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Should titanium miniplates be removed after bone healing is complete?

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Abstract. A prospective study of 32 patients was performed to analyze black pigmentation in the soft tissue covering titanium miniplates. This soft tissue was compared with the soft tissue covering Champy® stainless steel plates. All plates were removed 8 months after application. Macroscopically visible pigmentation was found in 25.6% of the soft tissue covering titanium miniplates and in none of the soft tissue covering Champy stainless steel plates. Microscopically visible pigmentation was found in 71.8% of the soft tissue covering titanium miniplates and in 65.3% of the soft tissue covering Champy stainless steel plates. Energy-dispersive x-ray analysis of the soft tissue covering titanium miniplates revealed only the presence of titanium dioxide. In the soft tissue near Champy stainless steel plates, chromium, nickel, iron, and molybdenum were found. Electron microscopy showed titanium dioxide to be mainly deposited between the collagen fibers, whereas stainless steel particles were mainly found in giant cells.

Key words: metallosis; titanium miniplates; Champy® miniplates.

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Most of the literature on osteosynthesis with titanium miniplates emphasizes the high compatibility and corrosion resistance of this material[2,3,7]. Because of these properties, it is generally considered unnecessary to remove titanium miniplates. Of course, this is of great benefit to the patient, who does not have to undergo a second operation.

MOBERG et al. analyzed the mucous membrane and bone tissue surrounding Champy® stainless steel plates, Vitallium® plates, and titanium miniplates in an animal experiment. Titanium dioxide was found in the soft tissue near titanium miniplates. Chromium, nickel, and molybdenum were found in the soft tissue surrounding Champy stainless steel plates. On the basis of the results of this study, MOBERG et al. emphasized the need to remove Champy stainless steel plates, and to use titanium miniplates when the plates are not to be removed. A prospective clinical study in man was therefore performed to confirm the results of the experimental study on monkeys by MOBERG et al.[8].

In the Department of Maxillo-Facial Surgery, Zurich, titanium miniplates are removed only if they cause complaints and in cases of wound dehiscence or infection. During occasional removal of titanium miniplates, a significant amount of black pigmentation in the covering soft tissue was noticed. The nature of this pigmentation was to be defined. In this study, we define metallosis as a deposition of metal particles in human tissue.

Material and methods

Between November 1990 and March 1991, all patients followed-up after osteosynthesis secondary to trauma, orthognathic surgery, or reconstructive surgery, were scheduled for removal of osteosynthesis material. Thirty-two patients (21 men, 11 women) were included in this study. The ages ranged from 15 to 70 years with a mean age of 32.11 years. The mean period between osteosynthesis and plate removal was 8 months, with a range from 3 months to 2 years and 8 months.

A careful examination took place before the plates were removed, with particular attention to the soft tissue covering the plates, to detect local inflammation or dehiscence.

At the time of plate removal, the osteosynthesis site was carefully examined to detect pigmentation in the soft and bone tissue, plate fracture, or screw loosening. After the removal of osteosynthesis material, biopsies of the soft tissue covering every plate were performed for microscopic examination of hematoxylin-eosin-stained sections. The results from the microscopic examination of the titanium miniplates and the Champy stainless steel plates were compared by the chi-square test.

From a biopsy containing macroscopic black pigmentation in the soft tissue near a titanium miniplate, a specimen was taken for energy-dispersive x-ray analysis and electron

Table 1. Indications for osteosynthesis

	No. of patients with titanium plates	No. of patients with Champy stainless steel plates
Fractures	14	8
Le Fort I osteotomies	8	
Bone grafts	2	
Total	24	8

Table 2. Complications after placement of titanium miniplates and Champy stainless steel plates

	Titanium plates	Champy plates
Dehiscence	3	1
Infection	1	
Plate fracture	2	
Screw loosening	3	2
Total no. of plates	39	16

microscopy. Because no macroscopic black pigmentation was found in the soft tissue near Champy stainless steel plates, a representative biopsy from the soft tissue was used for energy-dispersive x-ray analysis and electron microscopy. Both biopsies were compared.

Results

Titanium miniplates were removed from 24 patients; Champy stainless steel plates from eight patients. A total of 39 titanium miniplates and 16 Champy stainless steel plates was removed. Osteosynthesis was applied to stabilize fractures in 22 patients, Le Fort I osteotomies in eight patients, and free iliac crest bone transplants in two patients (Table 1).

The complications caused by the plates are listed in Table 2. Both types of plates had the same complication rate. No increased amount of pigmentation of the covering soft tissue was found in cases of plate fracture or screw loosening.

The intraoperative findings are shown in Table 3. Macroscopically visible pigmentation was found in 25.6% of the soft tissue covering titanium miniplates and in none of the soft tissue covering Champy stainless steel plates. Pigmentation of bone tissue was seen under three Champy stainless steel plates.

Histologic findings

The microscopic findings in the soft tissue surrounding the miniplates are shown in Table 4. Microscopically visible black pigmentation was detected in 71.8% of the soft tissue covering titanium miniplates. In the soft tissue covering Champy stainless steel plates, 65.3% of the cases revealed microscopic black pigmentation. The difference in the amount of microscopically visible black pigmentation between both types of plates was not statistically significant ($\chi^2 = 1.24$; $P > 0.05$).

The micrograph (Fig. 1) of the soft tissue covering titanium miniplates showed black pigmentation in connective tissue. Macrophagocytosis was occasionally seen. The macrophagocytes were sometimes clustered together, but giant cells were never found.

One black pigmentation in the soft tissue covering a titanium miniplate was investigated by energy-dispersive x-ray analysis to detect the nature of this pigmentation. In the case of a titanium miniplate, this analysis revealed only the presence of titanium dioxide (Fig. 2). Electron microscopy showed titanium dioxide particles in the connective tissue (Fig. 3). Collagen fibers were clearly visible, and very small titanium dioxide particles were situated between these fibers. In this biopsy, no titanium dioxide was found in macrophagocytes. The energy-dispersive x-ray analysis of the soft tissue near a Champy stainless steel plate revealed the presence of chromium, nickel, iron, and molybdenum.

Table 3. Incidence and sites of pigmentation observed

	Titanium plates	Champy plates
Pigmentation of soft tissue	10 (25.5%)	0 (0.0%)
Pigmentation of bone	0	3
Total no. of plates	39	16

Table 4. Microscopic presence of pigmentation

	Titanium plates	Champy plates
Metallosis/pigmentation	28 (71.8%)	9 (65.3%)
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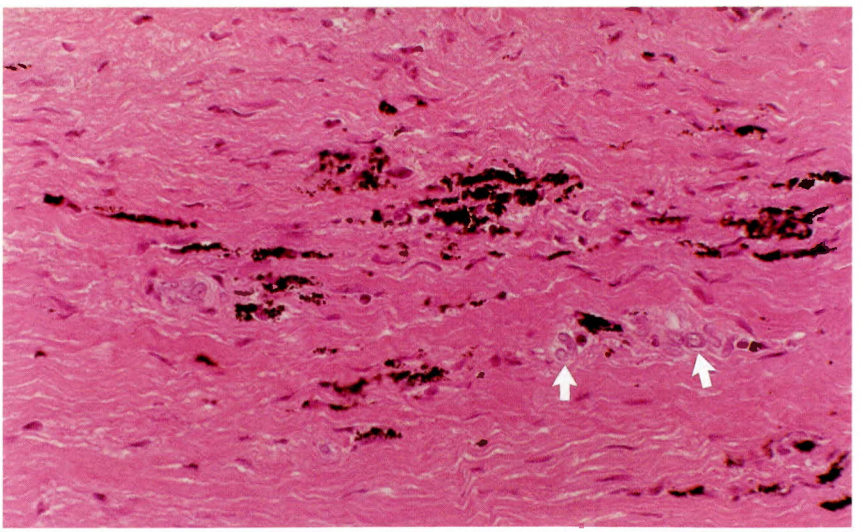


Fig. 1. Soft tissue covering titanium miniplate. Black pigmentation is visible in connective tissue. Macrophagocytosis is also visible (arrow) (HE, × 100).

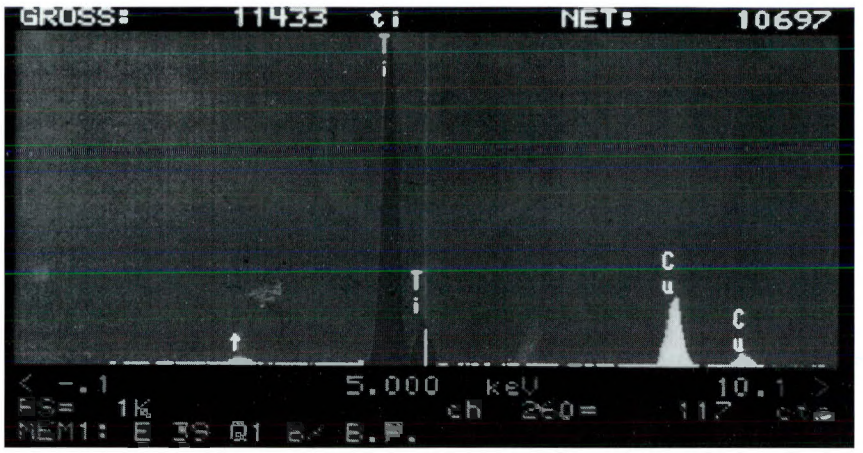


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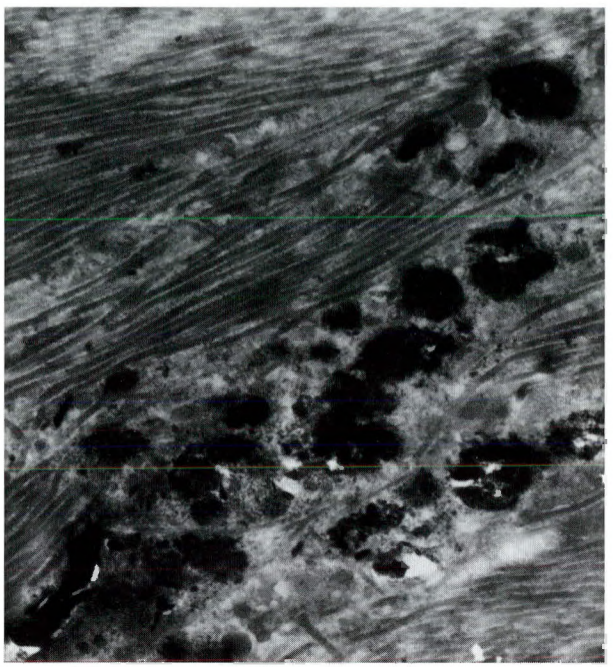


Fig. 3. Electron micrograph of very small titanium particles between collagen fibers (×27 300).

The electron microscopy showed small stainless steel particles, up to 0.05 mm in diameter, located in giant cells. In this biopsy, an infiltration of lymphocytes and plasmocytes was observed.

Discussion

Titanium dioxide is generally considered to be of low toxicity, although its metabolism and biologic behavior are not clearly understood[9]. There have been only a few reports of symptomatic metallosis caused by titanium dioxide. Most reports on this subject deal with titanium particles in lung tissue.

OLERU[10] reported 67 patients, all workers in a small paint factory in Nigeria, in which titanium dioxide (rutile) is used in white house paint. The mean duration of exposure was 8.3 years. However, the amount of inhaled titanium was not mentioned. Most patients (50–54%) had airway symptoms such as chest pain, coughing, and catarrh; 20–47% exhibited dizziness, visual blackout, and nausea. The report did not describe any histologic examination.

ELO et al.[6] demonstrated, in two autopsies and one biopsy, that titanium may accumulate in the lungs and subpleural tissues. They also demonstrated that titanium deposits in the pulmonary interstitium were associated with cell destruction and slight fibrosis. Titanium particles were found in the lysosomes of alveolar phagocytizing cells.

White pigment in pulmonary tissue was found coincidentally by RODE et al.[11], who reported the results of an autopsy of a patient with an undifferentiated bone tumor. The analysis revealed titanium dioxide. Microscopically, titanium dioxide was distributed in the perivascular tissue, but smaller amounts were also found in the alveolar walls and alveolar macrophages.

MORAN et al.[9] reported a patient who had a bilateral replacement of the head and collum of the femur by a titanium prosthesis. This prosthesis caused hyperplastic changes in the synovia of the hip joint, generating large numbers of histiocytes loaded with black particles. They also described three patients with diffuse fibrosing interstitial pneumonitis. In addition, they found large quantities of dark, granular pigment in macrophagocytes in the alveolar spaces, around bronchioles, and in pulmonary blood vessels.

VERBOV[12] reported a case in which a titanium pacemaker may have caused necrotizing pectoral lesions. In two other cases, balanitis was treated with topical ointments containing titanium dioxide. Both patients developed xantoma-like dermal lesions[4,5].

These case reports of symptomatic metallosis caused by titanium contrast with the long-term clinical results of BRÅNEMARK et al.[3] and ADELL et al.[1], who studied titanium in endosteal dental implants. They demonstrated the high compatibility of titanium. A 15-year follow-up failed to show any toxic side-effects.

The cause of pigmentation originating from titanium miniplates is still unknown. One cause might be the bending of titanium miniplates, inducing microfractures and loosening of titanium particles. This agrees with the observation that this pigmentation was almost exclusively located in the tissue covering the bent areas of the plates. However, the exact nature of the particle-transport mechanism remains unclear. Macroscopically, no pigmentation was found in the soft tissue covering Champy stainless steel plates, whereas in the soft tissue covering titanium miniplates, black pigmentation was seen in 25.6% of the cases. Microscopically, however, black pigmentation was found in 65.3% of the soft tissue covering Champy stainless steel plates, and in 71.8% of the soft tissue covering titanium miniplates.

Thus, both types of plates give rise to particles in the soft tissue. Titanium miniplates deposit titanium dioxide particles. Champy stainless steel plates deposit the toxic metals chromium, nickel, iron, and molybdenum in the soft tissue.

Our results are comparable with those of the experimental study of MOBERG et al.[8]. In both studies, plate elements were found in the soft tissue near the plates. However, Champy stainless steel plates release potentially toxic materials; therefore, such plates should be removed.

In contrast to the reports of massive deposition of titanium in lung tissue, our results show titanium deposition from titanium miniplates to be very small in amount and far less dense, and, in our cases, all pigmentation was asymptomatic. No relation was found between complications and pigmentation. Therefore, these complications have probably more to do with the plate as a foreign body than with soft-tissue changes.

The question of whether or not to remove titanium miniplates is difficult to answer, and it depends on the question, does titanium produce toxic side-effects when the plates have been *in situ* for a long time? In our study, as well as in the long-term investigations by BRÅNEMARK et al.[3], titanium dioxide did not produce any toxic side-effects.

In our opinion, the demonstrated changes in soft tissue near titanium miniplates should not be interpreted as a clear indication to remove the plates. The indication for removing titanium miniplates should be defined by patients' complaints in the first place. Therefore, one must discuss the removal of titanium miniplates with the patient in each case.

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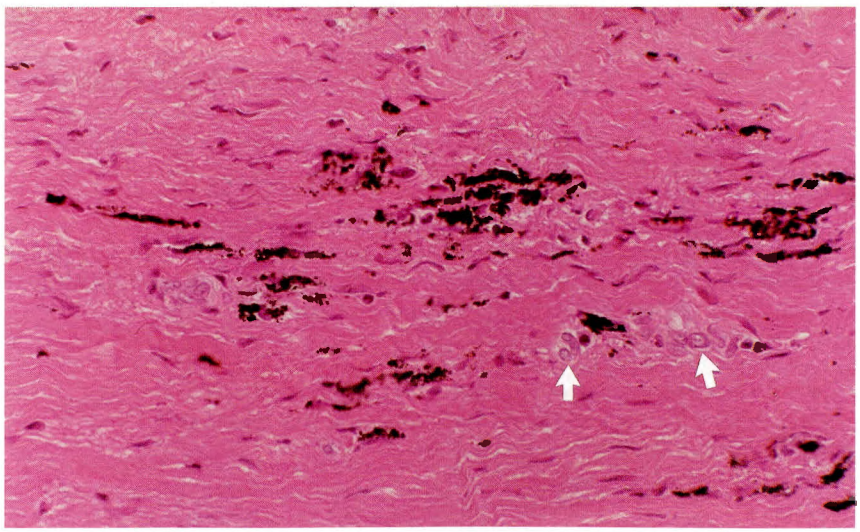


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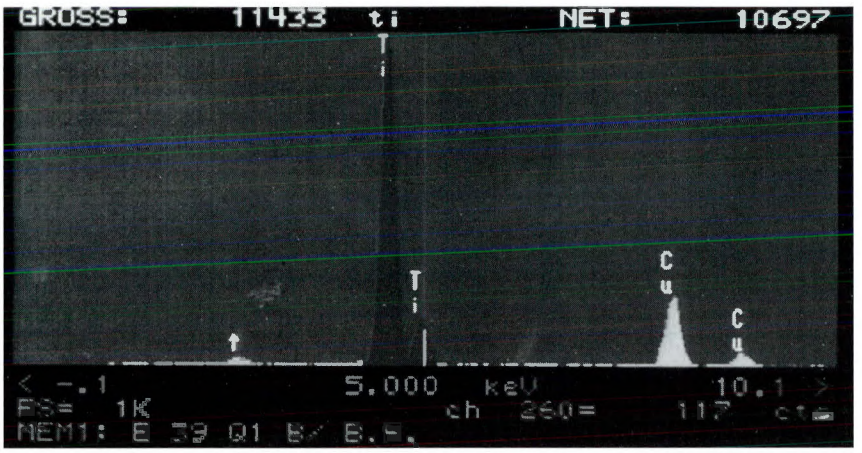


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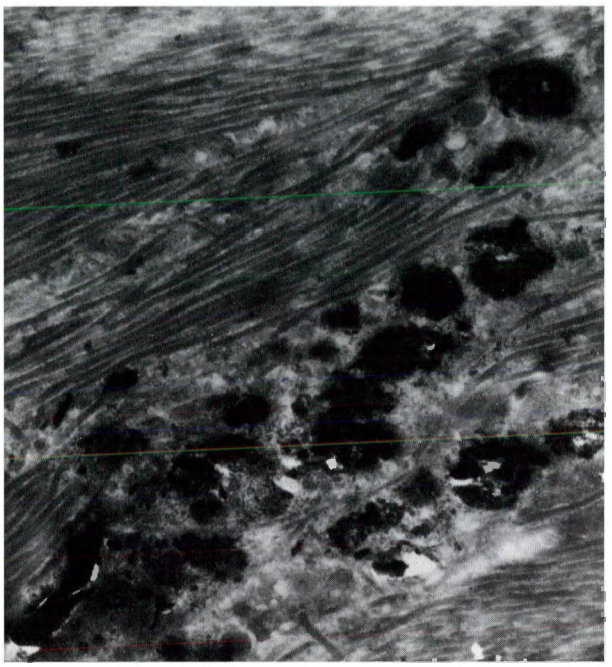


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