ORIGINAL ARTICLE

Preliminary Result of Randomised Controlled Trial of Three Different Coated Archwires Part 2: Colour Change and Patient Perception

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ABSTRACT

Introduction: Coated archwires improve aesthetics because of the tooth-coloured appearance. However, colour change of the coated archwires have been reported in vitro. Nonetheless, little is known to what extent this colour change occurs clinically. This second part of the multi-centre, double-blind, randomised controlled trial evaluated the colour change (ΔE*) of three coated archwires with their controls and patient perception. **Methods:** 84 patients who received treatment with upper and lower fixed appliance treatment were invited. Consented patients were randomised to receive one of four treatment interventions using 0.014" superelastic nickel-titanium archwires from (1) Orthocare (2) RMO (3) G&H, and (4) 3M Unitek® uncoated. These archwires were ligated during bonding and collected after 8th week. After removal, the digital images of the archwires were assessed for colour change using Adobe® Photoshop® software, and the CIE L*a*b* system was used to calculate the ΔE* values. Patient perception was measured using oral aesthetic subjective impact scale (OASIS) questionnaire. **Results:** For colour change and patient perception assessment, 132 archwires from 66 participants who had been treated with aesthetic archwires were collected. Two fractured archwires were excluded. Initial analysis revealed all three aesthetic archwires groups showed significant mean of ΔE* with the highest was found in Orthocare (23.9), and the lowest is G&H (16.8). Post hoc comparison revealed statistically significant mean of ΔE* in Orthocare when compared with other groups ($p < 0.001$). There was no statistically significant difference for patient perception between archwire groups. **Conclusion:** Preliminary results revealed that significant ΔE* in Orthocare group and patients showed positive perception following clinical use.

Keywords: Aesthetic archwires, Colour change, Patient perception, CIE L*a*b*

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INTRODUCTION

The main concern with aesthetic archwire for patient is the maintenance of 'tooth-coloured' coating. The colour of the coated archwire might be easily exposed to damage in the oral cavity due to mastication and enzymes activity. This may lead to delamination of the coated archwire and may impair the aesthetic properties of archwire thereby interfering with the patient's satisfaction (1). The colour of the coated archwire often changes as time goes on, followed by splitting of the coat and exposing the underlying metal in the oral cavity. It is very essential for aesthetic appliances and archwires to retain their colour as any staining and colour change would affect patients' acceptance and subsequently compromise patients' cooperation during treatment. The ideal colour for aesthetic appliances and archwires should be the equal of tooth enamel colour.

This has contributed to the increased demand for aesthetic orthodontic treatment modalities. This trend is understandable because patients hope for improved appearance provided by the aesthetic archwires. Bradley et al (2) evaluated perception of 61 patients following the treatment with the aesthetic archwires and reported that the coating loss is noticeable in the majority of the patients. Discolouration of aesthetic archwires is induced by internal and external causes (3). Colour assessment is an important determinant in the field of orthodontic research (4) in which it can be carried out using two different methods (5). The first method is known as subjective method as it is done by grading the intensity of the staining visually using a non-parametric rank and is assessed by independent observers. This is useful in measuring the colour stability of a material, however, the downside of this method is the risks of bias often found with human observer as

it is influenced by physiological factors such as age, eye conditions and also experience (6). The second method involves the use of colour measurement device and is called objective methods. The advantage of this method is quantification of the staining which can be determined using instruments such as optical devices, digital photography technology, and computer, which is important in scientific research reporting. With the leap in the technology of digital photography, the digital camera has been become a gold standard method and widely used by dental practitioners and researchers to capture good clinical image quality (7).

CIE L*a*b* assessments done on digital images taken using digital single lens reflex (DSLR) photography have been demonstrated to show strong correlation when compared to spectrophotometer readings for all colour axes and shades (8). This provides easier method to clinicians to carry out colour assessment and rectifies issues encountered with the use of spectrophotometry. Moreover, other factors such as experimental set-up, lighting quality, type of specimen and assessor variability also influence the accuracy of colour assessment, and not just error that arises from a single method (9). Commercially available digital cameras have been assessed for accuracy. Wee et al showed that DSLR cameras provide accurate image details when proper calibration protocol is used in assessing colour which is essential in dentistry (10).

Visual perceptibility is related to the ability of human eye to detect even the slightest colour differences in any objects. A small difference in colour can be clinically accepted despite being detectable by the human eye. For example, research has shown that half of the time, the non-dental materials show colour change about $\Delta E = 1$, however, this is untrue for dental materials as they often show colour readings which is beyond the range for tooth colours (11). About half of the assessors considered that colour difference that is equal to or more than 3.3 ($\Delta E > 3.3$.) for a sample is unacceptable. Nonetheless, due to variations in the photography set-up, lightings, and inter-assessor variability, the actual acceptable value for colour change is still debatable.

First part of the study reported on tooth alignment and coating loss of aesthetic archwire. The study continues with the second part of the preliminary study of a multi-centre, double-blind, randomised controlled trial, which aimed to report the initial findings on colour change (ΔE^*) in each L*a*b* component, within each group, and between the three coated archwires available commonly in the market and their controls, the inter-bracket distance factor, and patient perception towards them.

MATERIALS AND METHODS

This multi-centre, double-blind, randomised controlled trial is carried out at (1) Orthodontic Specialist Clinic, Advanced Medical & Dental Institute (AMDI), (2) Orthodontic Specialist Clinic, School of Dental Sciences (PPSG), USM, and (3) Desa Murni Dental Clinic (KPDM). This trial is now recruiting a total of 132 patients in which at the time of this preliminary reporting, 84 patients had completed the trial. Out of 84 patients, 66 of them who received intervention with the following aesthetic archwires were included for colour change and patient perception assessments; (1) RMO FLi® Tooth-coloured SE NiTi upper and lower round 0.014", (2) G&H G4 Tooth-coloured SE NiTi upper and lower round 0.014", and (3) Orthocare Euroform® Cosmetic Tooth-coloured SE NiTi upper and lower round 0.014". The unused counterparts of these archwires were used as controls.

The sample size calculation, sampling criteria, randomisation, allocation concealment, and outcome measures were explained in detail in the part one of this preliminary report. Patients were invited to participate in the study on the day of bonding. Consented patient picked the envelope containing the archwires randomly and archwires were ligated with elastomeric ligatures. At fourth week of follow-up, the same archwires had been retired. In case of fracture of the archwire, the fractured wire was recorded, disinfected and placed in the allocated envelope. The fractured wire would be replaced with conventional archwire and treatment continues. At eighth week of follow-up, the studied archwires were collected, disinfected, dried and placed back in the allocated envelope. The teeth were tied with suitable conventional archwires and treatment continues as planned. Participants answered the OASIS questionnaire. The questionnaire was adopted from Mandall et al. (12) and the word 'appearance' in each question was modified to 'archwires'.

Prior to capturing digital images of the archwires, an archwire holder made of acrylic resin was customised and embedded with one molar tube on each end (Fig. 1). Each archwire was placed in the acrylic archwire holder and the photography of the archwires were done under a photographic set-up as described by Ulhaq et. al (13). Despite some reflection was noted from the exposed core SE NiTi archwires, it did not affect the colour measurement as the measurements were done on the coatings.

Data collection

Colour change

The colour measurement was carried out using the L*a*b* slider tool found on Adobe® Photoshop® Creative Suite 6 software (Adobe Systems Inc., San Jose, CA, USA) on the digital images based on CIE L*a*b* system which is internationally recognised scale. The L*a*b* values were measured at three different points on the surface of the coating for each archwire. The location of the three points were standardised using a grid reference.

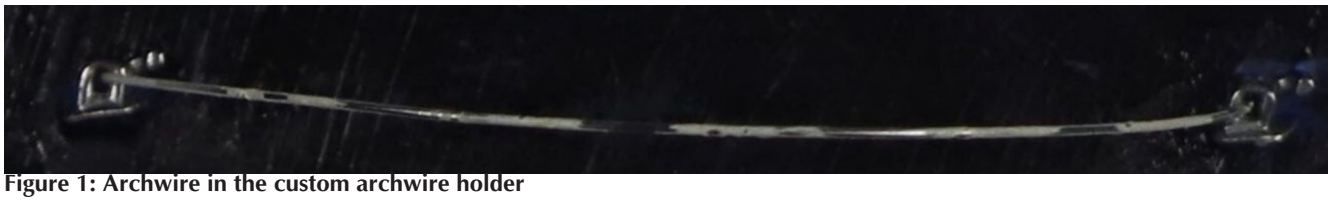

Figure 1: Archwire in the custom archwire holder

From these three readings, the mean of these values was obtained and recorded. The difference of the colour (ΔE*) was calculated by subtracting the mean values to the L*a*b* values measured on the unused archwires which acted as control.

The mean of these values was used to calculate the difference between the respective unused archwire to determine the ΔE* using the following CIE76 formula which is, $\Delta E^* = \sqrt{[(L2^* - L1^*)2 + (a2^* - a1^*)2 + (b2^* - b1^*)2]}$, where L*, a*, b* is the colour difference in CIE L*a*b* colour space. According to the definition, the L* component indicates the lightness coordinate whereas the a* indicates the red/green coordinate in which a positive value of a* (+a*) shows the redness and a negative value of the a* (-an*) shows the greenness. A positive b* component (+b*) indicates yellowness and a negative value of b* (-b*) indicates blueness.

Patient perception

Participants were given a set of questionnaires at eighth week after the archwires were removed. This questionnaire was answered by scoring one out of seven scales and collected on the same day. The OASIS scores were summed and analysed for the mean and standard deviation (SD). The perception was divided into positive (OASIS < 14) and negative (OASIS > 14).

Data analysis

Data was manually entered to a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) spreadsheet and then analysed using statistical software SPSS version 24 (IBM Corp, Armonk, New York). The analyser 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.

Reliability measurements

For colour change measurement, consistency in repeated measurements within one single examiner is crucial. No inter-examiner comparison was made to reduce measurement bias because of the measurement location that can vary widely. The intra-examiner calibration was repeated by taking ten measurements within two weeks apart from the first measurement. The reliability was analysed using intraclass correlation coefficient (ICC).

Ethical approval

Ethical approval was reviewed and approved by the The Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM USM), before the trial was commenced (USM/JEPeM/17010022).

Trial progression

The RCT is currently ongoing at the three centres. The results presented in this article are the preliminary analysis of the archwires that have been collected after completion. The flow chart of the study was presented in the part one of the articles.

RESULTS

Reliability of measurement

ICC score for intra-examiner reliability is 0.960 which indicates excellent consistency in repeated measurement within one single examiner.

Colour change

A total of 132 archwires were obtained from 66 participants who were assigned to intervention using aesthetic archwires. Because two archwires (one upper and one lower) were excluded due to fracture, the total archwires that were analysed were 130 archwires (n = 130).

Comparison of L*a*b* component between groups

Tables I shows the pre and post-intervention comparison between L*a*b* parameters for each group. There is a significant change on ΔL* parameter between groups ($p < 0.001$) whereas Δa* is only significantly different in RMO group ($p = 0.003$) and Δb* is significantly different

Table I: Paired t-test illustrating the comparison between L*a*b* parameters in all aesthetic archwire groups.

Archwire group	Component	Pre-intervention mean	Post-intervention mean	Mean difference, Δ (95% CI)	t statistic (df)	*p* value
		Mean (SD)	**Mean (SD)**			
RMO (n = 38)	L*	92.00 (0)	72.49 (4.501)	19.51 (18.03, 20.99)	26.72	< 0.001*
	a*	-1.00 (0)	-1.71 (1.403)	0.71 (0.25, 1.17)	3.12	0.003*
	b*	2.00 (0)	5.48 (3.314)	-3.48 (-4.57, -2.39)	-6.48	< 0.001*
G&H (n = 48)	L*	77 (0)	60.70 (8.713)	16.30 (13.77, 18.83)	12.96	< 0.001*
	a*	-1.00 (0)	-0.92 (0.908)	-0.08 (-0.35, 0.18)	-0.64	0.528
	b*	4.00 (0)	3.74 (2.577)	0.26 (-0.48, 1.01)	0.71	0.482
Orthocare (n = 44)	L*	83 (0)	59.12 (8.844)	23.83 (21.14, 26.52)	17.88	< 0.001*
	a*	-2.00 (0)	-1.74 (1.179)	-0.26 (-0.62, 0.10)	-1.45	0.154
	b*	12	10.55 (1.982)	1.45 (0.84, 2.05)	4.84	< 0.001*

*statistically significant at α = 0.05

in RMO and Orthocare ($p < 0.001$).

Comparison of ΔE* between groups

Table II shows the comparison of ΔE* values between the three studied archwire groups. The ΔE* values were calculated from the difference of ΔL*a*b* between the used and used and the unused counterparts that acted as control for this measurement. The Orthocare aesthetic archwires have the largest mean of ΔE* (23.9) following the eight weeks duration of clinical use and the G&H archwires have the lowest mean value (16.8).

Scheffe's multiple comparisons of means test was used in the the post-hoc analysis. From the comparisons, there was no significant difference between RMO and G&H. However, the colour difference for the mean ΔE* is found to be significant for G&H and Orthocare ($p < 0.001$).

Table II: Comparison of ΔE* values between the three aesthetic archwire groups.

Archwire group	*n*	Colour change, ΔE*			*F* statistic[a]	*p* value[b]
		Mean (SD)	Min	Max	(df)	
RMO	38	20.1 (4.31)	13.38	29.34	10.65	< 0.001
G&H	48	16.8 (8.14)	3.78	28.38	(2, 127)	
Orthocare	44	23.9 (8.76)	2.15	38.18		

[a]One-way ANOVA test
[b]Only Orthocare-G&H pair is significantly different by post-hoc Scheffe test

Effect size of ΔL*a*b* and ΔE* between paired groups

The effect size is represented by partial eta squared, ŋp2. Tables III displays the effect size and statistical significance between the archwire pairs which an indicator for clinical importance.

Table III: The effect size between pairs ΔL*Δa*Δb* and ΔE*

Dependant variable	Sum of Squares		Mean square	F (df)	p value	η_p^2
	Sum of effect	Sum of corrected total				
ΔL*	1307.45	8988.19	653.73	10.81 (2, 127)	< 0.001	0.145
Δa*	21.39	192.85	10.70	7.922 (2, 127)	0.001	0.111
Δb*	532.20	1419.68	266.10	38.08 (2, 127)	< 0.001	0.375
ΔE*	1195.18	8323.42	597.59	10.65 (2, 127)	< 0.001	0.144

Comparison between upper and lower archwires

Table IV illustrates the comparison of ΔE* values between upper and lower archwires in the three studied archwire groups. The upper archwires showed relatively higher mean of ΔE* following the eight weeks duration of clinical use compared to the lower counterparts. However, there is no statistically significant difference was found ($p > 0.05$).

Patient perception

Out of 68 questionnaires that were collected, only 62 were analysed as the other six were excluded because of incomplete answer. Table V shows the descriptive analysis of OASIS score between the three archwires. In all three groups, more than 70% of participants showed OASIS score of 14 and less.

Table IV: Comparison of colour change between upper and lower archwires for each group

Archwire group	Colour change, ΔE* Mean (SD)		Mean difference, Δ (95% CI)	t statistic (df)	p value[a]
	Upper	Lower			
RMO	20.31 (4.568)	20.04 (4.278)	0.27 (-2.64, 3.18)	0.19	0.853
G&H	17.00 (8.649)	16.61 (7.803)	0.39 (-4.40, 5.18)	0.16	0.870
Orthocare	24.53 (9.271)	23.51 (8.405)	1.02 (-4.37, 6.40)	0.38	0.705

[a]Independent t test

Table V: Descriptive analysis of OASIS score in three groups.

Archwire group	*n*	OASIS score			*F* statistic[a]	*p* value
		≤ 14 in %	> 14 in %	Mean (SD)	(df)	
RMO	18	83.3	16.7	11.78 (4.609)	1 (2, 59)	0.373
G&H	23	78.3	21.7	11.09 (6.037)		
Ortho-care	21	76.2	23.8	13.14 (3.410)		

[a]One-way ANOVA test

DISCUSSION

In colour assessment, the preliminary result revealed a statistically significant difference was found for L* component in all archwire groups with Orthocare showed the highest mean difference. This indicates that all archwires became darker following intraoral use and Orthocare group had the darkest colour change. For a* component, only RMO showed significant colour change in which, given by the positive Δa* value, the colour showed more redness. For b* component, only RMO and Orthocare groups showed significant colour change. The negative and positive Δb* value in RMO and Orthocare indicated that the colours showed more blueness and yellowness respectively. The difference in each L*a*b* component is important as it could reflect the underlying chemical reaction of certain coating polymer materials towards certain colour hue. G&H group showed good colour stability. This is also evident by the overall colour change, ΔE*. Orthocare group has been shown to show significant overall ΔE*. These early finding is so far in line with other previous studies. Noori and Ghaib (14) did an in-vitro study of colour stability by immersing aesthetic archwires into a staining solution (tea media) over a 21-day period which yielded significant colour changes in the archwires. This result also agrees with da Silva, Mattos (3) who reported that all the six aesthetic archwires that were assessed for colour stability showed noticeable colour change after 21 days of use.

The effect size shows the level of importance of the significance. The effect size for ANOVA test is represented by the value of partial eta squared, ŋp2. The effect size is low if the value is 0.01 to < 0.06, medium

if the value is between 0.06 to < 0.14 and large effect size when the value is 0.14 and above. From Table III, the effect size of Δb* is the largest compared to other CIE components which shows that is clinically important. However, overall colour change, ΔE*, has small effect size which means even it is statistically significant, it is not of clinical importance.

Comparison between upper and lower archwires was made to evaluate the effect of inter-bracket distance. The inter-bracket distance in the upper arch is bigger than the lower because of the bigger size of the upper teeth. From Table IV, the overall colour change is higher in the upper archwires than the lower in all groups, but this is not statistically significant. Therefore, this early data suggests that the inter-bracket distance does not play a role in increasing the colour change.

With regards to patient perception, Table V shows in general, all participants from all groups showed positive perception towards aesthetic archwires. Nevertheless, participants belonged to Orthocare group showed the lowest percentage of positive perception (OASIS score < 14). This could be related to the significant colour change in Orthocare group. Other factors that can contribute to this is the amount of coating loss as reported in part one of this preliminary study. This finding is in agreement with Elayyan, Silikas (15) who also found after 33 days of intraoral use, 25% of the coating were lost, contributing to low aesthetics. This is also supported by Bradley, Berzins (2) who assessed reported that the studied aesthetic archwires showed a mean coating loss of 26.4% to 44.3% over a four to 12 week period of use. They also reported that patient perception was unfavourable in their study.

From this preliminary study, further research can be expanded on looking at the effect of different types of archwire coating polymer not just on alignment but also on the levelling using rectangular coated archwires. Study on bacterial adhesion also can provide information on the staining produces by bacterial end-products on the polymer surface.

CONCLUSION

The G&H group showed better colour stability than other archwires. Overall colour change was significantly found in Orthocare group, but not of clinical importance. The inter-bracket distance between upper and lower archwires did not influence colour change. Most participants showed positive perception towards all archwire groups.

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