Early ISQ values of photofunctionalized dental implants: a double-blinded, randomized, clinical pilot study

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Purpose: This pilot study compared ultraviolet light-treated (UVLC)-treated implants for their level of osseointegration at six weeks after placement with those implants not exposed to UVLC photofunctionalization.

Materials and Methods: In a randomized, double-blinded format, 21 implants were placed in the second premolar or first and second molar positions of the mandible. One cohort received an implant photofunctionalized with UV light; the other did not. Osseointegration measured by the Implant Stability Quotient (ISQ) values was assessed at implant placement and again at six weeks.

Results: All implants showed high initial ISQ readings above 80. A Mann–Whitney U test was used to determine if the change in median ISQ differed significantly between patients with UVLC treatment and patients with no UVLC treatment. A Wilcoxon Signed-Rank test was used for subgroup analysis to determine if patients receiving UVLC treatment showed a significant difference in median ISQ. Median ISQ values did not significantly differ (P = 0.78) between patients receiving UVLC treatment (median = 0.63, IQR = [0.00 \sim 4.50]) and patients receiving no UVLC treatment (median = 1.00, IQR = [0.25 \sim 3.00]). No significant differences in the median ISQ values were detected when comparing the placement versus the six-week post-placement for UVLC-treated patients (P = 0.27).

Conclusions: This pilot study evaluated the ISQ levels of implants at placement and at six weeks to determine the difference between implants photofunctionalized with UVLC. These results showed no difference between the two groups and examined the reasons for this non-difference. (JOURNAL OF DENTAL IMPLANT RESEARCH 2024;43(3):47-53)

Key Words: Implant, Implant stability quotient, Osseointegration speed index, Photofunctionalization

INTRODUCTION

The process of osseointegration or attachment of the titanium surface to the peri-implant bone is well documented and requires a healing time of 3 to 6 months depending upon the bone quality, bone type, and characteristics of the titanium surface ¹⁻³. The titanium surface can be modified for enhancement of osseointegration by various methods, including plasma spraying, acid etching, or

sand blasting of the surface to gain increased adhesion and differentiation of osteoblasts^{3,4)}. This increases the percentage of bone to implant contact (BIC) at the implant interface³⁻⁵⁾. However, these modifications of the surface design do not address the increased accumulation of hydrocarbons on the titanium implant surface that occurs over time. The age-driven loss of titanium hydrophilicity is known as "biological aging" of titanium⁶⁻⁸⁾. Aged titanium surfaces show less protein absorption and

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inferior osteoblast attachment than a newly manufactured titanium implant, resulting in a decrease in the biomechanical strength of the bone to implant interface⁵⁻⁸⁾. When compared to a newly manufactured titanium implant, an aged implant has a BIC of 58% compared to a newly manufactured implant which has a BIC of 90% 5-8).

Modification of the aged implant surface is clinically desirable to enhance the osseointegration process by removing hydrocarbons. The removal of hydrocarbons returns the implant to a bioactive state, which leads to a conversion to hydrophilicity and an increase in osteoblast migration, attachment, and proliferation on the implant surface⁹⁻¹⁴⁾. One such method to enhance osseointegration and decrease surface hydrocarbons is through photofunctionalization. Photofunctionalization is defined as using ultraviolet light C (UVLC) to modify a titanium surface to remove hydrocarbons, restore hydrophilicity, bioactivity, and improve physiochemical properties 9-15). The purpose of this study was to evaluate UVLC treated implants for their level of osseointegration at 6-weeks after placement, compared with those implants which were not exposed to UVLC photofunctionalization. Osseointegration of the UVLC treated implant would be verified by the universally accepted method of an implant stability quotient (ISQ) using resonance frequency analysis (RFA)16-24).

MATERIALS AND METHODS

This prospective study was performed in the surgical suite of Midwestern University, College of Dental



Fig. 1. Sample of Surgical Guide used in study.

Medicine, Arizona. Participants were recruited from the clinic patient population who would receive one or more dental implants, limited to the second premolar or first and second molar region of the mandible. All edentulous sites used in this study were fully healed 5+ months post-extraction, and the variable of grafted socket or none was not included. The study included healthy male and female patients aged 18 to 99 who had the ability to communicate in English and who could provide written consent to participate in the study. Any patient presenting with corticosteroid use, immune deficiencies, uncontrolled systemic disease, history of severe mental illness, untreated periodontal disease, or use of tobacco in any form was excluded from the study. In addition, the study was closed to those in any vulnerable population, i.e., children, prisoners, or pregnant women.

The study (CIRB AZ 23005) was approved by the Office of Research & Sponsored Programs of Midwestern University. The hypothesis was that dental implants that were photofunctionalized, would show an increased osseointegration speed index (OSI) as measured with higher ISQ values at six weeks, versus implants that were not photofunctionalized.

No use of any generative, or non-regenerative AI-assisted technologies were used to produce any of the submitted work.

1. Participants and procedure

This pilot study was randomized and double-blinded. Twenty participants, each needing at least one dental implant in the aforementioned areas were assigned to one of two cohorts; one would receive a photofunctionalized implant, and the other would receive an implant not photofunctionalized. All implants were from one manufacturer, (DIO, Busan, Korea) and placed fully guided, aided by surgical guides (Fig. 1) and proprietary drilling protocols, by one of two blinded surgeons. Implants were placed with insertion torque of at least 35Ncm, and implant stability was measured by Osstell® (Göteberg, Sweden) ISQ values (Fig. 2). Measurements were done from buccal, lingual, mesial and distal, at placement, and at six-weeks post implant placement by a single, blinded investigator. The four readings were then averaged for each implant. Twenty-one implants were evaluated in



Fig. 2. Sample of ISQ testing utilized.

this pilot study (Table 1).

2. Statistical methods

A biostatistician, not involved with data collection, was responsible for the data analysis. The difference between averaged ISQ at placement and averaged ISQ six-weeks post placement was calculated for each implant. A Mann-Whitney U test was used to evaluate if the change in median ISQ significantly differed between patients with UVLC treatment versus patients with no UVLC treatment. For our subgroup analysis we employed a Wilcoxon Signed-Rank test to evaluate if patients experienced a significant difference in median ISQ at six-weeks versus at placement for both ULVC and no UVLC treatments separately. We reported the median, interquartile range (IQR), and p-value for each analysis.

All statistical tests were two-sided, used an alpha-level of 0.05 to determine statistical significance, and were performed in SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

A total of twenty-one implants met our inclusion criteria and were evaluated in this pilot study (Table 1). No other parameters of success, i.e. marginal bone loss, etc, were part of the study design, but all included and tested implants appeared to have a good long-term prognosis. Median ISQ values did not significantly differ (P=0.78) between patients receiving UVLC-treatment (median=0.63, IQR=[0.00~4.50]) and patients receiving no

Table 1. ISQ values

Patient #	ISQ @ Placement	ISQ @ 6 weeks	UV activated vs. non-UV activated
1	87	86	Non
2	85	87.25	UV
3	85	85	UV
4	88.5	89.5	Non
5	81	85.5	UV
6a	90	85.5	UV
6b	82.75	80	UV
7	86.5	86.75	UV
8	81.5	81.75	Non
9	80	81	UV
10	84.25	85.25	Non
11	86	85	Non
12	84.25	84.5	Non
13	80.75	87	UV
14	80	88.25	Non
15	82	88	UV
16	84	87	Non
17	85.25	85.5	Non
18	82.25	85	Non
19	86.25	86.25	UV
20	82	86	Non

Table 2. Change in ISQ^a for UVLC vs No UVLC Implants (n=21)

	No UVLC (n=11)	UVLC (n=10)	P value ^b
Difference			0.78
Median (IQR)	$1.00\ (0.25{\sim}3.00)$	$0.63\ (0.00{\sim}4.50)$	

^aCalculated as 6-week ISQ minus placement ISQ. ^bMann-Whitney U test.

UVLC-treatment (median=1.00, IQR=[0.25~3.00]). No significant differences in median ISQ values were detected when comparing placement versus 6-weeks post placement for UVLC treated patients (P=0.27), however, no ULVC treated patients saw a significant increase 6-weeks post placement (P=0.05) (Table 2, 3).

DISCUSSION

This prospective pilot study aimed to assess the effectiveness of UVLC exposure to dental implants and the effects on BIC. Our results demonstrated there were no statistically significant differences between the two observed groups, and the reasoning warrants discussion.

Researchers have attempted to improve titanium implant surfaces through different forms of modifications such as sand blasting, laser etching, and plasma spraying.

Table 3. Change in ISO from Placement by Treatment

	Placement ISQ	6-week ISQ	Change ^a from Placement	P-value ^b
Treatment, median (IQR)				
UVLC (n=10)	83.88 (81.00~86.25)	85.88 (85.00~87.00)	0.63 (0.00~4.50)	0.27
No UVLC (n=11)	84.25 (82.00~86.00)	85.50 (85.00~87.00)	$1.00\ (0.25{\sim}3.00)$	0.05

^aCalculated as 6-week ISQ minus placement ISQ. ^bWilcoxon Signed-Rank test.

These modifications are to increase the implant's surface area and the BIC percentage. While these modifications may have an improved effect on the BIC, there has been no impact on the osseointegration speed index (OSI), nor the enhancement of bioactivity of the implant surface. An implant surface modification that could reverse titanium degradation, restore bioactivity, strengthen the interface, and increase OSI could be quite beneficial for implant dentistry. As a dental implant osseointegrates, processes take place to reduce BIC to 50% and eventually to 0% of the implant being in contact with bone, which some characterize as the "stability dip" of the implant 25,26). There are many factors that can influence the ISQ values of a placed dental implant. These factors range from implant location, size and design of the implant, and insertion torque¹⁶⁾, and an attempt was made to control these variables in this study.

Insertion torque (IT) values can vary, depending on the bone type in which the implant is placed, and Sarfaraz et al, showed that an IT in the range of 30 to 60 Ncm is normal²⁷⁾. Additionally, some of the minor changes seen are ISQ differentials which could be influenced by the IT value of 35Ncm. Some researchers report that the gain in ISQ over a 3-month period is greater in implant fixtures placed with a lower IT compared to greater IT²⁸⁾. In a recent literature review, it was pointed out that there remains conflicting reports and observations on the correlation between IT values and ISQ readings at the time of implant placement 16). All of the implants in the present study were placed with an IT of at least 35Ncm and showed very high ISQ readings at placement (Table 1). In the work by Lalsare, implants that were placed with exceptionally low initial ISQ readings, showed the greatest increase in ISQ as their healing progressed. Conversely, the implants that showed the highest ISQ readings at placement showed the greatest decrease in stability at 6 weeks (about one and a half

months). Furthermore, most of the implants placed in this study (81%) whether they were UVLC treated or not, exhibited a slight increase in ISQ values or stayed the same from placement to six weeks²⁹⁾. This corresponds with work shown by Suzuki et al. that showed implants placed with high initial ISQ values, do not show an increase in ISO value during the early healing period³⁰. Also, that same systematic review concluded that photofunctionalized implants and those implants with a high initial ISQ, don't seem to undergo a 'stability dip' seen with other fixtures. Of interesting note, for No ULVC treatment, we get a significant result (P=0.05) showing the 6-week ISQ scores are significantly different than placement ISQ scores for this treatment.

Through the natural aging of titanium, carbon molecules accumulate³¹⁾, and UVLC photofunctionalization can be interpreted as the promotion of osteoconductivity by removing the accumulated carbon atoms from the surface of the titanium implant³²⁾. Furthermore, titanium wettability is significantly affected by the hydrocarbon pellicle and accumulated contaminants³³⁾. Another reason for the indifferences in ISQ readings observed between the two groups in this study may be due to the time rendered for photofunctionalization. Recent evidence has shown there may not be any biological evidence for obtaining photofunctionalization at 20 seconds³³⁾, which was the interval used in this study as prescribed by the implant manufacturer at that time. However, there is ample evidence to suggest hydrophilicity at 20 seconds, but not removal of the hydrocarbon layer. It should be noted, that removing hydrocarbons is the primary purpose of UVLC photofunctionalization, instead of obtaining hydrophilicity³⁴⁾. As far as photofunctionalization treatment time, recent experiments have revealed that UVLC treatment achieved maximum organic decomposition at 60 seconds³⁵⁾. It was also shown that proper titanium treatment with UVLC light is only possible with the synergy



Fig. 3. UV photofunctionalization unit.

provided by packaging the implant in quartz ampules, consistent with the dental implants used in this study³⁶⁾. Since the data collection for this study, DIO photofunctionalization time has been modified to the optimal interval of 60 seconds (Fig. 3).

Lastly, the high initial ISQ readings seen in this study may be attributed to two reasons. The first being the accuracy of the digitally planned implant guide and guided implant placement. A randomized clinical trial by Varga and others has shown that a static guided approach to implant preparation and placement significantly improves the accuracy and stability of implant placement compared to a freehand approach³⁷⁾. The higher accuracy of the guided system used in this study could be attributed to the utilization of a long drill key which yields an increase in accuracy of the initial pilot $drill^{37}$ (Fig. $4A \sim$ C). The drilling control of the first drill seems to be most important to help reduce deviation in subsequent drills. This correlates with findings reported by Choi et al, that the initial drilling channel was the controlling factor in reducing deviation in the implant axial angulation³⁸⁾. It

has also been shown that fully guided implant preparation is associated with higher initial implant stability³⁹⁾. The second reason of the obtained high ISQ values, may be due to limitations of the testing unit itself. Although the range of the Osstell $^{ ext{ iny @}}$ (Göteborg, Sweden) unit is $1\!\sim$ 100, the clinical range of ISQ is normally $55 \sim 80$ as stated by the manufacturer⁴⁰⁾. The unit has a detection limit like any device and the readings obtained in this study may be at the higher end of detection. Publications rarely report ranges of 90~100 and it may be possible that these readings show a limit of detection for the Osstell® device in which the actual osseointegration exceeds the limit of detection. We also realize that with the low number of implants evaluated in this pilot study, we may be failing to find a significant result, even if one exists. From a statistical standpoint, this pilot study was underpowered and limited, which may show that further evaluation is indicated.

It has long been held that photofunctionalized implants show an increase in BIC and osseointegration values³⁴⁾. which should extrapolate to higher ISQ readings, Why this was not shown more clearly in this study, may take additional investigation.

CONCLUSIONS

The results of this pilot study showed there was no statistical difference in ISQ readings between implants treated with UVLC light and those that were not. Reasons for this outcome may be attributable to the lack of sufficient photofunctionalization time, and/or, high degree of initial implant stability, and lack of 'stability dip' of all the implants at placement. Further work should be considered to build upon the findings observed in this pilot study. It would also be informative to conduct clinical research of photofunctionalized implants in patients with poor bone quantity and quality and those with advanced systemic disease.

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Fig. 4. (A) Example of tube extension with surgical guide. (B) Example of fit between the tube extension and the implant drill. (C) Example of fit between the tube extension, implant drill, and the surgical guide.

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