

Self-ligation shortens chair time and compounds savings, with external bracket hygiene compared to conventional ligation: Systematic review with meta-analysis of randomized controlled trials

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Abstract

Objective: To test if there are significant evidence-based differences in effectiveness between self-ligation (SL) and conventional-ligation (CL) brackets.

Materials and Methods: Popular clinical claims of SL were identified through a literature overview of PubMed, EMBASE, Cochrane Library, and Web of Science for the period 1965-2017. Additional hand searching of the references from retrieved articles was completed. The articles containing the inclusion criteria were qualitatively analyzed using the Cochrane risk of bias tool, and one other scale. Applicable RCTs were statistically analyzed with weighted means calculations and forest plots. RCT data that could not be synthesized with one other RCT at this time were reserved for discussion.

Results: The inclusion criteria were satisfied by a total of ten RCT studies, six of which were matched for meta-analysis of three popular clinical claims. Space closure rate, reduced incisor proclination, and the rate of mandibular alignment for SL compared to CL were not statistically significant with confidence intervals of 95%. The remaining four RCTs were collectively analyzed and found no statistically significant difference in discomfort between SL and CL.

Conclusion: The null hypothesis that there are no differences between SL and CL, was not rejected due to statistically insignificant results. Additional active SL studies, and well-designed RCTs for MA are needed that includes overall treatment time. SL chair time efficiency was consistently higher versus CL.

Introduction

Why do seasoned orthodontists continue to apply self-ligating brackets internationally? Self-ligation (SL) proponents and manufacturers of SL systems have made clinical claims of their effectiveness and efficiency over conventional ligation (CL), but the scientific evidence for several clinically relevant assertions appears to remain inconclusive. A few published systematic reviews (SRs), including one SR of in vitro studies, tried to address many of these questions, but there was a lack of high quality evidence available at the time of their publication, a chronic problem with the extremely high-bars to reach in SRs. Since that time, however, there has been a significant five-fold increase in the number of randomized controlled trials (RCTs) on SL compared to CL, that were suggested to be employed exclusively for meta-analysis (MA), and to prevent statistical errors [1].

Clinically, it may have been in 1935 that the first SL, single-wing bracket design was introduced, but SL for the most commonly used type of orthodontic brackets, like the siamese twin bracket design, was only developed recently within the last 18 years. This appears to be a central inflection point because it coincides with an increased frequency of use for twin SL and the associated claim of chair time efficiency. However, the number of other SL advantages began to escalate dramatically, with counter-arguments that refuted all advantages of SL. Significantly, there have also been two SL bracket mechanisms and schools of siamese twin

philosophies: the interactive (ISL) or active, and the passive (PSL) as 2 different groups for SL investigations.

Few differences were found for dental-occlusal dimensions such as molar and intercanine width comparing SL with CL. No adequate, evidence-based data were available that showed SL increased maxillary and mandibular buccal bone growth, reduced root resorption, improved torque, or increased bond failure rate. Since the publication of past SRs, many RCTs comparing SL with CL have been published in the peer-reviewed literature and inclusion of these recent RCTs for MA is indicated.

The aim of this SR with MA is to evaluate whether SL brackets are more effective than CL brackets by testing hypotheses generated from several popular clinical claims including that SL shows: 1) earlier in

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vivo space closure, 2) reduced lower incisor proclination, 3) earlier initial mandibular incisor alignment, 4) reduced initial discomfort and 5) reduced halitosis. The additional objective is to test if SL brackets are more efficient, defined as maximizing outputs of patient-doctor time, compared to CL in terms of 6) reduced overall treatment time, and 7) shortened chair time. By applying a search strategy to identify RCTs, the objective is to test if SL compared to CL has any treatment advantages. The higher filter for the data uses at least two RCTs for MA to determine statistical significance [1] The null hypothesis is that high quality evidence-based data do not substantiate a significant difference between SL and CL.

Methods and Materials

This review applied RCTs for MA of the clinically relevant questions. The treatment outcomes that could be studied statistically were determined by the number of RCTs matched for MA and followed the PICOS format. Inclusion and exclusion criteria were applied a priori to select articles.

Inclusion criteria

1. RCTs were assessed with other closely comparable RCTs using the Cochrane risk of bias, for MA (one other tool was used for the characterization of the good quality studies with a scale for low, moderate, and high-risk bias).
2. Studies including SL and CL orthodontic treatment that did not discriminate for age or gender.
3. Studies that compared SL with CL appliances concerning effectiveness (i.e. chair time efficiency).

Exclusion criteria

1. Studies that did not have a comparison cohort.
2. Animal studies, in vitro, or ex-vivo studies.
3. Editorials, opinions without age, gender, language discrimination or analytical outline.

Four main electronic databases, including PubMed, EMBASE, Cochrane Library, and Web of Science, were reviewed comparing SL to CL studies from 1965 until 2017. Search strategies and keywords were employed for each database (Appendix 1). The literature overview was used to identify the prevalence of SL clinical claims qualitatively by listing them in customized forms by two reviewers (U.V., W.X.).

Articles to be included were independently read, reviewed and discussed without language discrimination. Inclusion was based on consensus agreement by at least 2 of 3 investigators (U.V., W.X., Y.Z.) using independent search and custom data abstraction forms piloted on RCT, cohort and cross-sectional studies. Article references were also hand-searched. Quality investigations were included that had well-conducted statistical analysis (independent of a low, moderate or high risk of bias) and a statistics expert was consulted during statistical analysis. If there was disagreement, a third reviewer (U.V.) was used to reach consensus. Grey literature was evaluated for an overview but in the end peer-reviewed articles were included.

Independent quality assessment for bias (Appendix 2a,b), was conducted for the included, peer-reviewed studies using the Cochrane risk of bias assessment tool specific for RCTs and the modified Newcastle-Ottawa scale for also Non-Randomized Trials, (NRT's) by 2 researchers (W.X., Y.Z.). A third investigator (U.V.) was consulted

in areas of dispute to form a consensus. Seven criteria details in the Cochrane tool were applied separately for the RCTs. Low (+), high (-) or unclear (?) risk of bias was given to each criterion to determine overall level of bias. Qualitative assessment of each peer-reviewed study not only encompassed risk of bias, but also contained a detailed characteristics evaluation for each of the included investigations.

Quantitative assessment was then made using the RCTs that could be matched with at minimum, another RCT study for a MA to be performed. A threshold level of a low or moderate level of bias for each quality RCT was deemed to be acceptable for MA. If a MA could not be conducted using the articles included in the SR, it was not considered quantitative evidence. Additionally, a sensitivity analysis was performed, where necessary, with regard to qualitative analysis, risk of bias, and publication status.

Single good quality RCTs that met the inclusion criteria, but that could not be matched, and currently could not undergo MA were not included in the statistical results. Rather, they were reserved for discussion because of their potential to possibly guide the designs of future RCTs needed for MA [1].

Meta-analysis

A MA was performed to synthesize comparable RCT data for each clinical claim of interest using the metaphor [2] package in R software (MATLAB version 8.2, Mathworks, Natick, Massachusetts, United States). Heterogeneity was assessed for the included investigations. A fixed-effects model was used with less heterogeneous results (I^2 statistics < 75%). A random effects model was used for more heterogeneous results (I^2 statistics > 75%). Forest plots were constructed using weighted mean differences only from RCTs. If high quality RCT investigations with lowest possible bias could not be found for a specific claim, forest plots were not constructed. Dichotomous data was assembled with the use of odds ratios. Funnel plots were used to assess publication bias.

Results

The electronic search and overview of the orthodontic literature identified 236 studies for prevalence of clinical claims. The claims were divided into two groups, primary questions 1-7 and secondary questions 8-19 (Table 1), toward the preparation of the MA. From the 236 articles, 35 met the inclusion criteria (Table 2, 22 RCTs and 13 NRTs), including one from hand searching (Figure 1). Table 2 outlined the characteristics and details of each of the 35 studies including their risk of bias. The 13 NRTs were characterized and reserved for discussion.

Ultimately, 10 RCTs were found. For three relevant SL claims (in vivo space closure, incisor proclination and rate of mandibular incisor alignment in days,) a MA was performed using calculated weighted mean differences. There were two RCTs for each of three claims producing six matched RCTs and forest plots were constructed for the three relevant claims (Figures 2-4). In addition, the data of four RCTs on discomfort were synthesized for MA. The excluded studies did not provide useful data.

Rate of in vivo Space Closure

There were two in vivo studies on distal movement of canines for space closure on round wire that applied retraction forces directly on the canine hooks (Figure 2). The forest plot showed a mean difference of 0.17 mm for CL in the study by Burrow [3]. Compared to 0.06mm for PSL in the investigation by Mezomo, *et al.* [4] with both studies using 28-day intervals of canine retraction. However, this small effect

Table 1. Nineteen claims of self-ligation from electronic literature overview

Primary Claims			
1. Higher in vivo space closure	3. Faster initial mandibular incisor alignment	5. Lower overall treatment time	7. Shortened chair time
2. Reduced incisor proclination	4. Reduced initial patient discomfort	6. Halitosis and periodontal health	
Secondary Claims			
8. Improved oral hygiene, bacterial levels	11. Greater interbracket flexibility	14. Reduced bond failure	17. Bracket deformation
9. Lower moments of rotation	12. Reduced root resorption	15. Clip wear	18. Intercanine and intermolar width
10. Max & mand buccal bone formation	13. Improved torque	16. Reduced in vitro resistance to sliding	19. Bracket oxidization

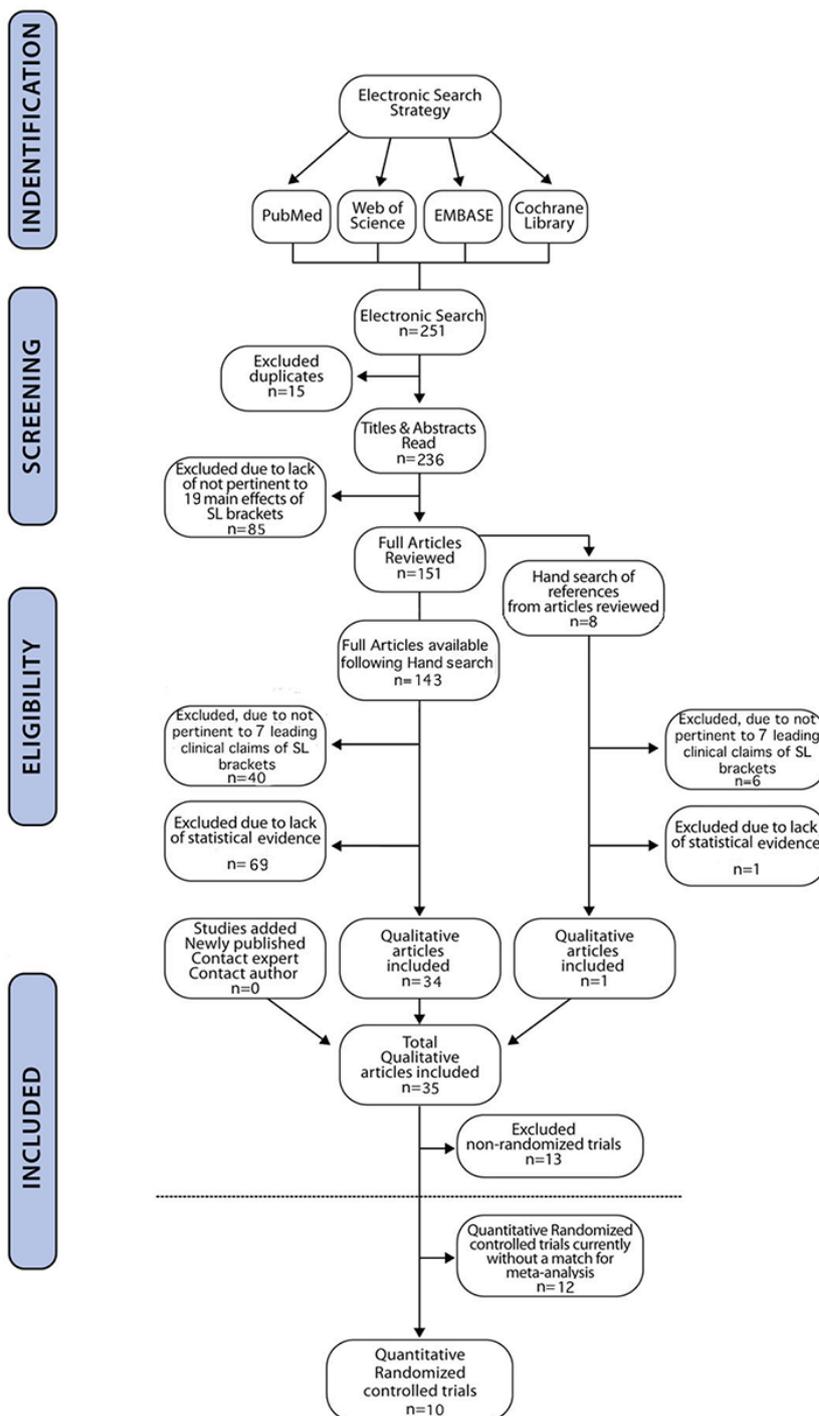


Figure 1. Flow Diagram for determining quantitative articles used

Table 2a. Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	Kaygisiz et al ⁴⁶	O'Dwyer et al ³⁰	Rahman et al ²⁶	Celikoglu et al ²¹	Uzuner et al ⁴⁷	Nalcaci et al ⁴⁵
Year	May 2015	April 2015	March 2015	March 2015	Nov 2014	May 2014
Design	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial
SL group (no. of patients)	Leone F1000 (20)	3M Smartclip (66)	3M SmartClip (66)	3M SmartClip (22)	Leone F1000 (20)	Ormco Damon Q (23)
CL group (no. of patients)	Avex MX (20)	3M Victory (71)	3M Victory (71)	3M Gemini (24)	Avex MX (20)	Rocky Mountain Orthodontics Mini Taurus (23)
Extraction or non-extraction	Unreported	Both	Both	Non-extraction	Unreported	Unreported
Pretreatment mean age (yrs.)	F1000: 14.7 Avex MX: 14 Control: 14.4	14 years 11 months	SmartClip: 15.5 Victory: 14.5	SmartClip: 15.48 Gemini: 14.65	F1000: 14.67 Avex MX: 15.05	Damon Q:14.48 Mini Taurus: 13.30
Conclusions of Study	No significant difference was found between SL and CL brackets with metal ligatures for periodontal status and halitosis. Data was obtained 1 week before bonding, immediately before bonding and at 1, 4, and 8 weeks.	No significant difference was found in regards to overall treatment time between SL and CL bracket systems. SPSS software with a frequency histogram was used for data analysis. The use of PAR or ICON was not reported.	No significant difference between SL and CL brackets in clinical discomfort experienced at intervals of 1, 3, and 5 days.	No significant difference was found in non-extraction patients for mandibular incisor alignment between SL and CL.	No significant difference was found between SL and CL brackets with metal ligation for periodontal status and colonization of Streptococcus mutans and Lactobacillus. Data was recorded before bonding and 1 month afterward.	SL brackets had significantly reduced halitosis and periodontal indices compared to CL brackets with elastomers. PSL may prevent patients from developing halitosis and increase the ability to maintain good hygiene. Data was obtained before bracket placement, and at 1 and 5 weeks after bonding.
Bias Risk	Moderate	Low	Low	Low	Moderate	High

* RCT included in meta-analysis

Ormco=SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

Table 2b: Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	Songra et al ¹⁹	Wong et al ¹⁵	Johansson, Lundstrom ³¹	Alper Oz et al ¹⁴	Wahab et al ²⁰	Mezomo et al ¹¹
Year	May 2014	June 2013	Sept 2012	March 2012	April 2011	March 2011
Design	Randomized controlled trial*	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial*
SL group (no. of patients)	Ormco Damon 3MX (41) In-Ovation R (37)	Damon 3MX (14)	American Time2 (44)	3M SmartClip (19)	Ormco Damon3 (14)	3M SmartClip (15)
CL group (no. of patients)	GAC Omni (20)	Unreported American CL with elastomeric ligatures (13) Unreported American CL with Super Slick elastomeric ligatures (13)	3M Gemini (46)	3M Mini Uni-Twin (19)	Ormco MiniDiamond (15)	3M Gemini (15)
Extraction or Non-extraction	Extraction	Extraction	Extraction	Extraction	Extraction	Extraction
Pretreatment mean age (yrs.)	11-18	Damon 3MX: 13.9 CL with elastomeric:14.1 CL with Super Slick:13.7	Time2: 15.3 Gemini: 15.0	13.6	14-30	18
Conclusions of Study	Time to initial alignment with four premolar extractions was shown to be statistically shorter with CL than either of the SL brackets with different recall intervals of 6 wks and 12 wks respectively. No significant difference in average response in mm, was found between active (ISL) and PSL brackets. No statistical difference was found between the 3 bracket types for space closure.	The bracket-ligature type was not found to affect the rate of space closure. Space closure involved en masse movement of the incisors and canines against the premolars and molars using coil springs.	Overall treatment time and number of appointments was not found to be significantly different between SL and CL. The ICON (Index of Complexity, Outcome, and Need) evaluation was utilized to form and analyze statistics.	No significant difference was found between SL and CL groups in regards to canine distalization using rectangular arch wire. TADs were used for posterior anchorage.	Tooth alignment in the initial stage with maxillary first premolar extractions was generally not higher for SL compared to the CL group over the first four months of treatment. However, CL alignment in the first month was higher than SL. CL showed 98% of crowding improvement compared to 67% with SL after four months using irregularity index.	In vivo, there was no difference in rate of space closure found between the SL and CL groups for the distal movement of upper canines and mesial movement of first molars. It was also concluded that there was less upper canine rotation with SL SmartClip compared to CL.
Bias Risk	Low	Low	Low	Moderate	High	Moderate

*RCT included in meta-analysis

Ormco = SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

Table 2c. Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	DiBiase et al ²⁹	Burrow ¹²	Pandis et al ⁵¹	Miles and Weyant ²⁵	Fleming et al ¹⁷	Pringle et al ²³
Year	February 2011	September 2010	June 2010 (e-pub 2009)	May 2010	September 2009	August 2009
Design	Randomized controlled trial	Randomized controlled trial*	Prospective cohort (completion of 2007 study portion)	Randomized controlled trial*	Randomized controlled trial (Part 2)*	Randomized controlled trial*
SL group (no. of patients)	Ormco Damon3 (33)	Ormco Damon3 (21),3M Smartclip (22)	Ormco Damon2 (27) (mandibular incisor torque= -6°)	In-Ovation C (34)	3M SmartClip (29)	Ormco Damon3 (24)
CL group (no. of patients)	Ormco Synthesis (29)	Victory Series (43)	GAC Microarch (27) (mandibular incisor torque= -1°)	Clarity (34)	3M Victory (31)	Ormco Tru Straight (28)
Extraction or Non-extraction	Extraction	Extraction	Non-extraction	Non-extraction	Non-extraction	Extraction
Pretreatment mean age (yrs.)	16.27	14.8	Ormco Damon2: 13.6, GAC Microarch: 13.9	In-Ovation C, Clarity: 12-15	3M SmartClip:16.32, 3M Victory: 16.37	Damon3: 15.2 Tru straight: 16.1
Conclusions of Study	The results on lower overall treatment time were divided for SL and CL groups. The SL group was also not found to reduce total number of visits or result in an improved occlusal outcome using PAR (Peer Assessment Rating) scores in comparison to the CL group.	In vivo, the results on rate of space closure were divided for SL and CL groups. The CL group showed faster distal movement of the upper canines, possibly because of the narrow bracket width of the SL group. Narrow brackets may bind with the archwire or notch the archwire.	Both SL and CL groups showed increases in mandibular incisor proclination and intercanine width that were not statistically significant. There was an additional intermolar width increase after treatment with SL group.	Shortened chairtime was found to be statistically significant for SL using 6 anterior brackets compared to CL. No significant difference in discomfort between SL and CL brackets was found at intervals of 4 hours, 1 day, 3 days, and 7 days.	Bracket type has little to no effect on incisor proclination in non-extraction patients. SL and CL groups had similar results. It was also determined that bracket type had little effect on positional changes, and inter-canine, inter-first premolar, and inter-second premolar dimensions. More incisor proclination results from greater alleviation of crowding.	SL brackets result in reduced intensity of discomfort compared to CL brackets at 12 hour intervals over 7 days.
Bias Risk	Low	Moderate	Low	Moderate	Low	Low

*RCT included in meta-analysis

Ormco = SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

Table 2d. Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	Fleming et al ⁵⁰	Fleming et al ²⁴	Scott et al ¹⁸	Jiang and Fu ⁴⁸	Hamilton et al ³²	Scott et al ²²
Year	May 2009	January 2009	October 2008	August 2008	July 2008	March 2008
Design	Randomized controlled trial (Part 1)	Randomized controlled trial*	Randomized controlled trial*	Prospective cohort	Retrospective cohort	Randomized controlled trial*
SL group (no. of patients)	3M SmartClip (32)	SmartClip (26)	Ormco Damon3 (32) (mand. Inc torq= -1°)	Ormco Damon3 (mand inc torq= -1°)	GAC In-Ovation R (379)	Damon3 (33)
CL group (no. of patients)	3M Victory (33)	Victory (22)	Ormco Synthesis (28) (mand. Inc torq= -1°)	CL metal preadjusted brackets (13) (Shinya, China) (mand. Inc torq= -1°)	3M Victory (383)	Synthesis (29)
Extraction or Non-extraction	Non-extraction	Extraction	Extraction	Non-extraction	Extraction	Extraction
Pretreatment mean age (yrs.)	3M SmartClip: 15.9,3M Victory: 16.6	SmartClip: 16.23 Victory: 15.65	Ormco Damon3: 16.2, Synthesis: 16.4	Ormco Damon3: 14.5, Conventional: 15.3	Unreported	16 years 3 months
Conclusions of Study	SL systems were found to be no more effective at relieving alignment irregularity than CL systems in non-extraction patients with mild mandibular crowding. A positive correlation was found for improved correction of irregularity and level of pre-treatment irregularity.	There was no difference in discomfort experienced between SL and CL brackets at intervals of 4 hours, 24 hours, 72 hours, and 7 days.	No difference in effectiveness for SL and CL groups in init. overall rate of mand. incisor align & mand premolar extraction. Intermolar width maintained increased. Intercanine distance, mild proclination of mand. incisor and mild arch length reduct for SL and CL. No signif diff for SL and CL groups.	Increased lower incisor proclination with both SL and CL groups in non extraction treatment of mild crowding. SL groups demonstrated greater intermolar width compared to CL group.	SL showed greater number of debonds and other emergency appointments. No advantages for treatment time, number of visits and time for initial alignment between SL and CL.	There were no significant differences in perceived discomfort at initial tooth movement and the discomfort did not differ at subsequent measurement times at intervals of 4 hours, 24 hours, 3 days, 7 days.
Bias Risk	Low	Low	Low	High	Moderate	Low

*RCT included in meta-analysis

Ormco = SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

Table 2e. Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	Paduano et al ⁵³	Pandis et al ¹⁶	Turnbull and Birnie ⁶⁰	Miles ⁴⁰	Miles et al ⁴¹	Pandis et al ⁵²	Miles ⁴²	Eberting et al ³³
Year	2008 (month) unreported	August 2007	March 2007	April 2007	May 2006	January 2006	November 2005	November 2001
Design	Cross-sectional	Randomized controlled trial*	Prospective Cross-sectional	Prospective cohort (split mouth design)	Prospective cohort	Prospective cohort	Prospective cohort	Retrospective cohort
SL group (no. of patients)	3M SmartClip (10) GAC In-Ovation R (10) AO Time2 (10)	Ormco Damon2 (27) (mand inc torq=-6°)	Ormco Damon2 (140)	3M SmartClip (14)	Ormco Damon2 (58)	Ormco Damon2 (43)	3M SmartClip (29)	Ormco Damon (108)
CL group (no. of patients)	GAC Ovation with STS ligatures (10), GAC Ovation with EL ligatures (10)	GAC Microarch (27) (mand. inc torq=-1°)	Ormco Orthos (122)	CL MBT twin (14)	3M Victory MBT (58)	GAC Microarch (19)	3M Victory MBT (58)	CL Bracket not indicated (107)
Extraction or Non-extraction	Non-extraction	Non-extraction	Non-extraction	Extraction	Extraction	Non-extraction	Extraction	Extraction and Non-extraction
Pretreatment mean age (yrs.)	Unreported 12-30 range	Ormco Damon2: 13.5, GAC Microarch: 13.9	Ormco Damon2: 13.7, Ormco Orthos: 14.4	13.1 (median)	16.3	14	17.1	Unreported
Conclusions of Study	SL showed more efficient arch wire removal and placement late in the orthodontic treatment. Type of SL bracket determined ligation time in the mandibular arch.	No statistical difference between SL and CL groups for overall increases in mandibular proclination and intercanine width treated non-extraction. For irregularity index <5, SL was 2.7x faster and showed a statistically higher increase in intermolar width. However, there were no significant differences in time required to align mandibular crowding between the SL and CL.	SL demonstrated significantly lower mean archwire ligation time for both placing and removing arch wires.	SL and CL with metal ligation groups showed no significant difference in rate of en masse space closure.	SL had a higher bracket failure. SL and CL groups showed no difference during initial alignment.	SL and edgewise brackets showed no significant difference in failure incidence using self-etching primer or acid-etching.	No difference between SL and CL groups for reducing initial stage irregularity.	SL group showed significantly lower treatment times than CL. It appeared that SL group had significantly higher ABO scores than those treated with CL edgewise brackets.
Bias Risk	High	Low	Moderate	Moderate	Moderate	Moderate	Moderate	High

*RCT included in meta-analysis

Ormco = SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

Table 2f. Characteristics of RCTs included (and other quality investigations by publication date, See Appendix 2 for qualitative assessment)

Author	Harradine ¹³	Berger and Byloff ⁵⁴	Maijer and Smith ⁵⁵
Year	November 2001	May 2001	January 1990
Design	Retrospective cohort	Cross-sectional	Cross-sectional
SL group (no. of patients)	Ormco Damon SL (30), Chair time study n=50, Bracket complications study n=25	Strite SPEED (20), Ormco Damon, Adenta Time, Ormco Twinlock	"A" Company Activa (14)
CL group (no. of patients)	Type not specified (30), Chair time study n=50, Bracket complications study n=25	Ormco Mini-twin (40)	"A" Company SWA brackets (14)
Extraction or Non-extraction	Extraction and Non-extraction	Non-extraction	Unreported
Pretreatment mean age (yrs.)	Unreported	Unreported	Unreported
Conclusions of Study	SL group showed four months shorter treatment time and needed four fewer visits on average compared to CL group. Both groups produced equal and good reduction in occlusal irregularity. SL opening and closing chair times were significantly shorter with SL compared to CL group.	Four different SL brackets showed significantly lower total opening and closing times than CL. Damon needed most time and SPEED least time to open and close.	SL brackets had a significantly shortened chair time advantage compared to CL brackets
Bias Risk	Moderate	High	High

*RCT included in meta-analysis

Ormco = SDS Ormco, 3M=3M/Unitek, GAC=Dentsply Sirona Ortho

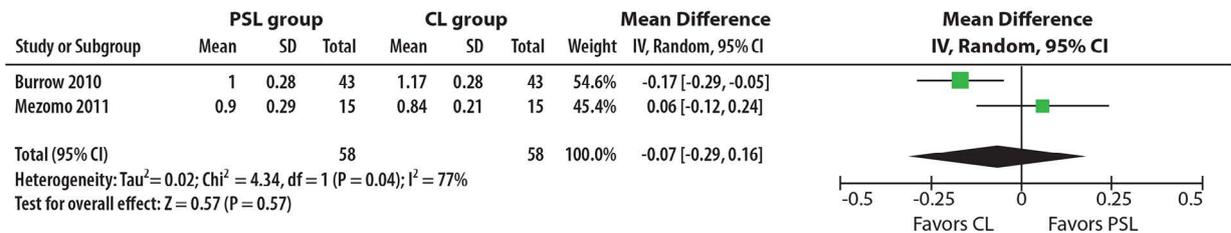


Figure 2. Forest plot of in vivo rate of space closure of two RCTS for meta-analysis (mm)

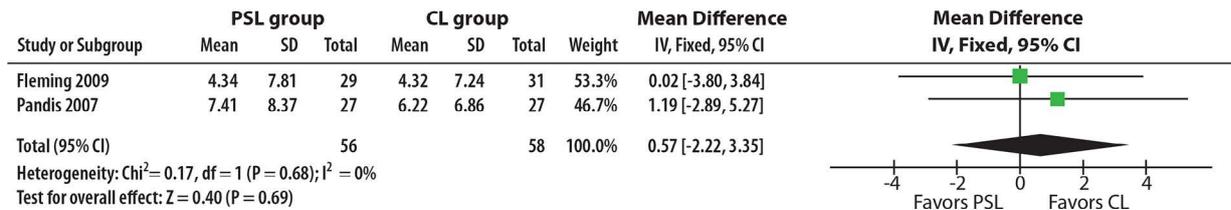


Figure 3. Forest plot of incisor proclination of two RCTS for meta-analysis (degrees)

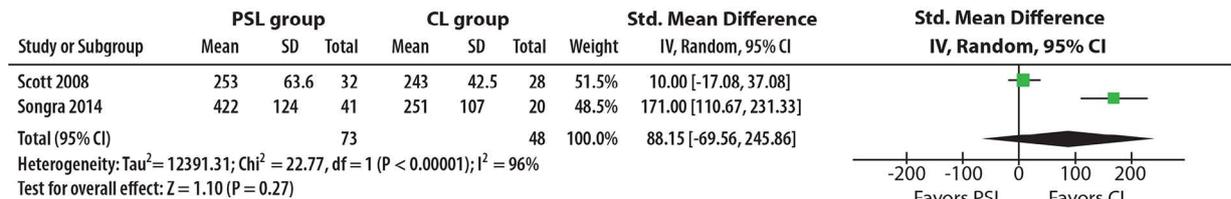


Figure 4. Forest plot of rate of mandibular alignment in days of two RCTS for meta-analysis (mm)

made no practical, clinical difference to a patient's treatment [5] and the MA also demonstrated no statistically significant difference. There was significant heterogeneity in studies on space closure. One RCT [6] investigated used large rectangular archwire rather than round archwire [3,4] and skeletal anchorage of TADs, and another RCT [7] used en masse movement of incisors and canines with a continuous arch where both RCTs did not allow inclusion of this data for MA.

Reduced incisor proclination

The two RCTs, by Pandis, *et al.* [8] and Fleming, *et al.* [9] were included since they used non-extraction to assess incisor proclination (Figure 3), but the differences were not found to be statistically significant. Another RCT [10] was not included because it studied incisor proclination with extraction treatment and moderate dental crowding.

Rate of initial mandibular incisor alignment (in days) in standardized mean difference

The RCT by Songra, *et al.* [11] and the data from Scott [10] including mandibular premolar extractions were used for MA, toward the construction of a forest plot (Figure 4). The results showed in the early alignment stage the difference was not statistically significant. The overall effect must be interpreted with reservation since the I² value was high, due to the heterogeneous methodology, where age ranges and time intervals were different [11]. However, the two RCTs were the highest quality studies currently available with continuity because both investigated mandibular incisor alignment with mandibular premolar extractions, and SL brackets with a control. One other RCT [12] used upper premolar extractions and had a high risk of bias, while another RCT [13] included non-extraction patients precluding MA.

Initial discomfort

Four RCTs [14-17] were found which had an acceptable risk of low to moderate bias and studied discomfort after 4 hours, 24 hours, 3 days and 7 days following archwire insertion and had reported a MA. They employed the VAS (Visual Analog Scale) assessment and found no differences in discomfort between PSL and CL. Another multi-centered RCT [18] compared PSL and CL at 24 hours and 3 days but this data was based on the VRS (Verbal Rating Scale) that produced inaccuracies since it relied on verbal responses compared to the tangible, visual analog scale, that precluded MA with the other 4 RCTs.

Overall treatment time

Three RCTs [19-21] on total treatment time with low risk of bias have been reported. None of these revealed any statistically significant differences in total treatment time between SL and CL. Other retrospective studies [5,22,23] investigated treatment time (and also used occlusal indices) that may have suffered from a higher risk of bias [1]. The significant, heterogeneous designs of these 3 RCTs above also required the use of standardized mean differences to minimize methodological differences among several investigations of overall treatment time [9,24-27]. In terms of assessing potential reduction in overall treatment time, results could not be synthesized with the three RCTs above for MA because of the different statistical analyses and ratings systems used (PAR, ICON, SPSS). Although PAR and ICON scores are not measures of treatment time, DiBiase, *et al.* [19] used PAR (Peer Assessment Rating) scores, O'Dwyer, *et al.* [20] used SPSS (statistical package for the social sciences, IBM Corporation) software with a frequency histogram and a different rating system, while Johansson and Lundstrom [21] used ICON (Index of Complexity, Outcome, and Need) evaluation. Consequently, a reduction in overall treatment time could not be reliably determined.

Halitosis and periodontal indices

One RCT by Nalcaci, *et al.* [28] found halitosis and periodontal indices were significantly increased for CL with elastomers compared to PSL. Another RCT [29] used CL with metal ligatures studying similar parameters and found no differences. However, the two different CL methods, did not permit MA. The data from a third RCT [30] studied periodontal indices and bacterial levels and this data also could not be synthesized for MA

Shortened chair time

One RCT by Miles and Weyant [17] found shortened chair time that was statistically and clinically significant of 130.2 secs/arch saved compared to metal CL, using six anterior esthetic brackets.

Discussion

This SR applied additional, high quality RCTs available for MA [1]. The synthesis of data from RCTs was possible for several clinical claims regarding SL in this SR. The electronic search led to the selection of 236 articles (Appendix 3). All were published in English except one, which was in Chinese [31] that were translated for use in this review. The final 35 SL studies expanded the qualitative analysis [3-26,28-38]. Due to the low number of RCT studies for each outcome, implications could not be derived from funnel plots to assess publication bias.

Rate of in vivo space closure

The great majority of SL brackets in the included RCTs were the PSL type, and additional interactive (active) SL studies were clearly needed. Space closure with narrower PSL brackets [3] can result in binding and notching of the archwire with conventional retraction forces that may have been higher for the narrower brackets compared to CL brackets. In the RCTs of this SR, the PSL brackets would have allowed a looser fit of the archwire in the slot compared to CL, greater tipping and consequently greater resistance to sliding. Other factors may have also affected space closure including bone density, occlusion, or dental interferences.

Reduced incisor proclination, rate of initial mandibular incisor alignment and discomfort

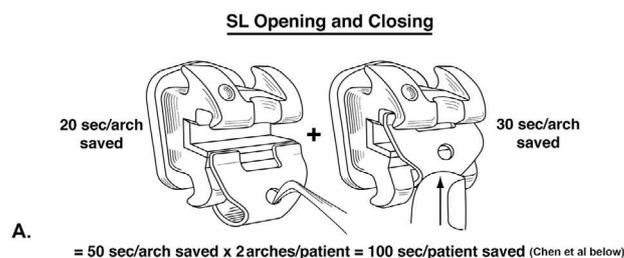
The NRT [31] for incisor proclination was not used in this SR because it had a high risk of bias. Although it was a non-extraction study, it also used only mild dental crowding (3mm) compared to an RCT [10] using extraction with moderate crowding. Due to the statistically insignificant difference found, the clinical relevance of incisor proclination requires further study [1].

Initial mandibular incisor alignment may have been limited because PSL brackets do not seat archwires into the base of the slot. More interactive SL studies are needed since they are designed to seat the archwire earlier than PSL, used in one RCT [11] although there was a concern for consistency in methods because CL brackets were evaluated every 6 weeks compared to SLs evaluated every 12 weeks. The RCT by Fleming, *et al.* [32] measured rate of alignment but was excluded in this MA because it used non-extraction treatment and the irregularity index rather than the measurement in days. Discomfort is a complex outcome to evaluate in patients because it is highly subjective with wide ranges of sensitivities and perceptions of discomfort. RCTs on discomfort can sometimes employ different scales such as the verbal rating scale (VRS) [18] rather than a visual analog scales (VAS) [14-17] although both can offer imprecise results. Contradictory results on discomfort can also be related to other factors such as age and gender.

Shortened chair time

From the electronic search, the finding by Miles and Weyant [17] of shortened chair time for six anterior, esthetic, SL brackets of 130.2 sec, or 2.2 minutes/(1 arch) that was statistically and clinically significant compared to metal CL in this one RCT reported, was also found in the majority of studies examined [5,27,35-37, and Appendix 4]. There was also support for the above RCT in the study by Turnbull and Birnie [38] (Appendix 2b). They demonstrated statistically significant SL clip closing ($P<.001$) and opening ($P<.01$) compared to elastomeric CL with a total SL chair time savings of 76.8 sec/arch, or 2.5 min/(2 arches) working with more posterior brackets (10 brackets/arch). Although archwire ligation is one of the most repetitive orthodontic procedures and clinical techniques vary, the compounding effect [27] of SL chair time savings of the lower 2.5min/patient [38] was calculated. Applying 40 patients/8hr-day, 4 days/wk produced an interesting potential savings of 102.4 min/day or 1.7 hours/day. Compounded chair time savings were similarly confirmed when the conclusions of Chen, *et al.*, 2000 were applied (Figures 5A and 5B).

Physically, external bracket hygiene for 20 brackets/patient, distinguished from patient oral hygiene, was also logically improved by the ligature-free nature of SL brackets (Figure 6). SL eliminated long-term repetitive errors discussed in industrial engineering by replacing 20 external ligatures/patient



Compounded statistical chair time savings with self-ligation* (compared to conventional ligation)

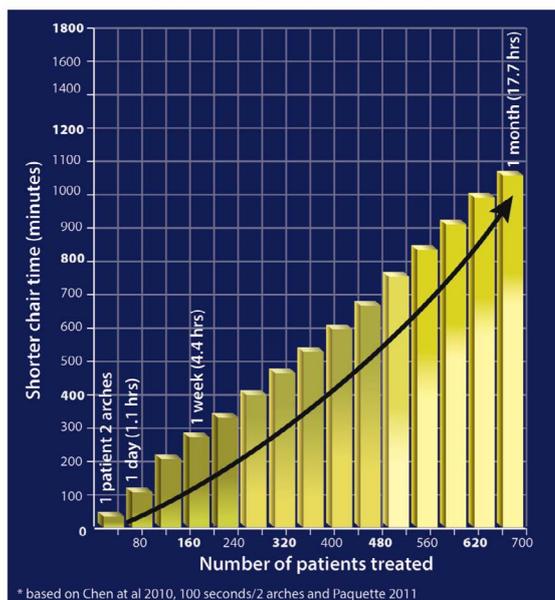


Figure 5. A) SL ligature-free opening, and closing appears to contribute to statistically shortened chair time. B) Demonstrates the compounding effect of the shortened chair time with SL in a medium-size practice treating 40 patients/day, 4 days/week over one month (17.7 hrs)

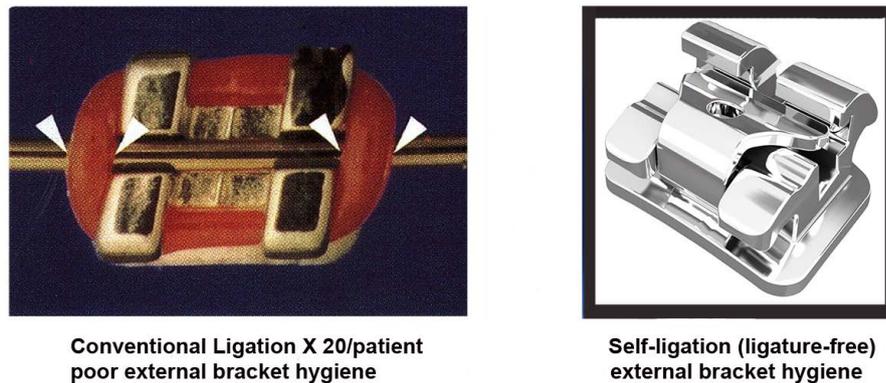


Figure 6. Comparison of conventional ligation (CL) external bracket hygiene confounded by decaying, distorting and hydrolytically decomposing elastomers X 20/patient repeatedly compared to SL (mini Prevail™) without elastomers

Conclusions

Rigorous, high standards in a systematic review were used including RCTs to study passive SL clinical claims and found:

1. Shortened chair time for SL was found in both one RCT, a good prospective, cross-sectional study and all five of the other investigations on chairtime efficiency. One further RCT would also allow for meta-analysis. When examining other outcomes, shortened chairtime appears to be one of the main reasons for the relatively high frequency of SL application by clinicians currently.
2. The logical question of whether the external hygiene of 20 brackets/patient was improved by SL with the removal of the 20 decaying and hydrolytically decomposing elastomers/patient after one month intraorally, eliminated by ligature-free SL, was another real advantage for clinicians. Multiple bracket hygiene was different, than unpredictable patients' oral hygiene.
3. Faster in vivo space closure during upper canine retraction into first premolar extraction sites, was not statistically significant, or clinically significant.
4. Reduced incisor proclination showed the effective amount was not statistically significant.
5. Reduced number of days for mandibular incisor alignment was statistically insignificant, with clinically insignificant differences.
6. Initial discomfort was highly subjective, and no differences could be found using four RCTs and meta-analysis.
7. Total treatment time, similar to halitosis, was not found to be different in three unmatched RCTs that precluded meta-analysis.

More well-conducted RCT's, and particularly of interactive SL are indicated because the majority study PSL (Table 3).

Table 3. Six cohorts of SL appliances

Metal ISL (twin)	Ceramic ISL (twin)	Metal PSL	Ceramic (or Clear) PSL	Metal ISL (single)	Lingual SL
Empower 2009 (AO)	Empower Clear 2012 (AO)	Damon SL, 2, 3, MX 1998 (Ormco)	Damon Aesth 2009 (Ormco)	Speed 1980 (Strite)	In-Ovation L 2006 (DSO)
Experience Mini 2014 (GCOA)	Experience C 2014 (GCOA)	Carriere SLX 2004 (Hen Schein OO)	Carriere SLX 3D 2016 (Hen Schein OO)	Time 1994 (Adenta)	Evolution LT 2002 (Adenta)
In-Ovation-R 2000, -X 2017 (DSO)	In-Ovation C 2006 (DSO)	Smartclip SL, 2 2004 (3M)	Clarity SL 2007 (3M)		Harmony 2012 (AO)
Sensation M 2010 (Hen Schein OT)	Sensation C 2012 (Hen Schein OT)	Opal Metal 2006 (Ultradent)	Opal 2004 (Ultradent)		
ZIP SL, LP 2014 (SIA Orth Manufact)	dynamique c 2016 (Dentaureum)	BioPassive 3G 2010 (Forestad)	Oyster 2001 (Gestenco)		
mini Prevail 2017 (G&H)	Krystal SL 2016 (Dynaflax)	Lotus 2008 (Henry Schein OT)	Velocity SLB C 2017 (Lancer)		
Endurance 2017 (Dynaflax)	QuickKlear 2G 2012 (Forestad)	Vision LP 2007 (AO)	Ascend SL C 2016 (RMO)		
Velocity SLB 2016 (Lancer)	Nexus Clear 2010 (Ormco)	Agility 2010 (ODP)			
dynamique m 2016 (Dentaureum)		Tenbrooke T1 2009 (Ortho Classic)			
Alpine SL 2017 (RMO)		Forces 2011 (Leone)			
Quick 2006 (Forestad)		FLI SL 2012, Altitude 2016 (RMO)			
Nexus 2010 (Ormco)		Glide 2006, Velocity 2016 (Lancer)			
BioQuick 3G 2010 (Forestad)		Activa 1986 ("A" Company/Ormco)			
Victory SL 2014 (3M)		Mobi-lok 1980 (Forestad)			
Lotus Active 2015 (Henry Schein OT)		Edgelok 1972 (Ormco)			
		Ford-lock 1942 (RMO)			
		Russell Lock 1935 (N/A)			

Ormco=SDS Ormco, 3M=3M/Unitek, DSO=Dentsply Sirona Ortho, AO=American Orthodontics, OT=Ortho Technologies, OO=Ortho Organizers, RMO=Rocky Mountain Orthodontics, Forestad=Forestadent, GCOA=GC Orthodontics America, C=Ceramic (some estimates of introduction yr)

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