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Original article

Replacement of bone defects of the femur and tibia by the double cementing method in the treatment of periprosthetic infection of the knee joint using a dynamic cement spacer

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Abstract

Currently, periprosthetic knee infection is a burden on orthopedic services worldwide. The gold standard for the treatment of periprosthetic infection is a two-stage revision arthroplasty, which

consists of removing the infected endoprosthesis, debridement, placement of a cement spacer with an antibiotic at the first stage, and installing a revision endoprosthesis at the second stage. Often, revision endoprosthetics results in bone defects that require replacement.

Objective. The aim of this study was to compare the use of a single layer of bone cement and the double cementing method for the replacement of bone defects in revision knee arthroplasty.

Materials and Methods. The patients were divided into the main and control groups of 20 people each. In the main group, revision knee arthroplasty was performed using a dynamic cement spacer with an antibiotic and the double cementing method. In the control group, revision knee arthroplasty was performed using a dynamic cement spacer with an antibiotic and one layer of bone cement. The volume of intraoperative blood loss, the length of the patient's stay in the hospital, and the length of stay in the intensive care unit were assessed. Knee joint function was assessed 6 and 12 months after surgery using the Knee Society Score and Oxford Knee Score scales. Radiological stability of the endoprosthesis was assessed using the Modern Knee Society Score scale.

Results. Statistically significant differences were observed between the two groups in the number of knee points according to the Knee Society Score scale ($p = 0.005$), in the number of functional points according to the Knee Society Score scale ($p = 0.01$), in the number of Oxford Knee Score points ($p = 0.007$). When comparing the frequency of instability of components between the main and control groups, a statistically significant decrease in cases of radiographic instability was noted in the main group ($p = 0.026$). A statistically significant difference in the volume of blood loss was revealed between the groups, in the main group, blood loss was 100 mL less than in the control group ($p = 0.03$). There were no statistically significant differences between both groups in the number of days in the hospital ($p = 0.073$) and intensive care unit ($p = 0.072$). There were no statistically significant differences in the duration of surgery between the groups ($p = 0.73$). When comparing the frequency of infectious complications between the main and control groups, no statistically significant differences were found ($p = 0.405$), however, the absolute number of cases of periprosthetic infection was lower in the main group.

Conclusion. The double cementing method has been shown to improve knee function and reduce the incidence of radiographic instability of spacer components in revision knee arthroplasty at 12 months postoperatively.

Keywords: double cementation method, revision arthroplasty, knee joint, bone defects, bone cement, dynamic spacer.

1. Introduction

Periprosthetic is one of the most serious and dangerous complications in large joint endoprosthesis [1,2]. In the Republic of Kazakhstan, the incidence of periprosthetic infection following total joint endoprosthetics has been increasing annually. For example, in 2012, 42 cases were registered, while in 2023, the

number rose to 403 [3]. The percentage of periprosthetic infection in 2023 was 2.5% of all cases of endoprosthetics, which is consistent with world statistics [4]. In the USA, the percentage of periprosthetic infection varies from 2.0 to 2.7% and up to 1.6% in Canada of all cases of total endoprosthetics [1,5].

The world practice of treating periprosthetic infection is revision endoprosthetics, which includes the removal of endoprosthesis components that have a biofilm on their surface, thorough debridement, copious rinsing of the joint cavity with antiseptic solutions and installation of a cement spacer with an antibiotic [6]. During the removal of endoprosthesis components and revision, bone defects may occur. The use of modern methods for replacing bone defects in revision endoprosthetics, such as modular metal augments, metaphyseal sleeves with pressed coating of porous titanium and structural cones of porous tantalum, autologous bone grafting, allogeneic bone grafting, impact bone grafting, structural bone allografts, mega-endoprostheses, or individual endoprostheses is limited due to the presence of periprosthetic infection [7].

In this case, the method of choice remains the use of thick layers of bone cement or factory-made cement spacers with tibial augments [7, 8]. Despite the fact that

the use of bone cement is acceptable in case of periprosthetic infection due to the possibility of loading the bone cement with an antibiotic, these methods have certain limitations. Thus, the use of thick layers of bone cement is limited to defects of type 1 and 2A according to AORI due to the risk of thermal necrosis of the adjacent bone [9-12]. Factory-made cement spacers with tibial augment have a limited range and are not registered in the Republic of Kazakhstan [8].

The aim of our study was to compare the use of the developed the double cementing method with the method of using a single layer of bone cement to replace bone defects in revision arthroplasty with a dynamic cement spacer for periprosthetic knee joint infection.

Hypotheses of the study: the use of the double cementing method improves the functional results of treatment and reduces the incidence of radiographic instability when using a dynamic spacer.

2. Materials and Methods

The described study was conducted in accordance with international standards and was approved by the Local Ethics Commission (Protocol No. 4 of December 21, 2020). All patients participating in the study provided written consent for data processing and publication.

The patients were divided into 2 groups: the main group included 20 patients (prospective study), the control group also included 20 patients (retrospective study). Patients were included in the studies according to the following criteria:

- Patients with a confirmed diagnosis of periprosthetic knee joint infection;
- Presence of bone defects of the femur and/or tibia of type 2A, 2B and 3 according to AORI;
- Patient age from 40 to 79 years;
- Patient consent to participate in the study.

The exclusion criteria were as follows:

- Patient age less than 40 and more than 79 years;
- Presence of bone defects of type 1 according to AORI;
- Hemiparesis on the side of the proposed operation;

- Neoplasms of other localizations with or without metastases;

- Patient refusal to participate in the study;

In the main group, patients underwent surgical intervention in the volume of revision knee arthroplasty with the installation of a dynamic cement spacer with an antibiotic and the use of the double cementing method. In the control group, patients underwent revision knee arthroplasty with the installation of a dynamic cement spacer with an antibiotic and the use of one layer of bone cement.

The formed groups were comparable by the following criteria: gender, age, size of defects, the number of revision surgeries on this joint.

During the patient's stay in the hospital and at the time of discharge, the following parameters were assessed: the number of hospital beds; the number of bed days spent in the intensive care unit; the duration of the operation; the amount of intraoperative blood loss; assessment of knee joint function, radiographic stability, the number of recurrences of cases of periprosthetic infection. A follow-up examination to assess the function and radiographic assessment of the installation of the

knee joint endoprosthesis components was carried out 6 and 12 months after the operation. Knee joint function was assessed according to the Knee Society Score scale (KSS) and the Oxford Knee Score questionnaire (OKS). Radiographic stability of the endoprosthesis was assessed using the Modern Knee Society Radiographic Evaluation System.

In the main group, all patients underwent revision knee arthroplasty using a dynamic cement spacer with an antibiotic and the double cementing method. Endoprostheses from Johnson & Johnson DePuy and Beijing Chunlizhengda Medical Instruments were used as spacers. Bone cement DePuy Synthes Endurance GMV Gentamicin, 40g was used. The essence of the double cementing method is the use of two layers of bone cement.

The first layer of bone cement acts as an augment and repeats the shape of the bone defect, the second layer of bone cement is fixative and serves to fix the endoprosthesis components in the bone. After access to the knee joint through medial arthrotomy, the endoprosthesis components are removed one by one, and a thorough debridement of the knee joint cavity is performed (Figure 1). Then the joint cavity is abundantly washed with antiseptic solutions up to 10 liters. After installing the trial components of the endoprosthesis and determining the volume of the resulting bone defects, augments are formed from bone cement. Augments can be formed in two ways: using the "cast" method or forming an augment of the required size.

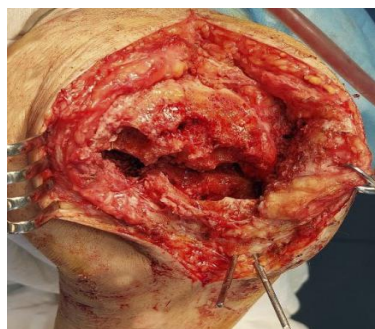


Figure 1 - Knee joint after endoprosthesis removal and tissue debridement. Extensive defects in the bone tissue of the femur and tibia are noted

Formation of an augment by a "cast" was used if the shape of the bone defect was irregular (Figure 2). After applying bone cement to the inner layer of a previously prepared dynamic spacer component and installing the component in the required position, a "cast" of the defect was formed in the area of the applied bone

cement (Figure 3). If necessary, excess bone cement was removed. After polymerization of the bone cement, a second layer of bone cement was applied and the components of the dynamic spacer were installed in the final position (Figure 4).

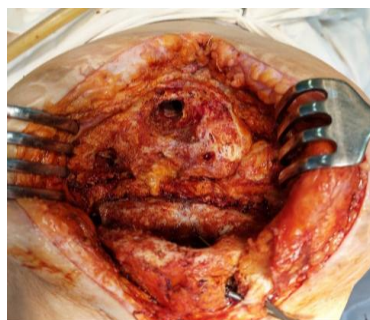


Figure 2 - Extensive defect of the femur of irregular shape



Figure 3 - Femoral component of the spacer with a cemented augment formed using the “cast” method



Figure 4 - Final installation of the dynamic spacer

The formation of an augment of the required size using the trial components was performed if the bone defect did not require significant processing of the bone edges. After selecting the necessary components of the dynamic spacer, bone cement was prepared and an augment of the required size was formed (Figure 5a). After polymerization of the bone augments, a second layer of bone cement is applied to the components of the

dynamic spacer and the formed augments (Figure 5b), the spacer is installed in the final position (Figure 6). The postoperative wound was sutured layer by layer and drained with active drainage.

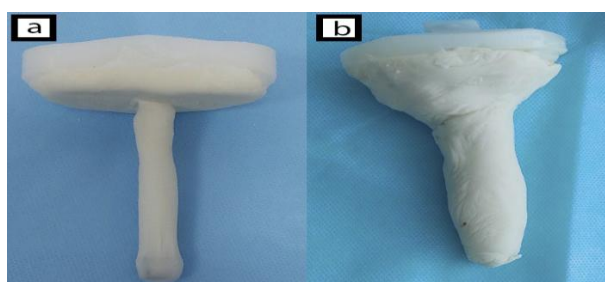


Figure 5 - (a) Tibial reinforced liner with 8 mm bone cement augment; (b) Tibial liner with cement augment with a second layer of bone cement applied

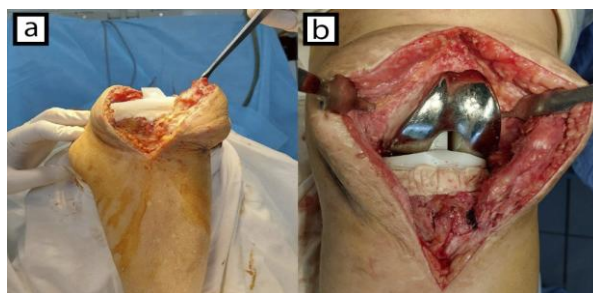


Figure 6 - (a) Installed tibial insert with cemented augment; (b) final placement of dynamic cemented spacer

In the control group, revision knee arthroplasty was performed using a dynamic cement spacer with an antibiotic and a single layer of bone cement. The essence of the traditional use of bone cement in a single layer is the application of bone cement in a single layer to the spacer components. After access to the knee joint through a medial arthrotomy, the endoprosthesis components are removed one by one, and a thorough debridement of the knee joint cavity is performed. Then the joint cavity is abundantly washed with antiseptic solutions up to 10 liters. After installing the try-in components of the spacer, bone cement is applied in one thick layer to the inner surface of the tibial component and it is installed. At this

point, the bone cement fills the bone defect. The postoperative wound was sutured layer by layer and drained with active drainage.

Statistical data were recorded and further processed in Microsoft Excel from the Microsoft Office 2016 package and Statistica 12.0 software for statistical analysis developed by Statsoft. The nonparametric Mann-Whitney criterion and the parametric Pearson's criterion χ^2 (chi-squared) criterion were used for data processing. Differences between the groups were considered significant at $p < 0.05$ [13].

3. Results

In the main group, the distribution of patients by gender was represented by 5 men (25%) and 15 women (75%), and in the control group - 4 men (20%) and 16 women (80%). The median age in the main group was 62 (Q25 - Q75; 6 - 68.5), in the control group 62.5 (Q25 - Q75; 28 - 65.5). Bone defects of the femur and tibia intraoperatively in the main group were assessed as F1 - in 6 cases (30%), F2A - 3 cases (15%), F2B - 11 cases (55%), T2A - 4 cases (35%), T2B - 13 cases (65%), T3 - 3 cases (15%). In the control group, bone defects were assessed as: F1 - 8 (40%), F2A - 4 (20%), F2B - 8 (40%), T1 - 1 (5%), T2A - 6 (30%), T2B - 11 (55%), T3 - 2 cases (10%). The median of previous revisions in the main group was 1 revision (Q25 - Q75; 1 - 1) with outliers in the amount of 2 and 3 revisions in different cases, and in the control group, the median was 2 revisions (Q25 - Q75; 1.5 - 2).

When analyzing the comparability of both groups of patients, no statistically significant differences were

found in gender, age of patients and the size of bone defects of the femur and tibia. In the control group, the median of previous revisions was 1 more than in the main group ($p = 0.04$) (Table 1).

When assessing the number of bed days in the main group, the median was 21 days (Q25 - Q75; 18.5 - 26.5). The median in the control group was 19 days (Q25 - Q75; 17 - 24). Assessment of days spent in the intensive care unit: in the main group, the median was 1 day (Q25 - Q75; 1 - 1), in the control group also 1 day (Q25 - Q75; 0 - 1). No statistically significant differences were found between both groups in the number of days in the hospital ($p = 0.073$) and intensive care unit ($p = 0.072$).

Table 1 - Comparative criteria of both groups

Comparison criteria	Main group	Control group
Number of men	5 (15%)	15 (75%)
Number of women	4 (20%)	16 (80%)
Age (Median)	62 (Q25 - Q75; 6 - 68,5)	62,5 (Q25 - Q75; 28 - 65,5)
The size of femur defects	F1	6 (30%)
	F2A	3 (15%)
	F2B	11 (55%)
The size of tibial defects	T2A	4 (35%)
	T2B	13 (65%)
	T3	3 (15%)
The number of postponed revision operations (Median)		1 (Q25 - Q75; 1 - 1)
		2 (Q25 - Q75; 1,5 - 2).

The median duration of surgery in the first group was 105 minutes (Q25 - Q75; 77.5 - 130), and in the second group also 105 minutes (Q25 - Q75; 92.5 - 127.5). The median intraoperative blood loss in the main group was 200 ml (Q25 - Q75; 100 - 300), in the control group 300 ml (Q25 - Q75; 200 - 625). A statistically significant difference in the volume of blood loss between the groups was revealed, in the main group there was 100 ml less blood loss than in the control group ($p = 0.03$). There was no statistically significant difference in the duration of surgery between the groups ($p = 0.73$).

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When assessing the function of the knee joint 12 months after surgery, the Knee Society Score and Oxford Knee Score scales were used. The median knee score according to the Knee Society Score scale in the first group was 83 points (Q25 - Q75; 83 - 88), while in the control group it was 78 points (Q25 - Q75; 71.5 - 83). In the double cementation group, the median functional score according to the scale was Knee Society Score 80 points (Q25 - Q75; 75 - 85), while in the single-layer bone cement group it was 65 points (Q25 - Q75; 60 - 80). In the main group, the median Oxford Knee Score was 18 points (Q25 - Q75; 15.5 - 20.5), while in the control group it was 24.5 points (Q25 - Q75; 18.5 - 31). When assessing knee joint function, statistically significant differences were found between groups in the median Knee Society Score ($p = 0.005$), in the functional Knee Society Score ($p = 0.01$), and in the Oxford Knee Score ($p = 0.007$).

When comparing the frequency of component instability between the main and control groups, statistically significant differences were found ($\chi^2 = 4.95$; $p = 0.026$). In the control group, instability was diagnosed in 65.0% of patients, while in the main group it was 25.0%,

indicating the potential clinical efficacy of the method used in the main group.

When comparing the frequency of infectious complications between the main and control groups, no statistically significant differences were found ($\chi^2 = 0.69$;

$p = 0.405$). In the main group, infection developed in 10.0% of patients, in the control group - in 25.0%. However, the differences did not reach the level of statistical significance.

4. Discussion

Bone cement is widely used in the treatment of periprosthetic infection, as it can be a carrier of an antibacterial drug and allows for a dosed release of the antibiotic [14, 15]. Bone cement also has the following advantages: availability, low cost and an easy-to-perform method.

Despite the obvious advantages, according to a number of studies, bone cement can only be used for small defects. According to the study by Qiu et al., the use of bone cement is permissible for type 1 defects according to the AORI classification (up to 5 mm) [9]. Thus, Dorr L.D. describes the result of using bone cement to replace type 1 defects in 54 patients with an observation period of 84 months. In 1 case, loosening and the presence of non-progressive lines of enlightenment at the cement/bone border were noted [7]. Similar conclusions were obtained in other studies. Thus, polymethyl methacrylate is proposed to be used only for the reconstruction of bone defects with two conditions. First, the articular surface defect should not exceed 50% of the area of the given surface and second, the depth of the defect should not be 5 mm or more [14-16].

Researchers Lotke et al. demonstrated the possibility of using bone cement for defects from 10 to 20 mm. 33 patients with a bone defect of 10 mm and 23 patients with a bone defect of 20 mm were operated on. After 7 years of observation, in 43 cases (76.8%) the authors noted the presence of non-progressive lines of enlightenment at the bone/cement border, in one case revision arthroplasty was performed [7].

Huten D. in his study shows the negative side of using thick layers of bone cement. The study concluded that there is a connection between the high frequency of loosening of the components of the knee joint endoprosthesis and the appearance of lines of

enlightenment at the cement/bone border during radiography when using thick layers of bone cement [17].

Also, when using bone cement to fix the endoprosthesis components, repeated revision is difficult and may contribute to additional bone loss when removing the cemented component [18-21]. The risk of thermal necrosis associated with an exothermic reaction during polymerization of large layers of bone cement increases the risk of instability of the endoprosthesis components [22]. When using an injection type of bone cement, there remains a risk of fat embolism, the possibility of increasing the cement pressure in the bone marrow canal [24, 25]. The use of thick layers of bone cement can lead to local disruption of the blood supply due to thermal necrosis, which can lead to instability of the prosthesis [25]. On the other hand, the double cementing method has shown its effectiveness. In our previous studies, a case from the practice of successful use of the double cementing method in a patient with recurrent knee joint infection was described. The patient has good knee function and no signs of inflammation at the control examination. The follow-up period was 4.5 years [26]. Also, in our other study, the method of double cementation was compared with the use of metal augments, which is a standard technique for replacing bone defects. All patients were diagnosed with aseptic instability of the components of the knee endoprosthesis. The method of double cementation showed the same functional effectiveness compared to the standard method of defect replacement, but the operation time and blood loss were less in the double cementation group.

Although there was no statistically significant difference in the number of cases of recurrent periprosthetic infection, the absolute number of cases was lower in the double cementation group. Perhaps, with a sufficient sample, this method can show

statistically significant results in reducing the incidence of recurrent periprosthetic infection.

The main limitations of this study are the limited sample of patients and an insufficiently long period of observation of treatment outcomes in patients.

5. Conclusions

The use of a dynamic cement spacer using the dual cementation method showed better treatment outcomes compared to the use of a single layer of bone cement. The method used allowed statistically significantly improving the function of the knee joint when assessed 12 months after surgery, reducing the number of cases of radiographic instability of the endoprosthesis components and reducing the volume of intraoperative blood loss. Based on the data obtained, it is possible to recommend the use of the dual cementation method to replace bone defects of the femur and tibia in revision knee arthroplasty using a dynamic spacer.

Author Contributions: Conceptualization - S.B.; methodology - A.B.; formal analysis - A.B.; investigation

- R.A.; resources - A.B.; data curation - A.M.; writing – original draft preparation - Ye.A., A.A.; writing – review and editing - Zh.R., A.K.; visualization - S.B.; supervision - A.B.; project administration - A.B.

All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest: The authors declare no conflicts of interest.

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Тізе буынының перипротездік инфекциясын динамикалық цемент аралықпен емдеуде қос цементтеу әдісімен жамбас және жіліншік сүйектерінің ақауларын ауыстыру

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Түйіндеме

Қазіргі уақытта перипротездік тізе инфекциясы бүкіл әлемде ортопедиялық қызмет үшін ауыртпалық болып табылады. Перипротездік инфекцияны емдеудің алтын стандарты екі кезеңді ревизиялық артропластика болып табылады, ол жұқтырған эндопротезді алып тастаудан, тазартудан, бірінші кезеңде антибиотикпен цементтік аралық орнатудан және екінші кезеңде ревизиялық эндопротездеуді орнатудан тұрады. Көбінесе ревизиялық эндопротестика ауыстыруды қажет ететін сүйек ақауларына әкеледі.

Бұл зерттеудің мақсаты ревизиялық тізе артропластикасында сүйек ақауларын ауыстыру үшін бір қабатты сүйек цементін қолдану мен қос цементтеу әдісін салыстыру болды.

Әдістер. Науқастар әрқайсысы 20 адамнан тұратын негізгі және бақылау топтарына бөлінді. Негізгі топта тізе буынының ревизиялық артропластикасы антибиотикпен және қос цементтеу әдісімен динамикалық цементті аралықпен орындалды. Бақылау тобында тізе буынының ревизиялық артропластикасы антибиотикпен және сүйек цементінің бір қабаты бар динамикалық цемент аралық құралын қолдану арқылы орындалды. Операция кезіндегі қан жоғалту көлемі, науқастың стационарда болу ұзақтығы, жансақтау бөлімінде болу ұзақтығы бағаланды. Тізе буынының қызметі операциядан кейін 6 және 12 айдан кейін Knee Society Score және Oxford Knee Score шкаласы арқылы бағаланды. Эндопротездің радиологиялық тұрақтылығы Modern Knee Society Score шкаласы арқылы бағаланды.

Нәтижелер. Екі топ арасында Knee Society Score шкаласы бойынша тізе ұпайларының санында ($p = 0,005$), Knee Society Score шкаласы бойынша функционалдық ұпайлардың санында ($p = 0,01$), Оксфорд тізе ұпайларының санында ($p = 0,007$) статистикалық маңызды айырмашылықтар байқалды. Негізгі және бақылау топтары арасындағы компоненттердің тұрақсыздық жиілігін салыстыру кезінде негізгі топта радиографиялық тұрақсыздық жағдайларының статистикалық маңызды төмендеуі байқалды ($p = 0,026$). Топтар арасында қан жоғалту көлемдерінің статистикалық маңызды айырмашылығы анықталды, негізгі топта қан жоғалту бақылау тобына қарағанда 100 мл-ге аз болды ($p = 0,03$). Ауруханада ($p = 0,073$) және қарқынды терапия бөлімінде ($p = 0,072$) күндер саны бойынша екі топ арасында статистикалық маңызды айырмашылықтар болған жоқ. Топтар арасында операция ұзақтығында статистикалық маңызды айырмашылықтар болған жоқ ($p = 0,73$). Негізгі және бақылау топтары арасындағы инфекциялық асқынулардың жиілігін салыстырған кезде статистикалық маңызды айырмашылықтар табылған жоқ ($p = 0,405$), алайда, негізгі топта перипротездік инфекция жағдайларының абсолютті саны төмен болды.

Қорытынды. Қосарланған цементтеу әдісі операциядан кейінгі 12 айда ревизиялық тізе артропластикасында тізе функциясын жақсартады және аралық компоненттердің рентгенографиялық тұрақсыздығы жиілігін төмендетеді.

Түйін сөздер: қос цементтеу әдісі, ревизиялық артропластика, тізе буыны, сүйек ақаулары, сүйек цементі, динамикалық аралық.

Замещение костных дефектов бедренной и большеберцовой костей методом двойного цементирования при лечении перипротезной инфекции коленного сустава с использованием динамического цементного спейсера

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Резюме

В настоящее время перипротезная инфекция коленного сустава является серьёзной проблемой для ортопедических служб во всем мире. Золотым стандартом лечения перипротезной инфекции является двухэтапная ревизионная артропластика, которая состоит из удаления инфицированного эндопротеза, дебридмента, установки цементного спейсера с антибиотиком на первом этапе и установки ревизионного эндопротеза на втором этапе. Нередко ревизионное эндопротезирование приводит к образованию костных дефектов, требующих последующего замещения.

Целью данного исследования было сравнение использования одного слоя костного цемента и метода двойного цементированья для замещения костных дефектов при ревизионном эндопротезировании коленного сустава.

Методы. Пациенты были разделены на основную и контрольную группы, каждая из которых включала по 20 человек. В основной группе ревизионное эндопротезирование коленного сустава проводилось с использованием динамического цементного спейсера с антибиотиком и методом двойного цементированья. В контрольной группе ревизионное эндопротезирование коленного сустава проводилось с использованием динамического цементного спейсера с антибиотиком и одним слоем костного цемента. Оценивались объем интраоперационной кровопотери, длительность пребывания пациента в стационаре и длительность пребывания в отделении интенсивной терапии. Функцию коленного сустава оценивали через 6 и 12 месяцев после операции по шкалам Knee Society Score и Oxford Knee Score. Рентгенологическую стабильность эндопротеза оценивали по шкале Modern Knee Society Score.

Результаты. Статистически значимые различия между двумя группами наблюдались по количеству баллов колена по шкале Knee Society Score ($p = 0,005$), по количеству функциональных баллов по шкале Knee Society Score ($p = 0,01$), по количеству баллов Oxford Knee Score ($p = 0,007$). При сравнении частоты нестабильности компонентов между основной и контрольной группами в основной группе отмечается статистически значимое снижение случаев рентгенологической нестабильности ($p = 0,026$). Выявлена статистически значимая разница в объеме кровопотери между группами, в основной группе кровопотеря была на 100 мл меньше, чем в контрольной группе ($p = 0,03$). Не выявлено статистически значимых различий между

обеими группами по количеству дней в стационаре ($p = 0,073$) и отделении интенсивной терапии ($p = 0,072$). Не выявлено статистически значимых различий по продолжительности операции между группами ($p = 0,73$). При сравнении частоты инфекционных осложнений между основной и контрольной группами статистически значимых различий не выявлено ($p = 0,405$), однако абсолютное количество случаев перипротезной инфекции было ниже в основной группе.

Выводы. Результаты исследования показали, что метод двойного цементирование улучшает функцию коленного сустава и снижает частоту рентгенологической нестабильности динамических спейсеров при ревизионном эндопротезировании коленного сустава через 12 месяцев после операции.

Ключевые слова: метод двойного цементирование, ревизионное эндопротезирование, коленный сустав, костные дефекты, костный цемент, динамический спейсер.