Self-ligating fully customized lingual appliance and chair-time reduction: a typodont study followed by a randomized clinical trial

Domenico Dalessandri*,**, Elena Lazzaroni*, Marco Migliorati***, Maria Grazia Piancino****, Ingrid Tonni* and Stefano Bonetti*

*Department of Orthodontics, School of Dentistry, University of Brescia, Italy, **Department of Medical, Surgical and Health Sciences, University of Trieste, Italy, ***Department of Orthodontics, School of Dentistry, University of Genova, Italy, ****Department of Orthodontic and Gnatology (Masticatory Function), Dental School, University of Turin, Italy

Correspondence to: Domenico Dalessandri, Department of Orthodontics, School of Dentistry, University of Brescia, p.le Spedali Civili, Brescia 25123, Italy. E-mail: dalessandridomenico@libero.it

SUMMARY In this study, we tested the hypothesis that self-ligation can reduce the chair time necessary for inserting and removing the archwire in a fully customized, multi-bracket, orthodontic, lingual appliance. A permuted-block, randomized trial design was employed to treat seven patients, each with Incognito® lingual appliances and Harmony® self-ligating lingual appliances. Three operators (a third year resident in orthodontics, an orthodontic specialist, and an experienced lingual orthodontist) were instructed, and they were allowed to familiarize themselves with two typodonts. Next, the operators were asked to insert and remove a 0.014 NiTi customized archwire for each patient, and they were timed. The time required for removing and inserting archwires decreased proportionally with operator experience: it was shorter when removing archwires (9.29 seconds versus 45.37 seconds, P < 0.001) and when with self-ligation (15.17 ± 9.29 seconds versus 45.37 ± 25.44 seconds, P < 0.001). In vivo performance improved after typodont training, allowing for difference reductions between operators. Lingual self-ligation appears to require less hands-on ability and training of the orthodontist, for reduction of chair time.

Introduction

Lingual orthodontics is the only fixed orthodontic technique that allows for full, three-dimensional control of tooth movement while maintaining the patient’s everyday aesthetic aspect. Lingual orthodontics is the only technique that has been described as completely invisible (Scuzzo and Takemoto, 2003).

The first multi-brace lingual appliances were introduced in the 1970s by Fujita in Japan and Kurtz in the USA, originating from vestibular brackets modified for lingual use. The lingual brackets invented by Kurtz evolved over the years until the seventh generation (Fujita, 1979; Alexander et al., 1982).

Having an accurate set-up is an important factor in all lingual techniques with rectangular wires for torque control, and it allows for the preparation of precise transfer trays for indirect bonding. This set-up is not as important as when applying the so-called two-dimensional techniques, which use only round archwires for first- and second-order tooth movement control (Soldanova et al., 2011).

Lingual tooth surfaces are more variable in shape than labial tooth surfaces, and these standard-shaped braces needs a composite base, prepared during the set-up using precise torque measurement instruments to fix them in their correct, individualized positions. This process allows for minimal need for finishing bends on the last stainless-steel archwire, which can, in rare cases, be completely excluded (Smith et al., 1986; Sapino and Zoccola, 1990; Hong and Soh, 1996).

Lingual orthodontic appliances had been looked on by clinicians with great initial interest but, due to their different biomechanical approach compared with labial orthodontics, which has not always been fully considered, and due to the resulting clinical problems, there was a rapid decline in interest and the onset of diffused prejudice concerning the possibility of obtaining the same results with lingual orthodontics as with labial orthodontics (Gorman and Smith, 1991; Poon and Taverne, 1998; Goren et al., 2003).

These prejudices, added to the more demanding chair time and the more complex orthodontic lab procedures, limited the diffusion of lingual orthodontics in the past (Artun, 1987; Ling, 2005).

The use of lingual orthodontics has progressively increased (Singh and Cox, 2011) due to the development...
of standardized clinical protocols and new, more advanced technologies.

The introduction of improved CAD-CAM technologies for single-patient, fully customized lingual brackets and for orthodontic archwire realization has certainly played part in it. These developments allowed the production of braces of reduced dimensions compared with traditional lingual appliances, improving patient comfort dramatically due to the reduced space requirements and the smoother shape of the new appliances (Stamm et al., 2005; Wu et al., 2010).

Highly precise production of robotically formed stainless-steel, NiTi, and titanium molybdenum alloy (TMA) archwires has led to an important reduction of chair time and the simplification of the orthodontist’s work while simultaneously improving the final results predictability and eliminating the variable of human error that had affected manual archwire bending (Wiechmann et al., 2003; Fuck et al., 2005; Mujagic et al., 2005; Grauer and Proffit, 2011).

The latest innovation in the field of lingual orthodontics was the introduction of a self-ligating (SL) approach.

A literature review on the topic of SL labial braces suggested essentially two advantages of these braces compared with traditional ligature vestibular systems: chair-time reduction and the reduction of unwanted frictional forces (Rinchuse and Miles, 2007; Fleming et al., 2008; Miles, 2009; Fleming and Johal, 2010; Saporito et al., 2011).

The aim of this study was to compare a customized, completely SL lingual technique (Harmony®) with a traditional, NSL, customized lingual technique (Incognito®), evaluating the chair time needed for routine archwire and ligation removal and insertion operations.

Materials and methods

This study was split into two arms: an in-vitro study using two perfectly aligned, dedicated typodons, one for each tested lingual appliance, and an in-vivo randomized clinical trial, which enrolled 14 patients from a private orthodontic practice.

Three operators, representing a wide orthodontic expertise range, were tested: an experienced lingual orthodontist (EL), an orthodontic specialist (EV), and a third year student (S3) from our post-graduate school of orthodontics.

EL, EV, and S3 were timed during the same period by three independent timekeepers, and the resulting mean time was used as a reference value.

The tested null hypothesis was that there are no differences between this two lingual appliances regarding the chair time needed for routine archwire and ligation removal and insertion operations, regardless of operator’s experience level.

Typodont sessions

At the beginning (t₀) of the study, all three operators were instructed, in a joint calibration session, regarding archwire insertion, ligation to the brackets, and removal.

Next, in separate sessions, the operators were asked to remove and insert a customized, robotically bent, super-elastic 0.018 NiTi archwire into the upper dental arch of an ideally aligned typodont with a fully customized, classical ligation lingual bracket system [non-self-ligating (NSL)] and a customized, robotically bent 0.016 NiTi archwire in the upper dental arch of an ideally aligned typodont, with a fully customized, SL lingual bracket system (Figure 1).

A NiTi archwire was ligated to the NSL brackets utilizing in separate, sequential sessions: only stainless-steel ligatures (SSL); only normal elastic ligatures (ELL); ‘reverse double-overtie’ elastic ligatures (REL) from the left canine to the right canine and normal ELL in the posterior sectors; and ‘power tie’ elastic ligatures (PEL) from the left canine to the right canine and normal ELL in the posterior sectors.

Each operator was timed, simulating the normal clinical procedure of removing and inserting the orthodontic archwire during each periodic appointment, starting from the moment when he began removing the first ligature before archwire removing and stopping when the last ligature was performed after archwire insertion.

These procedures were repeated three times, and the resulting mean time was used as a reference value.

One month later, after the repetition of the same calibration session, the trial was replicated (t₁), and after a 30-minute long training session, the study ended (t₂) repeating the same procedure for the last time.

Clinical sessions

A randomized, prospective, controlled clinical trial design was adopted: a minimum sample size of 14 participants, seven in each group, was proposed for 80% power at the 95% confidence interval to demonstrate a difference of 30 seconds in archwire removal/insertion time. The a priori power calculation was carried out with STATA 12 software (StataCorp LP, Bryan/College Station, TX, USA).

Fourteen adult patients, extracted from a group of 33, who were consecutively referred to three private orthodontic practices, were carefully selected by an external operator, blind regarding the aims of the study, to create a test group with similar orthodontic malocclusion type and dental discrepancy degree based on the Dental Health Component (DHC) Index of Orthodontic Treatment Need (IOTN), developed at Manchester Dental School (Shaw et al., 1991) and on space analysis results.

Inclusion criteria were complete permanent dentition, grade 2 (slight treatment need) DHC IOTN score, and space needed for resolving inferior anterior crowding comprised between 2 and 4 mm.

Exclusion criteria were one or more missing teeth (except wisdom teeth), extractive orthodontic treatment plan, and dental crowding preventing to apply all brackets at the same time.
An unstratified subject randomization sequence was created by a second external operator, blind regarding the aims of the study, with a computer-generated randomization programme (http://www.randomization.com) with 1:1 allocation and a random block size of 2, and each patient was assigned a study number.

Based on this list, the patients were immediately assigned to one of the two parallel treatment groups:

1. Incognito® fully customized lingual brackets and archwires and a treatment protocol according to the Incognito® Certification Course; or
2. Harmony® fully customized SL lingual brackets and archwires and a treatment protocol according to the Harmony® Certification Course.

Silicon impressions (Aquasil™ Ultra, Dentsply Caulk, Milford, DE, USA) of both dental arches of each patient were obtained using a two-step dual-phase putty/wash technique, and after approximately seven weeks, the lingual brackets were bonded using a dual-curing flowable composite (Maxcem Elite™, Kerr®, Kerr Corporation, Orange, CA, USA).

Next, in separate sessions, immediately after \( t_{1A} \), operators S3, EL, and EV were asked, simulating a normal orthodontic periodical appointment, to remove and insert a customized, robotically bent 0.014 NiTi archwire into each patient’s lower dental arches (\( t_{1B} \)).

Again, each operator was timed, starting from the moment when the first ligature was removed or the first bracket clip was opened, before archwire removing, and stopping when after archwire insertion, the last ligature was performed, or the last bracket clip was closed.

The same procedure was replicated at \( t_{1B} \), immediately after \( t_{1A} \), and \( t_{2B} \) immediately after \( t_{2A} \).

The procedures followed were in accordance with the ethical standards of our university’s responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983. The participants were fully informed of the study and its implications, and written consent was received from all of the subjects. On the contrary, the statistician that analysed the results, the three independent timekeepers, and the three orthodontic operators were blind regarding the aims of the study.

### Statistical analysis

All of the measurements were statistically analysed with parametric and non-parametric tests using SPSS® Statistics software, version 17 (IBM Corporation, Somer, NY, USA).

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**Figure 1** Occlusal image of self-ligation (A) and non-self ligation typodonts (B–E): (B) with stainless-steel ligatures; (C) with normal elastic ligatures; (D) with reverse double-overtie ligatures; and (E) with power tie ligatures.
Due to the small size of the tested group, a non-parametric Wilcoxon test was used to identify whether there were significant differences among the times required to remove and insert the archwires in different experimental sessions with each different ligature type (SL, SSL, ELL, REL, and PEL) and operator (EL, EV, and S3).

Next, the Wilk–Shapiro normality test confirmed that the data, grouped on the basis of the ligature type and the operator’s skills, were normally distributed.

Next, the following parametric tests were used: one-way analysis of variance was used to identify the sessions that differed using the same ligature type (SL, SSL, ELL, REL, and PEL) with different operators (EL, EV, and S3), and a paired t-test was used to obtain the mean difference values and the confidence intervals; the same tests were used to compare the results obtained with different ligature systems during the same sessions, regardless of the operator’s experience profile, in the two different experimental settings. Finally, 2 by 2 post hoc comparison was used to identify, for each type of ligature system, the significance of the differences existing between different operators.

Results
Enrolment started in January 2011 and was completed by June 2012. From the original 33 patients requiring completely invisible, fixed orthodontic treatment, 19 (57.58%) had to be excluded; 17 were excluded because they had heterogeneous orthodontic malocclusion types and dental discrepancy degrees, based on the DHC IOTN index and space analysis results, and two were excluded because they refused to participate in the study.

Seven patients were assigned to group A and seven to group B: they all received allocated intervention and any of them was lost to follow-up; consequently, they were all included in the final data analysis.

The average amount of crowding was 2.82 ± 0.7 mm for the group A and 3.08 ± 0.6 mm for the group B (Table 1).

The results obtained, clustered by session, were recorded on an Excel spreadsheet, reporting the mean times ± standard deviations employed by each operator in every experimental setting (SL, SS, ELL, REL, and PEL), both in the typodont and in the clinical samples.

Method error
The resulting timekeeping method error was small for all of the measurements with a high inter-rater correlation coefficient (0.999), thereby confirming the validity of the registered data.

Influence of ligature’s system
In every experimental setting, both with typodonts and clinical sessions, and in every session, there was a statistically significant difference (P < 0.01) between the time taken to remove and insert the archwires with every type of ligation (Supplementary Table 1, available online).

The time needed to remove and insert the archwire (Figure 2a) was shorter when using SL brackets (105.38 ± 13.74 seconds with typodonts; 124.27 ± 17.43 seconds in the clinical setting), with progressively higher values shifting from simple ELL (210.34 ± 18.83 seconds with typodonts; 241.45 ± 27.00 seconds in the clinical setting) to REL (414.20 ± 30.32 seconds with typodonts; 451.88 ± 41.33 seconds in the clinical setting), followed by PEL (750.82 ± 46.04 seconds with typodonts; 794.80 ± 56.27 seconds in the clinical setting), and finally normal metal ligatures (SSL: 922.33 ± 43.61 seconds with typodonts; 980.84 ± 60.63 seconds in the clinical setting).

Influence of operator training
For every operator, there were statistically significant differences (P < 0.05) among the required times measured for each ligature system’s utilization at t₁ versus t₀ (except EL when using SSL and REL during the typodont session), and at t₁ versus t₀ (except EL when using SSL, ELL, REL, and PEL during the typodont session), but not during at t₀ versus t₁ session (except EV when using REL during the typodont session) (Supplementary Tables 2 and 3, available online).

Influence of operator skills
The 2 by 2 post hoc comparison showed that in every experimental session for every ligature system, there were statistically significant differences (P < 0.05) among the archwire removal/insertion times employed by every operator (except EV versus S3 when using the SL braces during both typodont and clinical sessions; Tables 2 and 3).

Figure 2b and 2c graphically show the archwire removal/insertion times employed by every operator with every ligature system during typodont and clinical sessions.

Table 1 Baseline clinical characteristics for each group.

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*Index of Orthodontic Treatment Need.
Discussion

Although the clinical sample size was small, the statistical power of this study was high, thanks to the magnitude of the measured differences between different ligature type groups and thanks to the precision with which the data were measured.

The results’ analysis showed, as expected, that the time required for archwire removal and insertion decreased proportionally to the competence level of the tested operator: EL was faster than EV, and EV was faster than S3.

It is interesting to note the width of the time gaps among the different operators: the differences between EL and EV were greater than the differences between EV and S3, demonstrating that lingual orthodontics requires special, dedicated hands-on training that in large part cannot be replaced by conventional practice with vestibular techniques.

The time gaps were greater on patient samples (tB) and were smaller on typodont samples (tA), and they decreased during the study until its conclusion (tC). This result could be due to the greater handiness of the resin typodonts compared with patient samples, partly reflecting a difference in the level of difficulty in changing the wire in the upper typodont arch compared with the lower patient arch, and could also be due to the operator-learning curve, as a consequence of the possibility of continuously repeating the insertion and removal of the arc, which allowed for the improvement of manual skills, especially in less-experienced operators.

The data stratification according to brackets and ligature type showed that the time needed to remove and insert the archwire was longer when using NSL brackets, with progressively higher values shifting from simple ELL to REL, followed by PEL, and finally normal metal ligatures (SSL).

The time gaps among the different operators were lower with SL brackets compared with NSL brackets, especially...
when using more complex ligatures. During the last sessions of both typodont (t_e) and clinical (t_v) sessions, there were no significant differences between mean times employed by EV and S3, when using the SL braces. This result indicates that a SL approach requires less manual skill, allowing even those operators with less practice in lingual orthodontics to maintain shorter chair times.

The intra-operator correlation coefficient (Cohen’s $k$) between $t_0$ and $t_1$ was very good (values between 0.81 and 1.00), thereby demonstrating the measurements’ accuracy and reliability.

To our knowledge, this study was the first to regard SL, fully customized lingual orthodontic appliances; therefore, we can only compare our results with studies that analysed chair-time differences using vestibular appliances.

Occasionally, both in labial and in lingual orthodontics, it’s necessary to supplement the self-ligation mechanism with ligatures (stainless steel and/or elastomeric). Adding

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those ligatures may take longer to employ if self-ligation brackets are used because these may not have such prominent undercuts for installation of additional ties. During our trials with the Harmony® system, we never needed to supplement the self-ligation mechanism, probably due to its toughness and reliability.

Similarly, adding ‘power chain’ or similar closing attachments to self-ligation brackets can be more challenging, and this may hence take longer compared with conventional ligation: we did not investigate this topic because patients enrolled in this study were all presenting dental crowding, with any open space between adjacent teeth.

Chen et al. (2010) in a systematic literature review concluded that shortened chair time appeared to be a significant advantage of SL over conventional systems. Paduano et al. (2008) found that in completely aligned dental arches, SL appliances underwent quicker mean archwire ligation and removal time compared with conventional twin brackets ligated by means of SSL or ELL with a degree of influence due to the open/close clip mechanism but with no differences regarding mandibular versus maxillary arches; they did not analyse operator experience as a possible influencing factor. Turnbull and Birnie (2007), in their study on a wide range of patients in different treatment phases, found a mean per bracket time reduction ranging from 0.4 seconds to 1.6 seconds for wire removal and ranging from 0.9 seconds to 2.7 seconds for wire ligation, and they concluded that the Damon2 SL system offered quicker and arguably more efficient wire removal and placement for most orthodontic treatment stages. Harradine (2001) studied two homogeneous groups of 30 patients, each one being followed from the beginning to the end of their orthodontic treatment, and he found a small average savings of chair side time for ligation/closing and ligature removal/opening with Damon SL brackets compared with conventional, pre-adjusted brackets.

Theoretically another clinical advantage of self-ligation is that if no archwire activation or change is necessary, nothing needs to be done in that visit: while using in conventional ligation some or all of the elastomeric elements may have to be changed for reasons of the latter potentially disintegrating over time. Actually, archwires were removed during each visit, also in patients with Harmony® brackets, for oral hygiene concerns, in order to facilitate plaque and food remains professional removal.

On the other hand, failure of the self-ligation mechanism may necessitate replacement of the bracket, increasing chair side time: during both typpodont and clinical trials, using the suggested technique and the dedicated instrument for clip closing and opening, there were no self-ligation mechanism failures.

Our results confirmed what we found in the literature with the more significant time-saving values with lingual appliances probably due to the easier archwire insertion and removal procedure with vestibular appliances, which softens the differences between SL and NSL appliances.

As far as we know, this study was the first to analyse operator experience as a possible influencing factor to regard both vestibular and lingual SL appliances.

This study adds two substantially new concepts to the existing body of knowledge: first, time saving due to the SL technology is much more significant than in labial orthodontics, not only from a statistical point of view but also from a clinical point of view; second, hands-on ability is less important in SL compared with NSL lingual orthodontics, allowing, especially to less experienced clinicians, to dedicate most of the appointment duration to clinical observation and critical reasoning, or even allowing to delegate, if possible, the archwire removal and insertion procedure to a co-worker.

A limit of this study is that arch width and mouth opening, two other factors that could relate to the easiness of lingual archwire insertion, removal, and ligation, were not investigated.

Conclusions
1. Lingual self-ligation, compared with traditional ligature methods, may help reducing chair time when utilizing a customized lingual appliance.
2. Individual hands-on ability has a greater impact on ligation time when traditional ligature systems are used compared with a SL system.
3. Lingual self-ligation may improve efficacy of both experienced and novice operators.

Supplementary material
Supplementary material is available at European Journal of Orthodontics online.

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