Comparison of Perforated 3D Printed Metal Fixed Mandibular Retainer versus Conventional Fixed Bonded Retainer A Randomized Clinical Trial

تقييم سلك تثبيت الفك السفلي المعدني المثقب المطبوع ثلاثي الأبعاد مقابل سلك التثبيت التقليدي تجربة سريرية عشوائية

Protocol submitted to
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By

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BDS (2013), MSc (2020)

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Date

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I. Administrative information:

1. Title:

Evaluation of 3D Printed Metal Fixed Mandibular Retainer versus Conventional Fixed Bonded Retainer :A Randomized Clinical Trial

2. Protocol Registration:

Trial will be registered in www.clinicaltrials.gov.

3. Protocol version:

2024, Protocol Number: 1.

4. Funding:

Self-funding.

5. Roles and responsibilities:

Mariam El-Sebaay, BDS (Principle Investigator): will be responsible for clinical work of the study, follow up the patients, writing the thesis, interpretation of results and drawing conclusions.

Khaled Hazem BDS, MSc, PhD (main supervisor): helped in setting the study design, developing the idea of the research, will help diagnosis of the sample, interpretation of results and drawing conclusions.

Amr Ragab El-Beialy, BDS, MSc, PhD (Co-supervisor): will help in carrying out the measurements twice to measure the intraobserver error.

II. Introduction:

6. Background and rationale:

Achieving long-term stability of the orthodontic treatment is a significant challenge for many reasons such as age related changes or excessive arch expansion during orthodontic treatment especially in mandibular intercanine area[1]. Many studies have shown that long-term stability is problematic when retention is discontinued, with some degree of inevitable relapse inevitable[2]. Therefore, the use of long-term retention has been recommended because some patients would not tolerate minor irregularities of teeth[3]. Thus, *fixed retainers* can be used for long-term retention with minimal patient compliance[4].

Although many studies have shown that fixed retainers are safe and compatible with periodontal health, there are several *complications of fixed retainers*. These complications include failure of bonded retainer which may occur due to debonding of the composite adhesive from the tooth, failure of the bond between the wire and the composite, or fracture of the retainer. Failure rates may be affected by clinical technique, the choice of retainer design and material, adhesive used and the location of the retainer[5,6]. Fixed retainers may also result in adverse periodontal effects such as inflammation, bone resorption or gingival health[7]. Moreover, unwanted tooth movements were also recognized with bonded retainers in situ Unwanted tooth movement with the retainer in situ[8].

There is a lack of consensus among orthodontists regarding the optimal type of retainer wire regarding *design and material*[9]. The most commonly used materials for fixed retainers are either flexible multi-strand stainless steel wires bonded to all the anterior teeth, or thick monofilament stainless steel, cobalt-chromium or titanium-molybdenum wires bonded only on the canines. All multi-strand wires fulfil the criteria of having mechanical properties of the wire that allow physiological movement of included teeth while sufficiently splinting the teeth at the same time.; however, small diameter wires with fewer filaments are more susceptible to damage and have been reported to have increased failure rate due to lower bond strength and mechanical instability[10]. Retainers bonded only to canines are also easier to keep clean[10]. However, because they are not attached to the incisors, these teeth are more prone to movement[11]. Fibre-reinforced composite, fibre-reinforced plastic or even ceramic materials can be used. However, fibre-reinforced retainers are prone to greater failure rates due to a lack of flexibility unlike dead soft stainless steel wires[12].More recently, monofilament nickel-titanium wires constructed by CAD/CAM procedures have been described and are currently being investigated[13].

Several studies were conducted to reach a reproducible technique with standard results; however, none have reached the most reliable technique because of the human factor that can't be excluded and the evolution of different materials with various properties that can be used for fabrication of fixed retention wire. *Digitization* was recently introduced in orthodontic field with the evolution of 3D imaging & printing machinery. These new technologies offer superb accuracy as well as elimination of errors emerging from human variations. Intraoral scanner devices offer numerous applications in orthodontics such as digital storage of study models and advanced software for designing different designs of fixed retention wire, enabling fabrication of three dimensionally printed fixed lingual retention wire. Therefore, utilization of 3D imaging and metal printing techniques can help the orthodontist to

reach the most precise and reproducible design of lingual retention wire with more accurate and standard results.

Thus to overcome previously mentioned problems of conventional lingual retention wire, this study is conducted in an attempt to evaluate bond failure immediately and after 12 months follow up of novel three dimensionally metal printed fixed retention wire compared to conventional lingual wire.

Research question:

Will the 3D metal printed retainer reduce the immediate bond failure and bond failure after 12 months in patients with need of fixed bonded mandibular retainer, when compared to conventional fixed bonded mandibular retainer?

Statement of the problem:

Although different materials of mandibular fixed retainer were discussed in the literature, there is contradicting evidence regarding the bond failure of Titanium fixed metal retainer, whether immediate or after 12 months. Moreover, insufficient evidence is present regarding 3D metal printed fixed mandibular retainers.

Rationale for conducting the research:

To evaluate and compare immediate bond failure, bond failure after 12 months, chair side time, plaque accumulation, wire breakage and post treatment relapse of the 3D metal printed mandibular retainer and conventional fixed metal retainer.

Review of literature:

Conventional Fixed Retention

In 1973 Knierim introduced the direct bonded retainer[14], which is still frequently used to prevent the relapse of crowding in the mandibular anterior region. In 1977, Zachrisson introduced the multistranded bonded lingual retainer, which, although varying in different shapes, has become the gold standard[15]. Various types of retainers have been described with wires of differing materials, properties and diameters, or using different types of composites for the adhesion or with fiber reinforcement. The primary problem of multi stranded lingual wires is their high failure rate. Studies indicate that 27.2% of bonded mandibular retainers and 58.2% of bonded maxillary retainers fail during the retentive phase[16]. It has also been found that the plaque accumulation is more on the gingival aspect of the wire than on the incisal[17]. Ideally, fixed retainers should be flexible enough to allow some degree of physiologic movement of the retained teeth, hence, providing homeostasis to the periodontium as well as reducing tension within the composite bonding material[18]. However, multistranded wires are significantly more effective at maintaining incisor alignment[19]. Renkema et al. reported 90% of patients with a multistranded wire retainer to have perfect alignment of lower incisors after 5 years of retention[20]. Patients with relapse experienced only 0.8 mm of relapse, on average. Later on, different designs and materials were introduced to overcome previously mentioned problems. There has been introduced fibreglass bonded to each tooth, using composite techniques, with acid etching of the enamel[21]. Although they were aesthetically acceptable and non-metallic, they showed a higher failure indicator in maintaining bonding to enamel, and their rigidity prevented physiological tooth mobility. Moreover, modified multi-loop fixed retainers were known as hygienic retainer due to their less damage to periodontal apparatus[22].

3D Metal Printing of Fixed Retention Wire

In recent years a new possibility is available for dental practitioners: CAD-CAM technology and 3D printing, which find their application in all aspects of orthodontics. Orthodontists are already familiar with several products that use 3D printers (i.e. invisible aligners), also known as additive manufacturing, 3D printing is a technology whereby sequential layers of material are layered on top of one another to form an object[23]. Two recent articles reported the fabrication of a custom lingual retainer cut from a nickel-titanium block with CAD/CAM technology and a CAD/CAM Zirconium bar as a bonded mandibular fixed retainer[13,24]

In order to make a customized lingual retainer, a digital impression, generated by Intraoral Scanner, and its STL file are needed in the first place. Then the generated STL file will be elaborated by the software of the 3D printer and the final piece designed and printed. The main advantages to use digital impressions are essentially the higher comfort for the patient, the less working time needed, the relatively lower cost.

CAD/CAM fixed retainers are considered a potential alternative to conventional multistranded wires, and are claimed to deliver utmost accuracy, and to reduce chair-time[25]. Furthermore, they seem to offer high predictability when limited bonding surface is available, as well as in anatomically demanding regions[26]. In addition, CAD/CAM fixed retainers might provide a very accurate passive fitting to the lingual tooth surface, which is critical as wire tension produced during bonding procedure can result in undesirable adverse effects over the long term, such as unexpected post-treatment tooth movements; unrelated to the initial malocclusion, caused by residual stress between the bonding points[27].

In 2012 Memotain—a new CAD/CAM fabricated lingual retainer wire made of custom-cut nickel-titanium was introduced as an alternative to multistranded lingual retainers. Memotain is a CAD/CAM fabricated lingual retainer made of 0.014 3 0.014-in rectangular nickel-titanium[28]. The wire is highly flexible and custom cut to precisely adapt to the patient's lingual tooth anatomy. It was invented by an orthodontist, Pascal Schumacher. The name Memotain is a portmanteau from the combination of “memory” and “retainer” because of the uniqueness of using nickel-titanium for the lingual wire. Of particular interest is the potential for Memotain to provide minor tooth alignment. The idea of applying a nickel-titanium wire as an “active” lingual retainer was first reported by Liou et al in 2001[29]. Memotain's precision fit and memory enable its use passively for tooth maintenance, as well as actively to retreat mild mandibular anterior crowding without the need for brackets.

Explanation for choice of comparators:

In the ongoing study, conventional metal mandibular fixed retainer will be the control group using multistrand dead soft stainless steel wire. Thus, a well-designed randomized clinical trial will be conducted to evaluate the immediate bond failure and bond failure during 12 months of the 3D metal printed fixed retainer and conventional metal fixed retainer.

7. Objectives:

Primary objective:

To evaluate the immediate bond failure and bond failure during first 12 months after placement of 3D metal fixed retainer and conventional metal fixed retainer.

Secondary objectives

- To evaluate plaque accumulation after placement of each metal fixed retainer.
- To evaluate chair side time of placement of each metal fixed retainer.
- To evaluate wire breakage during 12 months of each fixed retainer.
- To evaluate post treatment relapse of each fixed retainer

PICOTs format:

P: patient with the need of fixed bonded mandibular retainer after orthodontic treatment

I: 3D printed perforated metal fixed retainer.

C: conventional fixed bonded mandibular retainer

O*:*

	Outcome Name	**Measuring Tool**	**Measuring unit**
Primary	Immediate Bond Failure	Counting number of teeth debonded immediately after placement of wire	Numerical
	Bond Failure during first 12 months	Counting number of teeth debonded during first 12 months of placement	Numerical
Secondary	Chairside Time	Digital stopwatch	Seconds
	Wire Breakage	Yes/No	
	Plaque Accumulation	Plaque Index	Numerical
	Post treatment Relapse	Little Irregularity Index	Numerical

T0*:* Immediate, **T1**: 3 month follow up, **T2**: 6 months, **T3**: 9 months and **T4:** 12 month follow up

S: Randomized controlled clinical trial**.**

Hypothesis:

At the start of this study, it is assumed that there is no difference between 3D metal printed retainer and conventional metal fixed retainer regarding bond failure.

8. Trial design:

This trial is designed as an interventional, parallel, randomized, controlled trial with allocation ratio 1:1. It will be performed at Department of Orthodontics and Dentofacial Orthopedics outpatient clinic of the educational hospital of the Faculty of Dentistry, Cairo University.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

- Source of patients: patients who finished their orthodontic treatment at the outpatient clinic of Orthodontic department, Faculty of Dentistry, Cairo University, Cairo government, Egypt.
- Time: 2024-2025 The study will last for 12 months.

10. Eligibility criteria:

All the recruited subjects will follow

Inclusion criteria:

1. Patients with properly finished orthodontic treatment.
2. No sex predilection.
3. The presence of 4 permanent mandibular incisors and 2 permanent mandibular canines.
4. No active caries, restorations, fractures, or periodontal disease of previously mentioned teeth
5. Patients with good oral hygiene.

Exclusion criteria:

1. Patients with no need of fixed mandibular retention.
2. Enamel hypoplasia or hypocalcification of mandibular anterior teeth.
3. Abnormal morphology of mandibular anterior teeth
4. Periodontal disease that contraindicates fixed orthodontic retention.
5. No or poor patient's compliance & bad oral hygiene.
6. Psychological problems.

11. Interventions

A) Treatment Group

After finishing orthodontic treatment, mandibular metal fixed retention wire will be placed on lingual surface of mandibular anterior teeth for all patients. The key of modification is digitally designing fixed metal retainer which will be custom made for each patient, and 3D metal printing of the fixed retention wire using *Riton Metal printer* (Riton Additive Technology Company, China) instead of using generic metal wire for all patients.

The sample selection and screening for inclusion of patients in clinical trial will be performed at clinic of Orthodontic department, Faculty of Dentistry, Cairo University.

The following steps will be performed for each patient:

Initial records:

- *Case History:* Personal information, Medical & Dental History.
- *Study Model:* An impression of upper & lower arches will be taken using condensation silicone elastomeric impression material in a metal tray with patient fully awake and without any anesthesia in a clinical setting.
- *Photographs:* Standardized digital photographs (frontal, profile, oblique) will be taken with a Canon EOS 750D digital camera (Canon, Tokyo, Japan) for all patients.

1. Scanning & designing fixed retention wire:

- The lower arches will be carefully scanned by intraoral 3D scanner of 3Shape Company (Copenhagen, Denmark) & 3D model will be used for making design of the metal fixed retention wire.

2. **Fabrication of fixed retention wire:** 3D metal printing of fixed retention wire for patients of treatment group. Wires will be printed using 3d Printer Fast Speed Sls Metal Printer DUAL150 (Riton, China). The printer also allows the use of any kind of printing metal powder.

3. Clinical application of fixed retention wire:

- Teeth to be bonded are polished and etched.
- Teeth isolation & moisture control are achieved.
- Adhesive bond is applied to teeth (3M Unitek, Monrovia, California, USA) and light cured.
- Placement of metal wire on prepared teeth carefully & ensure complete fitting of wire.
- Start curing of flowable composite (3M Unitek, Monrovia, California, USA).
- Chair side time will be recorded.
- Number of teeth that will be debonded immediately after wire placement will be counted & recorded.

4. 3 Months Follow up: Bond failure will be recorded every 3 months.

5. 12 Months Follow up: Plaque index and Little irregularity index will be recorded together with bond failure or any wire breakage.

B) Control Group

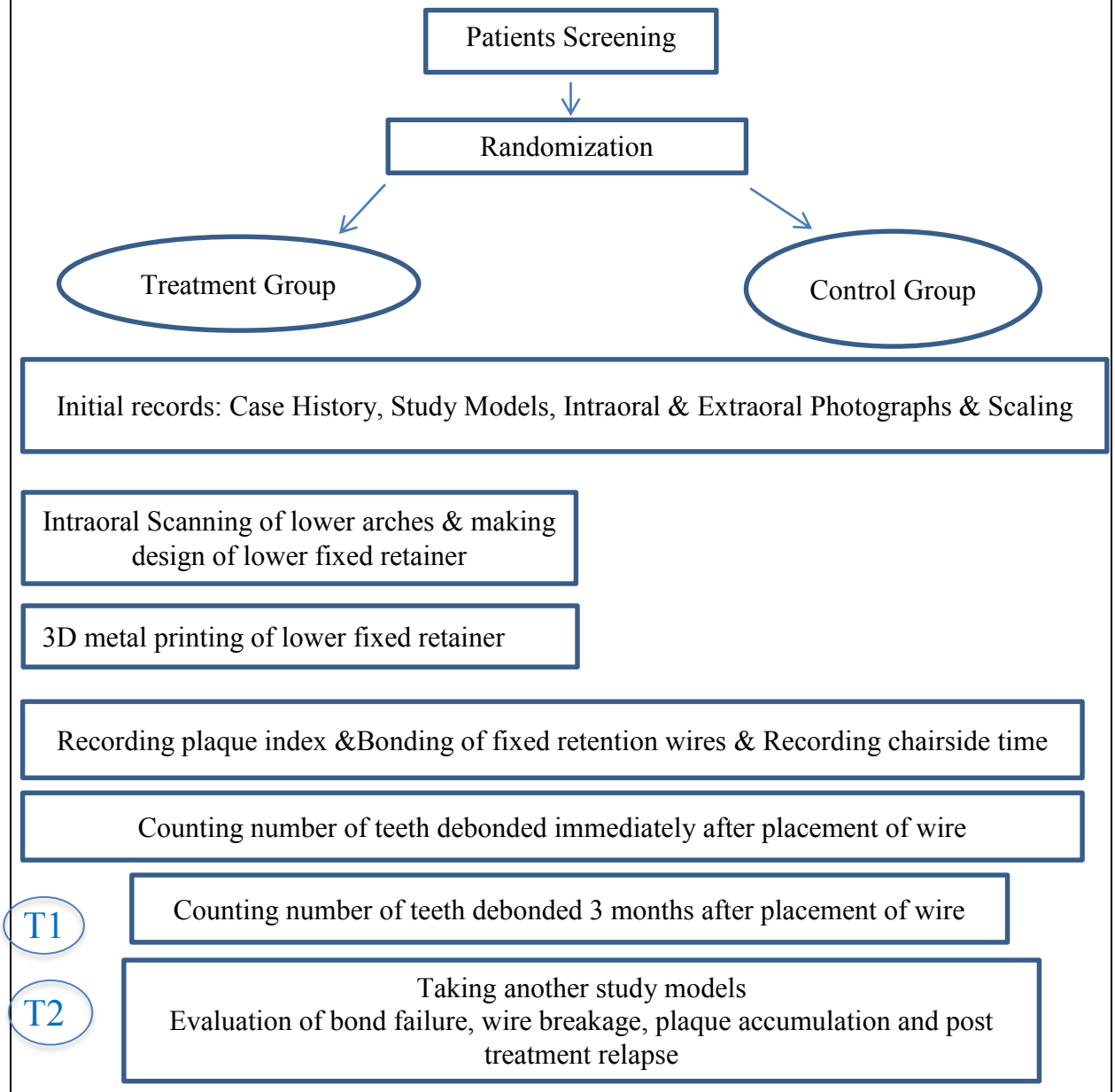
- All patients of this group will follow same steps of fixed retention procedure as treatment group but the metal wire placed will be conventional fixed retention wire (Retainium, Reliance Orthodontics).
- Chairside time will be recorded & number of debonded teeth after wire placement will be recorded.

12. Outcomes:

Primary outcomes: Immediate bond failure and bond failure during first 12 months after placement of 3D metal fixed retainer and conventional fixed metal retainer.

Secondary outcomes: Chairside time, wire breakage, plaque accumulation and post treatment relapse of 3D metal printed fixed retainer and conventional fixed retainer.

13. Participant timeline



14. Sample size:

Sample size calculated depending on a previous study[30] (***Nagani NI, et al 2020***) as reference. According to this study, the failure bond frequency in MSW was 31.41%. while the bond failure in the other group was 5%, we will need to study 32 case in each group with probability (power) 0.8. The Type I error probability is 0.05. The chi-squared test was performed by P.S.Power 3.1.6.

Total sample size = 32 per each group

15. Recruitment:

- Patients will be selected from the outpatient clinic of the orthodontic Department – Cairo University
- Consecutive sampling is done through screening of patients. This will continue until the target population is achieved.
- Identifying and recruiting potential subjects is achieved through patient database.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

It will be performed as 1:1 allocation. The sequence of the two groups (Conventional & 3D metal printed wires) will be done by computer generated random numbers. This will be done by using Microsoft Office Excel 2007 sheet.

16b. Allocation concealment mechanism:

Random numbers obtained by random sequence generation will be written on white papers, each paper will be kept in sealed envelope. Sealed envelopes will be kept in box at the secretary of orthodontic department office.

16c. Implementation

Implementation will be carried out in the secretary of the orthodontic department at the Faculty of Dentistry, Cairo University.

17. Masking/blinding:

- The statistician will not be blinded.
- Assessor (other than the operator performing fixed retention) will carry out measurements blindly on study models.
- Patients & Operator performing fixed retention will not be blinded as the operator knows the shape of the fixed retention wires.

C) Data collection, management, and analysis:

18. Data collection methods

Bond Failure Outcomes: This will be assessed by counting the number of teeth debonded immediately after placement of wire and after 3, 6, 9 & 12 months.

Chairside Outcomes: This will be assessed via measuring chair side time of bonding fixed retention wire by digital stop watch, starting from etching of teeth ending up with complete curing of flowable composite balls.

Plaque Accumulation Outcomes: This will be assessed via calculating score of plaque index before fixed retention wire placement and after its removal.

Wire Breakage Outcomes: This will be assessed by reporting any wire breakage interdentally during 12 months follow up.

Post Treatment Relapse Outcomes: This will be assessed by calculating little irregularity index before wire placement and during 12 months follow up.

19. Data management:

All Data will be recorded, organized, tabulated and stored electronically in the computer and statistically analyzed.

20. Statistical methods:

Handling of numerical / quantitative variables:

Numerical data will be explored for normality by checking the data distribution using Kolmogorov- Smirnov and Shapiro-Wilk tests. Data will be presented as mean & standard deviation. If data will be normally distributed comparison between 2 different groups will be performed by using Independent t-test, comparison between 2 related groups will be performed by using Paired t-test, while comparison between more than 2 groups will be performed by using One Way ANOVA test followed by Tukey`s Post Hoc test for multiple comparisons.

If data will be non-parametric data comparison between 2 different groups will be performed by using Mann-Whitney test, comparison between 2 related groups will be performed by using Wilcoxon Signed Rank test, while comparison between more than 2 groups will be performed by using Kruskal-Wallis test.

Handling of categorial / qualitative variables:

Data will be presented as frequency and percentages. All comparisons will be performed by using Chi square test.

Statistical analysis:

Data were collected, tabulated, and statistically analyzed using Microsoft Excel ® 2016, Statistical Package for Social Science (SPSS)® Ver. 24. and Minitab ® statistical software Ver. 16.

D) Data monitoring:

21. Monitoring

The results of the study will be monitored by Data Monitoring Committee that will be constituted o the trial's supervisors (Dr. Khaled H and Dr. Amr B). Interim data will be presented periodically to the committee; the committee will advise the operator to pause the trial if the interim analysis showed that the patients are subjected to high risks due to the intervention.

22. Harms

If any harm happens to the patient before starting of treatment, it will be reported as unrelated. If it happens after, it will be recorded and reported.

23. Audit

In the present study, auditing will be done by the main and co-supervisors to assure quality of the research methods.

IV. Ethics and dissemination

24. Research ethics approval

This protocol will be reviewed, approved and agreed by CEBD [Center for Evidence Based Dentistry CU] Cairo University, Egypt and approved by ethical committees.

25. Protocol amendments

The Ethics Committee/IRB will be notified of any modifications of the protocol.

26. Informed consent

The trial will be explained to the patients and they will receive information sheets regarding main aspects of the trial. The principal investigator will obtain signed consent from the patients willing to participate in the trial. All information sheets and consent forms will be translated to Arabic.

27. Confidentiality

Personal information about participants will be acquired during the process of trial recruitment, eligibility screening, and data collection. All study related information will be stored securely at the study site. All participant information and data will be identified by a coded ID number just to keep the participant's rights in confidentiality and will be stored in locked file cabinets in areas with limited access. Participants' study information will not be released outside of the study without the written permission of the participant.

28. Declaration of interest

No Conflict of interests for the supervisors is present. There will be no declaration of interests for the supervisors and the principle operator.

29. Access to data

Only the supervisors and the principle operator will have access to study data.

30. Post-trial care

Patient follow up will be done during completion of orthodontic treatment in outpatient clinic of the orthodontic Department – Cairo University.

31. Dissemination policy

We are intending to disseminate the results of the trial in the library of the Faculty, in the Egyptian Dental Journal and in the Journals of Orthodontics.

V. Appendices

32. Informed consent

Human Subjects Application Form

Kindly fulfill the following:

Research title: Evaluation of 3D Printed Metal Fixed Mandibular Retainer versus Conventional Fixed Bonded Retainer: A Randomized Clinical Trial.

Full name of the researcher(s): ***Mariam Alaa El-Din El-Sebaay***

Affiliation of the researcher(s): /

Category of study: Master [ ] PHD/D [✓]

Others [ ]

Type of study design: Randomized Clinical Trial

Objective of the research: To evaluate immediate bond failure and bond failure after 12 months of 3D printed metal fixed retainer. Moreover, to assess wire breakage, plaque accumulation, chair side time and post-treatment relapse of this novel 3D metal printed fixed retainer compared to conventional one.

Steps of the research in short including the following:

- ***Steps in short***

1. Patients Screening & Randomization.
2. Scaling will be done to treatment and control groups 2 days before application of fixed retainers.
3. Taking initial records for control & treatment groups: Case History, Study Models, Intraoral & Extraoral Photographs and Panoramic Radiograph.
4. Scanning of lower arches & performing digital design of fixed retainer.
5. 3D Metal printing of retainer for treatment group.
6. Bonding of fixed retainer in patient's mouth in treatment and control groups & Recording chairside time.
7. Checking bond failure immediately following bonding of fixed retainer and after 3, 6 & 9 months.
8. After 12 months, assess bond failure, wire breakage, plaque accumulation and post treatment relapse.

- ***Number of visits & follow up period***

1. First visit: taking records & scanning
2. Second visit: bonding of fixed retention
3. Third visit: after 12 months for assessment of plaque accumulation, wire breakage, bond failure and post treatment relapse.

Direct benefit of the research to the human volunteer: Receiving suitable fixed orthodontic retention they need.

The scientific interest and the desired public benefit of the research:

1. Digital designing of fixed retention wire is expected to be more accurate as it will be

customized personally for the patient, thus, bond failure will be eliminated and therefore risk of relapse will be reduced.

2. Perforated design of 3D metal printed fixed retainer is expected to decrease rate of bond failure on the long term, thus main problem of fixed retention will be solved.
3. Metal printed fixed retention wire is expected to be more precise and accurate that conventional generic one.

Side effects and the degree of risk and expected to occur and how to deal with them: Normal hazards of any orthodontic fixed retention as caries,and periodontal problems. Moreover, debonding of retainer may occur and if the patient did not fix it, relapse may occur.

Patient's full knowledge of the research steps: Reading [✓] Oral explanation [✓] Other [ ]

1. **I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.**
2. **The researcher has informed me of the possible therapeutic alternatives for this research.**
3. **The researcher has informed me of all the possible risks of this research and how to deal with it.**
4. **I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.**
5. **I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.**
6. **I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.**
7. **I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.**

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.

The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

Signature:

Date:

هذا البحث تمت موافقة اللجنه عليه برقم

33. Biological specimens

Not applicable

VI. Statement of originality

34. Statement of originality

The novelty of this research is based on applying 3D metal printing—a technique not yet utilized in the production of orthodontic retention wires. This method has the potential to transform the fabrication process, allowing for the creation of retention wires that are precisely customized to each patient while also enhancing mechanical properties and biocompatibility.

The study seeks to overcome the limitations of traditional fixed retention wire, such as continuous bond failure, plaque accumulation, and long chairside time. The hypothesis is that 3D-printed retention wires will provide retention stability and patient comfort better than existing methods. Thus, this research has the potential to redefine the approach to orthodontic retention, moving towards more efficient, customizable, and patient-specific solutions.

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