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Osseointegration specified grit blasting parameters

Alexandra Kemény^{a,*}, István Hajdu^a, Dóra Károly^a, Dávid Pammer^a

^a*Budapest University of Technology and Economics, Faculty of Mechanical Engineering, Department of Materials Science and Engineering, H-1111 Budapest, XI. Bertalan Lajos u. 7. Building MT, Hungary*

Abstract

Nowadays scoliosis is usually healed by surgery and fixed there for good. In the research, Ti-6Al-4V ELI disks were investigated. As blasting material alumina powder was used. In total 135 disks and 6 implants were used in the experiment. The ideal surface roughness to osseointegration is between 1-2 μm . Based on the experiments 1.5 μm roughness can be created on Grade23 Ti disks with the following parameters: particle size of 354-500 μm , time of 30 s, pressure of 4 bar, distance of 20 mm and angle of 75°.

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1. Introduction

Nowadays, it is very common to have spinal diseases such as scoliosis. When the curve of the spine reaches a certain deformation, it can only be healed by surgery. The patient is opened from the back with a 200-300 mm long cut. It is very important to achieve a good osseointegration and stability, because the reopen of the back is a dangerous process, so it should be avoided by better implants and surgical technique. In conclusion, these implants are staying in the patient forever.

* Corresponding author. Tel.: +36-1-463-1079.

E-mail address: alexandra.kemeny@edu.bme.hu

Osseointegration is a complex process. First, the implant needs to have a direct interaction with the bone. If the implantation is successful, and the surface of the implant is suitable for osteoblasts, these cells start forming new bone. This creates a strong bond between the bone and the implant [1].

The osseointegration highly depends on the material of the implant. It is important, that the implant is made from biocompatible material, so in the human body it can produce physiological relation with the cells. In the last 50 years, our knowledge has been greatly increased about these biocompatible materials. First, in the 1970's the most common material was stainless steel, nowadays it is the titanium and its alloys [2].

There are plenty of dental implants and hip prosthesis femoral stems on the market with grit blasted surfaces and great results in patients. Grit blasting creates a micrometer roughness which stimulates osteoblasts [3]. However spinal implants' surfaces are not yet treated this way.

Some researches already shown that grit blasted spinal implants needed twice the torque to remove from sheep vertebrae in vivo, twelve weeks after implantation than the smooth screws [4]. Other research has shown, that the success of an implant is highly dependent of the surface characteristics, and also the macro design of the implant. Surface microroughness has been well established to achieve better osseointegration [1].

The aim of our research was to optimize the blasting parameters on disks and then do the surface treatment on the spine implants.

2. Materials and methods

2.1. Design and manufacturing of the implant

The first step of the design was to study implants from the industry. Most of the spine screws are self-tapping but have small threads. We designed an implant which can adapt more to the low-density vertebrae. This monoaxial implant features a high thread pitched screw with great threads, and three symmetric self-tapping edges (Fig. 1).

The making of the implant starts with the head, where the place of the rod is expediently machined with milling. The inner thread is first prepared with drilling, and finished with a turning-machine. After these steps the fillets are come to the head, and the neck too, to prevent bacterial problems. After the making of the proper diameter, the threads are being turned into the material.

After the manufacturing, the implant goes to cleaning and crabbing with ultrasonic cleaner. When the surface is properly cleaned, the surface treatment is the next step. As we mentioned in the introduction, there are a lot of different solutions to make an implant more biocompatible and to reach better osseointegration with the bones. After the treatment, the final steps are cleaning, sterilization and packing.



Fig. 1. The designed and grit blasted implant

2.2. Used material

Implant materials can be very diverse. In spinal surgery the most used material is a titanium alloy, namely the Ti-6Al-4V ELI, where ELI means extra low interstitials. As its name shows, it contains approximately 90% titanium, 6% aluminum and 4% vanadium. The last two metals induce the mechanical properties of the material, but the corrosion resistance of the pure titanium is better than the alloy's, so its osseointegration is better too. Despite this

fact, and the because the implants should bear great loads, the alloy is more widespread in the industry. It is important to notice, that the titanium, and its alloys are paramagnetic, which made them a very good material in medical uses [5]. Table 1 shows the chemical composition of the used material.

Table 1. Ti-6Al-4V ELI chemical composition.

Component	t/t%
C	≤ 0.08
Al	5.5 – 6.5
N	≤ 0.03
O	≤ 0.13
Fe	≤ 0.25
V	3.5 – 4.5
H	≤ 0.013
Other	≤ 0.40
Ti	Res.

Bioinert materials have a stable oxide film on their surface which are only a few nanometers thick, but this is enough, to make the material corrosion resistant and biocompatible. It is important to say, that the titanium and its alloys are only slightly resistant to high concentrated hot acids, such as HCl, HNO₃ or H₂SO₄. The most common oxide on the titanium's surface is the stable TiO₂. This oxide can form in 3 crystals: rutile, anatase and brookite. The first two are tetragonal, and the last is orthorhombic. The oxide film on the material can contain different atoms than only oxygen and titanium, so it can contain other atoms than the implant's material. This difference only appears on the outer atomic layers. Recent studies shown that Cp-Ti and the Ti-6Al-4V ELI alloy shows similar properties in osseointegration, bacteriology analyzations, and with machinability too [6,7].

2.3. Grit blasting

Grit blasting is a surface modification treatment. The morphology of the surface changes significantly as the small particles hit the implant with high speed [8].

As blasting material alumina powder was used. The following five technological parameters of the sandblasting were investigated: size of blasting material, distance between the tip of the blasting pen and the samples, time, pressure and angle of the blasting pen and the axis of samples. Each parameter was tested in three different levels. The surface morphology changes when the small particles smash into the surface with high speed.

In total 135 disks and 6 implants were used in the experiment. The disks were 1.5 mm in thickness and 5.5 mm in diameter. Table 2 shows all of the used parameters.

Table 2. Used grit blasting parameters

Parameter	1 st value	2 nd value	3 rd value
Grit size [μm]	44-74	149-210	354-500
Time [s]	10	20	30
Distance [mm]	20	30	40
Pressure [bar]	2	3	4
Angle [$^{\circ}$]	60	75	90

Traditional experimental design procedures are too complicated and often not easy to use. When the number of process parameters increases, a large number of experimental works have to be done. The Taguchi method uses a special design of orthogonal arrays (OA) to study the whole parameter space with only a few experiments. This method has many benefits: cost reducing, saving experimental time and quick discovering of significant factors [9].

The following example illustrates how many time can be saved with the help of the Taguchi method: a two-level 15 factor complete experiment consists of 2^{15} , so 32768 tests. In contrast, one experimental design based on the Taguchi method requires only 16 tests to be performed [10].

In this research the effect of five three-level factors on a titanium disk was studied. A Taguchi OA L27 (3^5) design was applied to identify the critical parameters in the blasting process. This method requires only 27 different combinations of the parameters.

For the blasting process a clamping device was needed which helped to fix the disks during blasting. With this the angle and the distance was adjustable during the blasting process. To calculate the effect of parameters to the surface roughness, Minitab 17 statistical software was used.

After blasting the surface roughness (Ra) was investigated. For this measurement, a Mahr Pocket Surf IV profilometer was used. Olympus SZX16 stereomicroscope and Philips XL30 scanning electron microscope was used for taking images.

3. Results

The ideal surface roughness to osseointegration is between 1-2 μm [11]. Based on the experiments 1.5 μm roughness can be created on Grade23 Ti disks (Fig.2.) with the following parameters: particle size of 354-500 μm , time of 30 s, pressure of 4 bar, distance of 20 mm and angle of 75°.

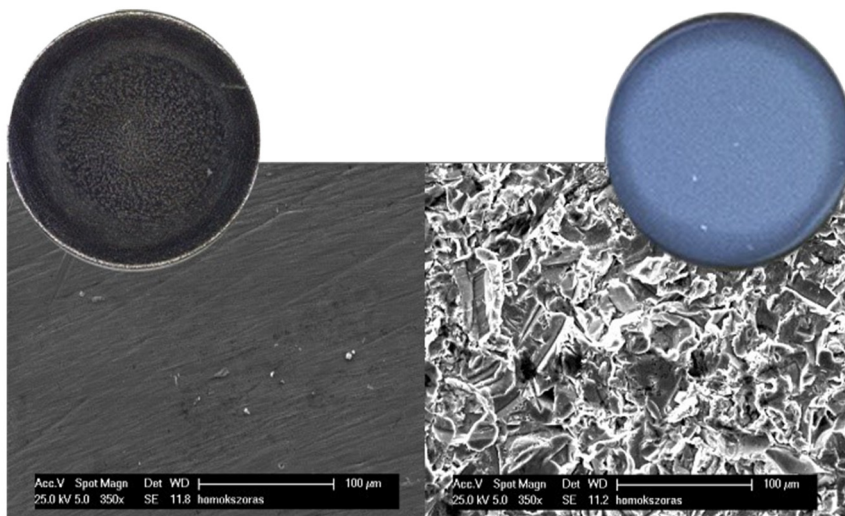
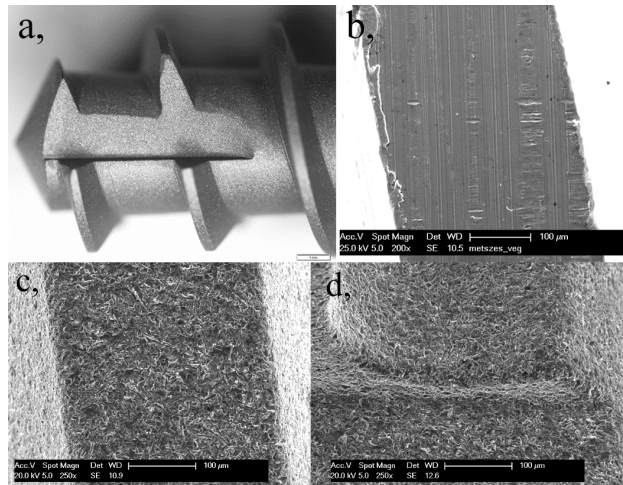


Fig. 2. Stereomicroscopic and SEM image of a disk before (left) and after (right) blasting

Using the mentioned blasting parameters, a consistent rough surface was reached with a treatment specific morphology on the implants, see Fig. 3. On Fig. 3. c it can be observed that even around the rough edges, a good surface was created with grit blasting.

Taguchi recommends signal to noise (S/N) ratio as the objective function for experiments based on orthogonal matrix. The S/N ratio is used as a number to measure the quality characteristics. With the help of this analysis a lot of information can be received from the error of the results. The following correlation (1) can be used only if the standard deviation of the data depends on the average [12].



(1)

Fig. 3. Stereomicroscopic image of the blasted implant (a) and SEM images before (b) and after (c,d) blasting

The signal to noise ratios of the 5 main factors shown on Fig. 4. The points were calculated from equation (1).

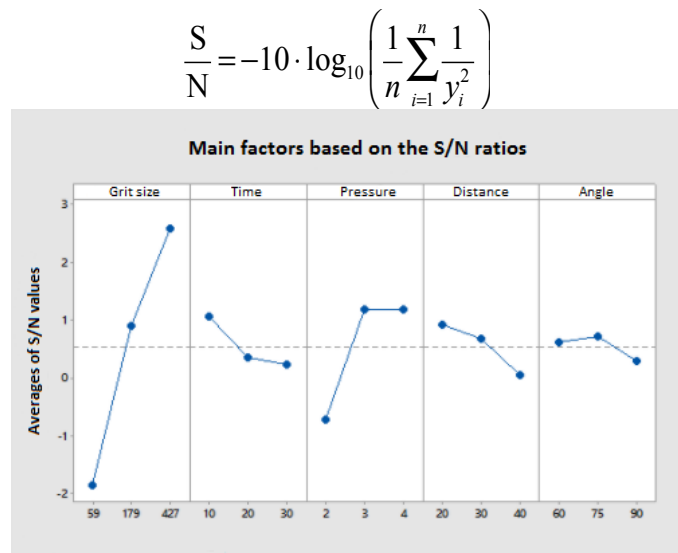


Fig. 4. S/N analysis

The results show that of the five investigated parameters the size of blasting material has the biggest influence on the surface roughness. This follows the pressure and the other three parameters are negligible, see Fig. 5.

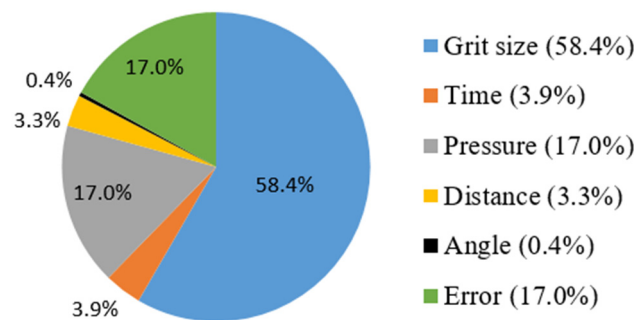


Fig. 5. Effects of the five technological parameters to the surface roughness

4. Conclusion

- With 354-500 μ m particle size, 30 s blasting time, 75° blasting angle, 4 bar pressure and 20 mm blasting distance, the 1.5 μ m surface roughness can be created on machined Grande23 Ti disks and implants.
- This experiment processes an important matter in material science, because the osseointegration of the mentioned surface roughness is far better.

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