

EVALUATION OF FIXED MANDIBULAR RETAINER USING 3D PRINTED POSITIONING TRAY VERSUS DIRECT BONDING TECHNIQUE: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: This study was conducted to compare the chairside time of fixed mandibular retainers when bonded using the conventional direct technique and the 3D printed positioning tray.

Methods: A randomized clinical trial was performed using the two techniques to directly and indirectly bond the fixed lingual retainers, 20 subjects who in need of fixed retainers showing no signs of enamel defects or signs of gingival inflammation were recruited in this study. 20 retainers were bonded to the lower anterior teeth. Group I was the intervention group (3D positioning tray technique) and Group II was the comparative (the direct technique). In the intervention group, lower impression was taken and the cast produced was scanned using desktop scanner to produce the digital model on which the virtual retainer was placed using the OrthoAnalyzer software. The tray was designed by using Appliance Designer software and printed with rigid resin to allow ease of insertion and removal. The wire was placed inside the 3D positioning tray and then transferred inside the patients mouth the chairside time was recorded. In the comparative group, same steps were done as intervention group, but with the exception of the bonding technique where the retainer was placed directly inside the patients mouth.

Results: the Chairside time in group I (3D printed positioner) was (15:35 ± 0.03) minutes while in group II (Control) was (17:52 ± 0.05) minutes.

Conclusion: The chairside time difference between the two bonding techniques was statistically significant, with the 3D positioning tray technique taking less chairside time than direct technique.

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INTRODUCTION

Retention is one of the controversial topics in modern orthodontics, Angle stated that “the problem involved in retention is as great as to test the utmost skill of the most competent orthodontist, often being greater than the difficulties being encountered in the treatment itself”⁽¹⁾.

Since relapse is unpredicted, retention is a must if the finished result is to be maintained. There is no agreement in the literature of specific retention protocol. Each orthodontist, in consultation with their patients, must determine the appropriate retention protocol⁽²⁾. Therefore, Long-term retention of orthodontic outcomes is important and fixed retainer is the common approach for preserving stability after treatment especially in the mandibular anterior region⁽³⁾.

Over the years many techniques for placing a bonded lingual retainer have been practiced whether directly or indirectly⁽⁴⁾. The most common technique used is the direct wire bonding where the composite pads are directly placed on the lingual surface of anterior teeth, with or without pre bending of the wire by a laboratory technician⁽⁵⁾. Directly bonded lingual retainers are not always easy because the available techniques do not hold the wire totally stable in its position and there is always the risk of moisture contamination and bond failure as well as prolonged chair side time and patient discomfort⁽⁶⁾.

Indirect bonding requires preparation of the composite pads on the cast of the patient and its transfer to the patient’s mouth by means of custom-made trays⁽⁷⁾. Indirect methods help keeping a moist-free environment but have some limitations, such as lack of control over the composite application leading to adhesive-tooth failure or undesirable flow of adhesive bond to the gingival embrasures.⁽⁴⁾ It was claimed that the time needed for indirect bonding of a mandibular fixed retainer is shorter than the time needed for direct bonding method.⁽⁸⁾ Therefore indirect bonding has the added advantage

of reducing the chair-side time, however little evidence is available at hand to support this belief.⁽⁸⁾

The recent years have shown a great development in the field of 3D-imaging systems. From the perspective of orthodontics, digital surface models are gaining importance. A significant inspiration driving this is no doubt the huge number of opportunities for improving workflows in the orthodontist’s office - ranging from saving time, material, laboratory capacity, decreasing costs and others to optimize treatment progress and result.^(9,10).

There are great possibilities of integrating CAD/CAM technology, and 3D printing. Fabricating a 3D virtual retainer with user-friendly software is a promising technique that could change the way we practice orthodontics today. They claimed it allows simplicity, speed, accuracy, and patient satisfaction. This opens the way for designing and manufacturing custom orthodontic appliances viable to the new digital orthodontic era.

So Present clinical practice demands a much convenient and effortless techniques for bonding fixed mandibular retainers. Hence was the idea of combing the advantages of both direct and indirect techniques and developing a novel 3D printed positioner tray for placement of fixed retainers. However, little evidence is available regarding the efficacy of 3D printed positioner for fixed lingual retainers. Hence was the idea of the current research to evaluate the chairside time and bond failure of these 3D printed positioning tray and to compare it to the conventional direct technique.

MATERIAL AND METHODS

Study design and duration

This randomized controlled trial was approved by the Research Ethics Committee of the Faculty of Dentistry, Cairo University. Patient selection for this trial was done from the outpatient clinic of the Department of Orthodontics, Faculty of Dentistry,

Cairo University, TimeLine was from March 2019 till March 2020. The study lasted for 12 months

Sample size

Sample size calculation was done using R statistical package, version 3.3.1 (21-06-2016). Copyright (C) 2016. The R* Foundation for Statistical Computing*.

Paired T test power calculation was used to detect the proper sample size. Mean difference and standard deviation were estimated according to Bovali et al⁽⁸⁾. (2014) regarding bonding time as an outcome. The sample size calculation was based on a more conservative mean difference of 10 seconds.

The results showed that a total sample size of 12 participants will be adequate to detect a mean difference in bonding time between study groups of 10 seconds (SD=5.96) with a power of 90% and a two-sided significance level of 5%; with equal allocation to two arms (6 patients in each group). To compensate for 30% non-response rate, 4 patients were allocated additionally in each arm; therefore the sample was increased to a total size of 20 participants; 10 in each arm.

Participants:

The selected subjects met the following criteria (Inclusion Criteria):

Patients with properly well finished orthodontic treatment indicated for placement of fixed lingual retainer.

- The presence of the 4 mandibular incisors and the 2 mandibular canines.
- No active caries, restorations, fractures, or periodontal disease of these teeth.
- Patient with Good oral hygiene.

The selected subjects should not meet the following criteria (Exclusion Criteria):

- Patients not indicated for fixed bonded mandibular retainer.

- Abnormal morphology or structure of anterior teeth.
- Bad oral hygiene

For each patient the following steps will be performed:

- Selection and examination of the patients according to inclusion and exclusion criteria were done.
- Scaling and polishing with pumice powder was carried out on lower anterior segment.
- The patient was instructed for oral hygiene measures.
- Then patient were allocated to their groups after randomization.

Treatment Group

After finishing orthodontic treatment, all patient received a modified indirect technique for bonding fixed mandibular retainer and the key of modification was the fabrication of 3D printed digital positioning tray for placement of retainer with holes for composite pads for its direct application using 3 shape Ortho planner Software ® instead of conventional indirect retainer fabrication method.



Fig. (1) 3D printed positioning tray

A) Scanning and designing the digital tray

Lower impression was taken for each patient and the cast was carefully scanned by 3 shape desktop laser® scanner for production of 3D digital cast, using 3 shape orthoplanner Software® then the tray was designed

B) Fabrication and printing of the digital tray

Trays were printed using formlabs 3 Printer® and The tray was printed using Anycubic Resin® a hard resin material, allowing the tray and the wire to be firmly adapted to the teeth.

C) Clinical application of the digital tray

Teeth to be bonded are etched then isolation & moisture control were achieved. Multistrand Round- Dead Soft Stainless Steel wire was placed and adapted in its place in the digital tray followed by Placement of the tray in the patient mouth on the prepared teeth as shown in figure 1 .3M ® universal Adhesive bond was applied to teeth and then curing of the adhesive bonding was done. Nano filled 3M ® composite (3M Unitek, Monrovia, California, USA) was placed in the printed tray holes and any excess composite was removed then light curing was done. Time was recorded during this step, after insuring complete curing of the composite the digital tray was removed from patient mouth.

Control Group

All patients of this group followed the conventional steps of direct bonding of fixed mandibular retainer, The retainer wire was prefabricated by incorporating perpendicular pieces of 1.5”-2” ligature wire at interdental region of respective teeth, The retainer wire was then adapted on the tooth surface. The short ligatures were passed interdentially one occlusal to contact point and other gingival to contact point and tied over. Bonding procedure after etching was carried out using 3M ® universal Adhesive and Light curing was carried out , Nano filled composite 3M ® (3M Unitek, Monrovia, California, USA) was then placed and light curing was done for 40 seconds., the ligature wires was cut and

pull labially to disengage. Time was be recorded during this step.

RESULTS

The results of the trial will be presented under the following headings:

1. Data normality (Table 1).
2. Chairside time between the two bonding techniques (in minutes) (table 2).

1. Data normality:

Exploration of the chairside time data was performed using Shapiro-Wilk test and Kolmogorov-Smirnov test for normality. As listed in table (1) it was revealed that the significant level (P-value) was insignificant as P-value > 0.05 and the concluded data originated from normal distribution (parametric data) resembling normal Bell curve.

TABLE (1): Normality Exploration chairside time data:

	N	P – value	
		Group I (3D printed positioner)	Group II Control group
Chair side time	10	> 0.05	> 0.05

N: retainers count

2. Chair Side Time between the two bonding techniques (in minutes)

Regarding chair Chairside time in group I (3D printed positioner) it was (15:35 ± 0.03) while in group II (Control) was (17:52 ± 0.05) as presented in table (2).

Independent t-test was performed to compare between group I (3D printed positioner) & group II (control group) and revealed significant difference between them as P <0.05 as presented in table (2).

Difference between both groups was calculated and revealed (02:17±0.02 min.) difference between both groups as presented in table (2)

TABLE (2): Showing Means and standard deviations in chairside time between 3D positioning Tray and direct technique as well as the difference between both groups:

Chair Side Time (in minutes)	Total N	Group I (3D printed positioner)		Group II (control)		Difference		P
		M	SD	M	SD	M	SD	
	10	15:35	±0.03	17:52	±0.05	02:17	±0.02	0.001*

N; Patients Count, M: Mean, SD: Standard Deviation, P: Probability level

**significant difference*

DISCUSSION

Fixed retention seems to be an effective mean for the preservation of the stability of the anterior teeth prior to orthodontic treatment by bonding a stainless steel wire on the lingual surfaces of the anterior teeth, usually from canine to canine in the mandibular arch, and that is considered a good mean for providing long term retention⁽¹¹⁾.

Different bonding techniques have been introduced to place a fixed lingual retainer. And the most technique used is the direct bonding method where the composite pads are directly bonded in the patient's mouth.

Direct bonding technique was introduced by *Zachrisson et.al* who used ligature wire to place fixed lingual retainer, hold it in place and ligated to one or two incisors to be firmly fixed and it remains undisturbed during setting of the adhesive and various modifications was introduced after^(12,13).

While the indirect bonding technique was introduced in the late Nineties by *Bantleon et.al* as a quicker and faster various to the direct bonding procedure. Indirect bonding needs preparation of the composite pads on the cast of the patient^(2,14).

The time needed for indirect bonding of a fixed mandibular retainer was shorter than the time needed for the direct bonding, and there was no difference in the risk of failure between the 2 methods as represented by *Bovali et.al*⁽⁸⁾.

So saving time is of great importance in a busy orthodontic clinic. And the Present clinical practice needs convenient and effortless techniques for placing fixed mandibular retainers.

Various modifications have been suggested to improve both direct and indirect bonding techniques, in order to yield better clinical results. With the evolution of 3D imaging techniques and 3D printing methods, the use of digital models in diagnosis and treatment planning has been a routine clinical procedure due to ease of storage, longevity and comparable accuracy to the plaster models which expected to be replaced by digital study models.

Hence was the idea of combing both the easiness of direct bonding technique and decreased chair side time, accordingly the novel of the 3D printed positioner was introduced. However, little evidence is available regarding the 3D printed positioner efficacy for fixed lingual retainers. Therefore the idea of the current research was to evaluate the chairside time 3D printed positioning tray and to compare it to the conventional direct technique.

To our knowledge this randomized clinical trial is the first to evaluate and compare the bonding times of mandibular fixed retainers with direct and 3D printed positioning tray indirect techniques.

In this study, patients were selected according to the following inclusion criteria, Good oral hygiene, No active caries, restorations, fractures, and periodontal disease to eliminate any factors that might jeopardize the accuracy the results.

For the software, designing was done using 3Shape Ortho System as it enables the use of DICOM, cephalometric, and 2D pictures, along with the intraoral scans for orthodontic case analysis and treatment planning, and designing and producing FDA-cleared orthodontic appliances.

In this study also hard resin was used for printing the 3D positioner tray, this resin was used for occlusal splints by *Venezia et al* it provided the suitable rigidity needed for adaptation of fixed retainer during its bonding⁽¹⁵⁾.

For the direct method, the wire was adapted to the lower anteriors by using ligature wire and that was according to *Zachrisson* who placed fixed lingual retainer and ligated to one or two incisors to be firmly fixed during bonding⁽²⁾.

Nano filled composite was used for bonding of the fixed retainer and that was according to *Talic* (2016) who tested the failure rates of fixed mandibular and maxillary lingual retainers bonded when bonded with light-cured nano filled flowable composites over 6 months⁽¹⁶⁾.

Moreover, in this study, we decided to light-cure each composite pad for 40 seconds according to *Alpöz et al*⁽¹⁷⁾ obviously, the difference in bonding time would be reduced if one used a shorter polymerization time, but this helped in decrease the risk of bond failure.

Concerning the participants they were encouraged to make full mouth scaling and polishing prior to bonding taking in order to ensure a healthy periodontium and provide a clean tooth surface ready for bonding. This decreases the chances of bond failure.

The indirect bonding technique was shown to be faster than the direct one by 2.17 minutes on average, representing a time gain of about 12%. Although the results showed a statistically significant difference, the relevance of clinical significance will be determined by each clinician according to his or her workload and flow. In a busy

practice debonding several patients per day, the time gain will be important, whereas it might not be clinically significant for an orthodontist debonding only 1 or 2 patients per day.

Although 3D positioning tray was shown to be faster and the chairside time was shown to be only shorter by 120 seconds in our study between 2 groups, that was for the time used in adaptation of the wire inside the tray, although infrequent, can prolong the bonding procedure, even though the 3D printed positioning tray was generally faster than the direct one. Checking the wire in transfer tray before placing it in the mouth, as well as decreased experience of the clinician, this lead to increase the time of bonding. Our results regarding Chairside time was comparable with *Bovali et al.*⁽⁸⁾ which was 80 seconds between the indirect technique and direct technique. And that could be explained due to difference in the bonding techniques as he used chemically cured composite in indirect and light cured composite in the indirect.

Nowadays mandibular fixed retainers are more commonly bonded on each anterior tooth instead of on the canines only, patients lack to be aware of a debonded composite pad.

Precise construction of 3D positioning tray and careful avoidance of moisture and contamination during the bonding procedure by the orthodontist might reduce potential failures of fixed retainers.

Torque differences has been reported by *Renkema et al*⁽¹⁸⁾ with the direct bonding technique after a 5-year posttreatment observation period. Subsequently, it would be interesting to determine if similar side effects could be avoided after the use of the indirect bonding technique.

A fixed position of the wire inside the 3D positioning tray could ensure absolute passivity of the wire during the bonding procedure. In contrast with the direct bonding technique, the 3D positioning tray ensures that the wire remains passive from fabrication to placement. Of course, orthodontist must consider that torque problems

could occur not only due to incorrect manipulation during bonding of the fixed retainer, but also due to patients' biting habits.

A longer follow-up of our patients was planned to investigate this hypothesis. If indirect bonding was associated with less torque problems in the long run, indirect bonding could be a better alternative to direct bonding because of the time saved in an orthodontic practice with a significant load of patients.

CONCLUSIONS

The chairside time difference between the two bonding techniques was statistically significant, with the 3D positioning tray technique taking less chairside time than direct technique.

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