METAL IMPLANTS IN OSTHEOSYNTHESIS – CONSTRUCTION SOLUTIONS, MATERIALS AND APPLICATIONS

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Abstract

Every day human bones undergo different injuries resulting from public transport accidents, diseases or trauma. Consequently, they cause temporary or constant patients disability or even death. Fractures happen not only to elderly people suffering from osteoporosis, but also more and more frequently to young people, who got some injuries as a result of life style, e.g. doing sports. The desire to enhance the physical well being and quality of patients' life, who got some injury causes constant development of medical devices for ostheosynthesis. In the case of complicated fractures, in which plaster treatment is not sufficient, surgical treatment and applying implant are indispensable.

The aim of the article is to present two case studies on intramedullary nails. The first one concerns a method of ostheosynthesis for a patient, who was injured in an accident. The second one presents the failure of the implanted intramedullary nail. The research included evaluation of the type of fracture and the analysis of microstructure, chemical composition and hardness of the implant materials.

Keywords*: metal implants, ostheosynthesis, intramedullary nail, fracture*

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Introduction

The metal implants application dates back to the ancient times. Up today, they are used in the ostheosynthesis techniques, although their construction or chemical composition underwent considerable modifications. Metal alloys improved throughout centuries became the essential material applied in bone surgery and orthopaedics. While choosing the biomaterial the biocompatibility is taken into consideration. This feature is strictly connected with proper functioning of the implant in the body, as well as its non-toxicity and no influence on the immunological system of the body. Materials designed for implants should be biofunctional and show compatibility with the body and not cause undesirable effects such as allergies and blood coagulation. In the case of metal alloys used for implants, static and dynamic endurance, corrosion resistance, frictional wear and suitable electromagnetic properties are of great importance [1].

The properties of the metal implants should be adapted to those of bone tissue. The mechanical properties of a bone are characterized by anisotropy resulting from their structure, and its structure is influenced by the inside tension and deformations. According to Wolf's law trabecular structure of bone tissue in balance adjusts itself to the direction of the main tensions. As a result any change in loading causes the adjustment of bone structure to a current tension. From physical point of view a bone is a unit composed of many solid phases surrounded by the liquid phase. The bone tissue has also an organic phase. Owing to that it is highly elastic and is resistant to loading. It stretches very little and bends only to some extent and then breaks. The mechanical properties of bones depend on the age (the greatest endurance is for people aged 30 and then it decreases), structure, the amount of collagen, type of loading and shape [2,3].

The elastic properties are the basic mechanical bone properties (Young's modulus, Poisson's factor, Kirchhoff's modulus, endurance to stretching, squeezing and cutting) [4]. Young's modulus has significant importance in implants. While producing implant materials it is desirable to lower the Young's modulus to the value typical of bone. The low Young's modulus is of great importance for eliminating stiff systems and obtaining elastic fixation of bone and implant. Of all known metallic biomaterials the lowest Young's modulus have titanium alloys, particularly the Ti-Nb-Zr-Ta alloy (FIG. 1) [5].

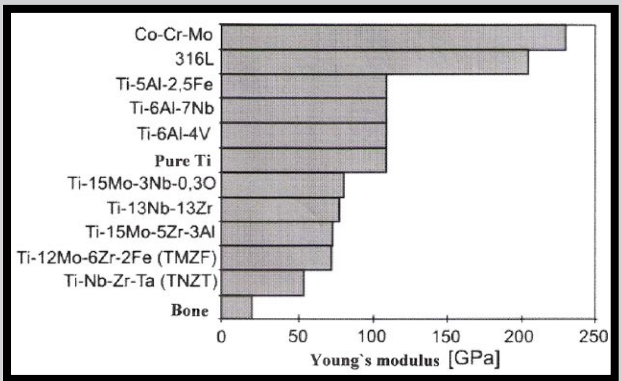


FIG. 1. The Young's modulus for different kinds of metallic materials used in implantology as compared with bone [5].

The aim of the implant is to join or replace bone tissue. Therefore it should be mechanically similar to bone, so that the system can cooperate. In the case of metals it is difficult to achieve it, however, the biomaterials made from different kinds of alloys are more and more effective in performing functions of bones enabling patients normal functioning in life. Implants are chosen separately for each patient according to their age, sex, weight, height as well as the condition of bone tissue. Therefore accurate analysis of mechanical properties is indispensable (TABLE 1) [2].

As far as metal implants are concerned it should be remembered, that human organism is a complicated working environment. The composition of body liquids can be compared with sea water. The Cl, Na, K, Ca, Mg ions and the organic compounds, which the environment contains, makes it aggressive [6]. Another important factor is pH, which in normal conditions in human body is 7.4 and in the place of implant may show acidic value. Constant and relatively high body temperature should be also taken into consideration in corrosion process of the implants. Additional difficulty results from constant loading of the implant connected with the structure and functioning of the human body or lack of loading, when the bone tissue around the implant is destroyed by excessive strength. All these factors are responsible for the destructive environment for an implant. When choosing proper material for the implant it should be remembered, that it must meet some requirements, which prevent it from destruction [7-9].

TABLE 1. The properties of implants used in bone surgery [2].

Physical properties	Human bone	CrNiMo 316L steel	Co-Cr-Mo alloy Protasul – 2	Ti-6Al-4V alloy
Chemical compounds	$Ca_5(PO_4)_3OH$ $CaHPO_4 \cdot 2H_2O$ $Ca_8H_2(PO_4)_6$ $2H_2O$ $CaCO_3$	Cr: 17-19% Ni: 13-15% Mo: 2.5-3.5% Mn: 2.0% Si: 1.0%	Cr: 26.5-30% Mo: 4.5-70% Ni: 2.5% Mn, Fe, Si: 1% Co: rest	Al: 5.5-6.7% V: 3.5-4.5% Ti: rest
Tensile strength R_m [MPa]	130	590-1100	665	850-1120
Compressive strength R_e [MPa]	200	-	-	-
Bending strength R_g [MPa]	120	-	-	-
Bending fatigue strength R_{zg} [MPa]	-	240	250	500
Yield point $R_{0.2}$ [MPa]	-	190-690	450	895-1080
Elongation A_5 [%]	0.02	12-40	8	10-15
Elastic modulus E [MPa]	$1.8\text{-}1.9 \times 10^4$	2.0×10^5	2.0×10^5	2.2×10^5

The cooperation between implant and tissue goes in two directions. It includes the impact of implant on tissue and reaction of tissue on a foreign body or products of its degradation. The reactions of human body on implant may result in different kinds of destruction. In the case of implants used for ostheosynthesis they are: fretting, pitting, galvanic corrosion, intercrystalline corrosion, hydrogen corrosion, fatigue as well as mechanical damage [7-9].

Each surgical procedure gives a risk of some complications. Apart from some mechanical and endurance properties the phenomenon of biocompatibility in the tissue and body fluids is of great importance. Biocompatibility and mechanical properties allow to diminish the danger of their destruction, as well as allergic reactions and some tissue irritation [10].

The existence of an implant encourages immunological system to create the antibodies, which gather around and penetrate it. As a result of aggressive environment corrosion process of the implant advances, which causes releasing of ions from the metal. That in turn causes undesirable and harmful reactions resulting in the failure of ostheosynthesis process [11-14].

Human bone structure is subjected to different injuries such as fracture. The fracture of femur stem is a very serious problem. It is the longest human bone and complete recovery takes long time. For treatment the most effective method should be chosen as it enables quick recovery and rehabilitation. The choice of proper implant made of proper material is necessary to achieve the proper treatment of the bone tissues.

FIG. 2. The fracture of femur stem.

Materials and Methods

The first case study concerned a male patient aged 25 suffering from uncomplicated fraction of calve bone (FIG. 2). The patient underwent patch test on metals to select the proper material for the implant. After 48 h the allergic reaction was checked. It turned out the man was allergic to chromium. Two of all metallic alloys used in orthopaedics contain large amount of chromium, they are: stainless steel and cobalt alloy (TABLE 2) [15]. Therefore for this patient titanium alloy implant was chosen. It is an implant commonly used for allergic patients in the case of long bone fractures.

The second case study concerned a patient with intramedullary nail fracture (Gamma nail) (FIG. 3). After retrieval from the patient the chemical composition of the Gamma nail material was examined by means of the Scanning Electron Microscope Philips XL 30 under with different magnifications (from 23x to 1000x), equipped with devices to analyse the chemical composition (EDS).

TABLE 2. Chemical composition of metallic alloys used in orthopaedics [15].

Alloy	Ni	Co	Cr	Ti	Mo	Al
Stainless stel	13-15	-	17-19	-	2-4	-
Cobalt alloy	-	62-67	27-30	-	5-7	-
Titanium alloy	-	-	-	81-91	-	5.5-6.5
Nitinol	45-49	-	-	51-55	-	-

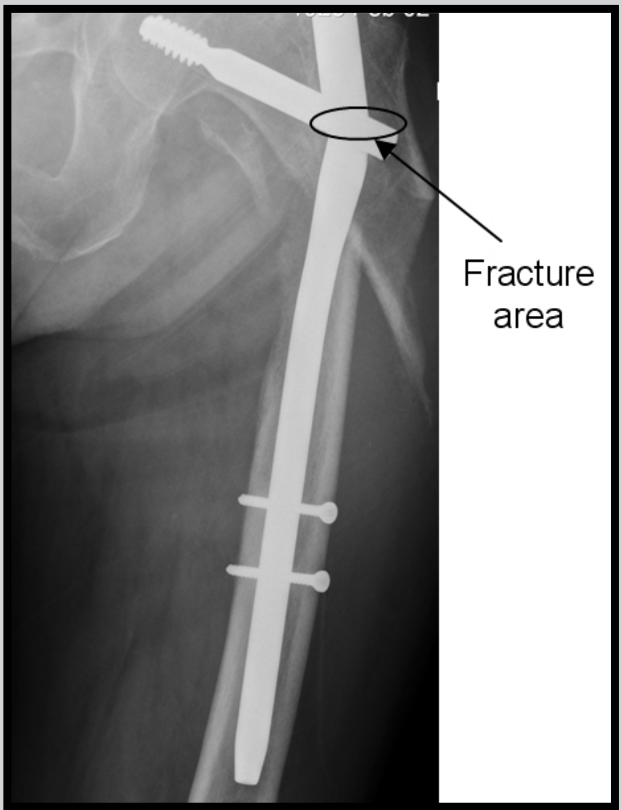


FIG. 3. The picture of Gamma nail in the leg after breaking.

Results and Discussion

The first case study

In cross-breaking of long bones, as in the first case the most effective method is the intramedullary method. It is a little invasive method and does not carry the danger of many complications. The healing process is similar to natural one and enables quick recovery of the injured bone. To avoid improper fixation of broken bone, the nail above and below the fracture should be fixed. This method depends on proper positioning of the screws in the nearest required distance of the bone and accelerates the process of bone fixation (FIG. 4). By means of X-Ray examination the length of the implant equal to 400 mm and diameter of 9 mm were chosen.

The process of bone fixation was controlled by X-Ray examination in order to place the implant in the proper place (FIG. 5a). Owing to proper and steady rehabilitation and the patient's cooperation, which started few days after the operation, the bone was united properly, which was confirmed by X-Ray photos two years later and than two and a half years after removing the implant (FIG. 5b and FIG. 5c).

The second case study

The analysis of Gamma nail fracture started with macroscopic observation of the outer surface as well as the whole surface in the fracture area. No signs of mechanical or corrosion destruction were observed on the outer surface, while some plastic deformation of the nail in the contact place with the screw was observed. The chemical composition of the Gamma nail material examined by means of the Scanning Electron Microscope Philips XL 30, equipped with devices to analyse the chemical composition (EDS) is presented in FIG. 6.

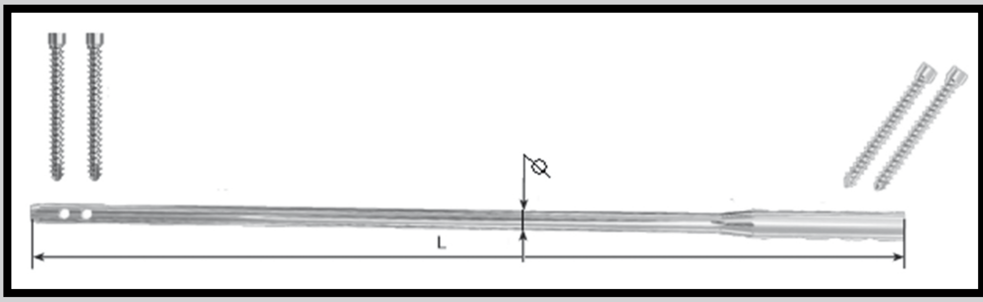


FIG. 4. The construction of the nail used in a given case.

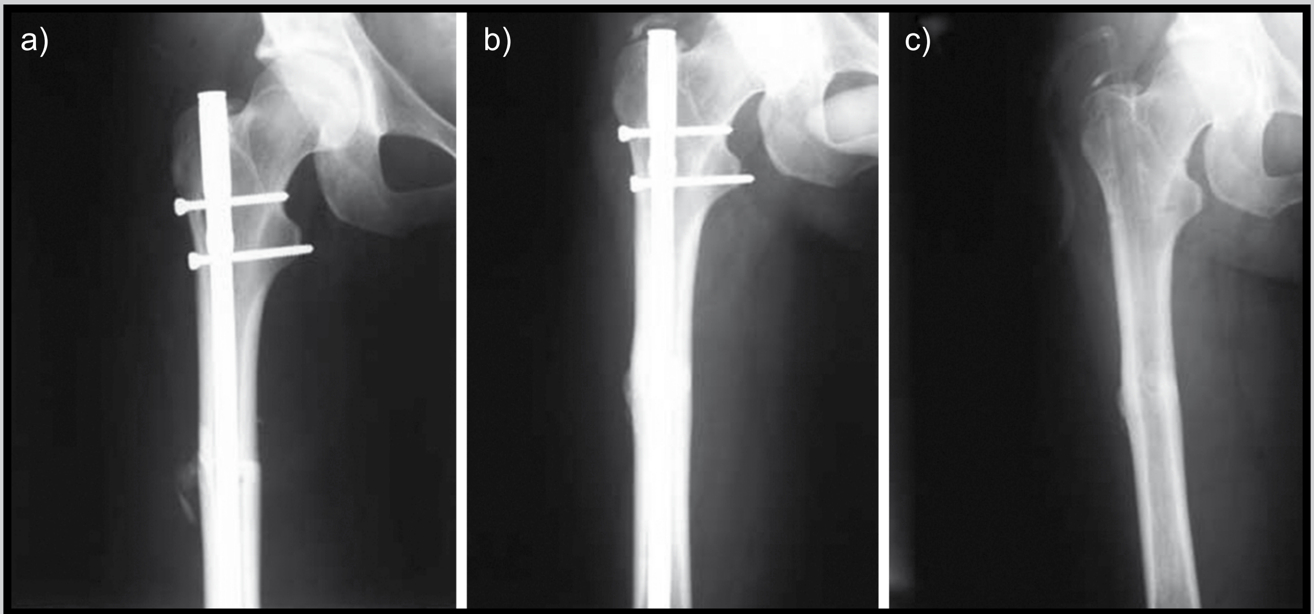
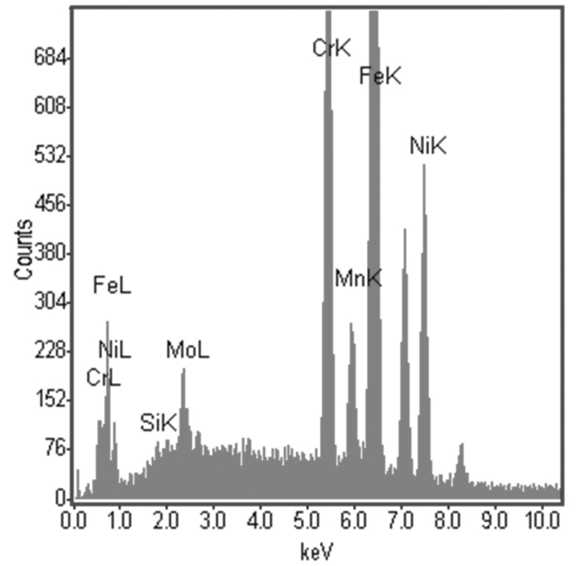


FIG. 5. X-Ray photos taken after: a) inserting the implant, b) two years after inserting the implant, c) two and a half years after removing the implant.



Element	Wt %	At %
SiK	0.58	1.16
CrK	17.57	19.09
MnK	1.93	1.99
FeK	59.97	60.68
NiK	14.29	13.75
MoK	5.66	3.34
Total	100.00	100.00

Element	Net Inte.	Bkgd Inte.	Inte. Error	P/B
SiK	2.34	4.71	14.66	0.50
CrK	151.88	6.61	0.85	22.98
MnK	13.25	5.77	3.76	2.30

FIG. 6. The spectrum and the chemical composition of the Gamma nail material.

TABLE 3. The hardness HV30 of the intramedullary nail.

The Gamma nail element	The average hardness HV30
Nail	321
Screw	320

The chemical composition analysis proves that the material of the examined nail is Cr-Ni-Mo alloy. According to the Schäffler's diagram [16], the austenitic structure of the examined material was found. Its hardness was defined by means of Vickers method of measurement by loading of 294.2 N. The average hardness of the Gamma nail and screw is presented in TABLE 3.

The pictures of the Gamma nail fractures are presented in FIG. 7. It was found that both the nail and the screw cooperating with it are equally hard (321 and 320 HV), which proves the proper combination of the materials in the construction of the examined nail. The observations of the Gamma nail fracture suggest that failure was due to fatigue. The analysis of biomechanical loading of the nail and the fracture indicates that concentration of variable stresses most probably appeared of the whole edge in the Gamma nail. It cannot be excluded that the fracture might have been started due to micro fractures caused by the impact of loading (for example a patient's fall) and its further advancement in the course of further use of the examined Gamma nail.

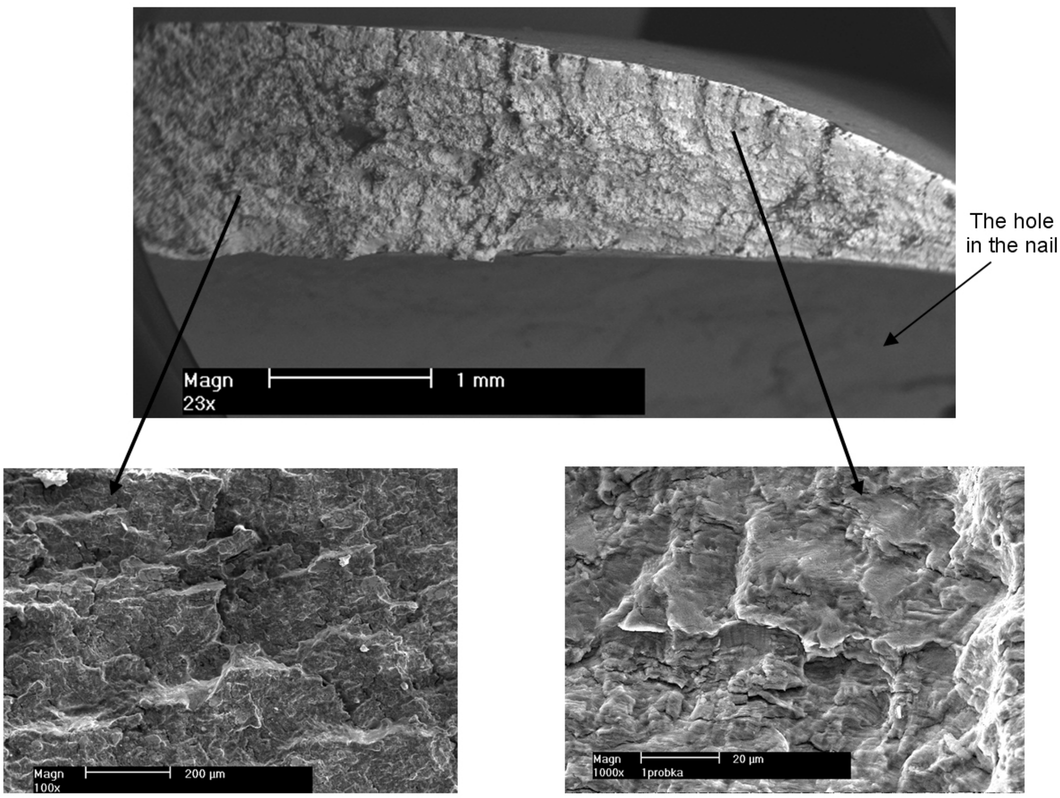


FIG. 7. View of the fatigue fracture of the Gamma nail.

Summary and conclusions

In this study it was found that:

1. The nails were made of Cr-Ni-Mo stainless steel and titanium alloy, commonly used in trauma surgery.

2. The failure of the Gamma nail showed the fatigue nature.

3. The fatigue fracture was initiated in the whole edge at the contact with the screw. The screw, which connects the nail with the bone was probably too tightly fastened, which resulted in the change of tension, causing the break of the nail.

4. During the rehabilitation period patients should absolutely adhere to doctor's instructions, dealing with moving and loading a broken bone that was stabilized with the Gamma nail.

5. The osteosynthesis methods with the use of metal implants carry different risks (inflammation, necrosis of the tissues). The aim is to achieve the best compatibility between the implant and the body, as well as the endurance in the environment in body fluids.

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