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RESEARCH ARTICLE

EVALUATION OF PERI-IMPLANT SOFT TISSUE AND CRESTAL BONE LEVEL OF NANOMETER SCALE SURFACE COATED (NANOTITE^{tm}) IMPLANTS: A CLINICO-RADIOGRAPHIC STUDY

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ABSTRACT

Aim and Objective: The objective of this controlled clinical trial was to clinically evaluate the peri-implant soft & hard tissues and to radiographically analyze the difference in crestal bone level both mesial and distal to the implant.

Materials and methods: A total of ten sites from ten volunteers were selected for the placement of the implants and were subjected to presurgical evaluation and clinical and radiographic parameter assessment.

Statistical analysis used: Mann-Whitey U test and Wilcoxon Signed Rank Test were used to find the significance of study parameters on continuous scale for the intragroup comparisons and the comparison between the mesial and distal bone levels.

Results: At baseline, 6 and 9 months there was a statistically significant overall decrease in the mean gingival index score around implants. The mean plaque index, sulcus bleeding score and mean difference in the peri-implant probing depth (mm) around the implants was statistically not significant. The mean width of keratinized mucosa and the mean papilla fill index remained constant throughout the study. On comparison between the mesial and distal implant site there was more crestal bone loss on the mesial than on the distal aspect.

Conclusion: Nanothin surface coating of calcium phosphate enhanced the biological response of bone to implant at the early implantation times, supporting opportunities for increased bone healing response in clinical practice.

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INTRODUCTION

The evolution of any dental implant modality is a multipart process. (Lemons and Dietsh, 1999) The interaction between the cells and tissues with biomaterials at the tissue–implant interface is a surface phenomenon thus *surface properties* play a major role in determining both the biological response to implants and the material response to the physiological condition. (Paital and Dahotre, 2009) Human compact bone is basically a hierarchical organization at different length scales ranging from nanoscale to mesoscale. Therefore, there has been a great thrust towards development of calcium phosphate (CaP) based nanometer scale surface coatings on dental implants. A variety of surface coating methodologies such as ion beam assisted deposition, plasma spray deposition, electrophoretic deposition, pulsed laser physical vapor deposition, micro-arc oxidation, magnetron sputtering, sol–gel derived coatings, etc. are being currently employed to deposit Ca–P on Ti-based alloys. Most of these techniques are aimed to enhance short- and long-term performance of implants by encouraging bone ingrowth and providing enhanced fixation. Further, coatings of these bioceramics on Ti-based alloys also provide the appropriate surface chemistry for tissue compatibility without altering the bulk mechanical properties of the material. (Paital and Dahotre, 2009) Materials and method: A total of ten sites from ten volunteers were selected for the placement of the implants and were subjected to presurgical evaluation and clinical and radiographic parameter assessment.

Selection criteria: Patients with a minimum age of 18 yrs, irrespective of sex who were cooperative, motivated, committed and willing to follow recommended plaque control and follow up regimen. Patients with one or more missing

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teeth and adequate amount of bone volume, bone quality, stable periodontal and dental status and site free from infection for implant placement were included in the study. Patients unable/unwilling to undergo minor oral surgical procedure with specific systemic disease that contraindicate any implant placement, with previous head and neck irradiation, parafunctional habits and with insufficient inter-arch space to accommodate the available restorative component were excluded from the study. In the present study Bicon's Nanotite™ implants (FDA approved; US Patent No. 6,227, 857; LIT-015 R0709; Boston, MA; USA.) of required lengths and diameters as per the selected site were used. These consist of nano-thin calcium phosphate compound on alumina-blasted, acid-etched surface (Fig 1).

The various clinical parameters assessed (Salvi and Lang, 2004) were

- Plaque Index [For full mouth (Silness and Loe 1964); Implant site [(Mombelli *et al* 1987 (mPI)] to assess biofilm formation in the marginal area around implants.
- Gingival Index [For full mouth (Loe and Silness 1967); Implant site (Apse *et al* 1991)] to assess the marginal mucosal conditions.
- Sulcus Bleeding Index (Mombelli 1987) to assess the bleeding on probing (BOP) to examine the health status of the sulcular epithelium.
- Width of Keratinized Mucosa (Cox and Zarb 1987). The presence of keratinized mucosa around implants seems to be correlated with optimal soft and hard tissue health.
- Jemt's Papilla Fill Index (1997) to clinically evaluate the degree of recession and regeneration of papillae adjacent to single implant restorations.
- Peri-implant Probing Depth to reveal tissue consistency, bleeding and exudate. Increasing probing depth is a significant sign of crestal bone loss.
- Clinical Implant Mobility Scale (Misch 1999) to assess the implant stability. Clinical mobility is a definite sign of osseointegration failure.

The various radiographic parameters assessed were peri-implant bone levels using dentascan (Fig. 2); Image J 1.34s and any Peri-implant Bone changes viz. radiolucency, bone loss etc.

Surgical procedure

Implant placement was carried out in two stage surgery. Ist Stage surgery: The placement of the implant comprised the following basic steps performed under local anesthesia. The mucoperiosteal flap was raised by limited flap design (GR German, 2001) (Fig.3). The goal of this surgical technique was less traumatic preparation of the soft tissues. After conforming the depth of the osteotomy to the depth gauge the implants of desired length and width were tapped into the site with a mallet and the straight/offset handle leaving the healing plugs intact covering the implant (Fig.3). The flap was then repositioned and secured in place by interrupted sutures using braided silk 3-0 sutures and periodontal (Fig. 3). The patients were prescribed with systemic antibiotics capsule Doxycycline 200mg for the first day followed by 100 mg for next four days; anti-inflammatory analgesic tablet Combiflam (ibuprofen 400mg, paracetamol 325mg) thrice daily for five days and were instructed to rinse with 0.2% Chlorhexidine digluconate twice daily for 1 week. The patients were then discharged from the hospital with postsurgical instructions. For the postsurgical followup the patients were called after 24 hours to evaluate postsurgical complications like hemorrhage, hematoma, edema, pain and discomfort. After this the patients were called after 7 days for suture removal.

IInd Stage Surgery: The second stage surgical procedure was carried out 6-8 weeks after Ist surgery to remove the healing plugs (Fig. 4) by using a small circular incisions on top of the crest. Guide pins and impression post were placed (Fig.). Prosthetic Phase: The prosthetic phase was carried out under the supervision of prosthodontist about 7-10 days after healing of the surrounding tissue around the implant. Impressions were made with a rubber base impression material (Fig. 4). Abutment was placed (Fig 4). The impressions were then sent to the prosthetic laboratory for the fabrication of the crown. The porcelain fused metal (PFM) crown was checked for its passive fit and for any interference with the adjacent and opposing teeth. If needed occlusal adjustments were carried out prior to cementation. The crown was then cemented with glass ionomer cement (Fig. 4)

Radiographic interpretation

Computer assisted Image analysis:

Bone loss was measured from standardized periapical radiographs. The\ radiographs were scanned at 600 dpi using a digital scanner (HP Scanjet 3010 series scanner) and then imported to laptop computer (Sony vivo CR VGN-CR363) for further analysis. The images were then analyzed using the Image J 1.34S software program (National Institutes of Health). This program was used to help calibrate each image so that accurate calculations could be made at each time interval. The image was calibrated based on a known measurement, such as the height and/or diameter of the implant. Once calibrated, measurements were made on the mesial and distal of the implant to determine the distance from a fixed reference point to the crest of the alveolar bone. (Avi *et al*., 2009) The fixed reference point used in this study was the apex of the implant (Job *et al*., 2008) since it was easily recognizable. The change in crestal bone level was assessed based on the bone levels found at baseline, 6 and 9 months of intervals (Fig. 5). All the obtained values of clinical and radiographic parameters were entered in the standard proforma drawn for this study and were subjected to statistical analysis.

Statistical analysis

Descriptive statistical analysis was carried out in the present study. Results on continuous measurements were presented on Mean ± SD (Min-Max) deviation. Mann-Whitey U test and Wilcoxon Signed Rank Test were used to find the significance of study parameters on continuous scale for the intragroup comparisons and the comparison between the mesial and distal bone levels.

Clinical observations

Gingival index (Table 1) Implant site Full mouth
Plaque index (Table 2) Implant site Full mouth
Sulcus bleeding index for Implant site (Table 3)
Width of keratinized mucosa for implant site (Table 4).
Jemt's papilla fill index for implant site (Table 5)
Peri-implant probing depth (Table 6)
Clinical implant mobility scale (Table 7)
Radiographic assessment of crestal bone level (Table 8)

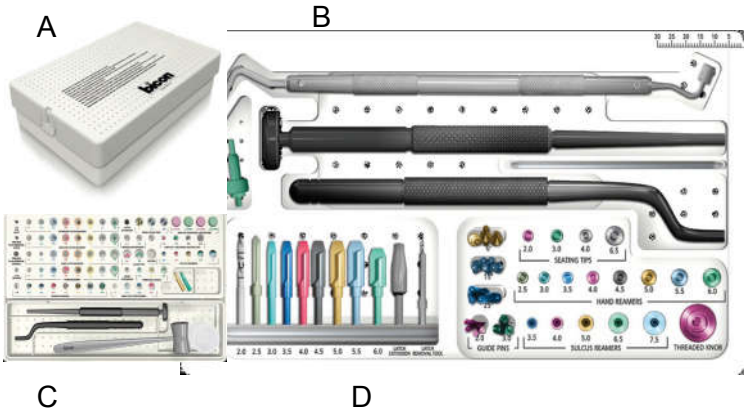

Fig 1: Materials Used for the study

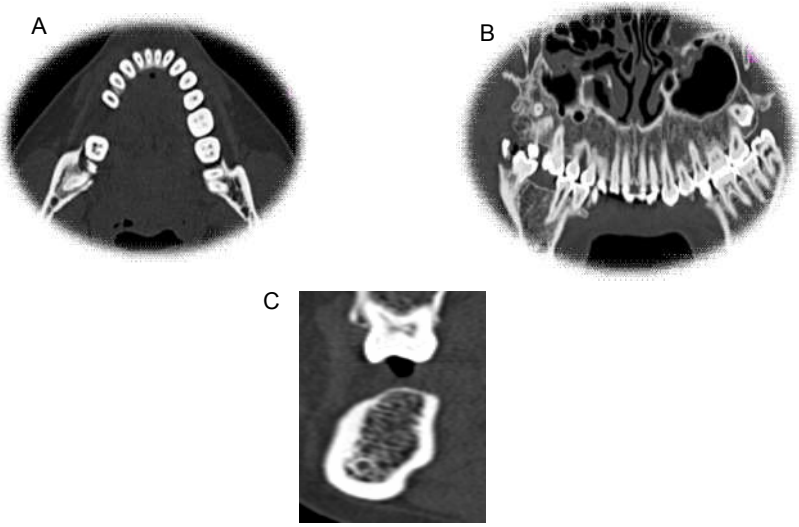

Figure 2 Dentascan Images Of The Implant Site

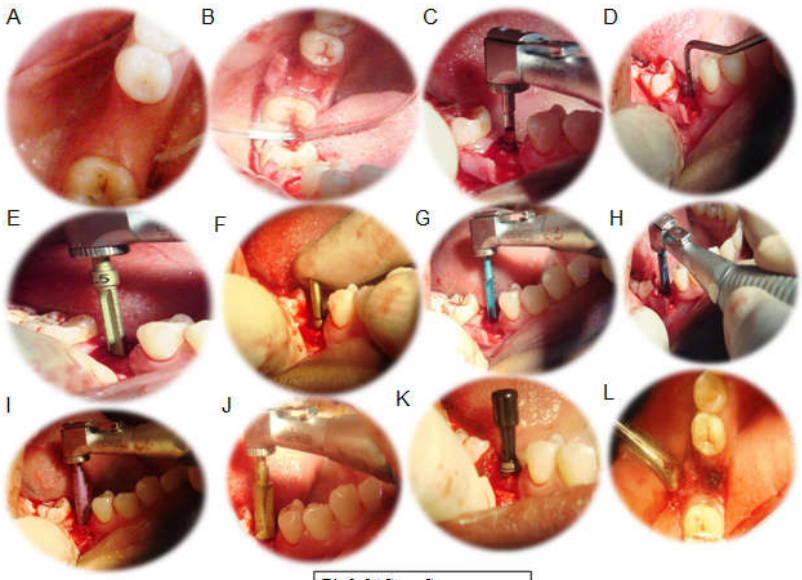

Fig 3: 1st Stage Surgery

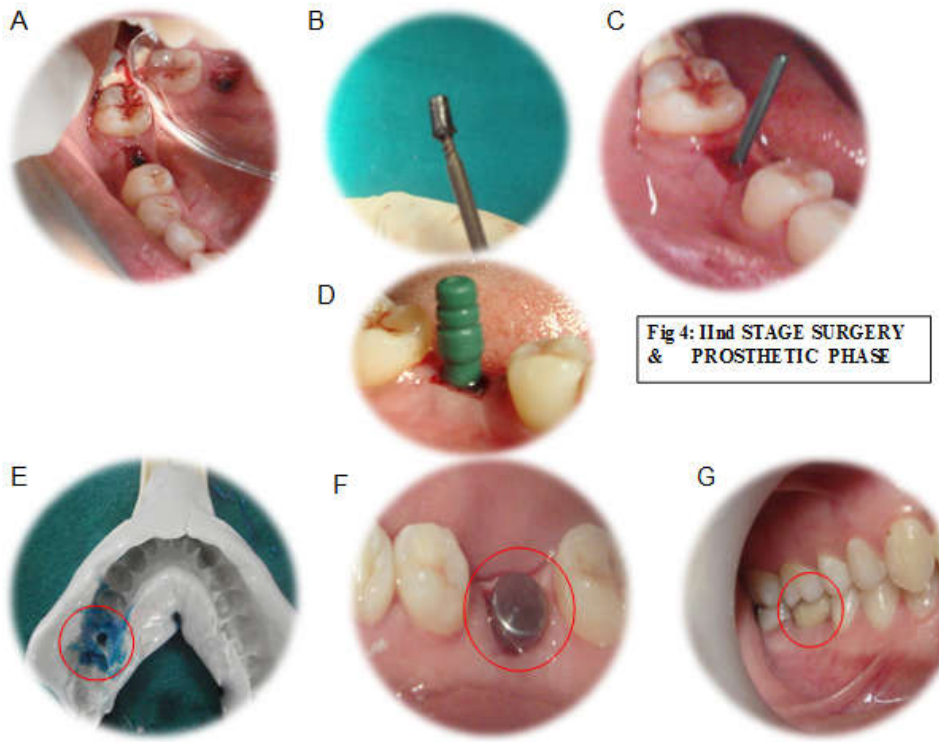

Fig.5. Radiographs

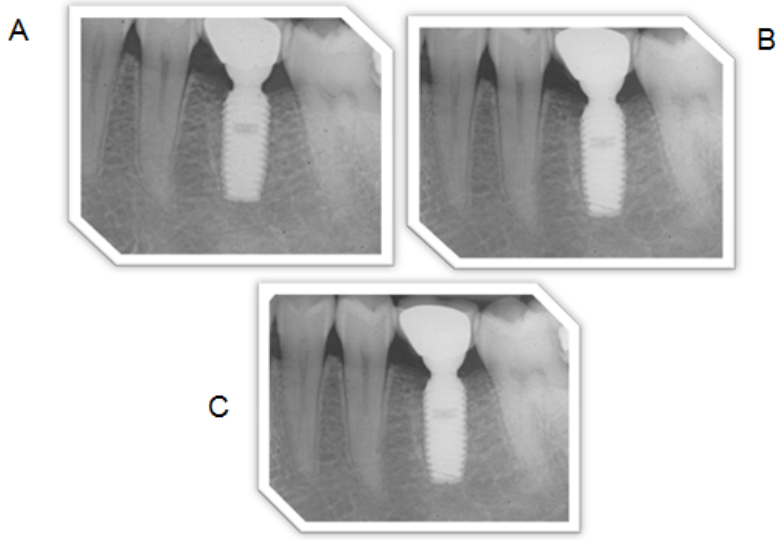

Table 1. Mean & Mean differences in gingival index for full mouth and around implant site at different intervals

	Gingival index (Full mouth)				Gingival index(Implant site) (Apse et al)			
Assessment time intervals	Mean ±SD	Mean Difference	z- value	p-value	Mean ±SD	Mean Difference	z-value	p-value
Baseline	0.47± 0.15				0.27 ± 0.17			
6 months	0.64± 0.12	0.17 ± 0 .08	2.850	0.004**	0.25 ± 0.19	0.02 ± 0 .31	0.086	0.931
9 months	0.68± 0.04	0.21± 0.17	2.694	0.007**	0.14 ± 0.09	0. 13± 0.04	2.070	0.038*

* Statistically significant ($p < 0.05$)
** Statistically highly significant ($p < 0.001$)

Table 2. Mean & Mean differences in plaque index for full mouth and around implant site at different intervals

	Plaque Index (Full mouth)				Plaque index(Implant site)			
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value	Mean ±SD	Mean Difference	z-value	p-value
Baseline	0.74 ± 0.10				0.24± 0.15			
6 months	0. 83± 0.10	0.09 ± 0.15	1.631	0.10	0.29 ± 0. 14	0.05 ± 0.17	0.75	0.45
9 months	0.72± 0 .07	0.02± 0.14	0.574	0.56	0.38 ± 0 .15	0.14 ± 0.18	1.89	0.05

Table 3. Mean & Mean differences in sulcus bleeding index around implant site at different intervals

	Sulcus Bleeding index(Implant site)			
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value
Baseline	0 .80 ± 0.42			
6 months	1.00 ± 0 .00	0. 20 ± 0.42	1.41	0.15
9 months	0.40 ± 0.51	0.40 ± 0.69	1.63	0.10

Table 4. Mean & Mean differences in width of Keratinized mucosa around implant site at different intervals

	Width of Keratinised mucosa			
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value
Baseline	2.90 ± 0.31			
6 months	2.90 ± 0.31	0.00	0.000	1.000
9 months	2.90 ± 0.31	0.00	0.000	1.000

Table 5. Mean & Mean differences in Jemt's Papilla fill index around implant site at different intervals

	Jemt's Papilla Fill Index (Mesial)				Jemt's Papilla Fill Index(Distal)			
Assessment time intervals	Mean ± SD	Mean Difference	z-value	p-value	Mean ±SD	Mean Difference	z-value	p-value
Baseline	3.00± 0.00				3.00± 0.00			
6 months	3.00± 0.00	0.000	0.000	0.000	3.00± 0.00	0.000	0.000	0.000
9 months	3.00± 0.000	0.000	0.000	0.000	3.00± 0.00	0.000	0.000	0.000

Table 6. Mean & Mean differences in peri-implant probing depth (mm) around implant site at different intervals

	Peri-Implant probing depth (mm)			
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value
Baseline	1.51 ± 0.37			
6 months	1.46 ± 0.40	0.05 ± 0. 15	1.000	0.317
9 months	1.46 ± 0.40	0.05 ± 0. 15	1.000	0.317

Table 7. Mean & Mean differences in implant mobility around implant site at different intervals

	Implant mobility			
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value
Baseline	0.00± 0.00			
6 months	0.00± 0.00	0.00± 0.00	0.00	0.00
9 months	0.00± 0.00	0.00± 0.00	0.00	0.00

* Statistically significant ($p < 0.05$)

Table 8. Mean & Mean differences in crestal bone level around implant site at different intervals

	Crestal bone level (mesial)				Crestal bone level (distal)				(Mesial Vs Distal)		
Assessment time intervals	Mean ±SD	Mean Difference	z-value	p-value	Mean ±SD	Mean Difference	z-value	p-value	Mean Difference	z-value	p-value
Baseline	0.00 ± 0.00				0.00 ± 0.00						
6 months	0.013 ± 0.014	0.013 ± 0. 014	2.366	0.018*	0.006 ± 0.007	0.006 ± 0.007	2.207	0.027*	0.006 ± 0 .005	0.928	0.353
9 months	0.014 ± 0.018	0.018 ± 0.018	2.524	0.012**	0.017 ± 0.012	0.017 ± 0.012	2.527	0.012**	0.000 ± 0.007	0.190	0 .849

** Statistically highly significant ($p < 0.001$)

DISCUSSION

Various studies (Marletta *et al*., 2007; Balasundaram and Webster, 2006; Tasker *et al*., 2007; Palin *et al*., 2005; Price *et al*., 2004; Price *et al*., 2003) indicate that bone surface crystalline nanoscale topography plays a significant role in bone and implant integration. From a surface chemistry modification standpoint, implant surfaces have been coated with biocompatible CaP based bioceramics, resulting in enhanced bone to- implant response at early implantation times. In an attempt to benefit from the increased osteoconductive properties observed in CaP based coatings while decreasing a long-term dependence on mechanical interlocking between coating and implantable device, smaller scale bioceramics coatings have been developed for implant surfaces through various processing techniques. (Paital and Dahotre, 2007; Kasemo, 1998) Of the several coating methods (Dunn and Reisbick, 1976; Brossa *et al*., 1994; Chen *et al*., 1997; Cook *et al*., 1988; Ong and Chan, 2000; Cui *et al*., 1997) being recently developed to resolve these problems, ion beam–assisted deposition (IBAD), a method that was introduced in previous studies (Jung *et al*., 2001; Lee *et al*., 2002) has shown promising results. The Nanotite^{tm} implants which have been used in the present study utilizes the recent concept that thin-film bioceramic coating obtained by Ion Beam Assisted Deposition (IBAD) on Ti-6Al-4V implants enhances the biological response of bone to implant contact as suggested by Coelho & Lemons (2005); Tohru *et al*. (2002). In the present study the gingival Index for the implant site (Table 1) there was a statistically significant overall decrease ($p<0.05$) in the mean gingival index score around implants at 9 months from the

baseline. This was similar to the study done by Adell *et al*. 1981 who reported a low prevalence of clinical inflammation around 731 successful Branemark's fixtures. In the present study there was a statistically highly significant *(p< 0.001)* increase in the mean gingival scores at 6th & at 9 months from the baseline assessment (Table 1). In this study, the mean plaque index score around the implants at baseline, 6th & at 9 months was statistically not significant (Table 2). The results of the present study were in accordance with the study by Julio *et al*. (2003) who found statistically no significance in the mean plaque score 12 months after implant placement. The difference in mean plaque index scores of full mouth at baseline, 6th & at 9 months was statistically not significant (p> 0.05) (Table 2). The plaque index has been shown to be an important indicator of peri-implant tissue health (Bauman *et al*., 1992). Lindhe (1984) in a longitudinal study on the long term maintenance of patients treated for advanced periodontal disease also reported that for well maintained patients, generally the mean plaque score is below 1.0. The mean difference in the sulcus bleeding score around implant sites was statistically not significant (p>0.05) (Table 3). This was similar to the observations made by Bragger U *et al*. 1997 who reported that the sulcus bleeding indices around implants were between 0.0 and 0.3.

The mean width of keratinized mucosa remained constant throughout the study with the score of 2.90 ± 0.31 at baseline, 6th and at 9 months (Table 4). This was similar to the observations made by Apse *et al*. 1991 who suggested that at buccal aspects of teeth and implants an approximately 3mm band of keratinized mucosa was found. In this study the mean papilla fill index remained constant throughout the study with the score of 3.00 ± 0.00 at baseline, 6th and at 9 months (Table 5). Jemt (1997) reported that the papillae adjacent to single –implant restorations regenerate to some extent after 1 to 3 years without any clinical manipulation of the soft tissue. These were similar to a study done by Lee, Park & Moon (2006) who assessed the soft tissue height between implants of two different systems (Brånemark Implant® and Astra Tech Implant® systems) and concluded that the height of the inter-implant "papilla", i.e. the height of soft tissue coronal to the bone crest measured in radiographs was about 3.1 mm for both implant systems. In this study each implant was examined and found to be asymptomatic and without any clinical evidence of mobility and scored 0 at all assessment time intervals (Table 7). This was in relevance with the statement made by Sekine *et al*. (1986) that a healthy implant moves less than 75µm; hence, it has zero clinical mobility. The results of the present study seem to correlate with this. In this study there was a statistically significant increase in the mean overall crestal bone loss on the distal and mesial aspect of the implant at 6th and at 9 months from baseline (p<0.05) (Table 8). The findings of the present study are very similar to the studies done by Behneke *et al*. (2002), Halbritter and Hart (2009) The amount of alveolar bone loss that occurred is well within the limit described by Albrektsson *et al*. (1986) regarding criteria for implant success. Thus the nanothin surface coating of calcium phosphate enhanced the biological response of bone to implant at the early implantation times, supporting opportunities for increased bone healing response in clinical practice.

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