

Trueness and precision of direct-printed and thermoformed clear aligners after artificial saliva exposure: A comparative in vitro study

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Introduction: This study aimed to compare the effect of artificial saliva (AS) aging on the trueness and precision of direct-printed aligners vs thermoformed aligners. **Methods:** Four types of aligners were manufactured from the same reference standard tessellation language (STL) file: using Duran Plus (n = 12) for thermoformed ones, and TC-85DAC (n = 12), Clear A (n = 12), or OD Clear TF (OC, n = 12) resins for direct-printed ones. A printed model was used for thermoformed aligners, whereas digital design models were generated for direct-printed aligners from the reference STL file. The samples were sprayed and scanned (Trios 3; 3 Shape, Copenhagen, Denmark) before and after aging in AS at 37°C for 24 hours, 7 days, and 14 days. STL files were imported into CloudCompare software (CloudCompare, 2.13.2 version, Paris, France) and superimposed on the design or digital model (trueness) or to each other within each group (precision) using a 7 reference-point algorithm. Two-way analysis of variance was performed to evaluate the influence of saliva aging and material type. **Results:** A significant effect of the material type was observed with a lower trueness and precision for Duran Plus aligners compared with the 3 groups of direct-printed aligners. A significant effect of AS aging, with a decrease of trueness and precision, was also noted for both thermoformed and printed aligners. **Conclusions:** This in vitro study demonstrated that direct-printed aligners provided higher trueness and precision than thermoformed ones. Exposure to AS decreased the trueness and precision for both types. However, further studies are needed to validate the behaviors of direct-printed aligners clinically. (Am J Orthod Dentofacial Orthop 2026; ■: ■-■)

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The growing demand for clear aligner therapy among adults, combined with advancements in computer-aided design/computer-aided manufacturing technology, now enables orthodontists to fabricate aligners in-office without relying on commercial providers.¹ In-office clear aligners are traditionally made by thermoforming transparent thermoplastic sheets on printed models.¹

Thermoforming involves heating the plastic sheets until they are soft enough to conform to the model.² Thermoformed aligners are usually made from noncrosslinked polymers, such as polyvinyl chloride, polyurethane or polyethylene glycol terephthalate, with the last 2 being the most commonly employed owing to their optimal balance between clarity, mechanical strength, and flexibility, which are essential for effective force application during orthodontic tooth movement.¹

The development of 3-dimensional (3D) imaging, digital modeling, and additive manufacturing (commonly named 3D printing) introduces new

perspectives in orthodontics.^{1,3} Some commercial 3D printing resins are intended for the direct fabrication of clear aligners, eliminating the need for a thermoforming step. This approach may accelerate the production process and reduce some environmental impacts, but such claims must be qualified. Comparisons between the direct-printing workflow and the thermoforming workflow are complex and depend on which steps are included in the analysis (raw-material production, model printing, support removal, waste handling, postcuring, end-of-life, etc.). Moreover, direct-printed aligners present their own environmental challenges, such as residual resin waste, support structures, washing and postprocessing steps that create additional inputs and outputs, and the eventual disposal of durable, nonrecyclable plastics.⁴ Recent life cycle assessment studies suggest that direct printing can reduce certain environmental burdens by avoiding model printing and thermoforming, but they also emphasize the importance of clearly defining system boundaries and accounting for all waste streams.^{1,3,4}

To achieve predictable and reliable orthodontic tooth movement during clear aligner therapy, the intaglio of the aligner and the teeth must be in close contact. Tooth movements of 0.25 mm per aligner are commonly prescribed, and aligners are typically changed every 1-2 weeks to reach the treatment goals.^{5,6}

Failure of teeth to follow the movements planned on the setup is a common complication during clear aligner therapy, which consequently requires refinements and could extend the treatment duration.⁵⁻⁸ Reduced movement accuracy is also caused by the discrepancies between the model and the aligner.⁶⁻⁹

Dimensional accuracy is a common research topic for clear aligners because this parameter can affect the achievement of the desired orthodontic tooth movements.⁷⁻⁹ Accuracy has 2 components: trueness and precision.¹⁰ For aligners, trueness refers to the deviation of the aligner from its reference model, whereas precision refers to the deviation between a set of aligners made from the same model.⁷⁻⁹ To 3-dimensionally investigate an object's accuracy, different software programs are available. Software usually calculates deviations between 2 files by superimposing them.¹⁰

For thermoformed aligners, several studies have reported inaccuracies related to thermoforming or with plaster or 3D-printed models.^{7,8,11,12} Owing to their recent introduction to the orthodontic practice, only a few studies have examined the fit of direct-printed clear aligners.¹³⁻¹⁸ Jindal et al¹⁴ found a greater accuracy of printed aligners compared with thermoformed ones. These results were confirmed by Koenig et al¹⁵,

whereas Park et al¹⁶ showed the least gap width with thermoformed aligners. Studies have mainly evaluated the influence of printing parameters, such as print orientation or postcuring duration, on the accuracy of printed aligners.¹⁶⁻¹⁸ Moreover, authors only assessed the trueness of these new aligner materials, and data concerning their precision, which is an important aspect for printed aligners, are limited. In fact, several aligners were fabricated at the same time during a printing batch, and several printing batches could be needed to fabricate the appliances, so assessing the aligners' precision helps ensure the repeatability of their printing process.¹

Another important factor regarding direct-printed aligners is the manner in which they react to aging, as the fit of the aligners could be influenced by dimensional changes within the aligner material because of water sorption, as aligners are placed in the wet environment of the oral cavity for 22 hours per day for 7-14 days. Some scholars have reported a negative effect of artificial aging with a change in surface morphology (presence of cracks and porosities) and a decrease in mechanical properties.¹⁹ Some studies have also described a negative effect of aging on the accuracy and dimensional stability of printing resin materials for casts or occlusal splints.²⁰

To our knowledge, studies have only assessed the accuracy of direct-printed aligners just after postprocessing, and no data have considered aging. In this context, this study aimed to investigate the effect of artificial saliva (AS) aging on the dimensional accuracy (trueness and precision) of direct-printed aligners compared with thermoformed aligners. The null hypotheses were as follows: (1) AS aging will not affect the dimensional accuracy of the direct-printed aligners and (2) there will be no differences between the thermoformed and printed aligners.

MATERIAL AND METHODS

The following 4 materials were tested: 3 resins intended for direct-printed aligners (TC-85DAC [GRA] from Graphy, Seoul, Republic of Korea; OD Clear TF [OC] from 3D Resyns, Barcelona, Spain; and Clear A [CA] from Senertek, Karatas-Izmir, Turkey) and 1 thermoformed material (Duran Plus [DP] from Scheu-Dental, Iserlohn, Germany). All the aligner materials used in this study are presented in [Table 1](#).

To obtain a digital model, the maxillary arch of the first author of this study (C.A.D.) was scanned with an intraoral scanner (Trios 3; 3 Shape, Copenhagen, Denmark). For the manufacturing of printed aligners, a design was created using this digital model with a

Table I. Name, abbreviation, manufacturer, composition, and batch number of the materials used

Material	Name	Abbreviation	Manufacturer	Composition	Batch number
3D printing resins	TC-85DAC	GRA	Graphy, Seoul, Republic of Korea	Aliphatic urethane acrylate oligomer 20%-60%	1-B0803G12-023
				Proprietary ingredient #1, 0%-20%	
				Proprietary ingredient #2, 30%-80%	
				Proprietary ingredient #3, 0%-1%	
				Photoinitiator 0%-10%	
	OD-Clear TF LTP	OC	3D Resyns, Barcelona, Spain	Proprietary information	20344301
	Clear A	CA	Senertek, Karatas-Izmir, Turkey	Proprietary information	SNR202300003
Thermoplastic sheet	Duran Plus, 0.75 mm	DP	Scheu-Dental, Iserlohn, Germany	Polyethylene glycol terephthalate	2722A

0.5 mm thickness using orthodontic software (Onyx-Ceph; Image Instruments, Chemnitz, Germany). Rectangular horizontal attachments were placed on the buccal side of first molars, premolars, and second molars, and a vertical rectangular attachment was placed on the buccal side of the left central incisor (Fig 1).

Then, the aligner design was imported into a software to prepare the file for printing with the chosen printing parameters and adding supports (Chitubox; CBD-Tech, Shenzhen, China). Supports were avoided in essential areas, such as the intaglio of the aligner.

The aligners were printed with Phrozen Sonic Mini 8K (Phrozen Tech Co, Hsinchu City, Taiwan) for GRA, OC, and CA resins. To print the aligners, a 100 μ m layer thickness and an orientation of 45° to the build platform were chosen. Twelve copies of the aligner design were printed for each resin in 2 print runs (6 per print run) per resin.

Postprocessing was conducted using the Phrozen washing unit (Phrozen Tech Co) and the Phrozen curing unit (Phrozen Tech Co) for OC and CA aligners. A glass container filled with glycerin for 10 minutes was used during postcuring. These 2 resins did not require the use of a postcuring unit equipped with nitrogen gas.^{21,22} For GRA aligners, according to the manufacturer's recommendation, Tera Harz Spinner V2 (Graphy) and THC2 curing unit (Graphy) were used.²³ After the curing process, all printed aligners (GRA, CA, and OC) were immersed in boiling water at 100°C for 2 min to standardize postcuring and ensure the removal of any residual unpolymerized resin. For CA and OC aligners, the glycerin used during postcuring was first thoroughly rinsed off under running warm water before this step. After the initial washing, flush cutters were used to remove the supports from each aligner, and a rag wheel provided a final polish only on their cameo.

For the manufacturing of thermoformed aligners, the same digital model obtained from the maxillary arch scan, with the same attachments placed on the

same teeth (Fig 1), was printed using model V2 resin, with the model positioned at 0° of angulation to the build platform and a Form 3B printer (Formlabs, Somerville, Mass). After printing, the model was posttreated according to the recommendation of the manufacturer.²⁴ DP sheets of 0.75 mm were thermoformed on the printed model using a thermoforming machine (Ministar S; Scheu-Dental).²⁵ The 0.75 mm sheets were selected because this thickness is widely used for clinical clear aligner fabrication and is recommended by the manufacturer for orthodontic applications. After thermoforming, this initial thickness typically results in a final aligner thickness ranging 0.5-0.6 mm over the tooth surface, which corresponds to values reported for commercial systems, such as Invisalign, ClearCorrect, and other commonly used aligners. This final thickness range provides an optimal balance between flexibility and stiffness, ensuring effective force transmission and patient comfort.^{9,26} Therefore, the choice of a 0.75 mm starting sheet was intended to reproduce conditions representative of actual clinical use. The aligners were then cut using a rotating disc and finally polished only on their cameo with a rag wheel. Twelve aligners were prepared.

Final polishing was carried out according to a standardized protocol by a single operator (C.S.) to avoid operator variability.

To facilitate scanning, the aligners of all 4 groups were numbered and individually sprayed with Cerec Optispray (Dentsply Sirona, Charlotte, NC). The spray layer was thinned with an air spray to minimize deviations owing to the spray coating. The spray application was carried out by a single operator (C.S.) to avoid operator variability. Then, to produce standard tessellation language (STL) files, the intaglio of the aligners was scanned using an intraoral scanner (Trios 3; 3 shape). For scanning, 1 aligner was placed on a work surface without any constraints on it, and the camera rotated around the aligner to avoid the risk of deformation.

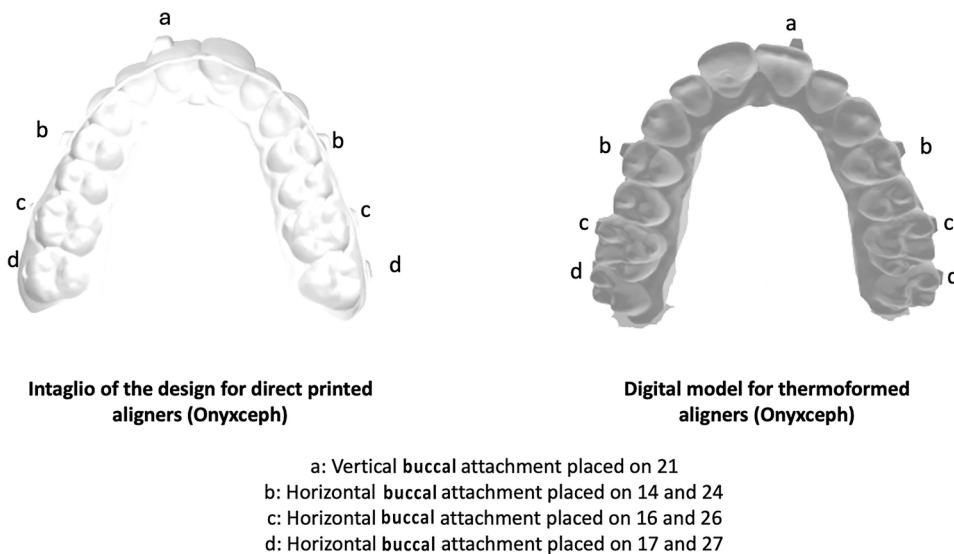


Fig 1. Views of the intaglio of the direct-printed aligner design and the digital model for thermoformed aligners.

The scanning procedure was carried out by the same operator to ensure repeatability (C.S.).

After this initial scanning, the aligners were cleaned in an ultrasonic bath to remove the spray coating and individually immersed in AS at 37°C and pH of 6.7 for 24 hours, 7 days, and 14 days. The AS was made with the same formula employed by Kotyk and Wiltshire²⁷

The aligners of all groups were scanned repeatedly with the same method after the 3 immersion periods to obtain the STL files and evaluate the effect of aging.

To assess the trueness of the aligners, all STL files were imported into morphometric analysis software (CloudCompare, 2.13.2 version; Paris, France). These STL files were individually superimposed on the clear aligner design for the printed aligners and the digital model for the thermoformed aligners.

For the superimposition of printed aligners, first, 7 points were placed on the attachments in the intaglio of the aligner design STL. The same 7 points were placed in the intaglio of the aligner STL obtained after scanning. Then, the software's algorithm determined the best fit between the 2 files using these 7 points, generating a color map illustrating 3D-surface deviations (Fig 2).

Seven reproducible reference points were selected on the intaglio surface of the aligner design: 6 on the gingival-mesial surfaces of premolar and molar attachments (R0-R2 and R4-R6) and 1 on the gingival-distal surface of the maxillary central incisor attachment (R3). Points were placed in the flat central area of each attachment surface to ensure reproducibility.

These landmarks were positioned only once on the baseline (T0) STL file, and the same coordinates were automatically used by the software for subsequent aligner scans (24 hours, 7 days, and 14 days), to avoid variability in landmark placement caused by material deformation over time.

Only the intaglio surfaces of the aligners were scanned and analyzed, as they represent the contact area with the teeth. For thermoformed aligners, the intaglio STL surface normals were inverted in CloudCompare prior to superimposition to match the orientation of the model surface (Fig 3). The entire intaglio surface was included in the analysis without trimming. The 7-point landmark alignment method was employed for all superimpositions, as it ensures reproducible positioning and has been reported to provide consistent accuracy compared with the best-fit methods.^{28,29}

For trueness determination, the root mean square (RMS) value was recorded and compared according to the type of the aligner material and the AS aging duration. This measurement is commonly used in the literature to determine the trueness of an object, as it is not affected by negative or positive values and is considered an absolute error index indicating the magnitude of error.¹⁶⁻¹⁸ This index has symmetry, allowing interchangeability of the data.

$$RMS = \frac{\sqrt{\sum_{i=1}^N (xi - \hat{xi})^2}}{N}$$

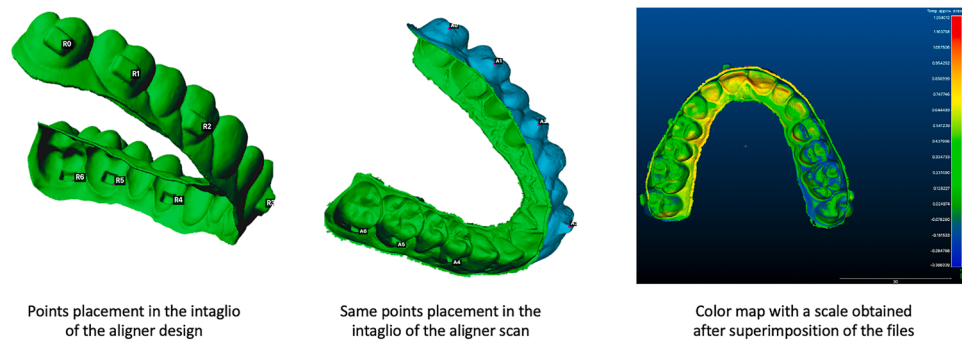


Fig 2. View of the points placed for the trueness assessment of printed aligners and the color map obtained after superimposition (eg, for an aligner of the OC group at 14 days).

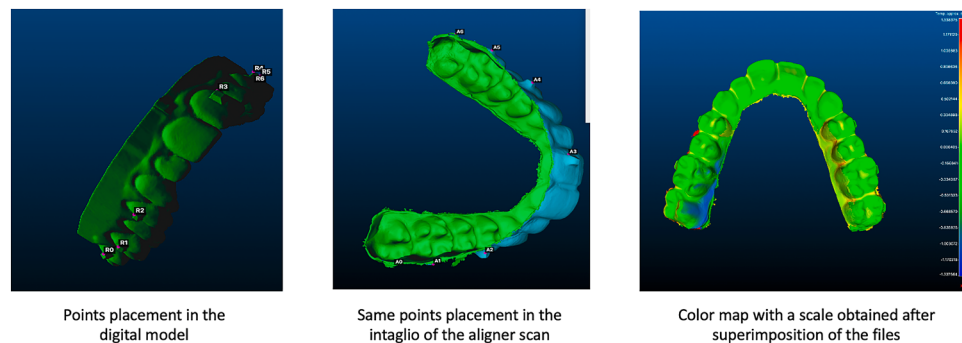


Fig 3. View of the points placed for the trueness assessment of the thermoformed aligners and color map obtained after superimposition (eg, for an aligner of the DP group at 7 days).

Here, i : measurement, N : number of measurements, x : reference value, and $\hat{x}$: measured value.

All measurements and superimpositions were performed by a single operator (C.A.D.), an orthodontist with 10 years of clinical and digital orthodontic experience, trained in the use of CloudCompare through certified courses and previous research work.

Intraexaminer reliability was tested by repeating the superimposition by the same examiner (C.A.D.) after an interval of 2 weeks.

The precision of the aligners was also determined. The obtained STL files of each printed or thermoformed aligner were matched to each other within each group (66 combinations per group and aging duration) using the same 7 points employed for the trueness assessment (Fig 4).

For each resin group, 12 aligners were printed in 2 separate print runs (6 per run) under identical printing and postcuring conditions. The precision analysis included all pairwise comparisons between aligners from the same group, regardless of the print run, to assess the repeatability of the printing workflow under standardized conditions.

Then, the RMS value between the 2 aligner scan STL files was noted and compared according to the type of the aligner material and the AS aging duration. Intra-examiner reliability was tested by repeating the superimposition by the same examiner (C.A.D.) after an interval of 2 weeks.

Statistical analysis

Power analysis was conducted to calculate the sample size (n) required to detect a 15% difference between groups, based on the variability reported in a similar study¹⁴ and setting α at 0.05 and power at 80%. By applying the Lehr formula,³⁰ $n = 16/\Delta^2$ (Δ being the standardized difference δ/σ , in which δ is the target difference and σ is the standard deviation [SD]), the calculated sample size was 12 aligners per group.

The results of trueness and precision are expressed as means and SDs of global millimetric distances and compiled in an Excel spreadsheet (Microsoft, Redmond, Wash). The normal distribution of variables was confirmed by the Shapiro-Wilk test, and equality of variances was assessed by the Levene test. A 2-way analysis of variance (ANOVA), followed by the Tukey honest

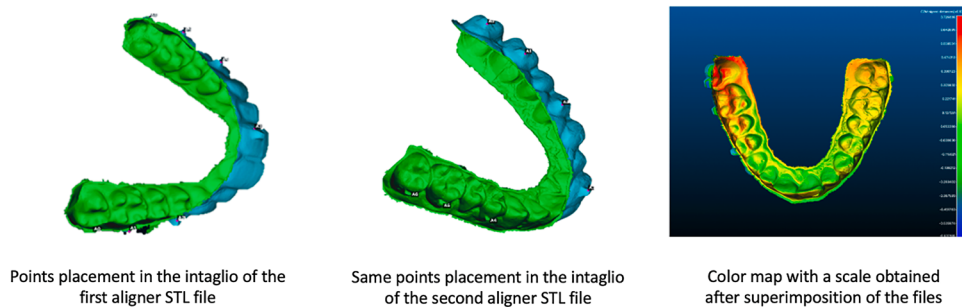


Fig 4. View of the points placed for the precision assessment of thermoformed aligners and the color map obtained after superimposition (eg, for 2 files of the DP group at 14 days).

significant difference test, was also performed to evaluate the influence of the material type and AS aging duration on the trueness and precision of the aligners. In all tests, the significance level was set at $P < 0.05$. Statistical calculations were performed using XLStat (Addinsoft, Paris, France).

RESULTS

The means and SDs of the RMS trueness values are summarized in Table II, with results of the 2-way ANOVA.

Initially, DP aligners showed the highest deviation (0.222 ± 0.054 mm; $P < 0.05$), whereas GRA aligners had the lowest (0.183 ± 0.034 mm; $P < 0.05$). The aligners of the GRA, CA, and OC groups did not demonstrate a significant difference in deviations ($P > 0.05$).

After 24 hours of immersion in AS, DP aligners showed the highest deviation (0.242 ± 0.045 mm; $P < 0.05$), whereas GRA aligners exhibited the lowest (0.194 ± 0.028 mm; $P < 0.05$). GRA, CA, and OC aligners did not demonstrate a significant difference in deviations ($P < 0.05$).

After 7 days of immersion in AS, DP aligners showed the highest deviation (0.259 ± 0.037 mm; $P < 0.05$), whereas GRA aligners had the lowest (0.223 ± 0.038 mm; $P < 0.05$). GRA, CA, and OC aligners did not demonstrate a significant difference in deviations ($P < 0.05$).

After 14 days of immersion in AS, DP aligners showed the highest deviation (0.282 ± 0.052 ; $P < 0.05$), whereas GRA aligners exhibited the lowest (0.251 ± 0.046 mm; $P < 0.05$). GRA, CA, and OC aligners did not demonstrate a significant difference in deviations ($P < 0.05$).

Between the initial scanning and 24 hours in AS, GRA and CA aligners showed the lowest deviation values, and the DP aligners exhibited the highest

deviation. Except for GRA aligners that exhibited the highest deviation values between 24 hours and 7 days in AS, CA, OC, and DP aligners showed the highest deviation between 7 days and 14 days in AS.

The results of the 2-way ANOVA in evaluating the influence of the material type (M) and duration of aging in AS (D) on the trueness of the tested groups demonstrated a significant effect of the material type, and a significant difference was noted in DP aligners when compared with those in the 3 groups of direct-printed aligners. A significant effect of aging in AS was also observed, with a decrease in the trueness with aging duration. Nevertheless, the difference in the combination of the material type and aging duration was not significant ($P > 0.05$).

The color maps generated by CloudCompare enabled the visualization of the deviations associated with the trueness of the tested aligners (Fig 5). The scale was set between 1.05 and -1.05 mm for all superimpositions. Areas in red, orange, and yellow corresponded to positive deviations, green to absence or weak deviation, and blue to negative deviations with the design or digital model.

For GRA and CA aligners, deviations were mainly located in the posterior edges and palatal surfaces of the molars and premolars (Fig 5, A-D and E-H). Positive deviations increased on the left side of the aligners between 7 and 14 days of immersion in AS.

For OC aligners, deviations were also mainly located in the edges and palatal and cuspidal surfaces of molars and premolars (Fig 5, I-L). At 7 and 14 days of immersion in AS, deviations were also observed at the palatal zones and anterior edges of the aligners.

For DP aligners, deviations were mainly observed in the posterior and lateral edges and palatal surfaces of the anterior teeth (Fig 5, M-P). At 14 days in AS,

Table II. Two-way ANOVA of the trueness of the tested groups

Factor	Group/duration	Mean $\pm$ SD	df	Sum of squares	F	Significance
M	GRA	0.213 $\pm$ 0.037 ^B	3	0.045	9.715	***
	CA	0.216 $\pm$ 0.040 ^B				
	OC	0.221 $\pm$ 0.034 ^B				
	DP	0.251 $\pm$ 0.045 ^A				
D	Initial	0.196 $\pm$ 0.039 α	3	0.118	25.358	***
	24 h	0.210 $\pm$ 0.035 α				
	7 d	0.234 $\pm$ 0.040 ^B				
	14 d	0.261 $\pm$ 0.043 ^B				
M $\times$ D	Initial-GRA	0.183 $\pm$ 0.034 ^a	9	0.001	0.088	ns
	Initial-CA	0.186 $\pm$ 0.032 ^a				
	Initial-OC	0.193 $\pm$ 0.026 ^{ab}				
	Initial-DP	0.222 $\pm$ 0.054 ^{bc}				
	24 h-GRA	0.194 $\pm$ 0.028 ^{ab}				
	24 h-CA	0.199 $\pm$ 0.023 ^{ab}				
	24 h-OC	0.204 $\pm$ 0.028 ^{ab}				
	24 h-DP	0.242 $\pm$ 0.045 ^{cd}				
	7 d-GRA	0.223 $\pm$ 0.038 ^{bc}				
	Δ Initial-24 h GRA	0.011				
	Δ Initial-24 h CA	0.013				
	Δ Initial-24 h OC	0.011				
	Δ Initial-24 h DP	0.020				
	7 d-CA	0.225 $\pm$ 0.034 ^{bc}				
	7 d-OC	0.229 $\pm$ 0.046 ^{bc}				
	7 d-DP	0.259 $\pm$ 0.037 ^d				
	Δ 24 h-7 d GRA	0.029				
	Δ 24 h-7 d CA	0.026				
	Δ 24 h-7 d OC	0.025				
	Δ 24 h-7 d DP	0.017				
	14 d-GRA	0.251 $\pm$ 0.046 ^d				
	14 d-CA	0.254 $\pm$ 0.044 ^d				
	14 d-OC	0.256 $\pm$ 0.045 ^d				
	14 d-DP	0.282 $\pm$ 0.052 ^c				
	Δ 7-14 d GRA	0.028				
	Δ 7-14 d CA	0.029				
	Δ 7-14 d OC	0.027				
	Δ 7-14 d DP	0.023				

Note. All values are presented as mean RMS $\pm$ SD in millimeters. Groups with the same capital letter are not significantly different for the material factor (M). Groups with the same Greek letter are not significantly different for duration of immersion in AS (D). Groups with the same lowercase letter are not significantly different within the interaction M $\times$ D ($\alpha = 0.05$).

M, material; D, duration; ns, not significant; df, degrees of freedom; Δ , difference between 2 time-points.

*** $P < 0.001$.

negative deviations increased in the posterior and lateral regions.

The means and SDs of the RMS trueness values are summarized in Table III, with results of the 2-way ANOVA.

Initially, DP aligners showed the highest deviation (0.084 ± 0.030 mm; $P < 0.05$). GRA and CA aligners did not demonstrate a significant difference in deviations ($P > 0.05$).

After 24 hours of immersion in AS, DP aligners showed the highest deviation (0.085 ± 0.029 mm; $P < 0.05$). Conversely, GRA and CA aligners did not demonstrate a significant difference in deviations ($P > 0.05$).

After 7 days of immersion in AS, DP aligners showed the highest deviation (0.088 ± 0.027 mm; $P < 0.05$). Conversely, GRA and CA aligners did not demonstrate a significant difference in deviations ($P > 0.05$).

After 14 days of immersion in AS, DP aligners showed the highest deviation (0.091 ± 0.025 ; $P < 0.05$). However, GRA and CA aligners did not demonstrate a significant difference in deviations ($P > 0.05$).

Between the initial scanning and 24 hours in AS, DP and OC aligners showed the lowest deviation, whereas GRA aligners exhibited the highest deviation. Between 24 hours and 7 days in AS, CA aligners showed the

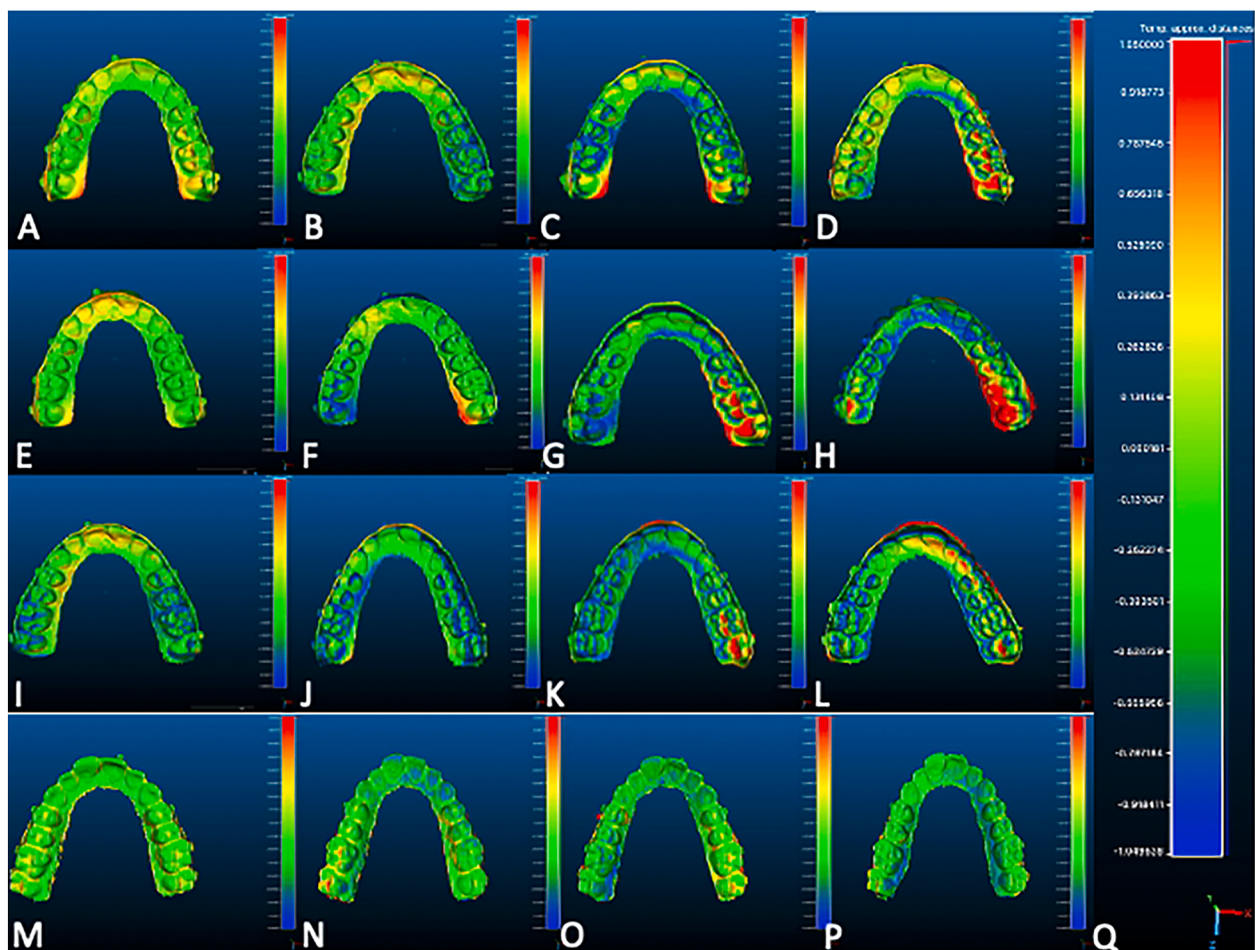


Fig 5. Examples of color maps obtained after superimposition illustrating localized deviations between the scanned aligner and the reference model. These qualitative visual deviations represent regional trends and may differ from overall mean deviation values shown in Tables II and III, which correspond to the entire intaglio surface: **A-D**, G group initially and at 24 hours, 7 days, and 14 days in AS, respectively; **E-H**, CA group initially and at 24 hours, 7 days, and 14 days in AS, respectively; **I-L**, OC group initially and at 24 hours, 7 days, and 14 days in AS, respectively; **M-P**, DP group initially and at 24 hours, 7 days, and 14 days in AS, respectively; **Q**, A zoom in on the scale bar used.

highest deviation, whereas DP aligners demonstrated the lowest. Between 7 days and 14 days, all aligners showed the same amount of deviation.

The results of the 2-way ANOVA evaluating the influence of the material type and the duration of aging in AS on the precision of the tested groups demonstrated a significant effect of the material type, and a significant difference was found in DP aligners when compared with those in the 3 groups of direct-printed aligners. A significant effect of aging in AS was also observed with a decrease in precision with aging duration. Nevertheless, the difference in the combination of material type and duration of immersion was not significant ($P < 0.05$).

DISCUSSION

To our knowledge, this is the first study that investigated the effect of aging in AS after immersion for 14 days on the dimensional accuracy (trueness and precision) of direct-printed aligners compared with thermoformed aligners to provide critical insights into the variations in aligner accuracy and their implications for manufacturing and treatment planning.

The results showed that the trueness and precision of the aligners significantly decreased with aging in AS, including those for the 3 groups of direct-printed and thermoformed aligners. Therefore, the first null hypothesis was rejected. The deviations reported at 24 hours, 7 days, and 14 days should therefore be

Table III. Two-way ANOVA of the precision of the tested groups

Factor	Group/duration	Mean $\pm$ SD	df	Sum of squares	F	Significance
M	GRA	0.071 $\pm$ 0.026 ^A	3	0.023	9.953	**
	CA	0.071 $\pm$ 0.026 ^A				
	OC	0.074 $\pm$ 0.028 ^B				
	DP	0.087 $\pm$ 0.028 ^C				
D	Initial	0.072 $\pm$ 0.030 α	3	0.008	3.408	*
	24 h	0.073 $\pm$ 0.029 α				
	7 d	0.077 $\pm$ 0.025 β				
	14 d	0.080 $\pm$ 0.028 δ				
M $\times$ D	Initial-GRA	0.066 $\pm$ 0.028 ^a	6	0.003	0.626	ns
	Initial-CA	0.066 $\pm$ 0.031 ^a				
	Initial-OC	0.070 $\pm$ 0.029 ^b				
	Initial-DP	0.084 $\pm$ 0.030 ^c				
	24 h-GRA	0.069 $\pm$ 0.028 ^b				
	24 h-CA	0.068 $\pm$ 0.027 ^{ab}				
	24 h-OC	0.071 $\pm$ 0.032 ^b				
	24 h-DP	0.085 $\pm$ 0.029 ^c				
	Δ Initial-24 h GRA	0.003				
	Δ Initial-24 h CA	0.002				
	Δ Initial-24 h OC	0.001				
	Δ Initial-24 h DP	0.001				
	7 d-GRA	0.073 $\pm$ 0.023 ^{bc}				
	7 d-CA	0.073 $\pm$ 0.022 ^{bc}				
	7 d-OC	0.075 $\pm$ 0.026 ^c				
	7 d-DP	0.088 $\pm$ 0.027 ^f				
	Δ 24 h-7 d GRA	0.004				
	Δ 24 h-7 d CA	0.005				
	Δ 24 h-7 d OC	0.004				
	Δ 24 h-7 d DP	0.003				
	14 d-GRA	0.076 $\pm$ 0.023 ^c				
	14 d-CA	0.076 $\pm$ 0.024 ^c				
	14 d-OC	0.078 $\pm$ 0.025 ^{cd}				
	14 d-DP	0.091 $\pm$ 0.025 ^g				
	Δ 7-14 d GRA	0.003				
	Δ 7-14 d CA	0.003				
	Δ 7-14 d OC	0.003				
	Δ 7-14 d DP	0.003				

Note. All values are presented as mean RMS $\pm$ SD in millimeters. Groups with the same capital letter are not significantly different for the material factor (M). Groups with the same Greek letter are not significantly different for duration (D). Groups with the same lowercase letter are not significantly different within the interaction M $\times$ D ($\alpha = 0.05$).

M, material; D, duration; ns, not significant; df, degrees of freedom; Δ , difference between 2 time-points.

* $P < 0.05$; ** $P < 0.01$.

interpreted as cumulative differences from baseline, illustrating the progressive dimensional changes induced by AS aging. Although 2-way ANOVA was performed on mean deviation values across aging time-points to evaluate the effects of material type and duration, these results reflect the evolution of deviations relative to the initial condition rather than independent absolute values.

To our knowledge, no study has evaluated the influence of artificial aging on the accuracy of aligners; thus, a comparison of our results was difficult. Nevertheless, studies for other applications, such as occlusal devices, showed the negative effect of aging on the accuracy of

3D-printed and milled occlusal devices, with a decrease in trueness and precision for the 2 types of occlusal devices analyzed, which confirmed our results.³¹

Several studies have indicated a negative effect of aging on the mechanical and surface properties and the thickness of direct-printed or thermoformed aligners, with a decrease in hardness, flexural or tensile strength, thickness variations, an increase in surface roughness, and the emergence of cracks.^{32,33} These factors, as reported in previous studies, could influence the fitting of aligners to the teeth during their wearing time. Although mechanical properties were not directly assessed in the present study, previous investigations

have shown that aging may reduce hardness and flexural strength, potentially increase the material's flexibility, and contribute to the deviations observed.^{31–33}

Moreover, thermoformed aligners are composed of a polymeric network. Resins for printing aligners are composed of methacrylate and acrylate monomers, such as urethane acrylate, which form a polymeric network after printing and allow appropriate postcuring.¹ During aging in saliva, water could infiltrate the polymeric network. Although our study did not directly quantify water sorption, several authors underscore its potential impact on dimensional stability and deviations.^{33–35} These studies have shown a higher water uptake for printing resins than thermoformed materials for aligners or milled materials for occlusal devices.³⁶ Although the DP aligners had the highest deviations from their model compared with the aligners of the 3 printed materials, a greater deviation delta was observed for the printed aligners between 24 hours and 7 days or 7 and 14 days of aging. In light of this evidence, water sorption and hygroscopic expansion should be considered as plausible contributors to the deviations observed in our results, and future work ought to include direct measurement of these phenomena.

When interpreting the results, it is important to consider not only the statistical significance of the differences observed, but also their clinical relevance. Previous studies have proposed a tolerance of approximately 0.25 mm per aligner, corresponding to the maximum amount of movement typically prescribed at each stage.^{8,14–19} In our study, the deviations measured for direct-printed aligners remained below or very close to this threshold until 14 days of aging in AS, whereas thermoformed aligners exceeded it after 7 days. This suggests that, although statistically significant differences were detected across groups, only some of these deviations may be clinically meaningful.

In this study, the color map for the trueness evaluation showed higher deviations in the posterior areas of the aligners, particularly those printed. These results could also be explained by a higher crack formation in the posterior region of the aligners, influencing the adaptation to the teeth.²⁷ Moreover, in this study, the color maps demonstrated higher deviations in the gingival areas of the aligners, increasing with aging, mainly for those that are printed. In direct-printed aligners, photopolymerization shrinkage occurs during the curing of each resin layer. As layers are added, the shrinkage effect may accumulate and generate internal stresses. These stresses can result in localized deviations, especially at delicate regions, such as the gingival margins, in which the geometry is thin and more susceptible to distortion, which increases the risk of discrepancies.¹⁶

Although the color gradient in Figure 5 visually emphasizes localized deformation, these patterns reflect regional deviations and do not contradict the mean RMS values reported in Table II and Table III, which represent whole-surface averages.

The results showed a significant effect of the material type (printing resins or thermoformed material) on the trueness and precision of the aligners—with thermoformed aligners showing lower trueness and precision than direct-printed aligners. Nevertheless, the 3 groups of direct-printed aligners did not show a significant difference. Therefore, the second null hypothesis was rejected, that is, direct-printed aligners appeared to be more accurate than thermoformed aligners. The results are consistent with the findings of the comparative studies of Jindal et al and Koenig et al, which revealed greater accuracy of printed aligners made of Dental LT Clear or GRA (also used in the present study) when compared with thermoformed aligners.^{14,15}

The manufacturing process of thermoformed aligners involves several steps, including printing the model, thermoforming, which consists of heating transparent thermoplastic sheets until sufficiently soft for molding to a model (a printed model in the present study), and cutting the aligners.² These steps increase the risk for errors during model printing, thermoforming, or both.² Direct printing of the aligners suppresses the need for thermoforming, limiting the risk of errors in printing.^{1,3,4} Several studies on the dimensional accuracy of thermoformed aligners have shown the effect of thermoforming, with underheating decreasing the accuracy.^{12,37}

In this study, thermoformed aligners were obtained from a printed model. The effect of the printing technology employed and the build angle for the model was also demonstrated, with the stereolithography (SLA) printer showing a lower accuracy than the digital light processing or the liquid crystal display (LCD) printers^{13,37} and a build angle of 0°–45° demonstrating a greater accuracy than other orientations for thermoformed aligners or splint manufacturing.^{12,38} Our model was printed with Form 3B and an SLA printer. Printing our model with an LCD printer would be preferable to increase the precision of the impression. However, the model was printed with a build angle of 0°, which provided better accuracy.³⁸ The lower accuracy observed in the thermoformed group should not be attributed exclusively to the thermoforming procedure, but rather considered as the possible cumulative effect of several factors, including the initial material thickness, the printing technology used for the base models, and the thermoforming process itself.

For printed aligners, their dimensional accuracy could be affected by the properties of the material itself (chemical composition, presence of light-blocking pigment, viscosity, etc.),⁵ printing factors, such as the printing technology (LCD printers providing more accurate aligners than digital light processing printers), print layer thickness, and build angle to the printing platform and postprinting factors, including the light intensity, curing time, and presence of nitrogen during curing.^{16–19,39,40} The 3 types of direct-printed aligners were printed and postcured, following each manufacturer's recommendations, with the appropriate devices. Calibrating the printing parameters and respecting the manufacturer's recommendations were found to enhance the printing accuracy of the printed object.^{1,16}

For GRA aligners, the postcuring process was performed with a THC2 device, providing postcuring under nitrogen conditions that prevent the formation of the oxygen inhibition layer, achieving better polymerization and better mechanical properties than without injecting nitrogen gas.^{17,19} This could explain the slightly better trueness obtained for GRA aligners at baseline. In the same way, CA and OC aligners were postcured while submerged in a glycerin bath, which also limits oxygen diffusion at the resin surface. This method similarly prevents the formation of an oxygen inhibition layer and promotes complete polymerization of the outermost layer, achieving an effect comparable to nitrogen purging.^{17,19}

The observed decrease in trueness and precision with the duration of aging in AS for both thermoformed and printed aligners may have potential clinical implications, although these results must be interpreted with caution, given the *in vitro* design of this study. The results suggest that prolonged wear could negatively affect the fit of aligners over time, raising the hypothesis that shorter wear intervals or adjustments to current protocols might help mitigate excessive loss of fit after 7–14 days. A clinical threshold of 0.25 mm corresponding to the prescribed amount of movement per aligner is commonly cited in studies evaluating trueness.^{8,14–19} In our experiments, deviations measured for direct-printed aligners remained close to or below this threshold, except after 14 days in saliva (0.251 mm for GRA, 0.254 mm for CA, and 0.256 mm for OC), whereas thermoformed aligners exceeded this limit earlier (0.259 mm at 7 days and 0.282 mm at 14 days). Although these findings cannot be directly extrapolated to patients, they emphasize the need for future *in vivo* research to clarify the clinical significance of these thresholds.

In this context, refining digital planning⁶ according to the specific properties of the materials used (printing resins or thermoformed polymers) could be an interesting avenue for future development. Advanced

software and artificial intelligence systems might eventually allow decomposition of tooth movements based on tailored objectives and individualized wear intervals, rather than relying on a single default protocol.^{8,41} This approach could, in theory, improve trueness during treatment and increase the predictability of planned movements.⁶

Furthermore, current aligner delivery protocols may need to be reconsidered. Providing patients with 30–50 aligners at the outset appears questionable, particularly given that nearly 50% of patients require 2–3 refinements during treatment.⁴¹ A more adaptive approach, as suggested by some authors, would be to integrate systematic refinements at defined intervals to realign the treatment objectives and limit the accumulation of deviations, particularly in the posterior regions, as shown in our color maps.^{7,41,42} Such deviations could, in theory, compromise the transmission of orthodontic forces and the success of complex movements (rotations, torque, intrusion, etc.), highlighting the need for clinical vigilance.^{41,42}

Finally, although direct-printed aligners demonstrated promising accuracy in our study, their long-term biocompatibility and safety remain less documented than those of thermoformed materials, which have been validated through decades of clinical use. Further *in vivo* studies are required before widespread clinical adoption of these newer materials.⁵

Although this is the first study addressing the influence of artificial aging on the dimensional accuracy of direct-printed aligners compared with thermoformed counterparts, several limitations must be acknowledged.

First, the sample size of 12 aligners per type limits the robustness of this study. A larger sample size would have increased the power of this study.

Second, to enable scanning of the transparent aligners, a contrast spray was applied, as also reported in similar studies.^{14–19} Although an air-spray was used to reduce the contrast spray to a thin layer, it may have introduced an additional error, as the thickness of such sprays can range 0.019–0.080 mm.³⁷ To minimize this variability, the same operator applied the scanning spray at all timepoints using standardized parameters (distance, duration, and air-thinning). Each aligner was visually checked to ensure homogeneous coverage. Although minor variability in spray thickness cannot be completely excluded, this error is considered random and was consistent across all groups and aging periods, thus unlikely to have systematically influenced the comparative outcomes. This could explain why some deviations measured in our study remained close to the 0.25 mm clinical tolerance.^{8,16–19}

Third, the accuracy of the scanner (Trios 3; accuracy 0.007 mm according to the manufacturer) and the method of superimposition could also represent the sources of error. In this study, attachments were placed on molars, premolars, and the left central incisor to establish 7 points for reference-based superimposition, a method reported to be more reproducible than best-fit alignment.^{28,29} Although the same landmark coordinates were consistently applied to all time points, increased deformation in the gingival regions after 14 days of aging may influence local alignment accuracy. This limitation is inherent to landmark-based superimposition and should be considered when interpreting changes over time.

Nevertheless, both approaches present inherent limitations. This study did not implement formal blinding of the assessor to group allocation during landmark placement and superimposition. Although the outcome metric (RMS) was computed objectively by the software and the workflow was standardized (same operator and fixed 7-point protocol) with intraexaminer repeatability verified, the absence of single-blind coding may introduce a risk of reporting bias. Future studies should anonymize and randomize STL files to ensure single-blind assessments.

Fourth, the differences in material thickness between groups must be considered. Thermoformed aligners were produced from 0.75 mm sheets, whereas direct-printed aligners were designed at 0.5 mm. These values were deliberately chosen to reflect clinical practice, as thermoforming is known to reduce sheet thickness by approximately 0.13–0.30 mm; although this reduction is not uniform across the appliance.^{2,9,26} In contrast, direct-printed aligners tend to show more consistent thickness.⁵ This discrepancy may have influenced trueness and precision outcomes, but it also reflects an intrinsic difference between the 2 manufacturing techniques. Future studies should record thickness at different time points to minimize this potential bias.

Fifth, the lower accuracy observed in the thermoformed group should not be attributed exclusively to the thermoforming procedure, but rather considered as the possible cumulative effect of several variables, including the initial material thickness, the printing technology employed for the base models (SLA in this study), and the thermoforming process itself.^{12,32–34}

Sixth, the deviations reported in our tables were calculated using RMS values, which consider absolute distances and avoid cancellation of positive and negative values. RMS values provide a global measure of accuracy, but they should be interpreted together with color deviation maps, which highlight localized

discrepancies, especially in the posterior and gingival areas.¹⁶

Seventh, our study did not directly quantify water sorption, although previous reports underscore its impact on dimensional stability and deviations.^{33,34} Several studies have shown higher water uptake for printing resins than for thermoformed materials or milled occlusal devices.^{33,34} Water sorption and hygroscopic expansion should therefore be considered plausible contributors to the deviations observed in this study.

Finally, this study was conducted under *in vitro* conditions, which do not fully simulate the complex intraoral environment. In the oral cavity, additional factors, such as intermittent occlusal forces, mastication, insertion and removal stresses, temperature fluctuations, salivary enzymes, and patient-specific behaviors, may significantly affect aligner deformation, stress relaxation, and dimensional stability.²⁸ In addition, because the aligners were not seated on the dentition during testing, the potential effects of creep and stress relaxation under functional load were not reproduced.²⁸ These viscoelastic behaviors, which occur when aligners are worn intraorally, may influence dimensional stability and force transmission over time. Furthermore, all scans were performed at room temperature, which does not reflect intraoral conditions and may influence the thermal-responsive behavior of printed aligner resins.^{17,19} Therefore, the clinical implications drawn from the present findings should be interpreted with caution, and future *in vivo* studies are necessary to confirm these results.

CONCLUSIONS

Under the conditions of this study, the results revealed that direct-printed aligners presented significantly higher trueness and precision than thermoformed aligners. The aging duration in AS demonstrated a significant negative effect on the trueness and precision of both thermoformed and direct-printed aligners. Moreover, direct printing of the aligners appears promising as it could overcome the inaccuracies associated with thermoforming. However, although dimensional changes were observed in a static *in vitro* environment, further clinical studies are required to determine their potential impact on treatment efficacy.

AUTHOR CREDIT STATEMENT

Claire-Adeline Dantagnan contributed to formal analysis, data curation, software, and writing—original draft and review and editing; Clara Salem contributed to

investigation, formal analysis, and writing—original draft and review and editing; Carole Charavet contributed to writing—original draft and review and editing; Julia Bosco contributed to writing—original draft and review and editing; Jean-François Nguyen contributed to conceptualization, supervision, methodology, formal analysis, and writing—original draft and review and editing.

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