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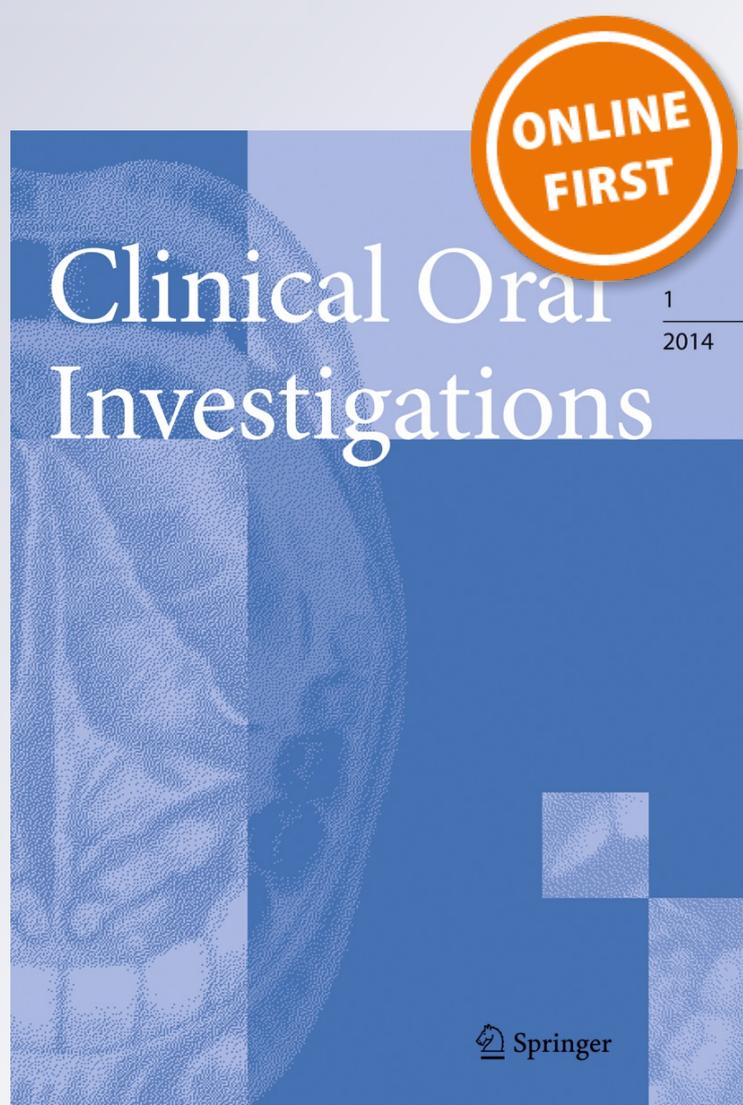
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# Impact of extracorporeal shock wave therapy (ESWT) on orthodontic tooth movement—a randomized clinical trial

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## Abstract

**Objectives** This randomized clinical trial investigated the effect of extracorporeal shock waves on the amount of orthodontic tooth movement and periodontal parameters.

**Material and methods** Twenty-six adult orthodontic patients participated in this clinical trial; all of them receiving lower second molar mesially directed movement. The fixed orthodontic device included superelastic coil springs (200 cN) and miniscrews as temporary anchorage device. The active treatment group received a single shock wave treatment with 1,000 impulses in the region of tooth movement. The placebo group was treated with deactivated shock wave applicator with an acoustic sham. The study period lasted 4 months with a monthly data exploration.

**Results** No statistically significant difference in posterior-anterior tooth movement between the treatment and placebo group was seen during observation period. Gender had no significant influence on tooth movement in either group. No significant difference occurred in mesio-distal tipping and rotation, but a significant difference ( $p=0.035$ ) in buccolingual tipping of the molars was found. Periodontal status

of the patients (sulcus probing depth, gingival index) did not significantly differ in both groups. The plaque index showed a significant difference ( $p=0.003$ ).

**Conclusions** Single application of extracorporeal shock wave treatment was associated neither with a statistically significant acceleration of tooth movement nor with an altered periodontal status in vivo.

**Clinical relevance** Shock waves showed no harmful effects in the investigated area. Their clinical use for lithotripsy during orthodontic therapy might be permitted.

**Keywords** Extracorporeal shock wave · ESWT · Tooth movement · Orthodontic · Periodontal

## Introduction

Orthodontic tooth movement is a combination of bone resorption at the compression site and bone formation at the tension site of the alveolar process [1]. When force is applied to a single tooth, bone and periodontal tissues are immediately involved in a biologic reaction resulting in a remodeling of mineralized and non-mineralized parodontal tissues (blood vessels, neural elements) [2]. Moreover, numerous biochemical networking reactions take place in and around both soft and hard tissue cells resulting in protein synthesis, cell division (mitosis), and cell differentiation [3]. Recent research in mechanobiology has spotted some of the sequential cellular and molecular events during orthodontic tooth movement [1, 4]. One very essential event in the periodontal tissue-remodeling cascade is the activation of the vascular system in the compressed hypoxic periodontal tissue [5]. Increased expression of cytokines was found to promote osteoclastic bone resorption. Vascular endothelial growth factor (VEGF) induces angiogenesis being a carrier of required cytokines and chemokines [1, 6]. Current in vitro investigation also

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suggested VEGF to act as accelerator of orthodontic tooth movement [7].

Non-invasive extracorporeal shock waves applied to a tooth during orthodontic movement may have a stimulating effect. Shock waves have become the treatment of choice not only for kidney and urethral stones, but also for the recovery of non-union of long bone fractures, for tendinopathies, and for wound healing [8, 9]. Shock waves showed significantly increased osteogenesis, angiogenesis, and revascularization for the latter, while local and systemic effectiveness is still unclear. Several cytokines and growth factors are released under the influence of shock waves influencing neovascularization in a positive manner [10–12].

In dentistry, the effect of extracorporeal shock waves has already been investigated to some extent. Shock wave therapy has been associated with a microbicidal effect against specific bacteria and with a bone and muscular regenerative effect [13–15]. Recently, Hazan-Molina et al. investigated the effect of extracorporeal shock waves on tooth movement in an *in vitro* model [16]. They found a significant increase of VEGF and interleukin-1 $\beta$ , which play a significant role during orthodontic tooth movement [7, 17, 18].

Recent orthodontic research focused on controlling tooth movement by adding adjuvant physical, chemical, or surgical methods [19–22]. Administration of drugs appeared to have a supportive effect on orthodontic tooth movement in laboratory animal studies [23]. However, only corticotomy in the dentoalveolar apparatus as an invasive procedure has been found to accelerate orthodontic tooth movement *in vivo* [19].

The purpose of this study was to investigate the effect of non-invasive extracorporeal shock wave therapy on orthodontic tooth movement and other clinical periodontal parameters *in vivo*. The null hypotheses stated that shock wave therapy does not accelerate orthodontic tooth movement and does not alter periodontal status.

## Material and methods

The study design defined the investigation as a single-center randomized, placebo-controlled trial at a university clinic approved by the Institutional Review Board (EK 134/2011). Protocol registration was performed at ClinicalTrials.gov of the US National Institute of Health, and publication was written according to the CONSORT statement.

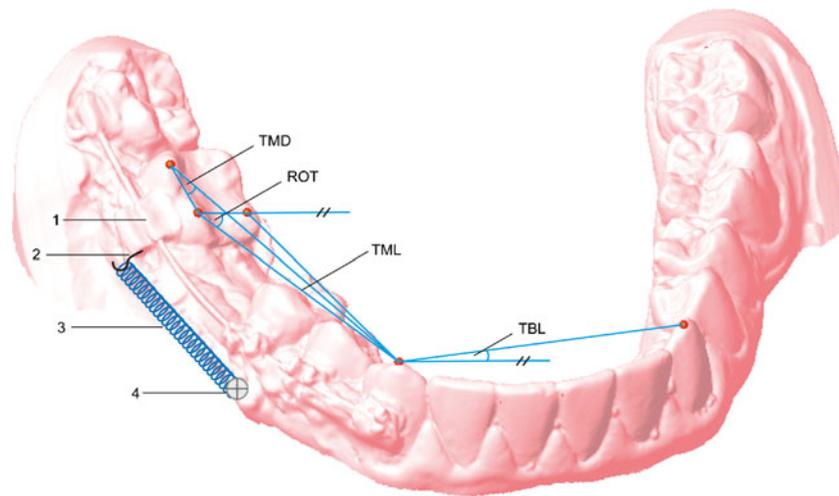
Informed consent was provided by the study participants. The participants were healthy adult male and female patients undergoing comprehensive orthodontic treatment. Female subjects had a pregnancy test (Femtest, Omega Teknika, Dublin, Ireland) before starting participation. Inclusion criteria comprised patients with mesially directed movement of the lower second molar due to an extracted first molar. The attending dentists defined decision for extraction due to non-

restorable reasons. Treatment commenced 4 months after tooth extraction according to Hasler et al. [24]. After the alignment phase, a 0.018 $\times$ 0.025-in. stainless steel archwire (SDS Ormco, Glendora, CA, USA) connected the posterior and anterior tooth segment. A 0.018 $\times$ 0.025-in. stainless steel lever arm (SDS Ormco) was inserted in the auxiliary tube of the molar attachment with the hook at the supposed center of resistance. A superelastic coil spring (Sentalloy<sup>®</sup>, GAC Dentsply, Bohemia, NY, USA) connected the molar with a temporary anchorage device (Dual Top G2 8x6mm, Jeil Medical Corporation, Seoul, Korea) delivering a force of 200 cN. The lower anterior teeth were bonded lingually with a passive 0.022-in. stainless steel retainer wire (Wildcat<sup>®</sup> wire, GAC Dentsply) as reference area for tooth movement measurement. Resin composite bite ramps (mini mold) were bonded on the lingual side of the upper central incisors to avoid occlusal contacts during tooth movement.

Lower dental arch impressions (Tetrachrom, Kaniedenta, Herford, Germany) for primary outcome measurement were done for 4 months at monthly intervals. Outcome measurements comprised posterior-anterior movement, tipping, and rotation of the molars. The dental casts of the lower jaw were trimmed and digitally scanned by a strip-light scanner (S600 ARTI Zirkonzahn GmbH, Gais, Italy). The digital data were analyzed externally using OnyxCeph software (Image Instruments Inc., Chemnitz, Germany). A three-dimensional analysis of the tooth movement (linear and angular) of the molars was performed with the rigid aligned lower anterior teeth as reference (Fig. 1). This analysis is crucial as the mesially acting force on the molar is buccally to the center of resistance. The center of resistance is within the bifurcation of the molar roots, and therefore, the acting force will be a combination of rotational and translational tooth movement. The systematic error for scanning and digitizing the dental casts was 0.05 mm. The random error for repeated positioning of the same measuring point on the digitally scanned dental casts was 0.1 mm. A second independent assessment of the mean tooth movement was performed by a second examiner using a digital caliper.

The periodontal status (sulcus probing depth, gingival index) was evaluated three times for secondary outcome measurement using a calibrated periodontal probe (click-probe<sup>®</sup>, KerrHawe SA, Bioggio, Switzerland) on three buccal and lingual (distal, middle, mesial) locations of the molar. Plaque formation was visualized (Mira-2-ton, Hager & Werken GmbH, Duisburg, Germany) for plaque index calculation. All data were stored digitally in a computer (MacBook Pro, Apple Inc., Cupertino, CA, USA).

For the single shock wave intervention, all participants received topical anesthesia (Xylocaine 2 % gel, AstraZeneca GmbH, Vienna, Austria) in the vestibulum between the second molar and the second premolar. Sonic gel liquid (Gerasonic, Gerot Pharmazeutika GmbH, Vienna, Austria)



**Fig. 1** Digitally scanned dental cast of the tooth movement situation. 1 molar attachment, 2 stainless steel lever arm, 3 open superelastic coil spring, 4 temporary anchorage device. *TML* tooth movement line (line connecting mesiobuccal cusp of lower second molar and cusp of the ipsilateral canine), *TMD* angle of mesio-distal tipping (angle between the line connecting disto- and mesiobuccal cusps of lower second molar and

the tooth movement line), *TBL* angle of bucco-lingual tipping (angle between the line connecting both mesial cusps of lower second molar and the line connecting both canine cusps), *ROT* angle of rotation (angle between the line connecting both mesial cusps of lower second molar and the tooth movement line)

was applied on the cheek as a conduct medium. An ear protector was provided to reduce acoustic disturbance. In the treatment group, the participants were treated with 1,000 impulses of extracorporeal shock waves at energy flux density of 0.19–0.23 mJ/mm<sup>2</sup>, with a pulse rate of five pulses per second by a focused shock wave device (Orthogold 100, MTS/TNT Konstanz, Germany). These parameters were defined according to previous shock wave studies focusing on orthodontic tooth movement and bone regeneration [14, 16]. Shock waves are interfusing soft tissues (silicone membrane of the applicator, skin, cheek, gingiva) and liquids (water, sonic gel liquid, saliva) almost without any loss of energy reaching the alveolar bone where the focus is positioned. The focal area at the used energy flux densities has the form of a cigar with about 3 cm of length and a diameter of 6 to 7 mm, which facilitated reaching the targeted alveolar bone [8, 16].

In the placebo control group, the participants were treated with an acoustic sham of the extracorporeal shock wave with the same pulse rate, volume level, and treatment time, while the shock wave applicator was used in deactivated form and in the same manner as in the treatment group.

The sample size for this clinical trial was calculated to allow detection of difference in tooth movement of one standard deviation between treatment and placebo group with 80 % power. According to Limpanichkul et al. [20], this would correspond to a difference of 0.08 mm.

Block randomization (size 4) was used to allocate patients to treatment or placebo intervention using digital randomization software (Randomizer, version 1.8.1, Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz, Austria). The random allocation sequence

was printed, enveloped, and locked until start of treatment by one operator (C.A.). Blinding was implemented for the participants as previously described and for the outcome assessor (C.K.). Blinding of the shock wave therapist (R.K) was not established. The results of the measurements were coded by one operator (R.M) for the outcome assessor to guarantee blinding.

The statistical analysis compared the primary outcome (tooth movement) between the treatment group and the placebo group using Wilcoxon rank sum test at a significance level of  $p < 0.05$ . Wilcoxon rank sum test was also performed to investigate the influence of gender on tooth movement. Digital and manual measurements of tooth movement were compared by scatterplot in combination with interclass correlation coefficient calculation. The secondary outcome (periodontal and plaque status) was evaluated using Wilcoxon rank sum test. All statistical calculations were performed with R 2.15.2 (R Foundation for Statistical Computing, Vienna, Austria).

**Table 1** Characteristics of the treatment (T) and placebo (PC) group

Variable	Parameter	T (n=13)	PC (n=13)
Sex (n)	Male	6	4
	Female	7	9
Age (years)	Mean	33.9	29.2
	SD	9.8	10.9
	Minimum	18	18
	Maximum	51	49

**Table 2** Mean monthly posterior-anterior tooth movement of the lower second molar in the treatment (T) and placebo (PC) group including confidence intervals (CI)

Period (months)	T (SD) (mm)	95 % CI	PC (SD) (mm)	95 % CI	<i>p</i>
1	0.58 (0.44)	0.32–0.84	0.45 (0.48)	0.15–0.74	0.27
2	0.49 (0.50)	0.19–0.79	0.38 (0.30)	0.19–0.56	0.80
3	0.45 (0.46)	0.18–0.73	0.41 (0.38)	0.19–0.65	0.96
4	0.45 (0.30)	0.27–0.64	0.38 (0.33)	0.18–0.58	0.41

## Results

The clinical study enrolled 30 individuals at initiation of the recruitment. Consecutively, four subjects declined participation immediately before treatment leaving two groups with 13 individuals each. Recruitment started in June 2011 and ended in April 2012. The investigation started in November 2011 and ended in December 2012. Patient characteristics have been shown in Table 1. The overall mean age was 31.5 years (SD 11; range 18–51 years) with prevalence of female gender (women 61.5 %; men 38.5 %).

Mean values and standard deviations of tooth movement (posterior-anterior movement, tipping and, rotation) are shown in Tables 2 and 3. No significant difference of posterior-anterior tooth movement between the treatment and placebo group was seen at any time point. The average tooth movement per month in the treatment group was 0.50+/-0.44 and 0.42+/-0.39 mm in the placebo group (Fig. 2). Gender had no significant influence on tooth movement in both groups ( $p=0.30$ ). The intraclass correlation coefficient showed a significant correlation ( $p=0.0006$ ) between digital and manual measuring of tooth movement at any time. There was a significant difference in bucco-lingual tipping in the first ( $p=0.04$ ), third ( $p=0.03$ ), and fourth month ( $p=0.05$ ) of tooth movement between treatment and placebo group. There was no significant difference of mesio-distal tipping ( $p=0.77$ ) and rotation ( $p=0.98$ ) of the molars in both groups.

Table 4 shows the periodontal status and the plaque index of patients at the beginning, in the middle, and at the end of the observation period. Wilcoxon signed-rank tests showed a significantly higher decrease of the plaque index in the

treatment group than in the placebo group ( $p=0.003$ ), but no significant difference in the changes of sulcus probing depth ( $p=0.52$ ) and gingival index ( $p=0.55$ ).

No unintended pernicious effects occurred after shock wave treatment during the whole study period. All participants tolerated the shock wave intervention sensibly and acoustically.

## Discussion

One major issue in dental research is acceleration of orthodontic tooth movement for shortening treatment time. Only invasive surgical methods such as corticotomy seem to be effective for this purpose [21]. As extracorporeal shock waves showed promising metabolic stimulation effects on hard and soft tissue in medicine, it was hypothesized that this method might have an impact on the rate of orthodontic tooth movement and periodontal status.

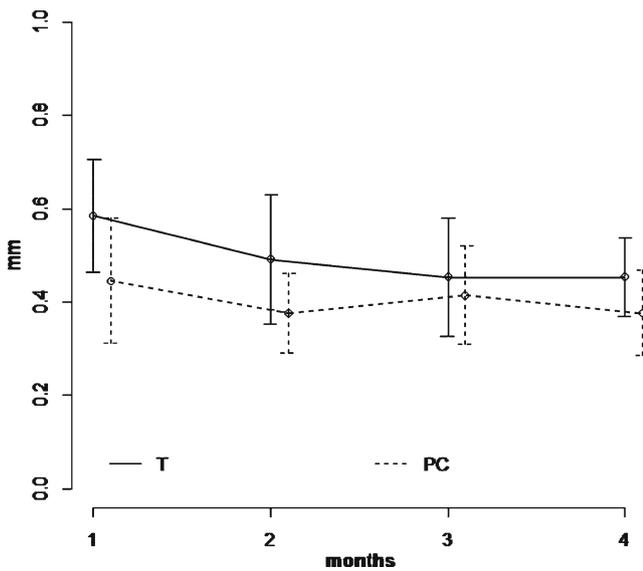
Patients treated with shock waves showed a higher mean tooth movement than the other patients in the present study. However, no statistically significant difference could be detected. It may be speculated that multiple interventions with shock wave treatment could have increased the amount of tooth movement significantly. In general, the mean rate of tooth movement showed values comparable to those seen with other randomized clinical studies within a range of 0.38 to 0.58 mm per month [20, 22].

Aboul et al. performed corticotomy in a split-mouth design with increased rates of tooth movement in treatment and control sites [19]. A systemic effect of corticotomy on the contralateral control site may be the influencing factor.

**Table 3** Mean monthly change (degree) of bucco-lingual (TBL), mesio-distal (TMD) tipping, and rotation (ROT) of the lower second molar

Period (months)	TBL T (SD)	TBL PC (SD)	<i>p</i>	TMD T (SD)	TMD PC (SD)	<i>p</i>	ROT T (SD)	ROT PC (SD)	<i>p</i>
1	-0.03 (0.51)	2.69 (0.62)	0.04 <sup>a</sup>	-0.73 (0.38)	-1.20 (0.52)	0.40	0.31 (0.69)	-0.34 (0.70)	0.47
2	-0.42 (0.81)	3.23 (1.06)	0.10	-1.56 (0.55)	-1.47 (0.47)	0.88	1.57 (0.93)	0.65 (0.61)	0.57
3	0.08 (0.66)	3.95 (0.78)	0.03 <sup>a</sup>	-2.56 (0.74)	-1.75 (0.70)	0.46	2.05 (1.07)	0.95 (0.90)	0.49
4	0.57 (0.60)	4.70 (0.88)	0.05 <sup>a</sup>	-1.72 (0.65)	-2.05 (0.66)	1.00	1.57 (1.05)	0.57 (0.94)	0.43

<sup>a</sup> Indicating significant difference



**Fig. 2** Mean monthly change of posterior-anterior position of the lower second molar in the treatment (T) and placebo (PC) group

Iwasaki et al. observed a lower rate of tooth movement in non-growing patients [17]. Adult age may account for biasing the differences in the present study. The standard deviation for the posterior-anterior tooth movement indicated lag phases during the 4-month observation period, which may represent undermining resorptions in the alveolar process [2]. The continuous acting force of 200 cN was delivered by a superelastic coil spring, which is a common practice in tooth movement studies [25, 26]. In contrast to the literature, the lag phases in this study occurred periodically [17, 18, 26].

Analysis of specific aspects of tooth movement showed minor mesial-in-rotation and mesial tipping of the molars as the stiff 0.018×0.025-in. rectangular stainless steel archwire in combination with the lever arm may have prevented these side effects of anterior tooth movement [18, 27]. A statistically significant difference was found in the bucco-lingual tipping of the molars with the placebo group showing a lingual tipping. This phenomenon might be a side effect of the eccentric force application on the lower second molar. The treatment group showed a more stable mesialization. However, the degree of tipping in the placebo group indicated only minor clinical relevance [18].

The periodontal status of the lower second molars, as assessed by sulcus probing depth and performing the gingival index, showed no significant difference between the groups [28]. This finding is in accordance with low-level laser irradiation and/or corticotomy in randomized clinical studies [19, 29]. However, the latter showed a significant increase of the gingival index in the experimental group. This could be a biological response of gingiva-to-alveolar bone healing following the surgical intervention [21]. A beneficial effect of extracorporeal shock waves on periodontal health had previously been confirmed in rats [14]. The lack of periodontal inflammation in the present study may limit this comparison.

Controlling plaque formation is an important factor in periodontal health. The plaque index was evaluated regularly in the present study, and interestingly, a significant difference between the treatment and the placebo group showed a lower amount of plaque formation in the treatment group. Extracorporeal shock waves had previously shown a significant antibacterial effect on *Streptococcus mutans* and *Porphyromonas gingivalis* which might strongly influence the formation of plaque [13]. However, there were no qualitative effects of shock waves on oral plaque bacteria investigated in the present study exacerbating correlations. The application of a split-mouth design in this aspect was avoided, as extracorporeal shock waves might have systemic effects, influencing the bacterial quantity and composition. On the other hand, plaque reduction may mainly be influenced by adequate oral hygiene, which seemed to be relevant in the treatment group. The limitations of the study further include the higher mean age of the participants and the sound periodontal status at the beginning of the investigation.

For the first time, extracorporeal shock waves were investigated on human dental material showing no kind of adverse effects on teeth and their surrounding tissue. It may be speculated that multiple applications, i.e., a monthly application up to 4 months or higher of energy flux densities of extracorporeal shock waves, would show different effects on these tissues. However, until now, no evidence is available concerning the frequency of shock wave application. Further investigations of this non-invasive method should be performed as the intraoral environment may offer further fields of application.

**Table 4** Mean sulcus probing depth (PD), plaque index (PI), and gingival index (GI) of the lower second molar during the investigation period

Time point	PD	PD	PI	PI	GI	GI
	T (SD)	PC (SD)	T (SD)	PC (SD)	T (SD)	PC (SD)
Start	1.75 (0.39)	1.84 (0.45)	0.54 (0.09)	0.48 (0.12)	0.58 (0.21)	0.79 (0.30)
Middle	1.57 (0.24)	1.52 (0.30)	0.34 (0.16)	0.37 (0.17)	0.52 (0.30)	0.63 (0.28)
End	1.60 (0.28)	1.55 (0.39)	0.15 (0.13)	0.29 (0.14)	0.31 (0.18)	0.46 (0.20)

## Conclusions

This randomized clinical trial investigated the effect of extracorporeal shock waves and concluded that:

- Single application of shock wave treatment did not statistically and significantly accelerate tooth movement.
- Single application of shock wave treatment did not alter periodontal status in vivo.
- The absence of any side effect will allow for further shock wave investigation in the oral cavity.

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**Conflict of interest** The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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