Original Article

Evaluation of biological changes at the proximal contacts between single-tooth implant-supported prosthesis and the adjacent natural teeth – An *in vivo* study

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Abstract

Aim: The aim of the study is to evaluate the proximal contact tightness (PCT) between single-tooth implant-supported prosthesis (ISP) and the adjacent natural teeth with and without the intervention of the Essix retainer at the end of 1 year.

Settings and Design: *In vivo* -experimental study.

Materials and Methods: Forty patients with a single ISP in the first molar region of the mandibular arch are included in the study who were randomly divided into two groups – Group I (20): those without an intervention of Essix retainer and Group II (20): those with the intervention of Essix retainer (2 mm thickness) (Thermo Vac, Inc. USA) delivered immediately after the restoration of implant with the definitive prosthesis. The groups are further subdivided into Subgroups A (control) and B within Group I and Subgroups C (control) and D within Group II. Mesial and distal PCT values were recorded in each quadrant using the digital force gauge, and values obtained at the end of 1 year were subjected for statistical analysis.

Statistical Analysis Used: Independent sample *t*-test was performed. $P < 0.05$ was taken as statistically significant.

Results: On nonusage of Essix retainer, in comparison to the control group, there were a 57.9% decrease in PCT values for the ISP on mesial contact ($P < 0.05$) and a 38.9% decrease for the distal contact ($P > 0.05$), whereas on the usage of Essix retainer, the PCT values for ISP on mesial contact decreased to 25.3% (not significant) and 33.7% on the distal contact ($P > 0.05$). The incidence of contact loss was found to be 30%, whereas it decreased to 15% on the usage of Essix retainer.

Conclusion: The usage of Essix retainer showed a significant difference in increasing the PCT values, especially on the mesial contact. The incidence of contact loss, which was found to be 30%, decreased to 15% on its usage.

Keywords: Essix retainer, implant-supported prosthesis, interventional clinical study, proximal contact, proximal contact tightness

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INTRODUCTION

An optimal proximal contact is of utmost importance for an implant-supported prosthesis (ISP) as they maintain arch integrity, enhances the masticatory efficiency, and reduces the peri-implant tissue health failures. Maintenance of the proximal contact in the natural dentition is given by two theories. The first theory suggests that the compression force occurs between the proximal surfaces of the adjacent teeth and keeps an active proximal contact. The second theory is the resistance theory, i.e., the teeth resist any force which tries to separate them as they touch each other passively in a nonforce mode.[1]

Age, tooth position, biting force, and crowding of teeth determine the size and location of the contact area. The contour of the contact interfaces is predominantly oval and usually found toward the buccal aspect of interproximal areas.[2] Sarig *et al*. reported that the interproximal interface with or without wear decreases in size from posteriors to anteriors.[3] They suggested that larger contact areas are needed in the posterior teeth to resist attrition where there is increased biting force. Over time, the morphology of contact areas changes from the oval contacts to kidney-shaped contact areas because of attrition and physiological drifting.

Unlike the natural teeth where they are surrounded by cushioning periodontal ligament and resilient bone, the normal physiological phenomenon such as the physiological drifting or the mesial drifting is not found with dental implants as they are ankylosed to bone[4,5] assuming it to be one of the reasons for the recent evident complication of proximal contact loss between the implant restoration and adjacent natural teeth. A high proportion of lingual and anterior component forces and high occlusal force distribution in the intercanine region have also been suggested as one of the factors enhancing the mesial migration of teeth, and they evaluated open contacts in 28 participants with 55 prostheses using three-dimensional occlusal imaging.[6]An ankylosed implant also faces the risk to be positioned in infraocclusion by time because of the continuous eruption of the adjacent teeth and/or facial bone growth even in adulthood, which affects the teeth alignment, suggested by Byun *et al*. where they reported open contacts at 34% of assessed sites.[7] The change in the positional relationship between the implant-supported fixed prostheses (IFPs) and the adjacent natural teeth results from a dynamic oral function or the changes in other oral structures.[8]

There are fewer studies that have focused on treating this complication of proximal contact loss. A clinical report described the management of proximal contact loss mesial to the cement-retained IFP by gaining access to the abutment screws, retrieving it, and adding porcelain on the deficient mesial aspect.[9] However, this can lead to other technical complications such as porcelain fractures and framework damages. Kurthy advocated occlusal adjustment to reverse the development of open contacts between natural teeth and implants if the open contact develops distal to an implant.[10] However, their technique cannot be used universally because most open contacts develop on the mesial aspect of an implant, and their technique applies to specific situations in which the implant would have to be next to the last tooth in the arch. Cowie *et al*. have suggested the use of night guard or retainer to ease the detrimental occlusal forces to preserve the tooth patterns and porcelain, thus reducing the open contacts,[11] but no evident studies are documented. Due to the paucity of data regarding these treatment modalities, this study is conducted to document the role of the Essix retainer in the developing interproximal gap.

The present interventional clinical study aims to evaluate the proximal contact changes with respect to time, to analyze the factors responsible for the contact loss, and to evaluate the proximal contact tightness (PCT) between ISP and the adjacent natural teeth using a digital force gauge for a period of 1 year with a regular follow-up of 3, 6, and 12 months.

MATERIALS AND METHODS

Forty patients who had been treated with single mandibular first molar ISP were included in the present intervention study. The sample size was chosen to be 40, estimated using a statistical software Minitab® version 19.2020.1 (64-bit).[12] The study included both males and females with the age group of 18–50 years. The range of age group started from 18 years as missing mandibular first molars, and their treatment with ISP was found from this lower age group onward. Moreover, the periodontal conditions were found healthy at the younger age group. Out of 40 patients, two patients were below the age of 21 years, and their mandibular growth completion was confirmed using hand and wrist radiograph, and one patient was above 45 years, included in the study as there was no periodontal disease and maintenance was strictly evaluated.

Patients were chosen from the outpatients, department of prosthodontics, crown, and bridge. Before commencing surgical and prosthetic procedures, written consent was obtained from patients. Ethical committee acceptance was obtained from the institutional ethical board

before taking up the clinical study (IRB approval number – IECMIDS/07/2018-2019) and was done in accordance with ethical standards.

Patients restored with the ISP in the mandibular first molar region were included in the study. All the restorations with adjacent and opposing natural teeth and adjacent quadrant with no prosthetic treatment or proximal restorations were included. All cases were thoroughly examined for mandibular growth completion with fully erupted third molars or its anodontia. Patients with impacted third molars were surgically removed and were later included in the study.

Exclusion criteria included severe periodontal disease, diastema between posterior teeth, adjacent teeth with a mobility score of >1, adjacent teeth with apical pathology, severe malocclusion, and individuals with erupting third molars. Individuals with smoking habits, immunocompromised state, and debilitating diseases, on medication known to interfere with wound and bone healing, and parafunctional habits, were also excluded from the study.

Armamentarium for checking the PCT includes a digital force gauge (FG 5000A, Lutron Electronic Enterprise Co. Ltd., Taipei) with a 50 μm thick metal strip (Matrizen, Stainless steel, Shiva Enterprises, Vasai, India).

All the 40 patients who were included in the study were surgically treated with dental implantation (Touareg™-Adin implant system) in the edentulous mandibular site by oral surgeons or periodontists of the hospital [Figure 1]. Before the implantation procedure, presurgical evaluation such as hemogram, premedication, and radiographic evaluation of the edentulous site using cone-beam computed tomography was done. Surgical placement of the implants was performed with appropriate torque and speed as per the bone quality (density) using the Physiodispenser (WH Si-923 Implant Motor Physiodispenser, Querencia Meditech Pvt. Ltd., Pune, India) and the surgical kit (Adin Dental Implant Systems Ltd., Israel). The osteotomy preparation was done by sequential drilling with drills of diameter 2.0, 2.8, 3.2, 3.65, 4.2, and 5.2 mm as per the manufacturer's instructions under adequate irrigation. All the implants were placed using the open flap method and were submerged under soft tissue during the healing phase, and delayed loading protocol after 3–4 months was planned.

Figure 1: Surgical placement of dental implant in 46 region with open flap method

After 3–4 months, second-stage surgery was done, and the healing abutments were placed over the implants. Gingival healing was allowed around the healing abutment for about 10 days. Later, a closed tray mandibular implant-level impression was made with addition silicone impression material (Aquasil, Dentsply, VASA Denticity Pvt. Ltd., New Delhi, India). The impressions were poured with dental stone (Kala Stone Kalabhai Dental Products Pvt. Ltd., Mumbai, India), and the models were retrieved. Crown height space was evaluated after placing maxillary and mandibular casts into occlusion. Castable abutment (RS Engaging plastic cylinder, Adin Dental Implant Systems Ltd., Israel) was selected when crown height space was 3–4 mm; its excess length was trimmed, waxed up to contours of molar teeth, and casted.[13] Metal trail of the obtained casting was done in the patient, followed by its crown buildup with ceramic (Vita Granito Pvt. Ltd., Jambudiya, Rajkot, India) in the laboratory. The insertion of the finished and polished prosthesis was done in the patient by placing it onto the implant, and the retention screw was tightened with 20–30 N torque using the torque wrench. Access hole was filled with composite resin (Ivoclar Vivadent Marketing Pvt. Ltd., Mumbai, India) and polished.

In situations with crown height space >5 mm, a stock metal abutment (Adin Dental Implant Systems Ltd., Israel) of appropriate angulation was selected laboratory milling keeping finish lines supragingival following the gingival contours. Over it, wax pattern was fabricated and casted and the metal coping was obtained. The fit of the coping was checked intraorally, and chairside minor adjustments were made. The final crown buildup was done with ceramic (Vita Granito Pvt. Ltd., Jambudiya, Rajkot, India) in the laboratory. Insertion of the prosthesis was done by seating the abutment onto the implant and tightening the retention screw with 20–30 N torque using a torque wrench. Access hole was filled with Teflon tape,

then the metal-ceramic crown was cemented over it with glass-ionomer cement (GC Gold Label 1, GC Asia, Singapore) placing a rubber dam, and the residual cement was removed. All the definitive prostheses were adjusted to achieve similar mesial and PCT values that of the adjacent quadrant first molars with implant-protected occlusion intraorally and finally glazed in the laboratory before the final cementation procedure [Figure 2].

Out of 40 patients, 10 received screw-retained prostheses, five cement-retained prostheses, and 25 received a combination of screw cum cement-retained prostheses. They were randomly allocated among Group I and Group II. Group II patients were intervened with Essix retainer immediately after delivery of the definitive prosthesis in the mandibular arch and were advised to wear it day and night except while eating.

Figure 2: Cement retained metal-ceramic definitive prosthesis in relation to 46 implant with adequate mesial and distal proximal contact tightness

Fabrication of Essix retainer

Essix retainer was fabricated over the model obtained by recording the impression of the mandibular arch with the ISP. The model was prepared by trimming the excess labial and lingual portion and was placed on the vacuum forming device (3A Medes Easy Vac) (IDS Denmed-Dentbay, Delhi). Clear resin sheet (Thermo Vac, Inc. USA), 1 mm thick hard, was placed on the frame of the machine and heated as per manufacturing instructions, later lowered onto the cast for adaptation evenly. After retrieval from the cast, the Essix retainer was trimmed along the gingival contour and polished [Figure 3].

Figure 3: Mandibular Essix retainer used for intervention for Group II

Group I included 20 individuals who received ISP without an intervention of Essix retainer, subdivided into Subgroups A and B, and Group II included 20 individuals who received ISP with an intervention of Essix retainer (hard consistency with 1 mm thick) (Thermo Vac, Inc. USA) in the mandibular arch after the restoration (delayed loading) and are further subdivided into Subgroups C and D [Figure 4].

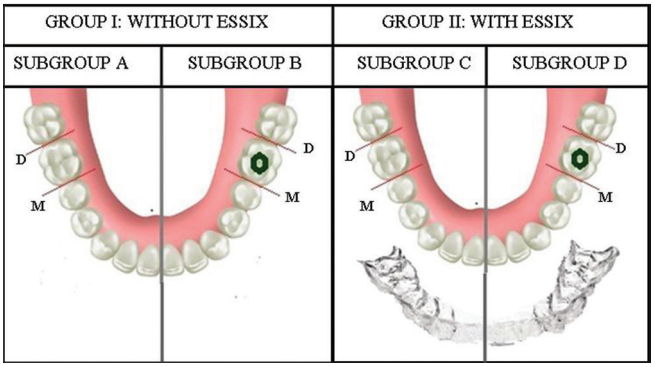


Figure 4: Illustration of study groups in the mandibular arch

Both Subgroups A and C are control groups, i.e., the quadrant with natural teeth of the mandibular arch (adjacent to the quadrant of the loaded implant), and Subgroups B and D are the study groups, i.e., quadrant with ISP.

Measurement of proximal contact tightness

All the patients were seated in the same upright position in the dental chair, by the Dental Unit's preset positioning system to measure the PCT. Measurements were done using the digital force gauge (FG 5000A, Lutron Electronic Enterprise Co. Ltd., Taipei) [Figure 5]. It has a metal shank with a hook connected to the sensor of the digital gauge. The hook holds a 50-μm thick metal strip (Matrizen, Stainless steel, Shiva Enterprises, Vasai, India) with the help of holes provided on the strip [Figure 6].

To measure the PCT, the metal strip was loaded onto the hook of digital gauge and was inserted interdentally from an occlusal direction and pulled buccolingually.

The tightness of the proximal contact was quantified as the maximum frictional force when the strip was slowly removed in a buccolingual direction. The output voltage is converted into Newton, and it could measure up to 5 N. The maximum force by pull was recorded by the digital gauge for each measurement when it was switched to peak mode. Four measurements were made at each site with the target maximum range of 5.0 N. Mesial and distal PCT values of the mandibular first molar (natural teeth) were recorded in Subgroup A, and mesial and distal PCT values of the mandibular ISP were recorded in Subgroup B of Group I (without the intervention of Essix retainers).

Mesial and distal PCT values of the mandibular first molar (natural teeth) were recorded in Subgroup C and between ISP having an adjacent natural tooth were recorded in Subgroup D in Group II, as shown in the Flowchart 1 and Figure 7.

All measurements were double-blinded, performed by a single calibered professional investigator to prevent bias. A single measuring site was checked four times, and the result was the mean value of those four outcomes. Contact tightness was recorded at four-time points: immediately after crown delivery (T0), at a 3-month follow-up (T1), at 6-month follow-up (T2), and at 1-year follow-up (T3). The PCT values at the end of 1 year were evaluated statistically. The data were tested for normal distribution, mean values, and standard deviations at the four-time points and were calculated. When no resistance to the buccolingual pull was seen, it was considered as an open contact.

Statistical analysis

Data were collected, cleaned, and entered in MS office excel and was transferred into IBM SPSS Statistics version 2.0. (Armonk, NY: IBM Corp.). An independent sample *t*-test was done. $P < 0.05$ was taken as statistically significant.

RESULTS

At the end of 1 year in Group I, six out of 20 patients showed no resistance of the metal strip to the buccolingual pull on the digital gauge on mesial contact showing 30% of contact loss, whereas, in Group II, three patients out of 20 showed a contact loss accounting to 15% after the intervention of Essix retainer.

The mean comparison within Group I, without the intervention of Essix retainer (independent sample *t*-test) showed no statistically significant difference in the distal contacts, whereas a significant difference was found on the mesial contacts in patients, as shown in Table 1. The mean comparison within Group II intervened with Essix retainer (independent sample *t*-test) showed no statistically significant difference in the mesial and distal contacts in patients, as shown in Table 2. As shown in Table 3, the comparison of contacts of the ISP between Group I and Group II showed a significant difference in

Figure 5: Digital force gauge with the hook (FG 5000A, Lutron Electronic Enterprise Co., Ltd. Taipei)

Figure 6: Metal strip (Matrizen, Stainless steel, Shiva Enterprises, Vasai, India)

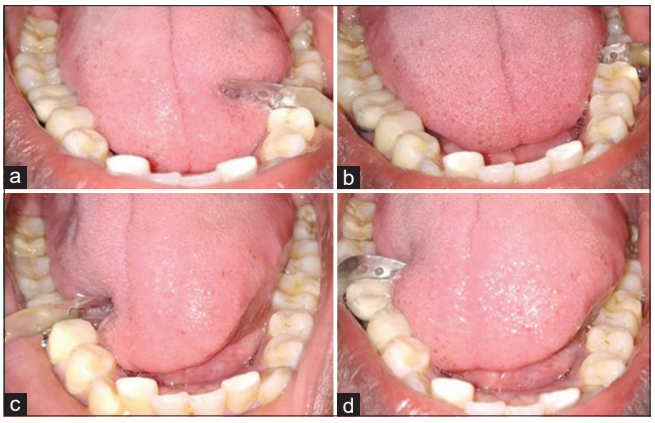
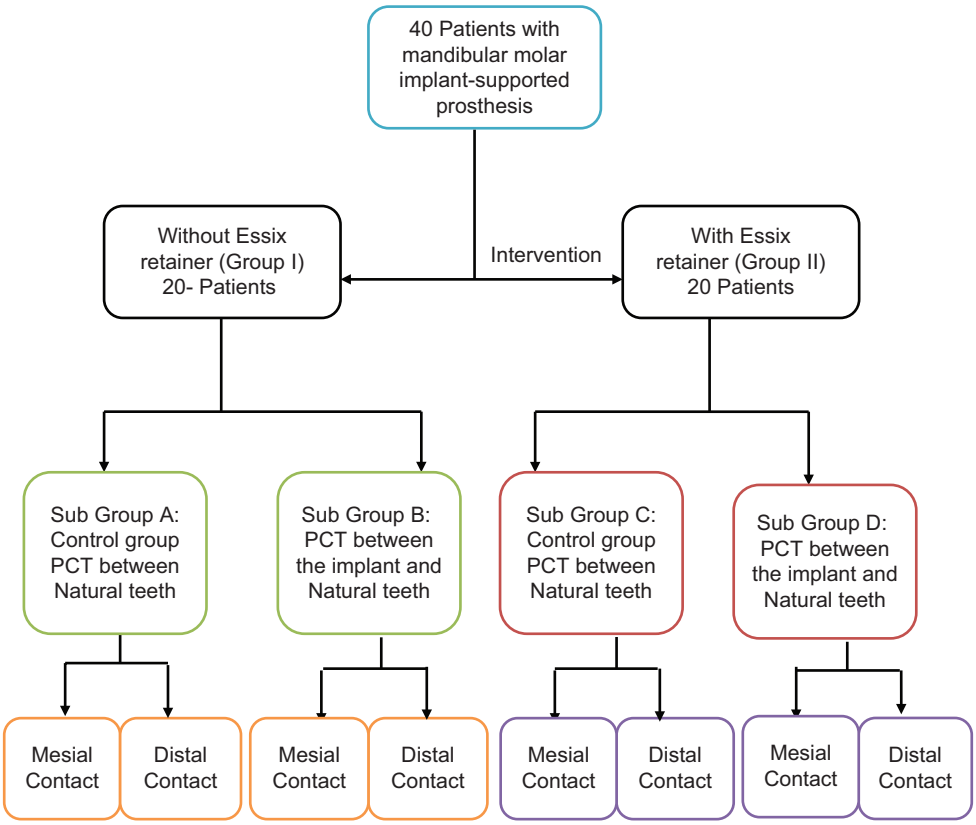


Figure 7: Evaluation of proximal contact tightness: (a) mesial contact of natural teeth (control), (b) distal contact of natural teeth, (c) mesial contact of ISP and adjacent teeth, (d) distal contact of ISP and adjacent teeth



Flowchart 1: The workflow of interventional clinical study

Table 1: Mean comparison between subgroups A and B on the mesial and distal contact of Group I (Newtons) without the intervention of Essix retainer

Mean comparison within Group I (Newton) without the intervention of Essix retainer independent sample *t*-test)					
	Mean	SD	Mean±SD	*t*	*P*
Mesial contact					
Subgroup A	2.78	0.92	1.61±0.08	4.087	0.001*
Subgroup B	1.17	0.84			
Distal contact					
Subgroup A	2.57	0.84	0.74±0.02	1.987	0.062
Subgroup B	1.83	0.82			

*Statistically significant if $P<0.05$. SD: Standard deviation

Table 2: Mean comparison between Subgroups C and D on the mesial and distal contact, Group II (Newtons) with the intervention of Essix retainer

Mean comparison within Group II (Newton) with the intervention of Essix retainer (independent sample *t*-test)					
	Mean	SD	Mean±SD	*t*	*P*
Mesial contact					
Subgroup C	2.88	1.17	0.73±0.26	1.560	0.136
Subgroup D	2.15	0.91			
Distal contact					
Subgroup C	2.99	0.97	1.01±0.09	2.448	0.125
Subgroup D	1.98	0.88			

*Statistically significant if $P<0.05$. SD: Standard deviation

the mesial contact, whereas the distal contacts showed no statistically significant difference when intervened with Essix retainer.

In Group I, the mean PCT in the mesial contacts between two natural teeth is 2.78 N and between ISP and the natural tooth is 1.17 N and the mean PCT in the distal contact between two natural teeth is 2.57 N and between ISP and the natural tooth is 1.83 N when no intervention with Essix retainer was given, as shown in Graph 1. Thus, at the end of 1 year, there was a 1.61 N decrease in the mesial contact, which accounts for 57.9% and 0.74 N decrease in the distal contacts, which accounts for 38.9% of PCT loss. However, on the intervention of Essix retainer in Group II at the end of 1 year [Graph 2], there was a minimum of 0.74 N mesial PCT loss, which accounts for 25.3% and distal PCT loss of 1.01 N which is about 33.7%. This shows that the percentage loss of PCT on the usage of Essix retainer is less on mesial and distal contacts when compared with the nonusage of Essix retainer.

The highest PCT value of 2.15 N was found on the mesial contact of ISP when intervened with the Essix retainer, as shown in Graph 3. Graph 3 also shows that ISP in Group II showed higher PCT values than Group I, implying that the usage of Essix retainer showed tighter contacts.

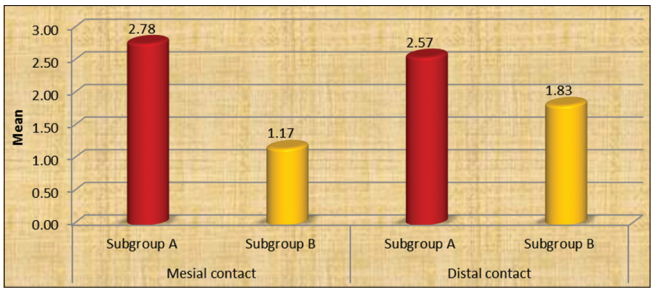
DISCUSSION

The present interventional clinical study evaluated 40 ISPs for the PCT with and without the intervention

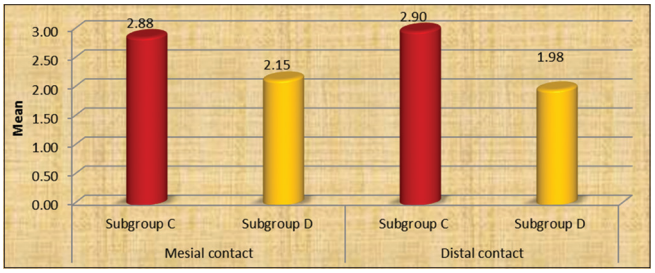
Table 3: Mean comparison between Group I (Subgroup B, without Essix retainer) and Group II (Subgroup D, with Essix retainer) on the mesial and distal contacts of implant-supported prosthesis

Mean comparison between mesial and distal contacts of the implant-supported prosthesis without and with Essix retainer					
	Mean	SD	Mean±SD	*t*	*P*
Mesial contact					
Subgroup B (Group I)	1.17	0.84	0.98±0.07	2.51	0.022*
Subgroup D (Group II)	2.15	0.91			
Distal contact					
Subgroup B (Group I)	1.83	0.82	0.15±0.06	0.402	0.692
Subgroup D (Group II)	1.98	0.88			

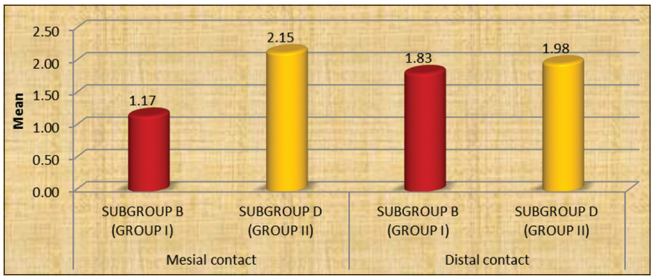
*Statistically significant if $P<0.05$. SD: Standard deviation



Graph 1: The mean comparison between Subgroups A and B on the mesial and distal contact of Group I, i.e., without the intervention of Essix retainer



Graph 2: The mean comparison between Subgroups C and D on the mesial and distal contact of Group II, i.e., with the intervention of Essix retainer



Graph 3: Mean comparison between Group I (Subgroup B) and Group II (Subgroup D) on the mesial and distal contacts

of Essix retainer at the end of 1 year. Previous studies reported contact loss ranging from 17.0% to 78.2% from a follow-up of 1 month to 13 years.[7,8,14-17] In Group I patients of the present study, open contacts were seen among 30% of patients, significantly in the mesial side than the distal contact of the implant prosthesis. In support of the present study, Koori *et al.* also revealed a significantly higher percentage of contact loss in the mesial aspect than the distal. The first contact loss was seen in the 3rd month of prosthetic loading, indicating that the contact loss can occur in the short term, in accordance with Wei *et al.*[6]

The present study intervened with the loss of open contacts by the usage of Essix retainer after implant prosthesis delivery as Group II showed a comparatively reduced incidence of contact loss, i.e., to about 15% predominantly in the mesial side. The contact tightness values were higher in Group II, i.e., between 2.5 N to 5 N, unlike those in Group I where it ranges between 1.5 N to 4 N. In the present study, out of three patients who had open contacts, two had undergone prior orthodontic therapy. Relapse might be one of the causes. Similar contact loss due to relapse was reported by Sheridan *et al.*[18] Hence, the intervention of the Essix retainer might have reduced the mesial drifting. Essix retainer was found to reduce the mesial drifting and distribute the high occlusal forces, thus maintaining the arch integrity.[19] The presence of contact loss despite wearing an Essix retainer could be explained by its nonusage during chewing and patient factors like negligence of wear.

In Group I, 30% of patients complained of food lodgment between the implant prosthesis and adjacent natural teeth in this study. According to Koori *et al.*, open contacts were found to cause periodontal and peri-implant complications and caries to the adjacent natural teeth.[8] French *et al.* reported that there was a higher mucositis index in the areas of contact loss but a reduced risk of peri-implantitis.[20]

Several studies have reported the higher contact loss rate in mandible compared to the maxilla, suggesting that the patients with high mandibular plane angle are more prone to mesial drifting as an anterior component of forces is active in high angle patients.[21] Lower teeth are typically tipped mesially and are also one of the more substantial reasons.[20] Other confounding factors such as occlusal forces, proximal wear, and location of contact surfaces are also involved.[22] Further studies are to be done to compare the PCT between maxilla and mandible wearing Essix retainers.

Apart from the usage of digital force gauge to evaluate the PCT, Byun *et al.* used waxed dental floss and reported 34% of open contacts in their cases.[7] However, the slightest change in the contact region will be difficult to achieve. The thin metal strip provides us with more

reliable information, as documented previously by Osborn, who first constructed a device based on the theory of frictional force to quantify the tightness of proximal contact.[23] Different thicknesses of strips were used 30 μm, 50 μm, and thinner strips.[24,25] However, thinner strips got torn off when there were used in tighter contacts. Boice *et al*., in the year 1987, established the fact that spaces of 50 μm exist naturally between teeth in 80%–90% of the proximal contacts, where previously, it was thought to get tighter with advancing age. They suggested that normal proximal contacts do not close with age but flatten due to wear as the periodontal ligament allows sufficient minor tooth movement.[26] Therefore, in the present study, a 50-μm thick metal strip was equipped, and the specified contact was adjusted to 50 μm.

Liu *et al*. described a clinical chairside technique for closing the open contacts adjacent to an implant-supported restoration in follow-up appointments by bonding composite resin to the implant-supported ceramic restoration extraorally. This chairside procedure was found to save time and improve patient comfort.[27]

Clinical implications include informing the patients about food lodgment before implant therapy and therefore educating them about oral hygiene maintenance, especially on the mesial aspect of mandibular posterior implants. Frequent regular follow-ups are advised. Retrievable implant restorations such as screw-retained restorations are recommended to correct the proximal contact if needed. Cement-retained restorations with provisional cement could be used for easy retrieval of the prosthesis. It is essential to decide on the choice of material for fabrication of implant crown because of differences in each material (such as esthetics, fracture resistance, and cost) and their ability to be modified.[28-31] For example, having porcelain fused metal or zirconia with feldspathic ceramic where ceramics can be reapplied to restore the contact area as long as they can be retrieved from the mouth keeping in the account of the finances, increased clinical time, and predictability of the potential modification as well as the expertise of the laboratory technician.

Limitations of the study

The present study evaluated contact loss at the end of 1 year, which was a relatively short period. Long-term follow-up studies are needed due to the variation in craniofacial growth patterns. Further clinical trials with a greater sample size are recommended to increase the sensitivity of the study.

CONCLUSION

Within the limitations of the study, we can conclude that:

1. The usage of Essix retainer showed a significant difference in increasing the PCT values, especially on the mesial contact
2. The incidence of contact loss, which was found to be 30%, decreased to 15% on the usage of Essix retainer.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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