

Fabrício Sanches Fernandes, Cláudia Trindade Mattos, Oswaldo de Vasconcellos Vilella

Effects of Class II maxillomandibular elastics on Invisalign aligners: An in vitro study



Fabrício Sanches Fernandes

KEY WORDS *aesthetic aligners, Invisalign, orthodontics*

Objective: To evaluate the effects of Class II maxillomandibular elastics on Invisalign aligners (Align Technology, San Jose, CA, USA) and assess whether the type of fitting or immersion in a medium simulating the oral environment influence possible dimensional changes.

Materials and methods: Twenty new pairs of Invisalign aligners were tested. Ten pairs had inserts for maxillomandibular elastics made by the manufacturer (precision cuts) and ten had cutouts. Epoxy resin casts were created for aligners, and were later mounted on articulators. Class II maxillomandibular elastics were attached to the fittings with a force of approximately 130 gf. The width and anteroposterior distance were measured at predetermined points prior to the use of elastics and 24 hours, 7 days and 14 days after force application began. Ten sets of models, each with a pair of aligners, were immersed in artificial saliva at 37°C over the experimental period, and the other 10 were kept in a dry environment.

Results: Statistically significant changes were observed mainly in the first 24 hours. In the dry environment, the aligners with precision cuts suffered the most considerable deformations. Dimensional changes increased in both groups when they were maintained in a simulated oral environment. The highest values of changes were observed closer to the site where the elastics were fitted.

Conclusion: Class II maxillomandibular elastics cause dimensional deformations of Invisalign aligners. The changes recorded in maxillary intercanine distance and the distance between mandibular first molars in the immersed aligners with both types of fitting were considered statistically and clinically significant.

Introduction

The idea of making removable and flexible devices to move teeth dates back many years. In 1945, Kesling¹ introduced the tooth positioner as a method of reducing the spaces left after removal of the orthodontic appliance. He realised that several minor tooth movements could be incorporated into the positioner, and that important tooth movements could be performed using a series of positioners manufactured from sequential setups as treatment progressed^{1,2}; however, the main limitation of this method is the difficulty of manually dividing a larger general tooth movement into small, precise stages³.

Fabrício Sanches Fernandes, MSc
Private practice, Niterói, Rio de Janeiro, Brazil

Cláudia Trindade Mattos, PhD
Associate Professor, Department of Orthodontics, School of Dentistry, Universidade Federal Fluminense, Niterói, Rio de Janeiro, Brazil

Oswaldo de Vasconcellos Vilella, PhD
Professor, Department of Orthodontics, School of Dentistry, Universidade Federal Fluminense, Niterói, Rio de Janeiro, Brazil

Correspondence to: Mr Fabrício Sanches Fernandes, 195 Tupiniquins Street, Niterói, Rio de Janeiro 24360-260, Brazil. Email: fsanchesf3@hotmail.com

Developments in materials and manufacturing technology have facilitated the manufacture of aesthetic positioners for orthodontic treatment. The use of these positioners in orthodontics, later called aligners, has spread rapidly, with an increasing number of patients seeking an aesthetic and comfortable alternative to fixed braces⁴.

The Invisalign system (Align Technology, San Jose, CA, USA) was introduced in 1998, and was the first orthodontic treatment method based solely on digital 3D technology³. From a single impression of the patient's teeth, it is possible to produce a final projection, plan the stages of tooth movement from the initial to the final state and create a series of aligners that are capable of moving the teeth according to the treatment plan⁵. The system generally requires patients to wear their aligners for a minimum of 20 hours a day and to remove them only when eating, drinking, brushing their teeth or flossing³.

Prior to September 2001, Invisalign aligners were made from a material called Proceed30 (PC30), a mixture of polymers that did not meet all physicochemical and clinical requirements for orthodontic movement⁵. Many disadvantages were reported, which in some cases limited the use of these aligners^{6,7}. PC30 was later replaced by the polymeric material Exceed30 (EX30), which exhibited 1.5 times more elasticity and improved aligner adaptation by four times⁸. In 2013, EX30 was replaced by Smart Track (LD30), a multilayer aromatic thermoplastic polyurethane/copolyester that displays greater consistency in the application of orthodontic forces, better elasticity and improved chemical stability⁸.

Maxillomandibular elastics can be combined with aligners to correct sagittal discrepancies between dental arches or control anchorage. These elastics can be supported by buttons bonded to the teeth or incorporated into the appliance using cutouts made by the orthodontist or requested during the ClinCheck (Align Technology) phase. In the latter case, they are called precision cuts⁹. Align Technology recommends a force of 128 gf for the elastics but warns that they can compromise the strength and durability of the aligner, and thus advises that only one precision cut be made per quadrant. Making precision cuts on teeth with conventional attachments can also affect the performance of both accessories¹⁰.

Thermoplastic polymers used to manufacture aligners have some limitations. They absorb water, which can cause

expansion and changes in their mechanical properties¹¹. It has been demonstrated that, in intraorally aged Invisalign aligners, the indentation modulus¹² and Martens hardness¹³ decrease during use, weakening the force delivery capacity and leaving the aligner less resistant to wear. The increase in the elastic index also contributes to its weakening¹³. Despite these limitations, the influence of maxillo-mandibular elastics on the dimensional stability of aligners remains unknown.

The present study aimed to verify the effects of Class II maxillomandibular elastics on Invisalign aligners and assess whether the type of fitting or immersion in a medium simulating the oral environment influence possible dimensional changes.

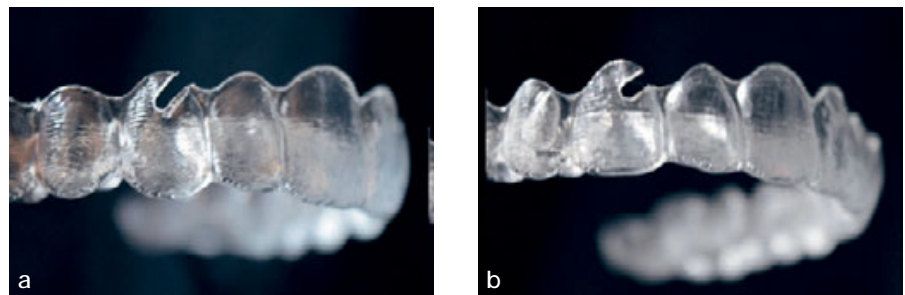
Materials and methods

Twenty new pairs of Invisalign aligners made from Smart Track material were used. The aligners had been made for orthodontic patients but, due to changes in treatment plans, they became redundant and were donated to be used in the present study. Each pair consisted of two aligners from the same individual, one for the maxillary teeth and one for the mandibular teeth.

The aligners were filled with epoxy resin (Redelease, São Paulo, Brazil) and their bases were constructed using the same material. Epoxy resin was chosen because it offers excellent reproduction of detail and stability^{14,15} and can be submerged without any change to its properties¹⁶. The casts were then mounted in articulators (Inova Pro, São Paulo, Brazil) that simulated the patients' occlusion.

Ten pairs of aligners were kept immersed in a laboratory water bath (model 100, Fanem, São Paulo, Brazil) filled with artificial saliva (Farmácia Formulando, Niterói, Brazil) at a constant temperature of 37°C for the entire experimental period. They were removed from the machine only to perform measurements and change the elastics. The remaining 10 pairs of aligners were tested in a dry environment.

For both the immersed and non-immersed groups, cutouts for five pairs of aligners for maxillomandibular elastics were made by Align Technology (precision cuts), while cuts for the other five pairs were performed manually in a laboratory by one of the researchers (FSF). A hole was created using a 1.5-mm diamond bur (KG Sorensen, Cotia, Brazil)



Figs 1a-b (a) Precision cut and (b) manual fitting.

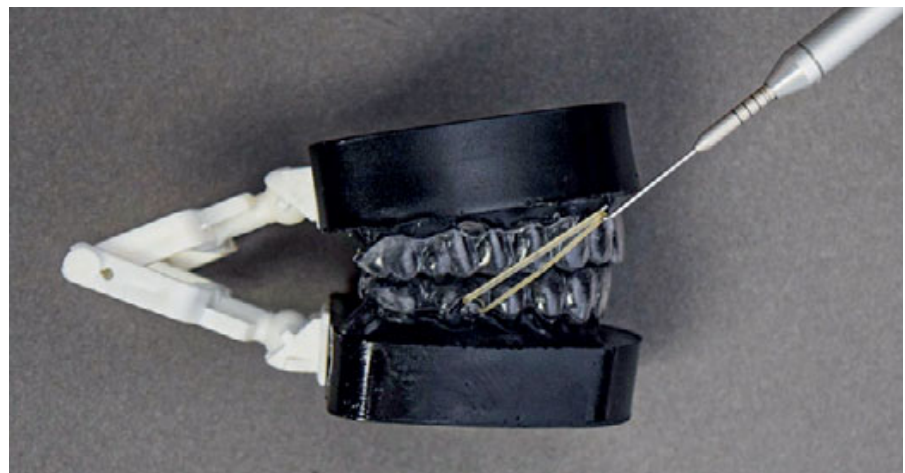


Fig 2 Measurement of force produced by maxillomandibular elastics using a tensiometer.

and finished with an orthodontic ligature cutter (#020-A, Orthopli, Philadelphia, PA, USA) to obtain a similar shape to that of the precision cut. The fittings were located in the canine site for the aligners for the maxillary teeth and in the first molar site for those for the mandibular teeth, to enable the placement of Class II elastics (Fig 1).

The 5/16 diameter maxillomandibular elastics (Morelli, São Paulo, Brazil) were inserted into the grooves using a tensiometer (SDS Ormco, Orange, CA, USA) and tensioned until they reached approximately 130 gf (Fig 2). They were changed every 24 hours and their thickness varied between light, medium and heavy so that the desired strength was achieved.

Marks were made using a permanent marker with a 0.1-mm line width (Pilot, Tokyo, Japan) at the highest point of the buccal surface of the right and left canines (intercanine), the right and left first premolars (1PM), the right and left second premolars (2PM) and the right and left first molars (1M). Marks were also made at the most anterior point, located in the uppermost part at the point of contact between the central incisors, and at the most posterior right

(AP right) and left (AP left) points, at the most distal points of the most posterior tooth of the aligner on each side (Fig 3). Linear distance measurements were taken using a digital caliper (Starrett, São Paulo, Brazil) just before and 24 hours, 7 days and 14 days after placement of the elastics.

Statistical analysis

An intraclass correlation coefficient (ICC) was used to assess operator calibration by comparing repeated measures. For this purpose, 24 measurements obtained from five pairs of aligners were repeated after 15 days.

Normality was confirmed using a Shapiro-Wilk test. A repeated-measures analysis of variance (ANOVA) was used to assess the differences between time points in each group. ANOVA and a Tukey post hoc test were used to evaluate the differences between the groups. The results are presented in Tables 1 to 4. The level of significance was set at 5% ($P < 0.05$) for all analyses. Differences greater than 0.5 mm for each side of the dental arch were considered clinically significant. The data were analysed using SPSS software (version 20.0, IBM, Chicago, IL, USA).

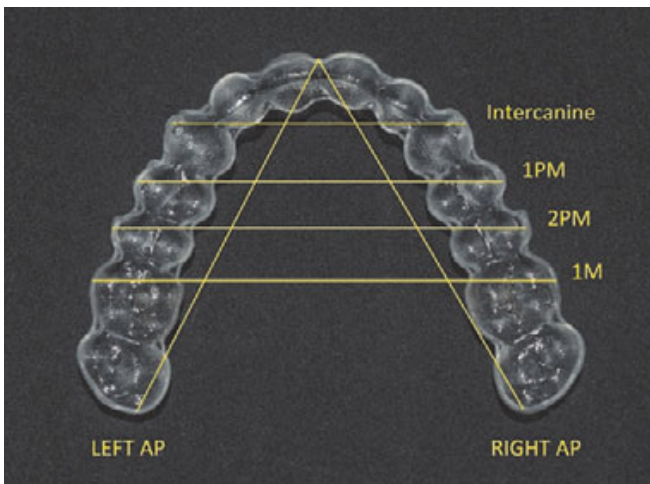


Fig 3 The evaluated linear distances.

A power analysis was performed for the intercanine distance, which was the primary outcome, considering $\alpha = 0.05$, a minimum detectable difference of 0.6 mm and a mean standard deviation (SD) of 0.2 mm, achieving a power of 80%.

Results

The ICC for intrarater agreement was 0.996 for intercanine distance, 0.991 for 1PM distance, 0.994 for 2PM distance, 0.974 for 1M distance, 0.905 for AP right distance and 0.824 for AP left distance; thus, the reproducibility of all variables studied was considered excellent.

Table 1 presents the means and SDs of the maxillary measurements for each group at each time point. In the immersed aligners group, a statistically and clinically significant difference ($P < 0.05$) was observed only for the intercanine distance in the precision cuts and fittings made in the laboratory after 7 and 14 days, respectively. A statistically significant increase ($P < 0.05$) was also recorded in many of the distances evaluated for the immersed aligners, especially in the first 7 days. Figure 4 illustrates the maxillary intercanine distances in the different groups.

Table 2 presents the means and SDs of the mandibular measurements for each group at each time point. For the immersed aligners, there was a statistically and clinically significant difference ($P < 0.05$) for the 1M distance only. In the precision cut group, this difference ($P < 0.05$) emerged

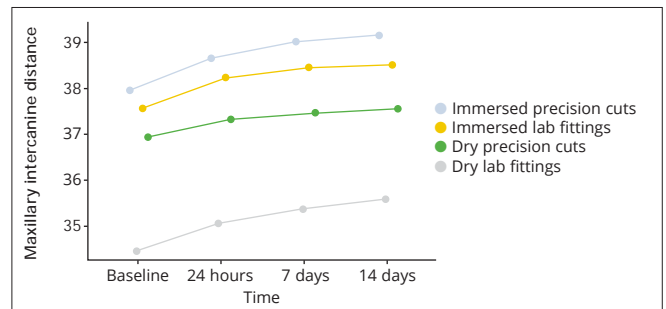


Fig 4 Intercanine distances in the different groups.

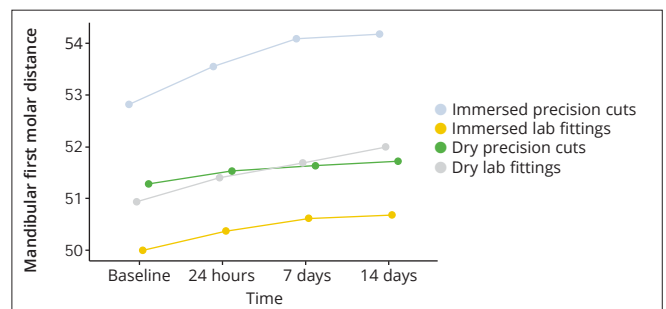


Fig 5 Intermolar distances in the different groups.

in the first 7 days, whereas in the laboratory fitting group, it was verified after 14 days. The non-immersed aligners with precision cuts showed statistically significant differences ($P < 0.05$) for all distances, except for the AP right and left distances, at different time points. The 1M distances in the different groups are shown in Fig 5.

The means and SDs of differences in the maxillary measurements between the groups for each time interval are shown in Table 3. The differences were calculated for each individual at each interval, then the means for each group and interval were calculated. In the first 24 hours, the immersed aligners with precision cuts showed significantly greater dimensional changes ($P < 0.05$) in transversal 1PM and 1M distances than all other groups. The immersed aligners with manual fittings presented statistically greater dimensional changes ($P < 0.05$) than all other groups in the 1M and AP right distances between 7 and 14 days.

The means and SDs of differences in the mandibular measurements between the groups for each time interval are shown in Table 4. The differences were calculated for each individual at each interval, then the means of each group and interval were calculated. Although the immersed

Table 1 Mean \pm standard deviation (SD) and statistical significance for variables evaluated in the maxilla. Different superscript letters in the same row indicate a statistically significant difference between the respective time points

Measurement		Mean \pm SD, mm			
		Baseline	24 hours	7 days	14 days
Intercanine distance	Dry lab fitting	36.95 \pm 1.78 ^a	37.33 \pm 1.50 ^a	37.47 \pm 1.53 ^a	37.57 \pm 1.52 ^a
	Immersed lab fitting	34.47 \pm 1.70 ^a	35.07 \pm 1.63 ^b	35.38 \pm 1.60 ^c	35.60 \pm 1.76 ^c
	Dry precision cut	37.58 \pm 0.22 ^a	38.23 \pm 0.31 ^b	38.49 \pm 0.35 ^b	38.54 \pm 0.37 ^b
	Immersed precision cut	37.96 \pm 2.39 ^a	38.67 \pm 2.16 ^{ab}	39.03 \pm 2.16 ^{bc}	39.18 \pm 2.22 ^c
1PM distance	Dry lab fitting	43.94 \pm 1.05 ^a	44.09 \pm 0.98 ^a	44.27 \pm 1.07 ^a	44.28 \pm 1.07 ^a
	Immersed lab fitting	42.76 \pm 2.89 ^a	43.00 \pm 2.81 ^b	43.17 \pm 2.81 ^c	43.31 \pm 2.81 ^{bc}
	Dry precision cut	45.10 \pm 0.20 ^a	45.19 \pm 0.26 ^a	45.23 \pm 0.32 ^a	45.23 \pm 0.30 ^a
	Immersed precision cut	45.60 \pm 3.28 ^a	46.35 \pm 3.31 ^b	46.57 \pm 3.30 ^b	46.59 \pm 3.29 ^b
2PM distance	Dry lab fitting	48.71 \pm 1.16 ^a	48.79 \pm 1.09 ^a	48.81 \pm 1.09 ^a	48.80 \pm 1.10 ^a
	Immersed lab fitting	48.65 \pm 2.51 ^a	48.82 \pm 2.52 ^b	48.93 \pm 2.55 ^c	48.98 \pm 2.55 ^c
	Dry precision cut	49.79 \pm 0.30 ^a	49.78 \pm 0.27 ^a	49.78 \pm 0.27 ^a	49.78 \pm 0.27 ^a
	Immersed precision cut	50.75 \pm 4.31 ^a	51.07 \pm 4.19 ^{ab}	51.22 \pm 4.30 ^b	51.23 \pm 4.30 ^b
1M distance	Dry lab fitting	53.72 \pm 1.34 ^a	53.86 \pm 1.07 ^a	53.88 \pm 0.98 ^a	53.86 \pm 0.98 ^a
	Immersed lab fitting	52.76 \pm 1.38 ^a	52.89 \pm 1.38 ^b	52.99 \pm 1.38 ^c	53.04 \pm 1.40 ^c
	Dry precision cut	55.34 \pm 0.40 ^a	55.31 \pm 0.39 ^a	55.33 \pm 0.38 ^a	55.33 \pm 0.38 ^a
	Immersed precision cut	55.97 \pm 4.57 ^a	56.46 \pm 4.55 ^{ab}	56.56 \pm 4.58 ^b	56.56 \pm 4.56 ^b
AP right distance	Dry lab fitting	53.03 \pm 3.08 ^a	53.06 \pm 3.03 ^a	53.04 \pm 3.02 ^a	53.02 \pm 3.04 ^a
	Immersed lab fitting	46.67 \pm 4.29 ^a	46.78 \pm 4.26 ^a	46.83 \pm 4.28 ^{ab}	46.88 \pm 4.29 ^b
	Dry precision cut	53.71 \pm 0.30 ^a	53.68 \pm 0.30 ^b	53.69 \pm 0.31 ^{ab}	53.69 \pm 0.32 ^{ab}
	Immersed precision cut	54.04 \pm 1.97 ^a	54.07 \pm 1.98 ^{ab}	54.13 \pm 1.98 ^b	54.12 \pm 1.98 ^b
AP left distance	Dry lab fitting	53.14 \pm 2.38 ^a	53.16 \pm 2.35 ^a	53.16 \pm 2.29 ^a	53.15 \pm 2.34 ^a
	Immersed lab fitting	48.74 \pm 2.78 ^a	48.85 \pm 2.77 ^b	48.93 \pm 2.74 ^{bc}	48.97 \pm 2.73 ^c
	Dry precision cut	51.11 \pm 0.87 ^a	51.09 \pm 0.86 ^a	51.10 \pm 0.86 ^a	51.10 \pm 0.87 ^a
	Immersed precision cut	51.70 \pm 3.32 ^a	51.77 \pm 3.31 ^a	51.87 \pm 3.33 ^a	51.89 \pm 3.35 ^a

aligners with precision cuts showed the greatest dimensional change for the 1M distance at 24 hours, the difference in dimensional change between the immersed aligners with precision cuts and the other groups was not statistically significant. In contrast, between 24 hours and 7 days, this group showed more statistically significant di-

mensional changes ($P < 0.05$) for the 2PM distance than all other groups. The immersed aligners with fittings made in the laboratory showed statistically greater dimensional changes ($P < 0.05$) for the 1PM, 1M and AP linear distances than all other groups between 7 and 14 days.



Table 2 Mean ± SD and statistical significance for variables evaluated in the mandible. Different superscript letters in the same row indicate a statistical difference between the respective time points

Measurement		Mean ± SD, mm			
		Baseline	24 hours	7 days	14 days
Intercanine distance	Dry lab fitting	29.23 ± 1.44 ^a	29.23 ± 1.43 ^a	29.19 ± 1.36 ^a	29.17 ± 1.37 ^a
	Immersed lab fitting	28.23 ± 0.56 ^a	28.36 ± 0.56 ^b	28.45 ± 0.56 ^c	28.50 ± 0.58 ^c
	Dry precision cut	28.25 ± 0.18 ^{ab}	28.23 ± 0.19 ^{ab}	28.26 ± 0.18 ^a	28.23 ± 0.18 ^b
	Immersed precision cut	29.21 ± 1.55 ^{ab}	29.59 ± 1.37 ^a	29.67 ± 1.38 ^b	29.68 ± 1.39 ^b
1PM distance	Dry lab fitting	38.97 ± 0.90 ^a	39.03 ± 0.89 ^a	39.05 ± 0.87 ^a	39.04 ± 0.87 ^a
	Immersed lab fitting	37.48 ± 1.09 ^a	37.65 ± 1.04 ^a	37.75 ± 1.02 ^b	37.84 ± 1.05 ^b
	Dry precision cut	36.35 ± 0.33 ^{ab}	36.34 ± 0.35 ^a	36.37 ± 0.35 ^b	36.37 ± 0.34 ^{ab}
	Immersed precision cut	38.15 ± 2.89 ^a	38.43 ± 2.79 ^a	38.60 ± 2.81 ^b	38.61 ± 2.81 ^b
2PM distance	Dry lab fitting	44.98 ± 1.61 ^a	45.02 ± 1.61 ^a	45.10 ± 1.62 ^a	45.10 ± 1.61 ^a
	Immersed lab fitting	44.54 ± 1.80 ^a	44.79 ± 1.81 ^b	44.92 ± 1.82 ^c	45.05 ± 1.82 ^c
	Dry precision cut	43.24 ± 0.45 ^a	43.27 ± 0.44 ^{ab}	43.30 ± 0.45 ^c	43.33 ± 0.46 ^{bc}
	Immersed precision cut	45.36 ± 3.98 ^a	45.68 ± 3.78 ^a	46.16 ± 3.87 ^b	46.22 ± 3.83 ^b
1M distance	Dry lab fitting	51.28 ± 2.33 ^{ab}	51.52 ± 2.09 ^a	51.63 ± 2.02 ^{ab}	51.72 ± 2.09 ^b
	Immersed lab fitting	50.94 ± 0.70 ^a	51.39 ± 0.72 ^b	51.68 ± 0.80 ^b	51.99 ± 0.73 ^c
	Dry precision cut	50.00 ± 0.54 ^a	50.36 ± 0.68 ^b	50.61 ± 0.83 ^{ab}	50.67 ± 0.84 ^{ab}
	Immersed precision cut	52.83 ± 4.71 ^a	53.55 ± 4.37 ^{ab}	54.09 ± 4.38 ^c	54.18 ± 4.43 ^{bc}
AP right distance	Dry lab fitting	49.82 ± 3.53 ^a	49.80 ± 3.55 ^a	49.77 ± 3.52 ^a	49.77 ± 3.53 ^a
	Immersed lab fitting	47.68 ± 3.38 ^a	47.76 ± 3.39 ^b	47.82 ± 3.42 ^{bc}	47.88 ± 3.43 ^c
	Dry precision cut	49.12 ± 0.18 ^a	49.08 ± 0.18 ^a	49.12 ± 0.18 ^a	49.11 ± 0.17 ^a
	Immersed precision cut	50.14 ± 2.73 ^a	50.19 ± 2.71 ^a	50.23 ± 2.74 ^a	50.25 ± 2.74 ^a
AP left distance	Dry lab fitting	50.27 ± 2.96 ^a	50.21 ± 2.95 ^a	50.01 ± 2.85 ^a	50.00 ± 2.85 ^a
	Immersed lab fitting	48.57 ± 2.49 ^a	48.67 ± 2.48 ^a	48.75 ± 2.49 ^b	48.80 ± 2.50 ^c
	Dry precision cut	50.43 ± 0.32 ^a	50.37 ± 0.30 ^a	50.40 ± 0.31 ^a	50.39 ± 0.32 ^a
	Immersed precision cut	50.11 ± 3.44 ^a	50.19 ± 3.43 ^a	50.24 ± 3.45 ^a	50.26 ± 3.46 ^a



Table 3 Mean \pm SD and statistical significance for differences in the maxillary measurements between the groups for each time interval. Different superscript letters in the same column indicate a statistically significant difference between groups

Measurement		Mean \pm SD, mm			
		Baseline–24 hours	24 hours–7 days	7–14 days	Baseline–14 days
Intercanine distance	Dry lab fitting	0.38 \pm 0.36 ^a	0.14 \pm 0.10 ^a	0.10 \pm 0.09 ^a	0.62 \pm 0.39 ^a
	Immersed lab fitting	0.60 \pm 0.19 ^a	0.26 \pm 0.17 ^a	0.21 \pm 0.18 ^a	1.12 \pm 0.15 ^{ab}
	Dry precision cut	0.65 \pm 0.23 ^a	0.30 \pm 0.05 ^a	0.04 \pm 0.03 ^a	0.95 \pm 0.31 ^{ab}
	Immersed precision cut	0.71 \pm 0.45 ^a	0.35 \pm 0.20 ^a	0.15 \pm 0.11 ^a	1.21 \pm 0.26 ^b
1PM distance	Dry lab fitting	0.14 \pm 0.15 ^a	0.18 \pm 0.17 ^a	0.01 \pm 0.03 ^a	0.34 \pm 0.24 ^{ab}
	Immersed lab fitting	0.24 \pm 0.11 ^a	0.17 \pm 0.02 ^a	0.13 \pm 0.11 ^b	0.55 \pm 0.13 ^b
	Dry precision cut	0.09 \pm 0.07 ^a	0.03 \pm 0.07 ^a	0.00 \pm 0.04 ^a	0.12 \pm 0.12 ^a
	Immersed precision cut	0.75 \pm 0.21 ^b	0.21 \pm 0.12 ^a	0.02 \pm 0.03 ^{ab}	0.99 \pm 0.19 ^c
2PM distance	Dry lab fitting	0.07 \pm 0.09 ^a	0.02 \pm 0.04 ^{ab}	-0.01 \pm 0.02 ^a	0.09 \pm 0.08 ^a
	Immersed lab fitting	0.17 \pm 0.05 ^{ab}	0.10 \pm 0.03 ^{ab}	0.04 \pm 0.02 ^b	0.32 \pm 0.07 ^b
	Dry precision cut	-0.01 \pm 0.03 ^a	0.00 \pm 0.02 ^a	0.00 \pm 0.02 ^a	0.00 \pm 0.04 ^a
	Immersed precision cut	0.32 \pm 0.16 ^b	0.14 \pm 0.12 ^b	0.01 \pm 0.00 ^{ab}	0.47 \pm 0.11 ^c
1M distance	Dry lab fitting	0.13 \pm 0.27 ^a	0.02 \pm 0.10 ^a	-0.01 \pm 0.02 ^a	0.13 \pm 0.37 ^a
	Immersed lab fitting	0.12 \pm 0.03 ^a	0.10 \pm 0.03 ^a	0.05 \pm 0.02 ^b	0.27 \pm 0.07 ^{ab}
	Dry precision cut	-0.03 \pm 0.02 ^a	0.01 \pm 0.02 ^a	0.00 \pm 0.01 ^a	-0.01 \pm 0.02 ^a
	Immersed precision cut	0.49 \pm 0.23 ^b	0.09 \pm 0.05 ^a	0.00 \pm 0.02 ^a	0.59 \pm 0.25 ^b
AP right distance	Dry lab fitting	0.03 \pm 0.11 ^{ab}	-0.02 \pm 0.02 ^a	-0.02 \pm 0.01 ^a	-0.01 \pm 0.13 ^a
	Immersed lab fitting	0.11 \pm 0.06 ^b	0.05 \pm 0.03 ^b	0.04 \pm 0.03 ^b	0.21 \pm 0.06 ^b
	Dry precision cut	-0.03 \pm 0.01 ^a	0.01 \pm 0.03 ^{ab}	0.00 \pm 0.00 ^a	-0.01 \pm 0.04 ^a
	Immersed precision cut	0.02 \pm 0.04 ^{ab}	0.06 \pm 0.05 ^b	0.00 \pm 0.01 ^a	0.08 \pm 0.02 ^{ab}
AP left distance	Dry lab fitting	0.02 \pm 0.06 ^{ab}	0.00 \pm 0.14 ^a	-0.01 \pm 0.05 ^a	0.01 \pm 0.21 ^{ab}
	Immersed lab fitting	0.11 \pm 0.03 ^b	0.08 \pm 0.03 ^a	0.04 \pm 0.02 ^a	0.23 \pm 0.05 ^b
	Dry precision cut	-0.01 \pm 0.02 ^a	0.00 \pm 0.01 ^a	0.00 \pm 0.02 ^a	-0.01 \pm 0.03 ^a
	Immersed precision cut	0.07 \pm 0.11 ^{ab}	0.09 \pm 0.05 ^a	0.02 \pm 0.02 ^a	0.19 \pm 0.13 ^{ab}



Table 4 Mean ± SD and statistical significance for differences in the mandibular measurements between the groups for each time interval. Different superscript letters in the same column indicate a statistically significant difference between groups

Measurement		Mean ± SD, mm			
		Baseline–24 hours	24 hours–7 days	7–14 days	Baseline–14 days
Intercanine distance	Dry lab fitting	0.00 ± 0.01 ^{ab}	−0.04 ± 0.08 ^a	−0.02 ± 0.02 ^a	−0.06 ± 0.07 ^a
	Immersed lab fitting	0.13 ± 0.03 ^{ab}	0.09 ± 0.03 ^b	0.05 ± 0.03 ^b	0.27 ± 0.08 ^{ab}
	Dry precision cut	−0.02 ± 0.01 ^a	0.02 ± 0.01 ^{ab}	−0.02 ± 0.00 ^a	−0.01 ± 0.01 ^a
	Immersed precision cut	0.37 ± 0.42 ^b	0.08 ± 0.03 ^b	0.01 ± 0.02 ^{ab}	0.47 ± 0.41 ^b
1PM distance	Dry lab fitting	0.06 ± 0.09 ^{ab}	0.02 ± 0.09 ^a	−0.01 ± 0.01 ^a	0.07 ± 0.10 ^a
	Immersed lab fitting	0.16 ± 0.08 ^{bc}	0.10 ± 0.02 ^{ab}	0.08 ± 0.04 ^b	0.35 ± 0.10 ^b
	Dry precision cut	−0.01 ± 0.01 ^a	0.02 ± 0.00 ^a	0.00 ± 0.02 ^a	0.01 ± 0.03 ^a
	Immersed precision cut	0.28 ± 0.14 ^c	0.16 ± 0.05 ^b	0.00 ± 0.01 ^a	0.46 ± 0.16 ^b
2PM distance	Dry lab fitting	0.03 ± 0.02 ^a	0.07 ± 0.07 ^a	0.00 ± 0.02 ^a	0.12 ± 0.07 ^a
	Immersed lab fitting	0.25 ± 0.08 ^{ab}	0.13 ± 0.04 ^a	0.13 ± 0.06 ^b	0.51 ± 0.15 ^b
	Dry precision cut	0.02 ± 0.01 ^a	0.03 ± 0.01 ^a	0.02 ± 0.03 ^a	0.08 ± 0.02 ^a
	Immersed precision cut	0.31 ± 0.27 ^b	0.48 ± 0.10 ^b	0.05 ± 0.08 ^{ab}	0.85 ± 0.30 ^c
1M distance	Dry lab fitting	0.24 ± 0.29 ^a	0.11 ± 0.09 ^a	0.08 ± 0.07 ^a	0.43 ± 0.34 ^a
	Immersed lab fitting	0.45 ± 0.17 ^a	0.28 ± 0.19 ^{ab}	0.31 ± 0.12 ^b	1.05 ± 0.09 ^{bc}
	Dry precision cut	0.36 ± 0.15 ^a	0.24 ± 0.15 ^{ab}	0.06 ± 0.05 ^a	0.67 ± 0.33 ^{ab}
	Immersed precision cut	0.72 ± 0.59 ^a	0.53 ± 0.23 ^b	0.09 ± 0.07 ^a	1.35 ± 0.42 ^c
AP right distance	Dry lab fitting	−0.01 ± 0.01 ^{ab}	−0.03 ± 0.05 ^a	0.00 ± 0.02 ^a	−0.04 ± 0.03 ^a
	Immersed lab fitting	0.08 ± 0.02 ^c	0.05 ± 0.04 ^b	0.06 ± 0.03 ^b	0.20 ± 0.06 ^b
	Dry precision cut	−0.04 ± 0.02 ^a	0.04 ± 0.02 ^b	−0.01 ± 0.01 ^a	−0.01 ± 0.03 ^a
	Immersed precision cut	0.05 ± 0.10 ^{bc}	0.04 ± 0.04 ^b	0.01 ± 0.01 ^a	0.11 ± 0.08 ^b
AP left distance	Dry lab fitting	−0.05 ± 0.08 ^a	−0.20 ± 0.35 ^a	0.00 ± 0.03 ^a	−0.26 ± 0.41 ^a
	Immersed lab fitting	0.10 ± 0.05 ^b	0.07 ± 0.03 ^a	0.04 ± 0.01 ^b	0.22 ± 0.02 ^b
	Dry precision cut	−0.05 ± 0.02 ^a	0.03 ± 0.02 ^a	−0.01 ± 0.02 ^a	−0.03 ± 0.04 ^{ab}
	Immersed precision cut	0.08 ± 0.11 ^{ab}	0.04 ± 0.03 ^a	0.02 ± 0.01 ^{ab}	0.15 ± 0.12 ^b

Discussion

The sequential use of aligners that gradually move teeth into the desired position forms the basis of orthodontic treatment performed with removable thermoformed devices. The optimal adaptability of the aligners is critical to the success of this type of treatment.

The Invisalign system permits the placement of maxillo-mandibular elastics in precision cuts. Cuts can also be performed chairside, for example using pliers (e.g., IX890, Ixion Tear Drop Aligner Pliers, DB Orthodontics, Silsden, UK or OLS-1502 Clear Aligner Punch drop shape, Carl Martin, Solingen, Germany). Elastics are indicated for anchorage control when treating sagittal discrepancies between the den-



tal arches, such as Class II malocclusions (according to the Angle classification). Although it is possible to simulate the result of use of these elastics virtually¹⁷, it is still unclear whether they influence the dimensional stability of aligners.

Thermoplastic polymers used to fabricate aligners absorb water¹¹. This absorption reduces moduli and the main glass transition temperature increases fracture strain and impact strength (softening or plasticising effect)¹⁸. Furthermore, changes to the dimensions of the appliance caused by hygroscopic expansion can affect its adjustment to the teeth and consequently modify the orthodontic forces¹³. The present study compared aligners submerged in artificial saliva (water bath maintained at 37°C, simulating the oral environment) with aligners kept in a dry environment to determine whether use of maxillomandibular elastics increases the dimensional changes caused by water absorption. The investigation was conducted over a 2-week period.

Galan-Lopez et al¹⁹ recommend a customised aligner change frequency depending on the complexity of the case and the degree of movement desired. Despite the lack of consensus regarding the aligner change frequency, Bollen et al² found that changing aligners every 2 weeks produces more efficient tooth movement when compared to changing them weekly.

In the dry environment, the placement of maxillomandibular elastics changed the dimensions of the aligners, specifically in the places where the fittings were located; thus, the closer the placement of maxillomandibular elastics to the fitting, the more significant the dimensional change. These changes may have occurred due to the force released by the elastics on the aligners being located in the fittings rather than being globally distributed. The aligners with precision cuts presented statistically significant changes in nine sites (considering both maxillary and mandibular sites), whereas those with fittings made in the laboratory showed significant changes only for the mandibular 1M distance. These findings suggest that the use of maxillomandibular elastics can produce dimensional changes in aligners, and that fittings made by an orthodontist are preferable to precision cuts, at least with regard to the prevention of possible deformations.

When the maxillomandibular elastics were placed in conditions simulating the oral environment, a significant change was noted in most of the measured sites, with the

exception of the AP left distance for the maxillary precision cuts and the AP left and right distances for the mandibular precision cuts. The immersed aligners with precision cuts displayed more significant changes in cross-sectional measurements, whereas those with manual fittings showed more significant changes in anteroposterior distances. These findings may be attributed to differences in how the fittings were produced, i.e., whether they were made by Align Technology or by the orthodontist. The manual fittings may have been located in a region closer to the centre of the aligner, which was more stable and less flexible, meaning that the strength of the elastics acted mainly in an anteroposterior direction. As the peripheral region is more flexible, the strength of the elastics could generate greater deformation in a transverse direction than in an anteroposterior direction. The immersion process increased the dimensional changes of the aligners.

For the immersed aligners, the most significant variation was observed in the intercanine distance in the maxilla after 14 days. An increase of 1.13 mm was noted for the aligners with fittings made in the laboratory and 1.22 mm for those with precision cuts. The greater height of the anterior teeth could explain the reduced resistance of the material in the most peripheral part of the aligner, thereby influencing the result. There were also significant variations in the distance between the first molars in the immersed aligners for the mandibular teeth 14 days after the start of the experiment. For the aligners with fittings made in the laboratory, a 1.05-mm increase was observed, and for those with precision cuts, the increase was 1.35 mm. Again, more significant changes were observed closer to the fittings. The use of buttons attached to the maxillary canines and mandibular molars might reduce the deformation in this region of the aligners.

The Invisalign system performs simultaneous tooth movements, and each tooth is moved by a maximum of 0.25 mm per stage¹⁷. The alterations in the maxillary intercanine distance observed in the first 24 hours were greater than this value and increased over time in the immersed groups. For the laboratory fitting group in the dry environment, the changes exceeded 0.25 mm from day 7. Changes of this magnitude were also noted from day 7 in the mandibular intermolar distance for the immersed group. The movements predicted for these teeth would not be achieved under these circumstances. Furthermore, the aligners that

suffered these dimensional changes have the potential to move teeth (e.g., maxillary canines and mandibular first molars) to a non-planned position. The present authors therefore agree with the criteria adopted by the American Board of Orthodontics²⁰ that state that differences greater than 0.50 mm for linear measurements in the mesiodistal, faciolingual and occlusogingival directions can be considered clinically relevant.

In general, torque movement is not planned in the locations of fittings for maxillomandibular elastics. Thus, if fittings for elastics are made during treatment, the orthodontist should verify which movements are programmed for the teeth near to the site where the cut will be made.

The orthodontic forces exerted by aligners are partly determined by the thickness and stiffness of the material used for their manufacture. When materials with a higher elastic modulus are employed, it is possible to reduce the thickness to achieve the desired forces¹³. In addition, these forces are less affected by the frequency of aligner removal during treatment²¹. According to Cowley²², one of the most significant flaws in removable thermoformed appliances is the excessive flexibility of the material close to the gingival margins. Invisalign aligners have a higher elastic index than other aligners made from thermoplastic polyethylene terephthalate glycol (PETG) materials¹³. Thus, the Invisalign system is hypothetically more susceptible to dimensional changes when acted upon by other forces, such as those exerted by maxillomandibular elastics, although further studies are required to confirm this.

In a study conducted in 2009, Kravitz et al²³ concluded that the mean accuracy of tooth movement with the Invisalign system was 41.0%. In 2017, this had risen to 87.7%²⁴. According to Houle et al²⁴, this increase is due to a new version of the ClinCheck software, changes in the algorithm and improvements to the technique. The dimensional changes produced by maxillomandibular elastics can decrease the accuracy of the system, making it difficult for the expected result to be achieved. It may be necessary to make adjustments during treatment, generate new scans and make revisions that are time-consuming for the orthodontist, and increase costs and treatment time. Then, when the orthodontist intends to include Class II maxillomandibular elastics in orthodontic mechanics, these dimensional changes must be considered during the planning process.

Oral environment conditions are challenging to reproduce *in vitro*. The present authors were unable to reproduce tooth movement, occlusal contacts and exposure to microbial species; thus, the use of elastics over 24 hours was not in accordance with what is expected in real treatment scenarios.

Data regarding the effects of maxillomandibular elastics on aligners can improve aesthetic aligner treatment. Over-correction during virtual planning can be necessary to achieve the desired position clinically, but the aforementioned data would help to achieve clinical outcomes closer to the predicted results, saving time and resources.

Conclusions

Invisalign aligners undergo dimensional deformation when Class II maxillomandibular elastics are placed. When immersed, the deformations suffered by the aligners with fittings made in the laboratory and with precision cuts increased. Changes observed in the maxillary intercanine distance and the distance between mandibular first molars with immersed aligners with both types of fitting were considered statistically and clinically significant. When Class II elastics are planned to be attached directly onto the aligners, these dimensional changes must be considered during the planning process.

Declaration

The authors declare there are no conflicts of interest relating to this study.

Acknowledgements

The authors thank the National Council for Scientific and Technological Development (CNPq) for the Master scholarship during the development of the present study. They also thank Dr Eduardo Kant Colunga Rothier for his generous donation of the aligners that composed the research sample.



References

1. Kesling H. The philosophy of the tooth positioning appliance. *Am J Orthod Oral Surg* 1945;31:297–304.
2. Bollen AM, Huang G, King G, Hujoel P, Ma T. Activation time and material stiffness of sequential removable orthodontic appliances. Part 1: Ability to complete treatment. *Am J Orthod Dentofacial Orthop* 2003;124:496–501.
3. Boyd RL, Vlaskalic V. Three-dimensional diagnosis and orthodontic treatment of complex malocclusions with the Invisalign appliance. *Semin Orthod* 2001;7:274–293.
4. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: A systematic review. *Angle Orthod* 2015;85:881–889.
5. Boyd RL, Miller RJ, Vlaskalic V. The Invisalign system in adult orthodontics: Mild crowding and space closure. *J Clin Orthod* 2000;34:203–213.
6. Lagravère MO, Flores-Mir C. The treatment effects of Invisalign orthodontic aligners: A systematic review. *J Am Dent Assoc* 2005;136:1724–1729.
7. Phan X, Ling PH. Clinical limitations of Invisalign. *J Can Dent Assoc* 2007;73:263–266.
8. Condo R, Pazzini L, Cerroni L, et al. Mechanical properties of “two generations” of teeth aligners: Change analysis during oral permanence. *Dent Mater J* 2018;37:835–842.
9. Rothier EKC. Afinal, o que podemos esperar do sistema Invisalign? *Rev Clin Ortod Dental Press* 2013;12:6–14.
10. Invisalign. Invisalign technique: Prescribing precision cuts. San Jose: Align Technology, 2013.
11. Ryokawa H, Miyazaki Y, Fujishima A, Miyazaki T, Maki K. The mechanical properties of dental thermoplastic materials in a simulated intraoral environment. *Orthod Waves* 2006;65:64–72.
12. Bradley TG, Teske L, Eliades G, Zinelis S, Eliades T. Do the mechanical and chemical properties of Invisalign appliances change after use? A retrieval analysis. *Eur J Orthod* 2015;38:27–31.
13. Sifakakis I, Zinelis S, Eliades T. Aligners for orthodontic applications. In: Eliades T, Brantley WA (eds). *Orthodontic Applications of Biomaterials: A Clinical Guide*, ed 1. Duxford: Woodhead Publishing, 2017: 275–285.
14. Aiach D, Malone WF, Sandrik J. Dimensional accuracy of epoxy resins and their compatibility with impression materials. *J Prosthet Dent* 1984;52:500–504.
15. Chaffee NR, Bailey JH, Sherrard DJ. Dimensional accuracy of improved dental stone and epoxy resin die materials. Part I: Single die. *J Prosthet Dent* 1997;7:131–135.
16. Woelfel JB, Paffenbarger GC, Sweeney WT. Dimensional changes in complete dentures on drying, wetting and heating in water. *J Am Dent Assoc* 1962;65:495–505.
17. Morton J, Derakhshan M, Kaza S, Li C. Design of the Invisalign system performance. *Semin Orthod* 2017;23:3–11.
18. Baschek G, Hartwig G, Zahradnik F. Effects of water absorption in polymers at low and high temperatures. *Polymer* 1999;40:3433–3441.
19. Galan-Lopez L, Barcia-Gonzalez J, Plasencia E. A systematic review of the accuracy and efficiency of dental movements with Invisalign®. *Korean J Orthod* 2019;49:140–149.
20. Grünheid T, Loh C, Larson BE. How accurate is Invisalign in nonextraction cases? Are predicted tooth positions achieved? *Angle Orthod* 2017;87:809–815.
21. Skaik A, Wei XL, Abusamak I, Iddi I. Effects of time and clear aligner removal frequency on the force delivered by different polyethylene terephthalate glycol-modified materials determined with thin-film pressure sensors. *Am J Orthod Dentofacial Orthop* 2019;155:98–107.
22. Cowley DP. Effect of Gingival Margin Design on Retention of Thermofomed Orthodontic Aligners [thesis]. Las Vegas: University of Nevada, 2012.
23. Kravitz ND, Kusnoto B, BeGole E, Obrez A, Agran B. How well does Invisalign work? A prospective clinical study evaluating the efficacy of tooth movement with Invisalign. *Am J Orthod Dentofacial Orthop* 2009;135:27–35.
24. Houle JP, Piedade L, Todescan R Jr, Pinheiro FH. The predictability of transverse changes with Invisalign. *Angle Orthod* 2017;87:19–24.