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QUESTION 7: Is there a role for intraoperative autoclaving and reuse of an infected prosthesis as a spacer during resection arthroplasty?

RECOMMENDATION: Multiple studies have demonstrated that the reuse of autoclaved prosthetic components during knee resection arthroplasty did not compromise the eradication of an established infection. Though a viable option, there are potential legal implications associated with the reuse of autoclaved components and a proper standard for autoclaving of these components is also not known. Reuse of autoclaved components in resection arthroplasty, particularly for the knee, may be suitable in scenarios when proper dynamic spacer components are not available or for economic considerations.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 82%, Disagree: 12%, Abstain: 6% (Super Majority, Strong Consensus)

RATIONALE

There are multiple types of antibiotic spacers reported in the literature. They are intended to preserve potential space for later reimplantation and to deliver high dose local antibiotics from the cement. Spacers are either static or dynamic. Dynamic spacers allow for motion in the hip and knee, limb length preservation in the hip and at least partial weight bearing during the treatment period. Dynamic hip and knee spacers may be constructed from new components, cement molds, or from autoclaved components matched to new tibial or acetabular inserts. The literature on static vs. dynamic knee spacers is mixed, but there is some evidence that eventual range of motion may be superior with the use of dynamic spacers [1].

The reuse of an autoclaved femoral component (AC-FC) as a spacer in prosthetic knee infections was first described by Hofmann et al. [2]. The clinical data from several subsequent studies supports the reuse of an AC-FC (Table 1), though they are Level III to IV evidence studies and are subject to being underpowered. Hofmann et al. reported on a 2- to 12-year experience using an AC-FC, demonstrating that 44 of 50 patients (88%) had successful reimplantation and were infection-free at latest follow-up [2]. Lee et al. reported that 19 of 20 patients were successfully treated using an AC-FC articulating against antibiotic cement [3]. Anderson et al. reported 25 consecutive knees treated with an AC-FC spacer and found a 4% failure rate with excellent motion and knee scores at final follow-up [4]. Emerson et al. compared patients treated before 1995 with a static cement spacer to patients treated after 1995 with an AC-FC dynamic spacer [5]. At final follow-up, the patients with AC-FC achieved a significantly better mean range of motion (107.8 vs. 93.7°), while there was no statistical difference in reinfection rate: 9% for AC-FC vs. 7.6% for static spacers. Chen et al.reported on a series of 18 patients: 10 treated with AC-FC and 8 treated with static cement spacers [6]. Similar to Emerson et al., they reported better eventual mean range of motion in the AC-FC group (94.5°) vs. the static cement spacer group (74.3°), with no statistical difference in reinfection rate. Jämsen et al. presented a retrospective series of 34 knees: 24 treated with AC-FC and 10 treated with cement spacers that were manually molded [7]. The authors described slightly better functional scores with AC-FC without increasing the risk for reinfection. Kalore et al. reported on a retrospective comparison of AC-FC vs. new femoral components and polyethylene vs. molded cement components in 53 patients [8]. The infection control rates were 66%, 87.5% and 63%, respectively, a difference that was not statistically different in this relatively small sample size. Importantly, the implant cost for the AC-FC group averaged $932 compared to about $3,500 for the other two groups.

To our knowledge, there is only one study on reuse of hip components in resection arthroplasty. Etienne et al. first reported the surgical technique to reimplant the autoclaved femoral stem or

TABLE 1. Summary of clinical studies

Study	Number of Knees	Autoclaving Protocol	Type of Femoral Component	Type of Tibial Insert	Follow-up Mean (Range)	Reinfection
Emerson [5]	48 Knees Study Group (AC spacer): 26 Control Group (Static spacer): 22	AC of FC (undetailed protocol)	Metal-on-PE cemented spacer	New PE insert	Study: 3.8 years (2.6-6.4) Control: 7.5 years (2.8-12.7)	Study: 2/26 (7.7%) Control: 2/22 (9%)
Cuckler 2005 [14]	44 Knees	AC of FC and PE insert for 10 minutes	Metal-on-PE cemented spacer	Autoclaved PE insert	5.4 years (2-10)	1/44 (2.27%)
Hofmann 2005 [2]	50 Knees	AC of FC (undetailed protocol)	Metal-on-PE cemented spacer	New PE insert	73 months (24-150)	6/50 (12%)
Huang 2006 [15]	19 Patients (21 Knees)	AC of FC and PE insert (undetailed protocol)	Metal-on-PE cemented spacer	Autoclaved PE insert	52.2 months (30-102)	1/21 (4.76%)
Jämsen 2006 [7]	32 Knees Study Group (AC Spacer):22 Control Group (Static Spacer):8	AC of FC and PE insert (undetailed protocol)	Metal-on-PE cemented spacer	Autoclaved PE insert	Study: 25 months (2–68) Control: 49 months (2-86)	Study: 2/22 (9%) Control: 2/8 (25%)
Pietsch 2006 [16]	33 Knees	AC of FC and PE insert (undetailed protocol)	Metal-on-PE cemented spacer	Autoclaved PE insert	28 months (12-48)	3/33 (9%)
Anderson 2009 [4]	25 Knees	NA	Metal-on-PE cemented spacer	New PE insert	54 months (24-108)	1/25 (4%)
Kalore2012 [8]	53 Knees Study group (AC Spacer): 15 New FC and PE insert (NFC): 16 Cement-on-Cement (SMCs): 22	FC scrubbed with betadine, then AC (undetailed protocol)	Metal-on-cement spacer	-	39 months Study: 73 months (37-105) NFC: 19 months (12-32) SMC: 32 months (14-56)	Study: 2/15 (13.3%) NFC: 1/16 (6.25%) SMC: 2/22 (9%)
Kim 2013 [17]	20 Knees	AC of FC at 137°C for 7 minutes	Metal-on-PE cemented spacer	New PE insert	22.3 months (14-60)	2/20 (10%)
Lee 2015 [3]	19 Knees	AC of FC at 132°C for 30 minutes	Metal-on-cement spacer	-	29 months (24-49)	1/20 (5%)
Chen 2016 [6]	18 Knees Study Group (AC Spacer): 10 Control Group (Static Spacer): 8	AC of FC at 137°C for 7 minutes	Study Group: Metal-on-cement spacer Control: Static Spacer	-	Study: 32 months (24-46) Control: 40.8 months (25-56)	Study: 2/10 (20%) Control: 1/8 (15%)

AC, autoclave; FC, femoral component; PE, polyethylene; SMCs, Silicon molded compnents

an inexpensive femoral stem with a new acetabular liner [9]. They published excellent results in 31 of the 32 patients; however, information on the number of patients receiving a resterilized stem and details of the autoclaving protocol were lacking.

There are questions about the ultimate sterility of autoclaved components because of the few studies directly examining the technique. Lyons et al. cultured swabs from six explanted femoral components both before and after a 45-minute autoclave cycle at 121°C [10]. Autoclaving was able to kill the majority of multiple bacterial species of both the planktonic and biofilm phenotypes on the surface of smooth cobalt and chromium (CoCr) material. The six sterile components were then inoculated with various organisms and the tests were repeated; again, no organisms grew after autoclaving. Additionally, electron microscopic analysis of the inoculated specimens demonstrated a dramatic decrease in biofilm after autoclaving. However, the study used relatively immature biofilms (only 24 hours of growth), whereas biofilm formation in vivo likely occurs over multiple days, if not months, on an implant surface. Leary et al. reported that autoclaving at 121°C for 30 minutes was not able to remove biofilms of *Staphylococcus aureus* or *Staphylococcus epidermidis* from the surface of CoCr discs, but that pre-treatment with a 4% chlorhexidine gluconate scrub brush did successfully remove all biofilm [11]. Additionally, in a more recent study, Williams et al. evaluated different flash autoclave temperatures and durations to remove monomicrobial and polymicrobial biofilms of eight days of maturation [12]. Although ten minutes of autoclaving at 132°C rendered all biofilm nonviable by culture, residual biofilm did remain on the titanium materials studied. The clinical importance of remaining nonviable biofilm is unclear, especially when translating these results from titanium material to the CoCr implants used with AC-FC. The use of 4% chlorhexidine gluconate scrub, as shown by Leary et al., may solve this potential problem [11].

All series in this area are small and subject to Type II error; however, the clinical literature taken as a whole consistently suggests equivalent infection eradication between the different strategies, including use of an AC-FC. Additionally, the laboratory study by Lyons et al. demonstrates the effectiveness of autoclaving at a microbiological and microscopic level [10] and the addition of a chlorhexidine scrub prior to autoclaving may further eliminate the potential for nonviable biofilm remnants [11]. While the available clinical evidence and cost-effectiveness of AC-FC make it an intriguing treatment option, many hospitals are restricting the reimplantation of hip and knee components after autoclave resterilization. The Centers for Disease Control and Prevention (CDC), Association of perioperative Registered Nurses (AORN), health care institutions, implant companies and medical consultation teams are understandably hesitant to temporarily reuse implants for medical, legal and financial reasons [10]. In 2016, a directive released by the Department of Veterans Affairs stated that nonbiological implantable devices are not to be sterilized by flash autoclave and should be used primarily in cases of emergency [13]. Given these restrictions, the AC-FC technique may be most appropriately utilized when proper dynamic spacer components are unavailable or when economic circumstances make it necessary. Future studies to standardize sterilization protocol and spacer techniques with larger patient series should be performed.

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QUESTION 8: Is it necessary to revise or reduce dislocated articulating antibiotic spacers?

RECOMMENDATION: Unless the spacer is pressing against the skin with imminent necrosis/ulceration, resulting in severe, progressive loss of essential soft tissue or bone, neurovascular compromise or notable pain and disability for the patient, a dislocated or fractured antibiotic-impregnated cement spacer is safe to leave in place until definitive second-stage surgery.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 89%, Disagree: 8%, Abstain: 3% (Super Majority, Strong Consensus)