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Immediately loaded machined versus rough surface dental implants in edentulous jaws: One-year post-loading results of a pilot randomised controlled trial



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Key words full edentulism, immediately loaded machined dental implants, roughened dental implants

Purpose: To compare the effectiveness of immediately loaded total prostheses supported by implants with a roughened surface versus implants with a machined/turned surface.

Materials and methods: Fifty edentulous or to-be-rendered edentulous patients requiring an implant-supported cross-arch prosthesis, were randomised either to receive four to eight implants with a roughened surface (25 patients) or with a machined/turned surface (25 patients). Provisional metal-reinforced acrylic prostheses were delivered 48 h after implant placement. Provisional prostheses were replaced after 4 months, by definitive screw-retained metal-resin cross-arch restorations. Outcome measures were prosthesis and implant failures, any complications and peri-implant marginal bone level changes. Patients were followed 1 year after loading.

Results: One year after loading no patient dropped out. No prosthesis failed, but two machined implants were found to be mobile at definitive impression taking in 1 patient (Fisher's exact test: $P = 0.312$; difference in proportions = 4%; 95% CI: -10 to 18). No complications occurred. Both groups presented a significant peri-implant marginal bone loss at 1 year after loading ($P < 0.0001$), -0.64 ± 0.20 mm for rough implants and -0.68 ± 0.23 mm for turned implants, respectively, with no statistically significant differences between the two groups ($P = 0.482$; mean difference = 0.04 mm; 95% CI: -0.17 to 0.25).

Conclusions: Up to 1 year after immediate loading, both implant surfaces provided good and similar results, however, the only two implants which failed early in the same patient had a machined surface. These preliminary results must be confirmed by larger trials with longer follow-ups.

Conflict-of-interest statement: I-RES, the manufacturer of the implants used in this study, donated their implants and prosthetic components, however, data property belonged to the authors and by no means did I-RES interfere with the conduct of the trial or the publication of its results.

Introduction

Nowadays the majority of dental implants sold on the market are characterised by surfaces which have been roughened using different technologies, in order to increase the bone-to-implant contact area,

with the aim of higher success rates, however there is not yet any reliable clinical evidence to substantiate this, although trends of early success rates are in favour of implants with roughened surfaces¹. On the contrary, data suggests that after 3 years in function, implants with a very rough surface have a 20%



increased risk of being affected by peri-implantitis¹. The difficulties in the treatment of peri-implantitis and the uncertainty of the long-term prognosis of implants affected by peri-implantitis^{2, 3} cast some doubts on the long-term outcome of implants, especially of implants with roughened surfaces, and in particular of those with very rough implant surfaces, such as those treated with titanium plasma-sprayed techniques, making the use of implants with machined surfaces interesting once again, although with a more aggressive design (tapered and wider cutting threads) and inserted with surgical techniques aimed at achieving higher insertion torques^{4, 5}, than those commonly used in the nineties.

The aim of this randomised controlled trial (RCT) of parallel group design was to compare the effectiveness of implant-supported total prostheses supported by four to eight immediately loaded dental implants with a roughened surface versus implants with a machined/turned surface. The test hypothesis was that there were no differences between implants with machined and roughened surfaces against the alternative hypothesis of a difference. This report presents the preliminary data up to 1 year after loading. At protocol stage, the plan was to follow the patients up to 10 years after loading. The present article is reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement for improving the quality of reports of parallel-group randomised trials (<http://www.consort-statement.org/>).

■ Materials and methods

This trial was designed as a single-centre randomised controlled trial of parallel group design. Any edentulous or to-be-rendered edentulous patients interested in having an implant-supported rehabilitation, being 18 years old or older and able to understand and sign an informed consent were eligible for inclusion in this trial. Patients who had residual teeth to be removed were treated with immediate post-extractive implants. Jaws of patients were able to receive four to eight implants which were at least 8 mm long. Residual bone thickness at implant sites had to be at least 5.5 mm as measured on computerised tomography (CT) scans. Only one jaw per patient was included in this study.

Patients were not admitted in the study if any of the following exclusion criteria was present:

- general contraindications to implant surgery;
- subjected to irradiation in the head and neck area;
- need of bone augmentation procedures at implant placement or previously augmented bone;
- immunosuppressed or immunocompromised patients;
- treated or under treatment with intravenous aminobisphosphonates;
- affected by untreated periodontitis;
- poor oral hygiene and motivation;
- uncontrolled diabetes;
- pregnant or lactating;
- known addiction to alcohol or drugs;
- psychiatric problems;
- lack of opposite occluding dentition/prosthesis;
- patients who cannot be restored with a retrievable prosthesis to allow individual implant stability assessment;
- unable to commit to a 10-year follow-up;
- participation in other trials, if the present protocol could not be properly followed;
- referred only for implant placement;
- missing 4 mm or more buccal bone plate at post-extractive sites to be used as implant sites.

Patients were categorised into three groups according to what they declared: non-smokers, moderate smokers (up to 10 cigarettes per day) and heavy smokers (more than 10 cigarettes per day).

Patients were recruited and treated in one university centre (Unit of Periodontology and Implantology, University of Bologna, Bologna, Italy) and two private practices by the same operators (Dr Pietro Felice placed the implants and Dr Cristiana Brecchia and Dr Michele Diazzi rehabilitated the patients prosthetically), using identical and standardised procedures.

All patients received thorough explanations and understood and signed a written informed consent form prior to being enrolled in the trial. Implant placement and prosthetic procedures were identical for both groups. All patients received prophylactic antibiotic therapy: 2 g of amoxicillin 1 h prior to implantation. Patients allergic to penicillin were given 600 mg clindamycin 1 h before. All patients rinsed

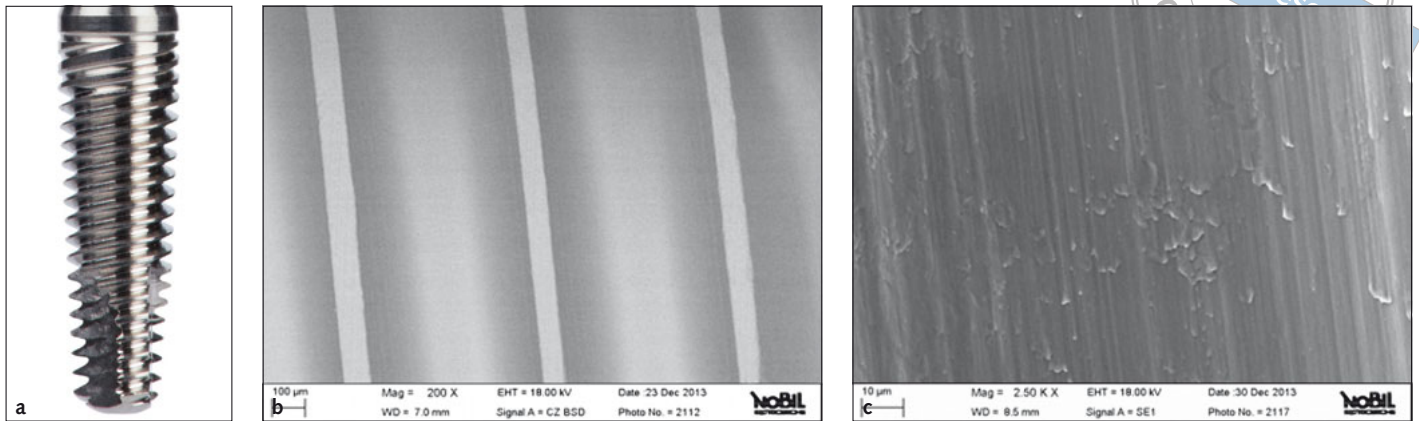


Fig 1 a) Illustrations of the implant iRES iPerio with a turned surface ($R_a = 0.40 \mu\text{m}$; $S_a = 1.19 \mu\text{m}$); b) at 200 x magnification; c) at 2500 x magnification.

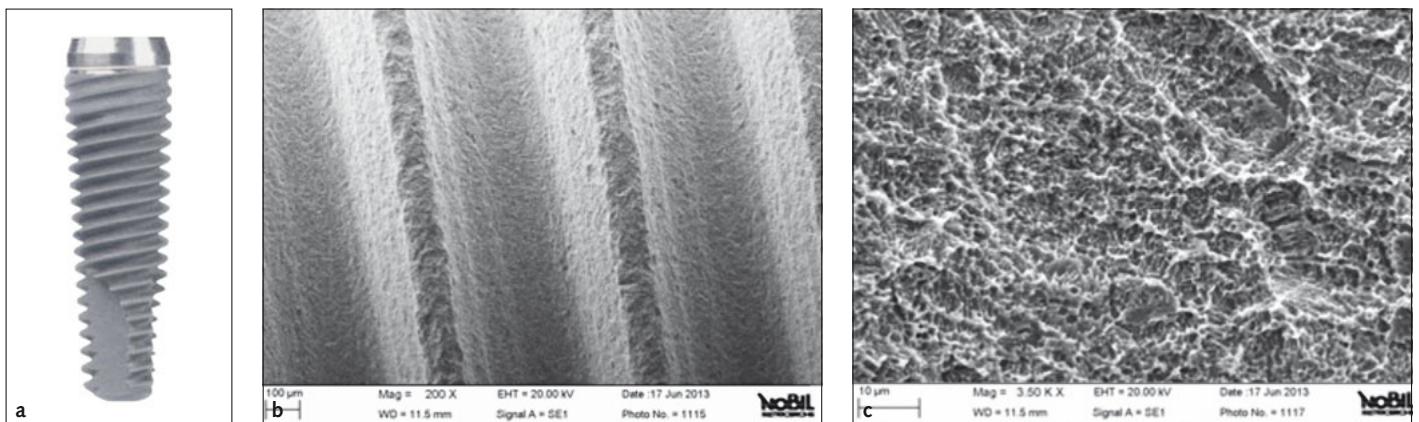


Fig 2 a) Illustrations of the implant iRES Shape 1BC with a surface roughened with sand blasting and double etching ($R_a = 1.42 \mu\text{m}$; $S_a = 2.48 \mu\text{m}$) and 1 mm of polished collar neck; b) at 200 x magnification; c) at 3500 x magnification.

with chlorhexidine mouthwash 0.2% for 1 min and were treated under local anaesthesia. The decision of whether or not to elevate a flap was left to the surgeon. When flaps were elevated, it was after crestal incisions. If present, residual teeth were extracted as atraumatically as possible, in an attempt to preserve the buccal alveolar bone. Sockets were carefully cleaned from any remains of granulation tissue. Patients were finally included if all post-extractive sites lost less than 4 mm in height of the buccal wall (assessed using the highest peak of the palatal wall as a reference point) at all implant sites. Implants were inserted under prosthetic guidance using surgical templates. Bone quality was subjectively evaluated at drilling by the surgeon and classified as hard, medium and soft. Implant sites were prepared according to bone quality: in the presence of hard bone drill diameters 2.3, 2.4 to 2.8 and 2.8 to 3.3 mm were used; in the presence of medium

bone quality only the 2.3 and 2.4 to 2.8 mm drills were used; and in the presence of soft bone the drill diameter 2.3 mm was used and the drill 2.4 to 2.8 mm, only for the first third of the preparation. In post-extractive sites, the site preparation included at least 3 mm beyond the previous tooth apex position. Once the first implant site was prepared, the patient was randomised to receive either implants with a turned surface or identical implants with a roughened surface, by opening the corresponding sealed envelope containing the group allocation code. The implants used in the current investigation were iRES iPerio (iRES SAGL, Lugano, Switzerland) with a turned surface ($R_a = 0.40$, $SD = 0.06 \mu\text{m}$; $S_a = 1.19$, $SD = 0.09 \mu\text{m}$) (Figs 1a to 1c), and iRES Shape 1BC with a surface roughened with sand blasting and double etching ($R_a = 1.42$, $SD = 0.20 \mu\text{m}$; $S_a = 2.48$, $SD = 0.39 \mu\text{m}$) and 1 mm of polished collar neck (Figs 2a to 2c). Apart from the surface, the



two implant types were identical and had the same macroscopic design: internal connection, tapered, self-tapping with a triple thread and were made of titanium grade 4. The operator was free to choose amongst four implant lengths (8.0, 10.0, 11.5 and 13.0 mm) according to the clinical indications. All implants were 3.75 mm in diameter.

Implant sites were slightly underprepared to increase the insertion torque and the motor was set with a torque of 35 Ncm. If the required insertion torque could not be obtained, in the presence of at least four implants placed with more than 35 Ncm, only the latter implants were loaded immediately, whereas the remaining implants were submerged and loaded with the existing provisional prosthesis after 4 months. Therefore, delivery of the definitive prostheses were delayed for 4 months. If less than four implants were inserted with a torque superior to 35 Ncm, they were left to heal submerged for 4 months. All implants were placed about 2 mm subcrestally. In the presence of a horizontal buccal bone-to-implant gap of 2 mm or more, they were filled with an haemostatic resorbable gelatine sponge (Cutanplast Dental, 1 x 1 x 1 cm, Oгна Lab, Muggiò, Italy) of porcine origin. Multi Unit Abutments (MUA) which were 1, 2, 4 and 6 mm long, straight or angled (18° or 30°) and consisting of 5 mm diameter, were placed. When needed, flaps were sutured back with Vicryl 4.0 sutures (Ethicon FS-2, Sint-Stevens-Woluwe, Belgium), until the incisions were perfectly sealed. Impressions with the pick-up impression copings were taken using a polyether material (Impregum 3M/ESPE, Montana, USA). The vertical dimensions were registered and models were made with class 4 precision plaster and mounted in a standard articulator. Ibuprofen 400 mg was prescribed to be taken two to four times a day during meals, as long as required. Patients were instructed to use 0.2% chlorhexidine mouthwash for 1 min twice a day for 2 weeks. Patients were reviewed after 1 and 2 weeks for suture removal and post-surgical control.

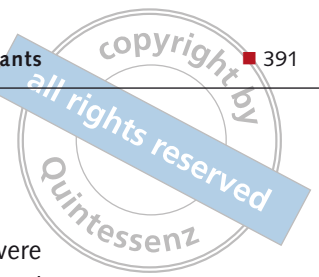
Patients received a provisional screw-retained full acrylic reinforced restoration rigidly joining all the implants within 48 h. Periapical radiographs (baseline) were obtained with the paralleling technique. In cases where the bone levels around the study implants were hidden or difficult to be estimated,

a second radiograph was obtained. Clinical pictures of the study implants were also taken. Four months after delivery of the provisional prostheses, implants were manually tested for stability using a torque of 20 Ncm, MUA titanium abutments were placed and new impressions were taken with the pick-up impression copings, using a polyether material (Impregum) and definitive screw-retained metal-resin cross-arch prostheses, rigidly joining the implants, were delivered.

Patients were enrolled in an oral hygiene program with recall visits at least every 6 months for the entire duration of the study. Follow-ups were conducted by a single independent outcome assessor (Carlo Barausse) together with the surgical operators.

This study tested the null hypothesis that there were no differences between the two implant surfaces against the alternative hypothesis of a difference. Outcome measures were:

- Prosthesis failure: planned prosthesis which could not be placed due to implant failure(s), loss of the prosthesis secondary to implant failure(s), or replacement of the definitive prosthesis for any reasons.
- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, or any mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant-abutment connection. Stability of individual implants was measured at delivery of the definitive prostheses (4 months after delivery of the provisional prostheses) and at 1 year after loading, by tightening abutment screws with a torque of 20 Ncm.
- Any biological or prosthetic complications.
- Peri-implant marginal bone level changes assessed on periapical radiographs taken with the paralleling technique at implant placement and at 1 year after loading. In the case of improperly readable radiographs, new radiographs were made. A blind outcome assessor (Dr Carlo Barausse) scanned the non digital radiographs in TIFF format with a 600 dpi resolution, and stored the radiograph files in a personal computer and measured peri-implant marginal bone levels using the OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. The software was calibrated for every single image using



the known distance of the two consecutive and more coronally positioned threads. Measurements of the mesial and distal bone crest level adjacent to each implant was made to the nearest 0.01 mm. Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of the bone-to-implant contact. Implants with bone above the coronal margin of the implant collar were given the zero value. Mesial and distal measurements of each implant were averaged and a mean calculated at patient level and then at group level.

One clinician (Carlo Barausse), not involved in the treatment of the patients, performed all radiographic and clinical assessments, without knowing group allocation, therefore the outcome assessor was blinded. Patients were also kept blinded to which type of implant surface was received.

No sample size was calculated and for this pilot study only 25 patients were recruited in each group. A computer-generated restricted randomisation list was created by one person, who was not involved in the study. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after eligible patients signed the informed consent form to be enrolled in the trial. Therefore, treatment allocation was concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses. A physician (Dr Giovanni Grandi) with expertise in dentistry analysed the data without knowing group allocation. Differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between groups using the Fisher's exact probability test. Paired t-tests were used to compare the mean radiographic values at implant placement, and 1-year after loading. Sample t-tests were used to compare the mean radiographic marginal bone level changes between the groups. All statistical comparisons were conducted at the 0.05 level of significance.

■ Results

Fifty patients were considered eligible and were consecutively enrolled and randomised in two equal groups of 25 patients each and received either implants with a machined surface (Figs 3a to 3f) or implants with a roughened surface (Figs 4a to 4e). Additionally, four patients were screened for eligibility but they refused to participate in the trial because they were counselled by their own referring clinicians to be treated with implants with rough surfaces and not with turned implants. The only type of protocol deviation which occurred was that 13 patients (10 patients with machined implants and three patients with roughened implants) refused to have the provisional prosthesis replaced by the definitive ones, and 1 year after loading, they were still wearing their original provisional prostheses. Patients justified their decision saying that they were having financial difficulties.

No patient dropped out up to 1-year post-loading. Data of all patients were evaluated in the statistical analyses. Patients were recruited and treated from January to April 2014. The follow-up of all patients was 1 year after implant loading.

The main baseline patient characteristics are presented in Table 1. One hundred and thirty-seven rough and 165 turned implants were placed. In Table 2 the frequencies of the implant lengths, bone quality and immediate post-extractive implants by study group and jaw type are shown. Implants with a machine surface were longer than roughened implants ($P < 0.001$) and there were on average more turned implants per patients than roughened ones ($P = 0.005$).

Two implants (one per type) did not achieve a torque superior to 35 Ncm. The machined implant was submerged unloaded since the provisional prosthesis could be loaded on the remaining five implants. The patient refused to have the definitive prosthesis for financial reasons, therefore the implant was still submerged at the 1-year follow-up. The same situation occurred for the rough implant, which was successfully loaded after 4 months, together with the other five loaded implants at delivery of the definitive prosthesis.

All prostheses could be placed and were successful 1 year after loading. Two machined surface implants failed in one patient versus no implant

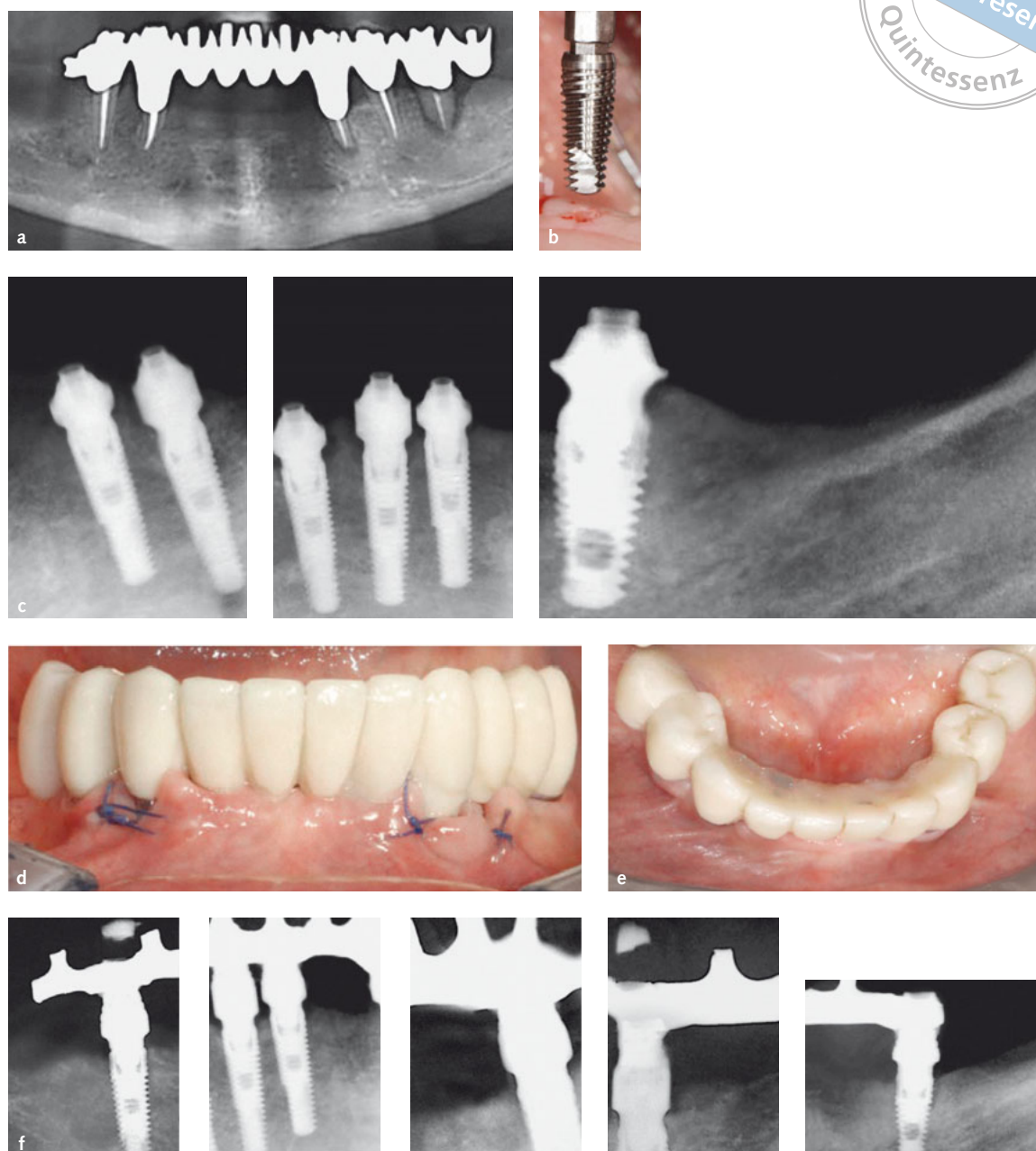


Fig 3 a) Preoperative panoramic radiograph of a patient randomly allocated to the group treated with implants with a machined/turned surface; b) an iRES iPerio implant with machined/turned surface just prior to its placement; c) periapical radiographs taken just after implant placement; d) clinical view of the provisional prosthesis; e) occlusal view of the definitive prosthesis; f) periapical radiographs taken 1 year after loading.

failures in the roughened implant group. Two out of six mandibular implants in positions 36 and 43 (both were immediate post-extractive implants) were found to be mobile 4 months after loading, when taking the impression for the definitive prosthesis. The patient felt moderate pain at percussion. They were removed and replaced by two rough

merged since they did not reach a torque superior to 35 Ncm. The original provisional prosthesis was adapted on the four remaining implants and the patient decided to keep the provisional prosthesis since he was afraid to lose any additional implants at impression taking. The differences in proportions for patients experiencing implant failures was not statistically significant (Fisher's exact test: $P = 0.312$;

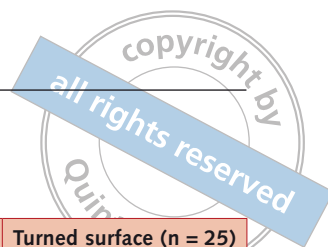


Fig 4 a) Preoperative panoramic radiograph of a patient randomly allocated to the group treated with implants with a roughened surface; b) an iRES Shape 1BC with a surface roughened with sand blasting, double etching and 1 mm of polished collar neck, just prior to its placement; c) baseline periapical radiographs taken just after implant placement; d) clinical view at immediate loading of the provisional acrylic prosthesis; e) periapical radiographs taken at 1 year after loading.

difference in proportions = 4%; 95% CI: -10 to 18). No complications were reported.

Peri-implant bone levels could be measured at all implant surfaces. There were no statistically significant differences for bone levels at implant placement and 1 year after loading between the two groups (Table 3). Both groups gradually lost marginal peri-implant bone and this was statistic-

ally significant ($P < 0.0001$) (Table 3). At 1-year post-loading, patients with roughened implants lost 0.64 ± 0.20 mm compared to 0.68 ± 0.23 mm for machined implants with the difference between groups showing no statistical significance ($P = 0.482$; mean difference = 0.04 mm; 95% CI: -0.17 to 0.25; Table 3).

**Table 1** Patient and intervention characteristics.

	Rough surface (n = 25)	Turned surface (n = 25)
Females	13	9
Mean age at implant insertion (range)	63.60 (47-80)	60.84 (38-81)
Smokers (moderate and heavy smokers)	7	4
Elevated flaps	2	1
Total number of inserted implants	137	163
Total number of immediate post-extractive implants	74	92
Total number of implants inserted in mandibles	58	65
No. of implants inserted with < 35 Ncm torque	1	1
Mean implant length (SD) in mm	10.67 (1.89)	11.39 (1.81)
Mean number of implants per patient (SD)	5.48 (1.19)	6.52 (1.29)
No. of prostheses inserted in mandibles	12	11
No. of prostheses supported by four implants	8	2
No. of prostheses supported by five implants	1	2
No. of prostheses supported by six implants	14	11
No. of prostheses supported by seven implants	0	1
No. of prostheses supported by eight implants	2	9

Table 2 Length of the implants, bone quality and immediate post-extractive implants in the mandibles and maxillas.

Implant length in mandibles	Rough implants (n = 137)	Turned implants (n = 163)
8.0 mm	13	8
10.0 mm	24	10
11.5 mm	7	21
13.0 mm	14	26
Implant length in maxillae		
8.0 mm	17	17
10.0 mm	26	17
11.5 mm	6	17
13.0 mm	30	47
Bone quality in mandibles		
Soft	1	3
Medium	24	38
Hard	33	22
Bone quality in maxillae		
Soft	30	40
Medium	49	58
Hard	0	2
Mandibular post-extractive implants	25	34
Maxillary post-extractive implants	49	58

■ Discussion

This pilot trial was designed to generate some preliminary data on whether implants with a machined/turned surface could be a reliable alternative to implants with a roughened surface over time. The present preliminary short-term results at 1 year suggest that similar clinical short-term outcomes can be expected using the two implant surfaces, however the only patient who experienced the failure of two implants belonged to the turned surface group. These two implants were placed in mandibular post-extractive sockets and were found to be mobile at impression taking for the definitive prosthesis and may be classified as early implant failures^{6,7}. It could be speculated that they were most likely to never be osseointegrated. The present data shows remarkable similarities with the data summarised in a review⁸ and in the more recent and well-conducted Cochrane systematic review¹ comparing early losses of turned implants versus implants with a rough surface. In a meta-analysis¹ which included seven randomised controlled trials,⁹⁻¹⁵ no statistically significant differences in early implant failures were observed between implants with machined surfaces and implants with roughened surfaces. However, the

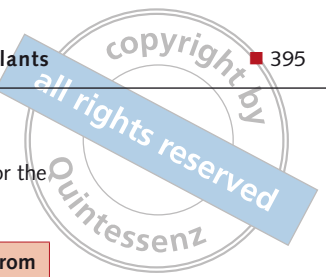


Table 3 Comparison between mean marginal bone levels (SD) in mm at implant placement and 1 year after loading for the two groups, and for changes from baseline within each group.

	Rough surface		Turned surface		Mean difference	95% CI of the difference	P-value from unpaired sample t-test
	N	mean (SD)	N	mean (SD)			
At implant placement		0.07 (0.08)		0.10 (0.08)	0.03 (0.10)	-0.07; 0.13	0.179
1-year post-loading		0.71 (0.19)		0.78 (0.22)	0.07 (0.27)	-0.20; 0.34	0.206
Mean changes at 1 year		0.64 (0.20)		0.68 (0.23)	0.04 (0.21)	-0.17; 0.25	0.482
P-value from paired t-test from placement to 1 year		< 0.0001		< 0.0001			
95% CI of the difference (1-year)		0.44; 0.84		0.45; 0.91			

P value of 0.08 was close to statistical significance, with eight patients out of 187 losing at least one machined implant versus only two patients out of 217 who lost at least one rough implant early on. Even if no statistically significant difference was proven so far, these figures suggest that there is a trend, where patients lose more implants early on with the machined surface. On the other hand a second meta-analysis¹, including four RCTs,^{11,15-17} showed that 3 years after loading, implants with machined surfaces had a statistically significant risk reduction of 20%, in terms of being affected by peri-implantitis (risk ratio = 0.80; 95% CI: 0.67 to 0.99). It should also be noted that in the present trial, implants were loaded immediately, whereas in the majority of previous RCTs, implants were conventionally loaded with the exception of one trial¹⁵. Immediate loading might challenge a machined surface more rather than a rougher surface.

There are two main limitations of the present trial: i) the small sample size, however this study was designed as a pilot study in order to gain a preliminary idea of the outcome of the comparison; and ii) the imbalance at baseline for implant length and number of implants per patient. In fact, implants with turned surfaces were on average significantly longer (0.7 mm) and there were more per patient (6.5) than implants with a roughened surface (5.5). The research protocol was not designed to balance these factors, although it should have. It is possible that the surgeon unconsciously tried to compensate for a perceived increased risk of failure for turned implants by placing more implants with a turned surface. It is difficult to say whether this baseline

imbalance can affect the clinical outcome, however this issue could have been controlled with a better designed protocol.

Both techniques were tested in real clinical conditions and patient inclusion criteria were rather broad, therefore the results of the present investigation can be generalised with confidence to a wider population with similar characteristics.

■ Conclusions

Up to 1 year after immediate loading, both implant surfaces provided good and similar results, however, the only two implants which failed early in the same patient had a machined surface. These preliminary results must be confirmed by larger trials with longer follow-ups.

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