Journal of the Serbian Society for Computational Mechanics / Vol. 18 / No. 1, 2024 / pp 94-109 / original paper
(10.24874/jsscm.2024.18.01.07)

OPTIMIZING TORP MIDDLE EAR PROSTHESIS MATERIAL PERFORMANCE USING FGM MATERIAL DEGRADATION APPROACH

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Abstract

The advancement of technology in the field of human health plays a significant and positive role, particularly in the realm of hearing. In this study, we propose a novel approach for middle ear prostheses. We constructed a finite element (FE) model of the ear with a pure titanium TORP prosthesis, which we validated using experimental results. Subsequently, we applied the FGM (material degradation) method to alter the prosthesis material, utilizing biocompatible materials that can be used as hearing prostheses. We found that steel and hydroxyapatite ceramic can be used as alloys with titanium, and even customized prostheses can be manufactured according to patients' needs.

Keywords: Middle ear, prosthesis, ossicles, FGM, vibration analysis, finite-element method.

1. Introduction

This scientific article meticulously explores the synergy between medicine and technology, paving the way for significant advancements in the field of auditory health. At the heart of this innovative symbiosis lies the middle ear implant, a crucial component in restoring hearing. Its effectiveness is anchored on four essential pillars: impeccable biological compatibility, easy accessibility, technically straightforward installation, and biomechanical properties that reach optimal levels (Menéndez-Colino et al. 2004; Hanawa 2022).

Since the 1990s, titanium implants have emerged as the predominant choice for addressing transmission hearing loss issues associated with ossicular chain abnormalities. Their dominance stems from their exceptional biological compatibility, unparalleled user-friendliness, and lightweight characteristics, making them ideal for delicate ossicular reconstruction (Vassbotn et al. 2007; Mosconi et al. 2023). Moreover, the ongoing evolution of titanium's biocompatibility, enhanced by the interaction with fibroblasts on conditioned surfaces, underscores its status as a preferred material for audacious medical applications.

Recent studies, including ours, have found no significant difference in complications post-tympanoplasty between bioceramic and titanium ossicular prostheses. Both materials demonstrate suitability for auditory rehabilitation, showcasing the breadth of options available for patient-specific treatment plans (Zhang et al. 2007). The rapid advancements in materials science not only broaden the spectrum of usable materials, but also enhance our understanding of how these materials can be tailored for specific biomedical applications.

The introduction of Functionally Graded Materials (FGM) for designing hearing prostheses represents a significant innovation in this field. By integrating two distinct materials within a single prosthesis, the FGM technique allows for a customized approach to biomechanical performance, offering a viable alternative to traditional titanium implants. This method facilitates a tailored variation in material composition along the prosthesis, optimizing mechanical properties to meet individual patient needs.

In our research, we have expanded the possibilities for middle ear implant design by combining titanium with additional materials, exploring new avenues in implant technology. This inventive approach not only broadens the scope of design possibilities but also enhances the potential for mechanical efficacy, promising significant improvements in patient outcomes.

2. Materials and Methods

Research in middle ear hearing prostheses has seen significant advances in recent years, offering innovative solutions to improve the quality of life for patients with hearing impairments. In this regard, our study focuses on exploring a new approach in the field of middle ear hearing prostheses.

We initially conducted a simulation of the total TTP-Tübingen AERIAL middle ear prosthesis in titanium, as depicted in Fig. 1, subjected to an acoustic pressure of 90 dB across a frequency range from 250 to 8000 Hz. However, to further enhance the performance and durability of these prostheses, we have embarked on a new method based on controlled degradation of functionalized materials (FGM).

In this study, we specifically focus on the application of the FGM material degradation method to the total TTP-Tübingen AERIAL prosthesis, as well as a reference prosthesis, as indicated in Fig. 2. To do so, we selected four biocompatible materials. Reference points PR1 and PR2 mark the beginning and end of the gradual degradation of materials, respectively, as illustrated in Fig. 3. In this region, we identified titanium as one of the materials present, allowing for a precise comparison of prosthetic behavior.

This innovative approach aims to evaluate the performance and durability of hearing prostheses under the influence of FGM material degradation, thereby paving the way for new perspectives in the development of more durable and effective hearing prostheses for patients with middle ear hearing impairments.

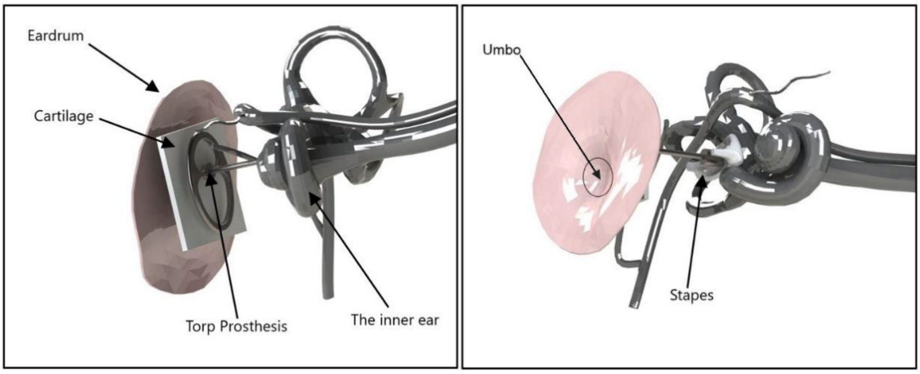

Fig. 1. Diagram of prosthesis placement in the middle ear

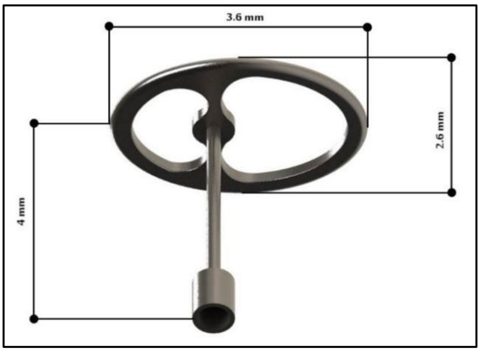

Fig. 2. TTP-Tübingen AERIAL total prosthesis Ref: 1004 238 (Kurz, Germany)

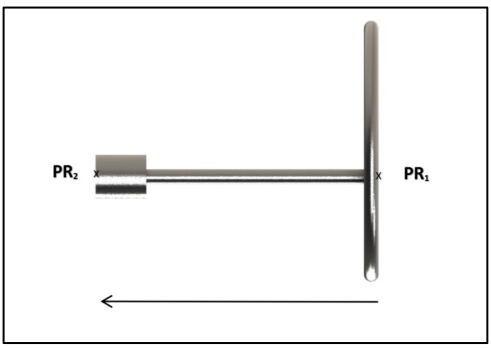

Fig. 3. Direction of material degradation

2.1 Geometry

As part of our research aimed at studying the behavior of middle ear prostheses using the FGM method, we utilized three-dimensional models that were previously digitized using a CT scanner, as demonstrated in Fig. 1. The design of the prosthesis itself was developed using Computer-Aided Design (CAD) software, referencing the prosthesis (1004 238 (Kurz, Germany)), while adhering to the construction standards established by the manufacturer KURZ, as also depicted in Fig. 2. The specific dimensions of the components used in our simulations are precisely listed in Table 1.

Anatomical structures	Data for FEM (mm)	Published data
Eardrum		
Diameter along manubrium	8.13	7.5[5]
Diameter perpendicular to manubrium	8.56	7.9[5]
Height of the cone	2.1	
Surface area(mm^2)	62.43	57 – 64[5]
Stapes		
Height	3.2	3.29[5]
Length of footplate	2.89	2.96[5]
Width of footplate	1.4	1.33[5]
Prosthesis		Computer-Aided Design in compliance with the referenced standard Ref: 1004 238 (Kurz, Germany)
Length	4	
Width	3.6	
Weight (mg)	4	

Table 1. Dimensions used in the middle ear FE model

[5] Kirikae, I. 1960.

2.2 Mechanical Properties

During our research, KURZ intentionally opted for the use of high-grade pure medical titanium, in accordance with the strict ASTM F67 standards, Grade 2. This selection stemmed from a meticulous assessment of its remarkable properties, including its exceptional lightweight nature, unparalleled corrosion resistance, proven biocompatibility, and advanced machining capabilities. Additionally, we also utilized biocompatible materials for simulating the degradation of Functionally Graded Materials (FGM). These mechanical properties, detailed in Table 2, are of crucial importance to ensure the optimal performance of our model components, namely the tympanic membrane, stapes, and cartilage. By combining the mechanical characteristics of pure titanium with the properties of these anatomical components, our study aims to deepen our understanding of the dynamics and functionality of these elements in essential biomedical applications.

Material	Young's Modulus (MPa)	Poisson's Ratio	Density (kg/m^3)
Tympanic membrane (flaccida) (Gan et al. 2002) pars flaccida pars tensa	10 20 (longitudinaldirection) 30 (radial direction)	0.3	1200
Stapes (Gan et al. 2002)	1.41×10^4	0.3	2200
Cartilage tympanoplasty (Lee et al .2006)	2.8	0.3	1300
Titanium pur (ASTM F67) Grade 2 (Niinomi 1998; Catherine et al. 2018)	102.7×10^3	0.37	4500
Stainless steel (Yao et al. 2013)	200×10^3	0.3	8000
Porous polyethylene (Yao et al. 2013)	0.7×10^3	0.3	970
Alumina ceramics (Yao et al. 2013)	375×10^3	0.3	3153
Hydroxyapatite ceramics (Yao et al. 2013)	155×10^3	0.3	1200

Table 2. Material properties used in the middle ear FE model

2.3 Mesh

In evaluating the performance of the entire middle ear prosthesis, a mesh convergence analysis was undertaken. Given the compact nature of this structure, achieving an adequate mesh resolution is vital for capturing deformations and stresses accurately. By setting a convergence criterion of 0.2 mm for the element size and adopting a tetrahedral mesh configuration, it was determined that this parameter offers the most effective method for obtaining dependable outcomes. This refined element size facilitates the incorporation of intricate variations within the middle ear while ensuring precise depiction of critical regions, such as interfaces and contact surfaces.

Instance Name	Element Type	Elements number	Nodes
Prostheses	C3D4	9840	2961
Eardrum	C3D4	8997	3097
Stapes	C3D4	8206	2160
Cartilage	C3D8R	400	882

Table 3. Mesh properties used in the middle ear FE model

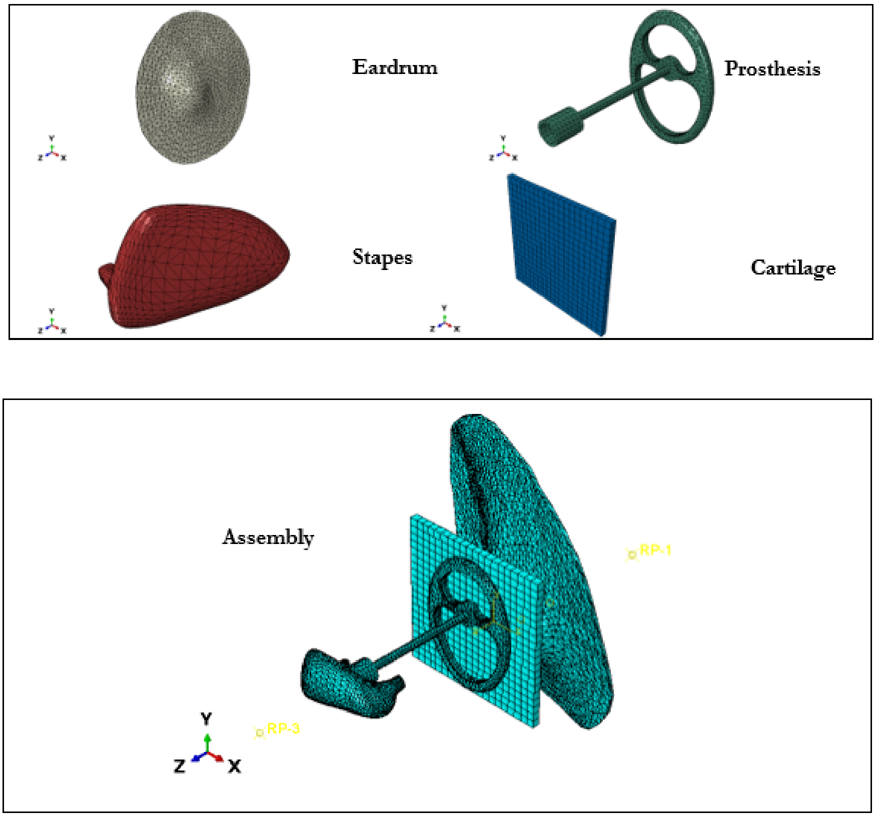

Fig. 4. Three-dimensional finite element mesh model

2.4 Boundary Conditions

Upon replacing the original elements of the middle ear, including the malleus and incus, with the Total Prosthesis TTP-Tübingen AERIAL, measuring 4 mm in length, as depicted in Fig. 6, substantial alterations were necessary. This substitution entailed not only the insertion of the prosthesis itself, but also the removal of ligaments and joints previously interconnected with the native components, constituting the entirety of the middle ear. For the malleus, when removed, ligaments C2, C4, and C7 were also eliminated as they are linked with the malleus, while for the incus, the same applied to ligaments C1, C3, and C5. Concerning cartilages, they play a crucial role in ensuring the stability of the prosthesis in the middle ear, protecting the tympanic membrane, and dampening sound vibrations. They provide essential structural support and promote optimal integration of the prosthesis, thereby contributing to improved post-operative recovery. Through these adjustments, our model was refined to mirror this drastic structural transformation, aiming to enhance comprehension of the prosthesis impact and implications within a physiological context. The outcomes stemming from these adaptations contribute to a more profound insight into the intricate dynamics within the middle ear, thereby paving the way for novel perspectives in the realm of auditory prosthetic devices.

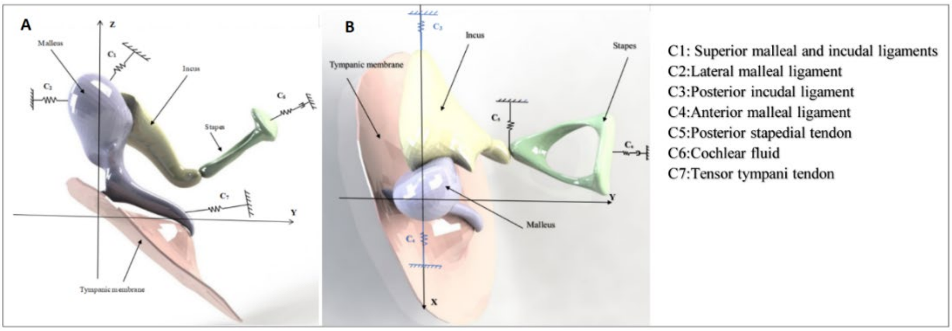

Fig. 5. Schematic of human right middle ear structure. A, anterior view; B, superior view. C1, C2, C3, C4, C5, and C7, attached ligaments and muscles; C6, cochlear fluid constrain (Gan et al. 2004)

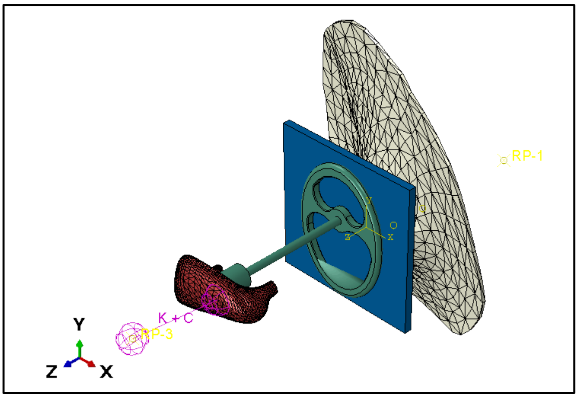

Fig. 6. Schematic of the structure of the human right middle ear with prosthesis

Ligaments or joints	Stiffness K/(N/m)	Damping parameters (Ns/m)
Cochlear fluid (Liu, H et al 2010) (C6)	60	0.054

Table 4. Boundary conditions of the middle-ear finite element model

3. Results

To ensure the successful implementation of our approach to FGM material degradation, it is critical to initially validate the model using titanium prostheses based on empirical data. We aligned our results with available experimental datasets, which primarily examine the displacements of the stapes and umbo, as reported in a study by Gan et al. (2004). The researchers employed ten temporal bone samples from human subjects of varied ages. In their experiments, they exposed the tympanic membrane to ten pure tones at an intensity of 90 dB SPL and subsequently measured the resultant displacements of the stapes and umbo using a Doppler effect-based laser vibrometer.

To guarantee the performance and reliability of our model, we incorporated the harmonic response of the model into our analysis. This inclusion is pivotal because the dynamic response of titanium prostheses to varying frequencies can significantly influence their operational behavior under real-world conditions. By validating our model against this spectrum of harmonic responses, we do not only corroborate the displacement data but also capture the intricate mechanical dynamics within the prosthesis that could impact its long-term stability and effectiveness. This phase is crucial for developing a robust model that can accurately forecast the degradation patterns of FGM materials in biomedical applications.

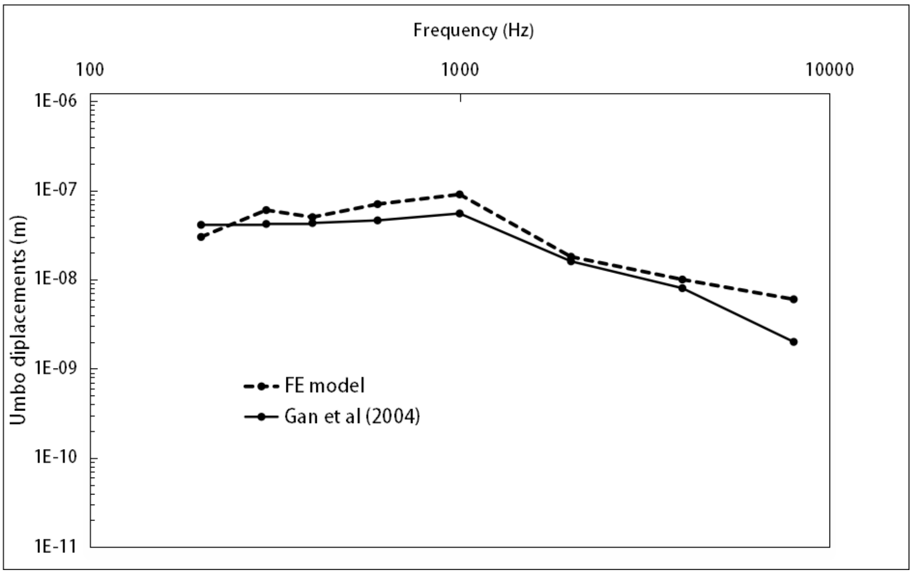

Fig. 7. Comparison of the displacements at the umbo

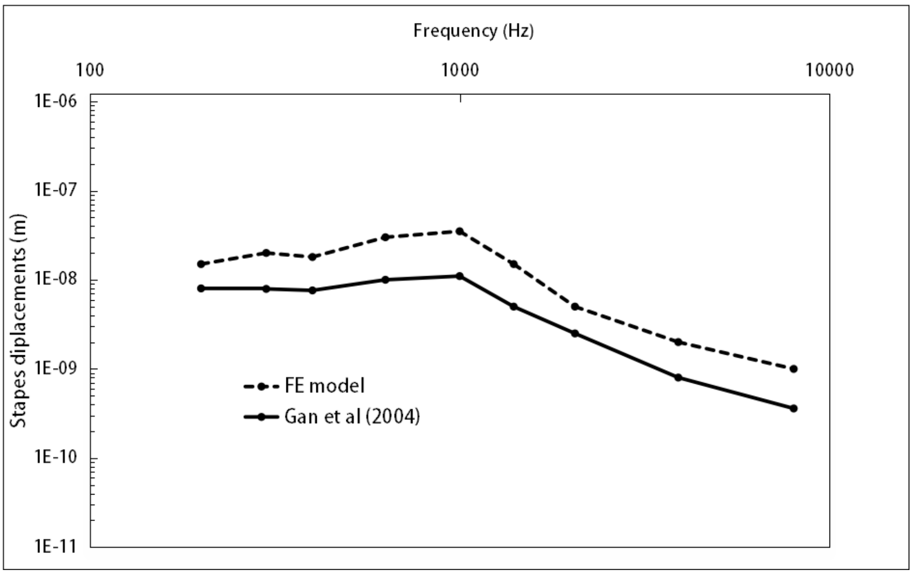

Fig. 8. Comparison of the displacements at the stapes footplate

In Fig. 7, we observe nearly identical curves, indicating that the pressure applied to real eardrums and our FE model does not have eliminating conditions at the onset of pressure. However, in Fig. 8, discrepancy can be observed. This shift is attributed to the boundary conditions that we have eliminated. In other words, our model is somewhat less constrained compared to the real ear.

We will now proceed to our FGM approach. As a starting point, in PR1, the titanium material behaves linearly, then in PR2, it undergoes degradation with the other 4 materials. Conversely, in PR2, titanium undergoes degradation according to PR1 for the other 4 materials.

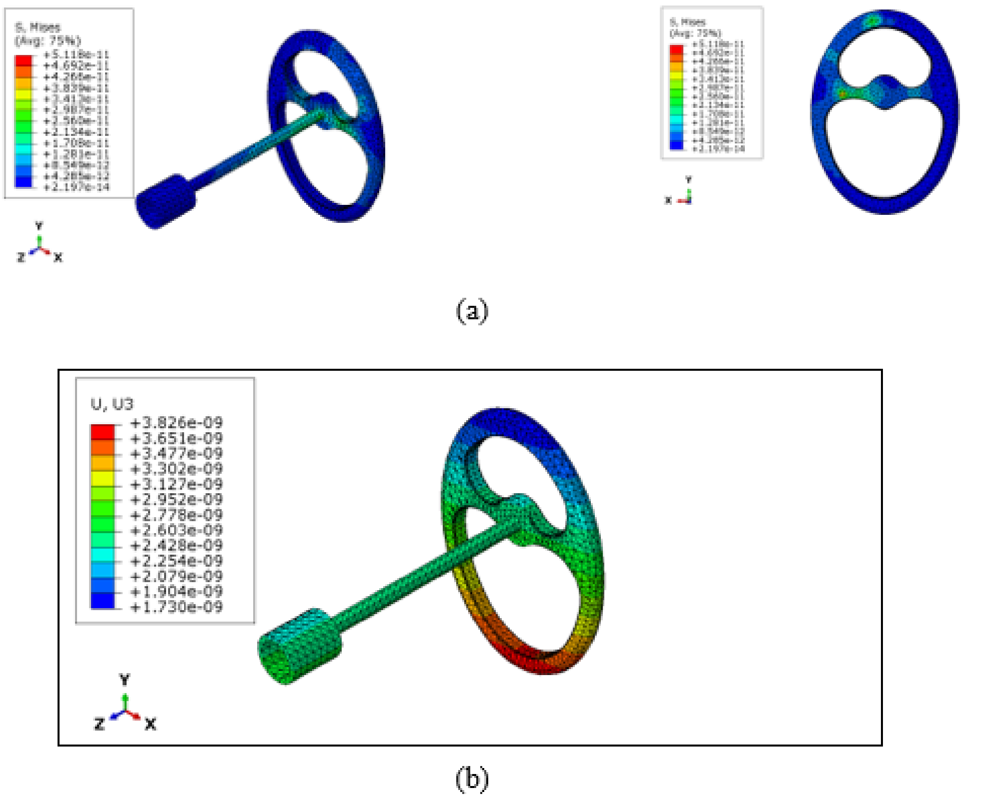

Fig. 9. Von Mises stresses and displacement distributions on the prosthesis and titanium in all FE models. (a) Vos Mises stress (b) Displacement U3

3.1 PR1 Titanium

Stresses

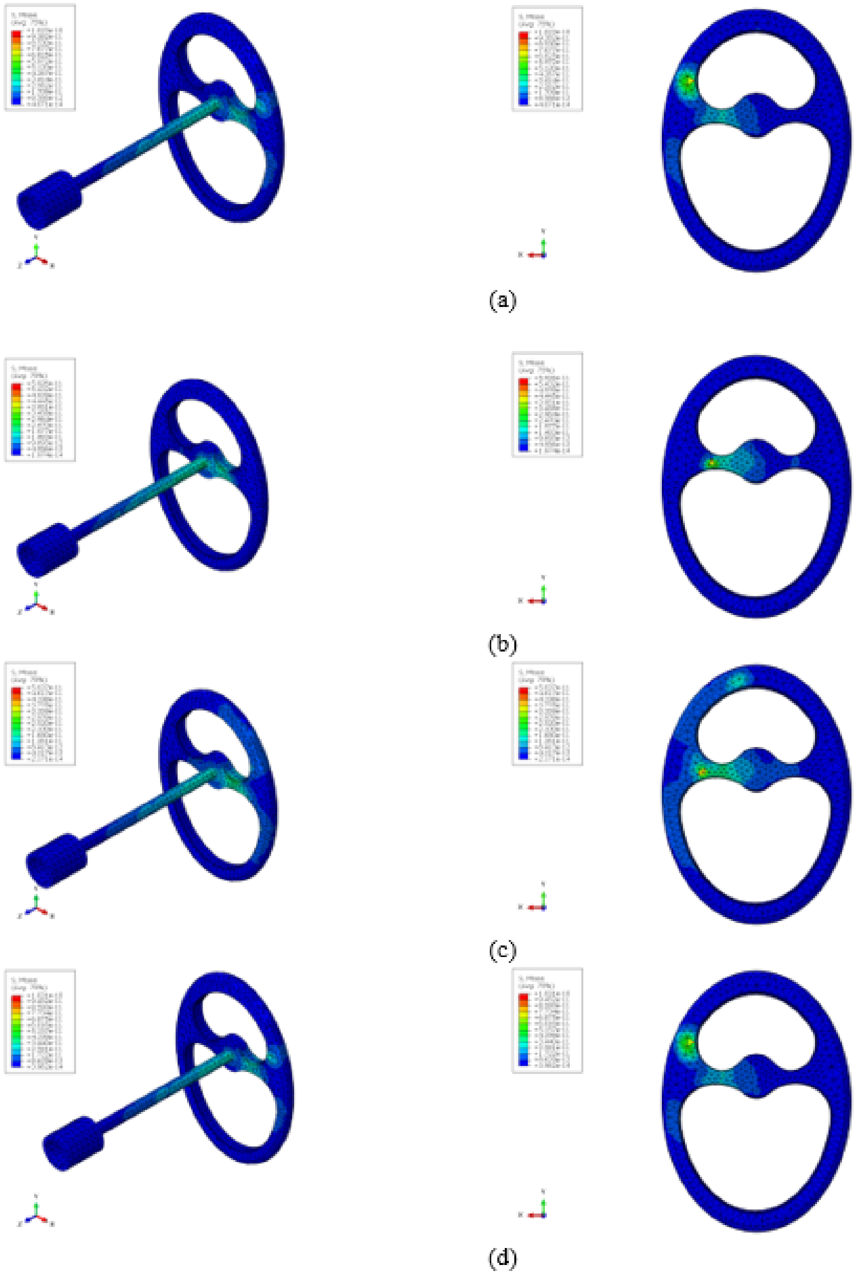

Fig. 10 Von Mises stresses distributions on the Prosthesis PR1 Titanium towards PR2 in all FE models. (a)Titanium-Stainless steel, (b) Titanium-Porous polyethylene, (c) Titanium-Hydroxyapatite ceramics, (d) Titanium-Alumina ceramics

•Displacement

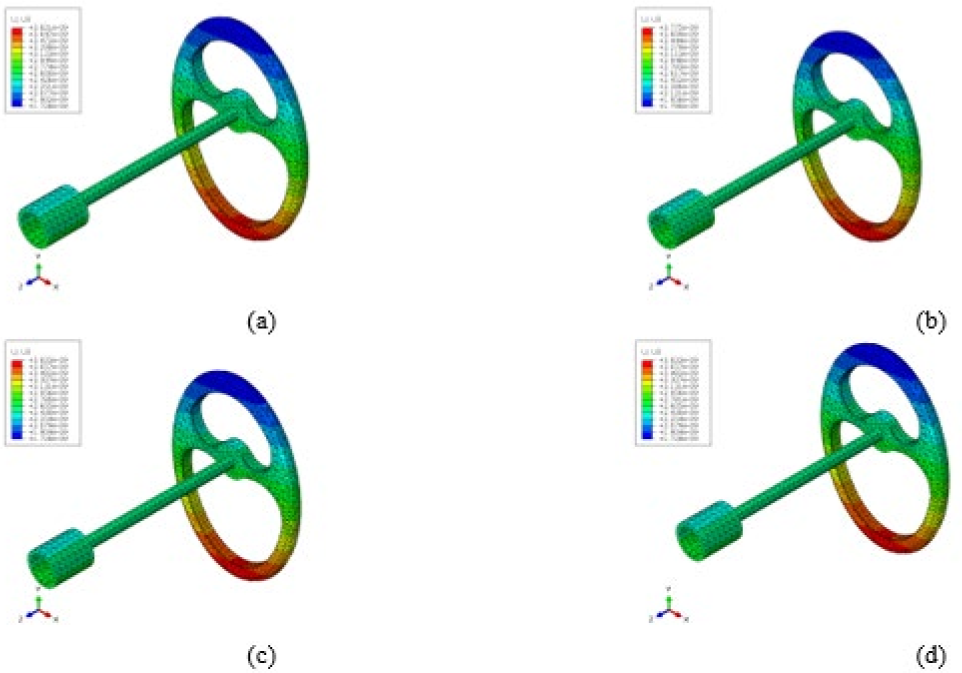

Fig. 11. Displacements U3 distributions on the Prosthesis PR1 Titanium towards PR2 in all FE models. (a) Titanium-Stainless steel, (b) Titanium-Porous polyethylen, (c) Titanium-Hydroxyapatite ceramics, (d) Titanium-Alumina ceramics

3.2 PR2 Titanium

Stresses

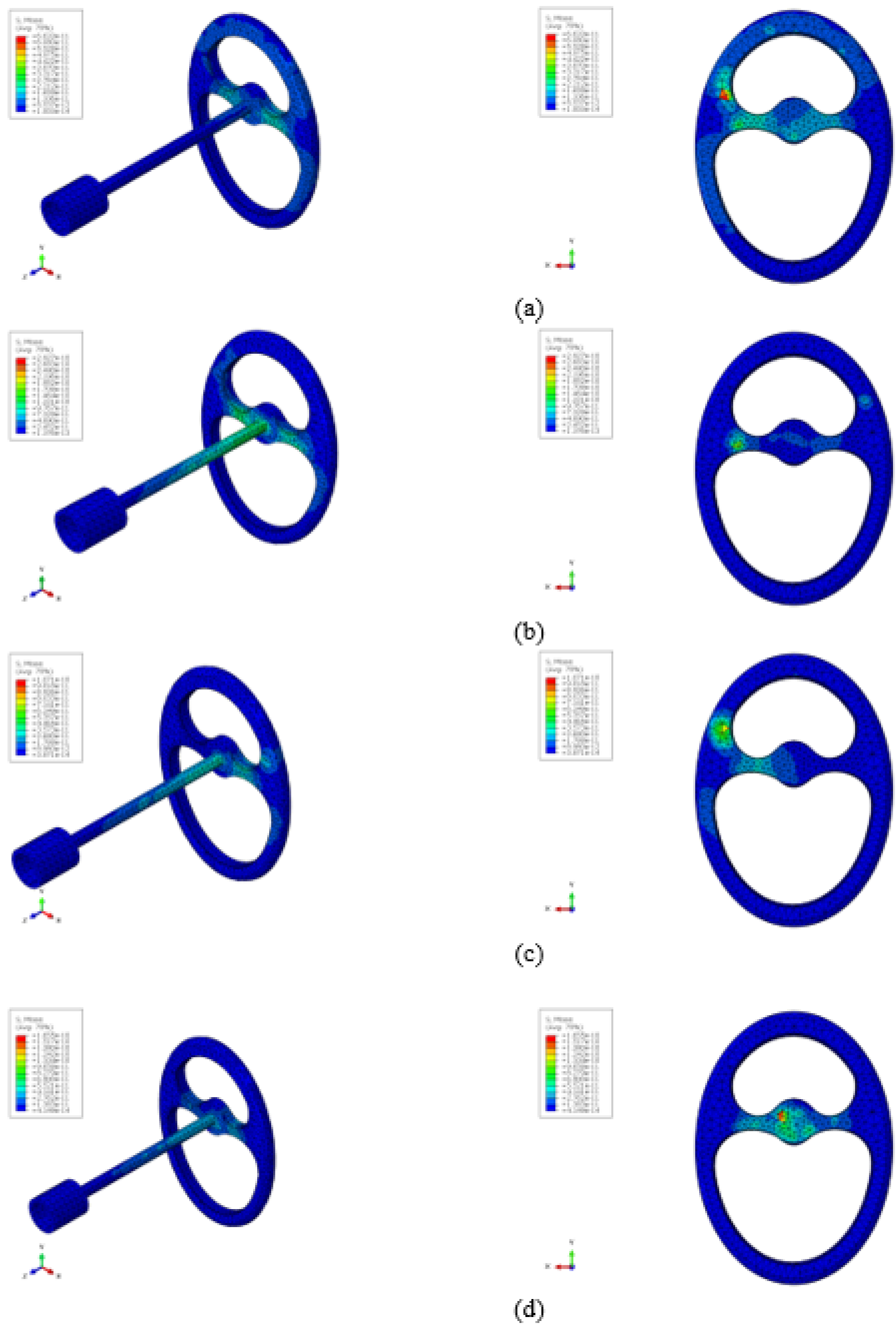

Fig. 12. Von Mises stresses distributions on the Prosthesis PR2 Titanium towards PR1 in all FE models. (a) Stainless steel-Titanium, (b) Porous polyethylene-Titanium, (c) Hydroxyapatite ceramics-Titanium, (d) Alumina ceramics-Titanium

Displacement

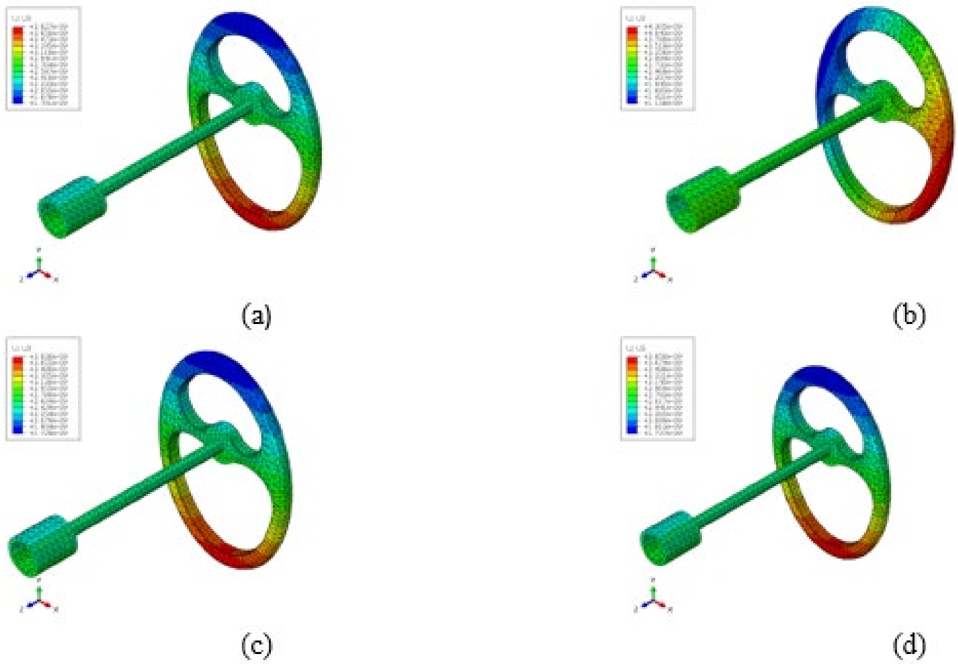

Fig. 13. Displacements distributions on the Prosthesis PR2 Titanium towards PR1 in all FE models. (a) Stainless steel-Titanium, (b) Porous polyethylene-Titanium, (c) Hydroxyapatite ceramics-Titanium, (d)Alumina ceramics-Titanium

4. Discussion

After simulating our FE model, we divided the work into two distinct parts:

1st part: We fixed titanium on our reference PR1 and conducted degradation according to the second set of references PR2 for the four materials: steel, porous polyethylene, hydroxyapatite ceramic, and alumina ceramic. We noticed that the stresses were minimal and uniform on the surface of the prosthesis crown, but varied at different locations as indicated in Fig. 10. When we compared the results with the fully titanium prosthesis as shown in Fig. 9, we found the same stress concentration. Regarding displacement, there was a difference between pure titanium and steel as well as porous polyethylene, but for hydroxyapatite ceramic and alumina, the displacement was similar.

2nd part: For this part, we reversed the process of the 1st part by inserting titanium into PR2 and using a different material each time for PR1. Regarding stresses, we observed that porous polyethylene had a significant value compared to other materials, while for steel, it was the opposite of porous polyethylene. The other two materials were almost similar to titanium, as shown in Fig. 12. As for displacement, we observed that porous polyethylene had an equally significant value compared to other materials, as illustrated in Fig. 13.

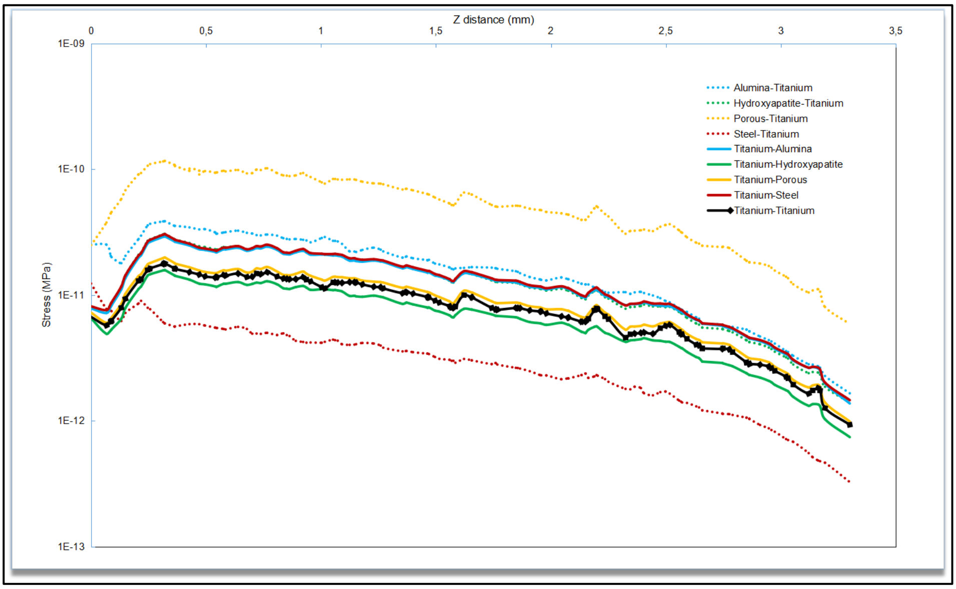

Fig. 14. Stress distribution along the length of the prosthesis in FE models

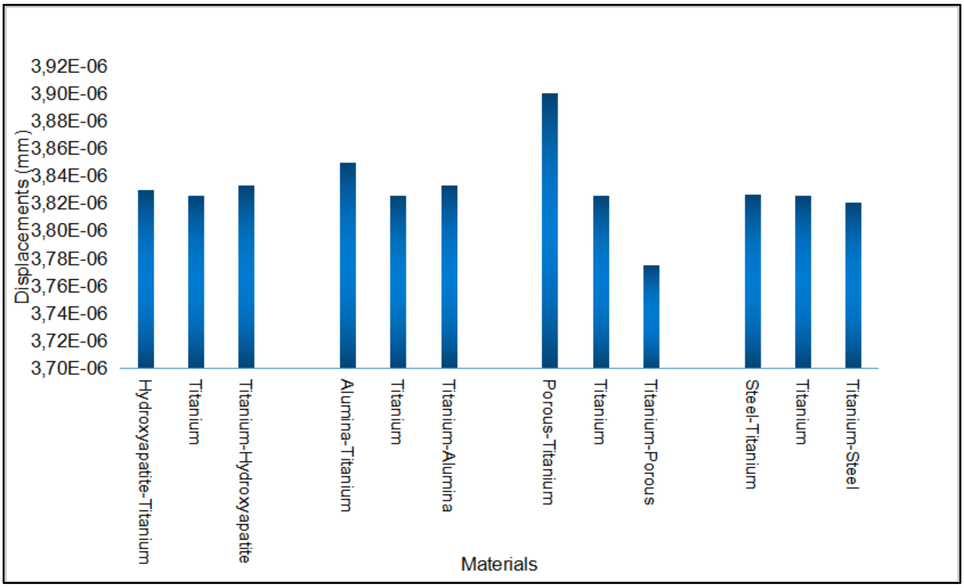

Fig. 15. Peak displacement of the prosthesis for all materials in FE models

In Fig. 14, we plotted the stresses along the length of the prosthesis along the Z-axis. We observed that the curve was divided into three distinct zones: in the upper zone, we had high stress values, where only the porous-titanium material combination was present, while in the lower zone, where stress values are minimal, we found the steel-titanium combination. The remaining zones exhibited stress values almost similar to those of pure titanium. Thus, we found that the steel-titanium material combination is subjected to less stress compared to other material combinations.

As for Fig. 15, where we compared our results with those of titanium and other materials, we noticed that the porous-titanium combination exhibits the greatest displacement compared to other combinations, while the steel-titanium combination shows displacements almost similar to those of pure titanium, whether with steel or pure titanium. This observation is also valid for the hydroxyapatite ceramic-titanium combination.

5. Conclusion

After our study and the application of the FGM method, we have discovered potential alternatives to titanium as a material for middle ear prostheses. It is noteworthy that steel, when combined with titanium, proves to be a high-performing alloy for the manufacturing of prostheses. The comparison of displacements and lesser constraints for this alloy shows that it is more effective than titanium, offering the potential for replacement. We found that the value of 66.33E-12 MPa for the stainless steel-titanium alloy is lower than that of a pure titanium prosthesis, which has a value of 51.18E-11 MPa for the same displacement. Additionally, promising results achieved with hydroxyapatite ceramics open new avenues in this field. These findings underscore the importance of diversifying materials used in middle ear prosthesis fabrication to better meet individual patient needs. Particularly, our observations on prosthesis displacement within the ear suggest significant improvement possibilities. Consequently, this study provides impetus for the exploration of novel methods aimed at optimizing human auditory performance and advancing the continuous development of hearing prostheses.

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