

# One-Year Results of a Prospective Multicenter Study on Brånemark System® Implants with a TiUnite™ Surface

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## ABSTRACT

*Background:* A moderately rough surface implant (TiUnite™, Nobel Biocare AB, Göteborg, Sweden) was introduced in 2000. Laboratory studies and some clinical studies have demonstrated excellent bone response in the early healing phase.

*Purpose:* The aim of this prospective multicenter study was to follow a large number of consecutively treated patients using Brånemark System® implants with the TiUnite surface. The current report constitutes the 1-year data of a planned 3-year study.

*Materials and Methods:* Originally, the study comprised 43 surgeons from 22 centers in Sweden, Norway, and Finland. Five centers were excluded from the study because of poor compliance. Thus, 187 patients treated with 478 TiUnite implants were followed during 1 year of function. The majority of implants were inserted in maxillae (357 implants), and 78 of the implant sites were assigned the quality 4 figure. Radiographic evaluations were performed.

*Results:* Five implants were lost up to and including the 1-year follow-up, revealing implant cumulative survival rates of 98.6% and 100% for maxillae and mandibles, respectively. Three implants failed in quality 4 bone (3.8%). The mean marginal bone resorption at the end of the study period was 1.4 mm. The number of withdrawals of patients during the first year was high (19.3%).

*Conclusion:* The present investigation showed a high implant cumulative survival rate of 98.9%. Values of marginal bone resorption were within normal ranges. No adverse effects of the TiUnite surface were reported, and complications during the study period were few and similar to those reported for the turned implant surface. However, the high number of excluded patients and the relatively high number of withdrawals must be observed and considered when interpreting data.

**KEY WORDS:** osseointegration, prospective multicenter study, rough surface

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Prospective multicenter studies are regarded as useful tools when analyzing and evaluating the behavior of routine and/or new components in oral implant treat-

ment. New implant designs or surfaces in the hands of many clinicians may clarify the advantages or disadvantages of the product and what may, in the future, be expected from a certain treatment procedure. By properly documenting these findings, preferably in published scientific reports, further developments of components and techniques may occur. Over the years, a series of prospective multicenter studies have focused on the 5- to 10-year behavior of various turned, minimally rough Brånemark System® implants in different jaw situations<sup>1-5</sup> and have shown very encouraging results.

An oxidized, moderately rough surface (TiUnite™) was introduced in 2000 by Nobel Biocare AB (Göteborg, Sweden). Comparative laboratory and clinical studies on turned and TiUnite Mk III and Mk IV implants have so far shown the early bone response to be significantly

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stronger with the TiUnite surface.<sup>6-12</sup> Thus, it was considered of great interest to follow TiUnite implants placed in consecutive patients using a prospective multicenter study concept. Such a study was initiated in 2000 to continue over a period of at least 3 years, and the preliminary results were presented in 2002.<sup>13</sup> The aim of the current report was to demonstrate the clinical and radiographic 1-year data.

**MATERIAL AND METHODS**

The outline of the research protocol for this 1-year prospective multicenter study was previously presented in brief.<sup>13</sup> The original group of 43 surgeons (22 clinical centers in Sweden, Finland, and Norway) was reduced over time. Five centers that did not comply with the study instructions were removed from the investigation, and the present report comprised 30 surgeons from Sweden and Norway. Thus, the group of 260 patients included from the beginning diminished to 187 patients, representing a mean age of 53 years (range 16–86 years). The reasons for withdrawals are listed in Table 1.

The originally included 584 Brånemark System implants with a moderately rough surface (TiUnite) diminished to 478, which were followed for 1 year with clinical and radiographic examinations. Various jaw situations were treated: single-tooth restorations (85 implants), partially edentulous patients (183 implants), and totally edentulous patients (210 implants). The distributions of implants with regard to jaw, tooth position, and bone quality and quantity are presented in Tables 2 to 4. The overall majority of implants were inserted in maxillae (75%); thus, a great number of implants were placed in softer bone sites assigned the quality figures 3 (48%) and 4 (16%), respectively.<sup>14</sup> Shape group classes B (50%) and C (37%) predominated,<sup>14</sup> which was also reflected by the high number of long (13–18 mm) implants used (Table 5).

| Reason         | Number of Patients |
|----------------|--------------------|
| Deceased       | 3                  |
| Moved          | 4                  |
| Other dentist  | 6                  |
| Complication   | 1                  |
| Unknown        | 6                  |
| Noncooperation | 16                 |
| Total          | 36                 |

| Location | n       |
|----------|---------|
| Maxilla  | 357 (5) |
| Mandible | 121 (0) |
| Total    | 478 (5) |

Failed implants within parentheses.

Distributions of implants with regard to other characteristics, such as design and platform, are presented in Tables 6 and 7. As can be seen, the Mk III design<sup>15</sup> with a regular platform (Ø 3.75 mm) dominated. Immediate insertion after extraction was executed for nine implants. A two-stage surgical procedure was the treatment of choice, and only 38 implants were inserted with a one-stage technique, of which 23 were immediately loaded.

Radiographs were obtained at the abutment operation, at the connection of fixed prostheses, and at the 1-year follow-up examination. One independent radiologist executed all radiographic readings. The fixture/abutment junction (FAJ) was used as the reference point, and implants available for radiographic evaluations were 121 from the connection of abutments to 1 year, whereas the corresponding figure from prosthesis insertion to 1 year was 128.

Special complication forms were used in connection to each treatment procedure and at the 1-year examination.

**STATISTICS**

The implant cumulative survival rate (CSR), based on all TiUnite implants inserted, was evaluated for the two jaws using life table analysis (Table 8).

**RESULTS**

As may be seen in Table 1, as many as 36 of the 187 patients (19.3%) withdrew during the first year for various reasons.

Five implants were found to be mobile up to and including the 1-year examination. All failures were registered in maxillae, revealing implant CSRs of 98.6% in upper jaws and 100% in lower jaws (see Table 8). None of the failures were recorded in relation to immediate insertion after extraction or in relation to one-stage surgery and immediate loading. Two implants were lost in patients with partial edentulism and two implants in patients with total edentulism, and one of

**TABLE 3 Distribution of Implants by Position**

|    | 8  | 31 | 33 (1) | 36 | 20 (1) | 55 (1) | 54 | 22 | 36 (2) | 30 | 28 | 3  |    |    |    |
|----|----|----|--------|----|--------|--------|----|----|--------|----|----|----|----|----|----|
| 18 | 17 | 16 | 15     | 14 | 13     | 12     | 11 | 21 | 22     | 23 | 24 | 25 | 26 | 27 | 28 |
| 48 | 47 | 46 | 45     | 44 | 43     | 42     | 41 | 31 | 32     | 33 | 34 | 35 | 36 | 37 | 38 |
|    | 2  | 10 | 16     | 16 | 8      | 6      | 3  | 4  | 4      | 8  | 15 | 15 | 11 | 3  |    |

Failed implants within parentheses.

the single-tooth implants failed during the study period. Three of the lost implants were placed in quality 4 bone; thus, 3 of 78 (3.8%) failed in such bone (see Table 4). As previously mentioned, the overall majority of implants were inserted in bone shape groups B and C, and all failures were also recorded in these shape classes (see Table 4).

Frequency distributions of implants with marginal bone loss are shown in Figure 1. The mean value of the marginal bone loss was 1.40 mm (SD 1.12 mm), as measured from abutment connection to the first annual examination. The marginal bone loss during the first year of loading was 0.68 mm (SD 1.06 mm), as measured from prosthesis insertion to the first annual examination.

The most important reported complications were altered (diminished) sensation of the lower lip in one patient, allergic reaction toward the gold material of one construction, phonetic problems with one fixed prosthesis, fistula with pus formation in relation to one implant, one exposed cover screw, and hyperplastic gingiva in relation to one implant.

**TABLE 4 Distribution of Implants with Regard to Assessed Bone Quality and Quantity Values**

| Quality  | n       |
|----------|---------|
| 1        | 12 (0)  |
| 2        | 158 (1) |
| 3        | 230 (1) |
| 4        | 78 (3)  |
| Total    | 478 (5) |
| Quantity | n       |
| A        | 35 (0)  |
| B        | 241 (4) |
| C        | 176 (1) |
| D        | 24 (0)  |
| E        | 2 (0)   |
| Total    | 478 (5) |

Failed implants within parentheses.

**DISCUSSION**

Prospective multicenter studies of such proportions as the present one, with many participating clinicians from several countries, are difficult to conduct. The high number of excluded patients, the relatively high number (19.3%) of withdrawals (see Table 1) of included patients during the first year, and the relatively low number of bone loss measurements on postoperative radiographs (see Figure 1) may bring up criticism and

**TABLE 5 Distribution of Implants by Length**

| Length (mm) | n       |
|-------------|---------|
| 7           | 8 (0)   |
| 8.5         | 3 (1)   |
| 10          | 56 (0)  |
| 11.5        | 10 (0)  |
| 13          | 178 (1) |
| 15          | 172 (2) |
| 18          | 51 (1)  |
| Total       | 478 (5) |

Failed implants within parentheses.

**TABLE 6 Distribution of Implants by Design**

| Implant | n       |
|---------|---------|
| Mk III  | 466 (4) |
| Mk IV   | 12 (1)  |
| Total   | 478 (5) |

Failed implants within parentheses.

**TABLE 7 Distribution of Implants by Platform**

| Platform | Number of Implants |
|----------|--------------------|
| NP       | 1 (0)              |
| RP       | 471 (5)            |
| WP       | 6 (0)              |
| Total    | 478 (5)            |

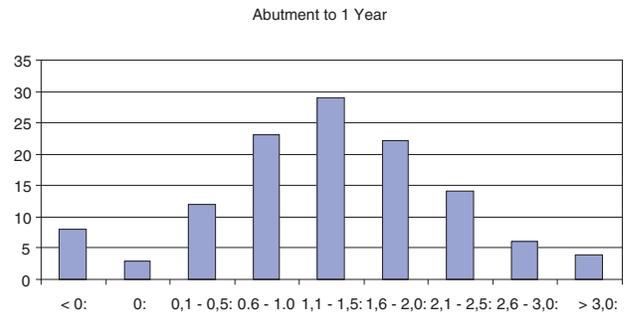
NP = narrow platform; RP = regular platform; WP = wide platform. Failed implants within parentheses.

**TABLE 8 One-Year Implant Cumulative Survival Rate (CSR)**

|                    | Implants | Failed | Withdrawn | CSR, % |
|--------------------|----------|--------|-----------|--------|
| <b>Maxillae</b>    |          |        |           |        |
| Placement–abutment | 357      | 2      | 8         | 99.4   |
| Abutment–bridge    | 347      | 2      | 5         | 98.9   |
| Bridge–6 mo        | 340      | 0      | 14        | 98.9   |
| 6 mo–1 yr          | 326      | 1      | 34        | 98.6   |
| 1 yr               | 291      | —      | —         | —      |
| <b>Mandible</b>    |          |        |           |        |
| Placement–abutment | 121      | 0      | 1         | 100    |
| Abutment–bridge    | 120      | 0      | 0         | 100    |
| Bridge–6 mo        | 120      | 0      | 5         | 100    |
| 6 mo–1 yr          | 115      | 0      | 4         | 100    |
| 1 yr               | 111      | —      | —         | —      |
| <b>Total</b>       |          |        |           |        |
| Placement–abutment | 478      | 2      | 9         | 99.6   |
| Abutment–bridge    | 467      | 2      | 5         | 99.2   |
| Bridge–6 mo        | 460      | 0      | 19        | 99.2   |
| 6 mo–1 yr          | 441      | 1      | 38        | 98.9   |
| 1 yr               | 402      | —      | —         | —      |

must be considered when interpreting data. We communicated with the chairmen of the five excluded centers, who have not noticed increased failure rates when using TiUnite implants.

Two implants were lost up to and including the prosthetic procedure, yielding an early failure rate of 0.8% (see Table 8). This figure is in accordance with the early failure rates of 1.5 to 3.6% formerly reported for the Brånemark System implants.<sup>16–18</sup> The 1-year result was 98.9%. By rendering the jaws separately, CSRs of 98.6% and 100% for maxillae and mandibles, respectively, were at hand (see Table 8). Although no losses were reported in mandibles, the CSR of 98.6% for maxillary implants is the most encouraging, especially when referring to the relatively high number of such implants placed (357) and the high number of surgeons involved (30). The outcome for both jaws was close to identical to the 1-year result reported by Widmark and colleagues on turned Mk III implants,<sup>15</sup> albeit the figures for the separate jaws were more or less the opposite: 100% and 97.1% for maxillae and mandibles, respectively. Thus, when comparing the present prospective multicenter study with the one presented by Widmark and colleagues,<sup>15</sup> it may be of interest to note that Mk III



**Figure 1** Frequency distribution of implants with marginal bone loss as measured from abutment connection (AC) to 1 year and from prosthesis insertion (PI) to 1 year.

implants with turned and oxidized (TiUnite) surfaces showed similar survival rates at 1 year when a two-stage surgical technique was used. This is in contrast to findings by Glauser and colleagues,<sup>10,11</sup> who compared Brånemark System implants with turned and TiUnite surfaces in relation to an immediate loading concept. Their reported survival rates at 1 year, when tested statistically, were significantly in favor of the TiUnite surface. The reason for this may be that the TiUnite surface, compared with the turned one, shows a stronger early bone response,<sup>6–9,12</sup> which may be of vital importance when handling the immediate loading concept.

It was gratifying to see that implants placed in quality 4 bone were not causing major problems and that only 3 of 78 (3.8%) implants failed in such bone. However, this is in accordance with several recent publications on successful implant placement in the soft bone texture of maxillae<sup>19–22</sup> and in stark contrast to the devastating 5-year results on implants placed in quality 4 bone presented by Jaffin and Berman.<sup>23</sup> Apart from the fact that clinicians of today have improved their technique, skill, and understanding when handling oral implants, one may consider that the TiUnite surface, with its stronger early bone response, could have had an impact on the present outcome.

The FAJ was chosen as the reference point from which the distance to the marginal bone level was measured, and this has been the standard procedure of many recent study protocols on Brånemark System implants. The mean marginal bone resorption, analyzed from radiographs of 121 implants, was 1.40 mm (SD 1.12 mm) from the abutment connection to the 1-year follow-up. The figures are similar to the ones reported on turned Mk III implants by Widmark and colleagues.<sup>15</sup> They analyzed radiographs from 143

implants and found the marginal bone resorption to be 1.15 mm (SD 1.09 mm) from abutment connection to the 1-year follow-up. In former studies, the reference point was instead chosen to be 0.8 mm apical to FAJ.<sup>17,24,25</sup> When extrapolating the figures of marginal bone resorption from these different approaches, the outcome of today is more or less equivalent to the outcomes obtained 10 to 25 years ago.

Registered complications during the various treatment procedures up to the 1-year visit of the present study were few and similar to the ones described in other prospective multicenter reports on Brånemark System implants.<sup>1-5</sup> Thus, it was not possible during the study period to show any complications specifically adhered to the rougher TiUnite surface.

## CONCLUSIONS

The present prospective multicenter investigation, comprising 187 patients and 478 Brånemark System implants with a medium rough surface (TiUnite), exhibited a 1-year CSR of 98.9%. Corresponding figures for maxillae and mandibles were 98.6% and 100%, respectively. The mean marginal bone resorption, as measured from the FAJ, at the end of the study period was 1.4 mm. Treatment complications were few and did not diverge from those reported in studies on turned Brånemark System implants. Five of 22 centers were excluded from the study owing to a lack of compliance, and the number of withdrawals of patients during the first year was high (19.3%).

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