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RESEARCH ARTICLE

Efficacy of Anterior Tooth Simulations with Clear Aligner Therapy - A Retrospective Cohort study of Invisalign and Flash Aligner Systems

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Abstract:

Purpose:

The purpose of this study was to compare the efficacy of tooth movement between two clear aligner systems by comparing the predicted treatment outcomes versus actual outcomes achieved using a 3D best-fit algorithm.

Materials & Methods:

Clear aligner therapy (CAT) was used to treat 62 patients; n=38 Invisalign® and n=24 Flash®. The Invisalign group had a male to female distribution of 13:25 and a mean age of 35.5, while the Flash group had a male to female distribution of 6:18, with a mean age of 29.2. Differences in predicted versus achieved actual outcomes were compared using eModel Compare 8.1 software.

Results:

1) Intra-group differences between predicted and achieved tooth movements for angular movements were statistically ($P<0.05$) and clinically (>2°) significant with both treatment methods, except for tipping of maxillary and mandibular incisors for Flash® (<2◦). 2) Inter-group results demonstrated statistically significant differences in favor of Flash® for maxillary central incisor Tip (1.3°), BL movements for maxillary canines (0.1mm), and mandibular central incisor Rotations (1°). These did not exceed the threshold for the clinical relevance of 2° or 0.5mm.

Conclusions:

There were no differences in clinical accuracy and efficacy between Invisalign or Flash aligner systems in achieving predicted tooth movement.

Keywords: Clear aligners, Invisalign, Flash, Digital orthodontics, Efficacy, Tooth simulations.

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1. INTRODUCTION

Clear aligner therapy (CAT) is an increasingly popular treatment modality in contemporary orthodontics [1]. Studies have evaluated the biological [2 - 4], esthetic [5, 6], and psychological [7 - 10] advantages that CAT promises over conventional pre-adjusted edgewise appliances. Although CAT is fast gaining popularity amongst care seekers, the orthodontic profession still has unanswered questions regarding the efficacy and efficiency of these appliances. Introduced into the market in 1999, Invisalign® (Align Technology, Santa Clara, CA, USA) has been the forerunner and mainstay in the aligner industry, having had the first-mover advantage. The marketing and advertising campaign of the company was aggressive [11]; at the same time, however, orthodontic literature regarding the efficacy and efficiency of CAT was scarce.

One of the first research articles comparing virtual treatment outcomes with actual achieved treatment outcomes appeared in 2009 by Kravitz *et al*. [12]. This prospective study found that the mean accuracy of anterior tooth movement with Invisalign® was 41%. The most accurate tooth movement was lingual constriction (47.1%), and the least accurate was

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extrusion (29.6%), particularly for the maxillary and mandibular incisors. Rotation of the maxillary and mandibular canines and the maxillary lateral incisor was significantly less accurate compared to the other teeth. In 2014, Simon *et al*. [13] reported that the overall mean accuracy of tooth movement was 59%. The mean accuracy for maxillary incisor torque was 42%. Premolar derotation showed the lowest accuracy with approximately 40%, and distalization of maxillary molars was the most accurate movement with 87%. In a systematic review by Rossini *et al*. [14], the authors concluded that CAT was an effective treatment modality and was able to align and level the arches in non-growing subjects. However, they warned that CAT was neither effective in anterior extrusion movements nor in rotation, especially for rounded teeth such as mandibular premolars. The authors suggested the use of auxiliaries (attachments, inter-arch elastics, IPR, or altered aligner geometry) to improve the predictability of orthodontic movement with CAT.

In 2013, Align technology® launched a new aligner material and improved tooth movement algorithms based on data obtained from treated cases since their founding in 1999. Since then, the orthodontic literature has reported more encouraging and improved outcomes [15 - 17]. In the quest for high-level evidence, a number of systematic reviews published on the Invisalign® system have appeared in the past few years [10, 18 - 20]. These reviews have all reported encouraging outcomes, and some have even compared their efficacy to fixed orthodontic appliances. A large issue is that the efficacy of one system cannot be a "state of the art" reflection on aligner science!

While Invisalign® is still considered the gold standard amongst CAT globally, numerous other CAT products have also been providing services in different regions of the world, usually at a lower price-point compared to Invisalign. However, the efficacy of other systems has not been evaluated by independent researchers. It is imperative to know the accuracy of achieving simulated tooth movements using different CAT products to understand the science of aligner treatment from a holistic perspective, rather than data generated from a single CAT brand.

Flash Orthodontics® [21] (Mumbai, India) is a relatively new aligner company established in 2016. Claiming better aligner quality (with 16-micron build quality and no striations) at a lower price point, they provide the intraoral scanning for their users, aiding in a complete digital workflow for aligner planning and manufacture. The tooth movements are formulated by their in-house orthodontic team with the treating doctor's final approval. Notably, they claim to deliver the aligners within five days of accepting the plan to offices in India.

The purpose of the present study was to compare the efficacy of tooth movement between Invisalign® aligners and Flash® aligners by comparing the predicted treatment outcomes versus actual outcomes achieved using a 3D best-fit algorithm. The null hypothesis was no significant difference in the efficacy of orthodontic tooth movement between Invisalign® and Flash® software predictions to achieve actual outcomes.

2. MATERIALS & METHODS

2.1. Sample

Ethical approval for this retrospective cohort study was obtained from the European University College IRB Committee (IRB/EU/PC-0456/18). 80 consecutively treated patients were initially selected, of which 62 patients fit the inclusion criteria (38 Invisalign®, 24 Flash®) (Table **1**). The 18 patients were excluded due to insufficient records and/or problems with tooth segmentation using the software. Based on the study by Grunheid *et al*. [15], 30 patients would have been sufficient. Hence, we aimed to have a minimum of 30 but included more to obtain greater power. The inclusion criteria for sample selection were as follows: 1) permanent dentition, 2) good oral hygiene, 3) anterior crowding or spacing in the maxilla and/or mandible <5mm with no extractions, 4) 10-day aligner changes, 5) motivated patients, and 6) complete pre- and post-treatment records. Exclusion criteria were as follows: 1) orthognathic surgery, 2) history of previous orthodontic treatment, 3) placement of restorations during treatment, and 4) patients using medications affecting bone metabolism.

All patients were asked to complete a daily compliance log during treatment; the goal was 22 hours of wear per day. Treatment was provided in a private practice setting in India by a certified orthodontist in the use of the Invisalign® and Flash® systems. Consecutively treated patients were selected between 2015 and 2018.

2.2. Procedure for Attaining Differences between Predicated and Achieved Tooth Positions

To obtain digital models of the predicted outcome, the digital models of the initial and final stage of each patient's virtual treatment plan were exported through Align Technology's ClinCheckPro® and Flash® plan programs. Pretreatment, posttreatment, and predicted digital models were imported into eModel Compare 8.1 software (GeoDigm Corporation, Falcon Heights, Minn), a 3-dimensional software independent of either aligner company. This software used a best-fit 3-dimension (3D) algorithm to compare virtual treatment outcomes to achieve treatment outcomes. The automation of the process precludes the measurement from any operator bias. This enabled the calculation of differences in both linear and angular dimensions for individual tooth positions between the two digital models [22]. The simulated virtual treatment plan models were segmented and compared with the unsegmented models of the achieved tooth positions. The dental arches were first aligned globally, and then individual teeth from the segmented model were superimposed on the analogous teeth of the unsegmented model using a best fit algorithm so that differences between tooth positions could be computed. The differences between tooth positions were computed in linear (mesial-distal, buccal-lingual, and occlusal gingival) and angular (tip, torque and rotation) dimensions. (Fig. **1**) Data from the patient's dentition was organized and compared in two categories, *i.e*., maxillary and mandibular anterior dentitions. The automation of the process precludes the measurement from any operator bias.

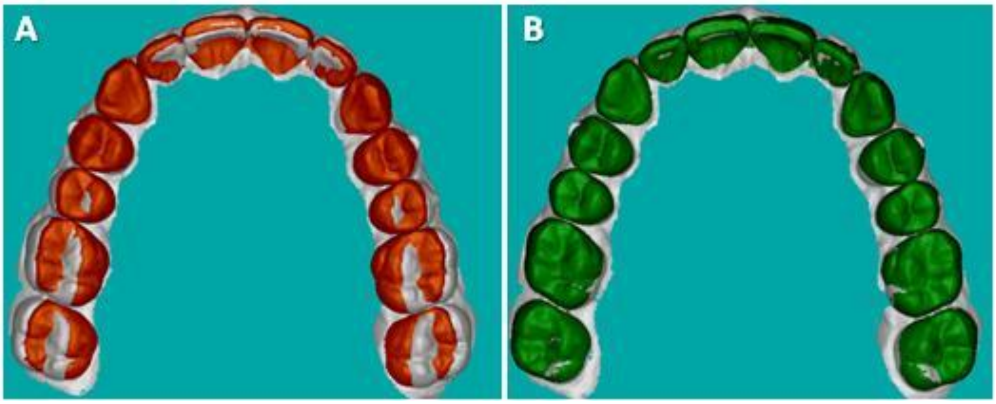

Fig. (1). Superimposition of digital models to compute differences between predicted and achieved tooth positions. (**A**) Global alignment of post treatment model (white) and virtual treatment plan model (orange). (**B**) Superimposition of individual teeth of virtual treatment model (green) and post treatment model (white), computing the achieved values.

Table 1. Sample demographics.

-	N	Male: Female Ratio	Mean Age	No. of Teeth Measured	Angle Class (I:II:III)	Mean tx Duration (months)	Mean no. Maxillary Aligners	Mean No. Mandibular Aligners	Mean No. Attachments both Arches
Invisalign®	38	13:25	35.5	1031	25:13:6	8.4	21.4	19.7	6.2
Flash®	24	6:18	29.2	607	14:10:0	6.9	20.7	21.4	11.3

2.3. Statistical Analysis

The data was collected and stored using Excel (Microsoft, Seattle, WA, USA) and then analyzed using SPSS® Statistics (Version 25, Chicago, Illinois, USA). *P*-values of less than 0.05 were considered statistically significant. Distributions of data for both samples were evaluated for equality of variance using the Shapiro Wilks test and found homogeneous (P>.05); nonparametric tests were used when nominal or ordinal data was evaluated. One sample t-tests were performed to compare the discrepancies between predicted simulations and the actual movement of each group. Independent t-tests were then performed to compare the discrepancies in achieving predicted tooth positions between the two groups.

2.4. Determining the Threshold for Clinical Significance

Because the software used for the superimpositions allowed for the detection of differences that were too small to be clinically relevant, threshold values were chosen in reference to the American Board of Orthodontics (ABO) model grading system for case evaluation [19]. According to the model grading system criteria, discrepancies in contact points and marginal ridges resulted in the deduction of points. A marginal ridge discrepancy of 0.5 mm equated to a crown-tip deviation of 2 degrees for an average-sized molar. Therefore, clinical significance was set in the present study for linear discrepancies greater than 0.5 mm and for angular discrepancies greater than 2 degrees.

3. RESULTS

Independent t-tests comparing the pretreatment mandibular incisor irregularity index demonstrated that the two samples were homogeneous (P>.05) for mandibular anterior crowding. The left and right dentitions were tested for differences using independent t-tests and no differences (P>.05) were detected, thus, right-left data were pooled per tooth type.

3.1. Intra-group Comparisons by Tooth Types

Predicted versus actual positions were compared within Invisalign® and Flash® samples by tooth types using one-sample t-tests with test value = 0. All linear and angular values were statistically significant ($P \leq .001$) for both treatment samples (Table **2**).

3.1.1. Invisalign

All differences for linear and angular variables were statistically significant ($P \leq .001$). Clinical significance for angular variables was demonstrated for tip, torque and rotation discrepancies for all anterior tooth types (>2°). In addition, the linear OG variable for maxillary central incisors (0.51mm) was clinically significant.

3.1.2. Flash

Likewise, the Flash® treatment sample demonstrated differences between the predicted achieved positions for each anterior tooth type for all angular variables ($P \leq .001$) except for Flash® maxillary central incisor Tip (1.63°) and mandibular central incisor Tip (1.692°).

3.2. Inter-group Comparisons by Tooth Types

Differences in predicted versus actual positions of tooth types between Invisalign® and Flash® groups were compared using independent t-tests. There were significant differences between Invisalign® and Flash® for maxillary canine BL and maxillary central Tip as well as for mandibular central Rotational discrepancies (Table **3**).

Table 2. One-sample t-tests with test value set = 0 were used to determine both statistical and clinical significance by anterior tooth group per Invisalign® and Flash® therapies for predicted *versus* actual tooth positions. All linear and angular values were statistically significant ($P \leq .001$) for both treatment samples.

-	-	-	Central		Lateral		Canine	
	Arch	**Variable**	**Mean**	*P* signif	**Mean**	**p value**	**Mean**	***P* signif**
Invisalign®	Maxillary	MD	.18	.000	.22	.000	.26	.000
		BL	.49	.000	.26	.000	.31	.000
		OG	.51†	.000	.34	.000	.33	.000
		Tip	2.92†	.000	2.78†	.000	2.93†	.000
		Torque	3.81†	.000	3.08†	.000	3.12†	.000
		Rotate	2.83†	.000	2.92†	.000	2.90†	.000
	Mandibular	MD	.17	.000	.19	.000	.25	.000
		BL	.27	.000	.25	.000	.21	.000
		OG	.39	.000	.38	.000	.32	.000
		Tip	2.19†	.000	3.33†	.000	3.47†	.000
		Torque	3.14†	.000	3.39†	.000	3.04†	.000
		Rotate	3.07†	.000	3.85†	.000	3.61†	.000
Flash®	Maxillary	MD	.17	.000	.19	.000	.25	.000
		BL	.47	.000	.27	.000	.20	.000
		OG	.41	.000	.33	.000	.27	.000
		Tip	1.63	.000	2.20†	.000	2.31†	.000
		Torque	4.50†	.000	3.87†	.000	2.64†	.000
		Rotate	3.57†	.000	3.67†	.000	2.38†	.000
	Mandibular	MD	.15	.000	.23	.000	.25	.000
		BL	.30	.000	.29	.000	.22	.000
		OG	.36	.000	.36	.000	.31	.000
		Tip	1.92	.000	2.45†	.000	2.29†	.000
		Torque	2.55†	.000	2.59†	.000	3.54†	.000
		Rotate	2.11†	.000	3.52†	.000	3.42†	.000

Note that all angular variables were clinically (>2°) significant (†) except for Flash® central maxillary and mandibular Tip, and no linear variables were clinically (>0.5mm) significant (†) except Invisalign® central OG.

Table 3. Comparison by tooth groups between samples using independent t-tests demonstrated significant differences between Invisalign® and Flash® for maxillary canine BL and maxillary central Tip as well as for mandibular central Rotation. NS = non-significant.

		Central		Lateral		Canine	
Arch	**Variable**	**Mean dif**	***P* signif**	**Mean dif**	***P* signif**	**Mean dif**	***P* signif**
Maxillary	MD	.01	NS	.04	NS	.01	NS
	BL	.02	NS	-.01	NS	.11	.036
	OG	.10	NS	.01	NS	.07	NS
	Tip	1.29	.013	.57	NS	.62	NS
	Torque	-.69	NS	-.79	NS	.48	NS
	Rotate	-.74	NS	-.75	NS	.52	NS
Mandibular	MD	.03	NS	-.04	NS	-.00	NS
	BL	-.04	NS	-.03	NS	-.01	NS
	OG	.03	NS	.01	NS	.01	NS
	Tip	.27	NS	.87	NS	1.18	NS
	Torque	.59	NS	.79	NS	-.50	NS
	Rotate	.96	.027	.33	NS	.19	NS

Table 4. Comparison by tooth groups within sample. Oneway ANOVA demonstrated significant differences between tooth groups for predicted *versus* actual positions in the maxillary arch. Maxillary central *vs* lateral and central *vs* canine differed for BL and OG in Invisalign®; Flash® showed the same except for OG but was different between central and canine for torque. NS = non-significant.

			Central *vs* Lateral		Central *vs* Canine		Canine *vs* Lateral	
	Arch	Variable	Mean dif	*P* signif	Mean dif	*P* signif	Mean dif	*P* signif
Invisalign®	Maxillary	MD	-.04	NS	-.08	NS	.04	NS
		BL	.22	.001	.18	.017	.05	NS
		OG	.18	.005	.18	.004	.00	NS
		Tip	.14	NS	-.02	NS	.16	NS
		Torque	.73	NS	.69	NS	.04	NS
		Rotate	-.09	NS	-.08	NS	-.02	NS
Flash®	Maxillary	MD	-.02	NS	-.08	NS	.07	NS
		BL	.20	.025	.27	.001	-.07	NS
		OG	.08	NS	.14	.034	-.06	NS
		Tip	-.57	NS	-.69	NS	.11	NS
		Torque	.63	NS	1.86	.002	-1.23	NS
		Rotate	-.10	NS	1.18	NS	-1.28	NS
Invisalign®	Mandibular	MD	-.02	NS	-.07	NS	.06	NS
		BL	.01	NS	.06	NS	-.04	NS
		OG	.01	NS	.07	NS	-.06	NS
		Tip	-1.14	NS	-1.28	NS	.14	NS
		Torque	-.25	NS	.09	NS	-.34	NS
		Rotate	-.79	NS	-.54	NS	-.24	NS
Flash®	Mandibular	MD	-.08	NS	-.10	NS	.02	NS
		BL	.02	NS	.09	NS	-.07	NS
		OG	-.01	NS	.05	NS	-.06	NS
		Tip	-.53	NS	-.37	NS	-.17	NS
		Torque	-.05	NS	-1.00	NS	.95	NS
		Rotate	-1.41	NS	-1.31	NS	-.10	NS

3.2.1. Maxillary Anterior Teeth

There was a significant difference in central incisor Tip (*P*=.013) and BL canine movement between the two groups (*P*=.036). Flash® showed better accuracy than Invisalign® for central incisor Tip (1.3°) and BL canine movements (0.1mm). However, both differences were not clinically significant (<2° or 0.5mm).

3.2.2. Mandibular Anterior Teeth

There was a significant difference in central incisor rotation between the two groups (*P*=.027). Flash® again showed better accuracy than Invisalign® (1.0°), but the difference was again not clinically significant (<2°).

3.2.3. Comparisons by Tooth Types

Differences between predicted and actual positions were compared among the three-tooth types (centrals, laterals, and canines) within Invisalign® and within Flash® samples using Oneway ANOVA per jaw. Statistically significant differences were observed for BL movements between central and lateral and between central and canine for both Invisalign® and Flash® groups as well as both groups for OG between central and canine. Invisalign® demonstrated a significant difference for OG movements between central and lateral and Flash® demonstrated a significant difference for torque between central and canine (Table **4**).

4. DISCUSSION

The aim of the current study was to evaluate the efficacy of predicted simulations for three-dimensional movements of anterior teeth with two aligner systems. The samples were consecutively treated cases by experienced clinicians in each respective group. Only adult patients were included in the study for the following reasons: 1) adults represented the majority of patients who requested CAT, 2) adults showed better compliance than adolescents [23, 24], and 3) confounding factors were minimized in adults. The present study was retrospective in nature, which presented a noteworthy limitation.

In the present study, the efficacy of Invisalign and Flash aligner systems has been compared by measuring the discrepancies between virtual treatment plans and actual treatment outcomes using a mathematical superimposition of digital models. In previous studies that assessed the accuracy of clear aligner therapy, the ABO model grading system [25 - 27], ToothMeasure® (Align Technology) [12, 28] or Surfacer® (Imageware, Plano, Tex) software [13] were used. While these tools were able to give a general evaluation of accuracy, the software used in the current study is uniquely able to quantify differences between objects with respect to six degrees of freedom [15, 22]. The eModel Compare software calculates the differences automatically and is not influenced by potential operator bias. It has been used previously by Grunheid *et al*. [15], Awad *et al*. [29], and Haoulli *et al*. [30]. In a 2017 retrospective study on the accuracy of Invisalign® in nonextraction cases, Grunheid *et al*. [15] found statistically significant differences between predicted and achieved movements for most tooth movements, however none were clinically relevant. These results are consistent with the results of the present study, which also showed that while all differences between predicted and achieved tooth movements with Invisalign® were statistically significant, all angular values exceeded the threshold for clinical relevance by greater than 2°.

Kravitz *et al*. [12] indicated that mandibular canine mesio-distal tipping was one of the least accurate tooth movements for Invisalign®. In addition, the systematic review by Rossini *et al*. [14] also concluded that teeth inclinations seem to be among the limitations of Invisalign® regarding accuracy. These findings were reflected in the Invisalign® results of the present study, with the discrepancies for the maxillary and mandibular tip for all anterior teeth being clinically and statistically significant. Both Kravitz *et al*. [12] and Charamlampakis *et al*. [16] indicated that mandibular canine rotations were also problematic for Invisalign®. These outcomes were reproduced in the present study, with the mandibular rotational discrepancy for all anterior teeth exceeding 2°. Castroflorio *et al*. [31] concluded that maxillary incisor torque could be accurately expressed using Invisalign® Power Ridges. On the contrary, however, Simon *et al*. [13] indicated that incisor torque accuracy was low. Results of the present study agreed with the latter, statistically and clinically significant discrepancies were observed for all maxillary and mandibular anterior teeth with regard to torque with Invisalign®.

Current scholarly literature states that there will always be a certain amount of discrepancy between the digital setup and the achieved clinical outcome [18 - 20, 32]. This is due to the inevitable deformation and loss of elasticity of the aligner when used for extended periods of time, reducing its efficacy in producing tooth movement [33]. According to our results, there were no clinically significant differences between the Invisalign® and Flash® groups, with Flash® being more (statistically) significantly accurate than Invisalign® in achieving predicted tipping movements for maxillary central incisors (1.3°), BL movements for maxillary canines (0.1mm), and mandibular central incisor rotations (1°).

On a detailed analysis of individual tooth movement accuracy, a trend of linear movements (MD, BL, OG) tracking better than angular movements (tip, torque, rotations) was observed (Table **2**). All Invisalign® angular discrepancies and most Flash® angular discrepancies exceeded the clinically acceptable threshold of 2 degrees. Between the three anterior teeth, the maxillary central incisors were statistically (not clinically) less accurate than lateral incisors and/or canines for BL, OG, and torque movements.

Our results suggest that the accuracy of virtual simulations with Flash® is comparable with Invisalign® despite the cost of Flash being lower than Invisalign, and hence the null hypothesis can be accepted. The factors that could influence the differences between the groups, however insignificant in the present study, are 1) aligner material, 2) staging parameters and algorithms, 3) demographics of patient selection between groups, 4) quantum of tooth movement in individual teeth in a given patient or group, 5) attachment geometry, size, *etc*., and 6) accuracy and staging of IPR [18 - 20, 32, 34].

The number of CAT service providers is increasing globally [35]. Newer CAT products, where orthodontists make simulations based on commercially available software, such as OrthoAnalyzer, uLab, Archform, Blue Sky Plan and Orchestrate, *etc*., are gaining immense popularity as well [36]. Flash® is one such provider in emerging markets. All scholarly literature evaluating the efficacy and other clinical outcomes are based on data derived from Invisalign® treated cases only. Independent peer-reviewed independent evaluation of data from other systems is imperative for quantification of the efficacy and development of aligner science in totality. The results of the present study indicate that the digital simulations used in both systems were not accurate, with clinically significant differences present for most angular movements. These results, however, should be interpreted with caution as these aligner systems use the treating orthodontist's input and technician's expertise for preparing digital simulations. These evaluations do not take into account clinical scenarios like refinement protocols [16] which are a given in contemporary aligner therapy, as well as do not account for the fact that over-corrections may be built into virtual simulations.

CONCLUSION

There were no clinically important differences in clinical accuracy and efficacy between Invisalign® and Flash® aligners in achieving predicted tooth positions.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the European University College IRB Committee (IRB/EU/PC-0456/18).

HUMAN AND ANIMAL RIGHTS

No animals were used for studies that are the basis of this research. All the humans used were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent has been obtained from the participants involved.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author [I.H.] on reasonable request.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest financial or otherwise.

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Declared None.

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