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The influence of new immediate tissue level abutment on crestal bone stability of subcrestally placed implants: A 1-year randomized controlled clinical trial

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Abstract

Background: The relation between implant abutment disconnection (AD) and increased crestal bone loss is still debated.

Purpose: To compare bone changes below implant-abutment junction of subcrestally placed implants between: (1) implant level restorations, that underwent four ADs and (2) implants with immediate tissue level abutment with no AD, 1 month (T2) and 1-year (T3) after final restoration delivery.

Materials and methods: Sixty-four patients received 64 bone level implants with platform-switching and conical connection in edentulous sites of posterior mandible and maxilla. All implants were placed 1.5 mm subcrestally and distributed among: (1) control group, that received a regular healing abutment and (2) test group with immediate tissue level (ITL) abutment, which was torqued to implants during surgery, transforming bone level implant to tissue level type. After 2–3 months of healing and a 1-month temporization, final zirconia-based screw-retained crowns were delivered to both groups. Crestal bone levels were calculated after final crown delivery (T2); after 1-year follow-up (T3) and compared using Mann–Whitney *U* test ($p \leq .05$).

Results: Early bone loss of the test and control groups was 0.14 ± 0.27 mm and 0.64 ± 0.64 mm, respectively; the 0.5 mm difference was statistically significant ($p = .0001$). Late bone loss was 0.06 ± 0.16 mm and 0.21 ± 0.56 mm for the test and control group, respectively; the 0.15 mm difference between the groups was no more statistically significant ($p = .22$). Both groups displayed bone gain, 0.08 and 0.43 mm, respectively, and the overall crestal bone loss was reduced.

Conclusions: Immediate tissue level abutments can significantly reduce early bone loss when measured 1 month after final prosthesis delivery, however, after 1-year follow-up, difference between the groups was no more statistically significant.

KEYWORDS

alveolar bone loss, definitive abutment, dental implant-abutment design, platform switching, randomized controlled trial

1 | INTRODUCTION

Although disconnection of abutment seems to be an inevitable part of implant treatment, there was always a prevailing opinion, that this procedure better to be avoided. Abrahamsson and colleagues were the first to describe, that repeated healing abutment disconnection may cause bone loss in a dog model.[1] Therefore, it has been suggested that moving of restorative procedures to abutment level does not disturb peri-implant seal, which, in turn, results in less bone resorption.[2] It could be assumed, that with time the protocol of "one abutment—one time" implant treatment was developed, when final prosthetic abutment is delivered at the time of a surgery.[3] This treatment modality was tested in several clinical situations, using cement-retained restorations—in fresh extraction sockets and in completely healed ridges. It was reported, that when immediate implant receives permanent abutment at the time of

What is known:

- Abutment disconnections may lead to crestal bone loss around implants.
- "One abutment one time" protocol using cemented restorations has been introduced to eliminate this issue.

What this study adds:

- How bone reacts to immediate tissue level abutment, when it is used for subcrestally placed implants.
- Provides "one abutment one time" protocol for with single screw-retained restorations.
- Offers possible explanation the process of bone regeneration, if bone is lost due to disconnection of abutment.

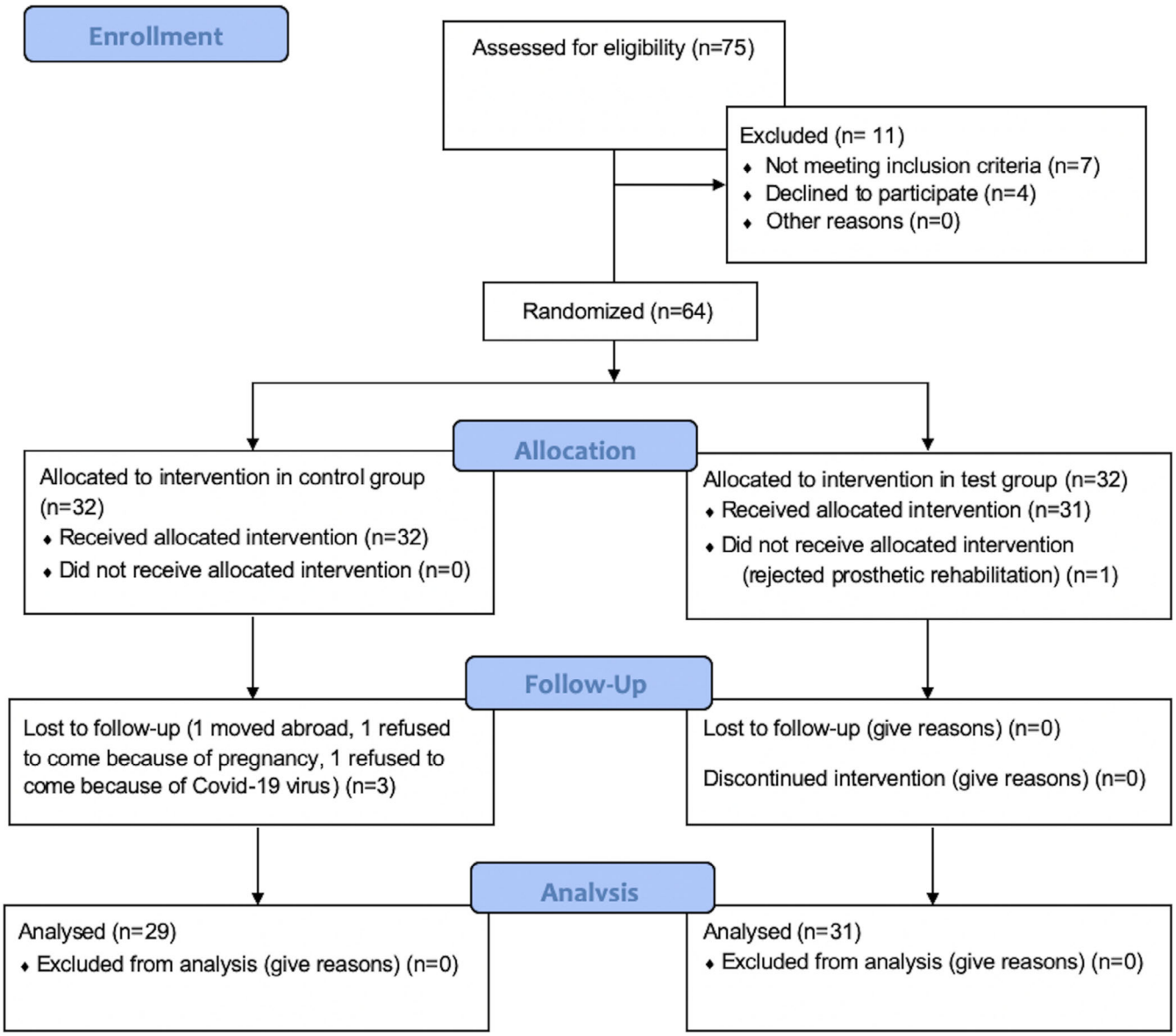

FIGURE 1 Flowchart diagram of the study protocol according to Consort guidelines

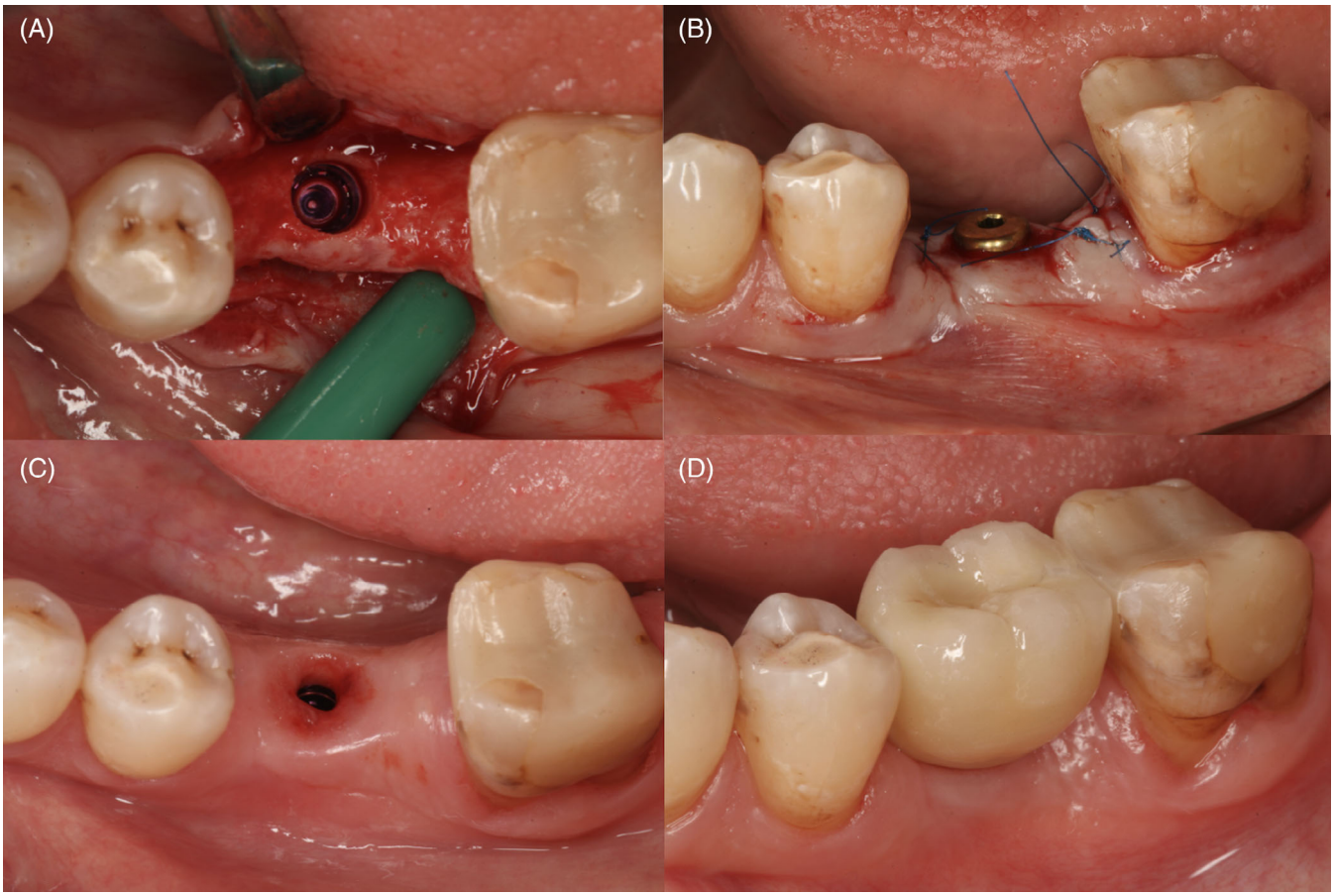

FIGURE 2 Implant level control group. (A) subcrestal implant position 1.5 mm below the bone level; (B) Healing abutment fixed during the surgery; (C) Healed situation before impression; and (D) Final zirconia-based screw-retained restoration affixed directly to implant

the surgery, less bone loss after 3 years is recorded, compared to implants with repeated abutment disconnections.[4,5] In contrast, clinical studies in healed ridges by Koutosis and colleagues, and Degidi and colleagues, failed to demonstrate the superiority of disconnection-free approach, as difference in bone loss between 0.13 mm (abutment level) and 0.26 mm (implant level) was deemed to be not significant.[6,7]

The use of "one abutment-one time" approach in screw-retained restorations present other challenges, as traditional cementable prosthetic abutments cannot be used. Instead, standard multiunit abutments are employed, which allow retaining of restorations by small screws. Only few clinical studies have dealt with comparison of implant or abutment level screw-retained restorations. Toya and colleagues, have found significantly better crestal bone stability in abutment group,[8] while Todisco and colleagues used interprosthesis comparison between multi-unit and implant level restorations' and reported no differences in crestal bone levels.[9] The reasons for this outcome might be standard multiunits' disadvantages, like bulky design, limited availability of different gingival height multiunits or inability to anchorage single restorations securely, caused by the lack of an antirotation features, resulting in often screw loosening.[10]

Recently, manufacturers have introduced an immediate tissue level (ITL) abutment to overcome these drawbacks.[10-12] It is to be placed immediately during surgery, has tissue-friendly design and possibility to harbor single restorations with reliable torque retention up to 30 Ncm. Obviously, the performances of these ITL abutments should be tested under different clinical situations before a clear conclusion about their efficacy can be drawn.

The corono-apical position of implants is a parameter that cannot be ignored when discussing marginal bone stability. Subcrestal implant placement has been recently suggested to be a reliable method to reduce crestal bone loss when the soft tissue is thin.[13,14] It was deemed interesting to assess if the "one-abutment one-time" concept using recent dedicated ITL abutments may benefit to the crestal bone stability of implant placed subcrestally in healed sites.

The aim of the present study was, therefore, to test the "one-abutment one-time" concept with a novel immediate tissue level abutment designed for screw-retained restorations in comparison to a conventional treatment involving four repeated abutment disconnections (ADs) and temporization with a resin crown. The null hypothesis was that the use of an ITL abutment will lead to less crestal bone loss when compared to the traditional implant level approach that involves multiple abutment disconnections.

2 | MATERIALS AND METHODS

2.1 | Study design and population

The present study is a crossover randomized controlled prospective clinical trial, which protocol was reviewed and approved by the local University ethical committee (BEC-LSMU[R]-36). The study was conducted according to the principles of Helsinki Declaration, following CONSORT guidelines for clinical trials. The study flowchart can be seen in Figure 1.

Patients were included in the study based on: (1) <3 mm in vertical soft tissue thickness; (2) ≥18-years old; (3) general healthy patients, no medical contraindication for implant surgery; (4) missing teeth in the lower and upper jaw posterior areas, premolar and molar; (5) minimum of 6 mm bone width and 10 mm height; (6) healthy soft tissue (bleeding on probing (BOP) < 20%, Plaque Index (PI) < 25%; (7) keratinized gingiva ≥4 mm, buccaly and lingually; (8) no bone augmentation procedures before or during implant placement; (9) implant primary stability ≥35 Ncm, enabling connection of a regular healing abutment or ITL abutment; and (10) informed consent form signed and permission to use obtained data for research purposes.

Exclusion criteria were as follows: (1) smokers (≥10 cigarettes per day), (2) systemic diseases, (3) drugs, influencing healing, (4) poor oral hygiene, (5) alcoholism and drug addiction, (6) uncontrolled periodontitis, and (7) pregnant or lactating women.

2.2 | Surgical procedures and randomization

Vertical soft tissue thickness before implant installation site was measured at the crest of edentulous ridge prior the surgery from CBCT scan (Icat, Kavo Dental, Germany), which was done with standard double cheek retractors to separate soft tissue contour.[15] After local anesthesia, a full thickness flap site for implant placement was prepared. The implant bed was designed to be at a distance ≥1.5 mm from the adjacent tooth/teeth or implants. A triangular-neck shaped implants of Ø 3.9 × 8–13 mm were placed 1.5 mm subcrestally following a one-stage approach according to the manufacturer's recommendations. To reach this precise 1.5 mm subcrestal implant position, osteotomy was prepared with longer drills, than the length of the implant to be placed. For example, the drilling sequence for a 10 mm long implant was as follow: (1) the Ø 2 mm pilot drill of

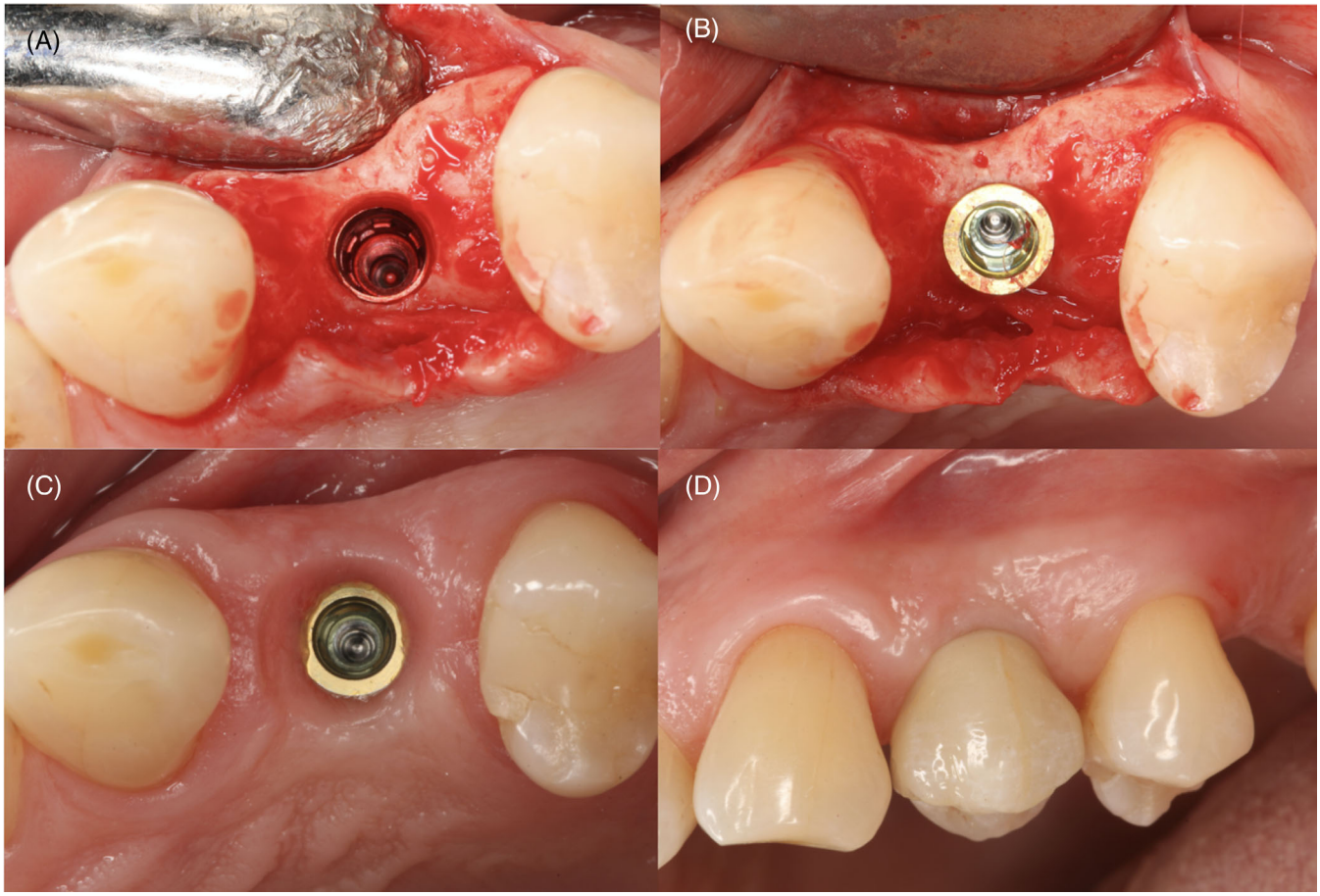

FIGURE 3 Immediate tissue level abutment group. (A) subcrestal implant position; (B) ITL abutment, placed on implant and torqued to 30 Ncm during the surgery; (C) Healed situation with ITL abutment visible; and (D) Final zirconia-based screw-retained restoration

11.5 mm with stopper, (2) the Ø 3.0 mm step drill of 11.5 mm, and (3) the Ø 3.5 mm step drill of 11.5 mm. After preparation of the implant bed, envelopes were used to randomize between the two treatment options:

FIGURE 4 Immediate tissue level abutment (left) and titanium base (right), both 3 mm gingival height

2.2.1 | Standard healing abutment group (control group)

After preparation of the bony site, implant was inserted 1.5 mm subcrestally and a 4–5 mm height healing abutment, treated with chlorhexidine gel, was connected, flap was sutured with 6/0 polypropylene monofilament (Prolene, Ethicon, USA; Figure 6). Sutures were removed after 10 days postsurgery (Figure 2A,B).

2.2.2 | Immediate tissue level abutment (test group)

After implant placement, a specific one-piece 3 mm high immediate tissue level abutment, was connected to the implant and torqued to 30 Ncm with a ratchet (Figure 3A,B). Further, 1.5 mm healing cap covered ITL abutment. Flap suturing and removal of the sutures was identical for both groups.

2.3 | Prosthetic protocol

The prosthetic treatment was initiated after 2 months of healing in the lower jaw and 3 months in the maxilla (Figures 2C and 3C). The

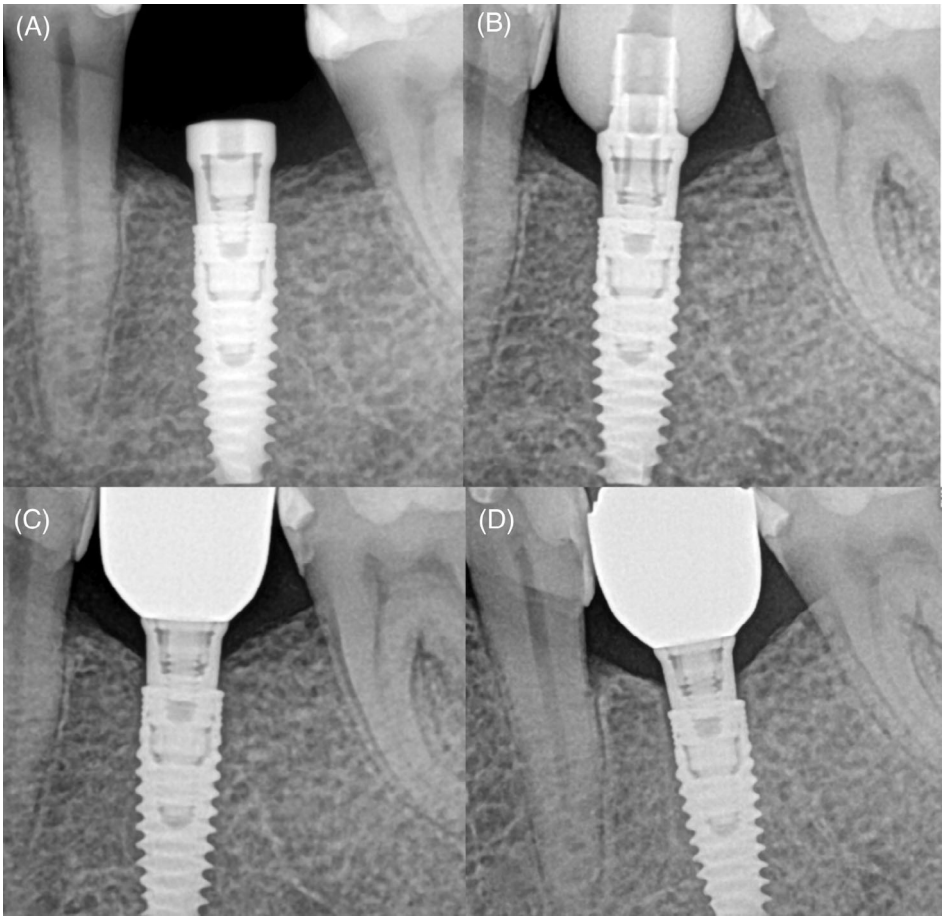

FIGURE 5 Radiograms of ITL abutment group. (A) after implant placement (T0); (B) after provisional restoration (T2); (C) 1 month post-delivery of final restoration (T3); and (D) 1 year follow-up (images are cropped and enlarged)

open-tray impression technique with direct impression copings was used to register implant position and the shape of the surrounding peri-implant tissues when both the provisional and final restorations steps were undertaken.

Provisional crowns were made out of PMMA resin relying on a titanium provisional abutment. In the control group, the temporary abutment presented a 3 mm high collar to match the height of the corresponding ITL abutment. After 1 month of soft tissue healing and maturation, permanent zirconia-based restorations were delivered. Again, and to match the height of the ITL abutment, the control bone level implant group received a titanium base abutment with a 3 mm high collar (Figure 4). The subgingival part of the zirconia framework was ultra-polished following the protocol suggested by Linkevicius and colleagues[16]; veneering ceramic was applied only on the supragingival part.[17] The final restorations of the control and test groups were torqued to 35 and 30 Ncm, respectively, as recommended by the manufacturer (Figures 2D and 3D).

2.4 | Abutment disconnections

The control group underwent four gingival seal disruption, when: (1) the healing abutment was disconnected 2 or 3 months after surgery to take an impression to prepare the provisional restoration, (2) the healing abutment was again disconnected 1 week later to deliver the provisional crown; (3) the provisional crown was removed 1 month later to take an impression to prepare the final restoration; and (4) the temporary crown was disconnected 1 month later to deliver the final crown.

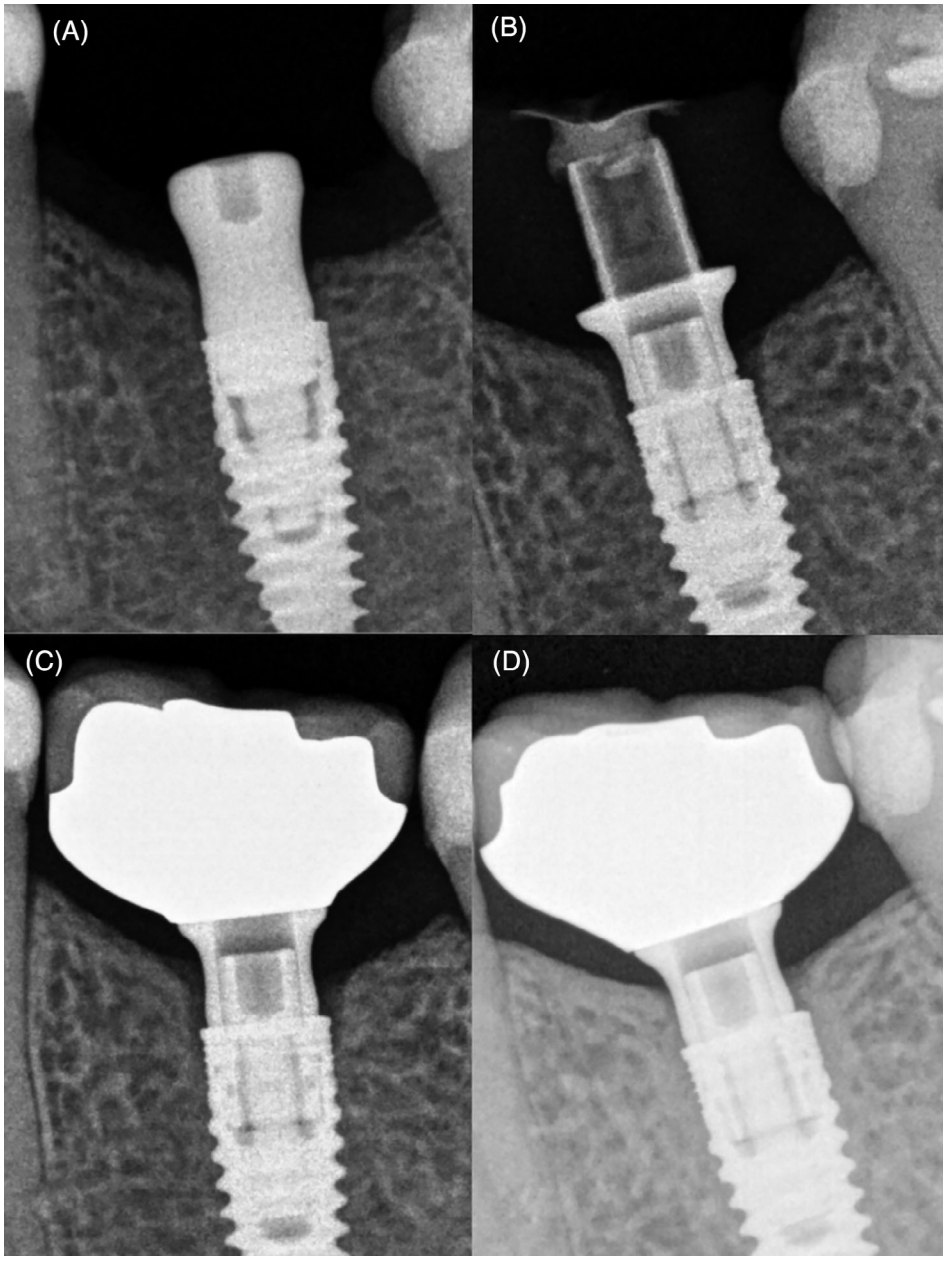

FIGURE 6 Radiograms of regular abutment group. (A) after implant placement (T0); (B) after provisional restoration (T2); (C) 1 month post-delivery of final restoration (T3); and (D) 1 year follow-up (images are cropped and enlarged)

The test group did not undergo any gingival seal disruption because the prosthetic steps happened at the soft tissue level.

2.5 | Radiological evaluation

Digital individual radiographs were taken in the high-resolution mode with a Rinn-like film holder using a long-cone paralleling technique to produce orthogonal radiograms of dental implants. The images were obtained in the way that nondistorted implant/abutment interface and implant threads would be clearly visible, as this confirms that radiographic image is parallel to the implant long axis and sufficient for accurate evaluation.[18]

Intraoral radiographs were obtained: (1) immediately after implant placement (T0); (2) at delivery of the provisional restoration (T1); (3) at delivery of the final restoration (T2); and (4) at 1-year after delivery of the final prosthesis (T3) for test (Figure 5) and control groups (Figure 6). Radiological measurements were performed using RVG Windows Trophy 7.0 software measurement program with a magnification (×20). The calibration of RVG images was performed using diameter of the 3.9 mm implant as a reference point. Bone loss was calculated as a distance between implant neck and first radiographically visible bone-to-implant contact. As the implant margin in all cases at the time of placement was subcrestal, the value was considered as zero. The mean value of the medial and distal measurements was pooled for each implant. Radiograms were analyzed by an experienced dentist, who was not aware of the purpose and did not take a part in the study.

TABLE 1 Distribution of implants, placed in the study

	ITL abutment level			Implant level		
	Premolar	Molar	Total	Premolar	Molar	Total
Maxilla	8	1	9	5	3	8
Mandible	9	14	23	4	20	24
Total	17	15	32	9	23	32

Note: Implant positions.

2.6 | Clinical examination

Peri-implant soft tissue measurements were performed twice during all the study, at T2 and T3 time points. Peri-implant health analysis was performed by measuring Probing Pocket Depth (PPD), Bleeding on probing (BOP), and Plaque Index (PI).

PPD was measured with a plastic UNC 12 periodontal probe (Hu-Friedy, USA) from the mucosal margin to the bottom of the pocket in millimeters. The measurements were performed at four sites—mesial, distal, lingual, buccal, and the mean value was calculated for each implant. Presence or absence of BOP was calculated in % of total probed sites (mesial, distal, lingual, and buccal). Plaque Index (PI) was scored as "0"—no plaque, "1"—a film of plaque adhering to the free gingival margin and adjacent area of the tooth, "2"—moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin, which can be seen with the naked eye, and "3"—abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. The mean of PI around all implant restorations was calculated.

2.7 | Power analysis and statistical analysis

Sample size calculation was based on primary outcome variable—crestal bone loss. G*Power 3.1.9.7 was used to calculate sample size. Effect size was calculated based on the data of Molina and colleagues (mean and SD of two groups: 1.21 ± 0.816 and 0.590 ± 0.322).[19]

In order to achieve power of 80% with and α level 0.05, it would require at least 29 patients per group. To compensate for attrition rate of 10% to accommodate possible dropouts, in total it was planned to enroll 64 patients, 32 in each group.

Statistical analysis was performed using IBM SPSS Statistics v20 software (IBM Corp, USA). Descriptive statistics of initial bone level, gingival thickness, crestal bone loss, bleeding on probing (BOP), plaque index (PI), and probing depth (PD) for both groups were described by mean, standard deviation, standard error of mean, median, minimum and maximum values, and interquartile rate (IQR) at different time points T2 (just after delivery stage), T3 (1 year after delivery). The Shapiro–Wilk test (α = 0.05) was applied for each outcome variable to test the normality of distribution. For normally distributed data (Shapiro–Wilk test $p > .05$) t tests were used, and for

TABLE 2 Crestal bone loss measurement in both groups and with-in groups at T2 and T3 follow-up points

Descriptive statistics										Difference between groups	Difference between time points
Time point	Group	*N*	Mean	SD	SE	Median	Max	Min	IQR	*p*	*p*
T2	Abutment level	31	−0.14	0.27	0.04	0	−1	0	0.9	<.0001[a]	.0005[b]
	Implant level	32	−0.64	0.64	0.11	−0.5	−2.5	0	0.93		<.0001[b]
T3	Abutment level	31	−0.06	0.16	0.03	0	−0.6	0	0	.223[a]	.0005[b]
	Implant level	29	−0.21	0.56	0.09	0	−2.4	0	0.08		<.0001[b]

Note: Statistical analysis of crestal bone loss (mm). T2—after delivery of prosthesis and T3—1 year after delivery.
[a]Mann–Whintey *U* test.
[b]Wilcoxon-signed ranks test.

not normally distributed data (Shapiro–Wilk test $p < .05$) Mann–Whitney *U* tests and Wilcoxon-singed ranks tests were used to compare results between groups and different time points. The criteria for significance was set at $\alpha = 0.05$.

3 | RESULTS

By the end of the enrolment, the sample size of the 64 patients consisted of 28 males and 36 females. Their mean age at implant surgery was 47.3 ± 1.2, ranging from 20 to 67 years. All patients received one implant to keep the one implant per patient ratio; therefore, 64 bone level implants with a triangular-shaped neck of Ø 3.9 mm and platform switching (V3, MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel) were placed 1.5 mm subcrestally. In the test group 32 immediate tissue level abutments (CONNECT abutment, MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel) were affixed after implant placement. The distribution of implants according to the site be seen in Table 1.

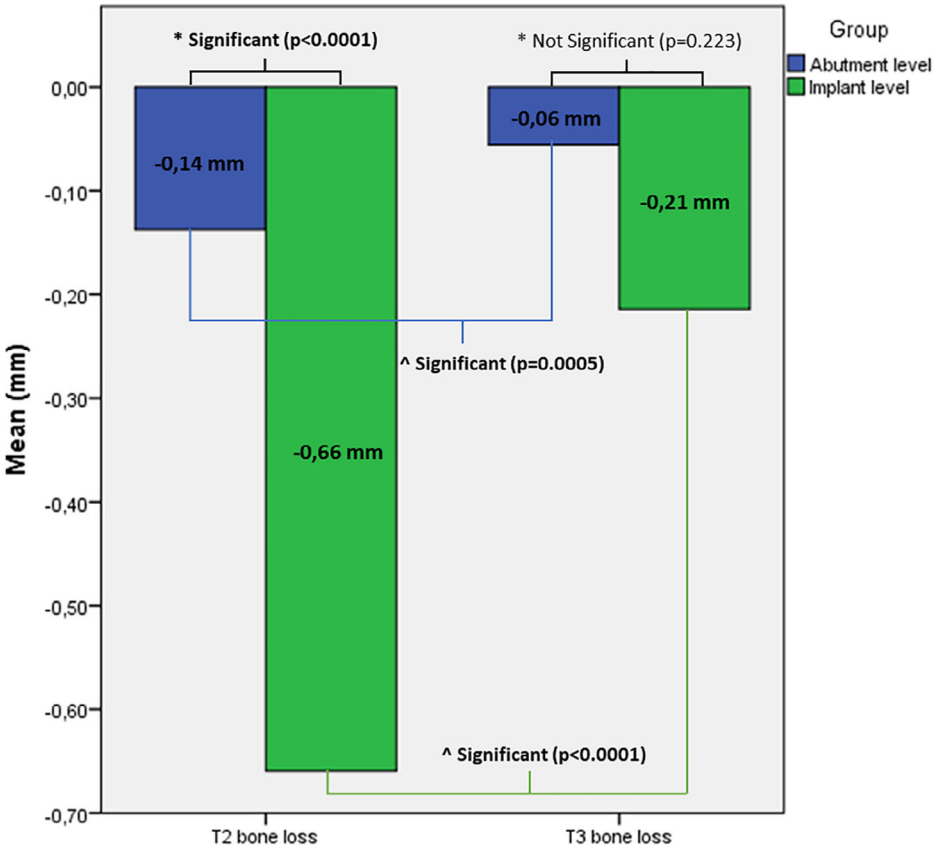

FIGURE 7 Box plot representation of statistical differences between the groups and with-in the groups at T2 and T3 evaluation time-points (Mann–Whintey *U* test; Wilcoxon-signed ranks test; $\alpha = 0.05$)

TABLE 3 Peri-implant health data between the groups in regards to plaque index, bleeding on probing, and probing depths

	Abutment level		Implant level		Difference between groups	Difference between time points (T2 vs T3)	
	T2	T3	T2	T3	*p*	Abutment level	Implant level
BOP (%)	13 (SD = 24); range 0–100	13 (SD = 23); range 0–100	10 (SD = 21); range 0–75	18 (SD = 20); range 0–75	.409[a]	0.957[b]	0.276[b]
PI	0.10 (SD = 0.29); range 0–1	0.34 (SD = 0.46); range 0–1	0.23 (SD = 0.42); range 0–1	0.42 (SD = 0.5); range 0–1	.138[a]	*0.036*[b]	0.197[b]
PD (mm)	2.47 (SD = 0.89); range 0.75–5.25	2.44 (SD = 0.77); range 1.25–3.75	2.46 (SD = 0.74); range 1.5–4	2.42 (SD = 0.75); range 1–4.5	.915[a]	0.949[b]	0.372[b]

Note: Statistical analysis of mean bleeding on probing (BOP), plaque index (PI), and probing depth (PD). T2—just after delivery of prosthesis, T3—1 year after delivery.

[a]Mann–Whitney *U* test ($\alpha = 0.05$).

[b]Wilcoxon-singed ranks test ($\alpha = 0.05$).

All implants integrated successfully; one patient decided to withdraw from the study before prosthetic rehabilitation. Therefore, the final sample size at T1 was 63. All implants were restored with 63 zirconia-ceramic screw retained restorations. By the end of the study, three additional patients dropped-out (one moved abroad, one refused to come because of pregnancy, and one was afraid of getting contaminated by the Covid-19 virus); therefore, at the 1-year follow-up visit the final sample size was $n = 60$, 31 implants in the test group and 29 in the control group.

The implant success rate after 1-year of function was 100% for both groups. Two final restorations of the test group underwent a prosthetic screw loosening; this adverse event was solved by retightening the abutment screws at 30 Ncm.

Analysis showed statistically significant less crestal bone loss in ITL abutment group compared to implant level crowns at the time of delivery of restorations, while there was no difference in bone levels after 1 year follow-up. Intergroup comparison showed statistically significant bone loss reduction in both groups after 1 year follow-up (Table 2 and Figure 7).

Peri-implant soft tissue conditions are presented in Table 3. It is interesting to see, that there was no difference between any peri-implant soft tissue parameter between both groups, except PI score was significantly higher in ITL abutment group at 1 year follow-up visit, compared to restoration delivery time-point.

4 | DISCUSSION

This is the first controlled clinical study to investigate the efficacy of immediate tissue level abutments, used to transform bone level implants into tissue level, according to the one-abutment one-time protocol. Results have shown that there was no statistically significant difference in crestal bone levels between the groups after 1-year follow-up, however, that difference was present at early stages of postrestorative evaluation. Therefore, null hypothesis can be rejected, since it is more relevant to consider 1-year data, than an early outcome.

Indeed, absolute numbers show that after 1-year follow-up, implant group with immediate tissue level abutments had three times less bone loss (0.06 vs. 0.21, see Table 2), however that difference could not be confirmed statistically. It is possible, that if the sample size of the study would have been higher, stronger statistical associations could be reported. So far, it seems that the choice whether to use or not to use a one-abutment one-time protocol for subcrestally placed implants, should be left to the preference of the treating team, according to the clinical situation and the patient, as previously suggested by Bressan and colleagues.[20]

The current study presented interesting data on early post-restorative bone levels, because evidently ITL abutment level group had significantly less bone loss, compared to the control group (0.14 vs. 0.64 mm, $p = .0001$, see Table 2). It is rather unusual to report early crestal bone loss after prosthesis delivery; however, this information might contribute to a better understanding of what is happening to the peri-implant tissues during the process of prosthetic implant restoration. The difference of the bone levels at that early time point might be explained by the fact that the control group underwent four abutment disconnections while the test group did not undergo any. It was suggested by Berglundh and colleagues, that any disturbance of the zone of connective tissue interaction may affect the marginal peri-implant tissues, including bone.[21] In subcrestal implant position scenario, disconnection of the abutment disturbs not only the soft tissues, but the bone as well, and may cause its' demineralization or loss. Another reason that might explain the difference between the early and late bone level data might be due to the different torque, exerted on both type abutments, and the corresponding stability of their respective implant-abutment junctions. The ITL abutments were torqued at a final stable 30 Ncm, while standard healing abutments were manually torqued and have best reached 10–15 Ncm.[22] Stability of the implant/abutment connection is probably an utmost factor for subcrestally placed implants.[23,24] In addition, bacterial leakage is probably more prone to happen at the weakly torqued implant-healing abutment junction as showed by Broggini and colleagues than at the stable one-piece ITL abutment, used in the test group.[25]

The present study reports, that bone loss decreased by 0.08 mm and 0.43 mm at 1 year follow-up for the test and control groups, respectively (Table 2). It can be speculated that when final restoration is delivered and the tissues are no more disturbed, bone regeneration process might be expected. This would support the hypothesis that the disruption of the gingival seal and the mechanical bone irritation, that are happening during abutment disconnection, do not lead to irreversible apical migration of the crest; rather it modifies the mineralization content of the irritated bone, which is radiographically seen as a crestal bone loss (Figure 6B,C). Evidently, the opposite process is possible as well, when mineral content of the bone intensifies, presenting itself as radiographic bone growth (Figure 6D).

Bone remineralization or bone gain, measured at the implant neck after removal of cement remnants, is a phenomenon, that was first described by Linkevicius in a case report.[26] A similar feature of bone gain was also reported by Tawil after correcting the occlusion of an overloaded implant.[27] Already back in 1976, Rosling and colleagues documented that when calculus or irritants around teeth are removed, regeneration of the soft tissue attachment can be expected.[28] For implants likewise, repeated ADs might be sensed by the tissues as an irritation, but when the latter is ended, bone healing can take over and the expression is bone gain. Delivery of the final restoration brings more stability to the implant-abutment junction because the permanent titanium base is more precise than the provisional or healing abutments. It might also be that the reduction of micro-movements results in less bone irritation and subsequently enhances bone remineralization. It seems, therefore, that the initial bone loss measured after delivery of the restoration may not necessarily progress and it can be overturned if certain conditions are met.

Toia and colleagues reported only 0.005 mm bone loss in abutment level and 0.08 mm in implant level restorations after 1 year follow-up[8] with statistically significant difference, what is in contrast to the outcome of the current study. Analysis revealed, that Toia and colleagues

used different subgingival restorative materials (titanium in implant level and chromium/cobalt alloy in abutment level), exposing non-biocompatible metal to the tissues, possibly influencing bone loss.[29] Additionally, multiunits of different gingival heights were used, which might distort the data, as the height of multiunit was shown to be a factor in crestal bone loss in many clinical studies.[30-32] All these differences potentially contributed to opposing outcomes of both studies.

In a previous prospective uncontrolled case-series, Rompen and colleagues tested a similar two-piece ITL abutment for single screw-retained restorations.[32] Crestal bone loss after delivery of the final prosthesis was 1.1 mm, while in comparison the present measurement at the test group was only 0.14 mm at the same evaluation period. This consistent difference could be explained by the bulkier shape of the two-piece ITL abutment compared to the present slender one-piece ITL abutment. Another explanation might be attributed to bacterial leakage and subsequent tissue inflammation at the 2-piece ILT abutment. It is obvious that the latter can happen at the hard and soft tissue levels, while leakage at the 1-piece abutment may take place at the soft tissue level only, but not at the bone level.

Although results finally have showed no statistical difference in bone loss, logic dictates that any bone harm is better to be avoided. It may be nevertheless better not to rely on a later bone gain, as any biological adverse event, like a transitory lack of hygiene or periodontitis, may interfere with this process of bone regeneration. It made sense to evaluate the efficacy of these ITL abutments in the posterior area, where aesthetics is less under scrutiny. However, results could be easily extrapolated to the smile region, where the possibility to keep the bone without any changes is desired goal, especially when two adjacent implants are placed.

A limitation of the present study was that standardized periapical radiographs were not obtained. While standardization of radiograms with individual paralleling devices remains the best available method to record bone levels, their implementation would require removal of the prosthesis to get direct access to the implant, which is agreed to be impractical and redundant.[33-36] In addition, supplementary disengagement of prosthesis would directly influence the outcome of the present study, because the effect of abutment disconnections onto peri-implant tissues was at the focus of this trial. Therefore, other accepted methods to ensure accuracy of radiographic images were chosen.[18] Similar approach without utilizing standardized periapical radiographic images has been used in many well-known clinical studies and seems to be acceptable practise.[5-7,13,29-31,36-38]

5 | CONCLUSIONS

Within the limitation of this study, it can be concluded, that together with platform switching and implant/abutment connection, the use of an immediate tissue level abutment did reduce crestal bone loss in the early postrestorative period of subcrestally placed implants. 1-year after permanent crown delivery, a bone gain was observed in both groups and initial difference, observed early in the study, became statistically nonsignificant, because bone gain was more pronounced in the control group.

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CONFLICT OF INTEREST

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AUTHOR CONTRIBUTIONS

Tomas Linkevicius made main contributions to study conception and design, interpretation of data, as well as drafting the article, securing funding for the study. Rokas Linkevicius made substantial contributions in collecting of data and analysis. Jonas Alkimavicius has contributed in data collection, analysis, and statistical evaluation. Evelina Gineviciute made substantial contributions to study conception and design, acquisition of data, as well as critically reviewed the article. Asta Mazeikiene critically reviewed the article. Laura Linkeviciene critically reviewed the article. All authors approved the final version of the article.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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REFERENCES

1. Abrahamsson I, Berglundh T, Lindhe J. The mucosal barrier following abutment dis/reconnection. An experimental study in dogs. *J Clin Periodontol*. 1997;24(8):568-572.
2. Abrahamsson I, Berglundh T, Sekino S, Lindhe J. Tissue reactions to abutment shift: an experimental study in dogs. *Clin Implant Dent Relat Res*. 2003;5(2):82-88.
3. Becker K, Mihatovic I, Golubovic V, Schwarz F. Impact of abutment material and dis-/re-connection on soft and hard tissue changes at implants with platform-switching. *J Clin Periodontol*. 2012;39(8):774-780.
4. Degidi M, Nardi D, Daprile G, Piattelli A. Nonremoval of immediate abutments in cases involving subcrestally placed postextractive tapered single implants: a randomized controlled clinical study. *Clin Implant Dent Relat Res*. 2014;16(6):794-805.
5. Canullo L, Bignozzi I, Cocchetto R, Cristalli MP, Iannello G. Immediate positioning of a definitive abutment versus repeated abutment replacements in post-extractive implants: 3-year follow-up of a randomised multicentre clinical trial. *Eur J Oral Implantol*. 2010;3(4):285-296.
6. Koutouzis T, Koutouzis G, Gadalla H, Neiva R. The effect of healing abutment reconnection and disconnection on soft and hard peri-implant tissues: a short-term randomized controlled clinical trial. *Int J Oral Maxillofac Implants*. 2013;28(3):807-814.
7. Degidi M, Nardi D, Piattelli A. One abutment at one time: non-removal of an immediate abutment and its effect on bone healing around subcrestal tapered implants. *Clin Oral Implants Res*. 2011;22(11):1303-1307.
8. Toia M, Stocchero M, Becktor JP, Chrcanovic B, Wennerberg A. Implant vs abutment level connection in implant supported

screw-retained fixed partial dentures with cobalt-chrome framework: 1-year interim results of a randomized clinical study. *Clin Implant Dent Relat Res*. 2019;21(2):238-246.
9. Todisco M, Sbricoli L, Ippolito DR, Esposito M. Do we need abutments at immediately loaded implants supporting cross-arch fixed prostheses? Results from a 5-year randomised controlled trial. *Eur J Oral Implantol*. 2018;11(4):397-407.
10. Huang Y, Wang J. Mechanism of and factors associated with the loosening of the implant abutment screw: a review. *J Esthet Restor Dent*. 2019;31(4):338-345.
11. Bichacho N, Feraru M. Replacing hopeless maxillary incisors with adjacent implants via an integrative biologically oriented approach. *Compend Contin Educ Dent*. 2019;40(7):434-443.
12. Davarpanah M, Szmukler-Moncler S, Rajzbaum P, de Murat T, Davarpanah K, Sater S. Nouveaux composants prothétiques pour optimiser la préservation des tissus péri-implantaires. *JPIO_Manuel_implanto*. 2018;14(14):700-718.
13. Vervaeke S, Matthys C, Nassar R, Christiaens V, Cosyn J, de Bruyn H. Adapting the vertical position of implants with a conical connection in relation to soft tissue thickness prevents early implant surface exposure: a 2-year prospective intra-subject comparison. *J Clin Periodontol*. 2018;45(5):605-612.
14. Linkevicius T, Puisys A, Linkevicius R, Alkimavicius J, Gineviciute E, Linkeviciene L. The influence of submerged healing abutment or subcrestal implant placement on soft tissue thickness and crestal bone stability. A 2-year randomized clinical trial. *Clin Implant Dent Relat Res*. 2020;22:497-506.
15. Januario AL, Barriviera M, Duarte WR. Soft tissue cone-beam computed tomography: a novel method for the measurement of gingival tissue and the dimensions of the dentogingival unit. *J Esthet Restor Dent*. 2008;20(6):366-373.discussion 374.
16. Linkevicius T, Valantiejiene V, Alkimavicius J, Gineviciute E, Andrijauskas R, Linkeviciene L. The effect of a polishing protocol on the surface roughness of zirconium oxide. *Int J Prosthodont*. 2020;33(2):217-223.
17. Linkevicius T. The novel design of zirconium oxide-based screw-retained restorations, maximizing exposure of zirconia to soft peri-implant tissues: clinical report after 3 years of follow-up. *Int J Periodontics Restorative Dent*. 2017;37(1):41-47.
18. Cameron SM, Joyce A, Brousseau JS, Parker MH. Radiographic verification of implant abutment seating. *J Prosthet Dent*. 1998;79(3):298-303.
19. Molina A, Sanz-Sanchez I, Martin C, Blanco J, Sanz M. The effect of one-time abutment placement on interproximal bone levels and peri-implant soft tissues: a prospective randomized clinical trial. *Clin Oral Implants Res*. 2017;28(4):443-452.
20. Bressan E, Grusovin MG, D'Avenia F, et al. The influence of repeated abutment changes on peri-implant tissue stability: 3-year post-loading results from a multicentre randomised controlled trial. *Eur J Oral Implantol*. 2017;10(4):373-390.
21. Berglundh T, Lindhe J, Ericsson I, Marinello CP, Liljenberg B, Thomsen P. The soft tissue barrier at implants and teeth. *Clin Oral Implants Res*. 1991;2(2):81-90.
22. Alikhasi M, Kazemi M, Jalali H, Hashemzadeh S, Dodangeh H, Yilmaz B. Clinician-generated torque on abutment screws using different hand screwdrivers. *J Prosthet Dent*. 2017;118(4):488-492.
23. Palaska I, Tsaousoglou P, Vouros I, Konstantinidis A, Menexes G. Influence of placement depth and abutment connection pattern on bone remodeling around 1-stage implants: a prospective randomized controlled clinical trial. *Clin Oral Implants Res*. 2016;27(2):e47-e56.
24. Weng D, Nagata MJ, Leite CM, de Melo LG, Bosco AF. Influence of microgap location and configuration on radiographic bone loss in nonsubmerged implants: an experimental study in dogs. *Int J Prosthodont*. 2011;24(5):445-452.
25. Broggini N, McManus LM, Hermann JS, et al. Persistent acute inflammation at the implant-abutment interface. *J Dent Res*. 2003;82(3):232-237.
26. Linkevicius T. Excess cement resulting in peri-implant infection presenting as a draining sinus tract. In: Wismeijer D, Buser D, Chen S, eds. *ITI Treatment Guide Vol. 8. Biological and hardware complications in implant dentistry*. Vol 8, Berlin, Germany: Quintessence; 2015:123-126.
27. Tawil G. Peri-implant bone loss caused by occlusal overload: repair of the peri-implant defect following correction of the traumatic occlusion. A case report. *Int J Oral Maxillofac Implants*. 2008;23(1):153-157.
28. Rosling B, Nyman S, Lindhe J, Jern B. The healing potential of the periodontal tissues following different techniques of periodontal surgery in plaque-free dentitions. A 2-year clinical study. *J Clin Periodontol*. 1976;3(4):233-250.
29. Galindo-Moreno P, Leon-Cano A, Monje A, Ortega-Oller I, O'Valle F, Catena A. Abutment height influences the effect of platform switching on peri-implant marginal bone loss. *Clin Oral Implants Res*. 2016;27(2):167-173.
30. Blanco J, Pico A, Caneiro L, Novoa L, Batalla P, Martin-Lancharro P. Effect of abutment height on interproximal implant bone level in the early healing: a randomized clinical trial. *Clin Oral Implants Res*. 2018;29(1):108-117.
31. Novoa L, Batalla P, Caneiro L, Pico A, Linares A, Blanco J. Influence of abutment height on maintenance of peri-implant crestal bone at bone-level implants: a 3-year follow-up study. *Int J Periodontics Restorative Dent*. 2017;37(5):721-727.
32. Rompen E, Fabbri G, Staas T, Valantiejiene V, Linkevicius T. Clinical investigation of the On1 two-piece abutment concept- preliminary results. *Clin Oral Implants Res*. 2018;29(Suppl. 17):319.
33. Cox JF, Pharoah M. An alternative holder for radiographic evaluation of tissue- integrated prostheses. *J Prosthet Dent*. 1986;56:338-341.
34. Meijer HJ, Steen WH, Bosman F. Standardized radiographs of the alveolar crest around implants in the mandible. *J Prosthet Dent*. 1992;68:318-321.
35. Payne AG, Solomons YF, Lowniw JF. Standartization of radiographs for mandibular implant-supported overdentures: review and innvation. *Clin Oral Implants Res*. 1999;10:307-319.
36. Naffah N, Chidiac JJ. A modified periapial radiographic holder used for standardized implant assesment. *J Prosthet Dent*. 2004;91:398.
37. Spinato S, Galindo-Moreno P, Bernardelio F, Zaffe D. Minimum abutment height to eliminate bone loss: influence of implant neck design and platform switching. *Int J Oral Maxillofac Implants*. 2008;33:405-411.
38. Spinato S, Galindo-Moreno P, Bernardelio F, Zaffe D. Hybrid implants in healthy and periodontally compromised patients: a preliminary clinical and radiographic study. *Int J Periodontics Restorative Dent*. 2017;37:195-202.

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