

# A 48-MONTH MULTICENTRIC CLINICAL INVESTIGATION: IMPLANT DESIGN AND SURVIVAL

Harold F. Morris, DDS, MS  
Sheldon Winkler, DDS  
Shigeru Ochi, PhD

## KEY WORDS

Dental implants  
Clinical studies  
Hydroxyapatite  
Dental prosthesis

Harold F. Morris, DDS, MS, is codirector, Dental Clinical Research Center and Dental Implant Clinical Research Group, Department of Veterans Affairs Medical Center, Dental Research (154), 2215 Fuller Road, Ann Arbor, MI 48106, and is also clinical professor of Restorative Dentistry, Temple University School of Dentistry, Philadelphia, PA 19140.

Sheldon Winkler, DDS, is professor of Restorative Dentistry, director of Removable Prosthodontics, and director of the Undergraduate Lecture and Laboratory Course in Oral Implantology, Temple University School of Dentistry, 3223 North Broad Street, Philadelphia, PA 19140.

Shigeru Ochi, PhD, is codirector and biostatistician, Dental Clinical Research Center and Dental Implant Clinical Research Group, Department of Veterans Affairs Medical Center, Dental Research (154), 2215 Fuller Road, Ann Arbor, MI 48106.

This report is based on a total of 2955 implants of 6 different designs, randomized and placed in 829 patients and followed for 48 months. Implant failure was defined as nonintegration at uncovering or removal due to mobility, persistent pain, infection, and evidence of radiographic bone loss. Failures were reported for 3 phases of treatment: implant placement to uncovering (phase 1), uncovering to loading (phase 2), and postloading (phase 3). Differences in survival were compared with Kaplan-Meier survival curves. The maxillary single tooth application resulted in 95.2% survival for the hydroxyapatite-coated grooved implants. In the maxillary completely edentulous application, survival of hydroxyapatite grooved and screw implants were considerably better compared with the titanium screw implants. The hydroxyapatite-coated cylinder had better survival than the titanium basket and screw designs in the mandibular completely edentulous application. The hydroxyapatite-coated cylinder and grooved implants in the maxillary posterior partially edentulous application had similar survival rates. The survival of the hydroxyapatite-coated cylinder exceeded that of the titanium basket in mandibular posterior partially edentulous applications. Analyses by phase of treatment indicated a pattern of early failure for nonhydroxyapatite-coated implants compared with hydroxyapatite-coated implants. The implant with the highest survival at all phases of treatment was the hydroxyapatite-coated press-fit cylinder. Two hydroxyapatite-coated implant designs performed well in the challenging posterior maxillary region.

## INTRODUCTION

Although most endosseous root-form implants are made from commercially pure (CP) titanium, several grades of the metal are available with slightly different properties. Titanium alloy

(Ti<sub>6</sub>Al<sub>4</sub>V) is also used for implants, with each alloy possessing different properties, depending on its composition. Surfaces of titanium alloy can be coated with hydroxyapatite<sup>1</sup> or titanium plasma spray<sup>2</sup> in an effort to enhance integration of osseous tissues to

implant surfaces. Metallic implant surfaces have been polished in a variety of ways, blasted, and etched in an attempt to improve integration. Hydroxyapatite-coated implants are available in various designs and sizes. Hydroxyapatite coatings can vary in composition, crystallinity, particle size, purity, density, and thickness.<sup>3</sup>

Structural and functional bonding between living bone and the surface of load-bearing implants is believed to be an important factor for implant success. One major factor in biocompatibility of an implant is its surface quality. The initial interaction between living bone and tissue and implant surface occurs as the surface of the implant biomaterial is exposed to tissue fluids. This produces a layer of macromolecules and fluids, which influences the behavior of cells when they encounter the implant surface. Following these events, a series of cell-material interactions takes place, leading to the release of growth and chemotactic factors, which may modulate cellular activity in the surrounding tissues.<sup>4-6</sup> The surface quality of the implant will depend on its chemical, physical, mechanical, and topographical properties.<sup>7</sup>

The optimization of implant surfaces in relation to surface energy and chemistry remains to be clarified. The effect of surface roughness on osteoblast metabolism or differentiation is also still unclear. Many studies on coatings, especially hydroxyapatite, have led to conflicting conclusions as a result of a lack of understanding of the actual surface composition.<sup>8</sup> Little information has been published on the precise surface composition, surface roughness, method of surface preparation, and cleanliness of commercially available implant systems.

Hydroxyapatite-coated implants have been the subject of considerable controversy. Hydroxyapatite-coated implants, when compared with those of titanium surfaces in animal models, have shown greater amounts of bone-to-implant contact at all time inter-

vals.<sup>9,10</sup> Few comprehensive clinical studies have been completed on the efficacy of hydroxyapatite-coated implants, and many questions remain unanswered. Zablotsky<sup>11</sup> reviewed the benefits and risk factors associated with hydroxyapatite-coated implants when compared with commercially pure titanium and titanium alloy. He concluded that hydroxyapatite coatings have a significant place in implant dentistry, especially for those sites that are considered initially compromised.

There is concern that hydroxyapatite coatings may not possess long-term stability.<sup>12-14</sup> Johnson<sup>13</sup> reported that hydroxyapatite coatings resorbed from the surfaces of some failed endosseous implants. Wheeler<sup>14</sup> reported lower cumulative survival of hydroxyapatite-coated implants compared with titanium implants over 8 years. The titanium plasma-sprayed systems evidenced failures predominately during the first 2 years after placement, while hydroxyapatite-coated systems experienced mathematically higher initial survival rates.

A Dental Implant Clinical Research Group (DICRG) study,<sup>15</sup> based on 36-month survival, reported that hydroxyapatite-coated implants appear to satisfy the basic requirements for the ideal implant design and material better than the nonhydroxyapatite-coated implants used in the investigation. Ideal implant design and material were defined as being easy to use, requiring average skills, involving minimal bone trauma, presenting a biocompatible contact surface, and producing a high rate of survival in most patients. The hydroxyapatite-coated implants were placed in the most challenging bone types and jaw regions in patients with compromised medical histories by dentists with different training, skills, and experience under less than ideal clinical situations.

Although the influence of implant design is generally recognized, a need remains for comprehensive evaluation in a long-term, randomized, prospective clinical investigation. The primary

purpose of this study was to separately examine a subset of data from the extensive DICRG database to determine what relationship, if any, exists between implant design and survival. Six implant designs were randomized to 5 restorative applications and subsequently evaluated.

#### MATERIALS AND METHODS

The DICRG initiated a long-term clinical study in cooperation with the Department of Veterans Affairs in 1991 to investigate the influence of implant design, application, and site of placement on clinical success and crestal bone height.<sup>16</sup> This report is based on 2955 implants that were placed, restored, and evaluated. The implants used in the DICRG study are generally representative of the designs and materials that are available from most implant manufacturers and include screw, basket, bullet, and grooved designs fabricated from commercially pure titanium and titanium alloy. Some of the implants had the hydroxyapatite coating applied to the titanium alloy substructure. The implants were randomized within 1 of 5 research strata using 6 implant designs, as specified in the DICRG protocol (Table 1).

The surgeon inserting the implant, in cooperation with the restoring dentist, selected the design, diameter, and length thought appropriate to meet the needs of the patient at the time of placement. Evaluation visits were scheduled at 3, 6, 9, 12, 18, 24, 36, and 48 months after uncovering.

Potential patients who volunteered to participate in the study were screened using broad criteria, including being able to benefit from endosseous implant treatment and demonstrating a willingness to return for the required number of visits. The patient population consisted mainly of white male veterans who were eligible for long-term dental care. The patients ranged from under 30 years of age to over 89 years, with females accounting for 5.5% of the study population. Approximately 55% of the implants were

TABLE 1

Implants as randomized to each jaw region\*

Completely Edentulous: Maxillary Anterior	Completely Edentulous: Mandibular Anterior	Partially Edentulous: Maxillary Posterior	Partially Edentulous: Mandibular Posterior	Single Tooth: Maxillary Anterior
...	HA-coated cylinder	HA-coated cylinder	HA-coated cylinder	...
HA-coated grooved	...	HA-coated grooved	...	HA-coated grooved
HA-coated screw	...	...	...	...
...	Ti alloy basket	...	Ti alloy basket	...
...	Ti alloy screw	...	...	...
Ti-CP screw	...	...	...	...

\*HA, hydroxyapatite; Ti, titanium; CP, commercially pure.

placed using preoperative antibiotics, while about 95% of the patients were provided with postoperative antibiotics. All patients were brought to acceptable levels of restorative and periodontal health before entering the investigation.

Failure was defined as removal of an implant for any reason. Criteria for implant failure included mobility, a peri-implant radiolucency, and/or persistent pain, discomfort, or infection associated with the implant.<sup>16</sup> In addition to radiographs, periodontal probing, and clinical mobility determinations, the Periotest<sup>17</sup> was used to evaluate the condition of the supporting tissue around all study implants. Implant failures were recorded on standardized forms that documented implant design, location, length, diameter, stage of treatment at removal, and reason for removal. All data were forwarded to the DICRG Data Management Center in Ann Arbor, Mich, for tabulation and analysis.

Failure rates were reported for the 3 phases of treatment: implant placement to uncovering (phase 1), uncovering to loading (phase 2), and post-loading (phase 3). The differences in failure patterns among the treatment phases were evaluated, and the survival of each prosthetic application was compared using Kaplan-Meier survival curves.

RESULTS

Maxillary anterior single tooth application

The hydroxyapatite grooved implant, restored with cemented crowns, was the only design used for this prosthetic application and experienced 95.2% survival to 48 months (Table 2). The failure rate to 48 months was 4.8%. The Kaplan-Meier survival curve for the hydroxyapatite grooved implant is shown in Figure 1.

Maxillary completely edentulous application

Maxillary completely edentulous cases were restored with an overdenture supported by a cast metal bar. Of the 631 implants placed, 39% were hydroxyapatite grooved (n = 247), 29.2% were hydroxyapatite-coated screws (n = 186), and 31.6% were commercially pure titanium screws (n = 200) (Table 3). Table 3 compares the failure rates for the 3 phases of treatment. Survival for the hydroxyapatite grooved implants was 86.2% compared with 93.0% for the hydroxyapatite-coated screws and 72.4% for the commercially pure titanium screws.

The survival curves for the 3 implant designs are shown in Figure 2. The commercially pure titanium screw was significantly worse (P = .000 log rank, P = .000 Breslow) compared with the other 2 designs.

TABLE 2

Maxillary single tooth survival to 48 months

Status	Implant Type		Total	
	Micro-vent		Count	%
Surviving	239	95.2	239	95.2
Failure	12	4.8	12	4.8
Total	251	100.0	251	100.0

Mandibular completely edentulous application

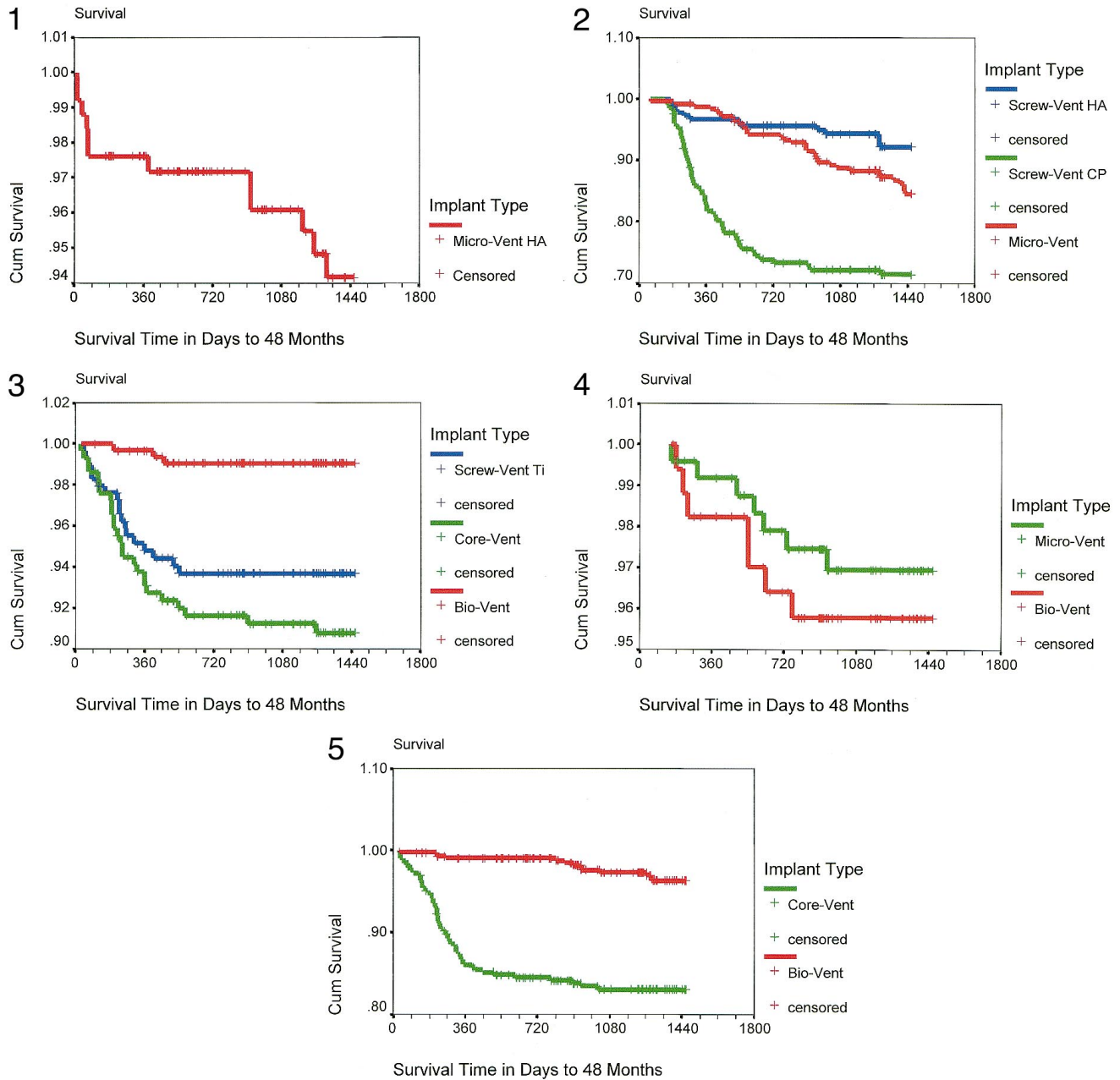
The completely edentulous mandible was restored with a screw-retained hybrid denture (Table 1). Three implant designs were randomized within this stratum: hydroxyapatite-coated cylinder, titanium alloy basket, and titanium alloy screw. Of the 904 implants placed, 35.6% were hydroxyapatite coated and 64.4% were titanium alloy (Table 4). Titanium alloy implants were equally divided between screw and basket designs.

Total survival for the hydroxyapatite-coated cylinder was 99.1% compared with 91.1% for the titanium alloy basket and 93.9% for the titanium alloy screw (Table 4). The Kaplan-Meier survival curves for the 3 implant designs are shown in Figure 3. The differences in survival for the designs are statistically significant (P = .000 log rank, P = .000 Breslow), with the hydroxyapatite-coated cylinder experiencing the best results.

Maxillary posterior partially edentulous stratum

The maxillary posterior partially edentulous stratum was restored with a screw-retained partial prosthesis. Of the 421 implants placed, 41% were hydroxyapatite-coated cylinders and 59% were hydroxyapatite grooved implants (Table 5).

Total survival for the hydroxyapatite grooved implant was 97.2% compared with 95.9% for the hydroxyapatite-coated cylinder (Table 5). Combined survival for all hydroxyapatite-coated implants in this stratum was



FIGURES 1–5. FIGURE 1. Survival curve for maxillary anterior single tooth implants over a 48-month period. During this period, about 6% of the implants failed and were removed. FIGURE 2. Survival curves for 3 different implant designs used in maxillary completely edentulous clinical cases during a period of 48 months. All implants were restored with the same dental prosthesis and were therefore subjected to similar conditions. The HA-coated screw design exhibited the best survival, followed by the HA-coated grooved design. The CP-titanium screw design exhibited the worst survival this period. FIGURE 3. Survival curves for 3 different implant designs, used in mandibular completely edentulous cases during a period of 48 months. The HA-coated cylinder exhibited the best survival, followed by titanium alloy screw. The worst survival was recorded for the titanium alloy basket implant. All implants were restored with the same prosthesis and were therefore subjected to similar conditions. FIGURE 4. Survival curves for 2 different implant designs used in the maxillary posterior partially edentulous cases during a period of 48 months. Both implants were HA coated. Both implants exhibited similar survival during this period. FIGURE 5. Survival curves for 2 different implant designs, used in mandibular posterior partially edentulous cases during a period of 48 months. One implant was a non-HA-coated basket and the other an HA-coated cylinder. The worst survival was recorded for the non-HA-coated basket and the best was the HA-coated cylinder.



96.7%. The Kaplan-Meier survival curves for the 2 implant designs are shown in Figure 4. There was no statistically significant difference in survival for the 2 designs ( $P = .5001$  log rank;  $P = .4712$  Breslow).

**Mandibular posterior partially edentulous application**

The mandibular posterior partially edentulous stratum was restored with a fixed partial prosthesis. Of the 748 implants placed, 56.1% were hydroxyapatite-coated cylinders and 43.9% were titanium alloy baskets (Table 6).

Total survival for the hydroxyapatite-coated cylinder was 96.9% compared with 83.5% for the titanium alloy basket (Table 6). The Kaplan-Meier survival curves for the 2 implant designs are shown in Figure 5. Survival for the hydroxyapatite-coated cylinder was significantly superior ( $P = .000$  log rank;  $P = .000$  Breslow) to that of the titanium basket design.

**DISCUSSION**

The phase in which implant failure is recorded is important, as strengths or deficiencies of specific implant designs may be identified at specified stages of treatment. If failure occurs before loading of the implant, surgical trauma is most likely a contributing factor. Failures after loading may be related to poor prosthesis design (occlusal overloading) and/or inadequate oral hygiene.

The maxillary single tooth stratum was restored with only 1 implant design, the hydroxyapatite grooved implant, which experienced a favorable 95.2% survival rate over 48 months. Most of the failures occurred during the healing phase.

Of the 3 different implant designs used to restore the completely edentulous maxilla, the 2 hydroxyapatite implants combined significantly outperformed the commercially pure titanium screw. A higher failure rate was recorded for the commercially pure titanium screw compared with both hydroxyapatite designs. The hydroxyap-

TABLE 3  
Maxillary completely edentulous survival by implant type to 48 months\*

Status	Implant Type						Total	
	Micro-vent		Screw-vent CP		Screw-vent HA		Count	%
	Count	%	Count	%	Count	%		
Surviving	213	86.2	144	72.4	172	93.0	529	83.8
Failure	34	13.8	55	27.6	13	7.0	102	16.2
Total	247	100.0	199	100.0	185	100.0	631	100.0

\*AA, hydroxyapatite; CP, commercially pure.

TABLE 4  
Mandibular completely edentulous survival by implant type to 48 months

Status	Implant Type						Total	
	Bio-vent		Core-vent		Screw-vent Ti		Count	%
	Count	%	Count	%	Count	%		
Surviving	316	99.1	265	91.1	276	93.9	857	94.8
Failure	3	.9	26	8.9	18	6.1	47	5.2
Total	319	100.0	291	100.0	294	100.0	904	100.0

TABLE 5  
Maxillary partially edentulous survival by implant type to 48 months

Status	Implant Type						Total	
	Bio-vent		Micro-vent				Count	%
	Count	%	Count	%	Count	%		
Surviving	165	95.9	242	97.2			407	96.7
Failure	7	4.1	7	2.8			14	3.3
Total	172	100.0	249	100.0			421	100.0

TABLE 6  
Mandibular partially edentulous survival by implant type to 48 months

Status	Implant Type						Total	
	Bio-vent		Core-vent				Count	%
	Count	%	Count	%	Count	%		
Surviving	407	96.9	274	83.5			681	91.0
Failure	13	3.1	54	16.5			67	9.0
Total	420	100.0	328	100.0			748	100.0

atite screw did better than the hydroxyapatite grooved implant. Perhaps the slightly higher survival curve for the screw design is due to more bone being deposited between the implant threads, which increases its stability.

Of the 3 different implant designs used to restore the completely edentulous mandible, the hydroxyapatite-coated cylinder had the highest survival, followed by the titanium alloy

screw and basket. Differences among the treatment phases were slight except that the basket failed more often from placement to uncovering. The hydroxyapatite-coated cylinder had considerably less than 1% failure for all phases of treatment.

For the maxillary posterior partially edentulous region, which represents a significant challenge to any implant design due to poor bone quality,<sup>18</sup> fail-

ure rates for hydroxyapatite-coated cylinders and grooved implants were somewhat similar during each phase of treatment. Overall, the grooved design did slightly better than the cylinder, with the survival curves not being significantly different.

The hydroxyapatite-coated cylinder was significantly better compared with the titanium alloy basket in the mandibular posterior partially edentulous stratum. Analysis by phases indicated a tendency for early failure of the titanium alloy basket ( $P = .000$  log rank;  $P = .000$  Breslow).

Higher survival curves were always encountered after loading. Rosenberg et al<sup>19</sup> suggested that early failures were largely the result of surgical trauma or infection. Hydroxyapatite implants generally do not exhibit a tendency to early failure.<sup>15</sup> The hydroxyapatite-coated implants in this investigation exhibited a higher survival rate to 48 months compared with nonhydroxyapatite-coated implants in each of the 3 research strata in which they were included.

Animal studies have suggested that a hydroxyapatite coating enhances bone response at the interface and promotes early integration.<sup>20</sup> Gerner et al<sup>21</sup> found evidence of more osseointegration when hydroxyapatite-coated implants were compared with pure titanium implants.

The combination of a hydroxyapatite coating and a press-fit placement technique, which can minimize trauma to the surrounding bone, appears to result in a reliable implant design from placement to 48 months postoperative.

## CONCLUSIONS

Within the parameters of this clinical investigation, which followed implants from placement to 48 months, the following conclusions can be drawn:

1. Postloading survival consistently resulted in more favorable data, suggesting that 48 months survival is a more accurate representation of implant success.

2. Hydroxyapatite-coated implants had higher survival rates compared with nonhydroxyapatite-coated implants in maxillary and mandibular completely edentulous and mandibular posterior partially edentulous applications.
3. Hydroxyapatite-coated cylinders exhibited the highest survival of all implant designs evaluated in this investigation.
4. The mandibular completely edentulous application resulted in good survival data for all implants randomized to that jaw region, which can be attributed to the favorable bone density characteristic of that location.
5. The mandibular posterior partially edentulous application exhibited mixed survival data. While the hydroxyapatite-coated cylinder's survival curve to 48 months was considerably more favorable compared with that of the titanium alloy basket, postloading data showed a decrease in the initial large difference between the 2 implant designs.
6. Although the maxillary posterior partially edentulous region is considered to be a challenging environment in which to place implants, hydroxyapatite-coated cylinder and groove designs produced acceptable survival data.

## ACKNOWLEDGMENTS

This publication is US government-supported research and there are no restrictions on its use. The results and opinions presented are those of the authors and do not necessarily reflect the opinions of the Department of Veterans Affairs, Medical Research Service, or the Office of Dentistry.

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