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Improvements of medical implants based on modern materials and new technologies

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ABSTRACT

Purpose: Modern medical implants are products with pretentious requirements regarding materials, machining technologies and their functionality. In general they are divided into two main groups which are permanent and temporary medical implants. To improve implant's performance in the working environment one of the main goals of research and development process is to improve implant's biofunctionality, biocompatibility, corrosion resistance, bioadhension, processability and availability.
Design/methodology/approach: Development of modern medical implants is a multi-stage design and manufacturing process primarily based on computer design, computer numerical simulations and in-vitro tests.
Findings: Some improvements could be done with reverse engineering technology which generates a numerical model from the workpiece in order to get a replica or geometric variant for the scanned data.
Practical implications: The surgical treatments of bone fractures (osteosynthesis) are divided into external fracture fixation or internal fracture fixation. One of the most common used medical implant for internal fracture fixation is bone fixation plate which holds together the bone fragments. In some cases the improved shape of the plate could results into better biofunctionality and bioadhesion.
Originality/value: In this contribution few examples of machining technologies based on CAD-CAM principle, modern materials and research/development process of modern medical implants is presented.
Keywords: Metallic alloys; Metallic biomaterials; Medical implant; Shape memory material; Rapid prototyping

1. Development process of medical implants

Development of medical implants is a multi-stage design and manufacturing process primarily based on computer numerical simulations and in-vitro tests. First stage is definition of the problem based upon needs and objectives of the working environment. At this point standardization of resembling fractures is reasonable. In the following, second stage preliminary ideas for implant are given and preliminary design is created on the basis of computer tomography (CT) or magnetic resonance imaging (MRI) scans which are used to process the medical image with high resolution and precision in the reconstructed contours (3D model). In the third stage of the process is this model the basis for numerical analysis (Finite Element Analysis-FEM), further prototype improvements and manufacturing of the prototype on a CNC machine according to the program which has been elaborated. Performance and functionality of the developed prototype are verified in the fourth stage with different mechanical, chemical, histological and cadaver tests (in-vitro tests). In case of positive expected results prototype is tested on patients (in-vivo tests) in the next, fifth stage. Finally, sixth stage of development is clinical use of developed implant, Figure 1.

Parallel to the medical implant prototype development an attendance instruments is developed and tested. It should be simple and effective.

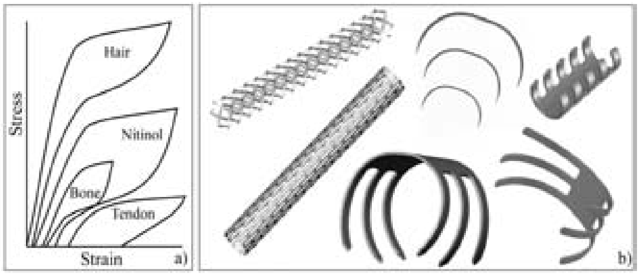

Fig. 1. a) The stress-strain diagram, b) Nitinol clamps and SE stents

2. Metallic biomaterials

Metallic biomaterials are divided into four subgroups: stainless steels, the cobalt-based alloys, titanium alloys, and miscellaneous others (including tantalum, gold, dental amalgams and other special metals). They are very effective in binding the fractured bone, do not corrode and do not release harmful toxins when exposed to body fluids and therefore can be left inside the body for a long period of time. Their disadvantage is a much larger hardness and stiffness compared to the bone and possibility of interfering with the regrowth of the bone.

In last two decades titanium alloy Ti6Al4V has become one of the most favourite biomaterial used for biomedical applications. Selection of titanium alloy for implementation is determined by a combination of the most desirable characteristics including immunity to corrosion, biocompatibility, shear strength, density and osteointegration, [1]. The excellent chemical and corrosion resistance of titanium is to a large extent due to the chemical stability of its solid oxide surface layer to a depth of 10 nm, [2]. Under in vivo conditions the titanium oxide (TiO_2) is the only stable reaction product whose surface acts as catalyst for a number of chemical reactions.

Processes of machining titanium alloys involve conventional machining operations (turning, milling, drilling, high-speed cutting), forming operations (cold and hot forming, hydroforming, forging) and alternative machining operations (laser cutting, water-jet cutting, direct metal laser sintering, targeted metal deposition technology). Machining techniques of titanium alloy represent a great challenge, due to its relatively high tensile strength, low ductile yield, 50 % lower modulus of elasticity (104 GPa) and approximately 80 % lower thermal conductivity than that of steel, [3]. The lower modulus of elasticity may cause greater ‘spring back’ and deflection effect of the workpiece. Therefore, more rigid setups and greater clearances for tools are required. In the tool contact zones high pressures and temperatures occur (the tool-to-workpiece interface). The amount of heat removed by laminar chips is only approximately 25 %, the rest is removed via the tool. Due to this phenomenon titanium alloys can be machined at comparatively low cutting speeds. At higher temperatures caused by friction the titanium becomes more chemically reactive and there is a tendency for titanium to »weld« to tool bits during machining operations. Over-heating of the surface can result in interstitial pickup of oxygen and nitrogen, which will produce a hard and brittle alpha case. Carbides with high WC-Co content (K-grades) and high-speed steels with high cobalt content are suitable for use as cutting materials in titanium machining operations, [3]. Turning operations of titanium alloys should have cutting depths as large as possible, cutting speeds Vc from 12 to 80 m/min and approximately 50 % lower when high-speed steel (HSS) tools are used. The heat generated should be removed via large volumes of cooling lubricant. Chlorinated cutting fluids are not recommended because titanium can be susceptible to stress corrosion failures in the presence of chlorine. Any type of hot working or forging operation should be carried out below 925°C due to high level of titanium reactivity at high temperature.

To stimulate ossteointegration, limit resorption and thus increase the implant lifetime, some designs (cementless prostheses) use roughened bioactive coated surfaces. One of the most popular bioactive coatings is hydroxyapatite (HA) which is similar to the mineral phase of natural hard tissue, i.e. about 70 % of the mineral fraction of a bone has a HA-like structure. HA can also be regarded as non-resorbable in a physiological environment, as long as it remains crystalline and is of high purity. It is the most stable calcium phosphate phase in aqueous solutions [4]. It has weaker mechanical properties and low resistance to fatigue failure. Surface treatments techniques for HA are plasma spraying (Vacuum Plasma Spraying-VPS) electrophoretic deposition of HA and micro-arc oxidation. Another form of implant coating is Diamond-like carbon (DLC) films. DLC coatings can address the main biomechanical problems with the implants currently used, e.g. friction, corrosion and biocompatibility, [5].

3. Shape memory materials

Shape memory alloys (SMA) have been given a lot of attention mainly for their innovative use in practical applications. SMA has an intrinsic capacity to return to a previously defined shape by increasing the alloys temperature. This effect arises from reversible and usually rate-independent martensitic transformation and resulting changes of crystal structure of the solid phases of the material. The low temperature phase is called martensite and the high temperature phase austenite. Large residual strains of even more than 10% can be recovered in this way and the process is often referred to as free recovery. The return to the original shape starts at a temperature called austenite start transformation temperature A_S, and completes at the austenite finish transformation temperature A_F. The other main property of some SMA is their superelastic effect. At constant high temperature, above temperature A_F, a mechanical loading-unloading cycle induces highly-nonlinear large deformations. At the end of the loading-unloading cycle no permanent deformations are present. The cycle usually presents a hysteresis loop, Figure 1a.

In 1962 shape memory effect was rediscovered with Ni-Ti alloy nowadays known in medicine as nitinol. Ni-Ti alloy contains approximately 50% nickel and 50% titanium. Small compositional changes around this ratio can make dramatic changes in the operating characteristics of the alloy. Slightly nickel richer alloys result in the effect known as superelasticity which could be exhibited in a narrow temperature range of the human body. Therefore superelasticity is utilized in vast majority of medical applications.

The Simon Inferior Vena Cava filter was the first SMA cardiovascular device. It is used for blood vessel interruption for preventing pulmonary embolism, [6]. The Simon filter is filtering clots that travel inside bloodstream. The device is made of SMA wire curved similary to an umbrella which traps the clots which are better dissolved in time by the bloodstream. For insertion, the device is exploiting the shape memory effect, i.e. the original form in martensitic state is deformed and mounted into a catheter. When the device is released, body heat causes the filter to return to its original shape.

Stents are most rapidly growing cardiovascular products which are used to maintain the inner diameter of a blood vessel. The product has been developed in response to limitations of balloon angioplasty, which resulted in repeated blockages of the vessel in the same area. Ni-Ti alloys have become the material of choice for superelastic self-expanding (SE) stents, Figure 1b, [7].

The self-expanding nitinol stents are produced in open state and later compressed and inserted into the catheter. The basic open form is obtained mainly by SMA tubing, the final shape is then obtained by alternative machining operations such as laser cutting. Stents can also be produced from wire and laser welded or coiled striped etched sheet. During the operation procedure, when the catheter is in correct position in the vessel, the self-expanding stent is pushed out and then it expands against the vessel wall due to a rise in temperature.

Orthopedic implants far exceed any other by weight or volume. They are used as fracture fixation devices, which may or may not be removed and as joint replacement devices. As shown in Figure 1a, bone and nitinol have similar stress-strain characteristics, which make nitinol a perfect material for production of bone fixation plates, nails and other trauma implants, [8]. In the past, acceptability of nitinol as material for permanent bone implants was conditioned by releasing Ni^{3+} ions from NiTi and integrity of contact between the bone and the implant. To solve these two vital problems, coating the bioactive layer on the device surface has been introduced, [9].

Superelastic SMA wires have found wide use as orthodontic wires as well, Figure 1b. Nitinol wires have large elastic deformation combined with a low plateau stress. This results a smaller number of visits to the orthodontist due to the larger elastic stroke and more comfort due to lower stress levels. In dental medicine, special plates for fixing a loose tooth have become available. They are produced with laser cutting from sheet metal.

Medical equipment is also a branch where nitinol has found its place. Because modern surgery is aiming less invasive operations, smaller diameters of tubing are very important. Reducing the diameters of medical devices was possible compared to polymer materials due to superelasticity when tubing of NiTi alloys became available.

Machining of SMA based on NiTi is difficult to process due to its high ductility and the high degree of work hardening of the alloy through the process. The cutting process is also influenced by the unconventional strain-stress behaviour of SMA which causes poor chip breaking and the formation of burrs in combination with high tool wear, [10]. Former investigation on cutting tool materials like polycrystalline diamond, cubic boron nitride, oxide ceramics, composite ceramics and cemented carbides show the best machining results are obtained by using a coated cemented carbide [11]. At turning operation of NiTi based alloy machinability can be classified into three different ranges. At low cutting speeds (Vc=20 m/min) the cutting forces and tool wear are very high. They can be reduced by emulsion lubricant. At cutting speed of about 100 m/min (second range) notch wear no longer appears. Cutting forces are almost constant, the tool wear increases slowly. At cutting speeds more than 140 m/min the cutting forces and the tool wear increase significantly specially for dry machining, [10]. Drilling operation is less complex than turning and with higher cutting parameters the extended tool life expectancy could appear. Deep hole drilling causes an increase of the micro hardness in the subsurface zone of the material.

4. Rapid prototyping

Good alternatives in manufacturing of modern medical implants are alternative techniques such as the rapid prototyping (RP) which is the name for a group of technologies where the 3D physical model is built directly from the CAD file without the intermediary action. The RP technologies are divided into two groups which are technologies adding the material during the prototype building and technologies removing the material during the prototype manufacture [12].

Laser technology is today widely used in manufacturing of modern medical implants. It can be used for cutting, selective hardening of implant surfaces, precision cutting, welding and drilling. The manufacturing accuracy is within the range of 10 µm. The CO2-, Nd:YAG- or diode lasers are available. The introduction of the 5 KW ray beam and linear drives in the laser cutting devices results in the increase of efficiency and accuracy of machining.

4.1. Laser sintering of prototype

The direct laser sintering of metallic powders is today one of the most important procedures for rapid prototyping and rapid tooling. It enables prompt modeling of metal parts with high bulk density on the basis of individual three-dimensional data, including computer tomography models of anatomical structures, [13]. The concept of layer by layer building rather than removing waste material to achieve the desired geometry of a component, opens up endless possibilities of alternative manufacture of medical devices and is more environment friendly.

4.2. Laser engineered net shaping technology

For the production, development and prototyping of special surgical instruments, trauma and orthopaedic high-performance hollow and thin walled implants, a highly targeted metal deposition technology called Laser Engineered Net Shaping Technology (LENS) is used. It produces a very fine weld bead, exposing the component to far less heat than conventional methods due to smaller and more controlled heat affected zone which does not damage the underlying part. Once a geometry and material or material combination has been identified, LENS can rapidly produce a 3-dimensional prototype with good mechanical properties. It enables the designer full functional and structural analysis. The tool-less process is driven directly from CAD data, so a prototype of a new design or design iteration can be produced in few hours, providing significant time compression advantages.

The process of manufacturing a prototype of medical implant (Fig. 2) is based on 3D CAD model which is converted into the STL file. The metallic powder of selected material in delivered by nozzle to the spot where it is melted via Nd: YAG or Fiber Laser and built in certain shape.

Fig. 2. Manufacturing of special shaped product by fiber laser using LENS Technology principle

5. Conclusions

As presented in the article, a variety of different materials and manufacturing technologies are available for modern medical implants. Which material should be used depends on the type of injury. Medical implants used for temporary healing should be made of conventional metallic materials. Medical implants used for permanent healing are made of titanium alloy due to its inertness and good material characteristics. SMA medical devices and implants have been successful because they offered a possibility of performing less invasive surgeries. Nitinol wires in medical instruments are more kink resistant and have smaller diameter compared to 316L or polymer devices. Research to develop a porous SMA which enable the transport of body fluids from outside to inside the bone is currently underway. Some new technologies as LENS offer new challenges in a way of special implant design such as thin walled and hallow medical implants.

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