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Evaluation and Comparison of the Mechanical Behaviors of a Middle Ear Prosthesis using the Finite Element Method

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Abstract: Advancements in audiology and medical engineering have generated growing interest in enhancing titanium implants for middle ear restoration. In our study, we employed a finite element model of the middle ear to assess the behavior of the TORP prosthesis and the stapes under an acoustic pressure of 90 dB across a frequency range of 250 to 8000 Hz. The results were compared to experimental measurements obtained using a Doppler-effect-based laser vibrometer while varying the materials of the prosthesis to evaluate their mechanical impact. A satisfactory correlation between the simulation and experimental measurements validated our model.

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

1. Introduction

The realms of medicine and technology intertwine in fascinating ways, ushering in impressive advancements in the field of auditory health. At the heart of this convergence lies the middle ear implant, a pivotal device in surgical interventions aimed at restoring hearing. For such an implant to be effective, it must meet four fundamental criteria: flawless biological compatibility, ease of accessibility, straightforward technical installation, and the best conceivable biomechanical properties [1,2].

Since the 1990s, titanium implants have been widely adopted to address conductive hearing loss issues caused by anomalies in the ossicular chain. This preference is due to their excellent biological compatibility, user-friendliness, and lightweight nature [3]. Furthermore, the enhancement of the biocompatibility of titanium middle ear implants, characterized by the properties of fibroblasts cultured on conditioned surfaces, has reinforced their status as an ideal biomaterial for ossicular chain reconstruction. Epithelialization of the implant surfaces proves crucial to ensure their stable integration in the middle ear [4].

In this innovative study, we embarked on an in-depth simulation to assess the performance of a 4mm total titanium prosthesis, specifically the TTP-Tübingen AERIAL, in the context of the middle ear (Figure 1). We then compared these results to experimental data obtained. Finally, we transitioned to two other biocompatible materials that could be considered as alternatives to titanium prostheses for the middle ear. This approach aims to provide crucial insights into the advantages and limitations of various materials in the development of high-performance hearing prostheses, thereby paving the way for significant advancements in the fields of audiology and

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auditory health.

Figure 1: TTP-Tübingen AERIAL Total Prosthesis Ref: 1004 238 (Kurz, Germany).

2. Materials and Methods

2.1 Geometry

In the scope of our study aimed at analysing the behavior of the middle ear prosthesis, we utilized 3D models of the tympanic membrane and the stapes, which had been previously digitized using a CT scanner, as illustrated in Figure (2). The prosthesis itself was designed using Computer-Aided Design (CAD) software in accordance with construction standards established by the manufacturer KURZ,

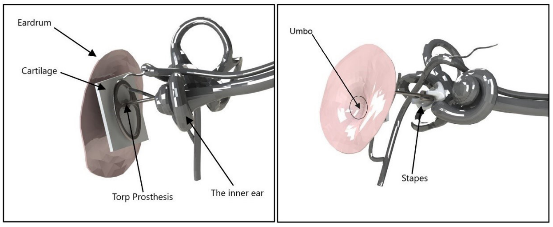

Figure 2: Diagram of Prosthesis Placement in the Middle Ear.

as depicted in Figure (1). The specific dimensions of the components used in our simulations are listed in Table (1).

2.2 Material

In the context of our study, KURZ deliberately chose to prioritize the use of high quality medical-grade pure titanium, in accordance with the stringent ASTM F67 standards, Grade 2. This decision is based on a meticulous evaluation of its exceptional characteristics, including its remarkable lightweight nature, unparalleled resistance to corrosion, proven biocompatibility, and advanced machining capabilities. These mechanical properties, detailed in Table (2), are essential to ensure the optimal performance of the components in our model, namely, the tympanic membrane, the stapes, and the cartilage. By combining the mechanical

Table 1: the dimensions used in the middle ear FE model.

Structure	*Data for finite element model*	*Published data*	
Eardrum			
Diameter along manubrium	8.13 mm	8.0 ~ 10.0 mm	*Gray, [5]*
Diameter perpendicular to manubrium	8.05 mm	7.5 ~ 9.0 mm	*Helmholtz, [5]*
Height of the cone	1.51 mm	2.0 mm	*Siebenmann, [5]*
Surface area	73.56 mm^2	55.8 ~ 85.0 mm^2	*Wever and Lawrence, 1954 [6]*
Thickness	0.05 ~ 0.073 mm	0.04 ~ 0.075 mm	*Kirikae, 1960 [7]*
Stapes			
Height	2.45 mm	2.5 ~ 4.0 mm	*Stuhlman, 1937, Wever and Lawrence, 1954 [5]*
Length of footplate	2.47 mm	2.64 ~ 3.36 mm	*Wever and Lawrence, 1954 [5]*
Width of footplate	1.21 mm	0.7 ~ 1.66 mm	*Helmholtz, 1863, Wever and Lawrence, 1954 [5]*
Protheses			
Length	4 mm		*Computer-Aided Design in compliance with the referenced standard Ref: 1004 238 (Kurz, Germany)*
Width	3.6 mm		
Weight	4 mg		
Cartilage			
Thickness	0.15 mm	0.1~0.2 mm	*Lee and Chia-Fone, 2006 [8]*

properties of pure titanium with the characteristics of these anatomical components, our study aims to gain a better understanding of the dynamics and functionality of these elements in critical biomedical applications.

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

Material	*Modulus of elasticity (MPa)*	*Poisson ratio*	*Density (kg/m³)*
Pure Titanium (ASTM F67) Grade 2 [9]	105e03	0.37	4500
Stainless steel [10]	200e03	0.3	8000
Porous polyethylene [10]	0.7e03	0.3	970
Tympanic membrane (flaccida) [11]	0.0111e03	0.3	1200
Stapes [11]	12e03	0.3	2200
Cartilage tympanoplasty [8]	0.0028e03	0.3	1300

2.3 Boundary Conditions

When we proceeded with the removal of the original components of the middle ear, namely the malleus and incus, as illustrated in Figure (3), and replaced them with the 4mm TTP-Tübingen AERIAL total prosthesis, significant adjustments were made. This substitution resulted not only in the placement of the prosthesis itself but also in the removal of ligaments or articulations that were once interconnected with the original components, as demonstrated in Figure (4) [12]. The latter represented the complete middle ear, incorporating all components. By making these changes, our model was adapted to reflect this radical transformation of the structure. This approach aims to better understand the impact and effects of the prosthesis in a physiological context. The results obtained through these modifications contribute to a deeper understanding of the complex interactions within the middle ear, while paving the way for new insights in the field of hearing prosthetic devices.

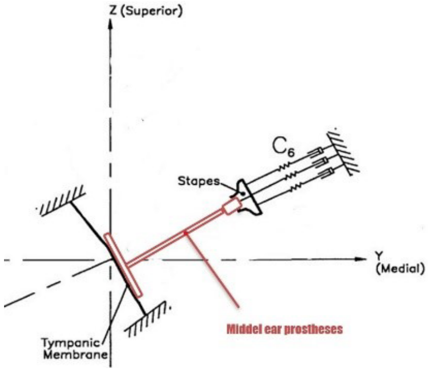

Figure 3: Diagram of the structure of the human right middle ear, C6: Constraints of the cochlear fluid.

The detailed modelling for the boundary conditions is shown in table 3 [13].

Table 3: Boundary conditions of the middle-ear finite element model.

Ligaments or joints	Stiffness K/(N/m)	Damping parameters (Ns/m)
Cochlear fluid (C6)	60	0.054

2.4 Convergence Study

In the context of evaluating the behavior of a 4 mm total middle ear prosthesis, a mesh convergence

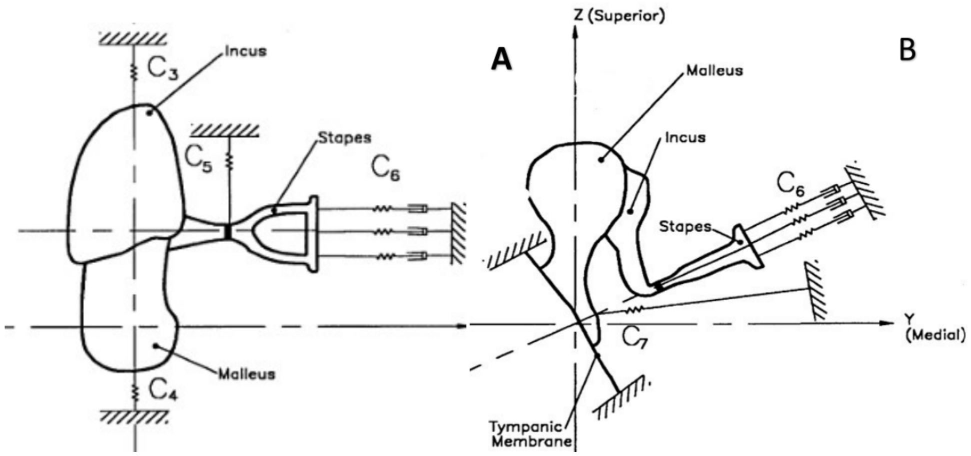

Figure 4: Schematic of human right middle ear structure. A, superior view B, an terior view. C1, C2, C3, C4, C5, and C7, attached ligaments and muscles; C6, cochlear fluid constraint.

study was conducted, as illustrated in Figure (5). Due to the compact dimensions of this structure, it is imperative to ensure adequate mesh resolution to accurately capture deformations and stresses. Using a convergence criterion of 0.2 mm for element size and opting for a tetrahedral mesh, as shown in Figure (6), it was determined that this value provides the best efficiency for obtaining reliable results. This optimized element size allows for accounting for complex variations in the middle ear while ensuring accurate representation of crucial areas, such as interfaces and contact surfaces.

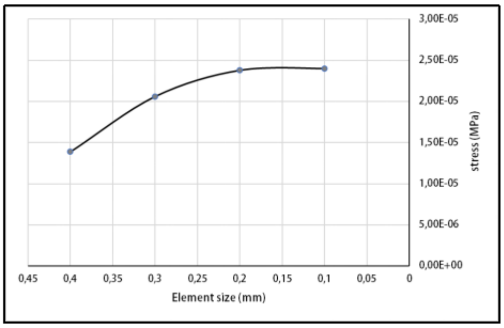

Figure 5: Mesh Convergence Check

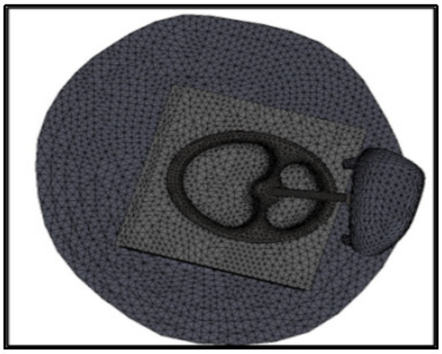

Figure 6: The Model after Meshing

3. Results

3.1. Evaluation and Validation of the Model

In order to evaluate our finite element model for the middle ear, we compared our results with experimental data. These data concern the displacements of the stapes and umbo and are derived from a study conducted by Gan et al [14], who used 10 samples of human temporal bones of different ages. In their experiment, they exposed the tympanic membrane to 10 pure tones at an intensity of 90 dB SPL and then measured the corresponding displacements of the stapes and umbo using a Doppler-effect-based laser vibrometer. To validate our model, we replicated the same sound pressure (90 dB SPL) applied laterally to the tympanic membrane in our finite element model of the middle ear. We then calculated the displacements of the stapes and umbo over a frequency range from 250 to 8000 Hz. The results of our calculations are presented in Figures (7) and (8) for reference and comparison with the experimental data.

To ensure the reliability of our model, we incorporated the harmonic response of the model into our analysis. This incorporation is crucial because the dynamic response of prostheses to different frequencies can significantly affect their behavior in real-world conditions. By validating our model against this range of harmonic responses, we not only confirm the displacement data but also capture the intricate mechanical dynamics within the prosthesis that could affect its long-term stability and effectiveness.

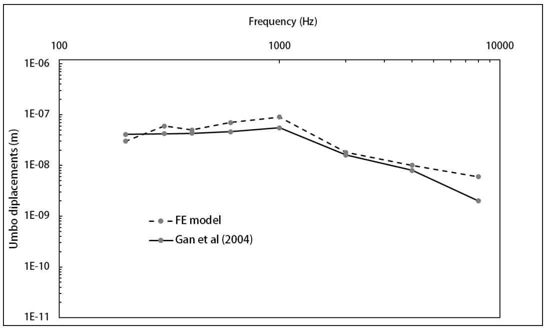

Figure 7: Comparison of the displacements at the umbo.

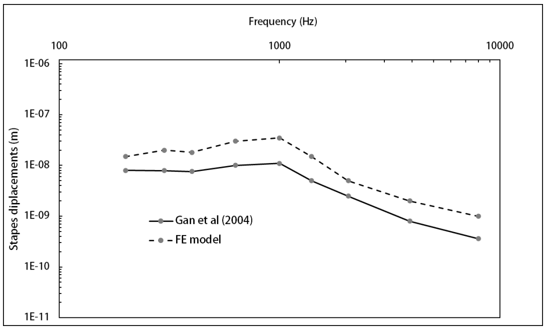

Figure 8: Comparison of the displacements at the stapes footplate.

In Figure (7), the data concerning the umbo displacement in our model show some instability compared to the experimental results, which is likely due to the reduced constraints imposed on the tympanic membrane. Nevertheless, the displacement curve exhibits similarities with the experimental results. However, in Figure (8), a clear difference is observed between the two curves. This difference can be attributed to the replacement of middle ear components, such as the malleus and incus, with our prosthesis model. This substitution led to the removal of specific constraints (C1, C2, C3, C4, and C5), as depicted in Figure (4), which were associated with the original components of the middle ear. Only constraint C6 remains in place. This modification explains the slight increase in stapes displacement compared to the experimental results. Despite this variation, our results remain promising and contribute to the validation of our model.

3.2. Performance Comparison

After successfully validating our model with an acceptable result, we proceeded to analyse the behavior of the prosthesis, as illustrated in Figure (9). This analysis highlights a Von Mises stress that reveals concentration at the crown end of the tympanic rod (Figure 9(b)). Regarding displacement, we used the displacements along the loading axis to evaluate their magnitude. Furthermore, it is important to note that, similar to the stresses, we observed a maximum displacement at the crown of the tympanic membrane (Figure 9(a))

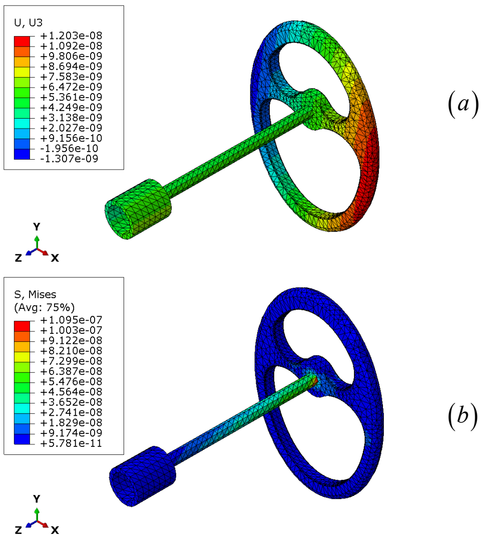

Figure 9. Titanium Prosthesis Behavior a: Displacement, b: Stres

In the context of the current study, two other materials, namely Stainless Steel and Porous Polyethylene, were used, as presented in Table (2), to compare the mechanical behavior of the Titanium prosthesis with these two (Figure (10) and (11)). It is worth noting that the selected materials are inherently biocompatible and may be considered for potential use as middle ear prostheses.

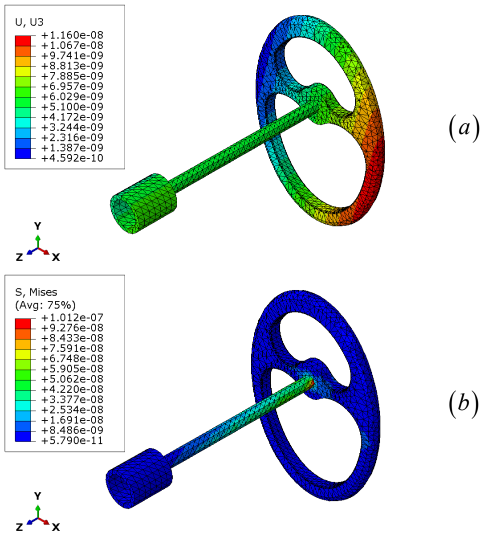

Figure 10. Stainless Steel Prosthesis Behavior a: Displacement, b: Stress.

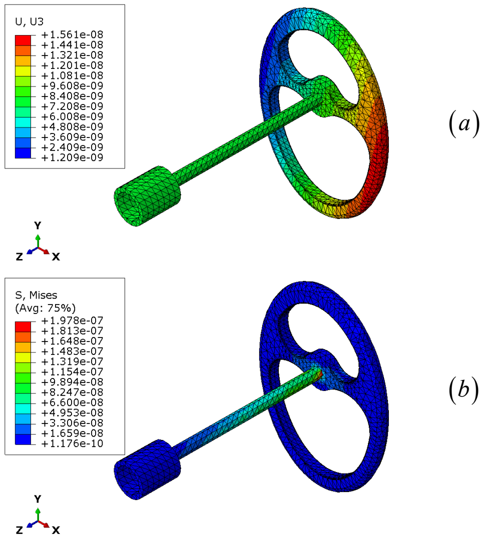

Figure 11. Porous Polyethylene Prosthesis Behavior a: Displacement, b: Stress.

After changing the material of the prosthesis, it's noteworthy that the displacement of the prosthesis remains primarily restricted to a specific area, namely the crown of the tympanic membrane. We can observe that the displacement of the titanium prosthesis is slightly higher than the desired experimental results, as illustrated in Figure (8) (1E-07 mm). Therefore, it is necessary to reduce the titanium displacement to approach the expected experimental results. As for porous polyethylene, the displacement is higher than that of titanium, which does not advance our goals. However, steel indicates lower displacement than titanium, making it a potentially viable alternative. After applying a maximum displacement in the Z-direction equal to 4.2E-08 m to the prosthesis (Figure (8)), we used the three previously studied materials to compare the stress distribution on the prosthesis, as shown in Figure (12).

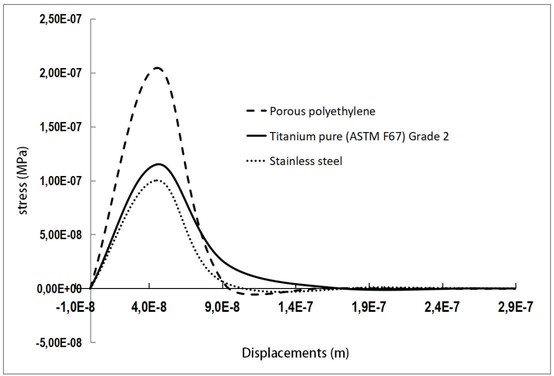

Figure 12. Stress Distribution on the Prosthesis for Maximum Displacement of Three Materials.

According to Figure (12), we can observe that porous polyethylene exhibits the highest stresses (2.1E-07 MPa), followed by titanium (0.9E-07 MPa), and then stainless steel (1.1E-07 MPa). This can be explained by the fact that the least rigid material (porous polyethylene in our case) will undergo more deformation under the same force, resulting in higher stresses. However, it is important to note that towards the end of the curves, there is a relaxation of stresses for all three materials. This relaxation is caused by the C6 constraint of the cochlear fluid, acting as a damper, restoring the middle ear system. For steel and titanium, this value is negligible, while for porous polyethylene, it holds significant importance.

4. Conclusion

In the context of our study on middle ear implants, we can conclude that titanium and stainless steel remain optimal materials in comparison to porous polyethylene for the design of the total TORP prosthesis. Titanium is already used as a material for prostheses, while our study on stainless steel aims to use it as an alternative due to its lower cost compared to titanium and good acoustic stability. However, it is essential to note that there is no "one-size-fits-all" material, as the choice will depend on the individual needs and preferences of the patients.

These results encourage us to continue our efforts in hearing prosthesis research and development. We plan to further explore opportunities for geometric and material customization to optimally address the specific needs of patients. This approach aims to enhance the quality of life for individuals with hearing impairments by providing more effective and tailored solutions, while paving the way for future advancements in the field of audiology.

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