No	S –0/0/120, F — 30/0/20, H — 25/0/20	Moderate	97
13 y.o., f	O+X	80	36	No	S — 10/0/135, F — 40/0/30, H — 45/0/20	No	97

X — chronic form of SCFE; O+X — acute situation along chronic form of SCFE.

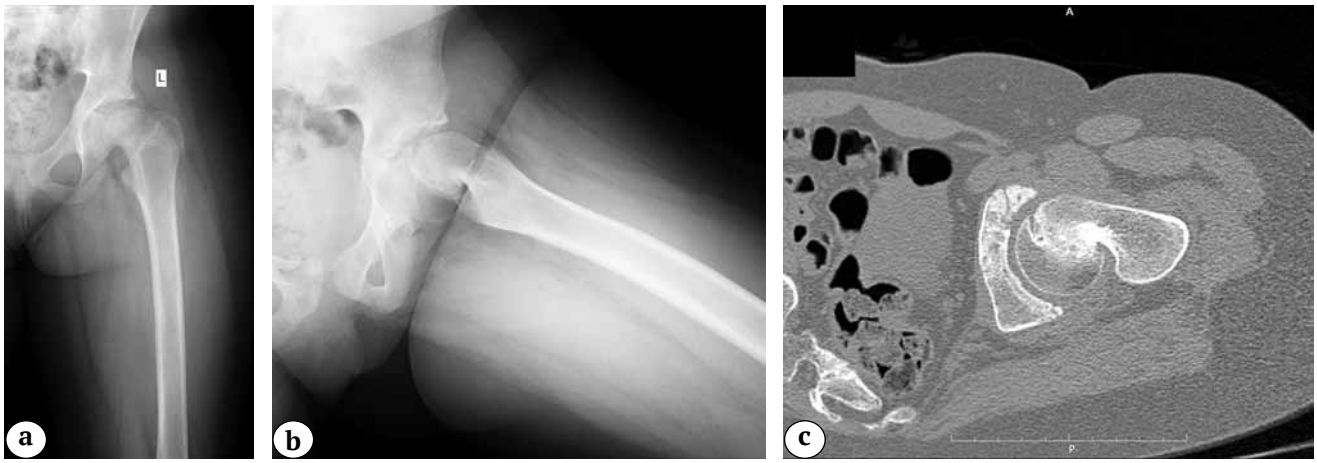

Fig. 2. X-rays of hip of female patient 10 y. o., prior to surgical treatment:
a — straight AP view;
b — Lauenstein position: epiphysis displacement at 90°;
c — computer tomography

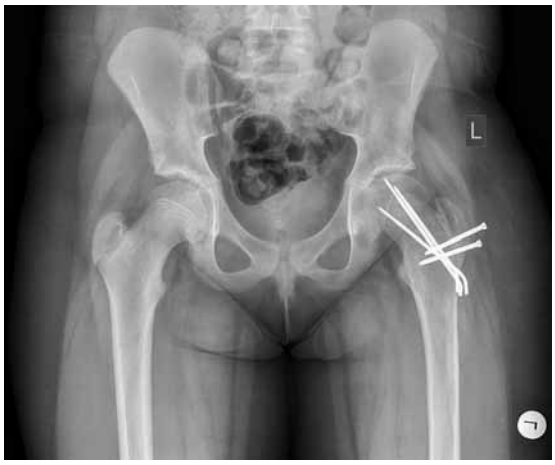

Fig. 3. X-ray of hip joints, female patient, after surgery: restored anatomical relations of epiphysis and femoral neck

Full range of active motion in hip joint was restored in 2 weeks after surgery. The patient was discharged for outpatient follow up in 3 weeks postoperatively. Healing was achieved in 5 months and weight load on the limb was allowed. Threaded wires were removed in one year postoperatively. At control examination in 3 years X-rays demonstrated correct position of femoral epiphysis without dystrophic changes (Fig. 4).

The patient has an active lifestyle and no complaints with full range of motion in the joint.

Discussion

Outcomes of modified Dunn procedure in the authors' clinic for treatment of patients with SCFE were quite promising.

In treatment of patients with severe epiphysis displacement of chronic and acute forms the authors did not observe development of aseptic necrosis of femoral head or chondrolysis. On the one hand, absence of such serious complications is due to rather accurate reproduction of surgical technique, on the other hand, probably, by a small number of cases.

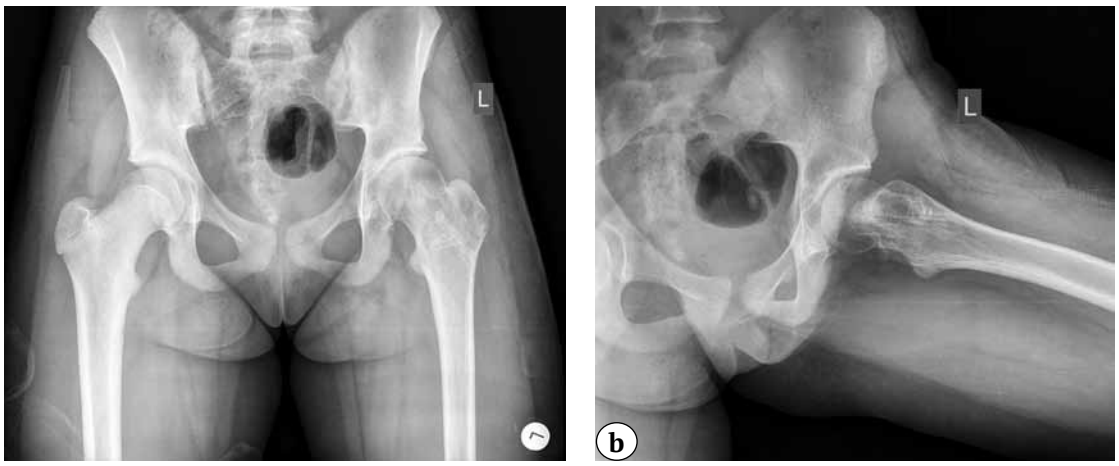

Fig. 4. X-rays of hip joint of female patient, 3 years after surgery in AP view (a) and in Lauenstein position (b): correct positioning of femoral epiphysis, no dystrophic changes

According to literature the rate of aseptic necrosis and chondrolysis constitutes from 0 to 26%. The lowest rate is reported by orthopaedic clinic of Bern university where the present procedure was developed and initially used, however, with increased number of procedures (from 30 to 43) the rate of aseptic necrosis also increased from 0 to 4% [25, 26, 27].

As the present technique is being spread and reproduced in other orthopaedic centers the rate of aseptic necrosis has increased up to 6–26% [28–34]. Such variations are probably related to severity and pattern of displacement, time elapsed from disease onset, as well as to technical features of procedure, the need for precise fulfillment of all manipulations in a confined space. V. Upasani in his research observed a clear inverse proportion between a surgeon's experience (number and frequency of performed procedures) and rate of complications [30].

Conclusion

A modified Dunn procedure provides for complete restoration of anatomical relations between femoral neck and epiphysis and, thus, of the hip joint biomechanics. Femur dislocation allows to form an extended flap to perfuse epiphysis which significantly improves blood supply to femoral head and decreases the risk of aseptic necrosis and chondrolysis.

Considering the world experience and own cases the authors make a conclusion that use of modified Dunn procedure can currently be the method of choice for treatment of patients with severe juvenile SCFE, however, relatively small number of performed interventions require further research.

All patients (their lawful representatives — parents) gave willful consent to examination, treatment, research analysis and publishing of outcomes in scientific literature.

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INFORMATION ABOUT AUTHORS:

Petr S. Vvedenskiy — Cand. Sci. (Med.), orthopaedic surgeon, Pediatric Orthopaedics Department, University Clinic, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Nikolay A. Tenilin — Dr. Sci. (Med.), leading researcher, Pediatric Orthopaedics Department, University Clinic, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Maxim V. Vlasov — Cand. Sci. (Med.), head of Pediatric Orthopaedics Depatment, University Clinic, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Alexandr B. Bogosyan — Dr. Sci. (Med.), leading researcher, Pediatric Orthopaedics Department, University Clinic, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Alexandr V. Novikov — Dr. Sci. (Med.), chief researcher, Consultation and Rehabilitation Department, University Clinic, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

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Avulsion Fractures Osteosynthesis in Patients with Normal Bone Mineral Density and Osteoporosis

L.B. Reznik [1], V.V. Guryev [2], M.A. Turushev [1], D.A. Negrov [3], R.E. Il'in [4]

[1] *Omsk State Medical University, Omsk, Russian Federation*

[2] *Semashko Road Clinical Hospital at st. Lyublino of Russian Railways, Moscow, Russian Federation*

[3] *Omsk State Technical University, Omsk, Russian Federation*

[4] *Noyabrsk Central City Hospital, Noyabrsk, Russian Federation*

Abstract

Objective: to compare the effectiveness of osteosynthesis for avulsion fractures using bioabsorbable versus titanium implants in patients differing in bone mineral density. ***Materials and Methods.*** In the experimental phase of study, two groups of bone blocks were singled out from patients' femoral heads to assess the anchoring properties of the implant in osteoporotic and healthy bone. The first group included blocks of 31 patients with osteoporosis, the second one — 27 blocks of patients without osteoporosis. In the first group, cortical bioabsorbable Poly-L-Lactic/co-glycolic acid (PLGA) screws were implanted into 13 bone blocks, titanium screws — into 10 bone blocks, and bioabsorbable pins (PLGA) — into 8 bone blocks. In the second group, 10 titanium screws, 10 bioabsorbable screws and 7 bioabsorbable pins were implanted. The anchorage of the implant in bone was evaluated by a pull-out test. Then, depending on the anchorage used, the studied bone blocks with osteoporosis, newly obtained from the first group, were divided into three groups for the purpose of evaluating the resistance to the damaging effects of the implant. In experiment, the osteosynthesis for avulsion fracture was simulated on these bone blocks. In the first group (11 bone blocks), the transosseous osteosynthesis of the bone fragment was carried out with a titanium screw, in the second group (9 bone blocks) with a bioabsobable screw, in the third group (11 bone blocks) with a bioabsorbable pin. The results of osteosynthesis were assessed based on how often a small bone fragment was damaged by an implant and on stability of the anchored implant. In the clinical phase of study, a comparative analysis of 65 surgical interventions (38 people with osteoporosis and 27 without osteoporosis) in patients with avulsion fractures was performed. In 24 cases, bioabsorbable screws were used for osteosynthesis, AO/ASIF titanium screws were used in 31 cases, and pins were used in 10 cases. ***Results.*** Experimental studies showed that the resistance to pull-out test of a bioabsorbable screw anchored in osteoporotic bone is 25.7% higher than a titanium screw. No statistically significant difference was found in bone without osteoporosis. Resistance to pull-out test of a bioabsorbable pin is 3% higher than a titanium screw. The model-based experiment with an avulsion fracture in osteoporotic bone using a titanium screw showed lower effectiveness of osteosynthesis: in 27.2% of cases the cortical titanium screw damaged a small bone fragment. Based on the clinical trial findings, no negative results were obtained using bioabsorbable anchorage. In 12.5% cases of osteosynthesis with a titanium screw, migration of a bone fragment was noted. The data obtained during the clinical study correlated with the experimental data. This makes the use of bioabsorbable implants advantageous. ***Conclusion.*** For avulsion fracture osteosynthesis in patients with normal bone mineral density, it is possible to use both titanium and biodegradable fixators with equivalent strength of fragment fixation. In osteosynthesis of fractures in patients with osteoporosis it is preferable to use bioabsorbable implants.

Keywords: avulsion fractures, osteosynthesis, osteoporosis, bioabsorbable screws, titanium screws, anchoring strength.

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✉ *Mikhail A. Turushev*; e-mail: mturush20@mail.ru

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Introduction

Metal implants made of titanium, tantalum, zirconium, cobalt and steel alloys [1–3] are mainly used for internal fixation of various fractures. Above implants feature certain disadvantages like tissues reaction to metal (metallosis) [4–6], instability [7–9], risk of infection complications [10, 11], implant breakage [12, 13], need for subsequent implants removal and related difficulties [14–16]. Treatment of small fragments fractures often results in unsatisfactory outcomes due to the further splitting of bone fragments during fixation and screws migration [17, 18]. Internal fixation of medial malleolus fractures, hand and foot fractures, shoulder epicondyles fractures and the like in patients with osteoporosis are also challenging due to impossible stable fixation of metal implant in the bone [19–23]. Currently a need for introduction of new internal fixation materials and techniques into the clinical practice is recognized such as bioabsorbable implants made of poly(lactic-co-glycolic) acid (PLGA) [10, 24, 25]. Biophysical features of those implants are maximally similar to the bone tissue parameters and their linear load strength is similar to the metal implants [24, 26]. In contrast to metal implants that create various artifacts the PLGA bioabsorbable implants do not impact visualization of bone regenerate during MRI examination [27]. Enhancement of internal fixation stability in patients with local and systemic osteoporosis when it's impossible to use metal fixations is the key purpose of the present study.

Purpose — to compare the effectiveness of internal fixation of avulsion fractures with bioabsorbable versus titanium implants in patients differing in respect of bone mineral density.

Materials and Methods

The authors conducted an open prospective comparative multicenter study on fixation rigidity of titanium screws and biodegradable implants in the bone of various bone density characteristics. The study was conducted in accordance with requirements of WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects 2013.

Experimental study

The authors simulated internal fixation in the experiment in accordance with theory of avulsion fracture. As the null hypothesis the authors considered a theoretical availability of advantages in case of bioabsorbable implants use for fixation of porotic bone in contrast to titanium implants based on the effect of self-compression of bioabsorbable implants and absence of substantial efforts to obtain fragments adaptation during internal fixation.

Bone blocks of femoral heads of the patients who underwent hip joint arthroplasty were used to evaluate anchor properties of implants.

Obtained bone blocks were divided into two groups: first one included 31 blocks from female patients with osteoporosis, second one — 27 blocks from patients with normal mineral bone density. Osteoporosis diagnosis in patients was confirmed by dual-energy X-ray absorptiometry (DEXA) in the program "femoral neck" in the contralateral joint and lumbar spine with T-criteria ≤-1.5.

Immediately after removal femoral heads were placed into normal saline for the mean term of 2 hours ± 25 minutes at room temperature. Parallelepiped block with length of 5 cm, width 1±0.2 cm and thickness of 0.5±0.2 cm was formed out of the femoral head. The superior pole of the block preserved a cortical layer which approximated the experimental model to the anatomical. To compare implants fixation strength during the experiment the following implants were used: bioabsorbable PLGA screws 3.5 mm in diameter, 40 mm long, with screw pitch of 2 mm and flat head (PLGA pins) as well as titanium self-threading screws 3.5 mm in diameter, 40 mm long, with screw pitch of 2 mm and flat head.

In the first group 13 blocks were fixed with cortex bioabsorbable screws, 10 blocks — with titanium screws, 8 blocks — bioabsorbable pins. For comparison 10 titanium, 10 bioabsorbable screws and 7 bioabsorbable pins were implanted into bone blocks of normal density (T-criteria not exceeding -1 SD). Strength of screw fixation was examined by pull-out test using tensile-testing machine (RM-0,5) designed for tensile testing of materials with breaking load of 500 kgf-m² and speed of 20 mm/min. Sample fixation was done at the screw head and at bone block. Testing was done to evaluate force needed to pull-out the screw from "implant-bone" complex. The data was recorded using force measuring unit calibrated in kilonewton (kN).

Considering the obtained data the authors again harvested bone blocks from femoral bones of 31 female patients of the first group with proven osteoporosis and simulated internal fixation of avulsion fracture. For this purposes cubical bone blocks of 4×4 cm were cut from femoral heads; one of the angles of bone block was cut off in a pyramidal shape with preserved cortex. The size of cut off pyramidal fragment was 1,5 cm³ which corresponded to the model of avulsion fracture (Fig. 1).

The experimental criterial for efficiency of internal fixation was obtaining of stable fragment fixation without its breakage during compression.

The bone blocks in experiment were divided into 3 groups. In the first group (11 bone blocks) internal fixation was performed after preliminary drilling according to AO recommendations [31] by titanium cortex screw with the full thread and in certain cases was accompanied by bone block fragmentation (Fig. 2). In the second group (9 bone blocks) the internal fixation was performed with bioabsorbable screw inserted by dynamometric screwdriver with torque of 0,8 Nm. In the third group (11 bone blocks) internal fixation was done with bioabsorbable pin (Fig. 3).

Fig. 1. Model of avulsion fracture on a cubic bone block

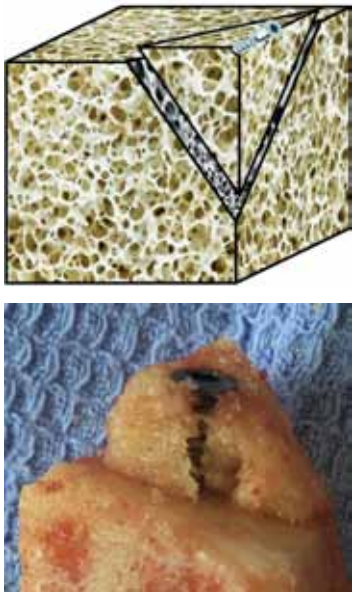

Fig. 2. Osteosynthesis with a metal screw resulted in bone fragmentation

Fig. 3. Schematic representation and model of the fracture osteosynthesis with a bioabsorbable pin

Clinical study

The clinical stage of the study included the outcomes of internal fixation of 65 patients, where 38 patients had a proven osteoporosis (T-criteria not exceeding -2,5 SD) and 27 patients without osteoporosis. The study included patients with avulsion fractures

of 44A1-44A2, 44B2 types by AO classification, where 47 had medial malleolus fractures and 18 — fractures of lateral malleolus below the syndesmosis.

In 24 cases bioabsorbable screws were used for internal fixation, in 15 patients with osteoporosis and in 9 — without osteoporosis. In 31 cases AO/ASIF titanium screws were used: in 16 patients with osteoporosis and in 15 — without osteoporosis. In 10 cases the PLGA pins were used: in 7 patients with osteoporosis and in 3 cases — without osteoporosis. Primarily the evaluation of internal fixation efficiency was performed visually during the surgery. The present study also evaluated the adaptation and integrity of bone fragments. Displacement of bone fragment after fixation, breakage or delayed healing was evaluated in dynamics by X-rays in standard views.

Results

Bench biomechanical testing of cortex titanium screws stability proved that maximal displacement of titanium screw (1.1–1.2 mm) in the bone with decreased mineral density occurs at 0.26 kN, of bioabsorbable screw (1.0–1.1 mm) at 0.36 kN which is at 25.7% higher as compared to titanium screw, t = 0.325, p = 0.749. Migration of bioabsorbable screw occurred gradually with reduction of motion in the interval 1.2–1.3 mm and at force of 0.14 kN. The migration of titanium screw occurred almost in a single step. Test completion at zero force for titanium screw occurred at 1.8 mm displacement and for bioabsorbable screws — at 1.7 mm displacement (Fig. 4).

When evaluating resistance to pull-out force during fracture fixation by titanium screw and PLGA screw in bone blocks without osteoporosis (T-criteria not exceeding -1) the authors did not obtain any statistically significant differences (p<0.05). Pull-out force for maximal displacement of titanium screw from healthy bone (T-criteria ≥-1.5) was 0,44 kN, which was 2.8% higher that for PLGA screw, Student's test = -1.698, p = 0.133 (Fig. 5). Test completion at zero force for titanium screw occurred at 1.8 mm displacement, for bioabsorbable screw — at 1.7 mm.

Comparative studies of pull-out resistance tests for titanium screws and bioabsorbable pins demonstrated that the difference of breaking load for pulling out the pin from porotic bone did not exceed 0.106 kN which is 3% higher than for titanium screw (t = -1.017, p = 0.324) (Fig. 6).

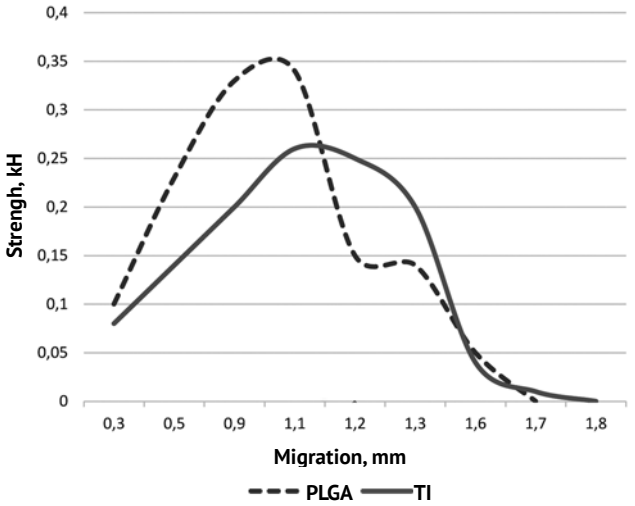

Fig. 4. Breaking strength for the titanium and bioabsorbable screw migration (T-score ≤-1.5 — osteopenia and osteoporosis)

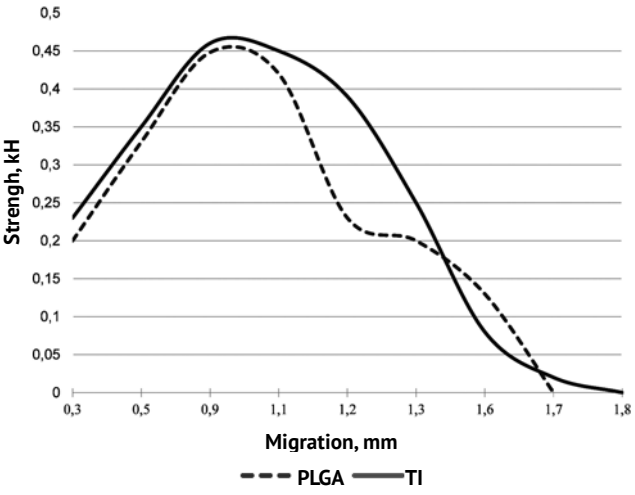

Fig. 5. Breaking strength for the titanium and bioabsorbable screw migration (T-score ≥ -1.5)

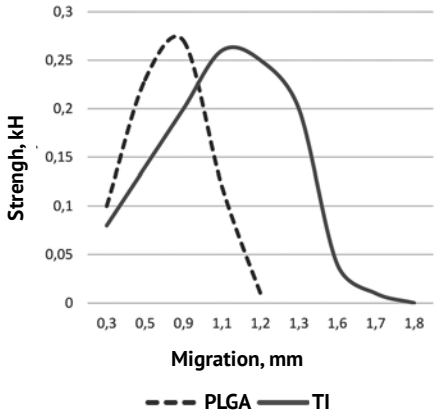

Fig. 6. Breaking strength for the titanium screw and bioabsorbable pin migration
(T-score ≤-1.5 — osteopenia and osteoporosis)

Maximum displacement of titanium screw (1.2–1.3 mm) in the bone with decreased mineral density occurs at force of 0.26 kN, of bioabsorbable screw (0.8–0.9 mm) — at force of 0.28 kN. Pin migration occurred almost in a single step while for titanium screw the process was gradual. Test completion for titanium screw occurred at 1.8 mm displacement, for bioabsorbable pin — at 1.2 mm.

During experiment the authors evaluated the efficiency of internal fixation for avulsion fracture by signs of fragment breakage and observed that in 27.2% (3) cases the cortical titanium screw was breaking the bone fragment (table 1).

Comparative outcomes of various internal fixation techniques in the clinical practice from 2015 to 2017 were evaluated roentgenologically in terms from 2 to 6 weeks postoperatively. When assessing X-rays in terms shorter than 2 weeks posteopratively the primary importance was given to preservation of adaptation and anatomical structure of bone fragments (malleolus).

In terms up to 6 weeks the authors assessed consolidation process and status of screw canal after insertion. Table 2 presents comparative outcomes after various fixation procedures on weaker bones.

Table 1

Efficiency of internal fixation for marginal fragments

Criteria	Implant type		
	titanium screw	bioabsorbable pin	bioabsorbable screw
Number of internal fixation simulations	11 (100%)	10 (100%)	9 (100%)
Breakage of bone fragment	3 (27,2%)	0	0
Stable fixation	8 (72,72%)	10 (100%)	10 (100%)

Table 2

Outcomes of internal fixation of marginal fragments in clinical practice (*n*)

Outcome	Implant type					
	titanium screw		bioabsorbable pin		bioabsorbable screw	
	osteo-porosis	healthy bone	osteo-porosis	healthy bone	osteo-porosis	healthy bone
Stable fixation	12	14	7	3	15	9
Breakage of fragment and Weber fixation procedure	2	1	0	0	0	0
X-ray confirmed pseudarthrosis	1	0	0	0	0	0
Bone fragment displacement after fixation and early screw migration	1	0	0	0	0	0

Clinical studies demonstrate absence of bone fragment splitting and migration of implants in the area of fixed fracture, preservation of fragments adaptation and regeneration in the area of porotic bone fracture (Fig. 7).

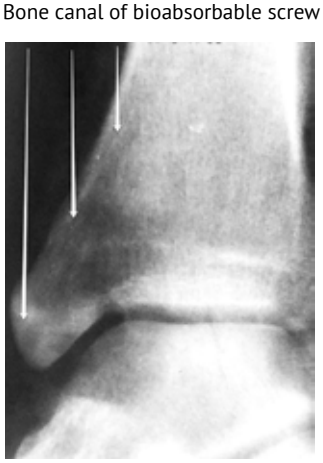

Fig. 7. X-ray of the medial ankle 2 weeks after osteosynthesis with a bioabsorbable screw

The analysis of outcomes after use of metal implants demonstrated risks of fragments breakage and secondary displacement (Fig. 8a) which required revision fixation and another technique — Weber procedure (Fig. 8b).

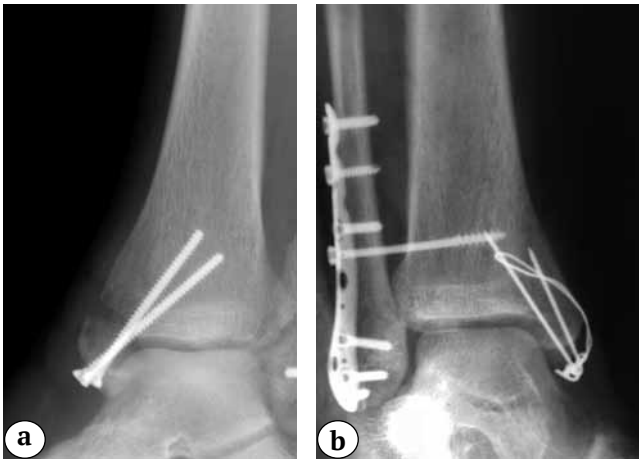

Fig. 8. X-rays of the medial ankle after osteosynthesis with a metal screw:
a — fracture and migration of bone fragment;
b — refixation by Veber in osteoporosis

In 12,5% (2) patients with avulsion malleolar fractures and osteoporosis the authors reported splitting and migration of bone fragment which required revision fixation (χ^2 Pearson df = 1, 1,41, p = 0.23, Mc Nemar χ^2 11.53, p = 0.007).

Discussion

Many authors report a growing number of avulsion malleolar fractures, first of all in elderly patients with low mineral density of bone and small fragments challenging for fixation which worsens surgery outcomes [18, 19]. The important predicting factor of stable fixation is the screw fixation strength in the bone. For 3.5 mm AO titanium screws O.C. Thiele et al demonstrated the dependency of strength fixation in the bone on osteoporosis degree where results of pull-out test for cortical bone decreased from 2500N in patients without osteoporosis to 1300N — with osteoporosis of severe degree [32]. Thus, conventionally applied fixation with screws of various thread types does not justify itself in trauma surgery for treatment of fractures in porotic bone.

Results of pull-out test obtained by authors during bench testing correspond to the data of Y.V. Lartsev et al on multi-stage migration pattern of metal AO screw during mechanical separation of fixed fragments at force of 0.09–0.14 kN [22]. Obtained experimental data on resistance of fixed fragments to pull-out forces after fixation by bioabsorbable screws as compared to titanium screws correlate to data of M.W. Kroeber et al study [33], where properties of bioabsorbable implants were significantly higher in cancellous bone fixation (68.5±3.3 N) versus titanium screws (3±1.4 N, p<0.05). Above allows to conclude about the advantages of bioabsorbable screws for some types of internal fixation. Described advantages of bioabsorbable pins and screws are explained by alterations in bioabsorbable implant size with arising geometry transformation, namely diameter increase with simultaneous shortening due

to molecular hydratation which leads to secure fixation of pins and screws in the bone [26, 28]. Uniplanar force pattern without any rotation during pin insertion into small fragments significantly decreases the risk of their breakage [30, 31].

Small volume of analyzed data is the limitation of performed study. However, the obtained statistically significant results confirm the hypothesis on anchorage insufficiency of metal screw for internal fixation of avulsion malleolar fractures in patients with disturbance of mineral bone density and decrease of fragmentation risk of the already small fragments along with osteoporosis when using bioabsorbable fixators (t = -1.017, p = 0.324). At the same time in the healthy bone the fixation strength of fragments by titanium screws was comparable with parameters of bioabsorbable implants (p = 0.133). The obtained data allows to recommend bioabsorbable pins and screws for internal fixation of porotic bone.

However, bench testing doesn't allow to evaluate comparative dynamics of fixation properties depending on rate of dioabsorption and resistance to various types of mechanical loads, which needs further research.

Conclusion

Metal and bioabsorbable implants can be used for internal fixation of avulsion fractures of 44A1-44A2, 44B2 types by AO classification in cases of normal mineral bone density.

For internal fixation of bones with altered biomechanical properties it's preferential to use bioabsorbable implants while metal fixators can cause splitting and migration of bone fragments. This is confirmed by experimental and clinical stages of the present study.

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INFORMATION ABOUT AUTHORS:

Leonid B. Reznik — Dr. Sci. (Med.), professor, head of the Department Traumatology and Orthopedics, Omsk State Medical University, Omsk, Russian Federation

Vladimir V. Guryev — Dr. Sci. (Med.), professor, head of the Trauma and Orthopedic Department, Semashko Road Clinical Hospital at st. Lyublino of Russian Railways, Moscow, Russian Federation

Mikhail A. Turushev — Cand. Sci. (Med.), assistant, Department Traumatology and Orthopedics, Omsk State Medical University, Omsk, Russian Federation

Dmitrii A. Negrov — Cand. Sci. (Med.), assistant professor, Faculty of Machine Building and Materiology, Omsk State Technical University, Omsk, Russian Federation

Roman E. Il'in — orthopedic surgeon, Noyabrsk Central City Hospital, Noyabrsk, Russian Federation

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Midterm Treatment Outcomes of Proximal Humerus Fractures by Intramedullary Fixation

K.A. Egiazaryan [1], A.P. Ratyev [1,2], D.I. Gordienko [1,2], A.V. Grigoriev [1,2], N.V. Ovcharenko [1]

[1] *Pirogov Russian National Research Medical University, Moscow, Russian Federation*
[2] *City Clinical Hospital No.1, Moscow, Russian Federation*

Abstract

Background. Treatment tactics of proximal humerus fractures remains a matter of dispute due to multiple cases of unsatisfactory outcomes and high rate of postoperative complications. ***The aim of the study*** — to evaluate midterm outcomes of intramedullary fixation for treatment the proximal humerus fractures in comparison with plate fixation. ***Materials and Methods.*** The authors evaluated treatment outcomes of 175 patients with proximal humerus fractures who underwent surgery in the period from 2012 to 2017. Depending on the fixation method the patients were divided into two groups: the main group consisted of 107 patients who underwent intramedullary fixation by a nail of third generation; a comparison group — consisting of 68 patients who underwent fixation by a locking plate with angular stability. ***Results.*** In one year after intramedullary nail fixation the authors observed the excellent and good outcomes on Constant scale in 83.2% of cases, satisfactory — 12.1%, unsatisfactory — 4.7%. Patients who underwent plate fixation demonstrated the following outcomes: excellent and good — 73.5%, satisfactory — 17.7%, unsatisfactory — in 8.8%. Constant score increase was equal in the main and control groups and varied depending on the fracture type. ***Conclusion.*** Intramedullary nailing is an option for treatment of all fracture types of proximal humerus as well as for the cases of combined humeral neck and diaphysis fractures. Functional recovery parameters were higher in the main group of patients after intramedullary nailing.

Keywords: proximal humerus fracture, intramedullary fixation, plating fixation.

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Karen A. Egiazaryan; e-mail: dr.grigoriev.gkb1@yandex.ru

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Introduction

Proximal humerus fractures belong to one of the most common types of injures in adults. They constitute 5–14% of the total number of skeletal fractures and 32–65% of humerus fractures [1–3]. Women are more likely to get this type of injury, their share accounts to 75% [4]. Frequency of such injuries increases with age: up to 70% of fractures of this localization are reported for patients over 60 years old with the peak incidence being at 80–89 years [4–6]. In 87–90% of instances, fractures in adults result from falling from their own height, and in younger people – from road accidents, catatrauma, athletic injuries, and work accidents [4, 6].

In 50–80% of instances, proximal humerus fractures are non-displaced or minimally displaced, which allows for conservative treatment with good outcomes [4, 5, 8].

In 15–20% of instances, proximal humerus fractures are multifragmentary and significantly displaced. The conservative treatment often leads to unsatisfactory functional outcomes resulting in the need for surgical treatment [2, 9].

As a rule, the Neer classification [10] is used for proximal humeral fractures. It divides the proximal humerus into four anatomic segments: humeral head, the greater tuberosity, the lesser tuberosity, humeral shaft. The classification includes non-displaced and minimally displaced fractures, as well as two-part, three-part, and four-part fractures. Last revised in January 2018, the Neer classification was integrated into AO/ASIF classification*.

There is still no consensus on indications for certain methods of surgical treatment. Choice of an optimal treatment policy and an implant model is remaining a subject of intense discussion [5, 8].

Today angular stable locking plates and locking intramedullary nails are primarily used for fixation of proximal humerus fractures. These types of implants fit the anatomic features of the proximal humerus and allow achieving primary angular stability due to locking screws oriented in three planes [11]. Each of the methods has advantages and disadvantages. Many authors consider open reduction and internal fixation (ORIF) using LCP plates [12] to be the golden standard of surgical treatment. Other authors prefer the intramedullary fixation method. There has been much research on using these implants, however, insufficient attention has been given to their comparison.

The purpose of the study is comparing midterm outcomes of surgical treatment of patients having proximal humerus fractures by intramedullary fixation and external fixation using an angular stable locking plate.

Materials and Methods

During the period from 2012 to 2017 the authors performed 317 internal fixation surgeries on patients with proximal humerus fractures, including 205 cases of intramedullary fixation by a proximal locking nail, and 112 cases of external fixation by a locking plate with angular stable screws. The research covered the outcomes of treatment of 175 patients.

The inclusion criteria were as follows: isolated trauma, no neurovascular injuries, age over 18 years. Humerus fracture-dislocations and ipsilateral injuries of the upper extremity were the exclusion criteria.

The research concentrated on monitoring midterm outcomes of 107 patients who underwent intramedullary fixation using short proximal humerus nails. Most of the patients were female – 79 (73.9%). The patients aged between 25 and 91 years, the mean age was 62 (±14.6) years. 61 (57.0%) patients were over 60 years old. According to the AO classification of proximal humerus fractures and fracture-dislocations (last revised in January

* https://www2.aofoundation.org/wps/portal/

2018), 42 (39.3%) fractures belonged to Type A (two-part fractures), 41 (38.3%) fractures – to Type B (three-part fractures), and 24 (22.4%) fractures – to Type C (four-part fractures).

The control group consisted of 68 patients who underwent external fixation of proximal humerus using an angular stable locking plate. Most patients of this group were also female – 47 (69.1%). The patients aged between 25 and 84 years, the mean age was 53 (±16.7) years. 40 (58.8%) patients were over 60 years. According to the AO classification there were 22 (32.4%) fractures of Type A, 29 (42.6%) fractures of Type B, and 17 (25,0%) fractures of Type C in the group.

The patients of both groups were monitored during period from 1 month to 5 years, the mean value was 1.9 years. The research covers the patients who were monitored for at least 12 months.

At admission to hospital patients were interviewed about circumstances of injury, their medical history was taken, and X-rays in at least two views were made. The following views are used for the shoulder joint: AP, transthoracic, axillary, and scapular. To determine quantity and a dislocation pattern of bone fragments, computed tomography (CT) with 3D reconstruction was carried out on the patients with fractures of Type B and Type C, which influenced the choice of a treatment method.

The patients of the main group with Type fractures and in some cases, Type B fractures, as well as combined fractures of the neck and the shaft of the humerus underwent closed reduction using minimally invasive access for nail insertion. In order to reduce the risk of secondary displacement and provide more stable fixation, the screw-in-screw locking method was used for treating the patients with multifragment fractures of the humeral head, as well as the patients with osteoporosis.

During the postoperative period, managing of all the patients was carried out in accordance with the AO standard rehabilitation protocol* which included immobilizing of the operated extremity by a triangular bandage for 2-3 weeks, early mobilization (in 24 hours after the surgery) under control of an exercise physiologist. At first, passive and pendulous movements were applied, which were gradually extended to active movements. After the fracture healing, a full exercise load was applied to the injured extremity. X-rays were taken in 1, 3, 6 and 12 months after the surgery.

On the average, the surgeries in both groups were performed in 3 days after the patients got injuries. The average duration of intramedullary fixation was 48.3 min (±13.3 min) for two-part fractures and 96.4 min (±32.5 min) for three- and four-part fractures.

The progress of the functional recovery of the injured upper extremity was evaluated in 1, 3, 6 and 12 months after the surgery. Treatment outcomes within the first 6 months were classified as short-term, from 6 months to 3 years – as midterm, and over 3 years – as long-term.

The main parameter was functional assessment of the shoulder joint according to the Constant Shoulder Score (CSS) [13]. It is a 100-point rating system consisting of several parameters that is designed for evaluation of a functional status after treating shoulder joint injuries. It consists of four subsections: pain (15 points), daily activities (20 points), muscle strength (25 points) and range of motion (40 points): elevation, abduction, external and internal rotation of the shoulder joint. The higher is the score, the better is the function [14]. In 12 months after the surgery, the CSS score of over 90 points indicated an excellent outcome, 90–80 points – a good outcome, 79–70 points – a satisfactory outcome, and <69 points – an unsatisfactory outcome.

Statistical analysis

Statistical analysis of the obtained data was carried out using Excel и OpenEpi Version 3.01. For quantitative characteristics the results were presented as absolute measures, arithmetic mean values (M) and standard deviations (σ); for qualitative characteristics – as relative measures expressed in percentage (%). For testing statistical hypotheses, the critical level of significance (α) was assumed to be 0.05. If normal distribution of values was confirmed, evaluation of statistical significance of differences between the groups was carried out using Student's t-test (*t*) for independent samples. In all instances, the differences were evaluated as statistically significant at $p<0.05$.

Results

The highest values in short-term and midterm periods, the highest improvement of function of the injured upper extremity and the shoulder joint according to the Constant score were observed in the patients with two-part fractures who underwent intramedullary fixation using a proximal humeral locking nail. The outcomes were evaluated as excellent and good. The outcomes of treatment in the control group were also evaluated as good and excellent, however, their Constant score was lower as compared to the score of the main group. The results did not reveal a statistically significant difference between the groups ($p = 0.067$).

The results of treating three-part and four-part fractures of the proximal humerus by intramedullary and external fixation are given in Table.

The results of comparing the midterm outcomes of treating various types of fractures in two groups of patients are given in Figure.

Thus, improvement of the CSS value is equivalent in both groups and varies depending on the fracture type. It should be noted, however, that the function recovery values are higher in the main group, and these differences are statistically significant ($p<0.05$; see Table for more detailed information about the values).

The following CSS values were obtained in the control group: 50 (73.5%) excellent and good outcomes, 12 (17.7%) satisfactory outcomes, and 6 (8.8%) unsatisfactory outcomes.

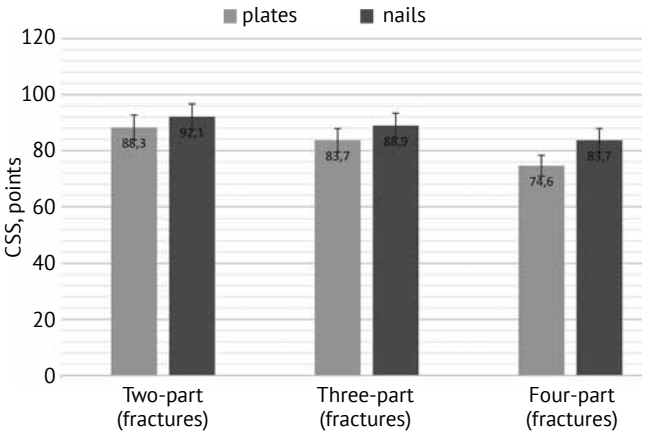

Fig. Results of treatment in 1 year (CSS), score

Table

Functional outcomes of treating three- and four-part fractures of the proximal humerus according to CCS

Groups	Fracture type	Score							
		1 month	*p*	3 months	*p*	6 months	*p*	12 months	*p*
Main group	B (*n* = 41) C (*n* = 24)	61.4±9.6 59.2±11.7	0.004	77.0±9.4 71.5±12.3	<0.001	84.8±9.4 79.8±13.2	0.001	88.9±10.3 83.7±15.4	0.032
Control group	B (*n* = 29) C (*n* = 17)	55.3±7.2 51.1±11.6	0.032	66.3±7.3 64.7±10.8	0.004	77.4±8.5 72.2±12.1	<0.001	83.7±9.5 74.6±16.8	0.027

The main group showed excellent and good CSS outcomes in 89 (83.2%) instances (mainly, these are the patients with the fractures of Type A and Type B), satisfactory outcomes – in 13 (12.1%) instances, unsatisfactory outcomes – in 5 (4.7%) instances. The most favorable outcomes were observed in the patients with isolated injuries that were treated using minimally invasive access, which reduced traumatizing the soft tissues, did not require open reduction of fragments, reduced the surgery duration and blood loss, and allowed starting more active rehabilitation during an early postoperative period. A higher CSS value observed during the first month after the surgery in the main group's patients as compared to the control group's patients demonstrated their faster and fuller function recovery of the injured upper extremity and the joint, which enabled the patients to return to their normal lifestyle earlier. It should be noted that operating on the patients later than 5 days after injury often resulted in difficulties, for example, it was difficult to perform accurate reduction during the surgery. Thus, in 6 cases (5.6%) it was required to extend an access to the fracture and perform open reduction. The patients who underwent surgeries within the first 3 days also demonstrated better functional outcomes.

The following complications of intramedullary fixation were discovered: osteonecrosis of the humeral head (in the patients with four-part fractures) – in 4 cases, fracture non-union – in 6 cases, osteolysis of the greater tuberosity – in 5 cases, migration of metal implants (mainly, these were proximal screws) observed in the elderly patients with the fractures of Type C – in 4 cases.

Complications of external fixation included osteonecrosis of the humeral head – in 5 cases, fracture non-union – in 3 cases, migration of metal implants (including screw penetration into the articular surface) – in 6 cases, subacromial impingement – in 4 cases. No infectious complications were observed in the patients after the surgery. The total number of compilations after intramedullary and external fixation were 8.4% and 15.7% accordingly.

Discussion

The literature describes many surgical methods of treating proximal humerus fractures. The choice of a method depends on the fracture type, state of bone tissue, a surgeon's experience and skills. Today the most frequently used methods are fixation by an angular stable plate, intramedullary nail fixation, minimally invasive fixation by screws or pins and shoulder replacement.

Several recent studies that compare the outcomes of intramedullary nail fixation and fixation by a locking plate in patients with two-part fractures have shown no statistically significant data about superiority of either method [15, 16]. For three-part and four-part fractures, the outcomes have been controversial, however, for these types of fractures most surgeons have recommended using external fixation by a locking plate [1, 17].

N.V. Zagorodniy et al. [17] describe excellent and good outcomes of treating two-part fractures of proximal humerus by external fixation using an angular stable plate, and good outcomes obtained by intramedullary fixation using second-generation nails. The average CSS scores after 1 year was 92.0±6.3 and 88.0±11.7 accordingly ($p = 0.96$). Application of these methods for treatment of three-part fractures has shown mostly satisfactory functional outcomes. Our research has shown similar functional outcomes of treating the patients with two-part fractures: 92.1±7.0 and 88.3±10.6 for treatment with nails and plates accordingly ($p = 0{,}067$).

ORIF LCP allows conducting more precise reduction but carries the risk of osteonecrosis of the humeral head as a result of impaired vascularization. The plate can cause subacromial impingement (usually, in case of its incorrect insertion), and there is the risk of external fixation failure in patients with

severe osteoporosis. According to T. Helfen et al. [18], application of angular stable locking plates in treating patients with osteoporosis for over a period of 10 years has shown mostly excellent and good results, however, there have been unsatisfactory outcomes in 16% of cases. The main reason was the need for revision due to secondary displacement (14%), which is also confirmed by other studies [19].

According to a meta-analysis conducted by R.C. Sproul et al. there is a high risk of secondary displacement for two-part fractures with gross dislocation or dislocation that affects the most part of the metaphysis (AO 11-A3), especially in patients with osteoporosis [20].

N.V. Zagorodniy et al. describe 5 cases of screw penetration into the articular surface of the humeral head as a result of applying plates, which is more often observed in patients with osteoporosis. The overall rate of complications was 31% in the group treated by external fixation [17].

V. Murylev et al. [21] describe a great number of complications observed in 12–35% of cases. In our research, unsatisfactory outcomes were observed in 8.8% of cases of external fixation using LCP plates, however, the number of observed complications was 15.7%, which is similar to the results obtained by T. Helfen. It should be noted that additional application of calcar screws that are inserted into the inferio-medial fragment of the humeral head during plate fixation is explained by a lower risk of secondary displacement as compared to fixation without using calcar screws [22].

The methods are constantly upgraded and supplemented by new capabilities depending on complexity of fractures, a patient's condition and requirements to health and functional outcomes. Locking fixation systems with angular stability have better internal stability; therefore they can better maintain fragments after reduction during the period of postoperative functional treatment [26, 27]. However, as to the proximal humerus, nails have significant advantages over plates [12]. One of the main advantages is maintaining blood circulation and minimizing surgically-induced soft-tissue traumatizing. Surgical access is usually carried out through small incisions without direct fracture intervention. An implant is inserted into the intramedullary canal along the biomechanical axis of the bone. Due to its centered position, the lever arm of the screws is lower than in a plate, in which the screws are in an eccentric lateral position. Also, nails are more biocompatible and easy-to-use for treating fractures of the humeral head that affect the diaphysis or segmental fractures of the humeral head and the diaphysis. Since a nail is inserted in the intramedullary direction and its proximal end is implanted in a subchondral direction, the risk of subacromial impingement is lower as compared to fixation by a plate (the latter needs to be removed because of that) [29]. In modern implants (third-generation implants), in order to enable proximal locking to be more stable, one can use the screw-in-screw method, which is not applicable in case of using nails of the previous generations [26]. This fixation method is especially relevant for elderly patients with severe osteoporosis.

In several recent studies, C. Cuny et al. have demonstrated good and excellent outcomes of treating two-part and three-part fractures [29, 30]. In the research by N.V. Zagorodniy et al. the complication rate for intramedullary fixation was 4% [17]. But it should be pointed out that this work describes patients with two-part fractures. In our research, the complication rate for intramedullary fixation was 8.4% in the patients with two-part, three-part and four-part fractures.

The conducted study has a number of restrictions that affect its quality and statistical significance. First of all, it is a retrospective study. All the surgeries were performed by different surgical teams with different qualifications. The observation period of 12 months was insufficient for a comprehen-

sive evaluation of the treatment outcomes. However, the authors consider the obtained results to be promising and encouraging further research. In the future the authors plan to evaluate long-term outcomes of surgical treatment by an intramedullary locking nail in comparison with external fixation by an angular stable locking plate in patients with proximal humerus fractures.

Conclusion

The research results demonstrated that fixation by a locking intramedullary nail is more efficient in the short-term and midterm post-surgical periods as compared to fixation by an angular stable locking plate. Due to an advanced screw locking system, nail fixation is suitable for treating proximal humerus fractures of all types. This fixation method is the treatment of choice for elderly patients as it ensures sufficient stability of fragments and outperforms other internal fixation methods in terms of treatment outcomes.

The study complies with the ethical standards of the Bioethical Committee of Pirogov City Clinical Hospital No. 1, Moscow Healthcare Department, that were developed in accordance with the World Medical Association's Declaration of Helsinki on ethical principles for medical research involving human subjects and the Rules of Clinical Practice in the Russian Federation approved by Order No. 266 dd. June 19, 2003 of the Ministry of Health of the Russian Federation. All the patients had given informed consent to participating in the research.

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INFORMATION ABOUT AUTHORS:

Karen A. Egiazaryan – chief, the Chair of Trauma, Orthopedics and Military Surgery, Pirogov Russian National Research Medical University, Moscow, Russian Federation

Andrei P. Ratyev — Dr. Sci. (Med.), professor, Chair of Trauma, Orthopedics and Military Surgery, Pirogov Russian National Research Medical University; orthopedic surgeon, City Clinical Hospital No.1, Moscow, Russian Federation

Dmitrii I. Gordienko — Cand. Sci. (Med.), assistant professor, Chair of Trauma, Orthopedics and Military Surgery, Pirogov Russian National Research Medical University; deputy chief, Trauma and Orthopedics Department, City Clinical Hospital No.1, Moscow, Russia.

Alexei V. Grigoriev — assistant, Chair of Trauma, Orthopedics and Military Surgery, Pirogov Russian National Research Medical University; chief of Trauma and Orthopedics Unit, City Clinical Hospital No.1, Moscow, Russian Federation

Nina V. Ovcharenko — resident, Chair of Trauma, Orthopedics and Military Surgery Pirogov Russian National Research Medical University, Moscow, Russian Federation

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Plastic Replacement of Palmar Defects

L.A. Rodomanova[1,2], G.V. Medvedev[1]

[1] *Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation*

[2] *Pavlov First St. Petersburg State Medical University, St. Petersburg, Russian Federation*

Abstract

Purpose — to present the results of palmar defect plastic replacement with a prelaminated tissues complex from the forearm. ***Materials and Methods.*** The authors have developed a two-step method of plastic substitution of the palmar defect, which had consisted in the preliminary preparation of the tissue complex on the own fascia of the forearm and then transposition it to the hand as island flap on the radial vascular bundle after the excision of the scar and eliminate flexion contractures of the fingers. According to the proposed method, 7 patients with vicious scars of the palmar surface of the hand and flexion contracture of the fingers were operated. Males prevailed, the mean age of patients was 39±12.4 years. In 5 cases, the cause of scar contracture of the hand was an open trauma with a tissue defect, in other cases, contact burn. ***Results.*** Patients were examined in 3, 6 and 12 months. The complication was noted in one case, which was a partial necrosis of the skin part of the flap, which required additional plasty with a split skin graft, which did not affect the final result. The flaps were stable and resistant to mechanical stress, no correction was required in any case. By 6 months protective sensibility in the hand recovered in all cases. ***Conclusion.*** The described method of substitution of extensive deep palmar defects can be applied after correction of scar deformation and elimination of flexion contracture of fingers. Prelamination provides reliable engraftment of a full-layer or thick split skin graft taken from any area of the human body. Strong fixation of the skin graft to the fascia provides a small displacement of the skin and and the lack of excess tissue. The flap is resistant to mechanical stress and provides restoration of protective sensitivity. The damage to the donor area is insignificant, as the scar on the forearm remains hardly noticeable. The disadvantages of the proposed method include the need to perform two surgical interventions.

Keywords: hand palmar defects, blood-supplied tissue complexes, prelamination.

Competing interests: the authors declare that they have no competing interests.

Publishing ethics: the patient provided voluntary consent for publication of case data.

Introduction

The skin of the palmar surface of the hand differs from it's dorsal surface: it is thicker, devoid of hair, immobile due to the cellular structure of subcutaneous tissue, tightly fixed to the skin and underlying tissues by fascial septums [1]. Defects of soft tissues of the palmar surface of the hand can be primary (due to injury) or secondary — after correction of scar contracture of various origins — post-traumatic, postoperative, post-burn. The tightening scars on the palm lead to the limitation of the extension of the fingers, that is, to the flexion contracture of varying degrees of severity. The most common cause of such contracture is post-burn scars. Hand injuries are observed in more than 45% of patients with burns. At the same time, deep burns of the hand make up 14% of the total number of injured persons. Joint contractures develop

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Lyubov' A. Rodomanova; e-mail: rodomanovaliubov@yandex.ru

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in 32.5 % of all post-burn deformities, in children this number is higher and is about 66 % [2]. Elimination of contracture after scar excision leads to formation of soft tissue defect with exposure of deep structures of the hand — tendons of flexors and neurovascular bundles. Such defects require plastic replacement with blood-supplied tissue complexes [3].

Replacement of extensive deep defects of tissues of the Palmar surface of the hand presents certain difficulties in connection with the special requirements of the palm as a recipient area, which are as follows: there should be no excessive volume of transplanted tissues, the skin should be little displaced, resistant to mechanical stress and devoid of hair, in addition, it is desirable to restore sensitivity [4]. The concept of «extensive tissue defect» implies that its size does not allow to perform plastic surgery by using the surrounding skin [5].

The possibility of replacing deep defects of the palmar surface of the hand using local tissues is limited. Therefore, in the presence of an extensive defect, tissue complexes taking from forearm — radial or ulnar flap, or free tissue complexes are most often used [4, 6, 7]. One of the significant disadvantages of the use of fascio-cutaneouse flaps as a plastic material to replace the palmar defects is excess tissue, which is often the reason for additional surgery.

Fascial and muscle flaps are devoid of this disadvantage, but their use requires covering the surface of the flap with a split skin graft, which can make it difficult to control the state of blood supply to the transplanted flap and cause complications. The above requirements of the palm as a recipient area ideally corresponds to the medial plantar flap or instep flap, but its size is limited, it can be used only as a free graft on the hand, and when it is isolated on the medial plantar artery, the length of the vascular pedicle is short [8].

Most surgeons choose the forearm as a donor area to replace extensive defects of the palm, where you can select a complex of tissues on the vascular pedicle with reversible blood on the base of radial, ulnar or posterior interosseous artery. The island fasciocutaneouse radial flap is considered to be the gold standard for replacing hand defects. Significant disadvantages of its use for plastic palmar surface of the hand are: excessive mobility and volume with a pronounced layer of adipose tissue, as well as noticeable cosmetic damage to the donor area. To avoid these negative aspects of the use of radial flap we propose a method of substitution of the palmar defects of the hand using preliminated tissue complex based on radial fascial flap (Patent RU No. 2275171).

Purpose — to present the results of plastic replacement of palmar defects using a prelaminated complex of tissues from the forearm.

Materials and Methods

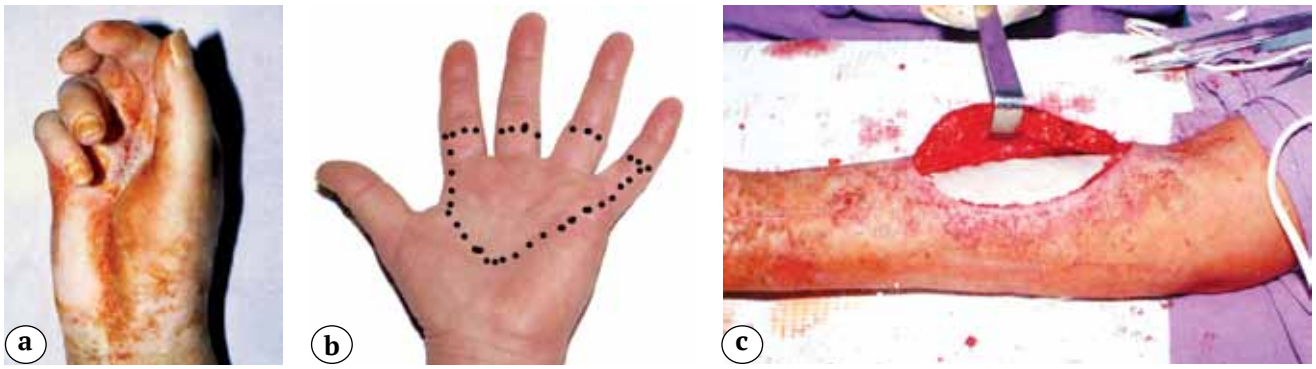
Surgery technique

This is two-stage method. The first stage involves the implantation of a full-layer skin graft under the skin of the anterior surface of the forearm on its own fascia in the projection of the future radial flap (Fig. 1).

After 10 days, the second stage is performed, which consists in excision of the scar on the palm, elimination of finger contracture and replacement of the defect with a prelaminated tissue complex, which is a fascial flap with a full-layer skin graft on its surface (Fig. 2). The skin of the created tissue complex is tightly fixed to the fascial layer, does not shift, and functionally and cosmetically is largely similar to the normal skin of the palm.

Patients

According to the proposed method, 7 patients with restrictive scars of the palmar surface of the hand and flexion contracture of the fingers were operated.



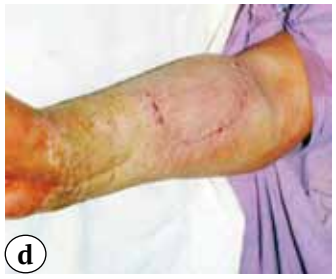
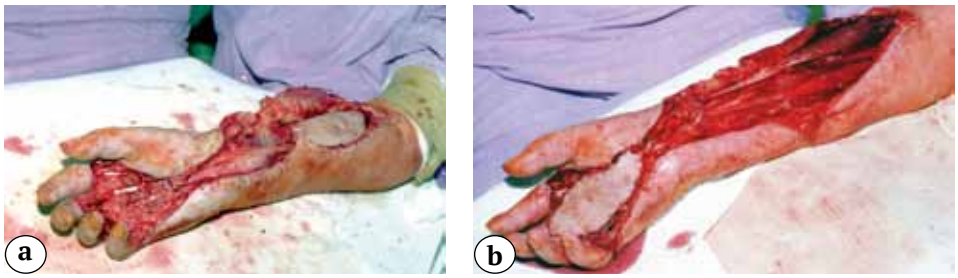


Fig. 1. The first stage of replacement of palmar defect with a prelaminated fascio-cutaneous radial flap:
a — fingers scar flexor contracture of the right hand before the operation;
b — estimation of the size of the expected defect on the palm by reference to the intact hand;
c — implantation of a full-layer skin graft on the forearm own fascia;
d — donor area of the forearm 10 days after the surgery



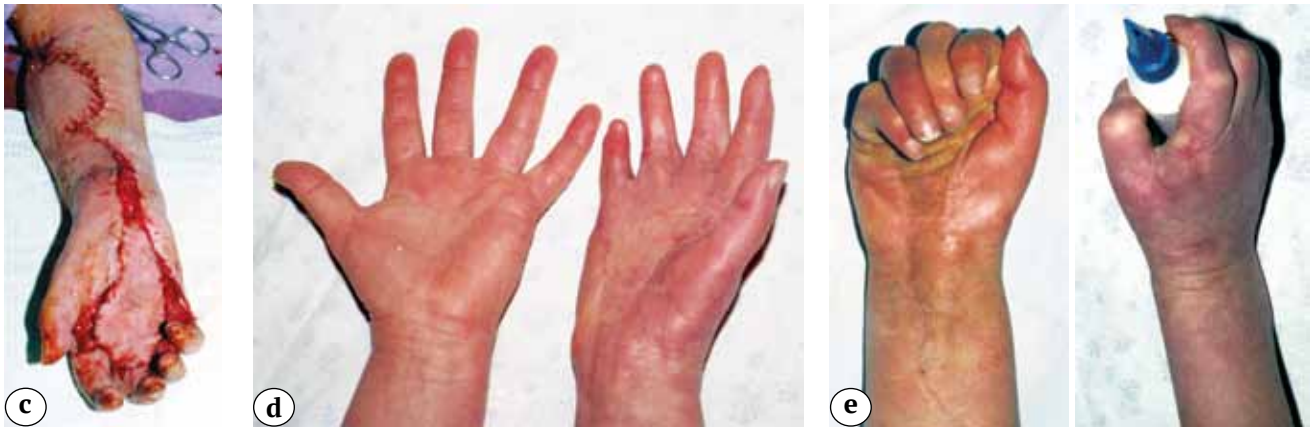


Fig. 2. The second stage of surgery:
a — eliminated contracture of the fingers, tenolysis of the flexor tendons; incision was made on the forearm along the scar for access the vascular pedicle and raising of the prelaminated fascio-cutaneous radial flap on the distal vascular pedicle;
b — flap transposition into the palm defect;
c — hand appearance at the end of the surgery;
d — palm in 6 months after surgery;
e — cylindrical grip and fist grip in 6 months after the surgery

Males prevailed, the mean age of patients was 39±12.4 years. In 5 cases, the cause of scar contracture of the hand was an open trauma with a tissue defect, in other cases, contact burn. Complications were observed in one case, which was a partial necrosis of the skin graft, what required additional skin graft, this did not affect the final result. In other cases, the engraftment was complete.

Results

All patients were examined through 3, 6 and 12 months after surgery. The condition of the restored skin and sensitivity were assessed. It should be noted that in all cases the skin of the palmar surface was resistant to mechanical stress, little displaced, tightly fixed to the underlying tissues, what allowed to perform all types of grips. To six months the protective sensibility was recovered in all cases.

Discussion

The choice of the method of plastic replacement of the extensive deep palmar defect is determined by its size and localization. Tubiana divided the palmar surface of the hand into functional areas that differ in the requirements for the restoration of the skin. The boundaries between the zones pass along the palmar folds separating the area of the ulnar edge of the palm (U), the Central zone (C), the area of the thenar (R) and the distal zone (D). For the U and R zones, thin sensitive skin is necessary, but stability and mechanical strength are not as important as for the C zone, where sensitivity restoration can be neglected [4, 9].

Taking into account these requirements, a suitable transplantat can be selected for each zone. So the restoration of sensitive skin can provide a thin radial fascio-cutaneouse flap, lateral flap of the arm and the dorsal foot flap. Mechanical strength and stability of the skin can be achieved by fascial or muscular flap covered with a split skin graft, especially taken from the unloaded plantar zone of the foot, and both these qualities are peculiar only to the medial plantar flap. A variety of fascial flaps: temporal, serratus anterior, radial are used for plastic purpose [4].

In 1985, Y.T. Jin et al presented their experience of using fascial radial flap. Fascia size 10–12 cm wide and 20–30 cm long can be raised through a curved incision on the forearm and reversed on vascular pedicle to cover the defects of the hand. A split skin graft is required to cover the fascial flap, but this method allows to close the donor defect on the forearm into a line [10].

In 1982, T.Y. Shen described the possibility of creating transplants with required properties and introduced the concept of «pre-fabrication». Preliminary preparation of tissue complexes or pre — fabrication is a method of formation of flap with axial type of blood supply and the desired composition of the tissues, suitable for subsequent transplantation into the recipient area [11].

The basis of the method of preliminary formation of flaps is the process of tissue revascularization, which can be achieved by two different ways: by implanting an axial vascular bundle with or without surrounding tissues in the selected donor area or by transplanting a complex of tissues with a random type of blood supply in the zone with an axial vascular pattern. In both cases, revascularization is carried out through anastomoses between the implanted vessels and the flap's own vessels, which are gradually formed from the implanted vascular bundle and form a complete network of blood vessels, which subsequently is the main source of blood supply to the flap [12].

J.J. Probass proposed the term «pre-lamination» to separate two very different ways of pre-preparation of tissue complexes. He expressed the opinion that the term «prefabrication» is best used in cases where the first stage is performed transplant vascular carrier to the zone of the flap formation, while the term «prelaminate» involves transplantation the unaxial tissue complex to the zone for-

mation of the flap or other effect on the flap to create the required tissue complex [13].

The word «lamination» means the binding of thin plates. In reconstructive surgery, the term «flap pre-lamination» was proposed to describe a two-stage operation. The first step is to combine the different layers into an area with axial blood supply, which takes some time to mature before transposition. At the second stage, the laminated layers are transplantated to the defect as a tissue complex based on the original axial blood supply. Like other complex of tissues, these added layers must be quite thin and small. The rational idea consists in the assumption that it provides the best chance for fusion, stabilization of the pre-laminated layers and creation of the expected structure if the structure is made on an acceptable vascular bed in a safer place with respect to possible complications [14].

N.O. Milanov et al developed a general systematization of microsurgical transplants, where they identified a group of «pre-fabricated» flaps as transplans, which include artificially created combinations of different anatomical tissues on the basis of one natural source of their revascularization [15]. The technique of preliminary preparation of tissue complexes is widely used in head and neck surgery [14], but, unfortunately, has not become popular in limb surgery, which in our opinion is unjustified, since the use of this technique can expand the possibilities of reconstructive surgery.

Conclusion

The described method of covering of extensive deep palmar defects can be applied after correction of scar deformation and elimination of flexion contracture of fingers. A prelaminated transplant has a number of advantages. The size and shape of it can be different, and is restricted to the anterior surface of the forearm. Prelamination provides reliable engraftment of a full-layer or thick split skin graft taken from any area of the human body. Strong fixation of the skin graft to the fascia provides a small displacement of the skin and the lack of excess tissue. The flap is resistant to mechanical stress and provides restoration of protective sensitivity. The damage to the donor area is insignificant, as the scar on the forearm remains hardly noticeable. The disadvantages of the proposed method include the need to perform two surgical interventions.

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INFORMATION ABOUT AUTHORS:

Lyubov' A. Rodomanova — Dr. Sci. (Med.), professor, head of Hand Surgery and Microsurgery Department, Vreden Russian Research Institute of Traumotology and Orthopedics; professor, Department of Traumatology and Orthopedics, Pavlov First St. Petersburg State Medical University, St. Petersburg, Russian Federation

German V. Medvedev — researcher, Hand Surgery and Microsurgery Scientific Department, Vreden Russian Research Institute of Traumotology and Orthopedics, St. Petersburg, Russian Federation

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The First-Stage Treatment Algorithm for Deep Infected Total Hip Arthroplasty

V.Yu. Murylev [1, 2], G.A. Kukovenko [1, 2], P.M. Elizarov [1, 2], L.R. Ivanenko [1], G.L. Sorokina [2], Ya.A. Rukin [1], S.S. Alekseev [1], V.G. Germanov [1]

[1] *Sechenov First Moscow State Medical University, Moscow, Russian Federation*

[2] *Botkin Moscow City Hospital, Moscow, Russian Federation*

Abstract

Background. Periprosthetic infection after total hip arthroplasty is a relatively common and severe complication. A two-stage revision with the temporary use of a spacer is the gold standard treatment for the deep infected total hip arthroplasty. Some authors report mechanical complications associated with spacers, which can lead to a poor functional outcome. Therefore, the aim of the study was to analyze the effectiveness of the first-stage of treatment of hip PJI with a two-stage method and to develop an spacer application algorithm in order to achieve the optimal functional result. ***Materials and Methods.*** Between 2015 and 2017, 38 patients with deep periprosthetic infection received an articulation spacer as part of a two-stage protocol in Botkin Moscow City Hospital. The mean age was 60.5 (interquartile range from 52 to 69) years. Five different types of spacers were used in the study, selected individually according to the Paprosky acetabular defects classification. The overall frequency of complications was evaluated. ***Results.*** The overall periprosthetic infection treatment effectiveness was 92.1%. There was the recurrent infection in 3 patients (7.9%), in 2 (5.26%) cases microbial associations were founded. Mechanical complications occurred in 8 (21%) patients. Spacer dislocation occurred in 4 (10.4%) cases, spacer fracture in another 2 (5.2%). There were also 2 cases of protrusion into the pelvis (5.2%). ***Conclusion.*** The first stage a two-stage revision hip arthroplasty should be carefully planned. To choose the appropriate spacer we proposed an algorithm based on our data to achieve a better functional result.

Keywords: hip revision hip arthroplasty, prosthetic joint infection, spacer, two-stage revision.

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Valery Yu. Murylev; e-mail: nmuril@yandex.ru

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Background

In connection with the increased number of performed primary hip joint endoprosthetics, the amount of complications and subsequent revisions increases. Today, the most serious complication is periprosthetic infection since it requires special diagnostic methods, and its treatment is associated with developing a technically sophisticated revision treatment plan. When acute pain occurs following hip arthroplasty, it is necessary to exclude a possible infection in the operated region [7, 16, 21].

Often, most surgeons of both community health centres and hospital outpatient units often are unable to diagnose or they choose the wrong strategy for managing periprosthetic infection. This leads to catastrophic consequences not only in the zone around the joint, but also in the patient's body as a whole. According to the literature database, the incidence of deep periprosthetic infection is 0.25–1% over the course of a year following primary hip arthroplasty [11]. It is the periprosthetic infection that is the third most common cause of revision arthroplasty, which ranges from 1 to 3% [12]. With other revisions, the risk of infection varies from 4% to 10%, but with revisions for periprosthetic infection, the incidence rate of complications reaches 27–32.3% [14, 18]. It is also necessary to note the high cost of treatment. For example, in the UK, the price of treating one patient is about 40 000 $, and in the USA the overall costs increased from 320 million $ in 2001 to 566 million in 2009. By 2020 they areprojected to exceed more than 1.5 billion $ [9].

Two-stage revision arthroplasty remains the gold standard for treatment of late, deep periprosthetic hip joint infection as classified by M.B. Coventry and D.T. Tsukayama [3].

The objective of the present study is to evaluate the effectiveness of the first stage of a two-stage treatment for deep periprosthetic hip joint infection and to develop an algorithm for choosing a spacer in order to achieve an optimal functional result.

Materials and Methods

In the Center for Bone and Joint Replacement at the S.P. Botkin Moscow State Clinical Hospital, in the period from 2015 to 2017, 38 patients underwent a two-stage revision hip joint arthroplasty for a deep periprosthetic infection. There were 20 women (52.6%) and 18 men (47.4%). The average age of patients was 60.5 years (interquartile range from 52 to 69).

The median manifestation time, i.e. the time from the primary operation to diagnosing septic instability of the components, was 9 months. The median time to complete the first stage of revision arthroplasty, i.e. the time from the diagnosis of periprosthetic infection to the completion of the first stage of revision, was 3.5 months.

Initially, all patients underwent total hip arthroplasty: for post-traumatic coxarthrosis — 10 (26.5%) patients, degenerative coxarthrosis — 17 (44.7%), dysplastic coxarthrosis — 5 (13.1%), hip fracture — 6 (15.7%). Of the 38 patients, 11 (28.94%) underwent a revision intervention for aseptic instability of the components.

A detailed examination of patients analyzing the clinical findings and medical history, X-rays of the pelvis, hip joint in two projections, lumbar spine and CT scan of the pelvis was carried out. In all patients, the pain severity, joint function and quality of life were assessed using the Harris Hip Score, WOMAC and VAS. The assessment was carried out just prior to the first stage, before the second stage and 6 months after the second stage.

If a patient was suspected of having a periprosthetic infection, a comprehensive survey of such patient was performed three times with one month intervals, including:

1) blood test for ESR and C-reactive protein;

2) arthrocentesis of the hip joint with ultrasound guidance;

3) rapid test for leukocyte esterase;

4) cytological and bacteriological examination of punctate with the determination of sensitivity to antibacterial drugs.

The main criterion of the diagnosis was the microflora isolation during bacteriological examination. The 'culture-negative' patients were the most problematic, i.e. those in which the bacterial culture extracted from the joint would not grow. In such cases, we focused on the physical, radiographic and laboratory findings of an infectious process in the joint area.

All patients diagnosed with a septic instability of endoprosthesis components underwent a two-stage revision arthroplasty.

At the first stage, we performed:

1) complete removal of all implanted components, regardless of their stability, along with any associated cement, if present;

2) at least four biopsy samples from the removed components for microbiological examination;

3) processing of the removed components of the endoprosthesis in the ultrasound chamber, followed by taking another bacterial sample;

4) the initiation of intravenous combined antibacterial therapy intraoperatively according to the findings on microflora sensitivity obtained during the examination; in 'culture-negative' cases, an empirical antibiotic therapy with anti-biofilm activity was initiated;

5) thorough debridement and pulsatile lavage;

6) placement of a spacer and its necessary additional fixation to the proximal femur with bone cement;

7) wound closure, including using a Collatamp sponge.

In all patients, after the removal of endoprosthesis components, we installed articulating spacers:

– officinal preformed spacers (Tecres medical) — 11 (28.9%);

– spacers assembled from standard components of the endoprosthesis 15 (39.5%);

– spacers fabricated in the operating theatre with the use of standard moulds — 4 (10.4%);

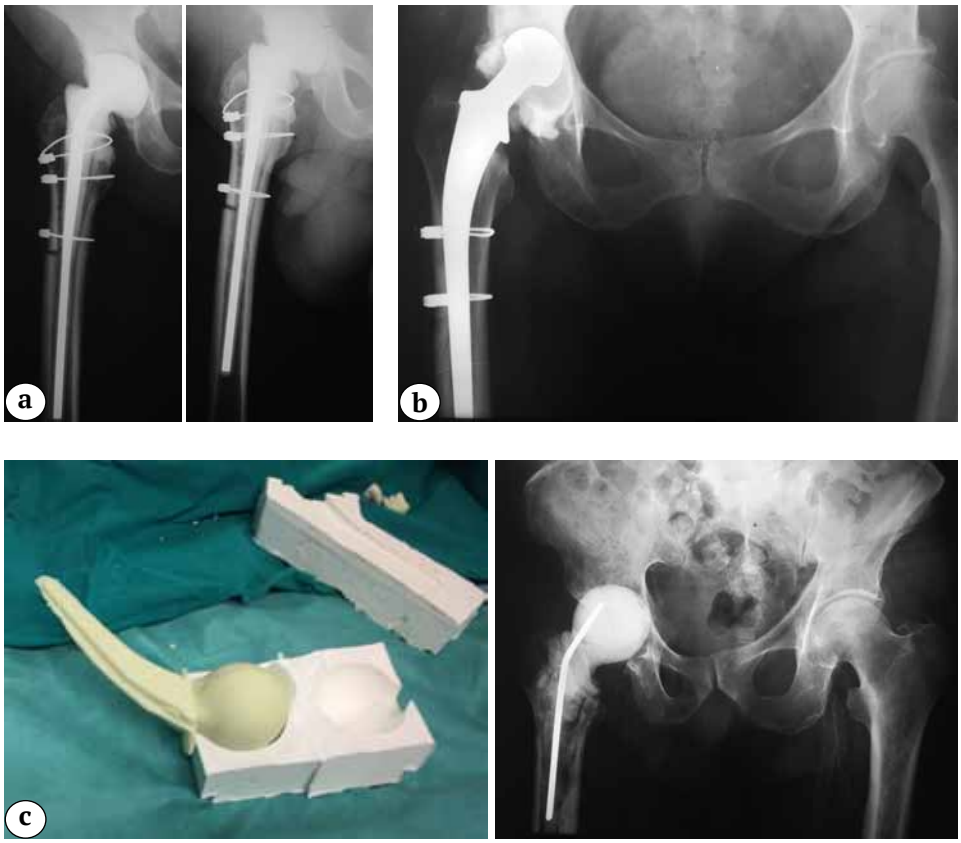
– complex modified spacers in the absence of acetabular shell support ability — 6 (15.9%) (Patent RU No 2675551);

– individual 3D-printed spacers — 2 (5.2%) (Fig. 1).

The officinal preformed spacers are fabricated in the factory from gentamicin-loaded bone cement. Their advantages are standard sizes, reduced time for preoperative planning and operational guidance, increased mechanical strength, and a longer effect of local release of the antibiotic. Disadvantages: narrow size range, excessive formation of scar tissue in the acetabulum, high risk of dislocation or protrusion when there are large defects of the acetabulum.

Spacers assembled from standard components of the endoprosthesis are often used in our work. Their main advantages are low cost, simplicity and speed of production, the possibility of using with defects of the acetabulum according to the Paprosky classification up to type IIC. However, they have a rather low mechanical strength. In the second stage, there is a risk of an increase in the defect of the acetabulum during the debridement of the cement mantle.

When choosing spacers fabricated in the operating theatre with the use of standard moulds, it is possible to fill the thigh and acetabulum with a large amount of cement, which allows to achieve a fairly high concentration of antibiotic in the surrounding region. In addition, it is a quite inexpensive and affordable method. This type of spacer can be used only with acetabular defects up to type IIB according to the Paprosky classification. The disadvantage of this type of spacer is its brittleness, despite its reinforcement with an iron curved pin, and the restriction in use for massive bone defects of the acetabulum and thigh.



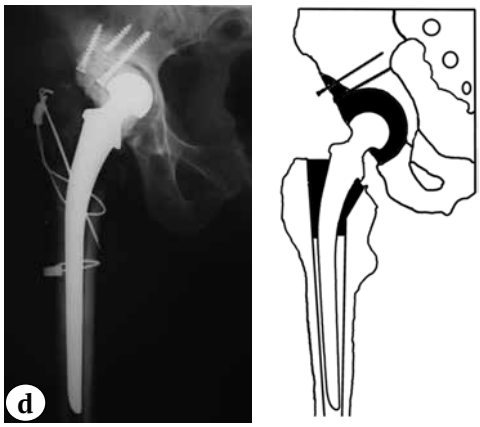


Fig. 1. Types of articulation spacers application in patients:
a — official preformed spacer (Tecres);
b — spacer made from standard endoprosthesis component;
c — spacer made in the operating room using a prepared sample form;
d — spacer in the absence of support of the acetabular ring (patent RU No. 2675551);
e — individual 3D spacer

With massive defects of the acetabulum in the absence of support ability of the acetabular shell, the spacer can be used due to screws fixed in the acetabulum roof. These reinforce the cement mass and do not allow it to migrate. Its main advantage is ease of manufacture and low cost, and the disadvantage is brittleness.

Individual 3D-printed spacers are modern types of spacers that can be used for any bone defects in the hip joint. They are easy to install and allow you to immediately achieve the support ability of the limb. The disadvantages of this spacer are its expense, as well as a long period of preparation and fabrication.

We used polymethyl methacrylate-based bone cement, which is laden with an antibiotic dictated by the obtained microbiological data from cultures. This antibiotic possesses a certain thermal stability and water solubility [2, 5].

Postoperative treatment included intravenous and intramuscular administration of antibiotics (including antibiotics with anti-biofilm activity) while the patient was in the hospital — an average of 12 days postoperation. In the culture-negative group of patients, we started empirical antibiotic therapy awaiting the results of a microbiological examination of biopsy specimens collected intraoperatively. After discharge from the hospital, patients continued to take oral forms of antibiotics for 6–8 weeks following the operation. Two–three weeks after antibiotic therapy ended, a comprehensive examination was conducted with another biopsy of the joint. Upon negative examination results, patients were directed to the second stage of revision arthroplasty.

We divided all patients into three groups. The first group consisted of 27 patients (71%), in which periprosthetic infection was successfully treated and who had no mechanical complications [maybe: complications in hip biomechanics]. The second group comprised 8 patients (21.1%), in which we also succeeded in eradicating the infection, but these patients had mechanical complications associated with the spacer. The third group consisted of 3 patients (7.9%), in which the infection was not eradicated (Table 1). The study of ESR and C-reactive protein levels was performed just prior to the first stage and 8 weeks following surgery (Table 2).

Table 1

Patient profiles in three studied groups

Indicators	First group *n* = 27	Second group *n* = 8	Third group *n* = 3	Total *n* =3 8	*p*
Median age (years)	63 (58–68)	59 (50–74)	50 (42–58)	60.5 (52–69)	0.38
Time of manifestation of infection (months)	9 (6–30)	10.5 (5–36)	7 (1–12)	9 (5–27)	0.88
Period prior to the first stage (months)	4 (3–4)	3 (2.5–3.5)	3 (2–8)	3.5 (3–4)	0.12

Data are presented in median format (interquartile range).

Table 2

ESR and CRP levels prior to the first stage and 8 weeks postoperatively

Variables	First group *n* = 27		Second group *n* = 8		Third group *n* = 3		Total *n* = 38		*p*	
	before	after	before	after	before	after	before	after	before	после
ESR, mm/h	42 (35–47)	21 (16–30)	54 (40–62)	40 (23–44)	37 (37–37)	38 (35–41)	44.5 (37–57)	25.2 (11.9–42.8)	0.21	0,21
CRP, g/l	11.6 (8.9–12.4)	5.8 (3/7–8.4)	42.8 (25.2–82.8)	5.5 (2.1–11.2)	31 (31–31)	37.2 (18.7–37.2)	26 (16–42)	6.8 (3.7–16)	0.03	0,06

Data are presented in median format (interquartile range).

The median manifestation time, i.e. the time from the primary operation to the diagnosed septic instability of the components was 9 months with no significant differences between groups. The median waiting time of the first stage, i.e. the time from the diagnosed periprosthetic infection to the first stage of revision arthroplasty was 3.5 months, also without significant differences between the groups.

In all groups the mean ESR level before treatment was an average of 44.5 mm/h without a statistically significant difference between the groups. In the first group, C-reactive protein prior to the first stage was 11.6 g/l, which statistically is significantly lower than in the second and third groups (42.8 g/l and 31 g/l, respectively).

In the first and second groups, spacer placement was followed by a significant reduction of pre-treatment ESR and C-reactive protein levels, and in the third group, these indicators did not significantly change.

Statistical analysis

Statistical processing of the obtained data was performed with software package STATISTICA 10 for Windows. We applied the following comparative nonparametric methods of descriptive statistics: Mann — Whitney, Kraskel — Wallis, Wilcoxon. Differences of $p<0.05$ were considered statistically significant.

Results

All patients came to our clinic a minimum of 3 months postoperatively. According to the Coventry & Tsukayama classification (1996), type II infection was detected in 19 patients (50%), type III — in 19 patients (50%).

In the microbiological examination of the punctate, bacterial flora was obtained only in 29 patients (76.4%):

Staphylococcus aureus — 4, of which 2 are MRSA [methicillin-resistant *Staphylococcus aureus*]; *Staphylococcus epidermidis* — 9, of which 4 are MRSE [methicillin-resistant *Staphylococcus epidermidis*]; Staphylococcus xylosus — 1; *Staphylococcus hominis* — 2; *Staphylococcus capitis* — 1; *Staphylococcus haemolyticus* — 1; *Escherichia coli* — 2; *Enterobacter cloacae* — 1; *Enterococcus faecalis* — 3; *Proteus mirabilis* — 1. In 4 cases, microbial associations were obtained: *Staphylococcus aureus* (MRSA) + *Proteus Mirabilis*, S*taphylococcus ligdunensis* + *Staphylococcus haemolyticus*, *Staphylococcus epidermidis* + *Enterococcus faecalis* in 2 patients.

In 9 so-called ‘culture –negative’ patients (23.6%), there was no growth of flora from diagnostic punctures. However, considering that the clinical findings and the evaluation of all other criteria indicated periprosthetic infection, these patients were still directed to a two-stage revision arthroplasty. Tissue specimens collected for microbiological examination intraoperatively did indicate periprosthetic infection: Staphylococcus aureus — 5 (MRSA 3) and Staphylococcus epidermidis — 4 cases (MRSE 2).

Despite the treatment, two months following spacer placement, 3 (7.9%) patients developed a reinfection which manifested itself in a fistulous form. It is worth noting that 2 patients (5.26%) had microbial associations. These patients underwent a re-debridement and replacement of spacer.

Prior to the first stage, an overall average Harris Hip Score was 31.5, which corresponds to an unsatisfactory function. Prior to the second stage, it averaged 54 scores, which reflects a statistically significant improvement of hip biomechanics. On the VAS score, the pain severity prior to the first stage averaged 8 scores; prior to the second stage — 3 scores. On the WOMAC score, prior to the first stage, the index averaged 74 scores; after the first stage was completed — an average of 38 scores (Table 3).

Table 3

Outcome assessments of the first stage of treatment, scores

Rating scales	Before spacer placement	After spacer placement	*p*
Visual Analogue Scale (VAS)	8 (6–9)	3 (2–5)	<0.001
Harris Hip Score	31.5 (26–36)	54 (42–64)	<0.001
WOMAC	74 (50–78)	38 (25–61)	0.001

Data are presented in median format (interquartile range).

In the postoperative period, complications such as dislocated spacer were observed in 4 patients (10.4%); fracture of reinforcing screws of the acetabulum, and their migration together with the spacer in 1 patient (2.6%); fracture of the spacer fabricated in the operating theatre in standard moulds in 1 patient (2.6%); spacer migration into the pelvic cavity in 2 patients (5.2%) (Fig. 2).

We noted that, using officinal preformed spacers for acetabular defects IIC, IIB and in 2 cases of IIIA according to the Paprosky classification, dislocations of the spacer were observed. In two patients with IIC defects, spacers migrated into the pelvic cavity. The fracture of the spacer, which was fabricated in the operating theatre in standard moulds, occurred in one patient with IIB defect. In one patient with IIIB defect, the fracture of reinforcing screws of the acetabulum, and their migration together with the spacer occurred as a result of trauma (a fall on the side).

Prior to performing the second stage, we analyzed separately the data of 8 patients (21%) with inadequate spacer function on functional scales: the VAS Score was 6.12; Harris Hip Score — 41.6; WOMAC — 65.8 scores. Together this was regarded as an unsatisfactory result. The above mechanical complications caused additional difficulties in performing the second stage.

Discussion

There are a great number of guidelines and methods for treating a deep periprosthetic hip joint infection, considering various factors. However, preference is given to a two-stage technique, which is regarded as the gold standard [7, 10, 16, 19].

According to various authors' data, the percentage of success with this method of treatment ranges from 60 to 95% [1, 19, 15]. D. Toms et al. reported 38% of reinfection [13], K. Uchiyama et al. reported 32.3% of relapses [14, 21]. M. Gomez et al. succeeded in 80% of cases [6], S. Lim et al. exhibited a 78% success rate [10]. In our study, the effectiveness of a two-stage exchange for periprosthetic infection was 92.1%. Additionally, the effective-

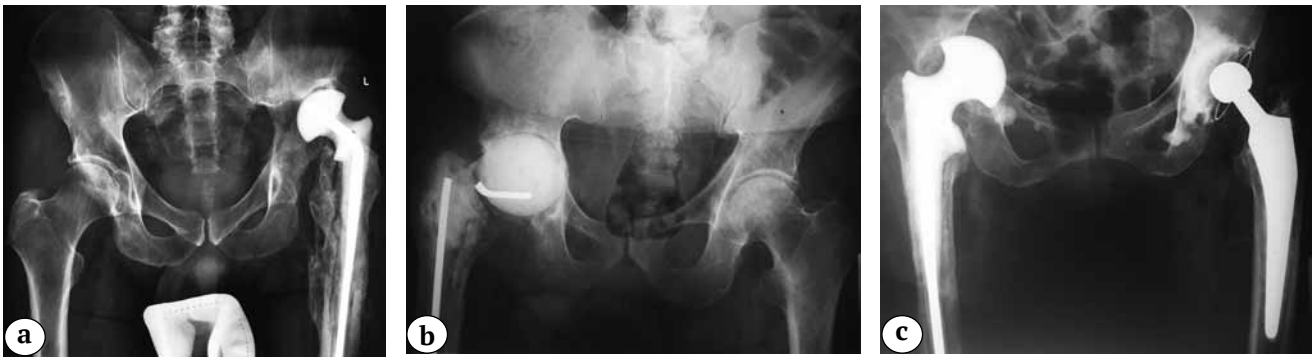


Рис. 2. Mechanical complications in the postoperative period:
a — spacer dislocation; b — spacer breakdown; c — spacer protrusio to the pelvic cavity

ness of a method to eradicate the infection does not depend on selected type of spacer.

An interesting position was taken by M. Gomez et al., who drew attention to the high heterogeneity of data about the effectiveness of two-stage exchange. They analyzed 178 patients with periprosthetic hip joint infection and found that, after the first stage, only 77% of patients underwent the second stage. In the remaining cases, due to various complications, reimplantation was not performed, and alternative techniques were used [6].

Our use of the diagnostic and treatment algorithm allowed for detecting the infection in 76.4% of cases. In the remaining 23.6% of patients ('culture-negative'), the microflora was obtained intraoperatively, enabling immediate administration of a targeted antibiotic therapy.

It should be understood that the purpose of the spacer is not only as a substrate when treating infection, but also to ensure the function of the joint. All our patients were equipped with articulating spacers, since they do not impose functional limitations and do not reduce the quality of life [1, 19].

A distinctive feature of our work was the study and evaluation of non-infectious complications, such as spacer dislocations, metal implant fractures with their subsequent migration, spacer fractures and their protrusion into the acetabulum, since a small number of studies highlight this problem. The total of mechanical complications was 21%, of which dislocation of the spacer was 10.4%; fracture of reinforcing screws of the acetabulum and their migration together with the spacer — 2.6%; fracture of the spacer fabricated in the operating theatre in standard moulds — 2.6%; protrusion of the acetabulum and migration of the spacer into the pelvic cavity — 5.2%.

J. Jung et al. reported the frequency of mechanical complications in 40.8% of cases (17% of dislocations, 10.2% of spacer fractures, 13.6% of hip fractures) [8]. M. Faschingbauer et al. analyzed 138 patients to which spacers were placed, and identified 19.6% of mechanical complications, including 8.7% of spacer fractures, 8.7% of dislocations, 0.7% of hip fractures, 0.7% of protrusions into the pelvis, 0.7% of fractures and dislocations of the spacer [4].

To prevent non-infectious complications, it is necessary to carefully plan the first stage of revision intervention. To this end, we propose an algorithm for choosing a spacer in patients with various defects of the acetabulum according to the Paprosky classification (Table 4).

Table 4

Algorithm for choosing a spacer in patients with variable acetabular defects according to the Paprosky–Perona –Lawrence classification

Type of defect	A	B	C
I	1. Preformed officinal spacers 2. Spacers assembled from standard components of the endoprosthesis	–	–
II	1. Preformed officinal spacers 2. Spacers assembled from standard components of the endoprosthesis 3. Spacers fabricated in the operating theatre in standard moulds	1. Spacers fabricated in the operating room in standard moulds 2. Spacers assembled from standard components of the endoprosthesis 3. Preformed officinal spacers (excessive internal rotation)	1.Complex modified spacers in the absence of support of the acetabular shell 2. Individual 3D-printed spacers
III	1.Individual 3D-printed spacers 2. Complex modified spacers in the absence of support of the acetabular shell	1.Individual 3D-printed spacers 2. Complex modified spacers in the absence of support of the acetabular shell	–

Before proceeding to the second stage, the functional result in 8 patients (21%) with mechanical complications of the spacer was separately analyzed according to the selected scales, and the result was unsatisfactory. Also, mechanical complications caused additional difficulties in accomplishing the second stage.

Assessment of the patient's quality of life and functional outcome after the second stage, depending on the use of different spacers at the first stage of revision arthroplasty, may be the subject of further research.

Conclusion

In two-stage revision hip joint arthroplasty, it is necessary to carefully plan the first stage and select the appropriate type of articulating spacer. A properly selected spacer is the basis of a good functional result and technically simplifies the second stage implementation.

In our study, we could achieve success in eradicating periprosthetic infection in 92.1% of the cases with articulating spacers implanted. Among the cases of reinfection, it is worth noting that a greater number of relapses were observed in 2 patients (5.62%) with microbial associations.

In 8 cases (21.05%), mechanical complications associated with the spacer occurred, significantly worsening the patient's quality of life and complicating the technical implementation of the second stage, but with no impact on eradication of the infection.

A two-stage revision arthroplasty should also be aimed at improving the patient's quality of life. To minimize the above complications and improve the functional result achieved in the first stage of treatment, an algorithm to choose an articulating spacer based on the defect of the acetabulum according to the Paprosky classification is presented. Thus, the proper implementation of the first stage naturally enhances the effectiveness of treatment of a deep periprosthetic hip joint infection overall.

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INFORMATION ABOUT AUTHORS:

Valery Yu. Murylev — Dr. Sci (Med), professor, Department of Traumatology, Orthopaedics and Disaster Surgery, Sechenov First Moscow State Medical University; head of Moscow City Arthroplasty Centre, Botkin Moscow City Hospital, Moscow, Russian Federation

Grigorii A. Kukovenko — PhD student, Sechenov First Moscow State Medical University; orthopaedic surgeon, Botkin Moscow City Hospital, Moscow, Russian Federation

Pavel M. Elizarov — Cand. Sci. (Med), assistant professor, Department of Traumatology, Orthopaedics and Disaster Surgery, Sechenov First Moscow State Medical University; orthopaedic surgeon, Botkin Moscow City Hospital, Moscow, Russian Federation

Leonid R. Ivanenko — PhD student, Sechenov First Moscow State Medical University, Moscow, Russian Federation

Galina L. Sorokina — orthopaedic surgeon, Botkin Moscow City Hospital, Moscow, Russian Federation

Yaroslav A. Rukin — Cand. Sci. (Med), assistant professor, Department of Traumatology, Orthopaedics and Disaster Surgery, Sechenov First Moscow State Medical University, Moscow, Russian Federation

Semen S. Alekseev — PhD student, Sechenov First Moscow State Medical University, Moscow, Russian Federation

Valery G. Germanov — Cand. Sci. (Med), assistant professor, Department of Traumatology, Orthopaedics and Disaster Surgery, Sechenov First Moscow State Medical University, Moscow, Russian Federation

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Antibacterial Activity of Antibiotic-Impregnated Bone Cement Based Coatings Against Microorganisms with Different Antibiotic Resistance Levels

D.V. Tapalski [1], P.A. Volotovski [2], A.I. Kozlova [1], A.A. Sitnik [2]

[1] *Gomel State Medical University, Gomel, Republic of Belarus*
[2] *Republican Scientific and Practical Centre for Traumatology and Orthopedics, Minsk, Republic of Belarus*

Abstract

Purpose — to evaluate the presence and duration of antibiotic activity of antibiotic-impregnated bone cement based coatings samples against antibiotic-sensitive and antibiotic-resistant microorganisms. ***Materials and Methods.*** Bone cement based coatings impregnated with antibiotics (gentamycin, vancomycin, colistin, meropenem, fosfomycin) are formed on titanium (Ti) plates. A plate rinse was carried out; antibiotic concentrations in the rinsed solutions were estimated by a serial broth microdilution method. Antibacterial activity of the control and rinsed samples against the antibiotic-sensitive and multiple-antibiotic-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa* strains was estimated by a bilayer agar method. ***Results.*** The meropenem and fosfomycin concentrations in the rinsed solutions obtained at a one-fold (16 μg/ml for both antibiotics) and two-fold treatment (2 μg/ml for meropenem and 8 μg/ml for fosfomycin) were sufficient to suppress the growth of the control strains. One-fold rinse of samples with colistin eliminated their antibacterial activity completely. The marked activity of the samples with meropenem and fosfomycin persisted against the antibiotic-sensitive *P. aeruginosa* ATCC 27853 strain after 2 rinse cycles; single-rinsed samples with fosfomycin also maintained the activity against the extensively antibiotic-resistant *P. aeruginosa* BP-150 strain. Vancomycin-containing samples possessed the sufficient antibacterial activity against both methicillin-sensitive (MSSA) and methicillin-resistant (MRSA) *S. aureus* strains; two-fold rinse of the samples eliminated their bactericidal properties. ***Conclusion.*** Bone cement based coatings impregnated with fosfomycin and meropenem possess the most marked and long-lasting antibacterial activity, manifested mainly against the antibiotic-sensitive strains.

Keywords: bone cement, meropenem, fosfomycin, colistin, local antibiotic therapy.

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Background

Gram-positive bacteria (*S. aureus* and coagulase-negative staphylococcs, *Enterococcus* spp., *Streptococcus* spp.) are the main etiological agents of bons and joint infections, while the amount of gram-negative bacteria accounts for no more than 10–22% of all cases, including 2–7% for *P. aeruginosa* [1, 2]. Gram-negative microorganisms are often detected in open fractures, chronic osteomyelitis and periprosthetic infections [3]. In cases of periprosthetic implant-associated infections, the proportion of *P. aeruginosa* in etiology may increase up to 20%. The constant increase of the etiological role of *P. aeruginosa* with multiple antibiotic resistance is noteworthy [4]. Cases of implant-associated infections and post-traumatic osteomyelitis caused by carbapenemase-producin, antibiotic-resistant (MDR and_XDR) *P. aeruginosa* strains have been

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Dmitry V. Tapalski; e-mail: tapalskiy@gsmu.by

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documented [5, 6]. Clinical outcomes of infections caused by *P. aeruginosa* are significantly less favorable than outcomes of infections caused by staphylococci [7].

Systemic antibacterial therapy of bone and joint infections caused by gram-negative microorganisms is often ineffective. This may be due to the multidrug resistant bacteria, the heterogenecity of the bacterial population and the transition of a part of microbial cells to metabolically inactive forms, as well as the formation of microbial biofilms on the bone surface or on the surfaces of incorporated implants [6]. The main method of local antimicrobial therapy for bone infections is the use of polymethylmethacrylate (PMMA)-based bone cement impregnated with antibiotics. Several types of bone cements containing antibiotics (gentamicin, tobramycin, vancomycin) are widely used.

Ready-made bone cements contain low antibiotic concentrations and are intended to prevent infections. With the spread of antibiotic resistance in bacterial populations, aminoglycosides are gradually losing their significance, and the antibacterial spectrum of vancomycin does not cover gram-negative microorganisms. Therefore, it is necessary to choose other antibiotics that are effective, including against numerous multidrug and extensively drug-resistant gram-negative pathogens. In addition, the antibiotic should have thermal stability, a wide range of bactericidal activity in low concentrations, as well as the ability to elute from PMMA for a long time and maintain sufficient local inhibitory concentrations that prevent the proliferation of bacteria and the formation of microbial biofilms [8]. In practice, various antibiotics are widely used in bone cement: aminoglycosides, glycopeptides, cephalosporins, fluoroquinolones, colistin, linezolid, daptomycin [9].

Techniques for applying a layer of PMMA with an antibiotic on the surface of the intramedullary nails are proposed for the treatment of infected nonunions and osteomyelitis. The antibacterial layer on the surface of an intramedullary fixation device is prepared during surgery [10, 11]. In the available literature there is no evidence about the mechanisms and kinetics of release of antibiotics from PMMA-based coatings applied on the surface of medical implants. The possibility of using polymyxins, carbapenems, fosfomycin (i.e. antibiotics that remain active against various antibiotic-resistant gram-negative pathogens) in bone cement requires study.

The purpose of the study is to evaluate the presence and duration of antibacterial activity of antibiotic-impregnated bone cement based coating samples against antibiotic-sensitive and antibiotic-resistant microorganisms.

Materials and methods

Under aseptic conditions, the appropriate portions of pure antibiotic substances (vancomycin, colistin, meropenem, fosfomycin) were weighed. They were incorporated in 10 g of dry powdered bone cement (Subiton Gun, Laboratorios SL S.A., Argentina), then thoroughly mixed using a sterile spatula. 5 ml of monomer were added to the mixture, mixed and applied by a continuous uniform layer 0.5–1 mm thick onto BT-6 titanium plates 12.5×50×0.5 mm. Additionally, titanium plates with gentamicin-containing bone cement were prepared (Subiton Gun G, Laboratorios SL S.A., Argentina). the amount of antibiotics per 40 g of powdered bone cement was as follows: gentamicin — 0.5 g, vancomycin — 2 g, colistin — 0.24 g (3 000 000 IU), meropenem — 2 g, fosfomycin — 2 g.

After polymerization, titanium plates with applied bone cement were placed into sterile hermetically sealed polypropylene containers, labeled and divided into 3 groups. Each included 3 samples of the same type. Samples of group 1 were not rinsed and were used as control specimens. Samples of groups 2 and 3 were submerged in sterile isotonic NaCl solution (INaC*) with a volume of 100 ml and thermostatically incubated within 7 days in an ES-20 shaker-incubator (BioSan, Latvia) at 100 rpm and 35°C. Samples of group 3 were rinsed again in a fresh volume of INaCS for 7 days. Awaiting further study, the run-off solutions were stored frozen at -80°C. Antibiotic concentrations in the run-off solutions were determined by the method of serial microdilutions in Muüller-Hinton broth based on their ability to suppress the detectable growth of *Escherichia coli* ATCC 25922, *P. aeruginosa* ATCC 27853 and *S. aureus* ATCC 29213 with known Passport values of the minimum inhibitory concentrations (MICs) of these antibiotics.

Evaluation of the antibacterial activity of bone cement applied to titanium plates (for the

control and rinsed plates) was carried out using a bilayer agar method [12]. Plates were placed on the surface of Mueller-Hinton agar (Mueller Hinton II Agar, BD BBL, USA) using sterile tweezers in 90-mm polystyrene Petri dishes. Then 15 ml of melted and cooled to 45°C Mueller-Hinton agar was poured into the dishes forming a second layer (Fig. 1).

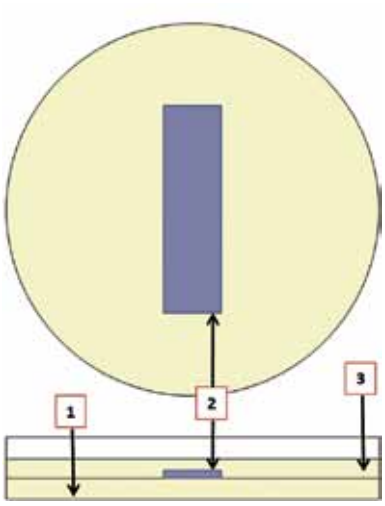

Fig. 1. Evaluation of the coating antibacterial activity by a bilayer agar method:
1 — 1st layer of nutrient medium;
2 — titanium plate coated with bone cement impregnated with antibiotic;
3 — 2nd layer of nutrient medium

The calculated thickness of the formed nutrient layer of the coated plate was 1.5–2 mm. The dishes were placed on a level horizontal surface until the medium completely set, then dried in a thermostat for 15 minutes.

Antibiotic sensitive microorganisms from the ATCC collection (*P.aeruginosa* ATCC 27853 and *S. aureus* ATCC 29213) were used as test cultures for inoculation of Petri dishes with plates. Additionally, antibiotic-resistant strains of microorganisms isolated from patients with post-traumatic osteomyelitis were included in the study: *P. aeruginosa* P*-150 (resistane to most antibiotics, with the exception of polymyxins, VIM metallo-β-lactamase-produceg) and *S. aureus* 43431 (methicillin-resistant isolate — MRSA, resistane to oxacillin, gentamicin, ciprofloxacin, levofloxacin, tetracycline, rifampicin).

Table 1 shows the MIC values of the antibiotics used in the bone cement composition for test cultures.

The Petri dishes were inoculated with bacterial suspensions (0.5 McFarland) using cotton swabs and incubated for 18 hours at 35°C. The presence of microorganisms and nature of their growth on the surface of Mueller-Hinton agar near the projection of plates with different coating compositions were evaluated.

Results

Table 2 shows the results of determining the antibiotic concentrations in the run-off solutions. Antibiotic-sensitive ATCC strains with the lowest MIC values were selected as indicator microorganisms. However, in some cases, the antibiotic concentrations did not inhibit the noticeable growth of test cultures, which was a limitation of the method. Thus, after the second rinsing of the gentamicin- and vancomycin-containing bone cement samples, the concentrations in the run-off solution were not sufficient to suppress the growth of test cultures.

Table 1

The MIC values of the antibiotics for test cultures of microorganisms

Microorganisms	MIC, μg/ml				
	gentamicin	meropenem	colistin	fosfomycin	vancomycin
E. coli ATCC 25922	0,5 (S)*	0,016–0,03 (S)	0,5–1 (S)	1 (S)	–
P. aeruginosa ATCC 27853	1 (S)	0,5 (S)	1–2 (S)	4 (S)	–
S. aureus ATCC 29213	0,25–0,5 (S)	–	–	1–2 (S)	1 (S)
P. aeruginosa PA-150	256 (R)	128 (R)	0,5 (S)	128 (R)	–
S. aureus 43431	64 (R)	–	–	–	0,5 (S)

*S — sensitive; R — resistant.

Table 2

Antibiotic concentrations in the run-off solutions

Antibiotic	Indicator microorganism to determine the antibiotic concentration	Antibiotic concentration, μg/ml	
		7 days	14 days
Gentamicin	*E. coli* ATCC 25922	4	<1
Meropenem	*E. coli* ATCC 25922	16	2
Colistin	*E. coli* ATCC 25922	<1	<1
Fosfomycin	*P. aeruginosa* ATCC 27853	16	8
Vancomycin	*S. aureus* ATCC 29213	8	<2

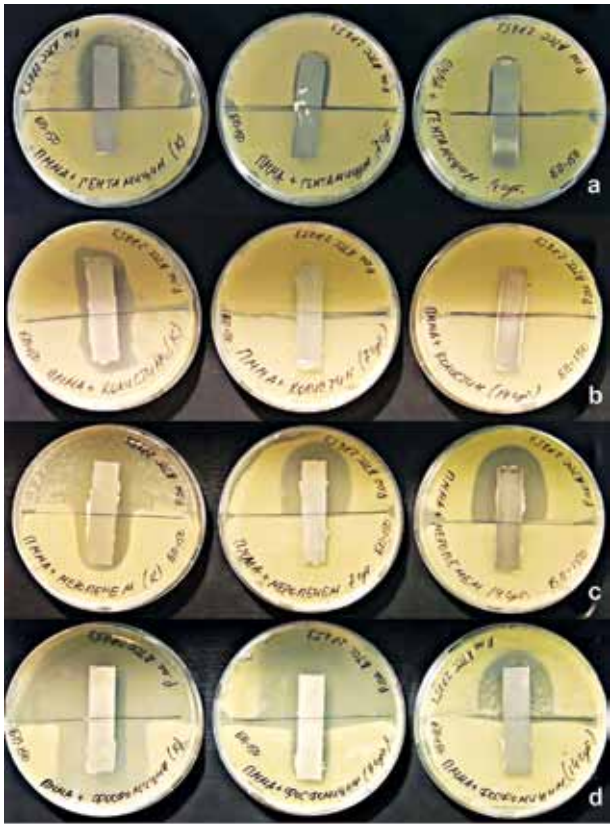

Fig. 2. Antibacterial activity of antibiotic-impregnated bone cement based coatings against *P. aeruginosa* ATCC 27853 (upper Petri dish sectors) and clinical isolate *P. aeruginosa* BP-150 (lower Petri dish sectors), a bilayer agar method:
a — gentamicin (0.5%);
b — colistin (0.6%);
c — meropenem (5%);
d — fosfomycin (5%)

The results of determining the antibiotic concentrations in the run-off solutions are consistent with the results of determining the antibacterial activity of the control and run-off samples (Fig. 2, 3). For control samples which weren't rinsed, in most cases antibacterial activity was revealed based on the absence of microorganism growth in the nutrient medium, both in the projection of coated plates and at different distances from them. The sizes of growth inhibition zones around the plates correlated with the MIC values of antibiotics of the studied strains. An exception was a gentamicin-containing bone cement which had antibacterial activity only against *P. aeruginosa* ATCC 27853 (MIC of gentamicin 1 μg/ml) and did not suppress the growth of an extensively antibiotic-resistant clinical isolate *P. aeruginosa* PA-150 (MIC of gentamicin >64 μm/ml).

Fig. 3. Antibacterial activity of bone cement based coating impregnated with 5% vancomycin against the antibiotic-resistant clinical isolate of *S. aureus* 43431 (MRSA), a bilayer agar method

Discussion

A detailed study of the kinetics of antibiotic release from bone cement in the form of spacers or beads in a fluid medium has been the subject of numerous earlier studies and therefore was not part of the objective of this work. It was shown that most antibiotic washout from bone

cement occurs during days 1–3 after implantation. Subsequently formed local concentrations fall below the MIC, which may induce the production of antibiotic resistance in microorganisms [13].

The concentrations of colistin in the run-off solutions (<1 μg/ml) obtained during this study were not sufficient to suppress the growth of *E. coli* ATCC 25922. This may be primarily due to the small amount of colistin compared to other antibiotics loaded in the bone cement (0.24 g per 40 g of cement). As shown in the research article by Gasparini et al., the elution of colistin from bone cement samples containing 0.6% (0.24 g per 40 g) of colistin sulfate ceased within 1 hour after being placed in the rinse solution of iNaCl, while barely 3.5% of the applied antibiotic was eluted. An increase of colistin to 2.4% in the content (0.96 g per 40 g of bone cement) prolonged its elution time to 7 days [14]. The inability of bone cement containing colistin (0.6%) and erythromycin (1.25%) to reduce the incidence of infectious complications in knee arthroplasty was shown in a randomized clinical study [15]. It is thought that the use of higher concentrations of colistin in the bone cement composition is associated with the risk of toxic effects. Thus, adding 2 g of colistin to 40 g of bone cement (5% concentration acceptable for most other antibiotics) would correspond to 400% of its maximum daily dose when administered intravenously [16, 17].

The most encouraging evidence was obtained for meropenem and fosfomycin. Their concentration in both rinse solutions (obtained 7 and 14 days after the elution started) significantly exceeded the MIC for antibiotic-sensitive strains. It was previously shown that bone cement containing 10% meropenem continues to release an antibiotic for 21 days, with 19% meropenem eluting into the solution [14]. The scientific work of V.A. Konev et al. shows a long-term (up to 28 days) antibacterial activity of bone cement containing 10% fosfomycin against antibiotic-sensitive *K. pneumoniae* and *S. aureus* strains [18].

A single rinse of the samples with colistin completely eliminated their antibacterial activity, which corresponds to published findings [14]. The pronounced activity of the samples against *P.aeruginosa* ATCC 27853 containing meropenem and fosfomycin was retained even after 2 cycles of rinsing. The samples containing fosfomycin also retained antibacterial activity against *P. aeruginosa* PA-150.

The *S. aureus* ATCC 29213 (MSSA) and *S. aureus* 43431 (MRSA) strains included in the study were not resistant to glycopeptides (MIC of vancomycin 1.0 μg/ml and 0.5 μg/ml, respectively), and similar results were shown when testing samples of bone cement impregnated with vancomycin. After a single 7-day rinse, the antibacterial activity of vancomycin-containing samples against *S.aureus* was retained. However, the size of growth inhibition zones around the plates was significantly reduced compared to the control samples (Fig. 3). A double 7-day rinse completely eliminated antibacterial activity.

In summary, bone cement impregnated with fosfomycin or meropenem coatings had the most pronounced and long-lasting antibacterial activity, which manifested itself mainly against antibiotic-sensitive strains. Effective use of colistin in coating composition is possible only with its increased concentration in the bone cement composition, which requires additional *in vitro* studies. Further research may be focused on the search for optimal antibiotic combinations in bone cement composition providing a more complete and prolonged elution into the surrounding tissues and having a synergistic effect on extensively antibiotic-resistant pathogens. Biodegradable polymers can be considered as alternative carriers for antibiotics capable of enabling a longer lasting local antibacterial effect against a wide range of antibiotic-resistant microorganisms. It seems appropriate to introduce into clinical practice standardized microbiological methods that allow evaluating the surface bactericidal activity of polymeric materials and coatings based on polymeric materials against clinical isolates of microorganisms obtained from specific patients.

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INFORMATION ABOUT AUTHORS:

Dmitry V. Tapalski — Cand. Sci. (Med.), associate professor, head of the Department of Microbiology, Virology and Immunology, Gomel State medical University, Gomel, Republic of Belarus

Pavel A. Volotovski — researcher, Laboratory of Traumatology of Adult Age, Republican Scientific and Practical Centre for Traumatology and Orthopedics, Minsk, Republic of Belarus

Anna I. Kozlova — senior lecturer, Department of Microbiology, Virology and Immunology, Gomel State medical University, Gomel, Republic of Belarus

Alexander A. Sitnik — Cand. Sci. (Med.), head of the Laboratory of Traumatology of Adult Age, Republican Scientific and Practical Centre for Traumatology and Orthopedics, Minsk, Republic of Belarus

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Pubic Rami Fractures Fixation by Interlocking Intramedually Nail: First Clinical Experience

P.A. Ivanov, N.N. Zadneprovsky, A.V. Nevedrov, V.O. Kalensky

Sklifosovsky Clinical and Research Institute for Emergency Care, Moscow, Russian Federation

Abstract

Background. Growing number of patients with pelvic fractures is associated with evolution of high-speed transport, high-rise construction and industrial production. The optimal surgical procedure for pubic rami fractures must ensure a stable fixation and simultaneously minimize the risk of postoperative complications. Purpose the study was to evaluate the efficiency of a new technique for pubic bones fixation by a titanium nail in patients with pelvic fractures. ***Materials and Methods.*** The authors present the experience on treatment of 18 patients who underwent 25 surgeries for internal fixation of pubic rami fractures by a designed solid titanium nail. Mean age of patients was 40.16±10.35 years. Proposed surgical method provides for mandatory use of image intensifier during all stages of the procedure. With patient in a supine position the authors performed internal fixation of pubic bones by a retrograde nail inserted using a navigating handle through a skin incision of 1 cm in the area of symphysis. After complete insertion into the bone the nail was interlocked proximally by two 3.5 mm cortex screws through an additional skin incision of 1.0 cm using a navigating handle and guiding sleeves. All pelvic ring fractures were classified according to AO/OTA classification and pubic fractures by Nakatani classification. Functional outcome was evaluated by Majeed score. ***Results.*** Bilateral fractures were diagnosed in 7 (38.8%) patients (floating pubic symphysis). 13 (72.2%) patients featured polytrauma with average ISS score of 25.1±7.8. 2 (11,1%) patients were diagnosed with open pelvic fractures, 3 (16.6%) patients had a concomitant acetabular fracture. The authors performed epicystostomy in two (11.1%) patients and laparotomy bringing out the drainages in 5 (27,8%) patients. Mean follow up was 7.8±6.2 months. Stable fixation was obtained in all patients. By the moment of the present publication X-ray healing of pubic bones was observed in 16 (64%) cases, in remaining 9 (36%) cases the follow up period was less than mean healing period (2 months). In 11 (68.8%) patients the functional outcome averaged 91±3.9 by Majeed score 6 months postoperatively, in 8 (50%) patients – 93.8±2.9 by Majeed score 12 months postoperatively and more. No complications like skin necrosis, secondary fragments displacement or infection were not observed. ***Conclusion.*** Preliminary results demonstrated the absence of wound infection and reliable fragments fixation. This technique can be applied in patients with stomas and drainages upon the anterior abdominal wall which extends the indication range for surgical treatment of anterior pelvic ring. High fixation properties of proposed nailing create conditions for early mobilization of the patients and for conducting the exercise therapy.

Keywords: pubic rami fractures, pelvic fractures, internal fixation of pubic bone, interlocking nail.

Publishing ethics: the study was approved by the local Ethics Committee, and it complies with the ethical principles of the Helsinki Declaration (2013 revision). All patients gave informed consent to participate in the study and its publication.

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Nikita N. Zadneprovskiy; e-mail: zacuta2011@gmail.com

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Introduction

Growing number of patients with pelvic fractures is associated with evolution of high-speed transport, high-rise construction and industrial production [1–3]. With that anterior and posterior pelvic ring structures are equally affected. There is the reason to consider restoration of posterior pelvic anatomy [4] as the primary goal. This principle postulates for pelvic stabilization to arrest intrapelvic bleeding and for the maximal restoration of the bearing function of the bony pelvic ring [5, 6]. Current theories as well as treatment algorithms reflect exactly such ideas –to fix posterior segment of pelvic ring as soon as possible [5, 7, 8] in the less traumatic manner and providing mechanical stability. With that, accompanying fractures of pubic and sciatic bones are often given little significance and disproportionately less attention is given to their early or delayed fixation.

Rate of pubic rami fractures according to R.M. Hill et al is 6.9 cases per 100 000 in the population younger than 60 years old and 25.6 cases in population older 60 years [9]. In younger patients the pubic rami fractures occur in result of high energy trauma especially associated with unstable pelvic fractures. Quite often pelvic fracture is an element of a combined and polytrauma which aggravates the general status of the patient and complicates the treatment of combined injuries, especially at the resuscitation stage when damage control algorithm dictates urgent pelvic ring stabilization as part of antishock measures [10, 11]. In elderly patients isolated fractures of pubic bones are diagnosed more often. As a rule, such fractures are low-energy but are often accompanied by a severe pain syndrome with loss of support ability and abrupt limitation of mobility. Conservative treatment with prolonged bed care for elderly patients is often combined with development of hypostatic pneumonia, decubitus ulcers and thromboembolic complications [7].

In the authors' opinion surgical fixation of anterior pelvic ring has a major importance for pelvic ring stability as a whole. This opinion is supported by some publications, where authors prove that secure stability of anterior pelvic structures significantly improves mechanical rigidity of the whole pelvic ring provided fixation of posterior fractures [12, 13]. This contributes to relief of pain syndrome and assists earlier mobilization of injured and supports prophylaxis of complications related to long bed care.

Currently used methods for anterior pelvic ring injuries fixation feature essential faults. External fixator doesn't provide conditions for good reduction and sufficient stability of bone fragments and can cause soft tissues inflammation around Schanz screws, create discomfort for the patient and inconvenience for examination and treatment [14]. Plate fixation demands extensive exposure, there is a risk of large vessels injury, and development of infectious complications in postoperative period. Minimally invasive screw fixation is combined with a high risk of implant migration and secondary fragments displacement, not mentioning the intricate surgical technique. These and other drawbacks of available techniques often force the surgeons to reject surgical fixation of anterior pelvic structures in favor of conservative treatment which dictates long bed stay for the patient [15].

The circumstances above constituted the ground for conducting a research aiming at creation of a new device for anterior pelvic half-ring fixation. In the result the authors developed a new surgical technique of pubic rami fractures fixation which stipulates the use of a unique internal locked fixator which ensures high fixation stability. The authors suggest a minimally invasive and safe internal fixation technique using the new device.

Purpose of the study — to evaluate the efficiency of a radically new technique for pubic bones fixation in patients with pelvic fractures.

Materials and Methods

In the period from December 2016 till December 2017 the authors fixed 25 fractures of pubic bones in 18 patients (10 women and 8 men) using the proposed surgical method. Mean age of patients was 40.16±10.35 years (27–64 years). Bilateral pubic fractures were diagnosed in 7 patients (38.8%) (Table).

Table

Pubic rami fractures distribution according to Nakatani classification [16]

Fracture type	Left	Right	Total
I	1	3	4
II	6	9	15
III	3	3	6
Total	10	15	25

Patients with pubic symphysis rupture in addition to pubic bones fractures were not included into the present study.

According to the algorithm of the authors' institution, the first stage of treatment included pelvic immobilization by pin external fixators in all patients with clear signs of pelvic ring instability. In some cases anti-shock C-clamp was additionally applied for posterior pelvic structures fixation. In patients with uncertain symptoms of pelvis instability the immobilization was gained by pelvic bandages or not applied at all. After general stabilization of the patient the second stage of treatment included definitive minimally invasive internal fixation of posterior half-ring pelvic fractures by cannulated screws and internal fixation of pubic rami bones by interlocking nails.

In patients with multiple and combined fractures the injury severity was assessed by ISS score, fractures of pelvic ring were assessed by AO/OTA classification, pubic fractures — by Nakatani classification [16, 20] (Fig. 1).

Indications for internal fixation of pubic rami fractures by proposed technique included:

1) vertically unstable pelvic fractures with fixed injuries of posterior pelvic half-ring by cannulated screws (61-c);

2) pelvic fractures resulting from lateral compression (61-B);

3) Fractures in all zones by Nakatani.

Contraindications: extremely narrow intramedullary cavity of pubic bone at the side of injury (less than 3 mm on X-ray) and presence of infection immediately at the area of nail or locking screws insertion. A relative contraindication was presence of non-mobile pubic fragments with inability to perform closed reduction (in this case it's possible to switch to semi-closed or open reduction of pubic bone fragments).

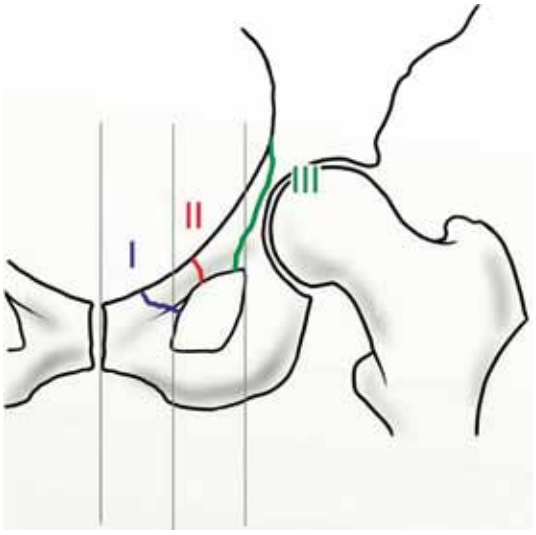

Fig. 1. The three types of the Nakatani classification system of pubic rami fractures: type I fractures medial of the obturator foramen; type II fractures of the middle zone; type III fractures lateral to the obturator foramen [20]

X-ray control of quality and outcomes of fixation was made in 1, 2, 3, 6 and 12 months postoperatively, in Judet, inlet, outlet projections and in standard overall pelvic view. Functional outcome was evaluated by Majeed score in 6 and 12 months postoperatively.

The authors managed to evaluate roentgenological and functional outcomes in 16 patients. One patient died due to severe craniocerebral injury and one patient refused from cooperation and further follow up.

Designed fixator and proposed surgical technique

The designed intramedullary fixator is made of titanium alloy and has 3 length options (110, 120 and 130 mm). The nail has a cylindrical form along the whole length (Fig. 2a). Nail diameter at the site of connection with guiding device is 5 mm with gradual conical taper up to 3.5 mm. There are two transverse open-end holes in the widest part of the nail, 3.8 mm in diameter, located 5 mm from each other, to enable nail interlocking. For internal fixation of pubic bone the nail was connected with guiding device consisting of two parts (handle and cover plate) and a connecting screw. Cover plate of the guiding device has two open-end holes for placing protective sleeves and for locking the nail by 3.5 mm screws using a screwdriver (Fig. 2b).

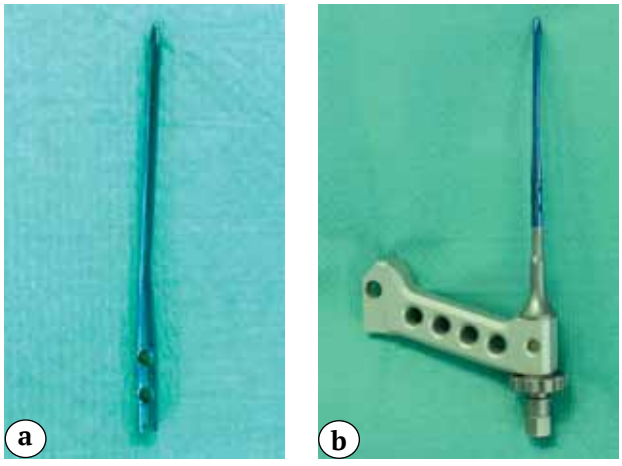

Fig. 2. The interlocking nail for pubic rami osteosynthesis (a); the nail in the handle of the targeting device (b)

The patient was placed on the surgical radiolucent table with rollers under knee joints to ensure 20–30° flexion. Foley catheter was applied to control diuresis and monitor intraoperative bladder injuries. Image intensifier was used during the whole surgical procedure to ensure intraoperative x-ray control of fragments reduction as well as nail and locking screws positioning. Surgical incision of 1 cm was made in the area of the superior border of pubic symphysis.

Scalpel blade end reached anterior superior angle of pubic bone body in the zone of medial pubic tubercle (tuberculum pubicum) immediately under the pubic crest (crista pubica). The operator was located on the opposite side to the pubic fracture site. 2.0 mm guiding wire was inserted using a cylindrical soft tissue protecting sleeve through the superior angle of pubic bone along its superior branch under image intensifier in inlet and outlet projections, trying to avoid perforation of the other cortical wall (Fig. 3).

Drilling of the anterior cortical wall of pubic bone was done under the image intensifier by a cannulated 6mm drill bit over the guiding wire (Fig. 4).

Nail fixed in the guiding device was inserted intraosseously through the surgical incision from intact side of the pelvis (Fig. 5).

Nail passing from distal fragment into the proximal fragment of pubic bone was done under image intensifier in inlet and outlet projections. Nail was introduced into the pubic bone by guiding device until its complete insertion in the bone in the inlet view. 1cm skin incision on the anterior abdominal wall was made for locking screws. This incision was used for drilling of holes in the bone by a 2.5 mm drill bit through the protective sleeve. Drill bit and protective sleeve were consecutively removed and the nail was locked by two self-tapping 3,5 mm screws of corresponding length (Fig. 6).

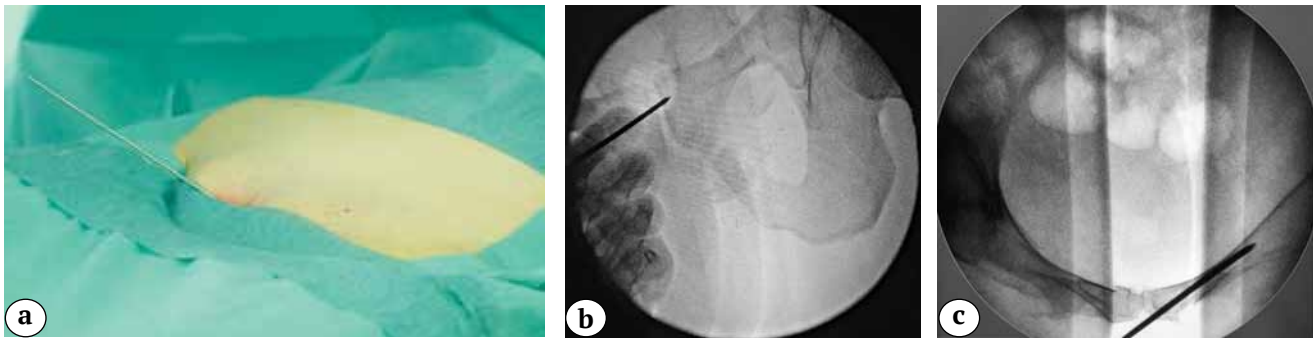

Fig. 3. Insertion of the guide wire into the distal fragment of the pubic bone:
a — photo; b — image intensifier control (outlet view); c — image intensifier control (inlet view)

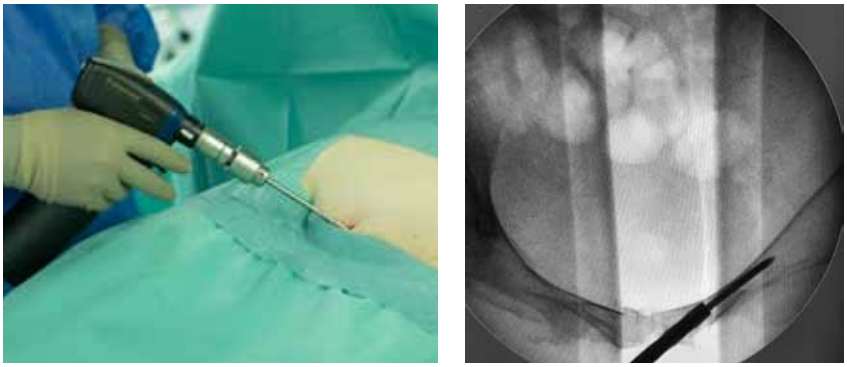

Fig. 4. Perforating of the outer cortical wall of the pubic bone

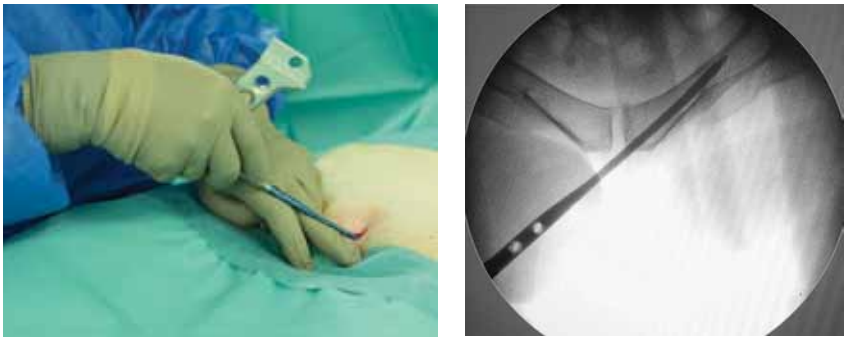

Fig. 5. Pubic bone osteosynthesis. Insertion of the nail from the distal to the proximal fragment of the pubic bone

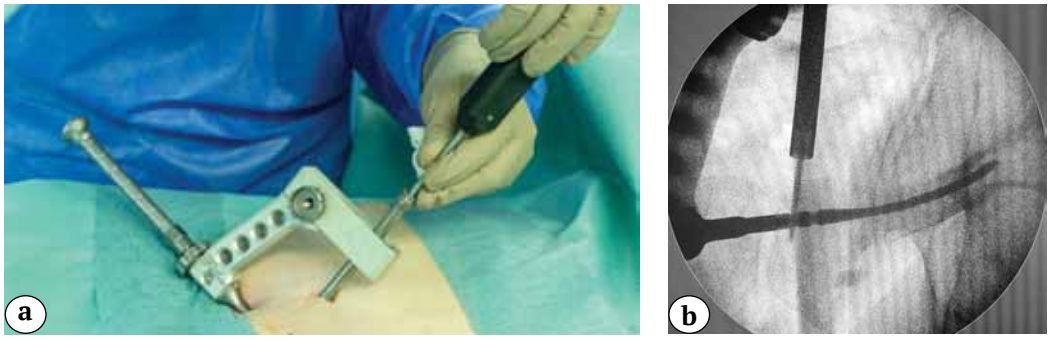

Fig. 6. Placement of the locking screws using a screwdriver through the targeting device (a); nail interlocking using a 3.5 mm self-tapping screw (b)

Use of two locking screws excludes the nail migration along intramedullary canal and its axial rotation. Final intraoperative x-ray was done to control nail and locking screws position inside the bone.

Guiding device was then detached from the nail and removed from the surgical wound (Fig. 7). Then the wound was sutured, and sutures covered by aseptic dressings.

After pubic fracture fixation the stabilization of posterior pelvic half-ring was achieved by cannulated screws in a minimally invasive manner. In 4 patients (22.2%) the posterior fixation was done as a next stage after C-clamp removal on days 1–4 after the clamp application. Sacroiliac joint ruptures were fixed by cannulated lag screws of 6,5mm and/or 7,3mm in diameter with partial thread (32 mm). Sacrum fractures were fixed by positioning cannulated screws of 6.5 mm and/or 7.3 mm with full thread at the S1 and/or S2 level (Fig. 8).

Patients who underwent treatment according to described technique were allowed mobilization and therapeutic exercises next day after the surgery. Patients with severe multiple and combined trauma were allowed to turn to side and over to abdomen to avoid decubitus and thrombogenesis. Sutures were removed on days 10–14 after the procedure.

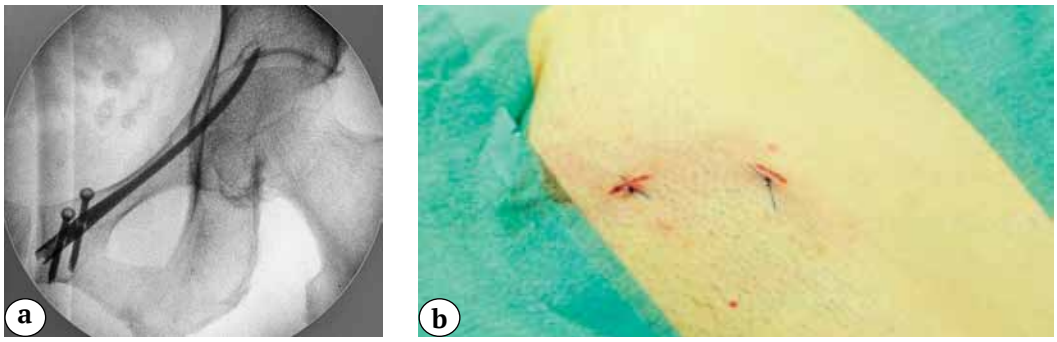

Fig. 7. Final X-ray image after fixation of the pubic rami fracture with the interlocking nail (a); postoperative view after osteosynthesis surgical field after wounds closure; surgical field after wounds closure (b)

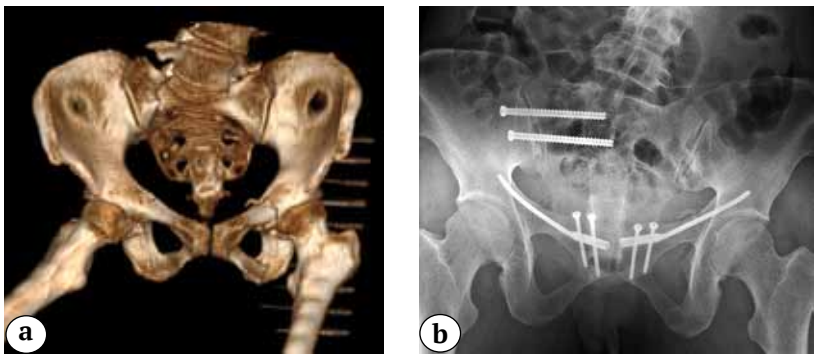

Fig. 8. Osteosynthesis of pubic rami fractures using the interlocking nailing technique: pelvic fracture AO/OTA 61-B, pubic bone fractures (Nakatani III — right, Nakatani II — left) (a); final X-ray image after fixation of the pubic ramii fractures with the interlocking nails and fixation of the sacrum with two cannulated screws (b)

Results

Mean follow up term was 7.8±6.2 months (from 1 to 24 months). Average ISS score was 25.1±7.8 (from 11 to 41) points. Thirteen (72.2%) patients sustained pelvic ring fractures as part of multiple and combined injuries, 3 patients (16,7%) had an accompanying acetabulum fracture, 2 patients (11.11%) had an open pelvic fracture.

A type pelvic ring fracture on AO/OTA classification was diagnosed in 1 patient (5.6%), B type — in 11 patients (61.1%), C type — in 6 patients (33.3%). External fixator was used to stabilize pelvic ring in 10 patients (55.6%).

The authors reported the following distribution according to mechanism of pelvic injury: fall from a height — 8 cases (44.4%), road traffic accident — 7 cases (38.9%), others (railroad trauma, airplane crash, industrial accident) — 3 cases (16.7%).

The authors performed laparotomy in 5 patients (27.8%) due to injury of abdominal organs, epicystostomy was done in 2 patients (11,1%) in suprapubic area due to bladder injury.

Mean time from admission to internal fixation of pubic bones was 6.12±2.9 (from 1 to 14) days, mean surgical time for pubic rami fracture fixation by interlocked nail — 37.6±17.3 minutes, mean intraoperative blood loss — 8.6±3.2 ml.

By the moment of writing the present paper x-ray signs of pubic bones healing was observed in 16 cases (64%), in other 9 cases (36%) follow up term was less than mean healing term (2 months).

6 months postoperatively the functional outcome in 11 patients (68.8%) averaged 91±3,9 by Majeed score. 12 months postoperatively and later, 8 patients (50%) demonstrated average Majeed score of 93.8±2.9. No neurological complications, surgical site inflammation, implant migration and secondary pubic bone fragments displacement was observed in all clinical cases.

Discussion

Until now conservative treatment pf pubic rami fractures is applied more often in the clinical practice than operative treatment and is accompanied by induced long term immobilization of the patient, continuous pain syndrome, late functional recovery and high rate of dangerous hypostatic complications [1]. Besides, conservative treatment can't always provide for pelvis anatomy restoration leading to healing of anterior pelvis half-ring fragments in malposition [5]. In turn, posttraumatic deformity of anterior half-ring provokes dysuria, erectile dysfunction in men and loss of reproductive function in women [17]. Surgical procedures to stabilize pelvic injuries were developed in order to improve treatment outcomes of patients with pubic rami fractures.

At present there are three major surgical fixation methods of pubic rami fractures: extrafocal by external pin fixators, open reduction and internal plate fixation, and finally, minimally invasive fixation by cannulated screws. The authors have to mention another two methods that are not so widespread in the clinical practice. One of those is subcutaneous fragments fixation of anterior half-ring by plates — Pelvic Bridge [2]. Another one (INFIX) consists of transpedicular screws placement into both pelvic half-rings, then those screws are connected to each other by a connective bar [18].

The most widespread is pubic rami fracture fixation by external pin fixators. Advantages of such method are evident — minimally invasive technique, availability of devices and relative simplicity. However, reinsertion of Schanz screws and re-mounting of fixator is needed n 12–64% of cases due to inflammatory complication. 4% of cases feature injuries of lateral cutaneous femoral nerve, so called "Bernhardt-Roth syndrome" [1, 19].

Second of the most frequently applied methods is the minimally invasive fixation by cannulated screws. Pubic rami fractures in

zones I and II according to Nakatani are the most optimal for retrograde screws fixation, in zone II — for antegrade screw insertion [16]. However, loss of fixation and implants migration were reported in 15% of cases. There is a risk of injury to femoral vessels and hip joint. In some cases the parabolic curve of the superior branch of pubic bone is so severe that makes impossible long screws insertion without perforating the acetabulum. In this case a short screw is inserted which decreases biomechanical rigidity of fixation [16].

Open reduction and internal fixation of pubic rami fractures by plates requires extensive surgical exposure with blood loss which may result in severe complications like injury to femoral artery, vena and/or nerve [21].

To solve the existing problems the authors propose a simple, secure and minimally invasive technique to fix pubic rami fractures by interlocking nails. An arched shape of nail and its elasticity allows to insert the implant bypassing the acetabulum with any curvature type of pubic bone (cannulated screws fixation is deprived of such advantage). Fixation rigidity is ensured by three-point implant fixation: first point — at insertion site, second — at fracture site or at the isthmus, and third — at site where proximal part of the nail is wedged in the dense bone of supraacetabular area or rests on its wall. Nail interlocking by two screws creates additional rotational and axial implant stability inside the medullary cavity.

The designed method of pubic rami fracture fixation allows to perform closed reduction of fragments on the nail similarly to joystick. Minimal blood loss, fast implant insertion without subsequent removal are the advantages of proposed technique. Besides, the presented method provides for stabilization of anterior half-ring in presence of colostomy, epicystostomy and drainages in the anterior abdominal wall without any inflammatory complications.

The described method allows to almost immediately relieve pain syndrome at the site of pubic fracture and mobilize the patient in maximally short term thanks to secure fragments fixation.

The authors did not find any literature on use of the same or similar surgical technique, which doesn't allow to compare the treatment outcomes to other data.

Proposed technique of internal fixation for pubic rami fractures is minimally invasive with minimal blood loss and low rate of possible inflammation in postoperative period. Interlocking nail allows retrograde fixation of fragments in all zone according to Nakatani from one approach without risk of hip joint injury. Minimally invasive technique can be applied in patients with wounds of anterior abdominal wall, for example, after laparotomy, in patients with colostomy, epicystostomy and various drainages in this area. Besides, the described method provides for healing of pubic rami fractures at the same rate as the standard methods and to obtain good functional outcomes in early terms. Fixation has the sufficient biomechanical stability to enable full support ability of the lower leg immediately after the surgery. Interlocking nail fixation is the definitive fixation method which doesn't need mandatory implant removal after confirmed healing.

The present research has limitations due to a relatively small number of patients and short follow up terms. Further accumulation of clinical data and statistical analysis of outcomes is required. The authors believe that the proposed treatment option has promising outlooks due to its advantages: simple surgical technique, minimal invasive procedure and high fixation properties.

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INFORMATION ABOUT AUTHORS:

Pavel A. Ivanov — Dr. Sci. (Med.), professor, head of the Polytrauma Department, Sklifosovsky Clinical and Research Institute for Emergency Care, Moscow, Russian Federation

Nikita N. Zadneprovskiy — research associate, Polytrauma Department, Sklifosovsky Clinical and Research Institute for Emergency Care, Moscow, Russian Federation

Alexander V. Nevedrov – Cand. Sci. (Med.), research associate, Polytrauma Department, Sklifosovsky Clinical and Research Institute for Emergency Care, Moscow, Russian Federation

Vsevolod O. Kalensky — research associate, Polytrauma Department, Sklifosovsky Clinical and Research Institute for Emergency Care, Moscow, Russian Federation

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Kirschner Wire Migration into Spinal Canal after Acromioclavicular Joint Fixation (Literature Review and Clinical Case)

D.A. Gulyaev [1], D.S. Godanyuk [1], T.A. Kaurova [1], P.V. Krasnoshlyk [1], S.V. Maikov [2]

[1] *Almazov National Medical Research Centre, St. Petersburg, Russian Federation*

[2] *Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation*

Abstract

Fracture and migration of metal implants is a well-known issue which is especially relevant for actively loaded zones with a high amplitude of physiological movements. The authors analyzed 17 publications dedicated to Kirschner wire migration into the spinal canal after fixation of acromioclavicular joint (ACJ) injury. The present paper contains literature review and own clinical case of the authors. The authors generalize the conceptions of migration causes, surgical tactics and prevention recommendations. The key reason of fracture and migration of Kirschner wires during fixation of ACJ injury is the instability of implants, trans-articular wire insertion during fixation of reduced dislocation of acromial end of the clavicle, insufficient immobilization and untimely implants removal after removal of immobilization. Implants migration into the spinal canal is the indication for their surgical removal irrespective of clinical signs. In the majority of studied publications authors described posterior approach or lateral approach aligned with the migration direction. No grafting techniques for dura mater defects were present in the studied literature. The authors of the current paper justify a surgical procedure for removal of migrated implant using a combined posterior and lateral approach on the own clinical case. The choice of procedure algorithm results from the need for prophylaxis of secondary spinal cord lesion and liquorrhea during removal of migrated implants from spinal canal.

Keywords: Kirschner wire migration, spinal cord lesion, liquorrhea, acromioclavicular joint, clavicle fracture.

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Introduction

Migration of implants is a serious complication after internal fixation which becomes especially hazardous in case implants shift into adjacent anatomical zones. Fractures with local displacement of Kirschner wires and other implants are frequently reported even after the correct initial insertion [1].

Mechanism of implants migration following ACJ fixation is not completely clear. The following reasons are considered the most probable: effect of multidirectional kinetic forces on acromial end of the clavicle [2], muscles contractions, respiratory movements, negative intrathoracic inspiratory pressure, gravitation forces and local bone resorption around the implant [3–7].

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✉ *Denis S. Godanyuk*; e-mail: godanyuk@gmail.com

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The studied publications report lesions of esophagus, trachea, great vessels of the neck, lungs, aorta and heart by implants in patients who underwent surgical treatment of clavicle and ACJ injury including the lethal cases [3, 8–12].

Migration of implants into the spinal canal is associated with risk of a severe neurological deficit [5, 7, 13, 15] as well as with lesions of spinal cord, large vessels of neck and pleura during surgical procedure [14, 15].

The aim — is to call the attention to the rare complication after fixation of ACJ — migration of implant fragment into the spinal canal with consequent lesion of dura mater and spine cord roots. The authors present also a literature review on above issue and justification of surgical tactics.

Literature review

The authors found 17 publications in available literature dedicated to implants migration into the spinal canal in patients who underwent fixation of ACJ and clavicle injuries by various implants.

In the studied publications age of patients varied from 22 to 72 years, with prevalence of middle-aged patients. Patients in 11 papers were male, in 2 — women, in 4 papers gender of patient was not indicated. Period of time between surgical stabilization and implant migration was from 11 days to 12 years. In 11 cases migration was observed during the first year after surgery, of those in 7 cases — within 2 to 6 months. In all cases the wire entered the spinal canal through radicular foramen at levels from C5-C6 to Th2-Th3, in 9 cases — at C7-Th1 level. In 7 out of 12 publications the patients were operated on the right side (in 4 papers the side was not identified).

Indications of causes for implant migration were reported in 6 publications. In all cases migration was accompanied by instability represented by bone resorption or wire fracture. Sivakon S.V. et al. [16] consider trans-articular wire insertion, insufficient immobilization and untimely implants removal after removal of immobilization as the possible reasons for instability. Other probable causes for wire migration include anatomical and biomechanical features of the upper shoulder girdle, insufficient arm immobilization, negative inspiratory pressure, falling, body features (obesity in one case), recurrent injuries (falling) and load on operated limb.

Clinical picture in five publications demonstrated signs of spinal cord damage such as inferior paraparesis, tetraparesis or Brown-Sequard's syndrome [5, 7, 14, 17]. Radicular pain corresponding to the level of wire intrusion into the spinal canal was reported in three cases [4, 13, 18]. In two cases clinical signs included lungs and pleura injury (emphysema and pneumothorax) without a neurological deficit [19, 20]. L. Minić et al. (2016) in their paper described liquor hypotension syndrome [13] as the key clinical sign. Asymptomatic migration of Kirschner wire into the spinal canal was described by S. Bennis [21].

In the majority of cases (10 publications) the authors used lateral approaches (supraclavicular, thoracotomy) for removal of a foreign body from the spinal canal ensuring wire removal along it's axis. Such tactics was utilized in patients without signs of spinal cord and roots injury as well as in patients with severe neurological symptoms (Loncán et al., 1998; Regel J.P. et al., 2014) [7, 17]. Nikolsky M.A. et al (2006) and P. Fransen et al (2007) used a combination of supraclavicular and posterior approaches to mobilize the wire in lateral direction and ensure control over its removal [7, 14]. P. Fransen et al. (2007) discuss in detail the advantages of approaches combination. In particular, the authors indicate the control over intradural hemostasis, sealing of dura mater and preventing displacement of distal wire end during its removal [14]. The similar advantages of control from the side of spinal canal are reported by W. Mamane et al (2009) [19].

In two cases the authors reported liquorrhea from defect of dura mater during the surgery [20, 21]. Postoperative liquorrhea was not described in any of the publications. At the same time the applied method of desling the dura mater is not described in the publications. When discussing surgical tactics [14, 19] some authors indicate a possibility to control liquorostasis from approaches through spinal canal. A combination of symptoms resembling liquor hypotensions was reported as a dominant clinical sign in the case of L. Minić (2016). Remarkably no signs of liquorrhea were observed [13] intraoperatively during wire removal through transthoracic approach. Yawei Li et al. (2011) reported liquorrhea in wound canal during wire removal from thoracoscopic approach. No signs of liquor hypotension and liquorrhea prior to surgery or postoperatively were described, grafting of liquor fistula was not performed [20].

The authors of referred publications indicate various methods to prevent implants migration including technical and organizational recommendations.

The majority of authors mention the need to inform surgeons on probability of such complications. Some publications stress the importance of patients' awareness on possible failure and migration of implants [6, 14, 18]. Regular X-ray control with an interval of 2–4 weeks and implants removal after fracture site consolidation or at appearance of instability signs are considered mandatory by the majority of the authors. Many authors recommend to remove wires in 6-8 weeks after the surgery [5, 6, 14]. A strict immobilization of injury site [19] and excluding the abduction of operated limb over 90° [5, 6] are mandatory. Sivakon S.V. et al. believe necessary to remove implants prior to starting rehabilitation and restoration of active limb movements [16].

J. Liberski emphasizes the need to evaluate the physical activity level of a patient, patient's ability to self-care as well as ability to comply with recommendations. The author recommends to choose other fixation methods in athletes and people with active way of life, in elderly people and people who need aid as well as in non-compliant patients (alcohol and drug abuse, mental disorders) [22]. Nikolsky M.A. also supports limitation of indications for wire fixation for treatment of clavicle and ACJ injuries [7].

Certain authors, in particular, P.Fransen, indicate increased reliability of fixation after bending the distal end of wire at 90° [14]. At the same time, Yawei Li considers that internal fixation using wires for clavicle and ACJ injuries should be acknowledged as a high risk manipulation. The publication underlines migration probability of all wire types — plain, threaded and wires bent at the end [20]. Saad Bennis also indicated insufficient reliability of wire fixation and considers plate fixation as a safer procedure with less frequent non-unions and migration risk [21].

Clinical case

64 year old patient underwent Kirschner wires fixation in 1997 for injury of right ACJ. Two years postoperatively, after working in a garage (repairing vehicle in a supine position), the patient felt pain and observed a skin contusion in the area of right shoulder joint. After another year patient started to feel pain in neck irradiating to the right arm. The patient did not seek medical advice or aid. During routine examination in 2016 the fluorogram revealed a foreign body of a metal density in spine projection.

CT scans of spinal canal on C6-C7 level confirmed presence of a 4.5 cm long foreign body (wire), located obliquely in the anterior third of spinal canal, it's proximal end located at the level of C7 arc root on the left, distal wire end was in right radicular foramen of C6-C7 at the level of lateral margin of articular facets (Fig. 1).

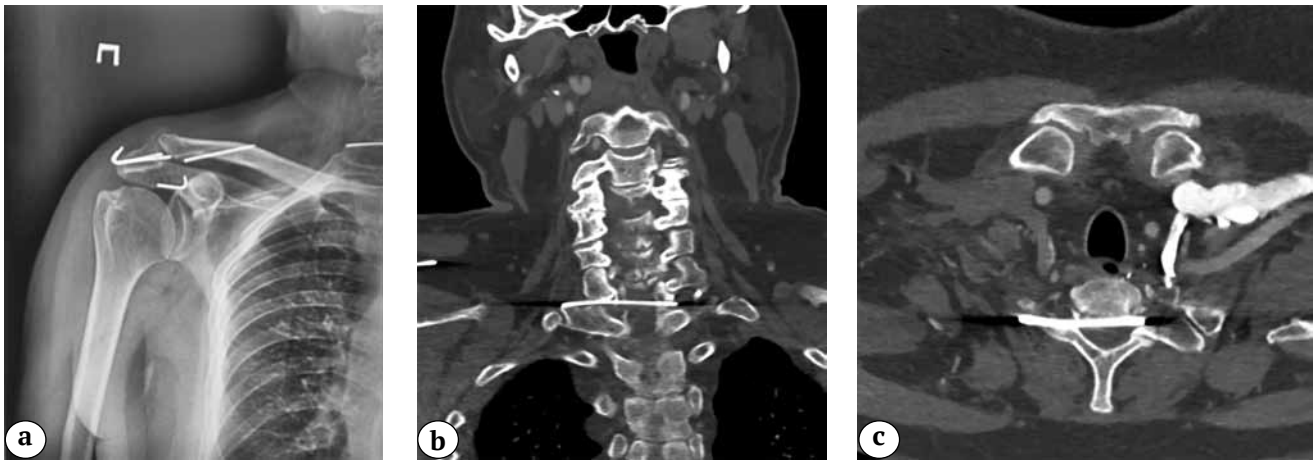

Fig. 1. Preoperative cervical spine X-ray images:
a — X-ray images of the right shoulder after acromioclavicular fixation with K-wire, the disruption of one of the spokes is seen, distal part of other spoke located at the level of C7;
b — CT-scan of the cervical spine, there is foreign body of metal density, penetrating right radicular foramen C6-C7;
c — axial plane — K-wire in the spine canal

At admittance the patients complained on local pain in neck irradiating along the medial surface of the right forearm and hand which increased during straining efforts and coughing. Neurological symptoms included root syndrome of C8 on the right. No general cerebral, conducting or meningeal symptoms were observed.

Surgery was performed on 3.05.2017: removal of intradural foreign body (K-wire fragment) at the level of C7-Th1 from combined approach, grafting of dura mater defect.

General anesthesia was applied with patient in the lateral decubitus. The authors used a lateral supraclavicular approach to first cervical rib on the right between trapezoid and posterior scalene muscles (Fig. 2 a). C8 nerve was identified over transverse process Th1 exiting radicular foramen C7-Th1, level of manipulations was verified by image intensifier. Visual examination and palpation did not reveal any foreign bodies in the zone of manipulations (Fig. 2 b).

Skin and subcutaneous fat incision was made in projection of spinous processes C6-Th1, periosteum detached from spinous process and lamina of C7 on the right, from the medial part of C7-Th1 joint. Flavectomy and medial facetectomy of C7-Th1 on the right were performed. A Kirschner wire fragment was visualized in the spinal canal, dura mater was perforated above root of C8. After mobilization of epidural veins and C8 root the wire was displaced into the right radicular foramen and removed from supraclavicular approach (Fig. 2 c). The authors observed transparent colorless liquor in the wound discharging from the defect of dura mater (Fig. 2 d). Defect of dura mater was closed by Tachocomb plates. Hemostasis was consistent at ABP of 130/90 mm Hg. Valsalva test proved no liquorrhea. Wounds were sutured in layers without drainage.

Postoperative period was uncomplicated, wounds healed by primary tension, patient discharged from the hospital on 6th day after the surgery. At control examination in 1.5 months after the surgery the scars did not demonstrate any inflammation signs, neurologically a regress of radicular pain was observed. The patient was sent to a trauma surgeon for removal of remaining fixation elements in the area of the right ACJ.

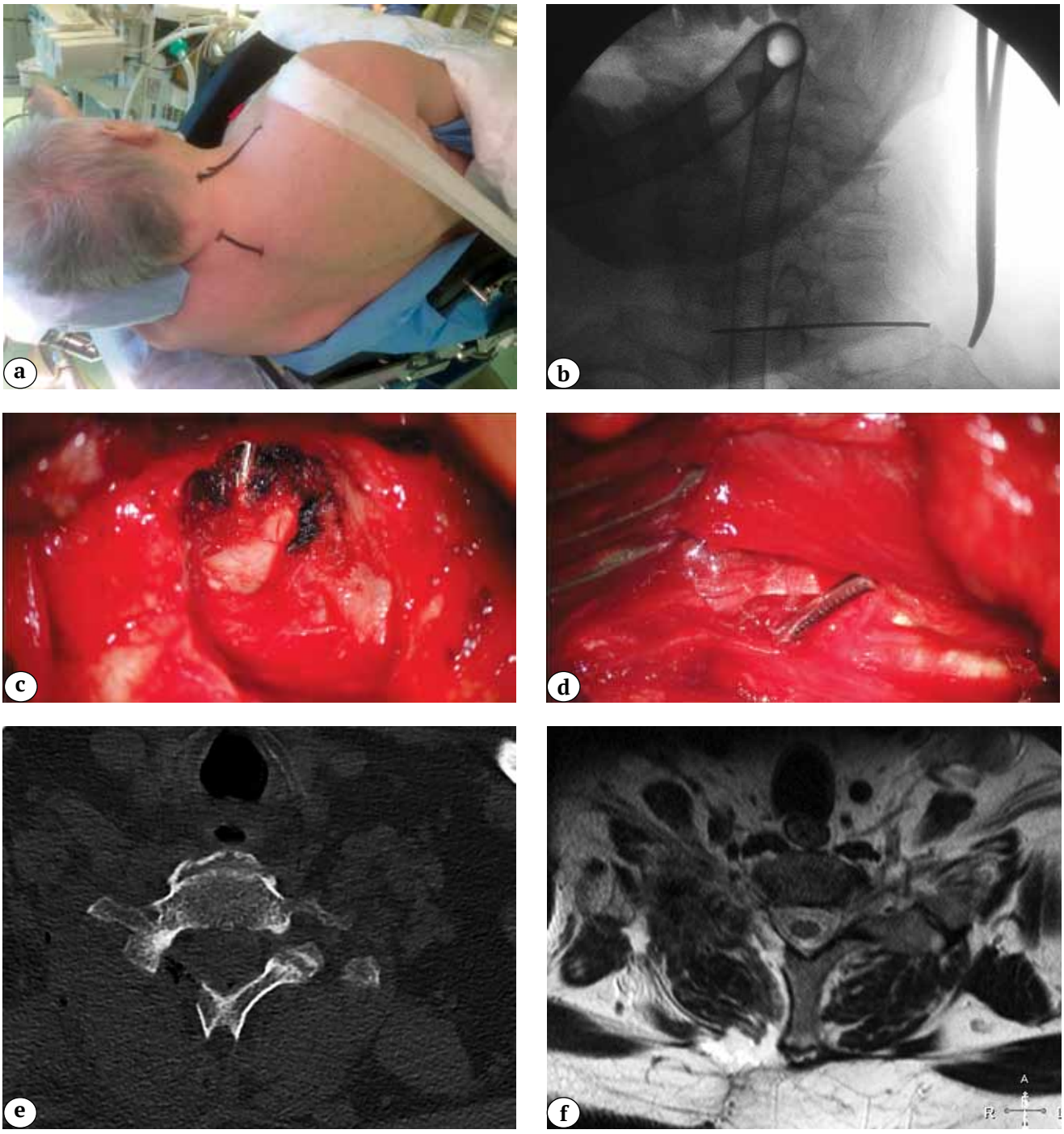

Fig. 2. Procedure stages and postoperative X-ray control:
a — patient positioning on surgical table — lateral decubitus, marked right supraclavicular and posterior median approaches;
b — intraoperative X-ray control during supraclavicular approach — manipulation area corresponds to level C7-Th1;
c — interlaminectomy, medial facetectomy on the right at level C7-Th1, wire is visualized, dura mater perforated at the level C8;
d — wire displaced in lateral director is seen at the level of exit from radicular foramen of C7-Th1;
e — CT after the surgery;
f — MRI after the surgery

Rationale for surgical tactics

Tactics for the procedure was chosen based on the analysis of the main surgical stages — visualization, mobilization and removal of foreign body from spinal canal. Insignificant prominence of proximal wire end from radicular canal and it's curvature created a potential risk of deflection of distal end of the implant with consequent lesion of neural tissue during implant mobilization, fixation and traction. Thus, to prevent a secondary injury to spinal cord during main surgical stages it's required to control positioning of the distal wire end in the spinal canal. Preliminary visualization of fragment exit point from the radicular canal C7-Th1 is necessary due to a potential damage to large vessels of the neck during wire mobilization laterally to the spine.

In the present case the authors observed a point-contact defect of dura mater localized on it's lateral surface superior to root origin, which stipulated choice of grafting method.

An opportunity to decrease risk of iatrogenic damage to spinal cord and postoperative complications by combination of lateral and posterior approaches stipulated the chosen surgical tactics.

Discussion

Migration of Kirschner wire fragments into spinal canal is one of possible complications with a high rate of neurological deficit [4, 5, 7, 13, 14, 17, 18] following fixation of ACJ injuries. Wire failure as a consequence of instable fixation is the main cause of such complication and demands close attention of the surgeon and patient during the whole period of fixation in place [6, 7, 14, 18, 20, 21].

Such complication is the indication for surgical treatment to prevent progressing of neurological deficit and further migration [7, 14, 19]. The authors consider it justified to use combined lateral and posterior approaches in all cases of intra-canal positioning of migrated implant irrespective of degree of neurological deficit. In such cases, the tasks of surgical manipulations through spinal canal are the prophylaxis of spinal cord lesions during wire removal, wire mobilization in lateral direction, control over intradural hemostasis and prophylaxis of liquorrhea.

Probably, the termination of liquorrhea described by Yawei Li and M. Ljubodrag [13, 20] in their cases without any supplementary manipulations during wire removal from lateral thoracotomic approach can be explained by a point-contact defect of dura mater and narrow wound canal in paravertebral soft tissues. At the same time, in authors' opinion the link between liquor routes and natural body cavities or surgical wound always poses a risk of liquorrhea and requires accurate defect sealing and isolation of area of dura mater grafting from natural and iatrogenic cativites.

Kirschner wires fixation of ACJ is accompanied with a risk of disabling and lethal complications [5, 7, 12–15]. Probability of life threatening complications due to migration of implants make us believe that the present method is not sufficiently reliable and safe.

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INFORMATION ABOUT AUTHORS:

Dmitry A. Gulyaev — Dr. Sci. (Med.), professor, chief of the Department of Neurosurgery N 5, Almazov National Medical Research Centre, St. Petersburg, Russian Federation

Denis S. Godanyuk — neurosurgeon, Department of Neurosurgery N 5, Almazov National Medical Research Centre, St. Petersburg, Russian Federation

Tatiana A. Kaurova — Cand. Sci. (Med.), neurosurgeon, Department of Neurosurgery N 5, Almazov National Medical Research Centre, St. Petersburg, Russian Federation

Pavel V. Krasnoshlyk — Cand. Sci. (Med.), head of the Department of Neurosurgery N 5, Almazov National Medical Research Centre, St. Petersburg, Russian Federation

Sergey V. Maikov — Cand. Sci. (Med.), researcher, Department of Sports Traumatology and Rehabilitation, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

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Regulatory Concerns about Medical Device Manufacturing using 3D Printing: Current State of the Issue

N.N. Karyakin [1], I.I. Shubnyakov [2], A.O. Denisov [2], A.V. Kachko [1], R.V. Alyev [1], R.O. Gorbatov [1]

[1] *Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation*

[2] *Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation*

Abstract

Custom-made implants, orthotics, orthoses, models for surgical planning and education, and much more are now created using 3D printers. In this article, the authors summarized information on laws and regulations in the domain of legal support for 3D printing of medical devices in Russia and abroad. 3D printing is one of the promising avenues in developing new methods of treatment, so immediate establishing of clear criteria for its legal regulation is necessary. As is, there are still many gaps in the legislative framework. The issues of the quality of 3D models, material standardization and manufacturing processes using 3D printing technologies remain unresolved. When using custom-made medical devices, respecting the rights of patients and preventing the use of prohibited or restricted materials are essential. Yet, legal barriers to this innovative direction of medicine must be avoided.

Keywords: legal regulation in medicine, 3D printing of medical devices, custom-made implants.

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Background

To date, medicine is likely the most rapidly growing branch of science, resulting in the emergence of new medical technologies. Up-to-date technical advances brought about the advent of 3D printers. This expanded significantly the possibilities for diagnosing and treating various pathologies through medical models created with their help.

3D printing provides the opportunity to create, layer-by-layer, a physical object from a mathematical model developed in the CAD system. Custom-made implants, orthotics, orthoses, models for surgical planning and education, and much more are manufactured now with the use of additive technologies [1–6]. Such a vast range of applications of medical devices manufactured using 3D printing necessitates their legal regulation. Since 3D printing is one of the promising avenues for developing new methods of treatment, both legal guidelines to its development and safety controls for medical devices manufactured using additive technologies [7, 8] are necessary.

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Roman O. Gorbatov; e-mail: gorbatov.ro@yandex.ru

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Legal regulation of the manufacture of medical devices using 3D printing in Russia

A medical device is legally defined in Para.1, Art. 38 of the Federal Law of November 21, 2011, No. 323-FZ "On Public Health Protection in the Russian Federation" as: "Any medical appliances, apparatuses, devices, equipment, materials, and other products used for medical purposes either separately or in combination with each other and with other accessories required for the use of these products as intended, including customized software, and designed manufacturer (producer) for the prevention, diagnosis, treatment and aftercare of diseases, monitoring of the human body for medical research, medical tests, rehabilitation, replacement, modification of anatomy or physiological functions of the body, pregnancy prevention or termination, the functional purpose of which is not implemented by pharmacological, immunological, genetic or metabolic impact on the human body. Medical devices can be recognized as interchangeable if they are comparable in functionality, quality and technical characteristics and are suitable to replace each other."

It should be noted that, according to Decree of the Government of the Russian Federation of December 27, 2012 No. 1416 "On Approval of the Rules for State Registration of Medical Products", mandatory requirements of effectiveness and safety are imposed on medical devices. When using medical devices in medical practice, a positive effect should be achieved. Harm to the patient is unacceptable.

In all cases of intervention in the sphere of human health by medical practitioners, healthcare professionals of scientific laboratories, and research institutes, a sound legal basis is needed to ensure the state's guaranteed protection of the human right to life, health and body integrity. Any intervention in the sphere of physical and/or mental health of a person should be prepared, organized and carried out in such a way that it does not violate the rights and legitimate interests of people, and it is these goals that legal science should serve [9].

The absence of legal instruments regulating the manufacture and use of custom-made medical devices does not allow for ensuring their safe use in patients. At present, the broad use of custom-made medical devices is governed by Para. 5, Art. 38 of the Federal Law No. 323-FZ of November 21, 2011 "On Public Health Protection in the Russian Federation", where it is determined that custom-made medical devices, manufactured to meet the specific requirements of medical specialists and intended solely for the personal use of a particular patient, are not subject to state registration. This is also confirmed by the Decree of the Government of the Russian Federation of December 27, 2012 No. 1416 "On Approval of the Rules for the State Registration of Medical Products" and a letter of the Federal Service for Healthcare Supervision of July 21, 2015 No. 04-21338/15.

Thus, custom-made medical devices manufactured using 3D printing, in conformity with the anthropometric indices of specific patients, are not subject to state registration. Based on the literal interpretation of the above statutory provision, it follows that the material from which the individual medical devices are made is subject to state registration.

However, this issue is not controlled by the executive authorities. Roszdravnadzor does not keep the state register of medical devices and organizations (individual entrepreneurs) that produce and manufacture custom-made medical devices. These medical devices are not subject to the provisions of Part 3, Art. 38 of the Federal Law No. 323-FZ of November 21, 2011 "On

Public Health Protection in the Russian Federation", providing for technical and/or operational documentation developed by a manufacturer (producer) of a medical device.

There are no clear regulatory laws regarding: quality of the 3D models themselves, standardization of materials and manufacturing processes using 3D printing technologies, assurance of the safety of objects printed using a 3D printer and reduction in the risk of printing prohibited or restricted objects [9–12] .

Another problem with manufacturing custom-made medical devices using 3D-technologies is copyright enforcement. The legal framework for copyright protection is determined in the Civil Code of the Russian Federation (Part 4). The systematic interpretation of Article 38 of the Federal Law No. 323-FZ of November 21, 2011 "On Public Health Protection in the Russian Federation", as well as Part 4 of the Civil Code of the Russian Federation, implies that the objects of copyright in the production of medical devices include regulatory, technical, operational documentation and other documents related to the broad use of medical devices (including technical tests, toxicological studies, preclinical and clinical trials), drawings and other documentation used in the manufacture of medical devices, as well as special software (Civil Code of the Russian Federation, Para.1, Art.1259).

However, custom-made medical devices do not undergo preclinical and clinical trials and are not subject to state registration. This raises the question: how will the original models created in the graphic editor be protected by copyright as intellectual property? Another concern that arises from the production of custom-made medical devices is how to not violate copyrights when printing a copy of a registered medical device using 3D printer?

Legal regulation of medical 3D printing in the USA

To date, the legal aspects of the regulation of additive technologies are most developed in the United States. 3D printing is widely used in all American lines of production: commercial, industry, medicine, construction, etc. However, there exist a number of unresolved legal issues. The legal norms for use of additive technologies in medicine for copying, quality, marketing and sales are not complete [13–15].

Technological development, as a rule, changes the established legal norms. In history, this happened more than once, starting with Johann Gutenberg and up to the IT revolution. Throughout history, in many countries, problems relating to the ban on the use of new technologies have been solved at the legislative level. It is believed that emerging technologies do not actually require changes in legislation. This strategy may work for some time, but sooner or later, lawmakers will have to face the need to adapt laws. Initially, legislation on product liability arose from contractual law, with many decisions made in the early 1960s in favor of manufacturers, since the general rule prohibited product users from suing manufacturers [16].

Medical practitioners and medical companies are increasingly using 3D printing to reduce the cost of vital personalized medical devices and implants. Specialists engaged in the study of the legal regulation of 3D printed objects argue that the legislation on 3D printing is slightly different from the legal regulation of conventional product manufacturing. Existing laws and subordinate regulations governing intellectual property rights were issued before the advent of 3D printing and therefore do not directly cover all of its capabilities. Medical devices are utilitarian, not artistic objects, and therefore have no basis for the protection of copyright [17, 18].

Activities related to 3D printing in the United States are controlled by three divisions of the U.S. Department of Health and Human Services: FDA's Center for Devices and Radiological Health, which regulates the use of medical devices; FDA's Center for Biologics Evaluation and Research; FDA's Center for Drug Evaluation and Research.

The Food and Drug Administration (FDA)* has developed a classification for 1.700 different devices and grouped them into 16 medical fields. This classification depends on the intended use, as well as on the indications for use, which can be found in the labeling of equipment. Each type is assigned one of three classes of regulation, depending on the level of control necessary to ensure safety and efficiency. The class to which the device belongs determines, among other things, the type of pre-marketing notification (price, trademark, etc.) required for FDA's approval for sale. Most class I equipment is exempt from notification, most class II and III devices require notification. In addition, the classification is based on risks for the patient. Class I includes devices with the lowest risk to health, class III - the highest risk. All three classes are controlled by the basic requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Regulatory control increases from class I to class III and is carried out throughout all 3D printing phases (Fig.) [19–21].

All registered institutions must be registered on the FDA website. By law, the FDA must issue a final decision within 30 days after the institution is accredited. All registration information is checked annually.

Control of quality and copying in the USA

Legal standards for the quality of 3D printed products include trademark law and product safety regulations. Manufacturers must guarantee their products.

Currently, the FDA is studying 3D printing technologies to gain the knowledge and experience necessary to evaluate the safety, effectiveness and quality of products developed as a part of the additive manufacturing process. As the 3D printed medical devices are commercialized, compliance with intellectual property laws will become increasingly important for medical device manufacturers [18, 19].

Anyone who uses or copies an existing CAD file to create a digital model for 3D printing is responsible to the owner of the file for copyright infringement. However, a person who uses a 3D scanner to create an image of an object for printing, and then creates a model from this image, can avoid liability for copyright infringement if he copies only the unprotected functional features of the object, and not an aesthetic or artistic element.

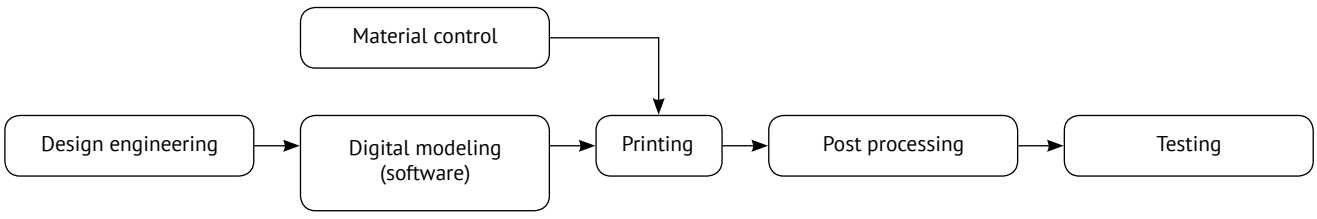

Fig. Regulatory control in the United States during 3D printing

On the one hand, trademarks help the device manufacturer to protect its products from counterfeiting. Printed on a 3D printer, an object that has a manufacturer's trademark will be governed by the Federal Law on Trademarks and Product Counterfeiting Law. On the other hand, 3D printed products that do not contain manufacturer's trademarks can easily be identified as unauthorized copies [20, 21].

Patent and trade secret in the USA

Patent law guarantees medical device manufacturers greater protection against unauthorized 3D printing and its products. It may be violated as follows:

– directly (the one who makes, uses, sells the claimed invention);

– indirectly (to those who consciously and actively advertise, promote, encourage others to violate the patent law).

Thus, the manufacturer of medical equipment, which patented his device or method of its creation, has the following rights:

– prohibit the production and sale of 3D-printed copies of his product;

– do not prohibit the use of 3D-printed copies of his product [19, 27];

– prohibit the use of 3D-printed copies of the product.

It is important to note that if a scanned product 3D-model is refined with new objects using computer_simulation that allows for avoiding copyright infringement. While a 3D-printed product or a method of its creation is protected by a patent, its further manufacture, use and sale are not considered a violation of the law.

A person not authorized to use the manufacturer's confidential and technical information when creating a 3D printed copy of a product is responsible for the misappropriation of the manufacturer's trade secret [22, 23].

Safety in production of 3D models in the USA

The FDA regulates medical 3D printing using the same mechanisms [*standards*] as conventional_medical devices. Therefore, they are also evaluated for safety and information effectiveness. It should be noted that when creating 3D-printed medical devices, it is necessary to observe labor protection rules for employees since plastic threads, combustible powders and high temperature are used [24–26].

The FDA determined the factors which may be grounds for bringing legal action against the manufacturer of a 3D-printed custom-made medical device:

1) use of a defective original product to create a digital model;

2) use of a defective original digital design;

3) use of a damaged digital file and its copies;

4) use of a faulty 3D printer;

5) use of damaged materials for 3D printing;

6) error in the computer simulation process by a specialist;

7) error in using a 3D printing technology by a specialist.

In the USA, hospitals are, in essence, "service providers". They are not associated with drug manufacturers, device manufacturers, or commercial marketers. Patients injured by the use of a 3D printed product face an additional obstacle: who is responsible — the 3D product manufacturer or the medical facility that provided services using the 3D printed product? [8, 30–33].

With intent to level the emerging concerns, on June 11, 2014 in New York, the Director of the FDA Biological Department, S.K. Pollack convened a workshop to amend legislation on the application of additive technologies, which, while only unilaterally, discussed a number of important issues.

How should the FDA certify "non-conventional manufacturers" (hospitals)? Will the FDA certify 3D printers? How will quality assessment systems be applied? Will the FDA deal only with 3D products and what are the requirements for manufacturers? [32]. As a result of the symposium, recommendations for regulating the use of additive manufacturing were drafted in 2017, which are intended to govern the design, manufacturing and production of devices, as well as software, the qualifications of bioengineers and the quality of the printer [33].

Legal regulation in Europe of the use of medical devices created by additive technologies

Monitoring the distribution and use of medical devices in European countries is regulated by various directives: Council Directive 90/385 EEC relating to active implantable medical devices, Council Directive 93/42/EEC relating to medical devices, Council Directive 98/79/EEC on *in vitro* diagnostic medical devices. All products are assigned the abbreviation CE. Medical devices, in particular custom-made implants created using additive technologies, belong to safety class III, but do not need direct CE certification [34, 35]. Currently, European regulators, in collaboration with the American Society for Testing and Materials, are also trying to improve the standardization process of 3D printing within the framework of the ISO and to rework European standards for supervision of the use of custom-made gadgets [36].

Conclusion

Interdepartmental commissions are currently working both in Russia and abroad to develop laws and regulations governing the manufacture and use of custom-made 3D printed medical devices. However, a legislative basis has not been finalized. Legislation in this sphere should ensure the following: safe use of custom-made 3D printed medical devices, respect for the rights of patients when applied, prevention of prohibited or restricted material use during their manufacture, and avoidance of legal barriers which could limit the development of additive technologies of 3D printing in medicine.

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INFORMATION ABOUT AUTHORS:

Nikolay N. Karyakin — Dr. Sci. (Med.), rector, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Igor I. Shubnyakov — Dr. Sci. (Med.), chief researcher, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Alexey O. Denisov — Cand. Sci. (Med.), executive secretary, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Anna V. Kachko — head of the Legal Department, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Ramil V. Alyev — orthopaedic surgeon, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

Roman O. Gorbatov — orthopaedic surgeon, head of the Laboratory of Additive Technologies, Privolzhsky Research Medical University, Nizhny Novgorod, Russian Federation

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Comparison Outcomes of Discover Total Disk Arthroplasty and Anterior Cervical Discectomy with Fusion in Surgical Treatment of Cervical Disk Degenerative Disease: a Meta-Analysis of Randomized Trials

V.A. Byvaltsev[1,2,3,4], I.A. Stepanov[1], M.A. Aliyev[1], B.M. Aglakov[1], B.R. Yussupov[1], V.V. Shepelev[1]

[1] *Irkutsk State Medical University, Irkutsk, Russian Federation*

[2] *Railway Clinical Hospital on the station Irkutsk-Passazhirskiy of Russian Railways Ltd., Irkutsk, Russian Federation*

[3] *Irkutsk Scientific Center of Surgery and Traumatology, Irkutsk, Russian Federation*

[4] *Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation*

Abstract

The purpose — to compare the effectiveness of Discover cervical disk arthroplasty (CDA) and anterior cervical discectomy with fusion (ACDF) in the surgical treatment of cervical intervertebral disk (IVD) degenerative disease. ***Study design*** — a meta-analysis of randomized clinical trials. ***Materials and Methods.*** Randomized clinical trials were conducted in the Pubmed, EMBASE, ELibrary and Cochrane Library databases published from 2008 to October 2018, which compared the results of Discover CDA and ACDF techniques in the surgical treatment of cervical IVD degenerative disease. For dichotomous variables, the relative risk and 95% confidence interval were calculated, standardized difference of mean values and their 95% confidence interval were used for continuous variables using the random effects model. ***Results.*** This meta-analysis included 9 randomized controlled clinical trials, including the results of surgical treatment of 513 patients with degenerative disease of the cervical IVD. In the CDA group, the operation time was significantly shorter, in contrast to the group of patients who underwent ACDF (p<0.0001). The values of blood loss (p = 0.89), levels of quality of life for patients according to the Neck Disability Index (NDI) (p = 0.22), severity of pain in the cervical spine (p = 0.50) and upper limbs on a visual analogue scale (VAS) (p = 0.16), as well as the prevalence of secondary surgical procedures (p = 0.68) and adverse events (p = 0.40) between the compared groups did not have significant differences. At the same time, significantly large values of the range of motion at the operated level were noted in the CDA group (p<0.00001). ***Conclusion***. Discover CDA in comparison with ACDF has a significantly large values of range of motion at the operated level. At the same time, there were no statistically significant differences in the NDI scores, VAS pain scores in cervical spine and upper limbs, and the prevalence of secondary surgical procedures and adverse events between the compared groups of respondents were not identified.

Keywords: cervical intervertebral disk, degenerative disease, Discover total disk arthroplasty, anterior cervical diskectomy and fusion, meta-analysis, randomized controlled trials.

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Vadim A. Byvaltsev; e-mail: vadimabyvaltsev@gmail.com

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Introduction

Anterior interbody fusion (ACIF) is the golden standard in surgical treatment of patients with degenerative diseases of cervical intervertebral discs (IVD). According to various authors ACIF is a highly efficient method allowing to level present clinical and neurological symptoms in patients with degenerative cervical IVDs [1, 2]. Nevertheless ACIF is associated with some adverse events like hypermobility, pseudarthrosis, dysphagia and degeneration of adjacent spinal motion segments [3]. At the end of the last century a method of total arthroplasty (TA) of cervical IVDs [4] was developed and introduced into the clinical practice.

Currently TA of cervical IVD is widespread in many neurosurgical clinics of the world [5]. Some researchers have the opinion that TA procedure has a high clinical efficiency in patients with degenerative diseases of cervical IVDs, allows to maintain physiological range of motion in the operated segment and to prevent degeneration of adjacent segments [5, 6].

Global medical industry developed a variety of prostheses for TA of cervical IVDs. Every prosthesis is featured by a special design, biomechanical parameters, implantation technique, clinical and roentgenological efficiency. Some promising randomized clinical studies were discovered during search through literature in the PubMed, EMBASE and eLibrary databases presenting outcomes of Discover prosthesis (DePuy Spine, USA) application for TA in patients with degenerative diseases of cervical IVDs [7–12]. The outcomes turn to be controversial to a large extent which stimulated the authors to conduct the present meta-analysis.

Purpose of the study — to compare the efficiency of TA by Discover prosthesis and anterior cervical interbody fusion (ACIF) in surgical treatment of degenerative diseases of cervical intervertebral discs (IVD).

Study design — meta-analysis of randomized clinical studies which compare methods of TA by Discover prosthesis and anterior cervical interbody fusion (ACIF) in surgical treatment of degenerative diseases of cervical intervertebral discs (IVD).

Material and Methods

Strategy of search and selection of literature

The authors performed search of randomized clinical studies in PubMed, EMBASE, eLibrary and Cochrane Library databases published in the period from 2008 to October 2018 where authors compare outcomes of TA methods by Discover prosthesis and ACIF in surgical treatment of degenerative diseases of cervical IVDs. Search of literature was conducted by two researchers. In case of disputes related to inclusion of studies into the meta-analysis the decision was made collectively by the whole group of authors. The search was done in accordance with international recommendations on preparing the systematic reviews and meta-analysis PRISMA [13].

The first stage included the search of literature using keywords «Discover cervical disk arthroplasty», «Discover cervical total disk replacement», «anterior cervical discectomy and fusion», «cervical spine degeneration», «cervical intervertebral disk degeneration» in English-language systems; and similar combination of words in Russian — in the National Russian Electronic Library. The second stage included review of abstracts to exclude publications not corresponding to such criteria. The third stage included review of full texts of publications to confirm correspondence to criteria and lists of references to see if those contain relevant studies (Fig. 1).

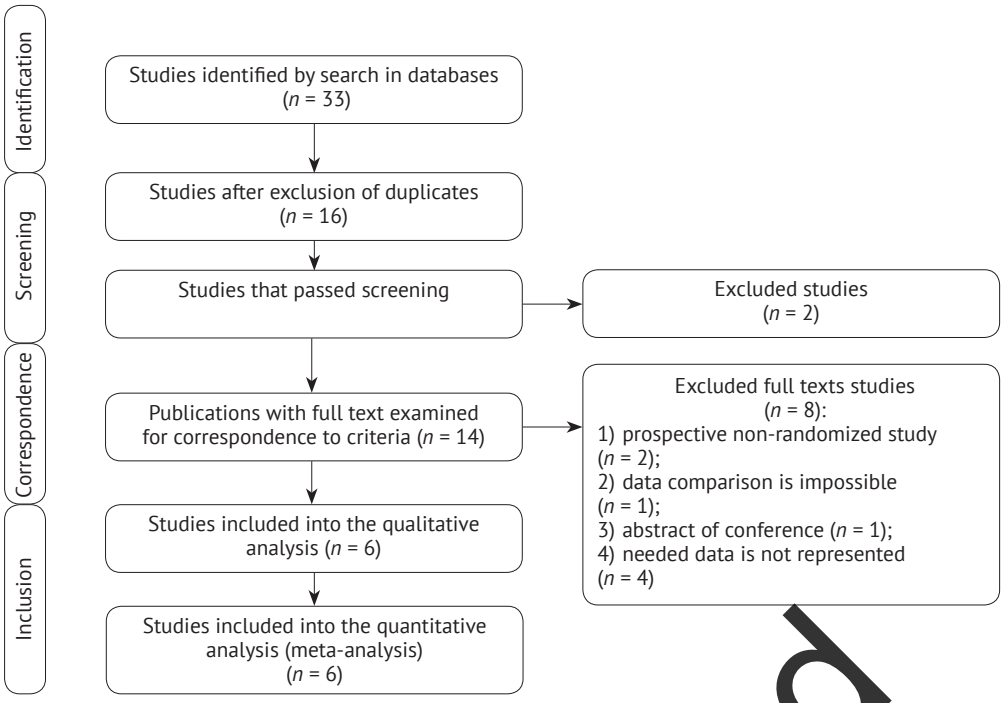

Fig. 1. Flow chart showing search strategy

Correspondence criteria

To compare efficiency of two mentioned surgical procedures the following correspondence criteria were defined:

1) included studies: randomized clinical studies examining outcomes of TA by Discover prosthesis and ACIF in adult patients with degenerative diseases of cervical IVDs along with clinical and neurological symptoms (radiculoneuralgia, radiculoneuritis, radiculopathy);

2) types of surgical procedures: studies comparing TA of cervical IVDs by Discover prosthesis and ACIF with various implants;

3) outcomes: studies analyzing clinical and instrumental outcomes of described procedures; life quality of patients related to limitation of motions in cervical spine by NDI (Neck Disability Index); severity of pain syndrome in cervical spine and upper limbs on VAS scale; frequency of adverse events and degeneration of adjacent spine motion segments; as well as rate of revisions;

4) study design: randomized clinical studies with methodology quality evaluation no less than 3 on Jadad scale [14] were included into the analysis.

Valuation of risk of bias

Each study included into the meta-analysis was evaluated using a Risk of bias tool under Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Denmark) on the following parameters:

1) data sequence generation;

2) hiding of study data;

3) use of blinding;

4) incomplete list of obtained data;

5) selective presenting of study outcomes;

6) other bias (table 1).

Total valuated risk of bias for all studies were distributed for “low”, “uncertain” and “high” (Fig. 2).

Table 1

Valuation of risk of bias for studies included into the meta-analysis

Studies	Bias parameters					
	data sequence generation	hiding of study data	use of blinding	incomplete list of obtained data	selective presenting of study outcomes	other parameters
Chen Y. et al., 2013	+	?	?	+	+	+
Luo C. et al., 2015	+	?	?	+	+	+
Rozankovic M. et al., 2017	?	?	?	+	+	+
Shi S. et al., 2016	?	?	?	+	+	+
Skeppholm M. et al., 2015	+	+	+	+	+	+
Sun Q. et al., 2016	+	?	?	+	+	+

+ — low risk; ? — uncertain risk.

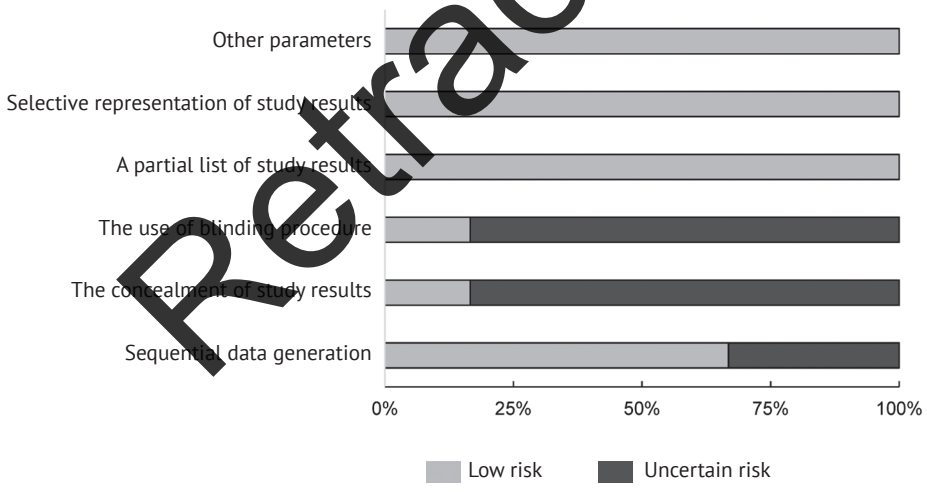

Fig. 2. Risk of bias assessment for all included studies

Statistical data analysis

The authors calculated a relative risk (RR) and 95% confidence interval (CI) for dichotomized variable. Standardized difference of average values (SDA) and 95% confidence interval (CI) with the random effects model (REM) was used for continuous variable. Coefficient I2 was used for evaluation of heterogeneity. With I2 coefficient value less than 25% the studies were considered homogeneous, from 25 to 50% — low rate of heterogeneity, from 50 to 75% — moderate heterogeneity, over 75% — high heterogeneity. Skewness of the study was analyzed

by plotting a funnel diagram and linear regressive Egger's test. Tree diagrams were plotted with Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Denmark). Differences were considered statistically significant with $p \leq 0,05$.

Results

Search of literature

Based on correspondence criteria the present meta-analysis includes 6 randomized controlled clinical studies with outcomes of surgical treatment of 513 patients with degenerative diseases of cervical IVDs. Overall characteristics of included studies are present in table 2.

All studies reflect the main clinical, instrumental and intraoperative parameters; contain information on application of an artificial Discover cervical IVD as well as cages and bone autografts for ACIF.

Time of surgical procedure

Three randomized clinical studies present information on time of operative procedures [10–12]. Cumulative analysis of obtained data indicates that in the group of TA for cervical IVDs the time of procedure was statistically significantly less as compared to the group of patients who underwent ACIF (SDA =-0.71, 95% CI: -1.07, -0.36, p<0.0001; I2 = 49%) (Fig. 3).

Blood loss volume

The authors included three randomized clinical studies which compared volume of blood loss after TA procedure and ACIF [10–12]. Meta-analysis of studies outcomes demonstrated the absence of statistically significant differences in volumes of blood loss in compared procedures (SDA = -0.02, 95% CI: -0.86, -0.20, p = 0.89; I2 = 87%) (Fig. 4).

Table 2

Overall characteristics of studies included into the meta-analysis

Study	Year	Country	Number of operated segements	Number of patients		Average age, years		Gender (male/female)		Time of follow up, months
				TA	ACIF	TA	ACIF	RA	ACIF	
Chen Y. et al. [7]	2013	China	1	16	16	43.2	46.5	9/7	8/8	24
Luo C. et al. [8]	2015	China	1	34	37	47.2	46.3	18/16	20/17	48
Rozankovic M. et al. [9]	2017	Croatia	1	51	50	41.3	41.9	25/26	25/25	24
Shi S. et al. [10]	2016	China	1	60	68	46.5	47.4	36/35	24/33	24
Skeppholm M. et al. [11]	2015	Sweden	2	81	70	45.3	46.7	40/41	33/37	24
Sun Q. et al. [12]	2016	China	2	14	16	46.7	48.1	9/5	11/6	32.4

TA — total arthroplasty of intervertebral disc; ACIF — anterior cervical interbody fusion.

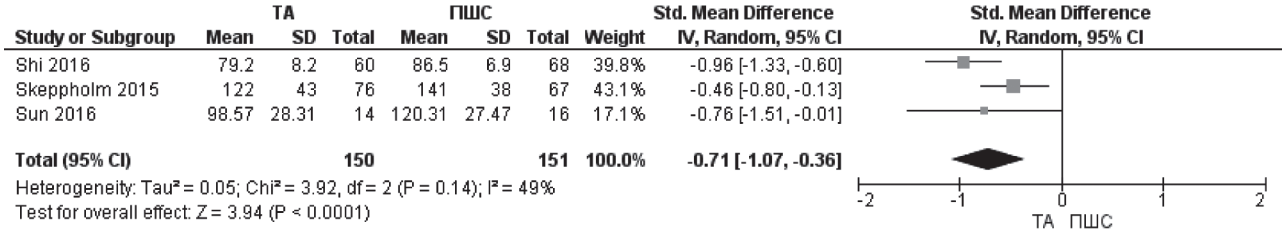

Fig. 3. Forest plot for operation time

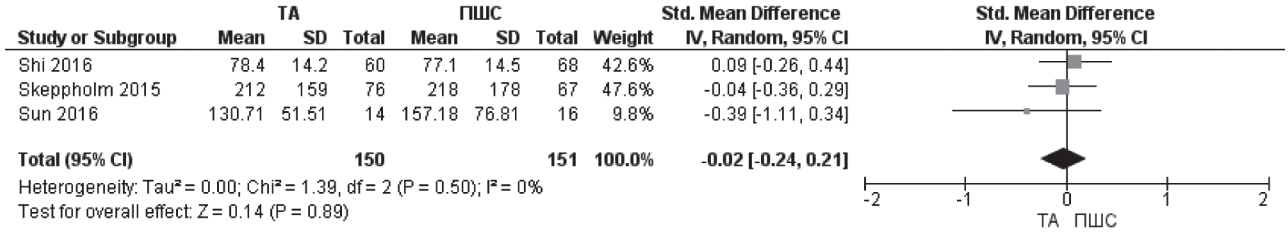

Fig. 4. Forest plot for blood loss

Life quality according to NDI

All studies included into the meta-analysis present information on life quality of the patients by NDI after procedures of TA and ACIF. High values of patients' life quality by NDI were verified in group of TA for cervical IVDs as well as in the group of patients who underwent ACIF (SDA = -0.33, 95% CI: -0.86, 0.20, p = 0.22; I2 = 87%) (Fig. 5).

VAS pain severity in cervical spine

Information on pain syndrome severity by VAS in cervical spine and upper limbs after TA of cervical IVDs and ACIF was reported in three studies [8, 9, 12]. No statistically significant differences in VAS pain severity values in cervical spine were observed between the groups (SDA = -0.37, 95% CI: -1.845, 0.70, p = 0.50; I2 = 95%) (Fig. 6).

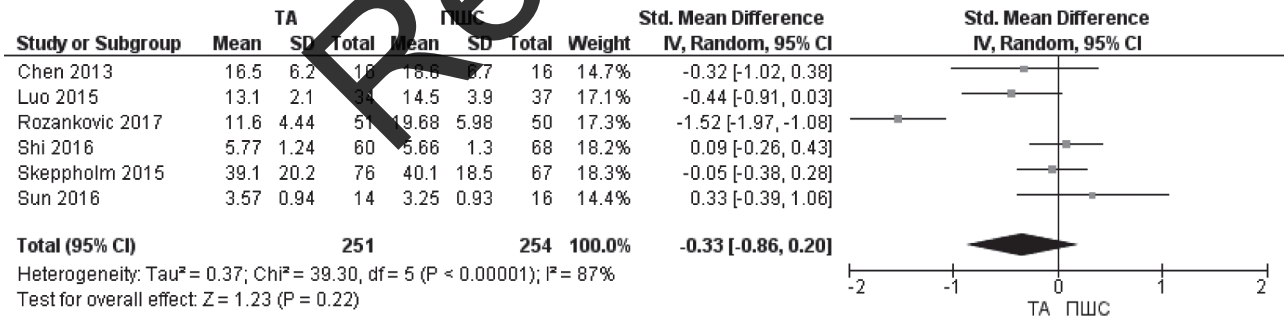

Fig. 5. Forest plot for NDI score

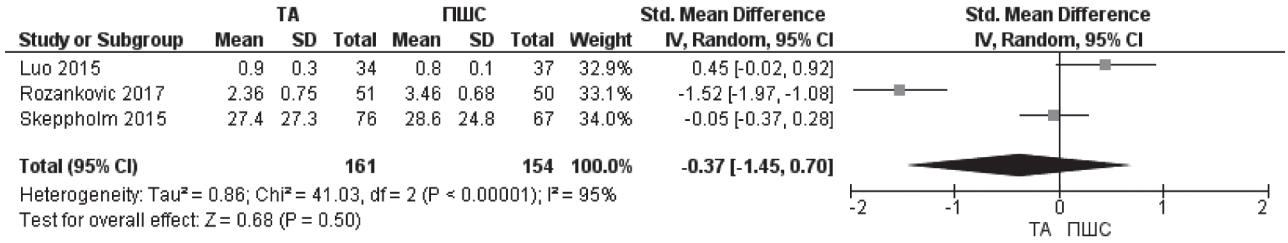

Fig. 6. Forest plot for VAS neck pain score

VAS pain severity in upper limbs

No statistically significant differences in VAS pain severity values in upper limbs were observed between the groups (SDA = -0.47, 95% CI: -1.12, 0,18, p = 0.16; I2 = 87%) (Fig. 7).

Range of motion in operated spine segment

Two perspective clinical studies presented information on range of motion values in operated spinal segments in patients who underwent TA of cervical IVDs and ACIF [8, 10]. Meta-analysis of studies evidently demonstrated significantly larger values of range of motion in operated spinal segments in TA group (SDA = 5.28, 95% CI: 4.69, 5.88, p<0.00001; I2 = 0%) (Fig. 8).

Revision procedures

Revision rates were present in three studies [8, 9, 11]. Cumulative analysis of outcomes of these studies demonstrated the statistically significant differences in prevalence of revisions between groups of TA and ACIF (RR = 0.69, 95% CI: 0.11, 4.14, p = 0.68; I2 = 68%) (Fig. 9).

Adverse events

Information on revision rates after TA and ACIF procedures was present in all studies included into meta-analysis [8–12]. No significant differences were observed (RR = 0.80, 95% CI: 0.48, 1.34, p = 0.40; I2 = 39%) (Fig. 10).

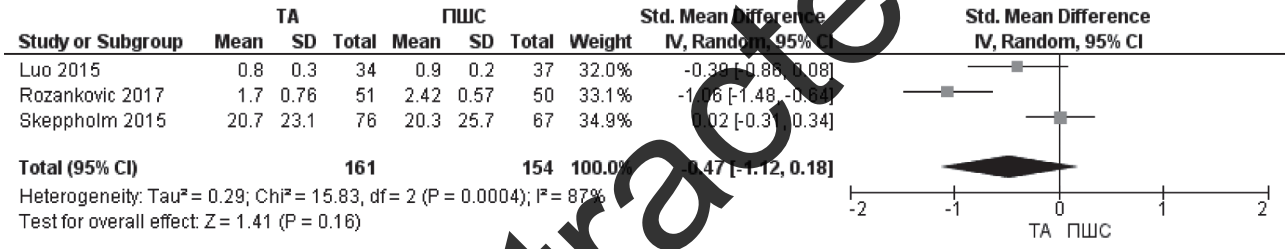

Fig. 7. Forest plot for VAS arm pain score

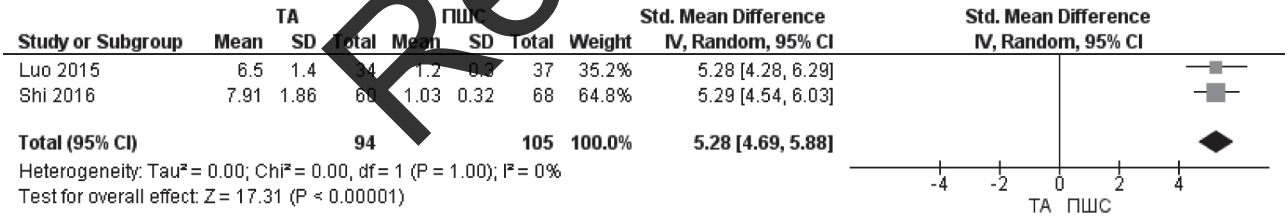

Fig. 8. Forest plot for range of motion at operated level

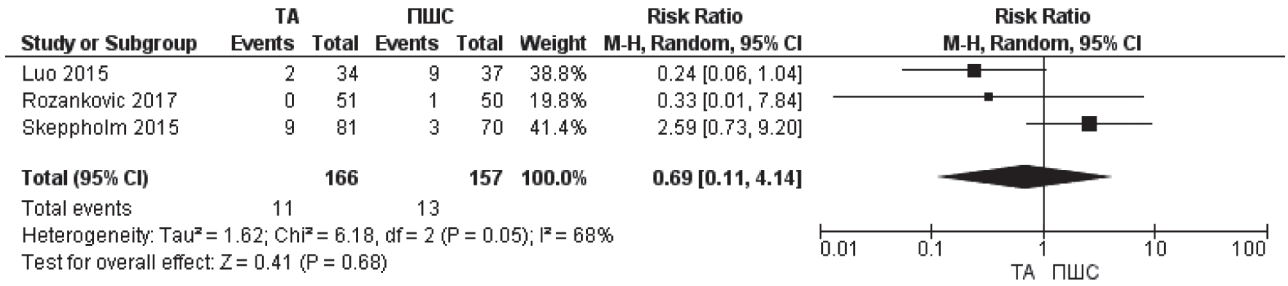

Fig. 9. Forest plot for secondary surgery

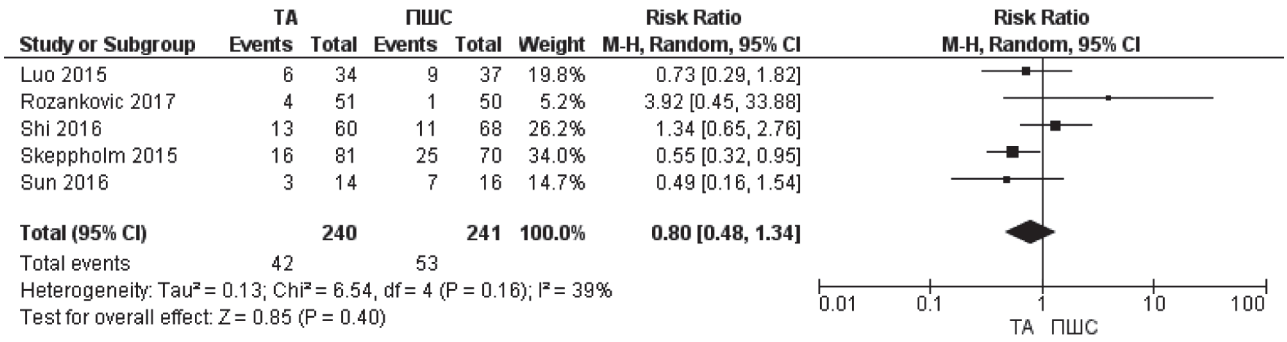

Fig. 10. Forest plot for adverse events

Discussion

Search of literature in databases revealed several meta-analyses comparing efficiency of TA and ACIF procedures in surgical treatment for degenerative diseases of cervical IVDs. Thus, L. Xie et al in his work demonstrated that TA is more efficient method for treatment of patients with degeneration of cervical IVD [15]. S. Zou et al [16] proved that TA method allows to obtain statistically significantly better clinical outcomes than ACIF in patients with two-level degenerative disease of cervical IVD [16]. With that the authors of mentioned papers consider that clinical efficiency of TA for cervical IVDs in patients with degenerative disease of discs depend at large on type of the prosthesis. Undoubtedly each artificial IVD has peculiarities of design, geometry of its components and biomechanics. For this reason the research on comparison of efficiency of various prostheses remains one the most important tasks of the current spine surgery.

The present meta-analysis demonstrates that time of procedure during TA is statistically significantly less as compared to ACIF. This data contradicts previous research [17–19]. Nevertheless some researchers consider that longer times of TA procedure can be due to specifics of implantation of artificial IVDs using many instruments in contrast to ACIF procedure. On the other hand use of implants during ACIF procedure also means use of additional instruments [20]. The authors of the present meta-analysis would like to note that data obtained on time of operative procedure in compared groups of patients is not convincing while various implantation techniques in included randomized studies and their high level of heterogeneity.

Some authors demonstrated that ACIF procedure allows to gain statistically significant improvement of patients' quality of life by NDI as compared to TA [21, 22]. It's worth noting that meta-analyses confirming significant improvement of life quality by NDI in ACIF group had a series of methodological disadvantages in the study design which doesn't allow to objectively assess the outcomes. According to the present meta-analysis no statistically significant differences in life quality by NDI were observed between the groups of patients.

As is known one of the adverse events after ACIF is the degeneration of adjacent spinal motion segment [23]. R. Davis et al consider that after ACIF procedure the range of motion in the operated segment is sharply decreased which is compensated by a significant increase in range of motion in adjacent spinal motion segments [24]. In contrast to ACIF the TA procedure allows to preserve normal biomechanics in the operated segment and the whole cervical spine, thus preventing degeneration of adjacent segments [25]. S. Yin et al report that TA of cervical IVDs allows to preserve a physiological range of motion in operated segment which is confirmed by re-

sults of the present meta-analysis. However for a more objective evaluation of the status of operated and adjacent spinal motion segments further research is needed to study biomechanical and kinematic features of those segments.

Conducted meta-analysis of prospective randomized studies did not reveal the differences in rate of adverse events in studies groups of patients. The data obtained by the authors is consistent with results of meta-analysis of S. Lei et al [27], S. Yi et al [28] and M. Qi et al [29]. The most frequent adverse event in both groups of patients was dysphagia.

Study limitations

The present meta-analysis has a series of disadvantages. Firstly, meta-analysis includes 6 prospective randomized clinical studies with minor number of respondents which had an impact on results of statistical data processing. Secondly, Major part of included studies had a short follow up period which significantly decreases validity of results. Lastly, only one randomized study had a low risk of bias on all parameters which also could impact the results of meta-analysis.

Conclusion

The present meta-analysis evidently demonstrated that procedure of TA for cervical IVDs by Discover prosthesis as compared to ACIF procedure provides for statistically significantly greater range of motion in the operated spinal motion segments. With that no statistically significant differences were observed in compared groups of respondents on values of life quality by NDI, pain severity by VAS in cervical spine and upper limbs, by revision rate and by frequency of adverse events. Undoubtedly we need further conducting of meta-analysis which would include methodologically high-quality randomized clinical studies with long term follow up of patients who underwent TA and ACIF of degenerative diseases of cervical intervertebral discs.

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INFORMATION ABOUT AUTHORS:

Vadim A. Byvaltsev — Dr. Sci. (Med.), head of Neurosurgery and Innovative Medicine Department at Irkutsk State Medical University; chief of Neurosurgery in the JSC «Russian Railways»; head of Neurosurgical Center at Road Clinical Hospital at «Irkutsk-Passazhirskiy» Station; vice-president of Irkutsk Scientific Center of Surgery and Traumatology; professor of the Department of Traumatology, Orthopaedics and Neurosurgery, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

Ivan A. Stepanov — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

Marat A. Aliyev — doctoral student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

Bakhyt M. Aglakov — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

Bobur R. Yussupov — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

Valerii V. Shepelev — doctoral student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

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Cuneo Tendinous Suture — the Story of One Publication

D.G. Nakonechny[1], A.N. Kiseleva[1], A. Cambon-Binder[2]

[1] *Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation*

[2] *Saint Antoine Hospital, Paris, France*

Abstract

In Russia and in post-Soviet countries tendon Cuneo suture is still widely known and is applied in clinical practice because of its strength and simplicity. One can find its sketch along with the sketches of Rozov and Kozakov sutures in most Russian handbooks on operative surgery. In foreign literature, however, this term is never used, and the authorship of the technique is attributed to S. Bunnell. According to the original source, the tendon suture technique suggested by S. Bunnell is different from that of B. Cuneo. Likewise, Cuneo tendon suture cannot be applied with the use of tendon forceps, as suggested by S. Bunnell. Besides, to confirm proper use of B. Cuneo's name in the case of the tendon suture in question, we cite an adapted translation of a certain paper by B. Cuneo and A. Tailhefer, devoted to a case study where the authors used suture of flexor tendon of little finger. We also provide historical background, concerning some interesting facts and people relevant to the topic.

Keywords: hand surgery, tendon suture, damage to flexor tendons of fingers, *fexor tendon repair, tendon suture, flexor tendon leasure.*

Competing interests: the authors declare that they have no competing interests.

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We thank E.T. Samitova for translating the article „Cuneo B., Tailhefer. Surun cas de suture secondaire des tendons flechisseurs ducinquieme doigt".

One can hardly find a surgeon in Russia who is not familiar, at least schematically, with the Cuneo[1] tendon suture technique. All Russian textbooks on operative surgery, inclusive of those published during the Soviet Union times, provide the image of this joining technique, usu. next to that by Rogov [1, 2]. Even now, many Russian surgeons choose the Cuneo for its simplicity and the repair strength. Interestingly, we failed to trace either the original article by B. Cuneo or any reference to it. This fact, which is not unfamiliar to other researchers, made some scholars doubt the existence of the original article explaining the technique, and thus the authorship of Bernard Cuneo [3].

[1] *Bernard Joseph Cuneo* (1873–1944), a prominent French surgeon and anatomist. In France, he is more famous for his seminal papers in anatomy [4]. While working at hisI biography, we chanced to come across only one of his publications (apart from that discussed in this study) related to the hand — it dwells on the physiology of the wrist joints [5]. At the time of the clinical observation described, he was the head of the department at Hôpital Lariboisière in Paris.

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✉ *Dmitrii G. Nakonechny*; e-mail: dnakonechny@rniito.ru

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There is an opinion that this tendon suture was first proposed by the American surgeon Sterling Bunnell[2]. Sometimes, both last names (the Bunnell — Cuneo suture technique) are used, although not exclusively in order to put the historical record straight, but simplify the matters to the reader. This hot-button issue made us turn to the primary source literature.

Professor B. Cuneo

It should be noted that the method of tendon repair using a tendon clip, as it was described by S. Bunnell in his first article and the *in vitro* picture of which was first given there [6], is not similar in appearance to what is traditionally called the Cuneo in our textbooks. In this description, the needle is firstly put transversally through the tendon, then the longitudinal component of the suture is placed obliquely to let the needle out of the tendon and through one of the gaps of the tendon clip (which looks like a claw clip); then an arc link on the tendon surface is made by transferring the needle transversally to the original puncture side, with the whole procedure repeated to finally pull the needle through the cut end of the tendon. The second end of the strand of the suture is used similarly. Then the whole design is repeated on the other tendon to finally knot the four ends of the two strands pairwise. The repair in Figure 1a exactly follows the description made by S. Bunnell and is similar to that in the picture published by him himself [6].

In his next article on tendon plastic surgery S. Bunnell explains that while pulling the strand through the tendon clip it could be enough to grasp just a certain amount of tendon tissue [7]. Both of these descriptions imply a method which is different from the familiar Cuneo technique. The latter exhibits some evident pros, as the strand is put through the thickness of the tendon, which reduces adhesion and minimizes the damage to the intrastem blood supply of the tendon (Fig. 1b). But theoretically, the strength of this tendon repair should be lower in comparison with the Bunnell, as there are no locking loops, the importance of which was to be theorized much later [8].

We posit that the name of S. Bunnell was mistakenly attributed to this type of repair on account of the similarity between the way the strands are drawn through the ends of the tendon in his another method of a removable wire tendon suture and the technique in question [9]. Apart from that, in his first two articles, Dr. Bunnell does not provide us with a schematic image of the repair, and gives a verbal description of the technique supported by the photos of the repair *in vitro*, which yielded little information.

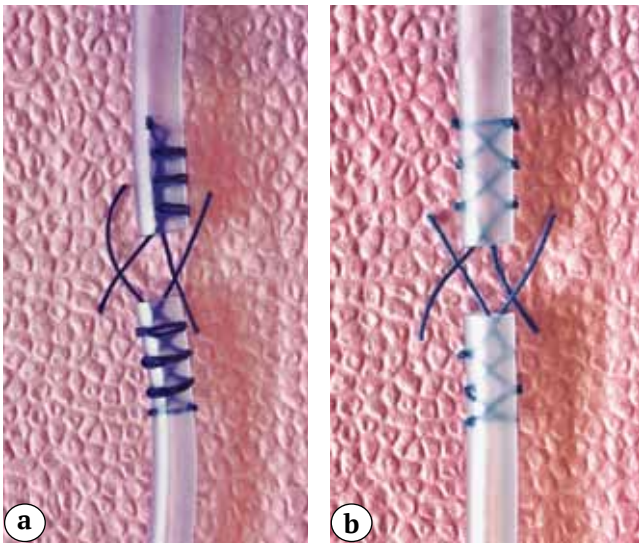

Fig. 1. Tendon sutures of Bunnell (a) and Kuneo (b) on the layouts *in vitro*

[2] *Sterling Bunnell* (1882–1957), a famous American surgeon. He was the one to popularize hand surgery as a freestanding discipline. He is also considered one of the founding fathers of the American Society for Surgery of the Hand (ASSH) – the parent organization of the International Federation of Societies for Surgery of the Hand (IFSSH).

An easy-to-understand image of the repair was firstly published in S. Bunnell's book (1944), and that explained the aforementioned removable wire tendon suture technique. But by that time, the term Cuneo repair with its familiar pattern had already been widely used, at least in the Soviet Union. Thus, we have come to believe that the Bunnell repair was falsely attributed in the literature. At the same time though, we also failed to confirm B. Cuneo's authorship.

The primary source of this misattribution of the technique to B. Cuneo, where the very repair was mentioned for the first time, is a rarely cited article describing a clinical case of a tendon repair co-authored by B. Cuneo and E. Teilhefer[3]. In this article, no scheme, description, or photo of the repair is given. There is only one simile to characterize the repair: "boot-lacing". Besides, this description fits the actual Bunnell repair much better.

In his study to follow, E. Teilhefer not only shares the views of S. Bunnell, preferring tendon plastic surgery to suture [10], but also, as it was noted by his science advisor A. Mouchet [11], uses a device similar to that described in S. Bunnell's aricle[4].

B. Cuneo himself pointed out that a detailed description of this tendon repair could be found in the dissertation of his apprentice Ph. de La Marnierre[5]. We chanced to come across an accurate explanation of the Cuneo tendon repair performed by Dr. Maurice Cazin [12]. Here is the procedure he suggested: the tendon is pierced frontally with one strand of suture 1.5 cm

Staff members and interns of St. Louis Hospital: second from the left in the second row is A. Tailhefer

[3] In the original text, Tailhefer's first name does not appear either in the article body or on its title page; however, the article review, which followed, implied that he was Dr. A. Mouchet's (1869–1963) assistant. At that time, Dr. Mouchet ran the pediatric surgery department of the Hôpital Saint-Louis in Paris, he is also reputed to have described two syndromes named after him: Mouchet I and Mouchet II. Later, he and Tailhefer co-authored a monograph on traumatology. Three years later, Emile Marie André Tailhefer (1896–1963) wrote a thesis on the flexor and extensor digitorum repair techniques, and also became prominent for his input in surgical oncology. Interestingly, he was both the co-author of the article, and the patient of the case described in it.

[4] It should be said in all fairness that later in his work Tailhefer quoted the Bunnell technique as it was described in Marc Iselin's (1898 – 1987) paper. It would look strange if there appeared no name of M. Iselin in this article, who is considered both an ardent partisan of the ideas propagated by S. Bunnell, and a hand surgery pioneer in France. But it is also noteworthy to say that at the time of the observation described in the article he was an intern.

[5] *Dr. Daniel-Robert Phelippes de La Marnierre* presented a thesis on the restoration of the flexor digitorum in 1924, he was a resident at L'hôpital Lariboisière in Paris.

away from the tendon end. Then, either needle is inserted near its exit into the tendon placing the longitudinal component obliquely, so that the needle could exit 5 mm distal of the other half of the strand, which, in its turn, is also placed similarly, in an oblique manner, to let it exit on the opposite side of the tendon. The routine is repeated once again to finally let both needles out through the tendon cut. The other tendon end undergoes the same procedure, after which the ends of the strands a tightened and knotted together. Bearing in mind that this description of the technique fitted the framework of discussion of then contemporary methods of tendon repair and was witnessed by B. Cuneo's opponents and his co-author E. Teilhefer, one may consider it authentic, and thus the authorship of B. Cuneo was a fact accepted by his surrounding. This description matches the familiar image of the repair fairly well.

The image of the Cuneo proper caught our eye only in several articles of Russian-speaking scholars, (which include the contributions to non-Russian periodicals), e. g. the article by A. M. Dychno[6] published in *Lyon Chirurgical* in 1937 (Fig. 2) [13].

Following this instruction, we performed this repair on a mock tendon (see Picture 1b) in order to compare it with the Bunnell, and with the pattern familiar to Russian-speaking surgeons. It is worth mentioning that B. Cuneo's article is of interest not only because it confirms the existence of the Cuneo repair and his authorship — it also gives a very detailed account of the method he used, and explains that, with the operation performed accurately and rehabilitation to follow, one can achieve a very good result in the primary tendon repair of the finger flexor. The matter is that such high-profile surgeons of the time as S. Bunnell, M. Iselin, and M.L. Mason [7, 14, 15] propagated a more delicate approach with their preference for the secondary tendon repair with the help of a transplant.

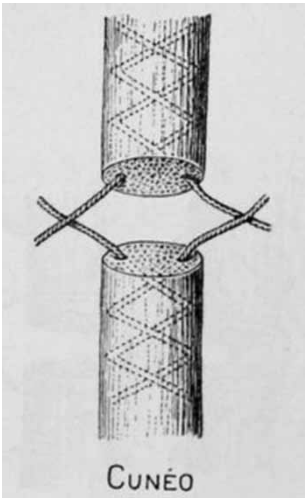

Fig. 2. Cuneo tendon suture (from the article of A. Dychno) [13]

The variant readings of the term Cuneo repair, and the popularity of other terms associated with the procedure in Russia, as well as certain difficulties we and our colleagues encountered at reference retrieval have determined our decision to provide the Russian reader with the possibility to find out more about the original article. Here you may find an adapted translation of it [16].

Notes on a Case of Secondary Tendon Suture of the Fifth Finger Flexor Digitorum[7]

B. Cuneo, E. Teilhefer

The message which our young colleague Mr. Teilhefer and I have the honour to direct to you concerns a case of tendon section in the human hand. Here is our observation:

OBSERVATION. — The accident took place on February 14, 1925. A shiver of glass crosscuts the ulnar border of the left hand at the lower palmar crease. The wound practically reaches the dorsal part of the hand on the one side, and on the other, it extends to the palm proper till the axis of the forth finger. A dissection of both flexor tendons of the little finger is diagnosed. Two hours after the accident, under regional anesthesia of the cubital tunnel and local anesthe-

[6] *Aleksandr M. Dykhno* was then a teaching assistant at the Department of Surgery of the Rostov School of Medicine. In 1935, he presented a thesis on the arterial blood supply of the arm, hand and finger tendons and tendon sheaths.

[7] An adapted translation of the original article: Cuneo B. & Tailhefer. Sur un cas de suture secondaire des tendons flechisseurs ducinquieme doigt // Bulletin set memoires de la societe de chirurgie. 1925. Vol. 51. P. 959-963. Translated by E. T. Samitova, sci. ed. by D. G. Nakonechny.

sia of the hand, followed by wound toilet, there was performed a classical tendon suture technique with a support thread and knots. The metacarpophalangeal joint, which had been cut open, was sutured, and the hypothenar muscles were reconstructed. But with this first intervention, the surgeon found only the central end of the flexor digitorum profundus, which was held by the corresponding lumbrical of the hand, and sutured it with the peripheral ends of the flexor profundus and flexor superficialis.

The finger was immobilized in its flexed position, a wick provided drainage for the wound for 46 hours. For two days the was a slight fluid oozing from the wound with 38.5°, then everything stabilized.

On the 17th day, the patient attempted to move the finger and the phalanges, and also performed finger extensions. In the following days, the 3rd phalanx could flex slightly, but later no motion was possible. One month later the situation did not improve; passive mobilization is possible, there is no joint rigidity, the extension is limited to 100°, an active flexion of only the first phalanx is obtained. The electro-stimulation performed in March, 20 in Salpêtrière[8] by Dr. Bourguignon[9] diagnosed the atrophy of the flexor longus digitorum.

It was then that this case was referred to Prof. Cunèo; the scar was fibrous, inhibiting the extension, with no sensitivity along the superficial branch of the cubital nerve. Any contact with the scar area was extremely unpleasant and provoked painful tingling, which made one think of the existence of a small neuroma. Apart from that, there were some trophic problems in this area: the skin was thin, shiny, dry and redder than around. A surgical intervention was considered necessary but was postponed by one month or so to improve the skin condition with massage and ion therapy, which brought splendid results after 25 treatment sessions.

The operation was performed under general ether anesthesia by Prof. Cunèo on 26 May, 1925. After the resection of the skin and scar tissue, it was found that the flexor tendon profundus had restored, and that the peripheral end of the flexor tendon superficialis had adhered to the suture of the flexor profundus in the way this tendon had been repaired during the first operation. The adhered tendons were released, and after a long and tiresome procedure the flexor profundus was literally sculpured from the fibrous tissue. The incision of the extensor retinaculum allowed to find the central end of the flexor digitorum superficialis, which was let out through the wound on the palm via the catheterized carpal tunnel. Then the flexor tendon superficialis was sutured with a linen thread following the "boot-lacing" technique, which had already been described by Prof. Cunèo in the thesis by Dr. de La Marnière; the tendons were isolated with artificial sheaths made from animal membranes after Rolland. By that moment Dr. Bourguignon had performed an electric test to verify the optimal length of the sutured tendons: the sutured flexor superficialis functioned normally and with its maximum effect, while the length of the flexor profundus turned to be excessive. But, as this tendon had cicatrized after the first operation, it was left intact in hope for its functional adaptation in the future. Then the neuroma of the superficial branch of the cubital nerve was partly excised, and the discovered peripheral end of the nerve collateral of the fifth finger was implanted to the base of it, though not sure of it exact identification. Finally, the palmar defect was covered with the Indian flap tailored from the dorsal surface of the hand along the ulnar margin. The region of the hand where the flap was retrieved from would soon recover. The hand was immobilized in a semi-flexed position. The surgical intervention continued for 95 minutes, which was certainly an important factor for the success — any surgery should be extremely meticulous.

The mobilization commenced on the 6th day, the spontaneous movements of the first two phalanges were perfect, as per the third phalanx, its movement was hardly noticeable, but the range of movement increased with each day. Active mobilization exercises were made for two hours every day, followed by massages and a one-week course of ion therapy. One month after the intervention, the restored movements were sufficient to allow the patient to play the violin, which required much accentuated flexion from the fifth finer. On June 22, the distal part of the transplant that formed a disgraceful flap was resected under local anethesia. On July 3, the dorsal scar in the donor area was excised, and the zone was restored by the neighbouring skin and the Thiersch graft. At the same time, the extensor tendon was freed from adhesions. The movements resumed the same day and were more effortless.

In August, three months after the suture, the movements of the phalanges are so smooth that it is

[8] L'Hôpital de la Salpêtrière is an ancient hospital in Paris, now the premises of a university clinical complex.

[9] D.G. Bourguignon was a French neurophysiologist. In his monograph [17] on electric stimulation, he dwells on a similar case. However, this observation is dated earlier than that described in this study. Presumably, the before-mentioned collaboration of D. G. Bourguignon and B. Cuneo in tendon surgery was a continuous process..

possible to talk about the full recovery of their amplitude and the movements of the finger. The sensitivity started appearing a month and a half after the suture. At present, the sensitivity stretches beyond the half of the distal phalanx, with only the anesthesia of the finger pulp remaining. A full recovery of the sensitivity is a matter of a few weeks.

If we dare to believe that this observation, humble at first sight, may draw your attention for some time, this is only because we retain the memory of the pessimism about the discussion on the finger flexor suture held two or three years ago. As a result of this discussion, it seemed that the suture of the finger flexor tendon, particularly in the introsynovial area, was doomed to failure.

I should confess that at that time I shared this pessimistic view, but since I started suturing tendons rigorously following the technique in every detail, I have always achieved success even in the cases which originally looked absolutely hopeless.

Without going into details of this technique, which was described in the thesis by my follower de La Marniére, I would like to put an emphasis on the following:

First and foremost, it is necessary to have the skin which covers the suture area in as good condition as possible, for there may frequently be necessary to resort to tentative or immediate autoplasties.

On the other hand, it is important to fully reconstruct the normal anatomical disposition. The synergy of finger flexor tendons is so subtle and delicate that the reconstruction of tendons by means of approximate procedures will definitely be doomed to failure. In this particular case, the suture of the peripheral ends of both tendons and the central end of the flexor profundus a priori would not have yielded any positive result. In effect, the length of the flexor tendons is accurate to the millimetre. It is related rigorously to the contractile part of the muscle, and is individual for each flexor. It is impossible to replace a tendon without correcting its length, the importance of which we still underestimate.

Based on our experience, we may speak of the importance of finding the right length of the tendon: in one of our patients, the retention of a newly formed fragment of the central end, which extended the tendon by only 2 mm, was enough to cause the impairment of the sutured tendon. After placing a temporary suture in the course of operation, it is necessary to cause the contraction of the muscle in order to fit the length of the tendon. If the patient is operated on under regional anesthesia, one can resort to voluntary contractions. As I use general anesthesia in many cases, I reach out to my friend Dr. Bourguignon to cause with due circumspection the contraction of different muscles via electric stimulation.

In my opinion, the suture of choice is the “boot-lacing” technique. I prefer either silk or finest and ultra-strong flax suture strands, lubricated with oil. Straight or slightly curved needles can be used. When choosing the latter, I prefer those used in opthalmology. The “boot-lacing” technique ensures perfect coaptation and strong connection of the ends; it stands in traction and causes no bulging in the suture area.

Every time it is possible, the synovial sheath should be reconstructed without narrowing it down. If it is impossible, I create an artificial synovial sheath by wrapping the suture with the intestinal membrane after Rolland, prepared by Lemeland. A number of tests have proven that such membranes inhibit adhesion of the tendon, allowing the latter to move smoothly. The edges of the artificial synovial sheath are to be attached to the neighbouring areas to avoid its crimping similar to that of an accordion when the tendon is in motion.

Among the technical details concerning tendon sutures, I think, a couple of words should also be said about suturing the nerve fibers that are probably a part of the medial collateral nerve of the fifth finger with the central end containing a neuroma. Unlike in classical approaches, I do not resect a neuroma while suturing nerve fibres. I am content with dissecting it from the end side where the ball is. I preserve that part of the central end where the rectilinear fibers and the peripheral membranes concentrate, and at the distal end of which I place a suture, which allows the suture to be located at a distance from the place where both ends meet. I attribute a relatively rapid restoration of sensitivity to this technique in particular.

The skin suture should be made with extreme attention, and any drainage should be avoided if possible. Total immobilization is mandatory for one week; at the same time, I deem it useless to put the hand in plaster.

I do not think it is necessary to talk about the considerable importance of after-treatment. Massages, passive and active movements, diathermy, ion treatment, all other known means should be used in oder to restore the flexibility of the operated organ as soon as possible.

Now we can see the crucial role which is played by intelligence, courage and patience in the surgical operations of this kind. As in arthroplasty, the success is 50 per cent dependent on these criteria — and there is not much to be added.

The splendid result which you were told about, and which you can judge about by yourselves, can oppose

the defeatist attitude toward the suture of the flexor tendon digitorum, the attitude which is now still shared by so many!

In the literature on flexor tendon repair of the time, many scholars preferred a tendoplastic surgery of the flexor digitorum profundus in order to minimize the damage to the carpal canal and to avoid adhesions. To some extent, B. Cuneo puts this observation up against other popular approaches. But as time and our efforts to retrieve the original article have shown, his words fell on deaf ears and got lost among other publications and reports which expanded the indications for tendoplastic surgery. Even B. Cuneo's co-author and patient E. Teilhefer, who successfully underwent the surgery and got inspired by tendon repair practices, was carried away by S. Bunnell's "modern" approach, propagated in France by M. Iselin. In effect, this method reflected the general tendency to increase treatment cases by means of choosing tendon plastic surgery (i. e., a replacement of a dysfunctional organ) in favour of anatomical reconstruction (i. e., tendon suture repair), despite the loss of natural biomechanics and proprioception. On the contrary, Professor Cuneo's approach implied a meticulous reconstruction of the anatomy of the organ, as well as strict postoperative management protocols, exercise and physical therapy, and revision operations if necessary. In this particular case, two revision surgeries were necessary, but they allowed the patient not only to play the violin but also build a career as a surgeon. The primary tendon suture technique would start flourishing only twenty years after, with C. Verdan's report [18] and the discovery of penicillin.

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INFORMATION ABOUT AUTHORS:

Dmitrii G. Nakonechny — Cand. Sci. (Med.), head of the Trauma and Orthopedic Department, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Anna N. Kiseleva — orthopaedic surgeon, Vreden Russian Research Institute of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Adeline Cambon-Binder — orthopaedic surgeon, hand surgeon, Saint Antoine Hospital, Paris, France