BUDAPESTI UNIVERSITY OF TECHNOLOGY AND ECONOMICS
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INVESTIGATION OF MEDICAL SCREWS PREPARED WITH RAPID PROTOTYPING TECHNOLOGY

PHD DISSERTATION THESES

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1. Introduction

The use of medical implants in modern reconstructive surgery goes back nearly 120 years. The first nickel-plated steel bone-fastening plates were used by Hansmann in 1886, but in 1912 vanadium steel was used for the same purpose, and by 1940 the first chromium-cobalt corrosion-resistant steel hip prostheses appeared. With the spread of metal implants their shortcomings gradually came to light. Their strength and Young's modulus significantly exceed those of bone and therefore cannot satisfy the most important engineering principle: the uniform strength of the construction. The significant difference in Young's modulus means the implants cannot respond flexibly to the mechanical loads the bone receives, which can lead to the loosening of the implant over time and finally to the damaging of the bone again. Another problem is that after healing the implant may have to be removed to complete the healing process, which requires another operation and may leave behind a mechanically weak spot.

As the plastic industry developed, synthetic polymers gradually appeared in medicine in the form of disposable syringes, and infusion and transfusion tools. Implants that are absorbed or degrade in the body were first marketed in the 1990s. The advantage of polymer implants is that they are far closer to bones in terms of strength and rigidity than metals therefore they satisfy the requirement of the uniform strength of the system much better. Degradable polymers can be filled with any bioactive substances, which can help the natural regeneration processes of the body as the polymer is gradually absorbed. Degradable polymer implants are increasingly replacing metal implants while it is still debated whether in a particular situation a metal implant or a degradable polymer implant is more advantageous. The issue is complicated by the different built in environments (pig, cattle, sheep or human) in which the various research groups investigated the implants which differed not only in material but also in geometry.

Rapid Prototyping (RPT) and Rapid Tooling (RT) technologies appeared on the market twenty years ago. They have been gaining ground continuously ever since but their applicability has still not be investigated in many areas. The principle of RPT és RT technologies is that they form the product layer by layer. RPT and RT technologies provide a unique opportunity in medical technology to manufacture unique implants and examine implants of identical geometry but different materials.

In my PhD work I was the first to apply RPT and RT procedures successfully in the development of medical screws. I ascertained that cross-linked, closed-cell PVC foams can also substitute human cancellous tissue in biomechanical tests. I proved that the material of the screw does not have an effect on the fixation strength of the screw if the geometry and built in environment are the same. Finally I pointed out that the screw profile and test speed have a significant effect on the fixation strength of the screw.

2. A summary and critical evaluation of the literature, and goals

Rapid prototyping technologies appear in more and more areas of industry now, twenty years after they appeared on the market. In spite of this, their application in medical technology is limited to visualization and the manufacturing of individual bone replacement implants. There are no reports of experiments made on model materials of bone, tendon or other implants made with RPT technology.

Rapid tooling technologies based on rapid prototyping technologies date back to 10-15 years. Based on the literature, it can be stated that metal injection molding tools made with the SLS (Selective Laser Sintering) procedure can be used very well for injection molding. In the case of polymer tools, however, the limits of the tool material have to be taken into account. Cycle time increases considerably, controlling the temperature of the mold is more complicated and due to the different thermal conditions the material cools, shrinks and warps differently. In the case of polymer tools, the literature reports SLA (Stereolithography Apparatus), and cast and filled resin-based tools. There is, however, no mention in the literature of injection molds produced with a RT procedure used for the manufacturing of medical technology products.

Although a lot of studies deal with the medical applications of absorbable polymers, the majority of authors are physicians or chemical engineers, therefore their approach is a little different from the approach of a mechanical engineer. Very few authors investigated the methods of processing the materials, and the manufacturing or design methodology of the implants.

In the case of interference screws, as in the case of countless other medical screws, there is a continuous professional and theoretical debate about the use of absorbable polymer or metal implants. Although medical aspects cannot be ignored (e.g. physiological effects), from an engineering viewpoint the difference between the materials of the screws and screw geometry are also important. When comparing the three basic groups of engineering materials

– metal, ceramics and polymers – from a medical technology aspect, it must not be ignored that a living organism itself, including the bones, are essentially composed of polymers. Only polymer or polymer composite implants – including medical screws – are able to satisfy the most important engineering principle: the principle of the uniform strength of the construction. A foreign body inserted in a living organism serves its function best if its strength, rigidity, and impact resistance is similar to those of the living tissue it substitutes.

When comparing metal and degradable polymer screws, the difference in the size of the screws of different materials is also important (length, outer/inner diameter, etc.). In the case of identical geometries, the literature does not investigate the effect of the material of the screw on its strength after the operation.

The comparison of screws on the market is complicated by the fact that test environments and conditions are rarely the same in the various studies, whether in the case of metal or polymer screws. There are porcine, cattle and sheep *in vivo* and *cadaver* experiments, and also human *cadaver* studies, whereas even between bones of the same species there can be considerable differences depending on gender, age and variety.

Based on the review of the literature I set the following objectives:

1. To design a unique screw geometry and to manufacture the screws from a degradable polymer with injection molding with direct and indirect RT technology,
2. To investigate the effect of the screw profile on the pullout force,
3. To investigate the effect of the screw materials on the pullout force,
4. To investigate the effects of the test parameters, especially the pullout speed on the pullout force when,
5. A comparative evaluation of the unique screw geometry in biomechanical tests conducted on animal cadaver bones.

3. The materials and technologies applied

3.1. Preliminary tests of foam materials and the bone

In order to eliminate the measurement errors caused by the varying properties of animal bones, I used three cross-linked, closed-cell, hard PVC foams of different densities and a low-density closed-cell two-component PUR foam (Table Table 1.).

Brand name	Material	Density [g/cm³]	Compressive strength [MPa]	Compressive Young's modulus [MPa]	Tensile strength [MPa]	Tensile Young's modulus [MPa]
AuroPUR iH1010	PUR	0.12	n.a.	n.a.	n.a.	n.a.
AIREX® C70.90	PVC	0.10	1.9	125	2.7	84
AIREX® C70.130	PVC	0.13	2.8	170	3.8	110
AIREX® C70.200	PVC	020	5.2	280	6.0	175
Cancellous bone	n.a.	0.20-1.8	0.2-35	n.a.	0.9-20	200-500

Table 1. The main mechanical properties of the investigated foams and cancellous bone

Compression tests were performed on foam cubes with dimensions of 10×10×10 mm, at a crosshead speed of 0.09, 0.9, 9, 30 and 90 mm/min. The 10×10×10 mm size is ideal for workability and is therefore widespread in compression tests of bones. The comparative tests of bone and foams were only performed with a crosshead speed of 9 mm/min. I used a Zwick Z005 materials testing machine, using a self-aligning compression plate (Fig. Fig. 1).

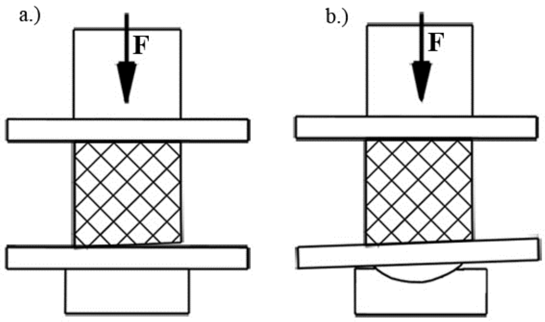

Fig. 1 Compression test measurement setup (a.) parallel plate b.) self-aligning compression plate

The compression tests were evaluated with the method developed by Li and Aspden for the comparison of human cancellous bone and the method developed by Patel for the grading of PUR foam as a bone replacement material. In the test the compression strength, compressive Young's modulus, yield strength and energy absorbed until yield of the foam was compared to the same properties of bone at a crosshead speed of 9 mm/min.

3.2. The designing and manufacturing of screws

I used individually designed and manufactured screws not available commercially. In the design process I took into account the opinions of practicing orthopedists, and standards describing orthopedic screws.

3.2.1. The geometry of the screws

To determine the final size, I conducted a survey among practising orthopedists and asked them about the most commonly used screw sizes. I asked members of the Hungarian Association of Arthroscopy (Magyar Artroszkópos Társaság – MAT). The cross section and main dimensions of the final screw used for the biomechanical tests can be seen in Fig 2. I used a hex key for the screw because it is easily available and its geometry is easily manufactured.

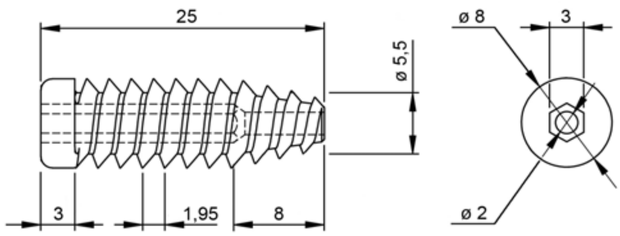

Fig 2 Screw with a contact shoulder and a circular end bore

The examined thread profile

I compared five different screw profiles, four of which were based on the thread profile of the standard metal medical screw (Fig. 3/a-d). The fifth thread profile was designed by me, after consultations with doctors, and taking into account manufacturability with injection molding (Fig. 3/e.).

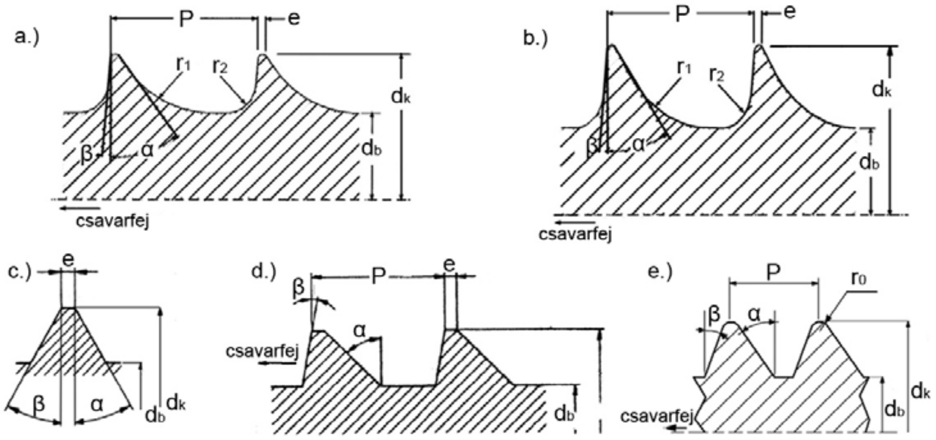

Fig. 3. Main dimensions of HA (a.), HB (b.), HC (c.), HD (d.) and the O profile I designed (e.)

The outer and inner diameters, and the pitch of the manufactured screws were identical, thus ensuring a constant Flank Over Area. The outer diameter was 8 mm, the inner diameter was 5.5 mm, and the pitch was 2 mm.

3.2.2. Manufacturing screws with RPT technology

The screws were manufactured with Selective Laser Sintering from GP1 stainless steel powder at 100% density. The building direction was parallel to the longitudinal axis of the screws. The composition of the material conforms to the European standard of stainless steel 1.4542. The metal screws were used when the effects of screw profile and pullout speed were examined, and in the comparative tests of screws of different materials.

Screws made of the Objet Fullcure® 720 photopolymer were made on the Objet Alaris 30 prototype manufacturing machine. The building direction was also parallel to the longitudinal axis in this case. These screws were used in the comparative tests of screws of different materials.

3.2.3. Injection molding of screws

Before injection molding, the manufacturability of the screws were checked with version 6.2. of the Moldflow Plastics Insight (MPI) program package. Injection molding simulation is a generally neglected area in the manufacturability examinations of medical technology tools, while in other areas there are many publications about its application.

The injection molded screws were molded with an ARBURG 320C 600-250 injection molding machine, from Natureworks 3051D polylactic acid. I used tools made from an acrylic resin-based photopolymer (Objet FullCure™ 720), and a filled (25m% Al_2O_3) epoxy resin (Eporezit AH-12/T-58) with a metal tool insert (Fig 4).

Fig 4 Assembled and fastened injection mold fastened on the stationary mold platen of an injection mold machine

3.3. Pullout tests of screws

In the case of foams foam blocks with dimensions 20×20×30 mm were used, cut from a foam plate 20 mm thick. In the preliminary experiments bores with a 5.2 mm drill bit were bored along the longitudinal axis of the foam blocks for the screws. The screws were driven into these bores, then pulled out at a speed of 50 mm/min.

In the case of porcine femur, The screw was fastened in the distal end of the femur cleaned of soft tissue in a bore made with a 5.2 mm drill bit in the place of the ligament. For pullout from bones A steel rod was used just as with foams. Pullout tests were performed with a crosshead speed of 200 mm/min in the case of bones. Screw pullout forces and the strength of bolting were examined.

The usability of PLA screws manufactured by me were proved on pig cadaver models in real built-in environments. The pig cadaver models were prepared by Dr. Pavlik Attila[1] and Dr. Hidas Péter[2] of the Országos Sportegészségügyi Intézet (National Sports Health Institute).

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4. Theses

Thesis 1

I showed that based on the parameters I examined (compressive Young's modulus, yield strength, energy absorbed until yield) normal and osteoporotic (OP) human cancellous bone can be substituted in biomechanical tests with hard, cross-linked, closed-cell PVC foams. I found that according to their Young's modulus and yield strength 0.10 and 0.13 g/cm^3 PVC foams are suitable for the substitution of OP bone, while normal bones can be substituted with 0.20 g/cm^3 PVC foam. Based on the energy absorbed until yield, 0.10 g/cm3 hard, cross-linked PVC foams can substitute Osteoporotic(OP) cancellous bone. Normal bones can be substituted with both 0.13 and 0.20 g/cm^3 density PVC foams [7].

Thesis 2

I showed that using the polylactic acid interference screw I designed (diameter=8 mm, length=25 mm) there is no significant difference in the pullout force pulled along the longitudinal axis of the bone whether the screw is inserted with BPTB (bone – patellar tendon – bone) graft fixation at the knee end of the femur, according to general operation practice, or simply driving the screw in a bore in the bone (772±225; 740±190 N). This means that under such conditions the more complicated bone block fixation is unnecessary in biomechanical tests concerning screw geometry. The above statement was proved with the comparison of a screw driven into a 10 mm diameter bore in the lower (distal) end of BPTB graft porcine femur, at the place of the front ligament and fixed with a 8 mm wide and 5 mm thick bone block, and a screw driven into an anatomically identical place, into a bore of diameter 5.2 mm parallel to the longitudinal axis of the bone [6].

Thesis 3

I proved with measurements that Objet Polyjet™ Rapid Prototyping technology is suitable for the making of an injection mold that can be used for the limited-run manufacturing of medical screws of thermoplastic polymer. Polylactic screws manufactured this way are suitable for the fixation of ligaments just like commercially available, mass-produced screws [2, 3].

Thesis 4

I proved with experiments that the three kinds of interference screws of identical geometry I used (screws injection molded from polylactic acid, and acrylic resin and stainless steel screws made with RPT technology) have the same pullout force when pulled from hard PUR foam and closed-cell, cross-linked PVC foams used in biomechanical tests. Based on the tests no significant difference is expected in a real built-in environment in the postoperative phase between the fixations made with metal and polylactic acid screws [13, 14].

Thesis 5

I have proved that in addition to the Flank Over Area (FOA) investigated in the literature, the screw profile also has a significant effect on the pullout force of the screw. I proved my hypothesis with screw pullout tests performed on hard, closed-cell, cross-linked PVC foams that substitute normal and osteoporotic (OP) cancellous bone, with standard HA, HB, HC and HD, and non-standard (individually designed) profile interference screws of identical outer diameter, thread groove depth, pitch and length [4].

Thesis 6

I have proved with experiments that when pulling medical screws from hard, closed-cell, cross-linked PVC foams, the pullout force is directly proportional to the logarithm of the pullout speed and can be described with the formula

$$F(v) = \rho \cdot (C_1 \cdot \ln(v) + C_2)$$

where $F(v)$ is the expected pullout force [N], ρ is the density of the foam [kg/m^3], v is the pullout force [m/s], and C_1 and C_2 are constants characteristic of the fixation. Pullout tests were performed at a crosshead speed of 1-10-50-200 mm/min, with hard, cross-linked PVC foams of 0.10, 0.13 and 0.20 kg/m^3 density. In the case of the examined foam and the screw I designed, C_1= 125,8 [m^4/s^2]; C_2= 6912 [m^4/s^2]. The cause of the phenomenon is the hardening observed at increasing speeds of deformation both in the case of polymers and polymer foams, and bones [13, 14].

5. Publications

Papers

1. Czigány T., Kiss Z., **Oroszlány Á.**, Szebényi G.: Önjavító polimerek és kompozitok - áttekintés; Műanyag és Gumi, 46, 206-213, (2009)
2. **Oroszlány Á.**, Kovács J.G.: Gate type influence on thermal characteristics of injection molded biodegradable interference screws for ACL reconstruction, Int. Commun. Heat Mass Transf. 37, 766-769 (2010)
3. **Oroszlany Á.**, Nagy P., Kovács J.G.: Injection molding of degradable interference screws into polymeric mold, Materials Science Forum, 659, 73-77 (2010)
4. **Oroszlany Á.**: Speciális Orvosi Csavarok Fejlesztése; GÉP, 61, 9-10, 67-70 (2010)
5. **Oroszlány Á.**, Kovács J.G.: Lebomló interferencia csavarok fröccsöntése Objet/PolyJet eljárással készült szerszámba; Műanyag és Gumi, 48, 54-58 (2011)
6. **Oroszlány Á.**, Kovács J.G., Nagy P., Pavlik A., Hidas P.: Testing of prototype interference screw for ACL reconstruction in porcine femurs; Biomechanica Hungarica, 4, 7-15 (2012)
7. **Oroszlány Á.**, Kovács J.G., Nagy P.: Compressive properties of commercially available PVC foams intended for use as mechanical models for human cancellous bone; Acta Polytechnica Hungarica, 2013 (accepted for publication)

Conference proceedings

8. **Oroszlány Á.**, Nagy P.: Absorbable, Orthopaedic implants and their polymeric materials, Gépészet 2008 Konferencia, 2008, CD kiadvány, p 12, ISBN:978-963-420-947-8;

Conference presentations

9. **Oroszlány Á.**, Nagy P.: Absorbable, Orthopaedic implants and their polymeric materials, Országos Gépészeti Konferencia: Gépészet 2008. Budapest, Magyarország, 2008.05.29-30, poster
10. **Oroszlany Á.**, Kovács J.G., Nagy P.: Injection Molding Simulation of Bioabsorbable Interference Screw, PPS-25 Konferencia, CD kiadvány; 25th Annual meeting of the Polymer Processing Society (PPS) in Goa – PPS-25, 2009.03.01-05; India, Goa, poster
11. **Oroszlány Á.**, Nagy P., Kovács J.G., Kovács N.K.: Gyors prototípus szerszámozás orvostechnikai alkalmazása, Mechanoplast Konferencia, 2009 márc. 17-19, oral presentation
12. **Oroszlány Á.**, Nagy P., Kovacs J.G.: Lebomló interferencia csavarok fröccsöntése polimer szerszámba, Országos Anyagtudományi Konferencia 2009, 2009.10.11-13, poster
13. **Oroszlány Á.**: Medical implant development and its evaluation, Qwaqwa, Dél-Afrika, 2009.11.27. oral presentation
14. **Oroszlány Á.**: Speciális orvosi csavarok fejlesztése, Géptervezők és termékfejlesztők XXVI. Szemináriuma, Miskolc, 2010.11.11-12, oral presentation