Handmade Articulating Antibiotic-Impregnated Spacer Production Techniques

Kabiru Salisu^{1*} and Fatih Küçükdurmaz²

¹Department of Surgery, Kaduna State University, Kaduna, Nigeria. ² Orthopaedics and Traumatology, Department of Orthopaedics and Traumatology, Istinye University, Istanbul, Turkey.

*Correspondence: Dr Kabiru Salisu. Department of Surgery, Barau Dikko Teaching Hospital Kaduna, Nigeria. **Email**: Kabiru.salisu@kasu.edu.ng Tel: +2348039277879

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ABSTRACT

We demonstrate the technique of Handmade Articulating Antibiotic Impregnated Spacer (HAAIS) with better anatomical conformity, flexible Antibiotic selection and less costly. The fabrication starts with preoperative sizing of the possible defect, fabrication of k-wire endoskeleton/sterilization, and antibiotic selection based on bacterial sensitivity. Following the debridement and removal of the infected prosthesis, the HAAIS is moulded to conform to the defect obtained. The cement powder was mixed thoroughly with antibiotics before adding the monomer and mixing. The cement is moulded over the K-wire endoskeleton to the required size. The spacer is then pressed fit after curing or shortly before curing is completed. The joint function and muscle action are preserved with post-operative physiotherapy. Control of infection in the management of prosthetic joint infection (PJI), joint mobility, and partial weight-bearing ambulation was achieved using this method.

Keywords: Handmade Antibiotic Spacer, Spacer Preparation Technique, Prosthetic Joint Infection

INTRODUCTION

Prosthetic joint infection (PJI) is a devastating complication of arthroplasty to both surgeon and patient. It also poses a great economic burden to the healthcare system. The prevalence of PJI ranges between 1-2% following primary arthroplasty,¹² and higher incidences were reported following revision arthroplasty.³⁴

Time-bound classification of PJI by Tsukayama et al³ is the most widely used. Acute PJI (early post-operative infection and acute haematogenous

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Website: www.jmbsr.com.ng eISSN: 2971-7833 pISSN: 2971-7108 [€] 10.5281/zenodo.8088250 infections) have immature biofilms and infection can be treated by debridement retention of implant and change of mobile part.⁶ Chronic PJI is difficult to eradicate due to established biofilms and is managed by either one-stage or two-stage revision. One-stage revision involved the removal of the old implant, debridement and reimplantation of a new prosthesis in one seating. This is considered in patients with No difficult to treat infection, no sinuses and good bone stock. High success rates

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Two-stage revision involves the removal of the old prosthesis and delayed reimplantation of the new implant, with up to 80 - 90% success rate.⁸⁹ It is suitable for patients that have compromised soft tissues or bone stock and in patients with difficultto-treat or unknown infections. It is identified as the gold standard for the treatment of these patients.¹⁰ The first stage of this revision involves thorough debridement, wound irrigation, removal of implants and application of antibioticimpregnated spacers. Spacers are used for dead space management, to maintain tissue tension and also to deliver antibiotics locally. To the best of our knowledge, there are fewdescriptions of the fabrication technique of Handmade Articulating Antibiotics Impregnated Spacers (HAAIS)."In this review, we aimed to discuss and demonstrate a production technique of handmade antibioticloaded spacers with K-wire endoskeleton in the treatment of PJI.

Classification of Spacers

The spacers can be classified in different ways; hand-made or pre-fabricated based on their production method and also as articulating and static spacers based on their structure. Hand-made spacers have some advantages over pre-fabricated such as; anatomical conformity, the flexibility of antibiotic selection and dosing, availability and more suitability for resource constraint settings due to their lower cost.²⁰⁰ On the other hand, prefabricated spacers have smooth articulating surfaces and a better range of motion.

Handmade Spacers

These types of spacers are made intra-operatively by mixing selected antibiotics with bone cement and moulding them over the endoskeleton. Handmade spacers have the advantage of anatomical conformity in a setting of a bone defect; it allows flexibility in antibiotic selection, combination and dosing. "Handmade spacers have the disadvantage of being time-consuming, it requires a learning curve and experience. Handmade spacers could be purely hand moulded or by use of commercially available moulds. Different types of mould are commercially available but may be short of anatomical conformity in the presence of a bone defect.

Pre-fabricated Spacers

Pre-fabricated spacers are produced in limited sizes and designs. Therefore, the available sizes are not always compatible with the existing bone structure not only in dimensions but also in shape. Also, it contains only one antibiotic with a fixed dosage. The relatively higher cost might be considered another disadvantage.¹⁵However, the pre-fabricated spacers allow for a better range of motion in the joint. It saves operation time during implantation and removal.

Hybrid Spacers

The spacers with hand-made extensions on prefabricated spacers are called hybrid spacers. Hybrid spacer achieves anatomical conformity and increased stability with preserved smooth articulating surface of pre-fabricated spacers. The major disadvantage is the difficulty during removal due to increased stem length, associated with the risk of fracture of the bone.

Static and Articulating Spacers

Spacers can also be classified as non-articulating (Static) or articulating (mobile) spacers. The static (non-articulating spacer is suitable in patients with compromised soft tissue coverage, ligament laxity and extensor mechanism insufficiency.¹⁶ Static spacer maintains the joint space, rests inflamed soft tissues and delivers antibiotics; however, it does not allow the physiologic function of the joint, leading to contracture, difficulty in exposure during second surgery and unexpected bone loss.¹⁷ Articulating spacers allow for movement at the affected joint, it has the advantage of preserving

affected joint, it has the advantage of preserving joint function, less pain and easier post-operative rehabilitation, it also prevents soft tissue scarring around the affected joint, muscle shortening, capsular stiffness and contracture but has a higher risk of dislocation and spacer fracture. Bearing surfaces in articulating spacers could be cementon-cement, cement-on-polyethylene or cementon-metal^{18,19}

COMPOSITION OF THE HANDMADE SPACER

Spacers are made of acrylic cement (Polymethylmethacrylate, PMMA), which is also known as bone cement. It comes in the form of sterile powder (co-polymer) and a liquid monomer which are mixed to form PMMA in an exothermic reaction with a curing temperature of 60° – 80° C.²⁰²¹ Spacers also contain antibiotics that are in powdered form, a broad spectrum bactericidal or bacteriostatic with a low risk of adverse effects. The antibiotics to be added to the spacer have to be thermostable, not degraded due to the heat produced during the exothermic reaction. Also, the mechanical properties can be affected by the antibiotics in the cement.

As the porous structure of the cement increases, the amount and duration of antibiotic release also increase. Unlike the cementation technique, while preparing the spacer, mixing in a vacuum-free container and by hand is recommended. Thus, the bubbles formed to increase the porosity and facilitate the release of the antibiotic.²²Although the

 Table 1. Suitable Antibiotics and antifungal

 for Spacers Production^{24, 25, 26}

Antibiotics	Low Dose	High Dose
	(g/40g of cement)	(g/40g of cement)
Vancomycin	1	3-9
Tobromycin	1.2	2.4 - 9.6
Amikacin	1	2
Clindamycin	1-2	4-8
Erythromycin	1-2	4-8
Cefuroxime	1.5	3
Cefazolin	1-2	4-8
Meropenem	0.5	4
Amphotericin B	0.2	1
Voriconazole	0.3 - 0.6	1.5

success rate is relatively lower, the PJI with fungal microorganisms can also be treated using antifungal-loaded bone cement.²³ Table 1 shows Suitable Antibiotics and antifungals for Spacers Production.



Figure 1. Different types of endoskeleton A, unipolar endoprosthesis. B, Kuntscher nail C, Kirschner wire

The spacers also require an endoskeleton which serves as structural support for the spacer. Kirschner wires (K- wires), small unipolar endoprosthesis, Kunscher nail (Figure 1), dynamic hip screw/side plate, intramedullary nail and Schanz screws are used to produce the endoskeleton, endoskeleton was proven to add strength and assist the function of the spacers.²⁷

TECHNIQUE FOR PRODUCTION OF HANDMADE SPACERS Preoperative Planning

Preoperative planning for the first stage of debridement and spacer implantation is required for the selection of antibiotics according to identified microorganisms and sensitivity. If it is a culture-negative PJI, then a broad-spectrum antibiotic is selected.

Although plain radiographs help estimates the size and shape of the spacer, one has to be aware that the bone stock can change during the surgery. Therefore, the definitive shape of the spacer cannot be prepared preoperatively.

ENDOSKELETON PREPARATION

Endoskeleton serves as the structural support for the cement which prevents the breakage of the spacer as well as preserves the integrity of the spacer during removal. Although the definitive shape of the spacer can't be given preoperatively, the k-wire endoskeleton should be prepared before the operation based on the size and design of the infected prosthesis.

Hip Spacers

The endoskeleton for hip spacers was made with kwire (2.5 - 3.0 mm diameter), and a circular shape is given to the proximal side of the k-wire which is for the head of the spacer. The neck-shaft angle of 125-135 degrees was factored in (Figure 2Aiii). The length of the removed stem and any medullary defect determines the length of the stem and the kwire in it. The distal end of the k-wire stem should be curved and folded on itself to aid the en-bloc removal of the spacer (Figure 2A and B i-iii).



Figure 2. A & B showing two types of hip endoskeleton production stages Knee Spacers

The knee spacer endoskeleton was made taking into consideration of the sizes and shapes of both the femoral and the tibial components of the prosthesis (Figure 3A and B) respectively. Endoskeleton should be made with k-wire (1.8 - 2.0 mm diameter). The stem of the tibial endoskeleton was placed more eccentric toward the anterior aspect to prevent anterior overhanging of the spacer (Figure 3Bii) that results in bump and pain.



Figure 3. A i - iii Femoral component endoskeleton, B i - iii Tibial component endoskeleton stages

Spacer Moulding

Two grams of vancomycin per 40g of cement was mixed thoroughly before the addition of liquid monomer, mixing continued to ensure homogeneous antibiotic distribution. Hand mixing is associated with high porosity of the cement and is noticed to have better elusion properties than vacuum mixing.²⁸Hand moulding was used and the entire bony defect should be taken into account. The explanted prosthesis should be used to guide good sizing. Articulating surfaces should be as smooth as possible.

The hip spacer was moulded in form of a unipolar endoprosthesis. The head of the hip spacer was moulded as closely as possible to the size of the acetabular shell.

The knee spacer was moulded for both components (Figures 4c and d). Femoral and tibial parts are prepared separately. The size of the polyethylene insert should be factored in while moulding the vertical width of the knee spacer. Cement - on - polyethylene surface can be made after resterilizing the polyethylene insert and incorporating it into the tibial component during moulding but this is associated with a significant increase in surgery time.



Figure 4. a,b- Two views of knee spacer endoskeleton using 2 mm diameter K-wire for both tibial and femoral components. c,d -Molded tibial and femoral spacer components

The stability of spacers on the bone should be achieved as much as possible. The spacers are inserted manually, after it is cured, gentle tapping with a mallet can be done to achieve the correct placement of spacers. The space may require some trimming if there is difficulty in insertion to prevent excessive stress and fracture of the bone. Figures 5a and b showed the knee space after insertion and post-operative radiograph respectively.

Another method to give a suitable size and shape may be to insert the spacer into the bone a short time before it is cured so that it is moulded according to its original space.



Figure 5. a, the knee after insertion of the spacer. b, AP and lateral post-operative radiograph.



Figure 6. a, Hybrid spacer size of existing prosthesis. B, Post-operative radiograph showing good dead space conformity and the extended endoskeleton.

Hybrid Spacer Moulding

The bone defect is accurately understood after the removal of all components. Pre-fabricated spacers usually have poor anatomical conformity in cases with bony defects. Especially, when there is a major defect, the size of the fabricated spacers may not be enough.

The antibiotic-loaded bone cement is prepared as above using the same antibiotic in a pre-fabricated



Figure 7. The patient after application of the knee spacer, notes the level of active knee flexion and weight bearing.

spacer or another synergistic antibiotic. The prefabricated spacer is then augmented taking account of the size of the existing implant and bone defect. Moulding is done over a K-wire looped around or by the side of the pre- fabricated spacer (Figures 6a and b). This augmentation may be necessary to take care of more dead space and improve stability.

Post-operative care

Partial weight bearing using a walking aid was allowed under the physiotherapist's guidance as soon as tolerated. Physiotherapy was suggested to the patients to preserve muscle function and joint range of motion. Targeted antibiotics therapy based on the culture result was commenced for 4-6 weeks. Monitoring of the patient with clinical and biochemical markers was done to determine the timing of the re-implantation, which should not be considered before 6 weeks. Figure 7 shows a postoperative clinical picture of a patient with a right knee spacer.

Removal of Spacer

Spacers should be removed en-bloc during the second stage surgery in the same manner the original implants are removed, however, removal could be difficult due to cement bone interface tightness from bony ingrowth or extensive soft tissue fibrosis. Stiffness of the joint may cause difficulty removal of antibiotic spacers. Piecemeal removal might be the only option in some cases, Osteotome, mallet, wire cutter and sequestrum forceps are required to break and remove the cement spacers in piecemeal.

Complication of Spacers

The most common complications of spacers include breakage or dislocation of the spacers (Figure 8A&B), bony erosion due to its motion, joint stiffness and antibiotic toxicity. The periprosthetic fracture may occur while inserting unfitting spacers or during removal, thus spacer trimming should be done in case of difficulty in insertion.²⁹ Spacer breakage dislocation or bony erosion usually doesn't require any active

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Figure 8. A, fractured spacer. B, dislocated space

intervention before the second stage surgery; nonweight-bearing ambulation suffices in most cases but may require special preparation before the second stage procedure.

Other Uses of Antibiotic Spacers

Dead space management in chronic osteomyelitis

Bony and soft tissue defects following debridement in the management of chronic osteomyelitis can be managed by the application of antibiotic-impregnated spacers. This enhances the eradication of infection by eluding high doses of antibiotics locally. It can be in the form of a handmade spacer or a preformed antibiotic bead. The hand-made spacer conforms to the dead space and gives more support to the bone, with high eradication of infection.^{30,31}

Induce Membrane (masquelet) Technique

This is a two-stage technique in the management of bone defects, it is also employed in the treatment of infected nono-union and chronic osteomyelitis. The masquelet technique involves the induction of membrane formation and cancellous bone grafting.³²In The first stage, the defect created following debridement is filled with an antibiotic-impregnated spacer, that result in the formation of a bioactive membrane within 4-8 weeks around the spacer which also eludes antibiotic that clears the residual infection. A cancellous bone graft is applied to the membrane after the removal of the spacer in the second stage.^{33,34}

CONCLUSION

Handmade articulating antibiotic-loaded spacer production using a k-wire endoskeleton has anatomical suitability, freedom of antibiotic selection and maintains joint function. We suggest this option in two-stage chronic PJI management.

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