Purpose: To compare the onset of peri-implantitis, incidence of failure, and peri-implant marginal bone level changes between implants with a roughened surface and those with a machined/turned surface. Materials and Methods: All patients needing two dental implants of the same size on the left and right sides of the same arch, and not scheduled for immediate loading, were enrolled between October 2012 and February 2016. The patients were randomly allocated either to Nobel Biocare MkIII or Sweden & Martina Outlink 2. Rough-surface implants and machined-surface implants were used from each company. After the preparation of two identical implant sites, each implant (rough or machined of the same group) was randomly allocated to the right and left sides of the same patient, following a split-mouth design. Outcome measures were peri-implantitis onset, incidence of failure, and peri-implant marginal bone level changes. Patients were followed up for 3 years after loading. Results: One hundred fourteen patients were enrolled and treated; nine patients dropped out. Following an intent-to-treat analysis to avoid overestimation, proportions are given related to the initial number of 114 patients. Peri-implantitis incidence was 4.39% for machined implants (5/114), 0.88% for rough implants (1/114), 1.75% in the Nobel Biocare group (2 cases), and 3.51% in the Sweden & Martina group (4 cases). The failure rate was 1.75% in machined implants (2/114), 0.88% in rough implants (1/114), 0.98% in the Nobel Biocare group (1/114), and 1.85% in the Sweden & Martina group (1/114). No statistically significant differences in marginal bone loss were found comparing different surfaces, while marginal bone loss was significantly lower in Nobel Biocare than in Sweden & Martina implants. Conclusion: Based on the results of this study, no significant differences can be demonstrated in either peri-implantitis or failure rate or in marginal bone loss between rough and machined implants. Marginal bone loss was significantly worse in Nobel Biocare implants compared with the original Brånemark protocol.6 However, few preclinical studies failed to demonstrate such a difference, since they demonstrated similar BIC and removal torque rates for different implant surfaces, including the machined ones.7,8 Another recent study with assessments using electron microscopy reported no differences in the BIC rates between the machined implants and those with oxidized rough surfaces 3 months after surgery.9

In fact, the difference in BIC rates seems to decrease over time, and the difference between the two surfaces in terms of osseointegration seems to be significant in the earlier months. This might suggest that semi-rough implants could be more advantageous in the initial phases of osseointegration.
period, leading to faster osseointegration, with the incidence of peri-implantitis after osseointegration being similar to that of smooth-surface implants. Moreover, comparative clinical studies have not led to unanimous results. Some studies record a difference in the success rate or in complications such as peri-implantitis between rough and smooth surfaces, while others fail to point out any difference. A few in vitro studies demonstrated that bacterial biofilms are more likely to stick to rough surfaces than to machined ones. Some authors particularly recommended polishing any rough threads that could arise in the mouth due to gingival retraction.

If machined implants are proven to show less tendency for peri-implantitis, a careful balance between the possibility of early implant loading and the chance of using a surface involving lower risks for complications could be an advantage in the long term, even if they were lower performing histologically.

Moreover, as mentioned above, implants that are smooth toward the coronal portion of the implant surface and microrough underneath could present a blend of the advantages of both surfaces.

The aim of this study was to investigate the difference in failure rate, peri-implantitis occurrence rate, and marginal bone loss between the machined implants and roughened implants in order to verify the weak evidence reported by the quoted systematic review, using a high-power sample size. Furthermore, this study aimed to test the reliability of implants with a turned machined surface in the first three threads of the implant and that of a roughened surface in the deeper part of the implant.

MATERIALS AND METHODS

This trial was reported according to the Consolidated Standard of Reporting Trials Statement (http://www.consort-statement.org/). All the procedures were approved by the Ethics Committee of Cuneo Hospital (approval date 19/04/2013) and carried out in compliance with the ethical principles for medical research involving human participants as stated in the Declaration of Helsinki.

This trial was designed as a double-blind randomized controlled trial with a split-mouth design, and it was conducted between October 2012 and February 2016 in a private practice in northern Italy.

All consecutive healthy patients who needed same-sized implants on both the right and left sides of the same arch and not scheduled for immediate loading or postextractive placement were considered eligible.

The exclusion criteria were as follows: clinically significant medical history (eg, systemic infective disease, heart and vascular disease, liver disease, hematologic disease, coagulation deficiency, diabetes, or neoplastic disease); immunosuppressed or immunocompromised status; history of radiotherapy to the head and neck area; need for bone augmentation procedures for implant placement; allergy to penicillin; ongoing antibiotic treatment for any reason; uncontrolled periodontitis (full-mouth bleeding score > 15 or full-mouth plaque score > 15); treated or under treatment with intravenous amino-bisphosphonates; and pregnant or lactating women.

All patients were informed about the clinical trial, and informed consent was obtained before enrollment. The included patients were randomly allocated to either the Nobel Biocare implant group or Sweden & Martina implant group via a computer-generated list. Patients in the Nobel Biocare group received two MkIII cylindrical implants (Nobel Biocare): one with a microrough surface obtained by an anodizing process causing its oxidation (TiUnite), categorized as a rough-surface implant, and the other with a machined surface. The latter has been used in case-control studies as a reliable control surface.

Patients in the Sweden & Martina group received two Outlink2 cylindrical implants (Sweden & Martina): one with a complete microroughened surface obtained by titanium-oxide-particle sandblasting following by acid processing (ZirTi), categorized as a rough-surface implant, and the other with a hybrid surface, categorized in the general analysis as a machined-surface implant; in the last implant type, the three top-most coronal threads were machined, while the others were roughened through plasma-spray titanium coating (Fig 1). All the operators involved in the surgical procedure were blinded to this randomization phase.

A second randomization step was needed to decide whether the rough implant had to be placed in the right or left side of the arch. The same operator, not involved in the surgical procedure, prepared two opaque envelopes with a sheet reporting “machined” or “rough” before the surgery. Once the envelopes were sealed, another blinded operator marked them as “right” or “left.”

The size of the implants, which was the same for the two implants in the same patient, was decided a week before the surgery based on the CBCT images.

All patients were informed about the surgical procedures, postoperative follow-ups, and potential complications, and informed consent was obtained 7 days before surgery.

One hour prior to implant placement, patients consumed a single antibiotic dose consisting of 2 g of amoxicillin orally (2 tablets of 1 g each) at the clinic, as well as 10 drops of ketoraloc. Patients rinsed their mouth for 1 minute, immediately before implant placement, with 0.2% chlorhexidine gluconate mouthwash.
After local anesthesia was administered (1:100,000 articaine plus adrenaline), a bilateral mucoperiosteal flap was elevated, and both implant sockets were prepared by the blinded surgeon (F.T.). The surgeon became aware of the implant type to be placed in each site only after socket preparation. Implants were placed with the connection at the bone level, and covered by suturing the flap with a 4-0 synthetic monofilament wire (Monomyd, Butterfly). The second surgical step was performed 2 months later.

Postoperative instructions included ice-pack application and administration of 10 drops of ketorolac, followed by a nonsteroidal anti-inflammatory drug 8 hours after surgery, which was continued for a few days if needed. Patients were also instructed to rinse with 0.12% chlorhexidine gluconate twice daily for 15 days following surgery and refrain from brushing the area of surgery for 2 weeks.

Follow-up visits were conducted at 1 week (suture removal) and 1 month after surgery. Eight weeks after surgery, stage two of the surgery was performed, implant stability was assessed, the first periapical radiologic examination was conducted, and impressions were obtained. Implants were loaded 2 weeks later and followed up for 3 years after loading. Every 6 months, the probing depths were recorded, and periapical radiologic examinations were acquired as part of an oral hygiene program.

The primary outcome measure was as follows:

- Implant failures (defined as implant mobility or implant removal due to pain or infection) assessed before or after prosthetic loading.
- Peri-implant marginal bone level changes, assessed on periapical radiographs obtained using the parallel technique during the stage-two surgery and every 6 months until 3 years after loading. A blind examiner (S.S.) measured the peri-implant marginal bone level on digital radiographs (VistaScan, Dürr Dental) using the DBSWIN software (Dürr Dental).

Sample Size
The sample size dimension of patients available was verified to be adequate to reach sufficient statistical power for bone reabsorption analysis (effect size = 0.029, $\alpha = .05$, power = 0.80; G*Power software, version 3.1). For peri-implantitis and implant failure, descriptive results are provided.

Statistical Analyses
To describe the differences in peri-implantitis and implant failure for the implants of the two different types (machined-surface and rough-surface) and models (Nobel Biocare and Sweden & Martina), the results were expressed as percentages, and the odds ratios were subsequently calculated.

Furthermore, after testing for parametricity of data, a multivariate generalized linear model was used to analyze differences in bone reabsorption (marginal bone loss) at the distal and mesial sides. Finally, to compare the different combinations of type and model, a one-way analysis of variance (ANOVA) followed by Sidak post hoc was used (SPSS Software, version 22).

RESULTS
Between October 2012 and February 2016, 116 patients were selected, of whom two refused to participate in the study. Finally, 114 patients were enrolled, randomized, and treated. The follow-up period focused on the time
between implant placement and 3 years after prosthetic loading. No deviations from the operative protocol occurred. Nine patients dropped out during the follow-up period; hence, data from 105 patients were used for statistical analyses. Figure 2 shows the flow diagram representing the patients’ enrollment and selection.

The patients and treatment characteristics are described in Table 1; 228 implants were placed, 114 in the Nobel Biocare group (57 machined and 57 rough) and 114 in the Sweden & Martina group (57 hybrid with three coronal machined threads, and 57 rough; Table 1). The split-mouth study design allows comparison of populations with an identical distribution of confounding factors; the case implant and the control are placed in the same patient, one on the right and one on the left side in the same arch.

Nine patients dropped out (n = 6 in Nobel Biocare group, n = 3 in Sweden & Martina), two for economic reasons and six for personal reasons, while one patient died during the follow-up period.

The results from descriptive statistics for the primary outcome measure are reported in Table 2 and illustrated in Fig 3.

**Primary Outcome**

Peri-implantitis was noted in 6 out of 114 patients (incidence = 5.26%) and 228 implants (incidence = 2.63%). Five peri-implantitis cases occurred in machined implants (4.39%), while one occurred in rough implants (0.88%), with an odds ratio = 5.183.

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**Table 1 Sample Characteristics**

<table>
<thead>
<tr>
<th>Sample Characteristics</th>
<th>Nobel Biocare</th>
<th>Sweden &amp; Martina</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>57</td>
<td>57</td>
</tr>
<tr>
<td>Implants</td>
<td>114</td>
<td>114</td>
</tr>
<tr>
<td>No. of dropouts</td>
<td>6</td>
<td>3</td>
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<tr>
<td>Implant failure</td>
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<td>2</td>
</tr>
<tr>
<td>Peri-implantitis</td>
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<td>4</td>
</tr>
<tr>
<td>Male</td>
<td>30</td>
<td>36</td>
</tr>
<tr>
<td>Female</td>
<td>27</td>
<td>21</td>
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<tr>
<td>Age (y)</td>
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<tr>
<td>Mandibular implants</td>
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<td>102</td>
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<td>Maxillary implants</td>
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<td>12</td>
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<tr>
<td>Smokers</td>
<td>7</td>
<td>11</td>
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</table>
Considering the different companies, the six peri-implantitis cases were grouped as follows: 2 in Nobel Biocare implants (incidence = 1.75%) and four in Sweden & Martina implants (3.51%), with an odds ratio of 2.036 (Sweden & Martina vs Nobel Biocare).

Secondary Outcomes

Three failures occurred in the whole sample (overall survival rate at implant level: 98.68%). Two patients were involved with failures: one patient in the Nobel Biocare group lost one implant, and one patient in the Sweden & Martina group lost two implants; thus, the total survival rate at patient level was 98.25%.

Two failures occurred in 114 machined implants (failure rate = 1.75%), and one occurred in 114 rough implants (failure rate = 0.88%), with an odds ratio of 2.018.

Considering the difference in the failure rate between the two manufacturing companies, the percentage of implants demonstrating failure was 0.88% (1/114) in the Nobel Biocare group and 1.75% (2/114) in the Sweden & Martina group, with an odds ratio of 2.018 (Table 3). Further details about the distribution of peri-implantitis and failures in the different subgroups are reported in Table 4. All failures occurred before prosthetic loading.

No significant difference was found in marginal bone loss between machined implants (distal side: mean = –1.572, standard deviation [SD] = 0.966; mesial side: mean = –1.556, SD = 0.856) and rough implants (distal side: mean = –1.314, SD = 0.876; mesial side: mean = –1316, SD = 0.839; F1,203 = 2.133, P = .121). Instead, comparing the two companies, a significant difference emerged. At the distal side level, Nobel Biocare implants (mean = –1.268, SD = 0.808) and Sweden & Martina implants were significantly different (F1,204 = 7.493, P = .007, partial η2 = 0.036). The same was noted at the mesial side: Nobel Biocare implants (mean = –1.276, SD = 0.779) and Sweden & Martina implants (mean = –1.595, SD = 0.893) differed in a significant manner (F1,202 = 7.406, P = .007, partial η2 = 0.035; Fig 4).

Table 2  Peri-implantitis in Machined and Roughened Implants at Implant Level

<table>
<thead>
<tr>
<th></th>
<th>No. of peri-implantitis</th>
<th>% of peri-implantitis</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machined</td>
<td>5 in 114</td>
<td>4.39</td>
<td>5.183</td>
</tr>
<tr>
<td>Rough</td>
<td>1 in 114</td>
<td>0.88</td>
<td>0.193</td>
</tr>
</tbody>
</table>

Table 3  Implant Failures in Machined and Roughened Implants at Implant Level

<table>
<thead>
<tr>
<th></th>
<th>No. of implant failure</th>
<th>% of implant failure</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machined</td>
<td>2 in 114</td>
<td>1.75</td>
<td>2.018</td>
</tr>
<tr>
<td>Rough</td>
<td>1 in 114</td>
<td>0.88</td>
<td>0.496</td>
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</table>

Table 4  Peri-implantitis and Implant Failure Distribution in the Different Subgroups

<table>
<thead>
<tr>
<th></th>
<th>No. of peri-implantitis</th>
<th>No. of implant failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobel Machined</td>
<td>2 in 57</td>
<td>1 vs 57</td>
</tr>
<tr>
<td>Nobel Rough</td>
<td>0 in 57</td>
<td>0 vs 57</td>
</tr>
<tr>
<td>Sweden Machined</td>
<td>3 in 57</td>
<td>1 vs 57</td>
</tr>
<tr>
<td>Sweden Rough</td>
<td>1 vs 57</td>
<td>1 vs 57</td>
</tr>
</tbody>
</table>
Fig 4  (top) Bone loss in machined and rough implant groups on the distal and mesial side (generalized linear multivariate model, Sidak post hoc [nonsignificant for both distal and mesial sides]). (bottom) Bone loss in Nobel Biocare and Sweden & Martina on the distal and mesial side (generalized linear multivariate model, Sidak post hoc \( P = .007 \) for both distal and mesial sides).

Fig 5  Bone loss at (a) distal and (b) mesial sides for the different combinations of model (Nobel Biocare and Sweden & Martina) and kinds of implants (machined and rough; generalized linear multivariate model, Sidak post hoc [rough Nobel Biocare vs machined Sweden & Martina; \( P = .005 \)).
minor bone resorption, and machined Sweden & Martina (distal side: difference = -0.601, SE = 0.178; P = .005, CI 50%: -1.074; -0.128; mesial side: difference = -0.554, SE = 0.164; P = .005, CI 50%: -0.989; -0.119).

DISCUSSION

This trial was designed to contribute to the evidence on whether machined-surface implants could be less prone to developing peri-implantitis compared with rough-surface implants. Available data on this topic have been derived from trials with a high risk of bias, with few participants and relatively short follow-up periods.1 This study was based on a split-mouth design, with an aim to compare machined and rough implants of two different models. A 3-year follow-up evaluation was performed to reduce the risk of bias, providing high-quality data for future meta-analysis. Considering the data reported by the only available systematic review on this topic, the sample reached by this study can be considered quite large; the four articles considered in the meta-analysis reported data from 144 patients, whereas 114 patients were treated in the present single study. High statistical power (0.80) was reached considering bone resorption analysis. For peri-implantitis and failure analysis, the sample was not powerful enough, and descriptive data are provided.

The split-mouth design is a good way to eliminate the influence of confounding factors, since the test and control samples are identical in this design. The authors used implants of two different companies to reduce the influence of the single implant model and of the particular surface treatment on the results. The medium-term follow-up data (3 years) must be considered preliminary. Patients in this trial have been maintained under follow-up, and long-term data will be published if possible.

All recorded failures occurred before implant loading; hence, they were classified as early failures. In the present study, no differences can be described in the early failures between Nobel Biocare and Sweden & Martina implants and between the machined- and rough-surface implants.

The aforementioned systematic review1 showed that machined implants had a 20% reduction in the risk of being affected by peri-implantitis compared with rough implants (risk ratio 0.80; 95% CI: 0.67 to 0.96), including in the meta-analysis cases from four articles,24–27 which together provided the data of 144 patients. By contrast, the present study could not demonstrate such a difference despite the similar sample numerosity (114 patients were treated in the single present study) and the same follow-up period. On the contrary, in this study, machined implants show a strong tendency to undergo peri-implantitis more frequently than roughened ones.

Based on the starting hypothesis of a lower risk of peri-implantitis occurrence in turned-surface implants and the reported evidence of better and faster osseointegration in rough-surface implants discussed in the introduction, this study aimed to verify the use of hybrid implants with the coronal-most threads machined and the apical-most ones roughened as reported in previous studies.12 This approach could theoretically link the advantage of faster osseointegration and a lower probability of implant infection. The results derived from this study cannot support this kind of suggestion because no advantages were found in cases treated with hybrid Sweden & Martina implants, and no advantages in general were found using machined-surface implants. By contrast, significantly less marginal bone resorption was observed in Nobel Biocare rough-surface implants compared with Sweden & Martina hybrid implants. In this study, the better clinical performance, in terms of bone resorption, was reached by the Nobel Biocare rough-surface implants, whereas the worst was reached by the Sweden & Martina machined (hybrid)–surface implants.

CONCLUSIONS

Up to 3 years after delayed loading, implants with a turned surface seem to show an increase in risk of being affected by peri-implantitis compared with implants with a rough surface. Considering marginal bone resorption and comparing different subgroups, Nobel Biocare rough-surface implants performed significantly better than Sweden & Martina machined-surface implants. Based on the results derived from this study, the use of rough-surface implants can be recommended because they seem to undergo peri-implantitis with lower probability compared with both machined and hybrid implants, and they show less marginal bone resorption.

ACKNOWLEDGMENTS

Sweden & Martina, one of the manufacturers producing the implants used in this study, donated their implants; however, data property belongs to the authors and by no means did I-RES interfere with the conduct of the trial or the publication of its results. The authors reported no conflicts of interest related to this study.

REFERENCES


