

# Oral Implant Surfaces: Part 2—Review Focusing on Clinical Knowledge of Different Surfaces

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**Purpose:** This article reviews clinical knowledge of selected oral implant surfaces.

**Materials and Methods:** The surfaces most commonly used in clinical practice, marketed by the five largest oral implant companies, are identified; their clinical documentation was scrutinized following a strict protocol. Experimental knowledge of the surfaces is briefly summarized. Retrospective, prospective, and comparative clinical studies were analyzed separately, as were studies of implants in conjunction with bone grafts. **Results:** TiUnite anodized surfaces are clinically documented in 1- to 2-year follow-up studies at best, with failures at about 3%. Sandblasted and acid-etched SLA surfaces are documented with good clinical results for up to 3 years. Osseotite dual acid-etched implants are documented with good clinical results for up to 5 years. Frialit-2 sandblasted and etched implants are positively documented for about 3 years in one study only. The Tioblast implant is the only design documented for survival over 10 years of follow-up and success over 7 years of follow-up. **Conclusion:** Generally, oral implants are introduced clinically without adequate clinical documentation. Implant companies initiate clinical documentation after product launch. The standards of clinical reporting have improved over the years. Proper long-term reports have been published for only one surface, Tioblast. *Int J Prosthodont* 2004;17:544–564.

Almost 20 years ago, one of the authors reviewed the clinical results of oral implant systems.<sup>1</sup> Follow-up articles on the state of oral implant systems were published in 1991 and 1997.<sup>2,3</sup> In previous publications, the authors point out the dearth of clinical information about oral implants and the fact that mainly one oral implant system—the Brånemark turned screw (Nobel Biocare)—had been adequately documented. Today, the situation is quite different, as a number of other implants have been adequately documented for a full 5 years.<sup>4–11</sup>

However, many clinically well documented oral implant systems have largely been abandoned for the potential benefit of new, untested devices. Oral implant

companies have continued to launch new products without any clinical documentation. One example is the TiUnite anodized implant (Nobel Biocare), probably the best-selling surface in the world today, launched around 2001 with an almost complete lack of clinical documentation. However, the TiUnite implant is not unique, as a great family of novel designs from different companies are marketed with commercial slogans rather than scientific scrutiny. Clinical documentation seems unimportant to companies, as they can market their products successfully without it. However, one cannot exclude clinical risks every time a new, clinically untested surface is put on the market.

A more critical attitude from the dental community toward new, untested models would seem a step in the right direction. From a scientific standpoint, it is of great importance to continuously follow the clinical documentation of oral implants. There is currently an overemphasis on hardware modification to achieve good clinical results; in reality, greater gain may be seen with improving surgical routines.<sup>12</sup> However, hardware changes to implants may also prove beneficial and improve success rates.

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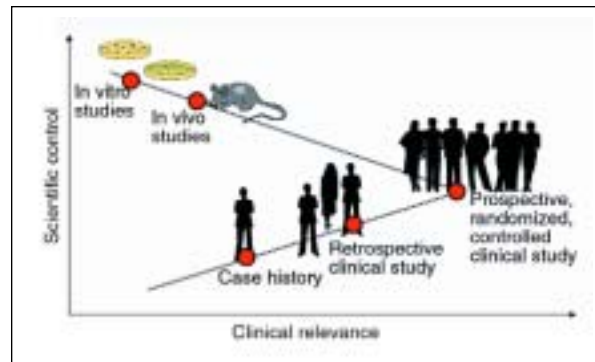
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Today, there are several hundred oral implant systems.<sup>13</sup> Because of this multitude of implants, this review concentrates on published evidence of the “big five,” ie, the most sold oral implant surfaces from five major suppliers: TiUnite, SLA (Straumann), Osseotite (3i), Frialit-2 and Cellplus (Dentsply/Friadent), and Tioblast and Osseospeed (Astra Tech). There are no reliable statistics, but based on collected information from the five companies involved, it is estimated that these surfaces have a joint world market share of 85% to 95% of oral implants. In other words, this review focuses on implants from these companies that are marketed in great numbers today, not on implants that were preferred and well-documented in the past. It is not uncommon to find one particular surface associated with several different implant designs. Implant design is one of the six parameters described by Albrektsson et al<sup>14</sup> as being important for osseointegration. If one particular surface has been well-documented with one particular design, this need not imply that the same good results are to be found with alternative designs.

The aim of this study was to investigate the published clinical evidence of implant surfaces. The attempt was not merely to summarize various published papers. Instead, the authors applied their own strict criteria to each paper; if they did not match the yardstick, it is reported. Having said this, the overall quality of clinical papers has increased compared to previous standards,<sup>15</sup> and further improvement would ensue if clinical studies adhered to a stricter protocol. Eckert et al<sup>16</sup> suggest that all survival/success figures be published with confidence intervals. Clinicians commonly place many hundreds of implants, of which only a few are actually followed for 5 years, and yet publish a 5-year success rate. If such “5-year success rates” were supplemented with confidence intervals, it would be obvious that the uncertainty in the evaluation is great indeed. The present review quotes the shorter term success rate in such cases where many more implants are included; hence, the uncertainty is much smaller.

The authors' yardstick not only refers to the few prospective, randomized controlled studies that exist, but also to studies that were only prospective or even retrospective. In a commercial situation where one implant type replaces another after only a few years, it is difficult to undertake relevant controlled randomized trials, since the compared objects will likely be obsolete when the study is published. Even the simplest case report is, from a clinical perspective, more relevant than most animal and in vitro data (Fig 1).

The authors applied the same approach when different oral implant systems are being scrutinized. A few selected and interesting experimental studies are covered in this section. Clinical studies are divided into categories:



**Fig 1** In vitro and in vivo animal tests are scientifically well controlled but of low clinical relevance. A simple case report is low in scientific control but more clinically relevant than any rat or glass disk.

retrospective studies, prospective studies, comparative studies, and implants in grafted bone. The authors analyzed whether every patient was reported and whether patients were consecutive. In prospective studies, inclusion/exclusion criteria were examined to see whether particularly rigid inclusion criteria were used or, alternatively, if strict exclusion criteria were applied. Prospective studies must include information about all planned recalls and what is to be tested/analyzed then. If no such information is provided, the study is not a true prospective investigation; this is pointed out in cases with an incorrect study design.

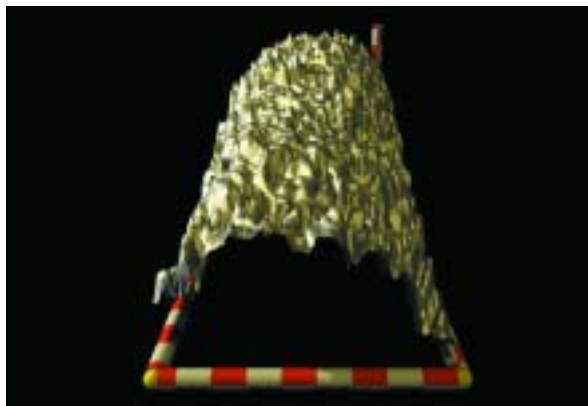
Survival data have been differentiated from success data. The latter include data from bone height measurements ensuring a steady-state situation, reports about complications, and information on implant stability.<sup>1</sup> Dropout figures have been analyzed. The greater the number of dropouts at a given time, the greater is the uncertainty of the reported results. Omission of dropout figures has been criticized. Mean follow-up times from different studies are reported as well. If no comment on the loading time in the studies reviewed is made, it was similar to the old Brånemark protocol, ie, about 3 months in the mandible and 6 months in the maxilla.

The use of life tables presenting cumulative survival or success data is an acceptable statistical method to hypothesize the results for a longer time than all placed implants have actually been followed up. However, simple life tables without any tabled data are useless. For those life tables with better written information, it is not uncommon to present hypotheses of long-term results when, in reality, too few implants have been followed up to allow for any reliable prognosis about the cumulative survival rate at that specific time period. Although seldom done in clinical papers, it is possible<sup>4</sup>



**Fig 2 (left)** TiUnite implant is prepared in a galvanic cell, leading to substantial increase in surface oxide thickness.

**Fig 3 (below)** TiUnite implant is moderately roughened. It must be regarded as unknown whether any other characteristics of the oxidized implant surface play any significant role in its clinical performance (each red and white section of the bars = 10  $\mu$ m).



and strongly recommended to insert additional critical data, such as bone height information, in life tables.

The present information about individual studies was collected from contacts with the five companies involved. To avoid overlooking potentially negative information about the surfaces involved, the following journals were also surveyed, at least since the publication year 1999: *International Journal of Oral & Maxillofacial Implants*, *Clinical Oral Implants Research*, *Clinical Implant Dentistry and Related Research*, *Journal of Periodontology*, *Journal of Prosthetic Dentistry*, and the 1999 to 2001 editions of the German implant journal *ZZI*.

## TiUnite Implants

### Background

The TiUnite surface is anodized, ie, it has been manufactured by electrochemical anodic oxidation in galvanostatic mode, using undisclosed electrolyte(s). Since the implant surface contains phosphorus ions, it seems that some type of phosphoric acid has been used as an electrolyte. This probably indicates that TiUnite surfaces lack bioactivity.<sup>17</sup> The surface has a relatively thin oxide layer (a few hundred nanometers) and is minimally rough (0.5 to 1.0  $\mu$ m) in the upper region, whereas the apical region displays an oxide thickness in the range of more than 10  $\mu$ m and a roughness of more than 2  $\mu$ m ( $S_a$ ). The TiUnite surface is used in combination with various implant designs (Fig 2) and was clinically introduced in 2001. Experimental documentation,<sup>18–21</sup> but no

clinical evidence, was available at the time of its introduction on the market.

Rocchi et al<sup>22</sup> performed a histologic analysis of one immediately loaded TiUnite implant placed in soft bone in the posterior mandible of a female volunteer and left in situ for 9 months. This single implant showed 93.3% bone-to-implant contact (BIC). A total of nine oxidized implants were removed from the posterior mandible in another study.<sup>23</sup> Mean BIC was  $84.2\% \pm 10.5\%$ . Ivanoff et al<sup>24</sup> report much smaller BIC percentages for TiUnite microimplants in place for 3 months in the mandible or 6 months in the maxilla. However, there was significantly greater BIC with the oxidized test implants than with turned controls (Fig 3).

### Published Clinical Studies

*Retrospective studies of TiUnite implants.* Glauser et al<sup>25</sup> placed 16 maxillary and 11 mandibular TiUnite implants in bone of quality 4; 25 of the 27 implants were placed in the posterior region. Although bone quality was poor, bone quantity was generally good, indicated by the fact that only two maxillary implants were less than 10 mm long. No implants were placed in bruxers. No implants were lost. There was a drop in stability during the first month after placement, but thereafter a gain in resonance frequency analysis (RFA). The bone loss at 1 year was  $1.0 \pm 0.7$  mm, and the success rate was 100%.

Calandriello et al<sup>26</sup> present preliminary data on a multicenter study of 50 TiUnite implants followed up for 6 months and 24 implants followed for 1 year; all

implants were placed in the molar region of the posterior mandible. One inclusion criterion was at least 10-mm-long implants, and one exclusion criterion was bruxing patients. No dropouts were reported, and no implant failures were seen. Marginal bone loss was  $1.0 \pm 0.5$  mm at 6 months and  $1.3 \text{ mm} \pm 0.6$  mm for the 24 implants followed up for 1 year. The cumulative survival rate at 6 months was 100%.

*Prospective studies of TiUnite implants.* Glauser et al<sup>27</sup> present a 1-year follow-up prospective study of 38 consecutive patients who received 38 maxillary and 64 mandibular TiUnite implants, 88% of which were placed in the posterior region. Exclusion criteria included parafunctional occlusal habits. Five implants were shorter than 10 mm. No dropouts were reported. Soft bone (grade 4) was diagnosed for 27 implants. Three maxillary implants were removed from one patient because of an infection associated with guided bone regeneration treatment. Bone height measurements gave a mean bone loss of  $1.2 \pm 0.8$  mm for these immediately loaded implants. However, 5 implants displayed more than 3 mm of bone loss, and 1 implant showed more than 1 mm. It could therefore be discussed whether the reported success rate of 97.1% would really be interpreted as a survival percentage.

Vanden Bogaerde et al<sup>28</sup> present the 18-month outcome of 111 TiUnite implants placed in the maxillae ( $n = 69$ ) or posterior mandibles ( $n = 42$ ) of 31 patients. The implants were loaded early (within 16 days of placement). Inclusion criteria were bone height adequate for at least an 8.5-mm-long implant and insertion torque before implant seating to a minimum of 40 Ncm. No information on how many patients were excluded because of failure to match the inclusion criteria was presented. Exclusion criteria included bruxism. Patients were consecutive and subject to informed consent to participate in the study. No patients dropped out. Bone resorption at 18 months was 0.8 mm (standard deviation [SD] 1.0). There was one failure, for an 18-month success rate of 99.1%.

*Comparative studies of TiUnite and turned implants.* Glauser et al<sup>29</sup> present a comparative, but not randomized, study of immediately loaded turned, machined ( $n = 27$ ) and oxidized TiUnite ( $n = 20$ ) implants placed in the posterior maxilla. A modified surgical technique was used to ensure primary stability for all implants. Evaluations were performed with repeated RFA measurements until 6 months after implant placement and loading. Although identical RFA values were recorded at the time of placement, significantly higher RFA values were reported for the oxidized implants until the 6-month evaluation, when the difference was no longer significant. The study suggests that oxidized

implants show less loss of stability during the healing period than turned, machined implants.

Friberg and Billström<sup>30</sup> report the preliminary results of a claimed prospective multicenter study on 584 TiUnite and 58 turned, machined implants. Inclusion/exclusion criteria were not presented. Only 85 implants had been followed up for 1 year. Six patients dropped out, one of whom had died. Failure was observed in two cases. However, only 387 (unknown how many of those that were not oxidized) implants had passed the abutment connection stage, so the presented cumulative survival rate of 99.7% must be interpreted with some caution. No turned implants had failed.

Rocci et al<sup>31</sup> performed a randomized study of 66 immediately loaded TiUnite and 55 turned, machined Brånemark implants. Patients were consecutively treated, with one inclusion criterion being "sufficient primary implant stability," but no information on how many patients were excluded because of this demand was given. There were no patient dropouts. Ten TiUnite and 6 turned, machined implants were shorter than 10 mm. Twelve TiUnite implants (of which 1 failed) and 11 turned implants (of which 5 failed) were placed in grade 4 bone. The total number of failures was 3 TiUnite and 8 turned implants. Mean bone height was 0.9 mm (SD 0.7, maximum 2.3 mm) for TiUnite and 1.0 mm (SD 0.9, maximum 3.25 mm) for turned implants. Cumulative survival rate was 95.5% for TiUnite and 85.5% for turned, machined implants at 1 year of loading.

Olsson et al<sup>32</sup> present a study on 10 patients who received 61 maxillary TiUnite implants, all loaded between 1 and 9 days after placement. Patients were consecutively included in the study, and all were followed up for a total of 1 year. Four implants were lost in 1 patient. The mean marginal bone level was  $1.3 \pm 0.6$  mm at 1 year, and the survival rate was 93.4%.

*TiUnite implants and bone grafts.* Lundgren and Brechter<sup>33</sup> present a preliminary study of 171 TiUnite implants placed in a two-stage procedure in conjunction with various bone augmentation procedures. Of those implants, 123 had been uncovered at the time of the report, and the mean follow-up time was 12 to 21 months. One failure was noted.

## Summary

The longest reported clinical follow-up of the TiUnite surface is 18 months, at which time steady-state bone heights and a 99.1% success rate were reported in one study. Several other studies report results of 93.4% to 100% with this implant surface in combination with direct or early loading and a follow-up time of 6 to 12 months. One randomized study reports 95.5% survival

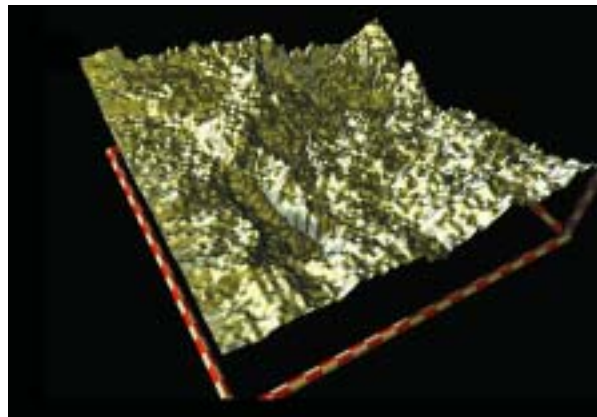
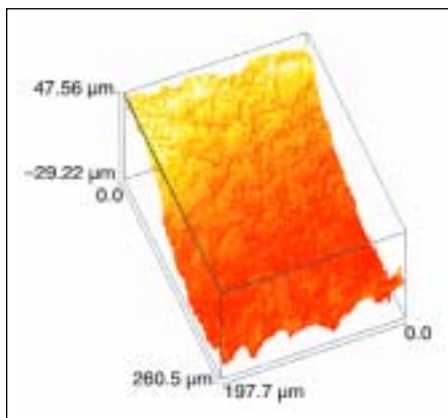




**Fig 4 (left)** SLA implant has been clinically documented for up to 3 years.

**Fig 5a (below left)** SLA implant is moderately roughened. It must be regarded as unknown whether any other characteristics of the SLA implant surface play any role in its clinical performance.

**Fig 5b (below)** Surface roughness of the SLA implant is relatively uniform along the length of the implant, with  $S_a$  of  $1.6 \mu\text{m}$  and Sdr of 68.5% (Sdr is the ratio of the developed surface area; each red and white section of the bars =  $10 \mu\text{m}$ ).



of TiUnite implants in comparison to 85.5% survival for turned, machined implants for a follow-up of 1 year. Another study reports about 99% survival for TiUnite implants used to secure a bone graft.

## SLA Implants

### Background

The SLA implant surface (Figs 4 and 5) is sandblasted and acid etched and was clinically introduced in 1997. Martin et al<sup>34</sup> demonstrated in vitro that alkaline phosphatase activity in osteoblast-like cells is greater on SLA surfaces than on titanium plasma-sprayed (TPS) surfaces. Several experimental studies report stronger bone response to this surface than to a polished surface,

ie, a surface of the roughness of an abutment (Fig 6).<sup>35,36</sup> Cochran et al<sup>37</sup> compared SLA and TPS surfaces in a dog study. The SLA implants had a significantly higher percentage of BIC than the TPS implants after 3 months of healing and later after 12 months of loading (15 months after placement). In terms of bone quality, there were no differences between the two surfaces. Cochran et al<sup>38</sup> report experimental evidence of less bone resorption around SLA implants than around TPS implants.

### Published Clinical Studies

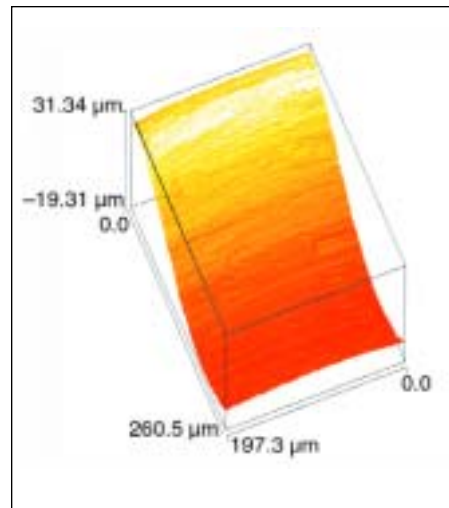
*Retrospective studies of SLA implants.* Rocuzzo and Wilson<sup>39</sup> report the fate of 36 SLA implants placed in the posterior maxilla and loaded after 6 weeks. Only

nonsmoking patients were accepted. The implants were not placed in consecutive patients, but in carefully selected patients who had all consented to be treated according to the study protocol including early loading of maxillary implants. The implant sites were without severe bone resorption, as a minimum of 9 mm in coronal height and 6 mm in buccolingual width were inclusion criteria. Results at 1 year showed 1 failure. There were no dropouts. Mean interproximal bone loss was  $0.55 \pm 0.49$  mm at 1 year of loading.

Levine et al<sup>40</sup> present a retrospective analysis of 675 posterior single-tooth implants, 74 of which were the SLA type. Patients were consecutive, and cumulative survival rates of 99% were reported. No bone height measurements were reported. No patients were reported to have dropped out of the study. It is difficult to separately evaluate the 74 SLA implants; individual loading times were not reported.

*Prospective studies of SLA implants.* Cochran et al<sup>41</sup> report a prospective multicenter trial from six centers that had followed 326 implants for at least 1 year; 138 of these had been followed for up to 2 years. A 6-week loading time was chosen for implants placed in Class I to III bone, whereas a 12-week postponement of loading was allowed for implants placed in Class IV bone. Inclusion criteria included adequate oral hygiene and, when applicable, a negative pregnancy test within 1 week prior to surgery. Exclusion criteria were moderate or heavy smoking and various diseases. Soft tissue parameters and bone height measurements were reported as analyzed, but results will be published first at 3 and 5 years. Therefore, only survival data apply. Two patients with 6 implants dropped out of the study. Three primary failures occurred in the mandible ( $n = 337$ ), whereas none occurred in the maxilla ( $n = 46$ ). Reported implant survival rates were 99% at both 1 and 2 years.

Bornstein et al<sup>42</sup> present a prospective clinical study of 104 SLA implants placed in grade 1 to 3 bone, loaded at 6 weeks, and followed up for 3 years. Heavy smokers were not included in the study. Eighty-nine implants were placed in the posterior mandible, and 15 were placed in the posterior maxilla. The patients had four recalls during the 3-year period after abutment connection. Various soft tissue indices, Periotest (Siemens) evaluation of implant stability, and careful radiographic analyses including bone height evaluations were performed. Criteria for success were presented. One mandibular implant failed during healing. A treatable peri-implant condition was found for 2 implants. One patient with 1 implant dropped out of the study. Periotest measurements indicated implant stability. Mean bone loss was less than 0.2 mm annually, for a 3-year success rate of 99%. This excellent study elicits only one minor comment: Critical readers would have liked more infor-



**Fig 6** Machined version of the SLA implant is used for animal experiments. However, the surface topography of this implant is much smoother than any surface ever applied for oral implants.

mation about the few implants that showed the greatest bone loss to enable evaluation of a potential steady-state bone height for these implants. However, the maximum bone loss of individual implants was reported.

*Comparative studies of SLA and TPS implants.* Rocuzzo et al<sup>43</sup> report 1-year clinical results of 68 SLA and 68 older TPS implants in a split-mouth, randomized controlled study. The SLA implants were loaded at 6 weeks, in comparison to a 12-week loading delay for the TPS implants. Exclusion criteria included excessive smoking. Soft tissue indices were compared and found to be similar around the two types of implants. Bone height measurements were not presented in great detail, but the means were similar for SLA and TPS implants and less than 1 mm. No dropouts or failures were reported over the 1-year follow-up. Three "spinning" implants were found in the maxilla at abutment connection and were therefore left unloaded for an additional 6 weeks; thereafter, they showed good function.

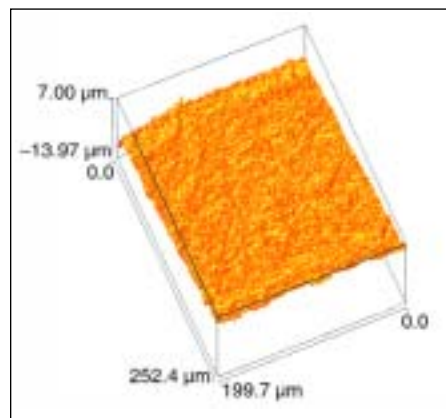
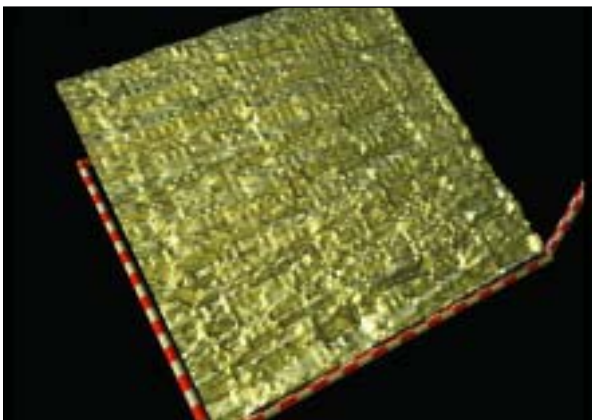
*SLA implants and bone grafts.* Stricker et al<sup>44</sup> report the outcome of 183 SLA implants placed with a maxillary sinus augmentation procedure in 41 consecutive patients. The maxillae were claimed to show "severe atrophy," but no measures of bone thickness were reported. Dropout patients were not mentioned. Follow-up time was 15 to 40 months; bone loss was  $> 1.5$  mm during the first year and  $< 0.2$  mm for the next year. Only 1 implant failed, for a cumulative survival rate of 99.5% and success rate of 97.8% at 1 year of follow-up. This study confirms good clinical results in grafting situations when using moderately roughened implants.



**Fig 7 (left)** Osseotite implant has a smooth implant collar, allegedly to minimize risk of peri-implantitis.

**Fig 8a (below left)** Anchorage part of Osseotite implant is minimally rough ( $S_a$  around  $0.5\text{ }\mu\text{m}$  and Sdr of 18.2%; each red and white section of the bars =  $10\text{ }\mu\text{m}$ ).

**Fig 8b (below)** There are no scientifically verified advantages of the Osseotite surface compared to other oral implants examined in the present study.



## Summary

The longest clinical follow-up of SLA implants is 3 years, with a reported 99% success rate in 104 implants. Shorter studies reported 36 implants followed up for 1 year for a success rate of 97.5% and 138 implants followed up for 2 years for a survival rate of 99% (loading after 6 weeks in both cases). A comparative study between 68 SLA and 68 TPS implants (where the latter were loaded 6 weeks later) showed 100% success with both systems. One report of grafts in combination with SLA implants showed a success rate of 97.8% at 1 year of follow-up.

## Osseotite Implants

### Background

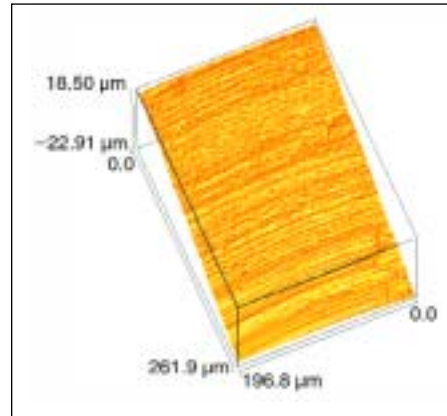
The Osseotite implant (Fig 7) is treated in a dual acid-etching procedure using hydrochloric and sulphuric acids. However, the top part of the implant is left as machined, allegedly to minimize peri-implantitis. The Osseotite implant has been claimed to show “de novo bone formation.”<sup>45</sup>

Lazzara et al<sup>46</sup> present the histologic outcome of mini-implants placed in posterior human maxillae for 6 months. One side of their miniscrews had a dual acid-etched surface (Fig 8)—Osseotite—and the other side was “machined.” Unfortunately, no quantitative surface roughness evaluation was performed, but it



**Fig 9a (left)** Brånemark system turned oral implant is no longer marketed in its original design.

**Fig 9b (below)** Surface roughness ( $S_a$  0.46  $\mu\text{m}$ , Sdr 11.6%) of the turned Brånemark implant is similar to the roughness of the Osseotite implant.



was assumed based on scanning electron micrographs that the roughness of the Osseotite surface was greater than that of the so-called machined surface. However, when analyzed with techniques developed by Wennerberg,<sup>47</sup> Osseotite implants are minimally rough. In fact,  $S_a$  values of the rougher part of Osseotite implants are similar to those of turned, machined implants (Fig 9). Whatever the clinical relevance, this has been a surprising finding, in contrast to repeated commercial claims from the company.

Testori et al<sup>48</sup> placed two immediately loaded Osseotite implants in male volunteers and retrieved them for histologic analysis at 4 months. Histologic sections were as thick as 30  $\mu\text{m}$ , and the outcome was 80.0% to 81.5% BIC. In their other retrieval study,<sup>49</sup> those authors report one submerged and one immediately loaded implant that were both retrieved 2 months after placement. Both implants were placed in soft bone and were 13 to 15 mm long, indicative of good bone quantity. The submerged implant showed 38.9% BIC; the immediately loaded implant displayed 64.2% BIC.

Trisi et al<sup>50</sup> present a mean BIC of 47.8% to the dual acid-etched halves of screws, compared to 19% BIC for the other halves of the same screws with a turned surface. The 11 implants had been in situ in human maxillae for 2 months.

### **Published Clinical Studies**

*Retrospective studies of Osseotite implants.* Lazzara et al<sup>51</sup> report the outcome of a claimed prospective

multicenter study of 429 Osseotite implants placed in 155 patients and loaded about 2 months after placement. The paper contains no information about inclusion/exclusion criteria or whether patients were consecutive and so cannot be accepted as a prospective study. Fewer than 5% of all implants were shorter than 10 mm. Mean follow-up time from implant surgery was 12.6 months, but the precise number of implants followed up for shorter times was not mentioned. Seven implants were failures, and 12 implants were in dropout patients. A so-called simple life table curve without any data was presented. No bone height measurements were published. This paper is a preliminary study, from which it is difficult to draw any reliable conclusions about the outcome of the implants.

Davarpanah et al<sup>52</sup> present a multicenter 3-year evaluation of 199 maxillary and 222 mandibular implants, of which about one third were anterior implants. There were no proper inclusion/exclusion criteria, nor any information about whether patients were consecutive, so the study cannot be accepted as prospective, although the term was used by the authors. Of the implants, 13.6% were shorter than 10 mm, and 29.8% were considered placed in "soft bone." There were no attempts to classify the soft bone other than the categories "dense," "normal," and "soft." Three patients with 5 implants dropped out of the study. Two mandibular and 5 maxillary implants were left as sleepers. The final analysis represented 401 implants, of which 16 failed to integrate. Bone loss was evaluated with respect to the number of threads, which makes it slightly difficult to



translate into millimeters (assuming some bone loss above the first thread). Seven implants showed bone loss to between the third and fourth threads. The overall success rate was quoted as 95.3% for a full 3 years.

Sullivan et al<sup>53</sup> report 3-year results of 147 Osseotite implants later included in their 5-year report.<sup>54</sup> Five failures were already recorded at 3 years. A careful bone height analysis revealed overall acceptable bone height levels, but also 4 implants with between 2 and 3 mm of bone loss and 1 implant with more than 3 mm of bone loss. These implants were associated with bone grafts and were reported to present a steady-state situation at 3 years. Few implants were placed in poor, grade 4 bone, where the results were poor (63.6% success).

In their longer term follow-up,<sup>54</sup> those authors report the outcome of 147 implants placed in 75 patients in a two-stage approach. No proper inclusion criteria were published. It is unclear whether patients were consecutive or selected based on unknown criteria. Implants were placed in posterior segments at three different treatment centers. The majority of implants were 10 mm or longer, indicative of most patients having at least good bone quantity; 72 implants were placed in the maxilla, and 75 were placed in the mandible. About one third of the implants were placed in anterior segments of the jaw; the remainder were placed in posterior segments. No further failures other than the 5 documented in the 3-year report<sup>53</sup> were recorded. However, since the 3-year report, 13 patients with an unknown number of implants had dropped out of the study. The mean follow-up was reported as 6 years, but unfortunately the spread of data was not reported. Furthermore, a life table without any data—and hence of little scientific value—accompanied the paper. Bone height measurements were not adequately reported; the few data points given do not permit calculation of annual bone loss. Six-year survival rates were claimed to be 96.6%, but there is a clear level of uncertainty, as the total number of implants followed up for 6 years was not revealed and there was a true dropout of more than 17% of the treated patients. Unfortunately, the quality of these reports does not allow for any reliable conclusion about the true outcome of the implants.

Schropp et al<sup>55</sup> compared the outcome of 46 Osseotite implants placed into extraction sockets and subjected to either immediate ( $n = 23$ ) or delayed ( $n = 23$ ) loading; 37 implants were placed in the maxilla, and 9 were placed in the mandible. Two immediately loaded maxillary implants and 1 delayed loaded maxillary implant failed over a follow-up of less than 1 year.

Testori et al<sup>56</sup> placed 103 mandibular Osseotite implants in 15 patients and immediately loaded 92 of the implants. Inclusion criteria demanded, among other things, that the bone quality be at least normal and that

implants were seated with a torque of at least 30 Ncm and displayed early stability. Exclusion criteria included smoking more than 10 cigarettes a day, any type of diabetes, bruxism, and pregnancy. Ninety-one implants were followed for up to 2 years, and 39 implants were followed for more than 4 years. The cumulative survival rate at 3 to 4 years was 98.9% for this selected group of patients.

Garlini et al<sup>57</sup> report a retrospective study of 555 implants with a mean follow-up of 26 months. Two hundred forty-four consecutive patients were entered into the study, passing exclusion criteria such as poor oral hygiene, bruxism, and heavy smoking; 214 implants were placed in the maxilla (159 in the posterior region), and 341 implants were placed in the mandible (234 in the posterior region). Implants were generally placed in a good quantity of bone, indicated by the fact that only 18 devices (3.5%) were shorter than 10 mm. All 244 patients are still undergoing follow-up examination, which seems to indicate that there were no dropouts. Eight implants failed, giving a survival rate of 98.5% at about 3 years. Since few implants were followed up for longer times, it is difficult to estimate a true 5-year survival rate in this paper.

*Prospective studies of Osseotite implants.* Testori et al<sup>58</sup> report the results of 219 mandibular and 266 maxillary Osseotite implants placed in 181 consecutive patients in a prospective multicenter study. Exclusion criteria included smoking more than 10 cigarettes a day and evidence of severe bruxing or clenching, two conditions known to be associated with secondary implant failure. However, despite using smoking as an exclusion criterion, it was later found that no fewer than 37 patients with 118 implants did smoke an average of 12.2 cigarettes a day. Short implants ( $< 10$  mm) were used in only 6.3% of the 485 implants, indicative of most patients having sufficient bone volume. Of the 485 implants, 130 were placed in anterior regions of the jaws, and 72% were placed in posterior regions. Dropouts were 8.8% of all patients, representing 39 implants (7.4%). Six implants, 5 of them maxillary, failed in 6 patients (primary failures). Although the numbers are small, the study confirmed that short implants failed in 1 of 31 cases, compared to 1 failure in 91 long implants; a lower failure rate is a general finding with long implants. Bone loss at the end of 2 years of follow-up was  $0.13 \pm 0.8$  mm. Of the 485 implants, 389 were followed up for 4 years or more.

Mayer et al<sup>59</sup> placed 47 maxillary and 24 mandibular Osseotite implants in 59 patients in a prospective clinical study. Informed consent was obtained from the patients. Exclusion criteria were comparatively wide, exemplified by smoking  $> 10$  cigarettes a day, any type of diabetes, postmenopausal women not undergoing hormone therapy, and clinical evidence

of severe parafunction. Only 10-mm or longer implants were used, and they were placed consecutively. Bone quality was given three grades—"soft" ( $n = 13$ ), "normal," and "dense"—making it difficult to compare with the commonly used Lekholm and Zarb<sup>60</sup> four-grade scale. Two implants were lost to follow-up, and 1 implant failed over a mean follow-up of 45.9 months (30.9 to 60.0 months). Mean bone loss was  $0.227 \pm 1.433$  mm at 2 years.

After a maximum of 3 years, Testori et al<sup>61</sup> report the outcome of a multicenter prospective evaluation of Osseotite implants loaded at 2 months. Static or dynamic bruxism was an exclusion criterion. Treated patients were consecutive if they matched the inclusion but not the exclusion criteria. Nineteen percent of the patients were smokers; 282 implants were placed in the posterior mandible, and 123 were placed in the posterior maxilla. For 5.4% of the components, lengths shorter than 10 mm were used. Bone height measurements were not reported. There were 206 implants followed for about 3 years; the remainder were followed for shorter times. Nine failures occurred, and 16 implants were placed in dropout patients. Survival rate for up to 3 years was 97.5% in the mandible and 98.4% in the maxilla.

*Comparative studies of Osseotite and turned implants.* Khang et al<sup>62</sup> present a comparative study of 432 Osseotite and machined implants. Of these, 225 were placed in the maxilla and 207 in the mandible over a mean follow-up of  $36.1 \pm 7.9$  months. The study was claimed to be prospective, randomized, and controlled, but much of the information needed to classify the study as such is lacking. Strict exclusion criteria, such as smoking more than 10 cigarettes a day, diabetes, postmenopausal women not on hormone therapy, and severe bruxing, were applied. Dropout patients were not reported, which is strange for so many implants. It was claimed that success criteria included crestal bone loss data, but no figures were presented. Bone quality was only termed "soft," "normal," or "dense," again compromising comparisons with other studies. The number of implants shorter than 10 mm was not revealed. There were 225 maxillary and 207 mandibular implants placed. Twelve dual acid-etched and 24 turned implants were failures. Survival rates were 95% for dual acid-etched implants and 86.7% for turned, machined implants after about 3 years. Too few data were presented to allow a proper success evaluation.

Feldman et al<sup>63</sup> present a meta-analysis of 557 Osseotite implants and 958 turned, machined implants followed up for 54 to 60 months. The study is a summary of several papers, three of which are quoted elsewhere in this review<sup>58,59,62</sup>; however, it presents interesting data, as 10-mm and shorter minimally roughened Osseotite implants showed a similar survival rate

to implants longer than 10 mm (97.7% vs 98.4%). Minimally roughened, turned, machined surfaces evoke a substantially greater difference between 10-mm or shorter implants when compared to implants longer than 10 mm (91.6% vs 93.8%).

*Osseotite implants and bone grafts.* Fugazotto and De Paoli<sup>64</sup> placed 167 Osseotite implants, of which 137 were restored in conjunction with a sinus graft of a bovine bone material. The thickness of the bone wall was not revealed. Heavy smokers were excluded from the study. Panoramic radiographs were claimed to have been used to assess bone height levels, but these were not reported; instead, only anecdotal results were stated: "no bone level changes greater than those deemed successful by Albrektsson et al (1986)." There were no comments on possible dropout patients. Three implants failed, for a success rate of 97.8% for the 137 implants, of which 105 were followed up for more than 1 year.

Raghoobar et al<sup>65</sup> placed 68 Osseotite implants 3 months after autologous, maxillary bone grafts in 10 different patients. Implants were loaded after 2 months in situ. One year later, there was a mean marginal bone loss of  $0.3 \pm 0.7$  mm. Three implants had failed, for a success rate of 95.6%.

## Summary

The maximum clinical follow-up of the Osseotite dual acid-etched surface is about 6 years (one study). In that investigation and in several others with a follow-up of between 3 and 5 years, the reported success/survival rates were all in the 95% to 99% region. With respect to immediately loaded implants, one study reported two failures among 23 immediately loaded implants, whereas another indicated 97% to 99% survival despite immediate loading. One comparative study reported a 3-year survival of 95% for dual acid-etched implants, in comparison to 86.7% for turned, machined implants. One study of sinus grafts in conjunction with Osseotite implants reported a success rate of 97.8% for 1 year.

## Frialit-2 Implants

### Background

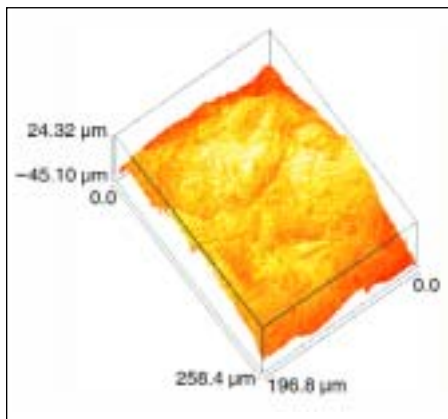
Dentsply/Friadent markets implants (Fig 10) with different surfaces such as the Deep Profile Surface (DPS), TPS, and Cellplus. The surface of the Frialit-2 implant is sandblasted and acid etched (Fig 11), similar to the SLA surface. The novel Cellplus surface is grit blasted and acid etched at a high temperature (Fig 12). Sammons<sup>66</sup> presents an in vitro comparative study in which different commercially available surfaces were compared with respect to cell attachment, migration,



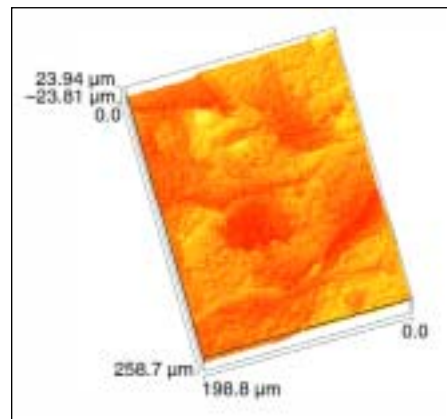
**Fig 10a** Frialit-2 implant is a stepped, threaded titanium cylinder.



**Fig 10b** XiVe implant, an alternative Dentsply design, with the novel Cellplus surface, which is currently without published clinical documentation.



**Fig 11a** Frialit-2 is a rough implant.



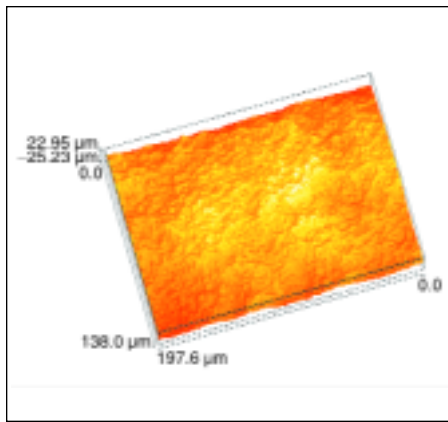
**Fig 11b**  $S_a$  value of Frialit-2 is 2.2  $\mu\text{m}$ , and  $S_{dr}$  is 198.8%.

proliferation, and differentiation. The Cellplus surface was claimed to show the strongest cell adhesion. Interestingly, the Cellplus surface was claimed to present de novo bone formation,<sup>45</sup> like the Osseotite implant.

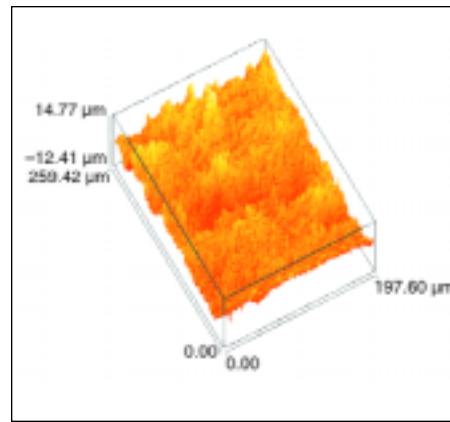
### **Published Clinical Studies**

*Retrospective studies of Frialit-2 implants.* Gomez-Roman et al<sup>67</sup> present up to 5-year data for 696 Frialit-2 single implants placed between 1990 and 1995. With

rare exceptions, the implants were of the stepped screw design. Dropouts consisted of 7 implants in two dead patients and 10 implants in nine patients for unknown reasons. Two hundred ninety of the implants were placed as single devices. Mean patient age was 38.8 years, and no implants were placed in grade 4 bone. Nineteen implants failed during follow-up. Soft tissue indices and Periotest values were acceptable. Mean bone loss at 1 year was 1.5 mm; thereafter, an average steady-state situation was reported up to 3 years, after which time there were too few implants to allow proper



**Fig 12a** Cellplus surface is moderately roughened.



**Fig 12b**  $S_a$  value of the Cellplus surface is  $1.7 \mu\text{m}$ , and  $S_{dr}$  is 145%.

estimations. Unfortunately, only a simple life table without precise data was published. It is unclear how many implants were actually followed for more than 3 years, since the mean follow-up time was not reported. The authors themselves mention that only a small number of implants presented for the 4-year recall, so it would seem possible to only quote a 3-year success rate of about 96%; even this figure is somewhat uncertain because of a lack of necessary information.

Krennmair et al<sup>68</sup> present a retrospective analysis of 146 Frialit-2 single implants followed up for between 3 and 80 months (mean  $35.8 \pm 16.5$  months). Thirty-eight implants were placed in the anterior maxilla, and 57 were placed in the posterior mandible. Most implants were of the stepped screw design ( $n = 134$ ); only 12 step cylinders were used. No implants were shorter than 10 mm. Various augmentation procedures were performed in 43 patients, whose implants were kept unloaded for longer times than the other patients. Dropout implants were not commented on, which makes true dropout figures difficult to assess. Two implants failed. Bone height was estimated based on a mixture of individual radiographs and orthopantographs (lower resolution), and a figure of  $1.3 \pm 0.8$  mm (maximum 2.5 mm) was quoted. Periotest values indicated implant stability. Cumulative implant survival rate at 3 years was 97.3%.

Wheeler<sup>69</sup> reports the outcome of 802 Frialit-2 implants, of which 503 were maxillary devices, in a retrospective study. Patients were not consecutively included. No comments were directed to the possibility of dropout patients. Mean follow-up time was not mentioned; whereas 643 implants were followed for up to 1 year, only 170 were followed for up to 2 years, and only 78 were followed for up to 3 years. Retrospective survival data were reported as 9 failures of 49 implants in heavy smokers (survival rate 82%),

16 failures of 503 maxillary implants (survival rate 96.3%), and 8 failures of 299 mandibular implants (survival rate 97%) followed for up to 2 years. Evaluating the outcome for longer than 2 years is uncertain because of the small proportion of implants followed up for longer periods.

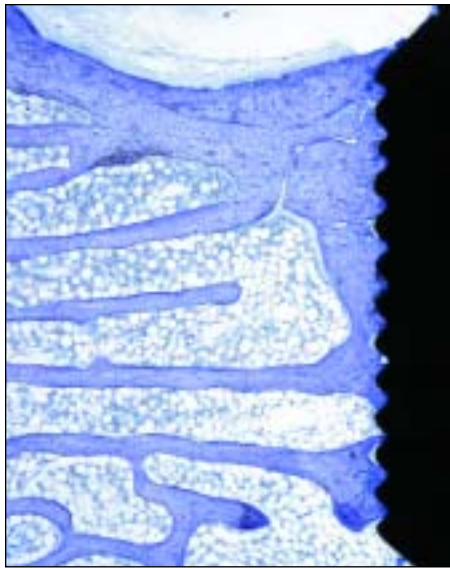
Lorenzoni et al<sup>70</sup> report the outcome of 12 immediately loaded Frialit-2 Synchro maxillary implants followed up for 1 year. Only nonsmoking and nonbruxing patients were allowed in the study. All implants were 13 to 15 mm in length, indicating good bone quantity. Only panoramic radiographs were used. With the obvious limitations of this approach, it seems that acceptable bone loss figures were reported. No implants failed; hence, the quoted 1-year survival rate was 100%.

*Prospective studies of Frialit-2 implants.* No prospective studies on Dentsply implants have been found in the literature.

*Comparative studies on Frialit-2 implants.* Degidi and Piattelli<sup>71</sup> tested 144 Frialit-2 implants in direct or "non-functional" loading situations. Eight failures were observed with Frialit-2 implants for a follow-up of 1 to 5 years, whereas no failures were observed for 502 other types of implants not placed in a randomized manner. Frialit-2 implants showed a 95.4% survival rate for 1 to 5 years.

*Frialit-2 implants and bone grafts.* Maiorana and Santoro<sup>72</sup> randomly selected 28 of 45 patients for treatment with 133 Frialit-2 implants following a bone grafting procedure to treat severe partial or complete maxillary or mandibular atrophy. A total of 8 implants failed, for a claimed success rate of 94.8% for an unpublished time of follow-up; an estimate from the published table





**Fig 13** Tioblast implant has a characteristic microthreaded upper part, which in animal experiments has been verified to show good bone anchorage (hematoxylin-eosin stain).

indicates a mean follow-up of about 2.5 years at most. Most failures occurred in the posterior maxilla. No criteria for success and no bone height measurements were published. Dropout figures were not commented on. Hence, the true outcome of this paper is difficult to interpret.

### Summary

The maximum clinical follow-up of Frialit-2 implants is up to 5 years. Success rates of 96% to 97% (two studies) for 3 years were published. Another study of more than 800 implants indicated a survival rate of 97% for 2 years. In the latter study, more than 50% of the failures occurred in heavy smokers. One hundred forty-four directly loaded Frialit-2 implants showed a 95.4% survival rate, whereas 502 other implant designs showed a 100% survival rate for a follow-up of 1 to 5 years. In a bone graft study with maxillary or mandibular atrophy, a 94.8% success rate was reported over a follow-up of between 2 and 3 years. To the knowledge of the present authors, there are no publications in peer-reviewed journals of the clinical results of the novel Cellplus surface, which was introduced clinically in 2003.

## Tioblast and Osseospeed Implants

### Background

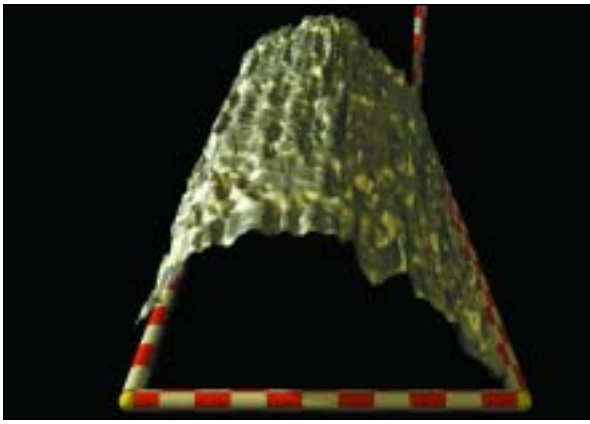
Hansson<sup>73</sup> presents a biomechanical analysis of whether the implant neck ought to be smooth or provided with retention elements (Fig 13). The retention elements showed an approximate 60% to 80% decrease in peak stresses. Hansson<sup>74</sup> presents a biomechanical analysis of flat-topped versus conical implant abutment connections and demonstrates that the latter exhibit lower stress levels. It was concluded that an implant with a conical interface can resist a greater axial load before triggering bone resorption. Hansson<sup>75</sup> further confirms the potential advantages of a conical implant-abutment interface at the level of the marginal bone. A series of studies<sup>47</sup> compared Tioblast-like surfaces (Fig 14) to rougher and smoother surfaces. Smoother (turned) and rougher (plasma-sprayed) surfaces showed a weaker bone response than the blasted surfaces of moderate roughness. Ivanoff et al<sup>76</sup> used microimplants that were either TiO<sub>2</sub>-blasted or turned, machined surfaces. In that clinical study, the TiO<sub>2</sub>-blasted screws showed much greater BIC than the turned, machined devices.

### Published Clinical Studies

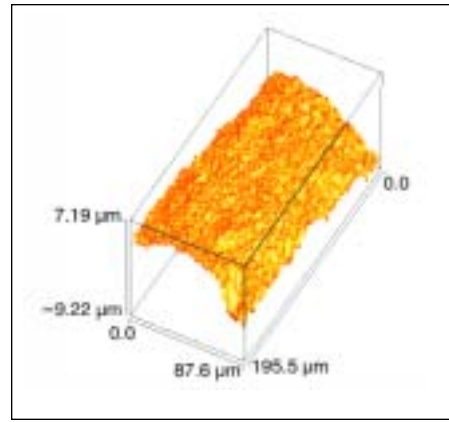
*Retrospective studies of Tioblast implants (Fig 15).* Steveling et al<sup>77</sup> investigated 17 patients and placed 44 maxillary implants loaded at 3 months and followed for up to 5 years. Inclusion criteria included minimum bone height of 9 mm at implant sites and primary stability at placement. This implied that bone quantity was never less than C, and in only one case was bone quality 4 according to the Lekholm and Zarb index.<sup>60</sup> Patients were consecutive, but nine did not meet the inclusion criteria during patient enrollment. There were no dropouts, but only 7 implants were followed up for the full 5 years; 22 were followed up for at least 3 years; and all 44 implants were followed up for 1 year. Mean bone loss at 3 years was  $0.4 \pm 0.58$  mm and at 5 years  $0.9 \pm 1.19$  mm. There were no implant failures. The 3-year success rate was 100% (ignoring the 5-year figures because of too few included implants).

Norton<sup>78</sup> reports the outcome of 27 Tioblast implants followed up for 4 to 7 years with a mean of more than 5 years. Only 12 implants were reviewed by the author and found to be survivals without clinical problems. However, the remaining implants were placed mainly in patients overseas who all dropped out of the study, making the true outcome of the treatment uncertain.

Cooper et al<sup>79</sup> treated 10 consecutive patients immediately after tooth extraction with Tioblast implants. Forty-eight of the 54 implants were selected for immediate



**Fig 14a** Tioblast implant was clinically introduced in 1993 as the first of all moderately roughened devices (each red and white section of the bars = 10 µm).



**Fig 14b** Tioblast implant is the only currently marketed design with published 5-, 7-, and 10-year clinical reports.

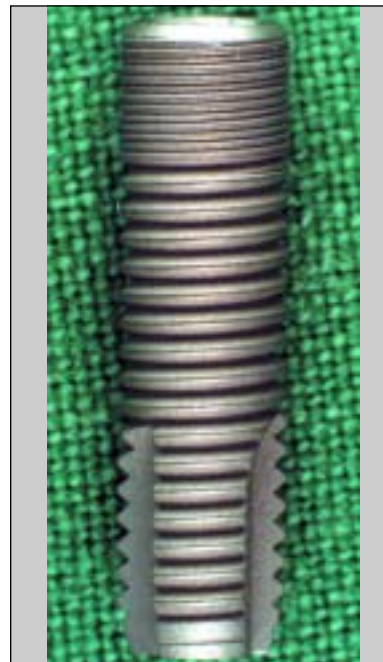
loading. The bone height was reported as maintained, and no failures occurred during the 6- to 18-month follow-up.

Warren et al<sup>80</sup> present a retrospective study of 102 Tioblast implants that were followed up for 3 years and analyzed with respect to maintained bone height. Sixty-one of the implants were placed in the posterior mandible, and 41 were placed in the posterior maxilla. The patients experienced no implant failures. The range of bone loss was 0.0 to 2.1 mm, and mean crestal bone loss was  $0.36 \pm 0.60$  mm. Bone gain occurred at 5% of the implants.

Collaert and De Bruyn<sup>81</sup> report the outcome of 114 Tioblast implants placed in the mandibles of 25 consecutive patients and loaded within 1 month. Four implants were shorter than 10 mm. Repeated radiographs were taken, but 1 elderly patient (5 implants) and 1 other patient (1 implant) did not participate in all radiographic procedures. Nineteen of the patients were followed up for between 13 and 14 months, whereas the other 6 patients were followed up for 7 to 12 months. No implant failures occurred, and mean bone loss at 1 year was 0.7 mm (maximum 2.2 mm) and at 2 years was 0.7 mm (maximum 1.6 mm).

*Prospective studies of Tioblast implants.* Gotfredsen and Holm<sup>82</sup> present a prospective study on the outcome of 52 Tioblast implants connected to mandibular overdentures. Soft tissue indices revealed healthy conditions at 5 years. The marginal bone loss at 5 years was 0.72 mm. One implant failed, for a 5-year success rate of 98%.

Palmer et al<sup>83</sup> present a 5-year prospective study of 15 patients who each received one implant. One patient dropped out of the study. There were no soft tissue problems at 5 years of follow-up, and mean bone loss was 0.39 mm. Success rate was 100%.



**Fig 15** One example of the Tioblast implant design.

Yi et al<sup>84</sup> present a prospective study of 43 consecutive periodontally compromised patients who received 125 implants after conventional periodontic treatment. About 35% were maxillary and 65% were mandibular implants (the precise number was not mentioned). All patients were followed up for 3 years, and repeated soft tissue examinations, bone height measurements, and implant mobility tests were performed. There were no dropouts. Soft tissue indices showed acceptable results, and no implants failed. Bone loss at 3 years amounted

to a mean of 0.21 mm, with a range of -1 mm (bone gain) to 2 mm. Of the 27 implants placed in type C4 bone, more than one third exhibited bone loss greater than 0.5 mm. The reported 100% success rate for 3 years is interesting, given that all patients were periodontally compromised before treatment and 90 of the implants were placed in partially edentulous jaws.

Gotfredsen<sup>85</sup> presents a prospective 5-year study of single-tooth maxillary implants placed in 20 consecutive patients. Ten implants were placed in extraction sockets. The remaining 10 implants were placed in the maxilla after a 12-week healing period. One patient dropped out at the 3-year recall but returned to the study at the 4-year registration. The marginal bone loss was  $0.34 \pm 0.57$  mm and  $0.26 \pm 0.38$  mm for the two groups, respectively, at a follow-up of 5 years. No implants were lost, for a 5-year success rate of 100%.

Rasmusson et al<sup>86</sup> present a prospective study of 199 consecutively placed Tioblast implants followed up for a full 10 years. One hundred eight implants were placed in the mandible, and 91 were placed in the maxilla. Forty-four implants dropped out of the study, and 3 mandibular and 3 maxillary implants failed, all during the first year. The first consecutive 100 implants seen at the clinic at the 7-year recall were individually radiographed, with a reported bone loss of 1.27 mm (SD 1.15). One individual had 5.2 mm of bone loss but was in a steady state with respect to the bone height, as evidenced by repeated radiographs. The success rate at 7 years was 96.9%, and the cumulative survival rates at 10 years were 96.6% in the maxilla, 97.2% in the mandible, and 96.9% overall.

*Comparative studies between Tioblast and turned implants.* A prospective, randomized controlled study between 184 Tioblast and 187 Brånemark turned implants has been reported after 1 year<sup>87</sup> and 3 years.<sup>88</sup> Originally, 68 patients were selected for the study; 2 failed to match the inclusion criteria because they needed some sort of bone augmentation procedure. By chance, 12 Tioblast and only 6 Brånemark patients were smokers. On the other hand, by chance, only 1 Tioblast but 8 Brånemark patients had bone quality 4. At 1 year, there were no significant differences between the two implant systems with respect to maintained bone height. Only 1 failure occurred among the Tioblast implants, compared to 8 failures for the Brånemark system. However, 5 of the latter failures occurred in 1 patient.<sup>87</sup> In the 3-year report,<sup>88</sup> there were 2 Tioblast and 9 Brånemark failures. Bone height levels were 1.7 mm and 2.2 mm, respectively. Success rates were 98.9% for Tioblast implants and 95.2% for Brånemark implants.

Van Steenberghe et al<sup>89</sup> present a 2-year comparison between 50 Tioblast and 45 turned, machined Brånemark implants in a split-mouth study in

18 patients. There were 28 maxillary and 22 mandibular Tioblast implants and 23 maxillary and 20 mandibular Brånemark implants. No differences in soft tissue indices were found between the two systems. Tioblast implants lost on average 1.48 mm of bone height, compared with 2.27 mm for the turned Brånemark screws ( $P > .001$ ). No Tioblast implants but 1 Brånemark implant failed, for 2-year success rates of 100% and 97.7%, respectively.

Gotfredsen and Karlsson<sup>90</sup> present a prospective, comparative study of 64 turned, machined and 64 Tioblast implants followed up for a full 5 years. Ten patients with 16 implants were lost to follow-up. Bone height measurements indicated bone loss of around 0.5 mm for both surfaces. Three machined and no blasted implants failed, for a 100% success rate in the latter.

Puchades-Roman et al<sup>91</sup> present a comparative study of 15 Tioblast and 15 Brånemark single-tooth implants, with special focus on microbiologic and radiographic parameters. They selected 30 partially dentate patients with single implants in their maxillae (1 implant in the mandible). Most of the Tioblast implants had been followed up for 6 years, whereas the majority of Brånemark implants had been followed up for fewer than 5 years. Probing depths and bone loss were greater for the Brånemark implants. No implant failures were reported.

*Tioblast implants and bone grafts.* Widmark and Ivanoff<sup>92</sup> placed autologous bone grafts to cover four or more exposed implant threads in 21 patients. The gain in bone coverage was estimated at 81.5% at 6 months. No implants were lost.

## Summary

The longest follow-up study of Tioblast implants spans 10 years and reports a 96.9% survival rate of 199 implants. The only 6 failures reported in this impressive study occurred during the first year. At 7 years, follow-up investigations including bone height measurements were positive, resulting in a 7-year success rate of 96.9%. The Tioblast surface has been positively documented for 5 years in several studies and is the only currently marketed implant with a 10-year follow-up. Steady-state bone levels have been repeatedly reported. Success rates in the vicinity of 100% have been reported in many papers. There is a tendency to better clinical results with moderately roughened Tioblast surfaces than with turned surfaces, but only rarely is this difference statistically significant.

## Discussion

It is obvious that clinical studies are perceived by major implant companies as unnecessary before marketing

a new implant surface. However, there is a strong focus on clinical reporting after the commencement of sales of these same surfaces. This is analogous to testing a new car only in limited subassemblies and demanding that the customer check its drivability. From the patient's point of view, such an approach is really unacceptable; if a novel implant does not function as predicted by the test bench, the patient will pay the major price. Government institutions only demand 510(k) acceptance (US) or CE marking (Europe), neither of which necessitate any clinical pretesting. Professional dental organizations have either kept a low profile or showed great generosity—even blade-vent implants have been found clinically acceptable, in obvious opposition to all attempts at clinical scrutiny.

Topographic surface evaluations have revealed strange conceptions about “machined surfaces.” Several studies present comparative data between a novel type of implant and a machined surface, generally without defining the latter. In fact, a machined surface may vary considerably in topographic characteristics: It may be smooth like an abutment ( $S_a$  0.1 to 0.2  $\mu\text{m}$ ); it may resemble turned, Brånemark surfaces (0.5 to 0.8  $\mu\text{m}$ ); or it may even be moderately roughened. It is therefore surprising that many comparative studies with machined implants do not topographically characterize the surfaces involved. Examples are several experimental and clinical studies between Osseotite and machined implants and between SLA and machined implants. In this study, we have discovered that Osseotite implants are minimally rough, ie, similar to machined Brånemark surfaces, at least with respect to the commonly quoted  $S_a$  value. SLA implants have been compared to the implant design before blasting and etching their machined surfaces. The problem with this comparison is that this machined surface in reality is of a smooth nature, similar to an abutment. Nobody has ever launched such smooth surfaces for bony anchorage.

A problem with surface roughness evaluations is how to perform the measurements. We prefer three-dimensional measurements. On screw-type implants, we have evaluated tops, valleys, and flanks of at least three samples in a batch. We have used defined filters to separate actual roughness from the form of the implant. At least one height, one spatial, and one hybrid parameter should be presented. Further information is found in one of our publications on surface evaluations.<sup>93</sup>

In the different papers, two approaches to evaluate implant stability have been applied—Periotest and RFA evaluations. A number of potential errors may influence Periotest readings, such as vertical measuring point on the implant, handpiece angulation, and horizontal distance of the handpiece from the implant.<sup>94</sup>

These shortcomings do not apply to RFA, a scientifically more controlled approach to evaluate implant stability.<sup>95</sup>

It is possible to summarize important information on oral implants from the five major companies in so-called four-field tables.<sup>96</sup> The four-field table displays success (Ss), survival (SI), unaccounted for (dropout) implants (U), and failures (F). However, some studies will not qualify for a four-field table. Studies with insufficient information about the precise number of followed implants at a precise time cannot be included. Furthermore, our classification of success follows the previously established criteria.<sup>1</sup> These criteria include a defined maximum bone loss per year, which necessitates proper bone height measurements. If no proper bone height measurements are presented at a given time, implants will only be judged as survivals.

Other survivals include sleeping implants (those not coupled to a superstructure) and implants still in the jawbone but with problems such as pain and infection. Unaccounted-for implants include those that dropped out of the study at one specific recall. However, if a former dropout patient returns to the study at a later recall, his or her implants may then be evaluated for success, survival, or failure again. Failures are those implants removed from the jaws or to which absolute failure criteria such as implant mobility apply. Failures are always cumulative, ie, there can never be fewer failures with increasing time.

The advantage of the four-field table is the possibility to scrutinize results at a glance. The percentage of successful versus surviving implants indicates an important difference. The number of the unaccounted-for implants is important, since the greater their number, the greater is the uncertainty. We believe this is a more realistic way of focusing on unaccounted-for implants than the alternative, the worst-case dropout, in which all unaccounted-for implants are termed failed.

TiUnite implants have been documented with good success rates when followed up for 1 year (maximum 18 months in one study<sup>28</sup>). Nobel Biocare claims that success depends on a number of unique characteristics of the oxidized surface, but there is no documentation that the porous surface, altered oxide crystallinity, or thicker oxide at all influence the clinical results. However, TiUnite surfaces are moderately roughened, which has been documented as one way to achieve at least slightly better clinical results than with smoother turned surfaces. From a commercial point of view, it is presumably undesirable to refer to the surface roughness of TiUnite implants, since many other companies introduced moderately roughened implants more than 10 years ago. Four different studies<sup>27,28,31,32</sup> qualify for a combined four-field table at 1 year of follow-up. It must be pointed out that the 340 implants in these studies were all loaded within about 2 weeks after placement.



Ss 95.0%	U 0%
SI 1.8%	F 3.2%
TiUnite 1 year (n = 340)	

SLA implants, with a moderately rough surface, have been documented for 3 years in one study.<sup>42</sup> Three studies qualify for 1-year four-field tables.<sup>39,41,43</sup> One of those studies<sup>41</sup> does not present any bone height measurements whereby these 326 implants could be evaluated with respect to implant survival. Loading time was 6 weeks.

Ss 24.0%	U 1.4%
SI 73.7%	F 0.9%
SLA 1 year (n = 430)	

Ss 98%	U 1%
SI 0%	F 1%
SLA 3 years (n = 104)	

The Rocuzzo and Wilson<sup>39</sup> study of SLA implants placed in the maxilla and loaded after 6 weeks suggests this type of implant is preferable in generally softer bone, since the success rate at 1 year was in the range of 97%. However, others report similarly high success rates in poor bone but using turned, machined Brånemark implants,<sup>97,98</sup> admittedly with a longer unloaded period. Notwithstanding, others<sup>97,98</sup> present good clinical data for implants placed in maxillary bone of poor quantity and quality. Interestingly, all three studies have in common a preferred surgical technique, without tapping the maxillary bone and using thinner drills than are generally advocated. In addition, highly experienced surgeons performed the operations. One cannot overlook the possibility that surgical routine may be as (or even more) important as implant hardware.<sup>12</sup> Having said this, some studies<sup>33,44,64</sup> show surprisingly good clinical results in grafting situations, where much poorer results had been reported by the same surgeons previously using other types of implants.

The Osseotite dual acid-etched surface is surely one of the best documented implant surfaces today, with a maximum follow-up of 6 years in one paper.<sup>54</sup> However, reported survival/success rates with this surface are difficult to compare to other reports for a number of reasons. First, many studies of the Osseotite implant claim to be prospective but are not supported by data demonstrating their prospective nature. Furthermore, exclusion criteria used in many studies with the Osseotite implant have been extremely strict—no patients with diabetes (whether controlled or not), no postmenopausal women not undergoing hormone treatment, no smokers, and no bruxers were allowed in several of the studies quoted. In addition, several Osseotite studies refer to short implants and include 10-mm-long components in

this category (whereas other studies report only implants < 10 mm as truly short implants), and bone quality is quoted on a three-point scale of dense, normal, or soft bone (whereas the commonly used Lekholm and Zarb index<sup>60</sup> has two, not one, soft bone categories). Taken together, in comparison with other systems, there is no doubt that Osseotite implant survival/success figures potentially benefit not only from the dual acid-etched surface, but also from the structure of clinical studies. Four-field tables have been applied for 4.5 to 5 years, reporting results of 10-mm-long or shorter implants,<sup>63</sup> for one 3-year study,<sup>52</sup> and two 2-year studies.<sup>58,59</sup>

Ss 91.4%	U 7.4%
SI 0%	F 1.2%
Osseotite 2 years (n = 556)	

Ss 91.7%	U 1.2%
SI 3.3%	F 3.8%
Osseotite 3 years (n = 421)	

Ss 0%	U 21.0%
SI 75.8%	F 3.2%
Osseotite 4.5 to 5 years (n = 557)	

Frialit-2 implants have been followed for up to 5 years in two studies. The most commonly used design is the stepped screw implant. The true long-term success rate for this implant is currently difficult to evaluate because of sparse information in the clinical documentation. For example, the only four-field table possible to construct is based on 1-year results of 696 implants.<sup>67</sup> That paper reportedly followed the implants for up to 5 years, but with too few data included at the long-term follow-up, a detailed analysis of the data is precluded.

Ss 94.8%	U 2.5%
SI 0%	F 2.7%
Frialit-2 1 year (n = 696)	

Tioblast is the only moderately roughened implant followed for up to 10 years, in one study with survival data only.<sup>86</sup> The bulk of information suggests that the Tioblast surface is indeed the best documented of all currently marketed oral implants from any of the five big companies. In addition, among these companies, there is only one exception to launching new products without prior clinical testing. This exception is the Osseospeed surface, a potentially bioactive implant. This surface was first tested in a prospective, randomized clinical study under the guidance of an ethical committee and with patients who gave consent to be treated with a clinically untested product. The surface

was applied on a novel type of hip arthroplasty, placed in 20 consecutive patients, and compared to 20 other patients with a traditional hip replacement. A 100% success rate was reported with the Osseospeed-surfaced implants at a follow-up of 1 to 2 years.<sup>99</sup> However, these are short-term results only, and they require clinical confirmation from the jaw region. The Osseospeed surface has since been launched for clinical testing of oral implants. If success rates remain positive, commercial launch is planned during 2004. This is definitely a safer way to introduce a new surface, rather than to just start marketing it and await later clinical follow-up. Four-field tables are possible to construct on 10-year survival rates,<sup>86</sup> 7-year success rates,<sup>86</sup> four 5-year papers,<sup>82,83,85,90</sup> three studies with 3-year follow-up,<sup>80,84,88</sup> one 2-year study,<sup>89</sup> and one 1-year study.<sup>77</sup>

Ss 100%	U 0%
SI 0%	F 0%
Tioblast 1 year (n = 44)	

Ss 100%	U 0%
SI 0%	F 0%
Tioblast 2 years (n = 50)	

Ss 99.5%	U 0%
SI 0%	F 0.5%
Tioblast 3 years (n = 329)	

Ss 92.0%	U 6.0%
SI 1.3%	F 0.7%
Tioblast 5 years (n = 151)	

Ss 74.9%	U 22.1%
SI 0%	F 3.0%
Tioblast 7 years (n = 199)	

Ss 0%	U 22.1%
SI 74.9%	F 3.0%
Tioblast 10 years (n = 199)	

The present authors agree with other colleagues<sup>100</sup> that only properly recorded clinical evidence can tell us the true value of an implant surface. We likewise concur with a recent report, approved by the Fédération Dentaire Internationale science commission,<sup>13</sup> which summarizes: "The scientific literature does not provide any clear directives to claims of alleged benefits of specific morphological characteristics of root-formed dental implants." The current uncritical approach when launching new surfaces is not without patient risks, as indicated by bad experience with two implant systems that were popular during the 1990s.<sup>101,102</sup> Another unsuitable oral implant design resulted in severe sequelae for numerous patients, as indicated by the legal outcome

of a recent Scandinavian trial (Haugesund local court, Norway, No. 99-00659A, 2000). The present authors share a fear that new surfaces launched in the future may occasionally represent a step in the wrong direction, with potential benefits outweighed by problems for the patient treated.

## Conclusions

1. All new implant surfaces are moderately roughened ( $S_a$  1.0 to 2.0  $\mu\text{m}$ ), with the exception of the Osseotite implant, which is minimally rough (0.5 to 1.0  $\mu\text{m}$ ) and in that respect similar to a turned, machined surface.
2. The standards of reporting results of oral implants have improved over the status found during our previous reviews.
3. Several oral implant systems have now been properly documented for 5 years or more.
4. The best-documented oral implants are no longer available from the major oral implant companies.
5. The only currently marketed long-term documented implants from the major companies are the Osseotite and Tioblast implants. The latter surface is also documented for 7 years with respect to success and 10 years with respect to survival.
6. Commercial companies have generally preferred to develop new, untested surfaces marketed without any prelaunch clinical investigations.
7. Such untested clinical implants have become extremely successful from a marketing point of view, ie, implant users do not see clinical documentation as necessary.
8. The new Osseospeed implant represents the only recently introduced surface from the five big companies for which at least some clinical trials have been completed before marketing.

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#### Literature Abstract

### Comparison of cast Ti-Ni alloy clasp retention with conventional removable partial denture clasps

Titanium-nickel (Ti-Ni) alloy has been used as a framework material of removable partial dentures. This article investigated the changes in retentive force of cast Ti-Ni clasps under clinical simulation. Ninety-eight clasps were prepared. Seven clasps were fabricated for each type of materials (Ti-Ni alloy, Co-Cr alloy, Type IV gold alloy, and wrought wire), depth of undercut (0.25 mm and 0.75 mm), and diameter (0.8 mm and 1.4 mm, except wrought wire). After evaluating for casting defects and porosity, the force to remove clasps was measured with a universal testing machine. The clasps were cycled on and off 500 times for each cycle. The cycle was repeated 10 times. After each cycle, the removing force was measured. Data were analyzed with two-way and four-way analysis of variance, followed by Scheffe's multiple comparison test. The results show that Co-Cr alloy and gold alloy clasps in the 0.25-mm undercut groups have gradual a decrease in retentive force, while the Ti-Ni alloy clasps maintained the force constantly after the first cycle. Similar results were found in the groups with a 0.75-mm undercut. The authors concluded that Ti-Ni alloy was a suitable partial denture framework material because of its ability to maintain constant retention during long-term function. Its casting ability without defects should be investigated further.

**Kim D, et al.** *J Prosthet Dent* 2004;91:374–382. **References:** 25. **Reprints:** Dr LeeRa Cho, Department of Prosthodontics, Kangnung National University, 123 Jibyeon-Dong, Gangneung, Gangwon Do 210-702, Korea. e-mail: lila@kangnung.ac.kr—Eunghwan Kim, Lincoln, NE

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