Personalized Cement Spacer Manufacturing Using Computer Assisted Design for the Treatment of Osteoarticular Infections

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Background: Infection is the most feared complication in every aspect of bone surgery. Antibiotic impregnated cement spacers and cement beads are widely used since 1972 for treating prosthetic infection. The delivery of a high concentration of antibiotics in a localized area is thought to be safer than systemic administration of intravenous antibiotics in such doses.
Materials and methods: Our clinic has more than 10 years of experience in using preformed and manufactured spacers, mostly hand made. A new method developed by us puts the designing in the preoperative planning phase. Antibiotics are chosen based on the antibiogramm the cement is chemically "configured". 3D design based on the previous implant or on the bony structure is done; negative molds are manufactured with CNC mill the manufacturing kit is sterilized with ethylene oxide. Intraoperatively the spacer is molded and implanted.
Results and Conclusions: We consider that our method meets almost all the conditions proposed by us. Problems were found with the inconsistent mechanical behavior. More studies are required regarding the mechanical properties of the bone cement in function of antibiotic concentrations and preparation methods.

Keywords: infection, spacer, CAD design

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Introduction

Infection is the most feared complication in every aspect of bone surgery. The treatment involves immeasurable physical and psychological suffering of the patient and can pose a considerable financial burden for both the patient and the institution.

The first surgical step after diagnosing a deep infection is a thorough debridement which involves soft tissue and bone, any metallic implant is removed. The problems arising after this step: what to do with the tissue loss / remaining cavity, how to achieve mechanical stability, how to achieve a high enough focal antiseptic concentration? External fixators, casting, continuous irrigation provide solu1tions for the problems but are very uncomfortable the patient and demanding for the healthcare staff.

Antibiotic impregnated cement spacers and cement beads are widely used since 1972 for treating prosthetic infection. The delivery of a high concentration of antibiotics in a localized area is thought to be safer than systemic administration of intravenous antibiotics in such doses. The increased resistance of microorganisms especially staphylococcus aureus make the premixed antibiotic bone cement less effective and/or demands for toxic dose of systemic administration.

Nowadays spacers are used for treating not only prosthetic infection but also treating other osseous infections. They provide a high local antibiotic concentration, certain mechanical stabilization, prevent the soft tissue retraction and conserve the anatomical layers so that the revision surgery approach doesn't require such extensive approach.

Materials and methods

Our clinic has more than 10 years of experience in using and manufacturing spacers. A suitable antibiotic spacer for our need has to meet the following conditions:

- has to contain an antibiotic which is effective against the isolated bacterial strain in conformation with the antibiogramm;
- has to maintain effective concentration till the revision surgery occurs (sometimes 10 months);
- has to be anatomically accurate;
- has to be mechanically stable for non-weight bearing conditions;
- the intraoperative part of the manufacturing process has to be easy and fast to perform;
- has to be available within 24–48 hours;
- has to be cheap.

There are two main types of spacers: preformed and custom made. There are a wide variety of prefabricated spacer systems commercially available. Main advantages of these: they are ready made, mechanically superior, structurally and chemically constant. Disadvantages are: not anatomically suitable in all cases, the isolated bacterial strain is resistant to the antibiotic in the spacer and specific antibiotic content would take too long to order and manufacture, they are unjustifiably expensive.

Custom made spacers are the hand made and intraoperative molded spacers. We have experience with both of the methods they meet almost all conditions although handmade spacers need "artistic" skills and precious intra-

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Fig. 1. Difference between handmade and molded spacer

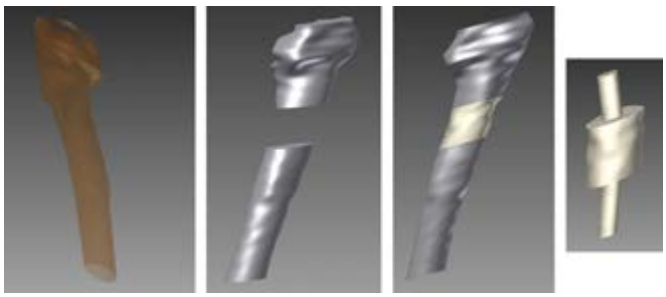

Fig. 3. Spacer for correcting bone loss

operative time to manufacture they are mechanically less stable, anatomically less perfect. So the "best fit" option for our purposes would be the custom made, molded spacers.

We divide the manufacturing in two parts: extra and intraoperative. The extraoperative part coincides with the preoperative planning: we choose the antibiotic agent based on the antibiogramm, we perform a CT scan for obtaining anatomical data.

At our clinic we use the following antibiotics to mix with the cement: Gentamycin, Cefuroxime, and Vancomycin based on the antibiogramm, Cefuroxime and Gentamycin mixture if the antibiogramm cannot be performed (emergency intervention). The maximum concentration used would be 1/5 so 8 g of antibiotics/40 g of cement for the cements Surgical Simplex and Cemfix. Above the

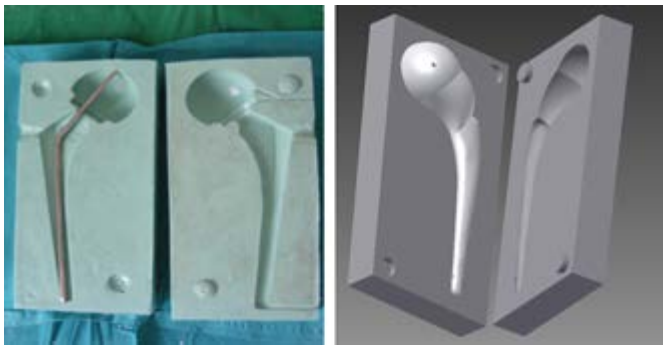

Fig. 5. Virtual and physical mold side by side

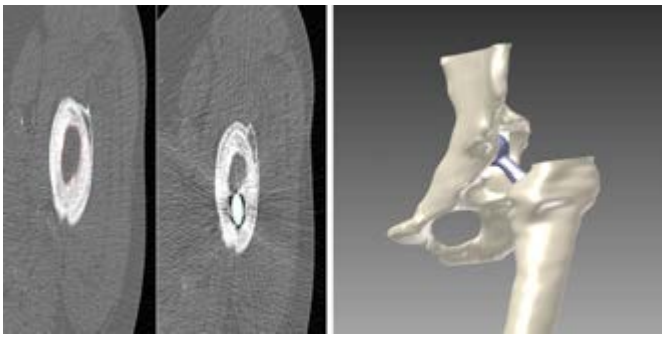

Fig. 2. Evolution from CT to 3D reconstruction

Fig. 4. Design phases of articular spacer

mentioned concentrations the cement won't set. However multiple studies suggest that using the maximum concentration would considerably weaken the maximum compressive strength of the cement so we used concentrations of max 1/10 [1,2,3,4].

On the CT slices we have selected the boundaries of the previous implant or the medullary canal of the bone. We have selected the outer and inner boundaries for the bones in the problematic segment. We have smoothed the boundaries, and performed a 3D surface reconstruction with 0.02 mm precision with our own algorithm. We have closed the surfaces to volumes. We have built our spacers based on the previous implant or on the remaining bony substrate where that was impossible because the extensive bone loss or other reasons. We have harmonized the spacer design with the patient's anatomy. After the design was ready metal reinforcement from K wires, Ender type elastic

Fig. 6. Molding kit

Fig. 7. Molding

nails or Kutscher centromedullary rods was added to the design.

A 3D Finite Element Analysis was performed for testing the expected mechanical strength of the spacer. The negative mold of the spacer was designed and saved in.stl file format. The physical mold was manufactured with the use of a CNC mill and sterilized in ethylene oxide.

The intraoperative phase takes up the thorough debridement removal of the metal implants, the assembly of the mold system with reinforcements and preparation of the antibiotic cement, molding with a commercial silicone gun, remodeling of the casted spacer with rongeur and implanting.

Results

The antibiotic cement spacer molded with our method meets almost all the conditions proposed by us: contains strain specific antibiotic agent/agents which can be selected from the available antibiotics based on the antibiogramm, is anatomically accurate easy fast and cheap to manufacture. Some reservations are due to the cement-antibiotic mixture preparation: if we want to match the minimum inhibitory concentrations specified on the antibiogramm for certain strains for the time between the operations which could be up to 10 months – it would require doses of antibiotics which would destabilize the polymerization (the cement would not set) or influences the mechanical properties of the spacer which would turn out friable and eventually break.

Discussion

Are spacers built with our technique just as good as the expensive preformed [5] ones? It depends. They are much cheaper, the antibiotics can be personalized [6], and they are anatomically more accurate since they are individualized they can be designed to replace bone segments not just prostheses [7]. Mechanically they are unforeseeable, presenting more complications as breakage because of air bubbles and fragile cement [8,9,10] (Fig. 8 Complications due to air bubbles). The same problems have been found by D'Angelo et al. Also as stated by Barrack et al. molded spacers can have a less bulky endoskeleton thus more antibiotic volume [11,1]. Most likely the high concentration of antibiotics changes the mechanical properties of the cement [12,13]. As compared to intraoperative handmade spacers this method is far superior because it takes no skill from the surgeon to manufacture and saves precious operation time by putting the design problems in the preoperative planning phase. Also because we have the tool of FEA for testing mechanical complications should be less. The air bubbles and preparing imperfections are far less to be expected. Comparing pricewise our method to the others: an original pre - molded spacer cost 6 to 10 times as much as with our method, the other molding techniques [14,15,16,17] we have read about for spacer personalization are almost as expensive as the preformed one and they take considerably more time to manufacture, the cheapest spacers will always be the handmade one but not by far, and with the above described limitations.

Fig. 8. Complications due to air bubbles

Conclusions

We consider that our method meets almost all the conditions proposed by us. Problems were found with the inconsistent mechanical behavior. More studies are required regarding the mechanical properties of the bone cement in function of antibiotic concentrations and preparation methods

References

1. Mohd Fuad D, Masbah O, Shahril Y, Jamari S, Norhamdan MY, Sahrim SH. Biomechanical properties of bone cement with addition of cefuroxime antibiotic. Med J Malaysia. 2006 Feb; 61 Suppl A:27-9.
2. Massimiliano Baleani, Cecilia Persson, Carola Zolezzi, Agne se Andollina, Anna Maria Borrelli and Domenico Tigani. Biological and Biomechanical Effects of Vancomycin and Meropenem in Acrylic Bone Cement. The Journal of Arthroplasty. 2008;23(8):1232-1238.
3. Wininger DA, Fass RJ. Antibiotic impregnated cement and beads for orthopedic infections. Antimicrobial Agents Chemotherapy 1996 Dec;40(12):2675-9.
4. Kirkpatrick DK, Trachtenberg LS, Mangino PD, Von Fraunhofer JA, Seligson D. In vitro characteristics of tobramycin-PMMA beads: compressive strength and leaching. Orthopedics 1985 Sep; 8(9):1130-3.
5. Soffiatti R. The preformed spacers: from the idea to the realization of an industrial device. Infection and local treatment in Orthopedic surgery. Berlin: Springer-Verlag; 2007. 201-4.

6. Bernd Fink. Revision of late periprosthetic infections of total hip endoprostheses: pros and cons of different concepts. International Journal of Medical Sciences 2009; 6(5):287-295.
7. Stephen J. Incavo, Robert D. Russell, Kenneth B. Mathi and Holly Adams. Initial Results of Managing Severe Bone Loss in Infected Total Joint Arthroplasty Using Customized Articulating Spacers. The Journal of Arthroplasty. 2009;24(4):607-613.
8. Kuo-Ti Peng, Liang-Tseng Kuo, Wei-Hsiu Hsu, Tsan-Wen Huang, Yao-Hung Tsai. The effect of endoskeleton on antibiotic impregnated cement spacer for treating deep hip infection. Musculoskeletal Disorders. 2011;12:10.
9. Sridhar M. Durbhakula, John Czajka, Marc D. Fuchs and Richard L. Uhl. Spacer Endoprosthesis for the Treatment of Infected Total Hip Arthroplasty. The Journal of Arthroplasty. 2004;19(6):760-767
10. D'Angelo F, Negri L, Zatti G, Grassi FA. Two stage revision surgery to treat an infected hip implant. A comparison between a custom made spacer and a preformed one. Chir Organi Mov. 2005 Jul-Sep; 90(3):271-9.
11. Robert L. Barrack. Rush Pin Technique for Temporary Antibiotic-Impregnated Cement Prosthesis for Infected Total Hip Arthroplasty. The Journal of Arthroplasty. 2002;17(5):600-603.
12. John Klekamp, John M. Dawson, David W. Haas, David DeBoer and Michael Christie. The Use of Vancomycin and Tobramycin in Acrylic Bone Cement Biomechanical Effects and Elution Kinetics for Use in Joint Arthroplasty. The Journal of Arthroplasty. 1999;14(3):339-346.
13. Bassam A. Masri, Clive P. Duncan, and Christopher P. Beauchamp. Long term Elution of Antibiotics from Bone-Cement. The Journal of Arthroplasty. 1998;13(3):331-338.
14. C. Schoellner, S. Fuerderer, J.D. Rompe, A. Eckardt. Individual bone cement spacers (IBCS) for septic hip revision. Arch Orthop Trauma Surg 2003;123:254-259.
15. DePuy Johnson&Johnson Company – PROSTALAC Hip System. 2006 DePuy Surgical Technique.
16. Kengo Yamamoto, Naoki Miyagawa, Toshinori Masaoka, Youichi Katori, Takaaki Shishido and Atsuhiro Imakiire. Cement Spacer Loaded With Antibiotics for Infected Implants of the Hip Joint. The Journal of Arthroplasty. 2009;24(1):83-89.
17. Biomet – Stage One Spacer Molds: Product Brochure. 2006 Biomet Orthopedics.