

The Self-tapping and ICE 3i Implants: A Prospective 3-Year Multicenter Evaluation

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This multicenter prospective clinical evaluation was undertaken to determine the therapeutic success and marginal bone level stability of 3i's self-tapping and ICE implants after 3 years of prosthetic loading. Between July 1995 and June 1996, 189 completely or partially edentulous patients were treated with 614 machined-surface screw-type commercially pure titanium implants (self-tapping or ICE). Two hundred seventy-seven self-tapping implants were placed in 85 patients (average age of 56 years), and 337 ICE implants were placed in 104 patients (average age of 61 years). A total of 360 implants (58.6%) were placed in posterior segments. Easier placement was reported with the ICE implant in normal or dense bone. For the self-tapping implants, survival rates of 92.9% and 91.6% were noted after 1 and 3 years of prosthetic loading, respectively. Survival rates of 95.4% and 93.8% were obtained with the ICE implant for the same periods. Late failures (after loading) were more common than early failures (before loading) for both types of implants. The marginal bone level of 238 self-tapping implants (85.9%) and of 307 ICE implants (91%) was radiographically evaluated at 3 years. Marginal bone level was at the first thread for 95.1% of implants. A loss of marginal bone level of 2 to 4 threads was noted for 4.9% of the evaluated implants. No implant showed bone loss greater than the fourth thread. Overall survival rates of 94.3% and 92.9% were obtained after 1 and 3 years of prosthetic loading, respectively, for 596 and 588 implants. (INT J ORAL MAXILLOFAC IMPLANTS 2001;16:52-60)

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Dental implants are a viable therapeutic option for the treatment of various phases of edentulism.¹⁻⁴ The original technique, developed in the

1970s (Brånemark System, Nobel Biocare, Göteborg, Sweden), was commercialized early in the 1980s.⁵ The first standard implant that was offered was fabricated in commercially pure (cp) titanium. The initial implant design necessitated tapping of the bony site before placement of the implant.⁵ In the early 1990s, Nobel Biocare offered a self-tapping implant to simplify the surgical protocol in bone of normal or dense quality. A preliminary study of this self-tapping implant revealed difficulties in attaining the correct implant position in the chin area without using a tap and/or without employing manual placement.⁶ A second-generation implant that had better self-tapping capabilities (Mk II) was thus logically introduced to facilitate placement of the implant. Various studies have documented good results with this implant.⁶⁻⁸

The 3i implant system (Implant Innovations, Palm Beach Gardens, FL) has been available since 1988. Studies have reported good results and excellent therapeutic viability.⁹⁻¹² The original implant design of this system (standard implant in cp titanium)

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rapidly evolved toward a first-generation self-tapping implant (self-tapping) and then toward a more effective self-tapping implant (ICE, for "incremental cutting edges"). The modifications of these various implant designs were aimed at simplifying surgical protocol and at improving primary anchorage of the implant. The apical part of the ICE implant had a truncated cone shape, which permitted progressive engagement in the bone. The implant apex had 4 open sections with larger cutting capacity (cutting flutes). The elimination of tapping for the great majority of bony sites (except for very dense bone) simplified the surgical technique.

The aim of this prospective multicenter study was to analyze the therapeutic viability and survival rate of self-tapping and ICE implants after 1 and 3 years of functional loading.

MATERIALS AND METHODS

Between July 1995 and June 1996, 189 completely or partially edentulous patients were treated with 614 screw-type machined-surface 3i (cp titanium) implants in 4 dental offices devoted exclusively to implant dentistry. All patients were treated by 5 surgeons with long clinical experience in implant surgery. Patients in each clinical center were admitted consecutively to the study. Patient selection excluded candidates with active infection in the area intended for implant placement, uncontrolled systemic disease, pregnancy, or a need for bone grafting combined with implant placement. Two hundred seventy-seven self-tapping implants were placed in 85 patients, who ranged in age from 27 to 75 years (average age of 56 years). Three hundred thirty-seven ICE implants were placed in 104 patients ranging in age from 20 to 78 years (average age of 61 years). The self-tapping implant was used during the first series of implant placements and the ICE was used in the second. The total number of patients included 109 females (57.7%) and 80 males (42.3%). Self-tapping and ICE implants were used to treat various types of edentulism (Table 1). Each patient was treated with only 1 type of implant, either self-tapping or ICE (Fig 1). No bone reconstruction (guided bone regeneration, onlay graft, or osteotomy technique) was performed during placement of the implants. In the majority of patients, a surgical guide was used to obtain the desired position of implants. Bone quality (dense, normal, or soft) was evaluated during surgical preparation with a 2-mm-diameter drill (tactile sensation).

The sequence of surgical tapping for both implant designs was similar, up to the 3-mm drill

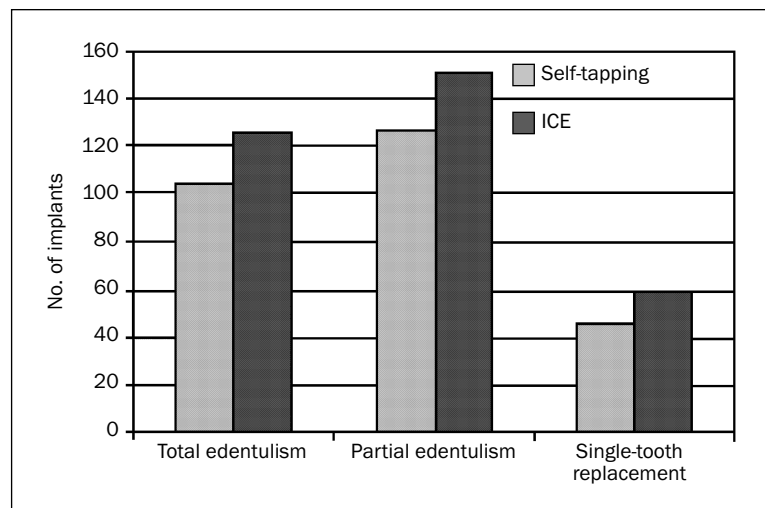
for all standard-diameter implants (both self-tapping and ICE). In the presence of dense bone, the 3.15-mm drill was used, followed eventually by tapping with the self-tapping implant. This tapping was rarely necessary with the ICE implant. Prophylactic antibiotic therapy was prescribed: 1 g of amoxicillin 2 hours before surgery, followed by 2 g each day for 6 days for those patients with no prior allergy to penicillin. For patients who were allergic to penicillin, a combination of spiramycin and metronidazole was prescribed (3 IU of spiramycin and 500 mg of metronidazole each day for 6 days). A solution of chlorhexidine (0.12%) as a mouthwash (twice per day) was used 2 hours before the surgical intervention, resumed 24 hours after surgery, and continued for 7 days. Wearing of removable prostheses associated with the implant sites was ceased for 15 days postoperative. The interior surfaces of all removable prostheses were then relieved and relined with soft acrylic resin to reduce harmful forces on the implants. Individual prostheses were specially designed to satisfy the esthetic and functional demands of the patient. Stage 2 implant surgery was performed after 3 to 4 months of bone healing in the mandible and after 6 to 7 months in the maxilla. Mucosal healing of 6 to 8 weeks was necessary before prosthetic treatment was started.

Clinical and radiographic examinations were conducted after completion of the prosthetic restoration and after 6 months, 1 year, and 3 years of loading. Five patients with 12 implants (8 self-tapping and 4 ICE) dropped out of the study; 3 of these changed residence, and 2 did not appear for periodic evaluations. The fixed prostheses (cemented or screw-retained) were not removed during evaluations if all clinical and radiographic parameters appeared to be satisfactory. However, implant suprastructures with removable prostheses were removed to clinically test implant mobility and the prosthetic attachments and to evaluate the peri-implant mucosa.

Radiographically, the stability of peri-implant crestal bone, the absence of radiolucent zones, and the adaptation of the various components of the implants were compared to the initial conditions. All bone loss at or above the first thread was considered physiologic. Initial non-standardized periapical radiographs (taken upon placement of the implants) and radiographs taken upon evaluation (at 6 months, 1 year, and 3 years) were made using angulators. This technique facilitates the achievement of an accurate picture of the threads because of an x-ray axis that is perpendicular to the axis of the implant. The crestal bone level was evaluated by each surgeon with reference to the threads of the implant.¹³

Table 1 No. and Type of Implants According to Type of Edentulism

Type of edentulism	Self-tapping	ICE	Total
Total, mandibular	60	66	126
Total, maxillary	44	60	104
Partial, anterior mandible	17	12	29
Partial, posterior mandible	38	53	91
Partial, anterior maxilla	34	42	76
Partial, posterior maxilla	38	44	82
Single-tooth, anterior mandible	5	5	10
Single-tooth, posterior mandible	29	37	66
Single-tooth, anterior maxilla	10	10	20
Single-tooth, posterior maxilla	2	8	10
Total implants	277	337	614

**Fig 1** Distribution of prosthetic treatment and implant types.

The criteria used to determine implant success were:

- Absence of mobility.¹⁴ Any mobile implant was removed. The stability of implants was tested directly during stage 2 implant surgery and during clinical examinations for those patients who wore a suprastructure implant prosthesis (44 implants). For the other patients, prosthesis stability was considered adequate in the absence of prosthetic mobility (cemented or screw-type) and any signs of pathology around the implant.
- Absence of painful symptoms or paresthesias.¹⁴ Any acute symptom that was treated and under control was not considered a failure but rather a complication.
- Absence of peri-implant radiolucencies during radiographic evaluation.¹⁴
- Absence of progressive marginal bone loss.¹⁴ An initial bone loss of up to 3 mm that stabilized with time (without peri-implant treatment) was

not considered to be a failure. An implant with bone loss greater than 3 mm (higher than the third thread) and stabilized over time was considered a surviving implant. (The distance between the platform and the third thread is 3 mm for a standard implant and 3.2 mm for a large 3i implant.)

Using the following criteria, the authors classified implants after clinical and radiographic evaluations:

- Success = Implant satisfied all success criteria.
- Not followed = Patient was unable to follow the evaluation regimen.
- Surviving = Implant showed bone loss greater than 3 mm, was stabilized, and supported a functioning prosthesis.
- Early failure = Implant failure occurred before the prosthesis was placed.
- Late failure = Implant failure occurred after the prosthesis was placed.¹⁵

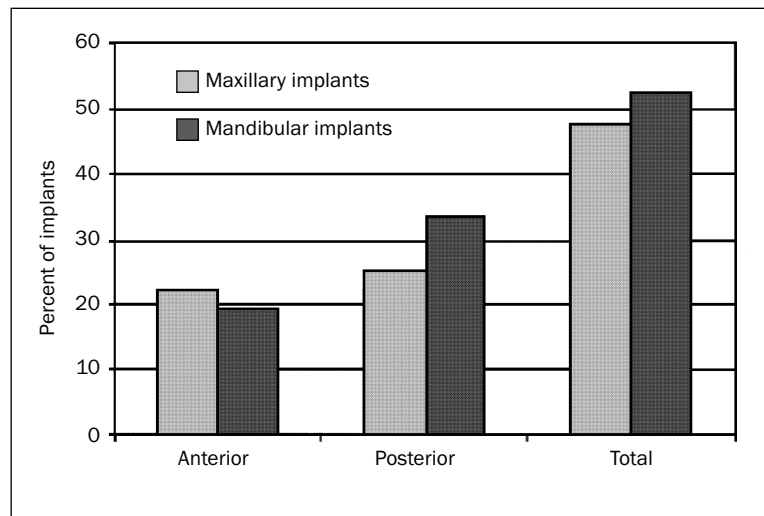


Fig 2 Distribution of implants by location.

Table 2 Length and Diameter of Implants

Length	Diameter						Total
	3.75 mm		4 mm		5 mm		
	ST	ICE	ST	ICE	ST	ICE	
8.5 mm	20	23	30	32	—	—	105
10 mm	30	27	42	49	5	18	171
11.5 mm	25	28	25	24	8	21	131
13 mm	25	24	19	29	4	17	118
15 mm	19	25	25	18	—	—	87
18 mm	—	2	—	—	—	—	2
Total	119	129	141	152	17	56	614

ST = Self-tapping implants.

After 3 years of prosthetic loading, the data were tabulated between November 1999 and March 2000. The final analysis, therefore, represents 602 implants (269 self-tapping and 333 ICE), because 12 implants (2%) placed in 5 patients could not be followed.

RESULTS

Among the original 189 patients, 19% were completely edentulous, 39% were partially edentulous, and 42% had only one missing tooth. The distribution of implants placed in the maxilla and the mandible was similar. In the mandible, 322 implants were placed (52.4%), and 292 implants (47.6%) were placed in the maxilla. More than half the implants (58.6%) were placed in posterior segments (Fig 2). Implants that were 10 mm or 11.5 mm in

length were most commonly used (49.1%), as compared to 8.5-mm implants (17.1%) and implants 13 mm or longer (33.7%). Implants with a diameter of 4 mm represented 47.7% of the implants placed, those with a diameter of 3.75 mm represented 40.4%, and wide-diameter implants (5-mm) represented 11.9% of those placed (Table 2). Seventy-four percent of self-tapping implants and 78% of ICE implants were placed in bone that could be characterized as normal or dense quality. The surgeons observed better self-tapping capacity for both types of implants (self-tapping and ICE) in normal and low-density bone. However, for all investigators, implant placement was much easier with the ICE implant in normal or dense bone. Before the ICE implant, the tapping technique was used only with very dense bone. No particular problems were noted during placement of the ICE implant. An obvious reduction in operating time was reported

Table 3 Distribution of Prostheses by Implant Design

Prosthetic restoration	Implant support		
	ST implants	ICE implants	Total
Mandibular complete overdenture	10	9	19
Mandibular complete fixed prosthesis	8	11	19
Maxillary complete fixed prosthesis	6	8	14
Mandibular posterior partial prosthesis	10	16	26
Mandibular anterior partial prosthesis	7	5	12
Maxillary posterior partial prosthesis	11	15	26
Maxillary anterior partial prosthesis	12	11	23
Mandibular posterior single crown	29	37	66
Mandibular anterior single crown	5	5	10
Maxillary posterior single crown	2	8	10
Maxillary anterior single crown	10	10	20
Total	110	135	245

ST = Self-tapping implants.

Table 4 Prospective Life Table Analysis Showing Cumulative Survival Rates

Evaluation period	Implants at start of period		Unloaded implants		Drop-out implants		Failed implants		Survival rate within period		Cumulative survival rate	
	ST	ICE	ST	ICE	ST	ICE	ST	ICE	ST	ICE	ST	ICE
Placement to stage 2 surgery	277	337	7	7	0	0	7	7	94.4%	97.9%	97.4%	97.9%
Stage 2 surgery to 1-year functional loading	263	323	—	—	3	1	12	8	95.4%	97.5%	92.9%	95.4%
1-year to 3-year functional loading	248	314	—	—	5	3	3	5	98.7%	98.4%	91.6%	93.8%

ST = Self-tapping implants.

during preparation of the surgical site, as well as during the placement of the implants (except in cases of very dense bone).

The majority of prostheses (92%) were fixed, of which 75% were screw-retained and 25% were cemented. A description of prostheses is included in Table 3. Of the 245 implant-supported restorations, 106 were single-tooth, 87 were fixed partial prostheses, 33 were fixed complete prostheses, and 19 were complete overdenture prostheses. Five patients dropped out of the study; 3 had fixed prostheses supported by 3 implants, 1 had a prosthesis supported by 2 implants, and 1 had a crown on a single implant. These represented 8 self-tapping implants (3%) and 4 ICE implants (1.2%). In addition, 7 self-tapping implants (2.6%) and 7 ICE implants (1.2%) were not restored (remained "sleeping") for prosthetic reasons (unfavorable implant axis or implant proximity). The prospective cumulative survival rates are reviewed in Table 4.

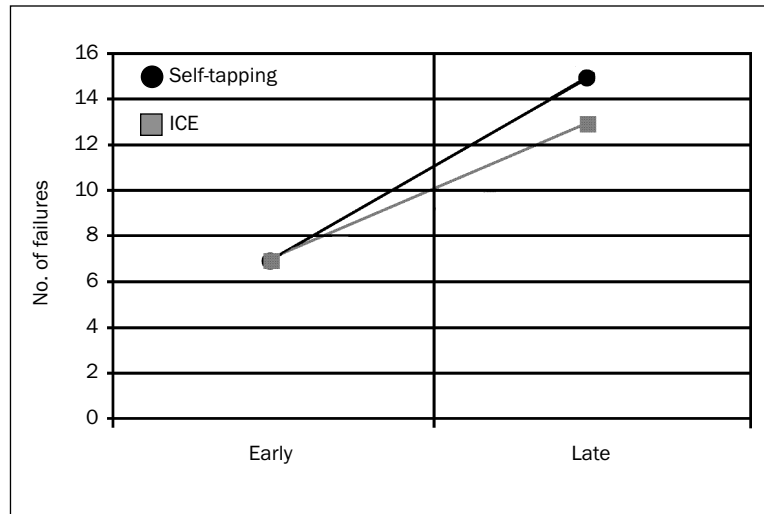
For the self-tapping implants, a survival rate of 91.8% was noted 3 years after prosthetic loading. A

survival rate of 94% was obtained with the ICE implants for the same period. The failure rate was similar in both arches with the self-tapping implant (8.1% in the mandible and 8.3% in the maxilla). However, with the ICE implant, the failure rate was greater in the maxilla (7.3%) than in the mandible (4.7%). Late failures (after prosthetic loading) were more common for both implant designs (4.7%) than were early failures (2.3%) (Table 5 and Fig 3).

After 3 years of prosthetic loading, the bone levels of 238 (85.9%) of the self-tapping implants and 307 (91%) of the ICE implants were evaluated radiographically with reference to the number of threads exposed (Table 6). Forty-one implants showed a bone loss of between 1 and 3 threads, and 11 implants showed a bone loss between the third and fourth threads. The latter 11 were, therefore, considered to be surviving implants (4 self-tapping and 7 ICE), since the loss was greater than 3 mm but they are still under prosthetic loading. No implant showed a bone loss greater than the fourth thread. Six self-tapping and 5 ICE implants that had

Table 5 Type of Implant Failure According to Implant Design and Arch

Implant failures	Self-tapping (%)		ICE (%)		Total (%)
	Mandible	Maxilla	Mandible	Maxilla	
Early	4	3	2	5	14 (2.3)
Late	8	7	6	7	28 (4.7)
Total	12 (8.1)	10 (8.3)	8 (4.7)	12 (7.3)	42 (7.0)

**Fig 3** Chronology of implant failures.**Table 6** Crestal Bone Level as Related to Implant Threads After 3 Years of Loading

Bone loss according to no. of threads	Bone loss (mm)		Self-tapping		ICE		Total (%)
	Standard	Wide	Mandible	Maxilla	Mandible	Maxilla	
0 to 1	0 to 1.05	0 to 0.9	116	102	146	129	493 (90.5)
1 to 2	1.05 to 1.65	0.9 to 1.8	8	3	4	10	25 (4.6)
2 to 3	1.65 to 2.25	1.8 to 2.7	3	2	6	5	16 (2.9)
3 to 4	2.25 to 2.85	2.7 to 3.6	2	2	2	5	11 (2.0)

Standard = standard-diameter (3.75-mm or 4-mm) implant; Wide = wide-diameter (5-mm) implant.

a large diameter (5 mm) showed bone loss greater than 2 threads. Five implants that were placed immediately after extraction showed a bone loss greater than 1 thread.

Clinically, 10 patients (12 implants) showed an operculization at the level of the cover screw during the healing phase. One patient (3 implants) showed repetitive abscess formation during the osseointegration phase, and the implants were removed after

radiographic proof of a lesion around the implant was established.

DISCUSSION

Overall survival rates of 94.3% and 92.9% were determined after 1 and 3 years of prosthetic loading for 596 and 588 self-tapping implants, respectively.

Table 7 Presumed Etiology of Implant Failures

Apparent etiology	No. of failures
Low-density bone	28
Patient smoked*	5
Harmful forces of removable prostheses	4
Localized infection	2
Progressive bone loss	1
No apparent etiology	2

*More than 15 cigarettes per day.

The cumulative survival rates for the self-tapping implants were 92.9% and 91.6% after 1 and 3 years of prosthetic loading, respectively. For the ICE implants, the cumulative rates for the same periods were 95.4% and 93.8%. These survival rates are similar to those reported in studies that have proven the effectiveness of the implant technique.^{1,4,10,16,17} The rate of late failures was greater than the rate of early failures; that is, more failures occurred after a prosthetic load was applied.¹⁵ The rate of late implant failures is of utmost importance for the restorative dentist. This delayed implant loss has also been extensively reported in the literature.¹⁸⁻²²

Among the 42 failures (Table 7), 5 implants were placed in patients who were smokers (more than 15 cigarettes per day), 4 implants were placed in contact with areas supporting removable prostheses, 28 implants were placed in soft bone, and 2 implants developed localized infection. One implant that was 8.5 mm long was lost because of progressive bone loss. Among the 42 failures, a significant number (17 failures) were observed for short implants (8.5 and 10 mm). The majority of failures occurred in bone of low density. Success rates published to date with respect to bone quality vary from 89% to 97% in Type I, II, and III bone and from 50% to 94% in Type IV bone.²³⁻²⁵ The other principal apparent causes of failures were a smoking habit and premature trauma to the implants, and these have also been extensively reported.²⁶⁻²⁸

Esposito et al¹⁵ published an analysis of the chronologic distribution of failure rate incidence for implants (cp titanium screw implants) used in various clinical situations followed for up to 5 years after loading. In a summary of 14 studies reporting on failure incidence, 256 failures (8.6%) were reported in 3,010 implants. Of the total number of failures, late implant losses accounted for 53%, of which about half were reported during the first year

of loading. It is interesting to note that late failures are generally more common than early failures.

Failure rates in the mandible and the maxilla were similar with the self-tapping implant (8.1% and 8.3%, respectively). Rates were slightly lower with the ICE implant, especially in the mandible, where the failure rate was 4.7%. In contrast, however, in the studies of Olsson and coworkers⁸ and Friberg and colleagues,⁷ the failure rate in the mandible was practically non-existent for self-tapping implants (0.5%), and it was greater in the maxilla (13.3%). Primary implant stability in low-density bone may explain this difference. It is important to note that in the present study, more than half of the implants (58.6%) were placed in posterior areas.

Physiologic stability of the marginal bone level was established around 493 implants (90.5%); bone loss was slightly increased around 25 implants. This stability of the crestal bone level is the result of the healing process of soft tissues around the implant and of bone adaptation during the first months of tissue maturation, which ensures the establishment of biologic width around the implant.^{13,29,30} This explains the operculization of 12 implants observed during the phase of tissue healing. The rearrangement of crestal peri-implant bone became stabilized after approximately 1 year of implant use.^{30,31} This bone adaptation at the cervical area or the formation of a biologic space is shown clinically by a bone loss of about 1.5 mm. However, this healing adaptation depends on the implant configuration (macrostructure). Different implant systems have different collar and thread pitch heights. Around the 3i implants (self-tapping and ICE), the distance between the platform of the implant and the first thread is 1.8 mm for the standard implant (3.75- and 4-mm-diameter) and 1.4 mm for the wide-diameter implant (5-mm-diameter). Greater reduction in the marginal bone level (from 2 to 4 threads) was noted in 27 implants (4.9%). Of these 27 implants, 11 were 5 mm in diameter. Many studies have shown greater bone loss around wide-diameter implants.^{32,33} Failure rates and bone loss with wide implants are apparently more frequent in the mandible.^{34,35}

Several factors may explain these complications, including bone overheating during preparation of the surgical site in cortical bone (mandible) or an excessive compression of cortical bone during placement of the implant.^{33,35} The placement of wide-diameter implants in ridges that are narrower than 8 mm, or allowing too little room between 2 wide implants, may also cause secondary bone loss.³⁶ The presence of too little bone thickness may promote bone necrosis by diminishing vascularization. The

lack of mastery of any new technique may also be a factor that results in failure and serious complications.³⁷ In the present study, all patients were treated by surgeons with long clinical experience in implant surgery and with self-tapping implant experience of at least 6 months.

In the first study reported by Friberg et al,⁶ the authors described the difficulties encountered when placing 13 first-generation self-tapping implants among 62 used in the mandibular symphyseal region. Similarly, in the present study, placement of the ICE implant was found to be much easier than placement of the self-tapping implant. All clinicians found that use of the 3i implant with factory-assembled implant mount reduced operating time.

CONCLUSION

This multicenter evaluation, which followed implants over 3 years of prosthetic loading, confirms the advantage of self-tapping implants in various qualities of bone, as well as the effectiveness of 3i self-tapping and ICE implants. Overall survival rates of 94.3% and 92.9% were obtained after 1 and 3 years of prosthetic loading, respectively, for 596 and 588 implants. More than half the implants (58.6%) were placed in posterior segments, and the survival rates after 3 years of loading were 91.6% for self-tapping implants and 93.8% for the ICE implants. The rate of late failures (4.7%) was greater than the rate of early failures (2.3%) for both types of implants. After 3 years of prosthetic loading, the marginal bone level was at the first thread for 95.1% of implants and between 2 and 4 threads for 4.9% of implants.

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