# implant clinical review









# Science-based products

BioHorizons is known for using science and innovation to create unique implants with proven surgical and esthetic results. Laser-Lok microchannels exemplify our dedication to evidence-based research and development.

The effectiveness of Laser-Lok has been proven with over 15 years of *in vitro*, animal, and human studies at leading universities. This patented precision laser surface treatment is unique within the industry as the only surface treatment shown to attract a physical connective tissue attachment to a predetermined zone on the implant while inhibiting epithelial downgrowth and preserving the coronal level of bone, long term.



# Game-changing innovation

Our highly advanced implant technologies, hard and soft tissue regeneration products, and computer guided surgery software have placed BioHorizons at the forefront of implant dentistry.

From surgical planning and site development to final restoration, BioHorizons is uniquely positioned to streamline the implant to restorative process, enabling clinicians to create a more efficient and effective continuum of care.



# Unparalleled service

BioHorizons understands the importance of providing excellent service with our global network of professional representatives and our highly trained customer care support team. BioHorizons is well-equipped to meet the needs of patients and clinicians across the entire continuum of care.

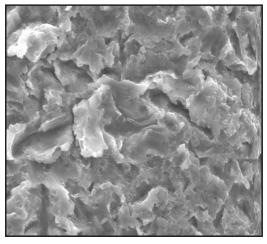
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# Research overview

### Innovative solutions

Since the beginning, BioHorizons has been committed to providing the most comprehensive line of evidence-based, scientifically-proven dental implants and tissue regeneration solutions. Our philosophy is that successful products are the result of rigorous Science and relentless Innovation. This approach to product development took root back in 1994 when the original Maestro implant design was first conceived in the biomedical engineering department at the University of Alabama in Birmingham (UAB). Throughout the years, BioHorizons has consistently applied biomedical engineering to numerous product innovations and today is the proud owner of 24 unique patent awards.

This implant clinical review is a compilation of many of the studies BioHorizons has supported over the years to guide implant and prosthetic development. The scientific method was followed using a wide variety of models including laboratory, animal and human. Within these models, implant performance was evaluated in many different conditions with special emphasis on load analysis including non-functional and functional immediate load as well as early and delayed load.



High magnification of RBT implant (1500x) showing highly irregular surface. (Courtesy of Jack Ricci, NYU)

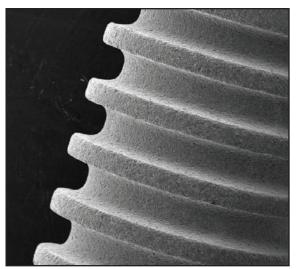
# In vitro validation

Laboratory tests were conducted to evaluate the amount of load implants can sustain both in static and fatigue. Whether evaluating the implant connection of the Maestro<sup>3</sup> or the implant design of the Onepiece 3.0, <sup>4</sup> BioHorizons implants have been shown to rank at the top when compared to competitive designs.



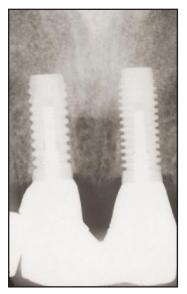
## In vivo research

To evaluate various features of the implants including thread design and implant surface, a series of animal studies were implemented with a focus on bone response. In these studies, it was shown that the BioHorizons thread design and implant surface exhibited higher bone-to-implant contact<sup>5-6</sup> and greater reverse torque measurements<sup>6</sup> than the designs typically used by other companies.



Scanning Electron Microscope (SEM) of BioHorizons square thread design.

# Research overview



Two maxillary centrals are splinted together, supported by Maestro D2 and D3 implants. The 1-year total bone loss is 0.4 mm on the D2 implant (left) and 0.5 mm on the D3 implant. This corresponds to the 0.5 mm smooth collar below the implant platform. (Courtesy of C. M. Misch)



# **Clinical evidence**

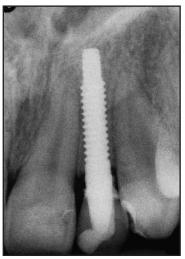
To assess how BioHorizons implants can benefit patients, a number of human studies were sponsored. Several clinical scenarios were used to determine how effective BioHorizons implants are when: immediately placed, immediately loaded, and in the posterior maxilla, we will used in sinus augmentations, we will used in poor quality bone and used in patients with compromised immune systems. In all these situations, BioHorizons implants have been shown to have an extremely high survival rate (99.2% average), excellent bone-to-implant contact and minimal bone loss.

# Improving patient's lives

Innovation in our industry is only significant if it gives the clinicians effective and reproducible results that materially improve the welfare of the patients. The success BioHorizons has shown in many research studies and in the marketplace with 8 consecutive years of 30% year-over-year growth is proof that BioHorizons continues to create innovative, relevant solutions for the dental community.



Restored One-piece 3.0 (1 week post-op)

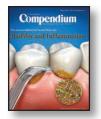


Radiographic appearance 6 mo. post-op





Definitive restoration at 12 months



# Functional surface area: Thread-form parameter optimization for implant body design

Strong JT, Misch CE, Bidez MW, Nalluri P. Compend Contin Educ Dent. 1998;19(spec issue):4-9.

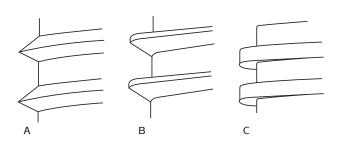
### Standard V-Thread

# $F_{shear1} = F_{axial} \quad Sin 30^{\circ}$ $F_{shear2} = F_{axial} \quad Sin 3^{\circ}$ $F_{shear2} = F_{axial} \quad (0.05)$ $F_{shear2} = F_{axial} \quad (0.05)$

Figure 1. With  $F_{axial}$  constant (i.e. applied load), the shear force on the V-thread face ( $F_{shear1}$ ), is approximately **10 times greater** than the shear force on the BioHorizons thread face ( $F_{shear2}$ ).

Table 1: Functional surface areas for the different types of commercially available thread forms (n=456)						
Thread-form geometry Functional surface area (mm²)*						
V-thread	136					
Reverse-buttress thread	117					
Square thread, D1	159					
Square thread, D2	187					
Square thread, D3	210					
Square thread, D4	245					

<sup>\*</sup> To make a valid comparison between different thread forms, a standard major diameter of 4.0mm and an implant length of 10mm were used for calculation purposes.

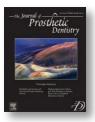


**BioHorizons Thread** 

Figure 2. Schematic of (A) a v-thread, (B) a reversebuttress thread, and (C) a square thread.

### **ABSTRACT**

In a root-form dental implant, functional thread surface area is defined as the area that is able to dissipate compressive and tensile (nonshear) loads to the bone and provide initial stability upon implant placement. Functional surface area establishes the portion of the implant surface that provides for initial osteoblast contact to the implant surface. Together, functional surface area and the host bone density determine the biomechanical load distribution of the implant. This investigation, based on mathematical models and validated by computer models, determined the functional surface area for three thread forms found in dental implant designs: the v-thread, the reverse buttress, and the square thread. The results of this investigation demonstrate that substantially greater functional surface area can be obtained in a square thread from, and that the surface area increases by varying geometric thread-form parameters, such as pitch and thread depth.



# Influence of hex geometry and prosthetic table width on static and fatigue strength of dental implants

Boggan RS, Strong JT, Misch CE, Bidez MW. J Prosthet Dent. 1999 Oct;82(4):436-440.

Table 1: Static and fatigue strengths of dental implant systems						
Implant type Material Static failure Fatigue failure load load						
1.0 mm external hex, 4mm platform diameter	Titanium alloy	966 N	350 N			
1.0 mm external hex, 5mm platform diameter	Titanium alloy	1955 N	625 N			
0.7 mm external hex*	Grade I CP titanium	756 N	242 N			
0.6 mm internal octagon*	Titanium alloy	587 N	400 N			
1.7 mm internal hexagon*	Titanium alloy	814 N	367 N			

<sup>\*</sup> Platform diameter was not stated, data from Balfour and O'Brien.

### **ABSTRACT**

Component fracture and screw loosening are prevalent concerns of contemporary dental implants. This laboratory investigation examined the influence of design factors such as the platform diameter and the hex height on the mechanical strength and quality of fit of the implant-abutment interface. Static and compressive bending tests were conducted on 4 and 5 mm diameter bone density-based implants. SEM evaluation of the implant-abutment interface was also conducted to assess the quality of fit between mating components. The 5 mm diameter implant was stronger in both static and fatigue conditions than the 4 mm diameter implants. A comparison of the results in published literature indicated that both implants were equal to or superior to alternative prosthetic connections in an identical testing configuration. Test results demonstrated the validity of wide diameter implants to reduce the likelihood of component fracture in contemporary dental implant systems.



# The impact of loads on standard diameter, small diameter and mini implants: A comparative laboratory study

Allum SR, Tomlinson RA, Joshi R. Clin. Oral Impl. Res. 2008 May; 19(6):553-559.

Tab	Table 1: Maximum loads sustained and the maximum bending moments recorded for each implant design					
Rank	Implant type	lmplant diameter	Maximum loads means (±SDs)	Maximum bending moments means (±SDs)		
1	Straumann Standard RN SLA	4.1 mm	989 N (107N)	11,558 N mm (1251 N mm)		
2	BioHorizons Maximus	3 mm	648 N (45N)	7050 N mm (560 N mm)		
3	Straumann Standard NN SLA	3.3 mm	619 N (50N)	6992 N mm (1317 N mm)		
4	NobelDirect	3 mm	572 N (53 N)	5598 N mm (623 N mm)		
5	Straumann Standard RN SLA	3.3 mm	515 N (39 N)	5311 N mm (455 N mm)		
6	Osteocare Mini	2.8 mm	237 N (37 N)	2319 N mm (411 N mm)		
7	Hi Tec	2.4 mm	261 N (31 N)	2251 N mm (297 N mm)		
8	Osteocare Mini	2.35 mm	147 (25 N)	1350 N mm (224 N mm)		

# **ABSTRACT**

Objectives: While caution in the use of small-diameter ( $\leq$ 3.5 mm) implants has been advocated in view of an increased risk of fatigue fracture under clinical loading conditions, a variety of implant designs with diameters <3 mm are currently offered in the market for reconstructions including fixed restorations. There is an absence of reported laboratory studies and randomized-controlled clinical trials to demonstrate clinical efficacy for implant designs with small diameters. This laboratory study aimed to provide comparative data on the mechanical performance of a number of narrow commercially marketed implants.

**Materials and Methods:** Implants of varying designs were investigated under a standardized test set-up similar to that recommended for standardized ISO laboratory testing. Implant assemblies were mounted in acrylic blocks supporting laboratory cast crowns and subjected to 30° off-axis loading on an LRX Tensometer. Continuous output data were collected using Nexygen software.

Results: Load/displacement curves demonstrated good grouping of samples for each design with elastic deformation up to a point of failure approximating the maximum load value for each sample. The maximum loads for Straumann (control) implants were 989 N ( $\pm$ 107 N) for the 4.1 mm RN design, and 619 N ( $\pm$ 50 N) for the 3.3 mm RN implant (an implant known to have a risk of fracture in clinical use). Values for mini implants were recorded as 261 N ( $\pm$ 31 N) for the HiTec 2.4 mm implant, 237 N ( $\pm$ 37 N) for the Osteocare 2.8 mm mini and 147 N ( $\pm$ 25 N) for the Osteocare mini design. Other implant designs were also tested.

Conclusions: The diameters of the commercially available implants tested demonstrated a major impact on their ability to withstand load, with those below 3 mm diameter yielding results significantly below a value representing a risk of fracture in clinical practice. The results therefore advocate caution when considering the applicability of implants  $\leq$ 3 mm diameter. Standardized fatigue testing is recommended for all commercially available implants.

### Notable quotes

- Fractures have been reported following the clinical use of well-documented implant designs. (Adell et al. 1981; Morgan et al. 1993; Rangert et al. 1995; Eckert et al. 2000)
- One recent systematic review reported that implant fractures constitute between 5% and 20% of all implants lost during function. (Ber glundh et al. 2002)
- Various workers have previously highlighted the risk of fatigue fracture of smaller diameter implants, especially in areas of high loading. (Rangert et al. 1995; Polizzi et al. 1999; Ronouard & Rangert 1999; Eckert et al. 2000; Zinsli et al. 2004)



# Histomorphometric analysis of the bone-implant contact obtained with 4 different implant surface treatments placed side by side in the dog mandible

Novaes AB Jr, Souza SL, de Oliveria PT, Souza AM. Int J Oral and Maxillofac Implants. 2002 May-Jun;17(3):377-383.

Table 1: Pe	Table 1: Percentages of bone-to-implant contact for all implants					
Implant no.	Machined	НА	TPS	SBM		
1	32.2	71.9	39.8	70.6		
2	53.3	36.4	26.4	29.4		
3	39.7	46.4	33.8	47.6		
4	34.7	73.9	34.5	87.6		
5	54.0	44.9	-	75.4		
6	29.0	49.0	44.8	84.3		
7	48.6	33.6	54.8	-		
8	41.7	86.1	39.5	78.9		
9	44.5	69.1	84.2	64.8		
10	48.5	67.7	82.6	77.7		
Mean	41.7	57.9	48.9	68.5		
SD	7.8	18.0	21.1	18.8		

Overall mean and SD: 54.0 ± 19.2%. HA = hydroxylapitite coating TPS = titanium plasma spray SBM = sandblasting w/ soluble particles



Figure 1. Bone-implant contact in an SBM sample (Stevenel's blue and alizarin red 5; original magnification X100).

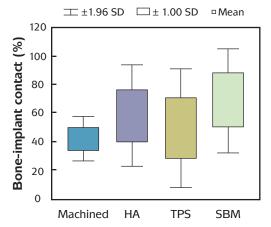


Figure 2. Mean percentages of bone-to-implant contact and standard deviations of the 4 implant surfaces examined.

### **ABSTRACT**

**Purpose:** The different implant systems available today present several types of surface treatments, with the aim of optimizing bone-implant contact. This study compared 4 different types of implant surfaces.

Materials and Methods: The first, second, third, and fourth mandibular premolars were extracted from five young, adult mongrel male dogs. Ninety days after removal, four 3.75-mm-diameter, 10-mm-long screw-type implants (Paragon) were placed with different surface treatments in mandibular hemiarches. The dogs received two implants of each of the following surface treatments: smooth (machined), titanium plasma spray (TPS), hydroxylapitite coating (HA) and sandblasting with soluble particles (SBM). The implants were maintained unloaded for ninety days. After this period, the animals were sacrificed, and the hemimandibles were extracted and histologically processed to obtain non-decalcified sections. Two longitudinal ground sections were made for each implant and analyzed under light microscopy, coupled to a computerized system for histomorphometry.

**Results:** The following means were obtained for bone-implant contact percentage: machined = 41.7%, TPS = 48.9%, HA = 57.9%, and SBM = 68.5%.

**Discussion:** The means for all treatments that added roughness to the implant surface were numerically superior to the mean found for the machined surface. However, this difference was statistically significant only between groups SBM and machined (Tukey test, P < .05).

Conclusions: The SBM-treated surface provided a greater bone-implant contact that a machined surface after 90 days without loading in this model.

Editor's Note: SBM (Sandblasted with Soluble Particles Medium) is equivalent to RBT (Resorbable Blast Texturing) surface treatment. Both surface treatments are performed by Bio-Coat in Southfield. Michiaan.



# Effects of implant thread geometry on percentage of osseointegration and resistance to reverse torque in the tibia of rabbits

Steigenga J, Al-Shammari K, Misch C, Nociti Jr. FH, Wang H-L. J Periodontol. 2004;75(9):1233-1241.

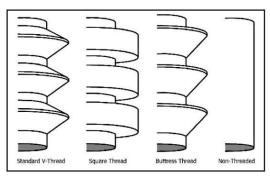


Figure 1. Standard thread shapes in dental implant design. The V, square, and reverse buttress threads were evaluated in this study.

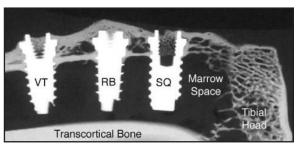


Figure 2. Radiographic bone density. VT: V-thread; RB: reverse buttress thread; and SQ: square thread. No significant differences were found in the radiographic density results.

	V-Thread	Reverse Buttress Thread	Square Thread
Reverse torque value (N = 36 implants)	15.58 ± 6.07*	15.46 ± 6.22 <sup>†</sup>	23.17 ± 9.68* <sup>†</sup>
Percentage of BIC (N = 69 implants <sup>‡</sup> )	65.46 ± 9.64*	63.05 ± 12.45 <sup>†</sup>	74.37 ± 8.63*†

Table 1. Reverse torque removal values (N-cm) and percentage of bone-to-implant contact (BIC) (N = 12 rabbits).

## **ABSTRACT**

**Background:** Dental implant thread geometry has been proposed as a potential factor affecting implant stability and the percentage of osseointegration. Therefore, the aim of this prospective, randomized, parallel arm study was to evaluate the effects of dental implant thread design on the quality and percent of osseointegration and resistance to reverse torque in the tibia of rabbits.

**Methods:** Seventy-two custom-made, screw-shaped, commercially pure titanium implants (3.25 mm diameter × 7 mm length) were placed in the tibiae of 12 white New Zealand rabbits. Each tibia received three implants of varying thread shapes: one with a V-shaped, one with a buttress, and one with a square thread design. The rabbits were sacrificed following an uneventful healing period of 12 weeks. Implants in the right tibiae underwent histologic and histomorphometric assessments of the bone-to-implant contact (BIC) and the radiographic density of surrounding bone, while implants in the left tibiae were used for reverse-torque testing. Differences between the three thread designs were examined using analysis of variance (ANOVA).

**Results:** Data showed that the square thread design implants had significantly more BIC and greater reverse-torque measurements compared to the V-shaped and reverse buttress thread designs, while no differences were found in radiographic bone density assessments.

Conclusion: These results indicate that the square thread design may be more effective for use in endosseous dental implant systems.

<sup>\*†</sup> Statistical significance (P < 0.05) when comparing square thread to V-thread and reverse buttress thread design

<sup>‡</sup> Three of 72 specimens could not be read due to a processing error.



# Preliminary evaluation of a new dental implant design in canine models

Bumgardner JD, Boring JG, Cooper RC, Cheng G, Givaruangsawat S Gilbert JA, Misch CM, Steflik DE. Implant Dent. 2000;9(3):252-260.

### **ABSTRACT**

Problems with crestal bone resorption and bone adaptation to dental implants in compromised and weak bone present clinical challenges due to insufficient bone volume. Mathematical models have shown that a new, square-thread, dental implant design increases functional surface area and reduces shear loading at the implant interface. The aim of this investigation was to evaluate the ability of bone to grow between the threads of the new implant and its general biocompatibility in a canine model. Test implants were placed in the mandibles of four beagle dogs after posterior partial edentulism. Three months after implantation, the animals received independent fixed partial dentures, were followed for an additional 6 months, and then euthanized for histological analyses. Analyses revealed that bone grew between the threads and closely apposed the new implant design. Histological observations also revealed that the inferior aspect of the test implant threads were apposed by more bone than the coronal aspect, suggesting a biological advantage for the compressive load transfer mechanism of the new implant design. The results of this study revealed that the new implant design became osseointegrated with bone growing between the threads of the device.



# The effects of loading time on osseointegration and new bone formation around dental implants: A histologic and histomorphometric study in dogs

Ghanavati F, Shayegh SS, Rahimi H, Sharifi D, Ghanavati F, Khalesseh N, Eslami B. J Periodontol. 2006;77(10)1701-1707.

### **ABSTRACT**

**Background:** Immediate loading of dental implants has been introduced as a method of reducing implant treatment time without compromising its prognosis. In this research, the effects of loading time on the amount of bone-to-implant contact and bone formation around dental implants were evaluated histologically.

**Methods:** Three months prior to implantation, the lower premolar teeth of 15 dogs were extracted. Three or four dental implants were placed in the healed extraction sites for each dog (N = 48). Dividing the dogs into three groups, the implants were either loaded 48 hours or 1 week later with metallic or prefabricated acrylic crowns or were left unloaded until the time of sacrifice. Three months after implant insertion, the animals were sacrificed and samples were investigated to define the amount of bone-to-implant contact, lamellar and woven bone percentage, and local inflammation of the newly formed bone.

**Results:** No significant difference in the observed criteria was reported among the three groups (P > 0.05); however, the unloaded group had the highest degree of bone-to-implant contact and the group loaded 48 hours after the primary implant insertion had the least. The prosthesis type had no significant effect on the implant success rate (P > 0.05). The lamellar and woven bone percentage of newly formed bone also did not differ in the three groups (P > 0.05). One implant from each group failed in this study.

**Conclusion:** Loading time does not seem to significantly affect the degree of osseointegration and bone-to-implant contact and the composition of newly formed bone around dental implants.



# A bioengineered implant for a predetermined bone cellular response to loading forces: A literature review and case report

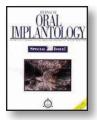
Misch CE, Bidez M, Sharaway M. J Periodontol. 2001 Sep;72(9):1276-1286.

### **ABSTRACT**

The presence of fibrous tissue has long been known to decrease the long-term survival of a root-form implant. Excessive loads on an osseointegrated implant may result in mobility of the supporting device, and excessive loads may also fracture an implant component or body. Although several conditions may cause crestal bone loss, one of these may be prosthetic overload. Excessive loads on the bone cause strain conditions to increase. These microstrains on the bone may affect the bone-remodeling rate in a direct relationship.

When strain conditions to the interfacial bone are in the mild overload zone, an increased bone remodeling response occurs, which results in a reactive woven bone formation that is less mineralized and weaker. Greater stresses may cause the interfacial strain to reach the pathologic overload zone and may cause microfracture of the bone, fibrous tissue formation, and/or resorption. Recent reports suggest that the bone remodeling rate next to an implant may be used to evaluate biomechanical conditions and their influences on the implant-to-bone interface. These include a number of factors, such as loading conditions, implant body surface conditions, and implant design. For a given load condition, the implant design is one of the primary factors that determine the resulting strain at the interface.

A predetermined goal was established to bioengineer a dental implant to load the bone at the interface in a predetermined stress/strain relationship, in order to maintain lamellar bone at the interface. A case report is presented of 2 bioengineered implants loaded for 1 year, which demonstrated that the bone was primarily lamellar in structure, the bone turnover rate was less than 5 microns/day, and was the same as the bone away from the interface. These findings corroborate those observed in a prior animal study reported with the same implant design. Although the number of implants evaluated in those two reports is few, they support a predetermined, histological outcome.



# A bone-quality based implant system: First year prosthetic loading

Misch CE, Dietsh-Misch F, Hoar J, Beck G, Hazen R, Misch CM. J Oral Implantol. 1999;25(3):185-197.



Figure 1. This mandibular first molar has bone above the Maestro D2 implant body platform after 1 year of loading. The total bone loss is recorded as 0 mm, rather than a positive number, which would decrease the mean vertical bone loss data. (Courtesy of F. Dietsh-Misch)

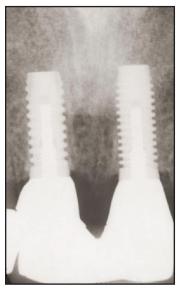


Figure 2. Two maxillary centrals are splinted together, supported by Maestro D2 and D3 implants. The 1-year total bone loss is  $0.4 \, \text{mm}$  on the D2 implant (left) and  $0.5 \, \text{mm}$  on the D3 implant. This corresponds to the  $0.5 \, \text{mm}$  smooth collar below the implant platform. (Courtesy of C. M. Misch)

# **ABSTRACT**

This report presents the data from a prospective study of a bone quality based implant system. The surgical survival of 975 implants was 99.4%, with 100% survival in D4 bone. Three critical phases of bone loss were identified: bone remodeling from stage I to stage II surgery; stage II uncovery to prosthesis delivery (transition period); and prosthesis delivery up to the first year loading (early loading bone loss). The stage I uncovery crestal bone remodeling resulted in a mean vertical bone loss of .021 mm to 0.36 mm (SD = 0.90 mm), dependent on whether the implant became exposed to the oral cavity during osseous healing. No statistically significant difference was found among the four implant designs, implant diameter, bone density or location. The stage II uncovery to prosthesis delivery mean vertical bone loss ranged from 0.12 mm to 0.20 mm. One hundred three consecutive patients were restored, with 360 implants and 105 prosthesis in function for a period of 12 to 26 months. No early loading implant failure occurred. The mean early loading bone loss was 0.29 mm (SD = 0.99 mm). Past clinical reports indicate most failures or crestal bone loss occur by the first year of loading. This study suggests the bone quality based dental implant design minimizes overall failure and crestal bone loss, regardless of bone density.



# Posterior implant single-tooth replacement and status of adjacent teeth during a 10-year period: A retrospective report

Misch CE, Misch-Dietsh F, Silc J, Barboza E, Cianciola EJ, Kazor C. J Periodontol. 2008 Dec;79(12):2378-2382.

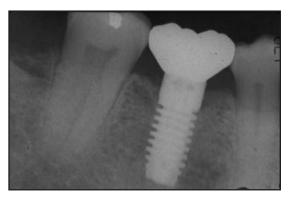


Figure 1. The teeth adjacent to an implant were virgin (second premolar) or minimally restored (second molar) in 76% of patients.

Period (years)	Implants at start of interval	Implants lost to follow-up during interval	Implant failures during interval	Interval survival (%)	Cumulative survival (%)
0 to 1	1,377	0	12	99.1	99.1
1 to 2	1,120	245	0	100	99.1
2 to 3	1,007	113	1	99.9	99.0
3 to 4	805	202	0	100	99.0
4 to 5	732	72	1	99.9	98.9
5 to 9	563	168	0	100	98.9

Table 1. Life-table analysis of implant survival.

### **ABSTRACT**

**Background:** The purpose of this case series study was to evaluate posterior single-tooth implant survival and the long-term conditions of the adjacent teeth.

**Methods:** A retrospective evaluation of 1,162 consecutive patients with a single missing posterior tooth treated with 1,377 external hex implants supporting 1,365 restorations surrounded by natural teeth over a 1- to 10-year period was reviewed from four private offices. Implant survival data were collected relative to stage I to stage II healing, stage II to prosthesis delivery, and prosthesis delivery to up to 10 years of follow-up. Long-term adjacent tooth conditions were assessed, including decay, endodontic therapy (root canal therapy [RCT]), and/or extraction during the follow-up period.

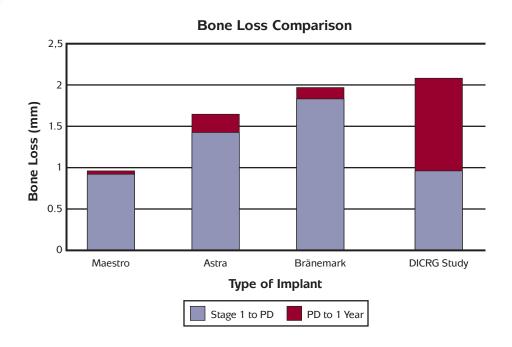
**Results:** Of the 1,377 implants inserted, there were 11 surgical failures from stage I to stage II healing. There was one failure from stage II healing to prosthesis delivery. There were two prosthetic-phase failures. The surgical success rate was 99.2%, whereas the overall survival rate was 98.9% at an average of 61 months of follow-up (range, 12 to 125 months). A total of 2,589 adjacent teeth were followed during the study. No natural adjacent tooth was lost during this period. Interproximal decay developed in 129 adjacent teeth (5%), and nine adjacent teeth required RCT (0.4%) as a result of decay or restoration.

**Conclusions:** The use of single-tooth implants as replacements for posterior missing teeth is a viable long term treatment. Adjacent natural teeth complications are minimal for as long as 10 years after implant insertion.



# A prospective multi-center clinical investigation of a bone quality-based dental implant system

Kline R, Hoar JE, Beck GH, Hazen R, Resnik RR, Crawford EA. Implant Dent. 2002;11(3):224-234.



# **ABSTRACT**

This article reports the five-year results of an independently monitored, prospective, multi-center, clinical trial of a bone quality-based implant design. At six study centers, 495 implants were placed in 151 cases with an average follow-up period of 1.6 years (range 1.0 to 3.6 years), following prosthesis delivery. The majority of the implants placed were D2 or D3 implants to support fixed partial dentures or implant-supported overdentures. Using strict success criteria, there were three implant failures, resulting in a cumulative 99.5% success rate according to Kaplan-Meier survival analysis. Radiographic analysis revealed a mean bone loss of 0.06 mm at one year and bone gain of 0.04 mm at two years following prosthesis loading. There were no statistical differences in the results by center, implant type, bone density, area of the mouth, or prosthesis type. The results of this five-year study revealed a high success rate and limited bone loss in all areas of the mouth, independent of bone quality.



# Initial clinical efficacy of 3-mm implants immediately placed into function in conditions of limited spacing

Reddy MS, O'Neal SJ, Haigh S, Aponte-Wesson R, Geurs NC. Int J Oral Maxillofac Implants. 2008 Mar-Apr;23(2):281-288.



Figure 1. 1 week postoperative appearance



Figure 2. Definitive restoration at 12 months

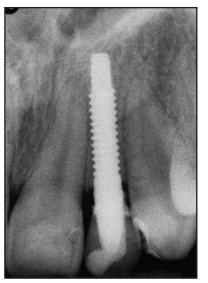


Figure 3. Radiographic appearance at 6 months postoperatively.

Table 1: Radiographic results: Radiographic bone level above the first thread					
Bone level Change from baseline					
Baseline	2.33 ± 0.73 mm				
6 months	1.75 ± 0.78 mm	-0.58 mm*			
12 months	1.63 ± 0.81 mm	-0.70 mm*			

<sup>\*</sup> p < 0.01

### **ABSTRACT**

**Purpose:** The objective of this study was to determine changes in interdental papillae, alveolar bone loss, esthetics, and initial healing survival when 1-piece narrow-diameter implants were immediately loaded in sites with limited tooth-to-tooth spacing.

**Materials and Methods:** One-piece titanium alloy implants with a maximum diameter of 3.0 mm and a resorbable blast surface texture on a squarethread form were evaluated. Digital photographs were made at each clinical visit to assess soft tissue healing. Interproximal soft tissue fill of the embrasure was assessed with a modified Jemt index. Standardized radiographs were made at baseline (implant placement) and at 6 and 12 months postsurgery. Radiographic bone height was measured from a consistent landmark on the implant. A 1-sided t test was used to determine statistical differences of bone height.

**Results:** Thirty-one implants were placed in 17 subjects. One implant had clinical mobility and was removed, for an overall survival rate of 96.7%. Mean bone height on the day of placement and restoration was  $2.33 \pm 0.73$  mm above the first thread. Mean bone height was  $1.75 \pm 0.78$  mm at 6 months postrestoration and  $1.63 \pm 0.81$  mm at 12 months postrestoration. There was a statistically significant loss of bone support over the initial 6 months (0.58 mm; P < 0.01), with no significant progression thereafter (0.12 mm; NS). Complete fill of papillae was found in 92% of maxillary lateral incisor sites and 60% of mandibular incisor sites.

**Conclusion:** The use of 1-piece narrow-diameter immediately loaded implants appears to be an effective prosthetic treatment for areas of limited space (Case Series).



# Histologic and histomorphometric findings from retrieved, immediately occlusally loaded implants in humans

Romanos GE, Testori T, Degidi M, Piattelli A. J Periodontol. 2005 Nov;76(11):1823-1832

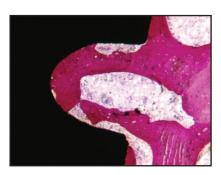


Figure 1. Maestro implant (Tolouidine blue and acid fuchsin; original magnification X50).

Implant System	Specifics	Loading (months)	N Implants	Area	BIC (%)
3i	Osteotite	4	1	Maxilla, 2nd molar	80
3i	Osteotite	2	1	Maxilla, 2nd molar	64.2
Nobel Biocare	TiUnite	6 <sup>*</sup>	1	Maxilla	60
IMZ Twin Plus	Sandblasted	10	2	Mandible	54.2 to 64.5
Maestro	HA-coated/sandblasted	6	3	Mandible	80.6
Ankylos	Sandblasted	7*	12†	Maxilla Mandible	65 59
Frialit-2	Sandblasted & etched	10	7	Maxilla (2); mandible (5)	66.8
XiVE	Sandblasted & etched	6	2	Mandible 2nd molar	61 to 72
Total					66.83 (±8.96)

Table 1. Histomorphometric data of immediately occlusally loaded implants (human biopsies).

# **ABSTRACT**

**Background:** The immediate loading treatment concept can be successfully used in implant dentistry. Bone cells migrate onto the implant surface and establish a stable anchorage on the titanium surface. When implants are loaded immediately after surgery, there is a high long-term success rate of the implant-supported reconstruction. Based on histologic observations from different animal studies, the interface of immediately loaded implants can have a direct bone-to-implant connection without any fibrous tissue formation. Mature bone formation is dependent on the loading period. The aim of this study was to demonstrate a histologic analysis of retrieved, clinically stable immediately loaded implants with different implant designs and surfaces. An objective demonstration of the bone-implant interface was presented for the implant systems used.

**Methods:** A total of 29 implants [N. BioHorizons = 6] with different implant designs and surfaces were retrieved from patients who were treated with implants using an immediate loading protocol and fixed immediate restorations placed the same day after surgery. The loading period was between 2 and 10 months. The bone-implant interface was examined histologically and histomorphometrically.

**Results:** A high bone-to-implant percentage of 66.8% ( $\pm 8.9\%$ ) [BioHorizons BIC% = 80.6%] was found in the examined retrieved implants. Some marginal bone resorption was observed in the crestal part of the implants.

**Conclusion:** According to the present histologic and histomorphometric evaluation of retrieved, clinically stable implants, immediate occlusal loading can present a high level of bone-to-implant contact in humans.

Heavy smoker undergoing chemotherap
 Six in the maxilla: six in the mandible



# Immediate functional and non-functional loading of dental implants: A 2- to 60-month follow-up study of 646 titanium implants

Degidi M, Piattelli A. J Periodontol. 2003 Feb;74(2):225-241.

Implant	N Implants	N Failures	% Implant Survival	% Prostheses Survival
Maestro	126	0	100	100
Total	422	6	98.6	98.5

Table 1. Immediate functional loading (IFL) implants.

Implant	N Implants	N Failures	% Implant Survival	% Prostheses Survival
Maestro	116	0	100	100
Total	224	2	99.1	98.3

Table 2. Immediate non-functional loading (INFL) implants.

# **ABSTRACT**

**Background:** The aim of this study was the evaluation, from a clinical point of view, of implants subjected to immediate functional loading (IFL) and to immediate non-functional loading (INFL) in various anatomical configurations.

**Methods:** The study included 152 patients who had given their informed consent. A total of 646 implants [N. BioHorizons = 242] were inserted. The implants were placed in 39 totally edentulous mandibles, 14 edentulous maxillae, 23 edentulous posterior mandibles, 16 edentulous anterior mandibles, 16 edentulous anterior maxillae, and 15 edentulous posterior maxillae. Fifty-eight implants were used to replace single missing teeth. In 65 cases, IFL was carried out for 422 implants. INFL was carried out in 116 cases, (224 implants).

**Results:** In the IFL group 6 of 422 implants failed (1.4%) [N. BioHorizons = 0/0%]; in the INFL group 2 of 224 implants failed (0.9%) [N. BioHorizons = 0/0%]. All the other implants appeared, from clinical and radiographic observations, to have successfully osseointegrated and have been functioning satisfactorily since insertion. All failures were observed in the first few months after implant loading.

Conclusion: Immediate functional and non-functional loading seems to be a technique that gives satisfactory results in selected cases.



# Five-year prospective study of immediate/early loading of fixed prostheses in completely edentulous jaws with a bone quality-based implant system

Misch CE, Degidi M.

Clin Implant Dent Relat Res. 2003 May;5(1):17-28

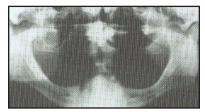


Figure 1. A preoperative radiograph of a completely

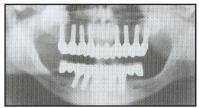


Figure 2. After 4-6 months, a maxillary porcelainto-metal restoration was delivered. A panoramic radiograph confirmed complete seating.

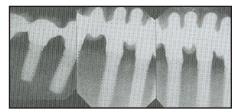


Figure 3. The first year loading periapical radiographs showed an average of 0.07mm bone loss from final prosthesis delivery. After the first year of loading, a slight bone gain was observed, but the vast majority demonstrated 0mm of bone loss.

	Table 1: Summary of the prosthesis and implant types and survival						
Arch	Immediate LoadEarly LoadImplantSurvival ofSurvival of(Prostheses)Number/TypeImplants (%)Prostheses (%)						
Maxillary	2	10	108 (38 D3, 70 D4)	100	100		
Mandible	14	5	136 (121 D3, 15 D2)	100	100		
Both	16	15	244	100*	100 <sup>†</sup>		

<sup>\*</sup> All implants were in Quality Scale group I to III through to last appointment

### **ABSTRACT**

Background: The concept of immediate loading of root-form implants for fixed restorations has received increasing interest over the last 5 years. Several authors have commented on parameters that may influence results, including implant number; implant length, bone density, and patient habits. The trigger for bone remodeling around an implant may occur from the surgical trauma of insertion or the mechanical environment of strain at the interface. In the classic two-stage approach, these were divided episodes, separated by 3 to 6 months. Immediate loading compresses this time frame; the two driving mechanisms for bone repair occur concurrently. A scientific approach to the interface development is to match the bone healing response of trauma (woven bone of repair) to the response of mechanical load (reactive woven bone), so the sum of these two entities does not result in fibrous tissue formation and clinical mobility of the implant.

**Purpose:** It is the purpose of this article to review the scientific rationale of these statements and coordinate them to bone physiology and bone biomechanics.

**Materials and Methods:** Findings from previous reports in the literature were reviewed and summarized to form the basis of a prospective study using a bone quality-based implant system (Maestro, BioHorizons Implant Systems, Inc., Birmingham, AL, USA). A transitional prosthesis was delivered either on the day of surgery or within 2 weeks for 30 patients and 31 arches. A total of 244 implants were used to support these restorations, for an average of 7.8 implants per prosthesis. After 4 to 7 months, the final restorations were fabricated. One year after the final restoration was loaded, the implant survival was 100%; the 31 restorations also had a survival of 100% over this time frame. This report presents these implants and restorations over a 1- to 5-year period, with an average follow-up period of 2.6 years.

**Results:** The bone loss from implant insertion to final prosthesis delivery averaged 0.7 mm. The first-year bone loss after final prosthesis delivery averaged 0.07 mm. A slight increase in bone height was observed after the first year, but generally no increase was observed over the remaining evaluation period.

**Conclusions:** In the current report, no implant failure occurred, and crestal bone loss values were similar to or less than values reported with the conditional two-stage approach. This may be related to the number and position of implants, implant design, and/or the surface condition of the implant loading.

<sup>†</sup> Average follow-up was 2.6 yr after final prosthesis delivery.



# Comparative analysis of immediate functional loading and immediate nonfunctional loading to traditional healing periods: A 5-year follow-up of 550 dental implants

Degidi M, Iezzi G, Perrotti V, Piattelli A. Clin Implant Dent Relat Res. 2008 Sep;9.



Figure 1. Five-year follow-up X-ray.

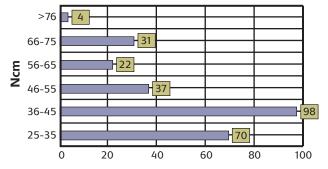


Figure 2. Immediately loaded implants. Insertion torque values.

Table 1: Immediately Loaded Implants						
	Number of Cases	Number of Implants	Number of Failures	Implant Survival Rate (%)	Number of Prosthetic Failures	Prosthetic Success Rate (%)
Single tooth	22	22	0	100	0	100
Edentulous mandible	15	102	0	100	0	100
Edentulous maxilla	4	28	0	100	0	100
Anterior mandible	8	22	0	100	0	100
Posterior mandible	16	43	3	93	0	100
Anterior maxilla	9	24	0	100	0	100
Posterior maxilla	8	21	0	100	0	100
Total	82	262	3	98.8	0	100

# **ABSTRACT**

**Background:** Clinical, radiographical, and histological findings have shown that immediately loaded implants show the presence of mineralized tissues at the interface.

**Purpose:** The aim of this study was to compare an immediate loading protocol with a two-staged one using an implant with a square thread design.

Materials and Methods: One hundred fifty-five consecutive patients (71 men, 84 women), aged between 18 and 78 years (mean: 54 years) participated in this study. A total of 550 implants (Maestro; BioHorizons, Birmingham, AL, USA) were inserted. In group A, 264 implants were inserted in 82 patients with immediate functional loading with occlusal contact if the patients were completely edentulous, or with immediate nonfunctional loading without occlusal contact if the patients were partially edentulous. In group B, 286 implants were inserted in 73 patients with a one-stage or two-stage surgical procedure. All patients were followed for at least 5 years.

**Results:** In the immediately loaded implants group, three implants failed, all in posterior mandibular sites, with an overall 98.8% 5-year survival rate. In the control group, no implant failed, with a 100% 5-year survival rate. No statistically significant differences were found in the survival rates of the implants in the two groups.

**Discussion:** A very high implant survival rate was also present in our series for the immediately loaded implants. All the three failed implants were retrieved from the same patient, who had poor oral hygiene, after a loading period of 5 years. These data can suggest that, from a clinical point of view, an abbreviated healing period is compatible with the development and maintenance over a longer time period (5 years) of mineralized tissues at the interface with dental implants.

Conclusion: We can then conclude that shorter healing periods can be highly satisfactory from a clinical point of view.



# Endosteal implants in the edentulous posterior maxilla: Rationale and clinical report

Misch CE, Poitras Y, Dietsh-Misch F. Oral Health. 2000 Aug;8:7-16.

Table 1: Implants (n=456)				
	No.	Туре	Success	Loss
	15	D2	15	0
	110	D3	109	1
	304	D4	302	2
	27	C-h	27	0
Total	456		453	3

	Table 2: Comparison of functional thread surface area (without coatings and all implants are 1mm length)			
	BioHorizons®a	Nobel BioCare <sup>b</sup>	Paragon™	Steri-Oss <sup>®d</sup>
Туре	(a) D2	Standard fixture	Screw-Vent®	Threaded implant
	(b) D3			
Diameter (mm)	4	3.75	3.75	3.8
Thread surface area	(a) 210	127	151	111
	(b) 245			
Туре	(a) D3	Wide platform	Screw-Vent®	0
	(b) D4			1
Diameter (mm)	5	5.5	4.7	2
Thread surface area	(a) 419	183	192	5
	(b) 468			134

a BioHorizons Implant Systems, Inc. Birmingham, AL 35243

# **ABSTRACT**

The maxillary posterior region of the mouth sustains greater bite forces compared to the anterior, yet often presents the poorest bone density. A biomechanical approach, often presented to decrease risk factors in regions of high stress or poor bone density, is to increase implant surface area. Most manufacturers provide implants in variable lengths. Sinus grafts permit longer implants; however, finite element analysis support the hypothesis that implant length is a secondary parameter for stress distribution. A more beneficial approach, to enhance implant surface area in the posterior regions, has primarily been to increase the implant diameter. However, when conventional designs and diameters are used, this only increases surface area by 30% yet bite forces increase by more than 300% in the posterior regions. A change in implant diameter and thread design (i.e. BioHorizons Implant Systems, Inc.) may increase surface area by more than 300%. This clinical report demonstrates an implant surgical success rate of 99.4% in the posterior maxilla, using the bone quality-based implant system from BioHorizons. In addition, there were no early loading failures and no prosthetic failures. Crestal bone loss during early loading averaged .71 mm or less, dependent upon a one-stage or two-stage surgical approach. The increase in surface area of this design, coupled with the compressive load thread of this design, may indeed be responsible for the decrease in early loading implant failure and also contribute to a decrease in crestal bone stresses, which may reduce crestal bone loss.

b Nobel BioCare, Inc. Westmont, IL 60559 c Paragon™ Implant Company, Encino CA 91436

d Steri-Oss® Yorba Linda, CA 92887



# Augmentation of the maxillary sinus with calcium sulfate: One-year clinical report from a prospective, longitudinal study

De Leonardis D, Pecora GE. Int J Oral and Maxillofac Implants. 1999 Nov-Dec;14(6):869-878.

Table 1: Implant Clinical Results				
	Pilot Group	Test Group	Total	
Placement data				
Immediate implants	16	40	56	
Staged implants	14	60	74	
Implant type				
Biolock	30	75	105	
BioHorizons	0	25	25	
Success/failure data at 12 months				
Successful implants	29	99	128	
Failed implants	1	1	2	
Total implants	30	100	130	

### **ABSTRACT**

The aim of the present investigation was to evaluate the clinical and histologic results of a sinus augmentation procedure performed using calcium sulfate as the grafting material. A group of 12 patients (15 sinuses) formed the pilot group. Based on the experience of the pilot group, the technique of calcium sulfate application was modified, and a second group of 45 patients (50 sinuses) was subsequently treated (test group). In the pilot group, a total of 30 implants (Biolock) was placed. In the test group, a total of 100 implants (Biolock and BioHorizons) was placed. The clinical data reported in the present study are related to the 1-year follow-up for both groups. Clinical evaluations, including assessment of implant mobility and probing pocket depth, were recorded on a monthly basis following implant uncovering until final prosthesis placement, and every 6 months thereafter. Radiographs were taken prior to sinus augmentation, monthly until 6 months postoperatively, 9 and 12 months after implantation, and at yearly intervals thereafter. One implant in the pilot group was not integrated at second-stage surgery, and 1 in the test group failed to maintain osseointegration after the abutment connection (at the 1-year evaluation). Based on defined criteria, the overall success rate for the 130 placed implants 1 year postimplantation was 98.5%. Clinical and radiographic evaluation revealed that the augmentation procedure resulted in new tissue formation within the sinuses. The technique used in the test group suggested a slowdown in material resorption and a reduction in graft shrinkage during healing. Bone biopsies were harvested for histologic evaluation. The application of a resorbable barrier membrane to the access window reduced the invagination of soft tissue at that level. The results of this study support the hypothesis that calcium sulfate may be a suitable material for sinus augmentation.



# Short dental implants in posterior partial edentulism: A multicenter retrospective 6-year case series study

Misch CE, Steignga J, Barboza E, Misch-Dietsh F, Cianciola LJ, Kazor C. J Periodontol. 2006 Aug;77(8):1340-1347.

### **ABSTRACT**

**Background:** Implants <10 mm long in the posterior regions of partial edentulous patients have a higher failure rate in many clinical reports. The purpose of this case series study was to evaluate implant survival when a biomechanical approach was used to decrease stress to the bone-implant interface.

**Methods:** A retrospective evaluation of 273 consecutive posterior partially edentulous patients treated with 745 implants, 7 or 9 mm long, supporting 338 restorations over a 1- to 5-year period was reviewed from four private offices. Implant survival data were collected relative to stage I to stage II to prosthesis delivery, and prosthesis delivery to as long as 6 years follow-up. A biomechanical approach to decrease stress to the posterior implants included splinting implants together with no cantilever load, restoring the patient with a mutually protected or canine guidance occlusion, and selecting an implant designed to increase bone-implant contact surface area.

**Results:** Of the 745 implants inserted, there were six surgical failures from stage I to stage II healing to prosthesis delivery. No implants failed after the 338 final implant prostheses were delivered. A 98.9% survival rate was obtained from stage I surgery to prosthetic follow-up.

**Conclusions:** Short-length implants may predictably be used to support fixed restorations in posterior partial edentulism. Methods to decrease biomechanical stress to the bone-implant interface appear appropriate for this treatment.

**Implant Design:** Thread Pitch. An implant body may be modified to increase functional surface area by varying the thread geometry parameter of thread pitch. Thread pitch is defined as the distance between adjacent threads or the number of threads per unit length in the same axial plane and on the same side of the axis. Restated, a decrease in the distance between threads will increase the number of threads per unit length. For example, the distance between the threads of different manufactured implant bodies ranges from 1.5 to 0.4 mm, with the latter having almost three threads for each thread of the former. The thread distance for the implant in the study presented in this report is 0.76 mm. The greater the number of threads, the greater the surface area, if all other factors are equal. The thread number may be more significant for the shorter implant in the posterior regions of the mouth with reduced bone density. The other implant thread geometry parameter that may also modify the functional surface area is thread depth.



# Short-term success of osseointegrated dental implants in HIV-positive individuals: A prospective study

Stevenson GC, Riano PC, Moretti AJ, Nichols CM, Engelmeier RL, Flaitz CM. J Contemp Dent Pract. 2007 Jan; (8)1:1-10.



Figure 1. Subject wearing maxillary complete denture and implant-supported mandibular overdenture.

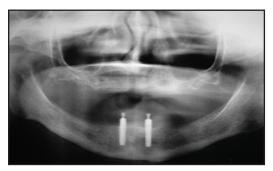


Figure 2. Panoramic radiograph taken when the implant supported mandibular overdenture was activated with o-rings (implant loading).

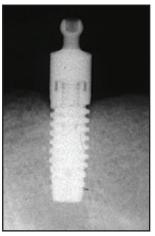


Figure 3. Periapical radiograph of an implant taken six months after implant loading.

# **ABSTRACT**

**Purpose:** Except for the occasional case report, there are no studies evaluating the success rate of osseointegrated dental implants in individuals infected with the human immunodeficiency virus (HIV). This study investigated the short-term clinical outcome of implant placement in a group of HIV-positive and HIV-negative individuals who required complete dentures.

**Methods and Materials:** Edentulous subjects were recruited from an HIV-dedicated clinic and a dental school clinic. Two BioHorizons® dental implants were placed in the anterior mandible to support an overdenture opposing a maxillary denture. Outcome measurements obtained six months after activation of implants were presence of pain, mobility, soft tissue status, and radiographic bone level. Descriptive statistics were used.

**Results:** Twenty-nine edentulous adults, including 20 HIV-positive subjects (test) and nine HIV-negative subjects (control), participated. The test group had six females, 14 males; 13 Whites, four African-Americans, and three Hispanics with a mean age of 48.9 years (range: 35-59). The mean CD4 count was 467 cells/mm³ (range: 132-948). The control group had six females, three males; seven Whites, and two Hispanics with a mean age of 65.3 years (range: 50-82). Short-term success rate was 100% for both groups. No difference in clinical outcome was found between the groups.

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J Periodontol. 2003 Feb;74(2):225-241.

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### **BioHorizons USA**

2300 Riverchase Center Birmingham, AL 35244

Customer Care / Servicio al Cliente: 888-246-8338 or 205-967-7880

# **BioHorizons Canada**

21 Amber Street, Unit # 6 Markham, Ontario L3R 4Z3

Customer Care / Service à la Clientèle: 866-468-8338 or / ou 905-944-1700

# **BioHorizons UK**

17 Wellington Business Park
Dukes Ride
Crowthorne, Berkshire RG45 6LS

Customer Care: +44 1344 752560

## **BioHorizons Australia**

25-33 Allen Street Waterloo, NSW 2019

Customer Care: +61 2 8399 1520

# **BioHorizons Spain**

Serrano Anguita, 10 28004 Madrid, España

Atención al Cliente: +34 91 713 10 84

# **BioHorizons Chile**

Cerro Colorado 5030, Officina 513 Las Condes Santiago, Chile

Atención al Cliente: +56 2 361 9519

# **BioHorizons Germany**

Marktplatz 3 79199 Kirchzarten

Kunden Service: +49 7661-909989-0

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REVAJUL 2009