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College of Dentistry

Effectiveness of tubular coaxial nickel-titanium and copper nickel-titanium orthodontic aligning archwires: A randomized clinical trial

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in Partial Fulfillment of Requirements for the Degree of Master
Science in Orthodontics

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Certification of the Supervisor

This is to certify that the preparation and organization of this protocol entitled **"Effectiveness of tubular coaxial nickel-titanium and copper nickel-titanium orthodontic aligning archwires: A randomized clinical trial"** had been made by the master student **Reyam Mohammed Noori** under my supervision, at the Department of Orthodontics/College of Dentistry/University of Baghdad in partial fulfillment of the requirement of the Master degree in Orthodontics.

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2021

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Introduction

The orthodontic market receives new products every day; consequently, a wide variety of options are available for orthodontists. New introductions in orthodontics have an ultimate goal of improving patient care including diagnosis, treatment planning, treatment mechanics, and treatment outcomes by making procedures more effective and efficient. Choosing bracket-archwire combination has a determining effect on the subsequent orthodontic outcomes **(Fleming *et al*., 2010; Montasser *et al*., 2016)**. In fixed orthodontics, wires are used for applying forces to the teeth, so selection of the appropriate wire is essential for success at various stages of treatment **(Jian *et al*., 2013; Mahmoudzadeh *et al*., 2018)**.

Controlled and predictable tooth movement with minimal damage to the teeth and their supporting structures can be obtained by using light continuous force which is ideal for orthodontic treatment. To be clinically efficient, this force should cause maximum tooth movement with minimum root resorption and pain **(Wang *et al*., 2018; Azizi *et al*., 2021)**. A combination of excellent springiness, excellent strength, and a large range of action that produces a flat load deflection rate has made NiTi wires ideal archwires to be chosen at the initial stages of orthodontic treatment **(Kapila and Sachdeva, 1989; Sebastian *et al*., 2019)**. In order to provide clinical advantages, different elements have been added since the introduction of NiTi archwires into orthodontics. Copper is one of these elements that have been added to nickel-titanium, to lower the loading stress while providing relatively high unloading

stress, which can result in more effective orthodontic tooth movement **(Gil and Planell, 1999; Atik *et al*., 2019)**.

Multistranding of archwires has been successfully attempted with stainless steel wire to gain mechanical advantages such as increased flexibility and a reduced load deflection rate **(Rucker and Kusy, 2002; Sebastian, 2012)**. The same principle was applied in case of superelastic NiTi, this resuls in introduction of Supercable, a seven-stranded round coaxial superelastic NiTi archwire which became commercially available in 1995. Laboratory tests seem to suggest that these wires exert only 36% to 70% of the force of solid NiTi wires **(Berger and Waram, 2007; Sebastian, 2012)**. Full bracket engagement with extremely low unloading force delivery is possible with this Supercable wire because of its high superelastic properties **(Berger and Jeffrey, 2008; Modi *et al*., 2020)**.

Recently, Speed six-stranded coaxial tubular superelastic NiTi is introduced into the market. It has many advantages over single-stranded superelastic NiTi, such as shortening of treatment time, increased spring back, resistance to deformation, and it delivers low-force **(Joseph *et al.*, 2019)**. It has an increased flexibility by a "hollow center" design to allow it to fold over on itself so it can be fully engaged in the severe malalignment, while applying only a portion of the force levels of conventional initial archwires **(Sebastian *et al*., 2019)**.

Manufacturers of archwires claim that some archwire is ideal for use in clinical orthodontics based on specific properties, determined by laboratory testing, the performance of these materials in vivo is much more important for orthodontists and their patients. Early clinical trials using new arch wire materials failed to demonstrate improved alignment and there are a number of factors that may be suggested to influence the performance of any given archwire clinically such as: type of wire and properties produced during manufacturing, size and type of brackets used,

interbracket distance, degree of initial malalignment of teeth and treatment duration may all effect the success of orthodontic treatment **(Wang *et al*., 2018)**.

Sebastian *et al.* (2019) reported in their study that there is no statistically significant difference between the alignment efficiency of coaxial tubular superelastic NiTi and single-stranded superelastic NiTi for relieving lower anterior crowding in extraction cases. In contrast, **Joseph *et al.* (2019)** concluded that coaxial tubular superelastic NiTi wires showed a significant effectiveness than single-stranded NiTi in reducing lower anterior crowding after 4, 8, and 12 weeks. This was supported by a systematic review and meta-analysis of experimental clinical evidence on initial aligning archwires and archwire sequences which revealed that a multistranded A_{act} NiTi archwires were significantly more efficient in terms of three dimensional (3D) contact point movement than its single-stranded analogs **(Papageorgiou *et al*., 2014)**.

Other studies concluded that both A-NiTi and Cu-NiTi archwires are equally effective for tooth alignment **(Atik *et al*., 2019; Azizi *et al*., 2021)**.

The Cochrane review by **Wang *et al.* (2018)** revealed that there is a need for further randomized clinical trials (RCTs) to determine the best aligning archwire. Therefore, since there is no clinical study has been conducted until now to assess the alignment efficiency of superelastic coaxial tubular NiTi wire compared to Cu-NiTi wire, and since there is insufficient evidence to determine whether any of these archwire materials is superior to the other in terms of alignment rate, time to alignment, pain and root resorption. Hence, this RCT will be performed to compare between superelastic coaxial tubular NiTi wire and Cu-NiTi wire to assess these aspects in crowding cases.

Aim and Objectives

Aim

The aim of this study is to compare the effectiveness of using coaxial tubular superelastic nickel-titanium and copper-nickel-titanium archwires during the initial phase of orthodontic treatment.

Objectives

Primary Objective

To compare the difference in the amount of crowding relief of the mandibular incisors after 4, 8, 12 and 16 weeks from the start of treatment.

Secondary Objectives

1. To compare the amount of orthodontically-induced inflammatory root resorption (OIIRR) in the apical region of mandibular central incisors, after 16 weeks, between the two groups of archwires.
2. To compare the amount of pain perception between the two groups of archwires during the 1st week after each wire placement.

The *null hypothesis* is that "*there is no significant differences in the effectiveness of using coaxial tubular superelastic nickel-titanium and copper nickel-titanium archwires during the initial phase of orthodontic treatment*".

Methodology

Study design

This will be a multicenter randomized clinical trial.

Settings

Different private clinics and general hospitals will allocate patients for this trial.

Subjects

Participants for this study will include any patient seeking fixed appliance orthodontic treatment according to the below criteria:

Inclusion Criteria:

1. Patients indicated for fixed appliance orthodontic treatment with 5-9 mm crowding of mandibular anterior teeth according to Little's irregularity index (LII).
2. Presence of all the mandibular permanent teeth, except the third molars.
3. Overbite and overjet that do not interfere with bracket placement on mandibular anterior teeth.
4. No history of trauma or root resorption in the mandibular incisors.

Exclusion Criteria:

1. Previous orthodontic treatment.
2. Less than 5 mm of mandibular incisors crowding (LII).
3. Severe crowding which requires treatment by extraction of premolars in the mandibular arch.
4. Blocked-out teeth that cannot be engaged with the aligning archwire.
5. Prior experience of periodontal disease and loss of attachment.

Sample Size

The sample size was calculated to detect a difference of 1.5 mm in the amount of crowding relief between the two treatment groups according to the data obtained from the study by **Nabbat and Yassir (2020)**. This revealed that 13 patients in each trial arm will be sufficient to detect this clinical difference (Totals 26 patients). In order to account for dropouts, a total of 30 patients will be calculated.

Intervention

Patient Identification and Informed Consent

The patients will be initially assessed for eligibility to be included in the study by the investigator (RM). Those who will meet the inclusion criteria will be informed about the nature of the study verbally to take the initial approval for participation. Then they will be provided by the *patient information sheet and consent form*.

Randomization

A simple randomization will be used for this study.

Blinding

As the study will be conducted in different clinics, all data collection and measurement will be completed with the investigator being masked to the allocation groups, though blinding of the operator will not be possible during the archwire placement.

Intervention Protocol

The patients will be treated with straight wire appliance using MBT prescription brackets with 0.022-inch slot (Pinnacle®, Ortho Technology, USA). Initially, teeth polishing will be performed with pumice and rubber cup, followed by water rinsing and air drying

Archwire sequence for each group will be as follows:

1. Coaxial tubular superelastic nickel-titanium Group (TuNT) (Speed tubular supercable, Speed System™ Orthodontics, Ontario, Canada):
   - 0.016-inch
   - 0.018-inch
2. Copper-nickel-titanium Group (CuNT) (Damon Optimal-Force Copper Ni-Ti®, Ormco, Glendora, Calif):
   - 0.014-inch
   - 0.018-inch

All the participants will receive a standardized treatment protocol. At the day of bonding, 0.016-inch archwire will be placed for the TuNT group. Eight weeks later it will be replaced by the 0.018-inch archwire for another eight weeks. While, for the CuNT group, 0.014-inch archwire will be placed at the day of bonding and eight weeks later it will be replaced by the 0.018-inch archwire for another eight weeks. Archwires will be tied to the bracket by elastomeric modules. If there is any debonding during treatment, this should be dealt with as an emergency case and re-bonded within 24 hours, otherwise the case will be considered as dropout. Since this study will be performed during the initial phase of treatment, no deviation in the protocol of treatment will be accepted (such as adding additional archwire in the sequence or using power chain). A good-quality alginate impression for the lower arch should be taken pre-treatment and after 4, 8, 12 and 16 weeks and a stone study model is obtained. Periapical X-ray for the mandibular central incisors will be taken pre-treatment and after 16 weeks. The participants will be provided by a visual analog scale (0-10) to record their pain perception during the first week after each wire placement.

<u>Data Collection and Measurements</u>

The following data will be collected and measured during the course of this trial for both groups:

Type of measurement	Pre-treatment T0	After 4 weeks T1	After 8 weeks T2	After 12 weeks T3	After 16 weeks T4
Little's irregularity index	✓	✓	✓	✓	✓
Root resorption using the scoring index that was provided by Malmgren et al. (1982)	✓				✓

Pain perception using visual analog scale (0-10)	24 hours	2nd day	3rd day	4th day	5th day	6th day	7th day

Study model which should be free from any discrepancy (such as bubbles) will be used to measure LII using a digital Vernier caliper to calculate the amount of mesial and distal contact displacement from the mesial contact surface of right mandibular canine to that on the other side, to the nearest 0.01 mm. The sum of these measurements represents the amount of LII **(Little, 1975)**.

Root resorption will be assessed using the scoring index by **Malmgren *et al.* (1982)**:

- ***Grade 0:*** Absence of apical root resorption.
- ***Grade 1:*** Irregular apical root contour.
- ***Grade 2:*** Minor apical root resorption, a small area of root loss amounting to less than 2 mm.
- ***Grade 3:*** Severe apical root resorption from 2 mm to one third of the original root length.
- ***Grade 4:*** Extreme apical root resorption exceeding one third of the original root length.

The participants will be asked to record their pain perception for the first seven days after placement of archwire using visual analog scale as shown below:

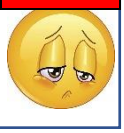
0	1	2	3	4	5	6	7	8	9	10
										

Figure 1: Flowchart of data collection and measurement during this RCT.

Timetable

Duty	Expected time
Patient identification and allocation	4 months
Intervention period	4 months
Data collection and analysis	1 month
Writing up the thesis	10 months (starting from the beginning of the trial)
Total expected time to finish	**About 10 to 11 months**

Stopping Roles

If there is a severe pain in one group that cannot be tolerated by the participants, the study should be terminated.

Budget and Funding

The study is self-funded.

Ethical Approval

The protocol will be submitted to ethics committee.

Data Management and Analysis

Data will be analyzed using the Statistical Package for Social Sciences for Windows, version 25.0 (SPSS Inc., Chicago, Illinois, USA). The following statistical analyses will be used:

Descriptive Statistics

These will include number, frequencies, percentages, mean, median, and standard deviation.

Reliability Statistics

Little's irregularity index: An intraclass correlation coefficient (ICC) will be used to test inter- and intra-examiner reliability of 10 study models measured twice with a four-week interval.

Root resorption: Weighted kappa test will be used to test inter-examiner and intra-examiner reliability of 10 periapical radiographs scored twice with a four-week interval.

Inferential Statistics

Homogeneity of variance between groups will be checked by Levene's test, while normality of data distribution will be checked by Shapiro Wilk test. Assuming that the data are normally distributed due to large sample size (≥ 30) according to the central limit theorem, the following tests will be used:

- *Independent samples t-test:* to test the difference in the amount of crowding between groups.
- *Wilcoxon signed-rank test and Mann-Whitney U test:* to compare the root resorption at T0 and T4 and within each group and between groups (categorical data).
- *Chi-square test:* to compare pain perception between groups.

The significance level will be set as $p < 0.05$

Further Considerations

Pilot Study

A pilot study will NOT be conducted.

Dissemination

Postgraduate M.Sc. Thesis.

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College of Dentistry – University of Baghdad

Patient Information Sheet

You are invited to participate in a scientific research. Please take your time to read the following information carefully before you decide whether or not you wish to participate. You can ask for clarifications or any more information about the study from the researcher and you can discuss this with outsiders.

Information about the research

1. **Study title**
   Effectiveness of tubular coaxial nickel-titanium and copper nickel-titanium orthodontic aligning archwires: A randomized clinical trial.
2. **What is the purpose of this study?**
   To compare the effectiveness of using coaxial tubular superelastic nickel-titanium and copper-nickel-titanium archwires during the initial phase of orthodontic treatment.
3. **Where will the study be conducted?**

   The study will be conducted in Different private clinics and general hospitals.
4. **What are the procedures to be followed and what will you be asked to do at each visit?**
   No specific procedure but you should follow your doctor instruction regarding the care of fixed orthodontic appliance and inform your doctor if there is any breakage or a problem.
5. **How long will the participation in the study last?**
   Four Months
6. **If you decided to taking part in the study, will the treatment be different from the treatment you would get otherwise?**
   There is no difference in the treatment plan that usually decided for your condition.
7. **Who should not enter the study?**
   - Previous orthodontic treatment.
   - Less than 5 mm of mandibular incisors crowding (LII).
   - Blocked-out teeth that cannot be engaged with the aligning archwire.
   - Prior experience of periodontal disease and loss of attachment.
8. **What will be the benefits of the study?**
   To the participant? Possibility of faster alignment of teeth with less pain and root resorption.
   To the investigator? To determine which archwire is more effective in alignment of teeth.
9. **What are the possible risks of taking part?** No risks
10. **If you feel severe discomfort or pain during the study, would you be able to take any relief medication?** Yes, you can. but the pain perception should be recorded before taking the medication.
11. **Will your participation in the study interfere with your daily activities?** No, it will not**.**
12. **Will you be informed of the results of the study?**
    If you like, it will be submitted to you.

If you agree to participate in this study, we will ensure your confidentiality with no one except the study researchers have the right to access your dental (medical) notes.
Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

Thank you for reading this Information Sheet and considering your participation in this study

Consent Form

	Please tick to confirm
I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without any medical/dental care affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the College of Dentistry – University of Baghdad where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.	
I agree to take part in the above study.	

Regarding any information and records taken during the research please specify your acceptance to share them as you desire:					
	Personal data	X-rays	Extra-oral photographs	Intra-oral photographs	Others
Confidential					
For consultation					
For teaching					
For conferences					
For publication					

	Name	**Signature**	**Date**
Participant			
Parent/guardian (if appropriate)			
Person taking consent			

Person to contact:

Name: Dr. Reyam Mohammed Noori

Phone No.: 07500535965

Email: dr.rmn2017.777@gmail.com

1 copy for the participant; 1 copy for the researcher