The potential for 3D technology to be used in the first-stage periprosthetic hip joint infection treatment

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Research article

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Abstract

Background. In two-stage deep periprosthetic infection treatment, many authors describe mechanical complications associated with the implantation of a spacer in the first stage that affect the functional outcome of the treatment.

Purpose. To evaluate the functional results of using 3D spacers for IIIA and IIIB defects according to the classification system described by W.G. Paprosky during the first stage treatment of hip deep periprosthetic joint infection (PJI).

Methods. From 2017 to 2020, 24 patients underwent first-stage revision arthroplasty with hip PJI and IIIA and IIIB acetabular bone defects according to the classification system described by W.G. Paprosky. The patients were divided into 2 groups: group 1 received articulating spacers, and group 2 received custom-made spacers made using 3D technology. Function was evaluated by the Harris Hip Score, WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) and VAS (visual analogue scale). Statistical analyses were performed using IBM SPSS Statistics version 22.0 for Windows. Student's t-test, Wilcoxon's signed-rank test (to compare parameters before and after surgery) and the Mann-Whitney rank-sum test were used.

Results. In the first group, the average VAS score was 3.3 (± 1.4), the Harris Hip Score was 51.3 (± 9.4), and the WOMAC score was 42.9 (± 5.9); in the second group, the VAS score was 1.3 (± 0.9), the Harris Hip Score was 69.7 (± 3.6), and the WOMAC score was 30.1 (± 2.4). The rating scale data showed a statistically significant improvement in the function of patients in the second group ($p < 0.05$).

Conclusion. Custom-made 3D spacers used during the first stage of treatment for deep periprosthetic hip infection yield larger improvements in function and quality of life than do articulating spacers.

Trial registration. Local Ethics Committee at the Sechenov First Moscow State Medical University Ministry of Health of Russia (Sechenov University) № 386 13.12.2016.

Background

Arthroplasty of the hip joint is a surgical intervention performed fairly commonly for various pathologies of the hip joint, after which patients demonstrate excellent functional results [1,2,3]. Every year, the number of times this surgical intervention is performed increases markedly [4,5]. As a result, as the volume of primary hip arthroplasties performed increases, the number of complications, including deep periprosthetic infection, which is the most severe complication, increases [3,6,7]. Periprosthetic infection is a catastrophic complication that can cause severe problems after arthroplasty, such as the development of systemic inflammation, sepsis, renal amyloidosis, chronic osteomyelitis, degenerative changes in parenchymal organs, the appearance of septicopyemic foci or even death [8,9,10]. It should be noted that according to the Russian Scientific Research Institute of Traumatology and Orthopedics and data from R.R. Vreden, the main reason for revision is periprosthetic infection (44.7%) [Shubnyakov I.I., 2019]. In the Australian register for the 2018, PJI is ranked 4th (18.1%) among the most common causes of revision surgery [11]. Periprosthetic infection is considered the leading cause of failure in the first two years after implantation according to a report on the Swedish Register of Arthroplasty [12]. Currently, two-stage revision remains the preferred method of treatment for deep periprosthetic hip infection [13]. A treatment success rate of 90% for two-stage surgery for periprosthetic infection was reported in previous studies [9,14]. Particular attention should be paid to patients with severe infection and bone loss who have developed II C, IIIA and IIIB acetabular defects according to the classification system described by W.G. Paprosky, including those in whom the integrity of the pelvic ring has been compromised.

Purpose of the investigation: To evaluate the functional results of using 3D spacers for IIIA and IIIB defects according to the classification system described by W.G. Paprosky during the first stage of treatment for late-onset deep periprosthetic hip infection.

Methods

From 2017 to 2020, in the Moscow city arthroplasty centre in the S.P. Botkin City Clinical Hospital, 24 patients underwent two-stage revision hip arthroplasty for deep periprosthetic infection with IIIA and IIIB acetabular bone defects according to the classification system described by W.G. Paprosky [15]. The average period from the last hip joint surgery to the development of deep periprosthetic infection was 163.8 weeks (range 9 to 832 weeks). Type II infection according to the method described by M.B. Coventry and D.T. Tsukayama [16] was detected in our study in 12 patients (50%), and type III was detected in 12 patients (50%). In the entire patient cohort, 13 women (54.2%) and 11 men (45.8%) were included. The average age of the patients was 60.5 years (interquartile range from 52 to 69 years). Seven (29.2%) patients had IIIA acetabular bone defects, and 17 (70.8%) had IIIB defects according to the classification system described by W.G. Paprosky. All patients underwent a detailed examination of their clinical and medical history; survey radiography scans of the pelvis, with the damaged hip joint in two projections and the lumbar spine in two projections; and pelvis CT (computed tomography) scans with a slice thickness of 1 mm. Before the first and second stages of revision surgery were performed, the severity of pain, joint function and quality of life were assessed using the Harris Hip Score, WOMAC and VAS. The X-ray and CT data were used to assess the bone defects of the acetabulum. All patients confirmed to have periprosthetic infection underwent two-stage treatment. We divided all patients into two groups (Table 1): group 1 included patients who underwent surgery with articulating spacers without using 3D technology, and group 2 included patients who underwent surgery with spacers individually manufactured using 3D technology. We did not find significant differences in age, body mass index (BMI), or the execution time of the second stage of revision between groups.

Table 1. Defects by patient group.

Group Defects	Group 1 Without the use 3D technology n=12	Group 2 With the use of 3D technology n=12	Total n=24
IIIA defects	6 (50%)	1 (8.3%)	7 (29.2%)
IIIB defects	6 (50%)	11 (91,7%)	17 (70.8%)
Dissociation of the pelvic bones	2	4	6

It should be noted that in 25% of patients, there was dissociation of the pelvic bones. Among the group 1 patients who underwent surgery without the use of 3D technology, 50% had IIIA and IIIB defects, as there were 6 cases of each type of defect. In group 2, in which the surgery was performed using 3D technology, 91.7% of cases presented with IIIB defects. In group 2, pelvic discontinuity was observed in 33.3% of cases, while in group 1, the rate was only 16.6%. To assess the extent of bone deficits in the acetabular region, all patients underwent CT scans with a slice thickness of no more than 1 mm. Then, the CT scans of the patients planning to undergo surgery with a 3D spacer were sent to an engineer, who created a 3D model of the pelvis defect and model fitting spacer components using PME Planner software (Fig. 1,2,3).

It should be noted that to stabilize the joint, we aimed to use femoral components with large-diameter spacer heads measuring 32 mm, 36 mm, and 40 mm. Additionally, the position of the centre of rotation of the contralateral hip was taken into account in the X-ray of the pelvis. Then, the 3D model was printed. The spacer models were filled with special medical silicone, and a personalized mould was formed for casting the spacer in the operating room. During the formation of the acetabulum, metal rods were additionally applied, which allowed the bone screws to be inserted in the appropriate direction according to the preoperative plans (Fig. 4). On the inner surface of the acetabular component, an additional recess was created under bonnet spongy bone screws with a diameter of 6.5 mm and a depth of not more than 0.2 mm.

Next, the silicone 3D moulds were sterilized and sent to the operating room. After removal of the endoprosthesis component and acetabular processing area according to the preoperative 3D plans, the 3D model was fit in the surgical wound, and its congruency and stability were evaluated. It should be noted that the designers, when creating the model, considered the presence of bone tissue only. However, during placement of the 3D model, soft tissues are often involved; therefore, it is necessary to carefully prepare the site for accurate implantation according to the preoperative plans. Furthermore, the prepared sterile silicone 3D mould was filled with bone cement and antibiotics (Fig. 5).

Statistical analysis was performed using IBM SPSS Statistics Base 22.0 for Windows. Student's t-test was used to analyse the data with a normal distribution, and to assess normality, the Kolmogorov-Smirnov test was used. For nonnormally distributed data, Wilcoxon's signed-rank test (comparison of the parameters before and after surgery) and Manny-Whitney rank-sum test (comparative analysis of groups

1 and 2) were used for comparative analysis of the quantitative indicators of the study. For categorical variables, the relative (%) and absolute frequencies were used. The continuous variables with normal distributions are presented as the M ± SD, where M is the sample mean and SD is the standard deviation. Differences with $p < 0.05$ were considered statistically significant.

Results

Pain and function were assessed in patients with rating scales (Table 2). The overall average score before the first stage was performed was naturally unsatisfactory in both groups. We noted a significant difference in the scores before the second stage of revision was performed.

Table 2. Characteristics of the patients in whom spacers were installed.

Indicators	**Group 1 Without using 3D technology, n=12**		**Group 2 Using 3D technology n=12**		**p test**
Average age, years	59 ±6,9		63 ± 2,8		p<0,05
BMI	29,3 ±2,1		28,9 ±4,3		p<0,05
Time until the second stage, weeks	44 ±9,1		39 ±6,2		p<0,05
Mechanical complications	2(16,6%)		0		p<0,05
Recurrent infection	1(0,83%)		0		p<0,05
	Before operation	After operation	Before operation	After operation	
Visual analogue scale (VAS) score	8,6 (± 1,4)	3,3 (± 1,1)	8,9 (± 1,7)	1,3 (± 0,9)	p<0,05
Harris Hip Score	32,2 (± 7,7)	51,3 (± 9,4)	30,3 (± 8,9)	69,7 (± 3,6)	p<0,05
WOMAC score	70,2 (± 6,4)	42,9 (± 5,9)	69,2 (± 8,1)	30,1 (± 2,4)	p<0,05

In the first group (Fig. 6), the average VAS score was 3.3 (± 1.4), the Harris Hip Score was 51.3 (± 9.4), and the WOMAC score was 42.9 (± 5.9); in the second group (Fig. 7), the VAS score was 1.3 (± 0.9), the Harris

Hip Score was 69.7 (± 3.6), and the WOMAC score was 30.1 (± 2.4). The rating scale data reflected a statistically significant improvement in hip joint function in patients in the second group ($p < 0.05$).

It should be emphasized that the functional results were worse in the group of patients who received articulating spacers without the use of 3D technology. There were no clinically or statistically significant differences in age, the time elapsed from the first to the second stage of surgical treatment or BMI between groups, and it cannot be said that these indicators are risk factors for the development of mechanical complications and unsatisfactory functional results. We also found that in the first group, one patient with dissociation of the pelvic bones had a mechanical complication.

We can assume that when pelvis dissociation occurs, it is logical to use 3D spacers because these spacers make it possible to link the pelvis and stabilize the joint.

We also noted that in the first group of patients, there were two mechanical complications associated with the migration of the spacer (Fig. 8).

Discussion

The most severe complication of joint arthroplasty is periprosthetic infection, which can lead to complications such as sepsis, renal amyloidosis, dystrophic changes in parenchymatous organs, and the appearance of septicopyemic foci [9,17,18]. Two-stage revision remains the gold standard for the treatment of deep periprosthetic hip infection [19]. Performing revision surgery on the hip joint in patients with severe defects in the acetabulum, especially those with pelvic discontinuity, remains a challenge for surgeons [20]. It is worth noting that the purpose of the spacer is not only to treat infection but also to improve the function of the joint. Previous studies have shown that functional outcomes in patients who have undergone articulated spacer implantation are significantly better than those in patients who have undergone non-articulating spacer implantation [21; 22].

However, when placing articulating spacers, there is a risk of mechanical complications. Some authors have demonstrated a 19.5% to 50% rate of mechanical complications, which included dislocation, breakage of the spacer, and peri-implant femur fracture due to acetabular protrusion and component migration into the pelvic cavity [23]. In a previous study, J. Jung et al. observed mechanical complications in 40.8% of cases (17% for dislocations, 10.2% for spacer breakages, and 13.6% for hip fractures) [24]. Faschingbauer et al analysed 138 patients who received spacers and found mechanical complications in 19.6%, including spacer breakage in 8.7%, dislocation in 8.7%, hip fractures in 0.7%, pelvic protrusions in 0.7%, breakdown in and dislocation of the spacer in 0.7% [25]. In our study, we evaluated groups of patients with massive bone defects of the acetabular region, namely, IIIA and III B defects according to the classification system described by W.G. Paprosky with dissociation of the pelvic bones. We observed mechanical complications in only 8.3% of cases. It should be emphasized that among the patients for whom we used 3D technologies to manufacture a spacer, we did not observe a single mechanical complication.

When the number of indications for primary hip arthroplasty increases, the number of operations performed increases, which subsequently increases the number of complications. Younger patients, despite their low rate of pre-existing comorbidities, are not exempt from a risk of deep periprosthetic infection. Naturally, young and active patients will place large demands on the implant, including the spacer.

In the study, the patients in whom we implanted spacers made using 3D technology showed significantly better functional outcomes than did the patients who received spacers not made with 3D technology. In our study, after the first stage of surgical treatment, 8 (33.3%) patients among the entire study population were able to return to their previous job.

The use of 3D tactile models helps plan the extent of surgery. The tactile models that are produced on a 3D printer enable us to analyse the already established hip pathological anatomy, classify the bone defects of each patient individually, and pick the most correct implant that can be used not only for the second stage but also for the first stage for the treatment of periprosthetic infections. Therefore, severe cases can be properly evaluated, which makes it possible to plan and personalize further treatment for each patient individually, which significantly reduces the execution time of each operating session and therefore reduces the number of complications [26].

With intraoperative 3D model fittings and evidence of the functional outcomes, doctors can be trained to think in 3D and help young surgeons overcome difficulties while performing primary surgery on a scale of 1:1. In addition, the results can serve as training material for future training of surgeons [27]. Some authors have highlighted the importance of tactile 3D basin models. In one study, the authors described 50 surgical interventions carried out with 3D models of the pelvis and demonstrated that printed models help reduce surgery time and improve the accuracy of positioning of the component [28].

The application of the 3D method allows good results to be achieved in hip revision surgery. At present, we should strive to improve the quality of life of patients after the first stage of revision surgery and to remember that the goal of the spacer is not only to stop progression of the infection but also to restore normal articulation of the joint. We also noted that the custom, individualized 3D models for the first phase of treatment can serve as a basis for the creation of the component for the second stage. 3D modelling is a promising direction in hip revision surgery, but because of its high cost, we cannot use it routinely when performing both the first and second stages.

Conclusions

The use of 3D technology in the first stage of treatment of deep periprosthetic infection in patients with IIIA and IIIB bone defects of the acetabulum according to the classification system described by W.G. Paprosky, especially in patients with dissociation of the pelvic bones, showed good functional results. Personalized and properly implanted 3D spacers can yield good functional outcomes and improve the quality of life of patients with massive acetabular bone defect areas. Additionally, the technology can help create a 3D component for two-stage surgery.

List Of Abbreviations

PJI - periprosthetic joint infection.

CT - computed tomography

HHS - Harris Hip Score.

WOMAC- Western Ontario and McMaster Universities Osteoarthritis Index

VAS - visual analogue scale

Declarations

Ethics approval and consent to participate: Local Ethics Committee at the Sechenov First Moscow State Medical University Ministry of Health of Russia (Sechenov University)

- **Consent for publication:** Not applicable
- **Availability of data and materials:** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- **Competing interests:** The authors declare that they have no competing interests" in this section.
- **Funding:** No funding
- **Authors' contributions:** MV is the principal researcher and editor of this manuscript, operate all patients in this research. KG made the design of this research and spacer engineering. MA performed the statistical analyses. and evaluation. GA was the assistant in surgeries and took part in treatment. AS performed the 3D group evaluation. CI performed CT segmentation and spacer model planning, EP evaluated the group with articulated spacer, SN performed PJI diagnostics, RA designed the 3D spacer type for pelvic discontinuity. EN collected data and evaluate scales.

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Figures

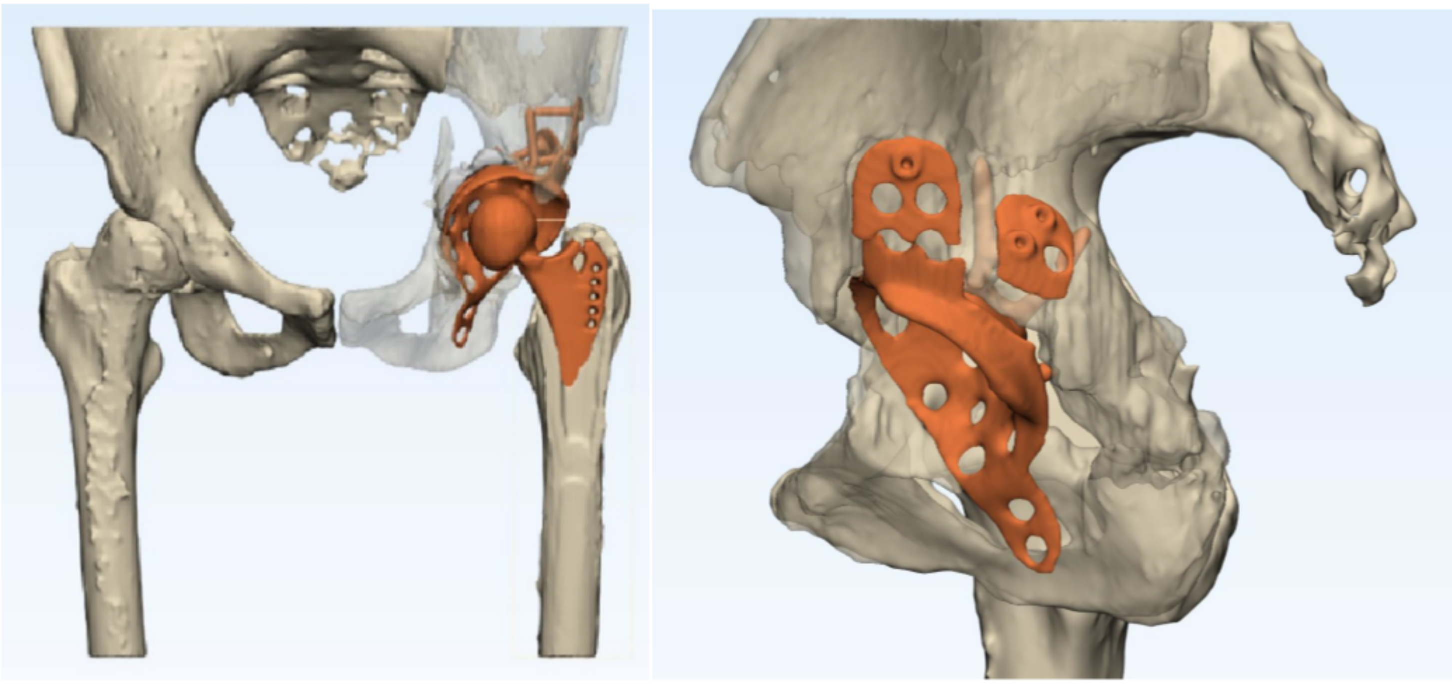

Figure 1

Preoperative planning based on 3D visualization. Assessment of the bone deficiency of the acetabulum.

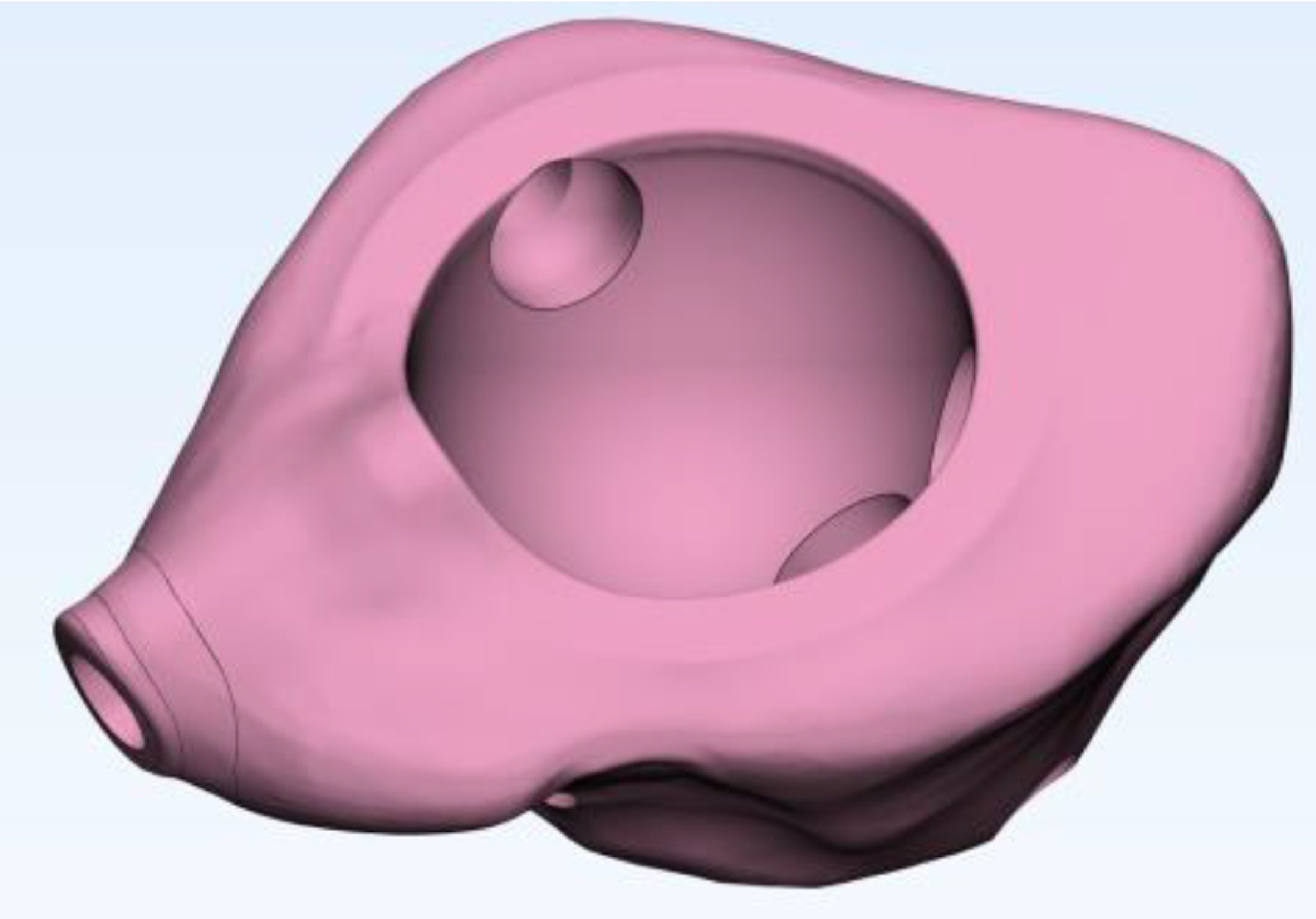

Figure 2

A digital model of a 3D spacer with holes for bone screws.

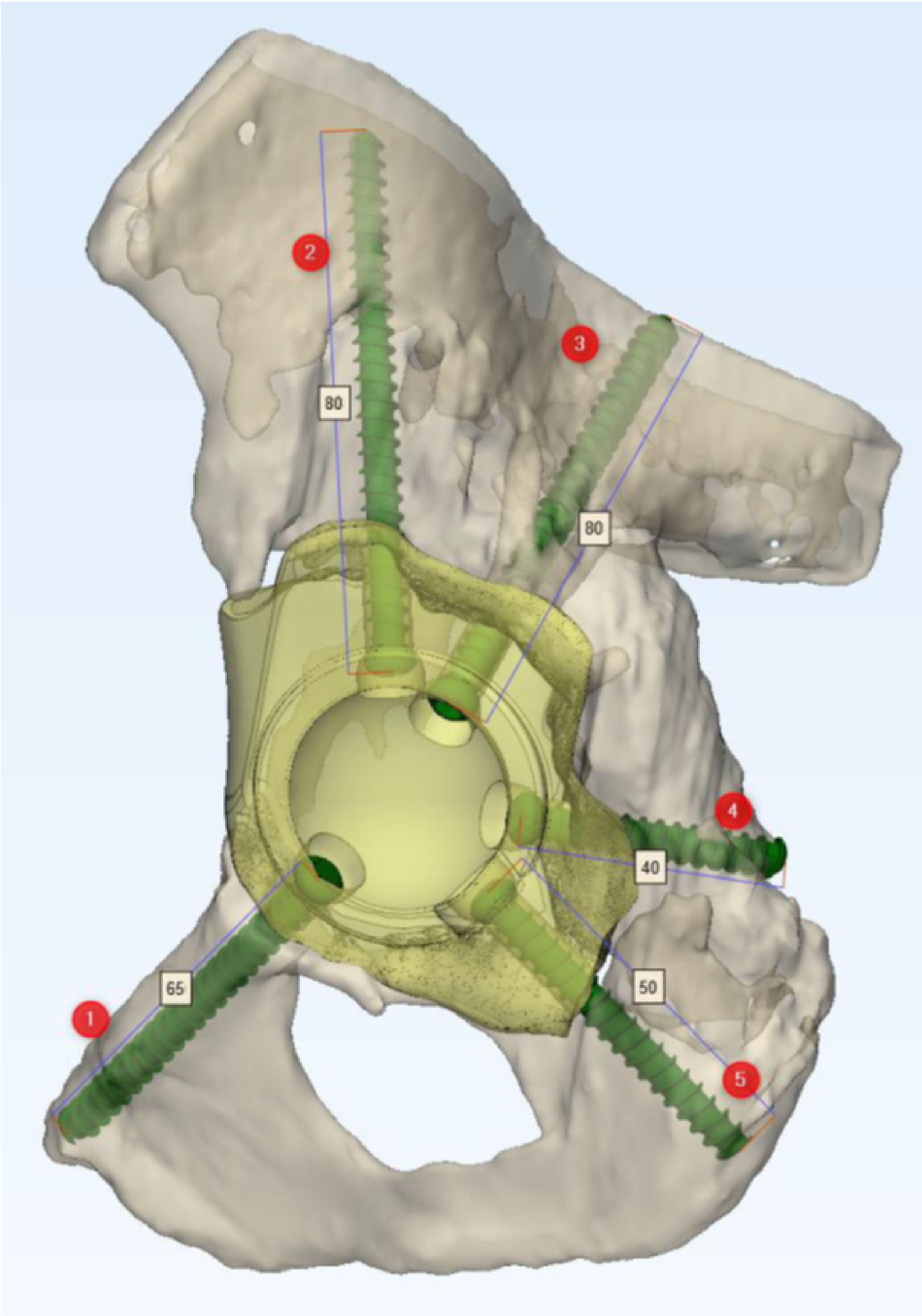

Figure 3

Digital preoperative planning. Fixation of the spacer in the acetabular region with bone screws.

Figure 4

Silicone mould for forming a 3D spacer with metal rods that form screw holes for further fixation in the bone tissue.

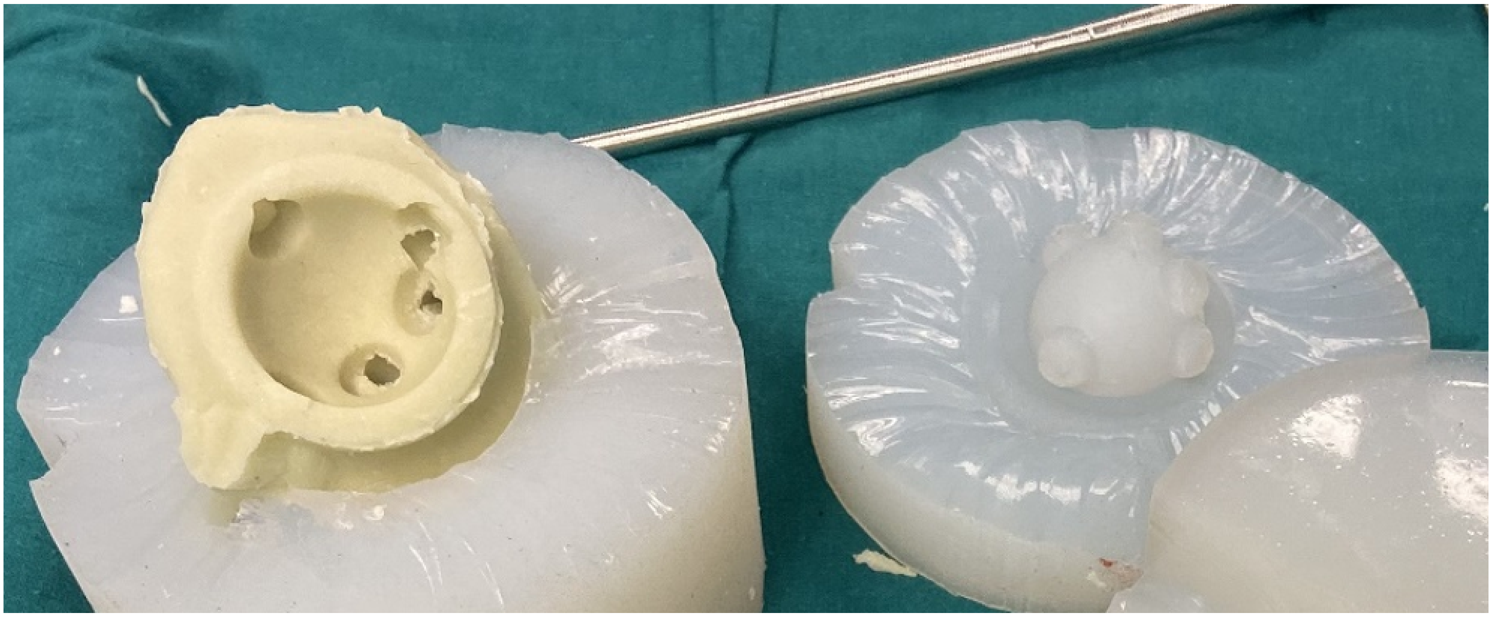

Figure 5

Intraoperative appearance of a custom-made spacer using 3D technology.

Figure 6

A. B. Plain radiographs of the pelvic bones of a 68-year-old patient with a left IIIB acetabular bone defect according to W.G. Paprosky classification. a. Acetabular component septic loosening. b. After implant removal and an articulating spacer implantation.spacer on the left.

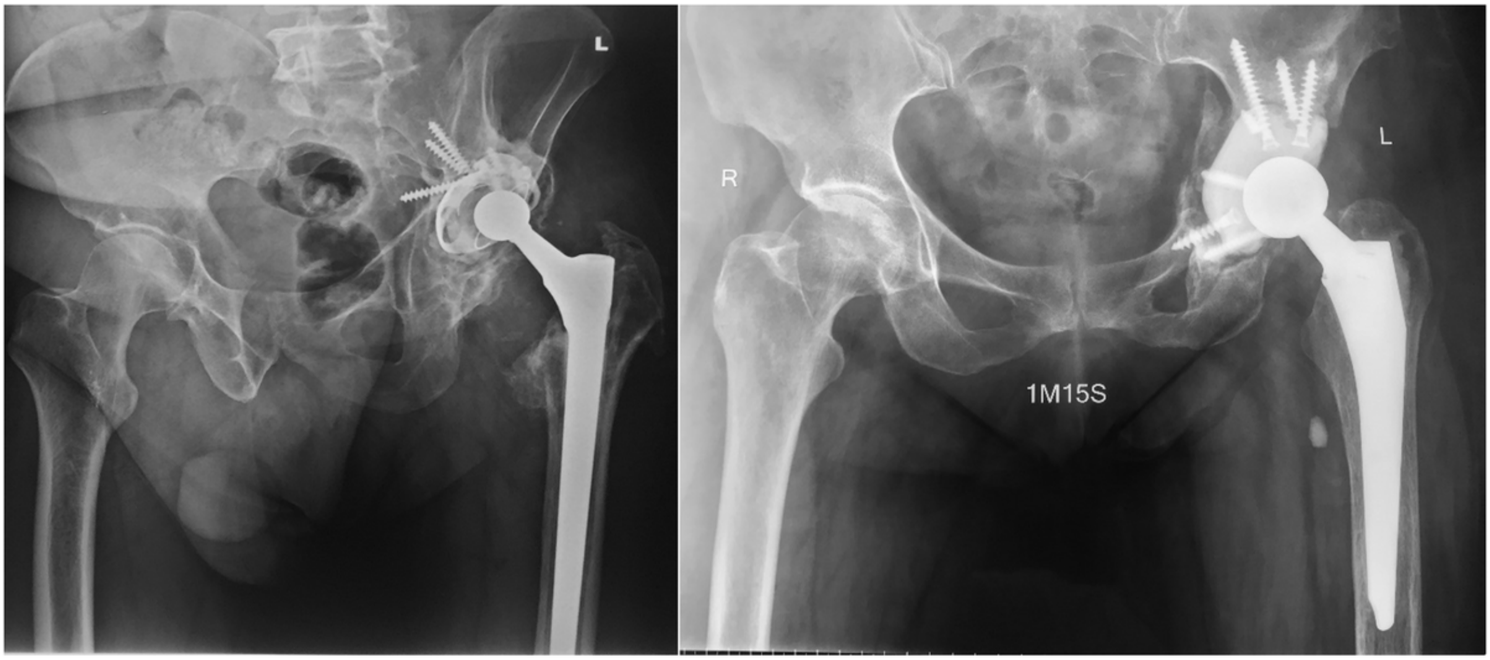

Figure 7

A. B. Plain radiographs of the pelvic bones of a 56-year-old patient with a left IIIB acetabular bone defect according to W.G. Paprosky classification. a. Septic loosening of the components of the endoprosthesis on the left. b. Condition after custom-made 3D spacer (acetabulum) implantation. 3D spacer (acetabulum).

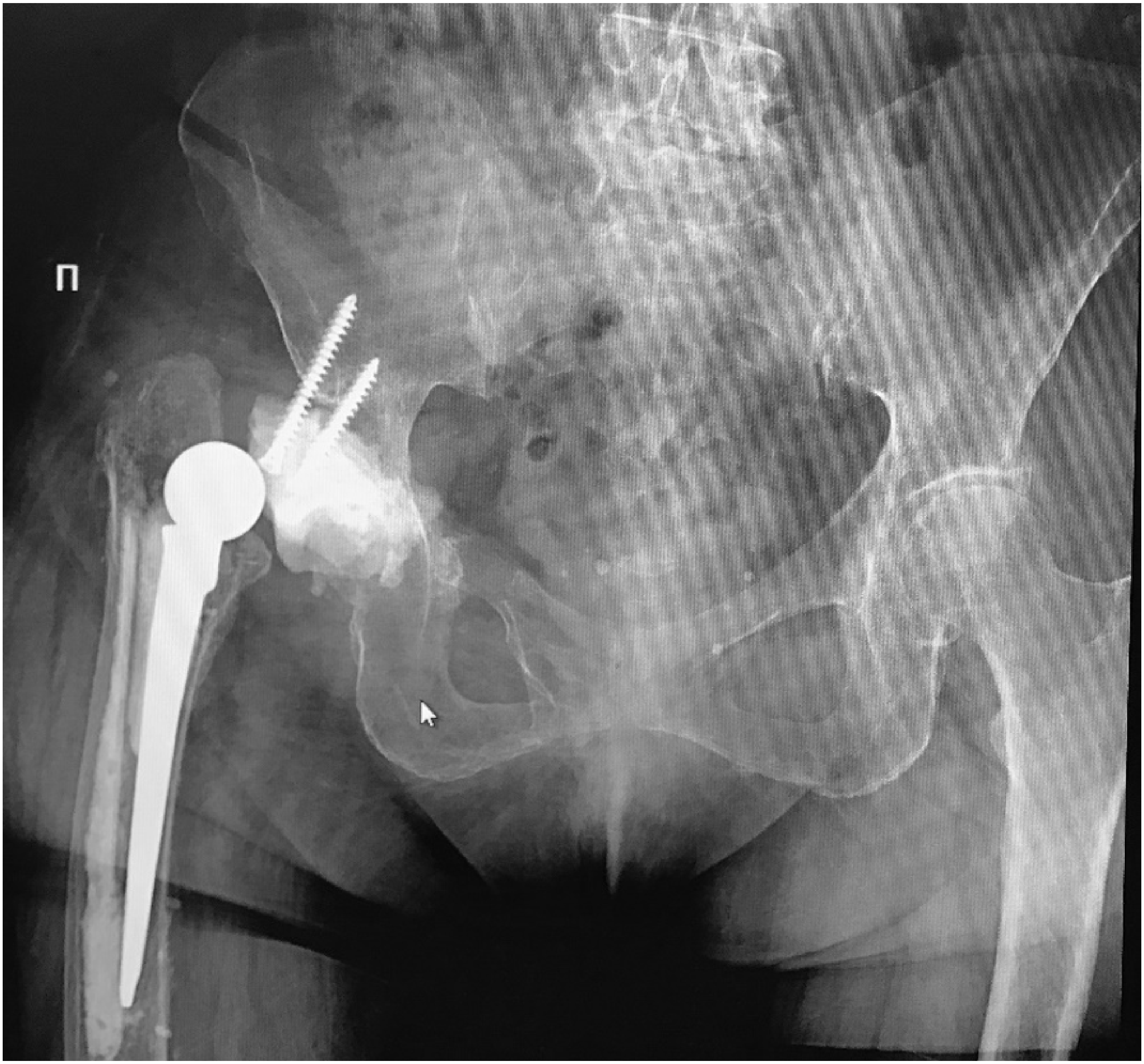

Figure 8

Plain radiographs of the pelvic bones with the spacer dislocation.