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Impact of Using an Original Guiding Device on Operative Time and Radiation Exposure in Minimally Invasive *Hallux Valgus* Correction

Igor' G. Belen'kiy [1,2], Gennadii D. Sergeev [1,2], Aleksei V. Oleinik [1,3], Mariya A. Sergeeva [1,4], Boris A. Maiorov [1,2,4]

[1] *St. Petersburg I.I. Dzhanelidze Research Institute of Emergency Medicine, St. Petersburg, Russia*
[2] *St. Petersburg State University, St. Petersburg, Russia*
[3] *St. Petersburg Clinical Hospital of the Russian Academy of Sciences, St. Petersburg, Russia*
[4] *Pavlov First Saint Petersburg State Medical University, St. Petersburg, Russia*

Abstract

Background. Minimally invasive Chevron and Akin osteotomy (MICA) for *hallux valgus* is a high-tech procedure, with certain stages potentially being time-consuming and requiring intraoperative fluoroscopic guidance.

The aim of the study – to evaluate the impact of the original guide device on the operative time, fluoroscopy time, and radiation exposure during minimally invasive Chevron and Akin osteotomy of the first metatarsal bone.

Methods. The study included 42 patients with *hallux valgus*, divided into two groups. All patients underwent surgery using a minimally invasive technique. The Guiding Device Group consisted of 21 patients who underwent osteotomy with the use of the original guide. The Freehand Group included 21 patients who underwent osteotomy without the guide. At the end of the procedure, the duration of the surgery and the radiation dose – measured using the image intensifier sensors – were recorded.

Results. The median duration of surgery in the Guiding Device Group was 25.00 minutes [25.00; 30.00], while in the Freehand Group it was 45.00 minutes [40.00; 57.50]. The observed differences were statistically significant ($p < 0.001$). The mean radiation dose was 0.30 ± 0.06 mGy in the group where the guide was used, and 0.79 ± 0.20 mGy in the group where guidewires for screws were inserted freehand. The mean difference between the groups for this parameter was 0.49 mGy (95% CI 0.39-0.58 mGy; $p < 0.001$). Pain intensity assessed by the VAS at 2, 4, and 8 weeks, and at 6 months postoperatively, was lower in patients who underwent surgery with the guide ($p < 0.05$ for all time points).

Conclusion. The use of the original guiding device in minimally invasive corrective osteotomies for *hallux valgus* deformity significantly reduced operative time and radiation exposure for both the patient and the surgeon.

Keywords: *hallux valgus*, bunion; valgus deformity of the first toe; osteotomy guide; minimally invasive corrective osteotomy; chevron osteotomy.

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✉ *Igor' G. Belen'kiy*; e-mail: belenkiy.trauma@mail.ru

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Влияние применения оригинального направителя на продолжительность операции и лучевую нагрузку при малоинвазивной коррекции *hallux valgus*

И.Г. Беленький [1,2], Г.Д. Сергеев [1,2], А.В. Олейник [1,3], М.А. Сергеева [1,4], Б.А. Майоров [1,2,4]

[1] СПб ГБУЗ «Научно-исследовательский институт скорой помощи им. И.И. Джанелидзе», г. Санкт-Петербург, Россия
[2] ФГБОУ ВО «Санкт-Петербургский государственный университет», г. Санкт-Петербург, Россия
[3] ФГБУЗ «Санкт-Петербургская клиническая больница Российской академии наук», г. Санкт-Петербург, Россия
[4] ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, г. Санкт-Петербург, Россия

Реферат

Актуальность. Малоинвазивная корригирующая остеотомия при вальгусной деформации первого пальца стопы является высокотехнологичным вмешательством, отдельные этапы которого могут быть длительными и требуют интраоперационного флюороскопического контроля.

Цель исследования — оценить влияние применения оригинального направителя при выполнении малоинвазивной корригирующей остеотомии первой плюсневой кости на продолжительность оперативного вмешательства, время работы электронно-оптического преобразователя и величину дозы рентгеновского облучения.

Материал и методы. В исследовании приняли участие 42 пациента с *hallux valgus*, разделенные на две группы. Все пациенты были прооперированы с использованием малоинвазивной хирургической техники. В группу «Направитель» вошел 21 пациент (21 стопа), которым была выполнена остеотомия с применением оригинального направителя. Пациентам группы «Свободная рука» (21 пациент, 21 стопа) остеотомия выполнялась без использования направителя. После завершения операции регистрировали ее длительность, а также дозу рентгеновского излучения, измеренную с помощью датчиков электронно-оптического преобразователя.

Результаты. Медиана длительности операции у пациентов группы «Направитель» составила 25,00 мин. [25,00; 30,00], а в группе «Свободная рука» — 45,00 мин. [40,00; 57,50]. Выявленные различия были статистически значимыми ($p < 0,001$). Средняя величина дозы облучения была равна 0,30±0,06 мГр в группе, где использовался направитель, и 0,79±0,20 мГр — в группе, где направляющие спицы для винтов проводились методом «свободной руки». Средняя разность между группами исследования по этому показателю составила 0,49 мГр (95% ДИ 0,39–0,58 мГр; $p < 0,001$). Интенсивность болевого синдрома по ВАШ на сроках 2, 4, 8 нед., 6 мес. после операции была ниже у пациентов при использовании направителя (для всех сроков $p < 0,05$).

Заключение. Применение оригинального направителя при выполнении малоинвазивных корригирующих операций у пациентов с вальгусной деформацией первого пальца стопы позволило сократить длительность оперативного вмешательства и лучевую нагрузку на пациента и хирурга.

Ключевые слова: *hallux valgus*; вальгусная деформация первого пальца; направитель для корригирующей остеотомии; малоинвазивная корригирующая остеотомия; шевронная остеотомия.

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Беленький Игорь Григорьевич; e-mail: belenkiy.trauma@mail.ru

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INTRODUCTION

Minimally invasive Chevron and Akin osteotomy (MICA) for *hallux valgus* is a high-tech procedure, the individual stages of which may be time-consuming and require intraoperative fluoroscopic control. The widespread adoption of this technique is explained by the fact that its radiological and clinical outcomes are comparable to, and in some cases surpass, those of open procedures [1, 2, 3, 4].

However, the technical complexity of minimally invasive *hallux valgus* correction increases the time required for surgeons to master the technique and to apply it effectively [5]. To facilitate the procedure, new instruments are regularly introduced (patent RU 229923 U1) [6]. One of the most time-consuming stages of MICA is the insertion of guidewires for subsequent placement of fixation screws. In addition, this step requires multiple intraoperative X-rays, which results in increased radiation exposure for both the patient and the surgeon.

To facilitate this stage of the procedure and to reduce the negative impact of X-ray exposure on patients and operating room personnel by decreasing the duration of fluoroscopy, in 2024 we developed a guiding device. The design of this instrument allows the lateralization of the first metatarsal head after osteotomy and enables the insertion of a guidewire for the fixation screw in the desired direction (patent RU 281344 C1). The use of this guide device may help shorten the duration of a technically demanding stage of minimally invasive *hallux valgus* correction.

The aim of the study — to evaluate the impact of the original guide device on the operative time, fluoroscopy time, and radiation exposure during minimally invasive Chevron and Akin osteotomy of the first metatarsal bone.

METHODS

Study design

The study design was a non-randomized prospective comparative study.

The study included 42 women (42 feet) with *hallux valgus* who received treatment at the St. Petersburg Clinical Hospital of the Russian Academy of Science or the St. Petersburg I.I. Dzhanelidze Research Institute of Emergency Medicine.

Inclusion criteria: *hallux valgus* deformity of grade I, II, or III according to Lewis et al. (2021) [7], age over 18 and under 80 years.

Non-inclusion criteria: decompensated comorbidities or exacerbation of chronic diseases, oncological diseases, or ongoing steroid therapy.

Following preliminary examination, the patients were hospitalized for elective corrective osteotomy. Preoperatively, based on foot X-rays, the surgeon measured the intermetatarsal angle (IMA) and the *hallux valgus* angle (HVA) in all patients. In addition, pain severity was assessed using a visual analogue scale (VAS), and functional status was evaluated with an individual questionnaire based on the American Orthopaedic Foot and Ankle Society (AOFAS) scale.

During 2024, all patients underwent corrective forefoot surgery – minimally invasive Chevron and Akin osteotomy (MICA). All procedures were performed by a single surgeon with more than 7 years of experience in this type of surgery. In half of the cases, the original guiding device for wire insertion was used, while in the other cases guidewires were placed using the freehand technique. Based on this technical difference, all patients were divided into two equal groups (21 feet per group), which were comparable in baseline characteristics. The overall characteristics of the patients are presented in Table 1.

Table 1

Baseline characteristics of patients in the study groups

Parameter	Guiding Device Group, n = 21	Freehand Group, n = 21	p	All patients, n = 42
Age, years, Me [Q_1; Q_3] (min-max)	51.00 [35.00; 57.50] (25.00-66.00)	45.00 [38.00; 55.50] (28.00-76.00)	0.930	46.00 [37.75; 56.50] (25.00-76.00)
HV grade, n (%): I II III	 1 (5) 14 (67) 6 (28)	 0 17 (81) 4 (19)	0.484	 1 (2) 31 (74) 10 (24)
Foot, n (%): right left	 9 (43) 12 (57)	 8 (38) 13 (62)	0.753	 17 (40) 25 (60)
Preoperative IMA, °, Me [Q_1; Q_3] (min-max)	16.40 [15.10; 18.20] (13.40-21.30)	16.70 [15.70; 18.30] (14.80-19.70)	0.529	16.45 [15.65; 18.25] (13.40-21.30)
Preoperative HVA, °, Me [Q_1; Q_3] (min-max)	35.40 [26.90; 39.75] (15.20-57.50)	32.50 [29.95; 39.10] (26.50-46.10)	0.763	34.95 [28.55; 38.98] (15.20-57.50)

Surgical technique

All procedures were performed under regional anesthesia. With the patient in the supine position, the operative field was prepared with antiseptic solutions and draped in a sterile manner. A 3-4 mm skin incision was made down to the bone along the medial surface of the forefoot, at the level of the distal quarter of the first metatarsal shaft. Osteotomy was performed with a 2.2-2.9 mm burr approximately 2.0-2.5 cm proximal to the radiographic projection of the first metatarsophalangeal joint space. After osteotomy, the first metatarsal head was shifted laterally. Depending on the technique applied, the insertion of the first guidewire was carried out either with the aid of the original guiding device or by the freehand method under intraoperative fluoroscopic control. The design of the guiding device and the method of its application were described in our earlier work [8].

Once the first guidewire had been placed, a 2 mm skin incision was made at its point of exit to reduce soft tissue trauma. A 2.7 mm cannulated drill was then advanced over the guidewire to create a channel for a cannulated fixation screw. Using a cannulated screwdriver, a 3.5 mm screw was inserted to fix the fragments of the first metatarsal bone. The second guidewire was placed freehand, parallel to the previously inserted screw. Following insertion of the second fixation screw using the same technique, both guidewires were removed.

The stability of the fixation of the first metatarsal fragments was verified clinically and radiographically. Excess bone tissue of the medial portion of the proximal fragment, and, if necessary, of the distal fragment of the first metatarsal bone was then resected with a burr. When indicated, correction of the first metatarsal axis was supplemented with Akin osteotomy of the proximal phalanx of the *hallux* and/or lateral release. These procedures were also performed minimally invasively. The Akin osteotomy was performed with a 2.2 mm burr and subsequently fixed with a 3.0 mm cannulated screw. The operation was completed by irrigating the wounds with antiseptic solutions and closing them after achieving hemostasis.

Assessment methods

Upon completion of operation, the following parameters were recorded: duration of the procedure, fluoroscopy time, and radiation exposure as determined by the fluoroscopy unit sensors. The following mobile fluoroscopy systems were used: Philips BV Pulsera C-arm (Philips Medical Systems Nederland B.V., Netherlands) and GE OEC Fluorostar C-arm (GE OEC Medical Systems GmbH, Germany). In addition, the performance of an Akin osteotomy

and lateral release during operation was noted separately. On postoperative X-rays, IMA and HVA were measured.

Postoperative period

In the postoperative period, pain severity was assessed using the VAS at 2, 4, and 8 weeks, as well as at 6 months and 1 year after operation. At 1 year following corrective osteotomy, patients also completed the AOFAS questionnaire again to assess functional status.

Statistical analysis

Data were systematized using Microsoft Excel (Microsoft, USA). Statistical analysis was performed with SPSS Statistics v.27.0.1 (IBM, USA). Quantitative variables were tested for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. In the case of normally distributed data, the mean (M) and standard deviation (SD) were reported as measures of central tendency. For comparative analysis, Welch's corrected Student's t-test for independent samples was used, since the Levene test indicated unequal variances between groups. Effect size was expressed as the mean difference with a 95% confidence interval (95% CI). For non-normally distributed variables, nonparametric statistical methods were applied. In this case, the median (Me), interquartile range [Q_1; Q_3], and minimum-maximum values (min-max) were reported as measures of central tendency. Comparative analysis was performed using the Mann-Whitney U test for independent samples and the Friedman test for dependent samples. Post-hoc pairwise comparisons were adjusted using the Bonferroni correction to the significance level.

Qualitative variables were analyzed using contingency tables. To identify statistically significant differences in event frequencies, Pearson's chi-square test, Fisher's exact test, and the Fisher-Freeman-Halton exact test (for multiway contingency tables) were applied. All relative values are presented as percentages. For this study, the level of statistical significance was set at $\alpha = 0.05$.

RESULTS

Descriptive statistics and the results of comparative analysis of the studied parameters are presented in Table 2.

In the group of patients where the guiding device was not used, the duration of operation, fluoroscopy time, and radiation exposure were significantly higher (for all parameters $p < 0.001$). The mean fluoroscopy time in the group with the guiding device was 66.3 seconds shorter (95% CI 52.1-80.5 sec). The mean radiation dose was also 0.49 mGy lower (95% CI 0.39-0.58 mGy) in patients in whom the original device was used for guidewire placement.

No statistically significant differences were found between groups in the frequency of Akin osteotomy – 3 cases (14%) in the Guiding Device Group vs. 6 cases (29%) in the Freehand Group ($p = 0.454$) – or lateral release – 10 cases (48%) vs. 15 cases (71%), respectively ($p = 0.116$).

Table 2

Comparison of intraoperative parameters between the study groups

Parameter	Guiding Device Group, n = 21	Freehand Group, n = 21	p	All patients, n = 42
Operative time, min, Me [Q_1; Q_3] (min-max)	25.00 [25.00; 30.00] (20.00-35.00)	45.00 [40.00; 57.50] (35.00-60.00)	< 0.001	35.00 [25.00; 46.25] (20.00-60.00)
Fluoroscopy time, sec, M±SD	45.7±9.1	112.0±30.1	< 0.001	78.8±40.1
Radiation dose, mGy, M±SD	0.30±0.06	0.79±0.20	< 0.001	0.54±0.29

In the postoperative period, X-rays were used to assess the degree of correction of *hallux valgus* deformity by measuring IMA and HVA. No statistically significant intergroup differences were found for these parameters. The obtained values and results of comparative analysis are shown in Table 3.

Analysis demonstrated that both IMA and HVA were significantly reduced after surgery in each study group ($p < 0.001$ for both parameters).

The results of pain assessment at different follow-up periods, as well as functional outcomes at 1 year after surgery, are presented in Table 4.

Statistical analysis of VAS scores over time showed that the reduction in pain intensity was significant in both groups ($p < 0.001$ for each group). Identical VAS values between groups were observed only at the 1-year follow-up. Interquartile range analysis indicated that at other postoperative time points, pain intensity was significantly lower in the Guiding Device Group, despite the fact that preoperatively these patients had higher VAS scores.

Table 3

Postoperative radiographic angle values,°

Parameter	Guiding Device Group, n = 21	Freehand Group, n = 21	p	All patients, n = 42
Postoperative IMA, Me [Q_1; Q_3] (min-max)	3.80 [2.65; 5.10] (1.90-6.20)	2.90 [2.45; 5.10] (1.90-9.70)	0.473	3.45 [2.50; 5.05] (1.90-9.70)
Postoperative HVA, Me [Q_1; Q_3] (min-max)	9.40 [7.60; 10.55] (3.20-16.80)	8.30 [5.95; 10.05] (2.50-18.30)	0.162	9.15 [6.30; 10.33] (2.50-18.30)

Table 4

Dynamics of pain intensity and functional status at 1-year follow-up, points, Me, [Q_1; Q_3], (min-max)

Scale		Guiding Device Group, n = 21	Freehand Group, n = 21	p	All patients, n = 42
VAS	Before surgery	7.00 [6.50; 8.00] (5.00-9.00)	7.00 [6.00; 8.00] (5.00-9.00)	**0.015**	6.00 [6.00; 7.00] (5.00-9.00)
	2 weeks	4.00 [3.50; 5.00] (2.00-5.00)	4.00 [4.00; 5.00] (2.00-9.00)	**0.005**	5.00 [4.00; 6.50] (3.00-9.00)
	4 weeks	3.00 [2.00; 3.00] (1.00-4.00)	3.00 [2.00; 4.00] (1.00-6.00)	**0.040**	3.00 [3.00; 5.00] (1.00-6.00)
	8 weeks	1.00 [0.50; 2.00] (0.00-2.00)	2.00 [1.00; 2.00] (0.00-5.00)	**0.007**	2.00 [1.00; 3.00] (0.00-5.00)
	6 months	0.00 [0.00; 1.00] (0.00-1.00)	1.00 [0.00; 1.00] (0.00-2.00)	**0.038**	1.00 [0.00; 1.50] (0.00-2.00)
	1 year	0.00 [0.00; 0.00] (0.00-1.00)	0.00 [0.00; 0.25] (0.00-2.00)	0.435	0.00 [0.00; 1.00] (0.00-2.00)
AOFAS	Before surgery	52.00 [34.00; 68.50] (29.00-80.00)	52.00 [42.00; 72.00] (29.00-80.00)	0.263	52.00 [42.00; 72.00] (29.00-75.00)
	1 year	95.00 [88.00; 97.50] (82.00-100.00)	95.00 [88.00; 95.00] (80.00-100.00)	0.855	95.00 [88.00; 95.00] (80.00-100.00)

$p < 0.05$ is shown in bold.

It is noteworthy that pairwise comparison of VAS scores at different time points revealed the most pronounced reduction in pain intensity between weeks 4 and 8 of follow-up in both groups. However, these changes did not reach statistical significance ($p = 0.158$ in the Guiding Device Group and $p = 0.314$ in the Freehand Group). Differences in functional outcomes assessed by the AOFAS scale before and after surgery were statistically significant ($p < 0.001$) in both groups.

No complications were recorded during the follow-up period.

DISCUSSION

During the preparation of this study, we noted the limited number of investigations addressing the impact of surgical technique and instrumentation on operative time and radiation exposure for both patient and surgeon. Therefore, our work not only aimed to evaluate the effectiveness of using the original guiding device during surgery, but also contributes additional data to the scarce body of evidence available.

The study groups were comparable in terms of the frequency of Akin osteotomy and lateral release ($p = 0.454$ and $p = 0.116$, respectively). This suggests that these two factors did not influence operative time, fluoroscopy time, or radiation exposure. However, it should be emphasized that patients who underwent operation without the guiding device spent significantly longer on the operating table ($p < 0.001$) compa red with those in whom the device was used.

In our opinion, the reduction in operative time and radiation exposure achieved with the guiding device not only simplifies the work of experienced surgeons but also facilitates the training process for young orthopedic surgeons. According to A. Toepfer and M. Strässle, MICA, unlike open techniques, is characterized by a shallow learning curve. Based on their experience, the authors argue that a surgeon who has performed a sufficient number of open corrective procedures quickly reaches high efficiency in surgical technique. At the same time, progress in training is less evident in minimally invasive surgery. In their study, the authors also reported operative times for MICA and total radiation exposure. According to their data, the mean operative time was 46.8 min (SD 12.1; range 31.0-90.0 min), and the mean radiation dose was 0.82 mGy (SD 0.51; range 0.27-1.06 mGy). For experienced surgeons, the mean operative time was 35.1 min, and the mean radiation dose was 0.67 mGy [9]. Notably, both of these values are higher than those obtained in our study in the Guiding Device Group.

Comparable mean radiation dose values were reported in 2021 by R. Hromádka et al. in their study of 93 procedures in 76 patients. According to their findings, the mean radiation exposure was 0.58 mGy [10]. The authors did not provide data on the mean operative time.

The angular parameters assessed in our study, reflecting the degree of correction of *hallux valgus* deformity, did not differ substantially from those reported in the scientific literature. X. Geng et al., based on the results of minimally invasive *hallux valgus* correction in 36 patients, reported the following values: preoperative IMA and HVA were 14.0±3.2° and 22.3±6.1°, respectively, while postoperative values were 3.7±1.0° and 7.0±1.8°, respectively [6]. These results are comparable to those obtained in our study.

Many authors have presented early and midterm outcomes of *hallux valgus* correction [11, 12, 13, 14]. V.V. Balesar et al. tracked changes in angular values compared with baseline measurements. In 42 patients prior to surgery, the median IMA was 28° [22-30°], and the HVA was 11° [10-14°]. At 6 weeks, the corresponding values were 9° [7-13°] and 5° [4-7°]. After 1 year, both parameters increased slightly to 11° [7-15°] and 6° [4-8°], respectively [11].

Similar results were reported by T.L. Lewis et al. In their study of 50 minimally invasive *hallux valgus* corrections, the IMA at 12 months postoperatively was 7.9°, compared with a preoperative value of 32.7°, while the HVA was 4.2°, compared with a baseline of 14.0° [12].

In our study, the dynamics of IMA and HVA changes over time were not assessed; however, it may be noted that the degree of correction of *hallux valgus* deformity was satisfactory. Based on our own clinical experience and published data, an increase in angular values over time can be expected. Analysis of these parameters in long-term follow-up will be the subject of future studies.

Analysis of pain intensity dynamics is one of the specific indicators of patient satisfaction with the operation. International studies

report a decrease in mean VAS scores from 5.2±2.4 preoperatively to 2.4±1.9 one week postoperatively ($p < 0.001$; $n = 93$). At an average follow-up of 1 year, pain intensity further decreased to 1.6±2.1 ($p < 0.001$; $n = 93$) [14].

Other surgeons report higher preoperative pain levels. In studies by G.A. Nunes et al. and K.A.M. de Carvalho et al., the mean preoperative VAS scores were 8.1 and 8.2±1.5, respectively. In both studies, pain decreased to 1.3 and 1.2±2.2 at approximately 2 years after surgery [15, 16].

In our study, pre- and postoperative VAS values were comparable to those reported by the above authors. Comparison of scores showed that patients who underwent surgery with the original guiding device experienced statistically significantly lower postoperative pain at all follow-up time points, except at the final 1-year assessment. This may be explained by the fact that the use of the guiding device reduced intraoperative trauma to soft tissues and bone by minimizing failed attempts at guidewire placement.

A similar pattern was observed for functional outcomes. The dynamics of AOFAS score changes will be analyzed in our future studies; however, it should be noted that at 1 year there were no statistically significant differences between the study groups. Both preoperative and midterm postoperative values were largely consistent with those reported in the literature [15, 16, 17, 18]. In the study by G.F. Ferreira et al., mean AOFAS scores improved from 57.0±8.6 preoperatively to 93.9±8.7 at 2 years post-correction [17]. According to T.J. Holme et al., functional scores increased from 48 to 93 on the AOFAS scale [18].

Despite the absence of statistically significant differences in pain intensity and AOFAS scores at the final follow-up, we believe that lower postoperative pain contributes to faster rehabilitation and greater overall patient satisfaction with surgical treatment.

CONCLUSION

The use of the original guiding device during minimally invasive corrective osteotomies for *hallux valgus* allowed a reduction in operative time and radiation exposure for both the patient and the surgeon. Additionally, patients who underwent operation with this instrument experienced lower pain intensity during the first six months postoperatively.

DISCLAIMERS

Author contribution

Belen'kiy I.G. — study concept and design, data acquisition, analysis and interpretation, drafting and editing the manuscript.

Sergeev G.D. — study concept and design, data acquisition, analysis and interpretation, statistical data processing, drafting and editing the manuscript.

Oleinik A.V. — study concept and design, data acquisition, analysis and interpretation.

Sergeeva M.A. — literature search and review, drafting and editing the manuscript.

Maiorov B.A. — study concept and design, editing the manuscript.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Authors' information

✉ *Igor' G. Belen'kiy* — Dr. Sci. (Med.), Professor
Address: 3, Budapeshtskaya st., St. Petersburg, 192242, Russia
https://orcid.org/0000-0001-9951-5183
e-mail: belenkiy.trauma@mail.ru

Gennadii D. Sergeev — Cand. Sci. (Med.)
https://orcid.org/0000-0002-8898-503X
e-mail: gdsergeev@gmail.com

Aleksei V. Oleinik
https://orcid.org/0000-0003-2748-0588
e-mail: oleynik77@gmail.com

Mariya A. Sergeeva
https://orcid.org/0009-0003-3255-1771
e-mail: masharik1990@mail.ru

Boris A. Maiorov — Cand. Sci. (Med.)
https://orcid.org/0000-0003-1559-1571
e-mail: bmayorov@mail.ru