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COULD PHOTOFUNCTIONALIZED EXPIRED DENTAL IMPLANTS BE CLINICALLY USED? IN VIVO STUDY

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ABSTRACT

Objective: This clinical trial study examined the success of clinical utilization of expired titanium dental implants following ultraviolet C light (UVC) photofunctionalization.

Patients and Methods: The study included the installation of 25 expired implants in 15 patients. The implants planned for installation were photofunctionalized using UVC (254nm wavelength) for 30 minutes on the day of implantation. All implants were installed following a two-stage protocol. Following implantation, all patients were followed up on the 3rd, 7th, and 14th days, then the 1st, 3rd, and 6th months for signs of infection or implant rejection. Postoperative cone beam computed tomography (CBCT) was acquired on the 3rd-day and 6th-month follow-up visits. Bone density at six areas around and marginal bone level at four sides of the implant were measured using CBCT scans of the two radiographic follow-up events. The postoperative and 6th-month CBCT measurements were statistically compared for significant differences.

Results: All installed implants showed proper healing without any sign of infection or rejection. Bone density showed statistically significant improvement in the six regions with a mean improvement of 293.50±230.80 HU. The marginal bone level of the measured four areas showed a statistically significant increase with a mean gain of 0.69 ± 0.86mm.

Conclusion: UVC photofunctionalized expired titanium dental implants could be used clinically without any complications and with improved quality of peri-implant bone.

INTRODUCTION

Dental implants are becoming the first option in oral rehabilitation. Titanium is the most used material in dental implant manufacturing due to its bioactivity, owing to the titanium dioxide surface layer that acts as a platform for osteointegration.[1-3] However, this surface bioactivity progressively degrades over time, especially when stored in gas-permeable packages, in a process called surface aging of titanium.[2,4-6] This aging process occurs due to the inevitable progressive deposition of

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hydrocarbons[2,6-8], estimated from 16% to 62% of the aged titanium surface[6,8,9]. The effect of this aging process is reflected in the reduced bone titanium contact percentage of the available titanium implants to about 45-65%.[1,10] This time-dependent aging process is magnified in expired titanium implants that usually aged more than five years.[11,12]

Expired titanium dental implants have two issues that could compromise their successful clinical use: loss of surface activity due to the aging process and sterilization expiration.[11,12] Several methods are used to improve titanium implants' surface characteristics, including ultraviolet C light (UVC) photofunctionalization. UVC is used to restore the surface activity of aged, non-expired titanium implants.[8,13] Moreover, a recent in vitro study by Al Kabany et al.[11] showed the ability of UVC to restore the expired implants' surface superhydrophilicity. Regarding loss of sterilization, it was found that implants kept in their intact packages retain sterilization.[11,14] Moreover, UVC was proven to have a significant sterilization effect.[11,15]

However, to the author's knowledge, no previous in vivo study has examined the success of photofunctionalized expired titanium implants despite economic merits. The current study addressed this missing point. The study examined the clinical and radiographic outcomes of implantation of the photofunctionalized expired titanium implants.

PATIENTS AND METHODS

The current clinical trial study was conducted in the teaching hospital's specialty clinics, Faculty of Dentistry, Umm Al-Qura University, Makkah Al Mukaromah. The study was approved by the Biomedical Research Ethics Committee at Umm Al-Qura University (HAPO-02-K-012-2023-06-1689).

Patient selection and preoperative preparation

Patients were selected from those admitted for dental implantation classified as ASA 1 and ASA 2 over 18 years old. Exclusion criteria included 1) patients with systemic diseases affecting bone healing; 2) Immunocompromised patients; 3) Patients on antiresorptive, antiangiogenic, or chemotherapeutic agents; 4) Patients on radiotherapy; 5) Pregnant ladies; 6) Patients with a history of allergies or tobacco-use.

The study included fifteen patients, nine females, and six males, with a mean age of 48.07±13.40 years. Twenty-five expired implants (Anthogyr, Axiom, France) were installed, sixteen and nine in the maxilla and mandible, respectively. The mean expiration period was 44.12±1.77 months. The details of the installed implants are presented in Tables 1 and 2.

Table (1): The frequency of implant installation related to gender, patient, jaw, and region.

		Freq	Total
Gender	Male	6	15 patients
	Female	9	
Implants/ patient	1 implant/patient	9	25 implants
	2 implants/patient	3	
	3 implants/patient	2	
	4 implants/patient	1	
Jaw	Maxilla	16	
	Mandible	9	
Region	Anterior	5	
	Premolar	15	
	Molar	5	

Patient preparation

Preoperative cone-beam computed tomography (CBCT) was made for all patients. CBCT was taken using (I-CAT FLX, USA) set at 120kV, 16 bits grayscale. The CBCT unit was set at 5mA, with a 6s exposure time. The usual dental implantation planning was done for all patients. The study procedures were explained to all patients, and approvals were obtained.

TABLE (2) Characters of the installed implants regarding length, diameter, and expiration periods.

	mm	Freq.		mm	Freq.		Months	Freq.	Mean ± SD
Length	8	3	Diameter	2.8	2	Expiration periods	42	5	44.12 ± 1.77 months
	10	3		3.6	1		44	17	
	12	5		4.0	12		47	1	
	14	13		4.6	7		49	2	
	16	1		5.2	3				

Day of implantation

A preoperative antibiotic (500mg Amoxicillin Trihydrate + 125mg Potassium Clavulanate) was taken 2 hours before the operation and continued for five days, t.i.d. The expired implants planned for installation were photofunctionalized using UVC (LAVAED UV Lamp, China, 254 nm wavelength and 8-watts power) for 30 minutes following the protocol proposed by Al Kabany et al.[11] The implant package was examined for any damage or loss of seal. Expired implants kept in intact packages were selected. Manufacturing and expiratory dates were recorded. The implant was carried out of the package using a 3D-printed implant-holder to avoid touching the implant surface. The implant-holder carrying the implant was inserted into the 3D-printed implant-holder tray, and the slot number was written on the package for identification. The implant holder tray was inserted into the UVC box. The box cover was seated, and the timer was set at 30 minutes. (Fig 1) The author did all installations under local anesthesia (Mepivacaine HCl 2% with Epinephrine 1:100,000). Implant installation was done according to the treatment plan. Primary closure was done for all cases following the two-staged implantation protocol. Verbal and written postoperative instructions were given to all patients. An anti-inflammatory agent (400mg Ibuprofen) and antiseptic mouthwash (Chlorhexidine Gluconate 0.1%) were prescribed for five days, t.i.d.

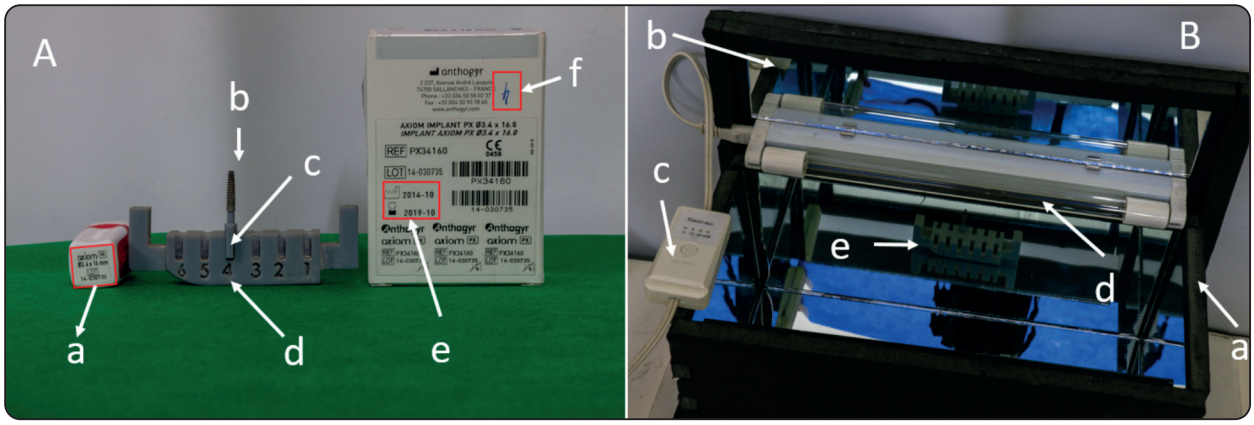

Fig. (1) A: (a) Implant specifications written on the implant pack, (b) Expired implant, (c) Implant-holder, (d) Implant-holder tray with numbered slots, (e) Manufacturing and expiratory dates, (f) Slot number written on the implant box. B: (a) UVC box, (b) UVC box cover, (c) UVC lamp timer, (d) UVC lamp, (e) Reflected image of the implant-holder tray carrying the expired implant.

Postoperative follow-up

All patients were followed up on the 3rd, 7th, and 14th days, then the 1st, 3rd, and 6th months for any signs of infection or implant rejection. Postoperative CBCT was done on the third postoperative day (0M) and after six months (6M) on the day of implant uncovering (stage 2). Bone density was measured in the 0M and 6M follow-up scans. The DICOM files were imported to SimPlant Pro (Ver 18.5, Dentsply Sirona). The axial images were reoriented to parallel the implant to the software vertical orientation line in the coronal and sagittal views. (Fig 2 (A & B)) A panoramic curve was created utilizing the axial image at the level of the midpoint of the implant length. The panoramic curve passed in the middle of the implant at the chosen axial cut. The software created a cross-sectional image perpendicular to the panoramic curve. (Fig 2 (C & D)) A virtual implant was drawn, fitting the installed implant in panoramic and cross-sectional images to facilitate the localization of the implant. (Fig 2 (E & F)) The installed implant was localized, and its length was measured in panoramic and cross-sectional slices. The measured lengths were recorded to aid in correcting the image scale during the marginal bone level (MB-Level) measurements. Panoramic and cross-sectional slices were saved for measuring the MB-Level in mesial and distal regions and labial/buccal and lingual/palatal regions, respectively.

Radiographic bone density measurements:

Bone density measurements were taken at the cervical, middle, and apical regions on the facial-lingual/palatal and mesiodistal views on the 0M and 6M CBCT studies. In the cross-sectional image of the localized implant, a vertical line representing the long axis of the implant was drawn. Three 2.00mm^2 bone density measuring circles were located facial or lingual/palatal to the implant. The first circle (the cervical) was located near the cervical end of the implant, touching the implant surface. The distance between the implant's top and the cervical circle's center was measured and recorded to standardize the 6M measurements. The second circle (the middle) was placed at the middle of the implant length, touching the implant surface. The third (the apical) circle was placed near the implant apex, touching the implant surface. The distance between the implant apex and the center of the apical circle was measured and recorded for standardization.

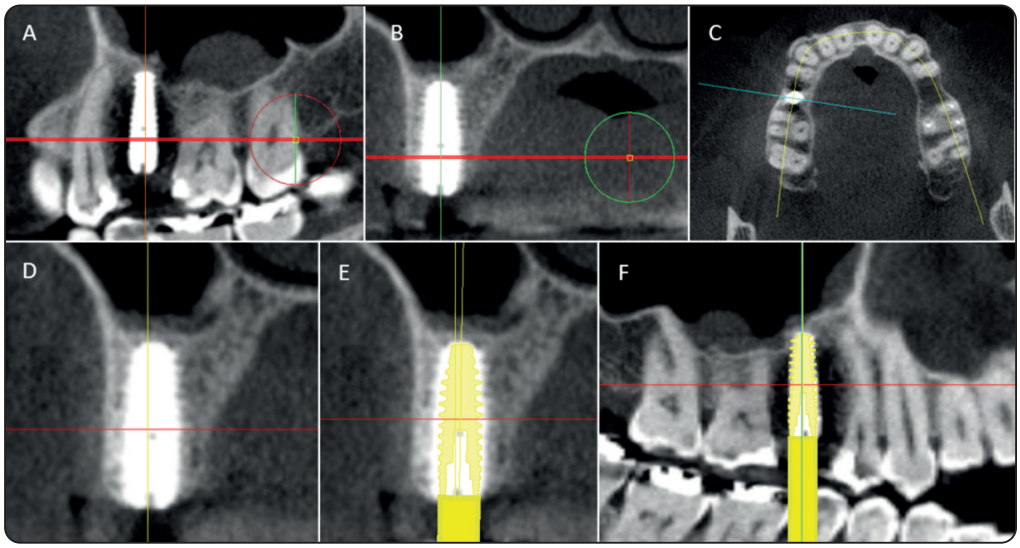

Fig. (2) 0M CBCT, (A & B) Orientation of axial images parallel to the software vertical line in the sagittal and coronal, respectively. (C) the panoramic curve passed in the middle of the implant at the chosen axial cut. (D) coronal view showing the level of axial cut passing at the midpoint of the implant length "red line". (E & F) A virtual implant is drawn parallel to the implant in cross-sectional and panoramic views.

The average bone densities at each of the three circles were recorded. (Fig 3 (A & B)) Implant-centric images were created, and an image representing the mesial and distal regions of the implant was selected. The selected centric-image number was recorded for standardization. Three circles were drawn touching the implant surface at the mesial or distal regions, measuring bone densities as previously (Fig 3 C & D).

Measuring MB-Level:

The saved panoramic and cross-sectional slices of 0M and 6M were imported to ImageJ (Ver 1.54f, National Institutes of Health, USA). The MB-Level in mesial and distal regions and labial/buccal and lingual/palatal regions were measured as follows. A vertical line representing the center of the implant was drawn. The measuring scale was corrected following the recorded implant lengths in the corresponding panoramic and cross-sectional images. A horizontal line was drawn, touching the tip of the implant. Two vertical lines were made from the horizontal line to the bone level at the implant's sides. The signed lengths of the lines were measured and recorded (Fig 3 E & F).

Statistical analysis

Mean and SD for all measurements were calculated using SPSS software version 25 (IBM). The Shapiro-Wilk test indicated the normality of 0M and 6M bone density and MB-Level data (p-value ranging from 0.896 to 0.051). Following normality testing, paired samples T-test was used to indicate a significant statistical difference between the means of bone density and MB-Level measurements on the two events. The p-value significance was set at $p<0.05$.

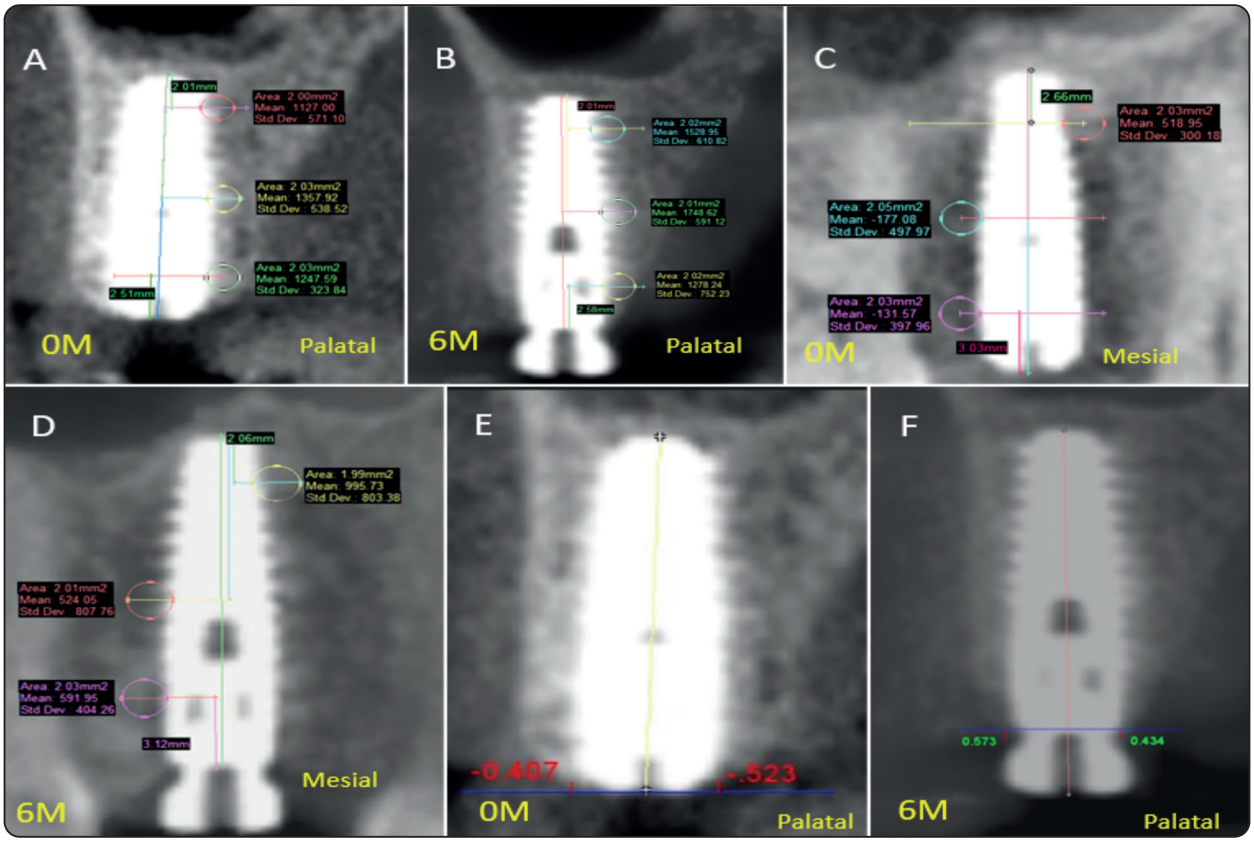

Fig. (3) (A & B) Bone density on bucco-palatal view on 0M and 6M measurements, respectively. (C & D) Bone density on mesiodistal view for 0M and 6M measurements, respectively. (E & F) MB-Level measurements on bucco-palatal view for 0M and 6M, respectively.

RESULTS

None of the installed implants showed signs of infection or rejection over the follow-up period. (Fig 4) The bone density at the six measuring sites showed statistically significant improvement at 6M with a mean increase of 293.50±230.80 HU. (Table 3) The MB-Level at the four measuring sites showed a significant increase at 6M measurements with a mean increase of 0.69 ± 0.86mm. (Table 4)

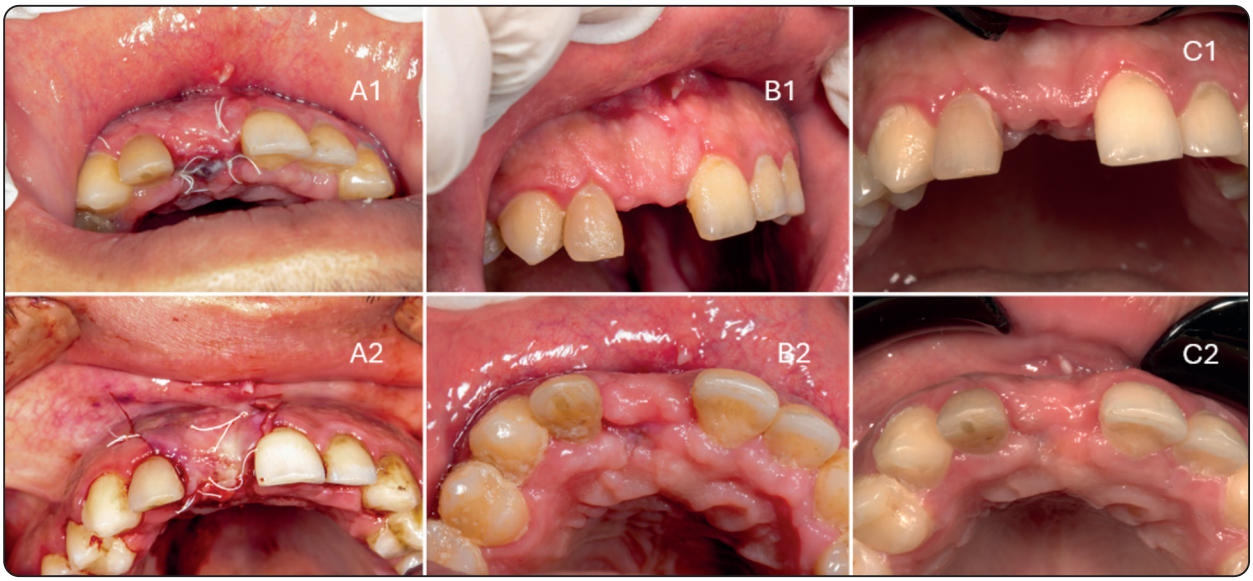

Fig. (4) A: (a) Implant specifications written on the implant pack, (b) Expired implant, (c) Implant-holder, (d) Implant-holder tray with numbered slots, (e) Manufacturing and expiratory dates, (f) Slot number written on the implant box. B: (a) UVC box, (b) UVC box cover, (c) UVC lamp timer, (d) UVC lamp, (e) Reflected image of the implant-holder tray carrying the expired implant.

TABLE (3) Means of bone density at different measuring sites on 0M and 6M (HU).

Tested pairs	Mean ± std. dev		Paired difference					
	0M	6M	M±SD	Std-em	95% CI	t	df	Sig
MD-Cervical-0M MD-Cervical-6M	319.04 ± 621.64	601.21 ± 646.01	282.17 ± 322.30	64.46	149.13 to 415.21	4.38	24	<0.0001
MD-Middle-0M MD-Middle-6M	572.27±640.88	903.04 ± 681.46	330.78 ± 232.46	46.49	234.82 to 426.73	7.12	24	<0.0001
MD-Apical-0M MD-Apical-6M	878.71±455.37	1198.25±496.60	319.54 ± 202.94	40.59	235.77 to 403.31	7.87	24	<0.0001
BP/L-Cervical-0M BP/L-Cervical-6M	1868.48±3835.58	2181.73±3839.45	313.25 ± 214.81	42.96	224.58 to 401.92	7.29	24	<0.0001
BP/L-Middle-0M BP/L-Middle-6M	1489.12 ± 490.98	1713.37 ± 425.86	224.24 ± 226.79	45.36	130.62 to 317.85	4.94	24	<0.0001
BP/L-Apical-0M BP/L-Apical-6M	1092.79 ± 663.53	1383.81 ± 579.30	291.02 ± 162.27	32.45	224.04 to 358.00	8.97	24	<0.0001
Mean	1036.74±1708.50	1330.23±1705.56	293.50 ±230.80	18.85	256.26 to 330.74	15.58	149	<0.0001

M±SD: Mean ± std. dev, Std-em: Standard error mean, CI: confidence interval, Df: degree of freedom

TABLE (4) Mean MB-Level at different measuring sites on 0M and 6M (mm).

Tested pairs	Mean ± std. dev		Paired difference					
	0M	6M	M±SD	Std-em	95% CI	t	df	Sig
MD-M-0M MD-M-6M	-0.47 ± 1.35	0.30 ± 1.33	0.76 ± 0.92	0.18	0.39 to 1.14	4.16	24	<.0001
MD-D-0M MD-D-6M	-0.45 ± 1.75	0.32 ± 1.75	0.77 ± 0.82	0.16	0.43 to 1.11	4.69	24	<.0001
BP/L-F-0M BP/L-F-6M	-0.05 ± 1.47	0.28 ± 1.28	0.33 ± 0.48	0.10	0.13 to 0.53	3.46	24	0.002
BP/L-P/L-0M BP/L-P/L-6M	-0.42 ± 2.00	0.48 ± 1.43	0.90 ± 1.06	0.21	0.46 to 1.33	0.26	24	<.0001
Mean	-0.35 ± 1.65	0.34 ± 1.44	0.69 ± 0.86	0.09	0.52 ± 0.86	8.02	99	<.0001

M±SD: Mean ± std. dev, Std-em: Standard error mean, CI: confidence interval, Df: degree of freedom

DISCUSSION

Successful clinical utilization of expired titanium implants faces two issues: aging of the titanium surface and loss of implant sterilization past the manufacturer's expiration date. The aging of titanium compromises the percentage of osteointegration of the commercially available titanium implants.[1,10] This aging process was noticed as early as four weeks following manufacturing. Compared to freshly manufactured titanium implants, the mechanical retention, albumen adsorption, and cell attachment of four-week-old implants were reduced to 50%, 40%, and 50%, respectively.[6,12,16] The aging process of titanium implants also increases surface hydrophobicity.[6,16,17] This aging process that reduces surface characteristics nearly to half after four weeks of manufacture is pronounced in expired implants. It was indicated that expired implants showed hydrophobic surfaces (with a mean surface contact angle of 125.47± 8.57°).[11]

Functioning implants installed following a 2-stage protocol pass through three stability phases: primary, secondary, and tertiary. The primary stability is shown at the time of installation. The secondary stability is measured following osteointegration before loading.[18] The tertiary (final) stability is manifested following functional adaptation of the peri-implant bone after loading.[19] The Final stability of the loaded implant depends on the primary and secondary stages.[20] The secondary stability phase is affected by implant surface characteristics. Any surface impurities formed during the manufacturing process[21] or post-manufacturing hydrocarbon formation will affect the secondary stage healing process[2,6-8]. These impurities affect tertiary stability stage functional adaption[20] and result in marginal bone loss (MBL) in the early stages[22,23], reducing implant life span[20]. Eliminating these impurities restores surface hydrophilicity and enhances protein adsorption on the implant surface.[24] These surface enhancements improve bone-implant contact percent.[18]

UV photofunctionalization was introduced in 1997.[25] UVC has a photocatalytic effect by eliminating surface hydrocarbon and increasing surface hydroxyl groups.[21] This photocatalytic effect reverses the aging process of titanium implants with various nanotopographic characteristics.[26-30] Photofunctionalization restored surface hydrophilicity, protein adsorption, alkaline phosphatase activity, osteogenic cell activities, and increased mineralized nodule regions of non-expired implants.[4-6,17,31,32] Moreover, Al Kabany et al. recommended a photofunctionalization protocol that restored

superhydrophilic surfaces of all tested expired implants and had an effective antibacterial effect.[11] The restoration of superhydrophilicity and surface activity of aged implants will improve the secondary stability stage healing process and, hence, osseointegration.

On the other hand, implant sterilization is assumed to be affected by the expiratory date.[12] However, it was shown that implants keep their sterilization as long they are kept in intact packages. Worthington, in 2005[14], indicated that implant sterilization is preserved for several years given they are kept in their intact package. Al Kabany et al. in 2023[11] showed a lack of bacterial contamination in all examined expired implants stored in intact packs. Moreover, UVC was proven to have efficient antibacterial and sterilization effects.[11,15]

The current study examined the clinical and radiographic outcomes of installed photofunctionalized expired implants. Regarding clinical outcomes, none tested implants showed signs of infection or failure following insertion and over the follow-up period. The radiographic evaluation focused on MBL and changes in bone density around the installed implant over the follow-up period. MBL is the bone loss around the implant margin following surgical placement.[33] MBL is an essential tool for radiographic evaluation of successful implantation and detection of possible failure.[34,35] Excessive MBL eventually leads to implant failure.[36]

MBL in two-stage implant surgeries can be categorized into; category I (MBL-I) following implant insertion till implant loading and category II (MBL-II) following loading. MBL-I ranges between 0.2mm to 1.68mm on second-stage implant uncovering.[37-41] MBL-II is acceptable below 1.5mm in the first year of loading and 0.2mm each year, adding MBL-I.[42] Reducing MBL-I or even gaining marginal bone before loading will reduce uneventful overall MBL, prolonging the life span of the functioning implant. The photofunctionalization protocol used in the current study resulted in MB-Level gain in the four measured areas around the implants with a mean increase of 0.69 ± 0.86mm at the 6M follow-up period.

Measuring MB-Level in the current study utilized CBCT at the four primary sites around the implant (i.e., mesial, distal, facial, Lingual/palatal). These CBCT measurements can give more significant evidence regarding bone defects around the implant.[43] On the contrary, measuring MB-Level using two-dimensional radiographic images suffers tissue overlap, affecting clinical judgment.[44]

Evaluation of bone density around dental implants is another essential implant success assessment tool.[45] Bone density could be measured radiographically using CT and CBCT. Several studies showed consistent bone density findings of CBCT and CT.[46-48] CBCT has lower cost, subjects the patient to smaller amounts of radiation dose, and has fewer artifacts than CT scans.[19,49] Bone density measurements in the current study were measured at six sites around the implant for a more significant representation of the quality of bone housing around the implant. Bone density at all measured sites showed significant improvement in the study period. At the implant-bone interface, artificial artifacts were within 0.5mm of the implant surface, which masks the evaluation of direct bone contact.[19] However, measuring bone denisty of an area of $2mm^2$ touching the implant surface, including the artifact region and bone region in both measuring periods, can show the change in bone density.

Zaheer et al.[36] measured bone density and MB-Level in different postoperative periods using CBCT, comparing non-photofunctionalized versus UVC photofunctionalized non-expired implants. The mean mesial change of the MB-Level of non-photofunctionalized and UVC photofunctionalized at six months were -0.54±0.40mm and -0.03±0.05mm, respectively. Those on the distal side were -0.85±0.41mm and -0.02±0.06mm, respectively. Zaheer et al. showed a reduction of MBL and improved bone density over the follow-up pe-

riod. The current study showed MB-Level gain on the mesial and distal sides of 0.76 ± 0.92mm and 0.77 ± 0.82mm, respectively. This difference could be attributed to more prolonged UVC exposure in the current study (30 minutes) vs the Zaheer et al. study (10 minutes). The more pronounced UVC effect at 30 minutes vs 15 minutes of exposure was also indicated in the study by Al Kabany et al.[11] in 2023.

The results of the current study demonstrated the successful use of expired implants following photofunctionalization. The photofunctionalization protocol is cheap and readily available, and the photofunctionalization device can be easily made. However, further assessment of photofunctionalized expired titanium following loading is required.

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