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Optimizing revision arthroplasty: the role of customized articulating spacers

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Abstract

Introduction The advancement of surgery is set against a backdrop of continuous development and surgical innovations have transformed the way clinical care is delivered. Revision surgery might be required to address complications of primary arthroplasty. The first stage of revision arthroplasty would involve removal of an implant and placement of an antibiotic-impregnated cement spacer to maintain the joint space and stability, prevent soft tissue retraction, provide local antibiotic release and preserve bone tissue for revision implantation at the final stage of revision. Custom-made articulating spacers are a promising tool for optimizing the first stage of revision arthroplasty.

The **objective** was to summarize the current data and present comprehensive information about spacers used in two-stage revision arthroplasty including manufacturing techniques, physical and chemical properties, clinical applications, the possibility of customization within the first stage of revision arthroplasty, current and promising directions for research.

Material and methods The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org), the Cochraine Library (www.cochranelibrary.com) between 2018 and 2023 using search words and phrases: total arthroplasty, complications, revision arthroplasty, articulating spacer, periprosthetic joint infection, additive manufacturing, 3D printing.

Results A comparative analysis of factory supplied, home-made, dynamic and static spacer models showed that the choice of articulating spacers for revision arthroplasty of major joints is of great relevance. Advantages of factory-made spacers include standardized range of sizes, the reliability and availability for medical institutions. They are characterized by limited use in repair of severe bone defects.

Discussion Custom-made articulating spacers enable specific tailoring to accommodate individual defects. Despite high expectations from custom-made spacers, development of optimal technologies for rapid prototyping is essential. Investments in research and development in this area have the potential to create innovative solutions that can significantly improve the results of revision arthroplasty.

Conclusion The paper explores the importance of systemization of knowledge about spacers and the role of new research in improving the design and functionality. Progress in the field of materials science, additive technologies and a personalized approach to spacer manufacturing can expand possibilities of revision arthroplasty and the effectiveness. Personalized approaches and improved methods of local drug delivery that provide controlled release of antibiotics can improve the results of treatment of periprosthetic joint infections.

Keywords: revision arthroplasty, articulating spacer, periprosthetic joint infection

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INTRODUCTION

Total joint arthroplasty is one of the most successful surgical treatments of degenerative diseases of major joints including osteoarthritis (OA) for restoration of the function and biomechanics of the joint [1]. However, patients who underwent primary arthroplasty (PA) require repeated surgical intervention of revision arthroplasty (RA) [2, 3].

New surgical techniques and technologies are developed to improve treatment results. Revision arthroplasty is a key direction in the field of orthopedic surgery and is becoming more important in the context of the increasing number of complications after primary arthroplasty. Periprosthetic joint infection (PJI) is a devastating complication after PA, accounting for 1 to 15.3 % of cases, giving way to aseptic loosening and dislocation of the implant [4]. Two-stage revision arthroplasty is considered to be the gold standard for the treatment of PJI and reported by Insall et al. in 1983 [5, 6]. The first stage consists of removing the previous implant and placement of a temporary implant made of bone cement with the addition of an antibiotic spacer. At the second stage, the spacer is removed and a revision endoprosthesis is placed. In addition to local antibiotic delivery, the spacer is aimed at maintaining mechanical stability of the joint ensuring optimal muscle tension and soft tissue tension, which would play an important role in the final functional outcome and treatment of PJI [7]. In recent decades, articulating individual spacers have been used to optimize the first stage of revision arthroplasty. Spacers can improve the surgical process and the efficiency compared to a one-stage procedure. A personalized approach to the manufacturing of articulating spacers based on individual biomechanical and rehabilitation characteristics of the patient can facilitate a higher degree of adaptation of the treatment process. The practice can improve surgical outcomes and accelerate restoration of joint functionality, which is critical for optimizing overall clinical results.

The **objective** was to summarize current data and provide information about spacers used in two-stage revision arthroplasty, manufacturing techniques, physicochemical properties and clinical use in the first stage of revision arthroplasty.

MATERIAL AND METHODS

The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org), the Cochraine Library (www.cochranelibrary.com) using search words and phrases: total arthroplasty, complications, revision arthroplasty, articulating spacer, periprosthetic joint infection, additive manufacturing, 3D printing. Articles that were most suitable to the topic of the study, containing relevant, significant ideas were selected from the resulting sample. Preference was given to publications brought out between 2017 and 2023 inclusive. We analyzed publications regardless of the language, without restrictions on study design.

RESULTS AND DISCUSSION

Epidemiology

The most common reasons for RA after primary knee arthroplasty are periprosthetic infection (PPI) (25.2–50.0 %) and instability of endoprosthetic components (16.1–36.5 %) [8]. The most common causes of RA reported in the United States between October 1, 2005, and December 31, 2006 included implant infections in 25.2 % and mechanical loosening in 16.1 %, with infection being the most common indication for arthrotomy and removal of the implant (79.1 %) [9]. In Russia, according to a study of 63,750 patients who underwent total knee arthroplasty (TKA), 2,573 patients (4 %)

required revision arthroplasty including 1,747 cases of PJI. The authors reported the inconsistency of accurate data on the number of infected patients due to problems with monitoring of patients who suffered PJI [2]. Epidemiology of PJI after TKA are presented in Table 1. By 2030, revision THA (rTHA) incidence is projected to increase by between 43 % and 70 %, whereas revision TKA (rTKA) incidence is projected to increase by between 78 % and 182 % [10].

A correlation can be seen in epidemiology of PJI in hip and the knee arthroplasties. In the German registry, PJI as the cause RA between 2004 and 2021 were aseptic loosening (49.2 %), infection (21.5 %), dislocation (13.4 %) and periprosthetic fracture (9.2 %) [11–13]. In Russia, the number of rTKA and rTHA caused by PJI was 2.91 % in 2019 [2]. Therefore, PJI is one of the major reasons for revision arthroplasty.

Table 1

Epidemiology of PJI in rTKA reported by different authors

Source of the publication	Period of study, years	Number of patients (*n*)		
		TKA cases	RTKA cases	PJI cases
The Swedish Arthroplasty Register [12]	2009–2018	127 060	4 669	1447
Levašič et al. [14]	2002–2018	10 698	870	109
Nham et al. [15]	2006 – third quarter 2015	5 901 057	465 968	114 721
Sereda et al. [2]	January 2019 – December 2019	63 750	2 573	1 747
Tarazi et al. [9]	01.10.2005 – 31.12.2006	–	60 436	15 233
Ivanov et al. [16]	2012–2016	483	–	39
Kornilov et al. [17]	2001–2016	373	28	4

Among the many treatment options for PJI, revision surgery (revision arthroplasty) is considered to be the best and can be divided into one or two stages [18]. One-stage operation suggests removal of the infected implant to be followed by debridement of soft and bone tissues and reimplantation of a new revision modality [19]. A two-stage RA can be used alternatively. The first stage of surgical treatment consists of removal of the infected implant and placement of a temporary implant made of bone cement and an antibiotic spacer. The main function of the spacer is to arrest the infection and fill in the "idle space" that appears after removal of the endoprosthesis and bone debridement. The second stage includes removal of the spacer and placement of a revision endoprosthesis. The treatment suggests an "intermediate stage" between removal and reimplantation with etiotropic antibiotic therapy administered based on intraoperatively cultured pathogen and its sensitivity to antibiotics. This stage allows for a proper assessment of the effectiveness of antibacterial treatment improving prognosis of treatment outcome through conservative therapy [15, 16]. Despite the recognition of two-stage RA as the "gold standard" for the treatment of PJI, the management is associated with high costs, greater risk of complications, mortality and longer hospitalization [20]. Modern studies indicate a comparable incidence of recurrent infection in one-stage and two-stage rTHA and rTKA, which emphasizes the need for an individual approach to the choice of a particular treatment method [19–22].

Knee and hip joint spacers can be presented in various types and shapes, depending on the manufacturing method and level of articulation [16–18]. Depending on the degree of mobility, spacers are classified into articulating (dynamic) and static (immobile) [23–25]. There is no consensus on which spacers are best to use. Foreign authors report no significant difference in the development of recurrent infection, however, the use of dynamic spacers allows for better functional results

after the second stage of the operation due to a range of motion in the joint. They are more practical for reimplantation, early rehabilitation and reduced length of surgery, and there is a lower risk of postoperative chronic infection and pain observed with static spacers [24–31].

As for a manufacturing method, spacers can be preformed and factory-made. Factory-made spacers are produced by medical companies for temporary use at the affected site [32]. This type of spacer has a specific shape and size that meets standard requirements [33]. Despite their versatility and availability, spacers have advantages and disadvantages. Advantages include standardization and immediate intraoperative use. Disadvantages include limited adaptation to the unique characteristics of each individual case, which may require additional adjustments during surgery (Table 2).

Table 2

Advantages and disadvantages of factory-made spacers [32–34]

Advantages	Disadvantages
— Wide selection of manufacturers — Extensive experience in clinical use — Does not require additional manufacturing steps for intraoperative use — The known mechanical properties and tribological characteristics	— Limited range of sizes — High cost — Short duration of antibiotic release — Cannot be used for various bone tissue defects or severely impaired joint anatomy — High risk of protrusion of the acetabulum — High risk of dislocations — Unstable fixation

Some patients can benefit from customized spacers that match the disturbed anatomy and characteristics of the patient [35–37]. This type of spacer can reduce the risk of secondary deformity, has a high postoperative WOMAC score, but is characterized by a higher cost [35–38].

In some cases, spacers can be made manually by the surgeon during surgery [39]. David et al. report a significantly higher rate of fracture of surgeon-fabricated spacers compared with preformed spacers. The author notes that spacers made by surgeons tend to degrade more aggressively than factory-made ones. This may be due to the method of mixing and delivery of cement during spacer preparation and placement, and disturbed congruence between articular surfaces. The combination of high-dose antibiotic mixing leads to a decrease in the mechanical strength of the spacer. A higher incidence of fractures can be ascribed to the lack of reinforcement with various metal structures [40].

A unique method of manufacturing and designing a spacer can be developed to combine standard techniques and customized components made from metal alloys, silicone, polyethylene and other materials (custom molds). The use of the combined technology provides the spacer with the necessary shape and enhances its mechanical properties, improves fixation, ensuring a reliable connection with bone structures. This increases the functionality of the spacer and reduces the risk of intra- and postoperative complications [35, 39].

Recent scientific advances in the field of medicine have led to the development of 3D printing technology and steady increase in its use in orthopedics [41]. These technologies allow the creation of customized spacers using precise models of the patient's anatomy [42–44]. Additive technologies are used to manufacture articulating spacers for the knee or hip joint; they represent an innovative direction in the field of medical implantation [41, 44]. Each method has advantages and disadvantages (Table 3), and their choice should be based on clinical and individual factors [41–44].

Table 3

Advantages and disadvantages of additive technologies in spacer manufacturing [41–44]

Advantages	Disadvantages
— Manufacturing a spacer of any shape, size and structure — Possibility of topological optimization — Manufacturing with regard to distured anatomy of bone structures and joint congruence, which is not available for factory-made spacers — Rapid prototyping — More stable fixation due to anatomical manufacturing, reinforcement and smaller cement mantle	— Prolonged manufacturing process — The need for specialized equipment and materials for the manufacture of customized spacers — Limited selection of materials

The choice of method for manufacturing knee and hip spacers depends on the specific situation, patient requirements, available resources and surgeon preference to ensure stability and functionality of the joint. Reinforcement suggests introduction of reinforcing constructs inside the spacer to improve the mechanical strength and increase stability increasing the resistance to wear and deformation and contributing to a longer service life. The spacer must survive to stage II RA [13, 45]. Reinforcement is developed for spacers with more complex shapes and constructs that would match the patient's anatomy. Reinforcement can be associated with disadvantages including higher costs of additional materials and an increase in the time and stages of manufacturing. Inadequate reinforcement or incorrect choice of materials can lead to complications, such as injury to the spacer or a fracture due to improper distribution of the load on the bone [46]. So, additional technology or methodology are needed for reinforcing constructs to be properly positioned relative to the spacer. Some types of hip and knee spacers, types and rates of mechanical complications are presented in Table 4.

Table 4

Types of spacer manufacturing and associated complications

Type of reinforcement	Manufacturing	Structural features	Number of spacers	Result	Source
Steinmann rod	Standard mold	The spacer is a femoral component of the implant, which is manufactured using a metal mold with additional reinforcement using a Steinmann rod	26	1 patient (3.8 %) had a spacer dislocation and 2 (7.7 %) had a spacer fracture	[47]
The authors do not report the type of reinforcement	Standard mold	The mold is made of polyoxymethylene	88	Spacer dislocation: *n* = 5 (17 %), spacer fracture: *n* = 9 (10.2 %), femoral fracture: *n* = 12 (13.6 %)	[48]
Steinmann rod	Standard mold	The spacer is a monopolar femoral component manufactured from a coated metal mold	138	Spacer fracture: *n* = 12 (8.7 %), spacer dislocation: *n* = 12 (8.7 %), periprosthetic femoral fracture: *n* = 1 (0.7 %), acetabular floor protrusion: *n* = 1 (0 .7 %)	[49]
Kirschner wire	Custom mold	The spacer is manufactured using a custom mold, which was obtained using additive technologies and computer modeling	1	The authors report a breakage of the spacer, which was associated with trauma (fall)	[38]
Kirschner wire	Mold	A Kirschner wire with a diameter of 5 mm was bent at an angle of 130° and filled with cement using a silicone mold	41	Spacer fracture: *n* = 2 (4.8 %), spacer dislocation: *n* = 3 (7.3 %), periprosthetic fracture: *n* = 1 (2.4 %)	[50]

Table 4 (continued)

Types of spacer manufacturing and associated complications

Type of reinforcement	Manufacturing	Structural features	Number of spacers	Result	Source
–	Factory-made	Factory-made sterilized components of implants used	21	Spacer fracture: *n* = 0, spacer dislocation: *n* = 1 (4.7 %), periprosthetic fracture: *n* = 1 (4.7 %)	[50]
Steinmann rod	Mold	Cement articulating spacers with vancomycin and two Steinmann rods were made using a homemade mold	266	Spacer fracture: *n* = 28 (10.5 %), spacer dislocation: *n* = 10 (3.8 %)	[51]
Implant components	Hand-made	Application of cement with the addition of 4.8 g of tobramycin and/or 4.0 g of vancomycin on the inner surface of the polyethylene liner of the acetabular or tibial component of the implant	54	The authors report no complications	[52]
–	Mold	The articulating spacer of the knee joint is made of femoral and tibial components manufactured using a mold	32	Periprosthetic tibial plateau fracture: *n* = 1 (3.125 %), patellar dislocation: *n* = 1 (3.125 %)	[53]
–	Mold	The spacer consists of femoral and tibial components made using a CR-type paraffin mold	66	Spacer instability: *n* = 3 (4.5 %), spacer fracture: *n* = 2 (3 %), periprosthetic fracture: *n* = 1 (1.5 %), dislocations: *n* = 20 (30 %)	[54]
–	Mold	The spacer consists of femoral and tibial components made using a PS-type paraffin mold	75	Spacer instability: *n* = 1 (1.3 %), spacer fracture: *n* = 2, periprosthetic fracture: *n* = 1 (1.3 %), dislocations: *n* = 1 (1.3 %)	[54]
Metal rod	Factory-made spacer	The spacer is made of acrylic cement impregnated with gentamicin and is a femoral component reinforced with a metal rod	23	Spacer dislocation: *n* = 2 (8.3 %)	[55]
K-wire	Mold	The spacer was a monopolar femoral component manufactured using a silicone mold and reinforced with a 5 mm diameter K-wire angled at 130°	13	Spacer fracture : *n* = 5 (38.46 %), spacer dislocation: *n* = 3 (23.08 %), periprosthetic fractures: *n* = 1 (7.69 %), partial or complete protrusion of the acetabulum: *n* = 3 (23.08 %)	[56]
Femoral component of the implant	Mold	The spacer was made using a silicone mold, but a fully functional femoral component without a head was used as reinforcement	10	Spacer dislocation: *n* = 3 (30 %), partial or complete protrusion of the acetabulum floor: *n* = 3 (30 %)	
Femoral component of the implant and polyethylene acetabular component	Hand-made	Antibiotic cement was applied to the femoral and acetabular components	13	Spacer dislocation: *n* = 1 (7.69 %), periprosthetic fractures: *n* = 1 (7.69 %)	

Reinforcement of spacers is aimed at improvement of mechanical properties, in segments with high axial loads, in particular. However, inadequate positioning, centration, type and shape of the reinforcement construct can lead to increased stress on the spacer or the bone with greater risk of complications including dislocations with the incidence of 4.86–16.4 % for the hip joint [57–59], periprosthetic fractures (1–3 % for the hip spacer), breakage of the spacer (3.0–5.9 %) [60, 61]. The incidence of medial-lateral dislocations and periprosthetic fractures varies between 9.1 % and 12.0 % for knee spacers [62, 63]. The frequency of complications may depend on the type of reinforcing construct, manufacturing technology and type of spacer, whether factory-made or home-made. Sambri et al. reported complications with use of different types of spacers in a systematic review. A total of 1659 spacers were analyzed including 798 factory-made, 301 preformed (made using molds) and 560 hand-made. A higher rate of mechanical complications was observed with preformed spacers 37.2 ± 21.6 %, handmade spacers showed complication rate of 19.2 ± 24.7 %, and factory-made spacers demonstrated 13.8 ± 5.2 % complications. However, no significant difference was found in the incidence of mechanical complications between spacers with and without different types of metal reinforcement: 18.2 ± 18.6 % and 23.2 ± 17.6 %, respectively [64].

Femoral offset adjustment

Adjustment of the femoral offset is an important aspect of revision hip arthroplasty [65]. Each patient has unique anatomy and functional needs, and proper adjustment and determination of optimal offset can improve surgical outcomes [66, 67]. Preoperative examination can help to adjust the femoral offset and plan the procedure. With modern technologies and methods including computer modeling, additive manufacturing and 3D planning, the stages can be faster and more predictable [68]. This can help to minimize errors and improve the results of the operation and restore biomechanics of the hip joint [69–71]. Inadequate adjustment of the femoral offset can result in limb length discrepancy, muscle tension imbalance, impaired load distribution, premature spacer wear and dissatisfaction with functional results [70]. Adequate customization will help the problems with optimal alignment and stability of the joint improving surgical results [71]. The femoral offset can be adjusted during the first stage of revision arthroplasty using a homemade articulating spacer with the femoral component and the head used for reinforcement. As for factory-made hip spacers with adjustable offset, there is no data on the availability of such medical devices.

Release of antibiotics

Prolonged release of antibiotics is an important aspect in the use of spacers in the treatment of PJI [72]. This approach allows for local, sustained release of antibiotics into the joint cavity to provide effective control of infection [73]. Various methods and technologies are used for prolonged release of antibiotics from the joint spacer. Antibiotics can be incorporated into the spacer during manufacturing, whereby the antibiotics are incorporated into the spacer and can be released gradually over time [74]. Antibiotics can be microencapsulated in spacer with microspheres or microbeads containing antibiotics being embedded in the spacer matrix, providing controlled release of antibiotics over time [75]. Reservoirs can be created inside the spacer in which antibiotics are placed, for example, before introducing the spacer into a joint. Coating the spacer with a thin layer of material containing antibacterial drugs is another way to introduce an antibiotic with the possibility of controlling the release of antibiotics over a long period of time [76]. Numerous studies have examined the suitability of different antibiotics for certain types of cement mixtures (Table 5).

Table 5

Concentration of antibiotic release with different types of cement combined

Cement	Antibiotic	Antibiotic concentration (g / per 40 g cement)	Antibiotic release time (μg/ml)					Source
			1 h	1 day	2 days	7 days	Total number of days	
Palacos	Vancomycin	2	–	72	–	6.6	up to 7	[82]
Palacos	Gentamicin	0.5	–	39	–	1.9	up to 7	[83]
Palacos	Gentamicin	1	30.61	–	53.9	–	up to 2	[84]
Simplex	Azertonam	4		1003	–	313.6	up to 7	[85]
Palacos	Voriconazole	8	–	–	–	–	up to 14	[85]
Cemex	Vancomycin	0.15–0.17	–	13.8–40	–	–	up to 1	[63]
ПММА	Moxifloxacin	4	–	–	29.8	27	up to 14	[83]
ПММА	Rifampin	4	–	–	21.7	23.2	up to 21	
ПММА	Meropenem	4	–	–	18	14	up to 14	
ПММА	Cefotaxime	4	–	–	15	11.6	up to 14	

The amount of antibiotic to be impregnated into the cement is one of the most important factors, since excessive amounts can alter the mechanical strength of the cement [72, 77]. The antibiotics are recommended to use in a volume of 10–15 % of the mixture. With greater amount, the mechanical properties of cement can deteriorate significantly. Manufacturers recommend to use 5 % of the mixture weight and the dose would depend on whether the antibiotic is being used to prevent or treat an active infection. A lower dose is used to prevent adverse mechanical effects on the implant and higher doses are required to ensure local prolonged release of the antibiotic during the treatment. For example, a prophylactic low dose is 0.5–1 g of antibiotic per 40 g of cement powder, a therapeutic dose is 1–2 g per 40 g of powder, and a high dose is about 4.6 g per 40 g of powder [77]. Manual addition of vancomycin to a spacer containing gentamicin indicated significantly increased rate of release of both antibiotics with a decrease in the compressive strength of bone cement. Antibiotics combined with polymethyl methacrylate cement is reported as the best strategy to broaden the antimicrobial spectrum. For example, gentamicin, vancomycin and tobramycin are mainly included in cement mixtures due to their ability to act on various gram-positive organisms such as *Staphylococcus aureus*, streptococci and gram-negative bacteria (*Pseudumonas aeruginosa*). Glycopeptides such as vancomycin are commonly used as a prophylactic agent or to treat severe infections caused by Gram-positive cocci. The medicine can effectively inhibit synthesis of the cell wall of gram-positive microorganisms having a bactericidal effect [77].

In recent years, interest has focused on the selection of different antibiotics combined with more than one drug and biomaterials with a particular emphasis on delivery systems such as implant coatings with hydrogels, ceramics, microcarriers, microspheres or nanoparticles [50, 78–80]. Rough surfaces commonly found on metal implants (cobalt-chromium or titanium alloys) have been shown to enhance bacterial colonization if the surface roughness approaches the size of an individual bacterium (1 μm) and inhibit colonization if surface pores are close to osteoblasts in size. Foreign authors reported the factors such as high surface hydrophobicity and low surface free energy, characteristic of cobalt-chromium surfaces being able to prevent the spread of bacteria on the surface [62]. Calcium sulfate is the most common bone graft substitute and can be formed intraoperatively into radiopaque capsules that dissolve at 30 to 60 days.

In vitro studies of antibiotic-loaded calcium sulfate showed superior performance compared to polymethimethacrylate (PMMA) [81]. Cyclodextrin is also used in clinical practice, which is a cyclic oligosaccharide consisting of 6–8 glucose monomers with a hydrophobic inner and relatively hydrophilic outer surface. Cyclodextrin bound to an insoluble polymer containing drugs forms a complex of cyclodextrin inclusions, which contributes to the controlled and prolonged release of the drug [62]. A comparative analysis of factory-made, home-made, dynamic and static spacer models shows a growing need for articulating spacers for revision arthroplasty of major joints in the Russian Federation and worldwide. This can be explained by the annual increase in the number of revision arthroplasties, taking into account the forecasts. Factory-made spacers have advantages, including a standardized range of sizes, reliability and ease of use in medical institutions where there is no technical ability to manufacture spacers. However, they have limitations in patients with severe bone tissue defects. In this context, customized spacers represents a promising direction, since they can be tailored to the unique characteristics of each specific case. Despite high expectations from individual spacers, development of optimal technologies for rapid prototyping remains challenging. Investments in research and development in this area open up the prospect of creating innovative solutions that can improve the results of revision arthroplasty.

CONCLUSION

A personalized approach to manufacturing the articulating spacers is promising and allows for consideration individual characteristics of the patient and selection of the optimal method for prolonged local release of the antibiotic and reinforcement. This goal can be achieved by improving scanning and rapid prototyping technologies to accurately recreate the anatomy of the joint.

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