Quantitative comparison of screw-shaped commercially pure titanium and zirconium implants in rabbit tibia

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Screw-shaped implants with an outer diameter of 3.7 mm and a total length of 8 mm were made from rods of commercially pure titanium (c.p. Ti) and commercially pure zirconium (c.p. Zr). Prior to insertion in rabbit tibia for 12 weeks, the surface roughness of two randomly chosen c.p. Ti and two c.p. Zr machined implants of the batch were numerically and visually described with a TopScan 3-D system. Irrespective of implant material, they demonstrated rather similar surface roughnesses, for example, the R_a and R_q values (that describe the average deviation from the mean line) were 0.79 and 1.18 for c.p. Ti versus 0.56 and 0.86 for c.p. Zr. Each rabbit had four implants inserted; two made of c.p. Ti in one leg and two made of c.p. Zr in the other. The bone tissue reactions to the materials were qualitatively and quantitatively examined. Removal torque tests were performed on the distal implants and histomorphometrical evaluations of the proximal ones. No qualitative or quantitative bone differences were observed. Removal torque measurements demonstrated a mean of 26.2 N cm $\pm$ 9.6 for c.p. Ti versus a mean of 25.9 N cm $\pm$ 7.1 for the c.p. Zr implants. Histomorphometrical comparisons of the bone-to-metal contact revealed a mean of 29 $\pm$ 10.2% for c.p. Ti and a mean of 19 $\pm$ 5.5% for the c.p. Zr samples. The mean bone area in the threads around the c.p. Ti samples was 49 $\pm$ 16.6% compared to 43 $\pm$ 7.9% for the c.p. Zr group. Commercially pure titanium and zirconium implants seemed to be well accepted by the bone bed after 12 weeks of insertion in rabbit bone.

1. Introduction

While commercially pure (c.p.) titanium is commonly used as a material for manufacturing of various medical implants this is not the case for c.p. zirconium. However, it is known that both metals exhibit similar good mechanical properties as well as an excellent resistance to corrosion [1]. The aim of the present study was to numerically and visually describe the surface roughness of machined implants, and to quantitatively and qualitatively examine the bone tissue response to c.p. titanium and c.p. zirconium implants after 12 weeks of insertion in rabbit bone.

2. Materials and methods

2.1. Animals, anaesthesia and surgical technique

Ten mature (average 10 months old) male New Zealand White rabbits were used in this study. At surgical procedures they were anaesthetized with intramuscular injections of fenthanyl and fluanizon (Hypnorm Vet., Janssen Farmaceutical, Belgium) at a dose of 0.5 ml kg^{-1} body weight and intraperitoneal injections of diazepam (Valium, Roche, France) at a dose of 2.5 mg per animal. Local anaesthesia with 1.0 ml of 5% Xylocaine (Astra, Sweden) was administered to the medial side of the upper proximal tibia (tuberositas tibiae) where the implants were to be inserted under aseptic conditions. At the preselected time of sacrifice, intravenous injections of a mixture of saline and barbiturates (Mebumal Vet., 60 mg ml^{-1}, Nord Vacc, Sweden) 1:4 were given. Each rabbit received two c.p. titanium implants in one leg ($n = 20$) while in the other leg two c.p. zirconium ($n = 20$) were placed. The implants were inserted at a distance of 5 mm apart. Two threads were left visible above the cortex and the implants were allowed to penetrate the first cortical layer only. Removal torque tests were performed on the distal implants and histomorphometrical test on the proximal ones. The follow-up time was 12 weeks.

2.2. Implants and surface roughness test

Square headed (2 mm) screw-shaped implants (with a distance of 600 μm between the thread peaks) with a total length of 8 mm and an outer diameter of 3.7 mm were machined in identical manners from c.p. Ti (99.75%, grade 1) and c.p. Zr (99.2%, grade 702) rods. The implants were ultrasonically cleaned in trichlorethylene and absolute ethanol prior to sterilization in an autoclave. Scanning electron microscopy (SEM) was performed using a Jeol JSM T 300 electron microscope (Fig. 1a and b). The surface roughness was characterized in a three-dimensional way, numerically as well as visually, for two randomly chosen implants from each group with help of the TopScan 3D system® (Heidelberg Instruments, Heidelberg, Germany). TopScan 3D is a non-contacting optical profilometer which uses the principle of confocal laser scanning microscopy for depth descrimination (described by Wennerberg *et al.* [2] in more detail). For each screw the measured areas were on the bottom, mid and top of the implant and for each site one thread-top, one thread-valley and one thread-flank were measured. The screw was then turned around and similar areas were measured on the opposite side of the screw. This makes a total of 18 measurement areas for each screw. The measuring area was for all measurement 245 × 240 μm For numerical description of the surface topography the following surface roughness parameters were used: R_a, R_q, R_t, R_{sk}, R_{ku}, Δ_q and λ_q. The R_a and R_q values describe the average deviation from the mean line, R_t is the distance from the highest peak to the lowest valley, R_{sk} or skewness describes the symmetry of the profile about the mean line, and R_{ku} or kurtosis describes how close the height distribution is to a Gaussian distribution curve; these five parameters are all height descriptive. We also used the so-called hybrid parameters Δ_q and λ_q, that give information about height as well as space [3].

2.3. Removal torque tests, preparation of specimens and histomorphometry

The design of the implants, with a square shaped head, enabled them to fit into a constructed pin which was connectable to a removal torque unit (Tohnichi 6BTG-N, Tohnichi MFG Co., Ltd., Tokyo, Japan) enabling implant stability measurements (in N cm). A slow gradual increase of the applied torque was used until loosening occurred. The technique allows for a comparison between test and control with respect to torque necessary for implant loosening. All implants were then retrieved with surrounding bone and further processed to be cut and ground [4]. Computer-based (Leitz Microvid® connected to a PC and a mouse) histomorphometrical measurements of the bone-to-metal contact (bmc) and the bone area in the threads were carried out directly in the eye-piece of a Leitz Aristoplan microscope using an objective of 10 × and a zoom of 2.5 × on the ground sections of the screwed implants with surrounding bone [5].

2.4. Statistics

Statistical evaluation was performed using student *t*-test (*p*-values for the surface roughness measurements are reported in Table I) and Wilcoxon signed rank test.

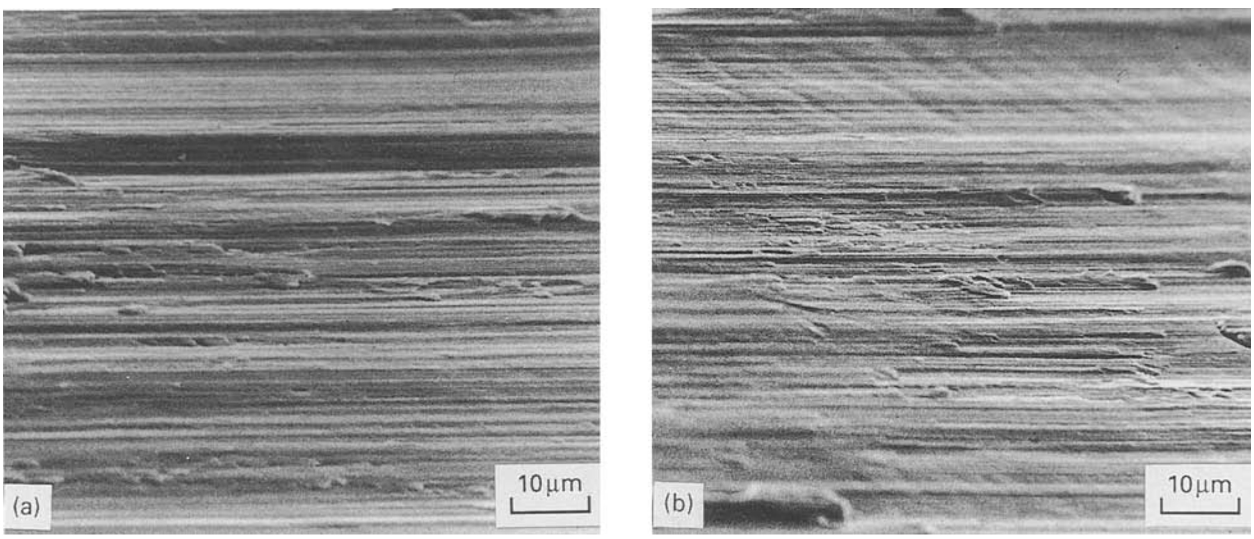

Figure 1 Scanning electron micrographs (SEM) of (a) c.p. titanium implant surface, and (b) c.p. zirconium implant surface. Ridges and grooves, typical of machined metal surfaces, are present in both cases.

TABLE I Mean values of 36 measured areas for each material

	R_a(μm)	R_t(μm)	R_q(μm)	R_{sk}	R_{ku}	Δ_q(degrees)	λ_q(μm)
Titanium							
Mean value	0.79	15.97	1.18	− 0.88	9.62	38.16	11.02
SD	0.27	5.03	0.41	0.70	3.18	8.97	1.95
Zirconium							
Mean value	0.56	12.97	0.86	− 0.93	15.37	31.6	9.78
SD	0.15	3.86	0.22	0.85	4.79	5.69	1.37
p-value student *t*	0.000	0.006	0.000	0.780	0.019	0.000	0.002

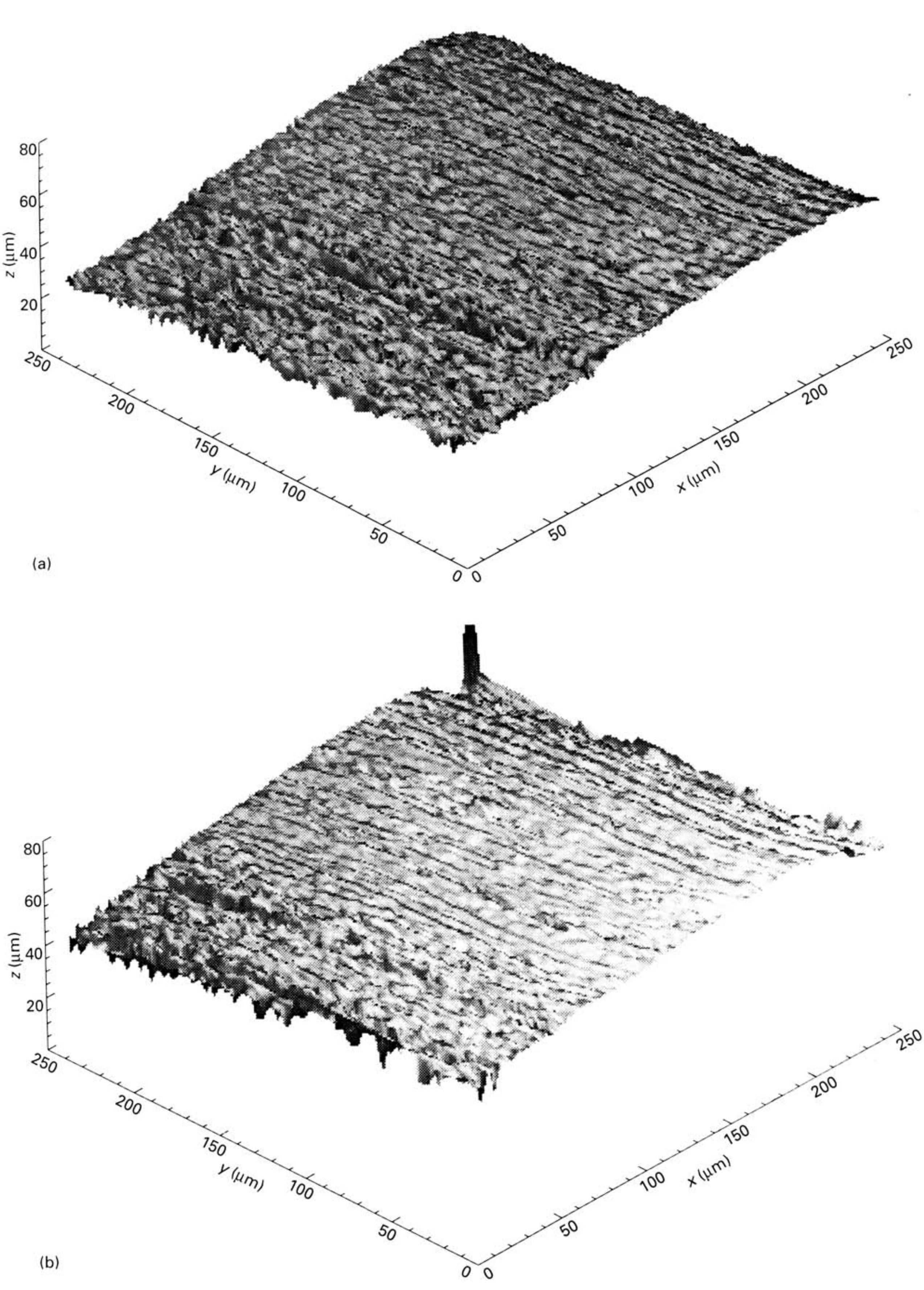

Figure 2 Surface topographical descriptions of (a) a c.p. titanium flank ($R_a = 0.64$; $R_t = 15.24$; $R_q = 0.95$; $R_{sk} = -1.55$; $R_{ku} = 13.05$; $\Delta_q = 40.00$; $\lambda_q = 8.53$), and (b) a c.p. zirconium flank ($R_a = 0.60$; $R_t = 20.38$; $R_q = 1.04$; $R_{sk} = -2.69$; $R_{ku} = 24.7$, $\Delta_q = 36.3$; $\lambda_q = 10.27$). Numerically and visually the two are very similar.

3. Results

Irrespective of implant surface microgrooves, elevated areas and small pits were observed under the scanning electron microscope (Fig. 1a and b). The various surface roughness parameters are summarized in Table I. A slightly rougher surface was found for the two c.p. Ti screws than for the two screws made of c.p. Zr. The R_{sk} value was very similar for the two materials,

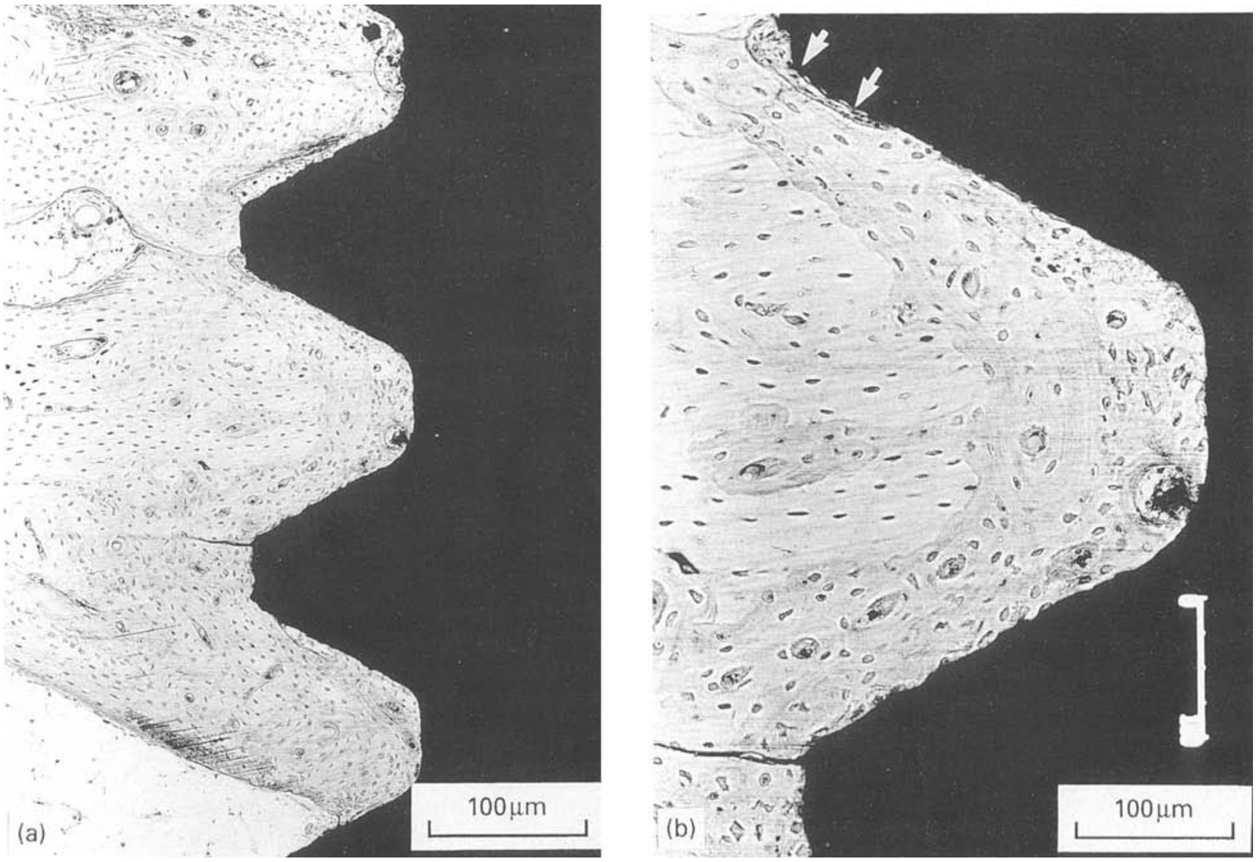

Figure 3 (a) Survey light micrograph of a c.p. titanium ground section. There is a distance of 600 μm between the thread peaks. (b) Mature bone, woven bone and soft tissue (indicated with arrows) are observed in close contact with the implant.

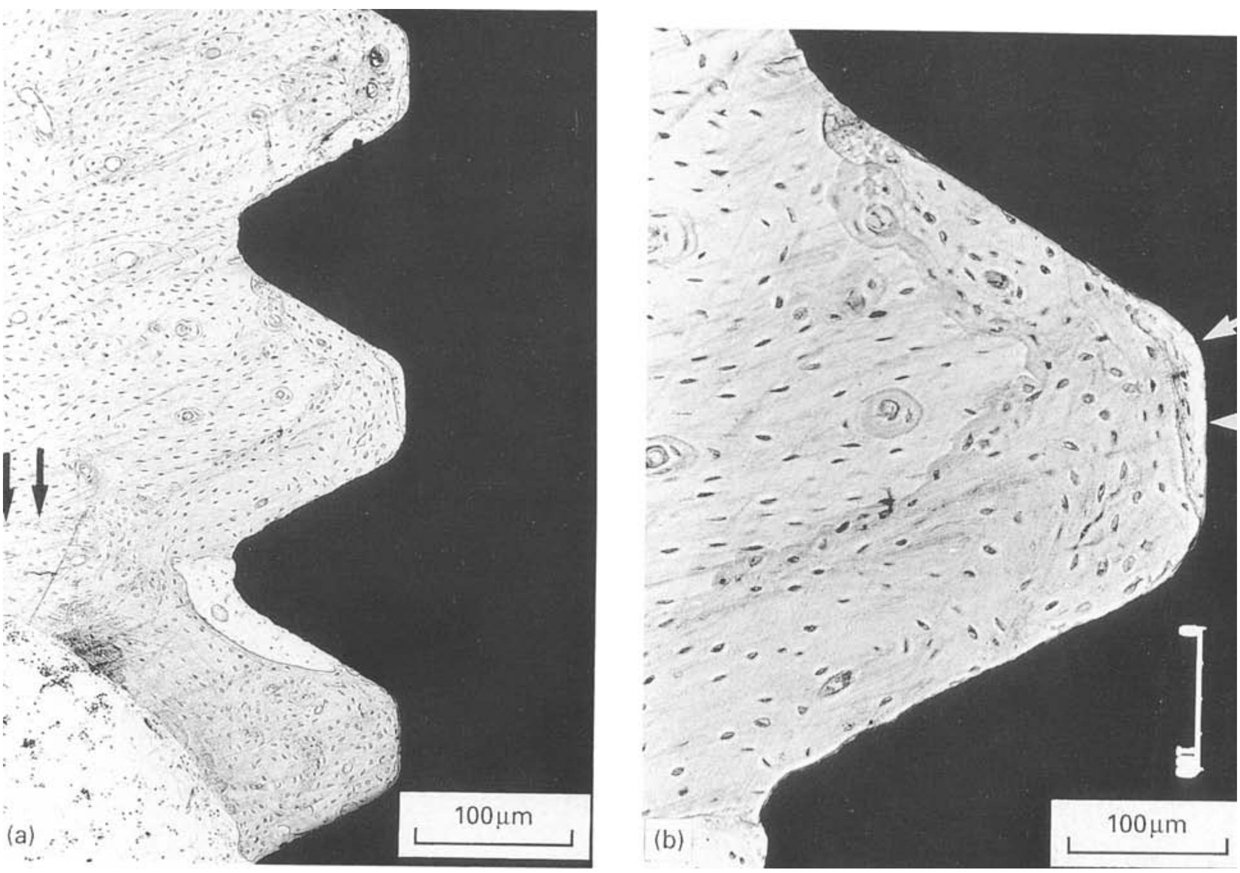

Figure 4 (a) Light micrograph of a c.p. zirconium ground section. There is a distance of 600 μm between the thread peaks. The border between the old endosteal surface and the newly formed bone is indicated (arrows). (b) Mature bone, woven bone and soft tissue (arrows) are observed in close contact with the implant.

the negative value indicating that the c.p. Zr as well as the c.p. Ti implants had slightly more valleys than peaks. R_{sk} is zero if there are as many peaks as valleys. The surface texture of the Ti screws was slightly more open. The machined surfaces of the two metals are exemplified numerically and visually by Fig. 2a and b.

There was no statistically significant difference in the removal torque measurements: for c.p. Ti 26.2 ± 9.6 N cm (range 11–47.5 N cm) versus 25.9 $\pm$ 7.1 N cm (range 16–39 N cm) for c.p. Zr. The bone-to-metal contact (bmc) and the bone area in the threads were calculated around the entire (total) implant as well as in the three best consecutive threads ($n = 6$ for each sample) on each side of the implant in the cortical region. The c.p. Ti implants demonstrated a mean total bmc of $29 \pm 10.2\%$ (range 17–49%) in comparison to $19 \pm 5.5\%$ (range 10–29%) for the c.p. Zr implants ($p = 0.037$). The three best consecutive threads demonstrated a mean bmc of $39 \pm 9.8\%$ (range 20–40%) for the c.p. Ti implants while in the c.p. Zr cases the mean was $27 \pm 8.2\%$ (range 17–41%) ($p = 0.0058$). The mean bone area within the threads around the entire c.p. Ti samples was $49 \pm 16.6\%$ (range 29–73%) compared to $43 \pm 7.94\%$ (range 17–49%) for the c.p. Zr. The three best consecutive threads in the cortical region demonstrated a mean bone area of $79 \pm 4.4\%$ (range 72–84%) for the c.p. Ti cases compared to a mean of $79 \pm 4.9\%$ (range 70–86%) in the c.p. Zr sections. No qualitative differences of the tissue surrounding the implants could be observed in the light microscope of the 10 μm thick ground sections (Figs 3a, b, 4a and b). Irrespective of which type of inserted implant, mature and woven bone was observed in the threads and on bone-free surfaces soft tissue with multinucleated cells and macrophages were present. Periosteal and endosteal bone formation had occurred.

4. Discussion

It should be stressed that the differences between the surface structure for the two investigated materials are small and the values for the two Zr screws and one Ti screw were very similar. The R_{ku} value showed that none of the screws surface topography had a perfect Gaussian height distribution, in which case R_{ku} should have been 3. There were, in other words, too many peaks and valleys for a Gaussian height distribution to be valid. The values for the hybrid parameters indicate that the surface of the Ti screws had a longer distance between the peaks and valleys than the Zr implants. However, one Ti screw exhibited a rougher surface which explains the somewhat higher mean values for the Ti screws. The present study qualitatively (on the light microscopical level) and quantitatively demonstrated that c.p. Ti and c.p. Zr seem to be well accepted in the rabbit bone bed after 12 weeks of insertion, which is in agreement with earlier qualitative bone tissue studies at the transmission electron micrscopical level [6]. Niki *et al.* [7] have reported on comparative push-out data performed on "materials of similar rugosity". In the latter paper the Ti implants had an R_z value of 4.4 versus 3.3 for Zr. The fracture strength after 24 weeks of insertion was 1.9 MPa and 1.1 MPa, respectively, with bone contact measurements of 50% (c.p. Ti) and 30% (c.p. Zr). In essence, the surface roughness values of c.p. Ti and c.p. Zr screws were rather similar. The observation of similar removal torque and histomorphometrical data indicate that bone tissue reactions to Zr and Ti do not differ significantly at a follow up of 3 months in rabbit bone.

References

1. J. GALANTE and W ROSTOCKER, *Clin. Orthop. Relat. Res.* **86** (1972) 237.
2. A WENNERBERG, T ALBREKTSSON, H ULRICH and J J. KROL, *J. Biomed. Eng.* **14** (1992) 412.
3. H. DAGNALL, "Exploring surface texture", 2nd Edn (Rank Taylor Hobson Limited, Leicester, England, 1986).
4. K. DONATH, *Der Präparator* **34** (1988) 197.
5. C. B. JOHANSSON. Thesis, Dept. of Handicap Research, University of Göteborg (1991).
6. T. ALBREKTSSON, H. A HANSSON and B IVARSSON, *Biomaterials* **6** (1985) 97.
7. M NIKI, G. ITO, T MATSUDA and M OGINO, "The bone materials interface", edited by J. E. Davies (University of Toronto Press, 1991) p. 350.