Impact of extracorporeal shock-wave therapy on the stability of temporary anchorage devices in adults: A single-center, randomized, placebo-controlled clinical trial

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Introduction: In this randomized, placebo-controlled clinical trial, we investigated the effect of noninvasive extracorporeal shock waves on the stability of temporary anchorage devices (TADs) under orthodontic loading. **Methods:** Thirty adult orthodontic patients of the Bernhard Gottlieb University Clinic in Vienna, Austria, were enrolled in this clinical trial and allocated by block randomization (size, 4) in a 1:1 ratio to either the treatment or the placebo group. Randomization was performed with software, and the allocations were concealed in sealed envelopes. Eligibility criteria included healthy adult patients with mesially directed orthodontic movement of the mandibular second molar into the extraction site of the mandibular first molar. The fixed orthodontic devices included active superelastic coil springs (200 cN) and TADs in the mandibular alveolar bone. Blinding was performed for the subjects and the outcome assessor. The treatment group received 1 shock-wave application with 1000 impulses at 0.19 to 0.23 mJ per square millimeter in the region of the TADs. The placebo group was treated with a deactivated shock-wave applicator and acoustic sham. The TADs positions were evaluated at placement and after 4 months. The reliability and precision of the impression process of the TADs were evaluated in an in-vitro model. **Results:** Thirteen participants finished the investigation successfully in the treatment group but only 12 finished in the placebo group because 1 TAD loosened. The difference of the total TAD displacement for the 4-month time period between the placebo and treatment groups was 0.17 ± 0.95 mm (95% CI: -0.96, 0.62). No statistically significant difference between the 2 groups was found when sex was evaluated. Primary stability of the TADs as measured by placement torque, amount of tooth movement, and age of the patients did not influence displacement of the TADs. The reliability and precision of TAD impressions were confirmed. No unintended pernicious effects occurred after shock-wave treatment during the study period. **Conclusions:** A single application of extracorporeal shock-wave treatment did not improve the stability of the TADs during orthodontic loading. Sufficient interradicular space should be provided to minimize the risk of periodontal and dental root defects. **Registration:** This trial was registered at https://clinicaltrials.gov. **Protocol:** The protocol was published before trial commencement, NCT01695928. **Funding:** No funding or conflict of interest to be declared. (Am J Orthod Dentofacial Orthop 2014;146:413-22)

Over the last decade, temporary anchorage devices (TADs) have become an essential tool in orthodontics as an alternative to compliance-dependent devices such as extraoral headgear traction and intermaxillary elastics. Various types of TADs are being used as aids in critical anchorage situations.[1-3] The success of any TAD will depend on several factors such as diameter, length, placement site, placement torque,

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inflammation, mobility, distance to the root, and soft-tissue type.[2,4-9] Recently, a meta-analysis described a success rate of 88%, whereas success rates in systematic reports have ranged between 80% and 100%.[1,3,10] However, these high success rates might not be representative for clinical settings, because loose TADs were also included in these numbers. This must be borne in mind, since several studies have reported displacement of TADs under orthodontic loading, which can also affect the surrounding tissue.[11-13] This issue is even more significant because most TADs are in contact with the periodontal ligament after placement.[14] Hence, an unstable TAD position might result in its loosening, periodontal defects, or root damage; consequently, a stable position of the TAD during orthodontic treatment is of major importance.[12,13]

Extracorporeal shock waves have become the treatment of choice for kidney and urethral stones in medicine as well as for the recovery of pseudoarthrosis after long-bone fractures, for tendinopathies, and for wound healing.[15,16] Shock waves can induce osteogenesis, angiogenesis, and revascularization, but their local and systemic molecular and cellular effects are still unclear.[17-19]

The effect of extracorporeal shock waves has already been investigated in dentistry. In animal models, shock-wave therapy showed a microbicidal effect against *Streptococcus mutans* and *Porphyromonas gingivalis*. Recently, Hazan-Molina et al,[20] Kohno et al,[21] and Iwasaki et al[22,23] investigated the effect of extracorporeal shock waves on tooth movement in an in-vitro model and found a significant increase of selected cytokines: ie, VEGF and interleukin-1β. Furthermore, a bone regenerative effect was found when extracorporeal shock waves were applied after artificial trauma.[24-26] Thus, shock waves might have a positive effect on TAD stabilization, accelerating the bone formation process from primary stability to secondary stability.[27]

Specific objective and hypothesis

The purpose of this study was to investigate the effect of noninvasive extracorporeal shock-wave therapy on TAD stability. The null hypothesis stated that shock-wave therapy does not stabilize the position of TADs.

MATERIAL AND METHODS

Trial design

The study design defined the investigation as a single-center, randomized, placebo-controlled trial with a 1:1 allocation ratio performed at the University Clinic of Dentistry in Vienna and approved by the institutional review board (EK 134/2011). The protocol was registered at ClinicalTrials.gov (NCT01695928) of the US National Institutes of Health, and this article was written according to the CONSORT statement.

Participants, eligibility criteria, and setting

All study subjects provided informed consent. They were healthy adults undergoing comprehensive orthodontic treatment (Fig 1). The women had a pregnancy test (Femtest; Omega Teknika, Dublin, Ireland) before inclusion. The inclusion criteria defined patients with mesially directed orthodontic movement of the mandibular second molar into the extraction site of the mandibular first molar facilitated by a TAD (Dual Top G2, 1.6 × 8-mm, self-drilling; Jeil Medical, Seoul, Korea). The insertion site of the TAD was between the mandibular first and second premolars in the attached keratinized gingiva.

The full-fixed orthodontic appliance included a self-ligating bracket system (Smartclip, 0.022-in slot; 3M Unitek, Monrovia, Calfi), an 0.018 × 0.025-in stainless steel archwire (SDS; Ormco, Glendora, Calif) connecting the posterior and anterior tooth segments, an 0.018 × 0.025-in stainless steel lever arm (SDS; Ormco) inserted in the auxiliary tube of the molar attachment, and an active superelastic coil spring (Sentalloy; GAC Dentsply, Bohemia, NY) between the second molar and the TAD, delivering a continuous force of 200 cN.[28]

Interventions

The insertion of the TAD was done transmucosally under local anesthesia (Ultracain dental forte; Sanofi Aventis, Paris, France) between the first and second premolars in the keratinized gingiva with a screwdriver perpendicular to the alveolar bone, including primary stability measurement: ie, placement torque (TSD Torque screwdriver; Checkline Europe, Enschede, The Netherlands).[29] All TADs were inserted to the contact between the TAD collar and attached gingiva. Root proximity was evaluated radiographically before and after TAD placement to check for sufficient space for insertion and exclude a contact between the TAD and the adjacent root surface at the end of the investigation. The mandibular anterior teeth were bonded lingually with a passive 0.022-in stainless steel retainer wire (Wildcat wire; GAC Dentsply), also serving as the reference area for TAD displacement measurement.

Outcomes (primary and secondary) and any changes after trial commencement

The major outcome of this trial was the TAD displacement measurement. Therefore, impressions of the mandibular dental arch (Flexitime easy putty; Heraeus Kulzer, Hanau, Germany) were taken twice: immediately after TAD placement and 4 months later with a bisected