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# Osseointegration of Rough Acid-Etched Titanium Implants: 5-Year Follow-up of 100 Minimatic Implants

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During 1992, 100 Minimatic screw implants made of titanium alloy (titanium-aluminum-vanadium) with a machined rough acid-etched surface were placed in 63 consecutive partially edentulous patients. At second-stage surgery, which was performed after a 4- to 6-month healing period, none of the implants showed signs of mobility, peri-implant infection, or bone loss from the crest of the ridge. Each patient was restored with a fixed prosthesis and reexamined every 3 months during the first year. Periapical radiographs were taken annually up to 5 years. These revealed no signs of peri-implant radiolucencies involving any of the implants, and mean alveolar bone loss was less than 1 mm at the 5-year examination. One implant was considered a late failure because of a peri-implant infection that developed during the first year, although the implant was still functional at year 5. Another patient with 2 implants dropped out during the fifth year of the study, although both implants had been considered successful up to that point. Based on annual measurements of Plaque Index, Sulcular Bleeding Index, pocket probing depth, attachment level, width of keratinized mucosa, and hand-tested mobility, 97 of the remaining 98 implants were considered successful, resulting in a 98% success rate. This 5-year study confirms that Minimatic machined acid-etched implants provide predictable osseointegration results and supports the conclusion of other reports that titanium implants with a rough surface can fulfill the requirements of Albrektsson et al (1986) for implant success. (INT J ORAL MAXILLOFAC IMPLANTS 1994;14:384-391)

**Key words:** acid-etched implants, five-year follow-up, osseointegration, rough surface implants

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**B**ased on clinical and experimental data, it is clear that the long-term clinical success of dental implants depends largely on osseointegration of the implant. Bone must integrate with the implant

without the infiltration of soft tissues, thus anchoring the implant in place, preventing mobility, and supporting the prosthesis.

The importance of osseointegration was first described by Brånemark et al,<sup>1</sup> and the original microstructural and macrostructural aspects of the standard Brånemark implant (Nobel Biocare, Göteborg, Sweden) were initially considered essential for ensuring adequate bone formation around any implant. These attributes include its cylindrical and threaded screw design, a machined surface, and commercially pure (cp) titanium composition.<sup>2</sup>

In recent years, however, some of these success criteria for shape, material, and surface have come under scrutiny. For instance, although a machined cp titanium surface was recommended for many years to ensure best results,<sup>3</sup> more recent studies suggest that other materials and surface characteristics may also be beneficial.

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**Table 1** Type and Location of Implants Placed

Type and location	No. of patients	Implant length (mm)			Total placed
		10	13	15	
Mandibular single implant	10	3	6	1	10
Maxillary single implant	20	7	9	4	20
Mandibular distal edentulous	17	18	14	4	36
Maxillary distal edentulous	8	6	9	3	18
Extended edentulous spaces	8	6	8	2	16
Total	63	40	46	14	100

First, the biocompatibility of a particular implant is determined by the distinct oxide layer that covers the surface.<sup>4,5</sup> Actual contact occurs only between the host tissue and these surface oxides, not the implant metal.<sup>6</sup> For both cp titanium and titanium alloy (Ti-6Al-4V) implants, a layer of titanium oxide covers the surface. Because this same oxide layer is also formed on rough surfaces,<sup>7</sup> a similar biocompatibility for machined and rough surfaces can be assumed.

Several *in vivo* studies have also reported that osseointegration is better facilitated by rough implant surfaces than by machined implants composed of identical material.<sup>8-11</sup> Gotfredsen et al<sup>12</sup> reported significantly better bone anchorage with titanium oxide-blasted (TiO<sub>2</sub>-blasted) screw implants compared with implants that were machined. In a comparison of 6 different surface structures, Wilke et al<sup>10</sup> reported that sandblasted and acid-treated screws with a rough surface required the highest torque removal. In another comparison of TiO<sub>2</sub>-blasted screw implants made of both cp titanium and Ti-6Al-4V, Han et al<sup>13</sup> reported that an increase in surface roughness significantly increased torque removal testing for both implant types. Sullivan et al<sup>14</sup> and Wennerberg<sup>15</sup> also reported improvements in bone anchorage of cp titanium and titanium alloy implants when the surfaces were roughened with chemical etching. Some of this evidence is preliminary.

In addition, Quirynen et al<sup>16</sup> and Albrektsson et al<sup>3</sup> have cautioned against extrapolating successful results from one implant to another, even if their design appears quite similar. Indeed, various laboratory experiments suggest that host cells can discriminate among very subtle differences in surface chemistry, roughness, and topography of particular implants.<sup>17-19</sup> Thus, it has been suggested that even minimal changes in material or design of an implant may have a significant impact on the clinical outcome.<sup>16</sup>

The present study was undertaken specifically to evaluate tissue integration of Minimatic Ti-6Al-4V implants (Minimatic Implants Technology, Boca Raton, FL) with a machined rough acid-etched surface and a modified thread design with a flat surface that faces the implant apex, allowing for self-tapping of the implant. This 5-year report is a follow-up to a 1-year study.<sup>20</sup>

#### Materials and Methods

In 1992, 100 Minimatic screw implants of varying lengths, each 3.75 mm in diameter, were placed in 63 consecutive partially edentulous patients (Table 1). The implants were machined, and the standard procedure reported by the American Society for Testing and Materials (ASTM) designated as B 600 was followed: implants were passed through emulsion soak-type cleaners to remove grease, oil, and lubricants from machining and fabricating operations and then were pickled in an acid solution composed of 15 volume % (225 g/L) of 70% nitric acid and 1.5 volume % (18 g/L) of hydrofluoric acid (60% at 120°F/49°C). Patients with systemic or local contraindications were excluded. Altogether, 54 implants were placed in the mandible, and 46 were placed in the maxillae of these patients. All procedures were performed by the same surgeon following standard protocol.

**First-Stage Surgery.** For this study, 2 major alterations were made in the surgical technique described by Lekholm.<sup>21</sup> First, the self-tapping design used here limited the need for bone tapping to implants placed in very dense bone, typically between the mental foramina. Second, external cooling with a syringe was not necessary because the osteotomy drills were equipped with an internal channel for chilled saline flow (in addition to the external flow provided by the handpiece).

The first gingival incision was made slightly lingually with respect to the midcrestal line, and a mucoperiosteal flap was created. Bone drilling was performed by first using a round bur to mark the implant site and make the initial entry into the cortical bone. Then, 5 sequentially larger drills were used, ranging from 2 to 3.5 mm in diameter, with copious irrigation. Finally, the coronal portion of the implant was countersunk.

To avoid contact with contaminants, each implant was transferred to the recipient site with the plastic cap left on the sterile vial that holds the implant. The cap was removed, and the final fitting (ie, screwing) of the implant was completed with a hand wrench. The mucoperiosteal flap was readapted and tightly sutured.

**Healing Phase.** During the initial 2- to 3-week healing phase, patients were instructed not to chew or brush in the surgical area, but to rinse for 1 minute twice daily with 0.12% chlorhexidine digluconate (Dentosan Mese, Pagni Raffaello, Florence, Italy). Systemic antibiotics were each administered twice daily for 7 days (1 g amoxicillin and 250 g clavulanic acid [Neoduplamox, Procter and Gamble, Rome, Italy]). The sutures were removed between 7 and 10 days after surgery. Follow-up visits were scheduled for 14 and 21 days after surgery, then on a monthly basis until the 4- to 6-month healing phase was completed.

**Second-Stage Surgery.** The timing of second-stage surgery for each patient was based on implant location. During the uncovering procedure, a mixed-thickness flap (ie, full thickness on and immediately around the implant and partial thickness in the adjacent areas) was made to provide complete vision and instrumental access to the implant and peri-implant bone.

Special care was taken to augment the width of peri-implant keratinized mucosa. If the implant was surrounded by mobile alveolar mucosa, a free gingival grafting technique was performed. Such grafting was performed at 7 sites— 6 in the distal mandibular region and 1 in the distal maxillary region.

In addition, an attempt was made in all patients to reduce the height of peri-implant soft tissues covering the implant to approximately 3 mm by using an apically positioned flap procedure. Special care was taken to enhance esthetics by avoiding tissue reduction around implants located in the maxillary anterior region.

If at this time the implant showed no signs of mobility and the appearance and consistency of the peri-implant bone were normal (ie, no indications of infection or bone loss), a healing screw was placed. After an additional 2-week soft tissue

healing phase, a custom tray was fabricated and the final impression and prosthesis were made. Thirty implants were restored with single crowns; the remaining 70 implants served as abutments for 33 implant-supported prostheses (Table 2).

**Postoperative Follow-up Visits.** After the prosthetic phase of treatment, all 63 patients were enrolled in a maintenance program, with follow-up visits scheduled every 3 months throughout the 5-year study period. During these visits, oral hygiene was checked, plaque was removed using a rubber cup and polishing paste, and if necessary, the patient was again informed about the importance of proper home care oral hygiene procedures.

Periapical radiographs were taken by the same operator preoperatively, immediately after surgery, at the time of the uncovering procedure (4 to 6 months after implantation), and then annually following surgery for patients who remained part of the study during the 5-year period. The radiographs were obtained with the long-cone technique, using Rinn film holders and an adhesive millimeter grid (X-ray Grid, General X-ray, Monte Carlo, Monaco). The radiographs were evaluated for any evidence of peri-implant radiolucencies, and the level of alveolar bone around the implants was also assessed. The distance between the implant shoulder and the first visible bone contact (DIB) was measured at the mesial and distal aspects of each implant (Fig 1). Based on these data, each implant was classified as either successful or failing according to the criteria of Albrektsson et al.<sup>3</sup>

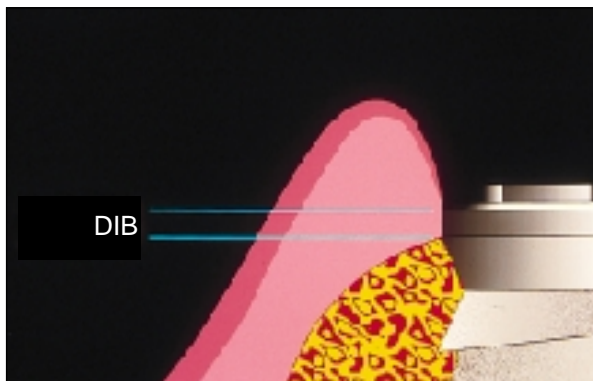
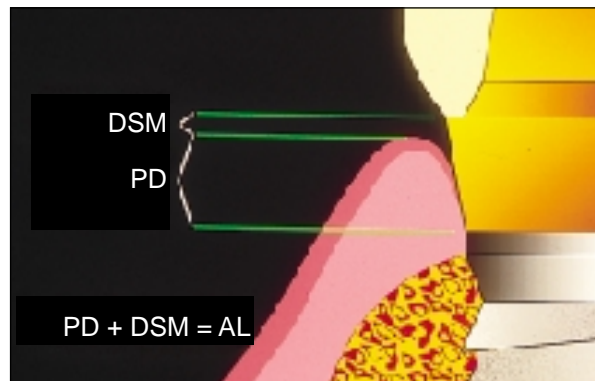
In addition, each implant was assessed using the following clinical indices: Plaque Index (PI), Sulcular Bleeding Index (SBI), probing depth (PD) of the pocket, distance between the UCLA abutment shoulder and the mucosal margin (DSM), attachment level (AL), width of keratinized mucosa (WKM), and hand-tested mobility.

The PI was determined on the mesial, buccal, distal, and lingual surfaces of the implant with the following scores assigned based on the amount of plaque: 0 indicated no plaque was detected; 1 meant that plaque was noted only by running a probe across the smooth marginal surface of the implant; 2 meant that plaque could be seen by the naked eye; and 3 indicated an abundance of soft matter.<sup>22</sup>

The SBI was assessed in the same places in which PI was measured, with the following scores based on the amount of bleeding: 0 indicated no bleeding when a periodontal probe was passed along the gingival margin adjacent to the implant; 1 meant that only isolated bleeding was visible; 2

**Table 2** Restoration of 63 Patients with 100 Screw-Retained Implants

Location of implant sites	Restoration		Total
	Crowns	Implant-supported prostheses	
Mandibular single-tooth space in mandible	10	—	10
Maxillary single-tooth space in maxilla	20	—	20
Mandibular distal edentulous space	—	17	17
Maxillary distal edentulous space	—	8	8
Extended edentulous spaces	—	8	8
Total	30	33	63

**Fig 1** Measurement of DIB as the distance between the first visible bone-implant contact and the implant shoulder.**Fig 2** Clinical attachment level (AL) is calculated by adding the probing depth (PD) to the distance between the UCLA abutment shoulder and the mucosal margin (DSM).

meant blood formed a confluent red line on the margin; and 3 indicated the presence of heavy or profuse bleeding.<sup>22</sup>

The PD of each pocket was measured to the nearest millimeter using a Hu-Friedy PGF-GFS periodontal probe (Hu-Friedy, Chicago, IL). Again, this was measured in the same places in which PI and SBI were assessed.

The DSM was measured to the nearest millimeter, with measurements made using the same probe in the same areas. For a subgingival abutment shoulder, the measurement was recorded as a negative value. The UCLA abutments used in this study were plastic, castable abutments. Prior to casting, the abutments were prepared by placing the shoulder in 3 possible locations: slightly subgingival for anterior, esthetically demanding implants; at the level of the gingival margin as it appeared on the master cast if esthetics were not crucial; or supra-gingival for posterior implants.

The AL was calculated for each site by adding the PS and the DSM (Fig 2). The WKM was measured in millimeters midbuccally and midlingually

for implants located in the mandible and midbuccally for implants in the maxilla. Implant mobility was tested manually.

## Results

During the first 4 years following implant placement, all 63 patients were available for evaluation, and each of the 100 implants originally placed was assessed. During the fifth year, only 61 patients with a total of 97 implants were evaluated. One of the patients, who had received 2 implants, dropped out of the study. Another had received 1 implant that exhibited peri-implant infection during the first year and was treated with antibiotics; this implant was considered a “late failure” based on the criteria of Buser et al.<sup>23</sup> Although this patient’s implant was still functional at the 5-year point, it was excluded from the following study results.

**Radiographic Evaluation.** At the 5-year follow-up visit, periapical radiographs of the 97 implants (61 patients) were obtained. The same patients had

**Table 3** Marginal Bone Loss Measured as Difference in DIB (mm) Between Baseline and Annual Follow-up Visits

	n	Marginal bone loss		
		Maxilla	Mandible	Overall
Year 1	99	0.76	0.80	0.78
Year 2	99	0.76	0.82	0.79
Year 3	99	0.78	0.82	0.80
Year 4	99	0.80	0.85	0.82
Year 5	97	0.80	0.85	0.82

**Table 4** Summary of Results of Implants at the 5-Year Follow-up

Parameter	n	Minimum	Maximum	Mean	SD
Plaque Index	388	0.0	3.0	0.53	0.64
Sulcular Bleeding Index	388	0.0	3.0	0.51	0.62
Pocket depth (mm)	388	1.0	6.0	2.77	0.85
Distance between abutment shoulder and mucosal margin (mm)	388	-2	3	-0.06	1.06
Attachment level (mm)	388	1	6	2.71	0.98
Width of keratinized mucosa (mm)	150	0.0	12.0	3.15	2.09
Marginal bone loss (mm)	194	0.0	2.5	0.82	0.83

SD = standard deviation.

been evaluated during each of the prior 4 years as well. The radiographs revealed no signs of radiolucencies in the peri-implant bone surrounding any of the implants. Changes in the alveolar bone height (DIB) were measured on the mesial and the distal surfaces of the implant by calculating the distance between the implant shoulder and the first visible bone-to-implant contact. These measurements were recorded on the day of implant placement and then annually. Table 3 shows the changes in DIB, or marginal bone loss, per year. At the 5-year examination, the mean DIB was 0.8 mm for the maxilla and 0.85 mm for the mandible. Compared with the 1-year data, this indicates an additional mean loss of 0.05 mm for implants in the mandible and 0.04 mm in the maxilla. The DIB for one implant measured 2.5 mm and was thus considered a failure based on the criteria for implant success proposed by Albrektsson et al.<sup>3</sup> All others fell within acceptable ranges.

**Clinical Indices.** *Plaque Index.* At 5 years after implant placement, most of the 61 patients still demonstrated good oral hygiene and adhered to the 3-month recall schedule for maintenance visits. The PI for each of the 97 implants was measured by assessing 4 surface sites on each of the implants for a total of 388 sites. The PI score was 0 on 248 surfaces (63.9%), 1 on 83 surfaces (21.4%), 2 on 49 surfaces (12.6%), and 3 on 8 surfaces (2.1%). The mean PI value was 0.53.

*Sulcular Bleeding Index.* In most of the patients, the peri-implant soft tissues appeared healthy. As with the PI, measurements were made on 4 surfaces of each implant for a total of 388 sites. The SBI score was 0 on 252 surfaces (64.9%), 1 on 81 surfaces (20.9%), 2 on 48 surfaces (12.4%), and 3 on 7 surfaces (1.8%). The mean SBI value was 0.51.

*Pocket Depth.* The probing depth of each pocket was again measured in 388 sites and ranged from 1 to 6 mm. Of the 388 sites, 86% had a PD less than or equal to 3 mm; the PD was 1 mm at 17 surfaces (4.4%), 2 mm at 130 surfaces (33.5%), and 3 mm at 187 surfaces (48.1%). Approximately 10%, or 39 surfaces, had a PD measuring 4 mm, whereas 4%, or 15 surfaces, measured 5 mm or more in depth. The mean PD was 2.77 mm.

*Distance Between Abutment Shoulder and Mucosal Margin.* The DSM was also measured at 388 sites. It ranged between -2 mm and +3 mm. The negative scores, which indicate a subgingival abutment shoulder, were recorded mostly in anterior maxillary implants, for which the crown margins were placed slightly into the peri-implant sulcus for esthetic reasons, or in sites adjacent to natural teeth. The DSM was -2 mm at 34 sites (8.7%), -1 mm at 85 sites (21.9%), 0 mm at 174 sites (44.6%), 1 mm at 69 sites (17.8%), 2 mm at 19 sites (4.9%), and 3 mm at 8 sites (2.1%). The mean DSM was -0.06 mm.

*Attachment Level.* The clinical AL, again calculated on 4 surfaces of each implant, was measured by adding the PD and DSM scores. The values ranged from 1 to 6 mm. Of the 388 surfaces, 86% had an AL of 3 mm or less: 32 surfaces (8.2%) had an AL of 1 mm, 139 surfaces (35.8%) had an AL of 2 mm, and 163 surfaces (42%) had an AL of 3 mm. In addition, 31 sites (8%) had an AL of 4 mm and 23 sites (5.9%) had an AL of 5 mm or more. The mean AL value was 2.71 mm.

*Width of Keratinized Mucosa.* The WKM was measured on 150 surfaces of 53 mandibular implants (on both the buccal and lingual surfaces) and 44 maxillary implants (on the buccal surface only). The WKM ranged from 0 to 12 mm. Six surfaces (4%) had a WKM of 0 and were localized in mobile, nonkeratinized mucosa. All other sites showed a WKM of 1 mm or more. The WKM measured 1 mm at 11 surfaces (7.3%), 2 mm at 42 surfaces (28%), 3 mm at 46 surfaces (30.7%), and 4 mm or more at 45 surfaces (30%).

*Mobility.* Clinically, all 97 implants included in this 5-year study showed stable anchorage in bone without any detectable mobility, based on manual testing. In addition, the 1 implant that experienced peri-implant infection during the 1-year follow-up study and was considered a late failure, for the purposes of this study, also showed clinically stable bone anchorage at the 5-year follow-up examination. This suggests that manual tests of mobility may not always be reliable indicators of peri-implant bone condition.

**Overview of Results.** Table 4 summarizes the minimums, maximums, means, and standard deviations of the radiographic and clinical index measurements used to evaluate the 97 implants 5 years after placement of the Minimatic machined acid-etched implants.

## Discussion

Some authors<sup>24-26</sup> have assumed that to attain clinical results similar to those yielded by the Brånemark system when using other implants, it is desirable to choose one with a smooth surface that closely resembles the standard Brånemark implant. However, as mentioned, many other authors have reported successful results in achieving direct bone-implant contact when using titanium implants with rough surfaces. In recent years, some explanations as to why surface roughness may increase the success of implants have been suggested. Increased surface roughness may enhance the mechanical interlocking between the macromolecules of the implant surface and the bone, resulting in a greater

resistance to compression, tension, and shear stress, as some authors have demonstrated.<sup>27,28</sup> Bowers et al found that surface roughness significantly increases the degree of cellular attachment of osteoblast-like cells in vitro.<sup>29</sup> Schwartz et al<sup>17</sup> found that as surface roughness increases, so might matrix production and RNA synthesis in mature chondrocytes increase in nongrowing areas. In another study, Schwartz et al<sup>30</sup> found that increasing the surface roughness of titanium implants also increased the production of certain cytokines and growth factors by host osteoblast-like cells, both of which may enhance bone formation. A review by Kieswetter et al highlighted evidence that osteoblasts tend to exhibit a more mature phenotype when grown on rougher surfaces.<sup>31</sup>

In the present study, the authors specifically assessed the clinical success of one type of surface-roughened implant—the Minimatic machined acid-etched titanium alloy implant with modified thread design to allow self-tapping. Although other acid-etched dental implants are now available, the success and predictability of a particular implant must be based on its own merits and specific clinical study, since even small alterations in an implant's design can dramatically affect its success.<sup>3</sup> This 5-year report follows the publication of preliminary 1-year data.<sup>20</sup>

Of the 100 implants placed, only 2 failures occurred. One was classified as a late failure,<sup>23</sup> meaning it occurred during the maintenance phase following successful osseointegration. At the 9-month recall visit, this problematic mandibular implant, already bearing a fixed prosthesis, showed signs of peri-implantitis (bleeding on probing, increased pocket depth, and peri-implant infection with mild suppuration). Although the failed implant showed no clinical signs of mobility, periapical radiographs obtained at this point revealed clear signs of crestal bone resorption. The patient was successfully treated with antibiotics. Although the patient's implant remained functional, it was considered a failure and not included in the 5-year data. Late failures are thought to be plaque-induced.<sup>23</sup> The second failure was classified as such because of inadequate osseointegration based on the criteria of Albrektsson et al.<sup>3</sup> A patient with 2 implants dropped out of the study in the third year. The other 96 implants included in this study demonstrated stable bone anchorage at the 5-year follow-up examination and no mobility when tested manually.

Throughout the 5 years, the patients' peri-implant soft tissues remained generally healthy, with little tendency to bleed (mean SBI score of

0.51) and a minimal probing pocket depth (mean score of 2.77 mm) similar to results reported by other authors.<sup>23-25</sup> Considering that about 30 of the original 100 implants were in critical esthetic locations, the mean DSM (-0.06 mm) indicates very minimal gingival recession and good acceptance by the marginal tissue.

The importance of keratinized mucosa width is unclear, since controlled clinical studies on its role are lacking. Nonetheless, the authors prefer that the transmucosal abutment pass through keratinized tissue, and this was achieved in 95% of the examined surfaces. This was attributed to particular attention paid to maintaining as much keratinized tissue as possible during second-stage surgery through an apically repositioned flap, and when needed, by increasing that with a free gingival graft. Similar results were obtained by Buser et al<sup>23</sup> using nonsubmerged implants. In studies of submerged implants,<sup>24,25</sup> WKM varied from 20% to 65%, perhaps because of different surgical approaches.

Albrektsson et al<sup>3</sup> noted that to be considered successful, a minimum 85% success rate over 5 years should be achieved and no more than 0.8 mm of vertical bone loss should occur between years 1 and 5. Based on these criteria, the Minimatic implant proved satisfactory in this study, with a 98% success rate over 5 years and a mean vertical bone loss of 0.04 mm for the maxilla and 0.05 mm for the mandible between year 1 and 5.

### Summary

Data from a 5-year follow-up of 100 Minimatic screw implants made of titanium alloy with machined rough acid-etched surfaces and modified thread design have been presented. At the time of second-stage surgery, following a 4- to 6-month healing period, none of the implants showed signs of mobility, infection, or bone loss. Treatment consisted of fixed prostheses. On an annual basis for 5 years following implant placement, the patients were evaluated and the 100 implants were assessed using the following clinical indices: Plaque Index, Sulcular Bleeding Index, probing depth, attachment level, distance between the UCLA abutment shoulder and mucosal margin, width of keratinized mucosa, and hand-tested mobility. These 5-year data include 61 surviving patients with a total of 97 Minimatic implants. Periapical radiographs were taken preoperatively, immediately after surgery, at uncovering, and annually following the surgery date. Based on these indices, 96 implants were considered successful (98%) and 2 failed. This study indicates that a rough acid-etched im-

plant, when used in conjunction with appropriate techniques, can become successfully osseointegrated and yield predictable results.

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