

Long-term Evaluation of Submerged and Nonsubmerged ITI Solid-Screw Titanium Implants: A 10-year Life Table Analysis of 468 Implants

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Purpose: Submerged and nonsubmerged ITI solid-screw titanium implants were followed retrospectively from 1989 to 1993 and prospectively from 1994 on to analyze long-term prognosis in partially and fully edentulous patients. **Material and Methods:** A total of 468 implants were consecutively inserted in 191 patients from 1989 to 1998. Two hundred twenty-eight successfully integrated fixed-restoration implants and 238 with removable restorations were restored following a healing period of 4 to 6 months (9 months in sinus floor elevation sites). From 1994 on all implants inserted were documented annually up to 9 years. During examination the clinical status of the implants was analyzed and evaluated according to predefined criteria of success and this allowed the calculation of 10-year cumulative survival and success rates for 468 implants. **Results:** Two implants (0.43%) did not successfully integrate during the healing period, and 8 implants (1.7%) were classified as failures during follow-up (1 late failure under load, 7 with a progressive bone loss from 1 to 3 threads). Including 68 implants in subjects who dropped out (with a dropout rate of 14.4%), the 10-year cumulative survival and success rates were 99.2% and 96.4%, respectively. **Discussion:** Over the course of this long-term study, osseointegrated implants, once used as a last possible solution, became nearly standard in cases of single-tooth implants because of the high rate of long-term success. Life table analysis not only determines whether an implant is functioning, it also makes a statement about its clinical status according to strict success criteria. **Conclusion:** The study demonstrated that ITI solid-screw titanium implants achieved success rates above 95% in a clinical center for an observation period of up to 10 years. (More than 50 references) INT J ORAL MAXILLOFAC IMPLANTS 2003;18:826–834

Key words: life table analysis, long-term evaluation, osseointegration, submerged implants, success rates, survival rates

In the past 30 years, criteria for the predictable integration of endosseous dental implants have been proposed, and fundamental experimental studies^{1–4} have demonstrated that titanium implants regularly heal with direct bone-to-implant contact, called “osseointegration” or “functional ankylosis.” In recent

years, many clinical studies have demonstrated that implant integration can be achieved and maintained in various areas of the mouth on a long-term basis using submerged and nonsubmerged titanium implants.^{5–13}

The implants in these clinical studies varied in shape, size, component fit, surface characteristics, surgical placement, and restoration. Successful osseointegration in accordance with established clinical guidelines (low surgical trauma, initial implant stability, functional load following 3 to 9 months of healing) has been demonstrated for submerged and non-submerged titanium implants.^{1–4,14,15} Success has been evaluated using specific criteria, such as lack of mobility, absence of persistent infection, lack of pain, and increasing peri-implant radiolucency.^{16–18} Successful osseointegration has been observed predictably for submerged and nonsubmerged (1-stage) titanium implants and documented in comparative^{19,20} and experimental studies.^{14,21,22}

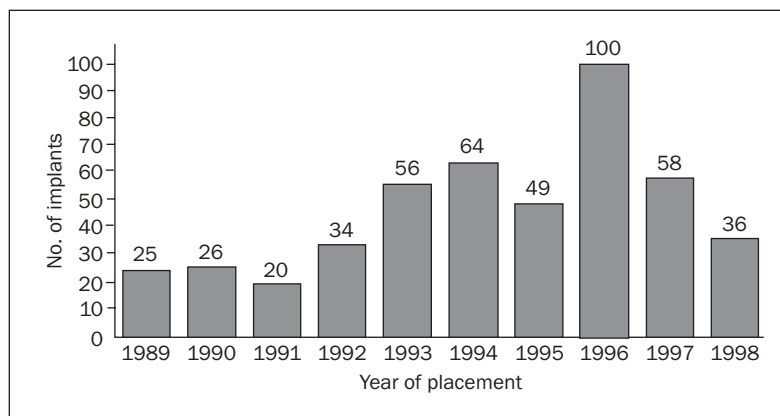
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Fig 1 Number of ITI solid-screw titanium implants placed per year between March 1989 and June 1998 (N = 468).



The purpose of the present study was to evaluate, using life table analysis,²³ the cumulative survival and success rates of 468 consecutively placed ITI solid-screw titanium implants (Institut Straumann, Waldenburg, Switzerland) over a period of 10 years.

MATERIAL AND METHODS

In a total of 191 patients (124 women, 67 men), 468 ITI solid-screw titanium implants were placed by 17 different oral surgeons between March 1989 and June 1998 at the Department of Oral Surgery, Oral Radiology and Oral Medicine, School of Dental Medicine, University of Basel, Basel, Switzerland (Fig 1).

The age of the patients at the time of implant placement ranged from 18 to 88 years, with a median of 58.2 years. Irradiated patients and patients with certain systemic diseases, such as diabetes mellitus and osteoporosis, were included in the study. As shown in Table 1, more patients (n = 66) presented with edentulous mandibles than with any other condition. These patients received 201 of the 468 implants. Other conditions presented were distal-extension situations in the mandible (37 patients, 93 implants), single-tooth gaps in the maxilla or mandible (56 patients, 60 implants), and edentulous maxillae (8 patients, 26 implants). Because of these different indications, 340 ITI solid-screw implants (72.6%) were placed in the mandible and 128 (27.4%) were placed in the maxilla. In total, 342 implants were placed using the submerged procedure and 126 using the nonsubmerged procedure.

Sinus Floor Elevation

Patients in whom the implants were placed with simultaneous sinus floor elevation are included

Table 1 Indications Presented by Study Participants

Indications	Patients*	Implants
Mandible		
Completely edentulous	66	201
Distal-extension	37	93
Single-tooth gap	26	30
Edentulous space	7	16
Maxilla		
Completely edentulous	8	26
Distal-extension	21	59
Single-tooth gap	30	30
Edentulous space	7	13
Total	191	468

*Eleven patients had more than 1 indication.

under the indication “distal-extension-space maxilla” or “edentulous-space maxilla.” Thirty-six implants were placed in 14 patients with simultaneous sinus floor elevation (16 sinus-lift procedures; in 2 patients a sinus lift was performed on both sides).

Healing Period and Prosthetic Treatment

Following a healing period of 4 months in the mandible and 6 months in the maxilla (9 months in sinus floor elevation sites), the 74 completely edentulous patients (227 implants) and 5 of the partially edentulous patients (distal extension mandible and maxilla, 11 implants) were treated with a removable overdenture retained by a bar, ball attachment, magnetic attachment, or conus.

All other implants (n = 228), except for 2 that were lost, were restored with crowns or fixed partial prostheses. Two of these implants, in 2 patients, supported a combined implant-tooth restoration. Only 18 implants placed for a single-tooth replacement were located in the maxillary anterior region (none were in the anterior mandible).

Table 2 Criteria for Success by Buser et al¹⁸

1. Absence of persistent subjective complaints, such as pain, foreign body sensations, and/or dysesthesia
2. Absence of recurrent peri-implant infection with suppuration
3. Absence of mobility
4. Absence of radiolucency around the implants

Table 3 Clinical and Radiographic Implant Classification at Annual Clinical Recalls

Interval (y)	Implant loss	Progressive bone resorption*	Total failures
0-1	2	1	3
1-2	0	0	0
2-3	1	2	3
3-4	0	1	1
4-5	0	3	3
5-6	0	0	0
6-7	0	0	0
7-8	0	0	0
8-9	0	0	0
9-10	0	0	0
Total	3	7	10

*Biologic failure.

Follow-up Examinations

The annual clinical analysis included the assessment of several clinical parameters for success criteria,¹⁸ such as Gingival Index,^{24,25} Plaque Index, and those included in Table 2.²⁶ For statistical analysis, only the implant site with highest index was considered. It also included a Periotest²⁷⁻²⁹ (Siemens, Bensheim, Germany) and radiographic examinations, either panoramic radiographs in cases of multiple implant placement or periapical radiographs in cases of single-tooth restorations. At each follow-up the radiographs were examined for signs of bone resorption by 2 calibrated examiners. The reference point was the border between the rough part of the implant and the smooth part. As soon as bone resorption reached 1 thread, the implant was considered a failure. If a patient could not be followed (eg, he or she was not interested, moved away, passed away) at consecutive annual recalls following 1994, the implants were classified as dropouts.

The statistical analysis was performed using the life table analysis.²² The data analysis began in October 1999, and all restored implants had completed at least the 1-year recall by June 1998. The entire group of 468 implants was included in the analysis of cumulative survival and success rates.

RESULTS

During the healing period, 2 implants were early failures and did not reach successful osseointegration. One implant had to be removed because of lack of sensibility in the lateral mandible (second premolar region). The nerve function recovered partially during the following 4 weeks. The other implant was lost because of soft tissue infection 3 weeks after surgery (mandibular first premolar region). A third implant, classified as a late failure, was lost 2.5 years following superstructure connection (ball attachment) in a patient who underwent irradiation. The corresponding early failure rate was 0.43%; 466 implants were restored and loaded with implant-supported restorations.

Implant Follow-up

Plaque Index. In the latest follow-up examinations of 397 implants, 56% of the implant sites showed a Plaque Index of 0. The index was 1 in 25% of the implants, 2 in 15%, and 3 in only 4%.

Gingival Index. The gingiva around the implants was without signs of inflammation (Index 0) in 76% of the latest follow-up examinations. A Gingival Index of 1 or 2 was found in 20% and 3%, respectively. Only 1% had an index of 3.

Radiographic Evaluation. Progressive bone resorption occurred in the beginning 5 years of the study, but bone levels were stable in the subsequent follow-up examinations (Table 3). In the latest follow-up of 397 implants, 7 implants (7 patients) had bone loss or a peri-implant radiolucency deeper than the first thread (Figs 2a and 2b). The other 390 implants had a stable bone situation at the reference point (Figs 3a and 3b).

Periotest Values. The Periotest values (PTV) ranged between -8 and -1 in 86% of the implants. The lowest measured value was -8 and the highest was +6 (Fig 4), with an average of -3.3. The lowest values were shown in the area of the mandible; the highest, in the lateral maxilla.

Various Implant Types. The presented analysis was done for ITI solid-screw titanium implants utilizing the criteria for implant success described in the introduction. The study included 394 standard-diameter implants (diameter = 4.1 mm), 73 narrow-diameter implants (diameter = 3.3 mm), and 1 wide-diameter implant (diameter = 4.8 mm), but no particular analysis of implant types took place. Of the 468 implants, 212 were 12 mm long, 109 were 10 mm long, 64 were 14 mm long, and 36 were 8 mm long (Fig 5).

Various Implant Locations. Of the 128 implants placed in the maxilla, none were lost, and only 1 was considered a biologic failure. Of the 340 implants

Fig 2a (Left) Peri-implant radiolucency at a 6-mm long implant in the premolar region.



Fig 2b (Right) Circular bone resorption around single-tooth implant.

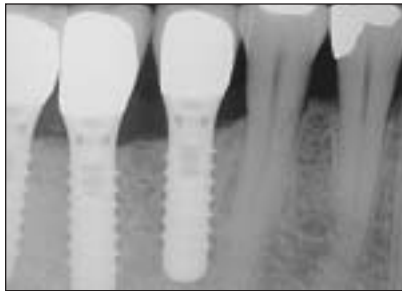


Fig 3a (Above) Stable bone situation at the level of the rough/smooth implant interface at 5-year follow-up.

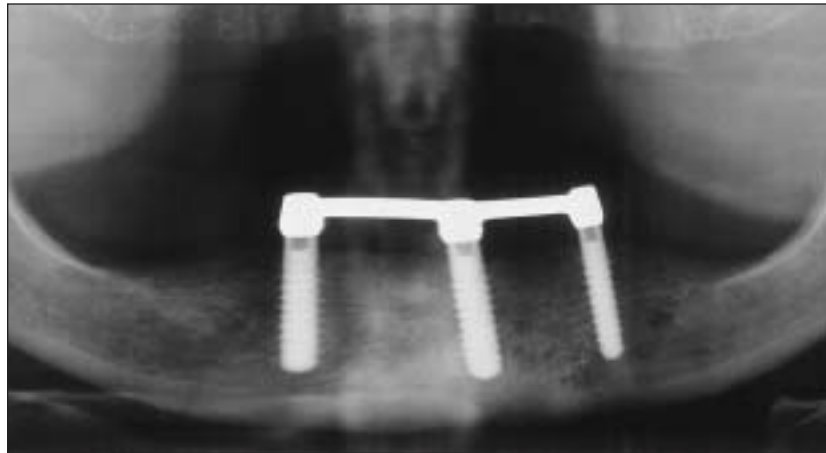
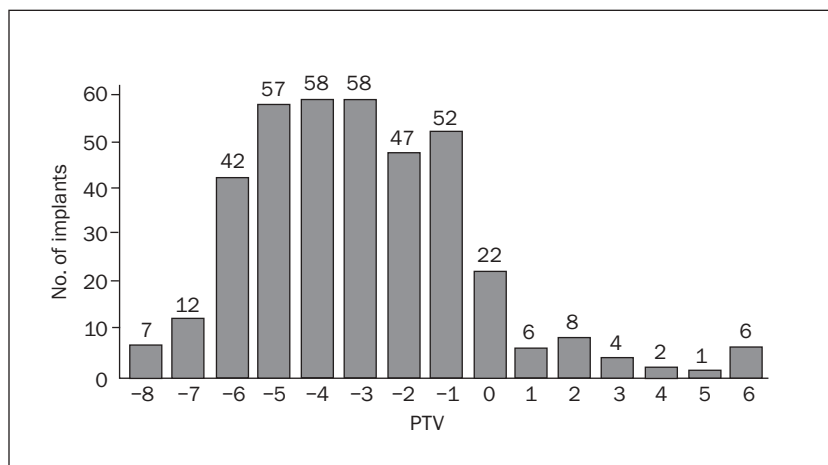


Fig 3b (Right) Stable bone situation at 8-year follow-up.

Fig 4 PTV at the latest follow-up dates (n = 397).



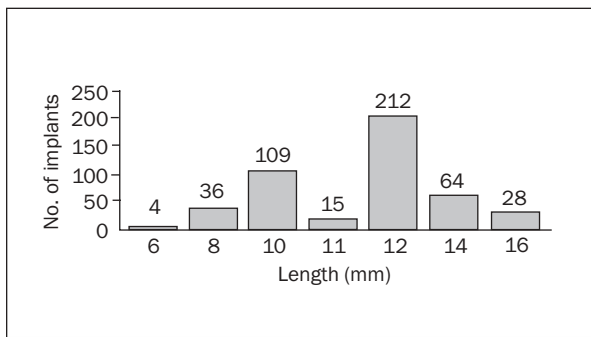


Fig 5 Length of the 468 implants.

placed in the mandible, 3 were lost and 6 were considered biologic failures. No further analysis regarding implant location was performed.

Results of the 10-year Life Table Analysis

Thirty-seven patients with 68 implants were permanently lost to follow-up. During the recalls, a total of 10 implants were classified as failures according to the success criteria (3 implants failed totally and 7 implants were biologic failures).

It was not possible to perform an analysis in the anterior and lateral regions of the jaws because of the low number of implant losses.

During examination, the clinical status of the implants was analyzed and evaluated according to predefined criteria of success, and this allowed the calculation of 10-year cumulative survival (Table 4) and success (Table 5) rates for 468 implants. In all, 2 implants did not successfully integrate during the healing period (0.43%) and 8 implants (1 late failure under load, 7 with a progressive bone loss from 1 to 3 threads) were classified as failures during follow-up (1.7%). Including 68 dropout implants (dropout rate of 14.4%), the 10-year cumulative survival and success rates were 99.2% and 96.4%, respectively.

DISCUSSION

This study evaluated 332 submerged and 126 non-submerged solid-screw ITI titanium implants. It was carried out under specific scientifically accepted conditions and criteria according to Shulman and associates,³⁰ Babbush and Shimura,³¹ Albrektsson and Zarb,³² Buser and associates,¹² and Levine and associates.¹³

Implants with peri-implantitis and bone loss to the level of the threads were stable and treated by rinsing and cleaning.³³ However, they were called failures for the purpose of the study. Albrektsson and Zarb³² required the inclusion of at least 50 con-

secutive patients at 2 centers, distinction of success and survival utilizing the aforementioned criteria of success, inclusion of dropout implants in the analysis, and prospective long-term documentation of at least 5 years. These requirements were fulfilled, with one exception: This study took place in a single center. The 468 implants in the follow-up were placed by 17 oral surgeons over 10 years and under 2 successive department chairs. This assures that implant placement was reproducible and independent from the surgeon.

Because regular, prospective recall of the patients started in 1994 following the known criteria inaugurated from 1989 to 1993, the study was called retrospective, although part of the analysis was performed prospectively. The dropout rate was close to 20% because of the high number of patients referred for surgical treatment at the Department of Oral Surgery, Oral Radiology and Oral Medicine, School of Dentistry, University of Basel, Switzerland, and later restored by their private dentists. During the study, a total of 68 dropout implants with 37 patients were recorded and included in the analysis. The rate was acceptable in view of the fact that a dropout rate of 5% to 20% was previously reported by Buser and associates,¹² Lekholm and associates,³⁴ and Behneke and associates.³⁵

For discussion of the survival and success rates, a review of the clinical and radiographic follow-up parameters was necessary.^{18,32} The literature suggested assessment of periodontal indices (Plaque Index and Gingival Index), bone loss, implant mobility (PTV), and pocket depth.³⁶⁻³⁸ In animal studies, increased indices for plaque, marginal inflammation, and pocket depth have been associated with the development of peri-implant lesions.³⁸⁻⁴¹

In the present study, clinical parameters, including Plaque Index²⁶ and Gingival Index,^{24,25} were applied. Both of these indices were low in recalled patients. Four percent of the patients had a Plaque Index of 3 in the latest recall; however, these patients ranged in age from 78 to 88 years and had reduced mobility and motor skills, making optimal cleaning impossible. In previous studies,^{18,20,35,42-45} plaque and gingival indices were 0 or 1 for up to 80% of subjects; this is also the case in the present study.

No correlation between oral hygiene and bone loss^{34,46,47} or between implants with a peri-implant radiolucency and a high Plaque Index could be found. The Plaque Index was not valuable for the early diagnosis of peri-implant bone loss.⁴⁸ According to Becker and colleagues,³⁶ plaque seems to be secondary to implant failures and was found following implant mobility or radiolucency; probably oral hygiene decreases with increased pain.

Table 4 Life Table Analysis of 468 Implants and Cumulative Survival Prognosis

Interval (y)	Implants at start	Dropouts	Failures	Withdrawn alive	Implants at risk	Survival rate	Cumulative survival prognosis (%)
0-1	468	12	2	1	461.5	0.995	99.5
1-2	453	25	0	50	415.5	1	99.5
2-3	378	6	1	77	336.5	0.997	99.2
3-4	294	4	0	83	250.5	1	99.2
4-5	207	17	0	48	174.5	1	99.2
5-6	142	1	0	47	118.0	1	99.2
6-7	94	3	0	35	75.0	1	99.2
7-8	56	0	0	9	55.5	1	99.2
8-9	47	0	0	18	38.0	1	99.2
9-10	29	0	0	29	14.5	1	99.2

See Cutler and Ederer.²³

Table 5 Life Table Analysis of 468 Implants and Cumulative Success Prognosis

Interval (y)	Implants at start	Dropouts	Failures*	Withdrawn alive	Implants at risk	Success rate	Cumulative success prognosis (%)
0-1	468	12	3	0	462.0	0.994	99.4
1-2	453	25	0	50	415.5	1	99.4
2-3	378	6	3	75	337.5	0.991	98.5
3-4	294	4	1	82	251.0	0.996	98.1
4-5	207	17	3	45	176.0	0.983	96.4
5-6	142	1	0	47	118.0	1	96.4
6-7	94	3	0	35	75.0	1	96.4
7-8	56	0	0	9	51.5	1	96.4
8-9	47	0	0	18	38.0	1	96.4
9-10	29	0	0	29	14.5	1	96.4

*Implant losses plus failures according to success criteria; see Cutler and Ederer.²³

The relation between plaque accumulation and inflammation of the peri-implant gingiva demonstrated that the Gingival Index was an effective procedure for follow-up, as reported by other authors.⁴⁹⁻⁵¹ In this study, 75% of sites showed a Gingival Index of 0 in the latest recall. In our study, plaque did not correlate with gingival inflammation, since some sites showed plaque accumulation but no signs of gingival inflammation. This was reported from other authors.^{18,35,44,45} The plaque and gingival indices were not used to demonstrate implant success; they were used only for monitoring the oral hygiene situation.

Exact measurements of peri-implant bone loss directly on the radiographs were not possible in this study because standardized radiographs of the implants are preferred for the procedure.⁵²⁻⁵⁷ In 1994, standardized dental radiographs were introduced in the study, using a Coltoflax silicon guide (Coltène/Whaledent, Cuyahoga Falls, OH), Rinn film holders (Dentsply-Rinn, Elgin, IL), and a

Digora digital x-ray system (Soredex, Helsinki, Finland).^{58,59}

In only 7 of 397 implants did a peri-implant radiolucency appear to be deeper than the reference point in the latest follow-up. As in other studies, the rate of bone loss was highest during second-stage surgery and after 6 months of loading. In the subsequent recalls, the bone situations remained stable or showed little resorption.^{12,32,34,47,60,61} There was no difference radiographically in crestal bone loss around either the submerged or the nonsubmerged implants. Bone loss occurred only as far as the reference point and remained stable in the follow-up examinations. The presented physiologic bone reaction down to the reference point in the study was previously reported by Abrahamsson and coworkers,⁶² Asal and coworkers,⁵⁹ Ericsson and coworkers,⁶³ and Hermann and coworkers.^{22,64}

Implant mobility was evaluated using the Periotest procedure. For all implants, the PTV ranged from -8 to +6; all implants were stable. The lowest

values were found in the interforaminal mandible.^{18,27,65} In patients with a low rate of bone loss, the Periotest procedure was not sensitive enough. Constant values were measured during follow-up; values only decreased after the bone loss already had reached some millimeters.^{43,66} A correlation between the Periotest and peri-implant bone loss was reported by Schulte and associates²⁸ but appeared nonsignificant ($r < 0.2$) for clinical diagnosis.^{67,68}

In this study, peri-implant pocket depth measurement was not performed because of controversy about possible tissue damage and the clinical relevance of pocket probing.^{69,70-72} Other parameters, such as Plaque Index, Gingival Index, and PTV, have shown no relation to the success prognosis either.^{70,71,73-75}

In the beginning of the study most of the implants were placed for anchorage of a prosthesis in the atrophic edentulous mandible. During follow-up the treatment changed more and more to support a restoration that closed an edentulous space with partial prostheses and single-tooth replacement.^{12,60}

Life table analysis was used to determine the cumulative implant survival and success rates for all implants at risk as a function of time.²² Life table analysis allowed these calculations, although a majority of the implants had not been followed the entire period. All 68 dropout implants (20%) were recorded and included in the analysis, and the 10-year cumulative survival rate was calculated at 99.2%, with a success rate of 96.4%. Analysis of the survival rate using the Kaplan and Meier⁷⁶ method was not performed. According to this method, survival can only be calculated until the last event loss. Because of the very early losses in this study, only a 3-year analysis would have been possible.

Seven implants with peri-implant infection were classified as biologic failures by the strict follow-up criteria, even though all were functional and clinically immobile. Three implants were lost, 1 because of irritation of the mandibular nerve 2 weeks following surgery, 1 because of infection after 3 weeks of healing time, and 1, after 3 years in function, in a patient who underwent radiotherapy. The low failure rate corresponds to other results evaluating the ITI system.^{12,34}

CONCLUSION

Survival and success rates above 95% were demonstrated for submerged and nonsubmerged ITI solid-screw titanium implants in a clinical center, using the criteria of a multicenter study, for an observation period of up to 10 years.

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