ORIGINAL ARTICLE

Preliminary Result of Randomised Controlled Trial of Three Different Coated Archwires Part 1: Tooth Alignment and Coating Loss

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ABSTRACT

Introduction: Coated archwires improve aesthetics during orthodontic treatment. However, little is known regarding their clinical benefit. This randomised controlled trial (RCT) compared the tooth alignment (TA), coating loss (CL), colour change (ΔE*), and patient perception of coated archwires with their controls. Details of ΔE* and perception were reported in the second part of the articles. **Methods:** This RCT was done at three centres. Participants were randomised to receive one of four treatment interventions using 0.014" superelastic coated nickel-titanium archwires from Orthocare, RMO, G&H, and conventional uncoated 3M Unitek® archwires. These archwires were ligated during bonding and collected after eighth week and questionnaires were distributed to participants in the experimental groups only. After removal, TA and CL were measured using Little's Irregularity Index and Autodesk® AutoCAD® software, respectively. At the time of this preliminary reporting, 84 participants had completed the trial. Two archwires fractured and were excluded. Therefore, 166 archwires (n = 166) were analysed. **Results:** Only non-extraction cases showed statistically significant differences in TA change between all groups (p = 0.005) and RMO showed significantly lowest mean of TA (1.5 mm). RMO and Orthocare showed significant TA change in the upper and lower arches (p = 0.037, 0.048). CL was found to be insignificant for both extraction and non-extraction cases (p >0.05). Comparison between upper and lower arches revealed no significant difference in TA and CL in all groups (p >0.05). **Conclusion:** From this preliminary analysis, Orthocare provides better TA in non-extraction cases despite highest percentage of coating loss.

Keywords: Coated archwires, Coating loss, Randomised controlled trial, Tooth alignment

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INTRODUCTION

An orthodontic archwire which produces continuous light force is ideal in orthodontic treatment as it brings out desirable tooth movement which is rapid and relatively painless with minimal tissue damage (1). Constant force level should behave elastically over a period of weeks to months as the appliance undergoes de-activation period which will provide maximum tissue response and ensure that the appliance to undergo large deflections with no deformation (2). Thus, careful selection of appropriate archwire will result in efficient and desired treatment results and minimum discomfort to patients (3). Coated orthodontic archwires offer aesthetic and some mechanical advantages over conventional metallic wires. However, benefits may be rapidly lost if the stresses of the oral environment lead to partial or complete loss of the coating. As these wires are produced for increased aesthetics, there has to be some concern regarding their performance as patients can be aware of textural, and colour changes after use (4). Coated NiTi archwires are a newly improved conventional archwires that have been coated with certain tooth-coloured polymers which have been added into the orthodontic inventory. In coating procedures, surface of the archwires is refined by oxides, ethylene, PTFE or nitride ions to cause a permanent modification of the surface (5). Manufacturers differ in the material of coating with a thickness of approximately 0.002 inches and the application procedure to increase aesthetics and mechanical efficiency (6, 7).

Tooth-coloured (aesthetic) orthodontic archwire complements the aesthetic of ceramic or plastic brackets. The first aesthetic archwire was introduced in the 1990s (8) and there are two types of aesthetic archwire; metal-coated and transparent non-metallic fibre-reinforced archwires. The metal-coated ones are available for clinical use in the market and they can

either be nickel titanium (NiTi) or stainless steel (SS) archwires, coated with polytetrafluoroethylene (PTFE), epoxy resin, parylene polymer or less commonly silver palladium coating to resemble tooth enamel colour (9). Transparent non-metallic fibre-reinforced archwires are still in the experimental stage (10) as they are brittle in nature (9) and sharp bends may result in fracture of the glass core. The inability to match the mechanical properties of metallic archwires using non-metal archwire alternatives has resulted in the development of metal coated archwires that allow some cosmetic improvements whilst maintaining the desirable mechanical properties of the metallic archwire.

Previous studies had shown some favourable mechanical properties of aesthetic archwires such as increased electrical resistance, high toughness and physical resistance, proper thermal conductivity adherence, good flexibility and chemical resistance to detergents, and excellent anticorrosive property (11). The aesthetic coating provides protection against corrosion processes on the archwire, however, cannot protect the archwires from being corroded following prolonged intraoral exposure because of the complex action from the oral fluids (12). The plastic coating also decreases friction between archwires and brackets. This property is desirable when a low coefficient of friction is required as in retraction of teeth and space closure but may not be favourable when high coefficient of friction is required for high anchorage cases (13).

The defects and discontinuity of the coating layer of as-received archwires (archwires that have not been used clinically) have been reported. This is associated with poor mechanical properties which cause undesirable and uncontrolled tooth movements (6).

Coated archwires deliver lower forces when loaded and unloaded compared to non-coated archwires of the same nominal diameter (14). The inefficiency of orthodontic treatment has been reported to be caused by the existing frictional force between the bracket slot and the archwire (15, 16), despite the low friction claim. Evaluation of the effects of intraoral ageing on the surface properties of aesthetic and conventional NiTi archwire after clinical use has revealed that aesthetic archwire develops heterogeneous surface with craters and bumps. As a result, friction on the surface of the metallic brackets increases (17). Accumulation of plaque often occurs on the irregular surfaces and affects the movement of the tooth due to the entrapment of brackets inside these defects (18).

Despite the abovementioned concerns of metallic coated archwires, manufacturers have claimed that the aesthetic archwires available in the market have good colour stability (remains unchanged for six to eight-week duration), good coating durability and low friction, allowing faster tooth movement. As these aesthetic archwires are much more expensive than the conventional superelastic NiTi, it is therefore important to establish a clinical data to allow clinicians and patients to make a justifiable choice on treatment and develop further research in this area. Therefore, the aim of this study is to compare and evaluate the tooth alignment (TA), coating loss (CL), colour change (ΔE^*) of three coated archwires available commonly in the market and their controls as well as patient perception.

Aesthetic archwires coated with PTFE and epoxy resin and partially coated with PTFE will be studied for its alignment efficiency, colour change, coating loss, and patient perception. It was hypothesized that 1) the aesthetic archwires provide faster tooth alignment while the coatings remain durable; 2) alignment is faster in extraction cases due to existing space; 3) there is an influence from inter-bracket distance on coating loss.

The aims of this study are to determine the change in tooth alignment between groups, evaluate the influence from inter-bracket distance of the upper and lower fixed appliances on the coatings, and evaluate the coating loss of the archwires between the experimental groups in both extraction and non-extraction cases.

MATERIALS AND METHODS

Study design

This study was a double-blind, randomised clinical trial involving orthodontic patients treated with fixed appliances.

Study area

Three orthodontic departments participating in this trial are (1) Orthodontic Specialist Clinic, Advanced Medical & Dental Institute (AMDI); (2) Orthodontic Specialist Clinic, School of Dental Sciences (PPSG), Universiti Sains Malaysia; and (3) Desa Murni Dental Clinic, Permatang Pauh (KPDM).

Study sample

The study archwires that were included in this study were (1) Orthocare Euroform® Cosmetic Tooth-coloured SE NiTi upper and lower round 0.014″; (2) RMO FLi® Tooth-coloured SE NiTi upper and lower round 0.014″; (3) G&H G4 Tooth-coloured SE NiTi upper and lower round 0.014″ and (4) uncoated 3M Unitek SE NiTi upper and lower round 0.014″.

These wires were selected because this dimension is commonly used as the first aligning archwire after the patient has been bonded up with fixed appliances. These three archwires differed from one another in terms of coating materials and coverage.

Sampling criteria

The patients were selected based on the inclusion criteria such as age 11 years old and above, patients were in

permanent dentition with all upper and lower teeth had fully erupted, required complete bond-up with upper and lower pre-adjusted edgewise bracket system (MBT prescription with bracket slot size 0.022") and able to give consent. Patients were excluded in the presence of the following exclusion criteria such as cleft lip and palate and other craniofacial deformities and syndromes, any medical problems or on medications that can influence the rate of tooth movement, ectopic teeth not allowing bracket placement and ligation at bond-up, hypodontia and history of previous orthodontic treatment.

Withdrawal criteria

Participants could withdraw from the study at any time without compromising the treatment. The trial also ended at any point of archwire fracture and the treatment continued as planned with conventional archwires.

Sample size calculation

The sample size was calculated using PS Software version 3.1.2 (Vanderbilt, USA) (19) based on comparing two mean formula. The power was set at 80% and the alpha was at 0.05. 264 archwires in total were required (132 participants). In this preliminary reporting, 84 participants had been included for preliminary analyses.

Participant enrolment

84 participants were invited and the ones who consented were enrolled to a logbook. Out of this 84, 56 were recruited from AMDI, 11 were from PPSG, and the other 17 patients were recruited from KPDM. They were randomised into 4 groups of intervention through blocked randomisation using a computer-generated random number, stratified for extraction and non-extraction. They were provided with written and verbal information by their orthodontist and given time to consider the information and ask questions before deciding whether to participate.

Each pair of the archwires was sealed in a coded opaque white envelope. These were done in AMDI and distributed to other centres. The envelope was opened once the participant was bonded.

Blinding

The operators, patients and statistician were blinded after assignment to interventions. The patients selected only one sealed envelope containing the archwires without looking at other archwires. Both operators and patients were not being informed of the brands of the coated archwires and they were not able to differentiate the coated archwires as the colours resembled one another. So, statistician analysed the data based on the assigned codes.

Intervention

On the day of bond-up, participants who gave their consent were explained verbally and in writing with regards to the procedures, risks and benefits. Oral prophylaxis was done on all the teeth with slurry pumice using slow speed handpiece followed by rinsing and drying using 3-in-1 tip.

The bonding procedure was carried out by the orthodontist in a properly moisture-controlled environment. Each tooth surface was etched with 37% phosphoric acid liquid for 30 seconds, followed by rinsing and drying until chalky white enamel appeared.

The etched tooth surface was applied with a coating of transbond primer (3M Unitek, St Paul, USA) using disposable cotton-tipped applicator. Pre-adjusted edgewise brackets were placed and cured for 20 seconds. The randomly allocated envelope was opened and archwires were ligated with elastomeric ligatures. At 4th week following bonding, the same archwires were retied. In case of fracture of the archwire, the fractured wire was recorded, disinfected and placed in the allocated envelope. The fractured wire was replaced with conventional archwire and treatment continued.

During the eighth week after bonding, the tested wires were collected, disinfected, dried and placed back in the allocated envelope. Upper and lower impressions were taken. The teeth were tied with suitable conventional archwires and treatment continued as planned. The post-experimental study models were labelled and stored in study model boxes for assessment. In case of fracture of the archwire, the fractured wire was recorded, disinfected and placed in the allocated envelope.

Outcome measurements

Primary outcome in this study is the percentage of alignment change between the pre-treatment and post-experimental study models. Secondary outcomes are coating loss, colour change, and patient perception. All measurements took place at eighth week after the bonding procedure.

Data collection

Alignment change

The measurements of tooth irregularity of pre-treatment and post-experiment study models were performed by one calibrated assessor (Alyassiri) using digital calliper to the nearest 0.01 mm, based on method described by Little using Little's Irregularity Index (20). The changes is calculated and recorded in percentage.

Coating loss measurement

Each archwire was placed against a black background and photographed using a digital single lens reflex (DSLR) camera with two LED lights illuminating the archwire at 45o angle on each side. Photography set up as described by Ulhaq et al was used in this study (21).

The images were measured for coating loss using Autodesk® AutoCAD® 2018 software (Autodesk Inc., Mill Valley, USA). Percentage of coating loss was

calculated using the following equation: % of coating loss = length of coating loss of archwire / the total length of the archwire. The measurements were made at the highest magnification to reduce error (Fig. 1).

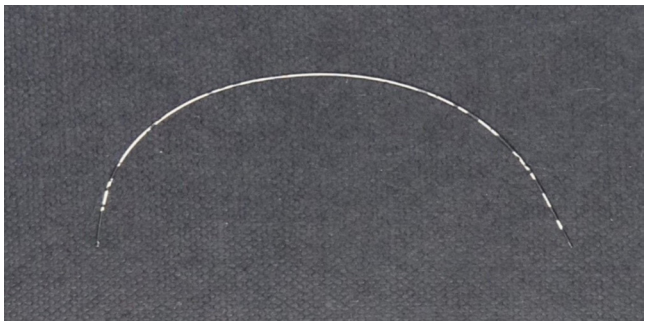

Figure 1: Illustrate the shape of the archwire with coating loss

Data analysis

Data was analysed using Statistical Package for the Social Sciences SS (SPSS) software version 24 (IBS Corporation, New York, USA). The statistician was blinded to the treatment groups. Statistical significance was set at the α level of 0.05. Confidence intervals (CI) are stated at the 95% level. The normal distribution of the data was tested using Shapiro-Wilk test which indicated an abnormally distributed data (p <0.001). Therefore, descriptive statistics, non-parametric Kruskal-Wallis test, post-hoc Dunn test, Mann-Whitney U test, and Wilcoxon-signed rank test were used.

Reliability measurements

All measurements were done by a single calibrated examiner. The reliability of the measurements was undertaken through intra and inter-examiner calibration. The intra-examiner calibration was repeated by taking ten measurements within two weeks apart from the first measurement and calculating the correlation coefficient by another orthodontist under similar setup and inter-examiner calibration was calculated.

Ethical approval

Clarification on the requirement for the necessity for ethical review was reviewed and approved by The Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM USM) prior to the commencement of the study (USM/JEPeM/17010022).

Trial progression

The clinical trial is currently ongoing, and the results presented here are an initial analysis of the archwires that have been analysed following completion. The flow chart of the study and the status of the trial is shown in Fig. 2.

RESULTS

Sociodemographic characteristics of the study subjects

A total of 168 archwires were collected, but two archwires (one upper and one lower) were excluded due to fracture, the total number of the archwires that were assessed were 166.

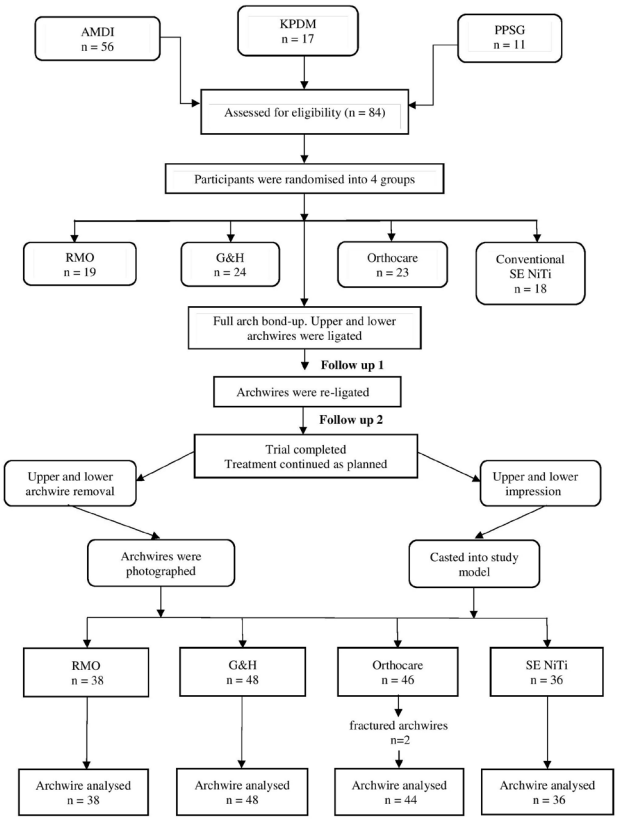

Figure 2: Flow chart of the trial

Reliability of tooth alignment and coating loss measurement

The reliability measurements for tooth alignment and coating loss are 0.95 and 0.92 respectively, which indicates an excellent reliability of measurement.

Tooth alignment

The amount of TA change for both extraction and non-extraction cases and the comparison between archwire groups are shown in Table I. In extraction cases, the preliminary results revealed that the G&H group had the lowest mean of alignment change (4.4, CI 3.11 – 5.70) compared to the other three archwires and no statistically significant difference was found (p = 0.298). Meanwhile, in the non-extraction cases, Orthocare group had the highest mean value (3.7, CI 1.74 – 5.60) and the RMO group was associated with the lowest mean of alignment change (1.5, CI 0.67 – 2.23). A statistically significant difference in alignment change was found between the four archwires types (RMO, G&H, Orthocare and conventional SE NiTi) for non-extraction cases (p = 0.005). The group that showed significant result was determined using multiple pairwise comparison.

The pairwise comparison that was shown in Table II revealed that the statistically significant group to be the RMO archwires when compared to both G&H and

Table I: Mean of TA change of different archwire groups for extraction and non-extraction cases

Archwire Group	n	Alignment change Mean ± SD	95% CI for Mean		χ^2 statistic (*df*)[a]	*p* value[a]
			Lower	Upper		
Extraction cases						
RMO	22	6.1 ± 4.18	4.28	7.99	3.68 (3)	0.298
G&H	28	4.4 ± 3.35	3.11	5.70		
Orthocare	32	6.1 ± 4.19	4.54	7.56		
Conventional SE NiTi	22	6.1 ± 4.01	4.30	7.85		
Non-extraction cases						
RMO	16	1.5 ± 1.46	0.67	2.23	12.99 (3)	0.005
G&H	20	3.2 ± 2.16	2.17	4.20		
Orthocare	15	3.7 ± 3.48	1.74	5.60		
Conventional SE NiTi	14	1.6 ± 1.48	0.77	2.49		

[a]Non-parametric Kruskal-Wallis test. Data from all groups are skewed to the left. Significant difference is detected if $p = 0.05$.

Table II: Post hoc multiple pairwise comparison between archwire groups for non-extraction case

Archwire pairwise comparison	Test statistic	Standard error	*p* value[a]
RMO vs G&H	-17.21	6.32	0.039
Conventional SE NiTi vs G&H	15.35	6.57	0.117
RMO vs Orthocare	-18.37	6.78	0.040
Conventional SE NiTi vs Orthocare	16.51	7.01	0.111
RMO vs conventional SE NiTi	-1.87	6.90	1.000
Orthocare vs G&H	-1.16	6.44	1.000

[a]Dunn test. Level of significance is set at 0.05

Orthocare groups respectively ($p = 0.039$, 0.040).

Tooth alignment between upper and lower dental arches

Table III illustrates the comparison of TA between upper and lower archwires of all the studied archwire groups. There was no statistically significant difference was found for the extraction cases. For the non-extraction cases, however, statistically significant differences were found between the upper and lower archwires in RMO ($p = 0.037$) and Orthocare groups ($p = 0.048$).

Coating loss

A total of 135 archwires were assessed for coating loss. Table IV shows the comparison of coating loss between the three aesthetic archwire groups. For extraction cases, RMO had the highest coating loss (25.3%, CI 19.3-33.4) whereas the Orthocare group had the lowest value (17.5%, CI 15.9-26.9). The results for the non-extraction cases demonstrated the highest coating loss was found in the Orthocare group (27.2%, CI 13.2-22.9) whereas the lowest value was found in the RMO group (18.0%, CI 16.9-37.5). Both analyses indicated that there was no statistically significant difference between the archwire groups for both extraction and non-extraction cases respectively ($p = 0.251$, 0.179).

Table III: Comparison of TA between upper and lower archwires for each group

Archwire group	TA change Median ± IQR		*Z* statistic[a]	*p* value[a]
	Upper	Lower		
Extraction cases				
RMO	6.2 ± 5.80	4.8 ± 8.00	-0.89	0.375
G&H	4.2 ± 5.90	3.3 ± 5.30	-1.08	0.279
Orthocare	5.4 ± 5.60	5.6 ± 6.20	-0.11	0.910
Conventional SE NiTi	6.5 ± 5.50	3.5 ± 5.50	-1.48	0.139
Non-extraction cases				
RMO	1.5 ± 1.18	1.0 ± 0.60	-2.08	0.037
G&H	4.2 ± 3.10	2.3 ± 2.40	-1.36	0.172
Orthocare	3.9 ± 3.60	1.0 ± 1.80	-1.97	0.048
Conventional SE NiTi	2.5 ± 2.70	0.5 ± 1.20	-1.16	0.248

[a]Mann-Whitney U test

Table IV: Percentage of coating loss between three aesthetic archwires

Archwire group	n	Coating loss, %		95% CI for Mean		χ^2 statistic[a] (*df*)	*F* statistic[b] (*df*)	*p* value
		Mean ± SD	Median ± IQR	Lower	Upper			
Extraction cases								
RMO	22	-	25.3 ± 19.70	19.3	33.4	2.76 (2)	-	0.251[a]
G&H	28	-	25.0 ± 21.33	21.0	31.9			
Orthocare	34	-	17.5 ± 20.36	15.9	26.9			
Non-extraction cases								
RMO	16	18.0 ± 9.06	-	16.9	37.5	-	1.78 (2, 48)	0.179[b]
G&H	20	23.5 ± 12.22	-	17.7	29.2			
Orthocare	15	27.2 ± 18.56	-	13.2	22.9			

[a]Kruskal-Wallis test. Data shows distribution to the left.
[b]One-way ANOVA test

Coating loss between the upper and lower archwires

Table V shows the comparison of coating loss between upper and lower dental arches in all three studied groups. The coating loss of the lower archwires in most of the groups (RMO and Orthocare for extraction cases; G&H and Orthocare for non-extraction cases) was higher than the upper counterparts, despite not statistically significant ($p > 0.05$).

DISCUSSION

Dental and facial appearance is one of the patients' main concerns when seeking orthodontic treatment. This has contributed to an increased demand for aesthetic appliances and auxiliaries. However, most fixed orthodontic appliances and their components are made

Table V: Comparison of coating loss between upper and lower archwires among the aesthetic archwire groups

Archwire group	Percentage of CL Mean ± SD		*Z* statistic[a]	*p* value[a]
	Upper	Lower		
Extraction cases				
RMO	26.3 ± 18.13	26.5 ± 14.14	-0.10	0.922
G&H	27.1 ± 15.62	25.8 ± 12.97	-0.05	0.963
Orthocare	21.2 ± 16.92	21.5 ± 15.05	-0.22	0.823
Non-extraction cases				
RMO	18.5 ± 7.48	17.6 ± 10.93	-0.32	0.753
G&H	18.3 ± 10.31	28.6 ± 12.23	-1.81	0.070
Orthocare	24.3 ± 22.41	29.8 ± 15.58	-0.69	0.487

[a]Mann-Whitney U test

of stainless steel or titanium which gives metallic and silver colour (18). This issue has been addressed by the emergence of aesthetic appliances such as ceramic or composite brackets, which have been widely accepted by the patients (22).

This study evaluated the aesthetic properties of three different commercially available orthodontic archwires. Different incubation periods were completed with ± 57 days, because most archwires during clinical used with this time range, although archwires can be used less or more than this period.

The clinical performance of an orthodontic coated archwire is determined by how much the coating remains adhered to the underlying core archwire. The durability of the coating is important to be reported as it will help clinicians to justify treatment based on scientific evidence, and not just by manufacturer's claim. Often, these archwires are more expensive than their uncoated counterpart and therefore there is even more need for the justification for this increased cost.

From this study, the highest mean of alignment reduction for the extraction cases was 6.1 mm, respectively, over a period of eight week. This amount was translated to 0.109 mm per day which is not much different to what have been reported previously that an average alignment rates for a coated archwire was 0.05 mm whereas for a copper NiTi, the average alignment rate was 0.135 mm per day (23, 24). Another study showed comparable results of 4.03 mm of reduction in irregularity after eight weeks of an uncoated 0.014-in NiTi wire (25). This study closely matches the average reduction in irregularity observed in our trial for the extraction cases. The current study agreed with the more recent study of Ulhaq, Esmail (26) who also found their reduction in the alignment of a coated archwires was 4.5 mm over a two months period, which translates to 0.08 mm per day. These support our finding that there was no significant difference between the four treatment groups in terms of alignment change for extraction cases in which the alignment effect is influenced by the presence of extraction space.

In the non-extraction cases, the highest mean of alignment reduction was achieved by Orthocare archwire group, which was 3.7 mm and the group with the lowest mean was the partially coated RMO archwires. Orthocare group was the archwires that were fully coated with PTFE polymer. PTFE polymer has been proven to have a more stable coating when exposed to the oral environment and can withstand various degree of salivary pH (27). A statistically significant difference was detected and post hoc multiple pairwise comparison was performed to determine the significant group. The result revealed that the RMO archwire group demonstrated a statistically significantly low alignment change when compared to G&H and Orthocare groups. As the coating polymer only partially coats the labial segment for aesthetic purposes, the rests of the core SE NiTi is exposed. This has led to increased friction during alignment as SE NiTi is known for its high friction (28). Nevertheless, Abdelrahman, Al-Nimri (29) reported that no statistically significant difference in the alignment change was found between three different types of non-coated archwires (conventional, superelastic, and thermoelastic NiTi wires) used in their study during the initial alignment stage.

TA between the upper and lower dental arches was insignificant in the extraction cases, yet, in the non-extraction cases, the RMO and Orthocare groups consistently demonstrated significant alignment change in the upper arch than in the lower. The upper brackets have increased interbracket distance than the lower, which is associated with relatively higher load-deflection property and reduced friction. This is confirmed by previous study which assessed the influence of load deflection and friction between various bracket-archwire load on different bracket designs (30). This is supported by West et al. (31) which showed that improved properties of SE NiTi are associated with increase in alignment in the lower arch which has reduced interbracket distance. However, this finding is not supported by Cobb et al. (32) who found more alignment change to occur in the lower arch regardless of the archwire type.

In this preliminary study, total amount of coating loss was assessed instead of comparing coating loss between the anterior and posterior segments as we are interested in the coating durability rather than its relation to aesthetics. RMO archwires was found to have the highest coating loss in extraction cases. The partial coating could have been easily detached from the core archwires than the full coating when being exposed to tooth brushing particularly in the extraction region. This warrants further investigation. In the non-extraction cases, however, the Orthocare group, which is fully coated with the PTFE showed the highest coating loss. It was reported that the PTFE coating had highly significant increase in the number of corrosion pits as

compared to epoxy resin coated stainless steel wires at different intervals, this is because the PTFE layer adds minimal thickness to the archwire while the epoxy resin coating does add more significant thickness to the archwire. This result agrees with other previous studies (33, 34).

The present study also revealed there were no statistically significant differences in coating loss between upper and lower archwires. Lower archwires experienced lower coating loss than the upper. This was similar to the results reported by the previous study (26) which showed that the coating losses was more in the mandibular arches.

CONCLUSION

Statistically significant difference was found between the four types of archwires in terms of alignment change in the non-extraction cases. Orthocare and RMO groups showed significantly highest and lowest alignment change, respectively. Both RMO and Orthocare groups also demonstrated significantly better alignment in the upper arch than the lower counterpart as in the non-extraction cases. Coating loss was highest in the RMO group for the extraction cases and Orthocare group for the non-extraction cases, with lower arch showed higher coating loss than the upper, despite no significant differences were found.

ACKNOWLEDGEMENTS

This research was funded by Universiti Sains Malaysia Short Term Grant (304/CIPPT/6315069). We would like to thank all dental technicians at Dental Technology Laboratory (Advanced Medical & Dental Institute), Dr Tengku Sharihan Tengku Shariffuddin, owner of Desa Murni Dental Clinic and all her staff, dental officers, therapists and nurses from Advanced Medical & Dental Institute and School of Dental Sciences.

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