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Żaneta Anna MIERZEJEWSKA
Paulina KUPTEL
Jarosław SIDUN

ANALYSIS OF THE SURFACE CONDITION OF REMOVED BONE IMPLANTS

ANALIZA STANU POWIERZCHNI USUNIĘTYCH IMPLANTÓW KOSTNYCH*

The requirements that must be met by implant materials are rigorous and diverse. These materials are tasked with supporting or replacing sick or damaged parts of the musculoskeletal system, where loads and a heterogeneous stress state frequently occur. Thus, they must have the appropriate strength properties and resistance to many types of corrosion, which is related to biotolerance, or neutrality of the material to the human body during use. This article presents the results of studies of three implant groups: set for stabilization of long bones made of 316L austenitic steel, set for intramedullary nail insertion in grafts of femur bones made of Ti6Al4V titanium alloy, and a straighty reconstruction plate made of Ti6Al4V titanium alloy coated with an oxide layer. These implants were implanted into the human body and then removed at the end of the treatment process or due to implant failure during its operation. Next, implants were studied in order to determine the level of wear. Investigations were carried out using an Hitachi S-3000N scanning microscope. Their results indicate a series of changes that took place on implant surfaces and confirm the existence of typical implant wear mechanisms presented in reports in the literature. Traces of corrosion, fatigue cracks, tribological wear, and traces of fretting were found on examined implant surfaces. The study of implant wear cases, determination of their character, and evaluation of the intensity of destructive processes may contribute to the improvement of both the mechanical properties of these implants and their shape, so that modern bone implants perform their roles without the risk of failure during their operation.

Keywords: *implant, surface analysis, operating wear, tribological wear.*

Wymagania stawiane materiałom na implanty są wysokie i bardzo zróżnicowane. Mają one wspomagać lub zastępować chore lub uszkodzone części układu kostno-mięśniowego, gdzie często pojawiają się obciążenia i różnorodny stan naprężeń. Muszą zatem charakteryzować się odpowiednimi własnościami wytrzymałościowymi i odpornością na różne rodzaje korozji, powiązaną z biotolerancją oznaczającą neutralność materiału wobec organizmu podczas użytkowania. W pracy przedstawiono wyniki badań trzech grup implantów: zestawu do stabilizacji kości długich, wykonanego ze stali austenitycznej 316L, zestawu do gwoździowania śródszpikowego do zespoleń złamań kości udowej, wykonanego ze stopu tytanu Ti6Al4V oraz płytki rekonstrukcyjnej prostej, wykonanej ze stopu tytanu Ti6Al4V pokrytego warstwą tlenków. Implanty te wszczepione były do organizmu ludzkiego, a następnie usunięte, wraz z zakończeniem procesu leczenia lub wskutek uszkodzenia implantu podczas jego eksploatacji. Następnie poddano je badaniom w celu określenia stopnia zużycia. Badania realizowano z wykorzystaniem mikroskopu skaningowego Hitachi S-3000N. Wyniki badań wskazują na szereg zmian, które zaszły na powierzchni implantów i potwierdziły istnienie typowych mechanizmów zużycia implantów prezentowanych w doniesieniach literaturowych. Na powierzchni badanych implantów zauważono ślady korozji, pęknięcia zmęczeniowe, zużycie tribologiczne oraz ślady frettingu. Badania zużycia implantów, określenie ich charakteru oraz ocena intensywności zachodzenia procesów niszczenia mogą w przyszłości znacznie wpłynąć na poprawę zarówno właściwości mechanicznych tych implantów, jak również na próbę zmiany ich kształtu tak, by nowoczesne implanty kostne spełniały swoją rolę bez ryzyka zniszczenia w trakcie ich eksploatacji.

Słowa kluczowe: *implant, analiza powierzchni, zużycie eksploatacyjne, zużycie tribologiczne.*

1. Introduction

The development of technology, mainly motorization, and active lifestyle of modern man that are currently being observed make a significant contribution to the growth of various types of injuries of the musculoskeletal system [1]. This is a challenge for reconstructive surgery of the skeletal system, and an effective search for solutions regarding selection of materials for implants and surgical instruments requires the direct cooperation of doctors and engineers [14].

Thanks to such cooperation, significant progress has taken place in the field of implantology over the last decade or so. The development of diverse techniques in the field of materials engineering for medical applications, particularly including materials and surface engineering, has expanded our ability to restore complete or partial functionality of parts of the musculoskeletal system [7, 10-11]. Bone implants make it possible to restore destroyed systems and improve a patient's health condition and functionality [15-17].

Implant is the name given to a foreign body made of one or more biomaterials that may be placed inside of the human body as well as partially or completely under the epithelium, which may remain in the human body for an extended period of time [1, 21]. Such long-term contact of an implant with the tissue environment necessitates many properties of implant materials. They must have specific physicochemical and functional properties, which will determine their suitability for application in the context of a bone-implant interface [12, 13].

(*) Tekst artykułu w polskiej wersji językowej dostępny w elektronicznym wydaniu kwartalnika na stronie ***www.ein.org.pl***

These materials must have the appropriate mechanical properties and lifetime in the biological environment appropriately to the functions that they are to perform in the body [5]. This particularly applies to materials used to manufacture joint endoprostheses and bone stabilizers, which are subjected to large loads, both static and dynamic, during operation [4, 22, 23]. Biomaterials work under a variable state of stresses and displacements as well as in the reactive environment of tissues and bodily fluids. This fact may lead to irreversible changes in such materials, and in consequence, to a loss of their functionality [2, 3 ,18-20].

During use of engineering materials applied in bone implants, significant changes take place in their structure due to operating conditions and the fact of operation itself [2, 3, 19]. The properties of materials change as their operating time increases, often leading to significant degradation [6, 24]. These processes of bone implant destruction, occurring during use under clinical conditions, are very interesting and important.

Investigations of how metal bone implants are worn or destroyed during their operation in a living organism are an interesting area of materials research [8, 9, 18]. By analyzing changes on implant surfaces, the factors having a decisive impact on the occurrence of a given type of damage can be identified. This type of analysis is the principal component of the presented article. The research problem that serves as the basis of the article is determination of what processes of surface destruction occur in metallic implants in the environment of the human body.

2. Materials and methods

Three groups of metallic orthopedic implants for bone grafts (Fig. 1), which were present in the human body for a period of approx. 6 months, were studied. Investigations of surface changes were carried out on the following elements:

- set for stabilization of long bones used for osseosynthesis of the femur shaft, consisting of a load-bearing plate, clamping plate, as well as joining screws and cortical screws (316L austenitic steel),
- set for intramedullary nail insertion for grafts of femur bone fractures (Ti6Al4V titanium alloy),
- straight reconstruction plate used to graft bones of the forearm (anodized Ti6Al4V titanium alloy).

The investigative part of the study was based on assessment of changes on the surfaces of bone implants that had been removed at the end of treatment or as a result of implant failure during its operation in the body. For this purpose, preliminary macroscopic assessment was conducted, followed by detailed examinations under the microscope.

Microscope observations were conducted at the Department of Materials Science and Biomedical Engineering of the Faculty of Mechanical Engineering at Bialystok University of Technology using an Hitachi S-3000N scanning electron microscope (with an attachment for X-ray microanalysis – EDS type NSS from the THERMO NORAN company, and an attachment for examination of biological specimens), located in the Laboratory for Structural Testing of Materials.

3. Research results and discussion

3.1. POLFIX stabilizer

Observation of the plate's surface under a microscope revealed visible corrosion pits formed due to the interaction of bodily fluids with the material of the implant. Furthermore, the presence of degradation products was observed on the plate's surface. These products were formed as a result of the reciprocal interaction of the surface of the plate's seat with the screw head during the implant's presence in the body. Adhesion of wear products to the implant's surface is the result of adhesive interactions (Fig. 2).

In implants used to stabilize bone fractures, such as plates, openings serving to fasten screws are particularly exposed to damage. In the case of the investigated plate, these are both threaded and tapered seats. Fretting was observed on the thread, as shown in the photographs below (Fig. 3). Characteristic pits and areas where fine microcracks are present are indicative of this.

Corrosion has developed near openings as a result of the impact of the body's aggressive environment on the implanted metal. Numerous corrosion pits are visible on the surface (Fig. 4a) along with discolorations indicating the initial stage of corrosion development (Fig. 4b). Traces of abrasive wear can also be found near openings. In addition, slight deformation of the shape of openings also took place. Both processes usually occur as a result of mechanical wear occurring when the screws are being fastened and during further exploitation of the implant.

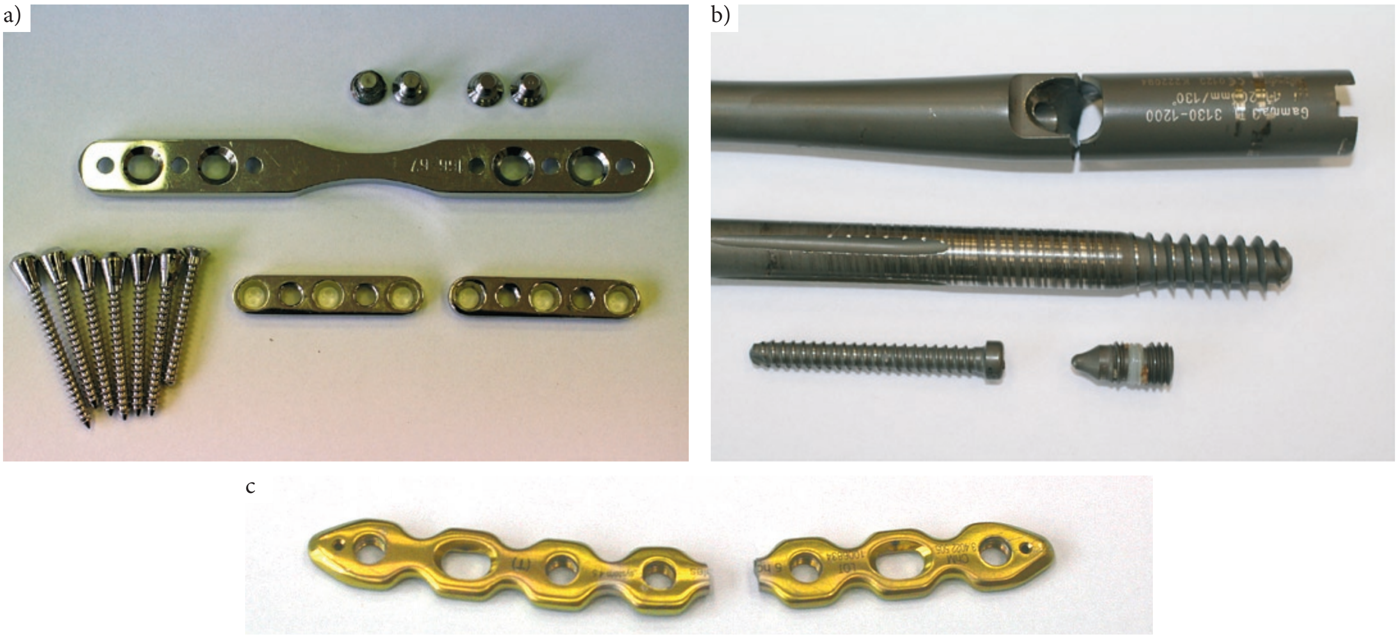

Fig. 1. Research materials: a) set for stabilization of long bones, b) set for intraosseous stabilization, c) straight reconstruction plate

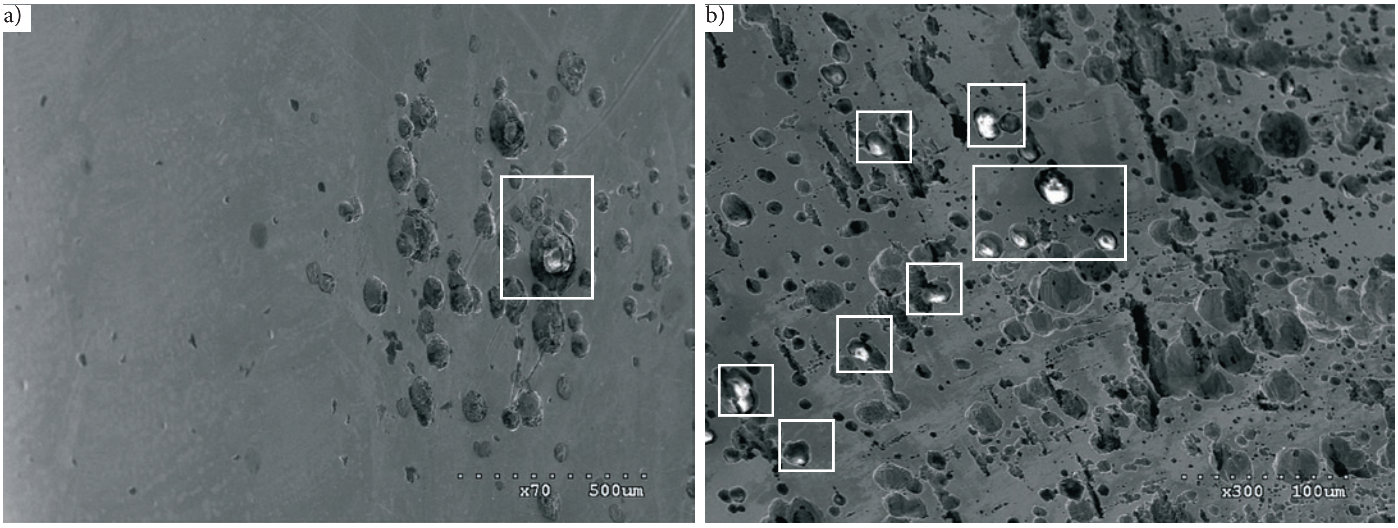

Fig. 2. Photograph of POLFIX plate surface, a) mag. x70, b) x300. Areas where metal particles formed during the wear process, adhere to the implant surface are marked on photographs

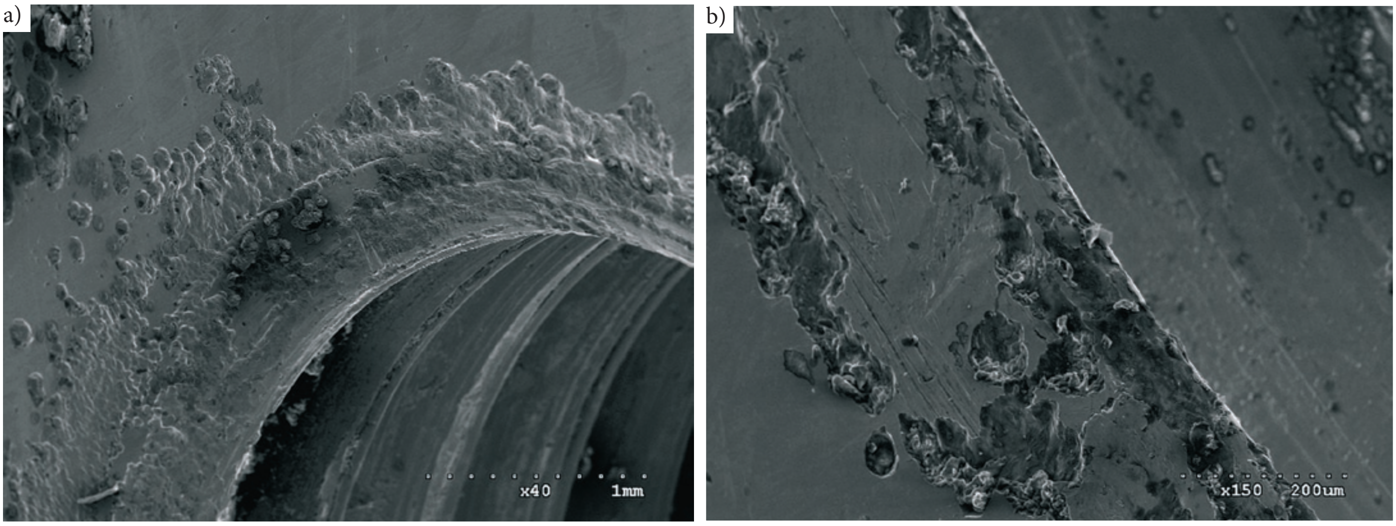

Fig. 3. Photograph of the surface of a threaded seat on the plate, mag. x40, mag. x150

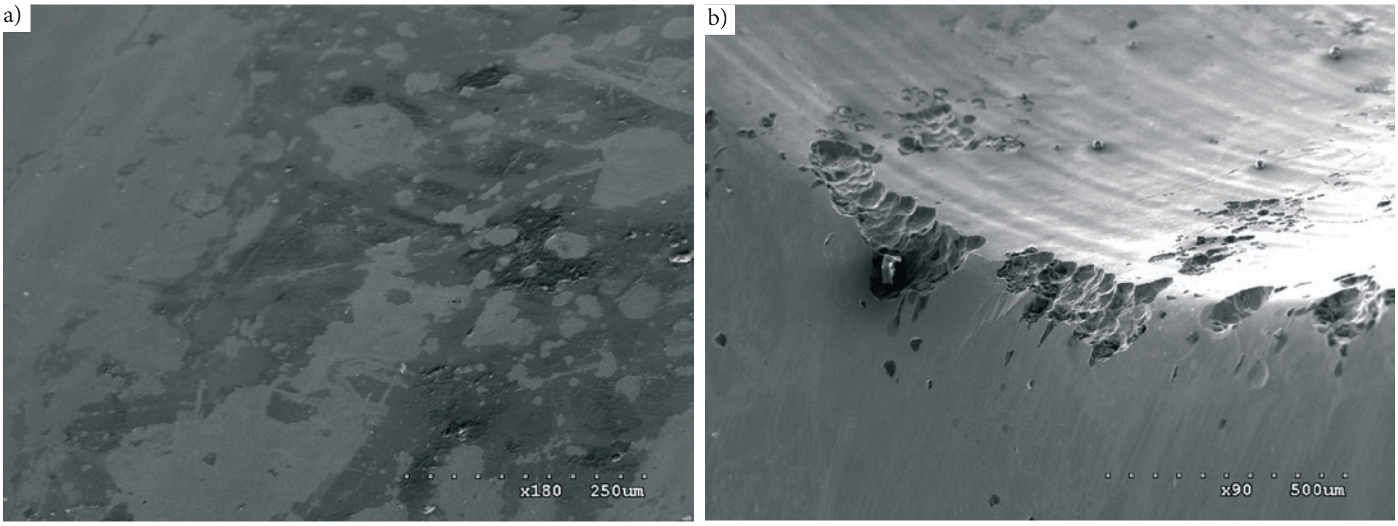

Fig. 4. View of the surface of the plate's tapered seat: a) corrosion pits (mag. x90), b) discolorations (mag. x180)

In the set for stabilization of long bones, the cortical screw is the element that fixes the plate's position after it is screwed into the bone. For this reason, this screw is subjected to large loads. The point of contact between the screw and the plate is the point where the greatest forces act on the screw.

Wear processes occurring near the screw head are already initiated during the surgical procedure, when the stabilizer is implanted. As the screw is fastened, its head is pressed down to the tapered seat, and because actual unit pressures are large, galling may occur when the screw is rotated. After initial installation of the stabilizer, final tightening of bone screws is performed. A diagram of the distribution of forces in the tapered joint: bone screw head – plate has been presented in figure 5.

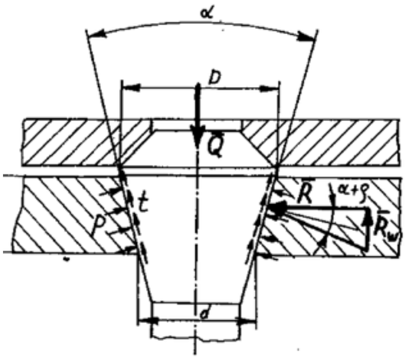

Fig. 5. Distribution of forces in the tapered joint: bone screw head – plate: Q – force of tapered joint assembly, R – radial pressure on contact surface, p – unit pressure on contact surface, t – infinitesimal friction force, R_w *– push-in force:* $R_w = Rtg(\rho + \alpha)$ *[16]*

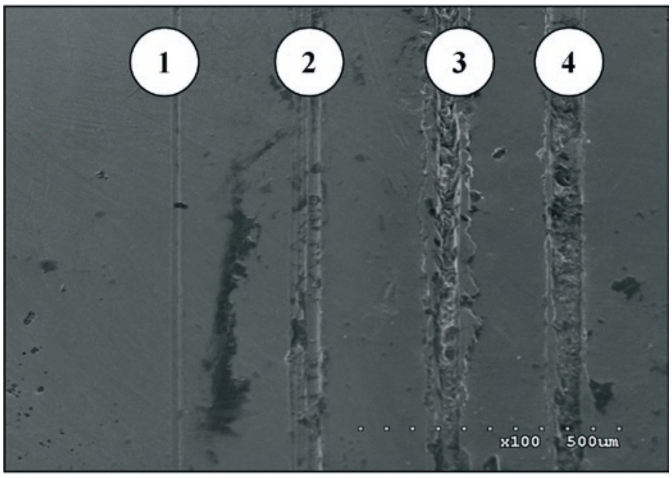

Fig. 6. View of the surface of a cortical screw with the development of successive stages of crevice corrosion, mag. x100

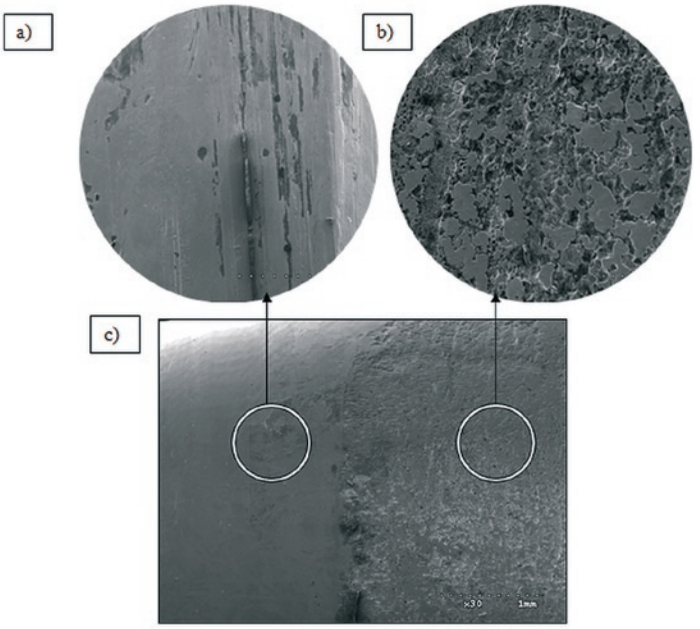

Fig. 7. View of the surface of a long POLFIX screw, a) mag. x100, b) mag. x200, c) mag. x30

Microscope observations of a cortical screw revealed traces of crevice corrosion on its surface. It developed in areas where the implant was scratched as it was fastened in the plate. Scratches occurred as a result of intensified friction between these components. The passive layer of the screw's material was damaged during installation of the implant, which initiated the development of crevice corrosion. The progression of expansion of this type of damage has been presented on the microscope photograph below (Fig. 6).

Fretting is another type of wear that was observed on screws. Due to micromovements with the involvement of elastic deformations occurring between the stabilizer's components, losses of material have developed on the screw's surface. These are chracteristic pits. This damage of the material is visible in figure 7b.

In addition, discolorations have formed and the pitting corrosion process has been initiated in areas on the screw's surface where there was intensive contact of the metal implant with bone tissue. The factor initiating pit development was the action of the surrounding environment with reduced pH relative to the proper acid-base equilibrium in the human body.

Microscope photographs of the investigated screws display the extent of destruction of their surface layer. Traces of abrasive wear were formed as a result of the mechanical interaction of the cortical screw head with the plate, initially at points of contact. As operating time increased and micromovements caused by variable loads took place, an increase in surface coarseness occurred. In the later period of fretting wear, recesses were formed in the material of screws. These changes, typical for fretting, are presented in figure 8.

Changes in areas where there was less interaction with the plate were also observed during investigations (Fig. 9). Discolorations and breaches of the continuity of the implant's surface layer were observed in the form of small corrosion pits. These pits were most likely

Fig. 8. View of the surface of the POLFIX fastening screw head: a) mag. x30, b) mag. x50

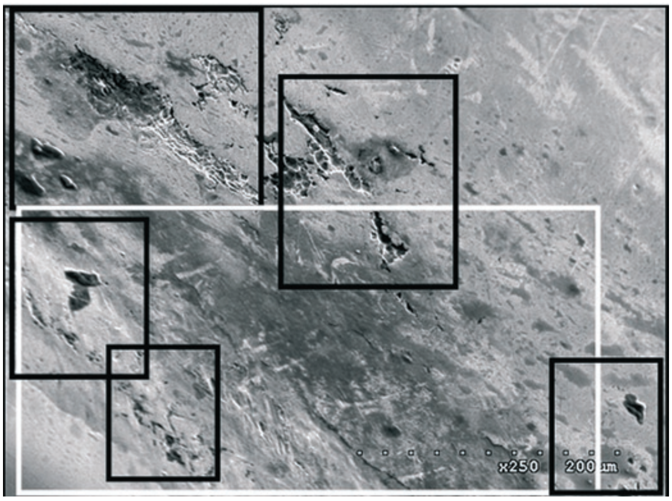

Fig. 9. View of the surface of the joining screw, mag. x250 (areas of visible corrosion pits marked in black frames and discolorations in white frames)

formed as a result of a breach of the metal's passive layer, maybe even during implantation. The corrosion process was initiated as a result of the action of the tissue environment, with a pH lower than 6.8, on the metal. The surroundings of the pit are a cathode, and oxygen reduction takes place there. During the first stage, discolorations are formed, and then an increase in the concentration of aggressive ions and significant pH reduction occur inside the pit. A layer of corrosion products is formed at the bottom of the pit. Exchange of electrolyte between the pit and surroundings takes place through openings and pores in the passive layer. The composition, thickness, and porosity of this layer have an impact on the quantity and size of pits and on the rate of their development.

Two primary types of damage were distinguished as a result of macro- and microscopic observations:

- damage of the first type – has a form typical of tribological wear; in macroscopic terms, these are traces of friction (Fig. 6) that are present on both the surfaces of tapered openings in clamping plates and on the seats of connectors and the bone screw heads inter-operating with them;
- damage of the second type – has a form typical of corrosion wear (Fig. 4); in macroscopic terms, these are matte areas where occasional pits are visible with the naked eye on the surfaces of tapered seats in clamping plates and seats of connectors as well as the bone screw heads cooperating with them.

3.2. Intramedullary nail

The set for intramedullary nailing of femur bone fractures consists of: the intramedullary nail and three types of screws – blocking, reconstruction, and plugging. Two components of the set were subjected to detailed microscope examinations: intramedullary nail and reconstruction screw.

An intramedullary nail is an implant that is subjected to the enormous loads resulting from human locomotion as it performs its stabilizing role. The examined nail was damaged during exploitation – it was broken due to material fatigue.

Macroscopic observation was already sufficient to observe some changes that occurred in the implant during its time in the tissue environment. Traces of abrasive wear and the development of corrosion processes can be observed at the fracture point of the intramedullary nail (Fig. 10a).

Scratches on the interior surface of the nail, visible on the microscope photograph (Fig. 10b), were formed during fastening of the reconstruction screw. These scratches were created as a result of friction between the screw surface and the nail surface. Moreover, plastic deformation of the seat resulting from cyclically variable loads occurring between these components is also visible. This deformation was caused by clearance between the screw and the nail, leading to micromovements.

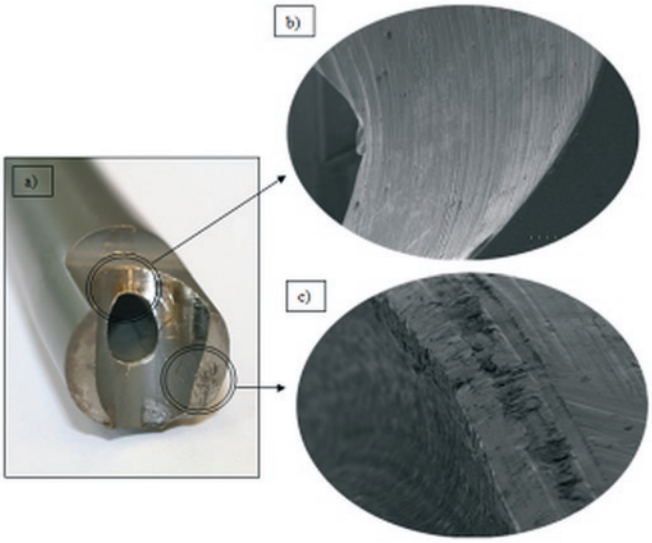

Fig. 10. Blocking screw, a) fracture, microscope photographs showing characteristic damage: b) mag. x30, c) mag. x300

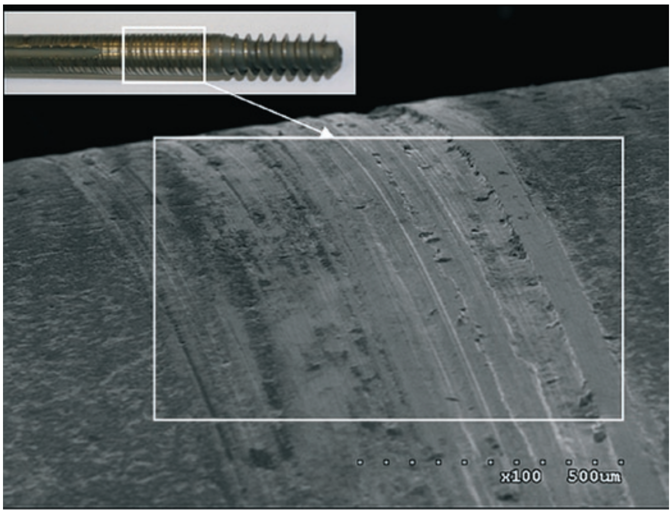

Fig. 11. Photograph of the reconstruction screw surface, showing scratches on the surface, mag. x100

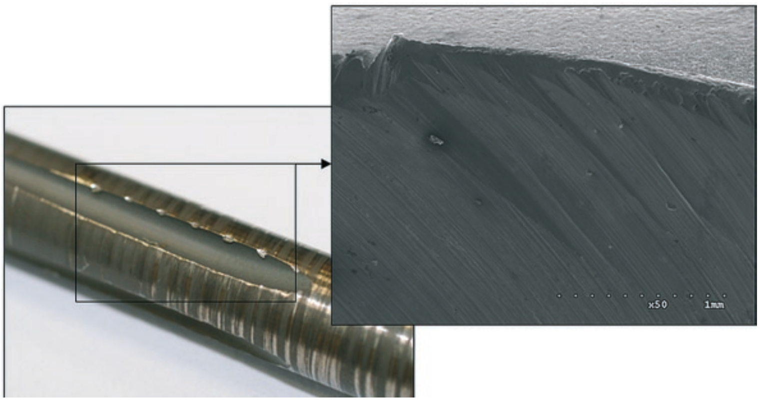

Fig. 12. View of damaged reconstruction screw surface, mag. x50.

The destruction of the fracture surface by corrosion is visible in figure 10c. This surface has increased coarseness and bears visible traces of corrosion pits. Damage of the reconstruction screw has the nature of abrasive wear. Scratches formed on its surface can be observed macroscopically (Fig. 11). The grooves visible on the surface were formed as a result of screw rotation while it was pressed to the surface of the nail seat. A slight loss of material is also visible (Fig. 11). The reconstruction screw was also mechanically damaged. Its surface was deformed during installation, and this deformation progressed over the course of further installation, as shown in the figure below (Fig. 12).

3.3. Straight reconstruction plate

The straight reconstruction plate (Fig. 1c) is made of Ti6Al4V titanium implant alloy. In addition, its surface was anodized to provide corrosion protection of the surface. The implant was damaged as a result of the action of variable loads and of the organic environment on the implant The plate cracked as a result of material fatigue. The surface of the plate and of its openings, as well as the plate's fracture, were observed under a microscope.

The results of microscope observations showed that the plate's surface underwent significant changes despite the application of additional protection against destruction. The presence of discolorations over a significant area and the initiation of corrosion pitting in the largest areas of discoloration were observed (Fig. 13). The aforementioned processes most likely took place as a result of elevated concentration of Cl^- ions on the surface layer of the implant material, which was in contact with electrolytes found in the bodily fluids surrounding it. The concentration of Cl^- ions has an impact on the incubation time of pitting corrosion. The greater the concentration and the higher the critical potential of pit nucleation, the shorter the incubation time.

Moreover, at greater magnification, increased coarseness of the plate's surface layer was also observed. Despite cleaning in an ultrasonic cleaner, the plate's surface bore contaminants in the form of irregular particles. Clear contamination sometimes remains on certain surfaces of implants implanted into a living organism. This contamination is sometimes difficult or even impossible to remove due to the presence of strong adhesive interactions. In this case, the adhering particles may be residue of peri-implant tissue (Fig. 14).

Observation of the plate's seat revealed damage of its surface layer in the form of abrasive wear. The scratches and grooves visible in the photograph (Fig. 15) are indicative of this. The plastic deformation that was observed most likely took place during the installation procedure, where a screw was inserted into the seat in order to fasten the plate.

Traces of fatigue wear of the reconstruction plate's seat are visible in the following figure (Fig. 16). Visible grooves were formed as a result of cyclically variable loads acting on components of the stabilizer and reciprocal interactions between the screw head and the surface of the seat in the plate. The cause of such deformation may have been clearance between the screw and the plate, which leads to micromovements of both components.

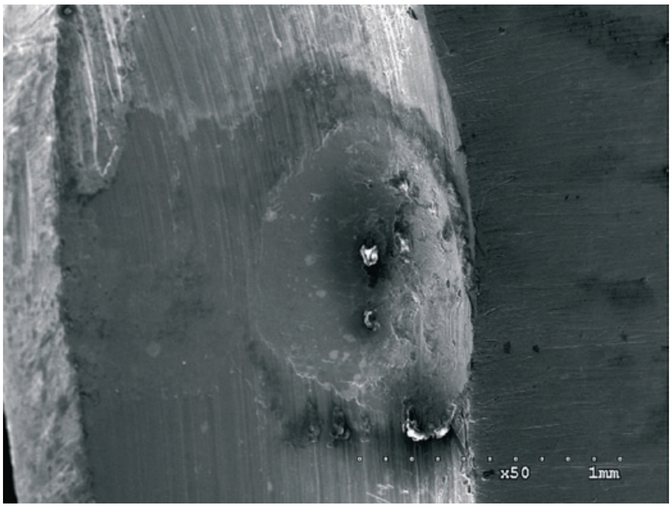

Fig. 13. Corrosion damage on the surface of the reconstruction plate

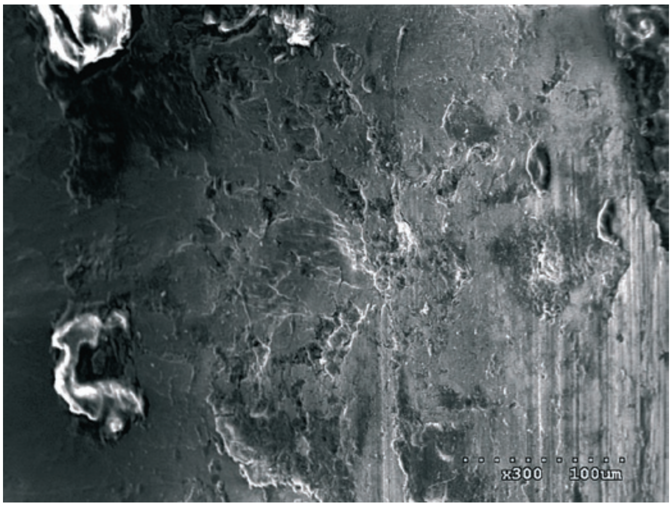

Fig. 14. View of the plate surface with visible irregular particles, mag. x300

Fig. 15. Photograph of the surface of the seat in the anodized plate, mag. x70. Scratches formed during implantation of the component are marked in the photograph

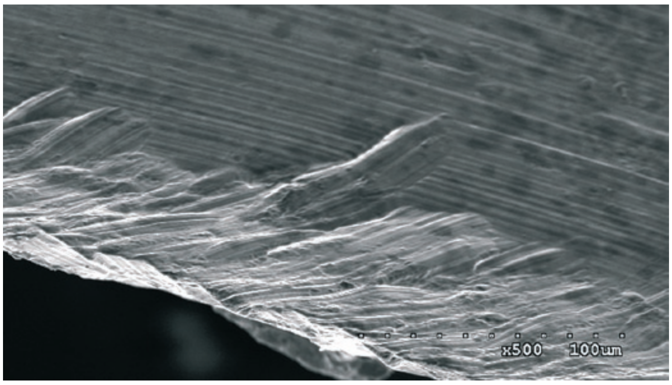

Fig. 16. Photograph of the surface of the seat in the anodized plate, mag. x500.

Because high loads are carried, this clearance may increase, making the entire system more susceptible to damage.

Both of the types of damage on seat surfaces in the anodized plate described above lead to a change of seat shape. Deformations of a plate's seats take place as a result of reciprocal interaction between the screw head and the plate. Deformation of an opening may occur as early as at first contact of the plate with the body, or during its installation, due to rotation of screws while their heads are pressed into seats in plates. Moreover, improper positioning of a screw may also cause deformations. In such a case, the micromovements taking place during exploitation are intensified as a result of the action of variable loads. This, in turn, exacerbates deformations of openings. It should be emphasized that deformation of plate seats is an undesirable process because it may lead to instability of the entire implanted stabilizer system.

4. Conclusions

Conducted macro- and microscopic investigations have revealed a series of changes occurring on implant surfaces and have confirmed the existence of typical mechanisms of implant wear presented in reports in the literature.

The largest areas of wear are visible on the inter-operating surfaces of plate seats and bone screw heads. Many types of damage typical of corrosion processes and tribological wear, mainly abrasive and fretting wear, are observed here. Traces of abrasive wear are present at points of contact between inter-operating parts. Wear processes are initiated during the surgical procedure - during installation, and develop with particular intensity in areas of microcontact between joining elements.

The following conclusions can be drawn based on conducted studies and analyses:

- typical implant surface wear mechanisms are: pitting corrosion, local material loss due to fretting, tribological wear, mechanical damage caused during the surgical procedure, and cracks due to material fatigue,
- wear processes are most commonly initiated during the surgical procedure - when the implant is introduced into the body, and develop with particular intensity in areas of microcontact between joining elements,
- tribological processes and their wear products initiate tissue reactions as a result of disruption of the acid-base equilibrium that threatens the organism (pH lower than 6.8), leading to an increase in the concentration of Cl^- ions, which are incubators of pitting corrosion.
- a technological change of the surface condition of components should decidedly limit damage during implantation as well as tribological and corrosive wear.

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Żaneta Anna MIERZEJEWSKA
Paulina KUPTEL
Jarosław SIDUN
Department of Materials Science and Biomedical Engineering
Bialystok University of Technology
ul. Wiejska 45 C, 15-351 Białystok, Poland
E-mail: a.mierzejewska@doktoranci.pb.edu.pl,
paulinakuptel@wp.pl, j.sidun@pb.edu.pl