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Retrieval study of stainless steel and titanium miniplates and screws used in maxillofacial surgery

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The surfaces of 43 stainless steel miniplates and 19 titanium miniplates with matching screws of the same materials were studied after retrieval with respect to surface degradation. Stereomicroscopic and scanning electron microscopic (SEM) examinations were performed, and surface roughness and hardness of the plates were measured. Defects of mechanical nature which could be traced back to handling procedures were found in all stainless steel and titanium devices. Metal tongues and splinters were occasionally found associated with screw threads and in the periphery of plate screw holes. Corrosion defects were observed in about 1/5 of the stainless steel plates, restricted to the countersink area. Corrosion defects were also found on the chamfer of the underside of stainless steel screw heads. None of the titanium devices showed evidence of corrosion. The surface roughness of the titanium plates was higher than for the stainless steel plates. The retrieved plates were rougher than the new plates.

1. Introduction

Miniplates have been used during the last decade to facilitate stability between bony fragments in the maxillofacial region, and are nowadays the preferred method for fixation of fractures and osteotomies [1]. Primarily, stainless steel (Fe–Cr–Ni–Mo alloys) and titanium (commercially pure Ti) are used as materials for these devices [1]. Metal implants have the potential to comode in body fluids [2]. This has been demonstrated in laboratory tests, both under simulated clinical conditions [3–5] and by electrochemical methods [2], as well as in studies of retrieved metal implants [6–10]. A high frequency of interfacial corrosion defects has been reported in multicomponent stainless steel orthopedic fixation devices [6–11]. Moreover, handling defects are observed, such as scratches, drilling defects, metal tongue formation, and splinters [9].

Stainless steel degrades in the biologic environment from a combination of electrochemical corrosion and wear [9, 12–14]. Degradation of titanium occurs mainly due to wear and particle release, although a minimal diffusion of ions through the titanium oxide surface layer is also postulated [2, 5, 14, 15]. Measurable amounts of metal are found in soft tissues and bone at the implant bed, in association with both stainless steel and titanium implants [9, 11, 16, 17]. Titanium as well as stainless steel particles cause discolouration which may be seen in the tissues surrounding the implant [9, 11, 13].

Corrosion and wear products either as metal ions or particles may give rise to changes in the tissues adjacent to implants, ranging from mild fibrosis to infection and necrosis [14]. Hypersensitivity reactions have been associated with implantation of some metal devices [18]. Stainless steel implants have frequently been accused of causing sensitization due to the nickel and chromium content [19, 20]. Recently, immunologic reactions caused by titanium have also been reported [21].

The objective of the present study was to examine the surface of retrieved stainless steel and titanium miniplates and screws which had served as internal fixation devices in maxillofacial fracture treatment.

2. Materials and methods

2.1. Patients and implants

The study included a total of 43 stainless steel miniplates with 172 stainless steel screws, and 19 titanium miniplates with 76 titanium screws, all made by Martin Medizin-Technik, Tuttlingen, Germany (Fig. 1). The manufacturer states that the stainless steel quality is in accordance with DIN 17443 vacuum-melted, high grade chromium–nickel–molybdenum stainless steel (AISI 316 LVM), and the commercially pure titanium (> 99.26% Ti) in accordance with DIN 17850.

The devices had been implanted for fixation after mandibular fractures. The stainless steel plates and screws were retrieved from 21 patients, and the titanium devices from 7 patients. Insertion of the devices was performed by three experienced oral surgeons. Plates with at least two screws placed on each side of the fracture line were examined. Adaptation to the

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bone surface by bending of the plates had been performed in all cases. The stainless steel plates had been *in situ* for 6–52 weeks (mean 28 weeks), while the titanium plates had been implanted for 35–52 weeks (mean 43 weeks).

2.2. Plate removal and cleaning

All the devices were removed without preceding clinical complications, except for two stainless steel plates and one titanium plate which were removed due to exposure through the oral mucosa, however, with no observed associated clinical infection. After careful removal (by one operator, ST) all metal components were immediately rinsed in tap water, carefully cleaned with a soft brush in an organic solvent detergent (IMI, Denofa Lilleborg, Oslo, Norway), followed by ultrasonic treatment in ethanol for 5 min. The specimens were stored dry until examination.

2.3. Light and electron microscopy

Stereomicroscopic (Wild M3C, Type-S, Heerbrugg, Switzerland, 6.4x, 16x and 40x magnification) and scanning electron microscopic (SEM) (Jeol JSM 6400, Scanning Microscope, secondary emission) examination of all plates and screws were performed. A semiqualitative examination by energy dispersive X-ray microanalysis (EDXA) (Tracor Northern, Series II X-ray Analyzer, SQ Standard less Quantitative Analysis Program) was performed to verify the type of material of all plates and screws.

2.4. Roughness and hardness measurements

Roughness of the plates was measured by a surface profilometer (Perthen, Mahr, Germany). The underside surface facing the bone of 10 retrieved plates of either material, including those with shortest and longest implantation duration was used. Roughness measurements were also taken on 10 corresponding new (as received) plates of both materials from the same manufacturer. The tip of the roughness measuring stylus had a diameter of about 3 μm. The roughness was expressed as the arithmetic average roughness, R_a, in micrometres [22], calculated from pooled values for each group. Each roughness scan covered 1.5 mm and the cutoff value was set to 0.25 mm [22]. A total of 30 parallel scans, separated by 0.2 mm, was performed on every plate in both the longitudinal and the transversal directions (Fig. 1).

The hardness of the plates was measured by a Vickers hardness tester with a force of 294 N for 15 s. The Vickers hardness number (H_v) was calculated from the diagonals of the indentation.

2.5. Data presentation and statistics

The data were processed by a statistical software system (Minitab Inc., PA, USA). Chi-square test (χ^2-test) and Mann–Whitney test were used to test for statistical significance. A p-value of 0.05 or less was considered statistically significant.

3. Results

Both the stainless steel and the titanium plates were found to be in accordance with the standards for implant hardware, as reported by the manufacturer. All defects on plates and screws could be classified as mechanical damage, corrosive degradation, or a combination of the two.

3.1. Plates

Mechanical defects on the surface of a majority of the plates could be observed without magnification. Handling defects (Fig. 2) were seen in all the miniplates studied (Table I), whether stainless steel or titanium, however, the distribution and severity varied. The stainless steel plates were found to exhibit a higher number and more severe tool marks than did the titanium plates. The tool marks on the free surface of the devices of either material had a character of sharp-edged scratches and were not involved with detectable corrosion (Fig. 2). Mechanical surface

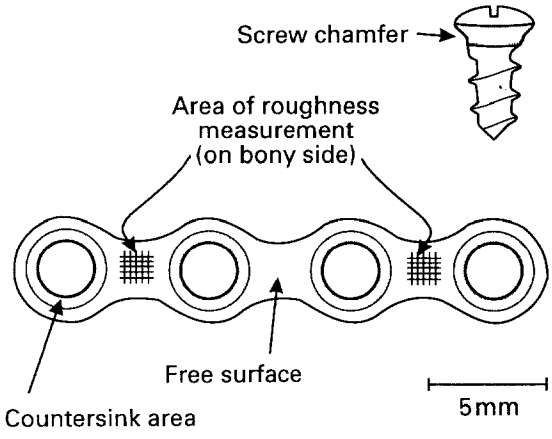

Figure 1 Shape and dimensions of stainless steel and titanium miniplates studied. The thickness of the plate was 1 mm. Localization of roughness measurement areas are indicated.

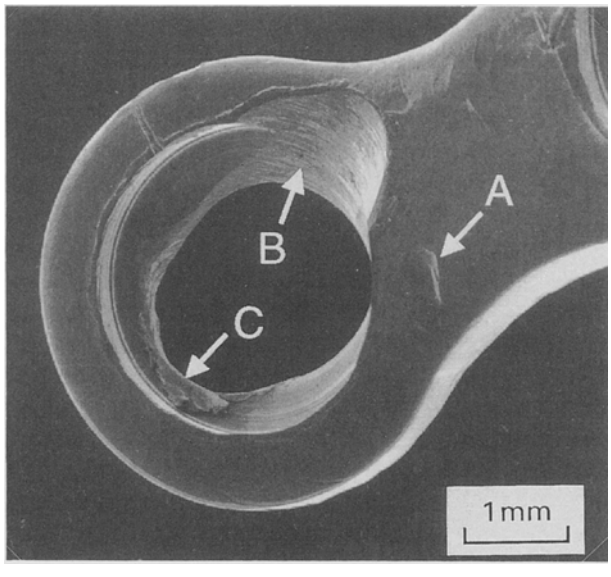

Figure 2 Sharp-edged tool marks on the free surface (A), together with drilling injury (B) and metal tounge formation in a screw hole countersink (C) of a stainless steel plate.

TABLE I The number maxillofacial plates and screws showing surface degradation defects

	Plates		Screws	
	Handling defects	Corrosion defects	Handling defects	Corrosion defects
Stainless steel	43/43	8/43	172/172	12/172
plates $n = 43$, screws $n = 172$	100%	19%	100%	7%
Titanium	19/19	0/19	76/76	0/76
plates $n = 19$, screws $n = 76$	100%	0%	100%	0%

defects in the countersink regions had a similar appearance to those appearing on the free surface. In contrast, corrosive degradation was, in two cases, observed in association with mechanical defects in the countersink regions of stainless steel plates. Typical drilling injuries in the plate countersink areas were common, and the most severe damage was found in the plates used to stabilize fractures in the mandibular angle regardless of material (Fig. 2). Occasionally metal tongue formation or splinters were seen in the periphery of screw holes in both the stainless steel and the titanium plates (Fig. 2).

Corrosion defects were localized to the countersink areas, often with a restricted and patchy distribution (Fig. 3), and were only found in the stainless steel plates (Table I), involving one or two countersinks within the same plate. Corrosion never extended onto the free surface outside the countersink area. None of the titanium plates showed evidence of corrosion (Table I). No relation was found between the frequency of corroded devices and implant removal earlier than 6 months or more than 6 months post-implantation. Bone tissue covering parts of the countersink region was seen associated with a screw hole in two of the stainless steel plates and in one of the titanium plates (Fig. 4).

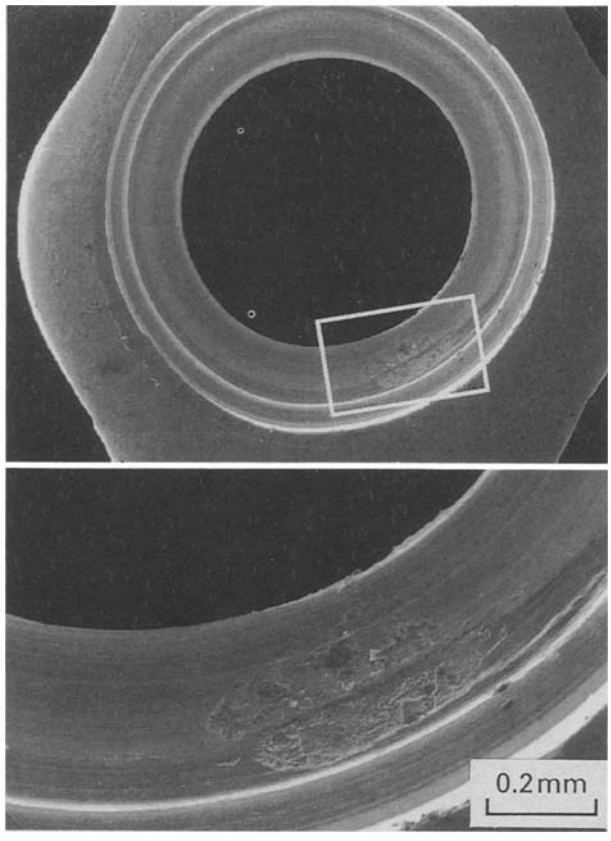

Figure 3 Typical appearance of a corrosion defect in a plate hole countersink of a stainless steel plate.

3.2. Screws

All screws, whether stainless steel or titanium exhibited handling defects visible as minor scratches on the screw heads, on the chamfer underside of the screw head and along the screw threads (Table I). In combination with the mechanical defects, minor splinters were infrequently observed under the screw head on both stainless steel and titanium screws (Fig. 5). There was no obvious difference between the two materials regarding the severity of mechanical screw defects. Corrosion defects on stainless steel screws were found under the screw head and at the transitional zone, screw head/screw threads (Fig. 6). In some stainless steel devices, corrosion defects at the screw chamfers corresponding to similar defects in the screw hole countersinks of the plate could be observed, so-called "kissing defects" (Fig. 7). Apposition of bone tissue was seen on one stainless steel screw chamfer (Fig. 8).

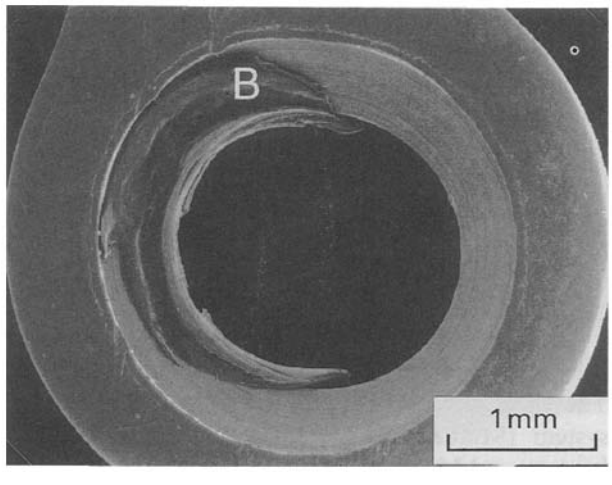

Figure 4 Bone (B) in close relation to the metal surface in the countersink region of a stainless steel plate.

3.3. Roughness and hardness of plates

There was a statistically significant higher surface roughness of the retrieved stainless steel plates

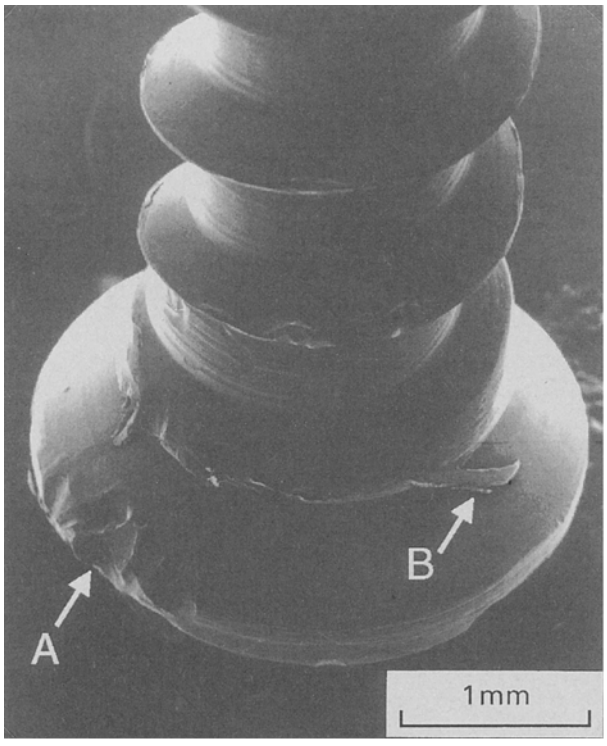

Figure 5 Handling defects (A) of a stainless steel screw, also showing metal splinter under the screw head (B).

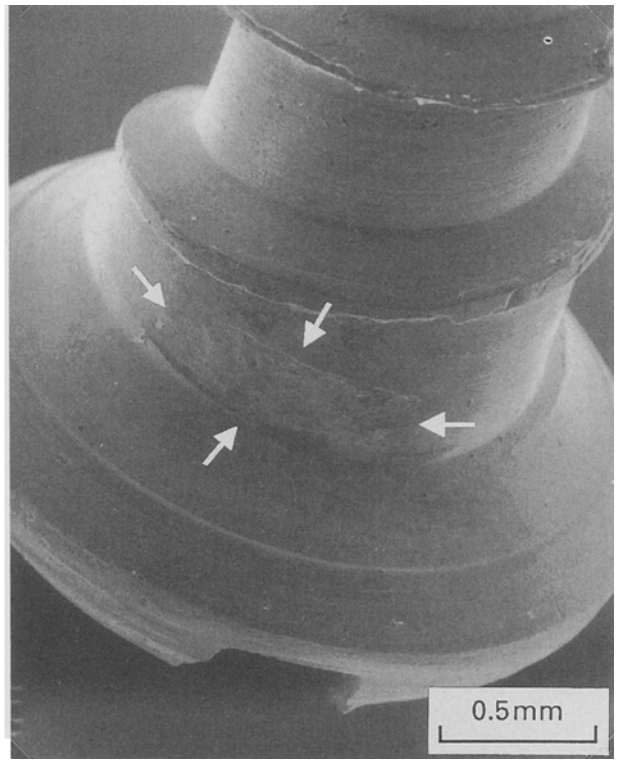

Figure 6 Corrosion defect of a stainless steel screw (arrows), where an interface between screw core and plate exists.

compared with the new ones (Fig. 9), and this was even more pronounced for the titanium plates (Fig. 9). The new titanium plates were also significantly rougher than the corresponding stainless steel plates ($p = 0.001$) (Fig. 9). The transversal and the longitudinal roughness measurements did not differ.

The hardness measurements revealed no significant difference between the two materials (H_v; stainless steel, pooled, median = 150.1, titanium, pooled, median = 147.6)

4. Discussion

The properties and quality of the implant material, the shape of the implant as well as the handling and surgical procedure are of crucial importance for an optimal biologic performance of any implant device [1, 9, 11].

The present study demonstrates that mechanical damage of plates and screws is common, although wide variations do occur with respect to distribution and severity. Handling defects of both plates and screws could easily be identified by their localization and shape, and traced back to the intraoperative procedures using pliers and screwdrivers, and the drilling of screwholes through the holes of the plate. The finding that there were fewer handling defects in the titanium plates than the stainless steel types might, at least partly, be explained by the different mechanical properties of the two materials. Titanium has an electric modulus, i.e. stiffness, about half that of stainless steel [14]. Consequently, the titanium plates most likely require less manipulation during insertion. On the other hand, the hardness measurements of the two materials did not differ significantly, thus their resistance to surface damage should be comparable.

The intraoral surgical approach and the anatomy of the mandible, especially in the angle region, can make it difficult to place the miniplates and screws in a correct position. Compromising with a perpendicular placement of the screws leaves a less than optimal screw/plate interface, creating crevices between the components. Obliquely inserted screws were also prone to force metal tongue formation and splinters, observed in the countersink areas of the plates and on the screws. Micromotion and friction (fretting) between plate and screws contribute to degradation of a mechanical nature [9]. Metal particles, originating from fretting conditions or implant insertion/removal, may separate from the devices and accumulate in the nearby tissue [9, 17, 13, 16].

Both stainless steel and titanium are dependent on surface oxides (chromium oxide and titanium oxide) to remain electrochemically passive in the biologic environment [2, 15]. A large number of factors present in various degrees affect the corrosion resistance and the long-term stability of the oxide layer. Except for the physical and mechanical properties of the implant device, creation of crevices, fretting conditions, pH and chloride ion concentration, composition and changes of tissue fluid with respect to oxygen and protein content and mechanical stress location are all contributing factors influencing the corrosion potential and rate [3, 4, 12, 15, 23]. The surgical stainless steels have shown an overall good passive behaviour as implant material [2]. The present study could not reveal corrosive attacks of the free surface of surgical stainless steel, a finding which is in accordance with

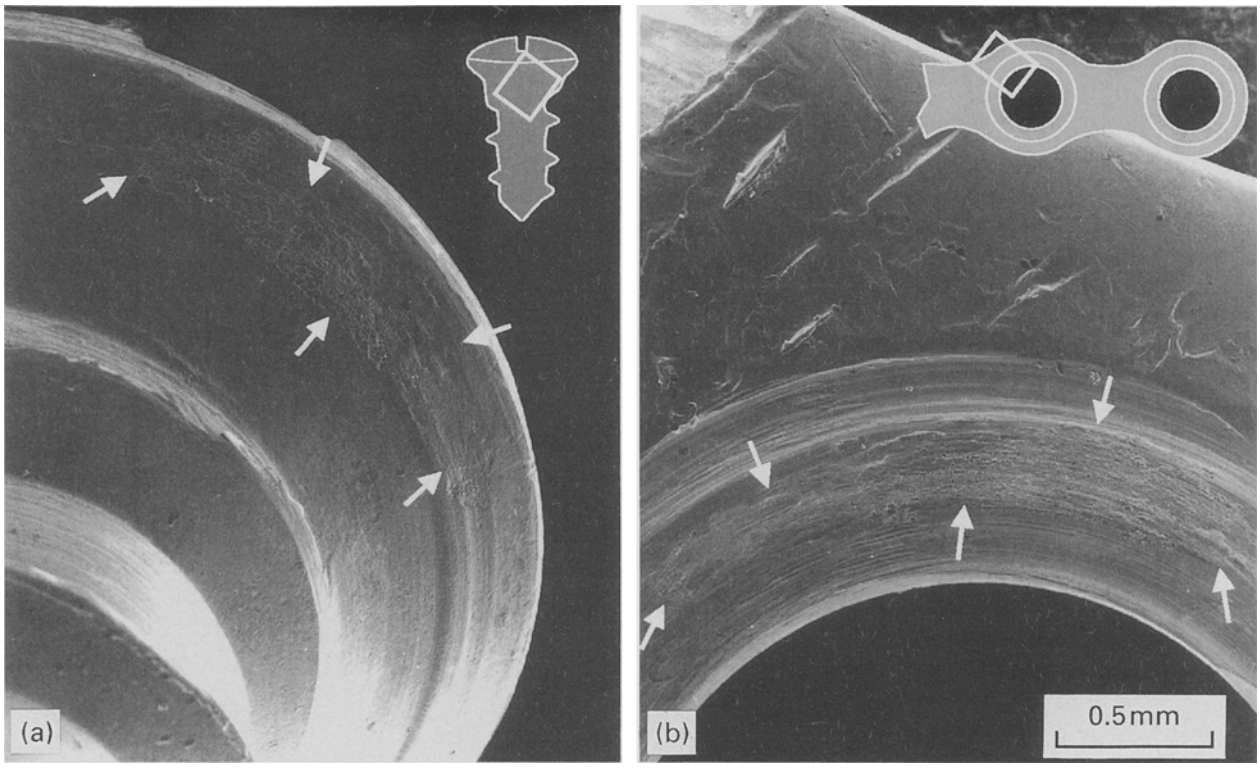

Figure 7 "Kissing defect" showing conformity between corrosion defect on the chamfer underside of the screw head (arrows) and plate hole countersink corrosion defect (arrows).

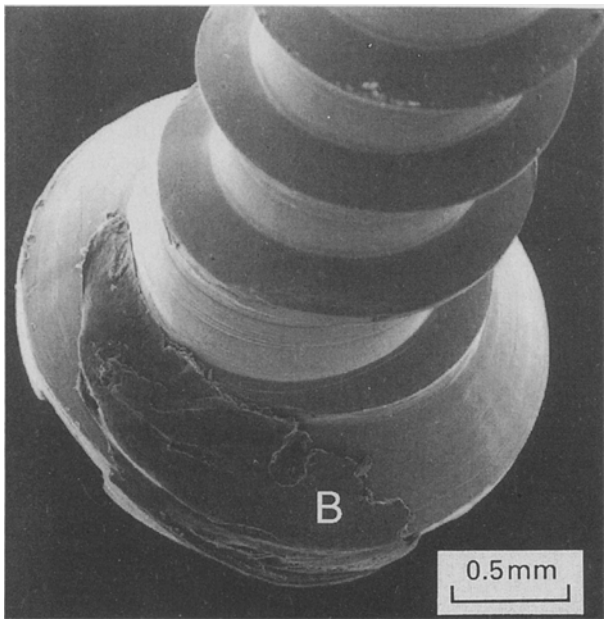

Figure 8 Bone fragment (B) in close relation to the underside of a stainless steel screw head.

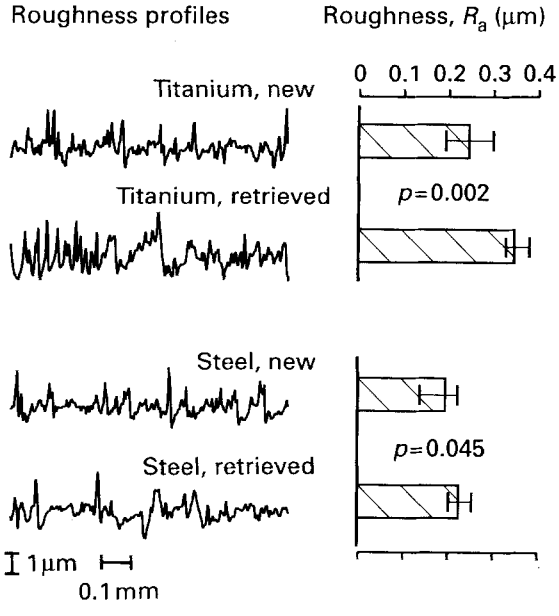

Figure 9 Profilometer recordings showing roughness of new and retrieved stainless steel and titanium plates. Examples of roughness profiles, and the average roughness (medians with quartiles), *p*-values refer to comparison between new and retrieved plates.

previous reports [7, 9], but in contrast to a report on orthopaedic devices showing pitting corrosion of the free surface [6]. Although mechanical defects were present at the free surface, repassivation mechanisms were obviously able to prevent breakdown [2, 9]. However, corrosion of multicomponent devices may occur in the biological environment despite a good corrosion resistance [3, 6, 7, 9, 12, 11]. The crevices created between the different components were the only site for corrosional attack observed in the present study of miniplates and screws, and about 1/5 of the stainless steel devices demonstrated such degradation. Metallurgical studies of retrieved plates and screws used in maxillofacial surgery are lacking. Retrieval analyses of stainless steel orthopedic fracture fixation devices have demonstrated corrosion defects of the countersink areas in 64–100% of the plates (6–11). Unstable conditions in the fracture area after osteosynthesis lead to continuous fretting at the screw/plate

interface. Removal of the passivating surface oxide and oxygen depletion in the crevices between plate and screws increase the risk of crevice corrosion attacks, which may be defined as a combination of fretting corrosion and pitting corrosion [23]. The frequency of corroded devices was not influenced by time *in situ*. It is speculated that an increased mechanical stability during healing may reduce the fretting component, and thereby the corrosion. However, when first initiated, corrosion is a process which may progress under *in vivo* conditions even after healing and stability is achieved.

The stability of the passivating oxide film of commercially pure titanium is claimed to be superior to that of stainless steel [2, 14, 15]. The surface layer of titanium has been proposed to consist of titanium dioxide (TiO_2) needles, which may wear off during fretting between plate and screws and accumulate in the surrounding tissues [15]. Despite the observed mechanical defects of the titanium plate/screw free surface and interfaces, which probably result in breakdown of the oxide, no corrosion degradation could be detected. The surface of titanium repassivates rapidly [2, 14, 15]. Corrosion of titanium may take place in chloride solutions under conditions which exeed the aggressiveness of the *in vivo* biological environment [2, 14, 25]. The general diffusion of titanium ions through the surface layer is low, estimated to reach about 12–30 $\mu g/cm^2$/year, and causes no breakdown of the passivating oxide film [5]. The metal loss is mainly supposed to take part in a slow thickening of the oxide film [14].

The finding that titanium plates are rougher than stainless steel ones is presumably a result of different material properties and manufacturing variables. Titanium wires used for othodontic purposes have been shown to be rougher than stainless steel types [26]. Individual batch variations, surface finishing differences, minor mechanical defects like occasional minor scratches or even submicroscopic corrosive alterations, may contribute to the measured differences in free surface roughness between retrieved and new plates [27]. The higher roughness, and thereby friction between titanium components, than with the smoother stainless steel components could explain the higher amount of metal found in tissue adjacent to titanium implants compared with that of stainless steel implants [9, 11].

The majority of the plates were removed on a routine basis, with no history of clinical adverse reactions. The observation that bone occasionally filled the microspaces between the components, indicates that the implant materials of stainless steel and titanium generally are biocompatible. Adverse reactions to metal implants are suggested to rise due to low-level exposure to biological active elements over time [28, 29]. Suspect elements as to hypersensitivity reactions include nickel, chromium, titanium, and aluminium [20, 21, 29]. Due to the lack of consistent information about the long-term effects of metal implants on the human body, an international study group has suggested that all non-functional implants should be evaluated for removal [30].

In conclusion, the present study has demonstrated that maxillofacial miniplate devices undergo both mechanical and corrosive degradation during handling and implantation. The most consistent findings were the handling defects occurred in all plates and screws whether stainless steel or titanium. Localized corrosion defects were observed, restricted to the countersink regions of plates and the underside of screw heads of stainless steel devices only.

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