Clinical Performance and 5-year Retrospective Evaluation of Frialit-2 Implants

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Purpose: *This retrospective study documents 5 years of clinical experience with Frialit-2 implants.* ***Materials and Methods:*** *A total of 1,215 implants (338 immediately placed, 877 placed according to a delayed-placement protocol) were placed in 487 patients. After exclusion criteria were applied, 1,099 implants (322 immediate, 777 delayed) in 442 patients remained. The influence of delayed versus immediate placement on the survival of these 1,099 implants was analyzed. The influence of diameter and location (maxilla versus mandible) on survival of the implant were also examined. Implantation sites included anterior and posterior regions; the surgical protocol (ie, immediate or delayed placement) was selected according to the indications for each site. Immediate implants were placed at the time of extraction, while delayed implants were placed 8 to 12 weeks postextraction. A 2-phase surgical protocol was used for all implants. Follow-up time ranged from 5.8 to 67.4 months.* ***Results:*** *According to the Kaplan-Meier method, the cumulative survival rate (CSR) was determined to be 90.05% at 5 years with 103 failures (32 immediate, for a CSR of 90.03%; 71 delayed, for a CSR of 90.04%). The lowest CSR (85%) was seen in the 3.4-mm-wide implants, while the 3.8-mm-wide implants had the highest CSR (93.16%). The CSR for implants in the maxilla was 91.08%; the CSR for implants in the mandible was 89.11%.* ***Discussion:*** *The CSR was relatively low compared to studies by other authors, who reported on implant populations much smaller than that presented here.* ***Conclusions:*** *A relatively low overall CSR was found, and more than 70% of the failures occurred prior to uncovering (loading) or within 2.5 months of uncovering in this patient population.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:887–891

Key words: *dental implants, dental implant survival*

Long-term success with implant dentistry was first achieved by Brånemark and associates, whose results using parallel-wall threaded commercially pure titanium dental implants and a 2-stage surgical protocol for the mandible of completely edentulous patients were first reported in the early 1980s.[1,2] In the 2 decades since then, the clinical indications and applications for implant treatment, the dental implant armamentarium, and involved protocols have evolved continuously.[3,4] Implants have been shown to succeed predictably in both maxillary and mandibular arches and in conjunction with full-arch, partial-arch, and single-tooth restorations.[5,6] As functional success has become increasingly predictable, considerations such as implant esthetics and treatment duration have received greater emphasis, resulting in an enlarged selection of implant designs and materials as well as new treatment protocols conceived to support the goals of improved esthetics and simplified treatment.[7,8]

Among the designs that have emerged is the tapered dental implant. To facilitate immediate and rapid secondary implant placement following tooth extraction, its tapered design more closely replicates the lost tooth root.[7,9] The purpose of this retrospective study was to analyze the clinical performance of one such implant system: the Frialit-2 Implant System (Dentsply Friadent CeraMed, Lakewood, CO), which features a stepped-threaded implant with an internal-hex connection.

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MATERIALS AND METHODS

Four hundred eighty-seven patients were treated consecutively in the authors' private practice between June 1998 and October 2002. Patients were included in the study if implant therapy was considered an acceptable treatment, they were physically able to tolerate conventional surgical and restorative procedures, and they were at least 18 years old. Patients who received maxillary sinus augmentation, block grafts, or sinus lifts and those in whom the use of osteotomes was necessary for ridge expansion or maxillary sinus floor elevation were excluded. The remaining 442 patients composed the population of this study.

Surgical Protocol

Once clinical and radiographic evaluations were completed, the implant sites were prepared according to the manufacturer's protocols. The implant surgeries were performed by 4 operators using identical procedures and equipment and the same surgical assistants. Initially, the implants were placed in fresh extraction sockets; subsequently, implants were used in all clinical situations. Implants that were placed secondarily were placed 8 to 12 weeks postextraction. For all patients in the study, Frialit-2 stepped-threaded implants were used. A 2-phase surgical protocol was used for all implants. A flat cover screw was placed at stage 1 surgery. Mandibular implants were uncovered at 3 months, and the maxillary implants were uncovered at 5 months.

Temporary healing abutments with the appropriate height were attached, and the soft tissues were sutured. Impressions for the definitive prosthesis were made according to the philosophy of the restorative dentist, generally 2 weeks following the second surgery. The recall protocol included office visits at 1, 3, and 6 weeks between the stage 1 and stage 2 surgeries, with periapical radiographic examination at the 6-week visit. Data regarding implant survival and radiographic appearance continues to be collected on a yearly basis.

Statistical Evaluation

For purposes of statistical evaluation, a failure was defined as an implant that was loose, infected, or exfoliated. The failure time of each implant was the elapsed time from placement to the date of failure. In cases where the terminal event was not reached (ie, the implant survived), the elapsed time between implant placement and the last observation visit was defined as the survival time. These calculated values were used in the Kaplan-Meier analysis[10] to determine the cumulative survival rate (CSR). The CSR is the probability that the implant will survive at least to a specified time within the time constraints of the study (for the present study, at least 5 years).

All data collected in regard to stage 1 surgery were obtained by patient chart review. Patients' names, chart numbers, dates of implant placement, and surgeon's names were recorded in a master file. Patient medical records were sequestered prior to the collection of data such as demographics, implant site location(s), size of implant(s), type of placement (ie, immediate versus delayed).

Using FileMaker Pro (Filemaker, Santa Clara, CA) this information was aggregated into a master database. Field validation and field parameters were used to decrease the probability of operator error. No data manipulation or calculations were performed within this database. The data necessary for statistical analyses were transferred to Microsoft Excel (Microsoft, Redmond, WA), where calculations were performed again to minimize the potential for user error. Computer software (SPSS, Chicago, IL) was used to produce related charts and graphs as well as to document the survival curves that the Kaplan-Meier estimator generated.

RESULTS

A total of 442 patients (248 females, 194 males), ranging in age from 17 to 92 years, with a median age of 55.78 years, were treated with a total of 1,099 Frialit-2 implants. Three hundred twenty-two implants were placed immediately in fresh extraction sites (immediate implants), and 777 implants were placed in healed sites (delayed implants).

Eight hundred forty-one implants were placed in the maxilla and 258 in the mandible (Table 1). The most frequent sites of implant placement were the second premolars and first molars. Ninety-three implants were placed in the maxillary right second premolar region and 97 in the maxillary left second premolar region. Fifty-seven implants were placed in the mandibular left first molar region and 53 in the mandibular right first molar region.

For all 1,099 implants followed, the follow-up period ranged from 5.8 months to 67.4 months (mean, 34.46 months). There were 103 failures. The CSR was 92.53% at 1 year and 90.05% at 5 years (Fig 1). Survival curves charting the life span of these implants demonstrated a significant decline up to 400 days and then minimal decline for the balance of the study period. Table 2 shows the number of failed implants, censored implants, and surviving implants as a function of time. For immediate implants, a CSR of 90.03% was achieved with 32 failures. For

Table 1 Distribution of Delayed and Immediate Implants by Location

Site	Delayed	Immediate	Total
2 (17)	16	3	19
3 (16)	53	12	65
4 (15)	57	36	93
5 (14)	62	22	84
6 (13)	28	15	43
7 (12)	30	24	54
8 (11)	38	25	63
9 (21)	37	18	55
10 (22)	31	25	56
11 (23)	41	18	59
12 (24)	50	23	73
13 (25)	70	27	97
14 (26)	49	12	61
15 (27)	14	5	19
18 (37)	20	2	22
19 (36)	51	6	57
20 (35)	25	10	35
21 (34)	8	5	13
22 (33)	0	3	3
23 (32)	1	2	3
24 (31)	2	0	2
25 (41)	2	3	5
26 (42)	3	2	5
27 (43)	5	2	7
28 (44)	9	4	13
29 (45)	16	8	24
30 (46)	45	8	53
31 (47)	13	2	15
32 (48)	1	0	1
Total	777	322	1,099

Tooth numbers are universal (FDI).

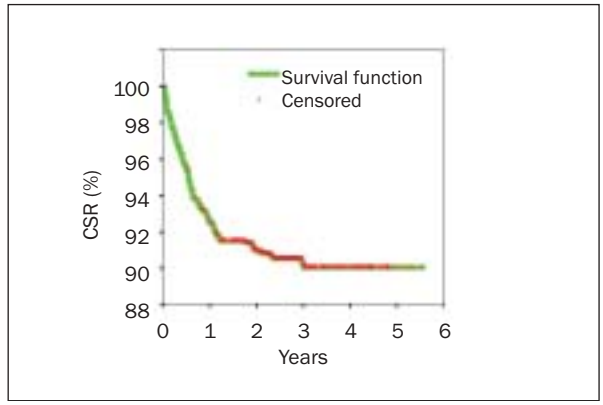

Fig 1 Cumulative survival for all 1,099 implants..

Table 2 No. of Implants at Risk as a Function of Time

Year	Failed implants	Censored implants	Implants at risk
0	0	0	1,099
1	82	15	1,002
2	98	216	785
3	102	635	362
4	103	823	173
5	103	971	25

delayed implants, the CSR was 90.04% with 71 failures. The CSR curve for immediate implants was initially more pronounced than that for delayed implants, although it became level over time (Fig 2). CSR curves were also generated for each of the 5 diameters studied. The CSRs ranged from 85.0% for the 3.4-mm-diameter (n = 40) to 93.16% for the 3.8-mm-diameter (n = 247) implants (Fig 3). Percent implant failure for all 1,099 implants by diameter and site is demonstrated in Table 3. The CSR for the 841 maxillary implants was 91.08%, with 75 failures (Fig 4). For the 258 mandibular implants, the CSR was 89.11%, with 28 failures (Fig 5).

Figure 6 shows the time of failure in days relative to uncovering (loading). Sixty-three implants failed prior to uncovering, and 40 failed after uncovering.

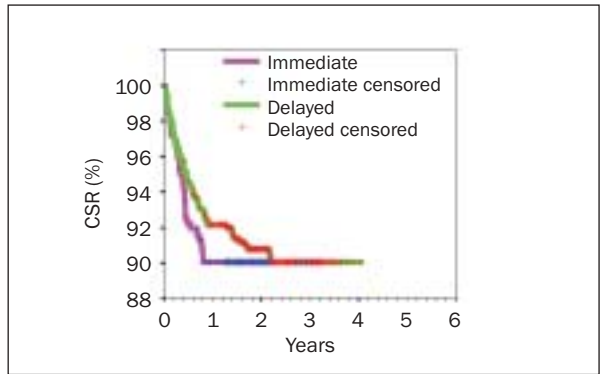

Fig 2 Cumulative survival of immediate versus delayed implants.

DISCUSSION

The Frialit-2 is the current-generation successor to the 1-piece Tübingen Implant (Friadent, Mannheim, Germany), which integrated but tended to fracture after loading.

The authors' experience with the Frialit-2 Implant System began in 1997, when they were seeking an implant with an internal connection for the prosthetic components that could be utilized for both immediate and delayed placement. A recently published study by Gomez-Roman and associates[11] claimed a 5-year

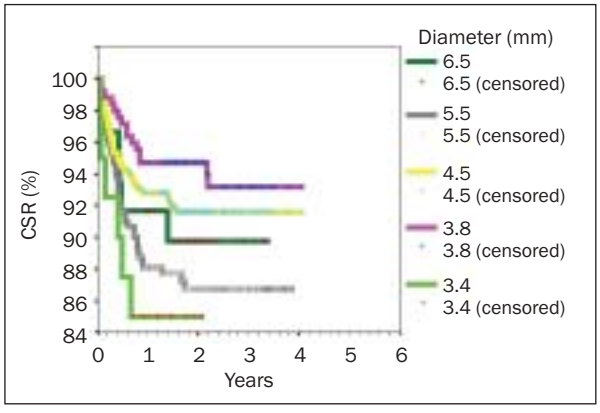

Fig 3 Cumulative survival by implant diameter.

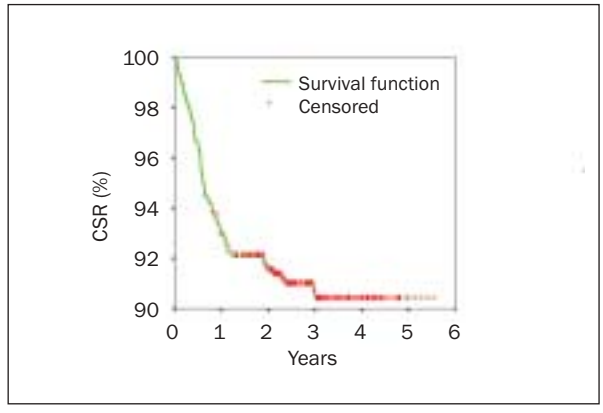

Fig 4 Cumulative survival for the 841 maxiillary implants.

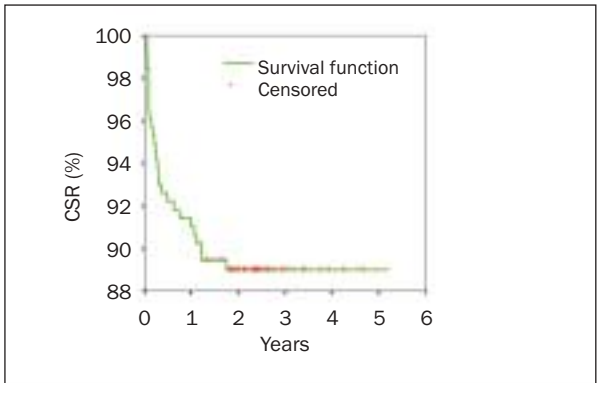

Fig 5 Cumulative survival for the 258 mandibular implants.

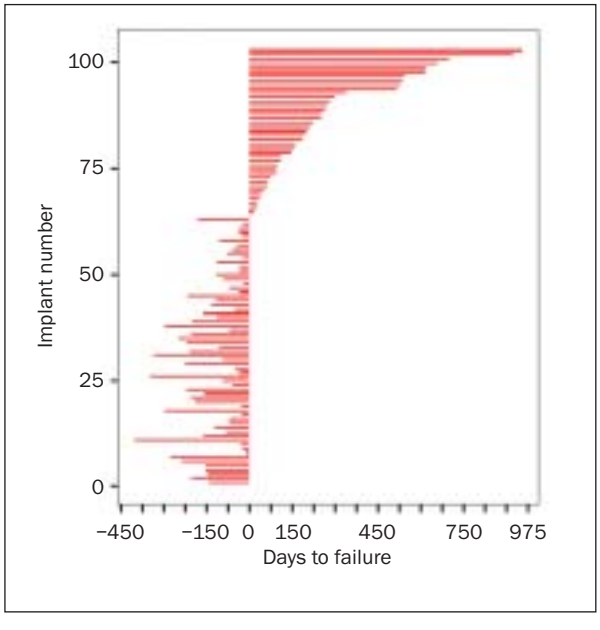

Fig 6 Time to failure relative to loading of failed implants (n = 103). Baseline (day 0) is implant uncovering (ie, loading). Negative values indicate failures that occurred before uncovering.

CSR of 96.0% with Frialit-2 implants. This study followed 696 implants placed in 376 patients. To assure statistical independence, the authors selected 1 implant per patient to study, thereby limiting the implant population to 376. There was no definition of the composition and distribution of this subpopulation. Therefore, the reader is unable to determine the validity of the stated CSR. Chuang and colleagues have shown that when the Kaplan-Meier estimator is large (> 90%), all implants in the same patient can be considered and utilized to generate the Kaplan-Meier estimator with virtually no effect on the CSR.[12] For this reason multiple implants placed in the same patient were included in the current study.

Although the validity of the CSR published by Gomez-Roman and associates is unknown, subsequent studies on the Frialit-2 implant by Krennmair and coworkers[13] and Wheeler[14] also reported higher CSRs than determined in the present study, 96.1% and 97.3%, respectively. It is noteworthy, however, that Wheeler's CSR of 90.8% for immediate implantation is similar to the results achieved by the present authors.

The CSR was 90.05% for all implants included in this study. When the study sample was divided into an immediate implant group and a delayed implant group, the former had a CSR of 90.03%, and the latter had a CSR of 90.04%. Analyzing further, the authors found that the implants had different CSRs depending on their diameter. The 3.8-mm-diameter implant had the highest CSR (93.16%), while the 3.4-mm-implant had the lowest (85.0%). There was little effect on CSR relative to jaw location (91.08% for the maxilla and 89.11% for the mandible). Table 3 may allow dental professionals to evaluate which implant diameters had high survival rates at each location in the mouth and utilize this information at the time of surgery.

To investigate the effect of the prosthetic restoration on the failed implants, the time of failure relative to loading was considered. Figure 6 shows every failed implant in the study (n = 103). Sixty-three implants failed prior to loading and 40 failed after loading. Of the implants that failed after loading, 10 failed within 75 days. If this population of 74 implants is considered as having no prosthetic influence, then 70.87% of the failed implants failed regardless of prosthetic loading.

CONCLUSIONS

Upon tracking the clinical performance of the Frialit-2 implant for 67 months, the authors have reported a lower CSR than have other investigators and no longer use this implant in their practice. They continue to utilize immediate implantation because of the procedural CSR, which is nearly identical to the CSR for delayed placement. As the majority of their failures occurred prior to loading, the authors agree with Gomez-Roman and associates,[11] who feel that losses that occur during the healing phase are often attributable to design flaws and indeed may be a common problem of the tapered-design implant.

Table 3 Percent Failure of Implants (n = 1,099) by Diameter and Site

	Diameter (mm)				
Site	3.4	3.8	4.5	5.5	6.5
1 (18)					
2 (17)				0.97	0.97
3 (16)			0.97	7.76	0.97
4 (15)			2.91	0.97	
5 (14)		1.94	2.91		0.97
6 (13)			0.97	1.94	
7 (12)		0.97	0.97		
8 (11)	0.97	0.97	3.88	1.94	
9 (21)	0.97	1.94	0.97	0.97	
10 (22)		1.94	1.94		
11 (23)	0.97	1.94	0.97	1.94	
12 (24)		1.94	2.91	0.97	
13 (25)		1.94	2.91	0.97	0.97
14 (26)			6.79	3.88	
15 (27)					0.97
16 (28)					
17 (38)					
18 (37)				1.94	
19 (36)		0.97	0.97	2.91	
20 (35)		0.97	0.97	0.97	
21 (34)		0.97		1.94	
22 (33)					
23 (32)					
24 (31)					
25 (41)	0.97				
26 (42)	0.97				
27 (43)					
28 (44)					
29 (45)					
30 (46)			2.91	7.76	
31 (47)				1.94	
32 (48)					
Total	4.85	16.49	33.95	39.77	4.85

Tooth numbers are universal (FDI).

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