

# Mandibular changes during initial alignment with SmartClip self-ligating and conventional brackets: A single-center prospective randomized controlled clinical trial

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**Objective:** To test the null hypothesis that SmartClip self-ligating brackets are more effective than conventional brackets for initial mandibular alignment and identify influential factors. **Methods:** Fifty patients were randomly allocated to two equal treatment groups by using an online randomization program: self-ligating group (SmartClip brackets) and conventional group (Gemini brackets). The archwire sequence was standardized. Changes in anterior irregularity index, intercanine width, and intermolar width were assessed on plaster models at 8th and 16th weeks. Changes in incisor position and inclination were assessed on lateral cephalometric radiographs at 16 weeks. Intragroup and intergroup comparisons were performed with paired *t*-test and Student's *t*-test, respectively. Multiple linear regression was performed to identify variables affecting improvement in anterior ambiguity. **Results:** Data of 46 patients were analyzed; those missing an appointment ( $n = 2$ ) or showing bracket breakage ( $n = 2$ ) were excluded. Incisor inclination ( $p < 0.05$ ), intercanine width ( $p < 0.05$ ), and intermolar width ( $p > 0.05$ ) increased at 8 and 16 weeks in both the groups; no significant intergroup differences were noted ( $p > 0.05$ ). Initial anterior irregularity index and intercanine width change were significantly associated with improvement in anterior irregularity ( $p < 0.001$ ). **Conclusions:** The null hypothesis was rejected. Bracket type has little effect on improvement in anterior ambiguity during initial mandibular alignment. [Korean J Orthod 2015;45(2):89-94]

**Key words:** Self-ligating brackets, Conventional brackets, Initial alignment

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## INTRODUCTION

Self-ligating brackets were introduced in orthodontics several decades ago and they experienced resurgence in the last decade with almost all major orthodontic companies offering a self-ligating bracket type.<sup>1</sup> Self-ligating brackets are popular among clinicians because of reportedly lower resistance to sliding, higher therapeutic efficiency, faster ligation and archwire removal, and shorter chair time,<sup>2,3</sup> all of which can reduce overall treatment time.<sup>4,5</sup> However, techniques, archwire types and sequences, operator experience, and recall intervals were not controlled in previous studies.<sup>6</sup> Further, self-ligating brackets are reported to produce less friction than other bracket systems *in vitro*.<sup>7-10</sup> Because many factors such as archwire dimensions and deflection, bracket slot dimensions and design, interbracket distance, archwire and bracket compositions, saliva, and perturbations can influence the amount of friction in a fixed appliance system,<sup>11-13</sup> whether self-ligating brackets clinically reduce friction is questionable.

Several prospective randomized clinical trials of self-ligating and conventional brackets have been published,<sup>1,6,14-24</sup> but only a few focused on initial mandibular alignment with SmartClip self-ligating brackets.<sup>6,14,15</sup> Two investigated irregularity changes but not incisor inclination and position or transversal changes.<sup>6,15</sup> The third compared relatively long-term (at least 30 weeks) changes in crowding, incisor position and inclination, and intercanine, interpremolar, and intermolar widths.<sup>14</sup> Unfortunately, none excluded patients with bracket breakage,<sup>6,14,15</sup> which could affect irregularity changes. In addition, other factors that might affect improvement in irregularity have not been completely evaluated.

The aims of this single-center prospective randomized controlled clinical trial were to compare the effectiveness of SmartClip self-ligating and conventional brackets for initial mandibular alignment and identify factors affecting improvement in anterior ambiguity. The null hypothesis was that SmartClip self-ligating brackets are more effective than conventional brackets.

## MATERIALS AND METHODS

Ethical approval from the local ethics committee (B302KTU0200000/490) and informed consent from the patients and/or their parents were obtained. The sample size was calculated by the Pandis method<sup>25</sup>: 21 patients were required in each group for 90% power to detect a difference of 2.0 ( $\pm$  2.3) mm in anterior irregularity index at a significance level of 0.05.

A single operator (M.C.) reviewed the initial data of 80 patients recalled from the orthodontic waiting list of Karadeniz Technical University. The inclusion criteria

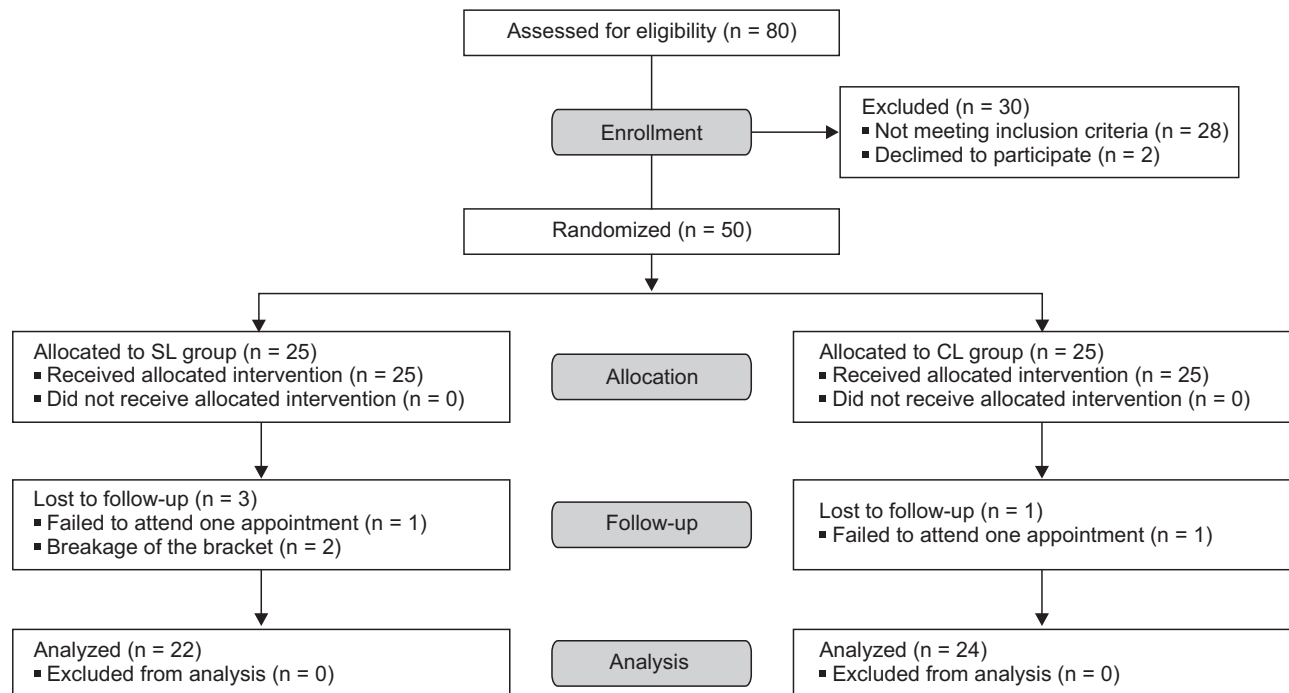
were as follows: (1) skeletal Class I malocclusion ( $0^\circ <$  ANB angle [the angle between Nasion-A point line and Nasion-B point line]  $< 4^\circ$  and overjet within 2–4 mm<sup>26</sup>); (2) permanent dentition; (3) nonextraction treatment of the mandibular arch in patients aged 12–18 years; and (4) over 3-mm irregularity in the mandibular anterior region. Those with previous orthodontic treatment, history of systemic diseases, congenital deformities, current medication, mandibular tooth agenesis, failure to attend one appointment, and bracket breakage were excluded. Finally, 50 patients were enrolled to increase the power and compensate for possible dropouts. These patients were randomly divided into two equal treatment groups by using a randomization program (<http://www.randomizer.org/form.htm>): self-ligating group (SmartClip brackets; 3M Unitek, Monrovia, CA, USA) and conventional group (Gemini brackets, 3M Unitek).

Bracket bonding, archwire insertion, and orthodontic treatment were performed by two nonblinded experienced operators (M.C. and M.B.) between June and December 2012 at the same clinic. Both types of brackets (0.022-inch slot) were bonded to all the teeth between the mandibular first molars by using Transbond XT (3M Unitek). The archwire sequence was standardized: 0.014-inch round heat-activated nickel-titanium archwire (3M Unitek) for 8 weeks and 0.016-inch round heat-activated nickel-titanium archwire (3M Unitek) up to 16 weeks. The archwire was cut distal to the molar tube without cinching. Intermaxillary elastics, headgear, lingual arch, or coil springs were not used. Conventional brackets were ligated with 0.01-inch stainless steel wire (3M Unitek). The patients were examined at 4-week intervals to ensure intact brackets.

Changes in Little's index,<sup>27</sup> intercanine width (distance between the cusp tips), and intermolar width (distance between the central and mesial pits) were assessed in plaster models at 8 and 16 weeks by using a digital caliper (Mitutoyo, Tokyo, Japan). Changes in incisor position and inclination (IMPA [the angle of mandibular incisor to mandibular plane]; I-NB angle, I-NB length [the angle and/or distance of mandibular incisor to Nasion-B point line]) were assessed with NemoCeph NX 2006 software (NemoTec, Madrid, Spain) on lateral cephalometric radiographs taken in a standardized position by an experienced technician. All measurements were performed in random order by one researcher (D.K.) blinded to the patient name and time point.

### Statistical analyses

To examine intraobserver reliability, the same researcher (D.K.) repeated all the measurements 3 weeks after the initial assessment in 15 randomly selected patients and intraclass correlations were calculated. Differences between the readings were tested with paired *t*-test to



**Figure 1.** Flow chart of the study. SL, Self-ligating group; CL, conventional group.

**Table 1.** Chronological age and gender distribution of the groups

	Group		p-value
	SL (n = 22)	CL (n = 24)	
Chronological age (yr)	15.48 ± 2.53	14.65 ± 2.02	0.221*
Gender distribution (male/female)	17/5	18/6	0.857 <sup>†</sup>

Values are presented as mean ± standard deviation or number. SL, Self-ligating group; CL, conventional group.

\*Student’s *t*-test; <sup>†</sup>Pearson’s chi-square test.

estimate systematic error. Intraclass correlation values above 0.931 (0.931–0.967) confirmed the reliability of the measurements. All the measurements were free of systematic error ( $p > 0.05$ ).

After the Shapiro-Wilk test was performed for determining normality ( $p > 0.05$ ), paired *t*-test and Student’s *t*-test were applied for intragroup and intergroup comparisons, respectively. Gender distribution was analyzed by Pearson’s chi-square test. Multiple linear regression was performed to identify variables affecting improvement in anterior irregularity: bracket type, chronological age, initial anterior irregularity index, initial intercanine and intermolar widths, initial incisor position and inclination, and mean changes in measured variables at 8 and 16 weeks. All statistical analyses were performed with SPSS software for Windows (version

**Table 2.** Comparison of the initial data

Variable	Group		p-value*
	SL (n = 22)	CL (n = 24)	
Little’s irregularity index (mm)	7.33 ± 2.06	6.03 ± 2.81	0.082
Inter-canine width (mm)	25.52 ± 1.55	26.32 ± 2.16	0.162
Inter-molar width (mm)	44.05 ± 2.48	44.10 ± 2.42	0.950
IMPA (°)	95.55 ± 7.71	92.51 ± 6.33	0.149
I-NB (°)	24.77 ± 6.80	24.7 ± 7.01	0.973
I-NB (mm)	5.35 ± 4.91	5.36 ± 4.33	0.995

Values are presented as mean ± standard deviation.

SL, Self-ligating group; CL, conventional group; IMPA, the angle of mandibular incisor to mandibular plane; I-NB, the angle and/or distance of mandibular incisor to N-B line (Nasion-B point).

\*Student’s *t*-test.

10.0; SPSS, Inc., Chicago, IL, USA). The significance level was set at  $p < 0.05$  for all the tests.

## RESULTS

One patient in each group failed to attend an appointment and two patients in the self-ligating group experienced bracket breakage. Therefore, data of 46 patients were analyzed (Figure 1). The self-ligating

**Table 3.** Comparison of mandibular arch changes

Variable	Group		p-value
	SL (n = 22)	CL (n = 24)	
Little's irregularity index T01 (mm)	-3.84 <sup>‡</sup> ± 2.38	-2.93 <sup>‡</sup> ± 2.41	0.207
Little's irregularity index T12 (mm)	-0.99 <sup>‡</sup> ± 0.76	-0.98 <sup>‡</sup> ± 1.37	0.982
Little's irregularity index T02 (mm)	-4.83 <sup>‡</sup> ± 2.64	-3.91 <sup>‡</sup> ± 3.02	0.282
Inter-canine width T01 (mm)	0.87 <sup>†</sup> ± 1.31	0.59* ± 1.23	0.464
Inter-canine width T12 (mm)	0.01 ± 0.62	0.09 ± 0.99	0.671
Inter-canine width T02 (mm)	0.88* ± 1.47	0.68* ± 1.48	0.696
Inter-molar width T01 (mm)	0.29 ± 1.02	0.35 ± 1.43	0.291
Inter-molar width T12 (mm)	0.22 ± 0.49	0.26 ± 0.73	0.471
Inter-molar width T02 (mm)	0.51 ± 0.92	0.61 ± 1.15	0.873
IMPA T02 (°)	5.25 <sup>‡</sup> ± 4.77	5.38 <sup>‡</sup> ± 3.37	0.921
I-NB T02 (°)	5.03 <sup>‡</sup> ± 5.37	5.44 <sup>‡</sup> ± 3.13	0.753
I-NB T02 (mm)	0.80 ± 3.93	0.56 ± 4.26	0.267

Values are presented as mean ± standard deviation.

SL, Self-ligating group; CL, conventional group; IMPA, the angle of mandibular incisor to mandibular plane; I-NB, the angle and/or distance of mandibular incisor to N-B line (Nasion-B point).

Mean value by paired *t*-test; *p*-value by Student's *t*-test.

\**p* < 0.05; †*p* < 0.01; ‡*p* < 0.001.

**Table 4.** Multiple linear regression results of potential variables affecting improvement in anterior irregularity

Variable	Little index change T01 (-3.37 ± 2.41 mm)		Little index change T02 (-4.35 ± 2.85 mm)		95% CI T01	95% CI T02
	r	p-value	r	p-value		
Bracket type	0.190	0.103	0.162	0.141	-1.07/0.59	-1.13/0.56
Chronological age	0.002	0.494	0.069	0.324	-0.09/0.17	-0.08/0.19
Little's index T0	-0.852	< 0.001	-0.891	< 0.001	-1.04/-0.64	-1.16/-0.77
Inter-canine width T01	-0.571	< 0.001			-0.45/0.32	
Inter-canine width T02			-0.547	< 0.001		-0.48/0.16

r, Regression coefficient; CI, confidence interval; T01, weeks 0–8; T02, weeks 0–16.

group consisted of 22 patients (17 male and five female subjects; mean age, 15.48 ± 2.53 years) and the conventional group comprised 24 patients (16 male and eight female subjects; mean age, 14.65 ± 2.02 years). The groups showed no significant differences in gender distribution and chronological age (*p* > 0.05; Table 1) as well as initial values (*p* > 0.05; Table 2).

Anterior irregularity index values significantly decreased up to 16 weeks in both the groups (*p* < 0.01; Table 3). Inter-canine width significantly increased at 8 and 16 weeks in the self-ligating (*p* < 0.05 and *p* < 0.01, respectively) and conventional (*p* < 0.05) groups, but intermolar width did not change significantly (*p* > 0.05). During 16 weeks of alignment, the mandibular incisors were significantly proclined (*p* < 0.001), but their position did not significantly change in both the

groups (*p* > 0.05). Student's *t*-test showed no significant intergroup differences in these changes (*p* > 0.05).

Initial anterior irregularity index and intercanine width changes were significantly associated with improvement in anterior irregularity (*p* < 0.001). None of the other variables had significant effects (*p* > 0.05; Table 4).

## DISCUSSION

Previous studies<sup>1,6,14,15</sup> showing no differences in the amount of irregularity change in the mandibular arch between self-ligating and conventional brackets did not exclude patients with bracket breakage and failure to attend an appointment. In this study, we excluded such patients and it eliminated the potential effects of bracket breakage on initial alignment in the mandibular

arch which was not previously done.

This clinical trial showed no significant difference in mandibular alignment, although slightly better correction (0.9 mm) was achieved in the self-ligating group. The finding is similar to that of Miles,<sup>6</sup> who reported 0.7-mm difference in correction between SmartClip self-ligating and conventional brackets. However, the author<sup>6</sup> did not investigate potential factors affecting Little's index<sup>27</sup> changes. We found that initial anterior irregularity index and intercanine width changes have significant effects on improvement in anterior irregularity during initial alignment. Although the groups did not show significant differences in these variables, the slightly higher anterior irregularity index before the treatment (~0.9 mm) and marginally larger intercanine width (~0.2 mm) in the self-ligating group might be responsible for this result. Fleming et al.<sup>15</sup> reported a similar relationship between initial irregularity and irregularity changes due to alignment with SmartClip self-ligating brackets over 8 weeks. They also reported that mandibular alignment is independent of bracket type, supporting our finding.

According to Fleming et al.,<sup>14</sup> the ideal alignment procedure would involve slight incisor proclination and intercanine expansion but considerable intermolar expansion, which are important for long-term stability.<sup>28</sup> SmartClip self-ligating and conventional brackets did not show significant differences in these parameters in the present study. Contrarily, Fleming et al.<sup>14</sup> reported approximately 1-mm greater increase in intermolar width with self-ligating brackets. This difference can be attributed to several factors including alignment and leveling over 30 weeks and use of 0.017 × 0.025-inch and 0.019 × 0.025-inch nickel-titanium and stainless steel rectangular archwires.<sup>14</sup> Alignment in the present study was performed for 16 weeks and only round nickel-titanium archwires were used.

Despite the recently reported advantages of self-ligating brackets,<sup>29,30</sup> the present and previous prospective randomized clinical studies<sup>6,14,15</sup> showed that such brackets do not affect initial mandibular alignment. In addition, Ong et al.<sup>19</sup> reported that self-ligating brackets are no more efficient than conventional brackets for anterior alignment or passive extraction space closure in the maxillary arch during the first 20 weeks. Clinicians should therefore consider the cost of these systems and their assumed advantages. SmartClip self-ligating brackets have some notable disadvantages including difficulty of archwire insertion on rotated teeth, disengaging of rectangular archwires,<sup>6</sup> and increased discomfort during archwire insertion and removal.<sup>16</sup>

This study showed relatively short-term outcomes. Therefore, prospective randomized clinical trials of long-term irregularity correction and transversal effects of both bracket types are warranted.

## CONCLUSION

The null hypothesis was rejected. SmartClip self-ligating and conventional brackets have similar effectiveness for initial mandibular alignment. Initial anterior irregularity index and intercanine width change are important predictors of improvement in anterior irregularity during initial mandibular alignment, but bracket type has little effect.

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