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MODELLING OF BONE FIXATION PLATE FROM BIODEGRADABLE MAGNESIUM ALLOY

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Abstract. Biodegradable materials are used in two key sectors of orthopaedics – to fabricate bone fixators and scaffolds for bone tissue regeneration. In case of osteosynthesis, fixators made from biodegradable materials disappear from the body after a certain time. So, a necessity of a one more operation for their removal is excluded. In the present study, the acromioclavicular joint osteosynthesis plates made of magnesium alloy (WE43), titanium alloy (Ti-6Al-7Nb) and stainless steel (316L) are compared utilizing the finite element analysis. The research showed that stresses in the magnesium alloy plate were lower, compared to the titanium alloy plate or the stainless steel plate. However, the tensile strength of magnesium is over 2 times lower, as compared to stainless steel and 5 times lower, than titanium alloys. Magnesium alloy is not suitable for manufacturing plates with low thickness (2 and 2.5 mm), because the stresses generated in them exceed the yield strength of the material.

Keywords: biodegradable materials, bone fixation, finite element analysis, magnesium alloy.

Introduction

Biodegradable materials intended for osteosynthesis of bone fractures and bone regeneration recently generated a great interest. Materials for bone repair can be classified into two groups: bioinert and biodegradable materials (Sheikh et al., 2015). A bone is a highly intellectual substance. If a bone is free of mechanical load, its durability becomes worse, it atrophies and begins vanishing. On the contrary, where the maximum loads are distributed, the bone forms an additional osseous layer to compensate them. One of the key problems of application of bioinert implants in orthopedics is a high difference between the elasticity modulus of the bone and the implant. For example, the elasticity modulus of steel is 10 times higher than the elasticity modulus of a cortical bone (Table 1). The said circumstance slows down the reconstruction and healing of the osseous tissue. The load usually distributes in the implant and the bone is less loaded. This is termed as "stress shielding" which results in unwanted bone resorption and implant loosening (Sheikh et al., 2015; Sumner, 2015; Chanlalit, Shukla, Fitzsimmons, An, & O'Driscoll, 2012).

Bone fixation means are usually produced of metals and their alloys (Goodrich, Sandler, & Tepper, 2012). In a majority of fracture fixation procedures, stainless steel or titanium and its alloys were used (Christensen, Dalstra, Sejling, Overgaard, & Bunger, 2000). However, these materials do not degrade in the body, so the second surgical operation for their removal is required.

Table 1. The comparison of mechanical properties of some materials and a cortical bone

Material	Tensile strength, MPa	Elasticity modulus, GPa	Elongation, %
A cortical bone	136	18	1
Ti6Al4V	860	110	12
Stainless steel	550	200	50
Co-Cr alloy	650	240	10
Magnesium	100	45	–
Poly (glycolic acid) PGA	340–920	7	15–20
Poly (L-lactic acid) PLA	80–500	2.7	5–10
Poly (lactic-co-glycolic acid) PLGA	40–55	2.0	3–10

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Biodegradable materials intended for osteosynthesis distinguish themselves for the following advantages: their elasticity modulus is lower, closer to properties of a bone, so such implants disappear from the body after a certain time. A second surgery for their removal is not required. In this sector, biodegradable synthetic polymers and magnesium alloys are used.

In order to establish the best fixation method, abundant tests are carried out where mechanical test stands, computer-based simulation or tests on living persons with sensors attached to them are used. Although application of a mechanical test stand was the most popular method for a long period (and remains such for the meantime), the computerized simulation of joint fixation step-by-step becomes, however, popular, too. The key advantage of this test method is that no physical bones and joint fixation elements are required for the tests. This circumstance causes a considerable reduction of the costs of the tests and enables to change the test parameters, such a fixation material, easier and more quickly. In addition, the computerized simulation enables to detect easier the weak points of joint fixation. At present, computer programmes are used almost only for modelling of a joint fixation plate. In such a way, it is strived to establish the optimum parameters of the joint fixation plate.

Works on computer-based simulation and investigation of bone osteosynthesis plates made of magnesium alloys are not abundant (Shirurkara, Tamboli, Jagtap, Dondapati, & Davidson, 2017). More frequently, bone fixations plates produced of the traditional materials (titanium alloys and stainless steel) are investigated (Lee et al., 2016; Shih, Huang, Pan, Lee, & Su, 2015; Hung, Su. Lu, & Lee, 2017; Cronskar, Rasmussen, & Tinnsten, 2015). In the work (Lee et al., 2016) a fixation of the acromioclavicular joint by titanium alloy and stainless steel plates was investigated upon applying the finite element method. In the said research work, the relation of the plate's hook depth and the material of the plate with the stresses appearing in the plate was examined. Three depths of the hook were chosen: 12 mm, 15 mm, and 18 mm. In course of the test, the maximum force affecting the hook of the fixation plate was found for a plate of stainless steel at 12 mm depth of hook. The minimum force affecting the plate was found for a plate of titanium alloy at 18 mm depth of hook.

In other work (Shih et al., 2015), models of the clavicle, a fragment of the shoulder bone and the joint fixation plates were developed. A simplified model of a joint fixation plate was developed upon taking into account the models offered in the market in that period. Four different plates were tested: a plate of stainless steel with 6 screws, a plate of stainless steel with 8 screws, a plate of titanium alloy with 6 screws and a plate of titanium alloy with 8 screws. It was found that that the maximum stresses were formed in the plate of stainless steel with 6 screws. The minimum stresses were detected in the plate of titanium alloy with 8 screws.

Scientists (Lee et al. 2016; Shih et al., 2015; Hung et al., 2017) explored only the traditional materials for fixation plates, i.e. titanium allow and stainless steel. In addition, various parameters of the plates, such as the depth of the hook, the number of screws, the angle of the hook, were changed during the tests. However, magnesium alloy, as a material for fixation plates, is little explored.

The aim of this paper is to compare the traditional materials for fixation plates, i.e. titanium alloy and stainless steel, to the new biodegradable material – magnesium alloy, to establish the stresses appearing in plates of different thicknesses and materials as well as displacements appearing in the bones.

1. Materials and methods

Magnesium distinguishes itself for rapid degradation in environment of an aggressive chloride, such as fluids of a human body. Implants of a magnesium alloy may dissolve in the body and may stimulate a formation of a new osseous tissue. The elasticity modulus of magnesium alloys is about 45 GPa (Table 1). It mostly conforms to the elasticity modulus of a bone. So, the said alloy will not affect the density of the bone, because it will transfer the loads to the bone. However, it is most important of all that magnesium is a natural element, so it is very well tolerated by a human body. Its biocompatibility is even better as compared to titanium.

Magnesium is not toxic and it is important for human metabolism. Its content in an adult human body is about 40 gr. Magnesium regulates the metabolism, improves blood circulation, strengthens the muscle tonicity and in such a way assists the body in calcium intake and suspending the process of osteoporosis. comparison with the traditional materials (stainless steel and titanium alloys), the advantage of magnesium alloys.

Magnesium alloys are typically very light since they are 1/3 less dense as titanium based alloys. The imperfection of magnesium is causes rapid biodegradation of it in the body.

The properties of magnesium alloy (WE43) used for production of the acromioclavicular joint fixation plates were examined upon applying the finite element method. In addition, the traditional bone fixation materials, i.e. titanium alloys and stainless steel, are used. The mechanical properties of the used materials are provided in Table 2 below. The composition of WE43 alloy includes: 4% yttrium, 3% rare earth and 93% magnesium.

A model of an acromioclavicular joint fixation plate was developed according to the plates available in the market at present (3,5 mm LCP Clavicle, 2007). For the tests, plates of 6 different thicknesses were used: 4.5 mm, 4 mm, 3.5 mm (the most frequently offered in the market), 3 mm, 2.5 mm and 2 mm. The total length of a fixation plate is 70 mm, the hook's depth is 12 mm. the lateral and the middle segments of the clavicle intersect at the angle of 150° (Qiu et al., 2016). A model of a fixation plate is provided in Figure 1 below.

Table 2. Material properties adopted in the study (C. Lin, Ju, & J. C. Lin, 2004; Hermawan, Ramdan, & Djuansjah, 2011)

Material	Elasticity modulus, GPa	Poisson's ratio	Yield strength, *MPa*	Tensile strength, *MPa*
Ti-6Al-7Nb	126	0.35	824	1045
316L	193	0.3	190	490
WE43	44	0.27	170	220

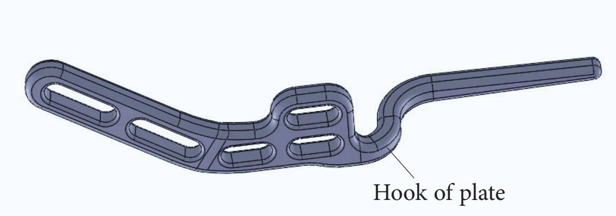


Figure 1. A model of an acromioclavicular joint fixation plate

For the scapula modelling, a scanned scapula 3D model from medical company database was chosen. The model was processed and transferred to *SolidWorks* program.

Modelling of the clavicle is performed by Solidworks programme. Both said models of bones are simplified: the internal structure of the bones is not modelled. The following mechanical properties (Sakai et al., 2014; Untaroiu et al., 2009) are provided to them: density – 1814 kg/m3, Joung's modulus – 10000 MPa; Poisson's ratio – 0.3, tensile strength – 110 MPa.

The plate's hook is pressed against the lateral end of the clavicle. The plate is fixed with 5 screws. The diameter of a screw is 3.5 mm, a screw is flathead and its material is chosen the same as the material chosen for the plate (for example, a plate of a titanium alloy is fixed by titanium screws). Then the model of the clavicle with the plate is connected to the model of the scapula.

When a person is relaxed and his (her) arms are at the sides, the following angles are formed between the clavicle and the scapula (Lawrence, Braman, Laprade, & Ludewig, 2014): in the transverse plane between the clavicle and the scapula 60° angle is formed (Figure 2a); when the clavicle-shoulder joint is observed in sagittal plane, the angle between the clavicle and the scapula is *2.5°* (Figure 2b), and in the frontal plane, the scapula is turned by 8° angle (Figure 2c). Then the lower part of the scapula and medial end of the clavicle are fixed. The lower part of the scapula is fixed by a rigid immovable connector and the clavicle is fixed in such a way that makes impossible any displacements of the medial end of the clavicle in X, Y and Z directions; however, a rotation of the clavicle remains possible.

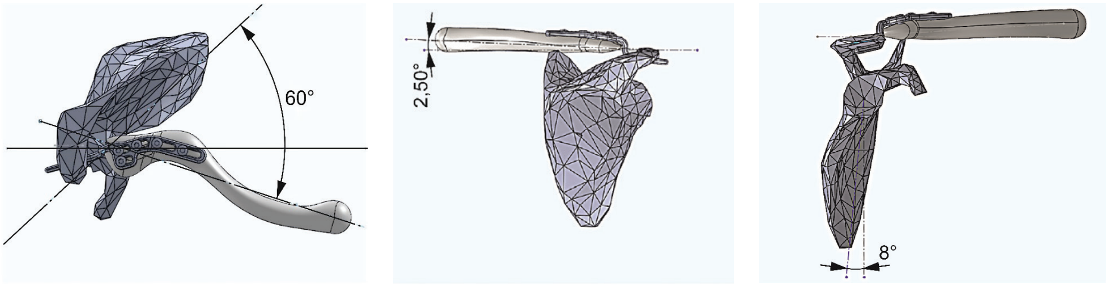
In the sagittal plane, the joint is loaded with a force of 70 N that is perpendicular to the axial line of the clavicle. The said size and direction of the load were chosen because such a force is formed in the joint when it is involved in its daily activity and in the rehabilitation period (Beitzel, Sablan, & Chowaniec, 2011). The models were divided into finite elements. The model of the joint was divided into 74581 triangular pyramid finite elements.

2. Results and discussion

After completion of the investigation, it was found that the location of the maximum stresses in the plate itself does not depend on the material or the thickness of the plate the position of the said location remains constant. The maximum stresses are formed in the lower part of the plate where the plate narrows and the hook begins (Figure 3).

On the base of the obtained maximum stresses, a comparative graph was formed (Figure 4). It can be seen from the Fig. 4 that the maximum stresses were formed in a 2 mm thick plate made of stainless steel (316L) – 458.9 MPa. The minimum stresses were formed in a 4.5 mm thick plate made of magnesium alloy (WE43) – 99.92 MPa. In addition, it can be seen that the minimum stresses were formed in the plates made of magnesium alloy (WE43) for all thicknesses of the plates, as compared to other materials, and the maximum stresses were formed in plates made of stainless steel (316L).

Although the minimum stresses were formed in plates made of magnesium alloy (WE43), nevertheless this material distinguishes itself for the lowest tensile strength – 220 MPa. For comparison: the tensile strength for stainless steel (316L) is 490 MPa, and for titanium alloy (Ti-6Al-7Nb) – even 1045 MPa. In the tested plates, stresses did not achieve the level that could cause breaking of the plate; however, the stresses in 2 mm and 2.5 mm thick plates



a) b) c)

Figure. 2. The acromioclavicular joint with a fixation plate in the transverse plane, the sagittal plane and the frontal plane

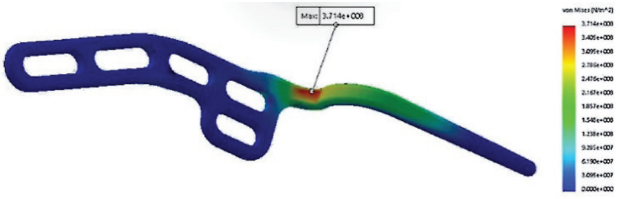


Figure. 3. The maximum stresses in the plate

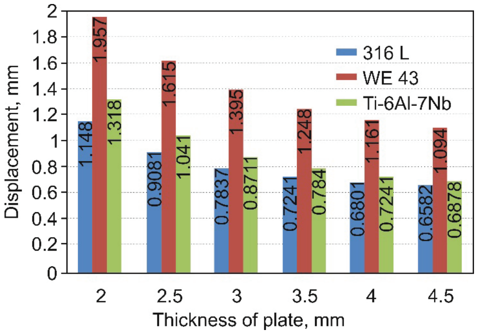


Figure 4. A comparison of the stresses formed in plates of different thicknesses made of different materials

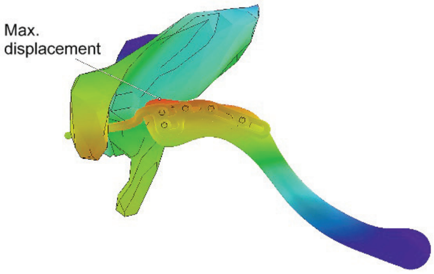


Figure 5. A model of the joint where displacement zones are shown

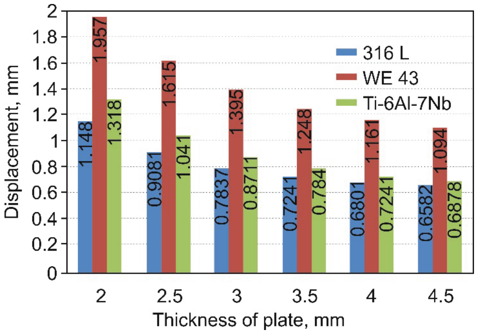


Figure 6. A comparison of the displacements appearing in the joint

made of magnesium alloy (WE43) exceeded the ultimate strength. Although the 2 mm and 2.5 mm thick plates made of magnesium alloy (WE43) as well as the 2 mm, 2.5 mm and 3 mm thick plates made of stainless steel (316L) will not break upon the chosen conditions, but their irreversible deformation will begin.

During the investigation, the displacements appearing in the joint were explored as well. After measuring such displacements, it is possible to establish whether the joint is fixed reliably and the joint fixation will maintain the joint stable enough. In Figure 5, a model with titanium alloy plate (2 mm thick) is presented.

It can be seen from Figure 5 that the maximum displacements appear in the lateral end of the clavicle. When the joint is loaded by forces, the lateral end of the clavicle is raised and because of deformations appearing in the plate, the displacement of the said lateral end is the maximum. During the investigation, it was found that the displacements appearing in the joint depend both on the material and the thickness of the plate (Figure 6). The maximum displacements (1.957 mm) appear when the knee joint is fixed by a 2 mm thick magnesium alloy (WE43) plate, and the minimum displacements (0.6582 mm) – when the joint is fixed by 4.5 mm thick plate made of stainless steel (316L). In general, it was found that the maximum displacements are formed in the joint fixed by a plate made of magnesium allow (WE43).

A joint fixation by a plate distinguishes itself for particularly good stabilization and fixation of the joint, so even the maximum displacement formed in the acromioclavicular joint (1.957 mm) is similar to the displacement formed upon applying other fixation methods. During the investigation carried out in (Costic, Labriola, Rodosky, & Debski, 2004), fixations were tested by a mechanical test-bench and the joint was loaded with forces up to 90 N. It was found that 1.5–1.9 mm larger displacements were obtained when the joint is fixed with cerclage. The maximum displacements were obtained when the joint was fixed by 2 mm thick magnesium alloy plate; however, 2 mm thick plates cannot be produced neither of a magnesium alloy nor stainless steel because of stresses in them.

In a joint fixed by 2 mm thick titanium alloy plate, displacements of 1.148 mm take place. Such a displacement slightly differs from the data obtained in the investigation carried out in (Ladermann et al., 2013) when in a joint fixed by "TightRope" system, the displacements of 0.77 mm (from 0.60 mm to 0.89 mm) and fixation with cerclage – the displacements of 0.76 mm (from 0.37 mm to 1.27 mm) were obtained. An analysis of the data of the investigation showed that a plate produced of titanium alloy (Ti-6Al 7Nb) can be thinned to 2 mm. In addition, it was found that a thickness of a titanium alloy plate might be reduced slightly more; however, plates of stainless steel and a magnesium alloy might be produced neither 2 mm nor 2.5 mm thick (and in case of stainless steel – even 3 mm thick).

Joint fixation plates produced of a magnesium alloy distinguish themselves for a property that is not typical for fixation plates produced of other materials. This property is its absorbability in biological tissues. This magnesium alloy is classified as a rapidly degradable metal; however, no data from research works show the changes of the metal when its absorption in tissues starts and how long a degradation of such a plate may continue.

Conclusions

The magnesium alloy (WE43) is highly perspective in production of bone fixation plates. It transfers force to the bones well enough; in addition, it was found during the investigation that the minimum stresses appeared in a magnesium alloy plate. However, the most important imperfections of the material are low values of the yield strength (170 MPa) and the tensile strength (220 MPa). Because of them, a magnesium alloy is not fit for producing plates of lower thicknesses (2 and 2.5 mm).

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KAULŲ LŪŽIŲ FIKSAVIMO PLOKŠTELIŲ IŠ BIODEGRADUOJANČIO MAGNIO LYDINIO MODELIAVIMAS

A. Šešok, M. Vaitiekūnas

Santrauka

Biodegraduojančios medžiagos ortopedijoje naudojamos dviejose pagrindinėse srityse: kaulų fiksatorių ir kaulų regeneravimo karkasų gamyboje. Osteosintezės fiksatoriai iš biodegraduojančių medžiagų po tam tikro laiko organizme ištirpsta. Nereikia daryti pakartotinos operacijos ir juos išimti. Straipsnyje baigtinių elementų metodu lyginamos raktikaulio ir mentės sąnario osteosintezės plokštelės iš magnio lydinio (WE43), titano lydinio

(Ti-6Al-7Nb) ir nerūdijančiojo plieno (316L). Tyrimas parodė, kad įtempiai magnio lydinio plokštelėje susidarė mažesni nei titano lydinio ar nerūdijančiojo plieno plokštelėje. Tačiau magnio stiprumo riba yra daugiau kaip perpus mažesnė nei nerūdijančiojo plieno ir net penkis kartus mažesnė nei titano lydinių. Magnio lydinys netinka gaminant mažesnio storio plokšteles (2 ir 2,5 mm), nes juose susidarė įtempiai, didesni už tamprumo ribą.

Reikšminiai žodžiai: biodegraduojančios medžiagos, baigtinių elementų analizė, magnio lydinys.