

# FIVE-YEAR PROSPECTIVE CLINICAL EVALUATION OF HIGHLY CRYSTALLINE HA MP-1-COATED DENTAL IMPLANTS

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Contemporary plasma-sprayed hydroxylapatite (HA) coatings with high crystalline content are much more resistant to in vivo degradation than HA coatings of a decade ago but reportedly exhibit reduced wettability, which could potentially negatively affect tissue adhesion and long-term clinical outcome. The present prospective study was undertaken to determine if highly crystalline HA MP-1-coated implants could meet a minimum 5-year implant success rate standard of 85% in view of their previously reported decreased wettability. Study subjects were consecutive patients with 1 or more missing teeth in the maxillary and/or mandibular jaw who presented in 3 university dental clinics and 1 private dental practice. A total of 120 patients were treated per protocol and successfully restored with implant-supported prostheses. Four implants failed in 3 patients and were withdrawn from the study. There were no other irresolvable adverse events. Cumulative implant success at 5 years was 97% (n = 184 implants in 88 patients), which exceeded the 85% standard for implant success after 5 years of clinical function.

**Key Words:** hydroxylapatite, HA, implant, crystallinity, wettability

## INTRODUCTION

Calcium phosphate materials have been clinically implanted for more than 80 years. In 1920, Albee and Morrison<sup>1</sup> first reported that implants of tricalcium phosphate (TCP) powder facilitated bone healing, while later researchers<sup>2,3</sup> found that hydroxylapatite (HA) powder provided no major clinical advantage.<sup>4</sup> Continuing research has primarily focused on HA and TCP, the polycrystalline ceramic forms of calcium phosphate, and on compounding calcium phosphate with silicon and sodium to form ceramic (bioactive) glasses. Of these materials, HA naturally comprises approximately 98% of enamel, 77% of dentin, 70% of cementum, and 60% to 70% of bone by weight in the human body.<sup>5</sup> Calcium phosphate ceramics were first used<sup>6</sup> as bulk implants for dental applications in 1971,<sup>4</sup> and during the early 1980s, the first commercially available HA-coated

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dental implants (Integral, Zimmer Dental Inc, Carlsbad, Calif) were introduced in the United States.<sup>7</sup>

Early reports<sup>8-13</sup> in the dental literature documented the ability of HA coating to significantly increase the percentage (range, 50% to >95%), development rate, and strength of bone-to-implant contact in comparison to machined and grit-blasted titanium surfaces. Numerous short-term<sup>14-17</sup> (<5 years) and long-term<sup>7,18-25</sup> (5 years and longer) studies have reported clinical success rates ranging from 93.4% to 100% and 93.2% to 99%, respectively, with no significant adverse events attributed to implant surface. Despite these and other widely documented findings on the clinical effectiveness of HA-coated implants, several case reports<sup>26-28</sup> during the early 1990s suggested that HA coatings were inherently unstable, susceptible to dissolution in the presence of bacterial infection, and possibly predisposed to rapid bone loss or saucerization around the cervical end of the implant. Such findings have not been substantiated by long-term clinical studies, nor do they reflect the current state of HA-coated implant technology.<sup>27,28</sup> Nonetheless, many manufacturers added a 1-mm metal collar around the tops of their HA-coated implant designs to resist the potential plaque formation and microbial colonization that some clinicians associated with HA coating.<sup>28</sup>

Research conducted over the past decade has documented that highly crystalline HA implant coatings exhibited greater resistance to dissolution and higher percentages of bone-to-implant contact in comparison to HA coatings with lower crystallinity.<sup>29-33</sup> Kay<sup>31</sup> stated that the percentage of the crystalline phase in HA coatings should be maximized to contain no less than 90% crystalline HA. Burgess et al<sup>32,33</sup> reported on a novel, pressurized, hydrothermal, post-plasma spray process, called MP-1 (Zimmer Dental Inc), that has been documented to convert the crystalline non-HA and amorphous components of plasma-sprayed HA coating back into crystalline HA. The resulting study coating was found to contain more than 90% crystalline HA.<sup>32,33</sup> Compared with the untreated control coating, the MP-1-treated surface exhibited equivalent adhesive strength to the implant surface but significantly decreased in vitro solubility over a wide range of pH levels.<sup>32,33</sup>

Almost immediately upon placement, dental implant surfaces absorb proteins from blood, tissue fluids, and cellular activities through a complex interaction between the implant's material composition and surface chemistry (eg, surface energy, surface charge, surface texture, etc).<sup>34,35</sup> The proteins help to mediate tissue-implant interactions by facilitating

cellular adhesion to the implant surface.<sup>34,35</sup> One fundamental aspect of this interaction is the wettability of the implant surface, which is the degree to which these fluids are able to spread across the surface and form a pertinacious biofilm or coating. Theoretically, the greater the wettability (or spreadability of pertinacious biofluids over the implant surface), the greater the percentage of cellular attachment can occur, resulting in increased tissue attachment to the implant.

Surface wettability is determined by measuring contact angle, which is the angle formed by a liquid droplet on a solid surface (ie, the line tangent to the droplet radius from the point of contact with the solid). Mekayarajananonth and Winkler<sup>36</sup> compared the contact angles of 8 different implant surface preparations and found that the standard, plasma-sprayed, HA-coated implant surface with 77% crystallinity<sup>32</sup> (Calcite, Zimmer Dental Inc) exhibited the lowest contact angles/highest wettability of all surfaces tested, while the heat-treated, HA-coated surface with 95% crystallinity<sup>32,33</sup> (HA MP-1) exhibited the highest contact angles/least wettability of all tested surfaces.

To initially determine if the lower wettability of HA MP-1 negatively affected implant survival, a comprehensive retrospective study of 3811 HA MP-1-coated dental implants was conducted to assess their outcomes.<sup>7</sup> The results showed a cumulative implant survival rate of 99.3% with up to 5 years of clinical follow-up.<sup>7</sup> The authors then began a 5-year prospective study to determine if HA MP-1-coated dental implants would achieve a cumulative success rate of at least 85% at 5 years postrestoration, which has been recommended as a standard of long-term success by Albrektsson et al.<sup>37</sup> This article reports on the results of that study.

## MATERIALS AND METHODS

### *Patient selection and evaluation*

Subjects for this prospective study were consecutive patients who presented with 1 or more missing teeth in the maxillary and/or mandibular jaw in 3 university dental clinics and 1 private dental practice. All patients were subjected to a preliminary evaluation that included careful review of their medical and dental histories, detailed clinical and radiographic examinations, evaluation of oral hygiene, and the ability to commit to a long-term treatment plan. Those patients who were deemed by the clinician as acceptable candidates and who met the inclusion criteria (Table 1)

TABLE 1

## Patient selection criteria

Inclusion	Completely or partially edentulous in either jaw Adequate available bone for implant placement At least 18 y of age Willingness to participate for study duration Willingness to provide informed consent
Exclusion	History of alcoholism or other substance abuse History of mental instability Smokers who exceed 1 pack/d Uncontrolled metabolic disease (eg, diabetes) Uncompensated systemic disease Immunocompromised status (eg, chronic steroid therapy) Untreated dental disease Evidence of severe parafunctional habits Prior irradiation of the treatment site Pregnancy

were admitted into the study after signed informed consent was obtained.

A diagnostic workup was performed for each patient to evaluate the volume and location of available bone, the esthetic and functional needs of the case, and the desires of the patient. A study cast was fabricated and mounted on a semiadjustable articulator using a facebow transfer and vertical registration to determine the jaw relationships, available occlusal dimension, proposed implant position, crown-root ratio, and potential complications. This allowed creation of a prosthetic wax up and fabrication of a surgical template to guide placement of the implants relative to the planned prosthesis.

### Implants

Threaded implants with highly crystalline HA MP-1 coating (Spline HA MP-1, Zimmer Dental Inc) were used in this study. Selection of implant length (8 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, or 18 mm) and diameter (3.75 mm or 5.0 mm) was left to the discretion of the clinician according to the prosthodontic needs and available bone of each patient.

### Success criteria

An implant was deemed successful if it was clinically immobile, load bearing, and functional at the time of evaluation. To be considered successful, a prosthesis was required to be in function and satisfactory to the patient in terms of comfort, use, and esthetics at the time of evaluation. Success rates were determined through evaluations of individual implant survival rates and prosthetic functionality. Overall success was evaluated through assessments of periodontal health, implant integration, and radiographic analyses to determine the presence or absence of peri-implant

TABLE 2

## Success criteria

Implants	No radiographic peri-implant radiolucency Clinically immobile when tested manually* Has not significantly damaged adjacent structures Load-bearing during function The presence of periodontally healthy tissues Meets the prosthodontic needs of the patient Marginal bone loss limited to 1.4 mm at 3 years and 2 mm at 5 years
Prostheses	Prosthesis is fully functioning Meets the patient's clinical needs Meets the patient's expectations for comfort, use, and esthetics

\*Testing was limited to single-tooth restorations and some removable prostheses.

radiolucency and any secondary marginal bone changes. Implant failure, site morbidity, other complications, and patient psychological, emotional, and esthetic satisfaction levels were also considered. Success criteria are summarized in Table 2.

### Surgical procedures

A conventional, 2-stage surgical approach was used, and implants were placed in accordance with the manufacturer's instructions for use. All implants were placed by one of the principal investigators or by associates under direct supervision of the principal investigators. After preparation of the osteotomies, minimum residual bone was required to be at least 1 mm on the buccal and lingual plates and 2 mm below the apical end of the osteotomy. If complications arose, such as the need for bone grafting, the patient was withdrawn from the study and treated according to need. All withdrawals were duly recorded and accounted in the final analysis. Stage 2 surgery was performed 3 months (mandibles) to 6 months (maxillas) after placement. Osseointegration was conventionally confirmed by radiographic appearance and manual manipulation of the implants.

### Prosthodontic procedures

Restorative procedures began minimum of 2 weeks after stage 2 surgery to allow for soft tissue maturation. All prosthodontic plans were developed by or with input from the principal investigator.

### Postrestoration monitoring

Baseline periapical radiographs were taken at delivery of the definitive prosthesis and then at annual follow-up visits through year 5. High-quality, long-cone periapical radiographs of each implant were taken using high-speed film (Kodak Ektaspeed Plus Dental

TABLE 3

## Periodontal health and implant stability indices recorded at follow-up

Index	Grade	Clinical Impression
Implant mobility index <sup>38</sup>	0	No visual movement upon palpation
	1	Visually mobile but less than 0.5 mm total buccolingual movement
	2	Greater than 0.5 mm but less than 1.0 mm total buccolingual movement
	3	Greater than 1.0 mm total buccolingual movement
Gingival bleeding index <sup>39</sup>	0	Tissue color normal; no bleeding on probing
	1	Tissue color normal to slightly erythematous, mild inflammation, slight edema; no bleeding on probing
	2	Tissue color red, moderate inflammation, edema and glazing; bleeding on probing
Plaque and calculus index <sup>39</sup>	3	Tissue color markedly red and edematous, severe inflammation; ulceration; tissue bleeds on finger pressure or spontaneously
	0	No plaque; no calculus
	1	Plaque can be scraped off but is not visible to the clinician or supragingival calculus extending no more than 1 mm below the free gingival margin
	2	Visible plaque within the gingival crevice or on the tooth and gingival margin or subgingival calculus extending more than 1 mm into the crevice or moderate amounts of supragingival and subgingival calculus
	3	Heavy accumulation of plaque within the crevice or on the tooth and gingival margin or heavy accumulation of supragingival and subgingival calculus

Film or Kodak Ultra-Speed Intraoral Dental Film DF-58, Eastman Kodak Co, Rochester, NY) in double-film packets. Clinicians were instructed to make every effort to ensure that the radiograph source was perpendicular to the long axis of the implant. Use of an intraoral positioner was allowed. No other standardized radiographic procedures were used.

Baseline clinical examinations occurred 2 to 3 weeks after delivery of the definitive prosthesis, at 6 months postrestoration, and then at annual follow-up visits through year 5. Clinical evaluations consisted of gingival bleeding, plaque and calculus indices, and evaluation of osseointegration radiographically (ie, lack of peri-implant radiolucency) and, whenever possible, by direct manual manipulation of the implant. Implant mobility was evaluated according to Miller<sup>38</sup> (Table 3). Single, unsplinted implants were required to be clinically immobile (Mobility Index grade 0; Table 3). If implant mobility was noted, the implant was recorded as a failure.

The Gingival Bleeding Index was used to determine the presence or absence of inflammation in the free and attached gingiva. A standard periodontal probe was applied to the internal aspect of the gingival margin with no attempt to probe the sulcus depth, and the Gingival Bleeding Index was evaluated according to Silness and Loe<sup>39</sup> (Table 3).

Plaque and calculus indices were used to measure the supragingival and subgingival plaque or calculus accumulation around the cervical end of the implant abutment as indicators of oral hygiene compliance by the patient and overall gingival health status according to Silness and Loe<sup>39</sup> (Table 3).

All adverse events, including peri-implant marginal

bone loss, were recorded and included in the data analyses.

### Patient satisfaction surveys

Before treatment and during annual postrestoration monitoring appointments, patients completed a self-evaluation of their functional, psychological, emotional, and esthetic satisfaction with their dental condition. Patients were also able to comment on their implant treatment procedures.

### Statistical methods

Data analyses on the individual periodontal indices, marginal bone changes, and, whenever possible, implant mobility were performed to determine their effects on implant success. Complication rates were reported and summarized over time. Time-specific implant failure rates were statistically analyzed and reported using survival analysis techniques. Implant and prosthetic success rates were analyzed by implant location in the anterior and posterior of each arch and by type of restoration. Patient satisfaction with restored implants was analyzed and compared with preoperative satisfaction levels. Ninety-five percent (95%) confidence intervals were constructed for all point estimates. Nominal statistical significance was assessed at  $\alpha = .05$ .

## RESULTS

A total of 145 patients (55 men, 90 women) ranging in age from 24 to 89 years (mean, 50–59 years) were enrolled in the study (intent-to-treat group). This

TABLE 4

## Distribution of implants placed

Intent-to-Treat Group		
Diameter, mm	Length, mm	No. Placed
3.75	8	5
	10	62
	13	106
5.0	15	29
	8	3
	10	34
	13	19
	15	1
	Total	259

population included 13 patients who smoked 1 pack of cigarettes or fewer per day; the remaining 132 patients were nonsmokers. Patients were treated with a total of 259 implants (Table 4). Within this group, 27 patients were withdrawn for various reasons prior to restoration (Table 5); the remaining 120 patients with 245 implants were successfully restored with implant-supported prostheses (treated-per-protocol group; Table 6).

The cumulative implant success at year 5 was 97% ( $n = 184$  implants in 88 patients). Four implants placed in 3 female nonsmokers failed after loading (Table 6): 2 implants supporting a fixed partial denture in the mandibular right first and second molar regions of a 50-year-old patient failed during year 1, a single-tooth restoration supported by 1 implant in the maxillary left first molar location of a 43-year-old patient failed during year 4, and 1 implant supporting a single-tooth restoration in the mandibular right second molar area of a 53-year-old patient failed in year 5. All failed implants were 3.7 mm in diameter: 3 were 10 mm long

TABLE 5

## Summary of patient withdrawals

Group No.		No. of Patients
1	Patient moved or refused follow-up*	27
2	Other (unspecified)*	16
3	Implant failed after loading	4
4	Insufficient available bone	3
5	Bone graft needed	2
6	Patient not a good candidate (unspecified)	2
7	Implant failed to osseointegrate	1
8	Patient began smoking more than 1 pack/d after study began	1
9	Patient developed cancer after study began (not study related)	1
	Total	57

\*Withdrawn before implant restoration: 9 patients in group 1 and 14 patients in group 2.

TABLE 6

## Distribution of patients and implant survival over time

Category	Time Interval				
	0*-1 Year	1-2 Years	2-3 Years	3-4 Years	4-5 Years
No. of patients					
Start of interval	120	114	104	99	92
Withdrawn for LTF†	6	10	5	7	4
End of interval	114	104	99	92	88
No. of implants					
Start of interval	245	232	208	205	198
Withdrawn for failure	2	0	0	1	1
Withdrawn for LTF	11	24	3	6	13
End of interval	232	208	205	198	184
% Implant survival					
Interval	99	100	100	99	99
Cumulative	99	99	99	98	97

\*0 = baseline delivery of the definitive prosthesis.

†LTF = lost to follow-up.

and 1 (single tooth restoration in the mandibular right second molar region) was 13 mm long. These patients were recorded as withdrawals because of implant mobility (Tables 5 and 8), and patients received corrective treatment outside of the study.

Results from the periodontal indices are summarized in Table 7. In year 5 of clinical follow-up, 99.45% of the patients had no bleeding on probing (grades 0 and 1) with little or no peri-implant soft tissue irritation, and 98.0% had little or no plaque or calculus (grades 0 and 1).

A total of 64 adverse events were reported (Table 8). Most of these events were unrelated health or medical events ( $n = 18$ ). Porcelain crown fractures ( $n = 10$ ) were the most common implant-related complication but were not listed as prosthesis failures because the implant-abutment assembly was not damaged and remained functional as soon as the fractured crown was replaced. The second most common adverse events were transient peri-implant infections, abscesses, or swellings ( $n = 7$ ), which were clinically resolved. The 4 implant failures previously listed as withdrawals (Table 5) were the most serious adverse events, followed by minor peri-implant marginal bone loss ( $n = 4$ ) that did not exceed 1.4 mm at year 5. All marginal bone loss occurred during the first 3 months of loading and then stabilized through year 5. There were 3 other infections unrelated to the implant itself and 3 reports of screw or abutment loosening. Space limitations required 1 implant to be splinted to an adjacent natural tooth, which was a protocol deviation that was listed as an adverse event. One dental implant appeared to exhibit

TABLE 7

Mean\* periodontal indices: percentage of responses

Time	Grade 0	Grade 1	Grade 2	Grade 3
Mean gingival bleeding index scores, %				
Baseline	91.70	6.45	1.00	0.85
Year 1	91.08	8.92	0	0
Year 2	84.30	14.20	1.35	0.15
Year 3	91.20	7.20	1.45	0.15
Year 4	92.45	6.025	1.525	0
Year 5	91.45	8.00	0.55	0
Mean plaque and calculus index scores, %				
Baseline	90.80	8.175	1.025	0
Year 1	81.10	15.375	3.525	0
Year 2	78.55	15.375	2.725	3.35
Year 3	84.5	12.025	3.325	0.15
Year 4	83.125	9.575	7	0.3
Year 5	85.85	12.15	1.85	0.15

\*Mesial, distal, buccal, and lingual measurements combined.

slight instability when clinically manipulated; it was closely monitored, and the condition clinically resolved without intervention. Various other minor adverse events are listed (Table 8).

Patient satisfaction survey results are summarized in Table 9. An overwhelming majority of patients rated implant treatment as good to excellent and did not significantly change these assessments between year 1 and year 5 for the outcome variables of function (year 1 = 98%, year 5 = 97.7%), esthetics (year 1 = 98%, year 5 = 98.8%), and ability to clean the prosthesis (year 1 = 94.2%, year 5 = 94.1%). In the same manner, the small number of patients who rated each clinical

TABLE 8

Summary of adverse events by jaw location

Adverse Event	Incidence (No.)
Various health/medical events unrelated to the study device	18
Porcelain crown fractures	10
Peri-implant infection, abscess, or swelling	7
Implant mobility (failure)	4
Peri-implant marginal bone loss	4
Infection (other)	3
Screw or abutment loosening	3
Crown loosening	2
Surgical drill complications	2
Maxillary sinus perforation	2
Gingivitis	2
Osteotomy too large	1
Fenestration	1
Implant instability (nonfailure)	1
Splinting to natural tooth required (protocol deviation)	1
Bony wall defect	1
Exposed implant thread	1
Paresthesia	1
Total	64

\*Listed as withdrawals in Table 5.

TABLE 9

Overall patient satisfaction with dental implants (percentage of responses)

Clinical Outcome	Year 1				Year 5			
	Poor	Fair	Good	Excellent	Poor	Fair	Good	Excellent
Function	1.0	1.0	15.2	82.8	0	2.3	10.5	87.2
Esthetics	1.0	1.0	18.2	79.8	0	1.2	18.8	80.0
Ability to clean the prosthesis	0	5.8	34.6	59.6	1.2	4.7	25.9	68.2

outcome variable as fair to poor did not significantly change between year 1 and year 5 for the variables of function (year 1 = 2.0%, year 5 = 2.3%), esthetics (year 1 = 2.0%, year 5 = 1.2%), and ability to clean the prosthesis (year 1 = 5.8%, year 5 = 5.9%).

DISCUSSION

Recent attempts<sup>40,41</sup> to ameliorate the reported roughness-induced hydrophobicity of sandblasted and acid-etched implant surfaces (SLA surface, Straumann Dental, Waltham, Mass) by increasing wettability (SLActive surface, Straumann Dental) have resulted in increased bone-to-implant contact in dogs compared with the original SLA surface with lower wettability.<sup>42</sup> In contrast, the reported diminished wettability of the HA MP-1 surface did not appear to negatively affect its 97% success rate after 5 years in function compared with reported<sup>18-21</sup> historical outcomes for its predecessor HA coating with lower crystallinity.

All 4 implant failures in the present study were standard-diameter (3.75-mm) implants used to replace first and/or second molars. Three of the 4 failed implants were 10-mm long. To improve the biomechanical performance of implant-supported restorations in the molar region, the use of wide-diameter implants (>3.75 mm) or 2 standard-diameter (3.75 mm) implants to support a single replacement molar has been advocated in the dental literature.<sup>43-46</sup> In a meta-analysis of 13 studies documenting the failure rates by implant length, Goodacre et al<sup>47</sup> reported that 2754 implants 10-mm long exhibited a cumulative failure rate of 10% in comparison to 3% for 3015 implants that were longer than 10 mm. Thus, the 4 failed molar restorations were already subject to questionable long-term predictability at the time of restoration.

There were no significant or irresolvable adverse events affecting the HA MP-1 and soft tissue interface in this study. This result affirms the findings of Meffert et al,<sup>48</sup> who evaluated hard and soft tissue responses

to HA-coated implants, machined-surface implants, and grit-blasted implants in 10 mongrel dogs. Of these, 61 implants were placed level with the crest of the ridge, and the remaining 40 implants were placed with 2 mm of the implant surfaces extending above the crest of the ridge.<sup>51</sup> Five of the 101 implants placed failed shortly after placement (1 HA, 2 machined, 2 grit blasted); the remaining 96 implants achieved osseointegration.<sup>51</sup> After healing and restoration, pocket depth measurements ranged from 2 to 8 mm for all implants, with no differences between surfaces.<sup>51</sup> Histological analysis showed fibrous tissue encapsulation of both machined-surface implants and grit-blasted implants, while HA-coated implants achieved bone-to-implant contact as early as 1 month after placement.<sup>51</sup> Bone contacted 70% of the HA-coated implant surface by 4 months and 90% of the surface by 10 months.<sup>51</sup> The HA-coated implants demonstrated the most normal soft tissue anatomy in terms of lack of apical migration of the junctional epithelium and lack of inflammation.<sup>51</sup>

### CONCLUSIONS

The 97% success rate of HA MP-1 implants exceeded the recommended standard of 85% for implant success after 5 years of clinical function.

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