



Optimization of the first stage of hip revision in 2-stage surgery to replace infected artificial hips using a new molding spacer tool

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Abstract

Introduction The first stage of two-step surgery to replace infected hip suggests the intraoperative fabrication of an articulating cement spacer. A critical step is manual holding the metal reinforcement in the mold for 8–12 minutes while the bone cement cures, which increasing the overall surgical time. Optimizing this stage is essential.

The **objective** was to evaluate the effectiveness of the first stage of hip revision in 2-stage surgery optimized with a new device for fixing reinforcement in the manufacture of a cemented spacer for the hip joint.

Material and methods A new device (RU Patent No. 232924 U1), made of medical-grade AISI304 stainless steel, which is reusable and sterilizable, allows for the fixation of reinforcement used to manufacture hip articulating spacers in a clamp and their positioning over the center of a mold cell sized to fit the acetabulum (diameters 46–62 mm in 2 mm increments). With the cell filled with cement, the reinforcement was inserted to the specified depth and secured with the device. After 8–12 minutes, to allow polymerization completed, the construct was removed for cementation of the femoral component. A retrospective analysis of 85 patients with infectious coxitis surgically treated between 2023 and 2026 was conducted: the spacer was made by manual retention of reinforcement in the control group ($n = 51$) and the spacer was made using a new fixation device in the study group ($n = 34$). Total operative time (min), the frequency of spacer revisions, and early complications were assessed. The groups were comparable for key parameters.

Results Operating time was reduced by 13.7 minutes in the study group ((84.5 ± 8.9) min versus (98.2 ± 12.5) min, $p = 0.008$). The frequency of intraoperative spacer adjustments decreased fivefold (6 % versus 29 %, $p = 0.012$). No dislocations were recorded early post-op in either group. No significant differences in the accuracy of radiographic parameters (offset, neck-to-shaft angle) were found.

Discussion There are no publications reporting similar devices for the fabrication of the acetabular component of the hip articulating spacers. Patients with an underlying infectious process (tuberculous or purulent coxitis) and frequent comorbidities (HIV, hepatitis) may benefit with even a relatively small reduction in surgical time improving the prognosis. The lack of need for spacer modification preserves the integrity of the femoral head surface and ensures a more uniform distribution of the antibiotic in the cement.

Conclusion The device offered can be recommended for clinical implementation reducing surgical time by an average of 14 minutes and the frequency of spacer modifications.

Keywords: two-stage hip replacement, hip spacer, infectious coxitis, optimization, operative time, fixation device

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INTRODUCTION

Two-stage hip replacement remains the main method of treating septic coxitis [1–9]. The first stage includes resection of the femoral head, debridement of the lesion, and placement of an articulating antimicrobial cement spacer to facilitate temporary weight-bearing capacity of the limb and local deposition of antibiotics [10, 11]. The use of a custom-made antibacterial spacer, manufactured intraoperatively manually, is practical in septic coxitis. The key advantages of such bone cement spacers over factory-made analogs include the ability to adapt the shape to the individual anatomy of the defect, optimization of the dosage and combination of antibiotics considering the resistance of the pathogen, a significant reduction in mechanical conflict with surrounding tissues due to re-modeling of the articular head in the wound [3, 4, 12, 13, 14]. However, as our clinical experience shows, intraoperative mold of the spacer head remains a technically complex stage requiring optimization. The surgeon must manually hold the metal stem reinforcement in the mold cavity until the bone cement has fully cured (8–12 minutes). This stage involves static muscle tension, increases the overall surgical time, distracts the surgeon from other important procedures (debridement, hemostasis), and, if fatigued (with less surgical experience), can lead to displacement of the reinforcement, requiring subsequent correction of the spacer shape [15, 16].

In mechanical engineering, coordinate posts and stands are used for similar tasks [17]. In medicine, attempts to adapt such designs are known [18, 19], however, they are not designed to fix reinforcement with complex cross-sections (round, oval, with a keel). We have developed a new device for fixing reinforcement of the femoral component of a spacer during polymerization [20].

The **objective** was to evaluate the effectiveness of the first stage of hip revision in 2-stage surgery optimized with a new device for fixing reinforcement in the manufacture of a cemented spacer for the hip joint.

MATERIAL AND METHODS

Description of the device (Patent RF № 232924 U1) [20]

The device (Fig. 1, 2) is made of medical stainless steel AISI304, which allows multiple sterilization. The design includes a rectangular frame (80 × 75 mm) — base (1), a vertical threaded rod (Ø 8 mm, L = 120 mm) (2) with a nut (3) for moving the carriage; guide post (Ø 10 mm, L = 120 mm) for stability (4), movable carriage (70 × 30 mm) with a vertical travel range of 50–100 mm (5), rotation unit (lever 50 × 17 mm) with tilt angle lock of 0–90° (6), angle lock nut (7), clamping device with a clamp and lateral movement of 0–10 mm for fixing reinforcement of different sections (8), low knurled nut (9), height lock screw (10).

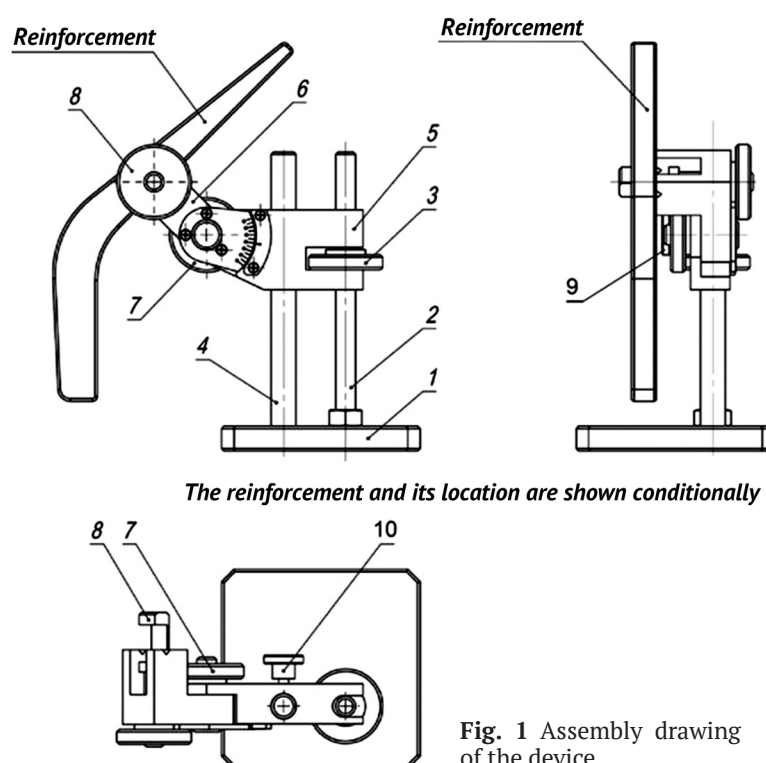


Fig. 1 Assembly drawing of the device



Fig. 2 Device for holding spacer fittings

Method of application

The device is placed on a separate table. The reinforcement is secured in a clamp and positioned over a mold cavity sized to fit the acetabulum (diameters 46–62 mm). An antibacterial agent is added to the bone cement powder, taking into account the individual sensitivity of the pathogen. Vancomycin, gentamicin, lincomycin, and amikacin are preferred for nonspecific infections, while amikacin, rifampicin, and isoniazid are used for tuberculous coxitis. The components are thoroughly mixed. With the cavity filled with cement, the reinforcement is inserted to the specified depth and secured using the device. Once polymerization is complete after 8–12 minutes, the device is removed for subsequent cementation of the femoral component.

Study design

The study was a single-center retrospective cohort.

Inclusion criteria:

- patients with infectious coxitis (of tuberculous and non-specific etiology);
- the first stage of a two-stage hip replacement with the installation of an articulating cement spacer being completed;
- availability of complete medical documentation (operation protocol, anesthesia chart, postoperative radiographs).

Non-inclusion criteria: lack of data on the time of surgery; radiographs unavailable for analysis.

The study was conducted at the Department for Patients with Extrapulmonary Tuberculosis of the National Medical Research Center for Phthisiopulmonology and Infectious Diseases between 01.01.2023 and 29.02.2026.

Characterization of the groups

The study included 85 patients who met the selection criteria. Distribution into groups depended on the availability of the device at the time of surgery:

- treatment group ($n = 34$): spacer made with the device developed to fix the reinforcement during polymerization.
- control group ($n = 51$): spacer made using the traditional manual method (the surgeon held the reinforcement in the mold until the cement was completely polymerized).

The groups were comparable in terms of gender, age, etiology of the process and initial radiographic parameters (Table 1).

Table 1

Comparative characteristics of groups

Description		Treatment (<i>n</i> = 34)		Control (<i>n</i> = 51)		<i>p</i>
Age, years		46.1 ± 13.2		47.5 ± 12.0		0.61
Acetabulum size, mm		50.8 ± 3.9		50.3 ± 4.0		0.57
Gender		abs.	%	abs.	%	
	Male	22	64.7	33	64.7	0.94
	Female	12	35.3	18	35.3	
Tuberculous coxitis		22	64.7	32	62.7	0.85

The total operating time (min) was defined as the interval between incision and dressing applied, as specified in the surgical protocols and anesthesia records. The frequency of intraoperative spacer adjustments was determined based on the presence of protocol entries. Postoperative radiographs were used to measure the offset (distance from the center of the femoral head to the femoral axis, mm); the femoral neck-shaft angle (°); and deviation from the preoperative plan. Early postoperative complications included dislocations and spacer instability within three months.

Statistical analysis

Statistical analysis was performed using Statistica 10.0 software (StatSoft, USA). Quantitative data are presented as $M \pm \sigma$. Groups were compared using the Student's t-test for independent samples (for normal distribution) and the Mann–Whitney U-test (for non-normal distribution). Categorical variables were compared using the χ^2 test with Yates' correction. Differences were considered statistically significant at $p < 0.05$.

RESULTS

A significant reduction in total operative time by 13.7 minutes was observed in the treatment group. The frequency of intraoperative spacer adjustments in the treatment group was five times lower (Table 2). No significant differences in the accuracy of reinforcement positioning were found between the groups. The deviation of the offset and the neck-to-shaft angle from the planned values was comparable (Table 3). Postoperative complications (dislocations and spacer instability) early post-op (up to three months) were not recorded in either group.

Table 2

Intraoperative parameters

Description	Treatment (<i>n</i> = 34)	Control (<i>n</i> = 51)	Difference	<i>p</i>
Operating time, min	84.5 ± 8.9	98.2 ± 12.5	–13.7	0.008
Spacer to be adjusted	2 (6 %)	15 (29 %)	–23 %	0.012

Table 3

Radiological parameters

Description	Treatment (<i>n</i> = 34)	Control (<i>n</i> = 51)	<i>p</i>
Offset deviation from plan, mm	3.2 ± 1.1	3.3 ± 1.2	0.69
Deviation of the neck-to-shaft angle from the plan, °	4.0 ± 1.6	4.1 ± 1.8	0.79

Clinical case

A 35-year-old patient was admitted to the NMIC FPI clinic with complaints of pain in the right hip joint and forced ambulation with crutches.

Anamnesis He experienced pain in the right hip joint for 18 months after a fall from a height. He developed fistula along the outer surface of the joint repeatedly. An abscessotomy was performed at the central district hospital at the place of residence. His concomitant disease included HIV

infection (stage 4B, progression phase with antiretroviral therapy (ART)), recurrent bacterial infections. The patient continuously took ART drugs for two years according to the following regimen: raltegravir 400 mg twice daily, etravirine 200 mg twice daily, lamivudine 150 mg twice daily. On admission: CD4⁺ = 360 cells/ μ L, HIV RNA < 20 copies/ml.

Objective status upon admission Functionality of the right hip joint demonstrated 33 HHS, 74 WOMAC and 7 VAS scores. Computed tomography of the right hip joint revealed destruction of the proximal femur and lysis of the head (Fig. 3).



Fig. 3 Computed tomography of the patient's right hip joint

Laboratory and instrumentation studies Immunological examination: CD4⁺ = 350 cells/ μ L, viral load < 20 copies/ml. Complete blood count: ESR, 61 mm/h. A trephine biopsy from the site of bone destruction of the femoral head was performed under radiation guidance. Microbiological examination of the biopsy yielded cultures of *Acinetobacter baumannii* (susceptible to amikacin) and *Staphylococcus aureus* (sensitive to all antibiotics tested). Pathohistological conclusion: signs of chronic nonspecific coxitis.

Diagnosis Based on clinical, radiological, microbiological and histological data, the patient was finally diagnosed with right-sided infectious coxitis (M00) of non-specific etiology associated with HIV infection.

Surgical intervention included resection of the proximal end of the right femur at the first stage of hip replacement. An antibacterial spacer was made on a separate table. The head of the spacer was formed using the device (Fig. 2). Powdered amikacin was added to the powdered polymer of bone cement at a rate of 2 g of the drug per 40 g of cement with the components mechanically mixed. The femoral component of the spacer was immersed in a mold filled with a cement-antimicrobial composition until hardening (10 minutes after mixing), after which the sample was removed from the plastic mold. The neck area of the spacer was additionally covered with a cement mantle.

The fabricated spacer was inserted into the femoral medullary canal, and the spacer head repositioned into the acetabulum (Fig. 4). The patient was verticalized on the second postoperative day. The postoperative wound healed by primary intention, with no signs of purulent-inflammatory complications. Pain relieved with nonsteroidal anti-inflammatory drugs. The patient was discharged after 10 days in satisfactory condition to be supervised by an infectious disease specialist and a traumatologist-orthopedist at his place of residence. He was recommended to continue ART, antibacterial therapy, and could receive the second stage of hip replacement at the National Medical Research Center of the Federal Pedagogical Institute after confirmation of joint debridement (normalized ESR, negative cultures, absence of clinical signs of infection for three months).

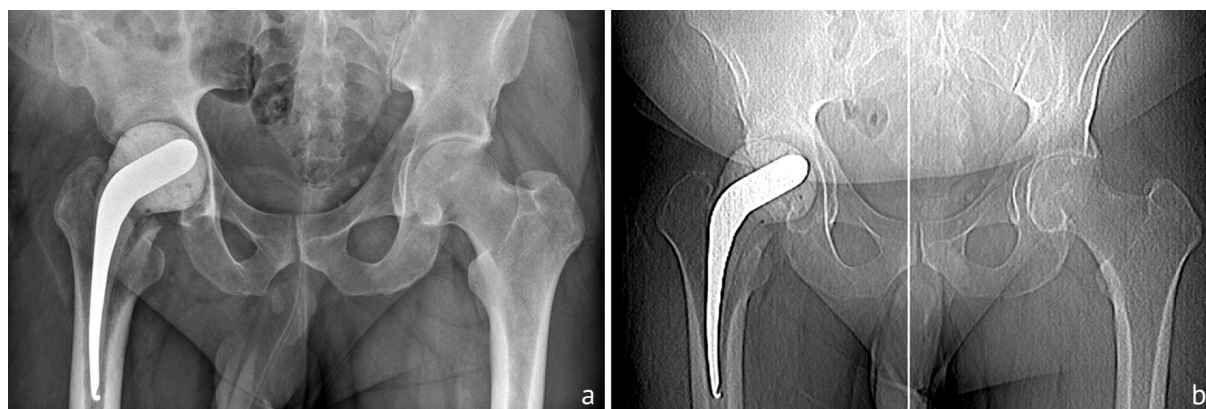


Fig. 4 Radiographs of the patient's right hip joint: (a) the first day after surgery with the articulating cement spacer placed; (b) at three months of surgery

DISCUSSION

We were unable to find any information in the literature on similar devices for the fabrication of the acetabular component of the hip articulating spacer. A significant reduction in the duration of the first stage of two-stage arthroplasty using the fixation device developed was the major result of our study. The difference of 13.7 minutes ($p < 0.01$) is clinically significant for a number of reasons.

Firstly, an increased length of surgery increases the risk of infectious complications [21–23]. A relatively small reduction in surgical time can improve the prognosis in patients with an underlying infectious process (tuberculous or purulent coxitis) and frequent comorbidities (HIV, hepatitis) [24, 25].

Secondly, a fivefold reduction in the frequency of intraoperative spacer adjustments (from 29 % to 6 %, $p < 0.05$) indirectly indicates a higher quality of primary positioning. Although we did not identify any obvious differences in radiographic parameters (offset, neck-o-shaft angle), the lack of need for spacer adjustments maintains the integrity of the head surface and ensures a more uniform antibiotic distribution in the cement, which is also confirmed by other authors [26, 27].

There was no evidence of the device being advantageous in terms of the precision of spacer positioning in the resected joint. We attribute this to the high level of surgical technique at the clinic: the surgeries were performed by experienced surgeons (with over 10 years of experience), which allowed us to achieve anatomical parameters even with the manual method. However, the stabilizing effect of the device may be more pronounced for less experienced surgeons or in high-speed surgical settings [23, 27, 28].

The absence of dislocations in both groups (0 out of 85) also indicates a high level of surgical technique and is not a limitation of the study. This means that the device does not worsen clinical outcomes, but does reduce surgical time and improve ergonomics. We believe the functional advantages of the device are also important.

Manually holding the reinforcement for 8–12 minutes is associated with certain static muscular effort, leading to fatigue, and can be accompanied by tremors. The surgeon can be relieved with the device and perform other stages of the procedure (debridement, hemostasis, drainage).

Limitations of the study:

- retrospective design (possible unaccounted systematic errors);
- lack of a formal assessment of ergonomics (for example, using a visual analogue scale of surgeon fatigue).

Prospects

A prospective, randomized study involving multiple centers and surgeons of varying levels of training would be practical. This would allow for the evaluation of the device's contribution to positioning accuracy and dislocation rates in a less selective population.

CONCLUSION

The use of a new device for fixing reinforcement during the intraoperative fabrication of a cemented hip spacer optimizes the first stage of two-stage hip arthroplasty reducing the overall operating time by an average of 13.7 minutes ($p < 0.01$), and decreasing the frequency of intraoperative spacer adjustments by five times ($p < 0.05$). The device is comparable to the traditional manual method in clinical outcomes (dislocation rate, positioning accuracy) and is superior in ergonomics and standardization of the polymerization stage. The findings substantiate the feasibility of clinical implementation of the device for optimizing the first stage of two-stage hip arthroplasty for infectious coxitis.

Conflict of interest The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this article.

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Ethical expertise The study was conducted in accordance with ethical standards and applicable Russian legislation. The study was approved by the local ethics committee of the National Medical Research Center for Pediatrics and Pedagogical Research of the Russian Ministry of Health (Protocol No. 3, dated January 31, 2023).

Informed consent The patients gave informed consent for publication of the findings without identification.

Information on the use of artificial intelligence The authors declare that they used the DeepSeek language model to improve the readability of the manuscript after writing the first draft. The authors are solely responsible for the content of the article.

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