Retrospective Evaluation of the Success of Oral Rehabilitation Using the Frialit-2 Implant System. Part 1: Influence of Topographic and Surgical Parameters

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Purpose: This retrospective longitudinal study evaluated the success of implant-prosthetic rehabilitation with the Frialit-2 implant system. ***Materials and Methods:*** The study was performed with 504 patients, from two treatment centers, who had received a total of 1,554 implants between May 1990 and May 2001. The data of these patients, who received the implants in various regions and for various indications, were analyzed with respect to clinical, topographic, and radiographic parameters. The mean observation period was 6.2 years, with a maximum of 134 months. ***Results:*** A survival rate of 94.8% was found for all implants. The implant survival rate of 92.6% in the maxilla remained constant after 68 months of observation. In the mandible, the implant survival rate of 96.7% showed no changes after 76 months. Kaplan-Meier analysis identified jaw, occurrence of postoperative complications, and region as statistically significant factors influencing implant survival. Multivariate Cox regression showed that gender, occurrence of postoperative complications, and jaw were factors that increased the risk of implant loss. Statistically significant correlations were found between the incidence of implant loss and vertical bone loss adjacent to the implant at the time of second-stage surgery. ***Conclusion:*** Implant survival rate is influenced by implant site, gender, and occurrence of complications. On the whole, the Frialit-2 system proved successful in all areas of indication after long-term observation. *Int J Prosthodont 2004;17:187–194.*

Therapy can only be considered successful if the objective and subjective complaints of the patient can be alleviated without causing lasting damage. In dentistry, and particularly in prosthodontics, success is rarely permanent, as complete restoration is almost never achieved.[1] On the other hand, both patients and clinicians demand a good prognosis, particularly with regard to elective treatment.

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Long-term studies of the results of medical therapy measures are necessary to predict a therapy's prognosis. Therapies involving implant prosthetics are dependent on long-term clinical observations to determine whether a treatment is safe and under what conditions it can be performed. Evaluation of a therapy's success is crucial to prognosis estimation. Because therapeutic success should be defined in standardized fashion, there is a necessity for comparable criteria and parameters established by uniform methods.[2–4] Given that implant prosthetics is a form of long-term therapy, the result of such treatment must be analyzed over its total duration. Some standardized procedures for gathering and analyzing data are recommended.[2–6] Over a longer period, however, examination parameters that have predictive function for the implant,[5,7] but are rational and less invasive,[6] have to be employed.

Differences in shape and surface of different implant systems may influence clinical success.[8] The Frialit-2 implant system (Friadent) has a specific macrostructure and broad variation with respect to implant length and diameter, which allows its use in a wide spectrum of

Table 1 Distribution of Patients According to Follow-up Period

Follow-up period (mo)	No. of patients	Σ%
> 134	4	1
> 120	31	7
> 108	55	18
> 96	54	28
> 84	56	40
> 72	59	51
> 60	58	63
> 48	72	77
> 36	68	91
> 24	25	96
> 12	5	97
≤ 12	17	100

anatomic situations.[9] Few studies on outcomes using Frialit-2 implants focus on special indications such as sinus floor augmentation,[10,11] single-tooth replacement,[12] or immediate postextraction application.[13] Therefore, treatment success with Frialit-2 implants concerning various indications and anatomic preconditions should be evaluated to investigate whether they have similar success rates compared with other implant types.

The purpose of the present study was to: *(1)* evaluate the clinical performance of the Frialit-2 implant system considering routine, noninvasive parameters, paying attention to preexisting anatomic situations; and *(2)* evaluate the influence of surgical parameters on implant success, prognosis, and survival.

Materials and Methods

Data gathering and analysis were done in bicentric retrospective fashion. Data were only included from patients who had been treated with the Frialit-2 implant system[8] in two treatment centers between May 1990 and May 2001. Information on 296 implants in 131 patients was gathered in treatment center 1, and information on 1,258 implants in 373 patients from center 2 was included. In total, information regarding 1,554 implants in 504 patients was gathered. The mean patient age was 48.3 years (standard deviation [SD] 14.5, normal distribution). Data were gathered on 301 women (60%, mean age 48.6 years, SD 14.0, normal distribution) and 203 men (40%, mean age 47.5 years, SD 15.1, normal distribution). The mean observation time was 74.7 months (SD 31.3), with a maximum of 134 months (Table 1).

The data were ascertained in the course of treatment preparation, implantation, second-stage surgery for healing abutment insertion, and prosthetic treatment, and at regular follow-up examinations in the functional phase of the implant-supported prostheses; or they were taken retrospectively from the patient files (patient-related data were immediately encoded by giving pseudonyms for reasons of data protection). Missing data were excluded from processing. All implantations, as well as the prosthetic treatment, were performed by two experienced operators. The patient files were analyzed by two experienced observers.

Examination Parameters

In addition to age and gender, the data included information regarding the class of indication, implant location, and mode of implantation (immediate implants, placed immediately after tooth removal or between tooth extraction and 7 days thereafter; delayed immediate implants, placed 4 to 8 weeks after tooth extraction; late implants, placed not earlier than 12 weeks after tooth extraction). Data were gathered concerning the configuration of the peri-implant alveolar ridge, steps taken to optimize the implant site (membrane guided bone regeneration [GBR], alveolar ridge expansion by bone spreading, sinus floor elevation and augmentation [SFEA]), the implant type and dimensions, frequency of complications during and following implantation, and length of the initial unloaded healing phase. Data on smoking habits of patients from treatment center 2 were missing; smoking status of the patients was detected by questionnaires in treatment center 1 only.

In addition to radiographic examination of the bone adjacent to the implant, the configuration of the bone was clinically ascertained during the operation. The gathering of data in the course of the recall investigation concentrated on the loosening or loss of implants and pathologic radiographic findings (following clinical determination that a radiographic examination was necessary). The frequency of postoperative radiographs was based on published recommendations.[14]

Following the criteria for judging the success of an implant,[4] the parameters "sensation deficit," "loss of implant" (because of clinical course, always coincident with the parameter "implant loosening"), "peri-implant translucence," and "vertical bone loss over one third of the endosseal implant region" were ascertained. The subjective evaluation of treatment outcomes by the patient was performed by questionnaires using the German school grading system. Criteria for success[4] were as follows:

- Implant in situ.
- Sulcus depth mesially, distally, buccally, or orally is not deeper than 4 mm in two consecutive follow-up examinations.
- Clinical mobility does not exceed looseness I° (DGP classification: I° = no tooth mobility; II° = horizontal mobility < 1 mm; III° = horizontal mobility > 1

Table 2 Distribution of Implants (%) According to Region for All Implants (n = 1,554) and Implants Randomly Chosen in Each Patient (n = 504)

Group	Maxillary region*			Mandibular region*		
	18 to 14	13 to 23	24 to 28	48 to 44	43 to 33	34 to 38
All implants	12	26	14	17	16	15
Randomly chosen implants	11	35	11	16	14	13

*Fédération Dentaire Internationale tooth-numbering system.

mm; IV° = extreme mobility by pressure of tongue, cheek, or lips[15]).

- Implant does not show a continuous gap of more than 0.5 mm between implant surface and bone on radiographs.
- Angular bone defect (mean of mesial and distal measurements on radiographs) no greater than $^3/_{10}$ of endosseal implant section.
- Subjective evaluation of implant by the patient no worse than 3 (German school grading system: 1 = very good; 2 = good; 3 = satisfactory; 4 = sufficient; 5 = unsatisfactory; 6 = insufficient).

The data were gathered from operation protocols, patient files, and radiographs after treatment planning, implant placement, and second-stage surgery, as well as during recall in the loading period after completion of prosthetic treatment. Pre- and postoperative panoramic radiographs and intraoral periapical radiographs taken with parallel and rectangular techniques, respectively, were used to determine the degree of vertical or horizontal bone loss. Implant losses were catalogued by date to allow for analysis of implant survival.

In a first step, the analysis took the data of all the implants into account. In a second step, one randomly chosen implant per patient was examined to prevent the accumulation of individual effects. All statistical calculations were performed for both groups (n = 1,554), as well as for the group made up of the randomly chosen implants per patient (n = 504). Deviations arising from the statistical test results are detailed below; in cases where parallel results were produced in both groups, the weaker levels of significance were used.

Statistical Analysis

The results of the implant follow-up examinations were processed with data-entry masks developed with SPSS, and were subsequently evaluated with SPSS software (version 11.0, SPSS). In addition to descriptive statistics and analysis of frequency distribution (cross-table analysis, chi-square test, calculation of association with contingency coefficient, Cramer V and φ), correlations between individual parameters and implant survival with respect to various parameters (Kaplan-Meier analysis[16]) were examined. In the case of a number of parameters where significant differences were seen in log-rank testing within the Kaplan-Meier analysis, the results were added to the multivariate Cox regression[17] to evaluate their significance. The suitability of the Cox regression model was proven by calculation of the Akaike information criterion (AIC),[18] which allows evaluation if the significant covariables are determined by the suitable model.

Table 3 Distribution of Implants (%) According to Indication for All Implants (n = 1,554) and Implants Randomly Chosen in Each Patient (n = 504)

Indication	All implants	Randomly chosen implants
Shortened dental arch	27	25
Interrupted dental arch	18	18
Combination of shortened and interrupted arch	1	1
Single-tooth replacement	13	32
Severely reduced dentition	11	5
Edentulous jaw	30	19

Results

The topographic distributions by region differed significantly in the maxillary anterior region ($P = .007$; Table 2). Significant differences became apparent with the indication categories "single-tooth replacement" and "edentulous jaw" ($P < .001$; Table 3).

Surgical Parameters and Implant Dimensions

The distribution with respect to the mode of implantation did not differ significantly between the groups and showed 5% immediate implants; 7% were delayed immediate implants, and 88% were late implants.

The median duration of the unloaded healing phase was 17 weeks (Q25% = 14 weeks, Q75% = 24 weeks), 20 weeks in the maxilla (Q25% = 15 weeks, Q75% = 29 weeks) and 16 weeks in the mandible (Q25% = 13 weeks, Q75% = 20 weeks).

Table 4 Frequency of Complications During or Following Implant Surgery (n = 1,554)

Complication	n	%
Perforation of nasal floor or maxillary sinus	34	2
Suture spreading	80	5
Edema requiring therapy	15	1
Sensation deficit	28	2
Infection	41	3

Implants of diameters of 3.8 mm (30%) and 4.5 mm (46%) were primarily used. Implants of 5.5 mm (in total 20%) and 6.5 mm (in total 3%) in diameter were used less often. With respect to mode of implantation, implants with smaller diameters (3.8 to 4.5 mm) were used more often for late implantations; implants with larger diameters (5.5 to 6.5 mm) were used more often for immediate or delayed immediate implantations ($P < .001$). Implants with larger diameters were used significantly more often in the treatment of shortened dental arches and for single-tooth replacement, whereas smaller diameters (3.8 and 4.5 mm) were mainly used in edentulous jaws or shortened as well as interrupted dental arches ($P < .001$).

Most often, implants with a length of 15 mm (49%) and 13 mm (36%) were used. While their use was particularly concentrated in the maxilla (21% and 34%, respectively) and in the anterior mandibular region (10% and 23%, respectively), implants with a length of 10 mm (14%) and 8 mm (1%) were used in the posterior regions of the maxilla and mandible. Late implantations were performed notably more often with implant lengths of 13 mm or less, whereas immediate and delayed immediate implantations were performed more often with larger implant lengths ($P = .016$).

Indication-broadening procedures were mainly performed in the course of implantation. In 32% of all implantations, GBR for lateral ridge augmentation was performed, whereas vertical augmentations and bone spreading (both 4%), as well as SFEA (8%), played a minor role. These procedures were rarely used prior to implantation for implant site development (2% to 3%). GBR and alveolar ridge expansion were primarily performed in the maxillary anterior region (66%). Alveolar ridge expansion was performed significantly more often in the maxilla ($P < .005$) and in single-tooth replacement ($P_{n = 1,554} < .001$), which was not reproducible in the randomized group ($P_{n = 504} = .141$). Complications during or after implant placement occurred rarely, showing a frequency of 1% to 5% (Table 4). No differences in frequency distribution were found between the groups.

Implant Loss and Parameters Limiting Prognosis

Five percent of the implants were lost during the whole observation period. Implant losses were more common in the maxilla (71.6% of all lost implants, corresponding to 3.7% of all implants) compared to the mandible (28.4% of all lost implants, corresponding to 1.5% of all implants) ($P_{n = 1,554} < .001$). Implant loss was significantly more common in both maxillary posterior regions compared to the maxillary anterior region ($P_{n = 1,554} < .001$). These correlations were not reproducible in the randomized group ($P_{n = 504} > .100$). The stratified analysis established a significant correlation between smoking and frequency of implant loss in the maxilla ($P = .006$), but not in the mandible ($P > .500$).

A significant correlation between the occurrence of intra- or postoperative complications (Table 4) and implant loss was established in both groups ($P < .003$). In particular, this correlation was seen between premature exposure of the implant and implant loss ($P_{n = 1,554} = .022$). This correlation could not be demonstrated in the randomized implant group ($P_{n = 504} = .220$).

The peri-implant alveolar ridge configuration with respect to the level of the implant shoulder had a significant influence on frequency of implant loss ($P < .001$), in particular exposure of the rough implant surface of 1 mm or more. Exposure of rough parts of the implant surface was significantly correlated with the presence of a vertical bone defect, determined radiographically ($P < .001$). The polished edge or rough surface of the implant neck was exposed significantly more often during second-stage surgery if GBR or bone spreading was applied before ($P < .001$). A vertical bone defect noted during the second-stage operation was significantly correlated with implant loss ($P < .001$).

In implants with lengths of 8, 10, and 13 mm, a vertical bone defect was seen significantly more frequently at the time of second-stage surgery, as well as after finishing the prosthetic treatment ($P = .001$). Implant diameter and length had no significant influence on the incidence of peri-implant translucence ($P > .200$). A peri-implant translucence correlated significantly with implant loss ($P < .001$).

Women suffered implant loss significantly more often than men ($P = .032$). Considering the criteria for success,[2,4] the following events were observed: 2% of patients demonstrated temporary sensory deficits, 5% lost implants over the course of the entire observation period, 3% had peri-implant translucencies, and vertical bone loss of more than one third of the endosseal implant section was seen in 7% of cases at second-stage surgery, and in 5% over the course of prosthetic loading.

Treatment outcomes evaluated by the patients were positive in 86% of cases (59% "very good," 25% "good,"

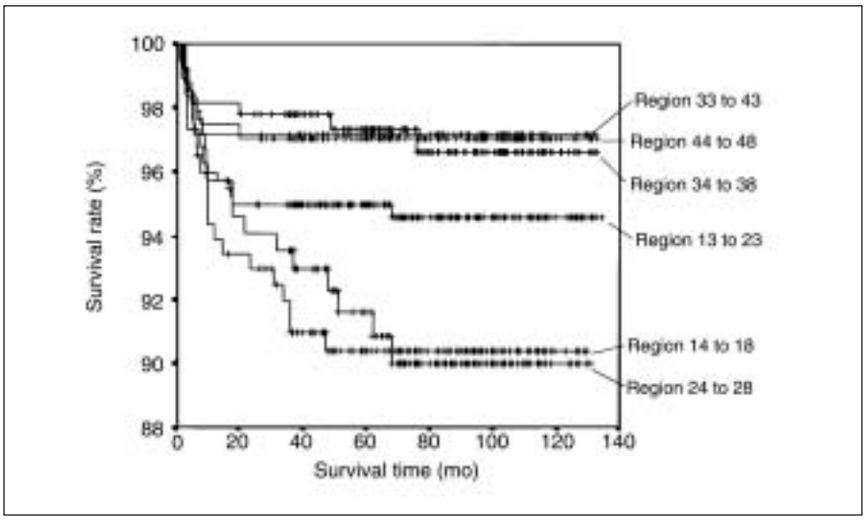

Fig 1 Kaplan-Meier survival analysis considering implant regions of all included implants (n = 1,554; log-rank test, $P < .001$). Intervals on the ordinate are limited to real value ranges. Fédération Dentaire Internationale tooth-numbering system used to indicate region.

2% "satisfactory"), whereas 1% of the patients judged the therapeutic result to be worse than satisfactory, and 13% did not respond.

The following parameters had no significant influence on the frequency of implant loss: indication group, mode of implantation, implant diameter, implant type (cylinder or screw), implant surface, presence of vertical bone defects at implantation, use of implant site conditioning, insertion depth considering level of implant shoulder, and treatment center ($P > .100$).

Implant Survival Rate

After accounting for the implantation data and information related to implant loss, calculation of the implant survival rate was performed.[15] Implants had a mean survival rate of $94.8\%_{n=1,554}$ and $95.0\%_{n=504}$ over a maximum observation period of 134 months. In the maxilla, a mean implant survival rate of 92.6% was determined; it remained unchanged after 68 months of observation. In the mandible, the survival rate was 96.7%; it remained constant after 76 months of observation.

Significantly different time courses were found for implant survival in the maxilla and mandible (log-rank test, $P_{n=1,554} < .001$), in cases where postoperative complications occurred (log-rank test, $P = .002$), and in individual regions (log-rank test, $P_{n=1,554} < .001$) (Fig 1). Here, the survival rates differed significantly between implant regions in the mandible and both maxillary posterior regions ($P_{n=1,554} < .007$). Calculated for the randomized group, implant survival did not differ significantly considering the jaw in which implants were placed or region (log-rank test, $P_{n=504} > .096$).

Calculation of Significant Covariables by Cox Regression

Parameters were included in the multivariate Cox regression if they revealed a significantly different time course of implant survival in the Kaplan-Meier analysis (log-rank test). These parameters were: site of implant placement concerning maxilla and mandible, respectively, implant region, gender, and occurrence of complications. Jaw, gender of the patient, and occurrence of complications were identified as significant covariables for implant loss for all implants (Table 5). Although the posterior regions of the maxilla were significant variables for implant loss in the sample of all implants, implant region was not a significant covariable with the Cox regression model if considered as a single variable. The AIC in parameters found to be significant covariables with the Cox regression was lower than in case of the parameters at the beginning of backward stepwise Cox regression.

Female patients had a 3.5 ($P_{n=504} = .023$) and 1.7 ($P_{n=1,554} = .037$) times higher risk of implant loss. The occurrence of intra- or postoperative complications increased the risk of implant loss 3.4 times ($P_{n=1,554} = .001$) and 4.8 times ($P_{n=504} = .011$). In the maxilla, the risk of implant loss was 2.1 times greater than in the mandible ($P_{n=1,554} = .003$). This result was not significant in the randomized group ($P_{n=504} = .900$).

Discussion

Studies of the quality of therapy results over a greater time span are necessary to determine which parameters

Table 5 Results of Multivariate Cox Regression Among All Implants (n = 1,554)

Covariable	Exp β	95% confidence interval	*P*
Implant placement (jaw); reference: mandible	2.149	1.305–3.538	.003
Region*; reference: 44 to 48			.179
13 to 23	6.968	0.945–51.370	.057
14 to 18	10.581	1.388–80.650	.023
24 to 28	10.415	1.468–73.866	.019
33 to 43	0.995	0.361–2.746	.993
34 to 38	0.977	0.354–2.695	.965
Gender; reference: female	0.598	0.369–0.969	.037
Complications during and after implantation; reference: no complications	3.419	1.641–7.162	.001

*Fédération Dentaire Internationale tooth-numbering system.

influence prognosis and judge their relevance in individual cases. For long-term success evaluation, a few parameters with predictive quality that can be measured noninvasively with simple means are necessary. In this respect, exclusion of pain and sensation deficits, loosening of the implant, and pathologic peri-implant soft and hard tissue changes has proven worthwhile.[2–4,6,7] For that reason, our study included ascertainable, noninvasive parameters within a system of regular recall. Data on implant loosening were not consistently gathered on every implant in both treatment centers, as this would have required invasive removal of prosthetic suprastructures, particularly in the case of connected implants. As such, the statements on success evaluation have limited value with respect to exclusion of implant mobility.[7]

Earlier investigations reveal a within-patient dependence on success rates among implants.[19,20] Therefore, implant success may be influenced by individual risk factors. To exclude cumulative effects of individual patient particularities, a second evaluation series was performed. In this series, one random implant per patient was examined. This explains the distribution differences in the indication categories "single-tooth replacement" and "edentulous jaw." Besides gender, the occurrence of complications was a characteristic parameter that may influence implant survival. The parameter "occurrence of complications" may comprise an individual cumulation of risk factors. The individual region, as well as the jaw where the implants are placed, seems to influence the risk of implant loss, with dependence on the number of implants. Therefore, a cumulation of individual risk factors should be assumed.

Because of its macrostructure, the Frialit-2 implant system is well-suited to implantation in an alveolus.[9] In the patients studied here, however, it was used primarily for late implantations. As such, implants of smaller dimension were predominantly used. Implants with increased diameter were mainly used for immediate or delayed immediate treatment of shortened dental arches, as well as for single-tooth replacement, demonstrating the multiple capabilities of Frialit-2 implants.

The evaluation of vertical bone loss was performed with studies on panoramic radiographs as well as intraoral films using rectangular or parallel techniques. Preventing positioning errors is a prerequisite for the comparability of multiple panoramic radiographs. Metric evaluations are difficult to reproduce, even with the use of intraoral films, so it is necessary to use radiopaque measurement references.[21] In our studies, the implant dimensions described in the patient files were used as measurement reference data.

Peri-implant vertical bone loss is considered an important radiographic parameter for judging treatment success.[4,6,7,22] In this respect, the success criteria are different. Independent of which implant system is used, generally applicable criteria consider an implant successful if vertical bone loss does not exceed $^3/_{10}$ of the length of the endosseal implant section.[4] Our studies revealed a significant association of both vertical bone loss at second-stage surgery as well as peri-implant translucence and frequency of implant loss. According to the evaluation criteria used in the present study,[4] 7% (vertical bone loss over $^3/_{10}$ of the length of the endosseal implant section) and 2% (peri-implant translucence) could be considered unsuccessful. In general, a vertical bone defect was seen significantly more often in shorter implants with lengths of 8 to 13 mm. The extent to which parts of the rough implant surface were exposed at the second-stage operation was significantly correlated to the frequency of implant loss. The placement depth, height and width of the alveolar ridge, and lateral augmentation were correlated with premature implant exposure.

Implant loss is the clear, final event, fixed with respect to time, that is used by broad consensus to evaluate the success of implant prostheses.[4,6,7,23] To estimate prognosis, it is also necessary to take other parameters into account. In our investigations, some parameters used in earlier studies on other implant systems, such as peri-implant or vertical bone loss, were confirmed as having

an influence on prognosis.[2,3,6,7] In addition to periimplant bone loss, seen as vertical bone loss at second-stage surgery, these included exposure of the rough surface of the implant, jaw where the implant is located,[5,22,24] and occurrence of postoperative complications.[25] The correlation between the frequency of implant loss and premature exposure, discussed in previous studies,[26] could only be confirmed by the data of the entire material. Implants in the maxilla revealed a significantly shorter survival time than in the mandible. Differences in bone quality and quantity have been discussed as causes.[24,25,27] Significant concentrations of implant loss in the maxillary posterior region and the implant loss risk calculated with Cox regression in the entire material confirmed these results, but the region considered as one single variable was not confirmed to be a significant covariable for implant loss.

Lateral alveolar ridge augmentation by GBR and bone-spreading techniques was used significantly more often in the maxilla, particularly in connection with single-tooth replacement. Although it showed no direct influence on the frequency of implant loss, the influence of GBR was clear at the time of second-stage surgery: The rough implant surface was exposed significantly more often following GBR. This was correlated with a vertical bone defect significantly more often, and this, in turn, was associated with a greater frequency of implant loss. Both the use of GBR and the existence of a vertical bone defect at second-stage surgery should be considered influential for prognosis because of their significant association with implant loss.

The findings of the descriptive statistical investigations were also reproducible in the Kaplan-Meier analysis: The survival probability for implants in the maxilla was significantly different compared to the mandible considering both groups. This became even more clear when the implant regions were studied in the Kaplan-Meier analysis: The survival rate of implants in the maxillary posterior region was markedly lower than in other regions. Postoperative complications also had a negative influence on implant survival rate. With respect to the frequency of occurrence, premature implant exposure should be mentioned. For Frialit-2 implants, an implant survival rate of 94.8% was found for a mean observation period of 6.2 years. This is comparable with the survival rates of 94% to 98% found for different implant types after 5 years of observation.[28–30]

The 5% implant loss rate in a group observed over a maximum of 134 months seems small. The fact that an implant remains in situ without taking its quality and function into account can mislead one to consider all of these implants successful. As such, the demonstration of a Kaplan-Meier probability of survival of an implant does not guarantee its success when evaluated with other criteria. Applying additional success criteria[4] to the data gathered, the proportion of implants that fall into the unsuccessful category lies between 1% and 7%.

The subjective judgment of implant success by patients is a particularly important part of the evaluation of success.[4,31] We used the German school grading system for this purpose.[4] It can be assumed that patients answer as they feel they are expected to by their treating clinician, so these results should be viewed critically.[32] Of the patients, 13% did not answer the questionnaires. These data were considered missing. High expectations lead easily to disappointment on the part of the patient. On the other hand, negative attitudes with respect to the therapeutic results can also be caused by the general social environment.[32] In our study, 86% of patients subjectively considered their therapy results to be "very good," "good," or "satisfactory." Only 1% judged their results to be worse than satisfactory, which would be considered unsuccessful.[4]

The extent to which the prosthetic indication class prior to and following implant prosthetic rehabilitation and the particularities of the prosthetic superconstruction influence the implant survival rate is the object of further studies.

Conclusion

The Frialit-2 implant system can be successfully used for long-term implant-prosthetic rehabilitation in all categories of indication. Long-term study over a maximum of 134 months showed an implant survival rate of 92.6% in the maxilla, with no changes after 68 months, and 96.7% in the mandible, which remained constant after 76 months. Therefore, the long-term implant survival rate of Frialit-2 implants is comparable to that of other implant types. The following factors are considered significant in influencing prognosis: implant location (maxilla, mandible, implant region), extent of exposure of the rough surface of the implant during second-stage surgery, and occurrence of postoperative complications.

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