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Knee Arthoplasty in Chronic Hemodialysis Patients: Standard Surgery or Complex Case?

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Abstract

Background. Chronic hemodialysis significantly increases the risks associated with knee replacement. Among the late complications of knee arthroplasty in hemodialysis patients, deep periprosthetic joint infection (PJI) and aseptic loosening are more frequent. The frequency of revision interventions in patients with end-stage kidney disease (ESKD) is substantially higher compared to patients with normal kidney function.

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The aim of the study — based on the perioperative parameters and midterm outcomes to justify the primary knee replacement in chronic hemodialysis patients as complex case of arthroplasty.

Methods. A retrospective randomized single-center cohort study was conducted, including 62 patients with various forms of knee osteoarthritis. Patients were divided into two groups: Group 1 - 29 (46.8%) patients with end-stage renal disease (ESRD) undergoing dialysis, Group 2 - 33 (53.2%) patients without kidney pathology. The average follow-up period in both groups was 3.7 years (min - 1, max - 6). The following parameters were assessed: patient age, length of hospital stay, morphocortical index, body mass index (BMI), duration of hemodialysis, functional assessment of the knee joint using the KSS Function Score and Forgotten Joint Score-12 (FJS-12), radiological results on the KRESS, and the frequency of various complications.

Results. In Group 1, patients had significantly lower BMI compared to Group 2. Length of hospital stay in Group 1 were 1.7 times longer. According to the KSS Function Score, no significant differences were observed between the groups in the first 36 months after the operation. However, by the 4th year of follow-up, average KSS Function Score in Group 1 decreased to 77.3 points, which was due to infectious complications. The FJS-12 showed worse scores in Group 2, averaging 68.7 points. After more than three years post-operation, no statistically significant differences were observed between the groups, which was associated with an increase in the number of complications in Group 1. Results on the KRESS after 43 months did not differ between the groups and averaged 4.8 points. Group 1 had more orthopedic complications and cases of PJI, accounting for 7 out of 37.

Conclusions. Age and constitutional characteristics of patients undergoing hemodialysis significantly differ from the normal population. The frequency of complications in Group 1 was 23.5%. These patients require the implantation of more constrained implant components and modular systems. Therefore, primary knee replacement in hemodialysis patients can be classified as a complex case of arthroplasty.

Keywords: knee arthroplasty, chronic hemodialysis, chronic kidney disease.

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Эндопротезирование коленного сустава у пациентов, находящихся на хроническом гемодиализе: стандартная операция или сложный случай?

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Реферат

Актуальность. Хронический гемодиализ существенно увеличивает риски при эндопротезировании коленного сустава (ЭП КС). Среди поздних осложнений ЭП КС у пациентов, находящихся на гемодиализе, чаще встречаются глубокая перипротезная инфекция (ППИ) и асептическое расшатывание. Частота ревизионных вмешательств у пациентов с терминальной стадией хронической болезни почек (ХБП) существенно выше по сравнению с пациентами без патологии почек.

Цель исследования — на основании оценки периоперационных показателей и среднесрочных результатов первичного эндопротезирования коленного сустава у пациентов, находящихся на хроническом гемодиализе, обосновать необходимость отнесения данной категории операций к сложным случаям.

Материал и методы. Проведено ретроспективное рандомизированное одноцентровое когортное исследование, в которое вошли 62 пациента с различными формами гонартроза. Пациенты были разделены на две группы: группа 1 — 29 (46,8%) пациентов с терминальной стадией ХБП, находящихся на диализе, группа 2 — 33 (53,2%) пациента без патологии почек. Средний период наблюдения в обеих группах составил 3,7 года (min — 1, max — 6). Оценивали следующие показатели: возраст пациентов, длительность нахождения в стационаре, морфо-кортикальный индекс, индекс массы тела (ИМТ), длительность гемодиализа, функциональные показатели коленного сустава в баллах по шкале KSS Function Score и шкале забытого сустава (FJS-12), рентгенологические результаты по шкале KRESS, частоту различных осложнений.

Результаты. У пациентов группы 1 ИМТ был значимо ниже по сравнению с пациентами группы 2. Сроки госпитализации в группе 1 были выше в 1,7 раза. По шкале KSS Function Score в первые 36 мес. после операции значимых различий между группами не выявлено, однако к 4-му году наблюдения в группе 1 средние показатели по KSS Function Score снизились до 77,3 баллов, что обусловлено инфекционными осложнениями. По шкале FJS-12 в группе 2 показатели были хуже — в среднем 68,7 балла. В сроки более трех лет после операции статистически значимой разницы между группами выявлено не было, что связано с увеличением количества осложнений у пациентов в группе 1. Результаты по шкале KRESS через 43 мес. между группами не отличались и составили в среднем 4,8 балла. В группе 1 было больше ортопедических осложнений и случаев ППИ — 7 из 37.

Заключение. Возрастные и конституционные характеристики пациентов, находящихся на гемодиализе, существенно отличаются от больных обычной популяции. Частота ортопедических осложнений в этой группе составила 23,5%. Им необходимо имплантировать более связанные компоненты эндопротезов и модульные системы. Поэтому первичное эндопротезирование коленного сустава у пациентов, находящихся на хроническом гемодиализе, можно отнести к категории сложных.

Ключевые слова: эндопротезирование коленного сустава, хронический гемодиализ, хроническая болезнь почек.

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BACKGROUND

Knee replacement is the most effective surgical treatment for all etiological forms of grade II-III knee osteoarthritis. Modern international and domestic publications indicate an annual increase in the number of knee arthroplasty with good long-term component survival rates [1, 2, 3, 4, 5].

The presence of end-stage chronic kidney disease (CKD) in a patient significantly increases the risks of complications during surgery, such as bleeding, acute cardiovascular events (atrial fibrillation, myocardial infarction, pulmonary edema, pulmonary embolism, etc.), and intraoperative periprosthetic fractures [6, 7, 8]. Late complications of knee arthroplasty hemodialysis patients include deep in periprosthetic joint infection (PJI), with rates up to 18% [9, 10, 11], and aseptic loosening, with a rate of 16% [12, 13]. In domestic publications, this problem is not sufficiently addressed.

The prevalence of end-stage CKD is exponentially increasing in all countries [14]. Given the increasing need for knee replacement, including in hemodialysis patients, there may be an increase in revision surgeries in the near future. Consequently, there is a growing need for a more thorough analysis of primary knee replacement outcomes in patients undergoing chronic hemodialysis and the development of preoperative preparation schemes, including correction of calcium-phosphorus metabolism disorders, acid-base status, anemia, bone mineral density, thromboprophylaxis, and reduction of the risk of infectious complications.

The aim of this study is to justify the classification of knee replacement in patients undergoing chronic hemodialysis as difficult cases based on the assessment of perioperative parameters and midterm outcomes.

METHODS

Study design

We conducted a retrospective randomized singlecenter cohort study, which included 62 patients with various pathogenetic forms of gonarthrosis. These patients underwent knee replacement performed by a single surgical team at the Pavlov First State Medical University of St. Petersburg from 2016 to 2022.

Inclusion criteria:

 – grade 2-3 knee osteoarthritis according to the N.S. Kosinskaya classification [15];

- bone defects of type 1-2A according to the AORI classification [16];

- no previous knee surgeries;

- no severe knee trauma with hemarthrosis;

– full weight-bearing allowed no earlier than 4 weeks post-surgery.

Exclusion criteria:

– grade 1 knee osteoarthritis according to the
 N.S. Kosinskaya classification;

- severe varus/valgus deformities of the knee;

 history of lateral or medial collateral ligament ruptures/injuries leading to knee instability;

– active infectious processes in the knee area in the preoperative period.

All patients were divided into two study groups: Group 1 consisted of 29 (46.8%) patients (34 knee replacement) with end-stage chronic kidney disease (ESKD) 5D stage (chronic hemodialysis), and Group 2 included 33 (53.2%) patients (37 surgeries) with various forms of knee osteoarthritis without kidney pathology. The average follow-up period in both groups was 3.7 years (min – 1, max – 6). The main characteristics of the patients are presented in Table 1.

Patients in both groups were comparable in terms of the severity of knee osteoarthritis, the extent of preoperative examination, and postoperative management. Patients in both study groups were randomly selected based on the use of implants from a single manufacturer (ZimmerNexGen, Warsaw, USA), but with different degrees of constraint, ranging from cruciate retaining (CR) to varus-valgus constrained (VVC). Fully constrained systems (RHK – rotational hinge knee) were excluded from the study during the group selection process (Table 2).

In both study groups, bone cement with gentamicin (Synicem 1G, 40 g) was used for component fixation.

The average duration of hemodialysis before surgery in patients in Group 1 was 7.7 years (min -1, max -15 years). Hemodialysis procedures were performed no later than 24 h. before arthroplasty to minimize complications related to the cardiovascular system and fluidelectrolyte balance during surgery. The quality of hemodialysis was assessed by calculating the kt/V clearance coefficient, which was 1.34

29) Group 2 (n = 33) Is 37 operations p	Group I (n = 29) 34 operations	Parameter
9 (27.7) – 24 (72.3) –	6 (20.6) 23 (79.4)	Gender, n (%) Male Female
$\begin{array}{c ccccc} & & 66.7 \pm 9.5; 64 \\ \hline 0 & & (60.00 - 76.00) \end{array} & 0.00002 \end{array}$	57.1±8.7; 58 (53.25–63.00)	Mean age, years , M±SD; Me (Q1–Q3)
30.9±4.3 0.00001	23.8±3.1	BMI, M±SD
18 (48.6) – 19 (51.4) –	19 (55.9) 15 (44.1)	Affected side, n (%) right left
34 (91.9) 3 (8.1) -	30 (88.3) 4 (11.7)	Deformation of knee, n (%) varus valgus
8.8; 9 (5/15) 0.00001	15.3; 14 (8/33)	Mean duration of hospital stay, days; Me (min/max)
40.8; 40 (28/51) 0.002	35.3; 33 (21/57)	Morphocortical index of tibial bone (Bernard-Lavallee-Zhentet)*, units.; Me (min/max)
$ \begin{array}{c ccccc} 18 (48.6) & - \\ 19 (51.4) & - \\ 34 (91.9) & - \\ 3 (8.1) & \\ 8.8; & 0.0000 \\ 9 (5/15) & 0.0000 \\ 40.8; 40 \\ (28/51) & 0.002 \end{array} $	19 (55.9) 15 (44.1) 30 (88.3) 4 (11.7) 15.3; 14 (8/33) 35.3; 33 (21/57)	right left Deformation of knee, n (%) varus valgus Mean duration of hospital stay, days; Me (min/max) Morphocortical index of tibial bone (Bernard-Lavallee-Zhentet)*, units.; Me (min/max)

Characteristics of patients

*Reference: Marx V.O. Orthopedic diagnostics. Minsk: Science and Technology. 1978. P. 504-505.

Main characteristics of implants

Table 2

Implant characteristic	Group 1 (n = 34)	Group 2 (n = 37)
Prosthesis fixation method: CR PS (posterior stabilized) VVC	2 (5.9%) 28 (82.4%) 4 (11.7%)	31 (83.8%) 5 (13.5%) 1 (2.7%)
Tibial component modularity: All Poly Metal-back Precoat + stem	7 (20.6%) 24 (70.6%) 3 (8.8%)	29 (78.4%) 7 (18.9%) 1 (2.7%)
Femoral component modularity: Standard femoral component Revision component + stem	33 (97.1%) 1 (2.9%)	37 (100%) 0
Bone defect replacement: Cement Autograft Allograft Metal augment	4 (11.7%) 2 (5.9%) 0 4 (11.7%)	2 (5.4%) 3 (8.1%) 0 1 (2.7%)

for all patients, indicating the adequacy of the dialysates used in the preoperative period.

Both groups of patients received tranexamic acid infusion and thromboprophylaxis according to the new guidelines for the prevention, diagnosis, and treatment of thromboembolic complications in traumatology and orthopedics approved in 2022 [17]. Standard antibiotic prophylaxis for hemodialysis patients, as approved by local regulations, involved the use of protected penicillins in reduced doses and less frequent administration for 5 days after the hemodialysis procedure. Full weight-bearing was allowed only 4-6 weeks after surgery.

The severity of osteoporosis in patients in both study groups was determined by X-ray using the Bernard-Laval-Zhentet morphocortical index. Normal values for this index are within 48±9 units, and a value below 40 units indicated osteoporosis of the proximal tibia.

Table 1

Results assessment

In the preoperative period, the condition and function of the knee joint were assessed using the KSS Function Score [18]. During the clinical examination, tests for varus-valgus stress, Lachman's test, "anterior and posterior drawer tests" were performed, and the degree of osteoporosis was assessed based on standard X-rays and, if necessary, CT data. During surgery, the average duration of the operation, the volume of perioperative blood loss, hemodynamic stability parameters, and the type of constraint of the components based on collateral ligament balance and the integrity of the posterior cruciate ligament (PCL) were evaluated. Functional parameters according to the KSS Function Score were assessed at 6 and 12 months, and then annually. FJS-12 scores after knee replacements were assessed at 12 months and subsequently annually [19]. Radiological criteria for aseptic loosening of components according to the KRESS (Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System) were scored on average at 43 months (min - 13, max - 72) [20]. The frequency of various complications was also assessed throughout the observation period.

Statistical analysis

Statistical data analysis was performed using IBM SPSS v. 20 software.

The normality of the distribution of quantitative parameters, such as age, duration of hospitalization, morphocortical index, body mass index (BMI), duration of hemodialysis, functional knee joint characteristics according

to KSS Function Score, FJS-12, and radiological parameters in KRESS, was tested based on criterion the Shapiro–Wilk (modified bv J.P. Royston). In case of non-normal distribution of related samples, the Wilcoxon test was used; for unrelated samples, the Mann-Whitney test was used. In cases of normal distribution, Student's t-test for related and unrelated samples was used. To assess the significance of the influence of complications on the presence or absence of chronic hemodialysis, the $\gamma 2$ criterion with a likelihood correction and the strength of association according to Pearson's contingency coefficient were used.

RESULTS

The average length of hospital stay differed between the groups. Patients in Group 1, who received hemodialysis three times a week, had a hospital stay that was 1.7 times longer, indirectly indicating higher economic costs for the treatment of one patient.

Functional results based on the KSS Function Score did not statistically differ between the groups in the preoperative period and averaged 48 points (Fig. 1). At 6, 12, 24, and 36 months after surgery, no statistically significant difference in KSS Function Score was observed between the groups. However, by the fourth year after primary knee arthroplasty in the group of patients receiving hemodialysis, the average KSS Function Score decreased to 77.3 points, which is likely due to infectious complications in five patients. In Group 2, only one infectious complication occurred 48 months after arthroplasty.



Fig. 1. Knee function assessed using the KSS Function Score in the study groups over the follow-up period

The assessment based on the FJS-12 at 12–36 months after knee replacement in Group 1 patients averaged 77.04 points (SD = 3.9) (Fig. 2). In Group 2 (without terminal kidney pathology), the FJS-12 was lower, averaging 68.72 points (SD = 4.8). A statistically significant difference (p < 0.0001) in FJS-12 results between the study groups was observed in the first three years after knee arthroplasty. However, no difference was observed between the groups after three years, likely due to an increase in complications in Group 1. The better FJS-12 in Group 1 in the early postoperative period are likely associated with the presence of severe forms of polyneuropathy that develop in the late stages of ESKD, resulting in a sharp decrease in pain sensitivity thresholds. Therefore, any improvement in physical and functional status, as well as the condition of the nociceptive system, leads to better FJS-12 in hemodialysis patients.

Radiological results according to the KRESS at 43 months did not show a statistically significant difference between the study groups (min – 12, max – 72). Table 3 shows the results based on the number of points obtained by counting the lucency lines in different zones at the "bone-implant" boundary on standard X-rays in anteroposterior and lateral views. There was no component migration observed in patients from both groups after primary knee arthroplasty. However, the high number of observations with borderline values (median = 3; 1–7) in Group 1 indicates

an increasing risk of revision interventions in patients with terminal ESKD after TKR. It is also important to note that according to the KRESS, in 89% of cases, lucency lines were detected on the tibial component.

An example of a clinical case of aseptic loosening of the tibial component leading to infectious complications in a patient from Group 1 after primary knee arthroplasty is shown in Figure 3.

Orthopedic complications after primary knee arthroplasty were predictably more frequent in Group 1 (Table 4).

It is important to note that the total number of complications did not differ between the groups, but the lack of statistical significance suggests the need for further research in this direction. With an increase in the sample size and longer follow-up, the frequency of orthopedic complications may statistically differ between patients who underwent knee replacement with terminal stage ESKD and patients without kidney pathology. However, the frequency of PJI was significantly higher among hemodialysis patients. Additionally, in one patient from Group 1, during the implantation of the tibial component, there was perforation of the lateral wall of the tibia due to severe osteoporosis. After an additional assessment of the severity of the periprosthetic fracture, the decision was made to immobilize the knee joint in an orthosis and restrict weight-bearing for up to 6 weeks.



Table 3

Radiological assessment results using the KRESS at an average follow-up period of 43 months

Radiolucent line	Group 1 (n = 34)	Group 2 (n = 37)	р
Less than 4 points – insignificant	23 (67.7%)	34 (91.9%)	0.06
5–9 points – requires dynamic observation	11 (32.3%)	3 (8.1%)	0.05
More than 10 points – component migration	_	_	_



Fig. 3 (a, b, c, d, e). A 32-year-old man with secondary osteoarthritis of the right knee. Concomitant diseases: end-stage chronic kidney disease (5D stage), chronic hemodialysis for 7 years, type 1 diabetes:

a — X-rays in two projections and CT scans before surgery: a bone defect is detected in the posterolateral part of the lateral femoral condyle;

b — knee after arthrotomy;

c — X-rays after knee replacement (a revision femoral component and a standard 100 mm stem; the bone defect was replaced with two metal blocks of 5 mm and 10 mm, posterior-stabilized insert; standard tibial component);

d - X-rays one year after knee replacement: no signs of osteolysis or component instability are observed; e - X-rays of the right knee three years after arthroplasty: radiolucent lines are noted in zones 3, 4, and 2 of the tibial component according to the KRESS (indicated by arrows)

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Fig. 3 (f, g). A 32-year-old man with secondary osteoarthritis of the right knee. Concomitant diseases: end-stage chronic kidney disease (5D stage), chronic hemodialysis for 7 years, type 1 diabetes: f - X-rays 3 years and 7 months after knee replacement (an articulating spacer was implanted); g - X-rays 4 years and 2 months after primary knee arthroplasty (an articulating spacer was replaced with a block spacer due to recurrent infection)

Table 4

Complication	Group 1 (n = 34)	Group 2 (n = 37)	р
Aseptic loosening	0	0	-
Periprosthetic fracture	1 (2.9%)	0	>0.05
Periprosthetic joint infection	6 (17.6%)	1 (2.7%)	>0.05
Residual joint contracture	1 (2.9%)	1 (2.7%)	>0.05
Total	8 (23.5%)	2 (5.4%)	0.05

Structure of complications in the study groups

DISCUSSION

Analyzing the average age of patients in the hemodialysis profile who underwent knee arthroplasty, we found that this value $(57.1\pm8.7;$ Me -58) was significantly lower compared to the average age of patients without end-stage kidney disease (66.7 ± 9.5 ; Me -64 years). This corresponds to the findings of N. Venishetty and colleagues [21]. According to the latest reports from the Swedish Joint Registry, the average age of knee arthroplasty patients is 69.1 ± 9.0 years, in the Joint Registry of England and Wales, it's 70.0 ± 7.0 years, and in the US Joint Replacement Registry, it's 67.2 ± 9.4 years [22, 23, 24].

According to the Vreden National Medical Research Center of Traumatology and Orthopedics joint replacement registry, this value was 63.4 years in 2019, increasing over the past few years [25]. The gender distribution of men and women with degenerative changes in the knee joint receiving renal replacement therapy corresponds to the general population (men – 20.6%, women – 79.4%; ratio 1:5).

Special attention should be given to the data obtained when analyzing the degree of constraint of knee arthroplasty components in patients with a hemodialysis profile compared to patients in Group 2 (see Table 2). According to the Joint Registry of England and Wales for 2022, the frequency of cemented knee replacements with retained cruciate ligaments was 62.7%, posteriorstabilized (PS) was 15.3%, and varus-valgus constrained (VVC) was 1.7% [23]. Similar data is presented in the US Joint Replacement Registry: CR knee replacements – 57.4%, PS – 42.5%, VVC – 0.2%, with a trend of increasing the use of less constrained knee implants in primary knee arthroplasty [24]. Despite the lack of reports in contemporary literature on long-term results of knee replacement using CR and PS systems [26], some studies, such as the work of G. Thuysbaert and colleagues, have reported statistically significant differences in FJS-12 when using CR and PS implants [27]. This largely explains the increasing frequency of less constrained systems in Western European countries. However, in our study, the proportion of CR knee replacements in hemodialysis patients was only 5.9%, PS – 82.4%, and VVC – 11.7\%.

The final choice of constraint level of the knee implant was made intraoperatively in both study groups based on the condition of periarticular soft tissues, collateral ligament elasticity, the status of cruciate ligaments, the degree of osteoporosis, and the presence and size of bone defects. In hemodialysis patients, we observed weakness and hyperelasticity of soft tissues, the posterior capsule, ligaments, and muscles surrounding the knee joint in most cases. These were associated with both concomitant renal myodystrophy and deposits of β -2 microglobulin amyloid fibrils around the knee joint, confirmed by histological studies. Additionally, there was the formation of bone cysts in the intercondylar notch of the femur and/or tibia, also filled with β -2 microglobulin amyloid complexes (see Fig. 4).

Similar results were obtained when analyzing the modularity of the tibial component. Among patients in Group 1 receiving hemodialysis, tibial metallic-backed components were implanted in 79% of cases, and only 20.6% had polyethylene monoblocks, which differs from the usage patterns of tibial components in patients without kidney pathology. The work of K.A. Gustke and colleagues reports more frequent use of polyethylene tibial monoblocks in elderly patients [28]. V. Apostolopoulos and colleagues report better 10-year survival rates of All Poly Tibial implants (97.1%) compared to Metal-back Tibial (93.2%) [29].

In patients in Group 1 who had been on chronic hemodialysis for an extended period, various methods of bone defect replacement were required in 29.4% of cases. Such a high frequency of compensating for bone mass deficiency is due to the formation of bone cysts in the intercondylar notch of the femur and/or tibia, also filled with β -2 microglobulin amyloid complexes. According to G.F. Scheumann and colleagues, the most typical locations for the formation of bone cysts in patients on long-term hemodialysis are the femoral head and neck, spine, distal metaphysis of the radius, and the intercondylar notch of the femur [30].



Fig. 4. View of knee joint in patients receiving hemodialysis after arthrotomy: a — inclusions of β -2 microglobulin amyloid fibrils along the capsule, ligaments, and muscle fibers; b — bone defect of the lateral femoral condyle with adipose tissue and proteinaceous amyloid complexes replacing the bone tissue in the background of chronic inflammation

One of the most common complications of knee replacement is PJI. According to A.I. Stavrakis and colleagues, the frequency of PJI development within 90 days after knee arthroplasty in patients with a hemodialysis profile is 2.66% [12]. In later stages of follow-up, infectious complications in patients on hemodialysis reach 18% or more [9]. In our study, the frequency of infectious complications among patients with end-stage kidney disease after 3.4 years was 17.6%, which is comparable to the literature data. Importantly, we did not observe early infectious complications in the first year after knee replacement, which may be due to both routine use of antibioticloaded cement for implant fixation and an individualized approach to extended antibiotic prophylaxis in this patient category.

CONCLUSIONS

Primary knee arthroplasty in patients undergoing chronic hemodialysis treatment can be classified as primary difficult interventions. This is due to the age and constitutional characteristics of patients in the hemodialysis profile, which significantly differ from patients without kidney pathology. The average length of hospitalization for patients with end-stage kidney disease is 1.7 times longer, and the complication rate was 23.5% during an average follow-up period of 3.7 years. During the first three years, better results were observed in terms of KSS Function Score and FIS-12, which may be attributed to concomitant polyneuropathy, reducing the renal pain threshold, and less demanding expectations regarding the outcomes of knee arthroplasty. undergoing hemodialysis Patients more frequently received more constrained knee implants (PS and VVC) compared to the general population, as well as modular tibial and femoral components. This is associated with the presence of significant systemic osteoporosis and the formation of β -2 microglobulin amyloid complexes along the joint capsule, ligaments, muscle fibers, and the formation of bone cysts in the intercondylar notch of the femur and tibia.

DISCLAIMERS

Author contribution

Tsed A.N. — study design, data collection and processing, literature search and analysis, writing and drafting the article.

Mushtin N.E. — data statistical analysis, literature search and analysis, drafting the article.

Dulaev A.K. — study concept, data analysis and interpretation.

Schmeljew A.V. — data collection and processing, literature search and analysis, writing the article.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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