A Prospective Multicenter Clinical Trial of 3i Machined-Surface Implants: Results After 6 Years of Follow-up

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Purpose: *In this prospective multicenter clinical study, 1,179 3i standard threaded and self-tapping implants were followed for up to 6 years and monitored according to established success criteria.* ***Materials and Methods:*** *A total of 493 patients (240 men and 253 women) with a mean age of 45.1 years at implant surgery were enrolled at 6 research centers after being screened for exclusion criteria. Implants were placed according to a 2-stage surgical protocol with a minimum of 4 months of submerged healing in the mandible and 6 months in the maxilla. Restorations included 633 prostheses, the majority of which were fixed partial dentures in the posterior mandible or maxilla or single-tooth replacements in the anterior maxilla.* ***Results:*** *One hundred four implants (8.8%) did not meet success criteria and were designated as failures, and 222 implants (18.8%) were lost to follow-up. The cumulative success rate according to life table methods was 91.1% at 6 years.* ***Discussion:*** *Sixty percent of the failed implants were short (≤ 10 mm long), and their cumulative success rate as a group at 6 years was 89.0%, compared to 93.1% for longer implants ($P < .05$). Thirty-three percent of all failures were implants placed in the posterior maxilla, for a 5-year cumulative success rate of 87.4%.* ***Conclusion:*** *It appears that limited bone dimensions and poor-quality bone have an impact on the performance of these machined-surface implants.* (Int J Oral Maxillofac Implants 2003;18:417–423)

Key words: *bone quality, clinical trial, endosseous dental implants, surface properties*

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The clinical use of endosseous implants has enriched the therapeutic spectrum of restorative dentistry like few other innovations in the last century. Since the introduction of the first well-documented implant system,[1] many others have followed, exhibiting similar as well as different material properties and design features. Because of the steadily increasing number of implant restorations, the necessity has emerged to establish objective, system-independent criteria for defining long-term success of dental implants. The search for such criteria was first initiated at the National Institutes of Health Harvard Consensus Development Conference in 1978.[2] The currently accepted and established criteria are based on a series of other proposals for implant success criteria[3,4] and were subsequently refined and reinforced in the Toronto Consensus Report in 1998.[5] To be considered successful, an implant must meet the following requirements[5]:

Fig 1 The 3i self-tapping implant.

1. The resultant implant support does not preclude the placement of a planned functional and esthetic prosthesis that is satisfactory to both patient and dentist.
2. There is no pain, discomfort, altered sensation, or infection attributable to the implants.
3. Individual unattached implants are immobile when tested clinically.
4. The mean vertical bone loss is less than 0.2 mm annually following the first year of function.

The objective of this study was to evaluate the long-term performance of 3i standard threaded and self-tapping implants (Implant Innovations, Palm Beach Gardens, FL). The following is the first description of a prospective clinical trial on 3i machined-surface implants with well-defined success criteria over an observation time of up to 6 years.

MATERIALS AND METHODS

Six research centers (5 university clinics and 1 private clinic) located in the United States (3 institutions) and in Europe (3 institutions) participated in this prospective, multicenter clinical trial. Patients had to be able to tolerate conventional surgical and restorative procedures and had to be willing and able to comply with all aspects of the treatment and follow-up schedule. The patients' health status was evaluated in a preoperative screening. Presence of 1 or several of the following conditions, determined either by direct examination or historical documentation, was reason for exclusion from the study: alcoholism or drug abuse, mental illness, evidence or suspicion of unwillingness to comply with long-term follow-up, uncontrolled diabetes, hemophilia, metabolic bone disorder, history of renal failure, corticosteroid treatment, anticoagulant therapy, radiation treatment to the head or neck, previous bone graft at the intended site, current chemotherapy, untreated or uncontrolled periodontal pathology, current pregnancy at the time of evaluation, and severe bruxing or clenching habits.

The test designs to be implanted in the patients were 3i standard threaded implants and 3i self-tapping implants (Fig 1). These implants feature a machined surface and an external hexagon. The lengths (7, 8.5, 10, 13, 15, and 18 mm) and diameters (3.25, 3.75, 4, 5, and 6 mm) of the individual implants varied from subject to subject, depending on the bone width and depth at each site. To standardize surgical procedures, all centers were equipped with the same surgical drill units, handpieces, and surgical instruments. Furthermore, study monitors assessed and reviewed all surgical procedures to ensure intercenter reliability. The implants were placed according to the manufacturer's guidelines in a 2-stage process to guarantee complete bony fixation before loading. Concomitant hard tissue grafting or augmentation procedures precluded inclusion in the study. At the time of surgery, the clinical assessment of bone quality was recorded based on hand-felt perception of the drilling resistance and categorized into 1 of 3 classes of bone quality. Bone quality was scored by the clinician as dense, normal, or soft. Surgical uncovering of the implants was done after a healing period of 4 months in the mandible and 6 months in the maxilla.

During soft tissue healing after stage 2 surgery, fabrication of the prosthetic restorations was completed. At the time of prosthesis placement, baseline measurements were obtained. They consisted of clinical and radiographic parameters and were repeated at 6 months, 1 year, 18 months, and 2, 3, 4, and 5 years after prosthesis placement.

Clinical parameters included the assessment of:

- Individual and unattached implant mobility, as determined by the lateral application of pressure by 2 opposing instruments to the implant
- Probing depths at mesial, distal, buccal, and lingual sites, ie, distance in mm between the mucosal margin and the bottom of the probable pocket with a non-standardized periodontal probe; care was taken not to disturb any soft tissue attachment
- Peri-implant mucosal health at 4 sites, including gingival levels, amount of keratinized gingiva, amount of recession, gingival inflammation, and presence of hyperplastic mucosa or suppuration

Table 1 Distribution of Implants by Study Center

Center	No. of patients	No. of restorations	No. of implants placed	No. of implant failures	Failure rate by center
1	47	64	160	18	11%
2	126	133	267	24	9%
3	116	144	274	22	8%
4	48	77	149	14	9%
5	70	85	85	3	4%
6	86	130	244	23	9%
Totals	493	633	1179	104	8.82%

In measuring gingival levels, a standard reference point was established from which measurements were made in millimeters, ie, the implant/abutment interface. All measurements apical to the reference point were expressed as negative numbers; all coronally oriented measurements were reported as positive numbers.

Gingival inflammation was categorized by severity using the following scale: 0 = no inflammation, 1 = mild inflammation (color change only), 2 = moderate inflammation (bleeding upon probing), and 3 = severe inflammation (spontaneous bleeding).

Radiographic parameters were obtained from periapical and panoramic radiographs made at baseline, 6 months, and 1, 2, 3, 4, and 5 years and included mesial and distal bone level measurements as well as descriptions of peri-implant radiolucencies. Acquisition of periapical radiographs was standardized by use of a customized template fabricated at the time of prosthesis placement. Bone level measurements estimated to the nearest 0.01 mm were performed by 1 calibrated examiner on serial radiographs according to standard operating procedures. Average mesial and distal bone level measurements were calculated for all implants. The mean implant value was the average of the mean mesial and distal measurements. Bone loss was the difference in bone level measurements from the baseline established at prosthesis loading compared to each follow-up evaluation.

In addition to the surgical and implant measurements, prosthodontic parameters were assessed at follow-up evaluations. Categories rated by the clinicians on a scale from 1 to 4 included prosthesis retention, prosthesis stability, esthetics, and phonetics. The Cornell Medical Index[6,7] was used to evaluate patient satisfaction in the categories comfort, fit, speech, appearance, ability to chew, ability to taste, and general satisfaction. Each category was graded as 1 (excellent), 2 (good), 3 (fair), or 4 (poor). Changes in medical status and disclosure of new adverse events (unanticipated negative effects, eg, implant failure, fracture of implant components) were also recorded at each recall visit.

In this study an implant was considered successful

- If it was immobile when tested individually and unattached to other implants
- In the absence of peri-implant radiolucency
- While no persistent or irreversible signs and symptoms such as pain, discomfort, altered sensation, or infection attributable to the implant were observed
- If there was loss of marginal bone crestal levels no greater than 0.2 mm per year after the first year of function
- If the resultant implant support did not preclude the placement of a planned functional and esthetic prosthesis that was satisfactory to both patient and the investigator

Implants were classified as successful, failed, or censored (eg, not used as a result of death, buried because of poor position for restoration, or if the patient was lost to follow-up) and analyzed by survival analysis distribution according to life table methods.

RESULTS

A total of 493 patients—240 men (49%) and 253 women (51%) with a mean age of 45.1 ± 15.1 years—were enrolled in the study across 6 investigational centers. Of these, 78 (16%) were smokers and 1% had diabetes. A breakdown of enrollment by center is included in Table 1.

A total of 1,179 implants were placed in the 493 patients. The diameters and lengths of implants used in this study are described in Table 2. The majority of implants (61.8%) were 3.75 mm in diameter. Of the implants placed, 48.5% were short in length, ie, 10 mm or less. Five hundred nine (41.4%) of the implants were placed in the maxilla and 972 (79.1%) in premolar or molar areas of the mandible or the maxilla. Two hundred seventy-four (23.2%) were located in the posterior maxilla

Table 2 Length and Diameter Distribution of Implants

Implant diameter (mm)	Implant length (mm)							
	7.0	8.5	10.0	13.0	15.0	18.0	20.0	Total
3.25	0	0	2	33	30	0	0	65
3.75	7	11	275	242	175	17	1	728
4.00	0	1	10	8	4	0	0	23
5.00	11	47	144	75	0	0	0	277
6.00	9	11	44	22	0	0	0	86
Total	27	70	475	380	209	17	1	1179

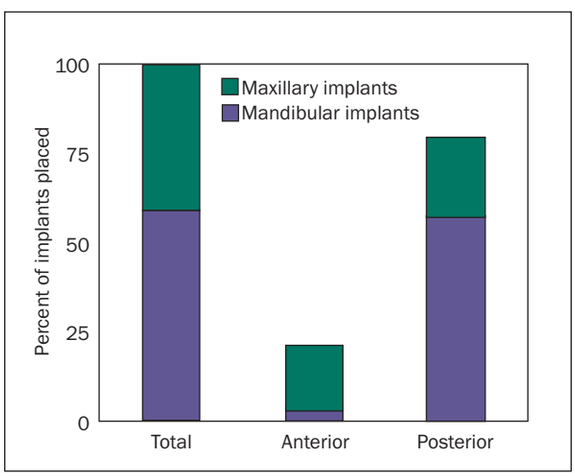

Fig 2 Proportion of implants placed by location.

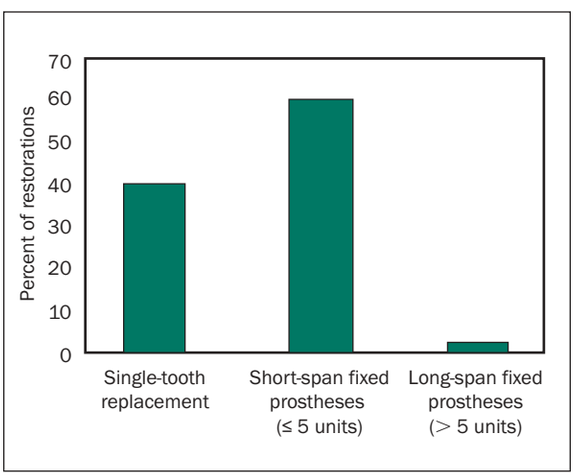

Fig 3 Distribution of prosthetic restorations.

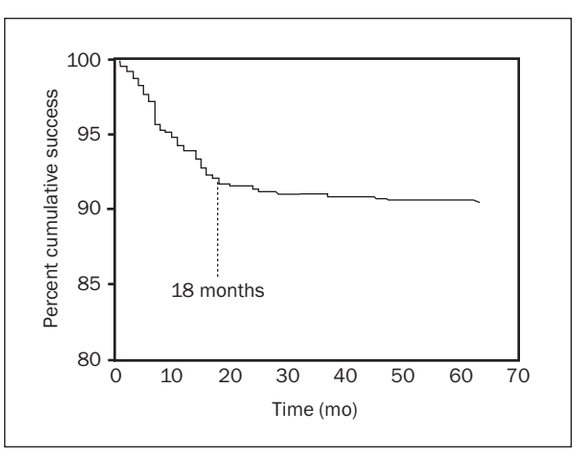

Fig 4 Life table distribution for all implants.

(Fig 2). One hundred eighty-three (15.6%) implants were placed in bone described as dense, 816 (69.5%) in normal bone, and 175 (14.9%) in soft bone.

Altogether, 633 prostheses were placed in the 493 patients. Distribution of these 633 prostheses can be seen in Fig 3. A majority of restorations (371, or 59%) were fixed partial dentures in the posterior areas of the mandible or the maxilla, followed by 253 (40%) single-tooth replacements, and a few long-span fixed prostheses (1%).

The results of gingival assessments (gingival levels, keratinized gingiva, probing depths, and gingival inflammation) indicated that peri-implant mucosa maintained good health throughout the follow-up period, with only slight changes from baseline. Stable marginal crestal bone levels were observed throughout the follow-up period, with a mean bone loss of 0.67 mm between loading and 4-year evaluations.

This report provides an interim analysis after a mean observation time of 72.0 ± 6.4 months after implant placement. Mean elapsed time from implant placement to stage 2 surgery was 6.8 months and from implant placement to loading was 15.5 months. Of the implants characterized as successful, 80.5% reached the 5-year evaluation time point. One hundred four implants (8.8%) did not meet success criteria and were designated as failures, and 222 implants (18.8%) were lost to follow-up. Reasons for loss to follow-up were death, geographic relocation, and economic reasons. Eight hundred fifty-three of the surviving 957 implants were considered successful according to the aforementioned

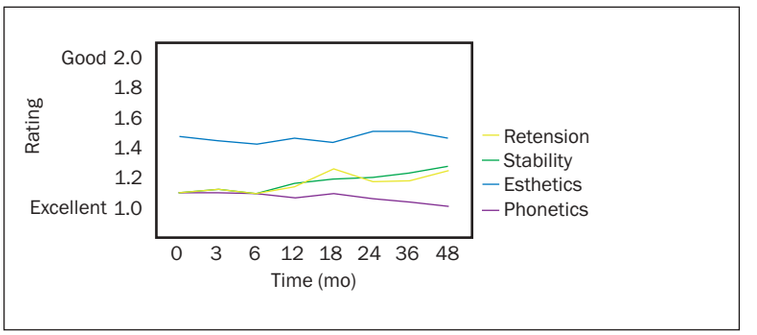

Fig 5 Prosthetic outcomes for all restorations, as rated by clinicians. 0 months = Prosthetic loading date.

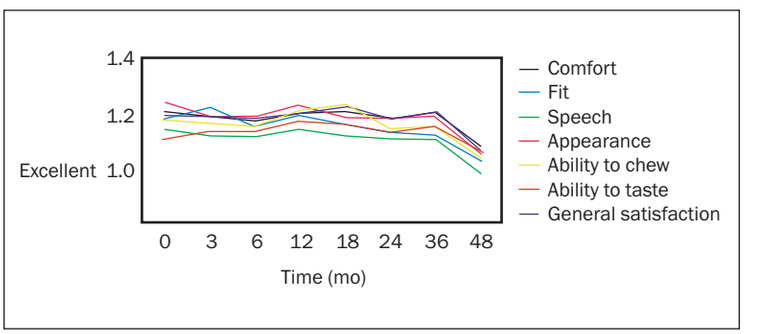

Fig 6 Cornell Medical Index of patient satisfaction as scored by patients. 0 months = Prosthetic loading date.

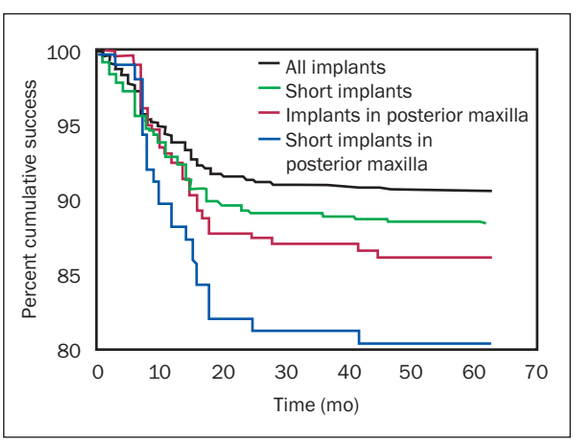

Fig 7 Life table distribution for implants by length and location.

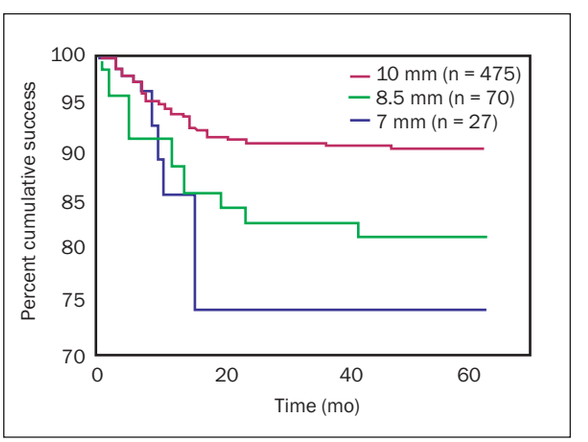

Fig 8 Life table distribution for short implants by individual length.

criteria. The cumulative success rate according to life table methods was 91.1% at 5 years post-loading, and the survival distribution is illustrated in Fig 4. Most implant failures (87, or 83.7%) occurred prior to prosthesis placement (ie, loading), and only 12 failures occurred 18 months post-prosthesis placement.

Most of the 104 implants designated as failures were subsequently removed. The reasons for failure were mobility (84), continuous radiolucency (20), persistent pain (20), persistent signs of infection (14), violation of the mandibular canal (1), and/or "other" (11). Prosthetic outcomes and patient satisfaction with their prostheses were favorable and are illustrated in Figs 5 and 6. The type of occlusion observed for most prostheses was group function or anterior disclusion. Most clinicians rated the retention, stability, esthetics, and phonetics of the prostheses as excellent or good.

Sixty percent of all failed implants were short (≤ 10 mm), and the cumulative success rate for these short implants was 89.0%, a significantly lower rate than the cumulative success rate for all implants of 91.1% (Fig 7). Failure of the short implants included 26% of 7-mm implants, 19% of 8.5-mm implants, and 9% of 10-mm implants (Fig 8).

Another group of implants that failed at a relatively higher rate were those placed in the posterior maxilla. These constituted 33% of all failures with a cumulative success rate at 5 years of 87.4% (Fig 7).

DISCUSSION

A major reason for the success of dental implants has been the development of implant designs and surgical procedures that result in a direct bone-implant interface that can be stable long term. This condition is generally referred to as osseointegration. It is achieved by careful control of the conditions of treatment, notably atraumatic surgical preparation of the implant site by the use of copiously irrigated drilling at low speed and high torque under aseptic conditions, use of biocompatible implant materials such as titanium, and the imposition of a healing period during which no load is placed on the implant.[8] Osseointegration is characterized by immobility of the implant, lack of radiolucency around the implant, and the absence of soft tissue between bone and the major portion of the implant surface on histologic examination.[9] Stable osseointegration can be considered a criterion of implant success, and the parameters established in the present study for implant success served to determine the existence of osseointegration.

Since the initiation of this study, implant designs have evolved to include surface modifications with greater roughness that act to not only anchor the implant more firmly in the bone soon after placement, but also to promote better clot retention and bone regeneration.[10] Prospective clinical studies have shown that an implant with a dual acid-etched surface performs at a high success rate.[11–14] While the 1,179 machined-surface implants in the present long-term study showed a cumulative success rate of 91.1%, which falls within the guidelines for implant success of at least 85% at 5 years[3] and is similar to success rates reported for other machined-surface implants,[15] they did not achieve success rates as high as the more recently manufactured acid-etched implants.

Because of the large number of implants in the current study, an attempt at failure analysis is possible. As can be seen from the Fig 4 life table distribution, there was a consistent decline in the cumulative success rate, and after 18 months the curve flattened out into a steady state with fewer failures. With respect to implant dimensions and locations, it appears that short implants (≤ 10 mm) failed at a higher rate than longer implants. This is also consistent with the findings of other clinical reports on machined-surface implants. The failure rate of these short implants increased as the length of the implant decreased. The cumulative success rate for the short implants was 88.7% at 6 years, which includes a 26% failure of 7-mm implants. In comparison, the 5-year cumulative success rate for long implants was 93.1%.

Frequently, short implants are placed where there are inadequate bony dimensions and the bone tends to be of a softer clinically assessed quality, such as in the posterior maxilla where space is limited by the maxillary sinus. Implants are at greater risk in areas of the jaw where bone density is often quite low, the bone height is reduced, and functional load is high. In this report there was a greater percentage of implant failures in the posterior maxilla, where a cumulative success rate of 86.2% was achieved for 274 implants. One third of all implant failures were those implants placed in the posterior maxilla, where 27.4% of the implants were placed in bone described as soft, which is almost twice the frequency of soft bone for all implants. Furthermore, for the short implants placed in the posterior maxilla the success rate was only 80.6%, perhaps indicating the contribution of implant length and bone quality to clinical outcomes. It appears that the limitations of bone dimensions and more common occurrence of poor-quality bone had an impact on the outcome of machined-surface implants placed in the posterior maxilla.

Another observation regarding the failure pattern in this study was that 95.2% of all implant failures (ie, 99 of 104) occurred within the first 3 years after implant placement. This finding is consistent with another study of machined-surface implants,[16] in which 97.9% of the failures occurred before the third year of follow-up (274 out of 280). Lindh and coworkers[17] conducted a meta-analysis of implants in partially edentulous patients. In 19 studies with a total of 2,686 predominantly machined-surface implants, 95.3% of all failures were recorded within 3 years after implant loading. These failure patterns seem to support the US Food and Drug Administration's recent proposal[18] to change the clinical follow-up period of root-form endosseous implants for Premarket Approval Applications from 5 to 3 years, at least as far as machined-surface implants are concerned.

CONCLUSION

Survival analysis indicated that after 6 years of follow-up, 3i machined-surface implants achieved a cumulative success rate of 91.1% in this patient population. Short implants failed at a higher rate (11.0%) than longer implants (6.9%), and more failures were located in the posterior maxilla (33% of

all failures). Additional analyses of this data set will be published in subsequent manuscripts.

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