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ORIGINAL ARTICLE

Effect of extracorporeal shockwave therapy (ESWT) on pulpal blood flow after orthodontic treatment: a randomized clinical trial

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Abstract
Objectives The effect of non-invasive extracorporeal shockwaves on pulpal blood flow in orthodontic patients who have undergone active treatment was investigated.
Materials and methods Seventy-two adult patients were enrolled in the clinical trial and allocated by block randomization to a treatment or a placebo group at a 1:1 ratio. The patients were required to be otherwise healthy. Blinding was performed for the subjects and the outcome assessor. The region of interest was the mandibular incisors and canines, which were vital, unrestored, and had experienced no trauma. The active treatment group received a single shockwave treatment with 1000 impulses at 0.19–0.23 mJ/mm^2 while the placebo group was treated with a deactivated shockwave applicator but acoustic sham. Pulpal blood flow was evaluated four times over a period of 6 months starting from the day of bracket removal, using a laser Doppler device.
Results Thirty patients were evaluated in each group. Orthodontic patients who have undergone active treatment tend to have high levels of pulpal blood flow which decrease over a period of 6 months. Pulpal blood flow did not differ significantly over 6 months between the placebo and treatment group. Shockwave treatment was associated with no significant effect in respect of tooth type, age, sex, or mean blood pressure, and had no unintended pernicious effects.
Conclusions Extracorporeal shockwaves had no statistically significant effect on pulpal blood flow. Multiple applications of ESWT in a pathological setup may be needed in future studies to demonstrate significant differences.
Clinical relevance The absence of any adverse effects justifies further principal investigations of the use of shockwave treatment in the oral cavity.

Keywords Extracorporeal shockwave · Pulpal blood flow · Laser Doppler · ESWT · PBF · LDF

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Introduction

Laser Doppler flowmetry (LDF) is regarded as the method of choice for the assessment of pulpal blood flow (PBF) when examining pulp vitality. LDF is a noninvasive, painless, semi-quantitative measuring device with proven accuracy, reliability, and reproducibility [1–4]. To maintain the sensitivity of the LDF probe, tooth movement must be avoided during measurement and the gingiva surrounding the tooth must be covered [2, 5–11]. LDF is superior to conventional tests in that it permits accurate assessment of the condition of pulp [10, 12].

In endodontics, LDF was used to study the effect of thermal changes and local anesthesia on PBF. The latter was found to be reduced transiently [13, 14]. Following restorative treatment, a permanent reduction of PBF in the molars was observed [15]. However, PBF after orthognathic surgery was evaluated in just two studies, which reported contrary data [16, 17]. Head, body posture, and hormonal status should be considered when assessing PBF in women [5, 6].

Orthodontic force exertion on PBF has been studied in the past. Specific tooth movement, such as displacement directed axially and laterally, resulted in a reversible reduction of PBF [18–25]. Orthodontists are concerned with the rehabilitation of endodontic and periodontal tissue after comprehensive therapy. Orthodontic tooth movement is facilitated by a sterile inflammation process in alveolar bone, resulting in greater pulpal blood supply; the latter is manifested as high PBF values [18, 21, 23]. This transforming tissue turnover continues after active orthodontic therapy and may be associated with several clinical signs, such as radiographic widening of periodontal tissue, increased tooth mobility, and resumption of the actual tooth position [26, 27].

A novel method that might be beneficial for the rehabilitation of tissues surrounding a tooth is extracorporeal shockwave therapy (ESWT). It is currently the treatment of choice for the removal of stones. ESWT is also employed to break up salivary gland stones in the oral cavity. In surgery, ESWT is used to assist a patient's recovery from pseudarthrosis after fractures of long bones, tendinopathy, and for wound healing [28, 29]. The mode of action of ESWT is not entirely known at the present time [30–32]. The effect of ESWT in periodontology has been investigated. In animal models, ESWT was found to exert microbicidal effects in the oral environment. Therefore, the use of ESWT has been advocated for the treatment of periodontitis and peri-implantitis, and to initiate periodontal and bone regeneration [33–35]. Shockwaves may also exert a rehabilitating effect on teeth after orthodontic therapy, reduce the sterile inflammatory process, and accelerate the rehabilitation of endodontic and periodontal tissue. Thus, the objective of the present study was to measure vascular reaction after orthodontic tooth movement, assuming that ESWT may accelerate the rehabilitation of endodontic tissue. Such rehabilitation would indirectly be expressed by PBF reduction. The null hypothesis stated no difference in PBF exists between ESWT and ESWT sham application in orthodontically aligned teeth.

Materials and methods

Trial design

The study was designed as a single-center, randomized, placebo-controlled trial with a 1:1 allocation ratio. It was approved by the institutional review board (approval number EK 1065/2010) and the protocol was registered at ClinicalTrials.gov of the US National Institutes of Health (NCT01600118).

Participants, eligibility criteria, and setting

Informed consent was provided by all patients; women underwent a pregnancy test (Femtest, Omega Teknika, Dublin, Ireland). Otherwise, healthy patients who had undergone fixed orthodontic treatment were included in the study. The mandibular anterior teeth had undergone no restoration and responded positively to sensibility testing (Endo cold spray, Henry Schein Inc., Melville, NY, USA), percussion, and palpation. No dental trauma had occurred prior to orthodontic treatment, which was performed to treat a deficiency in the length of the mandibular arch. The orthodontic appliance was a self-ligating bracket system (Smartclip 0.022 inch slot, 3 M Unitek, Monrovia, CA, USA) with a 0.018×0.025-in. stainless steel finishing archwire (SDS Ormco, Glendora, CA, USA). The appliance was removed and tooth surfaces were carefully inspected for remnants of the adhesive before starting the measurements. In accordance with the retention protocol, patients had an individualized passive aligner (Duran 1 mm, Scheu Dental Company, Iserlohn, Germany) in the mandibular dental arch full time over a period of 3 months, and at night for a further 3 months, in order to reduce the risk of tooth movement and ensure tooth retention.

Interventions

A single session of ESWT was used in the treatment group. All participants received topical local anesthesia (Xylocaine 2 % gel, Astra Zeneca Company, Vienna, Austria) in the mandibular anterior vestibulum. Sonic gel liquid (Gerasonic, Gerot Pharmazeutika Company, Vienna, Austria) was applied on the soft tissue between the chin and the lower lip as conduction medium. The treatment group was given 1000 impulses of focused ESWT (Orthogold 100, MTS/TNT Konstanz, Germany) at an energy flux density of 0.19–0.23 mJ/mm^2 and a pulse rate of five pulses per second. Members of the placebo group were treated with an acoustic sham of ESWT with the same pulse rate, volume level, and treatment time. The ESWT applicator was used in deactivated form, in the same manner as in the treatment group.

PBF was measured using a laser Doppler flowmeter (PeriFlux 4001, Perimed instruments, Stockholm, Sweden) with a laser wavelength of 780 nm. A laser Doppler probe (probe 416, Perimed instruments) with a fiber separation of 250 μm was used. An individualized silicone splint (Shera Duett, Shera Company, Lemförde, Germany) was fabricated for each patient on the dental cast, approximately 5-mm thick, and overlapping the gingival tissue by at least 7 mm (Fig. 1). The position of the probe in the splint was 3 mm in the incisal aspect from the gingival margin in the middle of each tooth crown, in accordance with Setzer et al. [10]. Probe tubes were drilled according to the probe's dimension in order to ensure accurate and reproducible positioning of the probe on each tooth at any session. The laser probe was calibrated before each measurement. The study participants sat upright for at least 10 min and underwent digital measurement of their blood pressure (M8 comfort, Omron healthcare, Kyoto, Japan). PBF was measured for a minimum of 90 s for each tooth. To

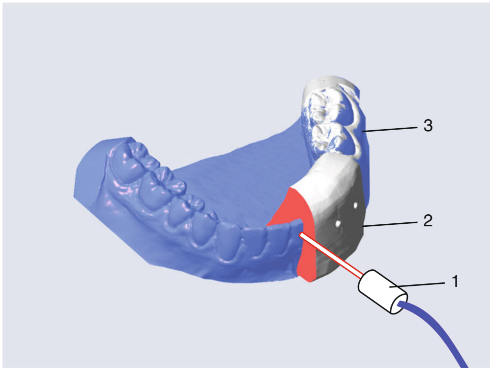


Fig. 1 Application of the laser Doppler probe (*1*) in the sectioned holding appliance (*2*) on a digitally scanned dental cast (*3*)

minimize bias during the measurement, the participants were asked to remain immobile. All measurements were performed at a constant room temperature of 22 °C.

Outcomes (primary and secondary) and changes after trial commencement

The primary outcome was the PBF of the mandibular anterior teeth, measured in perfusion unit (PU) values by laser Doppler software (Perisoft vers. 2.50, Perimed, Stockholm, Sweden) Data were stored digitally in a computer (MacBook Pro, Apple Inc., Cupertino, CA, USA).

Sample size calculation

In accordance with Chandler et al., the sample size was calculated on the basis of two groups consisting of 36 participants each, which yielded a difference of 0.7 standard deviation between groups with 80 % power by a two-sided t test, corresponding to a change of 3.5 perfusion units [15].

Interim analyses and stopping rules

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

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 and sealed in envelopes, with the participant's initials and age written on the outside. The envelopes were locked until the start of treatment. This process was performed and monitored by one operator (CA).

Blinding

Blinding was performed for the subjects and the outcome assessor (CK), but the shockwave therapist (RK) was not blinded. The results of the measurements were coded by one operator (RM) for the outcome assessor in order to ensure blinding.

Statistical analysis (primary and secondary outcomes, subgroup analyses)

The influence of the position of the teeth in the anterior segment was investigated as follows: For each tooth position, the time series of mean blood flow was plotted for the treatment and the placebo group. Wilcoxon's tests for differences between the two groups were performed for each tooth and each time point. The difference between the last measurement and baseline was studied in a mixed model, with baseline, treatment, and tooth position as fixed effects and the intercept for each patient as random effect. A linear mixed model was used for the difference between the last measurement and baseline, including the covariables of treatment, position, and baseline flow as fixed effects, and the intercept for each patient as random effect. The mean PBF of all tested teeth was calculated and plotted against the covariables of treatment, age, sex, position, and mean blood pressure for each participant. Bonferroni-Holmes correction of p values was performed to account for the simultaneous investigation of six factors potentially influencing blood flow. All statistical calculations were performed with R 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

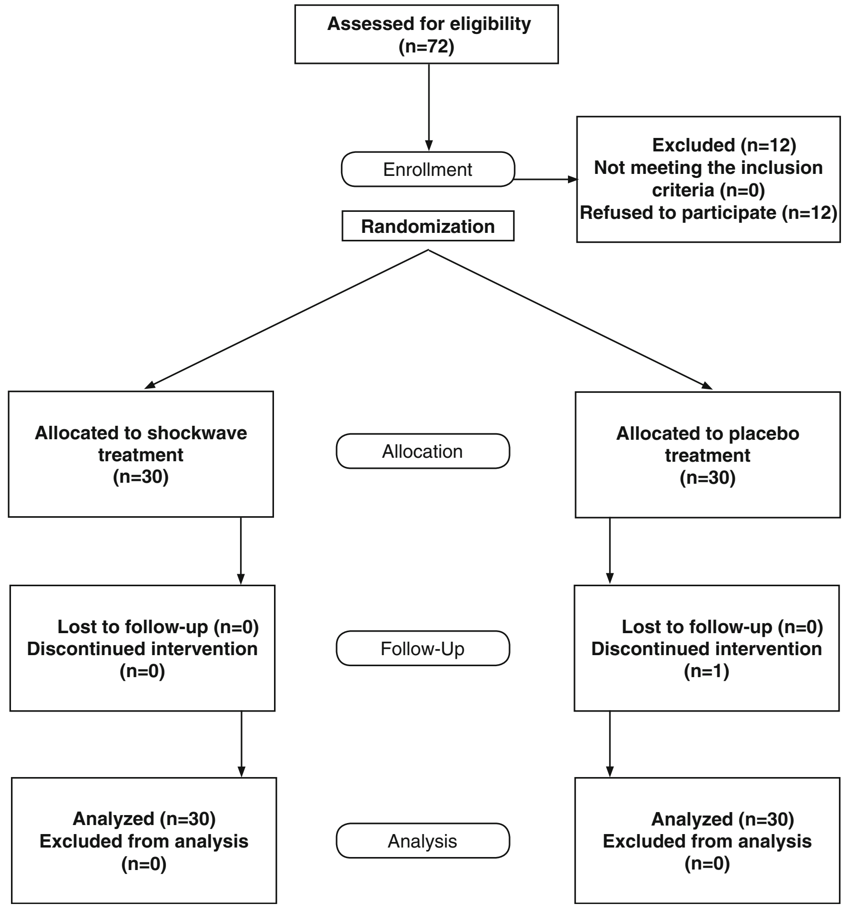
Participants (flow diagram and time periods)

Seventy-two persons were initially enrolled in the study. Twelve subjects declined participation immediately prior to treatment. One patient missed the third investigation appointment during the observation period (Fig. 2). Recruitment started in March 2011 and concluded in May 2013. The investigation was started in September 2011 and completed in November 2013.

Baseline data (baseline table)

Patient characteristics are shown in Table 1. The overall mean age was 26.9 years (SD 7.8, range 18–49 years). The majority of patients were women (women 57 %, men 43 %).

Fig 2 Flowchart showing participant allocation and follow-up during the investigation



Numbers analyzed for each outcome (estimation and precision, subgroup analyses)

Mean PBF data are shown in Table 2. The mean PBF of canines, lateral incisors, and central incisors differed significantly between the placebo and the treatment group at the first as well as the second observation. The course of PBF in the placebo and the treatment group did not differ significantly over the 6-month observation period. Only flow at baseline was significant before and after Bonferroni correction of p values (Table 3). No significant effect was registered for age (p=0.75), sex (p=0.36), and mean blood pressure (p=0.11) between the placebo and the treatment group over 6 months.

Table 1 Baseline demographics and clinical parameters of the placebo (PC) and the treatment (T) group

	PC n=30	T n=30
Age [years]	25.9±8.1	27.9±7.5
Male sex [no. (%)]	11 (36)	15 (50)
Systole [mmHg]	111.7±14.9	117.4±12.2
Diastole [mmHg]	73.1±10.4	73.5±9.1
Mean pressure [mmHg]	86.0±11.1	88.2±9.2

Table 2 Mean pulpal blood flow values [PU], including SD and p values of Wilcoxon's test for differences between groups for each tooth type and time point

Tooth type	Time point	PC	T	p value
Canines	0	16.7±6.5	12.5±5.6	0.006*
	1	14.2±6.2	11.5±4.8	0.08
	2	14.3±6.3	11.5±5.1	0.10
	6	14.8±6.2	11.6±4.4	0.04*
Central incisors	0	21.5±10.5	14.4±7.5	0.004*
	1	17.1±9	12.1±6.1	0.02*
	2	16.4±9.4	13±6.9	0.20
	6	16.4±8.6	12.5±5.4	0.14
Lateral incisors	0	19.3±9.2	13.7±7.3	0.004*
	1	16.1±7.4	11.9±5.3	0.03*
	2	15.4±7.4	12.2±5.1	0.11
	6	15.3±8.1	12.4±4.9	0.26

PC placebo, *T* treatment

*Statistically significant

Table 3 Estimates of the effects of treatment (with placebo as reference), tooth type (with canine as reference) and baseline pulpal blood flow on the difference between the last minus the first measurement, with confidence limits (CL) and *p* values:

	Estimate	95 % lower CL	95 % upper CL	*p* value
Treatment	−1.21	−3.34	0.93	0.27
Tooth type				
Central inc.	−0.01	−0.93	0.90	0.98
Lateral inc.	0.00	−0.90	0.90	0.99
PBF baseline	−0.63	−0.69	−0.56	<0.001

Harmful effects

No unintended pernicious effects occurred after ESWT during the entire study period. The sound of ESWT did neither alter the patients' sensitivity nor their acoustic sensation.

Discussion

Extracorporeal shockwaves were found to exert favorable effects in terms of tissue regeneration in general medicine and in traumatology [28–32, 36–38]. As periodontal and endodontic tissue regeneration tends to be slow after active orthodontic therapy, orthodontists try to accelerate this process. Reduction of the retention period might influence inflammatory activity in the alveolar process and the tissues surrounding the tooth, resulting in a gradual reduction of inevitable but undesirable tooth movement after active therapy [26, 27] Until now, the knowledge of PBF after active orthodontic tooth movement is limited. In the present *in vivo* investigation, the effect of ESWT on PBF in orthodontically aligned teeth was studied and we monitored the ESWT effect over a 6-month period. An anticipated PBF decrease could be interpreted as a rehabilitation activity, but the null hypothesis was not rejected. No difference exists between ESWT and ESWT sham application on PBF in orthodontically aligned teeth.

A statistically significant difference was noted between the treatment and the placebo group after the first and second month of observation. However, this fact must be interpreted with caution because baseline data differed in the two groups. By pure chance, initial blood flow differed significantly between groups. In this trial, we monitored the PBF before ESWT for baseline measurement. PBF was not measured directly after ESWT application as the absence of a transient short-time effect was surmised. An immediate measurement after ESWT application would have clouded the findings, but a monthly monitoring of the PBF would allow for a detection of a long-time effect. The ESWT group displayed a constant PBF during the investigation period perhaps due to the anti-inflammatory effect of ESWT described in the published literature but no long-time effect could be detected in this study [30–32].

A review of the literature shows that active orthodontic tooth movement was associated with a significant increase in PBF in every case [18, 21, 23]. A statistically significant reversible reduction of PBF under active loading has been observed in the past. Compression of microvascular pulpal blood supply persisted for just a short period of time [19, 20, 24, 25]. The observation period in this investigation was as long as 6 months. However, the findings cannot be compared with those of the above-mentioned authors because the latter studied PBF under active orthodontic loading.

Despite the difference in crown and root morphology, PBF values were similar when the incisors were compared with the canines. This has been confirmed by Norer et al. According to Yanpiset et al., however, tooth morphotype also influences PBF [39, 40]. At the end of the investigation period, the PBF values of pulp perfusion in the study were comparable to those reported in other investigations [2, 15, 16, 18, 39]. The lower PBF values registered in other studies might have been due to the manner of coverage of tissue surrounding the tooth [6–10, 17, 19, 25].

Ikawa et al. registered a significant reduction in pulpal hemodynamics with advancing age. As only young adults were investigated in this study, age had no significant impact on PBF measurements [41]. The hormonal status of premenopausal women influences PBF to a significant extent [6]. As only young adults in the study were included, gender had no significant influence on PBF.

The mean systemic blood pressure registered was similar to that reported by Ajcharanukul et al., who also tested their patients in upright sitting position [5]. Avoidance of any change of temperature, application of local anesthesia, and physical exercise are all factors that influence blood perfusion. This may well explain why no significant change in arterial blood pressure was noted in the study [8, 10, 11, 13, 14, 19].

The main finding of our study was the absence of an effect of single ESWT on dental pulp blood flow. This fact might be due to the physiological conditions under testing. Most of the studies concentrated on tissue exposed to ischemic conditions, associated with a significant increase in blood flow. It was found that under pathological conditions, ESWT does exert beneficial effects on various types of tissue, including those in the oral cavity [42–46]. Future investigations should be focused on PBF in the ischemic setting, such as that of undermining resorption of spongy bone. As the lowest ESWT energy flux densities were used in the present investigation, no block anesthesia was required. Nevertheless, the potential regenerative effect of ESWT was evident. Higher energy flux densities and pulse numbers may be needed in future studies to demonstrate significant differences.

Limitations

Owing to the fact that 12 patients dropped out of the study unexpectedly, it did not achieve the full power of 80 % with respect to the predefined difference between placebo and treatment groups. However, the observed differences between groups were so small that the conclusions were considered meaningful despite this limitation. Some bias may have been introduced by the differences between groups at baseline. Therefore, correction of baseline values was included in the model. The validity of the results was confirmed by the fact that no significant difference was noted between groups after correction. As LDF is a semiquantitative method, the availability of pure quantitative data would be more desirable.

Generalizability

The generalizability of the results may be limited by the fact that it was a single-center study investigation.

Conclusions

Pulpal blood flow in orthodontically aligned teeth was reduced during the observation period of 6 months. Single ESWT had no statistically significant impact on PBF of orthodontically aligned teeth. Multiple applications of ESWT in a pathological setup may be needed in future studies to demonstrate significant differences. The absence of any adverse effects justifies further investigation of the use of shockwave treatment in the oral cavity.

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Conflict of interest The authors declare that they have no competing interests.

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