Immediate Postextraction Implant Placement with Root-Analog Stepped Implants: Surgical Procedure and Statistical Outcome After 6 Years

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The present study investigated 124 stepped-screw implants (gritblasted and acid-etched surface) placed in 104 patients immediately after tooth extraction or implant explantation and followed between August 1990 and December 1996. Implants of varying diameters and lengths were used to cover a wide range of indications in both the maxilla and mandible; 68% of the implants supported single-tooth replacements. The study parameters included Plaque Index, Gingival Index, probing depth, Periotest values, and peri-implant bone loss. Statistical analysis according to Kaplan-Meier revealed a 97% survival rate. (INT J ORAL MAXILLOFAC IMPLANTS 2001;16:503–513)

Key words: *alveolar bone loss, bone level, dental implants, endosseous dental implantation, implant-supported prosthesis, surface properties*

The Frialit-2 dental implant system (Friadent, Mannheim, Germany) represents a further development of the Tübingen immediate implant[1] (Frialit-1 immediate implant) and has been available since its introduction in 1990[2] as a stepped screw and a stepped cylinder. The rationale behind the Frialit-1 immediate implant was to provide a mechanism that could prevent atrophy of the alveolar process by placing implants as early as possible after tooth loss.[3] The system is based on experience with the Tübingen implant.[4–8]

The Frialit-2 design concept presents different characteristics. A commercially pure titanium (cpTi) 1-piece stepped-screw or stepped-cylinder implant was designed similar to the original Tübingen implant.[1] However, the external dimensions of both implants are the same (Fig 1). Initial results have already been published.[2,9]

The goal of the present article was to summarize the statistical results after 6 years of clinical experience with the stepped screw as an immediate implant.

MATERIALS AND METHODS

The present evaluation comprises all patients treated by different surgeons at the Department of Oral Surgery and Periodontology (Dental School of the University of Tübingen, Germany) between the time of the first immediate implant placement on August 23, 1990, and the last definitive prosthetic treatment on December 20, 1996 (6.3 years). One

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Fig 1 *(Left)* Hydroxyapatite-coated Frialit-2 stepped-cylinder implant with a straight abutment; *(center)* Tübingen ceramic implant (Frialit-1); *(right)* Frialit-2 stepped-screw implant with angled abutment. The cervical groove of the Tübingen implant has been replaced by the mirror-polished transgingival portion of the Frialit-2 abutment. All other dimensions are identical.

Table 1 Distribution of Patients According to Gender and Age at the Time of Implant Placement

	Age (y)			
Gender	**15–20**	**21–40**	**41–60**	**61–88**
Females (n)	6	20	8	11
Males (n)	9	26	13	11
Total (n)	15	46	21	22
Percentages	14	44	20	22

hundred twenty-four Frialit-2 stepped-screw–type implants with a gritblasted/acid-etched surface (Frios surface, Friadent) were placed immediately after tooth extraction or implant explantation (tolerance range 0 to 6 days) in 104 patients (59 male, 45 female).

Patient Selection Criteria

Patients were accepted into the study based on the following inclusion criteria:

- The patient must have agreed to inclusion into the study.
- One of the prosthetic indications for implant placement must have been diagnosed: edentulous ridge, distal-extension situation, tooth-bound gap, or single tooth replacement. This included patients with tooth loss because of trauma, excessive internal tooth resorption, endodontic failure, root resorption after replantation, or retained primary teeth (in case of agenesis), as well as patients with tooth loss because of extensive caries or advanced periodontitis.
- Patients who had lost implant(s) also were eligible for treatment.

Exclusion criteria were as follows:

- No consent for inclusion into the study
- Poor oral hygiene with no possibility of improvement
- Chronic or acute systemic disorders (uncontrolled diabetes, hemorrhagic diatheses, general or autoimmunodeficiency)
- Poor interest and cooperation from the patient
- Existence of non-treated generalized progressive periodontitis
- Acute periapical pathology (tooth sensitive to percussion)
- Insufficient bone volume at the receptor site and patient's refusal of grafting
- Pathologic changes at the receptor site (cysts, tumors, osteomyelitis, etc)
- Irradiation in the implant area
- Patient still growing (ie, a child or adolescent)

The distribution of the patients according to gender and age is shown in Table 1.

Surgical Procedure and Indications for Immediate Implant Placement

The surgical technique first published by Schulte and Heimke[1,4–6] was modified and adapted for use with the Frialit-2 stepped-screw implant (Figs 2a to 2e).

In this study, in 29% of the implantations, tooth loss as the result of trauma was the main indication for immediate implant placement. Unsuccessful endodontic treatment represented 22% of the implants. Implants replacing teeth lost because of caries were less common (13%). Ten percent of implants represented patients with tooth agenesis, and implants were placed immediately after removal of the primary tooth. Following removal of fragments of fractured implants, immediate implant placement was accomplished in 10% of the patients. In 2% of the implantations, the reason for tooth loss was excessive internal tooth resorption (internal pulp granuloma) and in 14%, tooth removal was necessary because of advanced periodontitis. Information was gathered and recorded during implant surgery, including bony contour, bone quality,

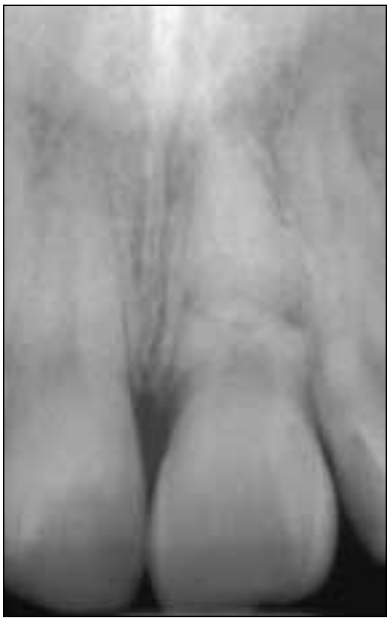
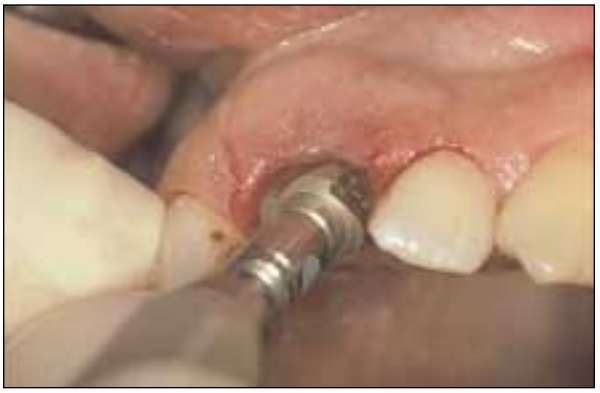


Fig 2a *(Left)* Preoperative radiograph showing traumatic tooth fracture.

Fig 2b *(Below)* Stepped drilling in ascending sequence to the predefined depth and mesiodistal diameter of the alveolus. The diameter should match the mesiodistal distance of the socket to avoid gaps between the alveolar wall and implant body. As first described by Schulte and Heimke,[1] the technique of immediate implant placement does not require any incisions.



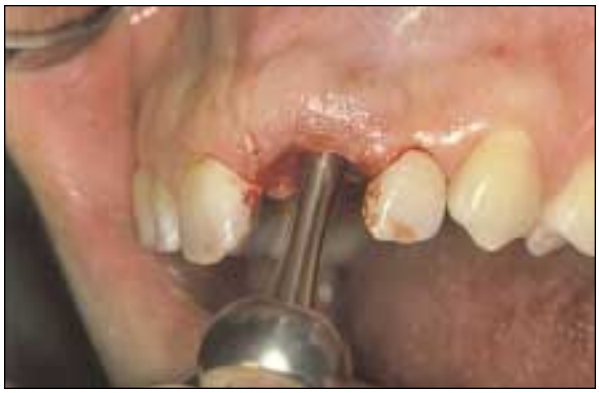


Fig 2c Placement of the implant. The implant is threaded in with the ratchet (approximately 3 turns) and a cover screw is placed.

Fig 2d Crestally, the socket is diminished by a purse-string suture of the soft tissue.

adjunct measures, and implant parameters. Distribution of implant sites according to tooth or implant loss was tabulated (Fig 3). Most of the implants were placed in the anterior region of the maxilla.

Antibiotics were administered to patients involved in 29 implantations. For 1 patient, a ridge-splitting procedure was used. Grafting was performed in situations having vestibular bone deficiency using autogenous bone (n = 9), or, where bone defects were small, bone substitutes (Algipore, Friadent, Mannheim, Germany) (n = 24). If the periosteum was not intact, grafting was combined with the use of membranes (Gore-Tex, Flagstaff, AZ) (n = 17). Osteotomies were performed to remove 6 failed

Fig 2e Crown in situ.

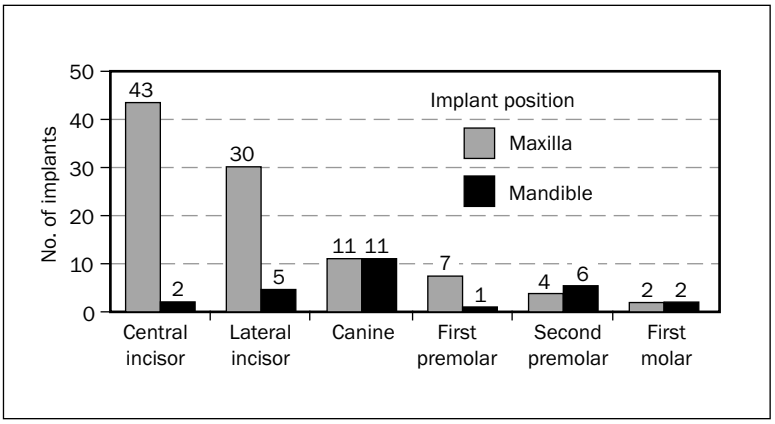


Fig 3 Distribution of implant sites in the maxilla and mandible.

Table 2 Dimensions of Implants Placed

	Length (mm)		
Diameter	**10**	**13**	**15**
3.8 mm	0	7	16
4.5 mm	4	5	17
5.5 mm	0	11	45
6.5 mm	0	1	18

implants. For some patients, it was necessary to combine several of the aforementioned treatments (eg, bone grafting plus osteotomy). For 71 implants, ancillary procedures were not necessary.

Seventy-eight percent of the implants placed were 15 mm in length, and 19% were 13 mm; other lengths were seldom used (Table 2). The most frequently used implant diameter was 5.5 mm (45%), followed by 4.5 mm (21%) and 3.8 mm (19%). The 6.5-mm-diameter implant was used in 15% of the sites (Table 2); consequently, 81% of the implants had a diameter of 4.5 mm or larger.

To avoid evaluation confusion, the participating surgeon verified all data on the documentation sheet immediately after surgery, certifying the accuracy of records.

Prosthetic Indications

Immediate implants were most frequently used for the tooth-bound gap (79%) and distal-extension situations (13%). In comparison, the number of implants placed in edentulous arches was small (8%). Sixty-eight percent of all immediate implants were placed for single-tooth restorations.

Recall Data

Follow-up findings were recorded not by the surgeon, but by specially trained dental hygienists and oral surgery staff. These were subjected to computerized processing and analysis. Data were collected at the time of patient selection, at the time of implant surgery, during the prosthetic phase, at each follow-up visit, and in the event of implant failure. Recalls took place 1 week after implant placement when sutures were removed, at the time of prosthetic restoration, 3 months after seating of the prosthesis, and at 1-year intervals thereafter.

All patients were examined and motivated to maintain good oral hygiene. Plaque Index and Gingival Index were determined according to Silness and Löe[10,11] to provide a record of peri-implant tissue quality. Probing depth was measured and recorded at the mesial, distal, lingual/palatal, and facial aspects of each implant using a periodontal probe (PCP UNC 15, Hu-Friedy, Chicago, IL). The mean value or average depth was calculated. Periotest measurements were made for all implants[12,13] at the time of prosthesis seating. In patients with splinted superstructures, the prosthesis was removed at each recall for measurement. The Periotest value (PTV) was registered by threading in a measurement post (Friadent) or directly on the implant crown.

Radiographic Examination

Standardized intraoral radiographs, and in several instances panoramic radiographs, were obtained at

recall appointments. An individual bite registration film holder was fabricated for each patient. This way, it could be ensured that all radiographs had the same position. For this purpose, commercial Rinn XCP holders were used (Emasdi, Brussels, Belgium). To allow for exact repositioning of the radiographic film, an autopolymerizing acrylic resin was used (Palavit G, Heraeus Kulzer, Wehrheim, Germany) to fabricate an occlusal registration. Radiographs were taken immediately postoperatively, at prosthesis placement, and then at 1-year intervals until the third year recall. When evaluating the radiographs,[14] the authors' main focus was to measure the peri-implant coronal radiolucency (bone defect). The measurements included, if existing, the degree of radiolucency (the depth of the bone defect) at the implant-bone interface at the mesial and distal.

Data Entry and Control

The study protocol[15] called for separate data sheets for operative data, prostheses, recall, implant loss, and exclusion from the study. A data sheet examination was completed first by a dentist, then individually by a documentation assistant and another dentist. Data were entered into a computer twice by 2 individuals, and entries were compared. Any discrepancies were checked against the original documentation, and faulty entries were corrected and again compared until data entries were in agreement. An assessment of plausibility was also conducted.

Statistical Methods

The survival time of implants was estimated from a representative sample using the method of Kaplan and Meier.[16] On the resulting Kaplan-Meier curve, an implant loss was represented by a discontinuity along the x-axis; the probability estimate of an implant remaining in situ up to a given point in time was depicted on the y-axis. To satisfy the requirement for independent data on implant life span, the evaluation was limited to 1 implant per patient. Selected for this purpose was the first implant placed in a given patient, or, in the case of 2 or more simultaneously placed implants, 1 chosen at random by a computer algorithm. Sample distributions were summarized by quartile box plots, a method introduced by Tukey.[17] Such a box shows the quartiles (25th and 75th percentiles) as its ends on the response axis and the median as a larger horizontal line within the box. To avoid overloading the figure with information, the diagram outliers were not included. Data evaluation, correctness, plausibility assessment, calculations, and randomizations were performed by SAS software (SAS Institute, Cary, NC).[18]

RESULTS

During the observation period, 124 implants were placed as immediate implants in 104 patients. The average observation period following prosthesis placement was 2.6 years, with the longest observation period (post–implant placement surgery) being 6.3 years.

Dropouts and Failures

Three patients with 4 implants died. Only 1 of the 3 had implants in place more than 1 year. Acceptable recall was defined (experimental protocol) as occurring within a period spanning the midpoints between subsequent scheduled visits. Hence, for yearly follow-up, a deviation of up to 6 months from scheduled visits was tolerated. Eleven patients moved outside the range of acceptable recall (with a total of 13 implants). All other patients maintained regular recall intervals, as defined above (Tables 3 and 4). Two implants required removal because of loss of stability and radiolucency at the interface.

Surgical Complications

No intraoperative complications were registered in 94% of the implantations. Perforations of the buccal or lingual plates, nasal floor, or maxillary sinus were noted in 5% of the surgeries. A fracture of the labial bone plate during tooth extraction occurred in 1 patient. Suture dehiscence, often the result of incomplete soft tissue coverage, occurred in 12% of the surgeries. Other complications were noted in 6% of the implants: postoperative swelling, multiple aphthae, or wound dehiscences related to guided tissue regeneration. In these patients, the membranes were removed and all implants remained in situ. Postsurgical inflammation occurred in 2% of the patients.

Prosthetic Complications

There were no signs of complications after prosthesis seating in 91% of the implants. Peri-implant inflammation was observed in 1% of implants. Eight percent of all restorations showed loosening of the fastening screws for crowns or abutments (first implant series without utilizing a torque wrench).

Clinical Parameters

Both the Plaque Index and Gingival Index revealed good oral hygiene in these patients (Figs 4a and 4b). No signs of plaque retention were detected in 65% to 76% of the implants over the 4 years of follow-up. The values for the Gingival Index were similarly positive, with no or slight inflammation in the majority of implants.

Table 3 Follow-up Examinations (After Prosthetic Treatment)

Time of examination	Implants in situ	Implants examined	Examinations missed
Prosthesis delivery	113	113	0
3 months	109	102	7
1 year	98	97	1
2 years	68	67	1
3 years	49	44	5
4 years	37	34	3
5 years	5	5	0
Total	479/100%	462/96.45%	17/3.55%

Table 4 Missing Implant Examinations

Patient no.	No. of implants	Implant location(s)	Missing examinations (m/y)
207	1	Mandible, canine	4y
212	1	Maxilla, premolar	3m, 1y, 2y, 3y, 4y
243	1	Maxilla, incisor	4y
280	1	Maxilla, premolar	3m
345	1	Maxilla, incisor	3m
350	2	Mandible, incisor and canine	3y
365	1	Maxilla, canine	3m
365	1	Maxilla, incisor	3y
437	1	Maxilla, canine	3m
728	1	Mandible, premolar	3m
756	1	Maxilla, incisor	3m
5016	1	Mandible, canine	3y

A box plot presentation according to Tukey[17] shows the changes in peri-implant probing depth since prosthesis placement (the initial value is the probing depth after prosthesis delivery, median = 2.5 mm) (Fig 5). Over the entire observation period, the median probing depth increased by only 0.5 mm.

Periotest values after prosthesis placement revealed a median of –1. The PTV showed a tendency to become more negative during the remaining period, indicating strengthened osseointegration (Fig 6).

The median amount of peri-implant bone loss (compared to the initial postsurgical value) was between 0.5 and 0.8 mm during the entire observation period (Fig 7). At prosthesis placement, the median value increased by 0.5 mm compared to the time of surgery. This had increased to 0.8 mm by 1 year and remained stable afterward.

Survival Curve Analysis

According to the Kaplan-Meier survival curve analysis[16] (Fig 8) (random choice of 1 implant per patient), the survival rate at the 1-year interval was 99% (confidence interval 97% to 100%); after 5 years, the survival rate was 97% (confidence interval 94% to 100%); and after 5.6 years, the survival rate was also 97% (confidence interval 94% to 100%). Two losses were registered in the anterior region of the maxilla (n = 84 implants). Of the 22 immediate implants placed in the molar and premolar regions, all are in function.

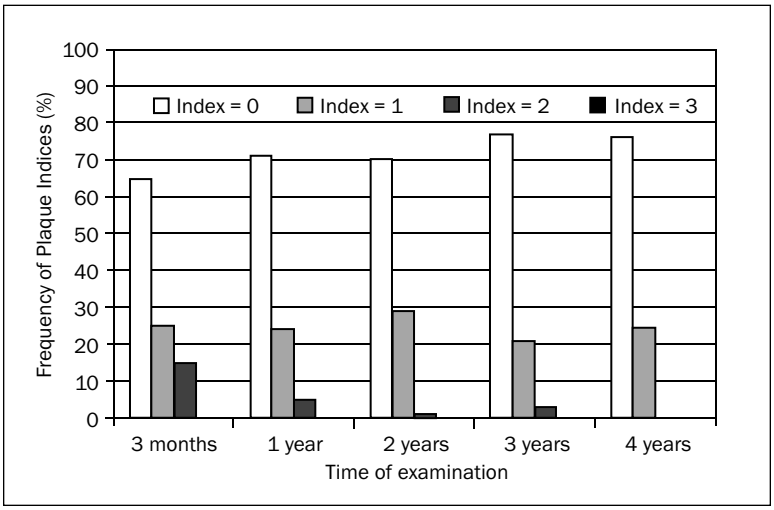


Fig 4a Plaque Index according to Silness and Löe,[10] shown as percentages at various follow-up intervals.

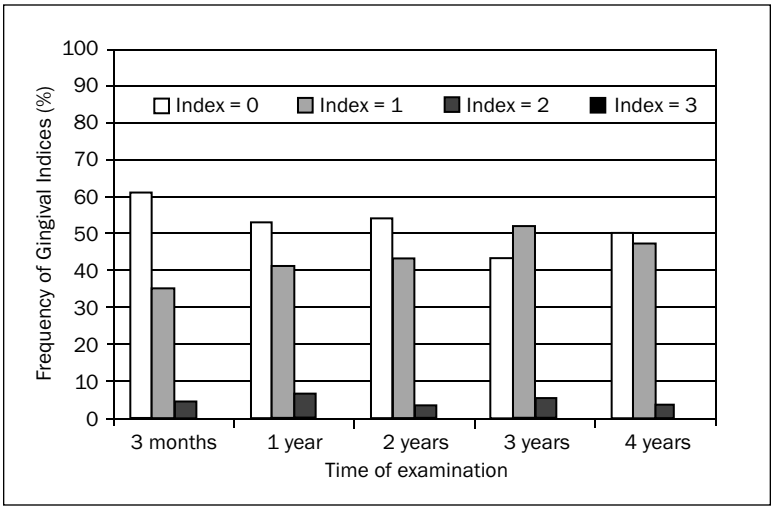


Fig 4b Gingival Index (Löe and Silness[11]), shown as a percentage of implants at recall.

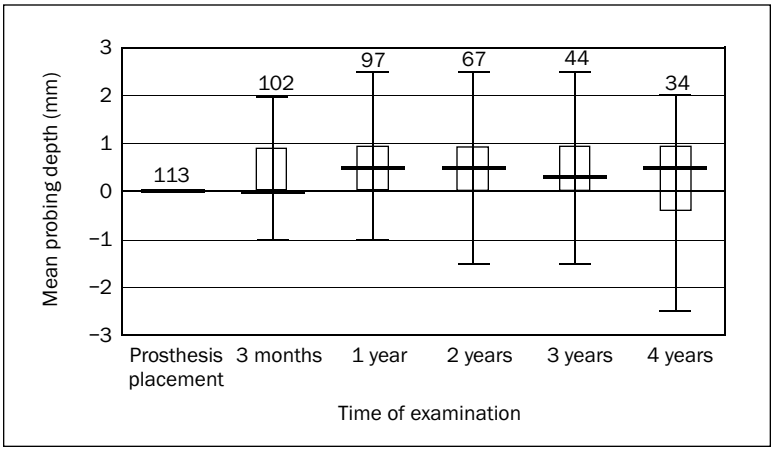


Fig 5 Changes in peri-implant probing depth since prosthesis placement (mean of 4 probing sites) at follow-up. The number of implants is noted above the box plots.

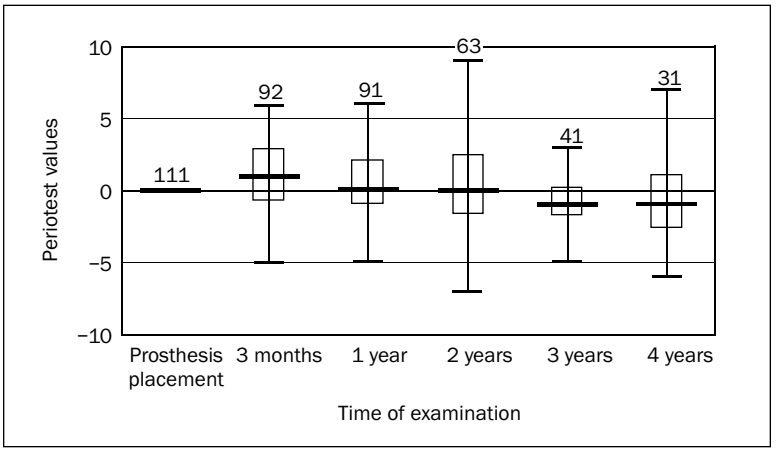


Fig 6 Changes in Periotest data since prosthesis placement at follow-up. The number of implants is noted above the box plots.

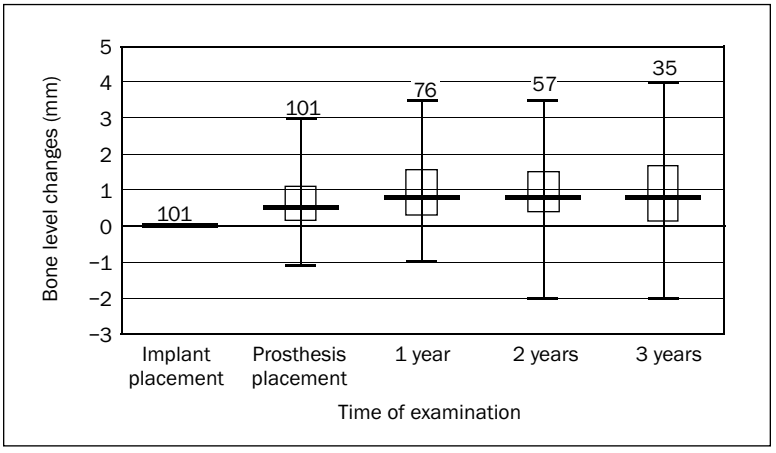


Fig 7 Bone changes since implant placement as the mean of radiographic measurements mesial and distal to implants. The y-axis indicates increases or decreases in coronal bone defect (difference in mm from the bone level measured at the time of surgery); the x-axis indicates follow-up intervals. The number of implants is noted above the box plots.

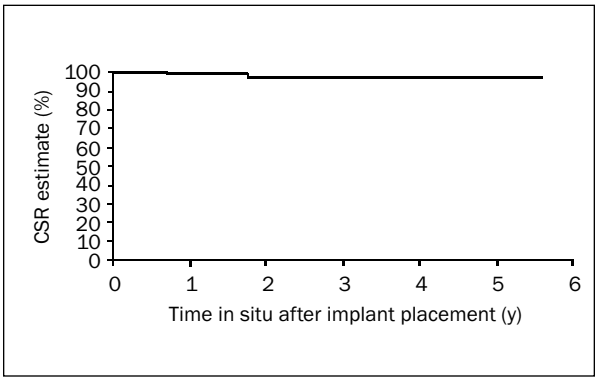


Fig 8 Implant life span for Frialit-2 according to Kaplan-Meier, with a random selection of 1 implant per patient. Observation time was from August 23, 1990, to December 20, 1996; 124 immediate implants were placed in 104 patients; 2 implants were lost. The cumulative survival rate (CSR) 1 year after implant placement was 99% (confidence interval 97% to 100%); 5 years after implant placement, the CSR was 97% (confidence interval 94% to 100%); and 5.6 years after implant placement, the CSR was 97% (confidence interval 94% to 100%).

DISCUSSION

In the present study, the most frequent indication for immediate implant placement was single tooth replacement in the anterior maxilla. Maxillary incisors and canines can often be replaced by implants immediately after tooth extraction or trauma. In the case of molars, which are typically lost because of inflammatory processes, implants are rarely placed immediately, but rather at a later time. Regarding implant placement techniques, the only difference with delayed implants is that flap reflection is necessary for access and a better overall view. This is not always required for immediate implants.

A gap greater than 0.5 mm between an implant and labial bone plate of the extraction socket should be avoided by the application of wider-diameter implants.[19] Since teeth are not perfectly round and small implants may have already been placed, the

crevice can be reduced either by manual compression of the thin vestibular bone lamella toward the implant, or by filling the space with bone chips and pulling the soft tissue over it for coverage. However, this procedure may cause a shift of the attached gingiva and impair esthetics, requiring the application of soft tissue grafts.

It is difficult to detect complications such as screw loosening at recalls, if loosening is not obvious. The Periotest was used to verify stability. A Periotest value above 5 is a possible sign of screw loosening, if there are no other signs explaining such an increased value. Screw loosening has been a general problem in implant dentistry and it has been discussed with regard to other implant systems in the literature.[20,21] Initially, no torque ratchet was available for tightening the screws of the Frialit system, which led to these problems. Since all crowns had either been screwed in horizontally or cemented temporarily (Temp Bond, Kerr, Karlsruhe, Germany), these could be removed and cleaned. A silicone ring (Hermetics, Friadent) was inserted to avoid microleakage at the abutment-implant interface,[22,23] and the abutments were then retightened with a new ratchet. No loosening of abutments has been reported since.

The Periotest procedure was developed to objectively diagnose periodontal mobility.[24] The median value increased at the 3-month recall by one Periotest value. This temporarily decreased stability was evidence of an even load distribution resulting from restructuring of the bone-to-implant contact. The median value showed decreasing tendency at further examinations, meaning that the implants were osseointegrated (Fig 6). High Periotest values do not necessarily mean that the implant is loose. They can also be the result of a loose abutment screw, which results in movement of the superstructure.

For the implants examined, the value of the coronal bone defect corresponds favorably to the analysis of other systems (late implants).[25,26] The median probing depth found in this study corresponds approximately to those of the Tübingen ceramic immediate implant and other implant systems.[27]

Regarding the 2 implant failures, it was noted intraoperatively that primary stability of these 2 single-tooth implants was not ensured after placement. However, the implants were not removed because the vestibular bone wall was not sufficiently wide for an implant of a larger diameter. One of the implants remained in function for nearly 1.5 years, despite a deep crevice in the vestibular bone wall that was evident during surgery. As for the second implant, treatment had been undertaken after fracture of a ceramic implant. A circular osteotomy was done to remove the apical fragment. Subsequent preparation of the implant bed provided little contact between bone and the implant. This resulted in reduced primary stability, which led to the loss of the implant prior to prosthetic restoration.

The present study revealed survival rates[16] of 99% after 1 year, 97% after 5 years, and 97% after an observation period of 5.6 years. Heners and coworkers[28] reported a survival rate of 60% after 5 years of observation of immediate Tübingen implants. For the molar region, Schulte and d'Hoedt[29] indicated a success rate of 87.5% after 48 months. The experience with immediate implant placement recently described in the international literature has been gathered mainly with implant systems initially designed exclusively for late implant placement.[30–37] An investigation of 11 patients with 41 immediate implants found a survival rate of 93% after 19 to 48 months.[36] However, some authors reported that with standard procedures, the difference between the diameter of the alveolar socket and that of the implant resulted in reduced primary stability, as the implant was anchored only apically. Consequently, radical alveolotomies were performed routinely. Because of the discrepancies between the size of the alveolar socket and the implant size that appeared after placement of those implant systems, membranes or barriers had to be used for guided bone regeneration,[30,32,38,39] which required additional prophylactic measures to prevent infection.

Several studies have reported on immediate implant placement in local bone after radical alveolotomy.[33,34,36] The technique has often been described in case reports[30,32] or animal studies[35,37] or utilizing different implant systems and times of implant placement.[40] Consequently, a comparison with the present results is probably inappropriate. With Frialit-2 implants, the implant diameter is adapted to the alveolar socket, which ensures close bone-to-implant contact and leads to good primary stability and healing. Parr and associates[41] and Akimoto and coworkers[19] demonstrated in histologic studies that close bone-to-metal contact is a prerequisite for achieving long-term success comparable to that seen with delayed implant placement.

The positive results seen in this investigation showed that immediate implant placement, as in the first reports on the Tübingen immediate implant, is a treatment advantage for the patient, who requires only one surgical procedure (extraction and simultaneous implant placement). Overall treatment time is significantly reduced and alveolar bone is preserved to the greatest possible extent.[3,42] Because no augmentative procedures are necessary (in case of an

intact alveolar socket), treatment is also much more cost-effective. Optimal esthetics can be achieved because of sufficient bone and soft tissue volume. The largest possible implant surface minimizes overloading of the alveolar process.

Although not all implants have been under observation for 6 years, it can be concluded that based on the biophysical concept of the Tübingen implant,[2] the Frialit-2 system is an option for use as an immediate implant. These positive results with the system, also reported in other studies,[2,9,43–45] are an indication that the implant system can be used for late as well as immediate implant placement.

CONCLUSION

The survival rates of 99% after 1 year and 97% after 5.6 years suggest that the Frialit-2 implant could be used satisfactorily for immediate placement in this patient population.

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