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Invisalign® vs. Spark™ Template: Which Is the Most Effective in the Attachment Bonding Procedure? A Randomized Controlled Trial

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Abstract: Aim: The primary aim of this randomized clinical trial was to evaluate the percentage of attachments' debonding at the template's removal both in Invisalign® and Spark™ systems. The secondary aim was to define the percentage of patients who did not show attachments' debonding at the template's removal. Materials and methods: Eighty patients who needed an orthodontic treatment were included in the study and randomly assigned to a treatment to be performed with Spark™ or Invisalign® clear aligners system. The patients were equally divided into two groups: Spark group ($n = 40$) and Invisalign group ($n = 40$). At the template removal by the teeth surface after the attachment bonding procedure, in each patient of both groups, it was assessed if some attachment debonding occurred and the number of attachments detached. Results: The Spark group showed, in general, a lower frequency in debonding in comparison with the Invisalign group, as 87.5% of patients in the Spark group did not show any bonding failure versus 27.5% in those of the Invisalign group. Conclusions: At template removal, the Spark™ template showed less attachment debonding compared to the Invisalign® template. The Spark™ template can be considered more effective in attachments' transferring to the tooth surface than the Invisalign® one.

Keywords: clear aligners; clear aligner's therapy; attachments; Spark™; Invisalign®

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Citation: Bruno, G.; Gracco, A.; Barone, M.; Mutinelli, S.; De Stefani, A. Invisalign® vs. Spark™ Template: Which Is the Most Effective in the Attachment Bonding Procedure? A Randomized Controlled Trial. *Appl. Sci.* **2021**, *11*, 6716. https://doi.org/10.3390/app11156716

Academic Editor: Giuliana Muzio

Received: 28 June 2021
Accepted: 20 July 2021
Published: 22 July 2021

1. Introduction

In recent decades, both in adult and adolescent patients, there has been a significant increase in the demand for orthodontic treatments that could be able to combine the characteristics of aesthetics and comfort required by the patient with the biomechanical performance required by the clinician.

In order to satisfy these requirements, various companies have started to produce and introduce in the orthodontic market the so-called clear aligners [1]. As early as 1946, Kesling introduced the possibility to consecutively use a series of thermoplastic tooth positioners to progressively reposition misaligned teeth [2,3]; but one of the pioneers in this panorama was Align Technology Inc. (Santa Clara, CA, USA), who in the late 1990s, introduced orthodontic treatments with clear aligners using sequential application of clear alignment devices made from thermoplastic material [2–6]. This system is called Invisalign®. As a result of modern technology and materials, thermoplastic appliances have evolved remarkably during the last years, so they can now be used for full orthodontic therapy [1] to treat a wide range of malocclusions.

One of the bases of the orthodontic therapy with clear aligners are the attachments that are composite resin buttons, which can be applied to the vestibular or lingual surfaces of the teeth, required as retention elements and/or to improve the efficiency of dental movements, especially if complex [4–7]. Therefore, they constitute fundamental mechanical components as they allow to transfer the determined forces from the aligner to the tooth root and crown for generating efficient tooth movement [4]. For these reasons, they have to remain intact for the entire duration of the treatment.

In clinical practice, as material for the attachment application to the teeth, flowable composites or packable composites can be used, in accordance with the producer company's instruction [8]. To allow and facilitate the attachments realization, the clear aligners' manufacturer company provides to the clinician a specific template. This is a "passive" thermoplastic device, i.e., not aimed to generate teeth movements, but only to allow the correct transfer of the attachments on the teeth surface. The template is generally constituted of a less rigid plastic material compared to the material of which the "active" aligner (i.e., those used during the treatment with clear aligners, capable of inducing teeth movement) is made.

Recently, Ormco Corporation (Orange, CA, USA) has introduced their Spark™ Clear Aligner System, of which, differently with respect to other typologies of aligners produced by other companies [5,9,10], scientific literature is not available. The members of this group of study, who have already used Invisalign® in their orthodontic practice for years, have started to used Spark™ too, by obtaining satisfactory clinical results.

The primary aim of this study was to evaluate the percentage of attachments' debonding during the template's removal both in Invisalign® and Spark™ systems. Furthermore, the secondary aim was to estimate the percentage of patients who did not show attachments' debonding during the template's removal.

2. Materials and Methods

Eighty patients who needed an orthodontic treatment were included in this study. The study design was a randomized clinical trial. The inclusion criteria used for the sample's selection were: permanent dentition; no previous orthodontic treatment with fixed appliances or aligners; no craniofacial anomalies; no dental fluorosis, enamel hypoplasia, dentin hypoplasia, or other abnormal teeth structure that could interfere with the process of adhesion; no full coverage crowns. No exclusion criteria were set regarding the kind of malocclusion treated. The attachments were digitally planned using the specific software. The shape, dimension and position of the attachments were decided according to the specific tooth movement.

2.1. Attachments Bonding Method

The attachments bonding method used was the same for both the clear aligner systems. A template was used to bond the attachments. Before bonding, patients' teeth were polished using a toothbrush attached to a low-speed handpiece. Then, the enamel surfaces were etched with 32% orthophosphoric acid (Scotchbond™ Universal Etchant Gel, 3M ESPE, St Paul, MN, USA) for 30 s, rinsed with water for 30 s and dried with an air stream to ensure the complete removal of the etching agent. Then the bonding agent (3M™ Scotchbond™ Universal Adhesive, 3M ESPE, St Paul, MN, USA) was applied to the teeth surface with a small brush, spread with air and light cured for 10 s using a light-curing unit (Valo, 1.000–3.200 mW/cm^2; Ultradent Products Inc., South Jordan, UT, USA). Then, the composite resin (Tetric EvoFlow Bulk Fill, Ivoclar Vivadent, Schaan, Liechtenstein) was applied to the attachment wells of the clear aligner template. The template was pressed on the teeth surface and light cured for 20 s using the same light-curing unit. Thus, the template was gently removed by the teeth.

2.2. Data Collection

After bonding, each patient of both Spark group and Invisalign group was assessed if some attachment debonding occurred at template removal and, in this case, the number of attachments that resulted detached. Data were then collected and organized in a table (Excel, Microsoft Office 365, Microsoft, Redmond, WA, USA), which can be found in Section 3.

2.3. Statistical Analysis

The statistical analysis was performed by firstly testing continuous and discrete variables (number of attachments and probability of failure) for normality. Since the variables were not normally distributed, the difference between the two groups was analyzed by means of a nonparametric test, the two-sample Mann–Whitney test. Subsequently, the sample was divided into four categories, on the basis of the number of debonded attachments at template removal (none, one attachment, two attachments and three attachments). The Fisher Exact test was run to evaluate the frequency distribution difference between the two groups.

The level of significance was set at $p < 0.05$. The data were analyzed with the software package STATA 16 (College Station, TX, USA).

2.4. Sample Size Calculation

The starting hypothesis was that, with the Invisalign® system, a detachment percentage during the attachment bonding procedure of about 8–10% would occur. The hypothesis set for the study was to evaluate a halving of the attachments detachment during attachments bonding with the Spark™ template (i.e., from about 7% to 3.5%) compared to the Invisalign® template. The sample size calculated in this way was 1160 attachments, i.e., about 78 patients.

3. Results

The sample comprised 80 patients randomly assigned to one of the two groups for clear aligners treatment: Spark group (n = 40) and Invisalign group (n = 40). For each group, the templates for attachment bonding provided by the respective manufacturer company were used.

The two groups were homogeneous for both baseline characteristics and also for the number of attachments bonded. In fact, the median number of attachments per patient and also their stratification for her/his maxillary and mandibular arch were not statistically different between the two groups (two-sample Mann–Whitney test; $p > 0.05$; Table 1).

Table 1. Attachments distribution per patient in the two groups.

Group	Number of Attachments in Full Mouth	Number of Attachments in Maxillary Arch	Number of Attachments in Mandibular Arch
Spark			
Median	15	7.5	8.5
25th percentile	10	5.5	6
75th percentile	18.5	8	10.5
Invisalign			
Median	14.5	7	8.5
25th percentile	11.5	5.5	6
75th percentile	18	8	11

Probability of Failure

The probability of failure in attachment bonding was estimated as the ratio between the number of attachments deboned at the template removal and the total amount of attachments sited in the template. In the Spark group, the probability of debonding was close to zero (median, 0; interquartile range, 0) versus a median value of 0.07 (interquartile range, 0.11) in the Invisalign group. The difference in probability of failure between the two groups was statistically significant (two-sample Mann-Whitney test; $p < 0.001$).

Regarding the number of attachments debonded, all of the samples were categorized in four categories comprising: patients who presented no bonding failure, and one, two and three attachments debonded. Patients of the Spark group presented, in general, a lower frequency in debonding in comparison with patients of the Invisalign group (Fisher exact test; $p < 0.001$). More specifically, 87.5% of patients in the Spark group did not show any bonding failure versus 27.5% in those of the Invisalign group. The maximum number of events was limited to three debonded attachments in four patients of the Invisalign group. The frequency distribution categorized for the number of deboned attachments in the two groups is reported in Table 2.

Table 2. Frequency distribution of attachment bonding failure in the two groups.

Number of Debonded Attachments	Spark Group	Invisalign Group
None		
Number of patients	35	11
Percentage of patients in the group	87.5%	27.5%
One debonded attachment		
Number of patients	2	12
Percentage of patients in the group	5%	30%
Two debonded attachments		
Number of patients	3	13
Percentage of patients in the group	7.5%	32.5%
Three debonded attachments		
Number of patients	0	4
Percentage of patients in the group	0%	10%

4. Discussion

Over the years, the use of clear aligners systems for orthodontic treatment has become increasingly frequent because of the indisputable advantages they offered, such as aesthetic, ease of use, comfort for the patient, ease in oral hygiene maintenance, and possibility to manage a variety of different malocclusions [4,11,12].

The rationale that guided the authors to conduct the research this paper is based on was that composite attachments bonded on teeth's surface constitute a fundamental component in clear aligner's therapy. The attachments are virtually planned and then precisely transferred on the teeth's surface using a template provided to the clinician by the clear aligners' manufacturer company.

Given this premise, an equally essential point is that the attachments have to be performed as perfectly as possible on the day of their bonding.

The bonding procedure in itself is relatively quick, as the attachments are pre-formed due to the presence of special attachment wells on the template that the clinician only has to fill with the composite resin; moreover, thanks to the template, all the attachments of the dental arch can be positioned simultaneously. However, if during the template removal an attachments' debonding occurs, the clinician should have to repeat the bonding procedure, greatly amplifying the required operative time.

With the same attachments bonding procedure, this study revealed that a lower frequency of attachment debonding occurred in the cases where the Spark™ system was used, with a percentage of patients who did not show any bonding failure considerably higher in the Spark™ group than in the Invisalign group. This evidence can be considered statistically significant ($p < 0.001$).

The sample size calculation performed during the study design phase allowed to include in this randomized clinical trial a number of patients adequate to exclude variables such as the attachments shape prescribed for different cases, the strength characteristics of the composite used and all the possible variables that could influence the bonding process. Therefore, the results can be considered indicative of the fact that the Spark™ template can be defined as more effective in attachments' transferring to the tooth surface than the Invisalign® one.

The hypothesis of the present study can be extended to try to explain the results that have emerged in that the Spark™ template appears to be less rigid than that of Invisalign®, and that, therefore, this might allow a less traumatic template removal from the dental arch and from the just-bonded attachments. However, this one derives from a tactile perception of the clinicians, as the clear aligners' manufacturer companies do not provide specific information regarding the production materials of the templates.

Furthermore, an analysis of the recent literature did not uncover studies specifically analyzing the characteristics of the template or its efficacy in the attachments bonding procedure, both for Spark™ and Invisalign® and for other clear aligners' manufacturer companies. For this reason, the authors do not have the possibility of comparing the results of their study with another similar study.

Therefore, this study could suggest other research ideas, with the aim of assessing what characteristics of the template provided by the different clear aligners' manufacturer companies could actually be determining components in the percentage of debonding encountered at template removal and, consequently, in the effectiveness of the template itself. Moreover, the authors suggest evaluating different adhesive materials for the bonding procedure in further studies.

5. Conclusions

The present study showed that the Spark™ clear aligners' system template removal by the dental arch resulted in fewer attachments debonding compared to that of the Invisalign® system template. This was demonstrated by the resulted percentage of patients with no attachment debonding at template removal of 87.5% versus 27.5% when the template used for the bonding procedure was, respectively, that of the Spark™ and Invisalign® system. Therefore, it might be asserted that the Spark™ template can be considered more effective in attachments' transferring to the tooth surface than the Invisalign® one. Further studies could be useful for defining what kind of template characteristics might be used to determine adequate attachment bonding to the teeth surfaces and to define a template as effective.

Author Contributions: Conceptualization, G.B. and A.D.S.; methodology, S.M. and A.D.S.; validation, G.B.; formal analysis, A.G.; investigation, A.D.S.; data curation, M.B. and S.M.; writing—original draft preparation, G.B. and M.B.; writing—review and editing, M.B.; supervision, A.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

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