

Single-Tooth Replacement with the Frialit-2 System: A Retrospective Clinical Analysis of 146 Implants

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Purpose: This study was intended to provide a report of experience and results with Frialit-2 implants used for single-tooth replacement. **Materials and Methods:** Over a 7-year period (1994–2000), 146 single-tooth implants (84 maxilla, 62 mandible) were placed in 112 patients (67 females, 45 males; 31.2 ± 16.4 years). The sites included maxillary anterior teeth ($n = 38$) as well as the mandibular premolars and molars ($n = 57$). Ninety-three crowns were cemented and 53 crowns were screw mounted (22 with vertical, 31 with horizontal screws) on standard abutments. The follow-up time varied between 3 and 80 months (35.8 ± 16.5 months). **Results:** Two implants (1.4%) were lost, 1 during early loading and the other after 6 years. The most frequent prosthetic complication was isolated crown loosening of cemented crowns requiring recementation of 9 crowns (9.9%). Crowns with vertical screws showed no crown and/or screw loosening. Four crowns (2.8%) were replaced because of ceramic fracture. **Discussion:** Peri-implant soft tissue condition, bone resorption, and Periotest values indicated satisfactory results. The cumulative implant survival rate during the follow-up period was 97.3%, and that of the crowns 96.4% (total cumulative survival rate 93.7%). **Conclusions:** With the low number of abutment screw loosening (3.5%), the deep internal hexagonal retention compared favorably to external retention methods. The predominant use of long implants ($98.4\% \geq 13$ mm) allowed a favorable implant/crown ratio with the potential for problem-free, long-term results. (INT J ORAL MAXILLOFAC IMPLANTS 2002;17:78–85)

Key words: Frialit-2 implants, implants, single tooth replacements

Loss of a single tooth, especially in the anterior tooth region, while associated with functional problems, is predominantly associated with emotional and esthetic ones.¹ Because of the variety of single-tooth restoration possibilities, choosing a prosthetic solution that meets all requirements is not always easy. Current prosthetic treatment options include the conventional removable partial prosthesis, fixed partial denture, resin-bonded prosthesis,

and the single-tooth implant. Before deciding on a conventional removable or fixed prosthetic restoration, the possible advantages of surgery, implants, or orthodontic solutions may be considered.^{2,3}

Results reported for the survival of fixed partial dentures have been variable, if not controversial.⁴ Palmqvist and Swartz⁵ described a 3% loss rate for prostheses within a period of 18 to 23 years, while Schwartz and associates⁶ reported a failure rate of 20% in a 3-year study. A meta-analysis of the survival of fixed-tooth replacements found an average survival rate of 74% after 15 years.⁷ As a limitation of these investigations, it must be noted that they not only evaluated 3-unit fixed partial dentures, but also included 3- to 4(5)-unit restorations. The most common causes for failure were secondary caries and endodontic follow-up treatment.⁸

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The pure resin-bonded prosthesis is one solution for single-tooth restoration involving the least loss of hard dental substance. In a clinical study of Creugers and van't Hof,⁹ the survival probability of resin-bonded prostheses was reported to be 74% after 4 years. However, in spite of the favorable initial assessment of survival time, an unexpectedly high number of complications were seen relative to the time of follow-up. This was also confirmed by a study of Haastert and associates,¹⁰ who reported a reduction of the survival probability for resin-bonded prostheses from 92% after the first year to 66% after 5 years. Nevertheless, the resin-bonded restoration probably can be an optimal temporary means for restoring a single-tooth gap in growing patients.

Several literature sources have reported high success rates for endosseous implants in the rehabilitation of edentulous or partially edentulous jaws.¹¹⁻¹³ Lindh and coworkers¹³ described a survival probability of 93.6% to 97.5% for implants in partially edentulous jaws and for single-tooth replacement. Various results reported for single-tooth implants and associated implant prostheses^{2,3,14,15} have encouraged the use of this type of rehabilitation.

The purpose of this retrospective study was to report the clinical experience and results with the Frialit-2 implant for single-tooth replacement. In addition, the incidence and the types of prosthetic complications encountered were also subjected to retrospective assessment.

MATERIALS AND METHODS

The causes of initial tooth loss were evaluated according to the following parameters (multiple reasons possible): trauma (13), caries (21), apical periodontitis (78), endodontia (59), apicoectomy (24), aplasia (8), marginal periodontitis (31), unerupted tooth (3), or other causes (6).

Step screws (n = 134) and step cylinders (n = 12) of varying length and diameter were used and placed as immediate (n = 7), delayed-immediate (6 to 8 weeks after extraction, n = 32), or late implantation (n = 107). In patients with bone defects or incongruences between implant and implant bed, augmentation using bone replacement material (Bio-Oss, Geistlich, Wollhausen, Switzerland) and (if necessary) a resorbable membrane (Bio-Guide, Geistlich, Wollhausen, Switzerland) was done. Exposure was carried out at 3 months after implantation in the mandible, and at 6 months in the maxilla. In patients having augmentation, an additional healing time of 4 to 6 months was allowed, depending on the extent of the initial defect. Following

exposure and a healing phase, prosthetic restoration of the implants was provided.

All patients included are part of a regular recall program and were initially (during the first year) evaluated at intervals of 3 months, and thereafter at 6-month intervals. For the most recent follow-up, peri-implant bone loss and pocket depth, as well as the degree of peri-implant inflammation and implant mobility, were evaluated in addition to implant survival time (months). Bone resorption for the Frialit-2 implants (Friatec, Mannheim, Germany) was assessed radiologically using the method of Gomez-Roman and associates¹⁶ and radiographic evaluation included an orthopantomogram and/or single periapical radiographs based on the paralleling technique. For this purpose, the primary post-operative radiograph was compared with the most recent one. A modified gingival index according to Silness and L oe¹⁷ and Haas and coworkers² was used for gingival assessment (grade 0 = no inflammation; grade 1 = slight inflammation, slight redness; grade 2 = moderate inflammation, redness, gingival hyperplasia, bleeding; grade 3 = significant redness, spontaneous bleeding, severe inflammation). Similarly, a plaque index (grade 0 = no plaque; grade 1 = plaque on the apical third of the crown; grade 2 = plaque on the middle third of the crown; grade 3 = plaque on the coronal third of the crown) was recorded and evaluated.¹⁸ Mesial, distal, lingual, and buccal pocket depths were measured using a calibrated periodontal probe (Hu-Friedy, Chicago, IL). Tooth mobility was measured with the Periotest instrument (Periotest, Siemens, Germany) at the healing abutment close to the implant edge.

Extraosseous length (abutment and crown height [mm]) was determined prior to integration, at crown removal for examination purposes, or based on the follow-up radiographs and was related to the implant length (mm). The implant/crown (I/C) ratio was graded in 4 categories: (1) I/C ratio < 1.0; (2) I/C ratio 1.01 to 1.2; (3) I/C ratio 1.21 to 1.4; and (4) I/C ratio > 1.4 and assessed as "inadequate," "satisfactory," "good," and "excellent," creating a prognostic value. Mean value and incidence of the I/C ratios were compared between lateral and anterior tooth region.

At the follow-up, prosthesis relevant parameters such as implant fracture, abutment screw fracture, abutment screw loosening, crown loosening (vertical/horizontal screw mounted), crown loosening (cement failure), ceramic fracture, vertical screw fracture, and soft tissue problems related to recession and fistulae were assessed. The parameters were recorded in descriptive statistical manner, tabulated, and evaluated. The survival times of the

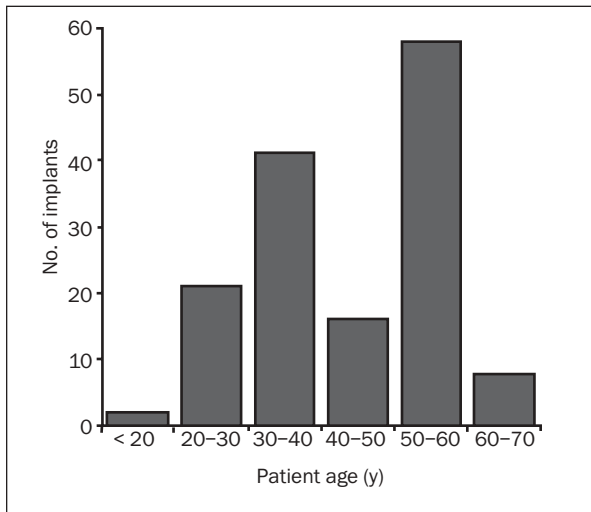


Fig 1 Distribution of placed implants with regard to patients' age.

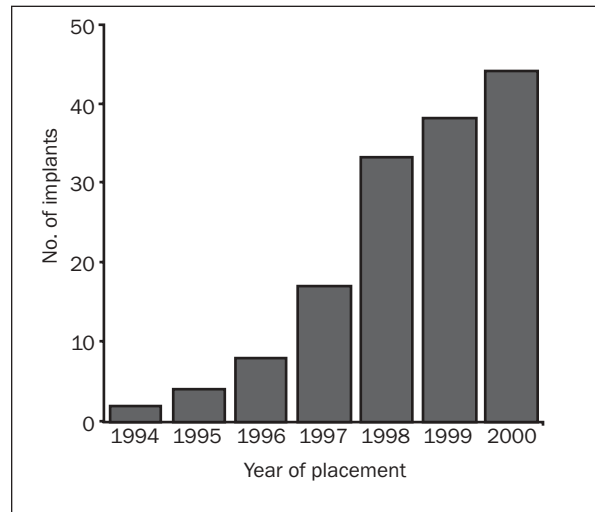


Fig 2 Number of implants placed per year during a 7 year period.

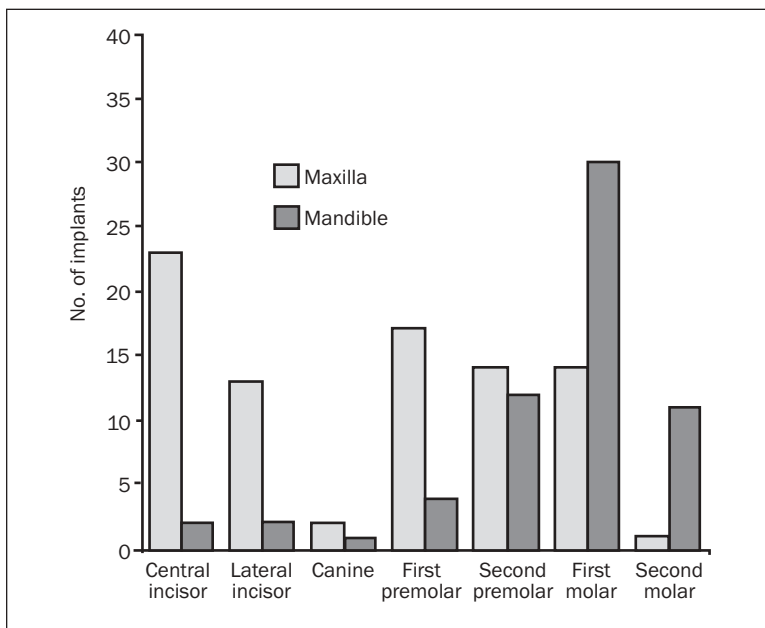


Fig 3 Location of implants in the maxilla (n = 84) and the mandible (n = 62).

implants and crowns were analyzed in a cumulative life-table analysis. Mean values were compared using the Student *t* test; nonparametric data used the chi-square test (χ^2 -test). $P < .05$ was taken as the statistical significance level.

RESULTS

Figure 1 shows the distribution of implants placed with regard to patient age. The numbers of single-tooth implants placed per year may be seen in Fig 2. Between February 1994 and December 2000, a total of 146 Frialit-2 single-tooth implants (88×1 , $15 \times$

2 , 8×3 , 1×4 ; 84 maxilla, 62 mandible) were placed in 112 patients (67 females, 29.2 ± 12.7 years; 45 males, 34.1 ± 22.7 years). Overall, a continual increase in the placement of single-tooth implants was seen throughout the observation period (Fig 2). Figure 3 shows the locations of Frialit-2 implants used for single-tooth restorations in the maxilla and in the mandible. The most frequent sites included the anterior maxilla (n = 38) and the premolars and molars (n = 57) in the mandible. The maxillary central incisor (n = 23) was the most frequently implanted tooth (Fig 3). Augmentation procedures (lateral augmentation, bone splitting, sinus lift) for cervical defects or apical perforation defects

Table 1 Distribution of the Various Implant Types with Regard to Implant Lengths and Implant Diameters (n = 146)

	Diameter		
	3.8 mm	4.5 mm	5.5 mm
Length			
10 mm	—	1 (0.7%)	1 (0.7%)
11 mm	0 (0%)	—	—
13 mm	31 (21.2%)	27 (18.5%)	13 (8.9%)
15 mm	36 (24.6%)	22 (15.0%)	15 (10.3%)

Table 2 Survival Rate of Implants and Crowns (n = 146)

Follow-up period	Implants	Loss	No follow-up in time period	CSR (%) implants	Crown fracture	CSR (%) crown	CSR (%) total
Placement— loading	146	0	—	100	—	—	100
Loading							
0–0.5 year	146	1	0	99.3	0	100	99.3
0.5–1 year	131	0	14	99.3	2	98.5	97.8
1–2 years	114	0	17	99.3	1	97.6	96.9
2–3 years	79	0	35	99.3	1	96.4	95.7
> 3 years	48	1	30	97.3	0	96.4	93.7

CSR = cumulative survival rate (for implants, crowns, and total).

were used in 43 patients. Augmentations were significantly more frequent in the anterior tooth region (n = 29) than in the lateral tooth region (n = 14, $P < .05$). Overall, the incidence of augmentation for 43 anterior tooth implants was almost 70%. In 6 patients, a (minimal) sinus lift operation was performed. Table 1 shows the lengths and the diameters of the implants used. Step screws were predominantly used (n = 134), because they allow for intraoperative adjustment of placement depth. Only 2 implants (1.4%) were shorter than 13 mm.

The majority of the single-tooth restorations were necessary because of tooth loss; aplasia was only seen in 3.3% of the patients. Apical pathology was the most common cause of initial tooth loss (32.1%) followed by endodontic failures (24.3%) and subsequent root resections (9.8%).

The follow-up period for all 146 implants ranged between 3 and 84 months, with a mean follow-up time of 35.8 ± 16.5 months. Overall 2 implants were lost, representing a cumulative survival rate of 97.3% (Table 2). One implant (first premolar left maxilla; 3.8/13 mm, cemented crown) failed during early loading (after 3 months) and the second after 6.1 years (first premolar right maxilla; 4.5/10 mm,

Table 3 Peri-Implant Bone Resorption, Pocket Depth, Periotest Values, and Soft-Tissue Conditions of the Followed Single-Tooth Implants and Crowns (n = 144)

Bone resorption (mm)	1.3 ± 0.8 (0 to 2.5)
Pocket depth (mm)	3.2 ± 1.4 (1.5 to 4.0)
Periotest values	-4.1 ± -2.6 (-1 to -7)
Plaque index	
grade 0	127 (88.2)
grade 1	17 (11.8)
grade 2	0 (0.0)
grade 3	0 (0.0)
Bleeding index	
grade 0	131 (90.9)
grade 1	13 (9.1)
grade 2	0 (0.0)
grade 3	0 (0.0)

cemented crown). Table 2 shows the implant survival times, those of the fabricated implant crowns and the cumulative overall survival rate throughout the observation period.

Radiographic bone resorption, pocket depth, plaque and gingival index, and Periotest values of the single-tooth implants followed-up are summarized in

Table 4 Prosthetic Complication Rate of the Followed Single-Tooth Crowns

Complications	Cemented (%) (n = 91)	Screwed		Total (%) (n = 144)
		Vertical (%) (n = 22)	Horizontal (%) (n = 31)	
Abutment (crown) loosening	4 (4.3)	0 (0)	1 (3.2)	5 (3.5)
Isolated crown loosening	9 (9.9)	0 (0)	3 (9.6)	12 (8.3)
Ceramic/crown fracture	2 (2.2)	1 (4.5)	1 (3.2)	4 (2.8)
Fistulae	1 (1.1)	0 (0)	0 (0)	1 (0.7)
Soft-tissue problems (recession)	3 (3.3)	1 (4.5)	0 (0)	4 (2.8)
Total complications	19 (20.8)	2 (9.0)	5 (16.0)	26 (18.0)

Table 5 Implant/Crown Ratio (I/C) in Relation to Anterior or Lateral Tooth Region

Ratio implant/crown	Anterior tooth region (n = 43)	Lateral tooth region (n = 103)
< 1.00	0 (0%)	0 (0%)
1.00–1.20	28 (65.1%)	12 (11.6%)
1.21–1.40	15 (34.9%)	42 (41.7%)
> 1.41	0 (0%)	48 (46.5%)

Table 3. The results show acceptable peri-implant soft-tissue conditions, high stability, a low degree of bone resorption, and satisfactory pocket depth.

Overall, 146 implant crowns (119 ceramometal crowns [79 titanium-ceramic crowns], 27 full ceramic crowns) were placed on standard abutments (Friatec, Mannheim, Germany). Ninety-three crowns were cemented, 22 were screwed to the abutment with vertical screws, 31 with horizontal screws. For cementing, a provisional cement (Temp-Bond, Kerr, Romulus, MI) was used. The prosthetic complication rate of the followed crowns (n = 144) is summarized in Table 4. Because a high number (n = 91) of crowns were provisionally cemented (Temp-Bond), isolated crown loosening caused by cement washout was the most frequent prosthetic complication and was seen in 9 cases (9.9%). Crown fractures occurred in 4 (2.7%) cases (3 full ceramic crowns, 1 ceramic fracture in a ceramometal crown). Overall, the number of abutment loosening (n = 5) was low (3.5%). During the observation period, no abutment/screw loosening was seen for single-tooth implants with occlusal screw retention (n = 22). For implants with horizontal screw retention, 3 instances of isolated crown loosening were seen. In 4 cases, buccal gingiva

recession was found (Table 4, 2 × anterior tooth region, 2 × lateral tooth region, 3 × augmented region). Development of a fistula was seen in 1 case (cemented crown).

The implant/crown (I/C) ratio is illustrated in Table 5. The ratio of implant length to crown (I/C) was always higher than 1.0. The mean value of this ratio in the lateral tooth region (1.42 ± 0.21) was significantly higher than that in the anterior tooth region (1.18 ± 0.14 , $P < .01$). Distribution of the incidence of the various I/C ratios showed significant differences between anterior and lateral tooth region ($P < .05$). Thus, an I/C ratio of 1.0 to 1.2 predominated in the anterior tooth region (65.1% versus 11.6%; $P < .01$, Table 5). In the lateral tooth region, the ratio was higher than 1.4 in 48 cases (46.5% versus 0%; $P < .01$).

DISCUSSION

The purpose for tooth replacement is the restoration of adequate function and esthetics without affecting adjacent hard and/or soft-tissue structures. The younger the patient receiving the tooth replacement, the higher the risk for future complications. For this reason, selection of a biologic alternative is frequently appropriate to preserve healthy adjacent structures. With adequate consideration of these requirements, the use of single-tooth implants in the rehabilitation of single-tooth gaps has significantly gained in importance.^{2,3,19–22}

Results of several studies have confirmed the high level of success for single-tooth implants, in the replacement of single teeth. Most publications which have reported on survival times of the implants and attached prosthetic components are

based on studies of Brånemark implants.^{2,3,19,20,22-24} Recent results reported by Scholander¹⁴ and Scheller and associates²⁵ have confirmed these reports with success rates of 98.5% and 95.9%, respectively. Long-term results for other implant systems have also documented the successful use of implant systems for single-tooth replacement.^{12,15,26-29} According to the manufacturer, the Frialit-2 implant is specifically intended for use as a single-tooth replacement because of its morphologic characteristics. However, no detailed, independent evaluation of Frialit-2 implants used for single-tooth replacement has been reported. A general follow-up of Gomez-Roman and coworkers¹² included a subgroup of 290 single-tooth implants among an overall 696 Frialit-2 implants. De Wijs and Cune³⁰ reported on 68 Frialit-2 single-tooth implants, but these had been exclusively placed in the anterior tooth region.

Hence, the present reported data provide detailed information on the use of Frialit-2 implants for single-tooth replacement. In this study, the main indication for implantation resulted from various endodontic failures and their consequences. This is consistent with the investigations of Priest³ and Kempainen and coworkers,³¹ but in obvious contrast to the findings of Ekfeldt and associates,²¹ Enquist and associates,²² and Scheller and associates,²⁵ who described trauma and aplasia as primary indications. The majority of implants were placed as delayed or absolute late implantations, which, like the differences in indication, reflect the patient population encountered in clinical practice. In clinical practice, financial considerations or the spectrum of prosthetic alternatives have rarely led to the use of immediate implants.^{12,32}

Overall, only 2 of 146 implants placed were lost, representing a cumulative survival rate of 97.3%. With regard to the general survival time, the Frialit-2 implant showed no differences to the published results with other systems.^{3,14,21,26-33} The favorable results seen for the peri-implant soft tissue conditions are also consistent with those reported for other studies.^{2,3} The favorite sites for implant placement were the anterior region of the maxilla and the premolar/molar region of the mandible. In comparison to other studies, a substantially higher number of molars were treated with single-tooth implants.²²⁻²⁴ This supports the fact that single-tooth replacements with implants are being increasingly used in the molar region,³⁴ even in cases which may require invasive augmentation procedures such as a sinus lift in the maxilla.³⁵ In the present patient population, sinus lift augmentations were done in 6 cases to ensure that an

implant with optimum length could be placed. In this respect, the findings of Mazar and coworkers³⁵ are supported. They claimed that the sinus lift is also justified for single-tooth implants when used to achieve sufficient implant length for optimum long-term results.

In addition to easy handling, a low rate of prosthetic complications provides positive rationale for the use of a successful single-tooth implant system. In the present study, successful prosthetic treatment incorporating Frialit-2 implants could be demonstrated by a general survival rate of the crowns of 96.4% and of a cumulative overall crown survival rate of 93.7%. No implant or screw fractures were seen and all complications could be satisfactorily addressed using simple measures. The most frequently encountered complication was isolated loosening of crowns cemented with provisional cement on the fixed abutments (9.9%). Since crown loosening may be caused by the cement wash-out, changes in the type of provisional cement may be desirable to reduce this potential source of failure.³⁶ Crown loosening with horizontal screw retention was probably the result of the low retention force of the relatively short screw.

Overall, and with due consideration of multiple entries, the prosthetic complication rate seen was 18%. With this rate, these data are similar to those reported by Priest and associates,³ but favorably differ from the substantially higher incidence rate of 77.4% described by Behr and coworkers.³⁷ For Brånemark implants and standard abutments, loosening of abutment screws seen with a rate of 25% to 40% has been the most common problem of implant-supported single-tooth restoration.^{19-24,34} However, Levine and associates²⁶ reported that screw loosening may also be seen at a rate of up to 20% with other types of implant systems. Changes in shape and modifications of prosthetic abutments as with the introduction of conical abutments,^{15,26,28,29} as well as the introduction of gold screws and/or the use of the CeraOne concept, have brought about a substantial reduction in the number of screw loosening^{2,14,24-29} and have yielded more favorable results.

The present results show that the internal hexagonal retention of the Frialit-2 implant considerably reduced the problem of screw loosening, even when using conventional abutments. As compared to the aforementioned studies with external retention, the incidence of abutment screw loosening was significantly lower with 3.5%. This likely was the result of the internal hexagonal retention extending 5.5 mm into the implant housing.³⁸ The importance of retention depth of the abutment and thus the strength of retention has been demonstrated by these clinical

data, which also confirm the experimental investigations of Möllersten and associates.³⁸

Moreover, the present study also illustrates the importance of the implant/crown ratio for the success rate achieved. While failures of the single-tooth implant were generally limited to isolated cases, the single-tooth implants lost were short in length and thus characterized by an unfavorable implant/crown ratio.³⁶ Thus, Haas and associates² and Priest³ both report loss of an implant being 10 mm in length. Also, 2 of the 3 single-tooth implants lost by Jemt and coworkers²⁰ had a length of 10 mm and 7 mm. Because of the relatively long implant length used in the study (98.4% \geq 13 mm), the ratio was invariably higher than 1.0. This was achieved by performing an augmentation in the maxillary lateral tooth area, if necessary, and by considering an optimal implant/crown ratio as a preoperative indication for the mandible. Nevertheless, the implant/crown ratio was less favorable in the anterior tooth than in the lateral tooth region because of the fabrication of the prosthesis suprastructure. The less favorable relationships in the anterior regions, as described by Polizzi and coworkers,³⁹ could be quantitatively substantiated in the present study and should therefore be considered when determining survival time. A favorable relationship of implant/crown length should contribute toward achieving optimal long-term results. With adequate consideration of patients' wishes and knowledge about the various rehabilitation options available, removable and conventional fixed partial prostheses for the replacement of single teeth are becoming increasingly less desirable. There is an increasing desire of patients to restore single-tooth spaces with endosseous implants because they can ensure adequate function, esthetic results, and optimal dental hygiene. Above all, they can fulfill the primary wish of the patient for replacement of what has been lost—namely, a single tooth.

CONCLUSION

In the present study, successful prosthetic treatment based on Frialit-2 implants could be demonstrated by a cumulative survival rate of the implants of 97.3%, of crowns of 96.6%, and with a total cumulative survival rate of 93.7%. The overall prosthetic complication rate seen was acceptable (18%) and included a rate of catastrophic crown fracture of 2.8%. Internal hexagonal retention considerably reduced the problem of screw loosening with an incidence of abutment screw loosening of 3.5%, even when using conventional abutments. The pre-

dominant use of long implants (98.4% \geq 13 mm) allowed a favorable implant/crown ratio ($>$ 1.0) with the potential for problem-free, long-term results.

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