A Novel 3D Printed Custom Antibiotic Spacer Mold for Osteomyelitis Cases which are Prone to Instability

Instabiliteye Yatkınlığı Olan Ostemyelit Vakaları için 3 Boyutlu Yazıcı ile Hastaya Özel Antibiyotikli Spacer Üretimi ve Uygulaması

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ABSTRACT

Presence of complex bone defects in osteomyelitis treatment may be challenging for the surgeon. Antibiotic cement spacers take a role in managing these defects. The available techniques and systems of antibiotic cement spacers have their pros and cons. There are cases in which these standard options may fail, mainly due to stability related issues. In this report, we present an antibiotic spacer technique in a very complex bone defect that is prone to failure if managed by routine spacer applications. Anticipating that any standard spacer application methodology will fail, we decided to make our own custom antibiotic cement spacer. We used the patient's uninjured side's tomography data to create a custom 3D spacer mold model with the help of a computer software. Later this 3D spacer mold model was printed with a 3D printer. The print out was sterilized and used to cast a custom antibiotic cement spacer resulting in a perfect fit in the defect.

Key Words: Patient specific, 3D print, antibiotic spacer, osteomyelitis, prosthetic infection

Received: 03.03.2018 **Accepted:**05.01.2018

ÖZET

Osteomyelitin cerrahi tedavisi eşlik eden büyük kemik defektlerin bulunması durumunda çok zor olabilir. Antibiyotikli çimento spacerları kemik defektleri belirgin vakaların yönetilmesinde sıklıkla rol oynarlar. Standard antibiyotikli çimento spacer yöntemlerinin kendilerine göre avantaj ve dezavantajları mevcuttur. Ancak, özellikle instabiliteye yatkınlığı bulunan vakaların yönetimi konusunda standart antibiyotikli spacer uygulama yöntemleri mekanik problemlere yol açabilmektedir. Bu vaka takdiminde ekleme yakın ve majör kemik stok kaybı nedeniyle instabiliteye aşırı yatkınlığı bulunan hastamıza uyguladığımız yenilikçi bir antibiyotikli spacer tekniğinden bahsediyoruz. Hastamızda bulunan majör kemik stok kaybına sekonder gelişebilecek mekanik problemlerin üstesinden gelebilmek için tamamen hastaya özel bir antibiyotikli spacer üretmeye karar verdik. Bilgisayar yazılımı ve tomografi verileriyle, hastanın sağlam tarafının anatomisinden esinlenerek, defektli tarafa bire bir uyum sağlayacak bir spacer için 3 boyutlu bilgisayar modeli oluşturduk. Sonra yine bilgisayar yazılımı yardımıyla bu spacer modelini üretmemizi sağlayacak 3 boyutlu bir kalıp modeli tasarladık. Bu kalıp modeli 3 boyutlu yazıcıda üretildikten sonra elde edilen fiziksel kalıp sterilize edildi. Ameliyat esnasında kalıba antibiyotikli çimento dökülerek hastanın defektine mükemmel uyum sağlayan bir antibiyotikli çimento spacer elde edildi.

Anahtar Sözcükler: Hastaya özel, 3 boyutlu yazıcı, 3D yazıcı, antibiyotikli spacer, osteomyelit, protez enfeksiyonu

Geliş Tarihi: 03.03.2018 **Kabul Tarihi:**01.05.2018

INTRODUCTION

Antibiotic-impregnated bone cement application is the most preferred type of treatment in osteomyelitis cases (1). Antibiotic embedded cement beads chain and various cement spacers are utilized to release antibiotic from cement (2). Both methods help the surgeon accomplish high local levels of antibiotics for prolonged times which cannot be accomplished by parenteral antibiotics. Doing so, it also minimizes the risks of high dose parenteral antibiotics' side effects (3).

Many ways of producing a cement spacer have been advocated (2,4-6). Hand forming the desired shape from viscous, slippery and dough like cement is hard to accomplish. Moreover, handmade spacers are more prone to loosening, breakage, and instability, limiting the use of handmade spacers (7,8).

To cover this issue commercially fabricated spacers have been advocated. It is for sure these commercial spacers save a lot of effort and operating room time. However, these ready spacers come with their own cons. Firstly, these spacers are almost always manufactured with only gentamicin premix with no way of adding other antibiotics. Secondly, and maybe as a more important factor, there are cases that a standardized form and size will not fit a specific defect, which may risk the stability and hamper the treatment (7).

The ideal cement spacer must be strong enough to not to break and stable enough to stay in its original position throughout the treatment course. However, defects always come in different shape and sizes and in different anatomical regions. Reconstruction of complex defects with cement beads or handmade spacers and even commercial spacers may and do cause stability issues (7,8).

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doi:http://dx.doi.org/10.12996/gmj.2018.71

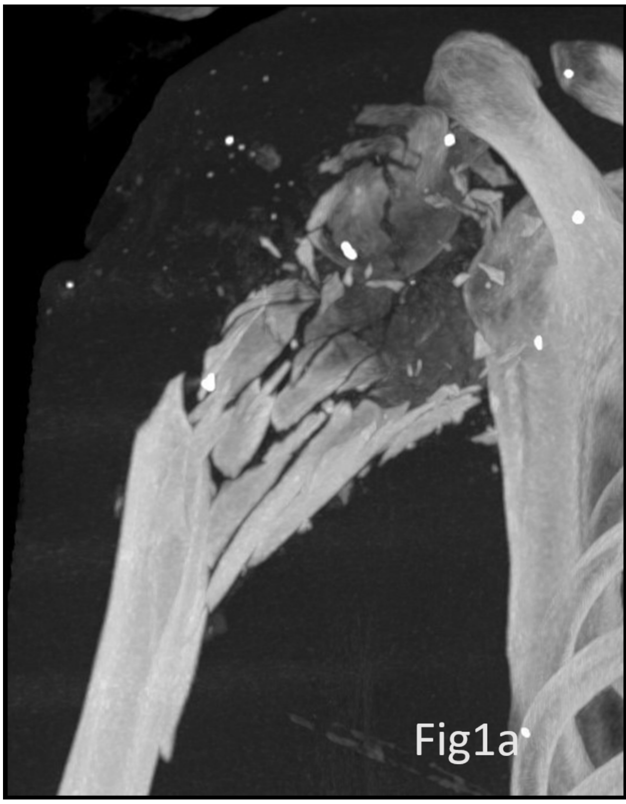
In this report, we present an antibiotic spacer technique in a very complex bone defect that is prone to failure if managed by routine spacer applications. Anticipating that standard spacer application methodology will fail, we decided to make our own custom antibiotic cement spacer. We used the patient's uninjured side's tomography data to create a custom 3D spacer mold model with the help of computer software. Later this 3D spacer mold model was printed with a 3D printer. The print out was sterilized and used to cast a custom antibiotic cement spacer resulting in a perfect fit in the defect.

CASE REPORT

Prior to preparation of this paper written consent for publication has been obtained from the patient. Our patient was a 32-year-old male with a Gustilo-Anderson grade 3A open right proximal humerus fracture because of a bombshell injury.

He administered to our hospital 15 days after the injury (Fig1a). His fracture showed advanced comminution of the proximal half of the humerus along with deep infection of polymicrobial origin with the destruction of the humeral joint surface and any muscular attachment to the proximal half except for deltoid muscle. His neurovascular examination including the sensation of skin above deltoid muscle mass to assess axillary nerve function revealed no pathology.

The treatment started with debridement of the wound for removal of foreign bodies, devitalized tissue and bone fragments along with parenteral wide spectrum antibiotics. Vacuum-assisted wound closure was preferred to facilitate wound healing and granulation. Tissue cultures isolated Enterobacter cloacae and Corynebacterium species as the infection cause. He was brought to operating room repeatedly for serial debridement and vacuum assisted wound dressing changes. Meanwhile, he was being checked for infectious parameters about every five days. After seven consecutive debridements, we were left off with a very complex defect, necessitating an antibiotic spacer to enhance limb alignment and eradication of infection (Fig1b).



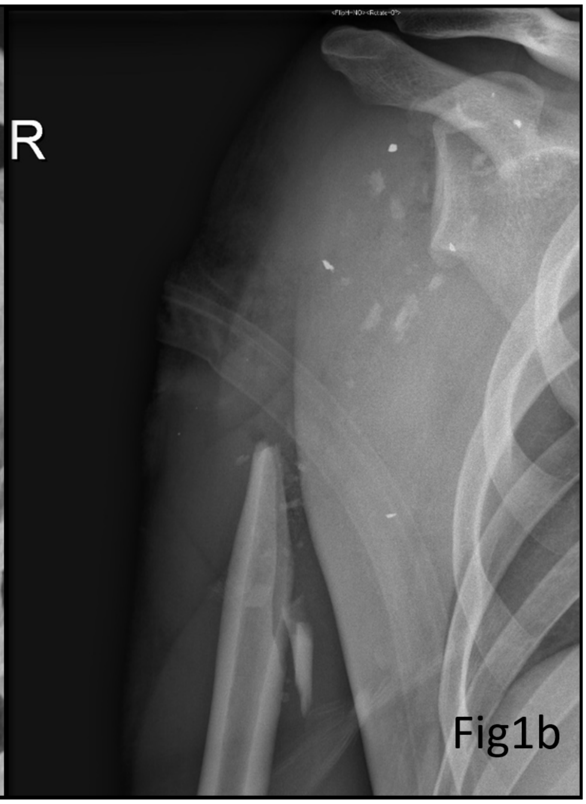


Figure 1a. Tomogram of the injured humerus.

Figure 1b. X-ray showing the left off defect in injured humerus.

There were two good reasons to think that the antibiotic cement spacer application was prone to failure with a standard approach and routine planning. The first of which is that glenohumeral joint is a very shallow ball and socket joint which is mainly dynamically stabilized by ligaments and muscle attachments which were totally lost to our patient. The other reason was that the defect was very large, reaching the shaft of the humerus. This results in the magnification of forces acting upon spacer because of a longer lever arm effect, which in return would jeopardize the stability of the spacer. Thus, we were quite sure that any commercial spacer or technique to make one would not do any good. We decided to develop a totally customized cement spacer to optimize limb alignment and stability for a prolonged time.

We used patient’s uninjured humerus computerized tomography data to fabricate a spacer which would resemble conformity to the remaining injured humerus. Advantages of such a spacer would be that, it would fill the void left by the defect seamlessly promoting stability, it would be durable and lastly, it could contain any antibiotic that was needed for the infection eradication.

We used medical imaging and graphics software to produce a 3-dimensional (3D) model of a mold which could then be 3D printed and used to fabricate an effective custom cement spacer in the operating room. First bone tissue was separated from other tissues in uninjured side’s CT (US-CT) and injured side’s CT (IS-CT). Later, US-CT images were mirrored and registered over IS-CT images layer by layer to match each other in 3D dimensional orientation. Afterward, IS-CT graphical bone details were graphically erased from US-CT scenes again layer by layer. This left us with the body of the spacer in a layered format. Finally, the stem piece was added to the body of the spacer manually and the layered format of the common CT computer file was converted to a 3D computer model completing the spacer model (Fig2a).

Thereafter, the 3D computer model of the custom spacer was subtracted from a rectangular prism computer model leaving the rectangular prism engraved with the custom spacer’s 3D form. The rectangular prism was bisected longitudinally to resemble both halves of a mold (Fig2b) and finally, both halves of the 3D mold model were printed commercially with an EOS M 280 model 3D printer from polyamide material. PA2200 is the generic name for the material which is biologically safe with a melting point of 172°C. The output of the printer was autoclaved and used as a mold to cast the anatomic antibiotic cement spacer.

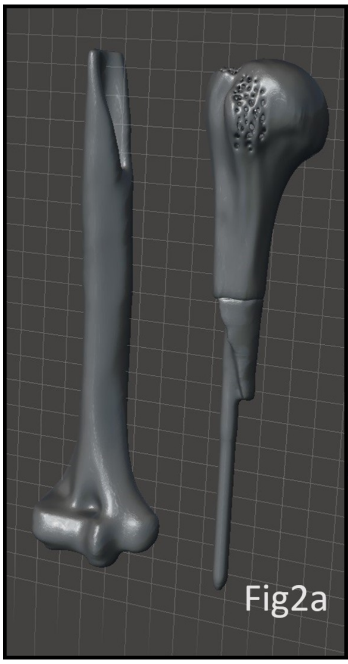


Fig2a Image showing the 3D spacer computer model (injured humerus model was also loaded for comprehensive purposes).

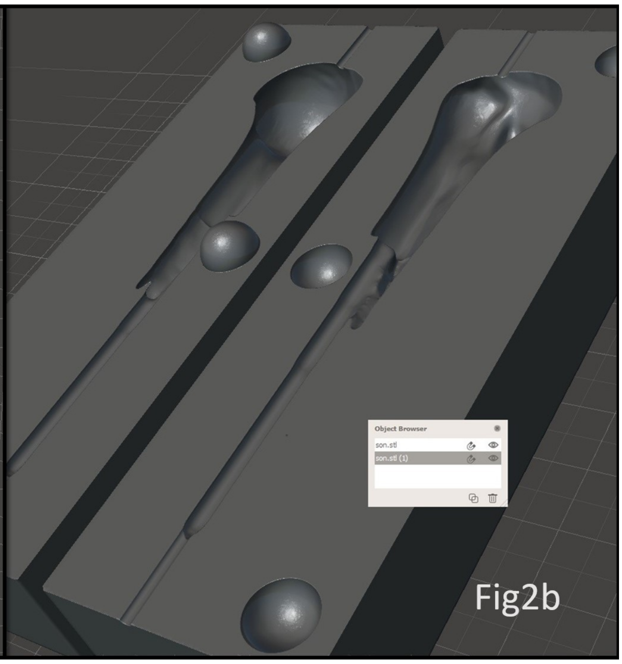


Fig2b The upper and lower mold parts which were engraved with spacer's form.

Three packages of 40-gram commercial gentamicin containing methyl methacrylate were mixed with 3.6 grams of teicoplanin. A Kirschner wire with a radius of 1.8 mm was aligned right in the center of the grooves of one pair of the mold. The obtained antibiotic cement mixture was filled in a 50-ml syringe with a broad aperture and was injected into both pairs of the mold just enough to fill them flush. After waiting for a while for the cement to gain some viscosity the pairs of the mold were brought together with the guidance of ball and socket joints on the molds. After giving enough time for the cement to set, the pairs of mold were separated using an osteotome and hammer. A spacer of the desired shape complementing the missing part of the right humerus was obtained (Fig3a).

Afterward, the spacer was introduced to the patient's right humerus which fitted very easily, snugly and showed no instability. Application of the cement spacer took no more than two minutes. The postoperative x-ray of the patient showed perfect conformity of the fabricated spacer (Fig3b). The patient's wound healed within 10 days after the surgery. He was screened by WBC, ESR and CRP levels which all returned to normal levels at 3rd week. At the 12th week, the spacer was still very stable, without any discomfort and without any signs of infection so the spacer was taken out and the defective joint was reconstructed by a custom-made proximal humeral prosthesis.

Fig3a Photograph showing the resulting antibiotic cement spacer (foreground) and the injured right humerus x-ray (background).

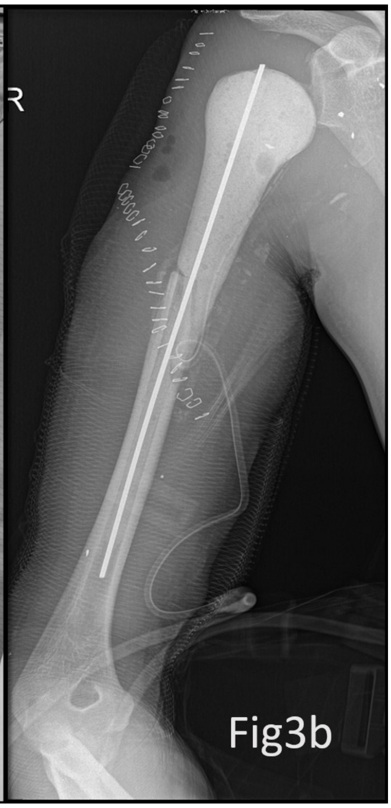


Fig3b Postoperative x-ray of the patient.

DISCUSSION

Treatment of osteomyelitis is a challenging problem for many reasons. It is seen often seen due to a prosthetic infection or an open fracture. Accepted methods of treatment focus on void filling and local release of high dose antibiotics by means of bone cement spacers (9).

In this study, we propose a new method to produce a fully customized antibiotic spacer for cases with marked bone loss and expected instability. The stability of the spacer is an important factor which may hamper treatment if experienced. In an article by Jawa and colleagues the outcomes of 30 patients with osteomyelitis related to failed shoulder arthroplasty were investigated (10). All patients underwent the standard debridement and irrigation procedures with removal of hardware followed by application of antibiotic-impregnated spacers. Three different type handmade spacers were used. The first type was handmade without any additional structural support (three cases), the second type was made around a one-third tubular plate (fourteen cases), and the third type was made around a 3.5-mm limited contact-dynamic compression plate (eleven cases). The plates were bent to reproduce neck-shaft angle of the prosthesis, and the length was made matching a humeral component of a prosthesis. The humeral head was created with a custom 44-mm mold. Eighteen of these patients underwent a second-stage procedure after infection subsided. These procedures included revision shoulder arthroplasty fifteen patients, two revision spacer implantations, and one resection arthroplasty. The remaining twelve patients declined additional procedures and retained the spacer implant. The mean follow-up length was reported to be 27.6 months (range, twelve to sixty-nine months). They reported four cases of complications due to physical reasons. One patient had a dislocation of the spacer implant; three patients had a spacer fracture. All three fractures were seen in spacers made with semi-tubular plates for structural support.

Another study by Coffey and colleagues seeking treatment efficacy of a commercial gentamicin antibiotic-impregnated cement spacer for glenohumeral sepsis, 16 shoulders were included in the study. Among these patients, 6 had an infected hemiarthroplasty, 5 had an infected total shoulder arthroplasty (3 of which were a reverse ball-and-socket prosthesis), 4 had primary osteomyelitis of the humeral head, and 1 had proximal humeral osteomyelitis with retained hardware from previous open reduction and internal fixation of a proximal humerus fracture (11). All patients were treated by debridement, irrigation, hardware removal and application of a commercial proximal humeral antibiotic-impregnated spacer which has only one size for all needs. While introducing the spacer to the defect they have applied a vancomycin impregnated handmade cement collar to overcome instability issues. After a mean follow-up time of 11.2 weeks (range, 6-30 weeks) twelve patients were treated with revision shoulder arthroplasty. The remaining four patients refused to undergo revision and preferred to retain their spacers. These four patients were followed up for a mean 19.25 months after spacer placement (range, 16-25 months). All patients were reported to use their arm freely to the limits of their comfort and no complication due to spacer instability was reported.

In another study by Stine and colleagues, thirty patients with chronic shoulder infections (4 primary and 26 postoperative) were treated with aggressive debridement, implantation of an antibiotic-loaded articulating spacer, and systemic antibiotics (12). All patients were reported to have a diagnosis with a presumably intact proximal humeral bony anatomy. A three-size standard spacer mold was used to manufacture antibiotic-impregnated spacers. Potential instability was also addressed by applying a handmade collar of antibiotic-loaded cement. Twelve patients (follow-up of 2.3 years) underwent reimplantation of a prosthesis. Eighteen patients elected to keep the spacer, but three patients later underwent reimplantation, thus fifteen patients were using the spacer as a prosthesis at their latest follow-up of 2.4 years. They have also reported no complication due to spacer instability or spacer fracture.

Treatment with cement spacers is always time taking, rough and uneasy. Unfortunately, spacer stability related complications may occur, which are discouraging for the patient and the doctor when encountered. Naturally, cement beads and handmade spacers are most prone to instability issues due to their amorphous shapes. Current literature suggests that commercial or custom-made spacers that resemble the form of a humeral component of a shoulder prosthesis provide good in-vivo stability when applied with a secondary mantle of antibiotic cement for cases which do not represent marked bone loss (11,12). On the other hand, the stability and mechanical reliability of a spacer may decrease if a spacer does not have a consistent shape or is handmade (10). Nevertheless, stability and other mechanical problems generally arise from the larger size and greater complexity of the bone defect. As a result, cases that represent larger defects and are thought to be prone to mechanical issues may be addressed with a custom made exact anatomic spacer to provide extra stability, thus safety.

CONCLUSION

Our experience with the above patient has proven that 3D printing a custom anatomic spacer mold and using it to fabricate an exact anatomic antibiotic spacer is a reliable choice, especially for osteomyelitis cases with complex and advanced bone defects. With recent implications of additive 3D printing technologies, this option has become very easy. 3D printing technology is changing the world as well as the medical methods.

Conflict of interest

No conflict of interest was declared by the authors.

REFERENCES

1. Rasyid HN, van der Mei HC, Frijlink HW, et al. Concepts for increasing gentamicin release from handmade bone cement beads. Acta Orthop. 2009;80:508-13.

2. Giavaresi G, Bertazzoni Minelli E, Sartori M, et al. New PMMA-based composites for preparing spacer devices in prosthetic infections. J Mater Sci Mater Med. 2012;23:1247-57.

3. Mounasamy V, Fulco P, Desai P, Adelaar R, Bearman G. The successful use of vancomycin-impregnated cement beads in a patient with vancomycin systemic toxicity: a case report with review of literature. Eur J Orthop Surg Traumatol. 2012;23:299-302.

4. Sener M, Kazimoglu C, Karapinar H, Günal I, Afşar I, Karataş Sener AG. Comparison of various surgical methods in the treatment of implant-related infection. Int Orthop. 2010;34:419-23.

5. Van Thiel GS, Berend KR, Klein GR, Gordon AC, Lombardi AV, Della Valle CJ. Intraoperative molds to create an articulating spacer for the infected knee arthroplasty. Clin Orthop Relat Res. 2011;469:994-1001.

6. Jung J, Schmid NV, Kelm J, Schmitt E, Anagnostakos K. Complications after spacer implantation in the treatment of hip joint infections. Int J Med Sci. 2009;6:265-73.

7. Pattyn C, De Geest T, Ackerman P, Audenaert E. Preformed gentamicin spacers in two-stage revision hip arthroplasty: functional results and complications. Int Orthop. 2011;35:1471-6.

8. Paley D, Herzenberg JE. Intramedullary infections treated with antibiotic cement rods: preliminary results in nine cases. J Orthop Trauma. 2002;16:723-9.

9. Jawa A, Shi L, O'Brien T, et al. Prosthesis of antibiotic-loaded acrylic cement (PROSTALAC) use for the treatment of infection after shoulder arthroplasty. J Bone Joint Surg Am. 2011;93:2001-9.

10. Coffey MJ, Ely EE, Crosby LA. Treatment of glenohumeral sepsis with a commercially produced antibiotic-impregnated cement spacer. J Shoulder Elbow Surg. 2010;19:868-73.

11. Stine IA, Lee B, Zalavras CG, Hatch G 3rd, Itamura JM. Management of chronic shoulder infections utilizing a fixed articulating antibiotic-loaded spacer. J Shoulder Elbow Surg. 2010;19:739-48.