RESEARCH ARTICLE

Design, 3D Development and Finite Element Analysis of Cylindrical Mesh Cage Bioimplants from Biometals

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The current research is aimed at design and 3D development of a degradable cylindrical mesh cage porous bioimplant for fixation to a segmental femur bone defect. The finite element analysis (FEA) was carried out to obtain the bone-bioimplant interface deformation and stress generated. The cylindrical mesh cage bioimplant was designed using a range of metallic biomaterials such as Magnesium (Mg) alloy (AZ31), Ti alloy (Ti-6Al-4V) and Stainless Steel (SS316L). The FEA was carried out for bone-bioimplant assembly in static and dynamic conditions. FEA results demonstrated that the values of the interface von-mises stress for the AZ31 Mg-alloy based bioimplant could fall with in the clinical acceptable domain at which the stress sheilding issues could be avoided. The results further suggested that Mg-based bioimplants could be promising and better alternative for use as a porous scaffold for repair and regeneration of a segmental femur bone defect.

Introduction

The repair of a femur bone segmental defect is challenging in the biomedical field [**1**]. Allografts are considered as standard bone grafts for filling of these defects. But various issues such as limited tissue availability, long surgery time, high cost, uncertainty in bone healing, the risk of disease transmission, and undesirable host responses are the current limitations [**2,3**]. Currently, the load bearing metal-based orthopedic bioimplants made from Ti, Ti-alloys and stainless steel (SS) are used as standard substitutes due to their high mechanical strength and better compatibility than other non-degradable biometals [**4**]. Further, the use of the bioimplants from these biometals often lead to the stress shielding effect due to their large modulus mismatch with the natural bone [**5-7**]. The implants from these biometals also have the possibility to release toxic metallic ions to further create the problems in adapting with the *in vivo* environment [**8**]. It also requires longer healing time and mostly post-surgical treatment, which is highly needed for the removal of these bioimplants. These complicated procedures often increase the risk of infection and morbidity [**8**]. Recently, Mg and Mg-alloys are evolved as promising degradable biometals for the preparation of biodegradable and resorbable bioimplants (e.g., porous scaffolds) for orthopedic applications [**9-12**]. The young's modulus for a typical magnesium Mg-alloy (e.g. AZ31) is equivalent to that of a cortical bone tissue. Hence, further reduction in stress shielding effect could be expected [**13–16**]. Mg and Mg-alloy based bioimplants have greater strength/weight ratios, larger fracture toughness and higher tensile strength than that of the other materials such as ceramics and polymeric biomaterials [**17**]. In addition, Mg is an essential element in human body responsible for the synthesis of proteins, activation of enzymes and central nervous system to ensure a proper thermoregulation [**18**]. Cylindrical Ti-mesh cage bioimplants are to be marketed for reinforcement and reconstruction of large bone defects [**19-21**]. The Use of Ti-cage bone grafts has been reported for the long bone segmental defect [**19-22**]. Its mechanical advantages include the hollow and fenestrated nature of the bioimplant, which provides the maximum strength for the least amount of metal, thereby minimizing the risk of stress shielding effect [**23,24**]. Cylindrical SS 316L-mesh cage is used as a bioimplant for the long segmental defect in bone because of its high mechanical strength [**25,26**]. In addition, it is high-grade steel having low carbon content. SS 316L is a cost-effective biometal for orthopedic applications**.** There are limited or no computational modeling reports on the design and 3D development of porous bioimplants using the emerging biometals such as Magnesium and Mg-based alloys. It is well understood that the 3D stress field near the fracture in bone of finite thickness is very complex. Due to difficulty in assigning the boundary conditions in bone-cylindrical cage assembly, the discrete solutions like finite element methods are available [**27**]. Considering bone fracture having arbitrary thickness, the simple analytical methods could also be applied for the stress-strain analysis. Plane stress and plain strain theories could also be used to obtain the stress intensity at the vicinity of the fracture [**27**]. It is understood that when the bone is weakened at the fracture site and subjected to bending and torsion in walking condition, the passion's effect leads to the generation of coupled out-of-plane singular mode. The plane stress problem was identified and 3D stress at the vicinity of the fracture has been calculated [**28**]. The effects played by singular and non-singular stress on the out-of-plane were investigated. No singular mode is present when terms linked to symmetric stress and displacements are applied [**28**]. The results from bone-cylindrical cage model and plate model subjected to anti-plane loading are quite similar. It is clear that a remotely applied load does produce a coupled load. The bending of cage or plate is increased for lower values of the plate and cage thickness [**29**]. The stress intensity surrounding the vicinity of the fracture has been used to identify the position of the most critical zone through the plate and cage. For both thin and thick plate, the maximum stress intensity could be observed at vicinity of the lateral surface. For the cage models, the observed trend was different and depended on the cage thickness [**29**].

The hypothesized approach in this work involves the design of porous cylindrical mesh cage bioimplant from few well established non-degradable biometals (Ti-6Al-4V and SS 316L) and a typical degradable Mg-alloy based biometal (AZ31). Further the designed porous bioimplants from different biometals were fixed to a large segmental bone defect. The finite element analysis (FEA) (in static and explicit dynamic mode) was carried out to obtain the bone-bioimplant stability at interface which was evaluated by considering the biomechanical parameters such as interface implant deformation and stress generated. The values of deformation and stress were compared. The Ti-alloy and SS 316L were considered as non-degradable mesh cage bone bioimplant while a AZ31was hypothesized for design of a degradable bioimplants i.e., as a porous scaffold for repair and regeneration of a long bone.

Materials and methods

Materials and their properties

Different biometals such as Magnesium (Mg) alloy (AZ31), Ti-alloys (Ti-6Al-4V) and SS 316L were used for design of cylindrical mesh cage bioimplant for femur segmental defect and fixation. **Table 1** summarizes the materials and the mechanical properties of various biometals used for this work. Among all the materilals, the values of density and young's modulus are highest for SS 316L and lowest for typical Mg-alloy (AZ31) which was found to be comparable to a cortical femur bone.

Table 1. Material properties of various biometals compared with a cortical femur bone [**30-32**].

Biomaterials	Density, ρ (Kg/m^3)	Young's Modulus, E (GPa)	Poisson's Ratio,υ
Cortical Femur Bone	2227	12	0.30
Magnesium (Mg)-alloy (AZ31)	1738	42	0.28
Ti alloy (Ti-6Al-4V)	4500	110	0.32
Stainless Steel (SS 316L)	7870	220	0.31

Femur bone and segmental defect generation

Computer tomography (CT) images of a 70 kg weight young healthy person were used to extract 3D models of the femur. The images were captured using a multidetector Siemens unit (Sensation 64; Siemens Medical Solutions, Malvern, PA, USA). The CT images were converted into the digital imaging and communication (DICOM) format and imported to the Mimics software (Version 13; Materialize NV, Leuven, Belgium). After creating the femur model in mimics, a tailor-made segmental defect was created using Solid Works software 2018 (version no. 26).

Cylindrical mesh cage bioimplant design and fixation

The cylindrical mesh cage porous bioimplant is 50 mm long having the outer diameter of 30 mm and a thickness of 5 mm. The diameters of all the holes (pores) on the cylindrical cage are equal (5 mm) [**33**]. The femur shaft length from distal to proximal end is 140 mm. The segmental defect is created at the mid span of the femur shaft, which is at the equal distance from both ends of the bone. The mesh cage bioimplants are designed using the biometals of AZ31 Mg alloy, Ti-6Al-4V and SS 316L. The fixation of the mesh cage bioimplant was carried out over the tailor-made segmental defect created in the femur bone. The detailed schematics of design and fixation of porous bioimplant over the segmental bone defect is shown in **Fig. 1**.

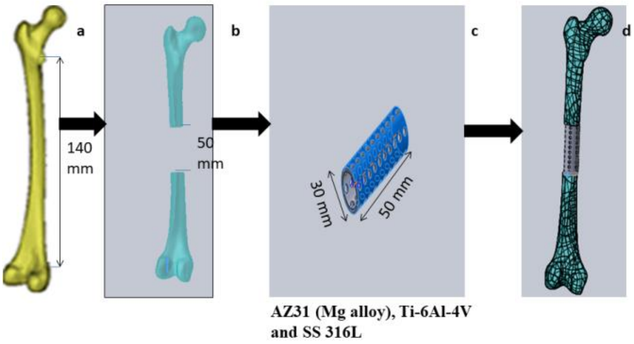

Fig. 1. (a) femur bone generated in mimics, (b) Tailor made segmental defect in femur bone, (c) Cylindrical mesh cage porous bioimplant and (d) Fixation of mesh cage bioimplant over the segmental defect in femur bone.

Static finite element analysis in ANSYS

The weight of the healthy young man was taken as 70 kg and the applied compressive force coming over the femoral head in upright standing position is considered as 1/3rd of the body weight i.e., 230N. The lower part of the femur (condyle) is fixed. In Ansys, the SOLID element was used for the bone and as well as cylindrical cage and the 10-noded Triangular Tetrahedral element was used in analysis. The CONTAC 75 and TARGE 70 elements were used for surface to surface and node to surface fixation respectively in order to reduce the sliding and deformation and also to minimize the interface stress and strain. The coefficient of friction at the joint of bone and cage was taken 0.3. The mesh size to refine the assembly meshing was taken as 5mm [**34**]. The FEA was performed using Ansys 19.2 to obtain the interface deformation (maximum) and Von-mises stress for the bone-bioimplant assembly.

Explicit dyanmic finite element analysis in abaqus

Quadratic Tet 10 node element was used for the bone-cage assembly. The SOLID element was taken for the bone-cylindrical cage assembly. The coefficient of friction at the joint of bone and cage was taken 0.3 and the mesh size used for meshing the assembly was 5 mm [**34**]. The applied compressive force coming over the femoral head in walking condition is considered as 4 times the body weight i.e., 2800 N [**34**]. The load of 2800 N was applied on the femur head in Y-direction downward as per cartesian system in Abaqus 2020 (Version no. 6.20). The lower part of the femur has been fixed. The simulation was run for 1.2s for each case considering 1.2s is the gait duration in walking condition [**35,36**]. The femur part and mesh cage were imported into Abaqus 2020 (Version no.6.20) and the explicit dynamic FE Analysis has been performed. The interface values of stress and strain was obtained in order to deduce the condition of optimum design of the cylindrical cage to avoid the bone-implant failure.

Results and discussions

Static FEA results using ANSYS

The porous bioimplants were designed from different biometals and fixed with the large segmental femur bone defect. The FEA results for bone-bioimplant assembly using various biometals such as AZ31 Mg-alloy, Ti-6AL-4V and SS 316L were compared and discussed. The detailed analysis results are depicted in **Fig. 2** and the obtained maximum values of stress and deformation is summarized in **Table 2**.

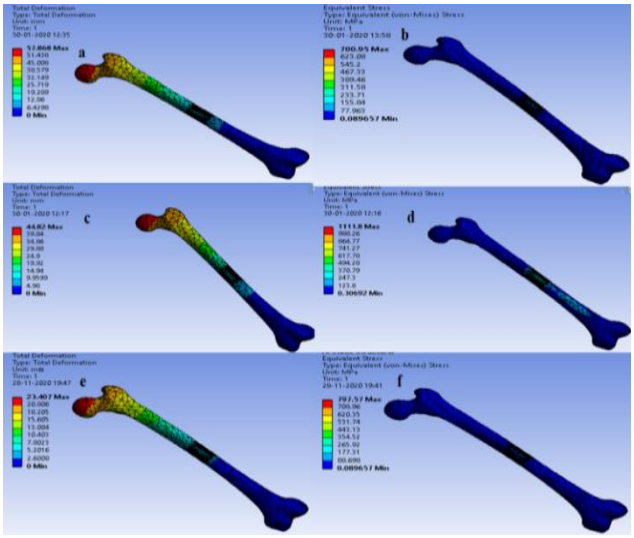

Fig. 2. FEA of assembly of segmental femur defect and repaired with cylindrical mesh cage: Total Deformations, Von-Mises stresses for AZ31 Mg alloy (a, b), Ti alloy (Ti-6Al-4V) (c, d) and SS 316L (e, f).

Table 2. FEA results of assembly of Segmental femur bone rapaired with porous cylindrical mesh cage bioimplant using various biometals (Static analysis).

Biometals	Total Deformation (mm)	Von-Mises Stress (MPa)
Magnesium alloy (AZ31)	58	701
Ti alloy (Ti-6AL-4V)	45	1112
Stainless Steel (SS 316L)	23	798

The FEA results demonostrated that the maximum deformation was observed at the femoral head and femur neck, as the load was applied at the femoral head. The minimum deformation was observed at the lateral and medial condyle surfaces, as the surfaces were fixed. The maximum stress was obtained at the segmental site as observed in **Fig. 2**. The maximum deformation and Von-mises stress obtained for the assembly are summarized in **Table 2**. For AZ31 Mg alloy, the maximum values for total deformation and stress are 58 mm and 701 MPa respectively**.** For Ti alloy the maximum values for total deformation and stress are 45 mm, 1112 MPa respectively. The values for SS 316L are 23 mm and 798 MPa respectively. Finite elemet analyses (FEA) results demonostrated that the values of the intereface stress for AZ31 is significantly lower than other biometals. It could also be observed that the values of the interface stress for AZ31 could fall under an acceptable values to the clinical settings[**1,9,11,23**]. A near value stress sheilding effect could be observed for the SS316L, however for these non-degradable metals, a revision surgery of the bioimplants should be an aditional issue. The Mg-based alloys being soft could demonostrate maximum differentation than other non-degradable metal based bioimplants. The elastic behavior of the implant may be favourable for the use of a porus scaffiold for tissue engineering applications. Further, the porocity of these degradable biometal based bioimplants could make them as a suitable candidate for the use of a porous scaffold for bone repair an dregeneration.

Explicit dynamic FE analysis results

To further strengethen the observation at bne-bioimplant interface , FEA results from dynamic loading condition was compaired with the results obtained from static analysis. The results of detailed analysis are depicted in **Fig. 3-5** and the values of Von mises stress and strain are summarized in **Table 3.** In dynamic analysis, it was observed that the bone-cage interface values of stress are higher than the values obtained from static analysis. The stress distribution for AZ31 was observed as more uniform than that of other biometals in both static and dynamic loading condition. A least number of stress shielding points could be observed for AZ31 compared to that of other biometals. Further, the deformation values obtained from the dynamic analysis are significantly lower than the deformation values observed from the static analysis results. AZ31 could demonostrate the higher value of deformation than other biometals as observed in both static and dynamic analysis.

The overall static and dynamic analysis results could demonostrate Mg-based biometal (AZ31) based bioimplant could demonstrate the behaviour as a porous scaffold which may be promising for bone engineering for large segmental bone defects.

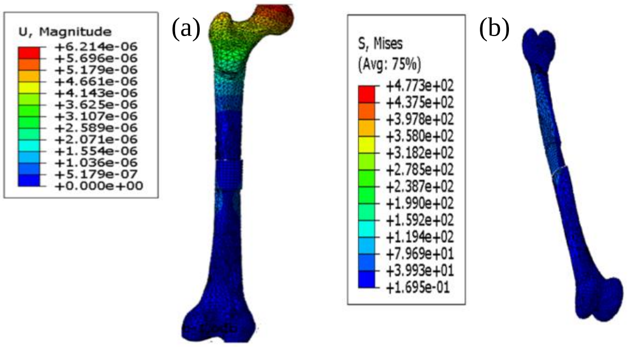

Fig. 3. FEA results for AZ31 Mg alloy cage: (a) Deformation, (b) Von-Mises stress.

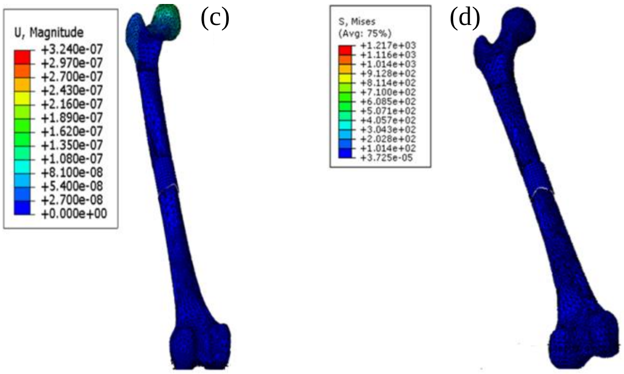

Fig. 4. FEA results for Ti alloy cage: (c) Deformation, (d) Von-Mises stress.

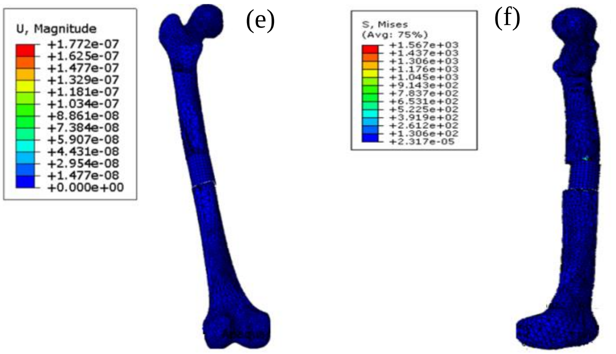

Fig. 5. FEA results for SS 316L cage: (e) Deformation, (f) Von-Mises stress.

Table 3. FEA results of assembly of segmental femur bone rapaired with porous cylindrical mesh cage bioimplant using various biometals (Explicit Dynamic FE Analysis).

Biometals	Total Deformation (mm)	Von-Mises Stress (MPa)
Magnesium alloy (AZ31	0.0062	477
Ti alloy (Ti-6AL-4V)	0.0003	1217
Stainless Steel (SS 316L	0.0002	1567

Conclusion

The Cylindrical mesh cage porous bioimplants were designed from different biometals. In this report, the designed mesh cage bioimplants were fixed to segmental femur bone defect and the FE Analysis was performed in order to obtain the total deformation and inteface stress for the various well established non-degradable biometal (Ti-6AL-4V and SS316) based cage bioimplant. The results were compared with the results obtained from the fixation of a degeradable biometal (AZ31) based cage bioimplant. The analysis was carried out under static and dynamic loading conditions. The values of the interface von-mises stress for the AZ31 was found to be significantly lower than the values obtained from the fixation of other non-degradable biometal based mesh cage bioimplant indicating its future use of the biometal-based porous bioimplant as scaffold for repair and regeneration of large bone defects. On the contrary, Ti-6AL-4V and SS 316L could be used as only a bioimplant for orthopedic implantation. The elastic behaviour of the AZ31 could be well-observed from deformation behavior of the Mg-based bioimplants compared to other non-degradaing biometal based porous cage bioomplants. Thus, AZ31 could be considered as a suitable degradable biometal for design and development of a porous scaffold based bioimplant for bone rapir and regeneration for large segmental defects. The current research work may also be useful to screen many bioimplant designs prior to their manufacturing for further reduction of the manufacturing costs associated with the development of degradable and non-degradable metal based bioimplants.

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Conflicts of interest

All the authors declare that there is no conflict of interest.

Keywords

Bioimplants, biomaterials, porous scaffolds, cylindrical mesh cage scaffold, segmental bone defect, Finite Element Analysis (FEA).

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