

### **Anesthetic Effective Potential of a Needle-free Injection System**

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### **Introduction**

In addition to different local anesthesia compositions, numerous local anesthesia application systems are available for the fields of dental, oral, and gnathic medicine.

The fear of needle injections has been widespread since the development of the conventional syringe 140 years ago. Associated problems are numerous and primarily characterized by the defense reflex of a needle phobia. Frequently, this results in the termination of the therapy or the refusal to accept treatment with the consequence that symptoms worsen. Improved application options can significantly contribute to solving this problem.

The INJEX system was developed by the company Rösch AG Medizintechnik, Berlin, in 1999. The study in hand examines this new needle-free injection system (Fig. 1) promising dosage reduced and less painful oral, dental, and gnathic work and directly compares it with conventional anesthesia systems.

### **Material and Method**

The change of the perception threshold for electrical pulpa stimulation was determined for the comparative measurement of the local anesthetic effect within the scope of the clinical test. The pulpa was stimulated according to the noninvasive method specified by Raab<sup>13</sup> and Raab<sup>17</sup>.

The sensation of pain was triggered at the receptive organ tooth pulpa by introducing a physiological condition. This method was used to ascertain the local anesthetic effect on the pain receptors over a period of time.

The compound Ultracain® D-S (Aventis, Bad Soden) was used as anesthetic in all cases. One application method for dental local infiltration anesthesia each was used with 10 test subjects ranging in age from 25 to 35 (5 male and 5 female) in random sequence on one upper center incisor during two examination days at least 1 week apart. A dose of 0.6 ml is was injected each time.

Several measurements were taken to determine the perception threshold for the electrical stimulation before the anesthetic was applied to establish the baseline. The program Reiz V1.02 was used to determine the subjective sensation of pain. This program allows test subjects to indicate the subjectively experienced sensation of pain using a joystick and monitor controls.

The electrical pain threshold was determined immediately after the injection process ended and then at intervals of 2 minutes each. Perception thresholds above 200  $\mu$ A corresponded with a complete elimination of pain. The following parameters were calculated to ascertain the effective profile:

- Uptake time = Time from end of injection until a perception threshold of more than 200  $\mu$ A is reached
- Therapeutic utilization time = Duration of threshold increase to more than 200 $\mu$ A
- Dissipation time = Time from drop of threshold below 200 $\mu$ A until initial value is reached

### **Results:**

The following are the results concerning the individual measurement parameters:

- Uptake time: There is a significant uptake time difference between the utilized anesthesia systems (Table 1 Fig. )
- Therapeutic utilization time: There is a no utilization time difference between the utilized anesthesia systems (Table 1)
- Dissipation time: There is a no dissipation time difference between the utilized anesthesia systems (Table 1)
- Subjective painfulness during application: The factor anaesthesia system proved to be not significant (Table 1)

## Discussion

A reliable and standardized method has to be applied to provide an accurate comparison between two different anaesthesia systems. Different methods are available to test for local anaesthetic effect; electrical pulp stimulation was considered a suitable method<sup>2,3,14,16,18,19</sup>

Different local anesthesia systems have been the subject of many studies as well.

The INJEX system has been tested with patients and different painful dental procedures by *Krug* and *Rahn*<sup>9</sup>. For comparison, some of the patients were anesthetized with a conventional injection.

Conditions have to be equal for both systems in order to allow a direct comparison of two systems, which is why in the study at hand INJEX and the conventional injection was used with the same test subjects and applied to the same tooth.

The INJEX system and the conventional anaesthesia system yielded approximately the same results. The statistical result analysis shows a significantly shorter uptake time for the INJEX system (cf. Fig.). The immediate effect of the anaesthesia when using INJEX was also noticeable clinically during the experiments.

In addition, the INJEX system exhibited a tendency towards a longer therapeutic utilization time in comparison with conventional anaesthesia; however, the value is without statistical significance.

The statistically insignificant but allusive higher subjective sensation of pain when administering with the INJEX system confirms experiences by *Krug* and *Raab*<sup>9</sup>. Most test subjects considered the placement of the instrument on the mucosa unpleasant. Responding to the results of our study, the manufacturer has developed a soft silicone cap (*Silitops*) (Fig. 14), which is applied between INJEX and mucosa, rendering the injection less unpleasant for patients. Additional research about this subject is planned.

Since INJEX has to be positioned on the mucosa exactly at a right angle, the product is only applicable to specific teeth. The system is well suited for dental local anaesthesia within this application scope.

Although the statistical results showed significant differences only for the uptake time, the time progression of the utilization profiles seem to provide clear benefits for clinical application of the INJEX system. This is due to the reliable and rapid hysteresis as well as the safe elimination of pain as early as 6 to 20 minutes after the end of the injection when using the INJEX method (cf. Fig. ).

The INJEX system allows for dosage-reduced anaesthetizing. This is a clear benefit especially for children due to their lower body weight and the therefore significantly lower maximum dosage<sup>6</sup>. Moreover, anaesthetizing without cannula offers without doubt a psychological advantage, especially with children and overly fearful or anxious patients.