An Analysis of the Auxetic Cranioplasty Implant

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Abstract

The following paper is a reflection on the advisability of using auxetic structures in medical devices. For this purpose, a model of a skull implant was designed. This implant could be used for cranioplasty of bone defects after neurosurgical procedures. The implant is made of a titanium alloy and has an auxetic "double arrow" structure. The behavior of the implant was investigated in two cases, under the influence of increased intracranial pressure and impact of an external force. The calculations were made with the finite element method implemented in the SolidWorks 2020 program. Moreover, the natural frequency of the structure was examined in the Comsol Multiphysics program.

Keywords: *auxetic structures, cranioplasty, skull implant, finite elements method*

1. Introduction

The bones of the skull provide a cover for the delicate tissues of the brain and support other head structures. Cranial bone defects may occur as a result of surgery to treat the build-up of edema in the skull bone, decompression surgery with uncontrolled cerebral edema, infectious complications, such as wound infection resulting in the development of osteomyelitis of the bone flap. Significant damage to the skull bones and / or removal of their fragment as a result of neurosurgical procedures requires their subsequent reconstruction. This is due to the need to restore the natural shape of the head and the need to protect the brain and other organs against mechanical injuries. Another important factor is the reconstruction of the original shape of the skull, as it has a great influence on the psychological aspect. The procedure for reconstructing the skull by supplementing the missing fragment is called cranioplasty. It is used for autografts, i.e., fragments of the patient's own bone tissue, or xenografts, i.e. implanting foreign material into the body, e.g., titanium implants, cyanoacrylate or polymers. Cranioplasty implants can be in the form of plates, plaques or meshes. An interesting solution is the use of titanium meshes with an auxetic structure [1-2].

Auxetics belong to the group of metamaterials and are characterized by a negative Poisson's ratio. This means that when they are stretched in one direction, they increase their dimensions or, similarly, when compressed - they decrease, not only parallel to the acting force, but also in perpendicular directions. Compared to traditional materials with a positive transverse to longitudinal deformation ratio, auxetics have different mechanical properties, such as better resistance to dents, shear and crack resistance. These types of metamaterials also exhibit synclastic behavior and absorb energy well, i.e., they are able to absorb shocks [3-5].

Auxetic materials and structures are rare in nature, but they can be manufactured[6] and due to their specific properties, they are increasingly used. One of the areas, in which auxetics are gaining popularity, is medical and peri-medical applications. The reason for this may be that they conform perfectly to the complex shapes of the human body and actively respond to changes in these shapes. Contrary to popular belief, auxetics were not invented by man. There are also substances exhibiting such properties in the nature. These include certain rocks and minerals, cork, cow and cat skins, and certain parts of bone or tendons. Due to the latter, auxetic materials are particularly desirable in prosthetics [7-9].

The field, in which the active adjustment of the prosthetic element to the tissues is of great importance, is neurology. Swelling around the nerves or brain is not only an uncomfortable defect, but can even be life threatening. Therefore, it is very important that the elements used for the reconstruction of the skull ensure their appropriate susceptibility to deformation.

2. Model of the cranioplasty implant

This article presents a procedure to simulate two load cases of a cranioplasty implant to determine its mechanical strength and suitability for clinical use. The implant model was created for this study using SolidWorks 2020 software.

The implant is intended to replace a fragment of the parietal bone in the area of the parietal eminence (parietal tuber). This is one of the most common places, where craniectomy is performed [10]. The geometry of the designed implant is based on a fragment of a sphere with a diameter of 155 mm. This is due to the shape of the skull in this area. The implant is to complement a round hole with a diameter of 100 mm. The implant is 3 mm thick and corresponds to the thickness of the skull bone. The following Fig. 1. shows a sketch of the implant's half cross-section. By turning it 360^{o}, the main implant profile was created.

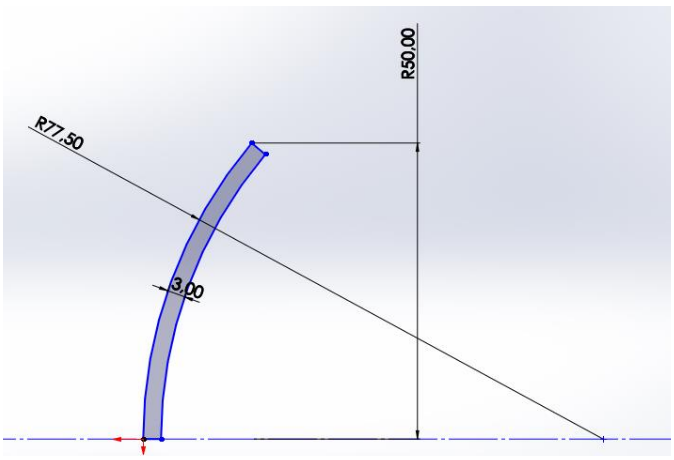

Figure 1. Sketch of the half of the implant cross-section with characteristic dimensions

In order to ensure the auxetic structure, the implant has holes with a concave angle inspired by the *double-arrowhead* structure [3]. The unit cell was based on the shape of an equilateral triangle with a side length of 10 mm. The area between one of the sides and the center of gravity of the triangle has been removed from it. The cell is shown in Fig. 2. below. Then the cells were replicated in rows in two perpendicular directions.

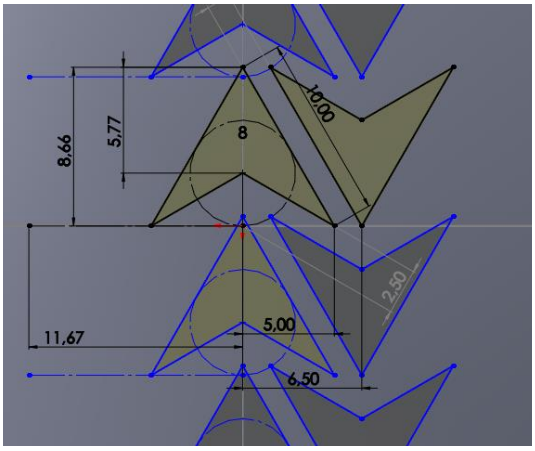

Figure 2. Elementary cell of the projected auxetic structure

The finished implant is in the form of a rounded mesh plate which is shown in Fig. 3A. All edges of the external walls of the implant were rounded with a radius of 0.2 mm (see Fig. 3B).

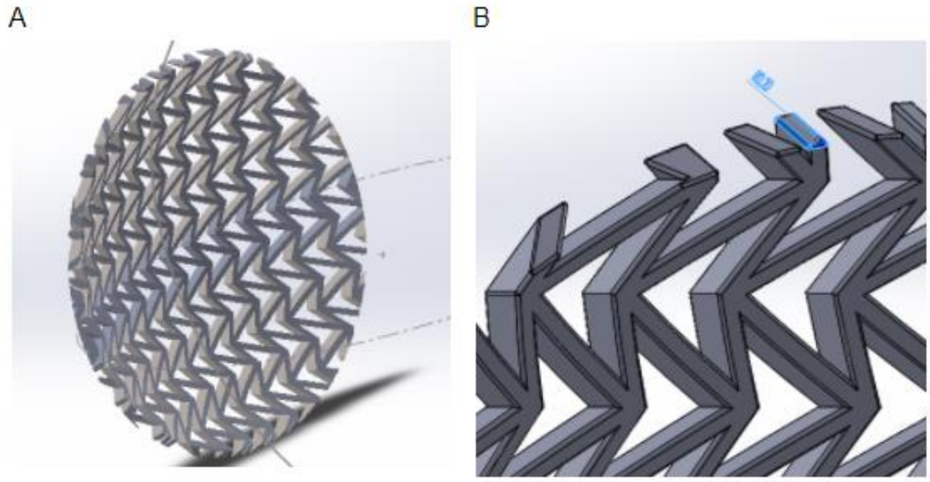

Figure 3. Finished implant model: A - Axonometric view,
B - Close-up showing the rounding of the implant edge

The implant was made of Ti-6Al-4V titanium alloy. Therefore, for the simulation purposes, the model was given *Ti-6Al-4V Etched and Aged (SS)* material from the SolidWorks library. It is a two-phase alpha-beta alloy. It has the highest strength to weight ratio among biometals. It has a high general corrosion resistance. It is biocompatible and has the ability to fuse with bones (osseointegration). That is why it is one of the most widely used alloys in medicine.

Mathematically the problem can be described with the use of Navier's equation of motion (zero volume force assumed)

$$\rho \frac{\partial^2 \mathbf{u}}{\partial t^2} - \nabla \cdot \mathbf{S} = \mathbf{0}, \quad (1)$$

where ρ is the density, $\mathbf{u}$ is the vector of displacements and $\mathbf{S}$ is the stress tensor. The equation is solved by means of FEM method assuming linear elastic material. The geometry was discretized into almost 30000 tetrahedral elements high-order with over 185 000 degrees of freedom. The same boundary condition was set on all nodes located on the circumference of the analysed sample – alee these elements were fixed. Several cases of loading were examined and results for each are presented in the section below.

3. Numerical results

The effects of intracranial pressure and external impact on the implant were examined. The results of the research are displacements and reduced stresses occurring in the implant during the action of pressure or force. Finally, the values of these results were compared with data on material strength and safe ranges for brain tissues.

To perform the simulation, it was necessary to define the place of attachment of the implant and its nature. For this purpose, all side walls of the implant located on its periphery were fixed as stationary. They were chosen due to the fact that after implantation they will be permanently connected with the patient's skull bones.

The first simulation reflects the normal operating conditions of the implant, i.e., the action of intracranial pressure from within. Normal intracranial pressure values in an adult are between 7.5 and 15 mmHg (1000 – 2000 Pa). Pressures above 20 mmHg (2667 Pa) usually require treatment, while pressures above 40 mmHg (5333 Pa) are life-threatening [7]. For the simulation, the value of 5333 Pa of pressure acting on the entire internal surface of the implant was assumed, because it is the highest value that can press against it. At higher pressure values, operations are performed to reduce it.

After the mesh was created, the test was started, as a result of which it was obtained that the highest reduced stress occurring in the implant is about 1.7×10^6 Pa. The distribution of reduced stresses in the implant is shown in Figs 4A and B. Taking into account that the yield strength of the Ti-6Al-4V alloy is about $8{,}3\times10^8$ Pa, it can be concluded that these stresses are safe for the implant. Another result of the study is the displacement graph. The greatest displacements of 9×10^{-4} mm occur near the center of the implant and are directed outside. There was a bulging of the implant. The distribution of displacements in the implant is shown in Figs 4C and D These displacements are so small that they will not cause visible distortions of the patient's head.

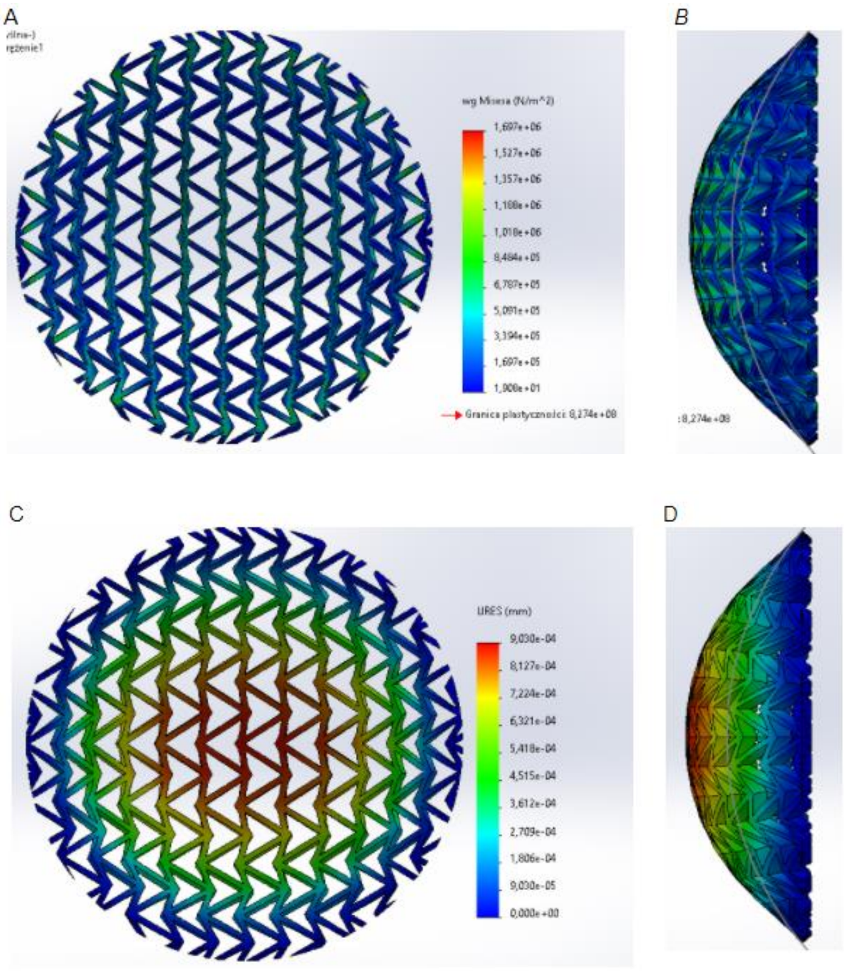

Figure 4. Distribution of stresses (A and B) and displacements (C and D) of the implant under pressure: view from the inside and the side

The second study is the simulation of a blow to the head at the implant site. Impacts are quite frequent, although usually their strength is so small that no injury is caused. Nevertheless, any blow to the head is potentially dangerous to the sensitive tissues of the brain. The task of the skull bones, and after cranioplasty - the implant, is to protect the brain against the effects of external forces. For simulation purposes, a force of 400 N was used as an external load directed from the outside to the inside of the implant.

Affecting 4 points located close to each other. This value of force corresponds to the strength of an average adult fist being struck.

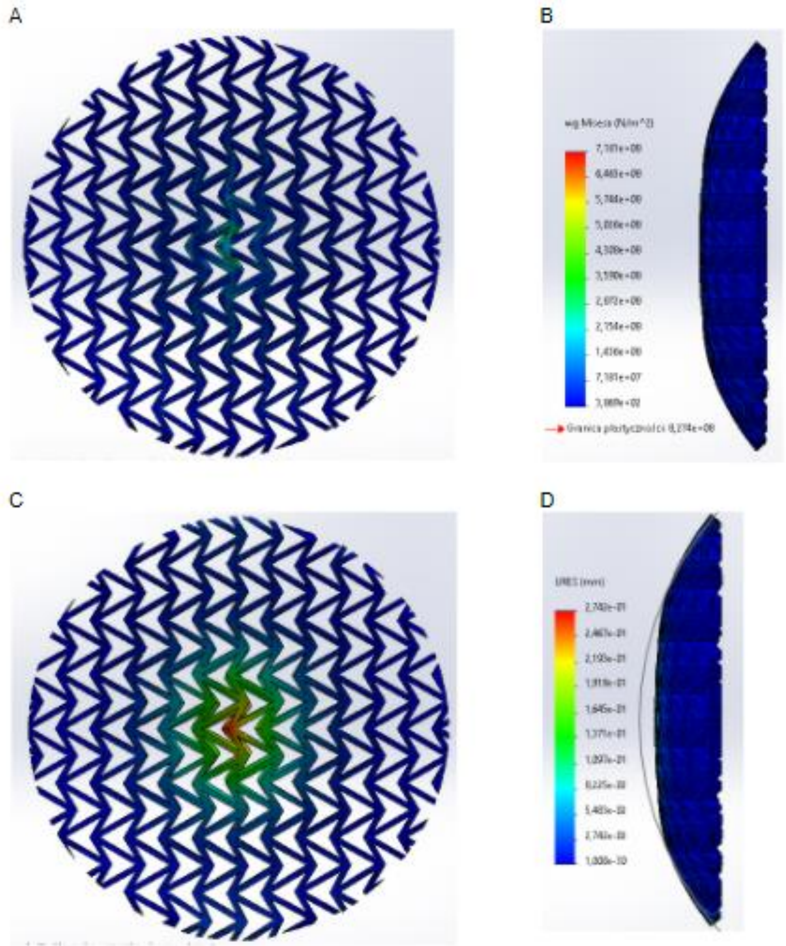

Figure 5. Distribution of stresses (A and B) and displacements (C and D) of the implant under the influence of an external impact: view from the inside and side

The greatest of the reduced stresses created in the implant is about 7.2×10^6 Pa. The exact distribution of reduced stresses in the implant is shown in Fig. 5 A and B. As can be seen, the stresses are concentrated mainly in the area of the force. Similarly to the previous study, the yield point for the Ti-6Al-4V alloy, amounting to approx. 8.3×10^8 Pa, was not exceeded here. Thus, it can be concluded that even with such a high impact force, the implant will not be damaged, so it is safe for the user. Another of the obtained results is the displacement distribution. The greatest displacement is about 0.27 mm. It is directed towards the inside and has the form of a recess. The distribution and nature of displacements are presented in the figure below (see Figs 5C and D). As in the case of stresses, the greatest displacements are also found in the area of force. The displacement of about 0.27mm has practically no effect on the brain underneath. It is so slight that it puts pressure only on the meninges and the cerebral fluid, which completely compensate for it. Frequency analysis was also performed and the results of the first six values are presented in Table 1.

Table 1. Values of natural frequencies of the analysed model

No.	frequency value [Hz]
1	0.016
2	0.033
3	701
4	737
5	1497
6	1597

Frequency analysis was made with the use of Solidworks and compared with modal analysis obtained with Comsol Multiphysics and the results agreed very well.

4. Conclusions

This paper presents the process of designing and strength analysis of a skull implant. In the presented example, the use of auxetic structures is of considerable importance. It allows for the perfect adjustment of this product to the constantly changing human body. Additionally, a significant advantage of using openwork structures is the reduction of the weight of the implant.

Taking into account that the implant is attached on the periphery to the bones of the skull, which by default are to fuse with it, it could be predicted that the highest values of both stresses, strains and displacements for the applied pressure would be near the center of the implant. In the case of local force - the effects of its action will occur in the area it affects. All of the obtained results are in the safe range, i.e. they do not exceed the permissible stresses, and the displacements do not put pressure on the brain. Thus, it can be concluded that the structure is also strong enough to be used with patients.

Acknowledgments

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