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A Literature Review**

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Are Preformed Articulating Spacers Superior To Surgeon-made Articulating Spacers in the Treatment Of PJI in THA ? A

Literature Review

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5

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Abstract:

Background and purpose:

Antibiotic-loaded cement spacers are typically manufactured by surgeons in the operating room. However, if the infecting organism is known preoperatively, the

cement spacer can be fabricated (Spacer-G® or the InterSpace® Hip) in advance. It is unclear if preformed hip spacers are superior to surgeon-made hip spacers in the treatment of periprosthetic joint infection following primary THA.

Methods:

A literature review of the peer-reviewed literature indexed by MEDLINE and Embase was performed to identify studies reporting the outcomes of preformed and surgeon-made hip spacers in the treatment of infection following primary total hip arthroplasty (THA). A total of 43 articles met the inclusion criteria and were included in the analysis to compare the reinfection rate, Harris Hip Score (HHS) and spacer complication rates between surgeon-made and preformed hip spacers.

Results and Interpretation:

The analyzed studies included a total number of 1631 infected THA cases (n=1027 surgeon-made; n=604 preformed spacers). We found similar reinfection rates (6.0% surgeon-made, and 5.5% preformed spacers) and similar mean HHS at latest follow-up after reimplantation (HHS=84.3 surgeon-made, and HHS=81.8 preformed spacers) between both groups. However, patients treated with a surgeon-made articulating spacer had a higher spacer fracture rate compared to preformed articulating spacer. The use of preformed articulating spacers in the treatment of infected THA is not superior to surgeon-made articulating spacers regarding infection control and functional outcomes. However, the use of surgeon-made antibiotic spacers increased the risk of spacer fracture.

Keywords: periprosthetic infection, articulating spacer, preformed spacer, surgeon-made spacer

Introduction:

Periprosthetic joint infection (PJI) after total hip arthroplasty (THA) is a devastating complication with infection rates varying from 0.5%-1.4% [1]. The standard of care for treatment of PJI has been two-stage revision arthroplasty with implantation of an

antibiotic-impregnated cement spacer to eradicate the infection prior reimplantation. The cement spacer in the interim period can be classified as either a static/ non-articulating spacers (e.g. traditionally simple cement blocks) or a mobile/articulating spacer. The main goal of the spacer is to provide a local delivery of a high dose of antibiotics directly to the infection site. In addition, an articulating spacer has the advantage over a static spacer of allowing more comfortable motion between spaces, maintaining limb length, preventing contracture and increasing patient comfort during the interval prior to reimplantation.

In the recent years, the use of articulating cement spacers has become increasingly popular in both the hip and the knee following resection. Traditionally, antibiotic-loaded cement spacers have been performed by surgeons intraoperatively using a variety of technique ranging from hand-made techniques using a bulb syringe to fashion a femoral head, to molded systems with or without a metal endo-skeleton to prevent fracture, to a sophisticated multi-size and multi-length spacer system with a large endo-skeleton and a constrained metal on polyethylene articulation to prevent both dislocation and fracture (PROSTALAC, DePuy, Warsaw, IN). However, in cases in which the infecting organisms are known preoperatively, prefabricated cement spacers may be utilized. The first preformed temporary hip spacer system for two-stage revision arthroplasty was Spacer-G (Tecres S. pA., Sommacompagna, Verona, Italy). The Spacer-G contains 1 gm of gentamicin per 40 gms of cement or gentamicin and vancomycin depending on the model preloaded into the cement that makes up the preformed hip spacer. The InterSpace® Hip (InterSpace® Hip, Tecres SpA, Verona, Italy - Hexactech Inc. Gainesville, FL, USA), is identical to the spacer G with the exception of having a stainless steel endoskeleton to help reduce the incidence of fracture.

In 2005, D'Angelo and colleagues performed a study comparing preformed and custom-made spacers with regards to functional outcomes and infection control in 20 patients [2]. The authors concluded, that preformed spacers were superior to custom-made spacer regarding functional outcome and complication rate, while the eradication rate was similar between both groups [2]. Since then, several authors have reported on the outcomes of preformed hip spacers (Spacer-G and InterSpace® Hip) in the interim period of two-stage revision arthroplasty [3-12]. Many of these studies are small case series and it remains unclear if preformed hip spacers are superior to surgeon-made hip spacers in the treatment of periprosthetic joint infection following primary THA. Therefore, we performed this literature review to analyze the outcomes between surgeon-made and preformed articulating hip spacers in the treatment of infected total hip arthroplasty. The goal of the study is to find possible differences in the treatment of periprosthetic hip infection using preformed and surgeon-made spacers.

Materials and Methods:

We systematically reviewed the literature for potentially relevant articles addressing two-stage revision of an infected total hip arthroplasty using the MEDLINE computerized literature databases. Following keyword terms „total hip arthroplasty or

total hip replacement“ and „spacer or spacers“ were used for initial search. The literature search was performed on May 1st 2013 considering all published articles prior to May 1st 2013. The initial search yielded 151 articles. Studies were included if they (1) described patients treated with surgeon-made and prefabricated/prefomed articulating spacers following primary total hip arthroplasty; (2) reported reinfection rates; (3) reported Harris Hip Score after reimplantation and/or complication rates; and (4) follow-up examination of minimum 12 months. Review articles, case reports, letter to the editors or technical notes were excluded from the study. Studies using non-human subjects or in vitro studies including biomechanical studies and studies without the use of antibiotic spacers for two-stage revision for infected total hip arthroplasty were also excluded. A total of 43 articles met the inclusion and exclusion criteria and were included for the analyzes (**Fig. 1**). We excluded 35 case reports, 9 case series (n<7), 7 technical notes, 12 review articles, 10 experimental studies and one brief communication. Furthermore, 15 studies reported on different functional outcomes (Merle d’Aubigné and Postel hip score, JOA hip score and WOMAC score) than HHS were also excluded. The remaining 17 articles were excluded due to follow-up examination of less than 12 months, reported outcomes in patients with fungal or multi-resistant periprosthetic joint infection and patients treated without the use of antibiotic spacers for two-stage revision for infected total hip arthroplasty as well as reinfection cases after two-stage revision for infected THA.

The authors assessed the integrity of the study design and the research methods for each study. The level of evidence (level I-IV) was noted in every study according to the criteria set forth by the Oxford 2011 guidelines for level of evidence [13]. According to these guidelines, there were 3 level II, 4 level III and 36 Level IV studies

(Table 1a and 1b) [2-12,14-45].

Author	Year of publication	Number of cases	Follow-up	Number of reinfections	Eradication rate (%)
Borowski	2012	29	not reported	3	89,7
Ben-Lulu	2012	11	15	1	90,9
Fleck	2011	14	46,3	1	92,9
Zou	2011	15	25	0	100,0
Fei	2011	51	61,4	0	100,0
Peng	2011	34	not reported	0	100,0
Liu	2010	107	34,3	6	94,4
Peng	2010	15	31,2	0	100,0
Dairaku K	2009	10	18	1	90,0
Biring	2009	99	144	11	88,9
Jung	2009	88	54	10	88,6
Kent	2010	15	38	0	100,0
Whittaker JP	2009	41	49	3	92,7
Fink	2009	36	35	0	100,0
Toulson	2009	84	64,8	4	95,2
McKenna	2009	31	35	0	100,0
Incavo	2009	12	24	2	83,3
Diwanji	2008	9	42	2	77,8
Masri	2007	29	47	3	89,7
D'Angelo	2005	8	40	1	87,5
Hoffmann	2005	27	76	1	96,3
Morshed	2005	13	42,6	3	76,9
Durbhakula	2004	20	38	0	100,0
Hsieh	2004	58	not reported	2	96,6
Hsieh	2004	42	55,2	2	95,2
Jahoda	2004	11	not reported	0	100,0
Yamamoto	2003	17	38	0	100,0
Takahira	2003	9	35,7	1	88,9
Koo	2001	22	41	1	95,5
Isiklar	1999	10	23,4	0	100,0
Leunig	1998	12	27	1	91,7
Younger	1997	48	43	3	93,8

Table 1 a: Included studies with surgeon-made articulating hip spacers in the treatment of PJI.

Author	Year of publication	Number of cases	Follow-up (months)	Number of reinfections	Eradication rate (%)
Romano	2012	183	60	10	94,5
Degen	2012	33	43	5	84,8
Neumann	2012	44	67	1	97,7
Romanò	2011	20	56,6	1	95,0
D'Angelo	2011	28	53	1	96,4
Pattyn	2011	61	36	2	96,7
Romanò	2010	40	52,1	1	97,5
Pignatti	2010	41	63,6	0	100,0
Gil Gonzalez	2010	35	32	5	85,7
Romanò	2010	102	48	4	96,1
D'Angelo	2005	12	40	1	91,7
Magnan	2001	10	35	2	80,0

Table 1b: Included studies with preformed articulating hip spacers

Data analysis:

All data regarding the methods and results of each of the articles included in the study were entered into a database and were analyzed. As available literature was

heterogeneous and did not provide complete and quantitative information, a qualitative and descriptive summary of the results was compiled with regard to infection outcome, complication rate and functional outcome using the Harris Hip Score between preformed and surgeon-made hip spacers. Premade spacers are antibiotic-loaded preformed hip spacers. The inner part of the spacer usually contains a stainless steel rod, which is covered by antibiotic loaded cement. The cement is preloaded by the manufacturer most often with 1.9 g gentamicin sulfate [3-12]. Surgeon-made spacers are intraoperatively preformed spacers ranging from hand-made techniques using a bulb syringe to fashion a femoral head, to molded systems with or without a metal endo-skeleton, while in the majority of cases, metal endoskeleton was not used.

Results:

The analyzed studies included a total number of 1631 infected THA cases, 1027 treated with a surgeon-made spacers and 604 treated with preformed spacers (**Fig. 1, Tab. 1**). The mean follow-up for the surgeon-made and preformed groups was at 43.7 months (range, 15 to 144 months) and 48.9 months (range, 32 to 67 months), respectively ($p=0.49$). Likewise, the mean patient age was similar at 63.9 years (range, 52.6 to 73.9 years; $SD=5.1$) and 64.7 years (range, 55.7 to 71.8 years; $SD=5.6$) ($p=0.58$), respectively (**Tab. 1**). The mean time at follow-up examination

($p=0.49$) and the mean spacer duration between stages were also not significantly different ($p=0.15$) (**Tab. 1**).

Regarding functional outcome, we analyzed the preoperative Harris Hip Score and Harris Hip Scores at latest follow-up in the two groups. Similar improvement in Harris Hip Scores was observed in the two groups (**Fig. 2 and Tab. 2**). Preoperatively, there was no difference in the Harris Hip Score between the surgeon-made group and the preformed group at 36.4 (range, 11.5 to 53) and 33.4 (range, 15 to 43.4), respectively ($p=0.53$). At latest follow-up, the mean HHS was 84.3 (range, 68 to 97.8) for the surgeon-made spacers and 81.8 (range, 71.2 to 92.3) ($p=0.5$) for the preformed spacers. (**Fig. 2 and Tab. 2**). We are unable to comment on the HHS between stages because the majority of the studies did not report on this.

Variable	Surgeon made	Preformed	p Value
	Spacers (range)	Spacers (range)	
No. of cases	1027	604	NC
Mean Age (years)	63.9 (52.6-73.9)	64.7 (55.7-71.8)	0.58
Mean spacer duration (months)	5,6 (3-9.4)	4.4 (2.9-5.6)	0.15

Table 2: Descriptive information of surgeon-made and preformed hip spacer studies.

*NC = not calculated. †Significant ($p < 0.05$).

Looking at infection control, preformed hip spacers were also not superior to

surgeon-made hip spacers in the treatment of infected THA (p=0.76). The eradication rate at latest follow-up after reimplantation was 94 % using surgeon-made hip spacers and 94.5 % using preformed hip spacers (**Tab. 2**).

Complications:

The overall spacer complication rate was 12.9 % in both groups, respectively (**Tab. 2, 3**) (p=0.92). However, the spacer fracture rate was approximately 12-fold higher using surgeon-made hip spacers compared to the use of preformed hip spacers (**Tab. 3**) (p=0.01).

Variable	Surgeon made Spacers (range)	Preformed Spacers (range)	p Value
Mean follow-up (months)	43.7 (15-144)	48.9 (32-67)	0.49
Reinfection rate	6.0%	5.5 %	0.76
Preoperative HSS score	36.4 (11.5-53)	33.4 (15-43.4)	0.53
Postoperative HSS score	84.3 (68-97.8)	81.8 (71.2-92.3)	0.50
Spacer complication rate	12.9 %	12.9 %	0.92

Table 3: Clinical data reported in the analyzed studies. †Significant (p < 0.05).

Variable	Surgeon made	Preformed	p Value
	Spacers	Spacers	
Spacer			
Complication rate	12.9 %	12.9 %	0.92
Overall			
Spacer dislocation	7.0 %	12.4 %	0.13
Spacer fracture	5.9 %	0.5 %	0.01

Table 4: Detailed information about the complications related to the surgeon-made and preformed cement hip spacers. †Significant ($p < 0.05$).

Discussion

Two-stage revision arthroplasty for the treatment of chronic periprosthetic joint infection of the knee or hip joint infection is currently considered the universal gold standard. The type of spacer utilized during the interim period can be either an articulating or a static/non-articulating spacer. Articulating spacer has become increasingly more popular as it maintains limb length and patient function/comfort between stages following resection and facilitates the ease of reimplantation.

Historically, spacers have been surgeon made at the time of the operation. This allows for the selection of bacteria-specific antibiotics to be added to the spacer. In the recent years; however, the use of preformed or prefabricated articulating hip or

knee spacers in the treatment of PJI has been increasing in some hospitals. These preformed spacers are preloaded with a set amount of antibiotics and preformed into the shape of the hip spacer. This has the potential to save time in the operating room and facilitates ease of reimplantation. However, Concerns have always remained regarding the amount of antibiotics in these preformed spacers as well as the cost associated with their use.

D'Angelo et al. reported superior outcome of preformed articulating spacers compared to custom-made spacers regarding functional outcome and complication rate, while the eradication rate was similar between both groups [2]. Since then, several authors reported on the outcomes using those preformed hip spacers (Spacer-G and InterSpace® Hip) in the interim period of two-stage revision arthroplasty [3-12]. Most of the studies are limited due to a small number of included cases or due to a relatively short follow-up time.

We therefore performed this analysis to compare the results using preformed and surgeon-made articulating hip spacers in the treatment of PJI.

In contrast to the study by D'Angelo and colleagues, our analysis of large series of both prefabricated and surgeon made spacers showed no differences regarding functional outcome. The analyzed HHS (preoperative HHS and HHS at latest follow-up) were comparable in both groups and as also reported by D'Angelo et al., the eradication rate was similar between both types of spacers. It must be noted that, we are unable to comment on the HHS between stages because the majority of the studies did not report on this.

In addition, our analysis showed a significantly higher spacer fracture rate in the

surgeon made fracture group compared to the preformed spacer group, although the spacer complication rate were identical between both groups. It seems that surgeon made spacers tend to fail in a more “aggressive“ way than preformed ones. This might be based on the “ratherinhomogenous“ way of cement mixing and delivery during spacer preparation and application into the situs. In addition, the combination of high dose antibiotics mixing might counteract the mechanical stability. The higher fracture rate might be due to the absence of a metal endo-skeleton of sufficient strength.

The exception is the PROSTALAC system, which has not had a single report of implant fracture due to the robust nature of its metal endoskeleton and its sophisticated molding system. It should also be noted that while not statistically significant, the preformed spacers had a higher dislocations rate. These preformed spacers may limit the ability of the surgeon to control leg length and offset thus potentially putting patients at risk for instability in the interim stage.

Our study has important limitations. First of all, as with all systematic reviews and/or meta-analyses, the study is limited by the inherent weaknesses of the component studies. Most of the included studies are Level-IV studies characterized by retrospective study designs, limited population sizes, and short- to medium-term follow-up time intervals. Interestingly, none of the included studies were level I or level II studies. Possible reasons of not existing of studies with high level of evidence could be that the technique is often based on surgeons preference and the general availability of pre-formed spacers in each country/region and the definition of clear contraindication for articulating spacers.

It must also be noted that, we did not control for confounding variables such as

comorbidities, body mass index and the infecting organism. Although our study showed a significantly higher rate of fracture for the surgeon made spacer, it should be noted that there can be significant variation in the way the spacers are fabricated among surgeons and this study could not account for those technical differences. For example, some surgeons may choose to utilize the metal endoskeleton to reinforce the cement spacer, and this will minimize the fracture risk.

Despite the drawbacks, our study makes important comparisons between preformed and surgeon-made articulating hip spacers regarding infection control, functional outcomes following reimplantation and complication rates.

In conclusion, our results present no differences regarding infection control and functional outcome at latest follow-up using preformed or surgeon-made articulating hip spacers in the treatment of PJI. However, it must be noted that the spacer fracture rate was higher using intraoperative surgeon-made spacers. Nevertheless, the use of more costly preformed articulating hip spacers should be scrutinized. Furthermore, our study shows the necessity of larger prospective, randomized controlled trials to further elucidate the superiority for periprosthetic joint infection following total hip arthroplasty.

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Conflict of Interest:

The author confirm that this article content has no conflict of interest.

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