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Effect of tissue environment on the structure and properties of Ti-6Al-4V alloy

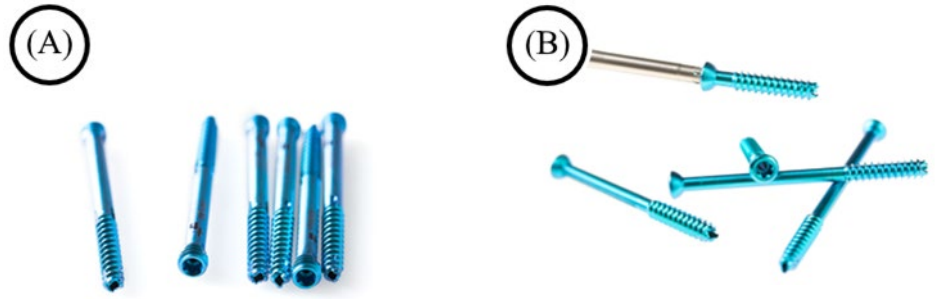
KEYWORDS
Metacarpal injury, treatment, Hofer stabilizing plates, scanning electron microscope (SEM)

ABSTRACT
Medical materials that come into contact with the human body must have the right properties, be biocompatible and bioinert. Among the most widely used materials that are biologically compatible and have optimal biotolerance are titanium alloys, which, in addition to their use for typical implants, are used as materials from which bone stabilizers are made. As is well known, any foreign material introduced into a living organism triggers various degrees of tissue reaction. Accordingly, the materials used in medicine have been studied and their effects on the living organism are known [1 – 6]. However, few studies [7, 8] deal with the reverse situation, i.e. the analysis of the effect of the tissue environment on the material used. In [7], inflammation and its effect on CoCrMo alloy were simulated, while in [8] the effect of tissue corrosion on the degradation of Ti-6Al-4V alloy was studied. Therefore, the present study focused on the material analysis of a plate made of medical titanium alloy, which was surgically removed after proper regeneration of a fractured metacarpal bone. The effect of the tissue environment on the structure and surface properties of the material was evaluated. Macroscopically, no changes were found during the observation, although in the case of the plate surgically removed from the patient's body, some deposits of material, not present on the plate in a new, unused state, was observed. When observing the screw component that is the fixture for the stabilizing plate, similar overlying foreign material was also observed. On the other hand, microscopic observation using higher magnifications detected small scratches, characterized by irregular directions of occurrence, in addition, after EDS analysis of the chemical composition, an assessment was made of the noted foreign material present on the plates in the worn state. It was found that the material accumulating locally in random areas of the plate and screws is not implant material (Ti-6Al-4V), but consists mainly of calcium (Ca), carbon (C) and oxygen (O).

1. Introduction

Bones are an integral part of the body, providing support for internal organs and the locomotor system. They perform a number of vitally important functions in the human body, from acting as muscle attachments to protecting internal organs from mechanical damage. In order for a person to function properly, it is essential that his bones are functional and free of deformities. Unfortunately, through daily activities and unfortunate accidents, bones can be here subject to various types of injuries, including fractures. Injuries can be caused by a variety of factors both diseases and disorders of the musculoskeletal system. Mechanical injuries are equally common in both children, adults and the elderly. One example of such fractures may be an injury to the metacarpal bone. Metacarpal bone fractures most commonly affect athletes who strike hard objects with a clenched fist – boxers are therefore a vulnerable group to this injury [9]. Yet, as noted [10], tennis players are even more likely to experience this injury. When a fist is clenched, stresses accumulate in the metacarpal bone, which, when coming into contact with an opposing force, can lead to its drastic damage. In medicine, there are known ways to treat fractures of the metacarpal bone [11–14], consisting of immobilizing it, giving it the correct position and strengthening it for recovery, which ultimately leads to proper fusion of the bone. Treatment of such injuries and fractures is determined by the degree, type and possible displacement of the bone. When there is a non-displaced fracture, a plaster dressing is usually applied. However, in the case of intra-articular fractures in which bone fragments have been displaced, repositioning is necessary [15]. Such procedures are performed percutaneously whenever possible, in an effort to avoid surgery. However, this is not always possible or advisable. Such an injury, if not treated properly, can result in abnormal fusion, resulting in recurrent pain that, in extreme cases, can prevent one from functioning properly in daily life or continuing a sports career [16]. The advancement of new technologies has increased the availability of information about tissue generation and diseases, and has also paved the way for the use of biomaterials. Various materials have been developed that are compatible with the human body, enabling them to serve as substitutes for both soft and hard tissues [17]. This necessitates the use of state-of-the-art materials and technologies to ensure that the structure of the substitute and its function are as closely analogous as possible [18]. The alloys Ti13Nb13Zr, stainless steel 316 LVM, CoCrMo alloy, and Ti6Al4V are technologically advanced materials designed for the manufacture of medical components that can permanently or temporarily replace

damaged tissues and organs or their parts. Thanks to their unique properties, these specialized materials enable the production of implants tailored to the individual needs of patients, representing a significant advancement in the field of biomedical engineering [19]. Most commonly, bone fragments are stabilized with Kirschner wires [15], which are shown on the Fig. 1. or with Hofer plates, which are shown on the Fig. 2. Proper stabilization of the bone is one of the factors that determine the success of the treatment, allows proper regeneration of damaged tissues and rapid recovery of the patient.



n (A) and cannulated (B) screws [20]

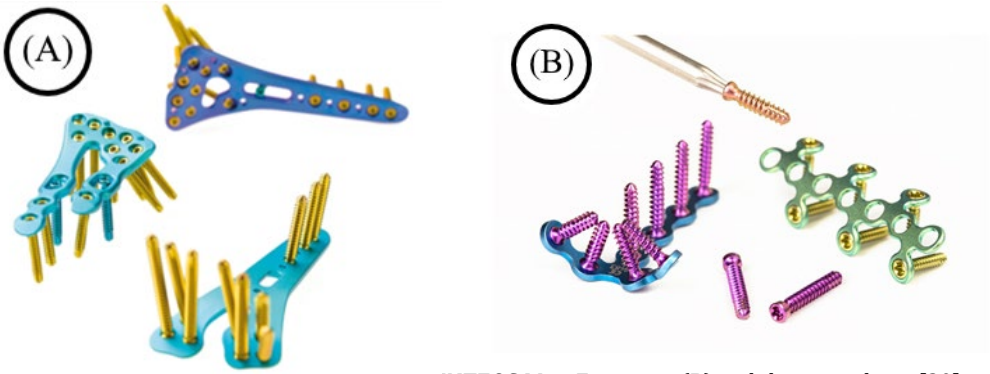


Figure 2. INTEOS Radius 2.5 (A) and INTEOS Mini Fragment (B) stabilization plates [20].

This study characterizes the material characteristics of the Hofer stabilizing plate, in the form of a used plate that resided in the tissue environment acting as a stabilizer for the spiral-fractured 3rd metacarpal bone and a new, unused plate.

Material and methodology

The study was carried out using for analysis the stabilizing plate "Y-Plate T 7 holes " (plate) and the screw "INTEOS 1.5 Standard screw as av st T 1.5 x 7" (screw), which are shown in Fig. 3. The tested material was a stabilizer for a fractured bone, made of Ti-6Al-4V titanium alloy. In the first case, the implant was in an unused state (left plate and the shorter of the screws in the figure), while in the second case, the implant was in the tissue environment of a 17-year-old patient for a period of 14 months (right plate and the longer of the screws in the Figure).

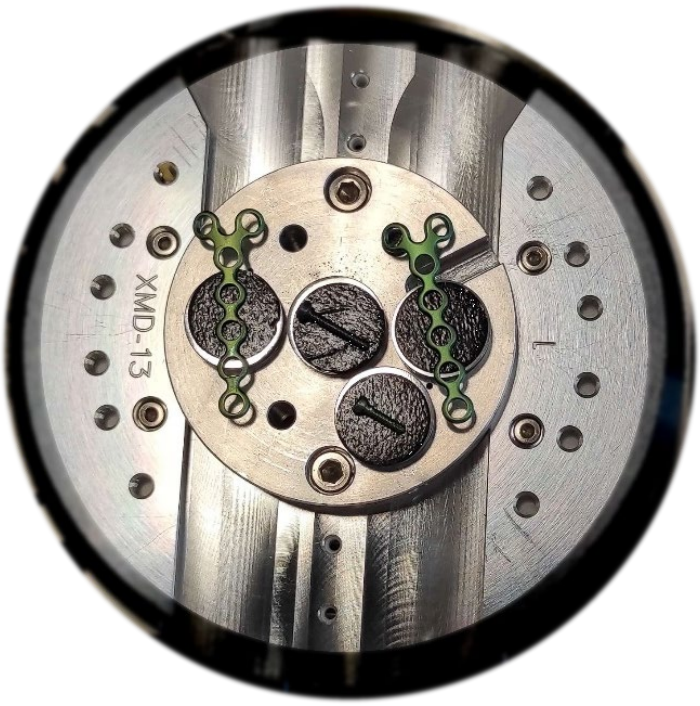


Figure 3. Hofer INTEOS Mini Fragment stabilization plate used for the study

The patient was admitted to the trauma and orthopedic surgery department with a diagnosed spiral fracture of the third metacarpal bone of the right hand, as illustrated in Fig. 4.

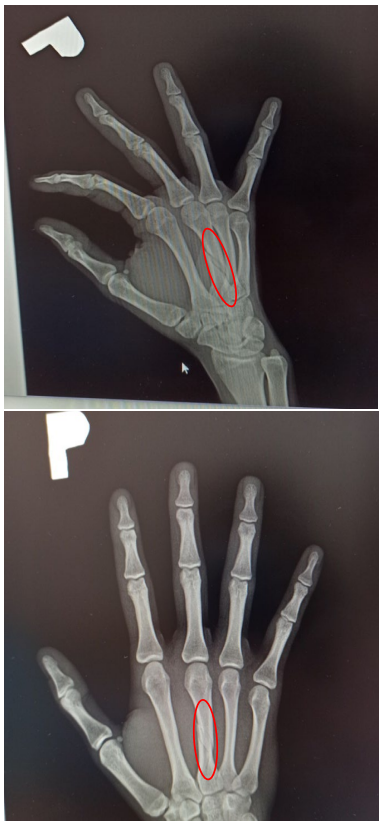
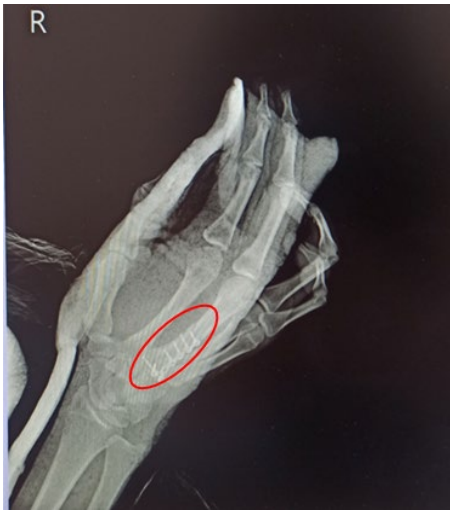


Figure 4. X-ray with the fracture site marked for later treatment

For the fracture, treatment was applied in the form of open repositioning and stabilization of the fracture using the kit mentioned earlier. The plate was inserted in the designated place, as shown in Figure 5. As a follow-up, the patient was given a plaster splint with support for fingers II and III and was discharged home. The issue of plate removal was left to the patient's discretion, after treatment was completed. The optimal time for removing the plate is considered to be between 1–2 years after its insertion. Removal of the material after a longer period of time, can be troublesome due to the possibility of complications when removing such a fine metal. Therefore, the target decision was to remove the bone-stabilizing material after a period of 14 months.



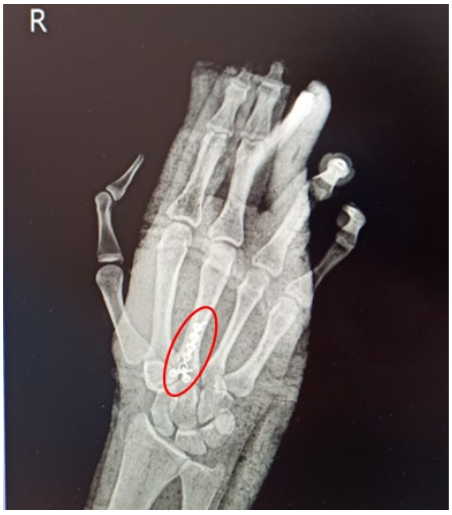


Figure 5. X-ray with the Hofer plate fracture stabilization site marked

The test material, obtained after the removal of the implant from the tissue environment, was used to conduct a material study to determine the effect of the tissue environment on the aforementioned elements. The study was performed using a Tescan Vega 4 scanning electron microscope (SEM) with EDS (Energy Dispersive Spectroscopy) chemical analysis. The chemical composition of the samples was studied using a low vacuum detector (LVD) at an accelerating voltage of 30 kV. Observations were carried out in a secondary electron (SE) detection system.

Samples previously placed on the microscope's work tray were then loaded into the interior of the vacuum chamber. The interior of the chamber allows for the creation of a vacuum, which is necessary to obtain test results unadulterated by the influence of the air atmosphere.

Results and Discussions

The material loaded into the chamber of the scanning electron microscope was subjected to the study of surface topography, the results of which are the images obtained of the stabilizing plate and the screw. The images taken were the basis for subsequent analysis of the effect of the tissue environment on the alloy under study. Images of the elements were obtained using various degrees of magnification, in order to analyse the entirety of the elements and the details present on their surfaces. The following figures (Fig. 6, Fig. 7.) show the elements of the stabilizing plate and the screw by the Hofer INTEOS Mini Fragment kit at magnifications of 9x for the plate and 18x for the screw element, respectively, in order to show the entirety of the test specimens.

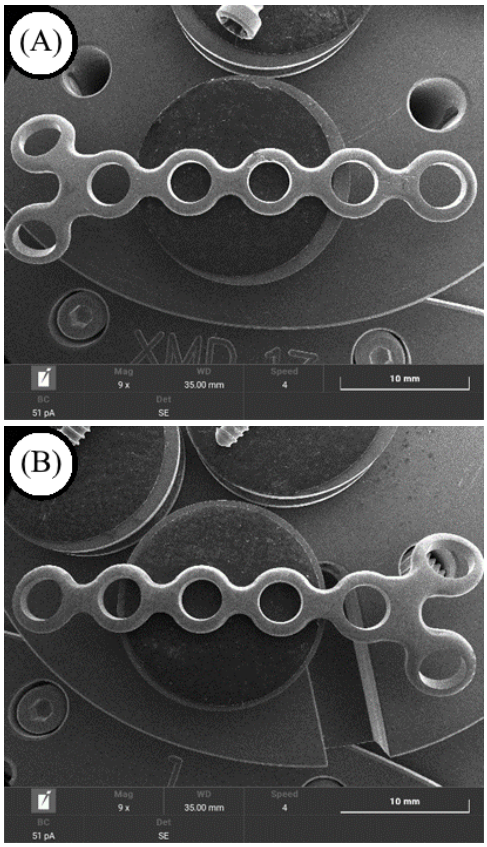


Figure 6. Images of the stabilizer plate: image of the worn plate (A), image of the new, unused plate (B)

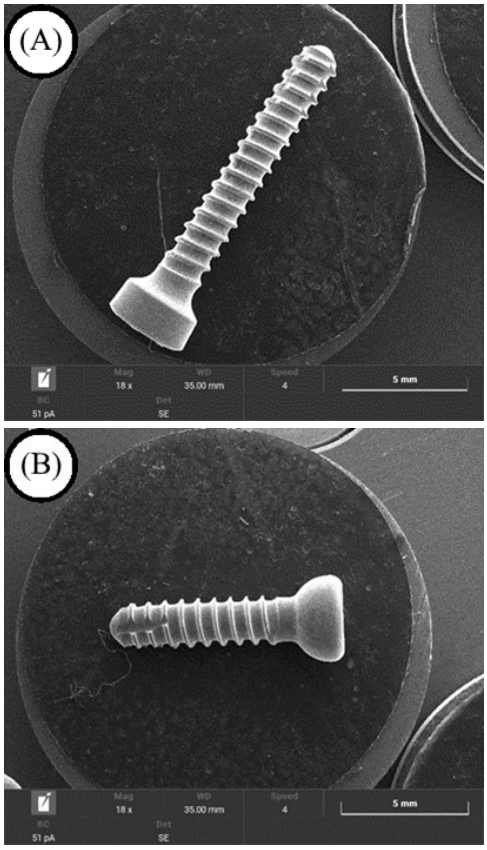


Figure 7. Images of the element in the form of a screw: image of the used element - the screw (A), image of an element – the new, unused screw (B)

For the preset magnifications, no major differences are noticeable, while there are locally different spots when comparing the two versions of the tested implant. These are described in more detail in the following figures (Figures 8, 9, 10), by increasing the magnification, which gave the opportunity to observe local irregularities in the structure of the tested material (this mainly concerns the version of the implant removed from the tissue environment).

Images of the stabilization plate component were taken at 77x magnification, which allowed better observation of the details found on the surface of both versions of the plate. In the case of the image of the plate that appears in Fig. 8, there are noticeable differences between the plate after removal (A) and the new one (B). The plate after removal (A) from the tissue environment is characterized by the presence of micro-scratches, as well as some areas with applied additional foreign material not present on the unused, new plate model (B). As for the surface texture, the new and worn parts do not differ.

In the case of the screw element, the images for both the used version (Figure 9(A)) and the new version (Fig. 9(B)) were taken using a magnification on the order of 83x, which made it possible to see in more detail the distinguishing elements between the different versions of the screw. A uniform structure is noticeable on the unused version, which is distinguished by its uniform white contrast. It also has no deposited foreign material, the presence of which is found on the element in Fig. 9 (A). In addition, the element in Fig. 9 (A) shows a differently contrasting color, which is directed more toward gray than white as in the screw in Fig. 9 (B), which may indicate some influence of the tissue environment on the color of the implant material.

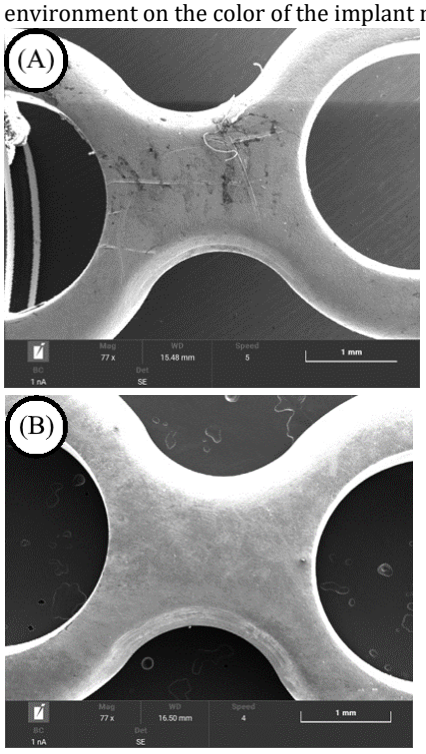


Figure 8. Images of the stabilizer plate: image of the used plate (A), image of the new, unused plate (B)

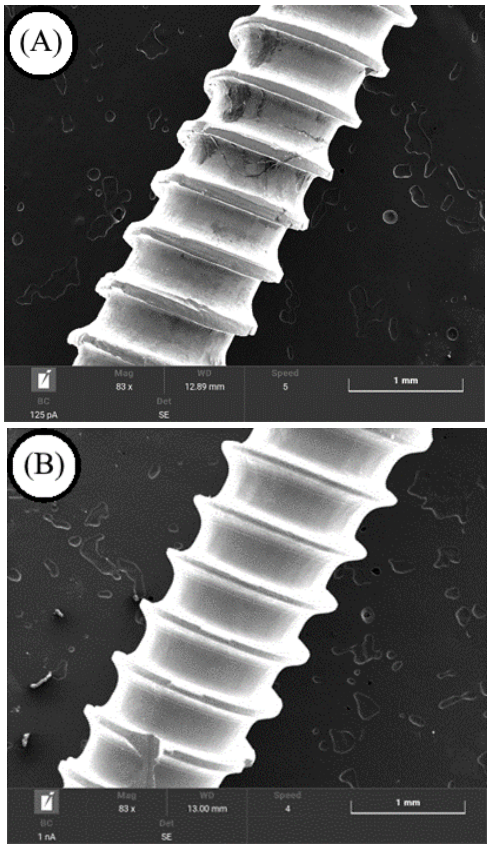


Figure 9. Images of the screw: image of the used element – the screw (A), image of the new, unused screw (B)

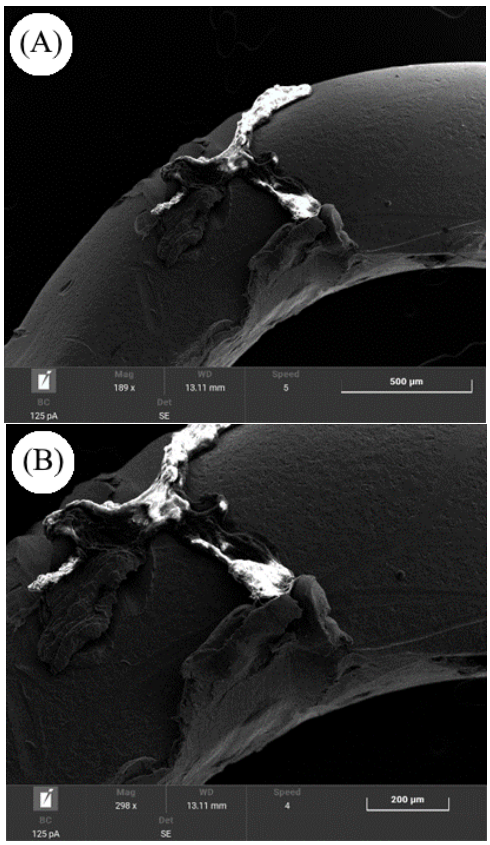


Figure 10. Images of the detail located on the stabilization plate

The Hofer INTEOS Mini Fragment, which was shown in its entirety in Fig. 6 (A), and its details shown in Fig. 8 (A), additionally displayed a spot that drew particular attention due to the presence of an unidentified object that was irregular in shape and did not look like a cavity. Its image is shown in Fig. 10. The object is characterized by a different contrast to the rest of the test plate (it contrasts brightly in the SEM image). From the images alone, it is not possible to determine the origin of the material excess. For this reason, in addition to the images showing the test material, an EDS chemical composition analysis was carried out. As a result of the analysis, graphs in the form of histograms of chemical elements detected on the surface of the material were plotted, as included in Fig. 11. The left part of the image (A) presents the results for the test material of the stabilizer plate in the worn state, while the right part of the image (B) presents the results of the chemical composition analysis for the plate in the delivery (unused) state.

The EDS analysis of the chemical composition was used to investigate the localized foreign body component, the results of which are shown in Figure 12 in the form of spectra located on the outer layer of the material along with the distribution of the elements detected. It is noted that the foreign body in the form of a material excess adjacent to the implant material is not the source material itself (Ti-6Al-4V alloy). The element spectra shown indicate the presence of calcium (Ca), carbon (C) and oxygen (O).

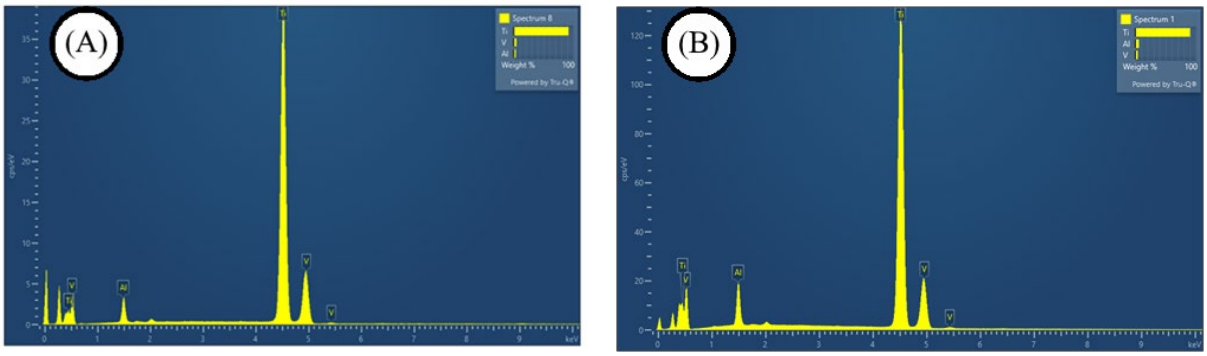


Figure11. Chemical composition analysis in the form of a histogram of the elements of the implant material: used (A), new (B)

On the basis of the plotted histograms of the chemical composition of the test material, tables were prepared containing the percentage content of the elements included in the test alloy. Accordingly, Table 1 shows the percentage content of the chemical composition of the sample – stabilizing plate in the worn state. Table 2 shows the percentage content of the chemical composition of the sample – stabilizing plate in the delivered (unused) state.

Table 1.
EDS analysis of the chemical composition for the worn plate

Element	Line type	Wt%	Atomic %
Al	K-series	3,54	6,13
Ti	K-series	91,91	89,69
V	K-series	4,55	4,17

Table 2.
EDS analysis of chemical composition for the unused plate

Element	Line type	Wt%	Atomic %
Al	K-series	5,83	9,92
Ti	K-series	90,28	86,57
V	K-series	3,89	3,51

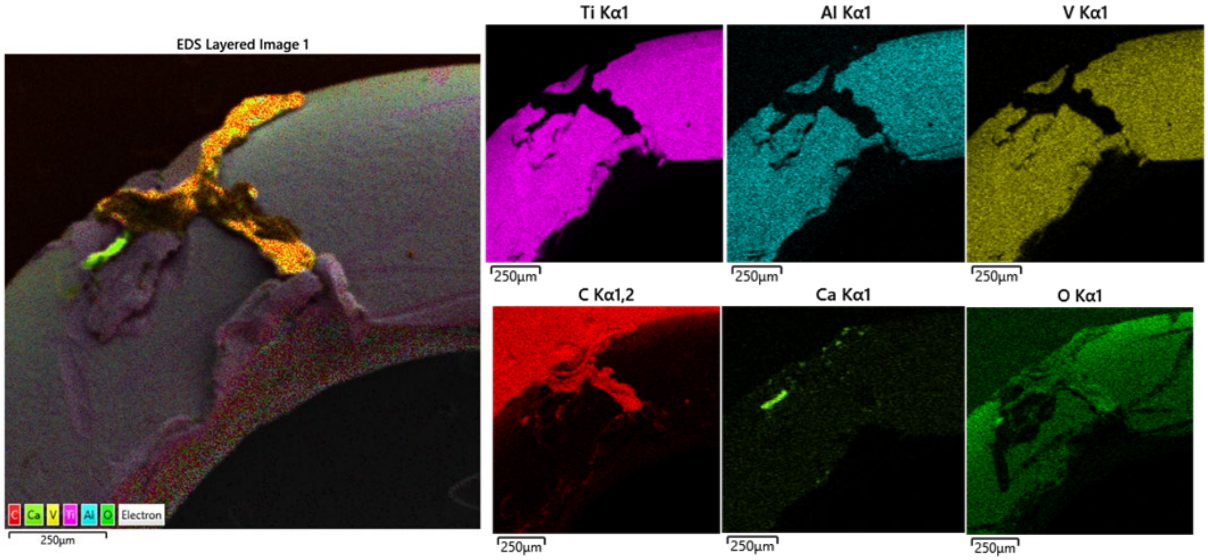


Figure 12. The analysis of the chemical composition of the localized detail of the deposited foreign body on the element of the stabilizing plate and the individual spectra of elements

The presence of carbon (C), calcium (Ca), oxygen (O) on the plate taken from the tissue environment may indicate the deposition of a layer of calcite (calcium carbonate) on the surface of the alloy, which may indicate that orthopedic implants can cause various tissue reactions, including mineral deposition. The tissues around the implant may try to "integrate" the foreign material, which can lead to the deposition of minerals, including calcite. However, this process is not dangerous to the tissue environment.

Conclusions

After the analysis, to which the images were subjected, and the chemical composition study for the Hofer INTEOS Mini Fragment stabilizing plate set in the variant of the worn plate and screw (surgically removed) and those in the state of delivery (new, unused material), the following conclusions were made:

(1) In principle, the implant material does not react with the tissue environment, while there are localized areas on the material surface itself where clusters of foreign materials have been observed. These materials do not correspond in any way to the material of the implant.

(2) Analysis of the chemical composition of the surface of the material in areas where there is no excess material in the form of residual tissue after removal from the treatment site showed no change in the chemical composition of the implant material itself (stabilizing plate and screw).

(3) The use of titanium alloy Ti-6Al-4V as a material for stabilizing plates for the treatment of metacarpal bone injuries is most reasonable, due to its demonstrated bioinertness and biocompatibility with the human tissue environment. Staying in the indicated tissue environment for a period of 14 months did not change the proportion of key elements in the tested material.

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