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A randomised clinical trial of the effectiveness of 0.018-inch and 0.022-inch slot orthodontic bracket systems: Part 1. Duration of treatment

SUMMARY

Objective: To compare treatment duration between 0.018-inch and 0.022-inch slot systems and determine predictive factors.

Subjects and Methods: Eligible participants aged 12 years or over were allocated to the 0.018-inch or 0.022-inch slot MBT appliance (3M-Unitek, Monrovia, California) using block randomisation in groups of ten. Outcome measures included duration of: (1) overall treatment (2) levelling and alignment (3) working and finishing, and (4) appointment numbers and other treatment-related factors. Parametric tests (independent samples t-test) and non-parametric tests (Chi-square with Fisher's exact tests and Mann-Whitney U-test) assessed differences between groups. A multiple linear regression analysis identified factors influencing treatment duration ($P < 0.05$).

Results: Of the 187 participants randomised (1:1 ratio), 34 withdrew or were excluded (protocol deviations or poor cooperation). There were 77 patients in the 0.018-inch slot group and 76 patients in the 0.022-inch slot group (overall mean age: 19.1 years). Baseline characteristics were similar between groups ($P > 0.05$). The mean duration of treatment for the 0.018-inch and 0.022-inch slot groups was 29.3 and 31.2 months, respectively. There were no statistically significant differences between the two treatment groups in terms of treatment duration, duration of the key stages of treatment, and number of appointments ($P > 0.05$). The regression analysis revealed 33.0% of variance in treatment duration was explained by age at bonding, Class II division 2 malocclusion, number of failed appointments, number of emergency appointments, and transfer to another clinician. There were no adverse events.

Limitations: It was impossible to blind clinicians or patients to allocation and oral hygiene and periodontal outcomes were not assessed.

Conclusions: There was no statistically or clinically significant difference in treatment duration between 0.018-inch and 0.022-inch slot bracket systems. Increasing patient age, Class II division 2 malocclusion, number of failed and emergency appointments, and multi-operator treatment all increase orthodontic treatment duration.

Conflict of interest: The authors declare no conflict of interest.

Registration: The trial was registered with ClinicalTrials.gov on 5th March 2014, registration number: NCT02080338.

INTRODUCTION

Contemporary fixed orthodontic appliances, with a few exceptions, are based on Edward Angle's edgewise appliance developed in the early 20th century. (1) The slot size of the brackets was 0.022-inch \times 0.028-inch and the wires were constructed from gold alloy and sometimes with platinum or silver alloy. In the 1930s, a cheaper and stiffer alloy of chromium steel called 'stainless steel' was introduced as an orthodontic material. The clinicians were tempted soon to replace the precious alloy with stainless steel, however many of them were worried about the higher force that would be generated from the stainless steel wires and their possible damaging effect on the oral tissues. (2) The capability of these wires to generate similar forces to that of the gold wires with smaller dimensions made it logical to decrease the slot size from 0.022 \times 0.028-inch to 0.018 \times 0.022-inch. (3-5) The introduction of nickel titanium alloy archwires in the 1970s was an advance in metallurgical technology since these wires could be considered comparable to gold wires in their stiffness with less cost and thus clinicians returned to the 0.022-inch bracket slot. (3)

Both systems continue to be widely used by clinicians worldwide with claims of clinical advantages and superiority of each system. However, to date, there is no robust scientific evidence to support orthodontic treatment with either slot size in preference to the other, as all the available comparisons between the two slot sizes are flawed and are of low quality. This leaves the choice of bracket slot size as subjective. Keim et al., in their surveys in the US (1986, 1990, 1996, 2002, 2008, and 2014), found that

there was a drop in the use of the 0.018-inch slot from 49.3% in 1986 to 25.0% in 2014. This mirrored an increase in the use of the 0.022-inch slot from 50.7% in 1986 to 70.0% in 2014 (Keim et al., 2002, 2008, and 2014), whilst 0.022-inch slot brackets were more popular than 0.018-inch slot brackets throughout all these surveys. (6-8) Similarly, in the UK, Banks et al. (2010) (9) and McNamara et al. (2010) (10) have reported that the overwhelming preference is for 0.022-inch slot brackets.

Only two retrospective studies have directly compared the duration of treatment for patients treated with 0.018-inch slot and 0.022-inch slot fixed appliance systems. (11,12) Both of these studies found there was a reduction in the mean treatment time using the 0.018-inch slot system, however, these results were statistically but not clinically significant.

Another two retrospective studies indicated a possible association between the 0.018-inch slot and shorter treatment duration. (13,14) Neither study specifically investigated bracket slot sizes, furthermore, selection bias influenced their results.

Specific objectives or hypotheses

This study was designed to compare the effectiveness of orthodontic treatment with 0.018-inch and 0.022-inch slot bracket systems in a randomised clinical trial. Here we present the primary outcome of the trial which compared the two bracket slot sizes in terms of duration of alignment and overall duration of treatment and to determine the predictive factors that influence treatment duration. The null hypothesis was 'There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of time required to complete alignment and overall orthodontic treatment'. Parts 2 and 3 (15,16) report the results for quality of treatment and biological side effects of treatment, respectively.

SUBJECTS AND METHODS

Trial design and any changes after trial commencement

This was a 2-arm parallel active group randomised clinical trial with a 1:1 allocation ratio. There were no changes to the method after trial commencement.

Participants, eligibility criteria, and setting

In the UK, state-funded orthodontic treatment is provided through the NHS for patients scoring Index of Orthodontic Treatment Need (IOTN) Dental Health Component (DHC) 3 Aesthetic Component (AC) 6 and above (moderate to complex cases) by office-based Specialist Orthodontists working with a team of Orthodontic Therapists, and hospital/faculty Orthodontists trained to Consultant level who also provide competitive-entry graduate programs for Specialist and Consultant-level training. All patients referred for hospital Orthodontic care from January 2010 to September 2014 with good oral hygiene and a caries-free dentition were invited to participate in the study. The study was conducted in three sites however, one site was unable to recruit to the study and so was withdrawn, leaving two sites that contributed the participants for the study. The participants were selected according to the following criteria: aged 12 years and above with any type of malocclusion who were scheduled for dual arch fixed appliance orthodontic treatment. The exclusion criteria for the study were patients who had [1] undergone previous orthodontic treatment/functional appliances, [2] orofacial clefts, [3] severe hypodontia, [4] special needs, and [5] required orthodontic-orthognathic surgery treatment. They did not take part and were not included in any analysis. Patients who met the inclusion criteria for the study received the patient information sheet and where relevant, the parent information sheet was also issued. The consent process was completed after obtaining patient/parent assent to participate in the study.

The work was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). Ethical approval was obtained from the NHS Tayside Committee on Medical Research Ethics (East of Scotland Ethics Service) in October 2009 (REC Reference: 09/S1401/56) and Research and Development (R&D) approval was obtained from the NHS Tayside Research and Development in November 2009.

Interventions

The treatment involved initially polishing the teeth with pumice and water, and using a self-etching primer (Transbond™ Plus Self Etching Primer, 3M-Unitek, Monrovia, USA) to prepare the teeth for bracket placement. Adhesive pre-coated (APC) brackets/buccal tubes (APC™ II Victory Series™ Twin MBT™, 3M-Unitek, Monrovia, USA) were bonded according to the allocation group, i.e. either 0.018-inch or 0.022-inch slot MBT prescription. Bands were used on molars where a transpalatal arch or quadhelix was required.

A predetermined archwire sequence for each bracket slot system was followed ([HYPERLINK "http://multimedia.3m.com/mws/media/736576O/wire-selection-for-optimal-biomechanic-efficiency-dr-d-segner.pdf"](http://multimedia.3m.com/mws/media/736576O/wire-selection-for-optimal-biomechanic-efficiency-dr-d-segner.pdf)). The archwire sequence for the 0.018-inch bracket slot system was: 0.016-inch super elastic nickel-titanium, 0.016 × 0.022-inch super elastic nickel-titanium, and 0.016 × 0.022-inch stainless steel archwires. For the 0.022-inch bracket slot system, the sequence was: 0.016-inch super elastic nickel-titanium, 0.019 × 0.025-inch super elastic nickel-titanium, and 0.019 × 0.025-inch stainless steel archwires. Appliances were routinely adjusted at an interval of 6-8 weeks. All appliances were ligated using conventional elastomeric ligation unless stainless steel ligatures were required for severely rotated or ectopic teeth. All the participants received a standard treatment regime according to the treatment protocol throughout the trial. Extraction spaces were closed using sliding mechanics with closed coil springs or elastomeric chains. Minor deviations from the standard protocol were accepted for certain clinical circumstances (e.g. use of “piggy back” wires), but no special techniques or additional appointments were required for the study. Appliances were debonded and retainers provided when a Class I incisor and canine relationship, a well interdigitating buccal segment relationship and all other treatment goals had been established. Prematurely terminated cases were due to poor patient compliance.

Periapical radiographs with a long cone paralleling technique for the maxillary central incisors were taken at the start of treatment and after nine months from the start of treatment. In addition, digital lateral cephalometric radiographs were taken at the start and near end of treatment (by the end of the finishing stage of treatment) [UK orthodontic radiography guidelines by Isaacson et al. (2008) (17), updated by Isaacson et al. (2015) (18)].

Outcomes and any changes after trial commencement

The primary outcome measure in this study was total orthodontic treatment duration. The duration of the levelling and alignment stage, the duration of the working and finishing stage, the number of appointments as well as the factors that influenced treatment duration were also investigated. During treatment, any appliance breakage was resolved by scheduling an emergency appointment which was not counted with the total number of appointments. Assessment of overall treatment duration was undertaken by the principal investigator who was masked to the study group allocation during the assessment. All the trial documents were labeled with study ID number, which together with the unique hospital identification number and model box number were used for participant identification and data collection. It should be noted that none of these numbers revealed the allocation group. The only document that could unmask the allocation group was the Allocation Table which contained the study ID and relevant allocation group. This was kept locked away from the investigator and analyst until the completion of data collection and measurement.

There were no outcome changes after trial commencement except for the dropout of one of the centres, however, since this was at the beginning of recruitment, it did not impact on the study results. The other two centres were able to recruit a sufficient number of patients.

The following dates were recorded: date of appliance bonding (D1); date of inserting rectangular stainless steel archwire (D2); and date of appliance debond (D3). The duration of orthodontic treatment was measured by the number of months required to complete treatment from D1 to D3. The duration of the levelling and alignment stage (from D1 to D2) and the working and finishing stage (from D2 to D3) were also calculated in addition to the total number of appointments. Different patient-related and treatment-related factors were collected to identify if they influenced the duration of treatment (Table 1). The effect of oral hygiene and gingival hyperplasia on space closure was not assessed in this study.

Sample size calculation

The sample size calculation was based on the primary outcome of duration of orthodontic treatment. Using nQuery Advisor 7.0, the sample size was calculated to detect a difference of three months in the mean duration of orthodontic treatment, which was considered as a clinically significant difference. A sample size of 92 patients in each group was expected to have 80% power to detect this difference with a standard deviation of 7.2 months (11,19) using a two group t-test with a 0.05 two-sided significance level. However, the publication of a recent systematic review with meta-analysis which included 18 RCTs and 4 controlled clinical trials by Tschlaki et al. (2016) (20) that aimed to determine the mean duration and number of visits required for comprehensive fixed appliance orthodontic treatment enabled the sample size to be recalculated with more robust evidence. An a priori power analysis was used. The effect size for detecting a difference of three months was recalculated using a standard deviation of 5.3889 which was derived from the meta-analysis by Tschlaki et al. (2016) (20). A sample size of 52 patients in each group was expected to have 80% power at $P = 0.05$ to detect a difference of three months.

Interim analyses and stopping guidelines

Any concerns in relation to severe apical orthodontically-induced inflammatory root resorption of more than one third of the root (21) being detected in the majority of patients in one group would mandate that the trial monitoring committee should be convened to consider whether the study would be terminated. (22) This evaluation was undertaken by an independent clinician in order to preserve masking regarding the study groups.

Randomisation

Block randomisation was used to form the allocation list for the two comparison groups. A computer random number generator was implemented to select random permuted blocks with a block size of ten and an equal allocation ratio ({ [HYPERLINK "http://www.graphpad.com/quickcalcs/randomn2.cfm"](http://www.graphpad.com/quickcalcs/randomn2.cfm) }). Then, the final Allocation Table for the participants in the study (which contained the study number and allocation group) was kept in a sealed envelope away from the clinical environment.

Allocation concealment was achieved with sequentially numbered, identical, opaque, and sealed envelopes which were prepared before the trial and contained the treatment allocation card. These were kept in a box and as the clinician obtained the informed consent, an independent dental nurse was responsible for identifying the next allocation envelope in the sequence to implement the randomisation process.

Blinding

Due to the nature of this orthodontic trial, blinding to treatment allocation was only possible for the investigator and data analyst, while it was not possible for the clinicians and patients. The data were anonymised using 1 and 2 codes for the appliance types during the analysis. Thus, the data analyst could not identify allocation group during data analysis. As soon as the allocation envelope was opened in preparation for appliance placement, both clinician and participant knew the type of appliance used. This allowed the clinicians to follow the recommended standard sequence of archwires for each appliance. Although patients were aware of the allocation group, they did not have previous experience with orthodontic treatment and could not recognise the difference between appliances.

Statistical analysis

The data were analysed using the Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, Illinois, USA). In addition to using descriptive statistics, Levene's test was used to compare between-group variation. Both "intention-to-treat" and "per-protocol" analyses were used. Tests used to compare between the two appliance groups involved an independent samples t-test for continuous data, and a Chi-square for categorical data. The significance level was set as $p < 0.05$ except where a Bonferroni correction was applied to control type I error. A 95% confidence interval was estimated for the

mean difference between the study groups. A multiple linear regression analysis was performed for the total study sample to identify predictive factors influencing the duration of orthodontic treatment.

RESULTS

Participant flow

One hundred and ninety-seven patients were enrolled in the study. Ten patients did not attend for appliance placement or declined to participate. Therefore, 187 patients were randomised to either the 0.018'' or 0.022'' group in a 1:1 ratio. The 34 (Figure 1) who were lost to follow-up or who either experienced a protocol deviation or where there was very poor compliance were excluded from the study. Therefore 153 patients were included in the analysis (overall mean age: 19.1 ± 8.5 years). Patient recruitment started in January 2010 and ended in September 2014 and the trial was completed as planned.

Baseline data

The data were assessed statistically in terms of normality, homogeneity of variance, and outliers and no anomalies were detected.

Baseline characteristics including; age at bonding, gender, type of malocclusion, pre-treatment Peer Assessment Rating (PAR) score, and the presence of extracted and impacted teeth were similar in both treatment arms ($P > 0.05$) (Table 2). The minority of cases that included anchorage reinforcement appliances were distributed equally between the groups.

Numbers analysed for each outcome, estimation and precision, subgroup analyses

During the recruitment stage 216 patients were invited to participate in the study however, 19 patients declined and 197 participants were enrolled in the study (Figure 1). The number of analysed participants was 77 for the 0.018'' group and 76 for the 0.022'' group (total: 153 participants). An intention-to-treat analysis was carried out utilising the data imputation wizard in SPSS for the total duration of treatment between groups (primary outcome) and it revealed a statistically non-significant difference ($P = 0.267$). However, it was decided to use a "per-protocol" analysis for two reasons: firstly, the excluded patients were either not eligible to fulfil the protocol, failed to comply with treatment or moved to another hospital or practice. Most of the dropouts neither had the treatment completed nor reached a stage where outcomes could be predicted from the available baseline data, so imputing their data may bias the results. Secondly, the analysed number was found to be adequately powered (92.8%). Patient cooperation and treatment modality descriptions are presented in Table 3.

For the overall duration of treatment (Table 3), the mean difference between the 0.018'' group (29.3 months) and 0.022'' group (31.2 months) was 1.9 months and this was not statistically significant ($t(151) = -1.074$, $p = 0.285$ with a 95% Confidence Interval of Difference: -5.410 to 1.601). Similarly, no statistically significant differences were found between the appliance groups for the number of appointments and duration of the main stages of treatment (Table 4).

For the duration of alignment (Table 5), the mean duration of alignment for the upper arch was 7.82 (SD+/-4.74) and 9.07 (SD+/-5.23) months for the 0.018 and 0.22 groups respectively; with a mean difference of 1.23 months 95% CI (-2.83, 0.35). In the lower arch, the duration of alignment was 8.78 (SD+/-4.55) and 8.45(SD+/- 4.38) months for the 0.018 and 0.22 groups respectively; with a mean difference of 0.33 months 95% CI (-1.09, 1.76). The differences in both dental arches were found to be statistically insignificant ($P = 0.12$ and $P = 0.64$ respectively).

In order to identify the predictors that influenced overall treatment duration, 16 independent variables (Table 1) that have the potential to influence treatment duration were included in the same model and a multiple linear regression analysis using backwards stepwise deletion was undertaken. The model was inspected for violation of the assumption of independence using the Durbin Watson statistic and multicollinearity using the VIF and Tolerance statistics. Neither of these was found to be problematic. Additionally, the ZPRED/ZRESID plot was used to inspect the model for violation of the assumption of homogeneity and Cook's distance was calculated for each subject to identify individuals

who were unduly biasing the model and no problems were observed. Therefore, no transformation was applied to the dependent variable.

The model showed that total treatment duration could be predicted significantly by five factors: age at bonding, Class II division 2 malocclusion, number of failed appointments, number of emergency appointments, and multiple operators (Table 6). The predictive power of this model (adjusted $R^2 = 0.330$) accounted for 33% of the variance in treatment duration.

Eventually, an equation for treatment duration could be derived from the regression analysis:
Treatment Duration = 15.261 + 0.395*Age at bonding + 4.741 (if Class II division 2) + 1.323*Number of failed appointments + 0.950*Number of emergency appointments + 4.071 (if number of clinicians more than one)

Harms

No adverse events were reported during treatment.

DISCUSSION

The 0.018'' group completed treatment about two months earlier than the 0.022'' group (29.3 ± 9.5 and 31.2 ± 12.3 months, respectively). This difference arose in the working and finishing stage as the levelling and alignment stages were similar in both groups. However, neither the difference in the total duration of treatment nor the differences in the duration of the two stages of treatment were found to be statistically or clinically significant. Therefore, the null hypothesis was accepted. The identification of the main stages of treatment was in accordance with Mandall et al. (2006) (23), Scott et al. (2008) (24), and Ong et al. (2011) (25). This separation was implemented to identify if any variation occurred during a specific stage. The small amount of difference in the duration of treatment between the two groups may be associated with the small amount of difference in the degree of bracket-wire play in the working archwire with the 0.018-inch bracket (0.016×0.022 -inch stainless steel) than that with 0.022-inch brackets (0.019×0.025 -inch Stainless Steel). As a result, the full expression of bracket prescription in the 0.018-inch slot bracket could be achieved slightly earlier than for 0.022-inch brackets and this may explain this minor difference.

When comparing the current finding with the 22 high quality clinical trials reported by Tsihaki et al. (2016) (20) it can be noticed that the total treatment duration was located in the upper limit for the duration of treatment, where only three clinical trials reported the duration of fixed appliance at 30 months or more. (26-28)

The long treatment duration in both groups may be related to the appointment intervals and/or to the type and severity of malocclusion where there were relatively high numbers of participants with Class II division 1, Class II division 2, and Class III malocclusion when compared to the prevalence for the Caucasian population. (29) Pre-treatment PAR scores were high in both groups (31.2 and 31.6) and these were higher than the pre-treatment PAR score for "difficult cases" provided by Cassinelli et al. (2003) (30) (27.5 ± 9.3). This may reflect complex case-mix in hospital service at specialist practice. It has been stated that the higher the pre-treatment PAR scores and the greater percentage PAR score reduction, the longer the duration of treatment. (31)

Only two retrospective studies have directly investigated the duration of orthodontic treatment with these two bracket slot sizes and found statistically but not clinically significant shorter treatment with the 0.018-inch bracket group. (11,12) The mean of treatment duration in the current study is positioned between these two studies. The reason for finding statistically significant differences in the Amditis and Smith (2000) (11) study but not in the current study may be due to the low variation present in that study as all cases were treated by a single clinician and hence a mean difference of 1.5 months was found to be statistically significant. Additionally, although Amditis and Smith (2000) (11) used an equal number of archwires for both groups, four rectangular archwires were used in the 0.018'' group while only two were used in the 0.022'' group in addition to the placement of the stainless steel working archwire 2.6 months earlier in the 0.018'' group. These factors could result in the 0.018'' bracket slot group achieving better control of tooth position earlier in treatment. In the current study, an equal number of round and

rectangular wires were used for both groups and this may have masked any difference between them. On the other hand, the significant difference in the Detterline et al. (2010) (12) study could be related to the greater mean difference between groups (3.9 months). The mean duration for both groups in Detterline et al. (2010) (12) (30.2 ± 12.9 for 0.018'' and 34.1 ± 14.4 months for 0.022'') were closer to our findings but both were much longer than that reported by Amditis and Smith (2000) (11) (20.2 ± 3.1 months for 0.018'' and 21.7 ± 3.5 months for 0.022''). This may be explained due to the [1] variation in patient cooperation [2] variation in technical skill and [3] greater number of clinicians undertaking treatment in both the current study and that by Detterline et al. (2010) (12).

This study aimed to overcome the limitations available in the above studies and other retrospective studies (13,14) by primarily investigating the effect of bracket slot in a prospective RCT so avoiding selection bias. Although the difference was not significant in this study, interestingly it followed a similar trend to previous studies.

The non-significant difference in the number of appointments between the 0.018'' and 0.022'' groups can be explained by the minimum variation present between the two groups due to comparable pre-treatment characteristics.

The mean duration of alignment stage for the upper arch was 8.45 (SD+/-6.53) and lower arch 8.62 (SD+/-4.42) months for the full study sample. These results are similar to that reported by Mandall et al (2006) (12) (30.2 ± 12.9 for 0.018'' and 34.1 ± 14.4 months for 0.022'') were closer to our findings but both were much longer than that reported by Amditis and Smith (2000) (11) (20.2 ± 3.1 months for 0.018'' and 21.7 ± 3.5 months for 0.022''). This may be explained due to the [1] variation in patient cooperation [2] variation in technical skill and [3] greater number of clinicians undertaking treatment in both the current study and that by Detterline et al. (2010) (12).

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The aim of this study was to compare three orthodontic archwire sequences. One hundred and fifty-four 10- to 17-year-old patients were treated in three centres and randomly allocated to one of three groups: A = 0.016-inch nickel titanium (NiTi), 0.018 x 0.025-inch NiTi, and 0.019 x 0.025-inch stainless steel (SS); B = 0.016-inch NiTi, 0.016-inch SS, 0.020-inch SS, and 0.019 x 0.025-inch SS; and C = 0.016 x 0.022-inch copper (Cu) NiTi, 0.019 x 0.025-inch CuNiTi, and 0.019 x 0.025-inch SS. At each archwire change and for each arch, the patients completed discomfort scores on a seven-point Likert scale at 4 hours, 24 hours, 3 days, and 1 week. Time in days and the number of visits taken to reach a 0.019 x 0.025-inch SS working archwires were calculated. A periapical radiograph of the upper left central incisor was taken at the start of the treatment and after placement of the 0.019 x 0.025-inch SS wire so root resorption could be assessed. There were no statistically significant differences between archwire sequences A, B, or C for patient discomfort ($P > 0.05$) or root resorption ($P = 0.58$). The number of visits required to reach the working archwire was greater for sequence B than for A ($P = 0.012$) but this could not be explained by the increased number of archwires used in sequence B.

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0.018-inch bracket slot system, Ong et al. {ADDIN CSL_CITATION { "citationItems" : [{ "id" : "ITEM-1", "itemData" : { "DOI" : "10.1179/14653121141218", "ISBN" : "1465-3133 (Electronic)", "ISSN" : "1465-3133", "PMID" : "21367826", "abstract" : "AIM: To compare the efficiency of orthodontic archwire sequences produced by three manufacturers.\n\nDESIGN: Prospective, randomized clinical trial with three parallel groups.\n\nSETTING: Private orthodontic practice in Caloundra, QLD, Australia.\n\nSUBJECTS AND METHODS: One hundred and thirty-two consecutive patients were randomized to one of three archwire sequence groups: (i) 3M Unitek, 0.018 inch Nitinol, 0.017 inch heat activated Ni-Ti; (ii) GAC international, 0.014 inch Sentalloy, 0.016 inch Bioforce; and (iii) Ormco corporation, 0.014 inch Damon Copper Ni-Ti, 0.014 inch Damon Copper Ni-Ti. All patients received 0.018 inch slot Victory Series brackets.\n\nOUTCOME MEASURES: Mandibular impressions were taken before the insertion of each archwire. Patients completed discomfort surveys according to a seven-point Likert Scale at 4 h, 24 h, 3 days and 7 days after the insertion of each archwire. Efficiency was measured by time required to reach the working archwire, mandibular anterior alignment and level of discomfort.\n\nRESULTS: No significant differences were found in the reduction of irregularity between the archwire sequences at any time-point (T1: P = 0.0712; T2: P = 0.0706; T3: P = 0.0721) or in the time to reach the working archwire (P = 0.0728). No significant differences were found in the overall discomfort scores between the archwire sequences (4 h: P = 0.0730; 24 h: P = 0.0718; 3 days: P = 0.0753; 7 days: P = 0.0747). When the time-points were analysed individually, the 3M Unitek archwire sequence induced significantly less discomfort than GAC and Ormco archwires 24 h after the insertion of the third archwire (P = 0.0702). This could possibly be attributed to the progression in archwire material and archform.\n\nCONCLUSIONS: The archwire sequences were similar in alignment efficiency and overall discomfort. Progression in archwire dimension and archform may contribute to discomfort levels. This study provides clinical justification for three common archwire sequences in 0.018 inch slot brackets. }, "author" : [{ "dropping-particle" : "", "family" : "Ong", "given" : "Emily", "non-dropping-particle" : "", "parse-names" : false, "suffix" : "" }, { "dropping-particle" : "", "family" : "Ho", "given" : "Christopher", "non-dropping-particle" : "", "parse-names" : false, "suffix" : "" }, { "dropping-particle" : "", "family" : "Miles", "given" : "Peter", "non-dropping-particle" : "", "parse-names" : false, "suffix" : "" }], "container-title" : "Journal of orthodontics", "id" : "ITEM-1", "issue" : "1", "issued" : { "date-parts" : [["2011"]] }, "page" : "32-9", "title" : "Alignment efficiency and discomfort of three orthodontic archwire sequences: a randomized clinical trial.", "type" : "article-journal", "volume" : "38" }, "uris" : ["http://www.mendeley.com/documents/?uuiid=66ec85e3-7561-4174-a8d2-869ee2ae0a8b"]], "mendeley" : { "formattedCitation" : "(22)", "plainTextFormattedCitation" : "(22)", "previouslyFormattedCitation" : "(22)" }, "properties" : { "noteIndex" : 0 }, "schema" : "https://github.com/citation-style-language/schema/raw/master/csl-citation.json" } } reported a substantially shorter duration of alignment (4.0-4.4 months) with the authors claiming the use of 0.018-inch bracket slot system as one of the factors reducing the duration of alignment.

Amditis and Smith {ADDIN CSL_CITATION { "citationItems" : [{ "id" : "ITEM-1", "itemData" : { "ISBN" : "0587-3908 (Print)", "ISSN" : "0587-3908 (Print)", "PMID" : "11201958", "abstract" : "The duration of fixed appliance Edgewise orthodontic treatment times using brackets with 0.018" and 0.022" slots was measured to determine whether there were any clinically or statistically significant differences between the two appliances. Sixty-four consecutively treated, fully banded patients were selected from two different practice locations. All 64 patients were treated by one clinician. Thirty-two patients (Group 1) were treated using the 0.018" slot bracket and 32 (Group 2) were treated using the 0.022" slot bracket. The patients in each group were treated to the same standard of care using the same technique. The mean duration of treatment for Group 1 was 20.2 months and for Group 2, 21.7 months. Although the mean difference (1.5 months) was not clinically significant, it was statistically significant at p < 0.05.", "author" : [{ "dropping-particle" : "", "family" : "Amditis", "given" : "C", "non-dropping-particle" : "", "parse-names" : false, "suffix" : "" }, { "dropping-particle" : "", "family" : "Smith", "given" : "L F", "non-dropping-particle" : "", "parse-names" : false, "suffix" : "" }], "container-title" :

"Aust Orthod J", "id" : "ITEM-1", "issue" : "1", "issued" : { "date-parts" : [["2000"]] }, "page" : "34-39", "title" : "The duration of fixed orthodontic treatment: a comparison of two groups of patients treated using Edgewise brackets with 0.018\ and 0.022\ slots", "type" : "article-journal", "volume" : "16" }, "uris" : ["http://www.mendeley.com/documents/?uuiid=78deda04-ae33-459a-8d7c-577c6521a8fa"] }], "mendeley" : { "formattedCitation" : "(25)", "plainTextFormattedCitation" : "(25)", "previouslyFormattedCitation" : "(25)" }, "properties" : { "noteIndex" : 0 }, "schema" : "https://github.com/citation-style-language/schema/raw/master/csl-citation.json" }} mentioned that 75% of the difference in the treatment duration between the 0.018 and 0.022-inch group was found before the ligation of stainless steel archwires. Identifying the duration of alignment according to individual arches in this study revealed that there was a greater difference in the duration of alignment in the upper arch between the slot sizes than in the lower arch. This difference represented almost two thirds of the difference in overall treatment duration between the two study groups.

Predictive Factors Influencing Treatment Duration

It was decided to exclude time-related factors from the model, namely number of appointments and appointment interval as it was not a surprise that treatment duration could be predicted from these and there was a possibility that these strong predictors might mask potentially interesting lower level effects.

Five variables described below explained 33% of the variance in treatment duration. This percentage is comparable to that reported by Vig et al. (1990) (32), Stewart et al. (2001) (33), Firestone et al. (1999) (34), and Skidmore et al. (2006) (35). However, it differs from other investigations. (13,14,36-45) These differences among different investigations can be attributed to the variation in the inclusion criteria as some studies included multiple phases of treatment, surgical cases, optimally finished and prematurely terminated case etc. This heterogeneity made the comparison of the current study results with previous investigations difficult.

Age

Age at bonding showed a positive association with treatment duration in the regression model. With the series of current predictors, for each year of age, duration increases by 0.395 months. This can be attributed to more complex treatment with increasing age. Since the all the patients included in the current study had a complete permanent dentition and underwent a single treatment phase, it can be expected that younger patients will have a shorter duration of treatment due to faster proliferation of the supporting tissues and easier tooth movement. The negative correlation between age and treatment duration in other studies has been mainly attributable to the presence of a mixed dentition, multiple treatment phases, or decreased cooperation for younger patients. (33,34,39,40,45-48) We excluded participants in the mixed dentition, those with multi-phase treatment and those with poor cooperation to eliminate confounding arising from these variables.

Class II Division 2 Malocclusion

This variable was “dummy coded” so that it revealed the effect of changing from Class I to Class II division 2 malocclusion. The model determined that this malocclusion group required an additional 4.741 months of treatment. Interestingly, this was similar to the finding of Vig et al. (1990) (32) who reported that an additional 4.5 months were required for the completion of treatment if the starting malocclusion was Class II division 2. However, unlike the current study, Vig et al. (1990) (32) depended on Angle’s classification not incisor classification. Taylor et al. (1996) (41) also determined that Class II division 2 was one of the factors that increased treatment duration. As Class II division 2 treatment usually requires a large amount of incisor root movement, this may explain the association with longer treatment duration.

Number of Failed Appointment

We found each failed appointment added 1.323 months of treatment time. This finding was similar to the finding by Beckwith et al. (1999) (13) and Skidmore et al. (2006) (35) where each missed appointment added 1.09 and 1.4 months to treatment time, respectively. More extremely, Vu et al. (2008) (14) found

that patients who missed fewer than two scheduled appointment completed treatment 7.2 months quicker than those who missed two or more appointments. This study was also in agreement with Shia (1986) (49) who reported broken appointments as one of the reasons for extended treatment duration, although there were no statistical tests to prove this. Broken appointments showed a positive correlation with treatment duration as in other studies. (36,38,42,43,48)

Number of Emergency Appointments

Each emergency appointment significantly increased treatment duration by 0.950 months. This could also be considered as a logical finding as each extra appointment may mean pausing treatment to repair the broken appliance. Only a few studies have included this variable in their regression model and they all agreed with the present findings. (14,35,48) Like failed appointments, this factor also reflects patient cooperation as it is usually scheduled due to appliance breakages/repair or trauma from the archwire that could happen from mishandling of the appliance by the patient.

Number of Clinicians

Where more than one clinician contributed to the treatment of each patient, the duration increased by 4.071 months. This can be attributed to various reasons, including patients treated in teaching centres where the treating clinicians move to other jobs at the end of their training leaving patients with longer treatment duration to be completed by other clinicians, which in turn compounds the appointment schedule for this group of patients. Only one study has directly investigated this correlation and found that if treatment was undertaken by more than one clinician the duration increased by an average of 8.43 months compared to treatment completed by a single clinician. (50)

Comparison of the quality and biological side effects of treatment between the two bracket slot size systems have been discussed in details in Part 2 (15) and Part 3 (16) of this study.

Limitations

Some patients were lost to follow up which did not allow their data to be included in the study. Nevertheless, the study was adequately powered (92.5%) whilst including participants with incomplete data may bias the results. As in most orthodontic RCTs, it was not possible to blind the clinicians and the patients to the allocation groups, but they were blinded to the allocation sequence whilst outcome assessment was blind. One of the trial centres dropped out after recruiting three participants for the current study due to difficulty in managing recruitment and maintaining the required records for the study. Since this was at the beginning of recruitment, it did not impact on the study results. The other two centres were able to recruit a sufficient number of patients. Due to the variable nature of oral hygiene during oral hygiene and periodontal were not included as outcomes.

Generalisability

The external validity of the study was high as all eligible participants were recruited from a complete cohort presenting for state-funded orthodontic treatment in hospitals in the same health board area. However, the current study was undertaken in a teaching hospital environment which might be different from orthodontic practice in primary care as the cohort included patients with all malocclusion types and both extraction and non-extraction cases.

CONCLUSIONS

The current trial could not detect a statistically or clinically significant difference in the duration of alignment and overall orthodontic treatment and number of appointments between the 0.018-inch and 0.022-inch slot conventional ligation MBT bracket systems.

Increasing patient age, Class II division 2 malocclusion, number of failed appointments, number of emergency appointments, and multi-operator treatment all increase the duration of orthodontic treatment.

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FIGURE LEGEND

Figure 1: CONSORT flowchart of participants through each stage of the trial

LIST OF TABLES:

Table 1: Independent variables with potential influence on treatment duration used for multiple linear regression analysis

Table 2: Baseline characteristics of the participants in each treatment group (with tests for between-group comparisons)

Table 3: Description of treatment factors and duration of phases that contributed to overall treatment time

Table 4: Independent samples t-test for duration of treatment stages and number of appointments between appliance groups

Table 5: Duration of orthodontic alignment comparison between 0.018 and 0.022 study groups

Table 6: Multiple linear regression analysis for predictive factors influencing treatment duration