

## Mid-term Outcomes of Using Custom-Made Implants for Revision Hip Arthroplasty

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### Abstract

**Background.** The surgeon's desire to preserve bone tissue as much as possible and at the same time ensure reliable fixation of the implant on the one hand and the increasing availability of additive 3D technologies on the other, resulted in the use of individual designs, which minimize bone processing and optimize the fixation possibilities of revision implants. Individual implants, as a rule, are used for the most complex acetabular defects and so led to the large number of unsatisfactory outcomes and complications. **Purpose** – to assess the mid-term results, the osseointegration of custom-made implants porous coating, the overall survival of structural components and to determine the causes of unsatisfactory outcomes and complications. **Materials and Methods.** During the study, it was possible to interview and evaluate radiographs of 48 patients operated from October 2015 to June 2018. Patients were interviewed before and after surgery on the Oxford hip score (OHS) quality of life score EQ-5D, visual analogue pain scale. Radiographs were evaluated for a period of at least 12 months for the presence of osseointegration of implants into the porous coating. **Results.** The average value on the OHS increased from 14.9 to 37.6 points ( $p < 0.01$ ). Quality of life according to the EQ-5D index increased from 0.2 to 0.7 ( $p < 0.01$ ). The average value according to the VAS decreased from 73 to 19 points ( $p < 0.01$ ). Osseointegration was observed in 98%. Migration of the structure with a fracture of the flange was observed in one case. **Conclusion.** The use of custom-made implants in the mid-term follow-up period significantly improves hip function and the quality of life of patients. Custom-made implants provide the possibility of primary reliable fixation in patients with complex acetabular defects. For a period of at least 12 months, there is a high rate of osseointegration of custom-made implants with porous-coated. Additional lengthy researches are needed to evaluate long-term results.

**Keywords:** custom-made implants, revision hip arthroplasty.

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## Introduction

All over the world, the number of the operations performed on primary hip replacement is growing, causing an inevitable increase in the absolute number of revisions [1, 2, 3, 4]. The revision operations are characterized by greater complexity, often require significant material costs and are accompanied by a significantly higher frequency of intra- and postoperative complications. The infection, dislocations, periprosthetic fractures, and aseptic loosening are observed 5–15 times more often during the revision than during the initial hip replacement in comparable periods of observation [5, 6, 7]. One of the reasons for the high frequency of fails during revision surgery is the various degree of bone defects that head off reliable fixation of components and require non-standard technical decisions.

Most of the bone defects in the acetabulum are increasingly found in our practice as an inevitable consequence of repeated operations on the hip joint, including those associated with the treatment of periprosthetic infection. The choice of a method for ensuring reliable fixation of the acetabular component and the method of replacing the defect depend on its size, nature (cavitary or segmental), clinic opportunities and the preferences of the surgeon. In the arsenal of surgeons today there are various techniques aimed at bone restoration: from implant bone grafting with cement fixation of the cup to replacing limited defects with allogeneic grafts in combination with highly porous acetabular components, and, if it is necessary, together with augments, anti-protrusion rings and various combinations [8, 9, 10]. However, the pronounced heterogeneity of bone defects in size, localization, and the reason for their occurrence requires a significant variety of technical solutions: preparation of a bone bed for serial acetabular components and metal augments sometimes makes it necessary to excise a signif-

icant amount of bone [11, 12, 13]. The desire of the surgeon to preserve the bone to the maximum and ensure reliable fixation of the implant, on the one side, and the increasing availability of additive 3D technologies, on the other side, have led to the expansion of the use of individual constructs (IC), which minimize bone processing and optimize the possibilities of fixation of revision implants. The individual implants, generally, are used for the most complex defects of the acetabulum, often as a despair operation, and so that, according to the literature, they are accompanied by a sufficiently large number of unsatisfactory results and complications [14, 15, 16].

So that, the following questions were posed in our:

- 1) how much improved the study function hip and the quality of life of patients after operations with IC;
- 2) what is the survival rate of IC and the degree of their osseointegration;
- 3) what are the causes of unsatisfactory results and complications.

## Materials and Methods

### *Study design*

In a prospective research, we evaluated the medium-term results of using implants individually designed and made by 3D printing for reconstruction of the acetabulum during revision arthroplasty. According to the state clinical testing program, from October 2015 to June 2018, one surgical team performed 75 revisions of the acetabular component using individual designs in 71 patients. Results with a follow-up period of at least 12 months were possible to evaluate in 50 cases (48 patients), which amounted to 67% of the total number of revisions performed.

### *Patients*

The research included 8 men and 40 women with an average age of 54 years (from 27 to 80) who underwent 50 revision operations (two women were operated on both sides).

The cause of the audit in 35 (70%) cases was aseptic loosening of the components of the endoprosthesis, and in 15 (30%) cases – the staged treatment of periprosthetic infection. The number of previous operations ranged from 1 to 4. In 33 cases, the acetabular and femoral components were revised, and in 17 cases, only the acetabulum was reconstructed while the femoral component was saved.

Acetabular defects were assessed with the W. Paprosky classification [17, 18], however, given the significant variability and limited validity of this classification [19, 20], preoperative acetabular defects were additionally evaluated using 3D modeling technology based on data from computed tomography with the following criteria: the degree of bone loss and the quality of the remaining bone. Defects of types 2A, 2B and 2C were observed in 6 patients, 3A – in 17 cases and 3B – in 25 cases, and in 2 patients pelvic ring dissociation was observed (Table).

*Individual implants*

In all cases, individual implants were designed by the 3D modeling laboratory of the

Vreden institute with the free software product 3Dslicer 4,5. The design was carried out on the basis of a CT study of the pelvic bones and the hip joint with a pitch of 0.6 mm, performed on a Toshiba Aquilon / Prime tomography. The 3Dslicer program segmented the pelvic bones and evaluated the acetabulum defect. All stages of engineering were agreed with the operating surgeon regarding the estimated area of contact with the bone, the direction of the screws, the position of the rotation center.

The planned anteversion and inclination of the three-flange acetabular component were 20° and 40°, respectively. The planned direction of the screws oriented to the zone of the most promising bone mass was most important for individual augments and hemispherical acetabular components of an individual design. The production of porous individual structures was carried out by Endoprint (Moscow, Russia) and LogeeksMS (Novosibirsk, Russia).

Individual augments were used when it was impossible to use serial trabecular metal augments (lack of appropriate sizes) or to replace several serial augments with one individual augment.

**The distribution of implants, depending on the type of defect**

*Table*

The classification of the defects by Paprosky	The implant				Total
	Augment	Hemisphere	Three flange construction	“Ice Cream Cone”	
2A	0	1	0	0	1
2B	1	1	0	0	2
2C	0	3	0	0	3
3A	11	4	2	0	17
3B	1	1	23	0	25
Dissociation of pelvic ring	0	0	1	1	2
Total	13	10	26	1	50

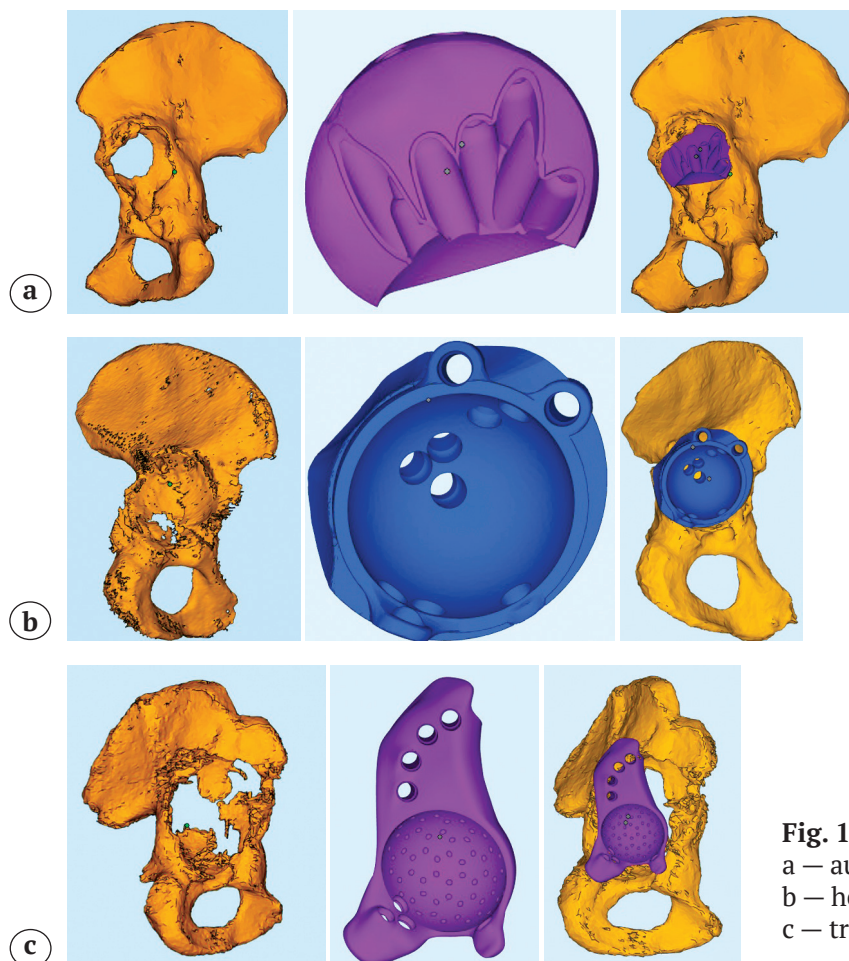
The individual hemispherical cups were used in situations of limited contact with a viable underlying bone, which need reliable screw fixation or, if it is necessary, the installation of acetabular components with dual mobility. The three-flange individual constructions were used in the conditions of the most severe bone defects, which need an expanded zone of contact between the implant and the remaining bone (Fig. 1).

### *Surgical techniques*

To perform the reconstruction of the acetabulum in 16 cases, approach was provided with an expanded trochanteric osteotomy of the femur to remove a well-fixed femoral component, external lateral approach

was used in 38 cases, posterior in 9 cases, and combined anteroposterior approach to the hip joint. Bone grafting with allogeneic crumbling was performed in all patients with limited acetabular defects. During the reconstruction of the acetabulum for exact intraoperative navigation used the patient-specific aids: test modular or monoblock implants, drill guides and three-dimensional anatomical plastic model of the half of the pelvis.

The stages of the operation included the treatment of the acetabulum with the removal of foreign bodies and scar tissue to the bleeding bone, followed by implantation of the IC and its fixation with screws. If it was necessary, bone alloplasty was used with crushed grafts.



**Fig. 1.** Options of custom-made implants:  
a – augment;  
b – hemispherical component;  
c – triflange component

At the final stage, a standard polyethylene liner or a cement fixation polyethylene cup, or, if necessary, a cemented cup with dual mobility technology, was installed with using bone cement.

### Study outcomes

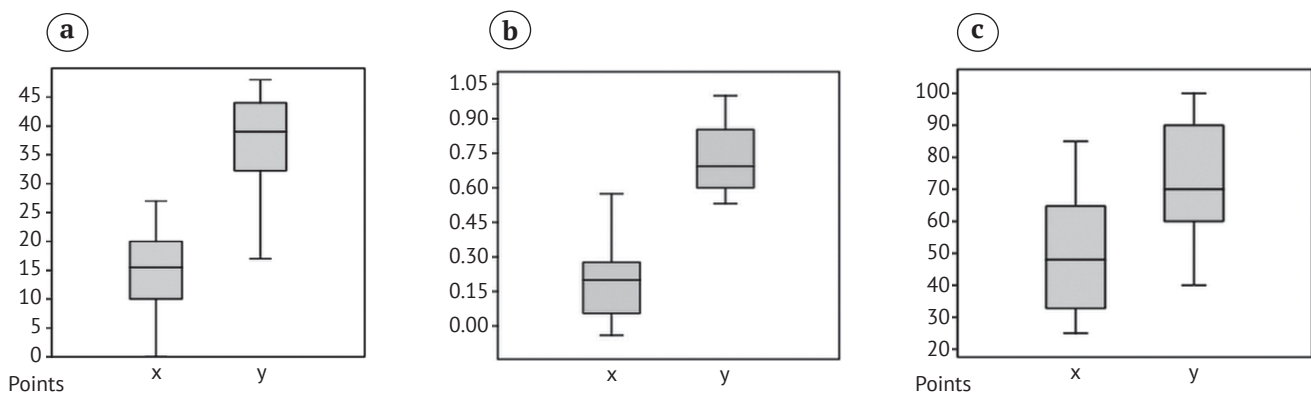
In the pre- and postoperative periods, the functional hip joint scores, Oxford Hip Score (OHS) [21], quality of life EQ-5D [22], visual analogue scales of general health and pain were used [23]. Postoperative radiographs assessed the presence of osseointegration using the criteria of Moore et al [24]: 1) the lack of radiolucent lines; 2) the presence in the upper lateral region of contact of a cortical or dense cancellous bone; 3) bone hypertrophy in the medial area of contact (medial stress-shielding); 4) the radial bone trabeculae directed perpendicular to the surface of the acetabular component; 5) the presence in the intermedial area of contact of a cortical or dense cancellous bone.

### Statistical analysis

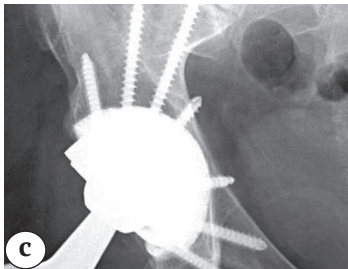
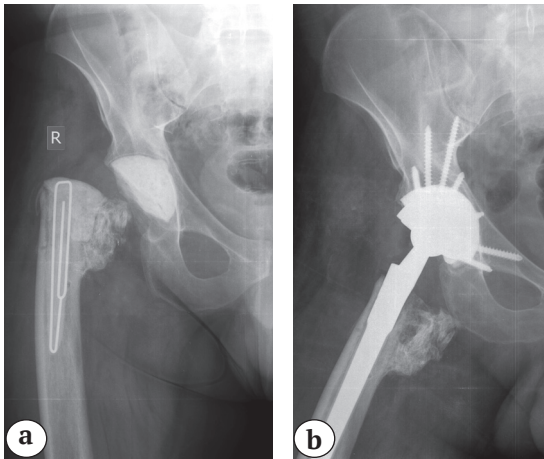
For the statistical processing, the non-parametric Wilcoxon test was used. The calculations were performed using the software package Past 3.14.

## Results

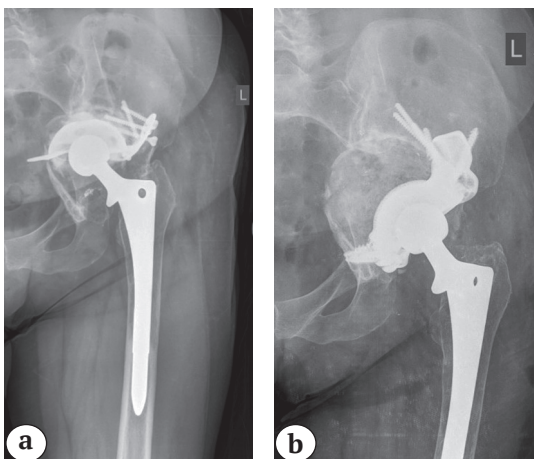
The average value on the OHS scale improved from 14.9 ( $\pm 7$ ) points before surgery to 37.6 ( $\pm 7$ ) points ( $p < 0.01$ ) after surgery (Fig. 2 a). The EQ-5D Quality of Life Index rose from 0.2 ( $\pm 0.2$ ) before surgery to 0.7 ( $\pm 0.2$ ) after it was performed ( $p < 0.01$ ) (Fig. 2 b). The average score on the general health scale was 49 ( $\pm 17$ ) points before and 73 ( $\pm 18$ ) points after ( $p < 0.01$ ) surgery (Fig. 2 c). The average severity of pain according to VAS decreased from 73 ( $\pm 10$ ) to 19 ( $\pm 19$ ) points after operations ( $p < 0.01$ ). The IC osseointegration according to M.S. criteria Moore et al. was observed in 98% (49/50) cases; in one case, structural migration was observed, which led to a fracture of the flange. The signs of osseointegration are most clearly manifested after implantation of individual hemispherical components (Fig. 3). In a series of 75 implantations, it is reliably known about sciatic nerve neuropathy in one patient, 2 cases of dislocations, 3 cases of infections and one fracture of the structure (Fig. 4), in which revision was not performed. All patients in whom infectious complications were observed after implantation of individual structures had a history of periprosthetic infections.



**Fig. 2.** Evaluation of functional status and life quality in patients prior to and after the surgery: a – hip function according to the OHS; b – Quality of Life Index EQ-5D; c – General Health Scale; x – before surgery; y – after surgery



**Fig. 3.** X-rays of male patient, 37 y.o.:  
 a – prior to revision: mild destruction of the acetabulum, significant defect in the proximal femur with loss of attachment site of the abductors;  
 b – postop: custom-made hemispherical cup with individual screw positions and a dual mobility system were used due to the high risk of dislocation;  
 c – 2 years after revision: no radiolucent lines around the acetabular component indicating osteointegration of the porous cup coating with the underlying bone



**Fig. 4.** X-rays of female patient, 66 y.o.:  
 a – prior to revision: aseptic instability of the acetabular component, contained acetabular defect;  
 b – postop: hip reconstruction with allogeneic bone chips and a custom-made triflange implant;  
 c – 2 years after revision: resorption of allogeneic bone, fracture of the sciatic flange

## Discussion

Using the individual acetabular components is not revolutionary. The first operations were carried out in the early 1990s, but this technology became widespread with the development and increase in the availability of 3D printing method from metal powders. In our country, the first operation with using an individual design was performed only in 2015 [25]. But thanks to state support, the widespread and increased availability of additive production in Russia has led to the fact that at the moment the number of implants of individual structures is estimated at dozens in large centers of endoprosthetics [26, 27]. However, given the increased complexity of operations and the lack of a clearly defined philosophy of using personalized implants for revision, many aspects of the using the individual constructions require study and careful observation. There are remain open questions of the necessary and sufficient contact area of the individual implant with the bone to achieve osseointegration, the minimum required number of additional fixing elements for reliable fixation, the possibility or necessity of using bone alloplasty.

In our practice, we used several options for individual constructions for revision reconstruction of the acetabulum. Using the individual augments, as well as individual hemispherical cups is not widely covered in the world literature [28]. But these types of constructions, in our opinion, have several advantages over serial augments, as well as hemispherical cups with a large number of holes: a more exact match to the size of the defect does not require excessive removal of intact bone, and screw holes are oriented to areas of the most durable bone. This allows us to ensure reliable primary fixation and create conditions for further osseointegration of IC. In turn, three-flange structures have the greatest potential in terms of increasing the area of contact with healthy bone and ensuring reliable fixation in the

most difficult situations (defects of type 3B according to Paprosky and pelvis discontinuity). If it is necessary, the size of the flange can be increased, and additional support on the sacral mass of the ilium is obtained using special fixing elements such as “ice cream cone” [29, 30].

According to the literature, the using of individual three-flange acetabular components and designs of the «ice cream cone» type is accompanied by a higher level of complications and unsatisfactory results. This is probably due, first of all, to the use of such implants in the most complex cases of revision of the acetabular component [14, 15, 16, 31]. But there is another problem — the violation of the positioning of individual structures [32, 33], which can potentially limit the area of contact with the bone. However, in our research with an average follow-up of 20.5 months 98% of patients on radiographs showed signs of stable fixation at the border of the bone and porous coating made by three-dimensional printing. This has sufficient clinical evidence — the average value on the OHS scale increased from 14.9 ( $\pm 7$ ) to 37.6 ( $\pm 7$ ) points, the quality of life index EQ-5D also increased from 0.2 ( $\pm 0.2$ ) to 0.7 ( $\pm 0.2$ ), the average value on the general health scale was: before surgery 49 ( $\pm 17$ ) points and 73 ( $\pm 18$ ) points after, and the average value according to the visual analogue pain scale decreased from 73 ( $\pm 10$ ) up to 19 ( $\pm 19$ ) points.

So that, the using the individual designs for revision endoprosthetics provides a significant improvement in the function and quality of life of patients. The ability to provide reliable primary stabilization of an individual implant under the most complex acetabular defects and the ability to secondary biological fixation with a preserved bone bed open up additional prospects for use in revision surgery. However, the complex geometry and solidity of such endoprostheses makes it difficult to position them during surgery, which can lead to

an incorrect IC setting, the wrong position frequency reaches from 44% to 75% [34], which can affect the its long-term effectiveness. Perhaps the further development of computer navigation will improve intra-operative visualization and the quality of IC positioning.

A sufficient frequency of infectious complications (4%) is associated with the initial heaviness of the condition of patients with a large number of risk factors and a history of infection.

Of the other problems in our research, we encountered only with dislocations and a fracture of the flange. Unfortunately, even the optimal anteversion and tilt of the acetabular component, planned on the basis of 3D visualization of the pelvis, do not prevent dislocations associated with muscle failure, disturbed spine-pelvis relationships and impingement of the components of the endoprosthesis.

The fracture of the flange was not associated with a defect in the production or design of the implant — as we know, the implant in the body is subjected to enormous loads, which even massive cobalt-chromium alloy implants sometimes cannot withstand. The problem of a flange fracture lies in the plane of biomechanics, which has not yet been sufficiently studied with respect to individual acetabular components. A patient with a structural fracture in our series had a limited defect in the acetabulum region, during the reconstruction of which allogeneic bone crumb plastic was used. The probable cause of the destruction, in our opinion, was the resorption of a plastic material. Perhaps it under cyclic loading led to the destruction of the flange.

A serious question also remains the replacement of a bone defect with a massive metal implant, which may lead to further destruction of the bone. So the future research should be aimed at finding ways to restore the bone base in terms of using individual implants.

### Publication ethics

The research has the approval of the local ethics committee; all patients signed a voluntary informed consent to participate in the research.

*Competing interests:* the authors declare that there are no competing interests.

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### Authors' contribution

*A.N. Kovalenko* — concept and design of the study, interpretation and analysis of the data, editing.

*A.A. Javadov* — collection and processing of material, research, statistical processing of the data, preparation of the text.

*I.I. Shubnyakov* — coordination of research participants, interpretation and analysis of the data, statistical processing, editing.

*S.S. Bilyk* — analysis and interpretation of the data, editing.

*A.O. Denisov* — analysis and interpretation of the data, editing.

*M.A. Cherkasov* — collection and processing of material, preparation of text.

*A.I. Midaev* — collection and processing of material, preparation of text.

*R.M. Tikhilov* — writing concept and design of the study, interpretation and analysis of the data, editing.

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