

Turned, Machined Versus Double-Etched Dental Implants In Vivo

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ABSTRACT

Background: Positive effects on the clinical outcome of moderately rough implant surfaces are described. Intercomparison of clinical data, however, is rarely found.

Purpose: The aim of this study was to compare the clinical results of two macroscopically identical implants, the one with a turned, machined and the other with an etched surface.

Materials and Methods: In a retrospective cohort study, the included implants followed the criteria: standard surgical protocol, >12 months in situ; minimally rough self-threading implants with a turned, machined surface (Mk IITM [Nobel Biocare AB, Göteborg, Sweden], $n = 210$); etched implants of the same macrodesign (3iTM [Implant Innovations Inc., Palm Beach Gardens, FL, USA], $n = 151$), length ≥ 10 mm. Clinical data and implant success were rated. Resonance frequency analysis (RFA) and Periotest[®] (Siemens AG, Bensheim, Germany) were measured and related to the corresponding implant survival rate in the respective group.

Results: The total number of implants was 361, of which 264 (73%) were subject to clinical reexamination. RFA and Periotest could be recorded in 25% of the implants. Neither clinically relevant nor statistically significant differences between the surface designs were found in the RFA (64 ± 8.6 vs 63 ± 9.7), in Periotest (-2 ± 3.3 vs -1 ± 5.1), and in mean survival periods (49 months, 95% confidence interval [CI]: 46–51 months, for the turned vs 46 months, 95% CI: 43–49 months, for the double-etched implant). After osteoplastic procedures, a significantly higher rate of implant losses in the turned, machined implant group was observed (17 vs 1) with a mean survival period of 43 (40–46) months for the turned and 46 (45–48) months for the double-etched implants.

Conclusion: No difference between implants with two different minimally rough surfaces was found. A positive effect of surface roughness is observed in poor quality bone, but the pivotal proof of this effect is still lacking.

KEY WORDS: clinical study, dental implant, resonance frequency analysis, success, surface

The use of dental implants has shown reliable long-term success rates when integrated into bone of good quality of healthy patients.^{1,2} Even minimally rough implants (turned surfaces) showed good and predictable

long-term results under these indications.³ In compromised bone (irradiated tumors, bone augmentation, softened bone), the requirements for the interaction of implants and biosystem increase.^{2,4} For critical bone situations in augmented or softened bone, moderately rough surfaces are recommended.¹ Comparative studies of the in vivo effect of surface modifications are only rarely found.³ In a patient study with unloaded turned and blasted implants, more intensive bone-implant contacts with the latter implants were found.⁵ Interestingly, this difference was found only in the mandible (after 3 months of healing), but not in the maxilla (after 6 months of healing). This emphasizes the experience from animal models, where (after a longer healing period) the differences between modern, moderately rough surfaces and their older counterparts had leveled off.⁴

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The possible advantage of moderately rough implants in animal models may predict a higher success rate of these implants in clinical studies. In a randomized clinical study in (uncritical) edentulous mandibular bone after 3 years, no difference between the survival rate of minimally rough self-tapping implants versus rough titanium plasma sprayed (TPS) coated nonself-tapping implants was found.⁶ This supports the hypothesis that in the case of favorable bone quality, the implant surface roughness plays a minor role.⁷⁻⁹ In a comparative study between minimally rough, turned and moderately rough (titanium oxide) blasted implants in the edentulous maxilla and mandible, significantly higher success rates for the rougher implants (95 vs 99%) were found.¹⁰ Furthermore, a positive influence of moderately rough surfaces to early loading concepts is suggested by many groups.^{5,11,12} Yet, it is unclear which type of surface modifications enhance the success rate in a clinical situation.¹³ An influence of the microtopography, as a result of different surface treatment, is assumed, but has not been proven in vivo so far clinically.^{14,15}

The aim of this study was to compare the clinical results of two macroscopically identical implants with a minimally rough surface but different topography in a retrospective cohort design. Long-term implant success is the main outcome variable for implant evaluation. However, because of the generally high rates of success and low numbers of implant losses ("events"), data of

clinical studies often reflect the situation of no longer marketed implants.

MATERIALS AND METHODS

In a retrospective cohort study, the survival rates of two minimally rough implants all inserted at the same clinical center were studied. The primary outcome criterion was the success rate of the implants according to Albrektsson and colleagues¹⁶ in the 2- to 4-year follow-up period. Secondary outcome criteria were implant stability (resonance frequency analysis [RFA] and Periotest® [Siemens AG, Bensheim, Germany]), patient satisfaction, and soft tissue parameters (probing depth, bleeding on probing). The inclusion criteria were: patients who had received a Nobel Biocare AB (Göteborg, Sweden) Mk II™ implant or a 3i™ (Implant Innovations Inc., Palm Beach Gardens, FL, USA) Osseotite® implant of a diameter of 3.75 mm and a length ≥ 10 mm (Figure 1) in the time period between 1998 and 2000 at the Oral and Maxillofacial Surgery Unit of the Medical Faculty of the J. Gutenberg University in Mainz, Germany. No other inclusion or exclusion criteria were applied. Both implants have an identical self-tapping screw design and an identical external hex for connection to the suprastructure. Every implant was rated as standing in original bone only or in an osteoplasty.

Patients were all examined by the same clinical observer (U.H.). Demographic and anamnestic data (eg, smoking and parafunctions) were recorded by an

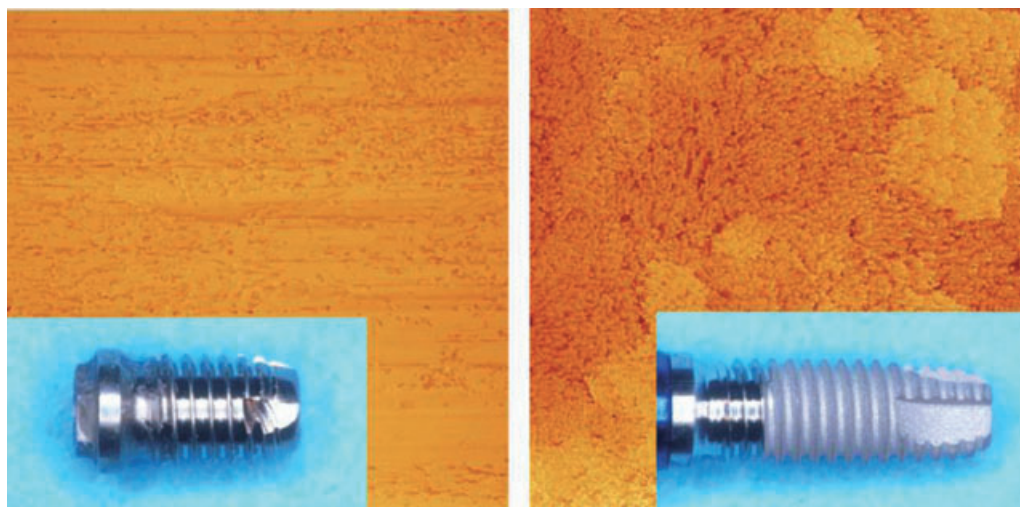


Figure 1 Photographs of the implant and confocal laser scanning microscope surface images of the turned, machined and etched implant surfaces (250 × 250 μm).

independent investigator. The patient's subjective satisfaction with the treatment outcome was recorded on a visual analogue scale. For each implant, a modified plaque index¹⁷ and the bleeding index were recorded. Probing depth was assessed by means of a Plast-O-Probe® (Dentsply, Konstanz, Germany). The vestibular dimension of the fixed mucosa was recorded as well. If possible, the suprastructure was removed, and implant mobility was tested with two opposing instruments and rated as "existing" or "absent" (<0.2 mm horizontal movement) by the clinical investigator.¹⁸

For the quantitative evaluation of implant stability, RFA was recorded with the Osstell™ device (Integration Diagnostics AB, Göteborg, Sweden). Both implant types were measured with the same transducer. The Periotest was recorded three times and the replicates' median value was documented. Orthopantomographic X-ray images were used for calculation of radiological bone loss and the respective success criterion.¹⁹ The primary outcome criterion was implant success ("yes"/"no") according to the criteria of Albrektsson and colleagues,¹⁶ which was recorded together with the respective implant's survival time or time to loss.

The patient's data were analyzed according to their scale level: categorical end points' distributions were described by appropriate relative frequencies, continuous end points' distributions by means, standard deviations, medians, and quartiles (graphically by nonparametric box plots, accordingly). Time-to-event data were numerically and graphically analyzed by means of Kaplan/Meier survival time estimates. The latter are a standard method to take account for notable "lost to follow-up patterns" over a longer recall period: the maximum available time period without implant failure (usually the time period between surgery and last documented routine recall) is analyzed as an information of implant success during this period. Loss to follow up can then be integrated into the resulting Kaplan/Meier estimates in terms of censoring information.

A corresponding multivariate analysis of the primary study hypothesis of different survival period distributions for the two implant designs under consideration was performed by fitting a multiple Cox regression model, which was adjusted for the patients' smoking habits and the implants' bone bed type as putative confounders. The results of this regression model (constituted via forward selection) were summarized by

p values of likelihood ratio (LR) tests and hazard ratio estimates (with corresponding 95% confidence intervals [CIs]) to characterize the association of the mentioned risk factors with the implants' event-free survival periods. Bearing the retrospective cohort design in mind, multiple testing adjustment of *p* values and CIs was omitted.

Within an extensive exploratory analysis, the risk factor's association with the time to event outcome was estimated in different subsamples (eg, smokers/nonsmokers), respectively, by means of univariate Cox regressions.

The above analyses were applied to the data set of all available implants (ie, more than one implant per patient for some of the study individuals). In terms of a sensitivity analysis, this implant-based evaluation was repeated on a patient-based data set; the latter was deemed necessary to quantify the possible effect of accumulation of increased implant losses in few patients with multiple implants.

All numerical and graphical evaluations were done using the SPSS® software (release 10.0 for Windows®) (SPSS Inc., Chicago, IL, USA).

RESULTS

The total number of patients fulfilling the inclusion criteria was 118 with a mean age of 51 ± 17 years, of which 60% were female. Seventy-eight (67%) of the patients were supplied with Mk II implants, 39 (33%) with 3i implants, and 83 patients (74%) were available for at least one clinical follow-up examination. Five patients had died. The remaining 30 patients were under regular recall, but seen at later time points and therefore not included in this evaluation.

Seventeen of the 83 patients, which were clinically examined, reported themselves as smokers (>10 cigarettes/day). Thirty-seven (44%) did not receive an osteoplastic procedure in relation to implant insertion; 24 (29%) had a bony reconstruction using autologous iliac crest, and 22 (26%) underwent regional osteoplastic procedures. The total number of implants was 361, of which 264 (73%) were subject to clinical reexamination during the study interval. The remaining patients with 97 implants were not available for a personal reexamination. The prosthetic restoration could be removed for Periotest and RFA measurements in 90 implants (25%).

The probing depth as demonstrated in Figure 2 revealed no difference between the two implant types

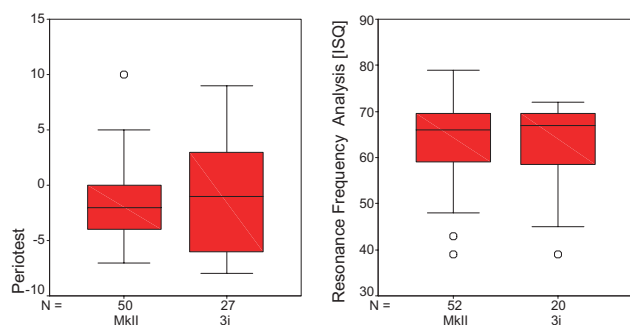
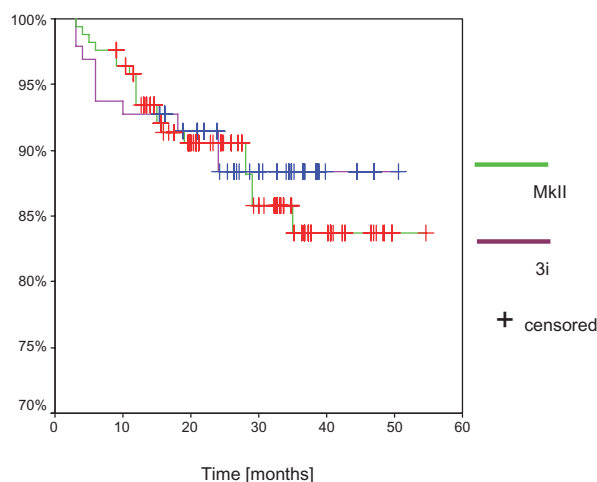


Figure 2 Box plots of Periostest and resonance frequency analysis (RFA) of the implant systems Mk II and 3i (horizontal lines indicate medians and quartiles, while verticals indicate minimum and maximum values; circles indicate statistical outliers). ISQ = implant stability quotient.

($p = .785$) with median values between 2 and 3 mm. Also, the Periostest values suggested no clinically relevant or statistically significant differences between the two implant types ($p = .485$). A similar result was seen for the RFA values ($p = .720$).

Figure 3 shows the survival curves for the two implant type samples. The mean survival periods for the Mk II implants (turned machined surface, 49 months; 95% CI: 46–51 months) and the 3i implants (etched surfaces, 46 months; 95% CI: 43–49 months) did not reveal clinically relevant or statistically significant differences between the implant systems (LR $p = .679$). Both success rates remained over 80%. Unacceptable radiologic bone



months	12	24	36	48
MkII: implant failures / at risk	11 / 152	4 / 90	5 / 36	0 / 7
3i: implant failures / at risk	7 / 89	3 / 57	0 / 33	0 / 1

Figure 3 Kaplan/Meier event free-survival estimate for the success rates of all 3i and Mk II implants (crosses indicate censored observations, which were lost to follow up event free).

TABLE 1 Mean Event-Free Survival Times and Corresponding 95% Confidence Intervals (CIs) Stratified for the Implant's Surface Roughness, Its Type of Bone Bed, and the Patient's Smoking Habits; p Values of Likelihood Ratio (LR) Tests and Hazard Ratio Estimates (with Corresponding 95% CIs) to Summarize the Association of These Risk Factors with the Event-Free Survival Times Were Derived by Multiple Cox Regressions

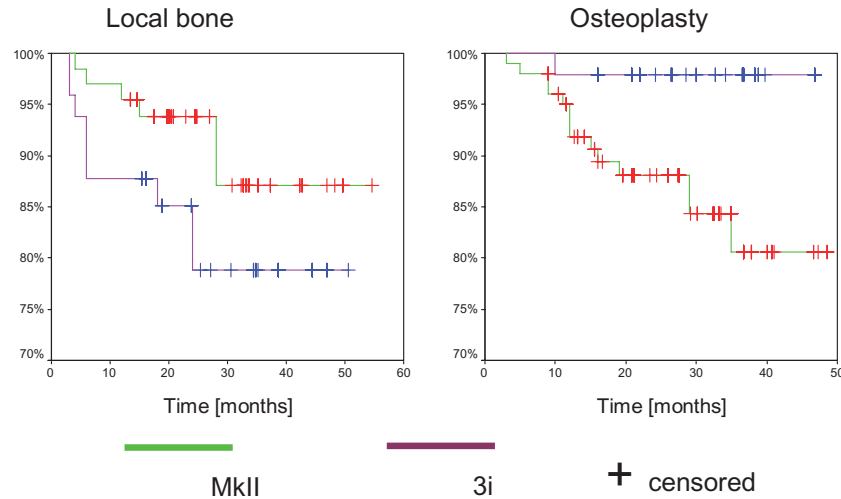
Risk Factor	No	Yes	Hazard Ratio (95% CI)
			p (LR Test)
Etched surface	49 (46–51)	46 (43–49)	0.7 (0.3–1.5) $p = .685$
Smoker	50 (49–52)	39 (36–43)	2.6 (1.2–5.3) $p = .017$
Osteoplasty	48 (45–51)	45 (43–46)	0.8 (0.4–1.4) $p = .432$

loss was found in 3/238 (1%) and 0/87 Mk II and 3i implants, respectively.

The multivariate analysis of the explanatory variables “surface roughness,” “osteoplastic procedure,” and “smoking” are summarized in Table 1. In this analysis, only smoking showed a statistically significant association with implant survival (LR $p = .013$).

In terms of a sensitivity analysis, the previous implant-based analysis was repeated on a patient-based data set; the latter was deemed necessary to quantify the possible effect of accumulation of increased implant losses in few patients with multiple implants: in 7 out of 37 patients without osteoplastic procedures, and in 9 out of 46 with osteoplastic procedures, the event of “at least one implant loss” was observed (LR $p = .584$). In 9 out of 66 (14%) nonsmokers, and in 7 out of 17 smokers, the latter event occurred (LR $p = .017$). The total of 16 out of 61 (26%) patients with Mk II implants, and 4 of 23 (17%) patients with 3i implants showed any minor or severe complication (implant loss, loosening of suprastructure, screw loosening); there was no statistically significant difference between the implant systems' complication profiles (LR $p = .294$).

During exploratory stratification of the total sample into “smokers” and “nonsmokers,” no differences in survival times between the two implant systems were found (Figure 4). Despite the putatively higher risk for “smokers,” no implant-related losses were found



months	12	24	36	48
local bone				
MkII: implant failures / at risk	3 / 64	1 / 33	2 / 14	0 / 5
3i: implant failures / at risk	6 / 43	0 / 25	0 / 15	0 / 1
osteoplastic procedure				
MkII: implant failures / at risk	8 / 86	3 / 55	3 / 22	0 / 2
3i: implant failures / at risk	1 / 46	0 / 32	0 / 18	0 / 5

Figure 4 Kaplan/Meier event free-survival estimate for the success rates of all 3i and Mk II implants (crosses indicate censored observations, which were lost to follow up event free) stratified for the type of bone bed.

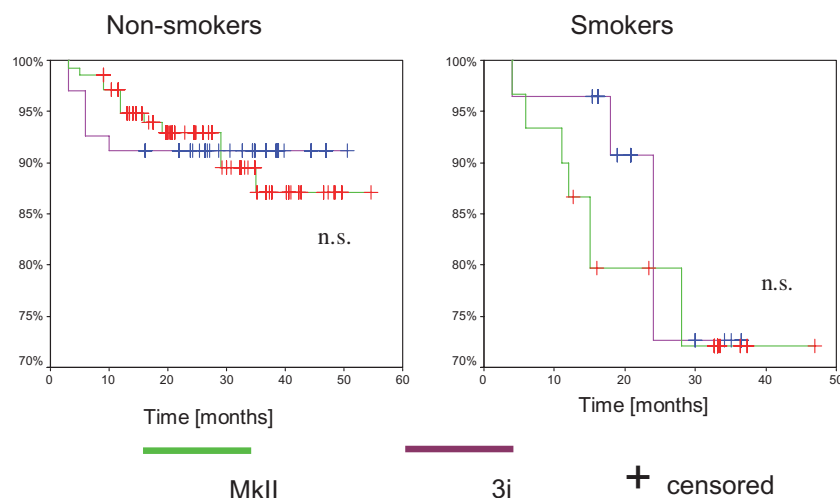
($p = .510$ and $p = .875$) (Table 2). The survival curves stratified for the cofactor “osteoplastic procedures” are displayed in Figure 5: a higher number of implants were inserted into transplanted bone than into local bone. Only in transplanted bone, an increased survival rate of etched implants was found (see Table 2).

DISCUSSION

The clinical data of two implant systems with similar macrostructure, but different surface, were examined in this retrospective cohort study. The functional parameters as well as the success rates did not suggest clinically

TABLE 2 Mean Event-Free Survival Times and Corresponding 95% Confidence Intervals (CIs) for Implant Cohorts Mk II and 3i, Stratified for the Implant's Type of Bone Bed and the Patient's Smoking Habits; p Values of Likelihood Ratio (LR) Tests to Summarize the Association of Implant Design with the Event-Free Survival Times in the Respective Subsamples (Local Bone/Osteoplasty and Smokers/Nonsmokers) Were Derived by Univariate Cox Regressions on Subsamples

Mean Survival Rates (95% CI)	Mk II	3i	p (LR Test)
Implants in local bone ($n = 116$)	50 (47–54)	42 (38–47)	$p = .159$
Implants in osteoplasty ($n = 149$)	43 (40–46)	46 (45–48)	$p = .048$
Implants in nonsmokers ($n = 207$)	50 (48–53)	47 (44–50)	$p = .875$
Implants in smokers ($n = 58$)	38 (33–44)	32 (28–36)	$p = .510$



months	12	24	36	48
non-smokers				
MkII: implant failures / at risk	7 / 124	2 / 69	3 / 33	0 / 7
3i: implant failures / at risk	6 / 62	0 / 49	0 / 33	0 / 1
smokers				
MkII: implant failures / at risk	4 / 26	2 / 21	2 / 3	0 / 0
3i: implant failures / at risk	1 / 27	3 / 8	0 / 0	0 / 0

Figure 5 Kaplan/Meier event free-survival estimate for the success rates of all 3i and Mk II implants (crosses indicate censored observations, which were lost to follow up event free) stratified for the patient's smoking habits.

relevant or statistically significant difference between the two implant systems under consideration. It should be kept in mind that not all implants are seen for follow up in this study. Theoretically, this might have altered the results.

Only a few comparative studies between different implant systems are found in the literature.^{6,8,9,20–22} The study with the longest recall time²² also showed no difference between TPS screw implants and ablative structured screw implants. Similarly, studies comparing turned with TPS implants,⁶ titanium-oxide blasted,²⁰ and aluminum oxide-blasted implants²¹ were not able to show differences between the implant systems. It should be noted that most prospective studies are lacking statistical power, if a 5% difference in survival rates is assumed as clinically relevant. All mentioned publications are lacking from explicit statistical power or sample size calculations. It should also be noted that most of the study samples rather consist of high-quality bone (lower jaw) with high success rates for all implant

systems. This clinical situation is changing in soft quality bone with success rates for turned, minimally rough implants lowering down to 70%.^{23–26}

Comparative studies of different implant systems in critical bone quality are rarely found.²⁷ The results of single samples as well as the results of our study in transplanted bone indicate advantages of rougher surfaces in these situations,^{8,9} but are lacking from randomization designs. However, the rapidly progressing market situation with a trend to moderately rough surfaces will rather inhibit the pivotal (ie, controlled randomized) proof of the postulated advantage of moderately rough implant surfaces in poor quality bone.⁷

The critical effect of smoking on the long-term success of implants is discussed in controversy,²⁸ but was confirmed in a prospective study in a large collective.^{29,30} Accordingly, smokers are excluded in some studies with early loading protocols.^{31,32} On the basis of our data, one may corroborate the increased risk of implant failure for smokers. Interestingly, and in contrast to the bone

quality, no difference between implants with different surfaces was observed. However, the limited statistical power (64%) of the investigation at hand and the dominantly confounding impact of smoking habits might have masked such an effect. However, bearing the results in mind, the hypothesis of etched implants being able to prevent implant loss in smokers seems to be questionable.

In conclusion, no difference between implants with two different minimally rough surfaces was found in the total sample. With respect to the literature, the clinical effect of implant surfaces on the long-term success seems to play a minor role. A positive effect of surface roughness is observed in poor quality bone, but the pivotal proof of this effect is still lacking.

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