



**CLINICAL**

Documentation Booklet

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PUBLISHED  
CLINICAL  
STUDIES

## Biocompatibility and osteoconductivity of PLCL coated and noncoated xenografts: An in vitro and preclinical trial



### Author:

Yaniv Mayer Ofir Ginesin Alaa Khutaba Eli E. Machtei Hadar Zigdon Giladi 

### Study device:

1. Alpha Bio's Bioactive bone® (BB) Natural Bovine Bone 0.25-1.0mm, Alpha Bio, Petach Tikva, Israel
2. BioOss® (BO) 0.25-1.0mm, non-sintered bovine bone matrix (NSBM), Geistlich Biomaterials, Wolhusen, Switzerland) - Control

### Study Objective:

The aim of the present study was to compare the viability and proliferation of MSCs onto two commercial xenografts (with or without PLCL coating). The second aim was to compare the histomorphometric bone formation in a socket preservation model in rats.

### Study design:

MSCs were seeded onto monolayers of BO or BB granules. Cell viability and proliferation were evaluated after incubation of 0, 2, 20, and 48 h. A total of 24 Sprague Dawley rats underwent unilateral extraction of maxillary molars. Rats were randomly divided into three groups: natural healing (nongrafted socket) or socket preservation with either BO or BB. Rats were sacrificed after 8 weeks, and histomorphometric analysis was done to evaluate bone formation and residual scaffold at the extraction site.

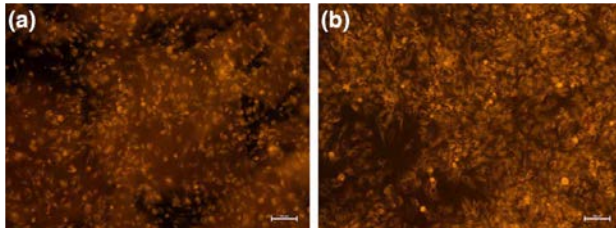


Fig. 2 Adhesion of MSCs over BO scaffold (A) and BB scaffold (B)

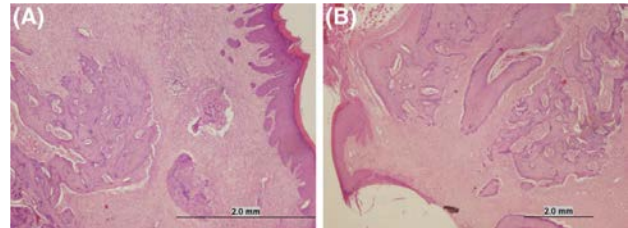


Fig. 3 Histological sections of sockets grafted with BO scaffold (A) and BB scaffold (B). H&E staining

## Results

Differences in the metabolic activity of MSCs that were seeded onto BO or BB was observed at 2 h after seeding: the metabolic activity was elevated compared to baseline in the BB ( $P=0.046$ ) and not changed in the BO wells ( $P=0.84$ ). After 20 h, the metabolic activity of MSCs seeded onto BO was decreasing ( $P=0.005$ ), while cell viability was not changed in the BB group ( $P=0.356$ ). Intergroup comparison revealed higher metabolic activity of MSCs seeded on BB after 48 h compared with BO ( $P=0.016$ ). The in vivo results demonstrated differences in socket healing between the groups: percentage of new bone was higher in the BB compared to BO group (39.1 14.3 vs. 23.7 10.8%, respectively,  $P=0.096$ ). Connective tissue portion was higher in the BO group compared with BB (73.7 11.1 vs. 49.6 13.7%, respectively,  $P=0.018$ ). Residual grafting material was higher in the BB (11.34 4.18 vs. 2.62 1.23%,  $P=0.011$ ).

**TABLE 1** Metabolic activity (fluorescent units) of bone-marrow derived human MSCs seeded on the scaffolds

Group	2 h	20 h	48 h
BB	$0.359 \pm 0.06$	$0.289 \pm 0.1$	$0.329 \pm 0.08$
BO	$0.277 \pm 0.06$	$0.144 \pm 0.01$	$0.129 \pm 0.01$
P value, BB vs BO at each time point	NS	.08	.016

**TABLE 2** Histomorphometric analysis (% total sample area, mean  $\pm$  SD)

Group	% bone	% connective tissue	% residual graft
BB	$39.06 \pm 14.26^{**}$	$49.6 \pm 13.67^*$	$11.34 \pm 4.17^*$
BO	$23.7 \pm 10.77^{\ddagger,***}$	$73.68 \pm 11.05^{*\ddagger}$	$2.62 \pm 1.23^*$
Negative control	$48.86 \pm 12.84^{\ddagger}$	$51.14 \pm 12.84^{\ddagger}$	-

\*BB-BO  $P < .05$ .

\*\*BB-BO  $P < .1$ .

$\ddagger$ BO-NC  $P < .05$ .

## Conclusion:

The results of this study demonstrating higher vitality and proliferation of MSCs seeded onto BB. Furthermore, following ridge preservation, higher percentage of new bone and lower residual scaffold were found in the BB compared with BO. This enhanced regenerative response might be the result of an enhancement of metabolic activity in cells attached to it. Further research will be needed to understand the precise mechanism.

Bioactive bone demonstrate higher vitality, proliferation and new bone formation than the other Xenograft.



## 2 years follow up performance of ICE implant by Alpha-Bio Tec: Retrospective field study



### Authors:

Jerry Kohen, Tal Bar, Sorin Moscovici and Ofer Moses 

### Study objective:

The purpose of this retrospective field study is to examine the marginal bone loss rate around ICE implants after 1 and 2 years of follow up.

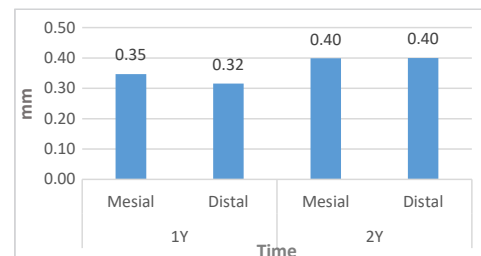
### Study design:

The study was performed in 3 private clinics in Israel on 96 patients over 18-years of age and in good general and dental health. They received a total of 238 ICE implants. Radiographic bone loss data was recorded and analyzed immediately after insertion of the implant (serving as the baseline) and retested after 12 and 24 months.

In the study, digital periapical X-rays and dental medical information were collected and summarized. Digital images were analyzed by an independent examiner for marginal proximal bone loss using ImageJ 1.33 open software (National Institute of Health, Bethesda, MD, USA). The implant length served as a reference for bone loss calculations and the bone level was defined as the distance from the most coronal part of the implant shoulder to the first radiological bone-to-implant contact. Mesial and distal bone level changes in this region were recorded, and the mean of these two values was used.

### Results:

231 implants out of 238 implants survived the 24-month evaluation period (7 implants - 2.9% - were lost due to peri-implantitis).



**Fig 1:** Total Bone Loss Over 2 Years. (Mesial teeth - #1-#2. Distal teeth #3-#6)



The mean change in the marginal bone level after 12 months was 0.35 mm mesial and 0.32 mm distal. The mean change after 24 months was 0.4 mm in both mesial and distal. (Fig. 1) The average increase in bone loss measured between the first and the second year of the study was calculated and found to be 0.065 mm. The effect of the implant dimensions on bone loss was also analyzed. After 12 months, wider implants (4.2 mm) showed less bone loss than 3.75 mm implants. After 24 months, the 4.2 mm implants showed a higher bone loss rate than the 3.75 mm implants. (Fig. 2)

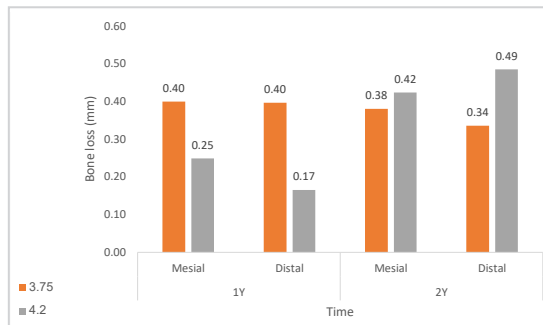


Fig. 2: Effect of Implant Diameter on Bone Loss Over 2 Years

Short implants (10 mm and less) showed higher bone loss after 24 months.

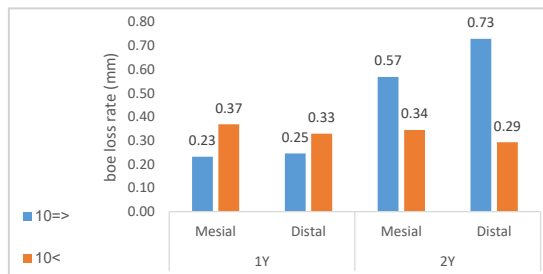


Fig. 3: Effect of Implant Length on bone loss

### Conclusion:

Alpha-Bio Tec's ICE implant system showed a high, 97% survival rate 24-months after implantation, with minimal bone loss levels of 0.4 mm. These results significantly exceed (according to the literature) those recorded by other implant manufacturers.

Alpha-Bio Tec's ICE implant system showed a high, 97% survival rate 24-months after implantation, with minimal bone loss levels of 0.4 mm.

## In-vitro comparative study of bacterial growth on grooved and smooth healing abutments



### Authors:

Ofer Moses, Carlos Nemcovsky, Israel Lewinstein Hasan, Zoabi Miron Weinreb, Shlomo Matalon



### Study device:

Healing abutments.

### Study Objective:

The aim of this in-vitro study was to evaluate the growth of 2 bacterial strains (*Fusobacterium nucleatum* and *Porphyromonas gingivalis*) onto healing abutments, with 2 different surface macro-morphology: one completely smooth and the other groove-marked.

### Study design:

Twenty 5mm-high implant-healing abutments were equally divided into two groups: I: smooth surface, II: groove-marked. *F. nucleatum* and *P. gingivalis* bacteria were cultured on five sterilized healing abutments of each type for 48 hours at 37°C under anaerobic conditions, yielding four experimental groups. Subsequently, abutments were examined under scanning electron microscopy. Attached bacteria were counted on the four vertical quarters of the grooved abutments and the most 2 coronal millimeters of smooth abutments.

### Results:

Bacterial counts in the marking (grooved) areas of the abutments were 20 times greater for *P. gingivalis* and 100 times greater for *F. nucleatum* compared with the smooth surfaces of the abutments ( $P \leq 0.0001$ ). Conclusion. Adherence of both bacterial strains was significantly enhanced within the grooves of the marked healing abutments, while very few bacteria adhered to the smooth zones between grooves and the smooth surface of the non-grooved abutments.

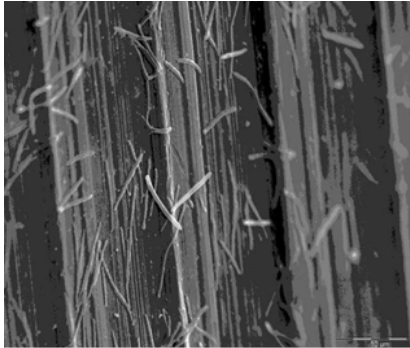


Fig 1: *Fusobacterium nucleatum* growth on a smooth surface. Note the low number of bacteria appearing on the machined surface. The scratches of the CNC manufacturing knife machine are clearly demonstrated in this SEM figure. (mag x2500)

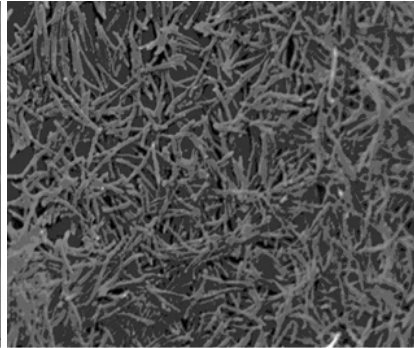


Fig 2: *Fusobacterium nucleatum* growth on the grooved part. The larger number of bacteria within the groove is visually evident.

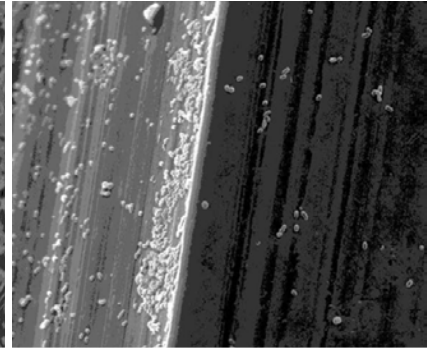


Fig 3: *Porphyromonas gingivalis* growth on the border between the machined surface (dark zone, right side of the photograph) and the groove area (bright zone on the left).

## Conclusion:

We can conclude that grooves marked on healing abutments significantly enhance adherence of *Porphyromonas gingivalis* and *Fusobacterium nucleatum* when compared to machined smooth healing abutments. Gingival wound healing following second stage implant exposure or one stage implant insertion with connection of a smooth healing cap may be better with lower bacterial count.

Gingival wound healing following second stage implant exposure or one stage implant insertion with connection of a smooth healing abutment demonstrated lower bacterial count.

## Differences in crestal bone-to-implant contact following an under-drilling compared to an over-drilling protocol A study in the rabbit tibia



### Author:

Cohen O., Ormianer Z., Tal H., Rothamel D., Weinreb M., Moses O.  

### Study device:

1. Alpha-Bio Tec ICE dental implants.
2. Alpha-Bio Tec SPI dental implants.

### Study Objective:

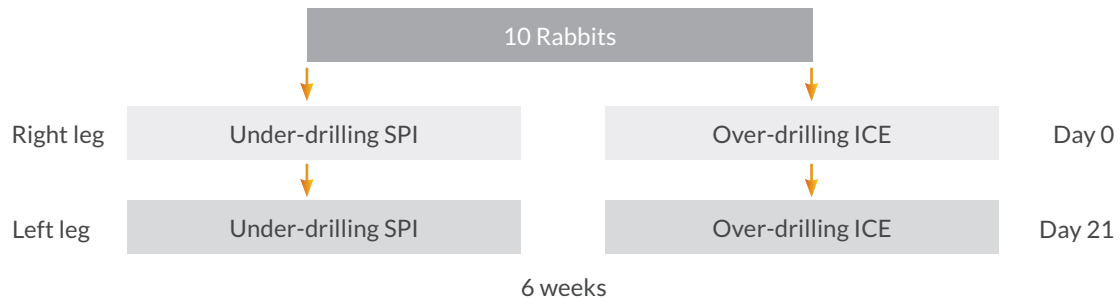
The aim of the study was to compare bone-to-implant contact (BIC) between implants inserted at high torque ( $\geq 35$  Ncm) due to under-drilling of the crestal bone to those inserted at low torque ( $< 10$  Ncm) due to over-drilling of the crestal bone.

### Study design:

Ten male New Zealand white (NZW) rabbits at 21–23 weeks of age (3–3.5 kg) were used in this study. In each tibia, one implant of under-drilling (UD) and one of the over-drilling (OD) were inserted alternately. A total of four implants (two OD and two UD) were installed in each rabbit. In the UD group, SPI® implants with a coronal diameter of 3.75 mm were inserted with bicortical stabilization at torque  $\geq 35$  Ncm. In the OD group, ICE implants with a coronal diameter of 3.55 mm were inserted with torque of  $< 10$  Ncm.

X-rays of the tibiae were taken before and following surgeries to verify the implant location. Twenty-one days following the first implantation, the left leg was subjected to the same surgical procedure. (Fig.1)

The animals were sacrificed 6 weeks after the second surgery implantation. The extracted blocks containing implants were dissected and stained with toluidine blue for evaluation of new bone formation. Crestal bone-to-implant contact (c-BIC, within the crestal compact bone) and total BIC (t-BIC, along the entire implant) were calculated with ImageJ at a magnification of  $\times 100$ .



## study design

## Results

Histological examination revealed that at 3 weeks, implants inserted with an under-drilling (UD) protocol presented areas of bone resorption along the thread pitch while areas of new bone formation were observed within the thread valleys. (Fig 2-3,5) At 6 weeks, histological sections of both groups presented extensive bone remodeling. No differences in t-BIC were noted at 3 weeks ( $18.3 \pm 1.6$  vs  $14.6 \pm 1.3$  %) and at 6 weeks ( $21.8 \pm 1.9$  vs  $23.8 \pm 2.0$  %) between the OD and UD groups, respectively. (Fig. 4)

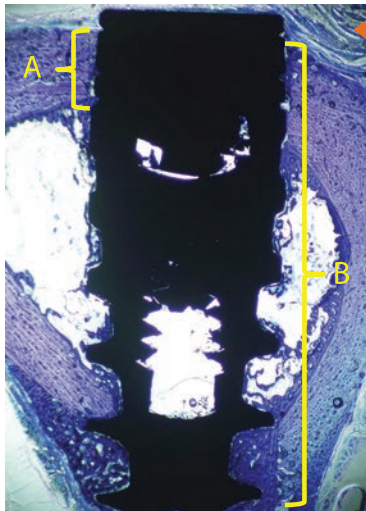
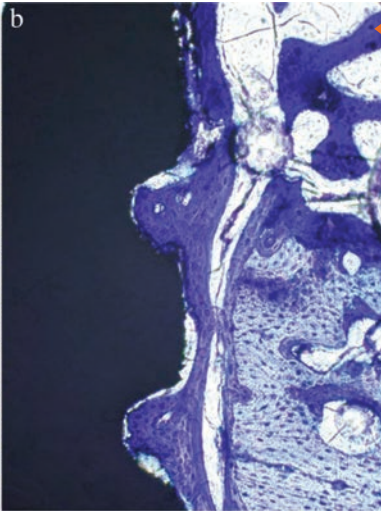
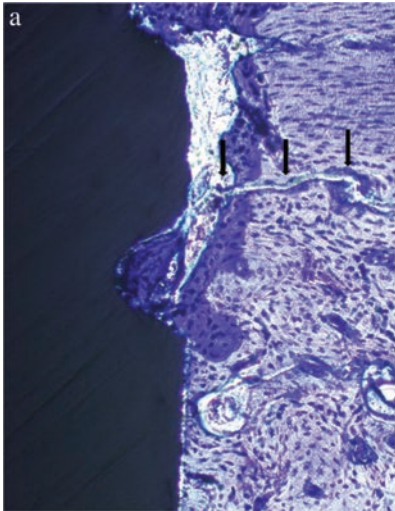


Fig. 2 Micrograph of a whole implant.

A represents the region of crestal cortical bone-to-implant contact (c-BIC).

B represents the region of total bone-to-implant contact (t-BIC).

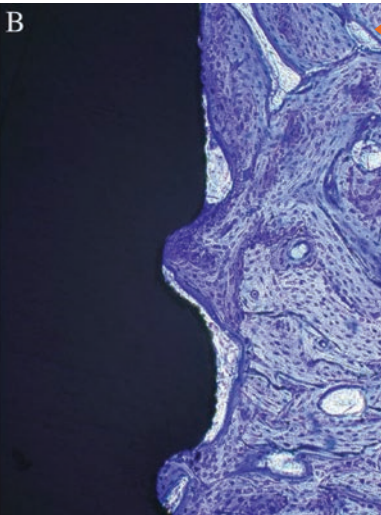
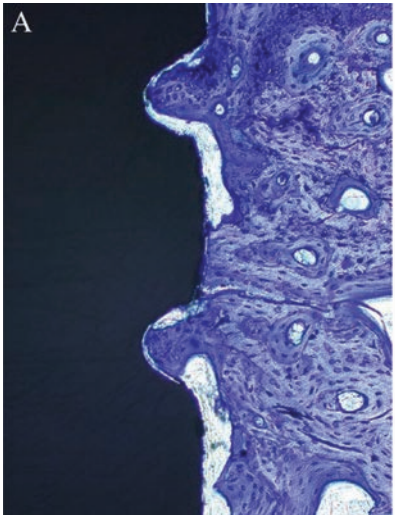
Magnification  $\times 10$



**Fig. 3** Micrographs of a 3-week site.

a Representative section of an implant from the UD group. Bone resorption is seen in areas of the thread pitch while new bone formation is evident in the threads valley. A microcrack (marked by arrows) can be observed.

b Representative section of an implant from the OD group. Extensive new bone formation along the implant surface can be identified. Magnification  $\times 100$



**Fig. 4** Micrographs of 6-week sites.

a Representative section of an implant from the UD group.

b Representative section of an implant from the OD group. Bone remodeling and maturation are apparent in both sections with a more mature bone in the OD group section. Magnification  $\times 100$

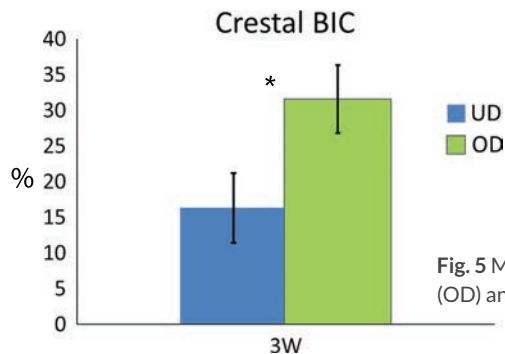


Fig. 5 Mean ( $\pm$ se) c-BIC at 3 weeks (3W) of implants inserted with an over-drilling protocol (OD) and implants inserted with an under-drilling protocol (UD). \* denotes  $p < 0.05$

## Conclusion:

Insertion of implants with a high torque following an under-drilling protocol (commonly used for immediate loading) may reduce short term crestal bone-to-implant contact. On the other hand, over-drilling of the crestal aspect of the osteotomy may result in increased crestal bone-to-implant contact. Further studies using other implant systems and animal models should be conducted to confirm these results.

Low insertion torque may result in increased BIC after six weeks.

## Effect of implant insertion and loading protocol on long-term stability and crestal bone loss: A comparative study



### Author:

Kohen J., Matalon S., Block J., and Ormianer Z. 

### Study device:

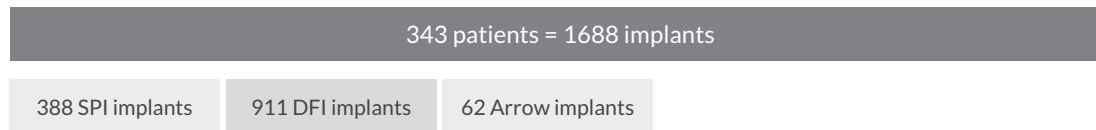
1. Alpha-Bio Tec SPI dental implants.
2. Alpha-Bio Tec DFI dental implants.

### Study Objective:

The purpose of this study was to compare the long-term outcomes of different implant insertion and loading protocols on crestal bone loss.

### Study design:

This retrospective comparative study was performed on a data of 1688 implants that were implanted in 343 patients. (Fig. 1)



**Fig 1.** Distribution of included implants



Patients' records were thoroughly reviewed for medical and dental histories, detailed clinical and radiographic examination, including CT scans, evaluations of oral hygiene, and performance of at least 1 annual hygiene prophylaxis and clinical monitoring. This study spanned 15 years, during which different materials and methods were in use. The surgical procedures were performed by 2 periodontists, 3 maxillofacial and oral surgeons, and 1 general practitioner. The implantation area was incised and flap was elevated. When the socket was more than 1 mm wider than an implant, a bone augmentation was performed with autogenic bone or Bio-Oss (Bio-Oss, Geistlich Sons Ltd.) At the end of the implant placement procedure, the implants were covered with soft tissue, covered with a healing cap, or restored with an interim restoration. Definitive restorations were fabricated 3 to 6 months after implant insertion.

All included in the study implants were divided into 3 different implant placement methods: (Fig. 2)

1. The teeth were extracted and implants were placed immediately.
2. Implants were placed 6 to 8 weeks after tooth extraction.
3. Implants were placed 4 to 6 months after tooth extraction. (Typically for patients with sinus lift augmentation).

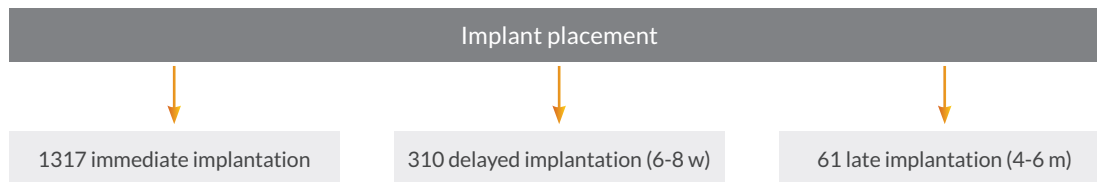


Fig 2. Implant placement methods

3 types of loading were implemented: (Fig. 3)

1. Restorations were fabricated and delivered with the occlusal contacts on the placed implants.
2. Implants were loaded within 4 to 10 weeks.
3. Implants were loaded 3 to 6 months after implant placement.

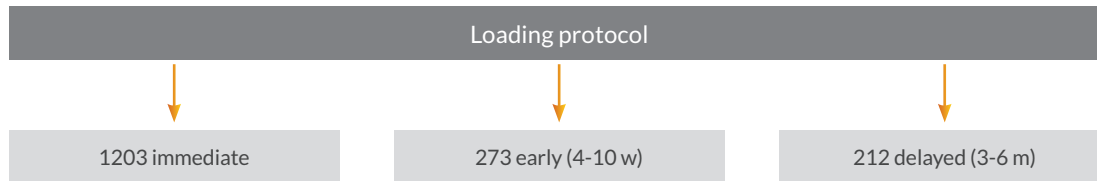


Fig 3. Loading methods

The average follow-up time was 107 months.

## Results:

The cumulative implant survival rate was 95.6%, and the average bone loss was 2.03 mm. No statistically significant differences in bone loss among the different insertion and loading protocol groups.

In further statistical analysis was shown statistically significant effect of SPI implant showing less bone loss than DFI (P=.015), regardless of the insertion and loading protocol.

## Conclusion:

The 3 implant insertion and loading protocols were found to have similar success rates for implant survival, but with marginal differences in bone loss that were not statistically significant. Further analysis of the study groups revealed that SPI types demonstrated less bone loss than DFI types, regardless of the insertion and loading protocol.

Alpha-Bio Tec has long-term (9 years) clinical follow-up with only ~2 mm crestal bone loss.



## Residual Roots as an Anatomical Guide for Implant Placement: Case Series With Two-Year Follow-up



### Author:

Maresh L., Kurtzman GM., Schwartz D., Shukla S.  

### Study Objective:

The aim of this study is to assess the success rate of 100 implants placed in 57 patients when the residual roots were used as anatomical guides for osteotomy.

### Study design:

One hundred implants were placed in 57 patients. Those patients selected for surgery had grossly carious teeth or root canal-treated fractured crowns. Three to 4 weeks after complete prophylaxis, patients were appointed for surgery. Osteotomies were placed through intact residual roots, which acted as anatomical guides for implant surgical placement. Four types of implants were used for this study: 47 Bioner TOP DM (Barcelona, Spain) implants with a diameter of 4 mm, 20 Nobel Biocare Replace (Yorba Linda, Calif) implants with a diameter of 4.3 mm, 25 Biohorizons (Birmingham, Ala) implants with a diameter of 4.6 mm, and 8 Alpha-Bio Tec (Tel Aviv, Israel) implants with a diameter of 4.2 mm. All implants received a 2-stage submerged healing protocol. Following 3 months of site healing to allow integration of the implant and maturation of the osseous graft, the implants were uncovered and prosthetics fabricated. X-rays were taken 2 years after restoration.

### Results:

Patients had a follow-up period of 2 years, and in that time none reported discomfort after implant placement. A radiograph taken at the routine prophylaxis appointment at 2 years postrestoration demonstrated a lack of bone loss at the crestal level and maintenance of the implants and surrounding bone. There were no signs of peri-implantitis observed in any of the patients. Of all the implants placed, the Bioner TOP DM implant showed the least amount of crestal bone loss. Placing implants through residual roots as an anatomical guide is a useful technique that shows good results over a 2-year follow-up period.

## Conclusion:

This treatment approach can be regarded as a useful method for placement of implants. On the other hand, the remaining root fragments do not pose any risk in the process of osseointegration. The results of the present series of cases showed no deleterious reaction during the healing period, during loading implant placement, or during the 2-year follow-up period. Radiographically, the bone-implant interface did not demonstrate any abnormal characteristics. Clinically, the reason for these positive results may be attributed to the fact that the sites were asymptomatic and free of inflammation before implant treatment. Otherwise, periapical inflammation can occur and endanger the implant.



SPI implants demonstrated lack of bone loss after 2 years of follow up.

**THE FULL ARTICLE** > <https://www.ncbi.nlm.nih.gov/pubmed/?term=Residual+Roots+as+an+Anatomical+Guide+for+Implant+Placement%3A+Case+Series+With+Two-Year+Follow-up>



## Dental Implant Thread Design and the Consequences on Long-Term Marginal Bone Loss



### Authors:

Ormianer Z., Matalon S., Block J., Kohen J. 

### Study device:

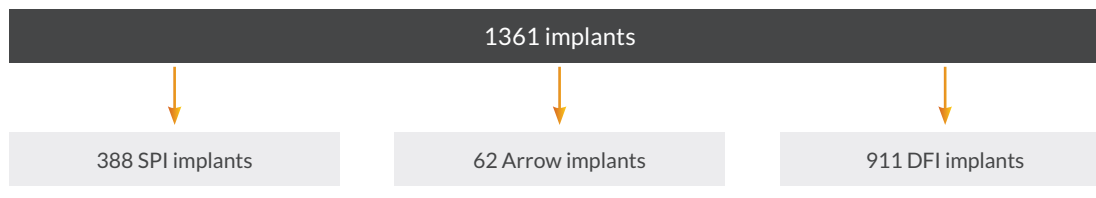
1. Alpha-Bio Tec DFI dental implants.
2. Alpha-Bio Tec SPI dental implants.

### Study Objective:

The aim of this study was to compare long-term bone loss around dental implants with 3 different thread designs. The 3 implant types studied are from the same company and have the same microstructured surface. Survival rates and average bone loss were evaluated.

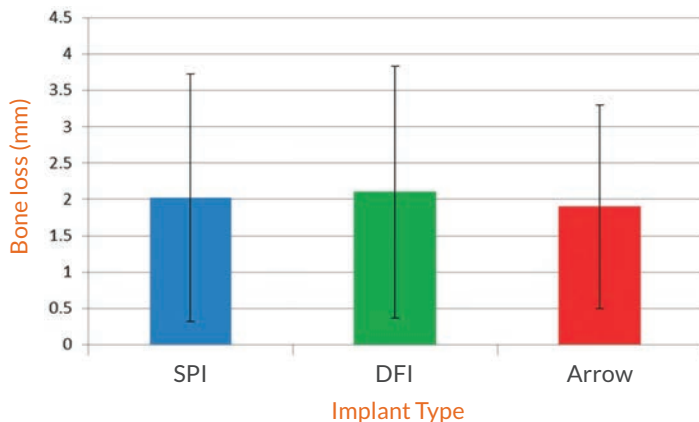
### Study design:

1361 implants were included in the study. The average follow-up time in this study was 107 months, with a minimum follow up time of 82 months. The implants were divided into 3 groups according to the implant type.



## Results:

Overall survival rate was 96.3% with 50 implant failing (3.7%) out of 1361 implants. Survival rates for the 3 groups were: group SPI 96.6%, group DFI 95.9%, and in group Arrow 100%. Average bone loss for groups SPI, DFI, and Arrow were 2.02 ( $\pm 1.70$ ) mm, 2.10 ( $\pm 1.73$ ) mm, and 1.90 ( $\pm 1.40$ ) mm, respectively.



Average mesial-distal bone loss as measured from implant/abutment connection to bone level. The average bone loss was 2.02 (61.70) mm for group A, 2.10 (61.73) mm for group B, and 1.90 (61.40) mm for group C.

## Conclusion:

Favorable long term bone loss results were found in implants with a larger pitch, deeper apical threads, and a narrower implant core (SPI). One-piece V-thread design implants (Arrow) demonstrated 100% survival rate.

SPI and DFI implants showed minimal bone loss (~2mm) after 9 years follow up.

THE FULL ARTICLE > <https://www.ncbi.nlm.nih.gov/pubmed/?term=Dental+Implant+Thread+Design+and+the+Consequences+on+Long-Term+Marginal+Bone+Loss>

## Alpha-Bio Tec's Bioactive Bone for maxillary sinus augmentation: A histologic study on bone regeneration



### Authors:

Delfo D'Alessandro, Giuseppe Perale, Mario Milazzo, Stefania Moscato, Cesare Stefanini, Gianni Pertici, Serena Danti.



### Study device:

Alpha-Bio's Graft Bioactive Bone (SmartBone®)

### Study Objective:

This study aimed at performing an extensive histological investigation to assess the biologic processes leading to new bone formation in 5 patients treated with granular SmartBone® for sinus floor augmentation.

### Study design:

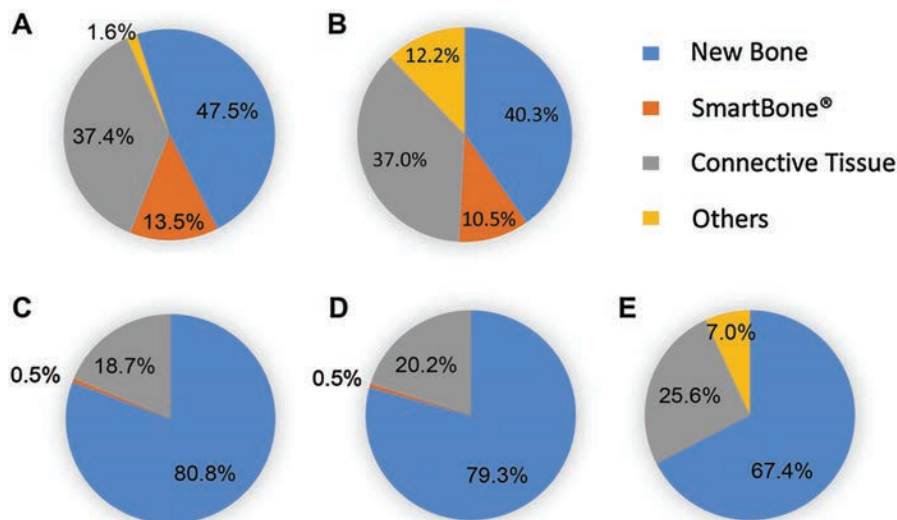
Biopsies were collected from 5 patients who underwent sinus lift procedure with granular SmartBone® (Industrie Biomediche Insubri S/A, Mezzovico-Vira, Switzerland) prior to dental implant placement. SmartBone® was applied by dental surgeons following the instruction for use, as reported by the manufacturer. Bone samples, routinely removed to create a pilot hole for further implant insertion, were used for this study. These samples were cut with a trephine burr and collected at different time points post SmartBone® implantation, namely 4, 4, 6, 7 and 9 months. Bone-particle conductivity index (BPCi) was used to assess SmartBone® osteoconductivity.



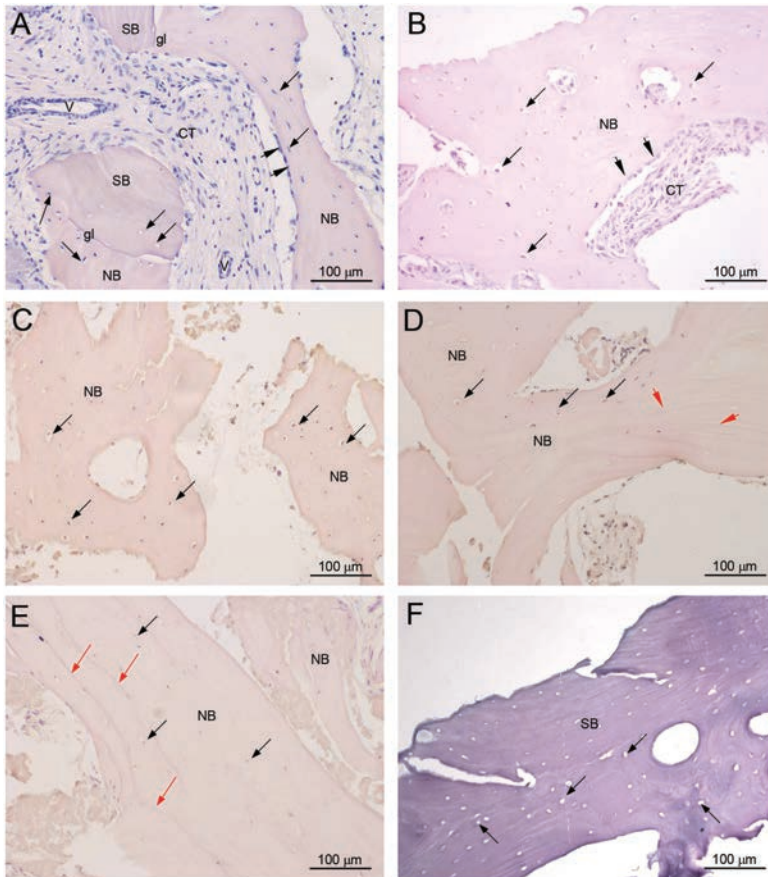
## Results:

At 4 months, SmartBone® (12%) and new bone (43.9%) were both present and surrounded by vascularized connective tissue (37.2%). New bone was grown on SmartBone® (BPCi = 0.22). At 6 months, SmartBone® was almost completely resorbed (0.5%) and new bone was massively present (80.8%). At 7 and 9 months, new bone accounted for a large volume fraction (79.3% and 67.4%, respectively) and SmartBone® was resorbed (0.5% and 0%, respectively). Well-oriented lamellae and bone scars, typical of mature bone, were observed. In all the biopsies, bone matrix biomolecules and active osteoblasts were visible.

The absence of inflammatory cells confirmed SmartBone® biocompatibility and non-immunogenicity.



Histomorphometric analysis showing volume percentages of new bone, SmartBone1, connective tissue, and other tissues in the biopsies taken at the following times post SmartBone® implantation: (A) 4 months (Biopsy #1); (B) 4 months (Biopsy #2); (C) 6 months; (D) 7 months; (E) 9 months. The results show the timeline of SmartBone® resorption (13.5% to 0%) and new bone formation (ranging in 40.3%–80.8%). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)



H&E staining of maxillary bone biopsies and pristine SmartBone1 material. (A) Biopsy #1 at 4 months. (B) Biopsy #2 at 4 months. (C) Biopsy at 6 months. (D) Biopsy at 7 months. (E) Biopsy at 9 months. (F) Plain SmartBone® material. (A-F) Original magnification  $\times 200$ . NB = new bone; SB = SmartBone1; CT = connective tissue; gl = growth line; V = blood vessels; black arrows = bone lacunae; red arrow = bone scar; black arrowheads = osteoblasts; red arrowheads = bone lamellae. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

At 4 months after implantation, both SmartBone® and new bone could be easily identified, due to absence and presence of cells inside bone lacunae, respectively (A and B). Differently, starting from month 6, SmartBone® was rarely observed, indicating that its resorption had already occurred (C-E). H&E performed on plain SmartBone® showed that the graft structure maintained the morphological features typical of bone tissue. In particular, empty bone lacunae, i.e. not occupied by osteocytes, were clearly observed, indicating complete graft decellularization (F).

## Conclusion:

The obtained outcomes showed that SmartBone® is osteoconductive, promotes fast bone regeneration, leading to mature bone formation in about 7 months.

Alpha-Bio Tec's Bioactive Bone promotes fast bone regeneration, leading to mature bone formation within approx. 7 months.

THE FULL ARTICLE > [https://www.ncbi.nlm.nih.gov/pubmed/?term=Bovine+bone+matrix%2Fpoly\(L-lactic-co--caprolactone\)%2Fgelatin+hybrid+scaffold+\(SmartBone%C2%AE\)+for+maxillary+sinus+augmentation%3A+A+histologic+study+on+bone+regeneration](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bovine+bone+matrix%2Fpoly(L-lactic-co--caprolactone)%2Fgelatin+hybrid+scaffold+(SmartBone%C2%AE)+for+maxillary+sinus+augmentation%3A+A+histologic+study+on+bone+regeneration)


The background of the page is a grayscale micrograph of a tissue section, likely stained with hematoxylin and eosin (H&E). It shows various cellular structures, including nuclei, cytoplasm, and extracellular matrix, with some larger, more complex structures that could be glandular or ductal in nature. The overall appearance is that of a histological slide.

We Utilize  
Research  
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## Implant-prosthetic rehabilitation of the edentulous maxilla and mandible with immediately loaded implants: preliminary data from a retrospective study, considering time of implantation



### Authors:

Strietzel FP, Karmon B, Lorean A, Fischer PP. 

### Study device:

1. Alpha-Bio Tec DFI dental implants.
2. Alpha-Bio Tec SPI dental implants.

### Study Objective:

This study sought to evaluate treatment outcomes of implant-prosthetic rehabilitation with implants in the edentulous maxilla or mandible that were immediately loaded by fixed prostheses. Special consideration was given to the time of implantation (immediate, delayed, or late implant placement).

### Study design:

Twenty-five patients who received 283 immediately loaded screw-type implants were included in this retrospective study. Data captured included patient file information, panoramic and periapical radiographs obtained during treatment, and clinical parameters examined during the recall period. Clinical and radiographic status of peri-implant soft and hard tissue was evaluated, as well as the function of prostheses and subjective assessment by the patients of the treatment. Survival/success rates were analyzed with respect to the time of implantation.

## Results:

Following a maximum observation period of 120 months (median 29 months) post-implantation and subsequent immediate functional loading, implant survival was 99.6% (one implant failed after 20 months). The success rates were 98.2% for implants and 88% for patients; five implants in three patients did not meet success criteria. Neither the implant site nor the time of implantation were associated with unsuccessful outcomes. Implant-related evaluations revealed a significant association between implant success and implant length of 10 mm or less ( $P < .018$ ).

## Conclusion:

Immediate loading of rough-surfaced, screw-type implants supporting fixed dentures for the treatment of edentulous maxilla or mandible appears to be a reliable treatment option with a high probability of success. The time of implantation (immediate, delayed or late) did not influence implant survival or success rates.

Alpha-Bio Tec's implant have 99.6% survival rate.



## The efficacy of full-arch immediately restored implant-supported reconstructions in extraction and healed sites: a 36-month retrospective evaluation



### Authors:

Artzi Z, Kohen J, Carmeli G, Karmon B, Lor A, Ormianer Z. 

### Study device:

1. Alpha-Bio Tec DFI dental implants.
2. Alpha-Bio Tec SPI dental implants.

### Study Objective:

The aim of this retrospective study was to compare the outcome of immediately loaded implants that were placed either in fresh extraction sites or in healed edentulous sites with 6, 18 and 36 months of follow up.

### Study design:

Treatment with a full-arch implant prosthesis, either screw-retained or cemented, was assigned to 54 patients. A total of 676 implants (DFI n=515, ITO n=20, SPI n=141) were placed in either immediate extraction sites (n = 367) or in healed alveoli (n = 309), followed by placement of a one-piece provisional prosthesis. The definitive restoration was placed 3 to 6 months after implant placement.

Clinical parameters were recorded and digital radiographs obtained at 6, 18, and 36 months.

## Results:

Osseointegration failed in 21 (3.1%) implants; 13 of these (62%) had been placed immediately after extraction. All occurred within 2 months of the surgical healing phase. Short (8-mm) and narrow (3.3-mm) implant configurations were significantly ( $P < .05$ ) associated with failure. At 6, 18, and 36 months, average crestal bone resorption was 0.18 mm, 0.55 mm, and 0.79 mm for implants placed in fresh extraction sites and 0.31 mm, 0.78 mm, and 1.1 mm for implants placed in healed alveoli, respectively. These differences were statistically significant ( $P < .05$  between sites at all examined periods). Crestal bone resorption also correlated to sites with simultaneous bone augmentation and implant placement.

## Conclusion:

Clinical parameters proved equable whether implants were placed immediately post-extraction or in a healed alveolar ridge. Cross-arch immediate loading of implants placed in extraction and/or healed edentulous sites were predictable and maintainable, as evaluated periodically after 3 years' observation.

Alpha- Bio Tec's implant demonstrated an average of 0.93 mm bone loss after 3 years of follow-up.



**THE FULL ARTICLE** > <https://www.ncbi.nlm.nih.gov/pubmed/?term=The+efficacy+of+full-arch+immediately+restored+implantsupported+reconstructions+in+extraction+and+healed+sites%3A+a+36-month+retrospective+evaluation>

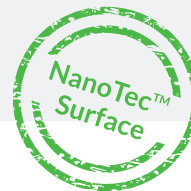






SCIENTIFIC  
AND  
TECHNICAL  
LITERATURE

## Titanium and its alloys in dental implantology: a review of physical characteristics, biocompatibility, and clinical applicability



### Author:

Roland Masa and Gábor Braunitzer 

Product: titanium grade 5 and NanoTec

### Pure titanium and titanium alloys for dental purposes

In contemporary prosthodontics, the use of dental implants is as self-evident as any other established method. Titanium and its alloys are still the most widely used materials for dental and orthopedic applications. Four grades of unalloyed, commercially pure (CP) titanium are available for dental applications, designated as Grades 1 to 4. The alloy Ti-6Al-4V is also referred to as Grade 5. The mechanical properties of the Grade 5 alloy are superior to grades 1-4.

### Adverse reactions to titanium and titanium alloys

Since titanium is a transition metal, allergy or metal hypersensitivity may be a matter of concern. In spite of titanium's excellent biocompatibility, allergy to this metal still can be observed in dental implant patients, although its prevalence is very low. It must be added that titanium exposure from personal care products and biomedical implants is common, and still there is no reliable evidence for actual toxicity or real allergic reactions.

According to the literature, it is the occasional and otherwise negligible "impurities" (i.e. extra elements beside titanium such as Ni, Cr, Cu, Pd, Mn) that trigger hypersensitivity reactions. Such cases, however, are rare, and titanium implants for prosthodontic purposes can be considered safe and reliable for the general population.

## Dental implant surface modifications

Both implant design and surface properties play significant role in implant success.

Various surface treatments have been developed, generally classified into two major categories: physicochemical and biochemical. The Sand blast Large grit Acid etch (SLA) method that combines two physicochemical methods. As the name suggests, the surface is first sand-blasted with large grit corundum ( $Al_2O_3$ ) particles, then acid-etched with HCl and  $H_2SO_4$ . The result is a moderately rough surface characterized by rapid osseointegration, and is therefore optimal even for early implant loading.

## Conclusion

The excellent biocompatibility and physico-chemical properties of titanium dental implants position titanium as the “gold standard” in implant dentistry. While the safety and success of Grade 4 titanium is well documented, Grade 5 offers better physical properties and similarly outstanding biocompatibility and survival. As for the various surface modifications, SLA appears to combine the advantages of the physical and chemical methods successfully, which makes it a favorable alternative. High levels of osseointegration and favorable long term survival of SLA dental implants were confirmed by several in vitro and clinical studies. Based on the current literature, we can conclude that Grade 5 titanium with SLA modified surfaces assure the best dental implantation outcomes. Hypersensitivity or allergic reactions to titanium or other alloy ingredients are extremely rare but still occur, necessitating the implant dentist to be aware of this possibility and to pay special attention to the patient’s history.

**Grade 5 titanium with SLA modified surfaces assure the best dental implantation outcomes.**



## Implant Collar Surface Properties and Marginal Bone Loss



### Author:

Helena Gryner, R&D, Alpha- Bio Tec 

Osseointegration is an essential requirement for allowing the survival of dental implants in the jaw bone. Factors such as unfavorable stress distribution, surgical trauma, implant-abutment microgap, and bacterial infiltration can detrimentally affect osseointegration (1, 2) and accelerate bone loss.

According to the literature, most if not all implants will cause to some extent marginal bone Loss (MBL) during their lifetime (3). Efforts have been made to reduce MBL and to avoid its associated complications. Studies have shown that several factors such as implant surface quality (4) implant neck macro and micro design (5) and crestal implant position (6) play particularly crucial roles in osseointegration.

Surface area may be increased using proper modification techniques, either by addition or subtraction procedures. Surface treatments can also be classified as mechanical, chemical, and physical methods. Surface treatments of dental implants are used to modify their topography and energy, resulting in improved wettability, increased cell proliferation and growth, and in accelerated osseointegration (7).

Alpha-Bio Tec's Sand blast Large grit Acid etch (SLA) implant surface is created through two processes: a sand-blasting process for a macro surface of 20-40 microns and a double thermal acid etching process to create micro pitting between 1-5 microns.

There is no consensus in the literature concerning the effectiveness of various implant surface neck configurations and their effect on MBL. The aim of this review is to compare the influence of machined and SLA neck surface on MBL levels during the implant's existence in the bone.

Limited available data suggests that smooth surfaces (machined) are less involved in peri-implantitis than rough surface implants (8). This observation is potentially supported by reduced plaque accumulation around the implants with a reduced roughness (9). However, further research has shown that surface porosity impacts on osseointegration by allowing direct 3D ingrowth of osteogenic cells into the implant, thereby strengthening the bone-implant interface (10).

Acid etched surfaces enhance the osseointegration by increasing cell adhesion and bone formation (7). This hypothesis was demonstrated in in-vitro studies showing osteoblasts growing on SLA surfaces. These osteoblasts are highly differentiated bone cells, suggesting that this pitted surface enhances bone cell-implant integration (11).

Preclinical and clinical studies suggest that there are several factors that individually and cumulatively influence MBL levels. Therefore, studies have been conducted that typically combine two or more crestal neck features to evaluate the best combination of features to reduce MBL.

Certain studies did not confirm that a rough surface combined with a microthreaded neck has a positive effect on the MBL (12). However, the majority of the reviewed works show a different picture.

Bratu et al. (2009) compared marginal bone loss between implants with SLA treatment and coronal microthreads and polished neck implants. The results showed statistically significant lower MBL in combined SLA/microthread implants.

Another study showed a greater bone loss in implants with a machined surface neck design without microthreads in the first year (9).

The long term study of Piao et al. showed that a rough surface with micro-threads at the coronal part of implant maintained the marginal bone level against functional loading better than implants without these two features after a follow up of one year (13) and confirmed these results after a three year follow up (14).

Additionally, Shin et al. (2006) have shown in their work that a rough surface and micro-threads at the implant neck not only reduce crestal bone loss but also help with early biomechanical adaptation against loading in comparison to the machined neck design. They concluded that a rough surface with microthreads at the implant neck is the most effective design in maintaining the marginal bone level against functional loading (15).

In another study, a correlation between collar design, implant placement and MBL in a canine model was evaluated. The study data showed that the placement of a polished area subcrestally facilitates higher rates of early MBL (6), whereas a rough implant surface placed at the bone level reduces the amount of this bone loss (16, 17).

## Conclusion:

Based on the reviewed literature, we can conclude that marginal bone changes around rough-surfaced micro-threaded neck implants are significantly lower than in polished or rough surfaced implants. All Alpha-Bio Tec's implants have rough SLA surface and microgrooves which contribute to osseointegration and reduce MBL.

**Ruff surface and micro-threaded neck are optimal conditions for minimal bone loss.**



## Advanced Drills Line Overview



### Author:

Assaf Sharon, R&D, Alpha- Bio Tec 

### Study device:

Alpha-Bio Tec advanced drills.

### Study Objective:

To validate drill performance with the Alpha Bio Tec's designed system which measures heat generation and mechanical forces.

### Study design:

A broad literature review was performed and summarized various design features that should be adjusted in order to:

- Create minimal temperature rise during the drilling process
- Optimize drilling stability
- Ease penetration

These features were implemented in Alpha-Bio Tec's advanced drills design and planning.

Drill Parameter Design	Literature Suggested	Selection Explanation	Alpha-Bio Tec Drills
Use of coolant	External irrigation	External irrigation is more efficient than internal irrigation on the surface and at the upper section of the osteotomy (dense cortical section). Field experience shows blockage on internal irrigation lumen.	External irrigation
Flutes	3 flutes	Three flutes exhibit superior bending stiffness. Theoretically, they should also exert less heat on the bone due to enhanced cutting efficiency and less torques at larger drill's diameter.	3 flutes design
Helix Angle	10°-30°	For surgical drills, the range of 10°-30° helix angle is recommended to have best cutting efficiency, according to literature and Alpha-Bio Tec's testing.	Within the range
Rake Angle	20°-30°	An optimum rake of 20°-30° was recommended to have best cutting efficiency.	Within the range
Relief & Body	With both	Clearance Both relief angle and body clearance reduce the heat generation due to the reduced bone to drill contact during osteotomy preparation.	Both included
Point Angle 90°	90° (Initial drill)	90° point angle for the initial drills.	90°
	100°-130° (all other drills)	Range of 100°-130° point angle for all following drills diameters.	Within the range
Step vs. Straight	Step	Step drill bit has a highly effective design that minimizes temperature elevation due to gradual removal of material from the drilling site. Step drill assists in centralizing the drilling process due to the lower drill step leading the way through the predrilled site. Step drills increase osteotomy accuracy in cases where drill sequence requires cortical release.	Alpha-Bio Tec supplies both Step & Straight

Alph Bio Tec drills have optimal design leading to better function and bone preservation.



## Quantitative and qualitative element – analysis of implant – surfaces by SEM and EDX



### Principal investigator:

Dr. Dirk Duddeck. 

### Study device:

SLA implant surface.

### Study Objective:

The goal of this study was to evaluate the behavior of neonatal rat calvarial osteoblast-like cells cultured on different titanium discs with different surface roughness properties and of different composition. DNA synthesis, number of cells, and cell viability were evaluated. Cells were also analyzed for the possible changes in morphology by scanning electron microscopy (SEM).

### Study objective:

The aim of the study is to verify improvements of manufacturing and quality management as well as to demonstrate the high quality level of the participating manufacturers and implant companies.

### Study design:

SEM device used for the acquisition of the surface topography (Phenom proX, Phenom-World, Eindhoven, Netherlands) has a highly sensitive detector for backscattered electrons (BSE) that facilitates inferences about the composition of the examined material as the so-called material contrast image emerges. Elements with a low atomic number, i.e. with fewer electrons, such as carbon or aluminium are shown as relatively dark areas, while elements with high atomic numbers such as titanium or zirconium appear relatively bright.





## Alpha-Bio Tec Quality Assurance (QA) department performs a routine Quality Assurance (QA) and Quality Control (QC) procedures

### Authors:

Polina Pavlovsky and Osnat Harari, QA, Alpha- Bio Tec and Prof Ofer Moses.



### Study device:

Alpha-Bio Tec SPI dental implants.

### Study Objective:

This study describes routine Quality Assurance (QA) and Quality Control (QC) procedures performed by the Alpha-Bio Tec QA department on implants, and to demonstrate the composition and chemical bonding analysis of Alpha-Bio Tec dental implant.

### Alpha-Bio Tec Implant Surface:

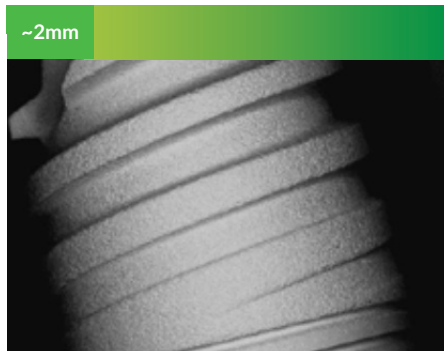
The Alpha-Bio Tec Implant Surface is created through a sand-blasting process to form a macro surface of 20-40 microns and a double thermal acid etching process to create micro pitting between 1 to 5 microns. The advantages of this implant surface - confirmed by retrospective clinical data showing an overall clinical success rate of 98.3% and a 99.6% when using the immediate loading procedure.

### QA, QC and Regulation:

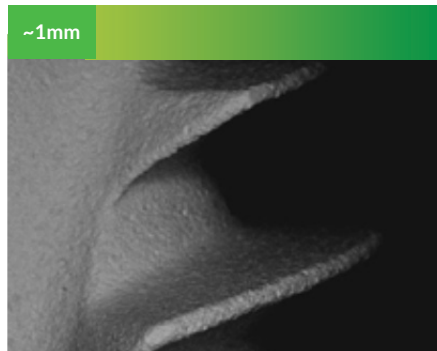
Alpha-Bio Tec products are compliant with the following systems and standards: ISO 13485:2003, The Canadian Medical Devices Conformity Assessment System, Council Directive 93/42/EEC. SPI implants have also the FDA approval for immediate loading.

### The Design:

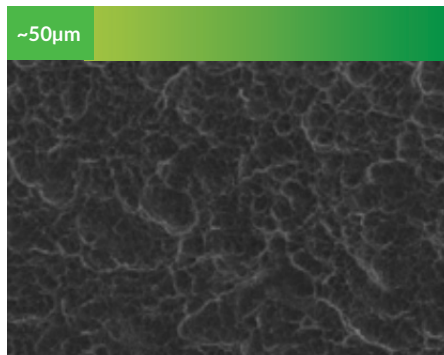
Implant surface was observed by SEM (Scanning electron microscopy) with (Backscattered electron imaging) BSE and (Secondary electron imaging) SE field. SEM images were taken from various parts of the implant.



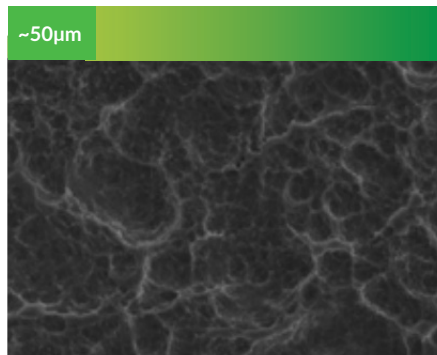
1. Coronal part overview as observed by SEM



2. Apical part overview as observed by SEM



3. Surface morphology of the coronal part



4. Surface morphology of the apical part

(X-ray photoelectron spectroscopy) XPS is a surface-sensitive quantitative spectroscopic technique measures the elemental composition.

## Conclusion:

The report demonstrates the excellent surface cleanliness and structure of Alpha-Bio Tec implants through SEM and XPS examinations. The atomic composition that is demonstrated in this report, proves the excellent purity of the ABT implant.

Alpha-Bio Tec's Implant's surface demonstrated excellent surface cleanliness.

THE FULL ARTICLE > <http://alphabioendpoint.azureedge.net/media/4049/995-0350-r2-05-15-implant-purity-report-english-email.pdf>

## The Influence of Titanium Surfaces in Cultures of Neonatal Rat Calvarial Osteoblast-Like Cells: An Immunohistochemical Study



### Authors:

Aybar B., Emes Y., Atalay B., Tanrikulu SI., Kaya AS., Issever H., Ceyhan T, and Bilir A.



### Study device:

NanoTec™ surface.

### Study Objective:

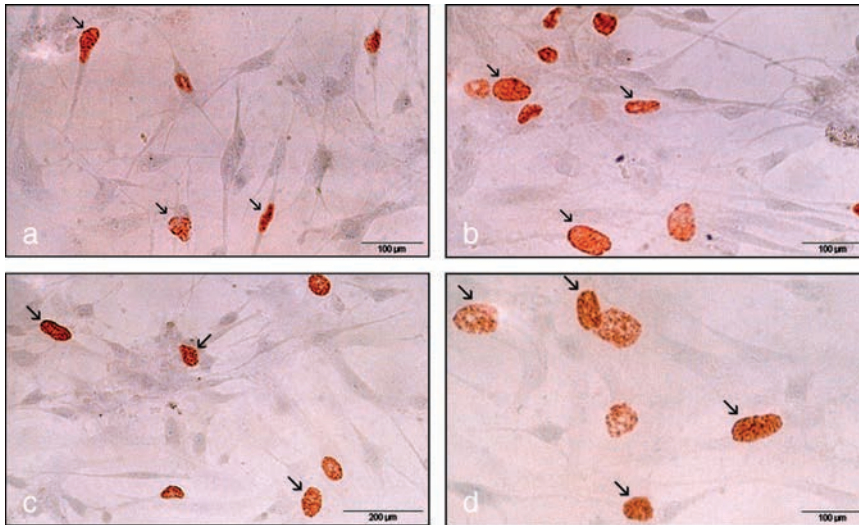
The goal of this study was to evaluate the behavior of neonatal rat calvarial osteoblast-like cells cultured on different titanium discs with different surface roughness properties and of different composition. DNA synthesis, number of cells, and cell viability were evaluated. Cells were also analyzed for the possible changes in morphology by scanning electron microscopy (SEM).

### Study design:

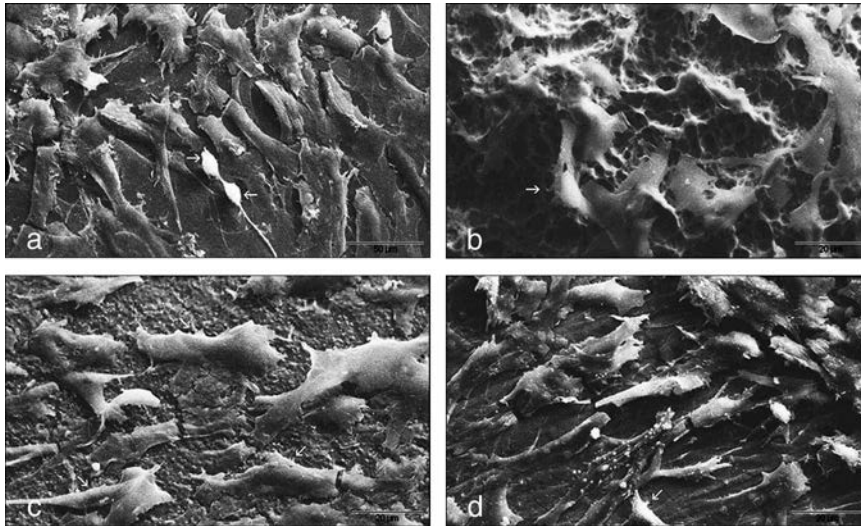
Sandblasted acid etched (SLA) surfaces of 2 different companies with different alloy properties were used. These were named as SLA-1 and SLA-2. The osteoblasts behavior were analyzed on sand blasted acid etched (SLA-1) surface (Straumann, Basel, Switzerland), sand blasted-acid etched (SLA-2) surface (Alpha bio, Petach-tikva, Israel), acid etched surface (Alpha bio), machined surface (Alpha bio). To analyze the effect of titanium surfaces on cell proliferation, cell numbers, and cell viability cells were cultured on titanium discs for 7 days and measurements were held out at 24 hours and on day 7. Cell proliferation rate was assessed by bromodeoxyuridine (BrdU) immunohistochemical technique. Cell morphologies were evaluated by scanning electron microscopy.

## Results:

The highest number of BrdU labeled cells were seen on SLA-1 group at the end of 24 hours. The number of cells was found to be the highest in the acid-etched group on the 7th day, even though there were no significant differences between the groups at the end of 24 hours. Scanning electron microscopy views showed the morphological differences between the groups. Osteoblasts were able to proliferate on all of the tested surfaces, with differences in cell count and DNA synthesis values between the groups.



BrdU incorporations of the SLA-1, SLA-2, AE, and MS groups on the 7th day. a, cells on 7th day on SLA-1 surface (bar 100 µm). b, cells on 7th day on SLA-2 surface (bar 100 µm). c, cells on 7th day on AE surface (bar 200 µm). d, cells on 7th day on MS (bar 100 µm).



SEM views of the osteoblast-like cells cultured on CD, SLA-1, SLA-2, AE, and machined surfaces on 7th day. a, SEM images of the SLA-1 group on the 7th day shows cells of polygonal shape. Mitosis dividing is also observed. And there is a firmly connection and decreased number of villi are seen in this group (bar 50  $\mu\text{m}$ ). b, SEM images of the SLA-2 group on the 7th day, cells with the loss of villi in the connecting surfaces of the cells (bar 20  $\mu\text{m}$ ). c, cells on 7th day on AE surface, shortening of cytoplasmic extensions is observed. Cytoplasmic extensions are fewer in number (bar 20  $\mu\text{m}$ ). d, cells on 7th day on machined surface (bar 20  $\mu\text{m}$ ).

## Conclusion:

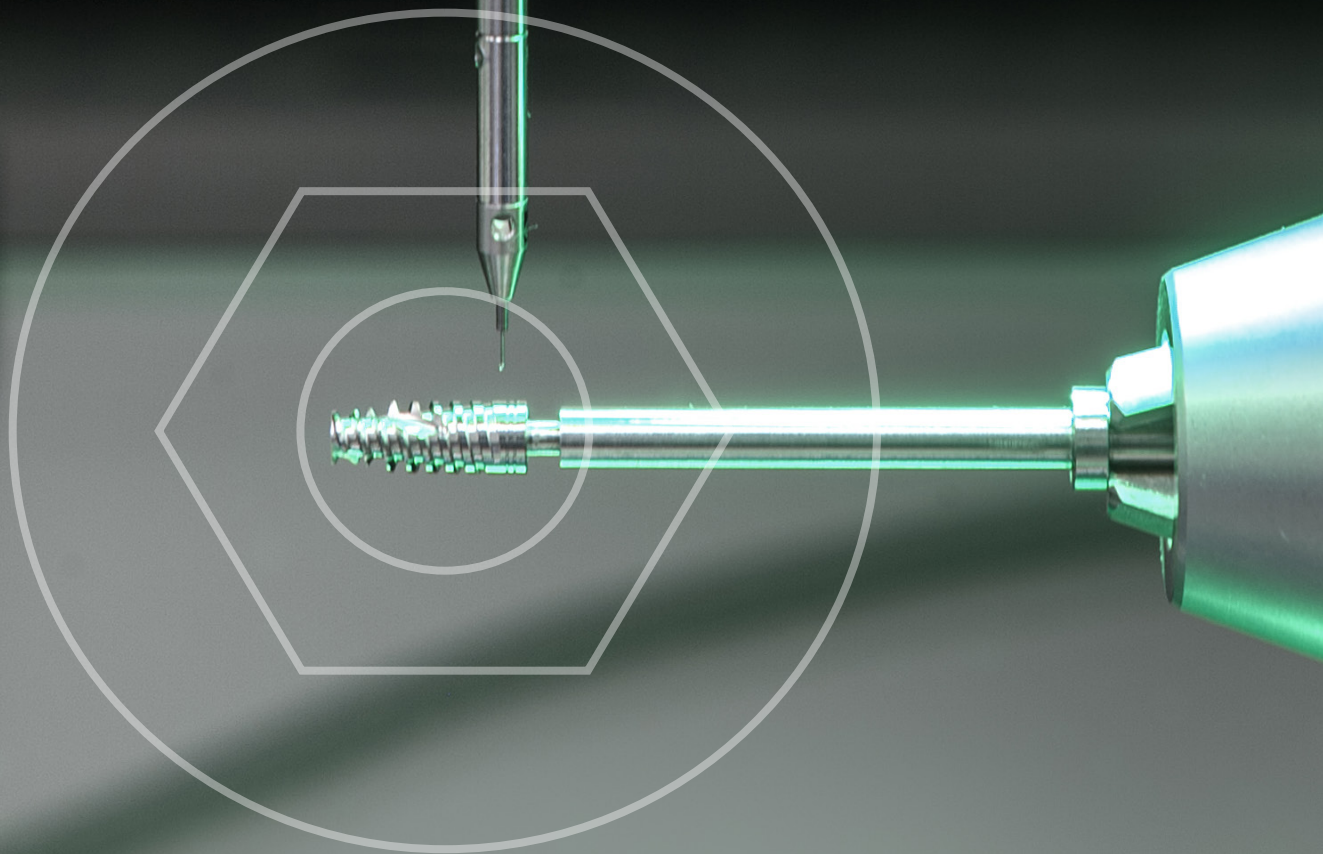
Even though our results show no differences between the groups for cell proliferation, cell viability, and DNA synthesis, which can be considered as clinically significant, SLA surface implants are being widely used today for their mechanical increased stability in bone. Implant surface characteristics may modulate the biological response of osteoblast-like cells depending on the manufacturing techniques and cell culturing procedures.

Alpha-Bio Tec's NanoTec™ surface induces bone cells for osseointegration similar to premium implant SLA surfaces.

THE FULL ARTICLE >

<https://www.ncbi.nlm.nih.gov/pubmed/?term=The+Influence+of+Titanium+Surfaces+in+Cultures+of+Neonatal+Rat+Calvarial+Osteoblast-Like+Cells>

SM25-1







POSTERS

## The effect of coronal implant design and drilling protocol on bone-to-implant contact



### Author:

Ofer Moses, Omer Cohen and Dieter Bosshardt.  

The aim of this preclinical study was to evaluate and compare various implant coronal part designs on the percentage of bone-to-implant contact (%BIC) and bone density by means of histomorphometry.

Within the limitation of this study, it can be concluded that the implants with 2 coronal flutes showed better %BIC values in the neck portion after 1 month and after 3 months and higher amounts of old bone ( $p < 0.05$ ) and lower amounts of new bone ( $p < 0.05$ ) compared to the other implant neck designs regardless of the drilling protocol. These data must be interpreted cautiously, since the influence of the implant design could be masked by the non-random position in the cranial bone displaying different bone densities.



### Background

Many factors have been found to influence the interfacial bonding between a dental implant and bone and thus the success of implants. Factors such as surgical technique, host bed, implant design, implant surface, material biocompatibility and loading conditions have all been shown to affect implant osseointegration. Understanding these factors and applying them appropriately in the development of dental implants can lead to achieve predictable osseointegration and thus minimizing potential implant failures. Reduced coronal stress might affect initial implant stability.

### Aim

The aim of this preclinical study was to evaluate and compare various implant coronal part designs on the percentage of bone-to-implant contact (%BIC) and bone density by means of histomorphometry.

### Methods and Materials

In 13 female Sinclair minipigs, 7.5 months of age and 48-53kg in weight, 102 NeO implants (Titanium Grade V, Ra-1.6µ) Ø3.75/7.5mm with **4 different coronal parts designs**: (6 coronal flutes and deep microthreads, 6 coronal flutes and regular microthreads, 2 coronal flutes, 0 coronal flutes) (Fig. 1) were placed in the parietal bone. Under general anesthesia, a linear skin incision was made to expose the bone surface. The osteotomies were prepared with 2 different drilling protocols (standard under-drilling protocol and "extra" under drilling protocol).

A cover screw was used to seal the implant's hexagon followed by suturing and wound closure. RFA measurements were taken before covering the implants. Healing periods were 1 month and 3 months. Non-decalcified ground sections of the methymethacrylate (MMA)-embedded tissue samples were produced with a diamond-coated wafer blade and stained with toluidine blue – fuchsin. In order to gain uniformity in the sectioning plane, a pre-positioning phase using micro-CT and cone beam CT (CBCT) scanning of the MMA blocks preceded the sectioning process. The percentage of bone-to-implant contact (%BIC) and bone density (i.e. area fraction) were

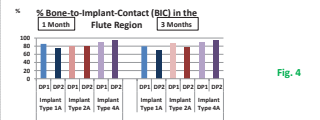
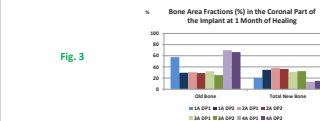
histometrically evaluated.

### Results

Healing occurred uneventfully in all animals. Low and high magnifications showed new bone close to the implant (Fig 2) profile along with blood vessels with no signs of inflammation. The implants have shown full integration and adaption of their macro- and microdesign to the surrounding bone.

The implant type with 2 flutes showed the highest total %BIC values after 1 and 3 months (Fig 3). The total %BIC values for the implant type with 6 flutes and deep microdesign were higher than those for the implant type with 6 flutes and regular microthreads. The 2 drilling protocols did not seem to have an influence on %BIC.

Regarding bone density after 4 weeks in the coronal implant part, the implant type with 2 flutes showed the highest values for old bone and the lowest values for new bone (both being stat. sign. different from the 3 other implant types) (Fig 4). These interesting findings support the assumption of a great influence of the pre-existing bone density on the outcome, possibly overruling or at least diminishing the influence of the implant neck design on bone formation.



### Conclusions

Within the limitation of this study, it can be concluded that the implants with **2 coronal flutes showed better %BIC values in the neck portion after 1 month and after 3 months and higher amounts of old bone (p<0.05) and lower amounts of new bone (p<0.05)** compared to the other implant neck designs regardless of the drilling protocol. These data must be interpreted cautiously, since the influence of the implant design could be masked by the non-random position in the cranial bone displaying different bone densities.

### References


1. Vivan Cardoso et al. (2015) Clin Implant Dent Relat Res. 17(4):639-45
2. Jimbo et al. (2104) Int J Oral Maxillofac Surg. 43(7):883-8



## In-vitro comparative study of bacterial adherence to grooved and smooth healing abutments.



### Author:

Ofer Moses, Carlos E. Nemcovsky, Israel Lewinstein, Hasan Zoabi, Miron Weinreb, Shlomo Matalon. 

This in-vitro study evaluated the adherence of 2 bacterial strains (*Fusobacterium nucleatum* and *Porphyromonas gingivalis*) onto healing abutments with 2 different surface macro-morphology: one completely smooth and the other groove-marked.

Twenty, 5mm-high, sterilized implant healing abutments (AlphaBio Tec LTD, Petach Tikva, Israel) were equally divided into two groups: I: smooth surface, II: groove-marked. They were dipped into anaerobic cultures of *F. nucleatum* or *P. gingivalis* (five abutments each) for 48 hours at 37°C, yielding four experimental groups. Subsequently, abutments were examined with scanning electron microscopy. Adhered bacteria were counted on the 2 coronal grooves of the grooved abutments and on the 2 most coronal millimeters of the smooth abutments. Results were analyzed by two-way ANOVA after application of square root transformation for normal distribution.

Bacterial counts in the marking (grooved) areas of the abutments were 20 times greater for *P. gingivalis* and 100 times greater for *F. nucleatum* compared with the smooth surfaces of the abutments ( $P \leq 0.0001$ ).

Bacterial adherence of both strains onto the grooves of the marked healing abutments was significantly enhanced while very few bacteria adhered to the smooth zones between grooves and the smooth surface of the non-grooved abutments.

# In-vitro comparative study of bacterial adherence to grooved and smooth healing abutments.

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## Abstract

**Objectives:** This in-vitro study evaluated the adherence of 2 bacterial strains (*Fusobacterium nucleatum* and *Porphyromonas gingivalis*) onto healing abutments with 2 different surface macro-morphology: one completely smooth and the other groove-marked.

**Materials & Methods:** Twenty, 5mm-high, sterilized implant healing abutments (AlphaBio Tec LTD, Petach Tikva, Israel) were equally divided into two groups: I: smooth surface, II: groove-marked. They were dipped into anaerobic cultures of *F. nucleatum* or *P. gingivalis* (five abutments each) for 48 hours at 37°C, yielding four experimental groups. Subsequently, abutments were examined with scanning electron microscopy. Adhered bacteria were counted on the 2 coronal grooves of the grooved abutments and on the 2 most coronal millimeters of the smooth abutments. Results were analyzed by two-way ANOVA after application of square root transformation for normal distribution.

**Results:** Bacterial counts in the marking (grooved) areas of the abutments were 20 times greater for *P. gingivalis* and 100 times greater for *F. nucleatum* compared with the smooth surfaces of the abutments ( $P \leq 0.0001$ ).

**Conclusion:** Bacterial adherence of both strains onto the grooves of the marked healing abutments was significantly enhanced while very few bacteria adhered to the smooth zones between grooves and the smooth surface of the non-grooved abutments.

## Methods and Materials

The study comprised of 20 Titanium implant-healing abutments (AlphaBio Tec LTD, Petach Tikva, Israel), divided into two groups: I- flat healing abutments with machined surface (Fig 1); II- healing abutments with a marked (grooved) surface (Fig 2).

**Bacterial culturing conditions:** *Fusobacterium nucleatum* (Becton, Dickinson and Company, USA) and *Porphyromonas gingivalis* (OXOID LTD, Basingstoke, Hampshire, England) were cultured on five smooth surfaced and five grooved healing abutments. Sterilized abutments were immersed in medium in a 96- well microtiter plate (Nunc, Copenhagen, Denmark). Bacteria were added to each well and plates were incubated for 48 hours at 37°C under anaerobic conditions. Subsequently abutments were examined with SEM (x2500).

Attached bacteria were counted on the four vertical quarters of the grooved abutments, separating smooth and groove areas and on the coronal 2 millimeters of the smooth abutments (surface area of 958  $\mu\text{m}^2$  for each quarter) using Image J 1.4 software (NIH Bethesda, Maryland USA).

Results were statistically analyzed by two-way ANOVA after square root transformation was applied for normal distribution.



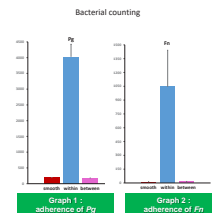
Fig 1. Smooth healing abutment



Fig 2. Grooved healing abutment

• Examples of smooth and grooved surfaces of the abutments seen under SEM are shown in figures 3-8. Bacterial adherence is much more pronounced in the groove areas of the abutments compared with the smooth areas between the grooves and the machined smooth abutments.

• Mean bacterial counts are presented in Graphs 1 (Fn) and 2 (Pg). First, bacterial counts for both strains were similar on the smooth areas between the grooves of the marked healing abutments and the totally smooth healing abutments. Second, bacterial adherence of Fn to the third and most important, total bacterial counts for both strains in the groove areas were significantly higher ( $p \leq 0.0001$ ) compared with those in the smooth areas. The mean Pg count was ~20-times greater and that of Fn, was over 100-times larger in the grooves compared with the smooth surfaces.



## Background and Aim

Healing abutments are usually placed on dental implants either immediately following their insertion or at the time of their exposure to the oral cavity.

Although these healing abutments are likely to remain in place for only a short time, they are exposed to bacterial colonization in the oral cavity. The abutment surface characteristics may have a relevant role in promoting or delaying plaque accumulation, which could have an effect on the peri-implant soft tissues (1,2).

The aim of this in-vitro study was to evaluate and compare adherence of these 2 strains of known periopathogenic bacteria (*Fusobacterium nucleatum* and *Porphyromonas gingivalis*) onto healing abutments, from the same manufacturer, made of the same titanium alloy, but with different surface macro-morphology: one completely smooth and the other, CNC machine-grooved for depth measurement.

## SEM Photographs of bacterial adhesion to grooved and smooth healing abutment

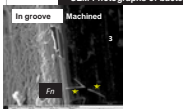


Fig 3. Fn on the border between smooth part and grooved part. Large bacterial colonies are present in the groove.

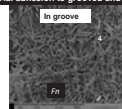


Fig 4. Large number of Fn within the groove area of the healing abutment.

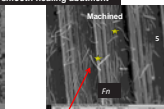


Fig 5. Fn on smooth surface. Note low bacterial numbers. Scratches created by CNC knife.

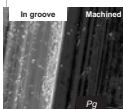


Fig 6. Pg on the border between smooth and grooved part. Large colonies present in the groove.

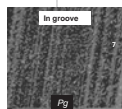


Fig 7. Large number of Pg within the groove area of the healing abutment.

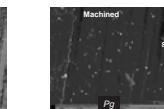


Fig 8. Low numbers of Pg bacteria on smooth surface. Scratches created by CNC knife.

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## Conclusions

Within the limitations of this in vitro study, we can conclude that grooves marked on healing abutments significantly enhance adherence of *Porphyromonas gingivalis* (Pg) and *Fusobacterium nucleatum* (Fn) when compared to machined smooth healing abutments. Further studies are still needed to elucidate the clinical relevance of these findings.

## Temperature changes in one-piece implants due to provisional restoration. The effect of implant diameter. An in vitro study



### Author:

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Limited number of studies investigated heat production during provisional restoration of implant abutment. Exposure of osteoblast culture to 42 °C induced activation of apoptosis mechanisms. To the best of our knowledge, heat production during provisional restoration of one-piece implants was never studied before.

To evaluate changes in temperature of one-piece titanium implant surface during the setting of acrylic resin temporary crowns and to correlate thermal changes to implant diameter.

Direct application of auto-polymerizing resin to the titanium abutment of one-piece implants significantly increased the cervical implant surface temperature. Implant diameter did not influence the temperature changes.

To avoid thermal injury to the surrounding bone it is recommended to constantly cool the implant with water spray during the setting of the provisional restoration.

## Temperature changes in one-piece implants due to provisional restoration. The effect of implant diameter. An in vitro study

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Topic: Basic research

### Background

Limited number of studies investigated heat production during provisional restoration of implant abutment. Exposure of osteoblast culture to 42 °C induced activation of apoptosis mechanisms. To the best of our knowledge, heat production during provisional restoration of one-piece implants was never studied before.

### Objectives

To evaluate changes in temperature of one-piece titanium implant surface during the setting of acrylic resin temporary crowns and to correlate thermal changes to implant diameter.

### Methods and Materials

Thirty-three one-piece implants (ARRP, Alpha-Biotec, Israel) were divided into 3 groups according to diameter size (G1=3 mm, G2=3.3 mm, G3=3.6 mm). Implants were mounted on an acrylic glass apparatus.(Fig 1.) Thermocouples were positioned at the most coronal thread. Lower incisor temporary polycarbonate crowns were filled with 80  $\mu$ L of self-curing acrylic resin and positioned immediately on the implant abutment.(Fig 2) Thermal changes of the implant surface were recorded continuously for 10 minutes. Data were statistically analyzed using one-way analysis of variance.

### Results

The mean initial temperature (C0) of groups G1, G2 and G3 was similar (24.79 $\pm$ 0.78°C, 25.26 $\pm$ 0.63°C, 24.97 $\pm$ 1.06°C, respectively). (Fig 3). The setting of the acrylic resin temporary crown resulted in a significant increase in the implant surface temperature of all groups. The mean thermal amplitude ( $\Delta$ C) for groups G1, G2 and G3 were 6.79 $\pm$ 1.02°C, 6.61 $\pm$ 0.94°C, 6.65 $\pm$ 1.26°C, respectively. The mean time to maximum temperature (Tmax) for groups G1, G2 and G3 were 337.38 $\pm$ 42.91 seconds, 324.69 $\pm$ 41.46 seconds and 317.98 $\pm$ 37.91 seconds respectively ( $P$ >0.05). (Fig 4.)

### Conclusions

Direct application of auto-polymerizing resin to the titanium abutment of one-piece implants significantly increased the cervical implant surface temperature. Implant diameter did not influence the temperature changes.

### Clinical relevance

To avoid thermal injury to the surrounding bone it is recommended to constantly cool the implant with water spray during the setting of the provisional restoration.



Fig 1. Mounting and fixing of an implant into machined slots in a custom-made acrylic glass apparatus



Fig 2. Placement of the filled crown on the implant abutment while ensuring that no resin flows on the implant surface.

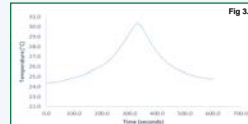


Fig 3. An example of recorded temperature over time. The thermal amplitude ( $\Delta$ C) was calculated by subtracting the initial change (C0) from the maximum change (Cmax).

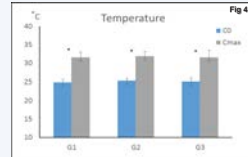


Fig 4. Baseline (C0) and maximal temperature (Cmax) recorded in groups: G1 (3.0 mm-implants), G2 (3.3 mm-implants), G3 (3.6 mm-implants). Data presented in Celsius degrees as mean value and standard deviation. \* denotes  $p$ <0.05

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Intra-sinus bone evolution around implants placed using  
Flapless and graftless transcrestal sinus floor elevation:  
5 years follow-up



**Author:**

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The transcrestal sinus floor elevation during implants placement is a widely discussed theme in the literature. This study describes the results of 5 years follow-up of intrasinus and cortical periimplant bone modelling in case of transcrestal sinus floor elevation without bone condensation and grafting material.



## Intra-sinus bone evolution around implants placed using Flapless and graftless transcrestal sinus floor elevation: 5 years follow-up.

Topalo Valentin, Mostovei Andrei, Chele Nicolae, Atarni Fahim, Sirbu Dumitru  
The State Medical and Pharmaceutical University „Nicolae Testemitanu”

Topic: Implant therapy outcomes, surgical aspects

### Abstract

The transcrestal sinus floor elevation during implants placement is a widely discussed theme in the literature. This study describes the results of 5 years follow-up of intrasinus and cortical periimplant bone modelling in case of transcrestal sinus floor elevation without bone condensation and grafting material.

### Background and Aim

Implant placement using osteotome technique for sinus floor elevation is a widely used and discussed method. Usually, during surgery, grafting material is protruded in the preparation site in order to complete the space between sinus floor and the elevated membrane as well as to decrease the shrinkage of intra-sinus bone during years. There are studies which demonstrate good and predictable results without using bone grafting material. Moreover, a native bone can adapt and physiologically handle the functional loading regardless the grafted bony tissue. It is necessary to appreciate the integration process, endo sinus bone formation and its evolution around implants installed using flapless approach, without condensation and without grafting material.

**Aim:** To evaluate the intra-sinus bone evolution around implants installed using flapless transcrestal sinus floor elevation, without bone condensation and without grafting material during 5 years follow-up.

### Methods and Materials

Five partially edentulous patients (mean age  $41 \pm 1.37$  years) received 10 two-stage dental implants (Alpha-Bio Tec, SPL, with diameter 3,75 to 5mm, and 8 to 11,5mm length) in posterior sides of upper jaw. The first surgical step was performed using flapless approach, using osteotomes for sinus floor fracture, without bone condensation and grafting material. All implants were installed in sites with D3 bone density (according to Misch). No perforation of the sinus membrane has been observed before implant insertion. According to orthopantomogram, implants sides were divided into anterior and posterior ones. Radiographic images were analyzed using Photoshop CS3 Program. The following indices were evaluated: residual bone height, the length of implant penetration into sinus, endo-sinus bone clot height, endo-sinus bone gain and evaluation of it during 5 years after prosthetic delivery. Crestal bone loss during this period was also evaluated. After a healing time of  $6.3 \pm 0.42$  months, the second stage was performed and prosthetic treatment was initiated after 2-4 weeks. All implants successfully integrated. The intra-sinus bone formation during healing and its evolution for a period of 5 years post-prosthetic were analyzed. Statistical analysis was made by calculating mean values and standard errors as well as Pearson's Correlation test.

Fig.1. Radiographic aspects: preoperative (a); postoperative (b); at the end of healing (c); 5 years after loading (d); introral aspect (e).

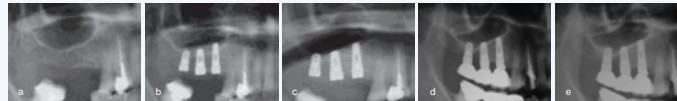


Fig.2. Radiographic aspects: preoperative (a); postoperative (b); at the end of healing (c); 3 years of after loading (d); 5 years of after loading (e).

### Results

The residual bone height on anterior and posterior sides consisted  $7.88 \pm 0.77$ mm and  $7.19 \pm 0.61$ mm. The degree of implant penetration into the sinus was  $1.95 \pm 0.305$ mm and  $2.08 \pm 0.433$ mm respectively. The bone clot after implant placement was  $2.88 \pm 0.315$ mm and  $3.01 \pm 0.438$ mm. During healing, a shrink of  $0.84 \pm 0.36$ mm and  $0.81 \pm 0.215$ mm occurred and an amount of  $2.03 \pm 0.438$ mm and  $2.19 \pm 0.425$ mm of new formed bone at the 2nd stage was observed. Five years post-prosthetic, the height of intra-sinus bone was:  $2.22 \pm 0.454$ mm and  $1.66 \pm 0.463$ mm. During this period, around 5 implants from anterior and 4 implants from posterior a shrink of  $0.63 \pm 0.311$ mm and  $0.73 \pm 0.293$ mm occurred, while the other ones showed a bone apposition of  $1.27 \pm 0.04$ mm and  $0.67 \pm 0.32$ mm. The crestal bone loss occurred between implant placement and 5 years post-prosthetic were  $0.67 \pm 0.53$ mm from mesial and  $0.92 \pm 0.382$ mm from distal aspects. The endo-sinus bone gain have a strong direct correlation with implant protruded height: mesial  $r=0.602$  and distal  $r=0.886$ .

### Conclusions

The implant placement by the described method leads to good and predictable results. During 5 years follow-up, the endo-sinus new formed bone remodeling manifested by a small shrink just for a part of implants, while other showed an increasing of bone height. A shrink less than 1mm in 5 years after prosthetic delivery demonstrates the possibility of avoiding grafting materials for transcrestal sinus floor elevations.

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## Endo-sinus bone gain in case of lateral sinus floor elevation



### Author:

Dabilja Ion, Chele Nicolae, Topalo Valentin, Mostovei Andrei, Atamni Fahim.



The usage of grafting materials in sinus floor elevations through lateral access is considered a necessity for good and predictable results. Few studies only describe the possibility of using blood clot as grafting material. This study describes the preliminary results in case of implants placement with lateral sinus floor elevation without grafting material.

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## Endo-sinus bone gain in case of lateral sinus floor elevation with immediate implant placement without grafting material.

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The State Medical and Pharmaceutical University „Nicolae Testemitanu”

Topic: Implant therapy outcomes, surgical aspects

### Abstract

The usage of grafting materials in sinus floor elevations through lateral access is considered a necessity for good and predictable results. Few studies only describe the possibility of using blood clot as grafting material. This study describes the preliminary results in case of implants placement with lateral sinus floor elevation without grafting material.

### Background and Aim

Many studies describes the necessity of using grafting materials in case of lateral sinus floor elevations. Besides the advantages of it, an important role plays the autogenous bone which is often mixed with xenograft or synthetic materials in order to achieve a better quality tissue. However, these methods are often related to complications like sinusitis or failures. Several articles only described sinus floor elevation by lateral access and implants placement without grafting material.

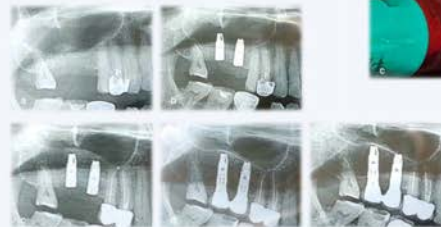
### Aim

To appreciate the endo-sinus bone gain in case of lateral sinus floor elevation with immediate implants placement without any grafting material.

### Methods and Materials

The study was axed on 5 patients (3 males and 2 females, mean age 38.23±12 years) who received 12 implants (Alpha Bio Tec, 3 patients with 2 implants and 2 with 3 implants) in posterior sides of upper jaw. The diameter of implants ranged between 3.75mm and 4.2mm while the length – 10mm and 11.5mm. The implants insertion was performed simultaneously with lateral sinus floor elevation using the trap door technique. Before implants insertion the sinus cavity formed after elevation were filled only with blood collected from peripheral vein. After suturing, platelet rich plasma was injected from buccal aspects. Sutures were removed after 10 days. Six months later, the second surgical step was performed, and the prosthetic treatment was performed after another 4 weeks. Perimplant bone loss as well as endo-sinus bone gain during healing and 1 year postprosthetic, has been evaluated. Statistical analysis was made by calculating mean values, standard errors and Pearson correlation test.

Fig 1. Radiographic images: preoperative (a); postoperative (b); at the end of healing (c); 6 months postprosthetic (d); 1 year postprosthetic (e).



### Results

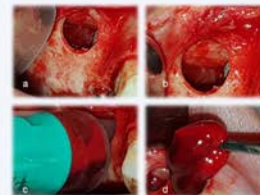
All implants successfully integrated. Residual bone height from mesial and distal aspects was  $5.96\pm 0.4\text{mm}$  and  $5.05\pm 0.21\text{mm}$ , while the length of implants protruded into sinus were  $5.81\pm 0.35\text{mm}$  and  $6.15\pm 0.19\text{mm}$  respectively. At the end of healing period, the endo-sinus bone gain consisted  $7.38\pm 0.402\text{mm}$  (mesial) and  $8.17\pm 0.11\text{mm}$  (distal), but radiographically it had a lower opacity than the native one. One year post-prosthetic, the bone became mature with good corticalization of the new sinus floor, with dimensions of  $5.93\pm 0.56\text{mm}$  and  $6.65\pm 0.087\text{mm}$  from mesial and distal aspects. During this period, a shrink of  $1.45\pm 0.16\text{mm}$  and  $1.51\pm 0.19\text{mm}$  occurred. The cortical perimplant bone loss around implants from mesial and distal aspects was:  $0.23\pm 0.066\text{mm}$  and  $0.21\pm 0.043\text{mm}$  during healing;  $0.4\pm 0.12\text{mm}$  and  $0.68\pm 0.07\text{mm}$  during 1 year postprosthetic. A strong correlation between implant protruded length and endo-sinus bone gain was observed: 0.92 (mesial) and 0.682 (distal).

### Conclusions

In appropriate conditions, the lateral sinus floor elevation without grafting material and with simultaneously implant placement lead to formation of an adequate amount of endo-sinus bone. By this way, it is possible to avoid the use of grafting materials. However, more studies and longer follow-up periods are necessary in order to appreciate the limits and indications of this method.

### References

Fig 2. Intraoperative view: after elevation (a,b); grafting with blood (c); aplication of blood clot (d).



## Narrow vs. standard implants in one-step flapless approach. One year follow-up



### Author:

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Numerous studies are published regarding the bone loss around narrow and wider diameter implants. Moreover, the effect of platform switching is also an intense discussed theme in the literature and the opinions about these two problems are divergent. Another factor which may influence the periimplant bone loss is the implant shoulder design. In some implants, due to constant platform dimensions, platform switching concept appears with the increasing of implant diameter. In order to achieve a correct opinion, it is necessary to appreciate the influence of implant diameter and the platform switching concept upon bone loss for each system separately.

The implant diameter as well as the platform switching effect seems to have no influence upon periimplant bone level and implants' stability during healing and 1 year post-prosthetic. The relation between the implant platform (microgap) and bone crest has a significant impact upon periimplant bone modeling, supracrestal position showing lowest bone loss values. The summary bone loss from the placement to 1 year follow up does not exceed values described in the literature for other implant types.

## Narrow vs. standard implants in one-step flapless approach. One year follow-up.

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Mostovei A., Topalo V., Chele N., Sirbu D., Atamni F., Gumeniuc A., Mostovei M.

The State Medical and Pharmaceutical University "Nicolae Testemitanu"

Topic: Implant therapy outcomes, surgical aspect

### Abstract

Numerous studies are published regarding the bone loss around narrow and wider diameter implants. Moreover, the effect of platform switching is also an intense discussed theme in the literature and the opinions about these two problems are divergent. Another factor which may influence the perimplant bone loss is the implant shoulder design. In some implants, due to constant platform dimensions, platform switching concept appears with the increasing of implant diameter. In order to achieve a correct opinion, it is necessary to appreciate the influence of implant diameter and the platform switching concept upon bone loss for each system separately.

### Background and Aim

In case of one-step placement of two-piece dental implants, the early bone loss begins from the moment of implant insertion, whilst in the two-steps approach - after the second surgical step. In such situations, the flapless approach has a positive effect upon biological width formation. It is necessary to state the effect of implant diameter and platform switching upon crestal bone loss in case of one-step flapless placement of two-piece dental implants.

**Aim**  
To appreciate the influence of the diameter of implants and the switch platform effect upon crestal bone modeling in case of one-step flapless placement of two-piece dental implants.

### Methods and Materials

One hundred and twenty five Alpha-Bio Tec Implants (SPI) were inserted in 69 patients (45;4-98 years) in the posterior sides of the mandible, using one-step flapless approach (with immediate connection of healing abutments). Seventy implants had the diameter of 3.3 and 3.75mm (Control) whilst the rest 55 implants - 4.2 and 5mm (Study Group, with the effect of platform switching). The socket preparation was initiated using spade bur, through the mucosa, without removing any part of it, and then the recommended surgical protocol was used (Figure 1). The integrity of the bone walls as well as the mucosal thickness at the top of the crest was checked with periodontal probes. The mean healing period was 13.67±1.05 (Control) and 13.03±1.03 (Study) weeks. At the end of the healing period the pre-prosthetic evaluation was performed. One implant from control group failed during healing. According to the orthopantomogram, implants' sides were divided into anterior and posterior ones. Due to the relation between bone crest and implant platform, three positions have been distinguished: suprcrestal, at the bone level and subcrestal. The following parameters were evaluated: primary and secondary stability (Periostet Classic), peri-implant bone modeling using Adobe Photoshop CS3 Program (at the end of the healing period and 1 year post-prosthetic). Statistical analysis was made by calculating mean values, standard errors, indices of Student's paired t test and Mann-Whitney U tests.

### Results

Primary stability was -5.18±0.116(Study) and -5.91±0.106 (Control) while the secondary were -8.09±0.104 (Study) and -5.85±0.111Control (p<0.05). In the Study Group, the perimplant bone loss at mesial and distal aspects were: 0.72±0.068mm and 0.48±0.05mm during healing period; 0.47±0.108mm and 0.37±0.062mm at 1 year follow up (p<0.05). In the Control Group, the perimplant bone loss at mesial and distal aspects were: 0.63±0.052mm and 0.48±0.047mm during period; 0.44±0.121mm and 0.54±0.219mm at 1 year follow up (p<0.05). The bone apposition has been observed around 2 Study and 10 Control implants (all in suprcrestal position). There was no statistical difference between bone loss of both groups, neither during healing, nor 1 year post-prosthetic. A statistical difference has been observed between bone loss values of suprcrestal implants position versus subcrestal ones (p<0.01 for mesial and p<0.05 for distal aspects) with lowest values in suprcrestal position.

### Conclusions

The implant diameter as well as the platform switching effect seems to have no influence upon perimplant bone level and implants' stability during healing and 1 year post-prosthetic. The relation between the implant platform (microgap) and bone crest has a significant impact upon perimplant bone modeling, suprcrestal position showing lowest bone loss values. The summary bone loss from the placement to 1 year follow up does not exceed values described in the literature for other implant types.

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**Fig.1** Flapless implant placement (SPI 4.2-13mm): preoperative view (a); after socket preparation (b); implant insertion (c); aspect of implant platform before healing abutment connection(d); healing abutment connection (e); primary stability appreciation (f); postoperative radiographic view (g); peri-implant mucosa at the end of healing period (h) and radiographic view (i); aspect of the prosthesis one-year after loading and radiographic view (j,k);

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