Clinical Report with Up to 4 Years of Follow-up on a Cervically Modified Stepped Screw-Type Implant

Gernot Weibrich, MD, DDS, PhD[1,2]/Philipp Streckbein, DDS[2]/
Frank Krummenauer, DSc, PhD[3]/Wilfried Wagner, MD, DDS, Univ-Prof[2]

Purpose: *In 1998, a modification of the macrostructure of the Frialit-2 implant in the cervical region was introduced to stabilize peri-implant bone. Limited data are available on the clinical effect of this modification. Therefore, the soft-tissue situation, marginal bone loss, and implant failure rate were analyzed after 4 years of clinical experience with the modified Frialit-2 Synchro implant.* ***Materials and Methods:*** *From 1998 to 2001, 190 cervically modified implants were placed and documented prospectively in 58 patients. Of these implants, 147 were placed in original jaw bone, 22 in areas augmented with local osteoplasty, and 21 in iliac crest bone graft. The main indications for implantation were an atrophic edentulous alveolar crest (n = 99) and support for a partial denture (n = 39), followed by restoration of a shortened dental arch (n = 28) and single tooth replacement (n = 24). In a special clinical examination, 39 patients with 134 implants were investigated.* ***Results:*** *The average in situ time of the 134 implants was 23.1 months. Failing osseointegration (n = 10), peri-implantitis (n = 1), and tumor resection (n = 3) in 8 patients resulted in the failure of 14 of 190 implants (7.4%). One patient with 4 implants died (2.1%). Currently, 3 patients with a total of 6 implants have been lost to follow-up (3.1%), and 166 implants remain in situ (87.4% of 190).* ***Discussion:*** *Using different implant success criteria, success rates of 88.8% and 82.8% were calculated.* ***Conclusion:*** *Based on the results, the Frialit-2 Synchro implant appears to be a useful implant system for the indications analyzed.* Int J Oral Maxillofac Implants 2006;21:795–800

Key words: *implant success criteria, macrostructure modification of implants, marginal bone loss*

The number of new implant systems available is increasing nearly as fast as the indications for dental implants. Often, these systems and their technical modifications are clinically available before long-term observations of the established system have been published. In the years since the Frialit-2 implant was developed, many studies with positive results have been published.[1–5] In 1998, a modification of the macrostructure in the cervical region was introduced as a clinical treatment option to help stabilize the peri-implant bone. Currently, only limited data are available on the clinical effect of this modification of the implant design on implant survival and on its effect on the stability of the marginal bone.[6–8] Therefore, the soft tissue situation, marginal bone loss, and implant failure were analyzed up to 4 years after placement of the Frialit-2 Synchro standard implant, an established ablative-surface enlarged self-tapping stepped screw-type implant with a macrosurface modification in the cervical area.

MATERIALS AND METHODS

Between September 1998 and January 2001, 190 standard implants (Frialit-2 Synchro implant system, Friadent, Mannheim, Germany) were placed in 58 patients. The most common implant lengths were 15 and 13 mm; the most common diameters were 4.5 and 3.8 mm (Table 1). The implants were placed in the maxilla and mandible, in both the anterior (including the canine) and molar regions (Fig 1). Implants were most commonly placed in the atrophic edentulous alveolar crest (n = 99 implants, 52.1%). Partially edentulous patients (n = 39 implants, 20.5%) and patients with a shortened

[1]Department of Prosthetic Dentistry, Johannes Gutenberg University, Mainz, Germany.
[2]Department of Oral and Maxillofacial Surgery, Johannes Gutenberg University, Mainz, Germany.
[3]Department of Medical Biometry, Epidemiology and Informatics, Johannes Gutenberg University, Mainz, Germany.

Correspondence to: Dr Gernot Weibrich, Department of Prosthetic Dentistry, Johannes Gutenberg University, Augustusplatz 2, D-55131 Mainz. Fax: +49 6131 17 5517. E-mail: weibrich@mkg.klinik.uni-mainz.de

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Table 1 Distribution of Implant Length and Diameter by Gender for 58 Patients

Length		Diameter							
		3.8 mm		4.5 mm		5.5 mm		6.5 mm	
	n	F	M	F	M	F	M	F	M
10 mm	17	-	-	4	7	3	3	0	0
11 mm	8	6	2	-	-	-	-	-	-
13 mm	78	16	15	18	10	4	11	1	3
15 mm	87	17	7	20	24	6	13	0	0
Total	190	39	24	42	41	13	27	1	3

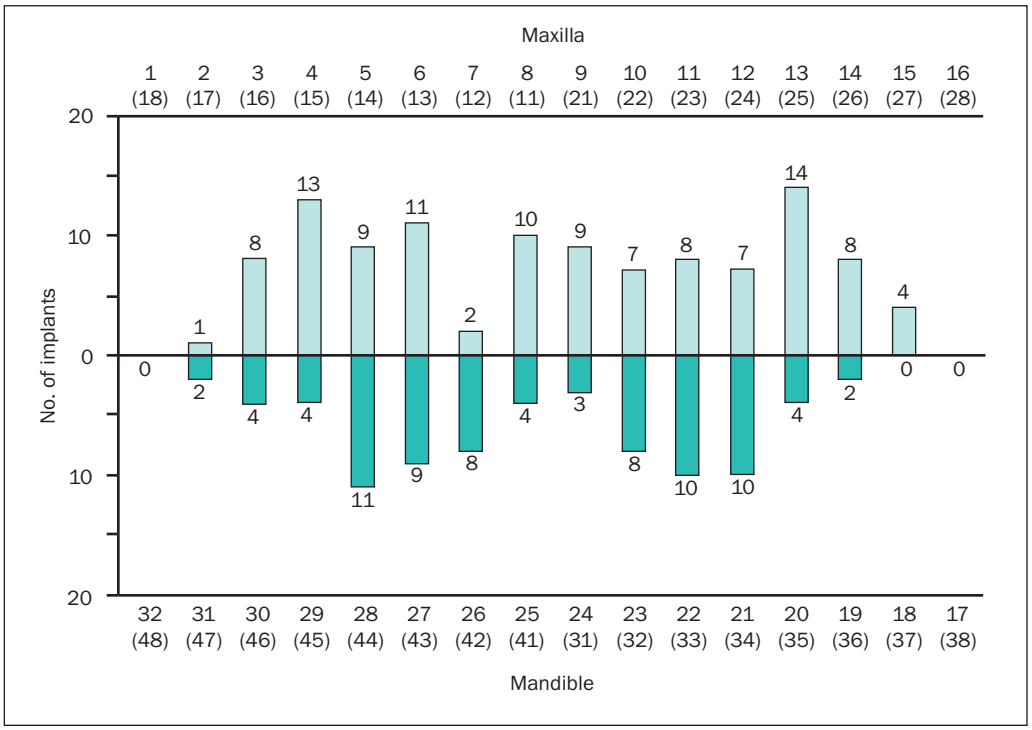

Fig 1 Frequency and location of the placed implants (n = 190 in 58 patients).

dental arch (eg, missing molars) (n = 28 implants, 14.7%) were also treated. Single-tooth replacements represented only a small portion of the implants (n = 24, 12.6%). Most implants (n = 147) were placed in native bone, but 22 were placed in local bone grafts, and 21 were placed in iliac crest block bone grafts. Tooth extraction (69 of 190) and bone atrophy (52 of 190) were the most common main indications for implantation, followed by tumor resection (n = 49), trauma (n = 6), cleft lip with cleft palate (n = 2), hypodontia (n = 2), and various other indications (n = 10).

Thirty-nine patients (134 implants) were available for recall for investigation of the peri-implant hard and soft tissues from May 2001 to September 2002. Of the 134 implants, 75 (56.0%) were in edentulous patients, 20 (14.9%) were in partially edentulous patients, 23 (17.2%) were placed in patients with a shortened dental arch, and 16 implants (11.9%) had replaced a single tooth. Consequently, a removable overdenture attached to a splinted gold bar (41.8%, n = 56) was the most common type of restoration, while 31 implants (23.1%) were restored with compounded crowns (implant-supported single crowns connected together), 17 implants (12.7%) with single crowns (not connected), and 14 implants (10.4%) with a fixed prosthesis. Four implants were used for a telescopic overdenture. Four implants had not been used for prosthetic reconstruction at the time of the investigation, and 8 of the 134 implants investigated had been explanted.

The patient subsample (n = 134) included 14 patients who had been treated with radiation therapy. Thus, 64 implants (47.8%) were placed in irradiated bone; 3 patients had had radiotherapy for malignant disease prior to implantation, 10 patients had radiotherapy after implant placement, and in 1 patient the tissue was irradiated both before and after implant placement.

The parameters observed were the modified Plaque Index (PI),[9] Sulcus Bleeding Index (SBI),[10] extension of the attached buccal and lingual gingiva, peri-implant pocket depth (Plast-o-Probe stylet; Dentsply, Ballaigues, Switzerland), Periotest measurement (Medizintechnik Gulden, Bensheim, Germany), and mobility index (German Society of Parodontology).[11] The actual bone loss was measured from a radiographic examination after comparison with a orthopantomogram obtained immediately postimplantation (orthopantomogram adjusted for magnification). All patients were asked to answer a questionnaire used routinely for recall investigation in the Department of Oral and Maxillofacial Surgery to rate their personal impressions of the surgical implant treatment and the condition of their implant-supported prosthetic restoration. Of 58 questionnaires mailed (190 implants), 47 were returned and subsequently analyzed (160 implants, 84.2%).

Statistical Methods

Data description was based on medians and quartiles for continuous variables and on absolute and relative frequencies for categorical endpoints. Kaplan-Meier estimates were used for time-to-event endpoints. Correlations between continuous endpoints were estimated using Spearman's correlation coefficient. Significance analysis was based on univariate and multiple logistic regressions modeling for binary endpoints and on Cox regression modeling for time-to-event end points. The results of these regressions are presented using likelihood ratio test *P* values, where $P < .05$ denotes local statistical significance. For statistical testing only 1 implant from each patient was selected (the implant with the deepest pocket depth was chosen). The statistical data on this small population (59 patients) are descriptively presented and may be used to generate new hypotheses.

RESULTS

For the entire study population (n = 190 implants), there was primary loss of 5.3% of the implants (10 implants in 6 patients). One implant was lost because of peri-implantitis, and 3 implants were lost with tumor resection. Five of the lost implants were in irradiated jaws (59 of 64 implants in irradiated jaws are still in situ; mean survival time, 1.7 years). The cumulative failure rate was 7.4% (14 lost implants in 8 patients).

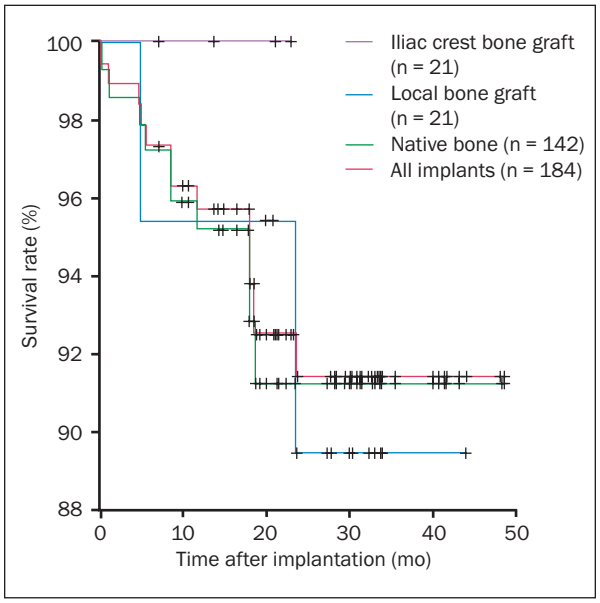

Fig 2 Kaplan-Meyer survival function of implants (184 implants in 55 patients; 6 implants in 3 patients were lost to follow-up).

At the time of this investigation, 166 implants remained in situ. During the observation period, 1 patient with 4 implants died. Three patients with 6 implants were lost to follow-up, and 14 implants were explanted. The average implant observation time (n = 170) was 2.1 years (25.4 months), with a maximum of 4.0 years (48.2 months). The Kaplan-Meier survival function is shown in Fig 2.

For 19 patients (56 implants), a recall examination was impossible during the period included in this study. One of these patients had died (4 implants), 3 patients (6 implants) were lost to follow-up, and 15 patients (46 implants) had already participated in the routine recall and were not interested in a subsequent investigation. Therefore, only 39 patients (134 implants) could be examined.

The 134 implants available for hard and soft tissue analyses had an average in situ time of 23.1 months. Eight implants in 3 patients had already been explanted. A clinical evaluation of oral hygiene using the SBI and PI showed sufficient hygiene (grade 0 or 1) in 90% (Fig 3). Grade 1 was most commonly observed, followed by grades 0 and 2. No patients were given either a PI score of 3 or an SBI of 3. Attached gingiva with a height > 1 mm was measured buccally in 65.1% of the implants and lingually in 88.1% (≥ 1 mm: 78.6% and 89.7%, respectively). The peri-implant pocket depth, which was measured

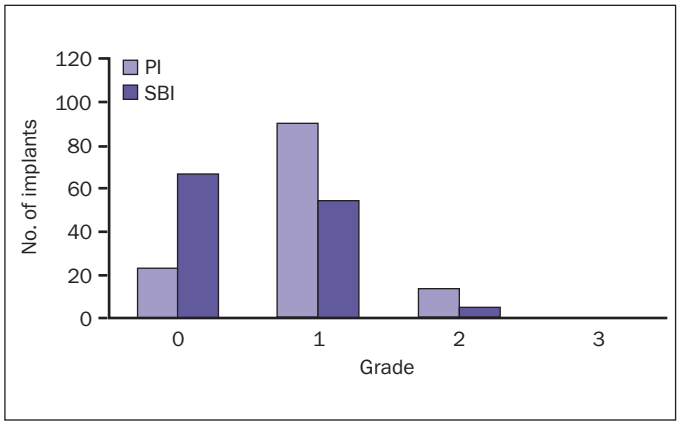

Fig 3 Distribution of the PI and SBI scores (126 implants; 8 implants had been explanted).

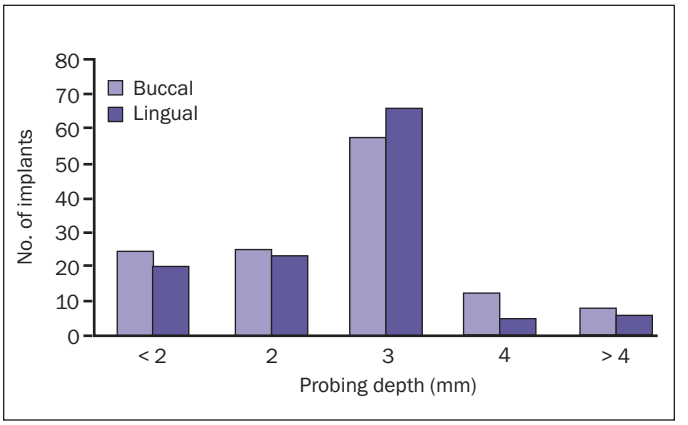

Fig 4 Distribution of probing depth (n = 126 implants).

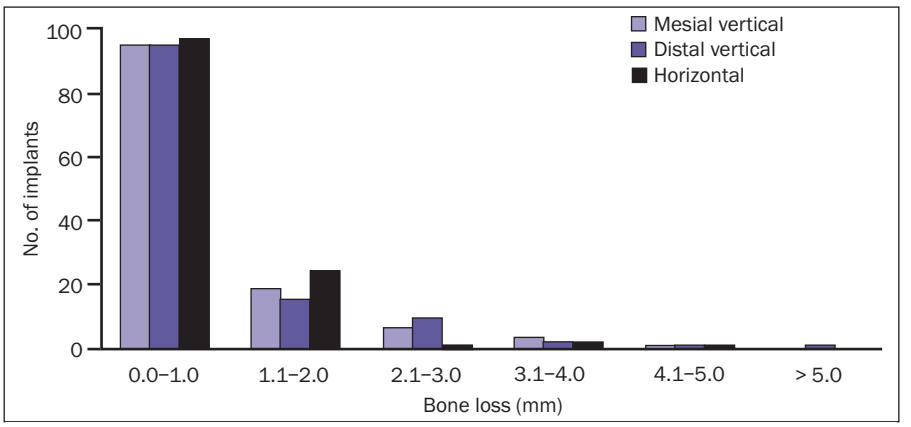

Fig 5 Peri-implant marginal bone loss (n = 126 implants).

lingually and buccally, was < 4 mm in 87% versus 84%, respectively (≤ 4 mm: 90.5% versus 93.7%, respectively) (Fig 4).

With respect to the Periotest measurement, 97% of the implants had Periotest values ≤ 8, indicating osseointegration, and only 3 implants had increased Periotest measurements (≥ 9). The manually and visually rated mobility index was 0 in most cases, but 11 implants were given a grade of 1 on the mobility index.

The mean marginal bone loss for the 134 implants investigated was 0.9 mm (range, 0.0 to 5.5 mm) after an average in situ time of 23.1 months. In 123 implants (97.6% of the 126 implants with radiographic documentation), the marginal vertical bone loss was ≤ 4 mm; it exceeded 4 mm for 3 implants. The average horizontal bone resorption was 0.7 mm (0 to 5 mm) (Fig 5). All implants with a mobility index > 0 (n = 11) or a Periotest measurement ≥ 9 (n = 3) had increased peri-implant bone loss (≥ 4 mm probing depth); a total of 17 implants had increased peri-implant bone loss.

Forty-seven of 58 questionnaires were returned. Thirty-nine patients (67% of the 58 patients surveyed) had participated in regular follow-up after implantation, and 36 patients (77% of those who returned their questionnaires) reported no problems (bleeding, inflammation, pain, or increased implant mobility) following implant therapy. Personal satisfaction was rated either excellent or very good (ie, a grade of 1 or 2, respectively) by 76.6% of patients after implantation and by 70.2% of patients after prosthodontic treatment. Patients reported an unsatisfactory implant or prosthetic outcome in only 4.2% and 6.3% of cases, respectively (Fig 6). Forty of 47 patients (85.1%) stated that they would undergo the procedure again, and 44 (93.6%) stated that they would recommend the procedure to someone else.

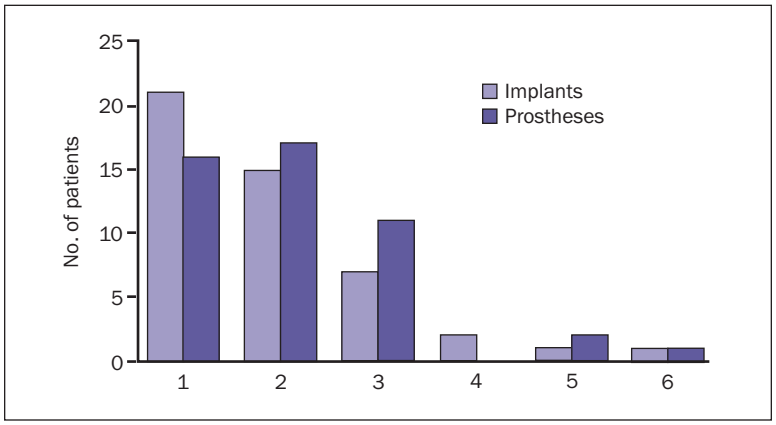

Fig 6 Evaluation of patient satisfaction with implant and prosthetic treatment where 1 is equivalent to a school grade of A, 2 to a B, 3 to a C, and so on, with 6 indicating an F.

Statistical Results

Primary Clinical Endpoint: Pocket Depth. Logistic regression (LR) modeling of the detection of increased pocket depth (> 3 mm, n = 40 implants) revealed that alcohol consumption and gender were statistically significant determinants (LR test, $P = .001$ and $P = .035$, respectively). Increased pocket depth was seen with 37% of the implants in male patients versus 25% among female patients. Forty-two percent of implants placed in patients reporting alcohol consumption had increased pocket depths versus 19% of those placed in the remaining patients. Neither augmentation, radiation, implant location (maxilla versus mandible), nor nicotine intake were significantly correlated with increased pocket depth (LR, $P = .877$, $P = .062$, $P = .090$, and $P = .635$, respectively).

The same LR modeling for increased peri-implant bone loss, based on radiographic analysis, revealed no statistically significant or clinically relevant findings because of the small number of observed cases with increased bone loss (5 cases with bone loss > 3 mm; 3 with bone loss > 4 mm).

Primary Clinical Endpoint: Time to Failure/Explantation. Multivariate Cox regression modeling of the implant survival times revealed no statistically significant or clinically relevant findings because of the small number of failures (n = 8 of the 134 implants were explanted). Univariate Cox regression models were also tried, but the results revealed no further statistically significant or clinically relevant findings.

Correlation Analysis. The Spearman's correlation analysis showed no clinically relevant correlation between the clinical parameters; the only correlation coefficient > .50 was between SBI and the deepest clinical probing depth ($r = 0.520$, $P < .001$). No clinically relevant associations were found between clinical endpoints, such as attached gingiva, probing depth (buccal and lingual), and radiographic bone loss, and subjective endpoints such as patient satisfaction with the implants or prosthetic restoration.

DISCUSSION

At the end of the study period, the overall in situ survival rate was at least 87.4% (166 of 190 implants). For the focal 39 patients with 134 placed implants, the in situ survival rate after a mean in situ time of 23.1 months was 94% (126 of 134 implants). These results are similar to the findings of other authors and other implant systems.[1,4,5,12]

The success rate of the focal 134 placed implants was 88.8% (n = 119 implants) according to the implant success criteria of Naert and colleagues,[13,14] whose definition of implant success combines "implant in situ" with "implant used for prosthetic reconstruction." Using these criteria, 12 implants (8 explanted implants and 4 implants that still have not been used for prosthetic treatment) were considered failures. Naert and associates used as a criterion of implant stability a Periotest measurement < +8. Based on this criterion, 3 implants were declared unsuccessful. Thus, using the criteria of Naert and colleagues, the treatment was judged unsuccessful in 8 patients. In addition, all implants with a mobility index score > 0 were considered failures. Thus, 8 more implants were deemed unsuccessful, for a total of 23 implants (17.2%).

The present study can be compared with a similar study by Gomez-Roman and colleagues[4]; both studies used the stepped screw Frialit-2 implant in similar indications and had similar observation periods. In the Gomez-Roman study, 42% of the implants were used for single-tooth replacement; while 12% were placed in support of a partial denture; 24% were placed in a shortened dental arch and 22% in an atrophic edentulous alveolar crest. It is necessary to use a reduced-diameter implant (3.8 mm) to replace a single tooth with a Frialit-2 implant. Thus, neither Gomez-Roman and associates[4] nor the present investigators could evaluate the differences between single-tooth applications and other ana-

lyzed implant-supported prosthetic restorations. In their study, 97% of the implants remained in situ, corresponding to a Kaplan-Meier survival rate of 96%, after a reported time interval of 4.5 years.[4] These results are slightly better than the results of the present study, which had a cumulative survival rate of 92% after 4.0 years of clinical experience (mean in situ time, 2.1 years). The slight difference might be the result of minor differences in the patients studied; in the present study, 64 of 190 implants were in irradiated bone, which may have diminished the long-term survival slightly, while Gomez-Roman and colleagues[4] did not report on whether implants were placed in irradiated bone. However, in the present study, implants placed in irradiated bone had a medium-term prognosis not much worse than that of implants placed in nonirradiated bone. Gomez-Roman and coworkers[4] documented 19 lost implants: 5 for iatrogenic or unknown reasons, 7 because of failed osseointegration, and 7 because of peri-implantitis. The focal group analyzed in the present study included 10 implants with early failures, while only 1 implant was lost to peri-implantitis. PI, SBI, and peri-implant pocket depth were similar for both studies (in both studies 90% of implants had PI and SBI grades of 0 or 1; in Gomez-Roman, mean peri-implant pocket depth was about 2.5 mm). The mean marginal peri-implant bone loss reported by Gomez-Roman and coworkers[4] was 1.0 mm after 1 year; it remained at this level for the second and third years. In the focal group examined, the mean marginal bone loss was 0.9 mm after an average in situ time of 1.9 years.

Gomez-Roman and coworkers[4] did not report the differences between the maxilla and mandible, and the present authors did not find a significant difference with respect to implant location (maxilla or mandible; $P = .09$). The modification of the cervical implant macrostructure did not significantly reduce the cervical bone during the time interval analyzed. Only a limited amount of bone loss was observed overall (about 1 mm).

The implant loss rate of 7.4% (14 of 190) with an in situ survival rate of 92.6% for the Frialit-2 Synchro implant system is comparable with the results previously reported for other implant systems. Using established implant success criteria, the rate of success decreased to 88.8% (n = 119 of 134 implants). Medium-term stabilization of the peri-implant hard and soft tissues related to the modified cervical implant macro-design could not be evaluated.

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