**INTRODUCTION**

Malocclusion, is a common dental problem in India and has a wide prevalence of 20 to 88 %.\(^1\) Orthodontic mechanotherapy is applied to correct these abnormalities, either by removable or fixed method. Archwires form a cornerstone of such mechanotherapy, by exerting mechanical forces to align maloccluded teeth.

Today’s armamentarium of archwires, range from older stainless-steel (SS) wires to newer NiTi (nickel-titanium), CuNiTi (copper nickel-titanium) and TMA (titanium molybdenum alloy) alloy archwires.\(^2\) Among these, NiTi wires have earned a special place due to their inherent properties of superelasticity and shape memory.\(^3\) Corrosion resistance of these wires is supposedly due to formation of a thin, stable titanium oxide layer during intra oral use.\(^4,5\) NiTi wires enable a clinician to apply, light continuous force, over large activation areas with reduced patient discomfort.

Development of dental caries during orthodontic therapy is common, hence orthodontists often recommend prophylactic use of fluoride containing mouthwash to mitigate it.\(^6,7\) There is current evidence to link use of fluoride mouthwashes and increase in the leaching of Ni and Cr ions from NiTi archwires.\(^8\) Fluoridated mouthwashes are commercially available in two strengths, sodium fluoride 0.05 % for daily use and sodium fluoride 0.2% for weekly use, and both are equally effective for prophylactic use.\(^9\)

Systemic consumption of fluorides in some endemic areas, through water and even accidental ingestion (common among small children while brushing with fluoride toothpaste) is detrimental to health (skeletal and dental fluorosis). Ni and Cr ion leaching have been...
associated with genotoxic and cytotoxic changes in mucosal cells.\textsuperscript{10,11} Further, corrosive damage alters the mechanical properties of NiTi archwires by reducing the ultimate tensile strength and increasing NiTi wire fracture rates.

It is widely known that older stainless steel archwires are more prone to corrosion than newer (NiTi) archwires.\textsuperscript{6} Many in vitro studies have been carried out on corrosive resistance properties of NiTi alloys in an artificial physiological solution (fluoridated and non-fluoridated Fusayama–Meyer artificial saliva).\textsuperscript{4,12-14} However, scant information exists today to interpret and compare “in vivo” effects of fluoridated mouthwashes on ultimate tensile strength of nickel-titanium archwires. The present study hypothesized that fluoridated mouthwashes alter the mechanical properties of NiTi archwires when used intra-orally for a period of 3 months.

The purpose of this prospective randomised “in vivo” study was to evaluate the effect of fluoride mouthwash when used for a period of three months on the ultimate tensile strength of nickel-titanium archwires.

**MATERIALS AND METHOD**

Sixty 0.014-inch NiTi archwires (Ormco Corp,Glendora, USA) were divided into three equal sub-groups of twenty each: (A) As-received wires which served as baseline (B) Intra-oral used wires exposed to placebo mouthwash, (C) Intra-oral used wires exposed to fluoridated mouthwash (0.05% sodium fluoride) Colgate Plax (Colgate-Palmolive Ltd, Thailand). All wires were evaluated for their ultimate tensile strength. The study was reviewed and approved by the Institutional ethics committee (ACDS/IEC/11/Jan/2019). All patients participating in this study signed an informed consent form. These 40 patients received MBT (McLaughlin, Bennett, Trevisi) 0.22”x 0.028” prescription brackets (MiniTwin, Ormco, Glendora, USA). Patients were randomly allocated to Groups B or C with the following inclusion criteria: (a) Patients requiring non-extraction orthodontic mechanotherapy (b) Moderate to severe lower crowding with irregularity index > 4 mm (c) No history of any previous orthodontic intervention (d) No visible signs of fluorosis.

Group A consisted of as-received wires. Placebo mouthwash was made by the authors by addition of blue-synthetic food colouring agent (Papilon food flavours and colors, India) to distilled water. Group B subjects were instructed to use 10 ml of this placebo mouthwash twice daily in addition to their routine oral hygiene regimen. Group C subjects were instructed to use 10 ml of “Colgate Plax (0.05% sodium fluoride)” mouthwash twice daily in addition to their routine oral hygiene regimen. All participants used a non-fluoridated toothpaste during the course of the study.

The placebo and fluoridated mouthwash were provided to group “B” and “C” subjects in clear unlabelled plastic bottles of similar size and shape. 0.014” NiTi archwires of group B and C, were retrieved after three months of intra oral use. All wires after retrieval were rinsed with distilled water to remove loosely bound precipitates and were individually stored in sterilized pouches. Wires from 3 groups were evaluated for ultimate tensile strength using a testing apparatus TA.XTplusC (Stable Microsystems, UK) (Fig1).
Methodology as described by Devaprasad and Chandrasekaran (2012), was followed in this study. The machine parameters were set to test a scale load of “1000 N”, and was operated in a “tensile” mode with a crosshead speed of “5 mm/min” to enable analysis of ultimate tensile strength of each wire. Each wire sample was cut at one end with a standardized span of 20 mm and was placed between the jaws of the machine (Fig 2). The maximum tensile load, which the wire could withstand prior to its failure, was noted (Fig 3).

The required sample size was estimated using G Power software Ver 3.1.9.2 (Fig 4). The measured effect size (f) at 48%, study power at 80%, and error margin at 5%, was considered for which the total sample size required was 45. So, to consider for the attrition bias, sixty subjects were included in this study. Quantitative analysis of tensile strength was evaluated statistically using one-way analysis of variance (ANOVA), with mouthwash serving as a predictor. Group differences were evaluated using Tukey HSD (honestly significant difference) with a p value < 0.05 considered as the level of statistical significance.

RESULT

Table 1 demonstrates the mean ultimate tensile strength measured in Newton (N) for each study group. The mean ultimate tensile strength for control group is 117.69 ± 0.66 N, for placebo mouthwash group, it was 99.95 ± 0.91N and for fluoridated mouthwash group, it was 79.45 ± 1.33N. This difference in the mean ultimate tensile strength between 3 groups was statistically significant at p <0.001. (Fig 5)

Multiple comparisons of mean differences between different groups revealed that the control group showed the highest mean ultimate tensile strength as compared to placebo and fluoridated mouthwash groups, both at p <0.001. This was followed by the placebo mouthwash group showing significantly higher mean ultimate tensile strength as compared to
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**Table 1: Comparison of mean Ultimate Tensile Strength (in Newton) between three groups using One-way ANOVA Test**

| Groups                | N  | Mean   | SD  | Min  | Max  | P-Value |
|-----------------------|----|--------|-----|------|------|---------|
| Control               | 20 | 117.69 | 0.66| 116.2| 119.1| <0.001* |
| Placebo Mouthwash     | 20 | 99.95  | 0.91| 98.8 | 101.5|         |
| Fluoridated Mouthwash | 20 | 79.45  | 1.33| 75.5 | 80.5 |         |

*statistically significant

**Table 2: Multiple comparison of mean difference in Ultimate Tensile Strength (in Newton) between three groups using Tukey’s Post hoc Analysis**

| (I) Groups          | (J) Groups          | Mean Diff. (I-J) | 95% CI for the Diff. | P-Value |
|---------------------|---------------------|------------------|----------------------|---------|
|                      |                     |                  | Lower | Upper |         |
| Control             | Placebo Mouthwash   | 17.74            | 16.98 | 18.51 | <0.001* |
| Control             | Fluoridated Mouthwash| 38.25          | 37.48 | 39.01 | <0.001* |
| Placebo Mouthwash   | Fluoridated Mouthwash| 20.50           | 19.74 | 21.27 | <0.001* |

*statistically significant

Fluoridated mouthwash group at p <0.001. This infers that the mean ultimate tensile strength is highest in the control group followed by placebo mouthwash group and least in fluoridated mouthwash group. (Table 2)

**DISCUSSION**

Arch wires play a major role in fixed orthodontic therapy. Ideal arch wire properties include a low load-deflection rate, flexibility with higher resistance to orthodontic forces, low elasticity, low friction coefficient with higher springiness, higher resilience, corrosion resistance and good biocompatibility. NiTi archwires are suitable and yield optimum results for treatment of most orthodontic problems in clinical practice due to their desirable wire properties. Wires with light mechanical force properties and a low load deflection ratio are more efficient and hence preferred for the initial alignment phase.

Keeping the crucial importance of mechanical properties of the wires, efficiency and duration of orthodontic treatment, it was decided to use NiTi archwires in the present study.

In general, mouthwashes are available in either non-fluoridated or fluoridated form. Fluoridated mouthwashes are prescribed to reduce the effects of enamel demineralization and white spot formation whereas, non-fluoridated mouthwashes are prescribed as antiplaque agents. Among the plethora of non-fluoridated mouthwashes, Listerine (Johnson and Johnson) caused significant surface corrosion of SS wire when compared to chlorhexidine mouthwash which was attributed to the acidic nature of Listerine. Although not statistically significant, 0.12% chlorhexidine and peroxide showed higher surface degradation of SS and NiTi wires respectively, compared to other mouthwashes.

Hence, fluoridated mouthwashes are usually recommended to patients undergoing orthodontic treatment to maintain oral hygiene. 0.05% fluoride mouthwash concentration was used in this study as it is commonly available and prescribed as the standard recommendation to an orthodontic patient.

All patients were instructed to rinse for 20 seconds with the given mouthwash twice daily for a period of 3 months. Duration of three months represented the time for which the initial NiTi archwires were placed intra-orally before it was to be replaced with a new archwire.

The tensile strength of orthodontic archwire is the ability of the material to withstand pulling (tensile) loads. Tensile strength determines the maximum force that can be distributed by archwires to move teeth orthodontically. It is directly proportional to the mechanical property of the archwire. A table-top tensile testing apparatus was used to measure the ultimate tensile strength. This apparatus is a miniature version of Universal testing machine (UTM), which is previously used in researches.
The reduced corrosion resistance of an archwire in turn, reduces the wire’s tensile strength. Factors which affect this corrosion resistance depend on manufacturing process (heat treatment, surface roughness of the alloy, composition) and clinical use (duration and pH of mouthwash used).23-25

It is known that titanium (Ti) has a unique property of enhancing corrosion-resistance of orthodontic archwires by forming a protective film of titanium oxide (TiO$_2$). But on surfaces of nitinol archwires, addition of nickel oxide or metallic Ni to TiO$_2$ makes it more susceptible to degradation.26

The oral cavity is constantly exposed to saliva, ingestion fluids and foods with different pH (right from alkaline food e.g. fruits to acidic e.g. soft drinks) and of variable temperatures. All these factors may alter the mechanical properties of wires. Fluoride and hydrogen ions noted inside the oral cavity after intake of fluoridated mouthwash, can form hydrofluoric acid (HF) which destroys the protective oxide layer. In an in vitro study, fluoride ions reduced the corrosion-resistance potential of archwires which was attributed to dissolution of TiO$_2$ in presence of fluoride.6 The corrosion behaviour of NiTi wire in presence of fluoride can be attributed to either an increase in hydrogen ion concentration intra-orally or the nature of fluoride as an accelerator ion. Further, in an active state and acidic environment, release of Ni ions occurs intra-orally which can cause corrosion and lead to reduction in the tensile strength of orthodontic archwires.5,7,20,27

A study by Heravi et al6 concluded that use of fluoridated mouth rinses destroys the surface of SS wires. Leaching of Ni ions after use of a fluoridated mouthwash can cause allergenicity, toxicity and carcinogenicity.10,13 an important draw back. This damage in turn may alter mechanical properties of NiTi archwires. Our study showed that ultimate tensile strength of used 0.014” NiTi archwires exposed to fluoridated mouthwash, is lower than that of archwires exposed to placebo mouthwash and as-received archwires. The results were statistically significant (p<0.05). Our results were in line with studies done by Ramalingam et al.28 and Walker et al.,29 who compared the exposure effects of fluoride rinse and fluoride gels on patients with NiTi wire,28 and found fluoride agents alter the mechanical properties of the wire28 and increase the duration of orthodontic treatment.29

Perinetti et al,30 in an in vitro study found no significant effects on the fracture resistance of two commercially available NiTi based archwires exposed to fluoridated agents. NiTi wires when used in-vitro are usually unbreakable,19 but they do break on intra-oral use. In moderate to severe crowding cases, which require use of an aligning archwire for an extended period of time, fractures of the initial wire were most common problems encountered.15

Possibly due to the small sample size, none of our group C patients had wire fractures. Our analysis revealed that, retrieved NiTi archwires are affected on exposure to fluoridated agents, with reduction (30%) in ultimate tensile strength and depicted an increased risk of wire fracture which may prolong orthodontic treatment. Hence, it is recommended to use a non-fluoridated mouthwash when NiTi aligning archwires are being used. Additional research with a larger patient sample and use of non-fluoridated and fluoridated mouthwashes and their effects on NiTi aligning wires could shed more light on this interesting phenomenon. Further, surface evaluation of the exposed archwires can also be done in future studies.

CONCLUSION

• There was a statistically significant reduction in the tensile strength of NiTi archwires after exposure to fluoridated mouthwash for a period of 3 months.

• Fluoridated mouthwashes must be used with caution in orthodontic patients who are in the 1st stage of leveling and alignment with NiTi aligning wires.

• Non-fluoridated mouth rinses can be prescribed by orthodontists as an adjunct to oral hygiene regime to orthodontic patients with NiTi aligning archwires.
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