УДК 616.728.3-089.844-089.193.4 DOI: 10.21823/2311-2905-2019-25-2-9-18

Early Outcomes of Patient-Specific Modular Cones for Substitution of Methaphysial and Diaphysial Bone Defects in Revision Knee Arthroplasty

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Abstract

The aim of this study was the assessment of early outcomes of patient-specific three-dimensional titanium cones with specified porosity parameters to compensate for extensive metaphysical-diaphyseal bone defects in RTKA. ***Materials and Methods.*** Since 2017 till 2019 30 patient-specific titanium cones (12 femoral and 18 tibial) implanted during 26 RTKAs. Clinical outcomes evaluated using KSS, WOMAC and FJS-12 scoring systems on average 10 (2–18) months after surgery. At the same time the stability of implant fixation analyzed using frontal, lateral and axial knee roentgenograms. ***Results.*** During all procedures there were no technical difficulties in positioning and implantation of custom-made titanium cones. At the time of preparation of the publication, none of the patients had indications for further surgical intervention, as well as intra- and postoperative complications. Six months after surgery all scores improved significantly: KSS from 23 (2–42, SD 19.96) to 66.5 (62–78, SD 7.68), WOMAC from 59 (56–96, SD 28.31) to 32.25 (19–46, SD 11.76), the index FJS-12 was 29.16 points (0–68.75, SD 30.19). The average scores continued to improve up to 18 months: KSS — 97.5 (88–108, SD 9.14), WOMAC — 16.5 (9–24, SD 6.45), FJS-12 — 45.85 (25–75, SD 22.03). No radiolucent lines were noticed during this period of observation. ***Conclusion.*** The original additive technology of designing and producing patient-specific titanium cones for compensation of extensive metaphyseal-diaphyseal bone defects in RTKA is a valid solution at least in the short term. A longer follow-up period is required to assess its medium-and long-term reliability compared to existing alternative surgical solutions.

Keywords: knee revision arthroplasty, bone deficiency, patient-specific implant, additive technologies, 3D printing.

Cite as: Cherny A.A., Kovalenko A.N., Bilyk S.S., Denisov A.O., Kazemirskiy A.V., Kulyaba T.A., Kornilov N.N. [Early Outcomes of Patient-Specific Modular Cones for Substitution of Methaphysial and Diaphysial Bone Defects in Revision Knee Arthroplasty]. *Travmatologiya i ortopediya Rossii* [Traumatology and Orthopedics of Russia]. 2019;25(2):9-18. (In Russian). DOI: 10.21823/2311-2905-2019-25-2-9-18.

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Received: 20.05.2019. Accepted for publication: 18.06.2019.

Background

Annually the number of primary knee arthroplasty in Russian Federation is growing from 36 843 in 2014 up to 42 904 in 2017 which reflects the global trend [1]. Consequently, the number of revisions is also growing: their share of overall primary procedures varies from 6 to 8% [2].

Restoration of bone defects in femur and tibia condyles is the integral and key stage of any knee revision arthroplasty. Standard modular components are used in the majority of patients for this purpose: metal blocks, metaphyseal cones or sleeves. However, bone deficit is often observed not only in metaphysis but also in diaphysis which substantially complicates reconstruction of joint line and compromises reliability of implant fixation while high variability of defect volume and shape restricts the possibility to apply standard compensatory methods. Alternative surgical options for solution of the this issue are not only cost consuming (porous tantalum cones, titanium sleeves with plasma spraying coating, mega prostheses) but are limited in clinical availability for a series of organizational reasons, consideration of which lies beyond this issues (structural allografts), and are also accompanied by rather high complications rate. Dimensions of standard sleeves and cones do not cover the full variety of bone defects seen daily in the clinical practice. According to literature data the use of segmental systems for knee arthroplasty is associated by 5 to 40% of infectious complications including 23.5–87% rate of secondary amputations risk due to persisting periprosthetic infection, as well as by 4.9–9.6% rate of early aseptic loosening [3]. Bone allografts possessing complete biological properties are available only in single hospitals of Russian Federation due to organizational and economic challenges in establishing and functioning of local bone banks for a number of organizational reasons, consideration of which is beyond the scope of this work, and also due to the lack of uniform regulations for preparation, preservation and storage.

Purpose of the study is the implementation, clinical evaluation and assessment of early outcomes for possible application of additive technology allowing to design and produce patient specific three-dimensional titanium cones with set-up parameters of porosity and adhesion for compensation of metaphyseal and diaphyseal bone defects in revision knee arthroplasty.

Material and Methods

Preoperative examination and planning

All patients underwent thin cut computer tomography (CT) of both lower limbs in increments of 0.5–1.0 mm covering hip and ankle joints and with metal artifact reduction sequence. Then computer reconstruction was used to create a 3D model of the knee of one to one scale. Preoperative planning (segmenting and design) was made using special software — 3D Slicer (version 4.10) and Blender (version 2.8) [4]. After creation of a virtual model, which in certain cases was printed on 3D printer to improve visualization, authors collectively evaluated the potential to use standard techniques for replacement of extensive bone defects and made a decision on designing a custom-made implant. Considering the fact that time from the moment of decision making until possible implantation might take from 2 to 8 weeks, this stage for majority of patients was done in outpatient setting.

Design. Three-dimensional positioning of revision implant and customized cone was made based on preserved anatomical landmarks aiming to achieve neutral mechanical axis of the limb in the frontal plane as well as simulation of individual flexion angle at the lower third of the femur and posterior tibial slope in the sagittal plane recommended by manufacturer of the prosthesis (Fig.1). Anatomical references of contralateral extremity (Fig. 2) were used to plan reconstruction in case of significant anatomical destruction on affected side. It should be noted that even in case of pathological changes in contralateral knee, three-dimensional virtual visualization allowed to minimize errors in orientation and positioning of components. Three-dimensional knee model was built basing on CT scans in DICOM format which contained data on joint positioning in respect to horizontal, vertical and sagittal planes, and the surface angle of designed cone in the three planes was set to a fraction of degree (Fig. 3).

Depending on defect shape the custom-made implant, as a rule, combined diaphyseal and metaphyseal parts simulating the lost bone morphology. Prior to creating the prototype, the authors marked certain segments on a bone model that can be additionally removed or flattened to facilitate insertion of implant which is especially important for areas where intramedullary elements of revision prostheses are placed. Non-porous parts of the implant were made considering need to ensure secure mechanical strength and resistance to typical load on revision knee prosthesis.

Surface structure of customized implant was designed depending on specific mechanical and biological tasks at its different elements. To optimize osteointegration the shape and size of pores on the surface contacting the bone simulated natural of 700 micron and strata size of 0,45 mm. Besides, these areas were made rough to improve adhesion and strength of primary fixation. Pores and strata size were invariable throughout the length of the augment. The external surface of custom-made cone in the areas with potential contact with soft tissues was glazed to reduce irritation in the joint during movements.

Afterwards, 3D printer was used to print plastic prototype together with a bone model of the patient to evaluate the positioning and matching with the defect. After final approval of implant design by the operating surgeon the authors proceeded to production.

Production technology. Technology stipulates layer-by-layer electron-beam melting or laser sintering of titanium powder which is known as additive manufacturing. 3D printing from titanium powder was used for all 26 cases of the present study with involvement of leading Russian technological bioengineering facilities (Moscow, Novosibirsk).

Surgical technique. As the first step the authors performed surgical approach sufficient for adequate visualization of remaining bone in the femoral and tibial condyles. Then implant to be revised was carefully removed paying special attention to precise debridement of bone surface of scar tissue and bone

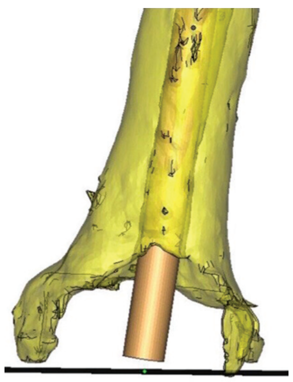

Fig. 1. Definition of anatomical limb axis and reference values during preoperative planning

Fig. 2. Stages of reconstruction and prototyping based on the CT scans of contralateral (intact) limb

Fig. 3. Preoperative planning of three-dimensional positioning of revision component

cement which interposition between bone bed and custom-made implant may inhibit correct positioning and fixation of the whole prosthesis (Fig. 4).

Intramedullary cavities of femur and tibia were prepared according to the instructions of prosthesis manufacturer and depending on length and fixation type of the stem. Then plastic model of custom-made cone underwent test-fitting and bone bed was adapted to achieve press-fit fixation, with that correctness of three-dimensional positioning was evaluated (Fig. 5). After test-fitting of prosthesis with cone model and ensuring achievement of planned three-dimensional positioning given the joint line level, the authors performed final press-fit implantation of custom-made cone as well as revision prosthesis using a hybrid or fully cemented fixation. The procedure was completed by layered wound closure (Fig. 6).

AP and lateral postoperative x-rays demonstrate implanted custom-made cone: the key element is to gain a tight contact of external cone surface with internal surface of metaphysis and diaphysis to ensure secure primary fixation and further osteointegration (Fig. 7).

Fig. 4. Debridement of femur and tibia surfaces after removal of antimicrobial cemented knee spacer and visualization of massive bone defects (types F3/T3 by AORI)

Fig. 5. Test-fitting of the plastic model of customized femoral augment for diaphyseal fixation (model based on the original component)

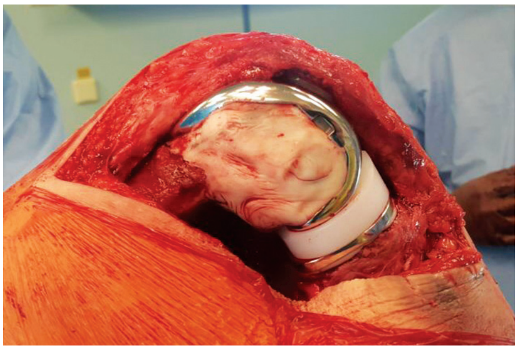

Fig. 6. Implanted customized titanium augment and revision knee prosthesis. Free lateral porous surfaces of the implant are covered by bone cement to prevent unwanted postoperative adhesion of soft tissues

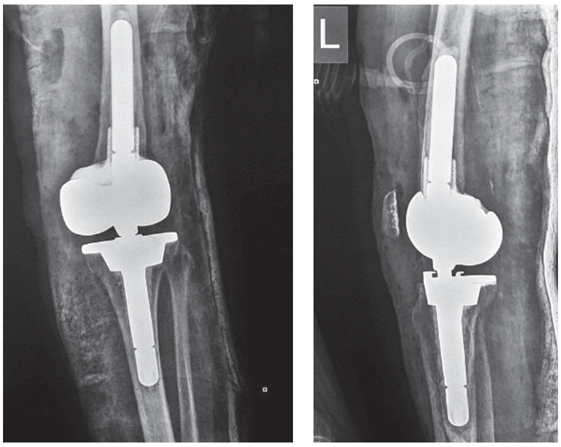

Fig. 7. Postoperative lateral and AP X-rays visualizing customized titanium femoral augment for diaphyseal fixation and revision implant with tantalum metaphyseal tibial augment

In the period since 2017 until 2019 the authors performed designing and implantation of 30 custom-made components (12 femoral and 18 tibial) in 26 patients during revision knee arthroplasty. Patients included 8 (30.8%) men and 18 (69.2%) women aging from 34 to 86 years (average of 63 years). Aseptic instability of prosthesis components (62.5%) and second stage of peri-prosthetic infection after insertion of antimicrobial spacer (37.5%) were the causes of revision surgery supplemented by custom-made augment in the majority of cases. Severity of bone defect was confirmed intraoperatively after removal of prosthesis and scar tissue by AORI classification (Anderson Orthopaedic Research Institute, USA) [5].

Clinical assessment of preoperative patients' status and treatment outcomes was done repeatedly in 11 patients by validated and adapted Russian language version of knee functional scores KSS, WOMAC, FJS-12 [6], averagely in 10 months after the procedure (from 2 to 18 months), in other patients — assessment was done twice due to short period after the surgery. Analysis of fixation stability for components by standard knee X-rays in three planes was done at the same timelines.

Statistical analysis

Statistical analysis was made by Microsoft Excel and Statistica software (version 12.5.192.7): mean score and standard deviation (SD) values were determined with 95% confidence interval of compared parameters pre- and postoperatively.

Results

Cones were used for replacement of an isolated 2B type defect in metaphyseal area (Fig. 8) in 15 cases, and in 11 cases cones engaged femoral diaphysis (9 augments) and/or tibia diaphysis (6 augments) (Fig. 9) to compensate type 3 defects by AORI. It should be noted that the present defects classification doesn't provide a complete understanding of bone deficit scope extending not only to metaepiphyseal area but to the diaphysis not allowing to adequately describe the lesion.

The authors used modular revision systems NexGen LCCK and RHK (Zimmer Biomet, USA) or LCS Complete Revision and Sigma TC3 MBT (DePuy Johnson&Johnson, USA) for all 26 cases. Surgery time varied from 90 to 285 min, mean 138 min (SD 54.19). Mean intraoperative blood loss was 278 ml (from 50 to 850; SD 205.72), however, it should be emphasized that the majority of procedures (68.75%) was performed under hemostatic tourniquet without drainages.

Revision procedures in all 26 cases were free of any technical difficulties related to positioning or implantation of custom-made titanium cones: augments exactly matched the size and shape of defect following minimal bone bed treatment to ensure precise fit. At the moment of preparing the present publication no indications for revision as well as no intra- and postoperative complications were reported for any of patients.

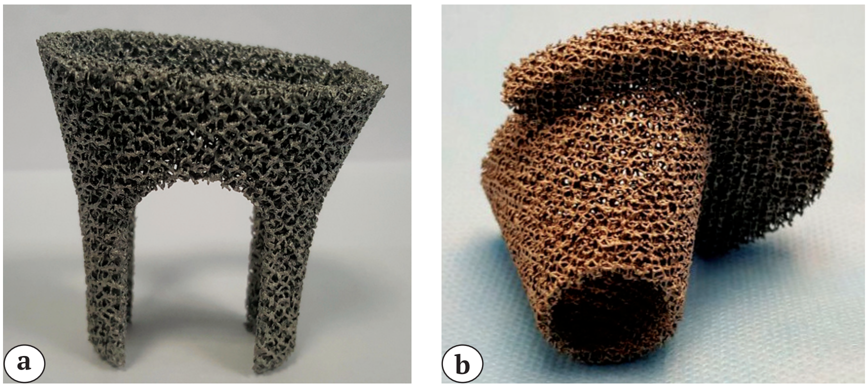

Fig. 8. Customized titanium metaphyseal augment:
a – for replacement of 2B type femoral defect;
b – for replacement of 2B type tibia defect

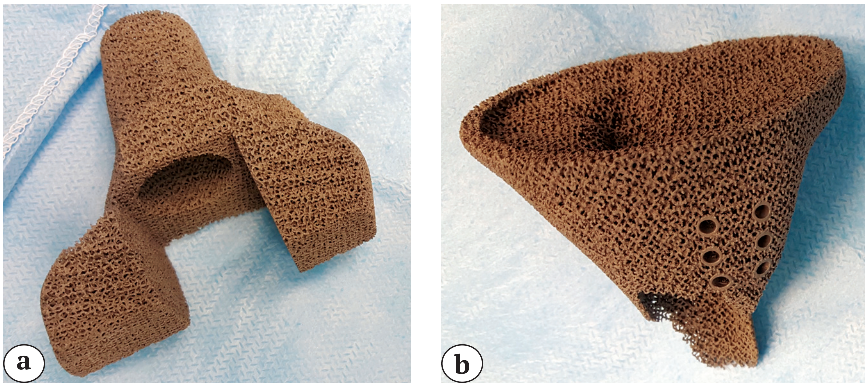

Fig. 9. Customized titanium augment for metaphyseal-diaphyseal fixation:
a — for replacement of 3 type femoral defect;
b — for replacement of 3 type tibial defect, holes are stipulated for re-fixation of extensor apparatus according to individual anatomy

Early functional outcomes were evaluated in all 26 patients, average in 6 and 18 months after the procedure (from 2 to 18 months). Mean functional knee scores in 6 months postoperatively demonstrated significant improvement: KSS from 23 (2–42; SD 19.96) to 66.5 (62–78; SD 7.68), WOMAC from 59 (56–96; SD 28.31) to 32,25 (19–46; SD 11.76), FJS-12 was 29,16 points (0–68.75; SD 30.19). Values in 18 months postoperatively were reported as follows: KSS — 97.5 (88–108; SD 9.14), WOMAC — 16.5 (9–24; SD 6.45), FJS-12 — 45.85 (25–75; SD 22.03). No roentgenological signs of components instability during follow up period were reported for any of the patients.

Discussion

The following should be noted among the key results of the present study. First, high precision of virtual reconstruction of femur and tibia with metaphyseal-diaphyseal defects as well as further designing and producing of custom-made cones with given porosity and adhesion parameters: all 30 augments were implanted without significant technical difficulties and precisely in respect of axes and bone landmarks planned during virtual reconstruction which significantly facilitated anatomical restoration. Second, early functional and roetgenological outcomes after clinical application of this technology do not substantially differ from alternative options which allows to consider this technology as promising. Conventionally extensive bone defects are replaced by a series of interchangeable methods during revision knee arthroplasty, like use of structural allografts, modular metal augments, sleeves with sprayed coating, tantalum or titanium cones and modular mega prostheses. Despite advantages and drawbacks of each of above methods, the choice is usually determined by surgeon's preferences and availability of each method in hospital.

Thus, use of structural allografts allows to compensate almost any volume of bone loss but their preparation and storing is accompanied by organizational and material costs needed to keep own bone bank while logistics of biological tissues between hospitals in Russia is complicated due to imperfect regulatory framework. Massive cortical-cancellous allograft is not remodeled over time but accretes with the host bone at the contact area. In case the mechanical strength of bone trabecules fails in late period after revision arthroplasty (histological studies demonstrated no revascularization of the grafts average in 41 months after the surgery) this results in implant migration and requires secondary revision (79.6% of good outcomes during the first year of follow up and 68.2% in 5 years) [7, 8].

Use of metal sleeves with sprayed coating and cone of porous metal allows to replace central defects: with that at least 70–75% of peripheral circumference of this type of augment should have a tight contact with host metaphyseal bone to ensure solid fixation. In case it's not possible and defect is extending into diaphysis we can utilize both, diaphyseal and metaphyseal cones, which are fixed to each other by bone cement: reliability of this solution has not been yet confirmed by follow up in late period [9].

Most often the cones are positioned eccentrically in relation to revision prosthesis while they are not directly connected, and during insertion the lengthening stem of the implant is cemented onto its internal surface. Due to this the process of bone bed preparation during revision arthroplasty is time and labor consuming. Preparation of bone bed for metaphyseal sleeve is faster and more technological, positioning is determined by the medullary cavity, and prior to insertion the sleeve is fixed to the corresponding component of the prostheses. For this method of reconstruction difficulties with correct three-dimensional sleeve positioning arise in case of deformations in femur or tibia diaphyses [10]. Thus, insertion of lengthening stem in some patients becomes impossible, and in case of additional epiphyseal bone deficit the fixation principle of revision prostheses at least in two zones is violated [11]. At the same time application outcomes of metal sleeves with coating (mean follow up of 3.6±1.4 years) and cones (mean follow up of 4.5±1.6 years) demonstrate good survivorship of augments in early and mid-term period (97.3 and 97.8% respectively) [12].

The following drawbacks of conventional cones and sleeves should be noted: need to adjust bone bed for standard type of implant which results in additional damage, their high cost especially in combination with supplementary modular blocks. Some costs arise also due to the need to keep at hospital stock products of the whole range of types and sizes as well as additional logistical issues including lack of manufacturing sites for such augments in Russia.

The most radical solution for reconstruction of extensive metaphyseal-diaphyseal knee bone defects is the use of mega prostheses. Despite fast and easy implantation technique there are still some unresolved aspects: unreliable single zone diaphyseal fixation (early aseptic loosening rate features unacceptable values) and high rate of periprosthetic infection [3]. Combination of above factors with extremely high costs for such implants and their incidental application in Russia.

Over the past decade, there has been a worldwide growth trend in the use of 3D technology in orthopedics. Mainly those are used for production of custom-made resection blocks for total knee arthroplasty as well as guides for corrective osteotomies in the upper and lower limbs [13–15]. Craniofacial surgery and bone oncology are the leading areas in respect of 3D printing use to compensate extensive bone defects. So, W. Luo et al demonstrated good results of this method in treatment of four patients aging from 35 to

68 years with giant-cell tumor of tibia, proving convenience of intraoperative implantation and absence of complications during 5 to 8 months follow up [16]. C.A. McNamara et al reported their experience in application of custom-made tantalum augment with diaphyseal fixationto replace femoral defects during secondary knee revision emphasizing the importance of preoperative planning for optimal implant selection and potential advantages of this new method like decreased surgery time and possible increase of implant survivorship [17]. Publication of L. Cavagnaro et al was the first work dedicated to outcomes after use of custom-made porous titanium implants during primary and revision knee arthroplasty accompanied by massive bone defects. The authors examined results of application of 8 custom-made augments in 6 patients (4 men and 2 women) with mean age of 63,7 years. The study demonstrated that custom-made implants are a good alternative to tumor prostheses and standard solutions like cones and sleeves allowing to gain good early clinical and roentgenological outcomes. None the less, the authors assigned the major importance to correct planning and intraoperative control over reconstruction precision and soft tissue balance [18].

Data obtained by the authors of the present study confirms above observations, however, promising nature of considering individual zonal porosity variances and adhesion degree of the implant, on the one hand, and prevention of unfavorable ingrowth of soft tissues, on the other side, should be emphasized.

Thus, the authors see the evident advantage of the discussed method in the individual approach to restoration of solid bone support for prosthesis and versatility in respect to type and shape of defect (specific shape and diaphyseal extension, damage of peripheral cortex, combination of central and peripheral defects) as well as to selected revision system, which altogether allow to restore failed anatomy and ensure reliable prosthesis fixation.

At the same time routine use of described method is inseparable from well coordinated teamwork of 3D modeling specialist and operating surgeon aimed at adequate evaluation of indications, designing and producing of implant, and precise prosthesis implantation.

The original additive technology of designing and producing of patient-specific titanium cones to compensate metaphyseal and diaphyseal bone defects in revision knee arthroplasty is a promising and clinically valid solution at least in the short term. A longer follow up is definitely required to evaluate its mid- and long-term reliability as compared to the existing alternative surgical methods.

Competing interests: The authors declare that there are no competing interests.

Funding: State budgetary funding.

Authors' contribution

A.A. Cherny — idea and design of the study, data collection and processing, evaluation and interpretation of results, drafting the manuscript

A.N. Kovalenko — data collection and processing, drafting the manuscript

S.S. Bilyk — data collection and processing

A.O. *Denisov* — idea and design of the study, data collection and processing

A.V. Kazemirsky — evaluation and interpretation of results

T.A. Kulyaba — evaluation and interpretation of results

N.N. Kornilov — idea and design of the study, data collection and processing, evaluation and interpretation of results, drafting the manuscript

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