

### ***Cost-effectiveness analysis of custom-made and serial acetabular components in revision hip arthroplasty***

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#### **Abstract**

**Introduction** Custom-made acetabular components demonstrate a higher clinical efficiency in revision hip arthroplasty for 3A and 3B uncontained acetabular defects and pelvic discontinuity in comparison with serial implants. However, the cost of customized implants still outweighs the cost of serial implants. Accordingly, the level of economic feasibility of using different implants for various defects of the acetabulum seems to be interesting to investigate. **Purpose** To analyze the economic efficiency of using customized acetabular implants for 3A and 3B uncontained acetabular defects and pelvic discontinuity in comparison with serial implants. **Materials and methods** To assess the economic efficiency, the Markov model was applied. The model was built on the basis of 4-year survival data for aseptic loosening, infection, and dislocation in 133 cases of revision hip arthroplasty. **Results** According to the results of modeling, over a 5-year cycle, customized implants showed a reduction in costs by 11.7 % and an increase in the quality of life of patients by 0.2 QALY in the group of patients with 3A uncontained defects in comparison with serial implants. In patients with 3B uncontained defects and pelvic discontinuity, custom-made implants also showed a reduction in costs by 20.8 % and 41.1 %, and QALY values were also higher in the groups of patients who had custom-made implants at 0.6 and 1.4 QALY units, respectively. **Conclusion** The use of custom-made implants is a more cost-effective strategy in comparison with the implantation of serial acetabular components.

**Keywords:** revision hip arthroplasty, cost-effectiveness, custom-made acetabular implants, serial acetabular constructs

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## INTRODUCTION

Primary total hip arthroplasty (THA) is one of the most effective operations to recover the hip joint (HJ) function and improve in the quality of life [1–4]. Thereby, the widespread use of this method contributes to a regular increase in the number of revision surgeries, including those for extensive defects in the acetabulum (AC) [5–8]. Various classifications have been developed to assess periacetabular bone loss in revision arthroplasty [9–11], but the most popular among surgeons is the Paprosky classification [12]. It distinguishes six types of defects, the most complex of which are type 3A and 3B defects. However, the Paprosky classification does not consider some important characteristics of the defect, such as whether the defect is contained or uncontained, and the discontinuity of the pelvic ring. Additional characterization of defects for contained or uncontained ones using the Gross/Saleh classification, as well as the identification of the patients with pelvic ring discontinuity has revealed that the highest incidence of aseptic loosening of the acetabular components after implantation of serial components was observed in patients with 3A and 3B uncontained defects and in patients with discontinuity of the pelvic ring [13].

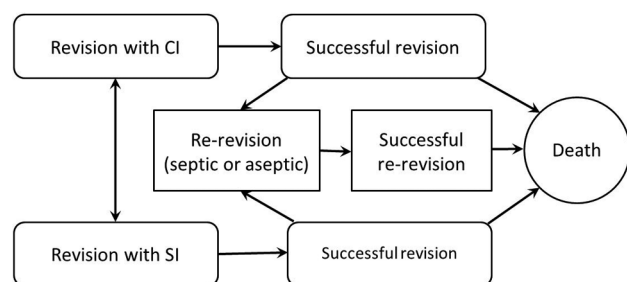
The rapid development of technologies for the production of endoprostheses predetermined the

emergence of customized implants (II) made by 3D printing and used for complex reconstructive operations in the AC region. Better availability of such production has significantly increased the use of customized implants (CI) in revision surgery, including in the Russian Federation [14–17]. The design of these implants is based on a three-dimensional reconstruction of the AC defect, and the number of screws and their trajectory depend on the geometry and density of the preserved bone tissue. Such constructs are implanted mostly for 3A and 3B uncontained AC defects and in discontinuity of the pelvic ring. They have shown higher clinical efficacy compared to commercial serial implants (SI) [13]. However, the cost of custom-made implants is significantly higher than the cost of serial products, even despite the need for additional use of support blocks and a large number of fixing elements. Therefore, it seems interesting to study the level of economic feasibility of using various designs for different defects of the acetabulum.

**Purpose** To analyze the economic efficiency of using custom-made acetabular implants for 3A and 3B uncontained acetabular defects and pelvic discontinuity in comparison with serial implants.

## MATERIAL AND METHODS

To assess the medical and economic efficiency of the use of custom-made and serial acetabular implants, the Markov model was applied. The model had a total duration of 5 years. The duration of each cycle in the model, within which the probability of transition is allowed, was 1 year. The clinical scenario used in the model is shown in Figure 1.



**Fig. 1** The clinical path of patients who require acetabular component replacement begins with revision arthroplasty using custom-made or commercial implants; patients remain in a "successful revision" state until they pass to an absorbing state ("death") or if they do not need re-revision. After a re-revision due to an aseptic or septic complication, a transition to the state of "successful re-revision" is expected; in this state, patients remain until the transition to an absorbing state ("death")

The probability of transition from the state of "successful revision" to the state of "re-revision" was established on the basis of 4-year survival data for aseptic loosening, infection, dislocation analyzing 133 cases of revision hip arthroplasty performed using custom-made and serial components for 3A and 3B uncontained defects and discontinuity of the pelvic ring (Table 1). The survival of acetabular components of serial and custom-made implants in the study groups was calculated using the Kaplan-Meier method [18].

Table 1

Use of custom-made and serial implants according to acetabular defects

Type of acetabular defect	Type of implant		
	Serial	Custom-made	Total
3A uncontained	39	19	58
3B contained	13	37	50
Pelvic ring discontinuity	6	19	25
Total	58	75	133

The age-related probability of death from causes not related to revision arthroplasty was equal to the probability of death at each specific age in the Russian Federation and corresponded to the data of the World Health Organization for 2016 [19].

An end point was used as an effectiveness criterion for evaluating treatment strategies with custom-made and serial designs which is a change in the quality

of life caused by health [20]. To assess the quality of life, the QALY indicator (Quality Adjusted Life Years or the number of years of preserved quality life) was used. The value of one QALY is equal to one year of life spent in perfect health. The QALY is calculated by adding the utilities of each cycle, which is the sum of the multiplication of patient's transitions from different states, and the utility levels for each of the states studied. The level of utility of each of the conditions was determined based on the interviewing of patients who underwent revision arthroplasty using the EQ-5D scale.

Costs were calculated in rubles based on the average cost of acetabular components implanted during surgery and the average cost of acetabular components used for re-revisions due to aseptic loosening. In the event of an infection, the average cost of spacers that were implanted at the first stage of re-revision and the average cost of acetabular components implanted at the second stage of re-revision was included. In dislocations, the cost of dual mobility systems, which were implanted during re-revision, was included.

The following general assumptions were made in the design of the model: 1) the mortality rates of patients who underwent revision of the acetabular component did not differ from the age-adjusted mortality rates of patients who did not undergo revision hip arthroplasty; 2) the negative assessment of the patient's health state (disutilities) as a result of the impact of such factors as decreased mobility, increased pain and increased risk of complications in the postoperative period, was set at -0.2 QALY; 3) all patients who underwent re-revisions remained in the "successful re-revision" state until they entered an absorbing state ("death").

Initially, the patients in the studied Markov model were in a state of successful revision performed with the use of CI or SI designs, then the patients, using the probabilities of transition between the states at the end of each cycle, either remained in the same state or passed to one of the following states: aseptic or septic re-revision, death. Thus, it was possible to calculate the costs and effectiveness of treatment for each studied strategy (Fig. 2).

The calculations of CER indicator (costs – effects) were performed according to the formula:

$$CER = (DC + IC) / Ef,$$

where DC – direct costs; IC – indirect costs; Ef – treatment efficiency [21].

Statistical analysis and processing were performed using TreeAge Pro 2012 software. All costs and health indicators were discounted after zero time by 3 % per year, which is in line with the practice of cost-effectiveness analysis in medicine [22].

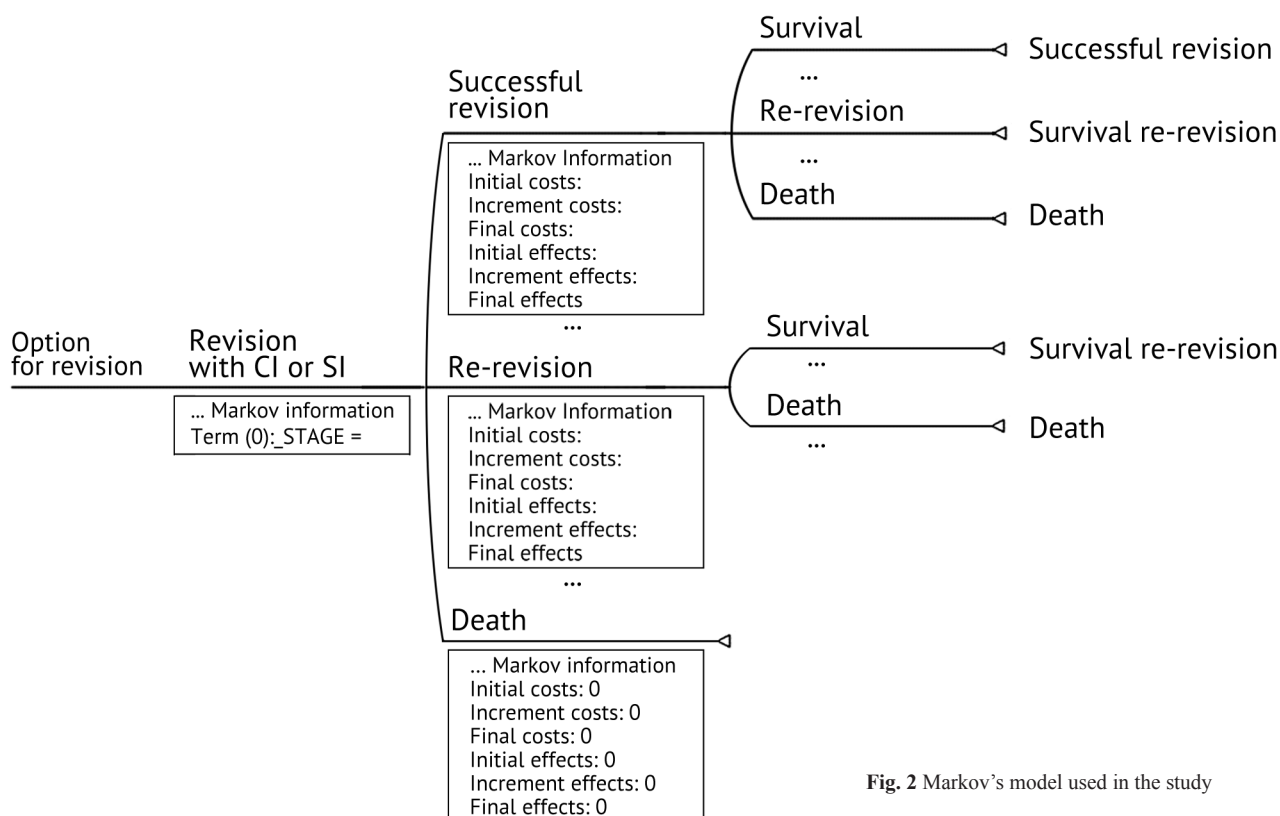


Fig. 2 Markov's model used in the study

## RESULTS

*Evaluation of the medical and economic efficiency of using serial and custom-made acetabular implants for 3A uncontained defects*

No complications were observed after implantation of custom-made acetabular components. Survival of custom-made designs for 4 years was higher than that with the use of serial acetabular components. The average cost of custom-made implants exceeded the cost of implanted serial components (Table 2).

Table 2

Survival and average cost of implants of customized and serial designs in 3A uncontained defects

Parameter	Serial implants (n = 39)	Custom-made implants (n = 19)
Complications (n, %)	3 (7.7)	–
Survival	0.9392	1.0
Average cost of implants (P)	53,199	107,124
Average cost of implants for re-revision (P)	136,575	–

EQ-5D values in the "successful revision" state were comparable in the groups (Table 3).

According to the results of modeling, custom-made acetabular components showed a cost reduction of 11.7 %, as well as an increase in QALY value by 0.2 in comparison with serial implants (Table 4).

Table 3

Value of the EQ-5D index for serial and custom-made designs used in 3A uncontained defects

State of the procedure	EQ-5D	
	Serial implants	Custom-made implants
Successful revision	0.6	0.64
Re-revision	0.16	–

Table 4

Results of economic efficiency for serial and custom-made designs used in 3A uncontained defects

Parameter	Serial implants	Custom-made implants
Costs (P)	120,018	107,124
Efficiency (QALY)	2.6	2.8

The CER analysis revealed that the cost per unit of effectiveness in case of custom-made designs was 38,258 P, and for serial implants it was 46,160 P. Thus, the strategy of custom-made designs for 3A uncontained defects is a more cost-effective method of treatment.

*Evaluation of the medical and economic efficiency of serial and custom-made acetabular implants for 3B uncontained defects*

Various complications occurred 1.9 times more frequent after implantation of serial acetabular components, and the survival of custom-made and

serial components in 3B uncontained defects differed significantly, 95 % versus 74 %. At the same time, the cost of custom-made implants was 1.8 times higher than the cost of serial acetabular components (Table 5).

The EQ-5D values in the case of “successful revision” were higher in the group of patients after implantation of serial components, and in the case of “successful re-revision” in the group of patients with custom-made implantation (Table 6).

The results of modeling in patients with 3B uncontained defects revealed a cost reduction by 20.8 % for custom-made designs, as well as an increase in the QALY value by 0.6 compared to serial implants (Table 7).

Table 5

Survival and average cost of implants of customized and serial designs in 3B uncontained defects

Parameter	Serial implants (n = 13)	Custom-made implants (n = 37)
Complications (n, %)	4 (30.8)	6 (16.2)
Survival	0.7419	0.9506
Average cost of implants (P)	59,417	106,389
Average cost of implants for re-revision (P)	114,071	245,875

Table 6

Value of the EQ-5D index for serial and custom-made designs used in 3B uncontained defects

State of the procedure	EQ-5D	
	Serial implants	Custom-made implants
Successful revision	0.68	0.56
Re-revision	0.18	0.22

Table 7

Results of economic efficiency for serial and custom-made designs used in 3B uncontained defects

Parameter	Serial implants	Custom-made implants
Costs (P)	267,214	211,539
Efficiency (QALY)	2.3	2.9

The CER analysis revealed that the cost per unit of effectiveness for custom-made designs was 72,994 P, and for serial implants it was equal to 116,180 P. Thus, the strategy of custom-made designs in 3B uncontained defects is a more cost-effective method of treatment.

Evaluation of the medical and economic efficiency of serial and custom-made acetabular implants in pelvic ring discontinuity

After implantation of custom-made components in discontinuity of the pelvic ring, complications were observed in 5.3 % of cases, while in the group of serial acetabular components they occurred in 33.3 % of cases. The cost of custom-made components in comparison with the cost of serial implants was 1.7 times higher (Table 8).

The EQ-5D values in the “successful revision” state were higher in the group of patients who received custom-made components (Table 9).

Markov modeling for groups of patients with discontinuity of the pelvic ring showed a 41.1 % cost reduction in the group of custom-made acetabular components along with an increase in QALY value by 1.4 compared to serial implants (Table 10).

Table 8

Survival and average cost of implants of customized and serial designs in pelvic ring discontinuity

Parameter	Serial implants (n = 6)	Customized implants (n = 19)
Complications (n, %)	2 (33.3)	1 (5.3)
Survival	0.7692	0.9756
Average cost of implants (P)	59,270	100,268
Average cost of implants for re-revision (P)	97,572	118,375

Table 9

Value of the EQ-5D index for serial and custom-made designs used in pelvic ring discontinuity

State of the procedure	EQ-5D	
	Serial implants	Custom-made implants
Successful revision	0.43	0.59
Re-revision	0.11	0.03

Table 10

Results of economic efficiency for serial and custom-made designs used in pelvic ring discontinuity

Parameter	Serial implants	Custom-made implants
Costs (P)	212,165	124,376
Efficiency (QALY)	1.4	2.8

The CER analysis showed that the cost per unit of efficiency for custom-made designs was 44,420 P, and 151,546 P for serial implants, they were. Thus, the strategy of custom-made components in discontinuity of the pelvic ring is a more cost-effective method of treatment.

## DISCUSSION

Recently, there has been an increased interest in publications on the evaluation of the cost-effectiveness

of using treatment methods in primary and revision hip arthroplasty [23, 24, 25]. Thus, a search for the



available literature in the MedLine database through the Pubmed platform using the keywords “total hip arthroplasty” or “revision hip arthroplasty” or “THA” and “cost-effectiveness” showed a growth by 2.8 times in the number of studies on this topic from 2011 to 2019 compared to the period from 2001 to 2009. This can be explained by the fact that the methods of economic analysis have the potential to evaluate the long-term use of new treatment strategies before obtaining long-term clinical results. Moreover, the results of a well-designed economic analysis are able to direct the vector of further clinical research into the study of factors that have the greatest impact on cost-effectiveness. Finally, the cost-benefit analysis framework can be easily updated as long as the information on the changes in the cost and clinical effectiveness of the applied technology becomes available [26, 27]. The application of analytical models is a useful tool in evaluating the cost-effectiveness of different methods of treatment, since almost all decisions on the use of new technologies in surgical practice face certain inconsistencies in the evidence base. It is no coincidence that the National Institute for Health and Care Excellence in England (NICE) points in its recommendations to the central role of analytical modeling methods for evaluating the results of using new technologies in the healthcare system [28].

Revision arthroplasty in severe AC defects and discontinuity of the pelvic ring is a difficult task in terms of restoring the biomechanics of the hip joint. The arsenal of commercial acetabular components does not meet all the needs of revision arthroplasty in the AC area and is characterized by a high rate of poor results, especially in the most severe AC defects [29, 30]. At first glance, the introduction of new technologies is the cause of additional financial costs. However, the assessment of economic efficiency in medical practice is not limited

to calculating the costs for the production cycle but also includes an assessment of the survival of implants and the quality of life of patients in the postoperative period. One of the most common methods used to evaluate these categories is the Markov mathematical model [31–33].

Our study is an attempt to conduct the first early analysis of the medical and economic efficiency of CIs using the Markov model. According to the results of the study, the cost reduced by 11.7 % and the QALY value increased by 0.2 in a group of patients with 3A uncontained defects treated with CIs over a 5-year cycle in comparison with serial implants. In patients with 3B uncontained defects and discontinuity of the pelvic ring, CIs also showed a cost reduction by 20.8 and 41.1 %, while QALY values were also higher in the groups of patients who received CIs by 0.6 and 1.4 units, respectively. The conducted cost-effectiveness analysis has revealed that the current use of custom-made acetabular components is a more cost-effective strategy compared to the implantation of commercial acetabular components in revision arthroplasty in 3A and 3B uncontained acetabular defects and in discontinuity of the pelvic ring.

Our study has several limitations. First, we assumed that the cost of acetabular implants has the greatest impact on total costs. Of course, future models for determining their cost-effectiveness should include all direct and indirect factors that have an impact on the final cost of treatment: labor costs, number of bed-days, rehabilitation, and drug therapy. Secondly, a four-year revision surgery survival period was used, which, of course, is not enough for such cases, since the survival rates worsen over time. However, the cost-effectiveness analysis framework using the Markov model can be easily updated as new information on the changes in the cost and survival of implants becomes available.

## CONCLUSION

The results of the study reveal that revision hip replacement in 3A and 3B uncontained defects of the acetabulum and discontinuity of the pelvic ring with the

use of custom-made acetabular components is a more cost-effective strategy compared to the implantation of serial acetabular components.

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