RANDOMISED CONTROLLED TRIAL OF COATED ARCHWIRES: EFFECT OF COATING TYPES AND RANGE ON TOOTH ALIGNMENT, COATING LOSS, PERCEIVED COLOUR CHANGE, AND PATIENT PERCEPTION

Anis F. Kamaruddin[1], Hassanin A. A. Alyassiri[1], Khoirulzariah Ismail[1], Noorayuni A. Shafiai[1], Norma Ab Rahman[2], W.M. Amir W. Ahmad[2]

[1]Craniofacial & Biomaterial Sciences Cluster, Advanced Medical & Dental Institute, Universiti Sains Malaysia
[2]School of Dental Sciences, University Sains Malaysia (Health Campus)

Abstract

Background: From the literature, coated archwires are associated with disadvantages such as lack of coating strength, surface roughness, and colour change. However, little is known whether types of coating polymers and range of coating (fully/partially coated) affect the clinical and surface performance of these archwires. **Objectives:** To investigate the effect of the coating types and range of coating on tooth alignment change, coating loss, perceived colour change, and patient perception between three different coated archwires. **Design and Methods:** This prospective, multi-centre, double-blind, randomised clinical trial (RCT) involving 134 participants who were randomly allocated (ratio 1:1) using block randomisation (eight/group) to receive one of these 0.014" superelastic nickel-titanium (SE NiTi) archwire interventions in both dental arches: (1) polytetrafluoroethylene (PTFE)-partially coated (RMO FLi®), (2) PTFE-fully coated (Orthocare Euroform® Cosmetic), (3) epoxy resin (epoxy)-fully coated (G&H G4), and (4) uncoated (3M Unitek) which served as control. The archwires were ligated during bonding. After eight weeks of use, the archwires were collected and photographed, dental impressions were taken, and questionnaires were answered. Outcome measures were tooth alignment change, percentage of coating loss, amount of perceived colour change, and patient perception. The trial was ended in the dental arches related to archwire fracture and treatment was continued as planned. **Results:** 115 participants completed the trial. Six coated archwires (2.59%) had fractured, and related dental arches were excluded from the analyses. A total of 224 dental arches (n = 224), 172 archwires (n = 172), and 89 questionnaires (n = 89) were analysed. Statistically significant difference (p = 0.014) was found in the % of tooth alignment change and perceived colour change (p <.0001). PTFE-partially coated archwires was identified as the influential group. No statistically significant difference was found for both coating loss, perceived colour change, and patient perception. **Conclusion:** PTFE-partially coated aesthetic archwires showed significant alignment change and perceived colour change when compared to the PTFE-fully coated and epoxy-fully coated aesthetic archwires. However, the types of coating and coating range did not significantly affect the coating loss and patient perception. **Trial registration:** This RCT was registered with ClinicalTrials.gov (Registration number: NCT03876184).

Research Background

Coating the conventional orthodontic archwires with tooth-coloured polymers complements the aesthetic brackets. It maximises patients' aesthetics during treatment. The tooth-coloured polymers like epoxy resin, PTFE, silver-palladium, and rhodium-implanted, are used as the coatings. These coatings decrease the friction between brackets and archwires which is a desirable characteristic when the required friction coefficient is low, for example, in tooth retraction (Pacheco et al., 2012). However, *in-vitro* research have reported that under prolonged exposure in the oral cavity, the coated archwires undergo ageing, which subsequently causes underneath metal exposure, coat splitting, and discolouration (Elayyan et al., 2008; da Silva et al., 2013). Partial or complete loss of the coating damages the aesthetic and physical properties, resulting in poor archwire performance and may affect patient satisfaction. To date, little is known whether different types of coating polymers and the coating range (partially/fully coated) can affect the clinical performance, surface quality, and patient perception. It is postulated that the types of archwires and coating range do not influence the tooth alignment, amount of coating loss, coating discolouration, and patient perception.

Objectives of Study

To investigate the effect of the coating types and range of coating on tooth alignment change, coating loss, perceived colour change, and patient perception between three different coated archwires.

Methodology

1) Ethical approval

The ethical approval was obtained from The Human Research Ethics Committee of Universiti Sains Malaysia on 8th June 2017 (USM/JEPeM/17010022).

2) Sample Size Calculation

PS software (Dupont & Plummer, 1997) was used with the power = 80%, alpha = 0.05, SD = 1.3 (Sebastian, 2012) and with anticipation of 10% dropouts, 132 subjects* are needed to detect the estimated difference of 1 mm of change in tooth alignment.

3) Inclusion & Exclusion Criteria

Inclusion criteria	Exclusion criteria
▪ 11 years old and above, requiring treatment with upper and lower pre-adjusted edgewise bracket system ▪ Able to give consent ▪ No history of orthodontic treatment before	▪ Craniofacial syndromes, medical problems or medications that can influence tooth movement ▪ Ectopic teeth not allowing bracket placement and hypodontia

4) Outcome measures

Primary	Percentage of tooth alignment change after 8 weeks of intraoral use.
Secondary	Percentage of coating loss, amount of perceived colour change, patient perception towards coated archwires after 8 weeks of intraoral use.

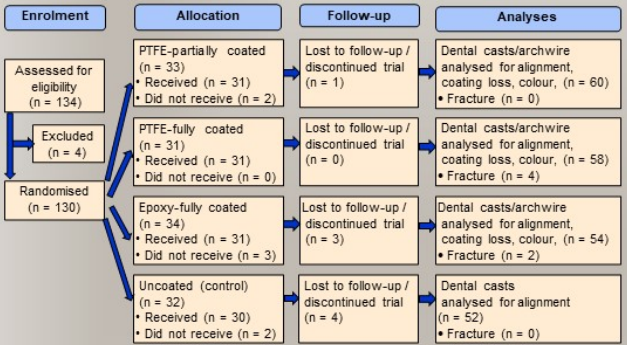
5) Intervention

Participants randomly selected the archwires which were sealed in coded, opaque white envelopes before bonding.

→ At 4 weeks of review, the archwires were retied. Any fractured archwire was removed and recorded. Trial was discontinued in the affected arch.

→ At 8 weeks of review, the archwires were collected, disinfected, and returned to the allocated envelope. Upper and lower impressions were taken. Modified oral aesthetic subjective impact scale (OASIS) questionnaires (Mandall, 2000) were answered by the participants in the coated archwire groups. Trial ended.

6) Trial flow chart



7) Data collection & analyses

The difference in the tooth alignment was measured using method as described by Little (1975) using pre- and post-intervention study models. Percentage of alignment change was recorded. For coating loss and colour change, the archwires were photographed and measured using set-up as described by Ulhaq et al. (2017). The ΔE values (perceived colour change) were calculated using CIE2000 calculator (https://cielab.xyz/pdf/CIE_dE_2000.xls). The questionnaires scores were calculated for positive and negative perception. All data were analyzed using SPSS version 24.

Results

1) Tooth alignment change

Table 1: Mean percentage of tooth alignment change between coated and control archwires

Archwire Group	n	% of alignment change Mean ± SD	95% CI for mean Lower	95% CI for mean Upper	F statistic[a] (df)	p value[a]
PTFE-partially coated*	60	77.1 ± 20.71	71.8	82.5	3.63 (3, 220)	0.014
PTFE-fully coated	58	68.7 ± 22.95	62.6	74.7		
Epoxy-fully coated	54	63.7 ± 26.55	56.4	70.9		
Uncoated SE NiTi	52	74.0 ± 23.23	67.5	80.4		

[a]One-way ANOVA. *Mean % are significantly different by post-hoc comparison (Scheffe test).

2) Coating loss

Table 2: Mean percentage of coating loss between coated archwires

Archwire Group	n	% of alignment change Mean ± SD	95% CI for mean Lower	95% CI for mean Upper	F statistic[a] (df)	p value[a]
PTFE-partially coated	60	27.8 ± 15.59	23.7	31.8	2.01 (2, 169)	0.137
PTFE-fully coated	58	33.4 ± 15.78	29.3	37.6		
Epoxy-fully coated	54	32.0 ± 16.41	27.5	36.5		

[a]One-way ANOVA

3) Perceived colour change

Table 3: Perceived colour change between coated archwires

Archwire group	n	Perceived colour change Mean (SD)	Min	Max	F statistic[a] (df)	p value[a]
PTFE-partially coated*	60	7.91 (2.555)	2.02	11.82	15.97 (2, 169)	< .0001
PTFE-fully coated*	58	6.44 (2.750)	1.01	12.66		
Epoxy-fully coated*	54	5.02 (2.866)	1.59	14.22		

[a]One-way ANOVA. *All 3 pairs of mean scores are significantly different by post-hoc comparison (Scheffe test).

4) Patient perception

Table 4: Association between patient perception and coated archwires

Archwire group	n	Positive perception Freq (%)	Negative perception Freq (%)	X^2 statistic[a] (df)	p value[a]
PTFE-partially coated	30	20 (66.7)	10 (33.3)	1.57 (2)	0.457
PTFE-fully coated	31	25 (80.6)	6 (19.4)		
Epoxy-fully coated	28	20 (71.4)	8 (28.6)		

[a]Chi-square test

Discussion

- One-way ANOVA (Table 1) showed significant change (p = 0.014) in tooth alignment. The Scheffe's post-hoc multiple pairwise comparison identified the PTFE-partially coated archwires as the influential group (p = 0.026) when compared to PTFE-fully coated and epoxy-fully coated archwires, with mean percentage of tooth alignment change of 77.1% (mean reduction of 5.92 mm).
- This finding is slightly higher than what was reported by the previous RCT in the UK. The alignment reduction was 4.5 mm over 8 weeks of use (Fully coated, Titanol® Cosmetic, Forestadent). Nonetheless, it is not significantly different than other studied archwires (Ulhaq et al., 2017). In this study, the types of coating polymer of these archwires were not mentioned.
- The PTFE-partially coated archwires allows more forces from the core NiTi wires to be delivered to the teeth because of the partial coating on the labial surface. Moreover, this type of archwires showed minimal coating loss (27.8 %) compared to other types of coated archwires (Table 2).
- The association of the coating loss to force delivery was discovered by Elayyan et al. (2008). They reported that the coating loss causes increased surface roughness which occurs following prolonged intraoral exposure and mechanical abrasion from the activity near the bracket-archwire interface, leading to low force delivery which in turn affect the orthodontic tooth movement. The PTFE-coated archwires had been shown to have lower friction than the uncoated archwires and has the potential to reduce resistance to sliding of orthodontic archwires (Farronato et al., 2012).
- Aesthetically, Table 3 showed that all coated archwires demonstrated significant perceived colour difference than their unused counterparts (p < .0001), with PTFE-partially coated archwires exhibited the highest perceived colour difference (ΔE: 7.91 – a very obvious difference) and the epoxy-fully coated archwires exhibited the least perceived colour difference (ΔE: 5.02 – an obvious difference). Previous laboratory study also confirmed that the archwires coated with the PTFE had a higher intense level of colour changes than the epoxy resin after 21 days of immersion in staining solution (Rego et al., 2017).
- Table 4 illustrated the patient perception towards the coated archwires after eight weeks of use. The highest positive perception was found in PTFE-fully coated, followed by epoxy-fully coated, and PTFE-partially coated archwires. There was no statistically significant difference was found between all groups (p = 0.457). Bradley et al. (2014) also reported that patients found the amount of coating loss of the aesthetic archwires is undesirable as patients find it noticeable.

Figure 1: Example of partially (left) and fully (right) coated archwires after eight weeks of intraoral exposure

Conclusion

The types of coating and coating range have a significant effect on tooth alignment and perceived colour change, but not on the coating loss and the patient perception. PTFE-partially coated archwires were significantly associated with tooth alignment change and highest colour change.

Further Recommendation

More RCTs should be carried out to compare the performance of coated archwires on ceramic brackets brackets with stainless steel brackets.

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