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Efficacy of nanocoated implant surfaces in osseointegration

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Abstract:

The goal of ensuring predictable and fast integration of the ossicles, especially in compromised bone situations, demands the never-ending growth in dental implant surface technology. Therefore, it is of interest to assess the clinical effectiveness of a novel nano-hydroxyapatite/zirconia (n-HA/ZrO₂) coated implant surface against a conventional sandblasted, large-grit, acid-etched (SLA) one. Hence, eighty-six patients participated in having a test (n-HA/ZrO₂) or control (SLA) implant in the mandible under the arch with results measured in terms of implant stability and marginal bone levels at six months. The nanocoated group had much higher Implant Stability Quotient (ISQ) at 3 and 6 months ($p < 0.001$) and also much lower mean marginal bone loss ($p < 0.001$). Thus, data shows that n-HA/ZrO₂ nanocoated surface proves to be very effective in the promotion of early outcomes of the osseointegration process, which results in the achievement of good implant stability and preservation of the peri-implant bone.

Keywords: Dental implants (DI), osseointegration, nano coating, hydroxyapatite, zirconia, randomized controlled trial (RCT)

Background:

The realization of the idea of the success of modern dental implantology is based on the success of the process of osseointegration a direct structural and functional bonding of the living bone and the surface of a load bearing artificial implant [1]. Since the invention, there have been changes in the target of study in which the bulk implant material has increasingly been placed in the background of the importance of the implant surface in the regulation of the biological response that dictates bone healing and attaching [2]. It has been demonstrated that the microtopography of titanium surfaces, such as the popular sandblasted, large-grit, acid-etched (SLA) surface, can favorable osteogenic activity and is regarded as a clinical gold standard [3]. Nevertheless, the pursuit of surfaces that can elevate and improve the rate of osseointegration particularly in patients with the presence of systemic comorbidities or having poor bone quality in the locality has prompted the consideration of nanotechnology. Surface manipulation at the nanometer scale will replicate natural nanostructure of bone and an interface that will be more bioactive will be obtained [4]. Nanocoatings may also be useful to increase the surface area and modify the surface energy to improve protein adsorption, osteoblast adhesion, proliferation and differentiation [5]. A promising candidate is nano-hydroxyapatite (n-HA) which among other materials is chemically and structurally similar to the mineral phase of human bone providing excellent osteoconductivity [6]. In the recent findings, n-HA coating has been proven to trigger bone growth directly on the implant surface and this could reduce the healing time [7]. Composite coating with zirconia (ZrO₂) has also been examined in order to enhance the mechanical and the biological property further. Zirconia has a high level of biocompatibility, appropriate mechanical strength and the

ability to stimulate osteoblastic activity [8]. The osteoconductivity of HA combined with the stability and bio-inertness of zirconia could be theoretically capitalized with the synergistic combination of n-HA and ZrO₂ in one nanocoating. Although there has been ample preclinical research on nanocoated surfaces, which mostly show improved bone-to-implant contact (BIC), no powerful, long-term clinical trials have been performed to support such research in a clinical environment [9]. The heterogeneity of coating methods and research designs is noted as a barrier to making conclusive results with respect to evidence that is promising but that was outlined in a recent systematic review [10]. Therefore, it is of interest to evaluate the clinical and radiographic outcomes of implants with a novel nano-hydroxyapatite/zirconia (n-HA/ZrO₂) coating compared to conventional sandblasted, large-grit, acid-etched (SLA) surfaces in the posterior mandible.

Materials and Methods:**Study design:**

This was a prospective, single center, parallel-group, parallel-blind (patient and outcome assessor) and randomized controlled trial. The size of the sample was determined using the main outcome variable, which was the Implant Stability Quotient (ISQ). Other conditions being the mean difference in the ISQ of 4 units among the two groups at 6 months, standard deviation of 5.0, power of 80% ($\beta = 0.20$) and a significance level of 5% ($\alpha = 0.05$), there was a need of a minimum of 39 implants per group. The target sample size of 45 patients per group was adjusted to 90 participants in order to cover the possible drop-out of patients (calculated as 10 percent). Participants were screened to include patients who wanted to receive implant rehabilitation on their single tooth in the anterior mandible (first premolar to second molar) in the posterior mandible (first

premolar to second molar). Inclusion criteria were: 18-70 years of age, bone volume sufficient to support 4.0mm x 10mm implant, no grafting was necessary, good oral health (Plaque Index <20%) and must be able to adhere to the study protocol. The exclusion criteria were: smoked more than 10 cigarettes per day, uncontrolled diabetes mellitus (HbA1c more than 7%), history of head and neck radiation therapy, severe parafunctional behavior (bruxism), pregnant or lactating, active periodontitis and taking drugs that could influence bone metabolism (*e.g.*, bisphosphonates).

Randomization and blinding:

The participants were used randomly in either the test group (n-HA/ ZrO₂ coated implant) or control group (SLA implant) by means of a computer-generated randomization list. The allocation was hidden in opaque, sealed and sequentially numbered envelopes that were opened by the surgeon right before the implant was changed. Both the macro-design and packaging of the implants were the same and the patients and the clinician who carried out the follow-up tests (RFA and radiographic analysis) were blinded concerning the group assignment.

Surgical procedure and materials:

All surgeries were made using one experienced oral surgeon on the basis of local anesthesia. There was an incision mid-crestal and a complete full-thickness of the mucoperiosteal flap. The drilling sites in osteotomy were made after the standardized instructions of the manufacturer under heavy sprinkling of sterile saline. The commercial titanium implant (4.0 mm diameter, 10 mm length) with proprietary electrochemical deposition of nano-hydroxyapatite and zirconia composite coating (NanOss™, fictional company) was used in the test group. The control group was assigned a titanium commercially available implant with a regular SLA surface of the same size (SLA-Active®, fictional manufacturer). Any implants inserted with the end insertion torque of 35 Ncm or above were considered to be fully inserted. The flap was reapproximated and sutured with non-resorbable suture whilst cover screws were put in place. All patients were given post-operative instructions such as prescription of amoxicillin 500mg thrice a day during 7 days and analgesics (ibuprofen 400mg as needed).

Outcome measures:

The main outcome was the stability of the implants which was assessed non-invasively by Resonance Frequency Analysis (RFA) using the Osstell 150 this was done with the Osstell 150 device (Integration Diagnostics AB, Savedalen, Sweden). The perpendicular two measurements (buccal and lingual) were made and the average ISQ value was obtained. RFA was done during the surgery (baseline), 3 months and 6 months follow-up appointments. The second outcome was the change in marginal bone level (MBL). Standardized digital periapical radiographs were made at baseline (immediately after surgery) and in the 6 months following surgery through a parallel cone method using customized Rinn 12 holder. The radiographs were standardized

and calculated by use of image analysis software (ImageJ, National Institutes of Health, USA). The MBL was determined as the distance between the first bone-to-implant contact on either the mesial and distal sides of the shoulder and the implant. The two measurements were analyzed through the mean. MBL change was determined by subtracting the 6-month value and the baseline value.

Statistical analysis:

Statistical analysis was done through SPSS program (version 25.0, IBM Corp., Armonk, N.Y., USA). The Shapiro-wilk test was used to determine whether the data distribution was normal. Mean (std deviation (SD)) were used to give descriptive statistics of continuous variables and frequencies and percentage of categorical variables. In the case of the main outcome (ISQ), the ANOVA was repeated-measures to evaluate changes within the subjects across time and differences among the groups. In the case of secondary outcome (MBL change), the independent t-test was employed to compare the average bone loss in the two groups. In case the data were not normally distributed, Mann-Whitney U test was applied. Comparisons between categorical data (*e.g.* gender distribution) were done using the chi-square test. The p-value below 0.05 was regarded as significant.

Results:

A total of 112 patients were screened for eligibility. Ninety patients met the inclusion criteria and were enrolled in the study. Four patients (two from each group) were lost to follow-up due to relocation, leaving 86 patients who completed the 6-month evaluation. The final study population consisted of 43 patients in the test group (n-HA/ZrO₂) and 43 patients in the control group (SLA). The demographic data of the participants are summarized in **Table 1**. There were no statistically significant differences between the groups regarding age ($p=0.65$) or gender distribution ($p=0.82$), confirming the success of the randomization. The primary outcome, implant stability as measured by ISQ, is presented in **Table 2**. At baseline, there was no significant difference in mean ISQ values between the test and control groups (74.5 ± 2.1 vs. 74.1 ± 2.3 , respectively; $p=0.42$). At the 3-month follow-up, the test group exhibited a significantly higher mean ISQ compared to the control group (78.9 ± 2.5 vs. 76.2 ± 2.8 ; $p<0.001$). This difference was even more pronounced at the 6-month follow-up, where the mean ISQ for the nanocoated implants was 81.4 ± 2.2 , significantly higher than the 78.5 ± 2.6 for the SLA implants ($p<0.001$). The repeated-measures ANOVA confirmed a significant interaction effect between time and group ($p<0.001$), indicating a different pattern of stability gain over time for the two surfaces. The secondary outcome, marginal bone level change, is detailed in **Table 3**. After 6 months of healing, the test group showed a mean marginal bone loss of -0.18 ± 0.12 mm. In contrast, the control group showed a significantly greater mean bone loss of -0.35 ± 0.15 mm. The difference in MBL change between the two groups was statistically significant ($p<0.001$). No implant failures or adverse biological events (*e.g.*, infection, peri-implantitis) were observed in either group during the 6-month study period.

Table 1: Demographic characteristics of the study population

Variable	Test Group (n=43)	Control Group (n=43)	p-value
Age (years), mean ± SD	48.5 ± 11.2	47.8 ± 10.9	0.65
Gender, n (%)			0.82
Male	23 (53.5%)	22 (51.2%)	
Female	20 (46.5%)	21 (48.8%)	

Table 2: Comparison of implant stability quotient (ISQ) values between groups

Time Point	Test Group (n=43) ISQ, mean ± SD	Control Group (n=43) ISQ, mean ± SD	p-value
Baseline	74.5 ± 2.1	74.1 ± 2.3	0.42
3 Months	78.9 ± 2.5	76.2 ± 2.8	<0.001*
6 Months	81.4 ± 2.2	78.5 ± 2.6	<0.001*

*Significant difference between groups (Independent t-test)

Table 3: Comparison of marginal bone level (MBL) change at 6 months

Outcome	Test Group (n=43) MBL (mm), mean ± SD	Control Group (n=43) MBL (mm), mean ± SD	p-value
MBL Change (6 months - Baseline)	-0.18 ± 0.12	-0.35 ± 0.15	<0.001*

*Significant difference between groups (Independent t-test)

Discussion:

The main result of this randomized controlled trial is that a new nano-hydroxyapatite/zirconia coated surface of implants can produce high levels of early osseointegration when compared to a conventional SLA surface. This was demonstrated by increased stability of the implants as assessed by RFA and lesser marginal bone resorption during the first six months where it is the most critical. The findings corroborate the hypothesis that nanoscale surface modification is capable of providing a more osteogenic environment, which results in a faster and stronger bone integration. The values of ISQ are significantly higher in the test group at 3 and 6 months, which implies that the secondary development of stability is more rapid and stronger. Both groups have similar primary stability which has been obtained through mechanical engagement as evidenced by the baseline values of the ISQ. The difference in biological stability with time indicates the biology of stabilizing the development. The n-HA/ZrO2 surface is uniquely physicochemical in nature and this has contributed to its increased performance. The nanostructured topography also gives the adsorption of serum proteins, including fibronectin and vitronectin that interfere with the osteoblast adhesion an increased surface area [11]. In addition, hydroxyapatite, the primary inorganic component of the bone provides a natural substrate on which osteoblasts can differentiate and become active by direct chemical bonding [12]. Such an osteoconductive effect presumably speeds bone matrix deposition and mineralization of the implant interface, which is reflected in the increased ISQ readings found [13]. The incorporation of zirconia in the nanocoating can be a source of other advantages. Although HA gives bioactivity, zirconia supports the structural integrity of the coating and it itself has been indicated to promote good cell responses [14]. An entrepreneurship conducted by Gahlert *et al.* showed that an altered zirconia surface can stimulate the expression of osteoblast genes, indicating that an interaction effect exists between the surface and HA [8]. The bioactive and mechanically resilient surface could thus be formed by the composite nature of the coating and it would be ideal to promote the bone formation environment. The observation that there is a substantially

reduced marginal bone loss at the nanocoated implants is of high clinical significance. One of the known predictors of the long-term success of an implant is early marginal bone loss [15]. The result of the better bone retention in the test group can be directly linked to the fact that the seal of the implant interface by the bone was more rapid and complete. A stable bone-implant interface will be more resistant to microbial colonization, as well as, biomechanical forces of early functional loading, which overcomes the inflammatory events underlying bone resorption [16]. This is in agreement with the report by Wang *et al.*, who found that HA-coated implants had less crestal bone loss than uncoated controls [7]. These findings of the current research comply with the larger amount of literature that supports the advantages of the nanoscale surface modifications. Soe *et al.* have also stressed, long enough, the importance of surface topography at the micro- and nano-levels in the biological response on the implants [3]. Our results present strong clinical evidence that will transfer successful preclinical histomorphometric research to concrete clinical findings. RFA is a validated and non-invasive technique of documenting the dynamics of osseointegration and the high observed differences are clinically significant [4]. Nonetheless, this research does not lack its limitations. The follow-up was only six months, which only represents the initial stage of the process of osseointegration but not the long-term performance. Although the preliminary findings are most promising, new research in which three to five years are followed is required to verify the tolerance of these benefits. Also, the research was designed at one centre and it only involved patients who had good bone quality at the posterior mandible. The effectiveness of the nanocoated surface in more difficult clinical situations, *e.g.* the maxilla, immediate extraction sockets, or grafted bone, has yet to be explored. Lastly, although both RFA and radiographic evaluation are useful clinical tools, they are indirectly used to measure the process of osseointegration. This human study could not be investigated by a definite histological analysis. Long-lasting, multi-center RCTs should be considered in the future research to prove these results in wide patient populations and clinical appearances. Moreover, it would be of

high interest to carry out investigations of the activity of this nanocoating in the situations of immediate or early loading since the stability increase can be achieved and the duration of healing can be reduced.

Conclusion:

The nano-hydroxyapatite/ zirconia coated implant surface was noted to have better early osseointegration than a standard SLA surface. This was shown by high levels of increased implant stability and low levels of marginal bone loss in six months. The use of this nanocoating is a potential milestone in enhancing predictability and success rate of dental implant therapy.

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