Original Article

Influence of abutment angulation on implant failure in immediately placed and restored implants in the esthetic zone: a randomized clinical trial

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Background: Tooth extraction socket in the aesthetic area is a major indication for immediate implant placement greatly improving patient satisfaction and preserving the alveolar ridge. However, the effect of non-axial force on the peri-implant bone with subsequent early implant failure remains unclear. **Objective:** Evaluate the prognosis of tilted implants immediately placed and restored with angled abutments in comparison to straight implants restored with straight abutments in the esthetic area (anterior or premolars) using computer-aided surgical guides. **Material and methods:** Badly decayed non-restorable teeth in the aesthetic zone (anterior or premolars) were extracted atraumatically. Immediately after guided implant insertion, the abutments were adjusted and placed according to the allocation group (0, 15, or 25-degree angle) then a temporary crown was performed out of occlusion in centric and eccentric relation. Early implant failure was assessed at three and six months. **Results:** There was no statistically significant difference between the two groups (P=0.305). Straight and angled abutment groups showed 6 (14.3%) and 8 (20%) failed cases, respectively. The post-hoc subgroup analysis showed no statistically significant difference between angle 15 and angle 25 degree groups where (P=0.686) or between Anterior and Premolar groups (P=0.853). **Conclusion:** There was no statistically significant difference in the failure rate when comparing angled to straight immediately placed & restored implants. This applies to both anterior and premolar implants.

Keywords: Weight-bearing. Immediate dental implant loading. Dental restoration failure. Dental implantation. Tooth extraction.

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Introduction

Superb esthetics delivered in a reduced treatment time with minimal or no complications is now the ultimate dream in the world of implant dentistry. Immediately placed and restored implants in the aesthetic zone (anterior or premolars) offer the advantage of keeping alveolar bone resorption to a minimum as well as better soft tissue remodeling sparing the need for hard and soft tissue augmentation procedures improving patient satisfaction[1,2]. However, the main challenge in immediate implants is the ability to use the available bone anatomy optimally gaining enough primary stability from the apical bone. Prosthetic teeth, on the other hand, should be planned to the best esthetic and functional position. If the difference between the two positions is large, this will prompt the use of the angled abutment[3].

The prognosis of immediately placed and immediately restored implants was questioned a lot in the literature. While many reported it can be implemented as a successful technique, risk factors should be kept in mind. In this clinical scenario, multiple risk factors are combined altogether[4]. The risk of immediate implant placement, immediate loading, placing the implant in poor bone quality due to nature of the maxilla, non-splinted prosthesis "single crowns", increased crown height space as in post-extraction socket. Usually, implants are placed more sub-gingival creating a vertical cantilever, with the use of angled abutments creating a horizontal cantilever[5].

Finite element analysis studies reported an increase in stresses with angled abutments mainly in the neck region up to 12% and 18%[6].

Several systematic reviews reported are comparing the effect of angulation in full arch splinted cases comparing the axial with the tilted implants in all on four prostheses or comparing single implants placed in extraction socket versus healed ridges but none are comparing the effect of angulation in single crowns immediately placed and restored where biomechanics differ significantly and the effect of forces can be more detrimental[7-10].

A very recent systematic review with meta-analysis published in 2020 was comparing biological and mechanical complications of angulated abutments connected to fixed dental prostheses. The review included nine studies only two studies included separable data on implant failure between angled and straight abutments where a higher risk of failure was observed in the angled group 11.7% failure compared to 1.6% for the straight group. Their results showed both statically and clinically significant differences. Three studies only included single crown restorations none of them was immediately placed or randomized controlled clinical trial[11].

To date, limited randomized controlled clinical trials were conducted to evaluate the difference in the failure rate of oral implants immediately placed and restored in fresh extraction sockets, and to assess the effect of different angulation in single crowns[12].

Objectives

Thus, a question has arisen to evaluate the prognosis of tilted implants immediately placed and restored with angled abutments in comparison to straight implants restored with straight abutments in the esthetic area using computer-aided surgical guides.

Hypothesis

The null hypothesis was that when comparing angled to straight abutments in immediately placed and restored implants in fresh extraction sockets in the esthetic zone (anterior teeth and premolars), there will be no difference regarding implant failure.

Materials and Methods

Trial design and Ethics approval

This study was designed as a randomized controlled clinical trial with two-arm parallel groups with an allocation ratio of 1:1. The study was approved by the Ethics Committee of Scientific Research of the University (approval number 17-9-6). The study was conducted according to the Declaration of Helsinki. This protocol was registered on clinicaltrial.gov (ClinicalTrials.gov ID: NCT03243695).

Participants

In this study, implants were immediately inserted and restored in place of badly decayed or non-restorable remaining roots or teeth in the esthetic zone (anterior teeth and premolars). Inclusion criteria included sites with an Intact buccal plate assessed after cone-beam computer tomography (CBCT) scan, presence of adequate mesiodistal width between the adjacent natural teeth (at least 7 mm), and presence of adjacent natural teeth to the tooth/teeth to be extracted. Patients with active signs or symptoms of acute infection or acute periodontal disease in the tooth or the remaining root were excluded from the study. Patients with para-functional habits, poor oral hygiene, severe over-eruption of the opposing teeth, any systemic condition that may interfere with osseointegration, heavy smokers (more than 2 packs per day), and pregnant women were excluded as well.

The study was conducted in the Prosthodontics Department (Faculty of Dentistry Cairo University, Cairo, Egypt) from January 2018 to December 2019 where a total of 90 patients (25-45 years age range with an average of 37.6 years) were recruited from the outpatient clinics fulfilling the inclusion criteria. The Department database was also checked and possible participants were contacted. All participants fulfilling the inclusion criteria were included in the study. The recruitment continued until the target population was achieved.

Interventions

Preoperative procedures

The investigator explained the study in detail to the eligible participants with all possible alternative treatment options and possible risks. When the patient accepted the

treatment, informed consent was signed by the patient. Then the investigator carried out standard extraoral and intraoral examinations and filled out the diagnostic charts including medical and past dental history.

Preliminary impressions (Tropicalgin, Zhermack SpA -Via Bovazecchino, Italy) were taken then the tooth to be extracted was trimmed from the cast and an ideal wax-up was performed. A hard vacuum stent of 2 mm thickness (Splint Material, Keystone Industries, Germany) was constructed over the cast with the wax-up for fabrication of the temporary crown later.

The patient was then imaged a CBCT. The acquired DICOM image (Digital Imaging and Communication in Medicine) were assessed on blue sky software® (Bluesky plan3, Bluesky Bio, USA). All the cases must have had an adequate buccolingual bone to accept either straight or angled abutment, jumping gap less than 2mm after remaining root extraction, at least 3-4 mm bone apical to the extraction socket to help to achieve sufficient primary stability as well as D2 bone according to Misch classification (porous cortical bone and dense trabecular bone), if not the patient was excluded from the study.

Planning phase

The case was planned on the blue sky software®. First, the DICOM images were imported to the planning software, then the image was adjusted so that the occlusal plane was made parallel to the floor and the focal trough was drawn running through the center of the arch. The cast was scanned using a lab scanner (Freedom HD scanner, DOF, Seoul Korea) and the file with an extension of standard triangulation language (STL) was imported to the planning software where it was aligned to the DICOM images through point registration.

A virtual wax-up was then simulated for the anterior & posterior teeth following the arch contour to serve as a guide for prosthetic-driven implant placement. Later the implants were then planned so that at least 3-4 mm of the implant engage the bone apical to the extraction to help to achieve sufficient primary stability allowing for pro-visionalization. Selected implant dimensions were 3.7 mm x 12, 3.7 x 14 mm, 4.1 mm x 12 mm, or 4.1 x 14 mm according to the case and the remaining root anatomy. The final implant position was then modified according to the allocation group to allow for the placement of either a straight or angled abutment (15 or 25 degrees depending on the case). This applies to both the anterior and premolar sites (figures 1A and 1B). The guide was then fabricated and exported from the planning software and sent for printing to the Prosthodontics Department Digital Lab by email for construction (Mogassam, Digital Dentistry, Egypt).
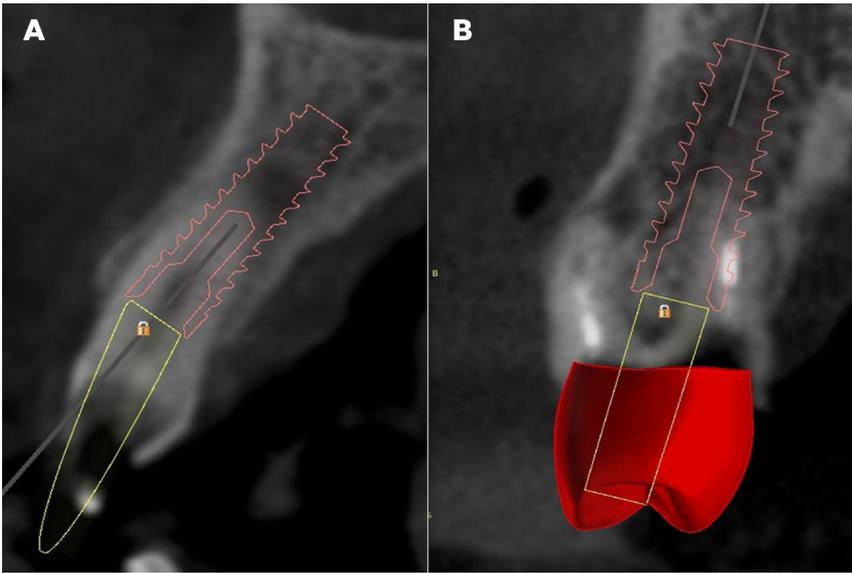
Figure 1. Implant planning: A- Angled implant planning in the angled group; B- Straight implant planning in the straight group.

Surgical procedure

Patients have been administrated a prophylactic antibiotic (Flumox 500 mg Capsules, E.I.P.I.Co., Tenth Of Ramadan City, A.R.E) one day ahead of surgery. The procedure was carried out under local anesthesia (Septanest SP, articaine hydrochloride 4%, France) under sterile conditions. The remaining tooth was atraumatically extracted using a lancet for cutting the attachment then periotome (Nordent Manufacturing, INC, USA) followed by remaining root forceps. After tooth extraction, the socket was curetted and irrigated with copious saline till fresh bleeding from the socket was observed and then the labial plate was checked for being intact (figure 2).

Figure 2. Labial bone checked for being intact after extraction

A surgical guide was placed and checked for stability and drilling was performed following the kit instruction using consecutive drills (Simple guide, DENTIS, Korea) (figure 3). Before implant insertion, the prepared osteotomy was lavaged thoroughly with saline to remove any drill debris from the socket. The implant (OneQ-SL, Regular, DENTIS, Korea) was placed and the insertion torque was checked using a manual torque wrench. Implants with insertion torque less than 35Ncm were not loaded and subsequently excluded from the study. Periapical radiographs were taken to ensure proper seating of the implant. Then the abutment was screwed to the implant fixture, whether straight or angled (15 or 25 degrees) according to the allocation group where it was trimmed to ensure sufficient clearance with the opposing dentition (figure 4 and figure 5).

Figure 3. Drilling performed through the surgical guide

Figure 4. Angled abutment before adjustment

Figure 5. Straight abutment after adjustment

Then the vacuum stent was placed over the abutment and a hole was performed buccally to inject the auto-polymerizing resin (Structure 2 SC, VOCO GmbH, Germany) to form the temporary crown (figure 6). After curing the material, the abutment was unscrewed and the stent was removed. The abutment was then screwed to implant analog to fill any deficient material. After that, the crown was checked to be out of occlusion in centric and eccentric occlusion to avoid any premature contact and subsequent overloading. Later the crown was screwed in position and the screw access hole was sealed with polytetrafluoroethylene (PTFE) followed by flowable composite (Flowable composite, VOCO GmbH, Germany) (figure 7).

Figure 6. Temporization using a vacuum stent

Figure 7. Temporization indicating no interference in a centric and eccentric movement

The patient was then called for follow-up a week later, then once a week for the first three weeks, then at one, three, and six months. The prophylactic antibiotic that was prescribed one day before the surgery was continued for another 5 days postoperatively. Analgesic drug (Ibuprofen 600 mg, Knoll AG, Ludwigshafen, Germany) was prescribed once daily or when needed up to 1 week. The patients were instructed not to bite on the immediately restored tooth and to eat a soft diet for the first 8 weeks. Oral hygiene measures required for proper maintenance were demonstrated to the patients. The patients were dismissed and recalled after 1 week for a checkup.

Final prosthetic procedures

At six months the patients were recalled for the second stage. The flowable composite was removed from the screw access channel as well as the PTFE. The temporary crown was unscrewed using a torque wrench. Closed tray impression transfers (Hex Impression transfer Coping DENTIS, Korea) were screwed to the implant and a periapical x-ray was used to verify the proper seating of the impression transfer. A closed tray impression (Zeta-plus, Zhermack SpA, Badia Polesine, Italy) was made. The abutment was selected according to the allocation group (0, 15, or 25-degree angle) and prepared to the proper height according to the occlusion and a crown was fabricated. The final crown was checked for any occlusal interference and then delivered to the patient after torquing the abutment at 25 Ncm and the screw access hole was sealed with polytetrafluoroethylene (PTFE).

Outcome assessment

The implant was removed under any of these conditions: (1) pain on palpation, percussion, or function, (2) horizontal and/or vertical mobility, (3) uncontrolled exudate, (4) uncontrolled progressive bone loss or more than 50% bone loss around the implant were confirmed radiographically. Two outcome assessors recorded the mobility of failing implants separately. In case of a difference between the assessors, a third assessor resolved the conflict.

In the case of abutment mobility, the abutment was re-torqued. In case of crown fracture or loss, a new crown was constructed. In case of implant failure, the site was left

to heal for 3 months after which time a new implant with delayed loading was planned and subsequently excluded from the study.

Sample size

Sample size calculation was done using the R statistical package (version 2.15.2 (26-10-2012). Copyright (C) 2012 - The R Foundation for Statistical Computing). Two-sample comparison of proportions power calculation was used to detect the proper sample size. Proportions of failed implants in both test and control groups were determined according to Chaushu et al. (2001) which showed that the test group had 3 failed implants out of 19 (15.79%) and the control group had none out of 9 (0%)[13]. The results showed that a total sample size of 80 implants will be adequate to detect a difference of 15.79% in proportions between study groups with a power of 80% and a two-sided significance level of 5% (p-value of 0.05); with equal allocation to two arms (40 implants in each group). This number was increased to 45 in each group to compensate for possible losses occurring during follow-up.

Randomization and allocation concealment mechanism

After participants were enrolled in the study, the participant grasped an opaque sealed envelope. The name of the participant was written on the envelope that contained a code referring to either the intervention or the control group. The participants were allocated using a computerized random allocation program. The code was kept away from the investigator, outcome assessors, and the statistician to ensure proper blinding.

Blinding

The principal investigator was not blinded due to the obvious difference between straight and angled abutments. Both the participant and statistician were blinded. The participant did not understand the difference between the two groups, so the participant was blinded. The outcome assessors blindly assessed the outcomes. The investigator sent the results to the statistician with codes, so the statistician was blinded as well.

Statistical Methods

Professional academic statistician analyzed the data using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 20 (SPSS Inc., Chicago, IL). Categorical data were described as numbers and percentages. The blinded statistician explored the data for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. The comparisons between two groups for normally distributed numeric variables were made using the Student's t-test, but for the non-normally distributed numeric variables the comparisons were made by Mann-Whitney test. A *P*-value less than or equal to 0.05 was considered statistically significant. All tests were two-tailed.

Results

Participants flow

One hundred and thirteen patients were assessed for eligibility out of which fourteen patients were excluded for not meeting the inclusion criteria and nine refused to join

the trial. Forty-five patients were allocated to each group. From the angled group, 5 patients dropped out while 3 patients dropped out from the straight group, so there was no need for intention to treat analysis. There was no statistically significant difference between the straight and angled groups where (P=0.305). The straight group showed 6 (14.3%) failed cases with 36 (85.7%) cases with no failure. The angled group, however, showed 8 (20%) failed cases with 32 (80%) cases with no failure.

Outcomes and estimation

A post hoc subgroup comparison for subgroups has been done based on the observed results aiming to assess whether the different angulations affect implant failure or not. A total of eight failures were observed in the angled group distributed between the angles 15-degree and 25-degree groups. There was no statistically significant difference between the two groups where (P=0.686). Angle 15-degree group (twenty-three implants) showed 4 (17.4%) failed cases with 19 (82.6%) cases with no failure. While Angle 25-degree (seventeen implants) showed; 4 (23.5%) failed cases with 13 (76.5%) cases with no failure.

Another post hoc subgroup comparison for subgroups has been done based on the observed results aiming to assess the effect of location on implant failure. There was no statistically significant difference between anterior and premolar groups where (P=0.853). The anterior group (thirty-seven implants) showed 6 (16.2%) failed cases with 31 (83.8%) cases with no failure. The premolar group (forty-five implants); showed 8 (17.8%) failed cases with 37 (82.2%) cases with no failure. The distribution of abutment angles among the different groups can be seen in the bar chart. (Figure 8).
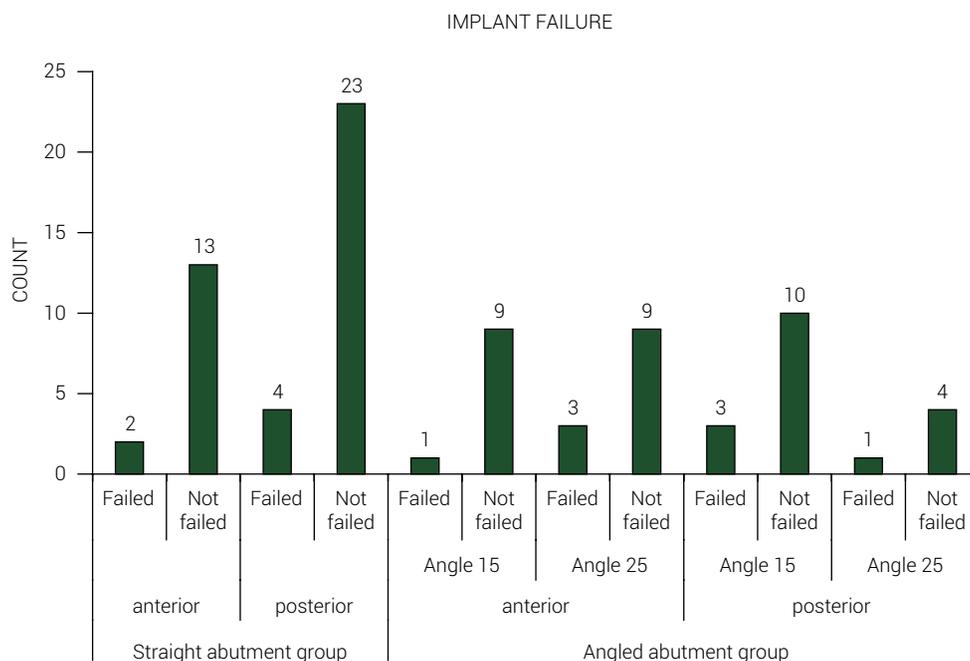
Figure 8. Bar chart for implant failure among different groups
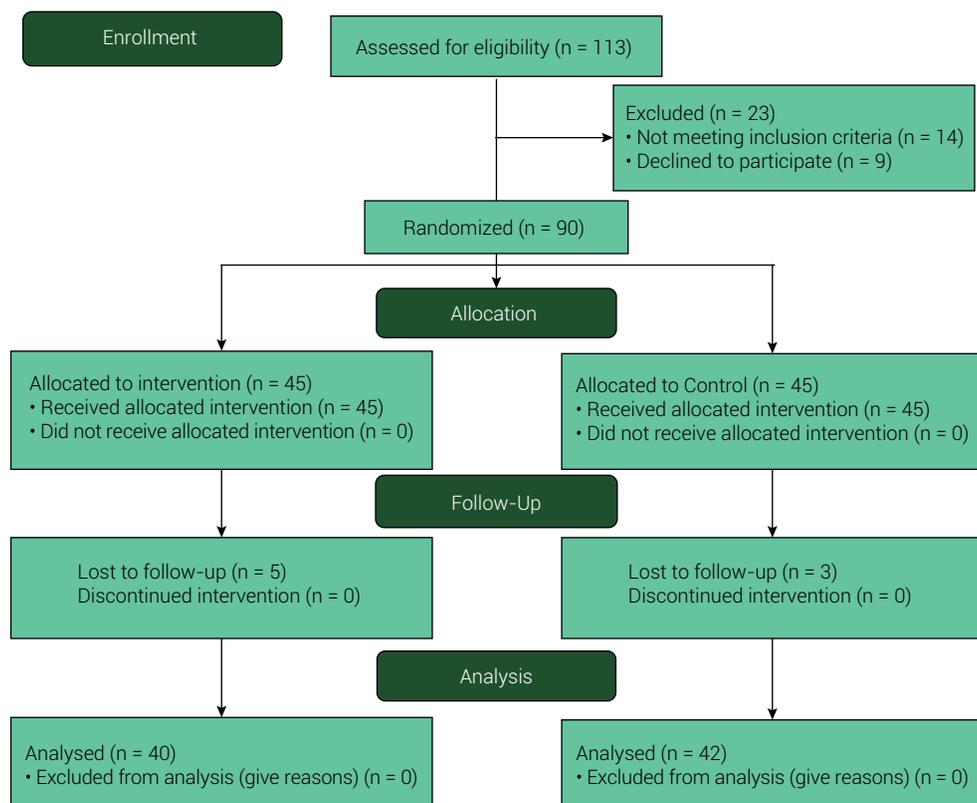
Figure 9. The final CONSORT flow chart displaying counts at each field

Discussion

In this randomized trial, early implant failure was assessed between angled and straight abutments in implants immediately placed and restored in the extraction socket in the esthetic area. The results showed a non-significant difference, and sub-group analysis showed a non-significant difference in the failure rate with increasing the degree of angulation. Regarding anterior versus premolar sites; a non-significant difference was also observed.

Several risk factors were combined in our study allowing measuring a vulnerable clinical situation. The results seem to indicate that each of the risk factors involved represents a healing determinant of extraction sockets implanted & restored immediately after tooth removal. Combining all these factors may outweigh the benefit gained from this treatment. Therefore, cases should be carefully selected.

Failure rate results in our study were considerably high around 17% in comparison to 2% failure rates reported in the literature in delayed loading protocol alone or implant in healed ridge alone[14]. Many of the failures might be attributed to combining several risk factors such as compromised bone quantity in immediate implantation, compromised quality, especially in the maxilla, absence of splinting (unlike full arch cases), the possibility of increased load due to immediate provisionalization, tilting, and fail-

ure to follow dietary recommendations in the first few weeks; all these factors combined might be the cause of the relatively high failure rate observed in our study[15-19].

This is consistent with a systematic review in 2015 comparing axial to tilted implants where sensitivity analysis performed for maxillary arch only, showed statistically significant difference favoring axial implants. The authors of this study as well as others concluded that the compromised bone density might be the reason and that combining risk factors might not be advisable[20]. Our results are also consistent with another systematic review reporting that immediate loading of post-extraction implants showed a 3.62 higher risk ratio compared to the healed ridge[15].

The finding of our study indicates that angles of the readymade angled abutments supplied by the implant company manufacturers are within the normally accepted range of bone tolerance and can be used safely if all other oral conditions are optimum.

Regarding the implant site, the results indicate that even though the premolar area may be associated with lower bone density or increased occlusal forces in the posterior maxillary arch immediately placed and restored implants can be safely implemented[20]. Another observation is that the position of the implant in the extraction socket relative to the remaining bone in the premolar area is usually centralized. This scenario offers less engagement of palatal bone consequently bone-implant contact is mainly confined to the bone apical to the extraction socket. Contrary to anterior teeth, more palatal bone engagement is usually available, and less occlusal forces are expected yet no statistically significant difference was found implying that sufficient primary stability if achieved, will favor the prognosis of immediately placed and restored implants.

Limitations of this study might be related to yielding different results if other implant systems were used as implants with aggressive threads which might have led to few failure results. Also, inability to control patients complying with post-operative instructions not to bite on the immediately restored tooth and to eat a soft diet for the first 8 weeks. Both factors can have a direct impact on failure results. Future studies with several implant designs should be put into consideration. However, researchers can now have a basic guideline for making decisions in selecting cases immediately placed and restored without compromising the outcome.

Conclusions

The angled (whether 15 or 25 degrees) or the axially placed implants can be immediately implanted in the anterior or premolar maxillary fresh extraction sockets, and immediately restored with provisional crowns.

Registration

This protocol was registered on clinicaltrial.gov (ClinicalTrials.gov ID: NCT03243695).

Funding

Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

Data availability

Datasets related to this article will be available upon request to the corresponding author.

Author Contribution

HF Fouad: Concept, design, definition and intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, funding, manuscript draft, manuscript editing & review.

AH Elkhadem: Concept, design, definition and intellectual content, experimental study, manuscript editing & review.

MW Elkerdawy: Concept, design, definition and intellectual content, experimental study, manuscript editing & review.

MM Elfar: Concept, design, definition and intellectual content, experimental study, manuscript editing & review.

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