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Comparison between the *in-vitro* cytotoxicity of three different multilayer thermoplastic clear aligner materials

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Abstract

Background: Clear aligner therapy (CAT) is a prominent orthodontic treatment option. CAT was formerly only used to treat mild malocclusions, but with developments in technology, it can now treat much more complex malocclusions. With the increasing popularity of CAT and technological improvements, led to the development of Invisalign's SmartTrack technology, the first commercially available aligner material that used multi-layer plastic to facilitate tooth movement. Multiple layers provide superior mechanical properties that eluded previous single layer plastics.

Aim: To study the cytotoxicity properties of different thermoplastic multilayer clear aligner materials on human primary gingival fibroblasts (HGFs).

Materials and methods: Three multilayered clear aligner materials were considered in this study: SmartTrack (Align Technology, San Jose, CA, USA), Zendura FLX (Bay Materials, Fremont, CA, USA), and ComfortTrack (Great Lakes Dental Technologies, Tonawanda, NY, USA). The samples were incubated at 37°C in DMEM (0.1 mg/mL) for 21 days. The cell viability of HGFs cultured with each sample medium was then compared to a negative control assessed by MTT assay.

Results: The results showed slight toxicity for each one of the samples tested. The highest cytotoxicity level seen in the HGFs was SmartTrack (65.5% ± 2.5 of cell viability), followed by Zendura FLX (72.3% ± 8.6), and the least was observed by ComfortTrack (80.8% ± 2.1).

Conclusion: The Under the experimental conditions of the study, all of the materials tested displayed slight levels of cytotoxicity. SmartTrack was measured as the most cytotoxic. There were no statistical differences found between the three aligner materials ($P < 0.05$).

Keywords: Clear Aligners, Cytotoxicity, Invisalign, Fibroblasts.

1. Introduction

Clear aligner therapy (CAT) has become a popular choice for orthodontic treatment. As more adults are seeking orthodontic treatment, there is a corresponding demand for esthetic treatment options [1-3]. Even children and adolescents show preference to orthodontic appliances that are less visible than traditional metal brackets and wires [4]. Other advantages of CAT over fixed appliances are fewer emergencies, shorter treatment visits, [5] and greater patient comfort [6].

As CAT's popularity has increased, so too has the technology improved. Most notable over the last decade is Invisalign's SmartTrack technology (Align Technology, San Jose, CA, USA). Released in 2013, it was the first commercially available aligner material that used multi-layer plastic to support tooth movement and has become preferred over previous materials by both clinicians and patients [7]. Multiple layers offer superior mechanical properties that eluded previous single layer plastics [8]. CAT was originally only used for the correction of minor malocclusions, but with technological advances, they now can treat much more complex malocclusions [9,10]. As a result of this, treatment times are increasing, and patients are required to wear their clear aligners for longer durations. Each stage of aligners is meant to be worn for about 22 hours a day for up to 21 days each. It has been shown that the thickness of the aligners can be diminished after exposure to the oral cavity over this time; [11] it may be possible that harmful molecules are being released into the oral cavity. Align Technologies shipped over 1.2 million cases in 2018, [12] thus the importance of investigating this issue further as millions of people are treated with CAT worldwide each year. There has been extensive research on the biocompatibility of other orthodontic materials such as brackets, [13] wires, [14] and adhesives, [15] but only three previous papers have focused on the potential toxicity of clear aligner plastics [16-18]. Furthermore, there have been several new multi-layer

plastics introduced to the market that have not yet been publicly tested.

The purpose of this study, therefore, was to test the cytotoxicity of 3 different multilayer thermoplastic materials - SmartTrack (Align Technology, San Jose, CA, USA), Zendura FLX (Bay Materials, Fremont, CA, USA), and ComfortTrack (Great Lakes Dental Technologies, Tonawanda, NY, USA).

2. Materials and Methods

The three materials that were evaluated in this study were SmartTrack (Align Technology, San Jose, CA, USA), Zendura FLX (Bay Materials, Fremont, CA, USA), and ComfortTrack (Great Lakes Dental Technologies, Tonawanda, NY, USA). The cytotoxicity of each material was tested after they had been thermoformed.

Each sample material was sterilized following the protocol defined by the International Standards (ISO) 10993-5 norm. The samples were immersed in Dulbecco's Modified Eagles Medium (DMEM) and stored under stationary conditions at 37°C in airtight test tubes for 21 days. The ratio between the weight of the samples and the volume of the dilutions was 0.1g/mL as recommended by ISO parameters. After the release interval, the extracts were sterile-filtered to eliminate solid particles and stored at -20°C until further use.

MTT assay [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide] was used to evaluate cell viability. Human gingival fibroblasts (HGFs) were plated into 48-well flat-bottomed, tissue culture plates, with a density of 208 cells/well. After 24 hours of incubation, the culture medium was replaced with 400 µL/well of clear aligner extract. After an additional 24 hours, the medium was replaced with 200 µL/well of the MTT solution (1 mg/mL), mixed gently for 10 minutes, and the cells were incubated for an additional four hours at 37°C. 200 µL of isopropanol with 0.04 N HCL was then added to each well and mixed thoroughly by repeated pipetting. The optical density of each sample was measured in a spectrophotometer at 600 nm. The optical density (OD) of the cells cultured in the DMEM medium without any clear aligner material sample extracts was used as a negative control for 100% cell viability and as a reference for the determination of the level of cytotoxicity in the assay. Cells treated with a 1% concentration of anionic detergent were used as a positive control [21].

2.1 Analysis

The optical density of each sample was used to calculate the cell viability using the following criteria:

- Cell viability = (optical density of test group/ optical density of cellular control group) X 100 as calculated by Vande Vannet *et al.* (2006) [20].
- Cell viability was scored using the classification of Sjögren *et al.* (2000) [19]:
  - >90% Noncytotoxic
  - 60-90% Mildly cytotoxic
  - 30-59% Moderately cytotoxic
  - <30% Markedly cytotoxic

Descriptive statistics and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS 27.0, SPSS IBM, Armonk, NY, USA). The normal distribution of the data was confirmed by the Shapiro-Wilk test at $p > 0.05$. Differences between mean values were determined by a one-way Welch analysis of variance (ANOVA) with the Games-Howell post hoc test at $p < 0.05$.

3. Results

The MTT assay is a colorimetric assay used to measure cellular metabolic activity as an indicator of cell viability. The yellow tetrazolium salt is converted to purple formazan crystals by mitochondrial reductase enzymes in metabolically active cells. The resulting-coloured solution is quantified by measuring the absorbance at 600 nanometers using a multi-well spectrometer. The greater number of viable cells, the darker the solution will be [29,30].

The raw OD readings from each of the materials are listed in Figure 1. All three samples showed significant differences when compared to both the negative and positive controls, but not when compared to one another. The cytotoxicity levels of each sample after the viability formula were applied (Cell viability = (optical density of test group/ optical density of cellular control group) X 100) is shown in table 1. All the tested plastics showed a mildly cytotoxic influence on the HGFs after 21 days of incubation.

The material that expressed the highest cytotoxicity was SmartTrack (65.5% ± 2.5 of cell viability), followed by Zendura FLX (72.3% ± 8.6), and the least was observed by ComfortTrack (80.8% ± 2.1). The positive control resulted in the viability of only 12.4% ± 0.8.

Table 1. Mean viability and standard deviation, cytotoxicity levels of materials.

Materials	Mean Viability ± SD[ǂ]	Cytotoxicity	Significance
Zendura	72.3 ± 8.6	Mild	NS*
Great Lakes	80.8 ± 2.1	Mild	NS*
SmartTrack	65.5 ± 2.5	Mild	NS*

*[ǂ] Standard deviation, * No significant difference*

4. Discussion

With the increasing popularity of CAT and the expiration of patents previously held exclusively by Align Technology, the orthodontic industry is currently seeing a flood of new aligner materials being introduced into the market. In addition, the accessibility of digital scanning and 3D printing have made it easier than ever for dental professionals to

provide effective in-office treatments without relying on large external labs. It is imperative that these treatments be administered in a manner that is efficient, predictable, and safe for patients. Ideal ortho-dontic movement occurs when a 'light and continuous' force is applied to the teeth, and ideally, any plastics used for CAT would deliver a constant therapeutic force over a relatively broad deflection range [22].

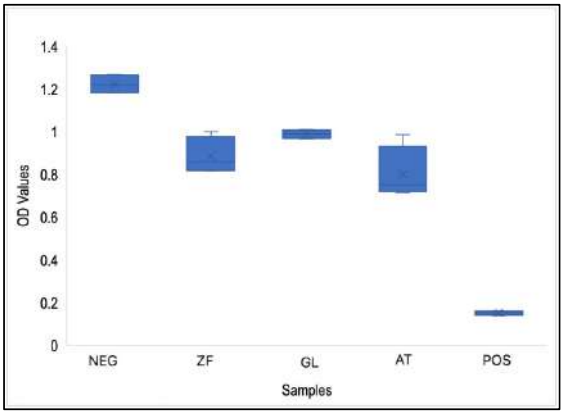

Figure 1. Optical Density of various materials used in the study

A study by Lombardo *et al.* in 2017 demonstrated that multilayer plastics initially display much less stiffness when compared to single-layered plastics, and their force decay showed far less deformation when prolonged stress was applied [23]. With such favourable force characteristics, there will certainly be more multilayered aligner materials available for retail in the future. Although several single-layer CAT materials have been shown to be safe in a clinical setting, there is little to no published evidence on the biocompatibility of these multilayered plastics at the time of the present study.

This study evaluated the in-vitro cytotoxicity of three different varieties of multilayered thermoplastic materials after 21 days of incubation in a simulated oral environment. Each sample extract was then exposed to a cell culture of HGFs, and the resultant cell viability was assessed. We chose gingival fibroblasts for our investigation because they are the most abundant cell type seen in the periodontal connective tissues, and they play a critical role in maintaining healthy gingival architecture [24]. They are commonly used in biocompatibility assessments of dental materials and are recommended for such assays by the International Standards Organization.

Mild levels of cytotoxicity were observed in all of the samples we tested, but none of them displayed levels that would contraindicate them for routine clinical use. This cytotoxic effect was similar to, and in some cases even lower, than that what has been observed in other orthodontic materials such as elastic ligatures, bonding materials, and molar bands [15,25,28]. Our findings align with the studies performed by Martina *et al.* (2019), who discovered that the thermoforming process may actually increase the cytotoxicity of each material when compared to their non-thermo-formed counterparts [18]. Conversely, other studies that have evaluated the biocompatibility of clear aligner materials found little to no negative effects in the past. An investigation of potential cytotoxicity and estrogenicity of Invisalign appliances by Eliades *et al.* (2009) revealed a complete absence of toxic effects, although it must be noted that this study was performed before the multilayered SmartTrack material was commercially launched [16,26]. Interestingly, the findings by Premaraj *et al.* (2014) showed similar cytotoxic results when samples were prepared in a saline solution, but cell viability significantly increased when exposed to a saliva-eluate; suggesting that saliva may offer protection against potentially harmful stimuli to the gingival tissues [17].

The cytotoxicity ranking system we used from Sjögren *et al.* [19] was further developed by Vande Vannet *et al.* in 2006 [20] by expounding the data from monolayer cell cultures and applying it to a three-dimensional epithelial model. They translated the [(1) noncytotoxic, (2) mildly cytotoxic, (3) moderately cytotoxic, and (4) markedly cytotoxic levels into a clinically applicable histological model. Their observations from the corresponding levels are as follows: (1) The epithelial tissues have a constant thickness, devoid of terminally differentiated cells (2) Minimal changes occur with slight edema. (3) The beginning of spongious tissue development in the upper layers with architectural atrophy and cellular irregularity. (4) Most of the upper cell layers of the epithelial tissues have disintegrated. There is cellular necrosis and loss of cellular junctions in the basal layer [20]. Using the data from Vande Vannet *et al.* (2006) [20], it is fair to extrapolate the present findings to determine that these materials are safe for clinical use. It must be acknowledged that our experimental conditions were not able to completely replicate the dynamic conditions encountered in the oral environment and therefore may be considered a limitation in the study. Variables in diet, hygiene, and salivary flow/composition can influence the chemical balance within the oral cavity. Mechanical forces from insertion, removal and non-nutritive mastication can potentially alter the physical properties of clear aligner materials *in vivo* [23]. Comparable in vitro experiments under similar conditions can offer viability to our study design and our current results, but further *in vivo* studies that take into consideration changes of pH and mechanical stresses of the oral cavity may improve experimental findings.

5. Conclusion

- In our experiment, all tested clear aligner materials showed mild levels of cytotoxicity.
- There were significant differences in cytotoxicity levels between the control and test samples, but not between the test samples themselves.
- Since the materials only showed mild levels of cytotoxicity, they can be determined as safe for clinical use.

Conflicts of interest: Authors declared no conflicts of interest.

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Comparative evaluation of remaining dentin thickness with three different rotary Ni-Ti File systems: an *in vitro* CBCT study

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Abstract

Background: Endodontic therapy and its success depend on effective cleaning and shaping the root canal without deviating from the original anatomy. Ideally, during root canal preparation, the instruments should always confine to and retain the original shape of the canal to maximize the cleaning effectiveness and minimize unnecessary weakening of tooth structure to achieve the optimal result. The remaining dentin thickness in endodontically treated teeth is a significant factor, which is responsible for its longevity.

Aim: This study aimed to evaluate the remaining dentin thickness after instrumentation with ProTaper Next (PTN), TruNatomy (TN), and Neohybrid (NH) file systems using cone-beam computed tomography.

Materials and methods: Thirty extracted single-rooted mandibular premolars were decoronated and divided into three experimental groups with ten in each. Groups I, II, and III were assigned to the file systems ProTaper Next (PTN), TruNatomy (TN), and Neohybrid (NH), respectively. Cone-beam computed tomographic pre-scans were taken, followed by the biomechanical preparation with the respective file systems. Post CBCT scans were taken and compared with pre-scans for remaining dentin thickness. The data obtained were statistically analyzed.

Results: Among the three file systems, TruNatomy rotary files resulted in significantly less dentin removal ($p<0.05$). The majority of the intergroup comparisons showed significant differences in remaining dentin thickness after biomechanical preparation at 3, 6, and 9mm.

Conclusion: TruNatomy (TN) exhibited the maximum remaining dentin thickness followed by Neohybrid (NH) and comparatively minimum with ProTaper Next (PTN) file systems.

Keywords: Cone-beam computed tomography (CBCT), Neohybrid, ProTaper Next, Remaining Dentin Thickness, TruNatomy.

1. Introduction

The success of root canal treatment varies on effective cleaning and shaping of the root canal system without deviating from the original anatomy [1]. Cleaning and shaping techniques, regardless of instrumentation approach, always result in dentin removal from canal walls. Excessive canal flaring can diminish dentin thickness, resulting in less residual dentin thickness and an increased risk of vertical root fractures [2]. NiTi rotary instruments made root canal preparation easier and faster than manual instrumentation, resulting in reliable and predictable root canal shaping. These instruments can improve both the morphological characteristics and safety of canal shaping because of the alloy's unique properties [3]. The ProTaper Next (PTN) (Dentsply Sirona Endodontics, Ballaigues, Switzerland) is an innovative NiTi file system made from M-Wire technology. It has a rectangular cross-section and an offset mass of rotation with a variable taper. Its off-centered design gives the file snake-like "swaggering effects" that decrease the screw effect and the taper lock minimizing the contact between a file and dentin [4]. TruNatomy (TN) and Neohybrid (NH) file systems that were introduced recently are made up of special Ni-Ti alloys and are subjected to various thermal treatments processes. TruNatomy (TN) (Dentsply Sirona, Ballaigues, Switzerland) file system is characterized by different geometries, sizes, memory, and specific metallurgical treatment. It is designed from a 0.8 mm NiTi wire that is heated by a special treatment, resulting in super-elastic properties and less memory. Also, this wire has been claimed to provide minimally invasive instrumentation because of its geometry, regressive tapers, and slim design [5,6]. Neohybrid (NH) (Orikam Healthcare India Private Limited) files are made of CTA (controlled thermal activation) wire with an off-centered rectangular cross-section that improves flexibility. Further, its swaggering

movement minimizes the engagement between the file and canal dentin, effectively reducing the taper lock and screw-in forces inside the canal [7].

A noninvasive Cone-beam computed tomography (CBCT) is used to evaluate the canal anatomy and compare the canal shape before and after preparation. Using Cone-beam computed tomography (CBCT), proper cross-sections of roots are provided, and 3-dimensional CBCT images are reconstructed simultaneously with more precision than other routine techniques [8]. Limited research is available on the comparison of the efficiency of TruNatomy (TN) and Neohybrid (NH) files in maintaining the remaining dentin thickness. Considering the factors mentioned above, Remaining dentin thickness after instrumentation with ProTaper Next (PTN), TruNatomy (TN), and Neohybrid (NH) Ni-Ti rotary file systems using CBCT were evaluated in this study.

2. Materials and Methods

2.1 Selection and specimen preparation

A total of thirty freshly extracted human single-rooted mandibular premolar teeth for orthodontic treatment purposes were gathered for the study. The calculation of sample size was based on a previous study using G power software at 80% confidence and a p-value set at less than 0.05 [1]. Teeth with any previous endodontic treatment, fractures, pathological root resorptions, calcifications, and immature teeth were excluded from the study. The presence of a single root and canal without any curvatures in each tooth was confirmed on radiovisiography (Digora, The Dental Imaging Company Ltd). The samples were standardized to a length of 16mm by decoronation using a double-faced diamond disc (KG Sorensen, Barueri, SP, Brazil). The root canal length was measured by the penetration of a size 10 K-file (Mani, Japan) until it reached the apical foramen and then subtracting 0.5 mm. Teeth were arbitrarily divided into three groups (n=10) and were embedded in the putty blocks to obtain a constant position.

2.2 Initial scanning

The template was horizontally fitted to chin support with its occlusal plane parallel to the plate. A pre-CBCT (CS 9000 3D, Rainbow CT, South Korea) scan was done for all teeth before instrumentation with the exposure period of 3.0 seconds at 75 kV and 2.0 mA. The scanned images were stored in the computer's hard disk for further comparison between pre and post instrumentation data using DICOM software.

2.3 Root canal preparation

After initial scans, root canals were instrumented as follows. Group 1: Canals were shaped using ProTaper Next (PTN) rotary files (X1; 20/0.04 taper and X2; 25/0.06 taper) Group 2: Canals were shaped using TruNatomy (TN) rotary file (25/0.04 taper) Group 3: Canals were shaped using Neohybrid (NH) rotary file (25/0.04 taper) till the working length with EConnect S (Eighteeth, China) Endo motor. All the instruments and techniques of usage were according to the manufacturing instructions. Biomechanical preparation was done using the respective files, and irrigation was done with 2ml of 3% sodium hypochlorite (NaOCl) (Parcan, Septodont Healthcare PVT LTD., India) for 1 min, and recapitulation was done after every instrument. After the instrumentation of the root canal was completed, 2 ml of 17% ethylenediaminetetraacetic acid (EDTA) (Dent Wash, Prime Dental PVT LTD., India) was applied for 1 min to remove the smear layer. Then, the canal was flushed again with 2 ml of 3% NaOCl and 2 ml of 0.9% normal saline solution for 1 min each to remove remnants of EDTA.

2.4 Final scanning and evaluations

The teeth were again prepared for post-operative CBCT scanning using the same parameters, and the pre instrumentation data stored were compared with post-instrumentation data using CBCT software (Kodak 9000 DICOM Software CS 9000 3D). Three axial tomograms were selected for each specimen. The first corresponds to the area located at 3 mm (apical third), the second at 6 mm (middle third), and the third at 9 mm (cervical third) from the root apex. The remaining dentin thickness was determined by subtracting the un instrumented canal from the instrumented canal, calculating the shortest distance from the outer wall to the inside canal wall on mesial and distal aspects at the levels of 3, 6, and 9mm of pre and post instrumentation [1] (Figure 1-3). Matam et al. used the formula RDT = D1–D2, where D1 is the pre instrumentation dentin thickness and D2 is the post instrumentation dentin thickness [9,10].

2.5 Statistical analysis

The data were subjected to statistical analysis using the Statistical Package for the Social Sciences IBM SPSS Statistics version 22.0 software and Oneway Analysis of Variance test for intragroup comparison and Tukey's post hoc test for intergroup examination.

3. Results

TruNatomy rotary files significantly resulted in a lesser amount of dentin removal among the three file systems ($p<0.05$). (Table 1). One-way ANOVA showed no significant difference in the intragroup comparison of group I and group II at 3,6 and 9mm. In contrast, a significant difference ($p=0.001$) is observed in group III at 3,6 and 9mm (Table 1).

In post hoc analysis, Group I showed significant differences with Groups II at 3mm, 6 mm, and 9 mm ($p=0.003$, $p=0.001$, and 0.030, respectively). Also, Group I exhibited a significant difference with Group III at 3 mm ($p=0.000$). However, no significant differences were observed between Group II and III at different levels (Table 2).

Table 1. Intragroup comparison of amount of dentin removal after biomechanical preparation with three different file systems at 3, 6, and 9 mm.

Groups	Levels	Mean	Standard Deviation	*p*-Value
Group I (PTN)	3mm	0.31	0.20	0.683
	6mm	0.29	0.19	
	9mm	0.26	0.13	
Group II (TN)	3mm	0.17	0.06	0.099
	6mm	0.13	0.04	
	9mm	0.17	0.07	
Group III (NH)	3mm	0.14	0.06	0.001
	6mm	0.23	0.11	
	9mm	0.25	0.10	

Table 2. Inter-group comparison of amount of dentin removal after biomechanical preparation with three different file systems at 3, 6, and 9mm.

levels	Groups		Mean difference	Standard Error	Significance*
3mm	Group I	Group II	0.14	0.04	0.003
		Group III	0.17	0.04	0.000
	Group II	Group III	0.03	0.04	0.750
6mm	Group I	Group II	0.16	0.04	0.001
		Group III	0.06	0.04	0.339
	Group II	Group III	0.10	0.04	0.055
9mm	Group I	Group II	0.09	0.03	0.030
		Group III	0.10	0.03	0.954
	Group II	Group III	0.08	0.03	0.060

**The mean difference is significant at the level of 0.05.*

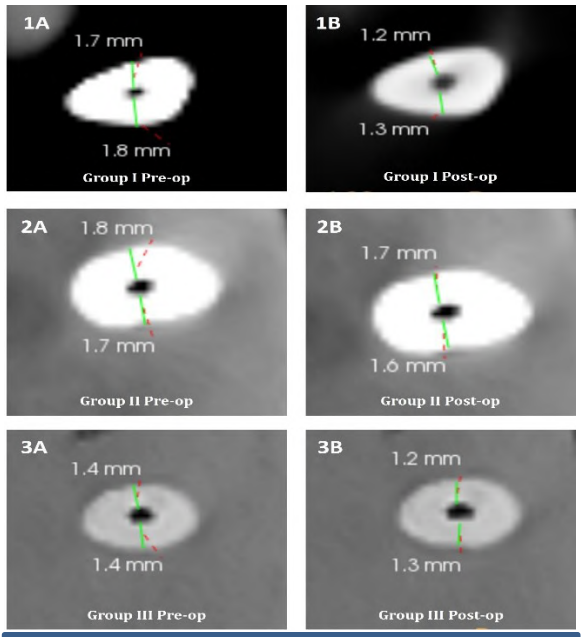

Figure 1-3. A Showing pre-instrumentation images; B. Showing post-instrumentation images of 1. ProTaper Next (PTN), 2. TruNatomy (TN), and 3 .Neohybrid (NH) at the region of 9mm from the apex.

4. Discussion

An ideally prepared root canal should have a progressively tapering conical shape that preserves the apical foramen and the original canal shape [3]. The thickness of the remaining root dentin following intraradicular procedures may be the most important iatrogenic factor that may lead to compromised fracture resistance of the root [3,10]. This study was performed on single-rooted, single canal mandibular premolars to avoid bias [9]. In this study, CBCT was used to evaluate the remaining root dentin thickness. There are several methodologies to evaluate different instrumentation techniques in preparing root canals. But one of the latest innovations in the medical field is the use of CBCT for study purposes and this scientific tool that could develop potential in endodontic research. Moreover, the quality of the three-dimensional images obtained by CBCT scanning is an accurate and efficient method of assessing root canal instrumentation [2,11,12]. The advantages of NiTi instruments in root canal preparation are well documented. However, their cutting ability is a complex interrelationship of multiple parameters such as the cross-sectional design, helical and rake angles, metallurgical properties, and surface treatments of the instrument [13].

In the present study, three file systems, namely, ProTaper Next (PTN), TruNatomy (TN), Neohybrid (NH) rotary file systems were used. The results of this study found that the mean value with more amount of remaining dentin thickness after biomechanical preparation at 3, 6, and 9 mm from apical foramen was seen in Group II (TN) followed by Group III (NH) and less in Group I (PTN). The results of this study were similar to the study done by Suhashini Ramanathan et al., who observed that the M two system removed less amount of dentin and better maintained the original shape of the root canal ($P < 0.05$) than ProTaper Next (PTN), and Protaper universal systems [14]. It can be mainly attributed to the progressive taper of the ProTaper Next (PTN) files along the cutting surface combined with sharp cutting edges. The results are analyzed both at 3, 6, and 9mm from the apex in all the groups to understand the effect of the shape of the instruments, a percentage increase in the taper of the instrument in cleaning and shaping the root canal, and its mechanical properties. It is known that rotary instruments with the same tip size and tapers would cause a similar amount of dentin removal, where the amount of dentin removed would be higher with a larger taper with the same tip size. Similarly, in the present study, ProTaper Next (PTN) files with a larger taper than TruNatomy (TN) and Neohybrid (NH) files removed more amount of dentin [15]. Regressive taper, make the instruments slimmer at the end of the working part than most conical NiTi instruments of comparable ISO size, preventing unnecessary loss of tooth substance in the coronal part [16]. As TruNatomy (TN) files having regressive taper preserved more amount of dentin in the coronal part. It has shown a significant difference in minimum removal of dentin thickness compared to the ProTaper Next (PTN) file system because of its characteristic slim wire design of having a maximum fluted diameter of 0.8 mm. It was stated that the TruNatomy (TN) instruments safeguard the structural dentin and tooth integrity due to their instrument geometry, regressive tapers, and slim design, along with the heat treatment of the NiTi alloy [6,17]. Neohybrid (NH) has removed less amount of dentin comparative to ProTaper Next (PTN) file system with a significant difference at 3mm from the apex. As given by the manufacturer, its swaggering movement minimizes the engagement between the file and canal dentin, effectively reducing the taper lock and screw-in forces inside the canal, attributing to minimal removal of dentin [7]. The more the dentin is retained, the more the longevity of the teeth. Thus, long-term retention and resistance to fracture of the tooth are directly related to the residual tooth structure.

The present study focused on evaluating the remaining dentin thickness on mandibular premolars. Only single-rooted teeth were evaluated, and in vitro studies do not fully replicate in vivo settings. Therefore, further studies may be focused on evaluating the RDT on molars.

5. Conclusion

Within the limitations of this study, it was concluded that maximum remaining dentin thickness was seen with TruNatomy (TN) followed by Neohybrid (NH), and comparatively minimum with ProTaper Next (PTN) file systems.

Conflicts of interest: Authors declared no conflicts of interest.

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A new technical study on the characteristics of Nickel-Titanium Orthodontic archwires using stimulated infrared thermography

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Abstract

Background: Orthodontic treatment becomes an essential field in dentistry since it creates a healthy, functional "bite," which promotes oral health and general physical health.
Aim: This study aimed to determine the defects in an old nickel-titanium orthodontic wire in the mouth after four weeks as compared to a new one, as well as their impact on orthodontic treatment quality, and to underline the necessity of restoring these defects using various methods.
Methods: For this reason, this research extensively differentiates between two sets of samples of orthodontic arches, both new and used, and quantified their deterioration condition by examining their thermal responses in static and dynamic systems and joule heating.
Results: The results showed that the used archwires bear more surface defects in terms of size and area when compared to unused ones. These affirmative conclusions were obtained with accurate results up to 99%.
Conclusion: The importance of this study lies in the repetition of this technique for three famous companies in this field that increases the quantity of wire used (291 wires used and new), as no previous study has ever experimented with this large number of patients, if this indicates anything, it is the validity followed in this research, which is reflected in the reduction of errors.
Keywords: orthodontics; Nickel Titanium; wire; tomography technic; used; new.

1. Introduction

Currently, the study on the nickel-titanium (NiTi) dental and orthodontic arches entails an assessment of the characteristics of new arches primarily. Only a few studies have focused on understanding the changes that occur when new arches are used intra-orally [1,2]. The current research attempted to bridge this research gap.

Uniformly corroded zones appear in used NiTi wires coupled with traces of organic deposits of substances such as salivary compounds, microorganisms, and other food materials. In a microscopic study, Eliades et al. found a layer of organic substances formation on the surface of NiTi causing roughness on it, which is responsible for undermining the sliding mechanism needed during orthodontic treatment [3].

Infrared Thermography (IRT), commonly known as thermal imaging, is a technology that is essentially based on the assumption that bodies generate magnetic radiations. According to this theoretical concept, some visible light is known to occupy only a narrow spectral range between 0.4 and 0.7 μm. In this case, the ability of the specialised imager to identify signals and radiation within a thermal region of the infrared spectrum light is critical [4].

IRT is used in the field of non-destructive testing to detect defects on the surface and subsurface, as well as to enable online monitoring. The ability to monitor the thermal patterns of the objects being tested is vital to IRT's performance. Typically, subsurface defects exhibit anomalies in thermal patterns, which are utilised as evidence of defect identification. Abnormal thermal patterns on the skin are utilised in medicine to detect underlying clinical illnesses [5,6].

In addition, thermal video is a classic example of a scientific infrared imaging technology. Typically, cameras detect identical radiation, with the exception that it occurs in a long band of the infrared electromagnetic spectrum or aggregately 9000-14000 nm. The images produced by this process are known as thermos-grams. Regardless of the existence of visible illumination, any infrared radiation emissions from an object with a temperature over absolute zero increases visibility of the environment.

It is evident from the preceding sections that all objects emit some form of thermal radiation that characterises their physical state. It has also been demonstrated that using a

particular device as a heat signature, it is possible to distinguish between different types of radiation. In line with this, IRT can detect radiation by characterising it in terms of several thermo-physical body properties such as emissivity, then analysing it, as illustrated in figure 1.

Figure 1. Visible Image (Left) and infrared (right) of a transformer of electrical connection.

Corrosion is a destructive process that occurs on all metal surfaces. There are several methods for measuring corrosion in the literature, but only a few of them have examined at approaches that are non-destructive, non-contact, or have direct features for accurately measuring corrosion range. Using a non-destructive infrared imaging device, IRT easily records electromagnetic waves emission from material and biological objects. IRT is a non-destructive test that analyses defects on a material by inducing temperature or using the temperature that is already present, making it a very safe and precise approach to utilise [7]. IRT's usage in medical science has received a lot of attention in the literature, and it's also popular in dentistry [8-10].

In the current study, our object was to detect the size of the area of defects and the number of areas with defects in old wires, which were materials studied, and to analyze the differences between new and old ones. The authors also hoped to be able to identify and quantify the extent of the alterations in maxillary and mandibular arches and reasoned that these alterations would be the surface defects attributable to the oxidation process and/or depositions, as well as subsequent to micro-cracks, porosity, striations, and micro-laminations.

2. Materials and methods

The wires were fabricated by three manufacturers; AZ Dent, American Orthodontic and Ortho Classic, were used in the study. Tests have been conducted on more than 180 patients including both men and women, teenagers and adults, and finally lower and upper arches were included in the study. So, all the variables needed to accomplish this study were presented including the patient's gender, age, type of arch, whether new or old, and the location of the arch in the lower or upper jaw.

2.1 Experimental protocol

Thermograms were extracted prior to heating and at the end of the warm-up phase, and then analysed at their peak temperature in the current study. Two major instruments were utilised to carry out this experiment: an electrode and a FLIR camera. A new technic for detecting defects in orthodontics archwires has been developed using infrared thermography. In this technique, a sample was attached to both of its ends using two connectors. An observation was then made using FLIR thermal imaging cameras clocked at 6.25HZ. During this period, the samples were placed at equilibrium with the ambient temperature.

The arch was held in position using the same devices and connectors, and a power stabilizer was used to traverse electric current through it. A dental arch was then used as an electric current resistance. Through observation of the joule effect, by use of a thermal camera, a dynamic model of studying is possible. A study of the stressed sections, situated between both terminals, in all samples of approximately 50mm, was then performed. A voltage of exactly 1.7v at a 2.4A was then applied to the sections for approximately 15secs and then observed for 35 seconds. Of these, 15 seconds were used to heat the sample and 20 seconds were used for cooling. By the use of thermal transition, it was possible to observe visualize the defects in the material studied. The procedure for observation was as previously reported. Vardasca devised an interpolation-based comparison technique for several areas of interest (ROI) from diverse thermal images to allow comparison between them. In this case, ROIs are aligned semi-automatically.

2.2 Thermal image of an electric current arc in dynamic test

The static analysis would help to concentrate on superficial defects as characterized by variations in emissivity since all the samples were in thermal equilibrium. The medium and the signal measures depended exclusively on the environment and emissivity parameters. Thermograms obtained using thermal cameras would assist in performing quantitative and qualitative analysis. The qualitative analysis would aid in sorting of samples, while the quantitative analysis would aid in classifying samples objectively.

Open-source software (both its image and counting module, "analysis particles") was then be utilized to count faults in each arch under the study, and in measuring, various parameters (see Figures 2). After a thermal holding operation, it will become easier to gather interesting information about the observed defects and their characteristics, including but not limited to area, parameters, and area. The information gathered would then be used to position arches according to their relative differences.

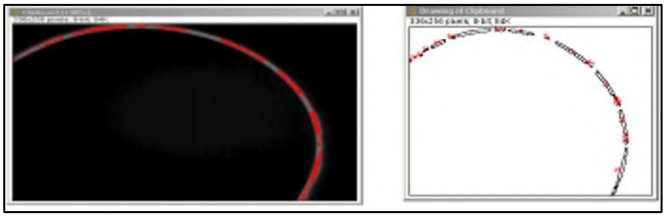

Figure 2. Transformation Using Special Software from Bit-Switching to Clear Image to Begin the Counting of Surface Defects.

As shown in the figure 2, the thermal effect was quite visible when the wire is in the dynamic model. The images avail crucial information on the defect of the wire.

3. Results

Tests have been conducted on more than 180 patients with a sample of 18 patients. The current analysis was limited to the description of thermograms. The focus of the current experiment was to observe the area of the defects and to detect absence/presence therewith.

3.1 In dynamic regime analysis

As previously described, imaging software was used to count the number of faults. The number of defects along with their area of both the used and new archwires are given in table 1.

Table 1. Comparison between new archwires and used archwires.

Status	Used Arch Wires		New Arch Wires	
Sample	Number of Defects	Total Area of Defects	Number of Defects	Total Area of Defects
1	3	84	15	86
2	0	0	24	166
3	4	4	10	18
4	9	13	6	16
5	5	6	19	167
6	5	5	12	41
7	5	14	12	411
8	5	98	23	225
9	2	80	18	385
10	3	3	13	38
11	6	357	9	226
12	2	167	17	226
13	5	45	26	194
14	0	0	15	104
15	3	19	10	205
16	2	77	27	188
17	4	179	24	254
18	8	30	15	153

Initially, this study looked at the validity of previous observations that had shown that the old samples had relatively a high number of defects. Figure 3 shows a true representation of this observation as a histogram. In each of the variants of the sample (material brand and diameter), the ratio of defects of new to used samples is shown to be greater than four in some cases (see samples 8 and 14 in figure 3).

3.2 Analysis by Manufacturer

Figure 4 demonstrate the results of various brands of archwires used in the study when the number of defects is added to their area. The data for new and used samples was then cross, yielding the results shown in figures 5 and 6 for the three manufacturers.

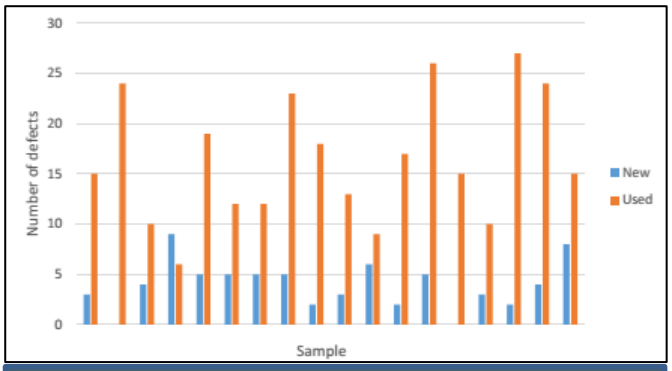

Figure 3. Comparison of number of defects in New and Used samples.

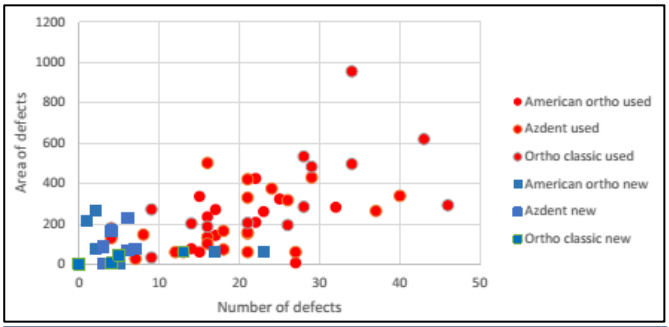

Figure 4. Number of defects vs. area of defects for all three manufactures.

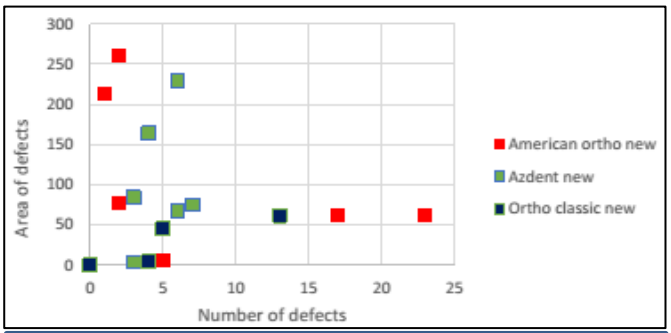

Figure 5. Comparison of all new samples.

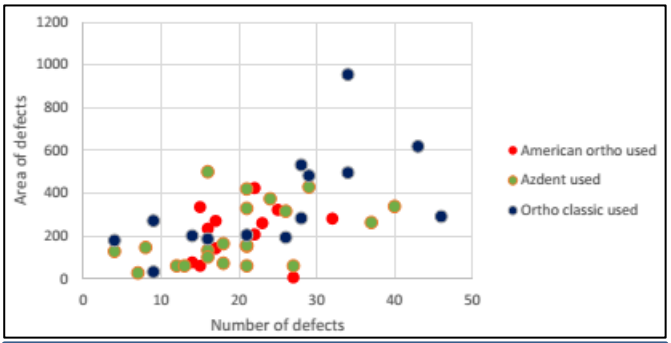

Figure 6. Comparison of all used samples.

3.3 Comparison of all Archwire Types Using a Higher Number of Samples

3.3.1 Comparison based on wires size, patient's gender, age, and arch location

This study demonstrated multiple defects in all types of arch wires compared to new ones. This section adds more parameters that include position, age and gender for more samples. An analysis based on these parameters showed substantial differences and between new and used samples (0.016 and 0.016-0.022 inch of rectangular wire). The figure 7 is a graphical view of the differences that arise between used and new arches, but only for 0.016 pieces of wire for all manufacturers. When different types of arches are analysed, the enormous scale of the variances in terms of mean was also evident. The estimated mean difference between used and new arch wires at 0.022 and 0.016-inch arch wires is depicted in figure 8. The results of the comparison of the area of defects of the samples from three manufacturers are as shown in figure 9. The number of defects in different archwires depending on the patient's gender, age and arch location are depicted in figures 10, 11 and 12, respectively.

4. Discussion

Based on the findings, it is obvious that the number of defects in old archwires is significantly higher than the number of faults in new archwires. Furthermore, greater damage between the archwire's surfaces has an impact on the wire's appearance [3]. In this study, various characteristics were compared, including wire diameters, patient age, gender, and wire position. The findings revealed that there are differences in the archwires used by adults and teenagers, implying that the differences are due to the age disparity. Differences in saliva discharges (i.e., its quality and quantity) may also contribute to the disparity between the upper and lower arches. The reasons for these differences are certainly complex, but the most important element is that the archwires that have already been used are more corroded by salivary secretions, chewing, grinding, and friction potency between the archwires and the braces [10,11]. Despite the surface quality of the same archwire changing slightly and the varying smoothness in the posterior and anterior sections, this study revealed undulated contacts with processing scratches and cracks.

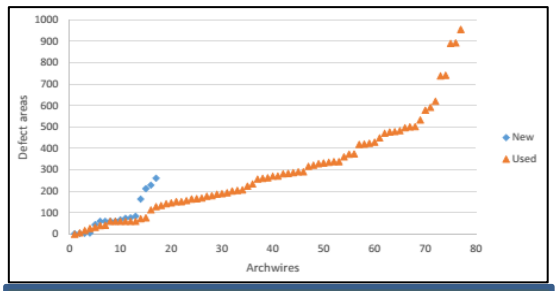

Figure 7. Difference in area of defects between New and Used for 0.016 inch wires.

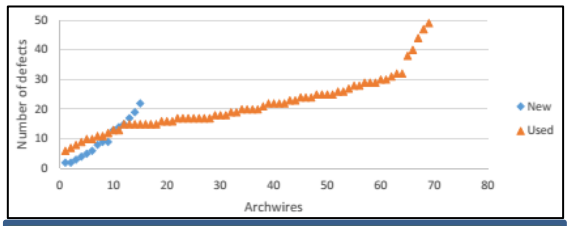

Figure 8. Number of defects between Used and New Archwires in 0.016-0.022 inch.

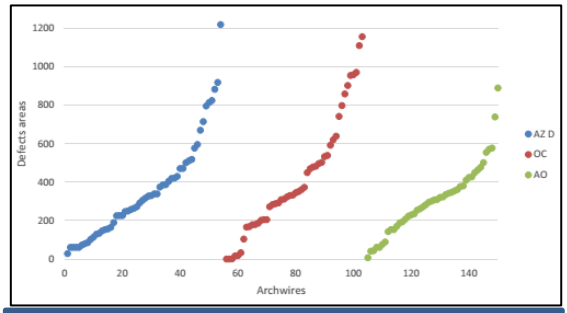

Figure 9. Area of defects of used 0.016 Archwires for all three manufacturers.

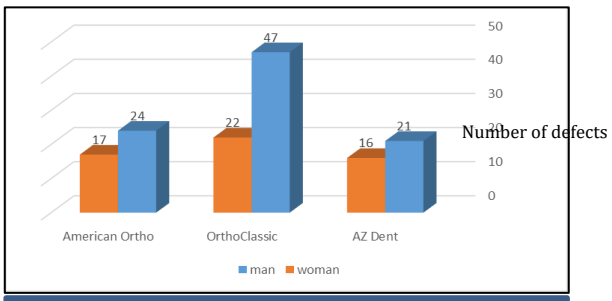

Figure 10. Number of defects based on gender.

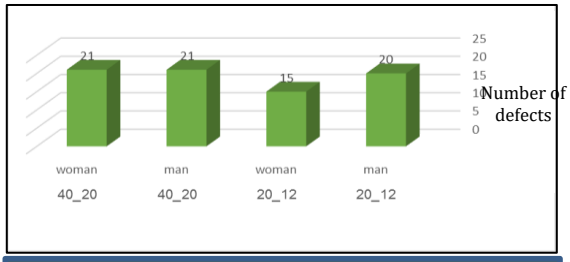

Figure 11. Number of defects based on age.

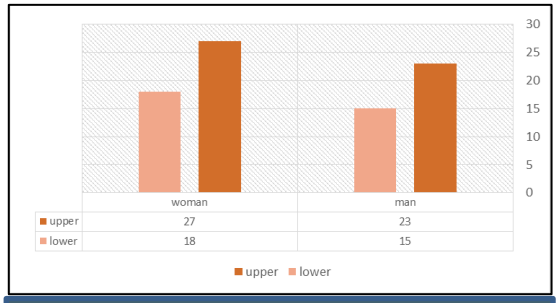

Figure 12. Number of defects based on arch location.

Microscopic analysis of NiTi wire exposed to static anodic polarity, (i.e., simulations of the oral environment) validated pitting and normal fields of corrosion, as well as the most crucial alterations in the surface morphology proceed by anodic dissolution. These outcomes of this study concur with the previous studies [3] demonstrated that the mineral-rich coating was suspected to convey better resistance to decay. Furthermore, it could also be the justification to the reason that metallic orthodontic devices indicate different outcomes in vivo in comparison with those in vitro experiment approaches [12]. Additionally, the extreme leaching of metal ions from orthodontic struts and NiTi cable were observed on the 30 days interval (trials tested before, at 30days, three months, and six months interim). As indicated in numerous studies [13], the likely justification meant for this occurrence could be the creation of crystal-like precipitates and very thin biofilms on trucks exterior surfaces, therefore, providing better protection.

The results of this study are in accordance with previous studies, which indicated that the discharge of metal ions from brackets and arch cables were implemented under clinical utilization circumstances. The quantity of metal ions discharged indicated an inclement when orthodontic devices remained exposed towards fluoride reactive agents throughout the span of utilization. Metal ions discharge furthermore would have an effect of oxidative stress and genotoxic harm to buccal mucosal tissues unattended for a period of time. Nonetheless, it is important to consider that a number of variables are accountable for total effect in vivo circumstances.

Though the risk of caries occurring during orthodontic treatment is low (rational arch arrangement, perfect enamel feature, no prevailing carious lesions, and repair of perfect mouth hygiene eminence), non-fluoridated toothpaste and mouth cleans, as well as changes in the exterior characteristics of brackets and arch wires, may be of great benefit in reducing metal ions discharged [14].

In comparison to the non-fluoridated set, the volume of metal ions discharged demonstrated a conclusive inclement in the fluoridated wire and brackets set. Usually, the effects of diet on changes in the surface appearances of orthodontic devices are difficult to distinguish, and food vary in origin and composition, so it breaks down and depreciates rather fast.

Furthermore, another research was scrutinizing the impact of nutrition on corrosion nature and frictional resilience of the orthodontic wires utilized Food Simulating Liquids (FSLs) to imitate the authentic type of food. Citric acid, heptane, and ethanol were utilized in the position of fatty diets, citric acid types of fruits, and alcoholic beverages. It was proven that the citric acid types of food indicated significant alterations impacting the corrosion resilience and frictional characteristics of the archwire. This specific concept was challenging to prove in some type of patients, which formed the basis for proposing an in-depth analysis for better understanding [15].

Endorsing the outcomes of this research, Parvizi and Rock stated that all tested NiTi arch wires indicated some grade of perpetual deformation, being importantly expressive only for heat stimulated NiTi arch wires [15]. In the midst of verified super plastics NiTi, the total recovery of the first configuration was kept between 88 and 96%, while for the heat simulated NiTi arch wires, it was maintained between 71 and 82% [15].

Additionally, on the other side, the outcome of this particular research was steady as indicated by Sakima et al. [16] which via Force System Identification (FSI), indicated that the Neo Sentalloy NiTi F200 (GAC) arch wires we the one presented the unloading plateaus amidst the maximum loadings, therefore, resulting to the most inflexible archwire in this study that is adapted to our research in that the examined NiTi intra-orally utilized archwire exposed clear signs of similar corrosions with the existence of a small field of organic deposits. The electron microscopic examination of the archwire intra-orally used piloted by Eliades et al. [3] have indicated the creation of a layer of organic matter on the exterior surface of NiTi arch wires may result into the amplified coarseness of the surface and indirectly affect the sliding mechanism.

The microscopic investigation of the intra-orally used arch wires was steered in a number of studies [17]. The authors observed that a loss of the beautiful cover is directly comparable to the time of intra-oral utilization. Elavyan [17] observed a destruction of the film coating in a proportion of 26% after 33 days of usage. The outcomes of this study are in line with Elavyan observations [17]: the damage of the coating being directly proportional to the period of exposure, albeit crucial damage was detected even when utilizing the arch wire for a period; less than one month in an intraoral atmosphere. The mechanical nature of NiTi arch wire is pretentious after only four weeks of intra-oral usage.

5. Conclusion

This study examined the thermal reactions of two sets of orthodontic arches, both new and used, and assessed their deterioration by analyzing their thermal responses in static and dynamic systems as well as joule heating. The dynamic study expressly stated that the new samples had less defects than the used samples, as expected. It has been established that stimulated infrared thermography is a reliable method of investigation that allowed to detect changes in the orthodontic arches. The source of these modifications, on the other hand, has never been established. The main findings are summarized below:

1. Used arch wires bear more surface defects in terms of size and area when compared to unused ones.
2. Arches used by females showed more defects to those won by males.
3. Ortho Classic brand had higher defects compared to that of other manufacturers.

4. In comparison with the other two manufacturers, the Ortho Classic presented the highest quantity of defects for the 0.016-inch mode.
5. Used adult archwires displayed an advanced number of defects in comparison to those used by teenagers.

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WHO/MOHFW- Guidelines to practice prosthodontics and implant procedures during COVID-19 pandemic

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Abstract

The high infectivity rate of the COVID-19 virus and its variations has had a significant influence on dentists and dental treatment. Because of the proximity of the patient and the prevalence of aerosol-generating procedures, governments and health authorities have implemented rules and regulations for practising dentistry, specifically aerosol-generating procedures in prosthodontics, to protect dentists and patients from infection, cross-infection, and re-infection. The current article focused on the World Health Organization's (WHO) and Ministry of Health and Family Welfare's (MOHFW) recommendations and guidelines for practicing prosthodontics and dental implant operations during the COVID-19 pandemic.
Keywords: Cone-beam computed tomography (CBCT), Neohybrid, ProTaper Next, Remaining Dentin Thickness, TruNatomy.

1. Introduction

SARS-CoV-2, the virus that causes COVID-19, is spread between people in close contact with one another (within 6 feet). Transmission is mainly by respiratory droplets produced when an infected person coughs, sneezes, or talks. Oral fluids and aerosols exhibit a long incubation period of the virus and have proven to be high-risk causatives for the transmission of the virus. Dental healthcare has faced several clinical, psychological and financial repercussions due to the risk involved. The significant reasons for fear and dilemma in the minds of practitioners is due to asymptomatic carriers [1,2]. The use of rotary dental and surgical devices in dentistry, such as airotors, ultrasonic scalers and air-water syringes, produce a visible spray including water, saliva, blood, microorganisms (bacteria, virus, etc.) and other debris. Mucous membranes of the mouth and nose are protected from droplet spatter by a surgical mask, but they do not provide complete protection against the inhalation of infectious agents [3,4]. As a result, during pandemics, modifications to the prosthodontic and implant procedures, as well as pertinent guidelines, are critical [1,5,6]. World health organisation (WHO) and Ministry of Health and Family Welfare (MOHFW) Government of India have given recommendations for the practice of general dentistry and prosthodontics in Covid times to facilitate the governments, institutions and clinics to carry on service effectively and safely.

2. General Considerations [1,7]

2.1 Recommendations for clinic designing set-up

The clinical setup needs separate areas for sterilization rooms. The feasibility depends upon basic infrastructure, the total number of areas available, the number of health care workers, and the number of patients reporting per day. These protocols applied to both private and government clinics.

2.1.1 Zone A: Reception and waiting area [1,2]

The two procedures to be carried out in this zone include,
a) Temperature recording using a digital thermometer, b) Arterial oxygen saturation monitoring using a pulse oximeter.

Facilities like sensor taps and contactless sanitizer dispensers are mandatory. A triple-layer face mask, disposable shoe covers, head cap and gloves should be provided. A glass barrier can be installed between the patient and the staff to prevent the transmission of droplets. The patient should fill out the informed consent in the language of his or her preference. The patient should be asked to remove accessories like jewellery, watch etc., and thoroughly sanitize their hands. Physical distancing and digital payments are a few other recommendations.

2.1.2 Zone B: Screening Area [1,2]

Sterilized instruments are used for initial screening and diagnosis. During the early onset of the disease, a maximum viral load (2.35×10^9 copies per ml of sputum) is present in the upper respiratory tract. The oral preparation of Povidone-iodine for 15 seconds is used as a preprocedural mouth rinse, which completely deactivates the virus. Other chemical preparations that disrupt the viral lipid barrier

include ethanol, chlorhexidine, cetyl pyridinium chloride, and hydrogen peroxide. OPG and CBCT are favoured over intraoral radiographs when taking radiographs to avoid salivary contamination. Digital radiographs are recommended.

2.1.3 Zone C: Non-aerosol generating area [4]

Airoter handpieces and ultrasonic scalers uses minimized. Hand instruments such as spoon excavators and chemical based caries removal agents are preferred. Personal protective equipment (PPE) is effective in preventing the spread of infection. Protocols for donning and doffing should be followed (Tables 1 and 2). Digital workflow is recommended. Double-layer bags are used for COVID waste disposal. Yellow bins are used for PPE disposal and biomedical waste management should be done properly (Table 3).

2.1.4 Zone D: Aerosol generating area [2]

Aerosols are most commonly generated during the use of high-speed handpieces and even after the completion of the procedure remain suspended in the air for 30 minutes and can reach up to 2 feet from the dental chair. Minimize the use of ceiling fans and air conditioners. High volume evacuators and high-efficiency filters (HEPA Filters) are used to filter the contaminated room air. In order to avoid direct contact with the splatter 8'o clock chair position should be avoided. Rubber dams, slow speed anti retraction handpiece and high-volume suction are preferred over chair side suction. 70% of airborne particles are minimized by using a rubber dam during procedures. 99.97% of the dust and other airborne particles are filtered using HEPA filters. Usage of an appropriate mask is mandatory. The Dos and DONTs of wearing the mask are tabulated in Table: 4.

3. Teledentistry/Tele Consultation/ Videoconferencing [5,7]

They are indicated during pandemic times in situations of lockdown for a remote dental screening, making the diagnosis, providing consultation and postponing treatment plans and prescribing medicines.

Table 1. Donning PPE: Step by step procedure [5,7]

Step 1	Put on scrubs
Step 2	Put on shoe covers/trauma boots as indicated
Step 3	Perform hand hygiene
Step 4	Put on N95
Step 5	Put on inner cap
Step 6	Put on surgical mask
Step 7	Put on goggles
Step 8	Put on outer cap
Step 9	Again, perform hand hygiene
Step 10	Put on gown
Step 11	Put on surgical gloves
Step 12	Put on double surgical gloves

Table 2. Doffing PPE: Step by step procedure [5,7]

Step 1	Remove gown and gloves, blending forward.
Step 2	Have gloves removed as one unit with gown. Do not touch outside of gloves with bare hands.
Step 3	Perform hand hygiene.
Step 4	Put on exam gloves.
Step 5	Remove outer cap, bending forward.
Step 6	Remove shoe covers/trauma boots.
Step 7	Remove gloves.
Step 8	Perform hand hygiene.
Step 9	Put on new gloves.
Step 10	Bending forward, remove goggles, surgical mask and cap.
Step 11	Remove N95.
Step 12	Perform hand hygiene and put on new mask and cap.

Table 3. Color coding for segregation of biomedical waste (1998) [2,8]

COLOR	WASTE	TREATMENT
Yellow	Human and animal anatomical waste/ microbiology waste and soiled cotton/ dressings/ linen/ bedding etc.	Incineration/deep burial
Red	Tubing, catheters, Intravenous sets	Autoclave/microwaving/ chemical treatment
Blue/white	Waste sharps (needles, syringes, scalpels, blades etc.)	Autoclave /microwaving/chemical treatment /destruction /shredding
Black	Discarded medicine /cytotoxic drugs, incineration ash, chemical waste.	Disposable in land fields

4. Disinfection protocols for dental clinics and laboratories [1,6,7] (Table: 5)

The clinics and laboratory should be disinfected. Cross infection and transmission should be prevented. The recommended solutions for surface disinfection are sodium hypochlorite solution, ethanol and vaporizer hydrogen. Terminal disinfection for dental clinic and laboratories: UV-C (germicidal effect, wavelength=200-280nm). Biomedical waste management should be done in an appropriate manner as described in Table 3.

4.1 Fumigation versus fogging [1,4]

The two methods which are used for disinfection of clinics and laboratories are fumigation and fogging. Fumigation - formaldehyde solution mixed with potassium permanganate in a fixed proportion is used in fumigation, which is very effective in killing bacteria, fungus and their spores. Fumigation is effective at above the temperature of 20°C and relative humidity of 65%. Step:1 Preparation: Thoroughly clean windows, doors, floors, walls, surgical table, dental

chair, and all washable equipment with soap water. Close windows and ventilators tightly in order to avoid the leak of fumes. Switch off all lights, AC and other electrical and electronic al items. Calculate the required amount of formaldehyde for available space. Step 2: Precaution: formaldehyde is irritant to the eye and nose, and it has also been recognised as a potential Carcinogen. So, the Fumigating person must be provided with personal protective equipment. Paste a warning notice on the front of the door indicating fumigation is in progress. Step 3: Fumigation: For every 1000 cubic feet, 500ml of formaldehyde (40%solution) is added in 1000ml of distilled water in an electric boiler. Switch on the boiler, leave the room and seal the door. After 45 minutes, switch off the boiler without entering the room. Step 4: Neutralisation: the toxicity of formaldehyde vapours should be neutralised by ammonia solution.

Fogging: The mixture of hydrogen peroxide and silver ion solution or third Generation quaternary ammonium compounds are used in fogging. They are effective against viruses and other biological agents in the air and on surfaces. Forty-five minutes are required for these non-touch surface disinfections. Circulation of clean and natural air is recommended for these procedures.

5. Prosthodontic considerations during COVID-19 era

5.1 MOHFW recommendations [1, 5-7]

All elective procedures are indefinitely postponed. Based on the risk profile the districts in India are classified as green, red and orange zones. Green Zone is zero confirmed cases or no confirmed cases for the past 21 days. Red zones or hotspots are districts with increased active cases, a faster doubling rate. Orange zone is districts, which fall between the green and red zones. Emergency procedures alone are managed in red zones. In orange and green zone surgery procedures can be done. All routine and elective procedures should be deferred for a later review until new policy /guidelines are issued. Due to the high risk associated with the examination of the oral cavity screening program should be deferred until new policy/guidelines are issued.

5.2 List of emergency and urgent dental procedures to be carried out

- Mobile/Faulty Prosthesis.
- Fixed faulty prosthesis.
- Infections around prosthesis.
- Periimplantitis.
- Sensitive/caries of abutment underneath fixed prosthesis.
- Fabrication of surgical and interim obturators.
- Dislodged prosthesis needing recementation.

5.3 Recommendations for removable prosthodontics [6-8]

Complete and partial dentures fabrication can be done in removable prosthodontics. Increasing covid – 19 mortality rate and co-morbidities are risk factors for geriatric patients. For geriatric patients thorough medical case history is a must before starting any procedure involving removable prosthodontics.

Table 4. Do's and Don'ts of wearing a medical mask safely [9]

Do's.	Don'ts
Wash your hands before touching the mask.	Do not wear a loose mask
Inspect the mask for tears or holes.	Do not touch the front of the mask
Find the top side, where the metal piece or stiff edge is.	Do not use a ripped or damp mask
Ensure the colored side faces outwards.	Do not wear the mask only over the mouth or nose
Place the metal piece or stiff edge over your nose	Do not remove the mask to talk to someone or do other things that would require touching the mask
Cover your mouth, nose, and chin.	Do not leave your used mask within the reach of others
Adjust the mask to your face without leaving gaps on sides	Do not re-use the mask
Avoid touching the mask.	
Remove the mask from behind the ears or head.	
Keep the mask away from you and surfaces while removing it.	
Discard the mask immedia-tely after use preferably into a closed bin.	
Wash your hands after discarding the mask	

Table 5. Disinfection of various materials and equipment in a dental setting [1,5,6]

Materials	Method and material of disinfection
Alginate and polyether	0.5-1% Sodium hypochlorite (1:10 dilution) or 1:213 iodophors (spray)
Zinc Oxide Eugenol impression paste	2% Glutaraldehyde or 1:213 iodophors: immersion for 10 minutes.
Impression compound	Sodium hypochlorite (1:10 dilution) (immersion)
Elastomers	2% Glutaraldehyde or cidex
Wax rims	Iodophors disinfection sprays
Acrylic appliance	Povidone-iodine/1% Sodium hypochlorite, store in mouth wash before use
Fixed prosthesis	immersion in cidex, or 1% Sodium hypochlorite
Gypsum casts	Microwave irradiation for 5 min at 100 W
Tips of intra oral scanners	Rubbing with alcohol-based disinfectant

5.3.1 Chairside protocol

a. Advise topical analgesic and antiseptic gels for ulceration and mucosal erosion through teleconsultation.
b. The patient should be asked to discontinue the prosthesis for some time in case of any irritation.
c. Before repairing the fractured prosthesis, first, disinfect it thoroughly.
d. A low-speed micro motor should be used for denture adjustment.
e. Snap impression should be done followed by disinfection using glutaraldehyde.
f. Modification of final impression for complete dentures with a single step border moulding technique.
g. Virtual face bow records and jaw relation records can be made.
h. Digital workflow for a precise prosthesis can be adopted.
i. For interim or cast partial denture prosthesis fabrication, CAD/CAM systems, which are precise and require lesser chair side adjustments can be used.

5.3.2 Laboratory protocol for Removable Prosthodontics

Record bases and wax rims should be adjusted before inserting them into the patient mouth. To adjust the occlusion, dentures should be remounted, and processing errors should be minimized. This will reduce the chairside time.

5.4 Recommendations for fixed prosthodontics [9,10]

In fixed prosthodontics crowns and bridges, inlays, onlays, smile designing, veneers, full mouth rehabilitation, post and cores are fabricated. Strict precautions and disinfection protocols are mandatory because these are elective and aerosol-generating procedures. Safe alternative methods such as digital impressions using intraoral scanners could be used. Digital workflow is preferred over conventional workflow.

5.4.1 Chairside protocol

During tooth preparation, the use of a rubber dam and high vacuum suction are recommended. Here supra gingiva margins are recommended. Undercuts, under reduction, should be avoided. A digital spectrophotometer is used for shade selection and consent of the patient should be taken. Crown removers for the removal of the fractured and faulty prosthesis. Frequent rinsing and spitting should be minimized. In 3-way syringes, air pressure should be reduced. 11 – 12 o'clock is recommended chair position to reduce contamination.

5.4.2 Laboratory protocol

Cross-contamination between clinic and lab is most commonly due to impressions. Impressions should be disinfected with sodium hypochlorite 1% for 10 mins and stored in disposable pouches. Computed aided designed and milled restorations should be preferred to avoid contamination. Conventional casting should be avoided during the pandemic time. The prosthesis should be immersed in disinfectant before sending it back to the clinic and before inserting it into the patient mouth.

5.5 Recommendations for implant surgery and prosthesis [6,7]

5.5.1 Chairside protocol

Slow Speed drilling with sharp drills is preferable. Intermittent external irrigation along with high volume suction should be done. The use of ultrasonic devices and piezoelectric surgery should be minimized, whereas the use of osteotomes should be encouraged in order to minimize aerosol formation. Avoid complex full mouth procedures. The digital impression is an alternative to conventional impression making.

5.5.2 Laboratory protocol

Implant impressions and components need to be carefully disinfected/autoclaved before reusing them. Careful impressions making using resin jig and precise pouring of the impressions are a must in order to prevent the repetition of any chairside step.

6. Intraoral and extraoral maxillofacial prosthesis

Fabrication of surgical and interim obturators must be done at this time to restore the function of patients with intraoral defects. Facial defects may act as esthetic urgencies. Additionally, psychological counselling and motivation for the maintenance of the prosthesis can be done through Tele dentistry.

7. Conclusion

In this COVID-19 pandemic, the mental health of the dentist and the dental health of the patient are in question. Care should be taken at every step namely, a collection of the dental impression, pouring of the models, designing and fabrication of prosthesis, finishing and polishing. Disinfection protocols should be followed to prevent the further spread of infection.

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Resin-bonded fixed partial denture as a cost-effective prosthesis for missing maxillary lateral incisor in a cleft lip and palate patient: a case report

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Abstract

Literature suggests 66.7% of dental abnormalities among patients with cleft lip and palate (CLP). Besides posing functional difficulties, dental anomalies also raise significant aesthetic concerns among these patients, especially with missing teeth in the anterior region. Among various treatment choices like a removable partial denture, fixed and implant treatments available in the prosthetic rehabilitation of missing teeth in CLP subjects, Maryland bridges offer a conservative and cost-effective alternative in short-span edentulous spaces while carrying the advantages of supragingival marginal preparations and less intensive working times. The availability of advanced self-etch adhesive systems that chemically bond to both the tooth and metal surfaces offer these prostheses more longevity. This case report presents the fabrication of a resin-bonded fixed partial denture in the prosthetic rehabilitation of a missing maxillary lateral incisor in a 23-year-old female patient with CLP who was unwilling for orthodontic care.
Keywords: cleft lip; cleft palate; Maryland bridges.

1. Introduction

Orofacial clefts constitute a majority of the congenital anomalies, with a global frequency of around 1 in 700 births [1]. There are many factors associated with the variable incidence of orofacial clefts, ranging from 1:500 to 1:2500, such as ethnicity, race, socioeconomic status, and environmental factors [2]. The incidence of orofacial clefts among the Asian population is considered to be higher compared to other populations [3]. Literature suggests an obligatory incidence of dental abnormalities conditional on the presence of cleft lip and palate (CLP) [4]. The most common dental abnormalities among subjects with CLP are hypodontia, oligodontia, transposition, microdontia, and impactions [5]. Deciduous and permanent maxillary teeth are the most typically affected in terms of hypodontia [6], with the maxillary lateral incisor on the cleft side having the greatest predilection for hypodontia among CLP patients [7,8]. Subjects with CLP encounter a wide range of physiological and esthetic difficulties which could also affect their social well-being [9,10]. The management of CLP is multidisciplinary and must be rendered starting at the right time. With increasing emphasis on interdisciplinary management and evolving scientific knowledge, prosthodontists' convention in CLP management after completing the gamut of other treatment has been broken. The continuing role of prosthodontists in CLP management at every stage right from birth is advocated [11]. From the perspective of rehabilitation, the following challenges are encountered in the prosthodontic management of CLP: limited facial support; reduced vertical dimension of occlusion; tooth wear and the associated symptoms; lack of functional occlusion [12]. With regard to the replacement of missing lateral incisors, a common occurrence among subjects with CLP, the available prosthodontic treatment options are removable partial dentures; conventional or resin-bonded fixed partial dentures; osseointegrated implants [13].

2. Case report

A 23-year-old female patient with CLP reported to the Department of Prosthodontics and Implantology, Vishnu Dental College, Bhimavaram, with a chief complaint of missing front tooth upper anterior region. The patient had reported cleft lip and palate on the left side from birth, for which she had undergone surgical treatment, the last operative procedure of which was carried out seven years ago when the patient was 16 years old. She had not undergone any orthodontic treatment, and neither did she receive any grafts. On examination, the patient had a residual palatal defect of 3 x 4 mm on the left side with missing maxillary left lateral incisor; severe crowding was also noticed. Class III maxilla-mandibular relation was observed with Veau's class III defect in the left maxilla. There was no

intercuspation on the right side with a crossbite with regard to #36 and #46. The pretreatment intraoral pictures of the patient from the occlusal view and in maximum intercuspation, protrusive positions are presented in Figure 1. A smile evaluation was done, and it was observed that the patient had a maxillary incisor exposure of 7mm with a smile, low lip line, and wide buccal corridor space. Diagnostic models were obtained, and model analysis was performed, which included: Carey's / arch perimeter analysis, Bolton's analysis; Ashley Howe's analysis; Pont's analysis. Carey's analysis revealed existing crowding in both the arches and Bolton's analysis suggested mandibular excess with overall and anterior ratios of 103% and 100%, respectively. According to Ashley Howe's analysis, premolar basal arch width (PMBAW) was 35mm, and PMBAW% was 40%, suggestive of a borderline case for extraction. Pont's analysis calculated premolar value (CPV) was more significant than the measured premolar value (MPV), indicating the possibility of arch expansion in the premolar region. Radiographic and clinical analysis revealed no bone loss around the maxillary left central incisor and left canine. Based on these findings, the following treatment plan was considered: orthodontic correction of alignment of maxillary and mandibular teeth followed by replacing the missing maxillary left lateral incisor with fiber-reinforced/resin-bonded fixed partial denture.

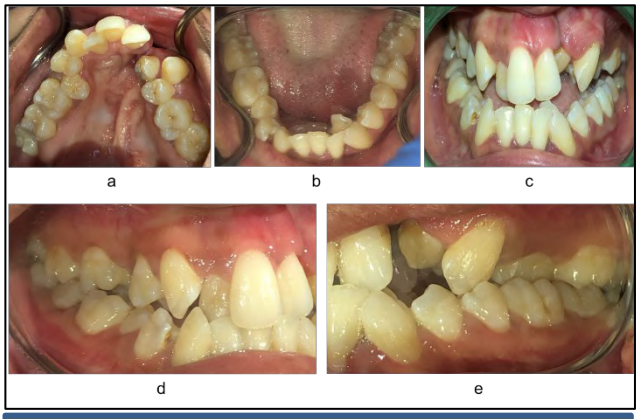

Figure 1. Pretreatment intraoral images; where, a) maxillary occlusal; b) mandibular occlusal; c) protrusive; d) maximum intercuspation position on right side; e) maximum intercuspation position on left side.

The proposed treatment plan was discussed with the patient in detail. As the patient was not willing to undergo orthodontic treatment and reported that her only concern was the missing tooth in the course of preparing for her wedding, it was decided to fabricate a conservative, minimally invasive resin-bonded fixed partial denture to replace the missing maxillary left lateral incisor after discussing with the patient the negative implications (like food lodgment and caries to the abutment teeth)of not undergoing orthodontic treatment before receiving a fixed partial denture. Following patient consent, minimal preparation of the palatal surfaces alone was done with #21, #23so that the preparations were confined within the palato-proximal line angles. On both the abutment teeth, parallel retention grooves were placed in proximity to the edentulous space. Primary impressions of maxillary and mandibular arches were made. A special tray was fabricated with auto-polymerizing acrylic resin using which final impressions of both the arches were made and sent to the laboratory. A metal framework was fabricated with 'wings' overlapping onto the prepared palatal surfaces of the abutment teeth. Figure 2 presents the frontal and occlusal views of the metal framework. No interferences were noted with metal try-in. Vita 3-D master shade guide was used for selecting the shade. To facilitate micromechanical retention, the fitting surfaces of the prosthesis was sandblasted with alumina 250 microns. The prosthesis was cemented with universal self-etch resin cement (Rely X U100, 3M ESPE). Figure 3 presents the frontal and occlusal views of the resin-bonded fixed partial denture. Occlusion was verified with no interferences, and post-cementation instructions like hygiene maintenance were given. The patient was also evaluated for improvement in phonetics disorder. Figure 4 presents the pre-treatment and post-treatment views.

Figure 2. Frontal (a) and occlusal (b) view of the metal framework.

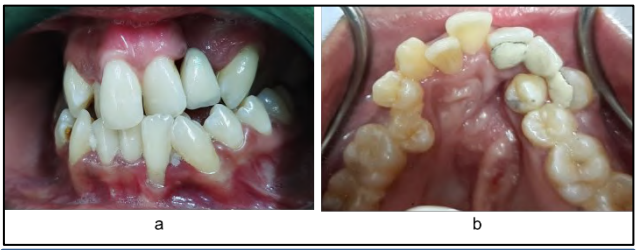

Figure 3. Frontal (a) and occlusal (b) view of the resin-bonded fixed partial denture.

3. Discussion

Patients with CLP demonstrate poor oral health-related quality of life for many reasons [14]. Regardless of the patient's age, hypodontia poses a significant aesthetic concern besides functional difficulties. The aesthetic concerns limit the eloquent social participation of these subjects due to stigma. Therefore, addressing the aesthetic concerns contributes vastly towards the psychological well-being of the patient [15]. In this case report, we discussed the prosthetic replacement of missing maxillary left lateral incisor in a female patient with CLP. Though the patient was advised orthodontic care before prosthetic replacement, she

Figure 3. Frontal (a) and occlusal (b) view of the resin-bonded fixed partial denture.

did not wish to undergo orthodontic treatment and reported that the missing tooth was her only aesthetic concern. Patient' autonomy has become an essential and integral part of the provision of evidence-based care [16]. Respecting the patient's independence, a prosthesis was therefore planned with resin-bonded fixed partial denture preceding orthodontic treatment after disclosing the negative implications to the patient. For prosthesis of missing anterior teeth among subjects with CLP, several rehabilitation options were proposed: removal of partial dentures; conventional or resin-bonded fixed partial dentures; precision prostheses; osseointegrated implants [10.13]. The majority of patients show reluctance for removable partial dentures because of the removable nature unless there are substantial edentulous spaces and RPDs form a definitive rehabilitative means. With implants, the possible challenges for placement among patients with CLP are the reduced availability of bone, the poor contour of the labial cortical bone, and proximity to the maxillary sinus, nasal cavity [17]. Conventional fixed partial dentures require preparation of the sound abutment teeth, and it has been recommended that two abutment teeth on either side of the cleft be included [18]. Furthermore, the maintenance of oral hygiene gets difficult, potentially compromising gingival health. Given these observations and to keep orthodontic treatment possible for the patient, should she wish to undergo in the future, the resin-bonded fixed partial denture was preferred in this case which is conservative and minimally invasive. Though resin-bonded fixed partial dentures have poor retention and limited longevity as drawbacks, the availability of advanced self-etch adhesive systems offers these prostheses more longevity [19]. Other common complications are the development of dental caries and debonding [20]; therefore, patient's compliance to instructions on oral hygiene maintenance and periodic recall evaluations are imperative.

7. Conclusion

This case report discussed the successful prosthesis of missing maxillary left lateral incisor in a 23-year-old female patient with CLP reporting aesthetic concerns by fabricating a resin-bonded fixed partial denture. This economical, conservative approach improved the patient's appearance satisfactorily besides bringing a positive change in her speech and lip contour. For short-span edentulous spaces, resin-bonded fixed partial dentures among CLP patients can be considered cost-effective prosthetic alternatives.

Conflicts of interest: Authors declared no conflicts of interest.

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