Use of the Frialit-2 Implant System in Private Practice: A Clinical Report

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This retrospective study presents the results of the use of the Frialit-2 System in a private practice setting. A total of 802 implants, both threaded and press-fit, were placed between February 2, 1996, and March 6, 2002. The overall success rate was 97%, and the cumulative survival rate using life table analysis was 96.1%. The statistical breakdown and an analysis of the results of the treatment of this patient population are presented. (INT J ORAL MAXILLOFAC IMPLANTS 2003;18:552–555)

Key words: *dental implants, immediate implant placement, survival rate*

The clinical efficacy of the Frialit-2 Implant (Friadent, Mannheim, Germany) has been well documented.[1–6] The system, developed from the Tübingen Implant, is based on over 25 years of clinical experience with root-analog implants.[7–10] The purpose of this study was to report the clinical experience and results with the Frialit-2 System in a private practice. The cause of implant loss was also subjected to retrospective analysis.

MATERIALS AND METHODS

All of the patients for this study were from the private practice of the author and treated sequentially as they presented for care. Patients were selected for Frialit-2 placement instead of other systems available in the practice based on referring doctor preference, implant location (Frialit-2 used most frequently in the esthetic zone), and bone morphology or immediate placement consideration (due to the taped design of the Frialit-2). As long as the patient's health did not contraindicate implant surgery, he or she was treated and included in this study. Reasons for exclusion were severe autoimmune disorders, uncontrolled diabetes, or lack of adequate bone to stabilize implants that was refractory to grafting techniques. The patient pool included 166 men and 237 women, for a total of 403 patients ranging in age from 16 to 92 years. There were 18 patients who admitted to smoking over a pack of cigarettes per day. Forty-nine implants were placed in these patients, with 9 failures (an 82% survival rate).

For this study, a failure was defined as an implant that was painful, mobile, or had radiographic signs of progressive crestal bone loss. Implants were placed by the same surgeon but were restored by 61 general dentists and 4 prosthodontists from the surrounding community. Most implants were primarily restored with single crowns (n = 639, of a total of 802 implants placed). Fifty-one implants were placed for mandibular overdentures, and 38 were placed for maxillary overdentures; 71 were splinted together to provide fixed prostheses from implant to implant, and 3 were splinted to natural teeth. Subjective patient evaluations, along with clinical assessment of soft tissue health and implant mobility, were performed at each restorative doctor's office. Mobility checking was accomplished on splinted implants by removing the bar or superstructure, unless this was permanently cemented. Periapical radiographs taken within 6 months of the end of the study were all evaluated by the surgeon and compared with second-stage (or immediately

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Table 1 Cumulative Survival Rate (CSR) for Implants Placed

Time (y)	No. of patients	Implants placed	Implants lost	SR (%)	CSR (%)
All implants					
0	399	802	7	99.1	99.1
0–1	327	643	16	97.5	96.7
1–2	76	170	1	99.4	96.1
2–3	30	78	0	100.0	96.1
3–4	18	35	0	100.0	96.1
4–5	6	14	0	100.0	96.1
In conjunction with GBR					
0	186	288	3	99.0	99.0
0–1	151	237	7	97.0	96.0
1–2	36	71	0	100.0	96.0
2–3	18	35	0	100.0	96.0
3–4	7	10	0	100.0	96.0
4–5	1	1	0		
With block onlay grafting					
0	17	39	0	100.0	100.0
0–1	14	35	0	100.0	100.0
1–2	3	8	0	100.0	100.0
2–3	2	5	0	100.0	100.0
3–4	1	1	0	100.0	100.0
4–5					
With sinus lift					
0	47	92	0	100.0	100.0
0–1	37	76	3	96.1	96.1
1–2	10	24	0	100.0	96.1
2–3	4	10	0	100.0	96.1
3–4	2	2	0	100.0	96.1
4–5					

GBR = guided bone regeneration.

pre-restoration) radiographs to determine any crestal bone loss greater than 1.5 mm in the first year or greater than 2 mm over the life of the study. Life table analysis (Triton Software; Marty Lumish, Yorktown Heights, NY) was then used to evaluate the statistical data. The data were collated according to various parameters, including location, type of implant, time of placement, and implant placement in conjunction with ancillary procedures.

RESULTS

Between February 2, 1996, and March 6, 2002, a total of 802 Frialit-2 implants were placed in this patient population. Overall, 24 implants were lost or considered failures assessed by clinical evaluation, representing a 97% success rate and 96.1% cumulative survival rate (Table 1). The majority of the implants were placed in the maxilla (n = 503). Sixteen maxillary implants were considered failures, resulting in a 96.3% 5-year survival rate. Of the 299 mandibular implants placed, 8 were considered failures, for a 97% success rate and a cumulative 5-year survival rate of 95.7%. Stepped screws were predominantly used (n = 462). The 17 threaded implants that were lost resulted in a 95.4% 5-year survival rate. Seven of a total of 340 stepped cylinders were lost, for a 97.3% 5-year survival rate.

To shorten patient treatment time and preserve alveolar bone, 160 implants were placed at the time of tooth extraction. Of these, 12 were lost, representing a cumulative survival rate of 91.8%. Initially, stepped cylindric implants were used in immediate extraction placement, until it was noted that there was a lower survival rate than with the threaded implants (85.4% versus 93.9%). Subsequently, the threaded implants were used for the majority of immediate extraction cases (n = 124). This finding adds credibility to the intended use of threads on this implant design to provide increased primary stability in extraction sockets.

Augmentation procedures were performed in conjunction with 419 implants. These ancillary procedures included guided bone regeneration, block onlay grafting, and sinus augmentation (Table 1).

Only 13 implants placed in conjunction with an augmentation procedure were lost, for an overall 5-year survival rate of 96.9%.

There were 24 failures noted, 23 of which occurred within the first year. One delayed failure occurred in the left mandibular molar area of a severe bruxer with limited vertical bone height. This patient had had previous implants from another system fail in the same area following 3 years in function. Subsequently, 1 of 2 Frialit-2 implants used as replacements was lost after 1 year in function. All other failures were implants that failed to integrate. There were 3 implants in the study with initial crestal bone loss to the top of the first step because of premature exposure during healing. All 3 of these implants have remained stable and asymptomatic following restoration, with no further signs of bone loss. Therefore, they have not been considered failures based on the criteria established for this study.

DISCUSSION

Classically, failed implants were considered to be mobile or sensitive at uncovering or during the early stages of restoration (removing or placing transfer copings or abutments). These implants typically did not show any inflammatory changes around them; nor were there any patient complaints until pressure was applied to the implant body. There also were no significant radiographic changes indicating failure. Upon removal, most implants had a thin fibrous seam around them, which was removed. All failed implants, except for 1 in a teenager who elected not to undergo surgery again, have been replaced or will be replaced after further healing.

Two patients who counted for 9 of the lost implants require further discussion. The first, a 62-year-old man, had both immediate and delayed implants placed in the anterior mandible for a fixed restoration in March of 1998. Five implants were placed—2 stepped screws and 3 stepped cylinders—with good stability and primary soft tissue closure. The mandibular denture was relined and the patient was placed on a soft diet. Within 8 weeks, all 5 implants were loose and were removed without any signs of tissue inflammation or infection. The implants were all evaluated at Friadent, and from a manufacturing standpoint, they were found to be within normal standards. The patient's health history was unremarkable except for smoking 1 pack of cigarettes a day. The patient elected not to have the implants replaced.

The author has had 3 patients with similar catastrophic failures (multiple or all implants lost in a single patient) using other implant systems. The other 2 patients were non-smokers. Based on these experiences, it would appear that there are patients who metabolically do not heal well with implants yet do not necessarily fit into any of the high-risk categories such as smoking or uncontrolled metabolic disease. In all 3 of these patients, all implants, whether titanium plasma-sprayed, hydroxyapatite-coated, or machined titanium, failed to integrate. It is hoped that further studies into bone healing, including genetic predisposition toward poor healing, will shed light on this particular patient type.

The other Frialit-2 patient with significant losses was a 51-year-old woman who had the maxillary right central incisor and left premolars removed and implants placed immediately using a 1-stage protocol and custom healing abutments on August 1, 2000. The temporary restoration was adjusted to avoid loading the healing abutments. Three months later, the patient presented with a fractured temporary restoration which she had "repaired" herself, complaining of pain in the first premolar and central incisor areas. It is the author's opinion that both implants had failed because of inadvertent "preload." They were removed and immediately replaced with larger-diameter implants. The temporary restoration was repaired properly and the patient given strict instructions for home care. Four months later the patient again returned with complaints in the central incisor area. The temporary restoration was again impinging on the healing cap, and the implant was loose. It was removed and replaced with a third implant followed by primary tissue closure. There was poor anchorage at this time, and this implant also failed to integrate. It was removed, and a block onlay graft was done in the left incisor/canine area in preparation for implant replacement later this year. In total, 7 of the failed 1-stage implants were the result of lack of patient compliance and inadvertent loading.

Three of 22 stepped cylinders utilized in immediate extraction cases were lost. While this was not a large number, it did result in the practice of using only stepped screws in extraction sockets because of what is believed to be improved primary stability. Many of the earlier failures with this technique may have been the result of a learning curve. Obvious factors that should be taken into account as to whether an implant can be placed immediately include an intact labial plate and no residual infection. Initial attempts to "obliterate" the residual socket using as large a diameter implant as possible lead to actual preparation with the drill of the

already delicate buccal plate. This in turn may have caused a breakdown of this buccal plate during healing. It is the author's opinion that the implant should engage the mesial, distal, and palatal/lingual walls. A small gap should remain between the labial aspect of the implant and the buccal/labial plate. This procedure avoids trauma to the thin plate and will ultimately lead to more bone encasing the implant and better prognosis.

Other major factors that could affect implant success include avoiding overheating the bone and not placing wider-diameter implants at the expense of the buccal/labial plates in delayed sites. While the goal with the Frialit-2 System is to place an implant that is similar in diameter to that of the tooth being replaced, the amount of bone at this site must be taken into account. Wider-diameter implants can be successful as long as they are fully encased in bone. Ideally, there should be at least a 2.0-mm thickness of bone around the crestal aspect of the implant. Methods to minimize the trauma when preparing the implant site are to drill at the proper speed, use copious internal irrigation, and replace the drills routinely.

This study demonstrates a cumulative survival rate of 96.1% using the Frialit-2 Implant System, with over 800 implants followed for up to 6 years in a practice that constantly is "pushing the envelope" with innovative techniques in immediate implant placement and grafting. There were no significant (*P* value) differences in survival rates when the system was used in the maxilla or the mandible, between press-fit or threaded implants, or when used with guided bone regeneration, block grafting, and sinus grafting techniques. There were lower 5-year survival data for smokers (82%) and for press-fit implants placed immediately into extraction sockets (85.4%). Twenty-three of the 24 lost implants failed to integrate prior to or during initial restoration. One other failure occurred during the first year in function, probably as a result of overload.

In this patient population, a significant number of the implants were placed into extraction sites (160/802). A higher number of failures were noted with immediate placement (9.2%), especially with press-fit implants. Many of these immediate implants were also placed with gingiva formers or custom healing abutments in a 1-stage protocol. Seven of the failed implants in this study were the result of excessive preload and poor patient compliance on 1-stage implants; 4 of these were in immediate extraction sites. Experience has prompted providing immediate 1-stage implant placement in a 1- to 2-tooth area, with surrounding natural teeth to protect the implant(s) from occlusal forces. A fixed temporary prosthesis would be preferable if possible. As techniques have improved, fewer failures have resulted with immediate placement, especially in the esthetic zone. This should help to improve clinical survival statistics in the future.

CONCLUSIONS

In a private practice patient population of 403, a total of 802 root-form endosseous implants were placed in a period from February 1996 to March 2002. Supporting single crowns, fixed partial prostheses, and overdentures, these implants demonstrated an overall success rate of 97% and a cumulative survival rate (life table method) of 96.1%.

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