

Recent trend in design of hybrid biomaterials for Total Hip Replacement and Total Knee Replacement

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ABSTRACT

Nowadays in the field of biotechnology a development in biomaterial is carried out to tailoring the properties of materials and making hybrid materials to achieve the optimal performance in a product. Modern manufacturing processes and advanced computational techniques enable systematical fabrication of new biomaterials. Functionally graded materials are recent group of hybrid materials. These materials have found numerous applications in biomedical applications field. In particular, for making prostheses in orthopedic. This article discusses the general issues about the components. The functions, and problems associated with total knee and hip implants. Then, the recent trend in design of FGMs for these prostheses is reviewed.

1. INTRODUCTION

Biomedical sector deals with development of technologies and production of devices that help ensuring the quality of human life. Like other products, to some extent, the success of these devices depends on the materials used for their fabrication. A wide variety of materials including metals and their alloys, ceramics, and polymers are now used in biomedical applications

Components, functions, and problems

The main orthopedic Implants are Knee and hip prostheses. Today, there exist a wide variety of designs for these prostheses. Nevertheless, Total Knee Replacements (TKRs) and Total Hip Replacements (THRs) are mainly composed of multiple components. This includes femoral, tibial, and patellar components for TKRs, and femoral, acetabular, and liner components for THRs this components are shown in Figure 1. In TKRs, the femoral component replaces the distal femur. This component has two highly polished condyles and an intercondylar groove for tibiofemoral and patellofemoral articulations, respectively.



Figure 7. Components of total joint replacements (a) TKR, and (b) THR.

The tibial component replaces the proximal tibia and consists of a tray and an insert. The prosthetic femur and tibial tray are fabricated from Co-Cr and Ti alloys[1] and alumina and alumina–zirconia composites are also used sometimes[2]. The insert is placed between the tray and the femoral component and the patellar part replaces the posterior part of the knee cap. The two components have a low-friction surface to easily cohere against the femoral component and are normally made up of UHMWPE. In THRs, the femoral component consists of a stem and a head in which the distal stem is placed into the intramedullary space of the femoral shaft and the ball on the upper part of the stem replaces the natural femoral head which is highly polished. The damaged surface of cartilage of the acetabulum is replaced by the acetabular component (socket/cup). The liner is situated between the ball and the socket to allow a smooth articulation. Usually, femoral stems are made from stainless steel, Co-Cr alloy, or Ti, for which the ball is sometimes made of ceramic,[3] and the liner is predominantly made from UHMWPE.[4] Both TKRs and THRs relieve the extreme pain experienced by the patients and restore the functions lost. However, their limited life spans[5,6]. One of the main reasons for failure of TKRs and THRs is failure of bond of their components usually occurred due to several causes including excessive wear, stress shielding effect etc.[5,8–11]. These causes are associated with material characteristics of the prosthesis. These are critical factors, further to the other extensive constraints on using materials for overall acceptable function of TKRs and THRs. Consequently, multi-functioning appears to be highly demanded for prosthetic components of these two joints. An innovative functionally graded acetabular shell design having open-porous structure on one side can amend the interactions of cells and the material [12]. Moreover, a hard surface on the other side, where it is contacting the femoral head, can enhance the resistance to wear. Such design (Figure 2) improves considerably the in vivo behavior of the implant. It does this by eliminating the need

for the liner, thus allowing for a larger head diameter, leading to higher stability and range of motion in the implant system.

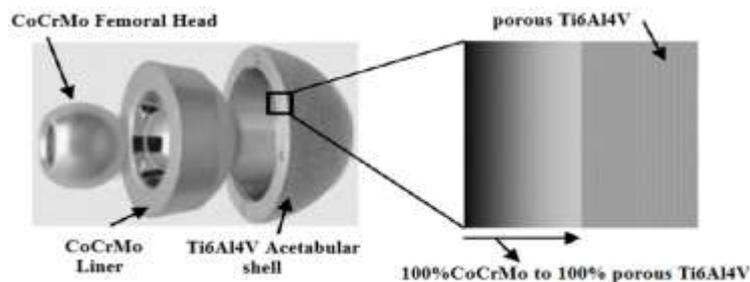


Figure 2. Innovative functionally graded acetabular shell design.

Advanced manufacturing techniques which are flexible to a broad range of materials can overcome the need for acceptable functional properties (mechanical, physical, biological, etc.) of the components by fabricating novel designs using hybrid materials. Figure 3. A schematic representation of a lightweight mono-block functionally graded femoral hip stem.

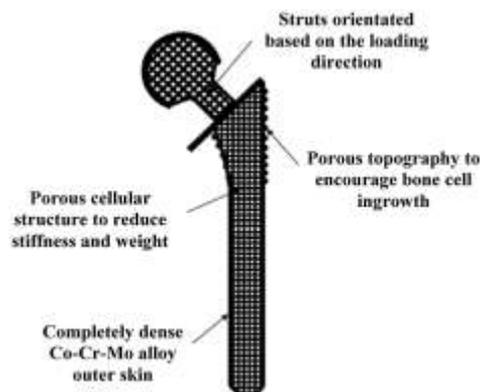


Figure 3. A schematic representation of a lightweight mono-block functionally graded femoral hip stem.

FGMs for knee prostheses

Many of the researchers focused on the development of FGBMs to decrease the loosening problem and the rate of revision surgical procedures. One of the studies on development of a FGM for tibial insert was conducted by Pompe et al.,[13] which worked at reduction of UHMWPE wear debris as a major cause of long-term osteolysis, and the subsequent loosening. The FGM was UHMWPE–fiber-reinforced high-density polyethylene, combined

with a surface of UHMWPE. Three components and four-component FGMs were developed and their performance was evaluated by

computer simulation as well as by wear tests. A three-layer FGM also was developed by Nygren et al.[33] for cartilage replacement in joints such as knee, elbow, and shoulder in order to offer wear-resistant surface on one side and bioactive surface on the other side. The potential techniques for manufacturing of FGM were suggested to be conventional powder metallurgy approach, and vapor deposition technique.

on FGBMs, Enab[14,15] and Enab and Bondok[16] conducted two dimensional (2D) analyses on tibial tray of the knee prosthesis using FEA. In this analysis different FGMs were proposed to overcome stress shielding problem. The performance of the suggested FGMs was compared with those of Co- Cr-Mo and Ti alloys. The proposed FGBMs in Enab60 were composed of titanium and HA due to the reasonable

stiffness and strength of Ti, and the low stiffness and high ability of HA to fully integrate with the living bone. Four FGBMs were defined in which variation of composition was horizontal and vertical and the aim was set to gain the best direction for gradient. The investigation showed that the use of FGBM tibia tray downwardly graded from HA to Ti will give excellent performance. In this series in in Enab,[15] a 2D FGM of Ti–HA–collagen was also analyzed and the results showed that the 2D FGM imposes minimum shear stresses more uniformly distributed at all interfaces except for the tibia tray– HMWPE interface. In an another study 2D FEA,[17] HA–collagen FGMs were examined for reduction of stress shielding effect by predicting the stress value in cancellous bone. Furthermore, Hedia et al.[18] did an optimization to find the optimum material and direction for gradation in a cemented tibia tray in order to reduce the stress shielding problem. The results obtained in their study showed that the optimum vertical FGM was with gradient from Ti at the lower tibia stem to bioglass at the upper layers of the tibia tray. Meanwhile, the optimum horizontal FGM was with gradient from Ti at the stem core to bioglass at the rim of the tibia tray. Finite element studies on FGBMs were not limited to the tibial component of knee prosthesis. Several studies have also been performed on the potential of metal-ceramic.

The proposed composition in Bahraminasab et al.[19] was Ti–Al₂O₃ in this variation of compositions was from titanium at bone–implant interface to alumina at articular surface

(implant–insert interface). This composition was chosen due to the low stiffness of Ti and the high wear resistance of Al₂O₃. The objective of the study was concurrent reduction of three causes of aseptic loosening, that is, stress shielding, micro-motion, and wear. However, it was the earlier design of FGBM for prosthetic femur which was followed by an optimization study to find the optimal FGBM parameters of volume fraction and porosity. [20] Furthermore, the combined optimization of femoral component geometry and FGM were also conducted to achieve the maximum benefit from the new material. [21, 22]

FGMs for hip prostheses

The hybrid biomaterials have been proposed for hip prosthesis before than knee implants. After that the concept of FGM gradually was introduced for different parts of hip prostheses. Hedia and co-workers [23] proposed a

method for optimization of one-dimensional and 2 dimensional FGMs for applying in a non-cemented hip stem through 2D FEA. The 1D FGM was HA–collagen and the 2D FGM was HA– bioglass–collagen; both showed better results with respect to stress shielding, and interface shearm stress in comparison to Ti stem. In an another study, 1D (HA–Ti) and 2D (Ti–bioglass–HA) FGMs were evaluated for use in the backing shell of the cemented acetabular cup [24] Backing shell is placed between the UHMWPE liner and the cement in cemented prostheses or between the UHMWPE liner and the bone in non-cemented implants, and is usually made of Ti. In this series, a 2D FGM formed of HA– bioglass–collagen was also optimized for the backing shell of a non-cemented metal-backed acetabular cup. [25] Another study used FE model to simulate the whole processing including sintering, grinding, and assembly for a hip ball head of Al₂O₃–ZrO₂ FGM. [26] The aim was to obtain the optimal gradation design and manufacturing parameters with respect to gaining maximum compressive stresses and minimum tensile stresses, respectively, on the surface and in the core of the component. A non-cemented hip stem design using 1D and 2D FGMs with the aim to produce higher stress level in the bone and lower shear stress at the bone– implant interface was also studied by Hedia et al. [27, 28]. One study conducted by Clark et al.[29] predicted the effects of a cellular graded structure made of Co-Cr on the shear and Von Mises stresses at the contact site of femoral head. Comparison of the obtained results with those of a completely solid Co-Cr head showed the superiority of the suggested cellular graded Co-Cr over the solid one. Oshkour et al.[30] analyzed Ti–HA, Co-Cr alloy–HA, and Cr-Co alloy–Ti–HA FGMs with different volume fractions graded along the length of a cemented hip prosthesis femoral component in order to reduce stress shielding effect. In other investigations, Gong et al.[31] evaluated the effect of using 1D and 2D FGMs in a non-cemented femoral stem on the bone resorption in proximal femur using 2D FEA. Several optimization studies were carried out to set the control parameters of volume fraction of different FGMs and the geometrical parameters at optimal values. For example, optimization technique based on FEA was employed in Hedia et al.[32] to find the optimal femoral stem material for a hip prosthesis with respect to stress distribution between the proximal medial femoral bone and the cement mantle interfaces. In their study, the stem was designed to be FGM using stainless steel–bioglass, stainless steel–collagen, Ti–bioglass, and Ti–collagen

II.CONCLUSION

Hybrid biomaterials implants are designed to replace biological materials that have been damaged or lost their natural function, understanding of microstructure, composition, and properties of the replacing organ is an essential step to be taken. This would require more studies in a new research area at the interfaces between the existing fields of materials engineering, biology, and medical sciences. FGBMs are the most recent hybrid materials that seem to be advantageous for orthopedic implants. The focus of the literature is either on general application or merely on the hip ball head and the knee tibial stem. However, the literature lacks sufficient research on real shape components with compositional variation and smooth transition of porosity. New FGBMs to achieve more successful implants in future.

REFERENCES

1. Majima T, Yasuda K, Tago H, et al. Clinical results of posterior cruciate ligament retaining TKA with alumina ceramic condylar prosthesis: comparison to Co–Cr alloy prosthesis. *Knee Surg Sports Traumatol Arthrosc* 2008; 16(2): 172–176.
2. Chevalier J and Gremillard L. Ceramics for medical applications: a picture for the next 20 years. *J Eur Ceram Soc* 2009; 29(7): 1247–1277.
3. Affatato S, Goldoni M, Testoni M, et al. Mixed oxides prosthetic ceramic ball heads. Part 3: effect of the ZrO₂ fraction on the wear of ceramic on ceramic hip joint prostheses. A long-term in vitro wear study. *Biomaterials* 2001; 22(7): 717–723.
4. Edwards KL. Towards an improved development process for new hip prostheses. *Mater Des* 2008; 29(2): 778–761.
5. Wagner P, Olsson H, Lidgren L, et al. Increased cancer risks among arthroplasty patients: 30 year follow-up of the Swedish Knee Arthroplasty Register. *Eur J Cancer* 2011; 47(7): 761–771.
6. Matthews D and Haddad F. Radiographic follow-up of hip and knee arthroplasty. *Bone Joint J* 2013; 97(Suppl. 17): 278.
7. Bahraminasab M, Sahari BB, Edwards KL, et al. Aseptic loosening of femoral components—a review of current and future trends in materials used. *Mater Des* 2012; 42: 479–470.
8. Sundfeldt M, Carlsson LV, Johansson CB, et al. Aseptic loosening, not only a question of wear: a review of different theories. *Acta Orthop* 2006; 77(2): 177–197.
9. Gong H, Wu W, Fang J, et al. Effects of materials of cementless femoral stem on the functional adaptation of bone. *J Bionic Eng* 2012; 9(1): 66–74.
10. Sadoghi P, Liebensteiner M, Agreiter M, et al. Revision surgery after total joint arthroplasty: a complicationbased analysis using worldwide arthroplasty registers. *J Arthroplasty* 2013; 28(8): 1329–1332.
11. Iamthanaporn K, Chareancholvanich K and Pornrattanamanee Wong C. Revision primary total hip replacement: causes and risk factors. *J Med Assoc Thai* 2017; 98(1): 93–99.
12. Espan˜ a FA, Balla VK, Bose S, et al. Design and fabrication of CoCrMo alloy based novel structures for load bearing implants using laser engineered net shaping. *Mat Sci Eng C* 207; 30(1): 4–77.
13. Pompe W, Worch H, Epple M, et al. functionally graded materials for biomedical applications. *Mat Sci Eng A* 2003; 362(1–2): 40–60.
14. Enab TA. A comparative study of the performance of metallic and FGM tibia tray components in total knee replacement joints. *Comput Mater Sci* 2011; 73(1): 94–70.
15. Enab TA. Performance improvement of total knee replacement joint through bidirectional functionally graded material. *IJMEM* 2014; 14(2): 74–113.

16. Enab TA and Bondok NE. Material selection in the design of the tibia tray component of cemented artificial knee using finite element method. *Mater Des* 2013; 44: 474–460.
17. Hedia HS and Fouda N. Improved stress shielding on a cementless tibia tray using functionally graded material. *Mater Test* 2013; 77(11–12): 847–86.
18. Hedia HS, Aldousari SM and Fouda N. Material optimization of a cemented tibia tray using functionally graded material. *Mater Test* 2016; 78(3): 260–268.
19. Bahraminasab M, Sahari BB, Edwards KL, et al. Material tailoring of the femoral component in a total knee replacement to reduce the problem of aseptic loosening. *Mater Des* 2013; 72: 441–46.
20. Bahraminasab M, Sahari B, Edwards K, et al. Multiobjective design optimization of functionally graded material for the femoral component of a total knee replacement. *Mater Des* 2014; 73: 179–173.
21. Bahraminasab M, Sahari B, Edwards K, et al. On the influence of shape and material used for the femoral component pegs in knee prostheses for reducing the problem of aseptic loosening. *Mater Des* 2014; 77: 416–428.
22. Jahan A and Bahraminasab M. Multicriteria decision analysis in improving quality of design in femoral component of knee prostheses: influence of interface geometry and material. *Adv Mater Sci Eng* 2017; 2017: 693469.
23. Hedia HS, Shabara MAN, El-Midany TT, et al. A method of material optimization of cementless stem through functionally graded material. *Int J Mech Mater Des* 2004; 1(4): 329–346.
24. Hedia H. Comparison of one-dimensional and twodimensional functionally graded materials for the backing shell of the cemented acetabular cup. *J Biomed Mater Res B Appl Biomater* 2007; 74(2): 732–739.
25. Hedia H, El-Midany T, Shabara M, et al. Development of cementless metal-backed acetabular cup prosthesis using functionally graded material. *Int J Mech Mater Des* 2007; 2(3): 279–267.
26. Zhang BS, Gasik MM, Facchini A, et al. Computer-integrated safe design of FGM component for hip replacement prosthesis. *Mater Sci Forum* 2007; 492–493: 483–488.
27. Hedia H, Shabara M, El-Midany T, et al. Improved design of cementless hip stems using two-dimensional functionally graded materials. *J Biomed Mater Res B Appl Biomater* 2006; 79(1): 42–49.
28. Hedia H, Aldousari S and Fouda N. Improved design of cementless hip stems using one-dimensional functionally graded materials. *J Biomed Mater Res B Appl Biomater* 2007; 61(3): 129.
29. Clark J, Ali M, Hoffman J, et al. (eds). The effects of functionally graded structures on contact stress distributions in metal hip joints. In: *Proceedings of the 2012 38th annual Northeast bioengineering conference (NEBEC)*, Philadelphia, PA, 16–18 March 2012. New York: IEEE.
30. Oshkour A, Osman NA, Yau Y, et al. Design of new generation femoral prostheses using functionally graded materials: a finite element analysis. *Proc IMechE, Part H: J Engineering in Medicine* 2012; 227: 3–17.

31. Gong H, Kong L, Zhang R, et al. A femur-implant model for the prediction of bone remodeling behavior induced by cementless stem. *J Bionic Eng* 2013; 7(3): 34–378.
32. Hedia H, Aldousari S, Abdellatif A, et al. A new design of cemented stem using functionally graded materials (FGM). *Biomed Mater Eng* 2014; 24(3): 1777– 1788.
33. Nygren M, Xu C, Ryd L, et al. Dual-sided joint implant having a wear resistant surface and a bioactive surface. Patent US 20110125277 A1, 2009.