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Influence of needle bevel design on injection pain and needle deformation in dental local infiltration anaesthesia – randomized clinical trial

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Abstract. The aims of this *in vivo* study were to evaluate the impact of needle bevel design on patients' pain perception and the mechanical deformation of the needle tip after the injection. In a prospective single-blinded trial, 150 patients received conventional infiltration anaesthesia for dental treatment by one examiner. Patients were randomized for one out of three different needle bevel types (scalpel-designed bevel needle (SB), $n = 50$; triple bevel needle (TB), $n = 50$; regular bevel needle (RB), $n = 50$). Subjects' self-reported injection pain perception was evaluated using a numeric rating scale (NRS). For each needle tip, deformations after single use were measured using SEM. A significant lower injection pain level was found in SB (mean 2.1 ± 1.2) than in TB (mean 3.5 ± 1.6;) and RB (mean 3.4 ± 1.0; all $P < 0.001$). A needle deformation was detected in about 97.3% of all needles (SB 50/50, TB 50/50, and RB: 46/50). A higher number of barbs were found in SB (29/50) versus TB (17/50) and RB (19/50). For dental local infiltration anaesthesia, injection needles with a scalpel-designed bevel demonstrated significantly less injection pain. Needle tip deflections after anaesthetic agent infiltration, especially barbed hooks on the non-cutting edge may result in greater soft tissue trauma.

Key words: dental infiltration anaesthesia; needle bevel design; injection pain; needle deflection; clinical study.

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The majority of dental procedures require local injection of anaesthetic solution. The pain caused by those injections is one of the primary sources for fear and anxiety in dental patients[1,2]. This might result in patients' avoiding dental care and follow-up[3,4]. For reduction of pain during injection, topical anaesthetic agents prior to puncture were used[1,5,6] as well as warming up[7,8] and/or buffering of anaesthetic agents[9]. A slower delivery of anaesthetic solution[10] and topical pre-cooling[11] have been clinically used and reported as well. Other useful approaches have been applied, such as application of vibration[12] or pressure[13] at the injection site[14].

The size and the design of the dental needle seem to be of little influence in

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reducing the pressure during injection[15,16]. Nevertheless, to the best of our knowledge, there are few reports in terms of a possible association between the needle bevel design and the patient's pain experience. In a non-clinical study, Steele et al. reported that an asymmetrical bevel requires the lowest penetration force compared with a standard needle[17], but the clinical impact of these findings remains unclear. In a small-scale trail, Omoigui et al. described a possible influence of bevel design on injection pain[18]. However, this non-dental related study lacks strong evidence because of the small number of patients ($n = 20$). Besides, sharper and more pointed needle bevel designs may also result in a higher rate of needle deformations by soft tissue and bone contact. Regarding the source for nerve damage after dental anaesthesia two hypotheses are discussed. On the one hand, it is hypothesized, that transient or even persistent nerve damage may be caused by the neurotoxicity of local anaesthetics[19–21]. On the other hand, direct trauma of the penetrating needle respectively by retracting a (barbed) needle might be the reason for the nerve damage[22–24] as this may result in intraneural bleeding and haematoma with subsequent constrictive scarring within the nerve itself[25]. Stacy et al. found barbed needles in about 60% of cases after local anaesthesia delivery[24]. Therefore, the aims of this study were to evaluate the impact of the needle design on patients' injection pain perception in dental local infiltration anaesthesia and the associated mechanical transformation of needle tips after the respective single injection.

Material and methods

Patients

In a prospective single-blinded design, patients referred to the Department of Oral, Maxillofacial and Plastic Surgery of the University Medical Centre Rostock, Germany, between October 2015 and January 2016 were included. Patients had to be older than 18 years and in need of dental treatment under local infiltration anaesthesia. Patients with a need for regional anaesthetic block, intraosseous anaesthesia, or general anaesthesia were excluded. Prior to treatment, informed consent and ethical approval (A 2015-0114, ethics committee at the University Medical Centre Rostock, Germany) including IRB information were obtained.

Materials and methods

In total, 150 patients met the inclusion criteria for the study and received conventional submucosal infiltrational anaesthesia. With a maximum group size of 50 per needle type, the patients were randomized to one of the three different needle types tested. Equal randomization was achieved by using a computer-generated random number list. A dental nurse prepared the different needles together with identical syringes marked with the patients' randomization number only. Every needle had a similar needle diameter with about 0.3–0.4 mm but a different bevel design (Fig. 1). Needles in the SB group had a scalpel-designed bevel (Septoject Evolution® G30 short 0.3 × 25 mm, Septodont GmbH, Niederkassel, Germany). The TB group had a triple bevel (Septoject® G30 extra 0.3 × 25 mm, Septodont GmbH, Niederkassel, Germany) and the RB group had a regular bevel design (BD Microlance 3™ G27 ''3/4'' 0.4 × 19 mm, Becton, Dickinson and Company, Franklin Lakes, NJ, USA). Randomization was achieved using a computer-generated list. In all cases, 4% articaine with an epinephrine adjunct of 1:200 000 (Septanest®, Septodont, Niederkassel, Germany) was used. The guidelines for submucosal infiltration anaesthesia[26] were followed and each patient was blinded in regard of the used needle type. All injections were conducted by one examiner to avoid the possible influence of different examiners.

Following the conditions in this study in a clinical setting in which every patient needed anaesthesia for a specific treatment (mostly extraction of teeth), no randomization of injection sites was done. No further anaesthesia, systemic or topical, and no further methods for decreasing the sensitivity were used.

The measurement of the subjective injection pain was performed using an 11-point unit numeric rating scale (NRS). After the respective single injection, the needles were fixed on an object slide and prepared for microscopic examination. The obtained data on injection pain SEM (scanning electron microscope, DSM960, Zeiss, Jena, Germany) measurements of each needle were conducted. The images were obtained and processed with the computer software Photoshop CS5 (Adobe Systems Incorporated, San Jose, CA, USA). The needles were aligned on 5-μm box grids (Fig. 2). The vertical and horizontal deviations were calculated in arbitrary box units (box numbers). The direction of deviation (deviation to cutting side or to opposite, non-cutting side) was measured. The deviations with an angle of more than 90 degrees, in relation to the longitudinal direction of the needle, were counted as barbed tips (Fig. 2).

Statistics

Results were expressed as arithmetic means ± standard deviation (SD). As this is the first study on this topic, no *a priori* power calculation could be performed. Testing for statistical significance was done by one-way ANOVA tests or by χ^2 tests. P-values ≤ 0.05 were seen as significant. All statistical analyses were performed with SPSS statistical package version 20.0 (SPSS Inc., Chicago, IL, USA).

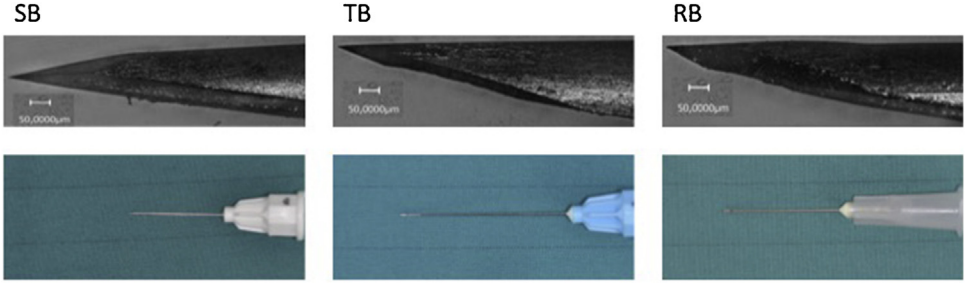

Fig. 1. Scanning electron microscope pictures (first line) and incident-light photomicrographs (second line) of used dental injection needle tips (SB – Septoject Evolution® G30 short 0.3 × 25 mm; TB – Septoject® G30 extra 0.3 × 25 mm; RB – BD Microlance 3™ G27 ''3/4'' 0.4 × 19 mm).

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