



Original Article

EFFECTIVENESS OF TOOTHBRUSHES ON GINGIVAL HEALTH IN PATIENTS UNDERGOING ORTHODONTIC TREATMENT

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ABSTRACT

Aim: To evaluate and compare the effectiveness of two different manual toothbrushes on gingival health among patients undergoing orthodontic treatment. **Methodology:** In the present randomized cross-over controlled trial, 60 subjects were recruited, to receive either crisscross or multilevel bristle design. Modified Gingival Index (MGI), Modified Silness and Loe Plaque Index, and Gingival Bleeding Index (GBI) and were assessed for 120 days. Statistical analysis was done using SPSS version 21 (SPSS; Chicago, IL, USA). Owing to the ordinal nature of the indices, non-parametric tests of significance were used. **Results:** The efficacy of the two-bristle design brush showed an overall reduction in the mean score. Overall significant differences were seen in the efficacy of the two different bristle designs. Both the study groups showed a reduction in the mean MGI, PL, and GBI with a P value less than 0.001 which was statistically significant. **Conclusion:** In the present study, the criss-cross bristle design was found to be significantly more effective as compared to the multilevel toothbrush design for reducing MGI, PL, and GBI scores.

Keywords: Manual toothbrushes, Mechanical plaque control, Orthodontics, gingival index, plaque index, bleeding index, plaque control, manual brushing.

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INTRODUCTION

After tooth eruption, bracket bonding is considered the second moment of change in the intraoral environment for a longer duration i.e., on average of 1-2 years. The oral microbiota changes occur both qualitative and Quantitative with an abundance of microorganisms in both saliva and dental plaque. It is a known fact that fixed appliances encourage oral biofilm accumulation as the bands, brackets, orthodontic wires, and accessories act as plaque retentive sites. These increases in biofilm retention cause an ecologic shift of perio-pathogenic oral flora leading to the deterioration of clinical parameters in hard tissue or soft tissue destruction.^[1,2]

It is well established that the presence of supragingival biofilm is the root cause of dental caries and gingivitis. This risk of enamel decalcification and damage to periodontal supporting tissues have long been recognized as problems during orthodontic treatment and is major concerns, especially in patients with fixed orthodontic appliances.^[3]

The plaque formation is initiated or favored in the cervical area of the brackets, below the leveling arch which in a period collects and makes inability or barrier in cleaning which makes the maintenance phase difficult. When the periodontium is affected the purpose of orthodontic treatment is nullified.^[4] The mechanical removal of microbial biofilm is essential in maintaining the microbial ecosystem in equilibrium with healthy tissues.^[5]

Toothbrushing carried out with an effective technique and for an adequate duration of time is a highly effective measure of plaque control.^[6, 7] The design of the modern conventional manual toothbrush can be attributed to Dr. Robert Hutson, a Californian periodontist, who, in the early 1950s, developed a multi-tufted, flat-trimmed, end-rounded nylon filament brush.^[8, 9] The design of a toothbrush especially its size and contour should be such that it aids in the mechanical removal of plaque. The efficacy depends on the type, design of the brush, method of brushing, and time is taken. The more basic designs include toothbrushes with standard (straight) bristles and more advanced models include angled bristles especially aimed at helping the removal of plaque from teeth and along the gum line.^[10] On the other hand, there have been conflicting results as to which design is more capable of effective plaque control maintaining at the same time gingival health.^[11] The present cross-over trial was conducted to evaluate and compare the effectiveness of two different manual toothbrush bristle designs on gingival health among patients undergoing orthodontic treatment.

METHODOLOGY

The study was a Randomized controlled cross-over trial with two groups. The purpose of the crossover study is for the effectiveness of the outcome and for each subject to act as his or her control. To prevent bias, the data analyst was blinded for patients' allocation to the group. The trial was followed in accordance with the Declaration of Helsinki and Consolidated Standards of Reporting Trials (CONSORT) guidelines.^[12, 13]

The present randomized controlled trial was registered. Ethical clearance was sought from the Institutional Ethical Committee of the college where the trial was executed. The information sheet was provided to each participant before taking written consent from them.

Sample size estimation was done by using GPower software (version 3.0). A minimum total sample size of 60 (30 in each group) was found to be sufficient for an alpha of 0.05, power of 80%, and 0.67 as effect size [assessed for the difference in gingival scores of two different bristle designs.

All the measurements of the referred patients in this study were conducted in the Dental center of the University. Orthodontic patients of both sexes aged 16-24 years who had received fixed orthodontic treatment on both the arches pre-adjusted edgewise appliance therapy simultaneously, at least 20 teeth present, minimum of 16 brackets or bands on teeth, brushing habit of at least once per day.

Participants with medical conditions or pregnancy, poor manual dexterity, and compliance, poor periodontal health, active caries, oral prophylaxis in the previous 4 weeks, use of antibiotics or mouthwashes in the past 3 months, smoking habits, and failure to obtain informed consent were excluded.

TRIAL PROCEDURE

Recruitment began on 1/1/2020 and the study was completed by 31/10/2021. Subjects were randomly assigned to either of the groups in a 1:1 ratio, to receive either Group A: crisscross bristle design (Oral-B Cross Action All-In-One Manual Toothbrush) or Group B: multilevel bristle design toothbrush (Oral-B Deep Clean brushes multi-level bristles). The participants were randomly assigned to one of the two groups using sealed opaque envelopes.

The selected patients were recruited, and they were assigned to respective interventions according to what was mentioned in the envelope. They were given the allotted toothbrush bristle design along with the same Naf2 dentifrice (Crest® Cavity Protection, Procter & Gamble, Cincinnati, OH, USA). The clinical personnel assigned the product in a separate area, so blinding was followed. Instructions were given in both verbal and written on oral hygiene with product usage in the same area followed by brushing with modified stillman method was used in front of a mirror under supervision by another researcher. Dietary advice not to use sticky and sugary food was given as it accumulates on the brackets, with a caution of instruction not to use mouthwash during this study.

The patients were given the desired toothbrush for 90 days, after which a washout period of 30 days was given, then they were switched to the next group i.e., after 120 days from their day of recruitment. American Dental Association (ADA) standard toothbrushes were given for the washout period.

On the day before their examination, a reminder call was given to the patients, where they were instructed to abstain from brushing and performing any oral hygiene procedure 6 hours before their baseline visits, and to restrain from having food or chewing gum after performing brushing in the morning of their appointments (If need a scanty amount of water was allowed Thirty minutes early to appointment). At the baseline visit, participants had an Initial oral examination, followed by 90 days then on the 210th day from their date of recruitment.

The primary outcome of the study was the assessment of gingivitis using the Modified Gingival Index (MGI) and Silness and Loe Plaque Index (PI), Gingival Bleeding Index (GBI) for both the study groups.^[14, 15]

Overall compliance was assessed by diaries that documented the day and time of the product use and patients were also asked to get their toothpaste at their every routine visit for orthodontic treatment. They were reminded weekly to use the intervention through WhatsApp messages.

CLINICAL ASSESSMENT

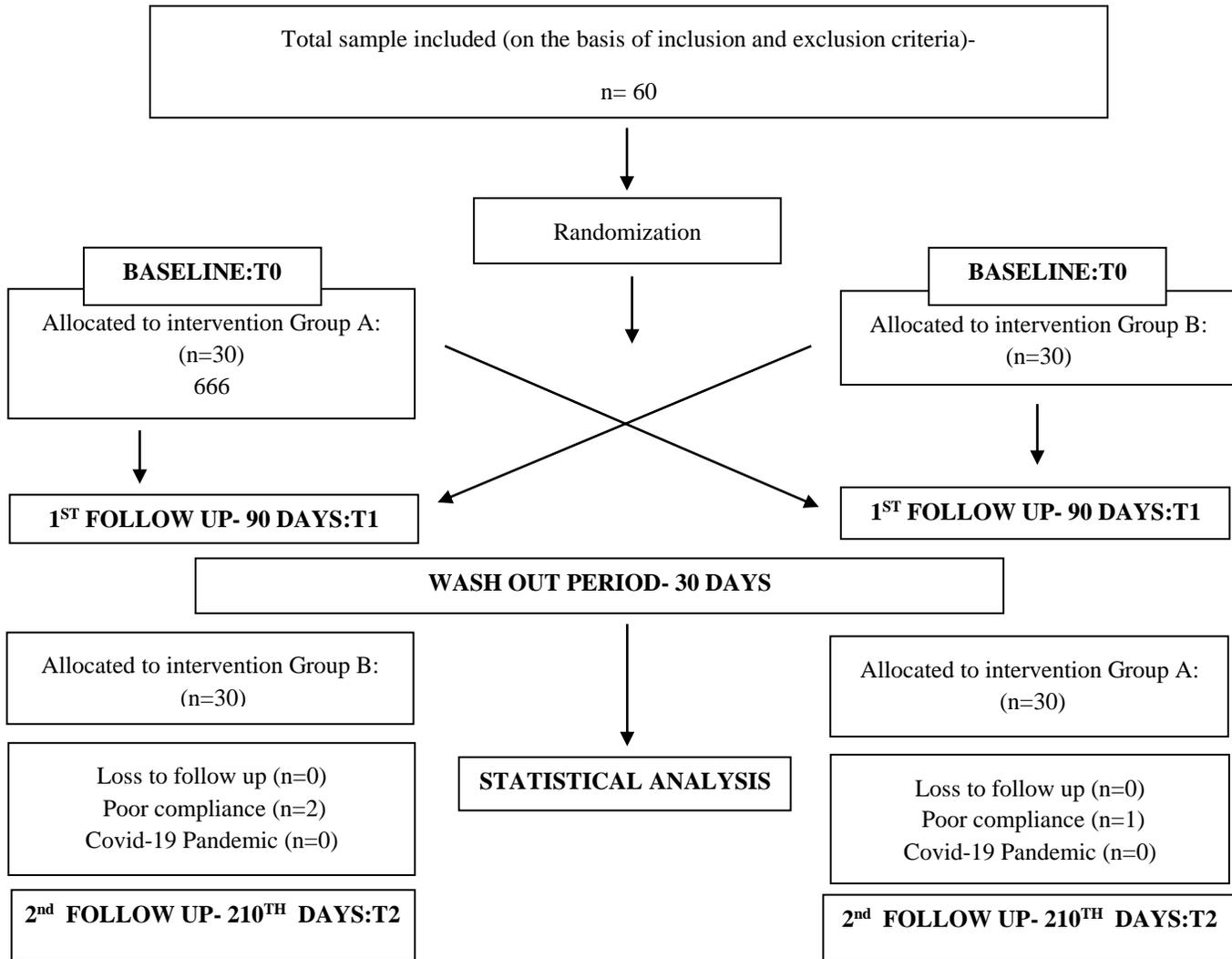
Data for the present study were collected by a proforma designed for this study. It included demographic details of the patient as well as the Modified Gingival Index (MGI)^[15], Silness and Loe Plaque Index (PI)^[16] and Gingival Bleeding Index (GBI)^[17]. The results were presented according to intention to treat (ITT) analysis i.e., analysis based on the recruitment of all the research participants. As statistically similar results were obtained through per protocol analysis, reporting of results analyzed for ITT only is presented in the present research.

The primary investigator: was trained and calibrated before the start of the study on orthodontic patients reporting as an outpatient to the Department of the institution. The clinical examination and outcome assessment of all the subjects was done by this primary investigator. Intra examiner kappa co-efficient values were calculated by repeat measurements that were done on 20% of patients participating in the study, within an interval of 1 hour. It was found to be more than 0.80.

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS version 21 (SPSS; Chicago, IL, USA). Owing to the ordinal nature of the indices used, non-parametric tests of significance were used. For intergroup comparison at various follow-up visits, Mann Whitney U test was used. Intragroup comparison at different time intervals was done using the Friedman test followed by the Wilcoxon sign rank test for pairwise comparison. Effect sizes were calculated to quantify the magnitude of the difference between the two study groups. Significance was set at $P < 0.05$.

Figure 1:Flow chart describing patient recruitment



RESULTS

The trial comprised of 60 subjects with a mean age of participant of 19.7 ± 5.6 years, majority of them were females with two subjects were right-handed.

MGI, PL, and mSBI

The statistical difference between baseline groups for MGI, PI, m SBI scores was insignificant. At the first and second follow-ups, significantly lower scores were seen for MGI, PI, and mSBI scores ($p=0.001$) among patients belonging to Group A as compared to group B (Table 1). The percentage of reduction at various follow-up visits:(T1, T2) from baseline (T0) for MGI, PI, mSBI scores showed significantly higher in patients belonging to group A in contrast to group B ($p=0.001$).

The maximum percentage reduction was seen for a period: second, follow-up visit-Baseline. (Table 2) For T2-T0, The percentage reduction for MGI scores was 42.87 % for group A and 26.15% for group B. The percentage reduction for PI scores was 62.6 % for group A and 17% for group B. The percentage reduction for GBI scores was 80.0 % for group A and 69.7% for group B. On intra-group comparison, a significant percentage reduction for MGI, PI, and mSBI at T2 from T1 and baseline was seen for Group A and Group B (Tables 3 & 4). No adverse events were reported during the trial period.

Table 1: Comparison of modified Gingival index, Plaque index, and Gingival bleeding index, at various follow-up visits between Group I and Group II.

			Mean	Std. Deviation	z value	p value	Mean difference
T0:AT BASLEINE	MGI	Group A	1.7267	.21797	-1.657	0.097,ns	0.09467
		Group B	1.6320	.34387			
	PI	Group A	1.2713	.20781	-1.342	0.179,ns	0.060
		Group B	1.3570	.25938			
	GBI	Group A	14.7867	6.62771	-1.206	0.228,ns	2.271
		Group B	17.7557	10.52709			
T1: First follow up	MGI	Group A	1.3787	.24091	-0.762	0.446,ns	-0.093
		Group B	1.4720	.34387			
	PI	Group A	.62733	.216985	-6.190	0.001*, sig	0.061
		Group B	1.23767	.259624			
	GBI	Group A	7.5357	4.31887	-3.722	0.001*, sig	1.480
		Group B	13.2977	6.86050			
T2: Second follow up	MGI	Group A	.99667	.217974	-3.012	0.003*, sig	-0.2253
		Group B	1.22200	.343866			
	PI	Group A	.49333	.227328	-6.094	0.001*, sig	0.0635
		Group B	1.11667	.263522			
	GBI	Group A	6.0293	3.99717	-2.566	0.001*, sig	1.350
		Group B	9.7647	6.22210			

WILCOXON PAIRED TEST, LEVEL OF SIGNIFICANCE SET AT P < 0.05.

*STATISTICALLY SIGNIFICANT.

NS: NON SIGNIFICANT.

Table 2: Comparison of reduction at various follow up visits from baseline: modified Gingival index, Plaque index, Gingival bleeding index among Group I and Group II.

			N	Mean	Std. Deviation	z value	p value	Mean difference
Modified gingival Index	TO-T1	Group A	30	20.539	4.352	-5.990	0.001*, sig	11.820
		Group B	30	10.205	1.999			
	T0-T2	Group A	30	42.879	4.961	-6.599	0.001*, SIG	12.849
		Group B	30	26.150	5.123			
	T1-T2	Group A	30	28.146	4.283	-6.182	0.001*,sig	9.783
		Group B	30	17.840	3.866			
Plaque Index	TO-T1	Group A	30	51.768	9.436	-6.655	0.230,ns	42.7
		Group B	30	9.062	2.394			
	T0-T2	Group A	30	62.644	11.159	-6.418	0.001*, sig	45.01
		Group B	30	17.624	9.479			
	T1-T2	Group A	30	23.856	9.120	-5.878	0.001*, sig	14.41
		Group B	30	9.444	9.963			
Gingival bleeding Index	TO-T1	Group A	30	74.891	12.543	-3.741	0.001*, sig	16.49
		Group B	30	58.397	18.005			
	T0-T2	Group A	30	80.023	11.942	-2.572	0.010*, sig	10.29
		Group B	30	69.731	17.589			
	T1-T2	Group A	30	22.881	17.621	-2.881	0.779,ns	-4.59
		Group B	30	27.480	29.325			

WILCOXON PAIRED T Test, Level of Significance Set At $P < 0.05$.

*Statistically Significant.

Ns: Non Significant.

Table 3: Comparison of reduction at various follow up visits from baseline : Modified Gingival index, Plaque index, Gingival bleeding index among Group A.

				Mean	Std. Deviation	F value	p ^a value	Pair wise ^b
MODIFIED GI	1	T0-T1	Group A	20.539	4.352	1913.082	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group A	42.879	4.961			1&3: 0.001*, SIG
	3	T1-T2	Group A	28.146	4.283			2&3: 0.001*, SIG
PI	1	T0-T1	Group A	51.768	9.436	706.047	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group A	62.644	11.159			1&3: 0.001*, SIG
	3	T1-T2	Group A	23.856	9.12			2&3: 0.001*, SIG
GBI	1	T0-T1	Group A	74.891	12.543	754.599	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group A	80.023	11.942			1&3: 0.001*, SIG
	3	T1-T2	Group A	22.881	17.621			2&3: 0.001*, SIG

Friedmann Test^a, Level of Significance set At P < 0.05

Wilcoxon paired t test^b, *statistically significant ns: non-significant

Table 4: Comparison of reduction at various follow up visits from baseline: modified Gingival index, Plaque index, Gingival bleeding index among Group B

				N	Mean	Std. Deviation	F value	p ^a value	Pair wise ^b
MODIFIED GI	1	T0-T1	Group B	30	10.205	1.999	729.797	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group B	30	26.15	5.123			1&3: 0.001*, SIG
	3	T1-T2	Group B	30	17.84	3.866			2&3: 0.001*, SIG
PI	1	T0-T1	Group B	30	9.062	2.394	97.972	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group B	30	17.624	9.479			1&3: 0.001*, SIG
	3	T1-T2	Group B	30	9.444	9.963			2&3: 0.001*, SIG
GBI	1	T0-T1	Group B	30	58.397	18.005	273.545	0.001*, SIG	1&2: 0.001*, SIG
	2	T0-T2	Group B	30	69.731	17.589			1&3: 0.001*, SIG
	3	T1-T2	Group B	30	27.48	29.325			2&3: 0.001*, SIG

Fried Mann Test^a, Level of Significance set At P < 0.05

Wilcoxon paired t test^b, *statistically significant ns: non-significant

NS: NON SIGNIFICANT

Discussion

The present study was designed in which every subject act as his or her control hence crossover study was designed for effective outcome. This crossover trial was with two groups with 60 subjects with all efforts to reduce the bias with effective blinding in allocation of the subjects in the group. The present study was aimed at to evaluate and compare the effectiveness of two different manual toothbrushes on gingival health among patients undergoing orthodontic treatment. The placement of fixed appliances during orthodontic treatment not only encourages biofilm formation but also raises the level of acidogenic bacteria inside the biofilm. If patients do not maintain good oral hygiene, the dental biofilm will produce acids that lead to enamel demineralization and white spot lesions around the orthodontic appliance. Development of the biofilm is also related to the presence of gingivitis, and the greater the accumulation, the higher the gingival bleeding index. Orthodontic treatment can therefore affect periodontal health, compromising oral health in general. Direct damage to the periodontium because of excessively extended orthodontic bands can lead to loss of attachment, causing the gingival recession. A toothbrush is one of the most commonly used for maintaining oral hygiene, although it can be complemented by interdental cleaning aids, and secondarily by other devices such as oral irrigators, chewing sticks, and so on. It remains the gold standard as it significantly removes plaque.

It is very well known that it is very difficult to influence personal tooth-brushing behavior to maximize efficacy. Most people brush their teeth for a shorter-than-optimal period, many of them using techniques that are inadequate to remove plaque from the gingival margins and approximal surfaces, areas that are important in maintaining periodontal health. Given these constraints, a practical approach to improving dental health is to develop a more effective toothbrush, one that has the potential to remove plaque more completely from tooth surfaces, is less dependent on tooth-brushing technique, and provides positive sensory cues that may improve motivation and possibly increase brushing time. The evidence from the literature supports the use of toothbrush Head design which plays a vital role in efficacy and safety.^[18-22]It is necessary to utilize the evidence in determining the toothbrush.

The present crossover study design was carried out to assess the effectiveness of two different manual toothbrush bristle designs on gingival health among patients undergoing orthodontic treatment. It provided the benefits of recruiting fewer participants, the effects of the different bristle designs being measured in the same person, and confounding factors within the participants (e.g., age, gender, and hand skills). However, to minimize the carryover effect, which is the main concern during the use of a crossover design, a washout period of 30 days, was given where the patients were instructed to use their normal toothbrushes.

Regular toothbrushing, independent of educational level or social status, is a significant factor in oral health. Moreover, meticulous toothbrushing and interproximal care depend on several factors i.e., motivation, knowledge, and manual dexterity. In the present study, only 3.4% of participants were left-handed. Hence it was not subjected to statistical analysis concerning dexterity. The present research was conducted for 90 days (s) for each of the phases. According to a study by Cohen, trial periods of 3 weeks are advisable if a toothbrush needs to be tested accurately. A significant reduction was found for gingival, plaque scores, and gingival bleeding sites were seen in the present

study. These findings are in accordance with Naik SP et al.^[4] Cohen^[23], and Scopp et al.^[24] depicting the trend toward progressive reduction in scores among all the types of toothbrush bristle designs used during the trial.

At baseline, the GI, PI, and bleeding scores were similar among the two groups during the test phase. The results showed statistically significant differences between the two toothbrushes. At the first follow-up visit, significantly lower plaque scores were seen for the crisscross bristle design as compared to Group B: multilevel bristle design. These findings are similar to that reported by Naik SP et al, where crisscross bristles showed the highest mean plaque reduction among the patients undergoing fixed orthodontic treatment. The findings highlight the fact that a criss-cross array of angled bristles in opposing directions can reach distant approximal surfaces, removing plaque, a contributing factor towards gingivitis development.

Claydon et al.^[25], Ashri et al.^[26], and Versteg et al.^[27] among patients without ortho treatment reported the pre- and post-brushing plaque scores among toothbrush with crisscross bristles was more than compared with the other two toothbrushes. The present trial emphasized that crisscross bristles (in opposite directions) can clean those hard-to-reach inter-dental areas (area between the teeth) better than multilevel bristles. Compared with most dental procedures, a good toothbrush is relatively very economical. Appropriately choosing the best toothbrush requires choosing the right bristle designs. In general, individual preference governs the selection of bristle design.^[28]

However, the efficacy and relative effectiveness of various types and designs of toothbrushes should be confirmed through long-term studies with larger sample sizes, with further assessment of the plaque removal efficacy along with a long-term follow-up throughout the orthodontic treatment. Fixed orthodontic treatment makes the patients vulnerable to plaque accumulation around the orthodontic brackets and gingival margins, complicating the maintenance of good oral hygiene. Hence, it is suggested to use specially designed toothbrushes for easy and effective tooth brushing.

Strength: The cross-over study design eliminated subject variability especially, in trials related to symptomatic clinical assessment and patients' change of mind toward preferences in receiving a particular treatment instead of multiple treatments.

Limitations : No clinical trial comes without limitations. One of the major limitations of the trial was patients' compliance which could be standardized. Future trials where periodic Computer-based intraoral image analysis of the clinical plaque can be done to detect small differences.

CONCLUSION

The trial was successful in achieving the effectiveness of both toothbrush designs in the removal of plaque, minimizing bleeding sites, and Gingival Inflammation in Fixed orthodontic patients. The crisscross bristles showed superiority over the multilevel bristle design.

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The authors have no external sources of funding to declare.

CONFLICT OF INTEREST

The authors have no conflict of interests to declare.

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