



Special Supplement

Summaries of Scientific Publications

BIOMET **3i** PREVAIL[®] Implants

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The Journal of Implant and Reconstructive Dentistry® (JIRD®) is the official publication of The Institute for Implant and Reconstructive Dentistry, BIOMET **3i** LLC, 4555 Riverside Drive, Palm Beach Gardens, Florida, USA 33410. Telephone: 561.776.6700.

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Immediate occlusal loading of NanoTite™ PREVAIL® Implants: A prospective one-year clinical and radiographic study

Östman PO,† Wennerberg A, Albrektsson T.

Clin Implant Dent Relat Res 2010;12(1):39-47.

Study Design: Prospective, Single-Center, Observational
Major Product(s): BIOMET NanoTite PREVAIL Implants
Clinical Scenario: Immediate Loading
Sample Size: 102 Total Implants
Reported Outcome(s): The average marginal bone resorption was 0.37mm during the first year of function.

Background

Recently, a new implant surface texture, featuring application of nanometer-scale calcium phosphate, has been shown in pre-clinical and human histomorphometric studies to enhance early bone fixation and formation, which may be beneficial in immediate loading situations.

Aim

The purpose of this present one-year prospective clinical study was to clinically and radiographically evaluate nanometer-scale-surface-modified implants placed for immediate loading of fixed prostheses in both maxillary and mandibular regions.

Researchers report 0.37mm bone resorption and 99.2% survival after one year with NanoTite PREVAIL Implants.*

Materials and Methods

Thirty-five out of 38 patients who needed implant treatment and met inclusion criteria agreed to participate in the study and were consecutively enrolled. Surgical implant



placement requirements consisted of a final torque of at least 25Ncm prior to final seating and an implant-stability quotient above 55. A total of 102 NanoTite PREVAIL Implants (BIOMET **3i**, Palm Beach Gardens, FL) (66 maxillary and 36 mandibular) were placed by one investigator, and the majority of these were placed in posterior regions (65%) and in soft bone (69%).

†Author has a financial relationship with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services.

*Summary statement derived from article abstract or poster.

A total of 44 prosthetic constructions were evaluated, including 14 single-tooth restorations, 26 fixed partial dentures, and four complete fixed restorations. All provisional constructions were delivered within one hour and the final constructions were placed after four months. Implants were monitored for clinical and radiographic outcomes at follow-up examinations scheduled for three, six, and 12 months.

Results

Of the 102 study implants, one implant failed. The simple cumulative survival rate value at one year was 99.2%. The average marginal bone resorption was 0.37mm (SD 0.39) during the first year in function. According to the success criteria of Albrektsson and Zarb, success grade I was found with 93% of the implants.

| Marginal Bone Resorption at One-Year Follow-up | | |
|---|---------------------------|------------|
| | NanoTite™ PREVAIL® | |
| | (m + d)/2 | (%) |
| Number | 101 | |
| Mean value (SD) | 0.37 (0.39) | |
| <0 | 9 | 9 |
| 0 | 17 | 17 |
| 0.1–1.0 | 69 | 68 |
| 1.1–2.0 | 6 | 6 |
| 2.1–3.0 | 0 | 0 |
| >3.0 | 0 | 0 |
| Total | 101 | 100 |

Conclusion

Although limited to the short follow-up, immediate loading of NanoTite PREVAIL Implants seems to be a viable option in implant rehabilitation, at least when a good initial fixation is achieved.

Peri-implant bone level around implants with platform-switched abutments

Fickl S,[†] Zuhr O,[†] Sein J, Hürzeler M.[†]

Int J Oral Maxillofac Implants 2010;25:577-581.

Study Design: Prospective, Single-Center
Major Product(s): BIOMET **3i** OSSEOTITE® Certain® Implants
Clinical Scenario: Two-stage Protocol
Sample Size: 89 Total Implants
Reported Outcome(s): Bone loss at time of definitive prosthesis insertion and at one year was 0.30mm and 0.39mm respectively for platform-switched implants.

Purpose

The purpose of this clinical trial was to evaluate whether the crestal bone height around dental implants could be influenced by the use of a platform-switching protocol.

Materials and Methods

All implants placed in 2006 into healed bone without any need for ridge augmentation were included in this study. The following groups were created: (1) wide-diameter implants were placed subcrestally and regular-diameter cover screws were connected; (2) regular-diameter implants were placed at the crest and regular-diameter cover screws were connected. Standardized radiographs were obtained after insertion of the definitive prosthesis and after one year. Calibrated measurements were conducted initiating from the mesial and distal bone peaks to the implant-abutment junction. The average value of the mean medial and mean distal values were calculated and analyzed with an unpaired two-tailed *t* test. P values <.05 were regarded as statistically significant.

European investigators report statistically, significantly less bone loss with OSSEOTITE Certain Platform-Switched Implants at one year; 0.39mm(±) vs. 1.00mm(±) for non-platform-switched implants.*

| Crestal Bone Levels Around the Platform-Switched and the Non-Platform-Switched (Control) Implants | | | |
|---|-----------------------|-------------|-------------|
| Implant group | Prosthesis insertion* | 12 mo | Difference |
| Platform switched | 0.30 (0.07) | 0.39 (0.07) | 0.10 (0.05) |
| Control | 0.68 (0.17) | 1.00 (0.22) | 0.23 (0.18) |

*Insertion of definitive prosthesis.

[†]Authors have a financial relationship with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services.

*Summary statement derived from article abstract or poster.

Results

In all, 89 dental implants were evaluated in 36 patients. The implants with a platform switched configuration (n=75) exhibited statistically significantly less bone loss at the time of insertion of the definitive prosthesis ($0.30\pm 0.07\text{mm}$ versus $0.68\pm 0.17\text{mm}$; $P<.05$) and at one year ($0.39\pm 0.07\text{mm}$ versus $1.00\pm 0.22\text{mm}$, $P<.01$) when compared to the non-platform-switched implants (n=14).



Standardized radiograph at the time of insertion of the definitive prosthesis supported by test and control implants in one patient.



Standardized radiograph after 12 months in function. Note the difference in crestal bone loss around both types of implants.

Conclusion

Platform-switched implants seem to limit crestal bone remodeling.

The effect of abutment dis/reconnections on peri-implant bone resorption: A radiologic study of platform-switched and non-platform-switched implants placed in animals

Rodríguez X,[†] Vela X,[†] Méndez V, Calvo-Guirado J,[†] Tarnow D.[†]

Clin Oral Implants Res 00, 2011, 1-7 doi:10.1111/j.1600-0501.2011.02317.x.

Study Design: Pre-clinical

Major Product(s): OSSEOTITE® Platform-Switched and Non-Platform-Switched Implants

Clinical Scenario: Immediate Loaded Post-Extractive Implants in Dogs

Sample Size: 30 Total Implants

Reported Outcome(s): For platform-switched implants, the average vertical bone loss was 0.24mm. The average horizontal bone loss was 0.24mm vs. 1.09mm and 0.98mm respectively for non-platform-switched implants.

Objectives

The purpose of this animal study was to radiologically measure the influence of abutment disconnection on bone resorption and to compare this influence on platform-switched versus non-platform-switched implants.

Methods

The study design included extraction of all mandibular premolars in five canines. After two months, six implants were placed in each dog. Four of them were platform-switched (PS) implants and two were non-platform-switched (NPS) implants. Some or all of the abutments connected to the implants were disconnected at pre-ordained post-surgical intervals. Radiographs were taken at the time of implant placement and at every handling. The values for mesial (horizontal and vertical) and distal (horizontal and vertical) bone resorption were taken and compared for each implant at every abutment dis/reconnection.

Results

The average vertical bone resorption around NPS implants after four dis/reconnections was 1.09mm (SD 0.25mm), and the average horizontal bone resorption was 0.98mm (SD 0.27mm). The average vertical bone resorption around PS implants after four dis/reconnections was 0.24mm (SD 0.08mm), and the average horizontal bone resorption was 0.24mm (SD 0.13mm). The difference between the average horizontal and vertical bone resorption around NPS (site D) and

Researchers report implants with a platform-switched design show less peri-implant bone resorption as their abutments are dis/reconnected during the healing process.*

[†]Authors have a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.

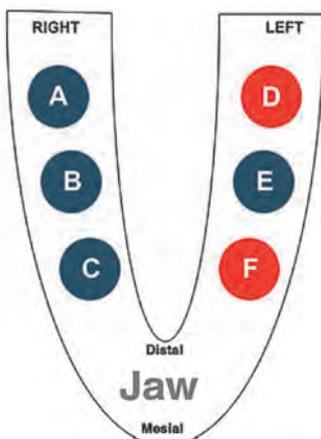
*Summary statement derived from article abstract or poster.

PS (site A) implants was statically significant ($P < 0.05$). The average mesial and distal bone resorption values around PS (site A) implants adjacent to a tooth were compared, and statistically significant differences were found ($P < 0.05$).

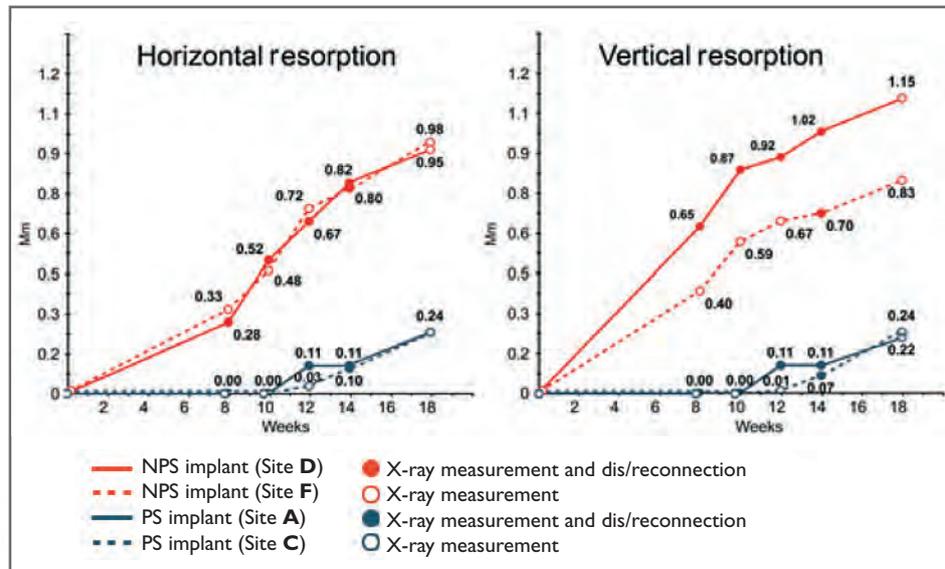
Conclusions

Implants with a PS design show less peri-implant bone resorption during the healing process and as their abutments are disconnected than do comparably dis/reconnected NPS implants. The location of the PS implant next to a tooth may decrease radiographically visible peri-implant bone resorption significantly.

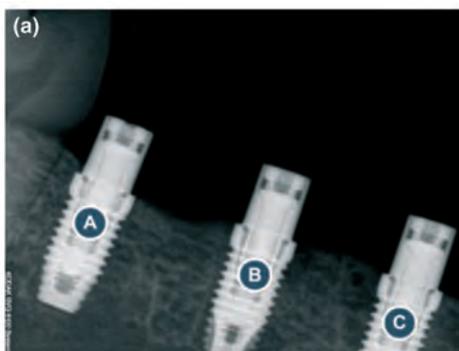
Implant distribution along the jaw.



- A** Platform-switched Implant
4 dis/reconnections and 5 X-rays
- B** Platform-switched Implant
2 dis/reconnections and 5 X-rays
- C** Platform-switched Implant
1 dis/reconnections and 5 X-rays
- D** Non-platform-switched Implant
4 dis/reconnections and 5 X-rays
- E** Platform-switched Implant
3 dis/reconnections and 5 X-rays
- F** Non-platform-switched Implant
1 dis/reconnections and 5 X-rays



Mean bone resorption of the NPS and PS implants used in the study during the six stages. On the mesial (tooth-free) side, mean bone resorption shown on PS implants with four dis/reconnections was double (0.41 mm on the vertical axis and 0.37 mm on the horizontal axis) than found for PS implants with one dis/reconnection (0.24 mm on both axes). This difference was statistically significant ($P < 0.05$).



(a) X-rays obtained from all implant sites displaying the peri-implant bone resorption four weeks after the fourth disconnection. A (four dis/reconnections), B (three dis/reconnections), and C (one dis/reconnection) sites, where (PS implants) were placed.



(b) Radiographs obtained from all implant sites showing the peri-implant bone resorption four weeks after the fourth disconnection. D (four dis/reconnections) (NPS implant), E (two dis/reconnections) (PS implant), and F (one dis/reconnection) (NPS implant).

Three-year analysis of PREVAIL® Implants supporting short-span restorations in a randomized-controlled study: Effect of platform switching on marginal bone remodeling

Del Castillo R,[†] Frederico G, Bianchessi C, Baumgarten H,[†] Reddy M, Cocchetto R, Del Lupo R, Zetterqvist L, Wennstrom J.

Poster Presentation: American Academy of Osseointegration, 27th Annual Meeting: 2012 March 1-3; Phoenix, AZ, USA.

Study Design: Prospective, Single-Center, Randomized-Controlled

Major Product(s): BIOMET 3i OSSEOTITE® PREVAIL Platform-Switched and OSSEOTITE Non-Platform-Switched Implants

Clinical Scenario: Single-Stage, Delayed Loading

Sample Size: 383 Total Implants

Reported Outcome(s): There was no more than 0.45mm bone remodeling after more than two years post-placement follow-up.

Introduction

The technique called platform switching comes from the observation that a mismatched pairing of a smaller abutment with an implant medializes the implant-abutment junction (IAJ) and moves the inflammatory cellular infiltrate inwards from the crestal bone, leading to crestal bone preservation. The objective of this prospective, randomized, longitudinal study was to evaluate crestal bone levels adjacent to platform-switched implants when placed in support of short-span fixed prostheses.

Materials and Methods

Study implants were Ti Alloy threaded, internal connection implants with an expanded collar. Test implants with medialized abutment seating surfaces (BIOMET 3i PREVAIL Implant) and control implants (abutment-matched) were randomly assigned to positions in the same 2-4 unit prosthesis to ensure equivalence in baseline variables. Implants were placed in a single-stage surgical approach and allowed to heal for two months, at which time provisional restorations were inserted. Definitive restorations were placed within six months. The marginal-bone-analysis method involved capture of digitized images with high-resolution scanners, identification of anatomic bone levels by an independent and blinded evaluator, and use of imaging software for calibration, normalization, and measurement of bone levels to the nearest 0.01 mm.

Multicenter, controlled study reports 0.45mm of marginal bone remodeling for the BIOMET 3i PREVAIL Implant.*

[†]Authors have a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.

*Summary statement derived from article abstract or poster.

Results

At 14 study centers, 142 patients (56% men and 44% women) were enrolled, and 167 prostheses were placed, supported by 198 test and 185 control implants, of which 75.4% were in mandibles and 26.4% were in maxillae. PREVAIL® Implant diameters were 75% 4mm and 25% 5mm. Outcomes for marginal bone remodeling were reported as changes from baseline (implant placement). For the test implants group, the difference at provisionalization in comparison to control implants was 0.1mm. At the latest time interval, 24 months, it was 0.2mm. Differences were statistically significant ($P<.05$). Crestal bone remodeling for either group through 24 months of follow-up did not exceed 0.75mm.

Conclusions

The outcomes of this clinical follow-up of short-span restorations showed significantly less crestal bone loss for PREVAIL Implants in comparison to matched-abutment implants, suggesting that platform switching is a viable technique for preserving alveolar bone.

| MARGINAL BONE REMODELING | | | | | | | DIFF | BONE PRESERVED |
|--------------------------|---------------|------|-----|------------------|------|-----|------|----------------|
| | TEST IMPLANTS | | | CONTROL IMPLANTS | | | | |
| INTERVAL | mm | SD | N | mm | SD | N | mm | PERCENT |
| PLAC BL | 0 | | 148 | 0 | | 139 | | |
| IMP 1 | 0.35 | 0.57 | 109 | 0.45 | 0.58 | 100 | 0.10 | 22.2 |
| TEMP 2 mos. | 0.46 | 0.65 | 66 | 0.56 | 0.69 | 58 | 0.10 | 17.9 |
| IMP 2 | 0.45 | 0.58 | 11 | 0.51 | 0.68 | 12 | 0.06 | 11.8 |
| PERM 6 mos. | 0.68 | 0.66 | 109 | 0.71 | 0.68 | 104 | 0.03 | 4.2 |
| F-UP 12 mos. | 0.54 | 0.65 | 87 | 0.54 | 0.61 | 80 | 0 | 0 |
| F-UP 24 mos. | 0.45 | 0.57 | 45 | 0.65 | 0.69 | 46 | 0.19 | 29.2 |
| F-UP 36 mos. | - | - | 2 | - | - | 2 | | |

Marginal bone remodeling was measured (mm) as the mean change in bone levels at each interval from Baseline (BL) = implant placement (PLAC).

Platform switching vs. conventional technique: A randomized-controlled clinical trial

De Angelis N,[†] Nevins M,[†] Camelo M, Ono Y, Campailla M.

Poster Presentation: American Academy of Osseointegration, 27th Annual Meeting: 2012, Mar 1-3; Phoenix, AZ, USA.

Study Design: Prospective, Randomized-Controlled

Major Product(s): BIOMET **3i** NanoTite™ Tapered PREVAIL® Non-Platform-Switched Implants

Clinical Scenario: Two-Stage Protocol

Sample Size: 78 Total Implants

Reported Outcome(s): 0.197mm of bone loss with PREVAIL Implants vs. 0.597mm with non-platform-switched implants

Background

The platform-switching technique consists of using an abutment that has a smaller diameter than its implant. The aim of this multicenter, randomized clinical trial (RCT) was to compare the efficacy of platform switching vs. non-platform switching for preserving crestal marginal bone.

Materials and Methods

Patients needing multiple restorations had their sites randomly assigned to receive either test or control implants. Test sites received NanoTite Tapered PREVAIL Implants. Intraoral radiographs were obtained with a paralleling technique at abutment delivery, provisionalization, and after six months and one year of loading.

European study reports 0.2mm(±) bone loss six months post-loading with PREVAIL Implants vs. 0.6mm(±) bone loss with non-platform-switched implants at the time of prosthesis insertion.*

Results

At this interim analysis, 78 study implants were being followed with 41 test and 37 control cases. Many patients had both test and control implants, making the baseline variables for the two groups evenly balanced for gender, age, and smoking. Average duration from implant placement to provisional loading was 5.1 months. All but one NanoTite Implant integrated successfully and maintained function. Average crestal bone loss for the PREVAIL platform-switched implants was 0.197 ± 0.31 mm and for control implants was 0.597 ± 0.49 . Additional radiographic data will be collected at follow-up intervals to determine the long-term effects of this technique.

Conclusions

In this study, platform-switched implants preserved crestal bone more than for implants with matched-abutment cases.

[†]Authors have a financial relationship with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services.

*Summary statement derived from article abstract or poster.

A prospective, randomized-controlled evaluation of the OSSEOTITE® Certain® PREVAIL® Tapered Implants for preservation of crestal bone

Pavez M, Soriano M.

Poster Presentation: Academy of Osseointegration, 27th Annual Meeting: 2012 March 2-3; Phoenix, AZ, USA.

Study Design: Prospective, Randomized-Controlled

Major Product(s): BIOMET **3i** OSSEOTITE Tapered PREVAIL and OSSEOTITE Tapered (non-platform-switched) Implants

Clinical Scenario: Two-Stage Protocol

Sample Size: 90 Total Implants

Reported Outcomes(s): At the time of both provisionalization and definitive prostheses insertion, PREVAIL Implants showed greater bone preservation.

Objective

This prospective, randomized-controlled, split-mouth-design clinical study evaluated the crestal-bone-preserving performance of the OSSEOTITE Certain PREVAIL Tapered Implant system when compared to similar implants that did not have a platform-switched feature.

Materials and Methods

Patients requiring multiple implants had the sites randomly assigned to receive a Tapered PREVAIL Implant (test) or a similar non-platform-switched implant (control). Implant insertion force was recorded using a BIOMET **3i** High Torque Indicating Ratchet Wrench (H-TIRW). The wrench was used to rotate the implants into position, recording the torque resistance at each 1mm of the implant's descent into the osteotomy and final seating. ISQ values were obtained at baseline and at prosthesis insertion. Baseline radiographs obtained at implant insertion were made with an occlusal registration technique that was used for all subsequent serial radiographs. Radiographic outcomes were measured by one periodontist. Patients were followed clinically for two years.

Results

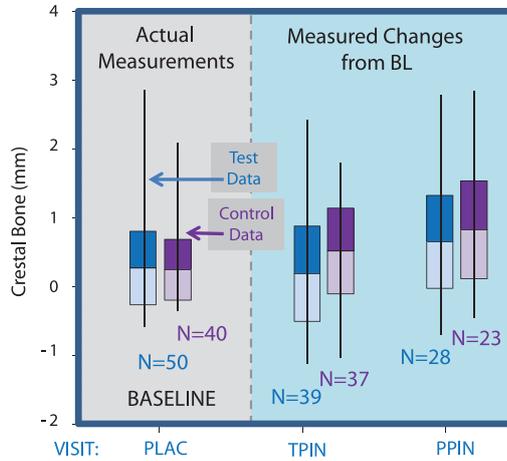
At the time of this interim analysis, a total of 41 patients were enrolled with 90 study implants under evaluation, evenly divided between test and control cases. All but one implant achieved initial integration, and all other implants remained in function. Radiographic processing is underway, and outcomes for all implants will be presented. The insertion-torque profiles for all implants will be analyzed to determine if there is a correlation between insertion variables and crestal-bone-remodeling outcomes.

In this study, OSSEOTITE Certain Tapered Implants and PREVAIL Implants have a high integration rate. The split-mouth study design allows for a sensitive analysis of the effect of platform switching on crestal bone preservation.*

*Summary statement derived from article abstract or poster.

Conclusions

Presently, in this study, OSSEOTITE® Certain® Tapered Implants and PREVAIL® Implants have a high integration rate. The split-mouth study design allows for a sensitive analysis of the effect of platform switching on crestal bone preservation.



| A. TEST GROUP | | | | | | |
|---------------|-----------|-------------|------|----|----------|----------|
| Visit | Mean (mm) | Median (mm) | SD ± | N | MAX (mm) | MIN (mm) |
| TEMP | 0.29 | 0.18 | 0.69 | 39 | 2.42 | -1.12 |
| PERM | 0.70 | 0.65 | 0.67 | 28 | 2.78 | -0.70 |

| B. CONTROL GROUP | | | | | | |
|------------------|-----------|-------------|------|----|----------|----------|
| Visit | Mean (mm) | Median (mm) | SD ± | N | MAX (mm) | MIN (mm) |
| TEMP | 0.48 | 0.52 | 0.62 | 37 | 1.80 | -1.03 |
| PERM | 0.88 | 0.82 | 0.71 | 23 | 2.84 | -0.44 |

Plots of crestal bone data for test (blue) and control (purple) implant groups measured at baseline (implant placement = PLAC) and evaluated at temporary prostheses insertions (TPIN) and permanent prostheses insertions (PPIN). N = number of radiographs evaluated at each visit.

Change from baseline outcomes for crestal bone at each visit from implant placement for test and control implant groups. At TEMP and PERM intervals, the test group showed greater bone preservation.

Data reported at baseline were actual crestal bone levels (mm). Data for crestal bone remodeling are reported here as change-from-baseline-values. Positive measurements were bone loss. Box-plots include the median and one standard deviation in either direction. The “whiskers” extend to maximum and minimum data values.

Crestal bone changes on platform-switched implants and adjacent teeth when the tooth-implant distance is less than 1.5mm

Vela X,[†] Méndez V, Rodríguez X,[†] Segalá M, Tarnow D.[†]

Int J Periodontics Restorative Dent 2012;32:149-155.

Study Design: Retrospective, Radiographic Analysis

Major Product(s): BIOMET **3i** FOSS OSSEOTITE[®] Certain[®] PREVAIL[®] Implants

Clinical Scenario: Various

Sample Size: 70 Total Implants

Reported Outcome(s): Mean vertical bone loss was 0.43mm, horizontal bone loss was 0.36mm, and bone-peak reduction was 0.37mm.

Background

Because of the peri-implant bone resorption that occurs when a non-platform-switched implant is exposed to the oral environment, it has been recommended to maintain 1.5mm between the tooth and implant to preserve the bone adjacent to the teeth. Several studies have documented that platform-switched implants have less peri-implant bone resorption than matched implants.

This retrospective radiographic analysis studied 70 platform-switched implants placed less than 1.5mm from an adjacent tooth and prosthetically loaded for a minimum of six months.

Materials and Methods

All implants were BIOMET **3i** FOSS (Full OSSEOTITE[®]) Implants. Two types of implant configurations were used: 50 implants were PREVAIL[®] 4/5/4, and 20 were PREVAIL 4/3 Straight. The implants were placed at the lower bone level of the peri-implant bone tissue so that the entire implant platform was covered by bone.

Multicenter study shows no more than 0.43mm of mean horizontal, vertical, and peak bone loss with study PREVAIL[®] Implants.*

Periapical radiographs were taken using the Kodak RVG 6000 Digital Radiography System (Eastman Kodak) in high-resolution mode. Bone loss was measured using the previously calibrated Kodak Trophy software (Eastman Kodak). Then, the following measurements were taken and recorded: distance between the implant and tooth (ITD), horizontal bone resorption (HBR), vertical bone resorption (VBR), distance from the implant shoulder to the interproximal bone peak the day of abutment connection (BPO), distance from the implant shoulder to the bone peak at least six months after loading (BPI), and bone-peak reduction (BPR).

[†]Authors have a financial relationship with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services.

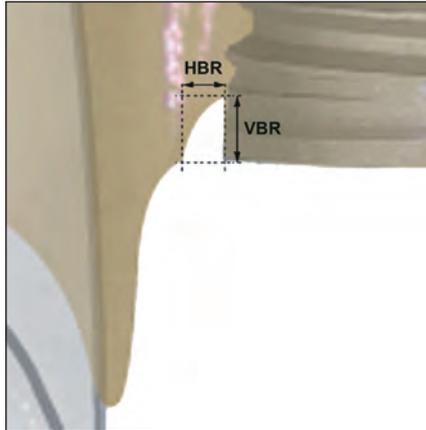
*Summary statement derived from article abstract or poster.

Results

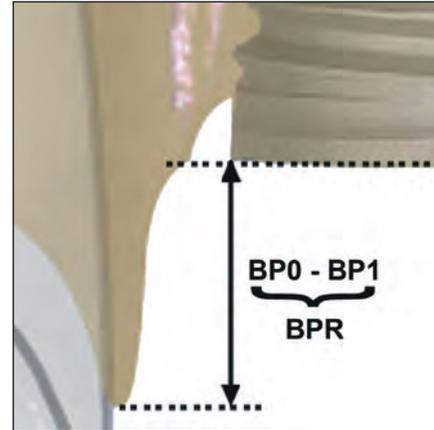
The mean distance between the implant and tooth was 0.99mm (range: 0.20 to 1.49mm); the mean horizontal and vertical bone resorption was 0.36 and 0.43mm, respectively. The mean bone-peak reduction was 0.37mm.

Conclusion

The results confirmed that the use of platform-switched implants reduces bone resorption after two-piece implants have been uncovered and that it is possible to place this type of implant 1mm from teeth while maintaining the bone level adjacent to the bone peak.



Horizontal bone resorption (HBR) measured from the shoulder of the implant laterally to the adjacent bone and **vertical bone resorption (VBR)** measured from the implant shoulder to the most coronal point of bone contact.



Measurement of bone-to-implant contact. **BPO** = distance from the implant shoulder to the interproximal bone peak the day of abutment connection; **BPI** = distance from the implant shoulder to the bone peak at least six months after loading; **BPR** = bone peak reduction ($BPO - BPI$).

Means, Standard Deviations (SDs), and Minimum and Maximum Measurements Obtained for ITD, HBR, and VBR (mm)

| | N | Minimum | Maximum | Mean | SD |
|-----|----------|----------------|----------------|-------------|-----------|
| ITD | 70 | 0.19 | 1.49 | 0.99 | 0.35 |
| HBR | 70 | 0.02 | 1.00 | 0.36 | 0.26 |
| VBR | 70 | 0.02 | 1.90 | 0.43 | 0.37 |

ITD = distance between implant and tooth.
HBR = horizontal bone resorption.
VBR = vertical bone resorption.

SD = standard deviation.

Bone Peak Values

| | N | Minimum | Maximum | Mean | SD |
|-----|----------|----------------|----------------|-------------|-----------|
| ITD | 70 | 0.20 | 1.49 | 0.9987 | 0.35291 |
| BPO | 70 | 0.00 | 4.65 | 1.6854 | 0.96803 |
| BPI | 70 | 0.00 | 3.80 | 1.3133 | 0.94531 |
| BPR | 70 | 0.00 | 1.61 | 0.3721 | 0.41489 |

ITD = distance between implant and tooth.
BPO = bone peak at abutment connection.
BPI = bone peak after six months of loading.
BPR = bone peak reduction.

SD = standard deviation.

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