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Hip Arthroplasty in Patients with Hip Dysplasia by Individual Augments: Early Results

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Abstract

Background. The altered hip anatomy makes total hip arthroplasty in patients with hip dysplasia a difficult and non-standard task. The acetabulum is deformed with femoral head in subluxation or dislocation. The most important task of surgery is to restore the anatomical position of the hip center of rotation. ***The study purpose*** — to evaluate the early results of hip arthroplasty with individual augments in the patients with hip dysplasia. ***Materials and Methods.*** Since 2017, nine patients with hip dysplasia have undergone surgery using individually printed augments. All patients were women with average age 51.3±14.5 years (23 to 67). The mean follow-up was 14.3±5.2 months (8 to 20). Patients were evaluated using follow-up X-rays, a visual analogue scale (VAS), Harris Hip Score (HHS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC). ***Results.*** There was no a single case of endoprosthesis dislocation, loosening of components, prosthetic infection or revision surgery in the analyzed group of patients. The planned sizes of the acetabular components were equal to the placed in 7 cases (77.8%). In two cases (22.2%), the acetabular components were 2 mm larger because the surgeon wanted a greater degree of press-fit fixation. The restoration of the anatomical position of the acetabular component was noted. Before the surgery, the femoral head was on average 22.7±11.7 mm (10 to 43 mm) higher. After the surgery, the level of the acetabular component was on average only 0.75±2.1 mm (1.7 to 5 mm), $p = 0.008$. Also, there were a decrease in pain and quality of life improvement by VAS from 6.78±1.39 before surgery to 2.22±1.09 at follow-up ($p = 0.007$), HHS increase from 30.5±18. 1 to 77.59±14.26 ($p = 0.008$), and WOMAC decrease from 73.3±14.1 to 18.22±8.2 ($p = 0.008$). ***Conclusion.*** The individually printed augments have shown high efficacy for restoration of the anatomical center of rotation and good early results in the patients with hip dysplasia undergone hip arthroplasty.

Keywords: hip dysplasia, total hip arthroplasty, individual augments, 3D printing.

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Introduction

Hip dysplasia is a common disease. Approximately one out of 1,000 children is born with a hip dislocation, and 10 out of 1,000 are diagnosed with subluxation [1, 2]. Hip dysplasia of varying severity is diagnosed in more than a third of patients with coxarthrosis [3]. The altered anatomy of the hip makes total arthroplasty in dysplastic hip osteoarthritis a difficult and non-standard task [4, 5]. Some authors note a change in the proximal femur anatomy, namely a narrowing of the intramedullary canal and an increased femoral neck anteversion [6, 7, 8]. To restore normal joint kinematics, the extramedullary part of the femoral component should not only correct the increased neck anteversion, but also its offset [9, 10]. Besides, in a high hip dislocation, there exist difficulties associated with thigh descent, which may require an osteotomy.

No less difficult arthroplasty is associated with a change in the acetabular anatomy. The femoral head is subluxated or dislocated, the true acetabulum is flattened, filled with scar tissue, and formed by bone never experienced stress. The location of the acetabular component in the anatomical position leads to the supporting bone deficiency, more often in the anterior lateral section. One of the solutions is a higher placement of the acetabular component. This ensures its more complete bone coating and does not require the use of plastic materials. However, this may lead to a difference in the length of the lower extremities and an increase in the frequency of early loosening of the acetabular component [11, 12, 13, 14]. The acetabular component position and center of rotation in in dysplasia often requires bone grafting of the anterior lateral defect [14, 15, 16, 17]. But there are publications indicating the resorption of both allo- and autologous bone grafts [18, 19]. Delimar et al. note that allografts are resorbed twice as often as autografts [20].

An effective method for acetabular defects reconstruction in dysplasia is the application of trabecular metal augments [21, 22]. These materials, unlike bone, are resistant to lysis and show good results with respect to osseointegration, strength and biocompatibility [5, 23, 24, 25, 26].

In our opinion, one of the main disadvantages of augments available on the market is their discrete, standardized sizes. In dysplasia, the true acetabulum often has very small dimensions and a small defect. The latter, however, compromises the stability of the hemispherical acetabular component. In addition, the implantation of a standard augment often requires excessive bone resection. This explains the search for other solutions in hip dysplasia arthroplasty.

Customized metal implants become increasingly common in traumatology and orthopedics [27, 28, 29, 30]. One of the key areas of these technologies development is acetabular defects reconstruction [31, 32, 33, 34, 35].

The purpose of this study was to evaluate the early outcomes of hip arthroplasty using custom-made augments for acetabular defects replacement in the patients with hip dysplasia.

Materials and Methods

Patients

Nine female patients with hip dysplasia have undergone hip arthroplasty using 3D printed augments since 2017. Their average age was 51.3±14.5 years (23 to 67 years). All of them were available for follow-up. The mean follow-up was 14.3±5.2 months (from 8 to 20 months). The study was approved by the local ethics committee. According to the Crowe classification, which is based on the assessment of the femoral head cranial displacement level [7], the patients were distributed as follows: Crowe II — 3 patients, Crowe III — 6 patients. In 5 patients, the arthroplasty was indicated only on one side. In 4 patients (44.4%), the surgery was planned at the contralateral side as well.

Two patients (22.2%) had a history of corrective femur osteotomy. Although, by the time the arthroplasty all metal structures were already removed. According to the anamnesis and available medical records, no one had any previous acetabular surgery.

Outcomes assessment

To assess the treatment outcomes, X-rays dynamics was analyzed. The patients were also evaluated with a visual analogue pain scale (VAS), Harris Hip Score (HHS), and the Western Ontario and McMaster Universities Arthritis Index (WOMAC).

The technology of manufacturing an custom-made implant

All the patients underwent computed tomography (CT) of the pelvis, hip, and upper third femur on the same Toshiba Aquilion ONE with a pitch of 0.5 mm. It was important that a short period of time was between the CT and the surgery. In our work, it was no more than 1 month. The obtained CT data in the DICOM standard (Digital Imaging and Communications in Medicine) were processed using the Materialize Mimics 21.0 software (3D Medical Image Processing Software). Then a digital 3D pelvic model was made, based on which, we printed the undergoing surgery half of the pelvis. The Crowe degree of hip dysplasia was determined using X-ray, CT, pelvis digital and plastic models data.

In the pelvis digital model, the hemisphere was placed in the acetabulum so that its lower point was located at the level of the lower point of the "teardrop figure" with the anteversion angle of 15–20°, the abduction angle of 45°, and the diameter maximally contacting the acetabular bone, assuming that the latter was processed sufficiently, although not excessively. The bone thickness in the contact areas with the acetabulum should not be less than 3 to 5 mm (Fig. 1).

If the contralateral hip was intact, the center of the hemisphere was placed at the level of the normal femoral head center. Then the extra marginal bone growths were removed. The size and shape of the upper defect, which had to be filled for complete coverage of the acetabular component, were evaluated. Any existing small irregularities were smoothed out. The required augment was planned according to the shape of the defect. Two-three holes in the augment were provided for inserting standard 6.5 mm spongy screws into the bone. Their directions were set taking into account the longest screws. It also meant that the screws should not interfere with each other and the acetabular component. If the augment was small for 6.5 mm screws driving through it, an additional pad was planned to fix it to the ilium body (Fig. 2).

The surface of the augment contacting with the soft tissues was smooth, with the bone and acetabular component — porous. The cell shape of the porous structure was the dodecahedron. The cell size was 1.8×1.8×1.8 mm, the diameter of the cell

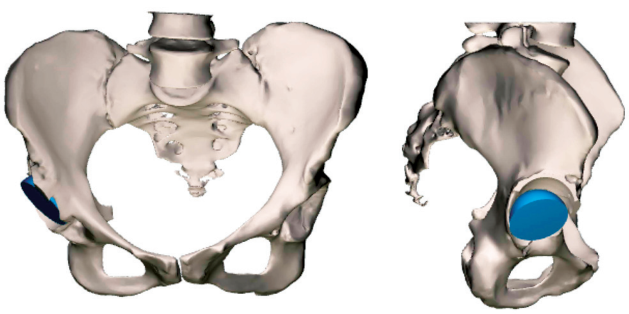

Fig. 1. A hemisphere with a diameter of 44 mm and angles of anteversion 15° and abduction 45°. Hip rotation center in anatomical position.

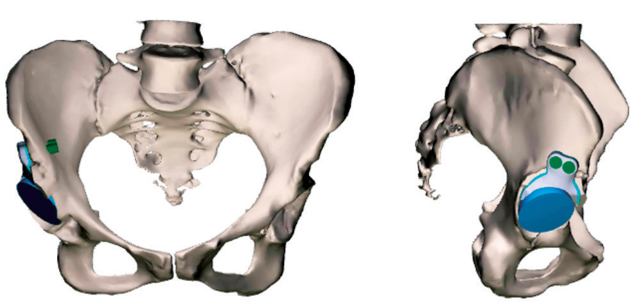

Fig. 2. Planning of individual augment (in gray) and screws (in green).

edge of the porous structure — 0.45 mm, the minimum thickness of the porous structure — 2 mm. After the final agreement, a sample polylactide augment was printed. Polylactide is biodegradable, thermoplastic, aliphatic polyester, the monomer of which is lactic acid. Annually renewable resources, such as corn and sugarcane, serve as raw materials for polylactide production.

The definitive augment was made by 3D printing on a Concept Laser M2 Cusing printer (Concept Laser, Germany) from Ti-6-Al-4V titanium alloy powder, certified for the manufacture of medical implants.

Planning and 3D printing were carried out jointly with the specialists of Endoprint (Moscow, Russia). The time from the date of CT to the finished product did not exceed 10 days. The implant was sterilized by autoclaving.

Surgical technique

After standard preoperative preparation, the hip was accessed by anterolateral Watson-Jones approach. The hip dislocation was performed anteriorly. The femoral neck was resected at the planned level. The acetabulum was exposed using retractors. Bone growths were resected according to the 3D model preoperative planning. The acetabulum was rimmed at the level of the anatomical center of rotation without exceeding its height (Fig. 3).

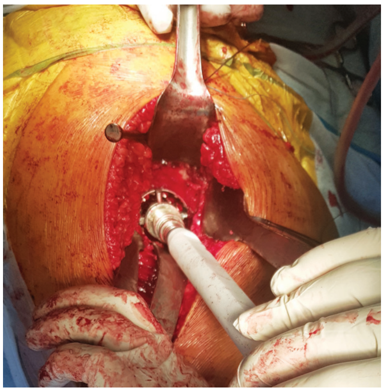

Fig. 3. The treatment of acetabulum with a rimmer keeping the anatomical center of rotation without exceeding its height.

The diameter of the last rimmer corresponded to the diameter of the planned acetabular component. Using a small-sized acetabular rimmer (36–38 mm), the augment bed was treated. Small irregularities were removed. All of these were also planned using digital and real 3D models. The next step was the sample acetabular component placement. Or the acetabular rimmer was left, and the fitting of the plastic augment was carried out. If required, the bone was finalized with trimmers or nippers until the augment fit perfectly. Then augment was implanted with achieving press-fit fixation using the porous part and fixed with screws of the planned length in a given direction (Fig. 4).

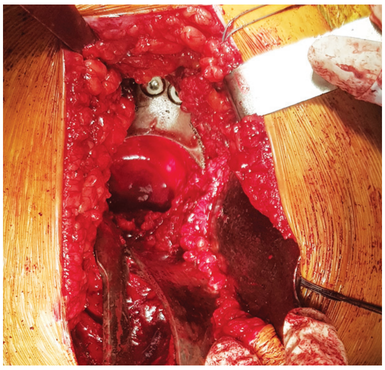

Fig. 4. The augment, placed in the upper anterior part of the acetabulum, was fixed with two 6.5 mm screws.

The edge of the augment, contacted with the acetabular component, was treated with a small amount of bone cement. After that, the acetabular component was placed and fixed with one to three 6.5 mm screws. In all cases, the acetabular components “Continuum” were used. These constructions are coated with trabecular tantalum (ZimmerBiomet, USA) and used with a polyethylene liner. The femoral component Wagner Cone (ZimmerBiomet, USA) was placed by standard method. The implant reduction was performed after selecting the required head lenth (Fig. 5).

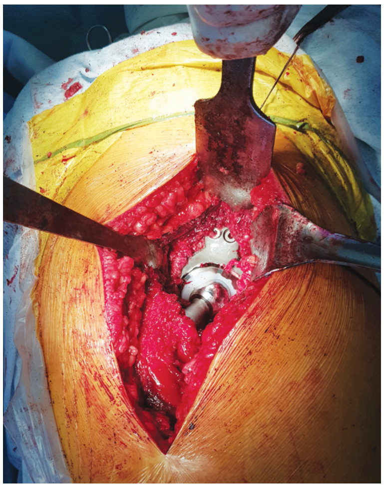

Fig. 5. A hip endoprosthesis with an individual augment was placed. A thin layer of bone cement is visible between the augment and the component.

After endoprosthesis placement, the wound was repeatedly washed with a pulse-lavage system and sutured tightly, leaving drainage. The postoperative X-ray showed that the center of the femoral head rotation was restored respectively to the healthy side (Fig. 6).

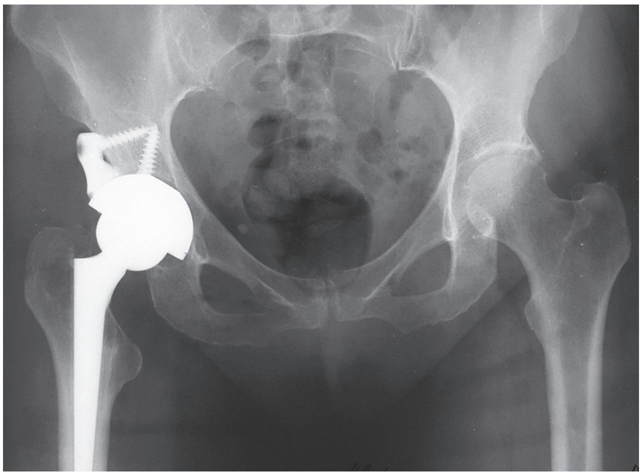

Fig. 6. X-ray of a female patient with hip dysplasia after the surgery. Using an individually printed augment, the restoration of the anatomical center of rotation, the length of the lower limb, and the complete coverage of the acetabular component was achieved.

Cranial displacement of the femoral head before surgery was determined as follows. On a digital X-ray or CT, a line was drawn through the lower points of the “tear shapes”. A parallel line was drawn through the lower point of the femoral head not considering ossifications. The distance between these two lines, the perpendicular, established the vertical position of the femoral head (Fig. 7).

The position of the acetabular component in the X-rays was also determined relative to the line passing through the lower points of the “teardrop figure”. In parallel, a line was drawn through the lower point of the acetabular component. The distance between the two lines indicated the level of the acetabular component. The ruler was calibrated using the known diameter of the acetabular component (Fig. 8).

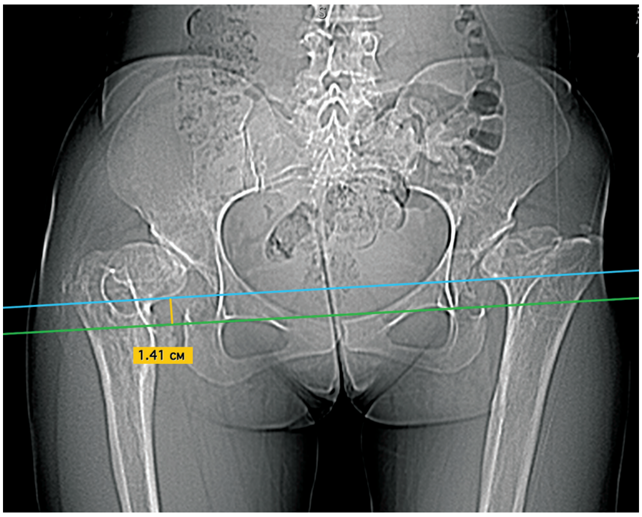

Fig. 7. The vertical position of the femoral head determination: in green — the line drawn through the lower points of the “tear shapes”; in blue — a line drawn through the lower point of the femoral head; in yellow — the distance between these lines.

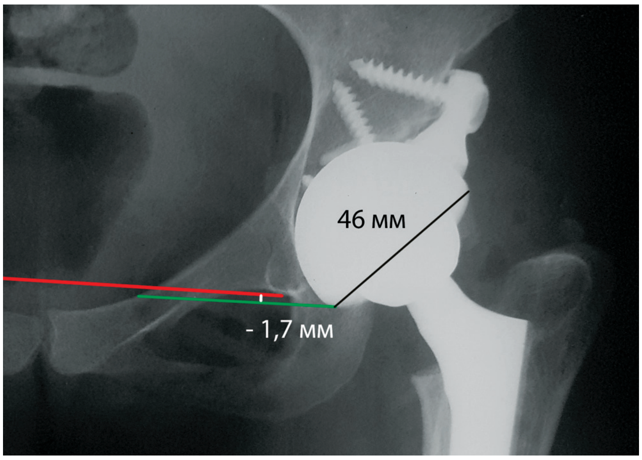

Fig. 8. The position of the acetabular component determination: in red — the line drawn through the lower points of the “tear shapes”; in green — a line drawn through the lower point of the femoral head. The distance between these two lines indicates the level of the acetabular component.

Statistical analysis

Statistical analysis was performed using Microsoft Excel for Mac (ver. 16.26) and IBM SPSS Statistics Subscription (ver. 1.0.0.1347). The average values of quantitative indicators (age, scores on rating scales) and standard deviations were assessed. The nonparametric Wilcoxon T-test was used to compare the position of the femoral head and the acetabular component before and after surgery, as well as for evaluation patients’ VAS, HHS and WOMAC scales before and after surgery. The *p* criterion of less than 0.05 was considered statistically significant.

Results

We did not have a single case of endoprosthesis dislocation, loosening of endoprosthesis components, prosthetic joint infection, or revision hip arthroplasty. The use of a preplanned augment made it possible to save the operative time spent on standard augment selection and to minimize the time needed to prepare the bone bed “for augment”. The planned sizes of the acetabular components were equal to those placed in 7 cases (77.8%) and in 2 cases (22.2%) it was 2 mm more. The cranial displacement of the femoral head before surgery averaged 22.7±11.7 mm (10 to 43 mm). The displacement of the acetabular component relative to the tear figure after surgery was 0.75±2.1 mm, from 1.7 to 5 mm ($p = 0.008$). The results of the assessment by the scales are presented in the Table.

Discussion

The 3D printing technology and the 3D technology and custom-made implants increasingly develop in traumatology and orthopedics. This is also true for Russia and confirmed by domestic publications [30, 36]. However, as with the introduction of any other technology in medicine, care must be taken, given that we place these implants directly into the human body. The Association of 3D Printing Specialists in Medicine, organized in 2016, combines the experience of leading Russian specialists performing surgery us-

Table

Functional results by scales VAS, HHS and WOMAC before and after surgery

Scale	Before surgery			Follow-up after surgery			*P*
	Mean	Min	Max	Mean	Min	Max	
VAS	6.78±1.39	5	9	2.22±1.09	1	4	0.007
HHS	30.5±18.1	8.38	57.55	77.59±14.26	51.4	97.6	0.008
WOMAC	73.3±14.1	54	92	18.22±8.2	10	31	0.008

ing such implants. Perhaps, the integration of their efforts will facilitate the introduction of individual implants into practice.

Deformed acetabulum in hip dysplasia makes it difficult to implant a hemispherical acetabular component. Cranial displacement of the rotation center, the use of auto- or allografts does not always show optimal results [11, 12, 13, 14, 15, 16, 17, 18, 19, 20]. C.D. Watts et al., in their over 35 years analysis of the hip arthroplasties outcomes in the patients with Crowe type II dysplasia, revealed longer survival of both the acetabular and femoral components in the case of restoration of the anatomical rotation center [12]. D. Delimar et al. in their follow-up for 10 years showed a high rate of acetabular components instability when the upper lateral defect was replaced with structural bone grafts [20].

In our study, the use of individual augments for acetabulum defects replacement showed promising early results. In no case did we have any difficulty in such structures placement. On the contrary, advantages were noted in comparison with the standard augments. No additional time was required for augment selection and excessive resection of the bone for implantation. The line of standard augments of one company implies the presence of at least 20 positions at the same time, which creates difficulties. When used correctly, 3D technologies (high-resolution CT, software for image cleaning and processing, competent interaction between the surgeon and the engineer) show high accuracy. In 7 cases out of 9, the acetabular components diameter was completely to the planned one, in 2 cases it turned out to be 2 mm larger, which is due to the surgeon's desire to achieve more stable press-fit fixation. Perhaps, the weakest point of such technologies is the transfer of computer planning to operating room and accurate reproduction of what was planned. It is possible, that this was happened in a case of the acetabular component cranial displacement by 5 mm. The surgeon first began to process the acetabulum somewhat higher. This resulted in additional bone resection for the individual augment. Probably, one of the promising tasks of the clinical implementation of individual implants will be the solution of precisely the mentioned above issues, in which robot-assisted surgery can help [37]. The properties of 3D printed materials remain debatable in comparison with the materials produced by conventional methods. D. Mah et al. showed that Ti-6-Al-4V 3D-printed material had lower corrosion resistance compared with forged Ti-6-Al-4V alloy [38]. K. Karolewska et al. did a comparative analysis of the Ti-6-Al-4V alloy made using SLM technology with the Ti-6-Al-4V alloy made by metallurgical methods and concluded that the SLM alloy had higher values strength (1360 MPa versus 1255.7 MPa) [39]. This was confirmed by M. Shunmugavel et al. [40].

In our series, we combined the tantalum surface of a standard acetabular component with a titanium alloy augment. T.-X. Ling et al. presented good results with the opposite combination: augment from porous tantalum and a cup with an acetabular component from titanium alloy [21]. These materials do not react between themselves in vitro and in vivo, which makes such combinations possible and safe. The results of using custom-made augments for dysplasia are comparable to the results of applying augments from trabecular tantalum. T.-X. Ling et al. analyzed the outcomes of using tantalum augments for primary hip arthroplasty in 19 patients, with 9 patients with dysplastic hip osteoarhritis among them. They did not reveal a single case of endoprosthesis dislocation or PJI with an average follow-up of 5.1 years [21].

The study limitations. So far, the surgery has been performed on a small number of patients with short follow-up. In addition, the patients' follow-up extremums had a wide range of values, from 8 to 20 months.

That is why, it is too early to make any definite conclusions concerning the prospects of using individual augments. The accumulation of experience in making and placing of such type of individual components will definitely help us in specifying indications for these systems. Nevertheless, in our series, the individually printed augments were effective in restoring the anatomical center of rotation after hip arthroplasty in the patients with hip dysplasia, demonstrating good early results.

Publication Ethics

All the patient gave an informed consent for participation in this clinical study.

Conflict of interest: The authors declare no conflict of interest.

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Authors' contribution

Ya.A. Rukin — research design, data collection, research conduction, editing.

A.V. Lychagin — research conduction, literature data analysis, editing.

V.Yu. Murylev — research design, editing.

A.V. Garkavi — text preparation.

D.A. Tarasov — research conduction.

M.P. Elizarov — research conduction, data analysis, data statistical processing, text preparation.

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