## **ORIGINAL ARTICLE**



# Extraction of mandibular premolars and molars: comparison between local infiltration via pressure syringe and inferior alveolar nerve block anesthesia

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#### Abstract

Objectives The purpose of this study was to evaluate the anesthetic efficiency of local infiltration anesthesia administered with a pressure syringe (P-INF) via a special technique versus direct block anesthesia of the inferior alveolar nerve (IANB) for tooth extraction in the posterior mandible.

Materials and methods In a prospective randomized study, 101 teeth in 101 patients were extracted in the posterior mandible under local anesthesia whereby two different administration techniques were used (P-INF n=48; IANB n=53). Primary objectives were comparisons of anesthetic success rate (yes/no) and efficacy (full/sufficient vs. insufficient). Secondary objectives were patients' pain perception during treatment, pain of injection (numerical rating scale), need for second injections (always IANB), time until onset of anesthetic action (min), and duration of local numbness (min).

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Results IANB was successful in all cases, whereas initial P-INF achieved 35% of success only. Furthermore, IANB reached significant higher values of anesthetic efficacy compared to P-INF (P < 0.001). Concerning pain of injection, patients rated IANB to be more painful (P = 0.039). Second injections were significantly more often necessary for P-INF (P = 0.006) whereas duration until onset of action as well as the duration of local numbness were found to be equal.

Conclusions For anesthetic efficacy as well as anesthetic success, block anesthesia of the inferior alveolar nerve (IANB) turned out to be more proficient to local infiltration via special delivering system with a special technique.

Clinical relevance Infiltration, even when performed with 4% articaine and a pressure syringe system, is not a suitable method of anesthesia in the posterior mandible.

**Keywords** Anesthetic success · IANB · Mandibular molar tooth extraction · Molar region of the mandible · Local anesthesia · Pressure syringe system

#### Introduction

Local anesthesia plays a pivotal role in modern dentistry and anesthetic agents rank among the most frequently used drugs both in medicine [1] and dentistry [2, 3]. It is known that a patients' anticipation of pain may compromise dental treatment [1, 4] and that administration of local anesthetic drugs typically triggers anxiety [5].

Inferior alveolar nerve block (IANB) still is the most frequently used anesthetic technique for surgical and restorative treatments in the posterior mandible [6, 7]. When administered successfully, IANB provides enough anesthesia to perform surgical and restorative procedures in a large area of the posterior mandible [8, 9]. However, it is associated with



relatively high failure rates of 7 to 75% [10–15]. Additionally, major intra- and postoperative complications may occur such as systemic toxicity from iatrogenic intravascular injections, severe bleeding from adjacent blood vessels injury, prolonged mandibular anesthesia, as well as transient, or even permanent paresthesia of the inferior alveolar and the lingual nerves [16-19]. To avoid these disadvantages, investigators have looked for alternative techniques such as periodontal intraligamentary injection anesthesia (PDL). Compared to IANB, PDL is considered as a sufficient alternative method for single tooth anesthesia [20] providing a less painful method of injection without the risk for nerve damage [20] with a circumscribed effect on the adjacent soft tissue only [21]. PDL is commonly performed with specialized high-pressure syringe systems [22, 23] or computer-controlled local anesthesia devices [4, 24] with special 30-gauge short needles. Advantages are single tooth anesthesia, minimal anesthetic dosage, rapid onset, and safety in patients with bleeding problems as well as in medically compromised patients [22, 25]. Further, commensurability of anesthesia and selected treatment should be assessed since a shorter and controllable duration of ILA would be inadequate for extended dental and alveolar surgery of the mandible. However, damages to the periodontal tissue and root resorption [26] as well as severe bacteremia up to 100% [27] are reported. Hence, an alternative technique which is simple in its application in combination with modern instruments and anesthetic agents would be beneficial. In adults, local infiltration anesthesia (INF) has shown to be successful for surgical and restorative treatments in the maxillary as well as the frontal mandibular region, though INF has not been used commonly in the mandibular posterior region due to the dense bony architecture at this site [28]. However, recent studies showed that when using 4% articaine with epinephrine 1:200,000, successful anesthesia could be achieved even in the posterior mandible region. Corbett et al. reported no statistical difference between INF (1.8 mL of 4% articaine with 1:100,000 epinephrine) and IANB (2.0 mL of 2% lidocaine with 1:80.000 epinephrine) when performing electronic pulp testing of mandibular first molars without dental treatment [29]. Another recent study using INF with a high dose of 1.8–3.6 mL of 4% articaine in the posterior mandible found its anesthetic success to be mainly dependent on the mandibular cortical bone thickness and described onset durations of up to 5 min [30]. In the literature, INF success rates in the posterior mandible ranged from 54 to 94% [29, 31].

It is beneficial that local infiltration provides a shorter duration of anesthesia as well as decreases the patients' discomfort of a painful injection when compared to IANB. Even though the incidence of adverse effects using local infiltration anesthesia is lower, numbness of the lip and tongue cannot be entirely avoided with buccal and lingual infiltration. A novel pressure syringe system (Biofeedject<sup>®</sup>; P-INF) has been

developed with the aim of providing successful anesthesia, while avoiding lip and tongue numbness. Therefore, P-INF uses a pressure-guided injection technique to administer the anesthetic solution.

The aim of this study was to evaluate the anesthetic efficiency of infiltration anesthesia using Biofeedject<sup>®</sup> (P-INF), as compared to the routinely used direct IANB regarding success of anesthesia on patients undergoing tooth extraction in posterior regions of the mandible.

#### Materials and methods

#### **Patients**

In this prospective, randomized study, 101 patients received either inferior alveolar nerve block (IANB) or a special form of infiltration anesthesia (P-INF) for tooth extractions (simple or surgical) of mandibular premolars or molars. The study was conducted after the approval of the local ethics committee of Rhineland Palate [No. 837.192.13 (8877-F)] and in accordance with the Declaration of Helsinki. Inclusion criteria were at least 18 years of age (or younger with approval of parental authority) with clinical indication for tooth extraction in the posterior mandible (premolars and molars) under dental local anesthesia (4% articaine with 1:200,000 epinephrine). Exclusion criteria were contraindications for components of the anesthetic solution (articaine, epinephrine, sulfite), physical and mental retardation, inability to open the mouth for injection of the local anesthetic, chronic or occasional abuse of psychotropic drugs, lacking compliance, patients with American Society of Anesthesiologists (ASA) classification level > 2, as well as infection in and around the area of injection. An oral questioning and a written health history were used to ensure the subjects were in good health and that they were not taking any medication which could possibly affect pain sensation. Prior to dental treatment, all patients signed an informed consent. The study was performed in a private dental practice specializing in oral surgery in cooperation with the Department of Oral and Maxillofacial Surgery, at the University Medical Center of Johannes Gutenberg University, Mainz, Germany. All treatments were conducted by one single experienced surgeon (FS). Each participant in this study received dental treatment of one tooth only.

## Equipment and performed technique

For local anesthesia, a solution of 4% articaine with epinephrine 1:200,000 (Ultracain DS®; Sanofi-Aventis GmbH, Berlin Germany) was used. Local anesthesia was either administered as P-INF ( $4 \times 0.3-0.5$  mL) with a pressure syringe (Biofeedject®; SMJM Inject GmbH; Aachen, Germany) or with a conventional syringe (IANB;  $1 \times 1.2$  mL) in a direct



technique as described before [9]. The Biofeedject<sup>®</sup> system consists of a syringe and a standardized 1.8 mL single-use glass cartridge, containing the anesthetic solution. For injection, a 25-gauge short needle (Septoject®, Septodont GmbH, Germany) was used. To initiate the Biofeedject<sup>®</sup>'s injection process, a dosage button needed to be activated, which in turn moves a dispensing piston toward the anesthetic solution in the glass cartridge (Fig. 1). The duration and intensity of the applied pressure determine the flow rate and velocity of the anesthetic solution. For precise pressure control, multiple feedback mechanisms, such as three different rings colored in red, green, and blue are integrated to display the current changes in infusion velocity. Submucosal injections (n = 4/ 0.3 to 0.5 mL) were performed directly around the treatment area at the mesial and distal (lingual and vestibular) sites, respectively, as advocated by the manufacturer. Each injection was set in the labial and lingual regions at an angle of 45° to the tooth's axis without bone contact.

#### **Treatment protocol**

Patients were randomly assigned to either P-INF or IANB by a computerized random generator. Preoperative radiographs were obtained. The treatment procedure and the use of the pain scale (numeric rating scale (NRS) 0–10), in which the respondents had to select a whole number from a horizontal bar (0–10; 0 = no pain, 10 = extreme pain) that best reflected the intensity of their pain level, were explained to the patients.

- Prior to treatment, a questionnaire (Suppl.) was given to all patients. The participants had to document their personal data first, and afterwards they were instructed to mark their current pain level.
- IANB was conventionally performed [3], whereas P-INF was administered by Biofeedject<sup>®</sup>.
- 3. Patients were asked to quantify the pain of injection (NRS).
- 4. The onset of anesthetic action (min) was timed with a stopwatch. Prior the treatment, numbness was tested with a probe on the soft tissue around the tooth each 30 s after injection whereas treatment did not start before subjective symptoms of numbness were reported by the patient.
- Patients subjectively rated (NRS) local anesthesia for its anesthetic efficacy, prior, during, and after the treatment. Anesthesia was fully sufficient when local numbness occurred.
- 6. Patients continuously noted their pain level before and during the treatment (NRS).
- 7. Local anesthesia was denoted successful when the procedure could be completed without pain. Pain during the procedure led to a second injection or if still not controllable, then to a change of the anesthetic method (IANB instead of P-INF) or even a termination of the treatment.

8. The following day, the patients were contacted via phone call and asked for the duration of anesthesia and adverse effects whereby the time period from the onset of complete numbness to its complete fading was measured.

Other parameters such as the amount of used anesthetic solutions as well as the frequency of required additional injections were also assessed.

#### **Statistics**

Prior to the statistical analyses, questionnaires were numbered and data were automatically randomized. Continuous variables were summarized as median, maximum, minimum, and mean with standard deviation (mean  $\pm$  SD) as well as categorical variables were summarized as frequencies and percentages. All analyses were carried out using the statistics software SPSS version 22.0 for Macintosh (SPSS, Chicago, IL, USA) whereby P values of  $\leq 0.05$  were termed significant for descriptive reasons only. Anesthetic efficacy was categorized into full/sufficient and non-sufficient. Normal distribution was tested using the Kolmogorov-Smirnov test as well as non-parametric Mann-Whitney U tests were performed for independent testing (IANB vs. P-INF). Pearson's chi-square statistic was used to test the mutual influence of two categorical variables. Graphics were created using the statistical software GraphPad PRISM® v. 6.0d (GraphPad Software, Inc., CA, USA).

#### Results

#### **Patients**

In total, 101 patients (male n = 43, female n = 58; mean age 33.3 years ( $\pm 15.9$ )) with 101 teeth were included in the study. Twenty-four simple and 77 surgical extractions were performed. Table 1 shows the exact distribution of treatment procedures.

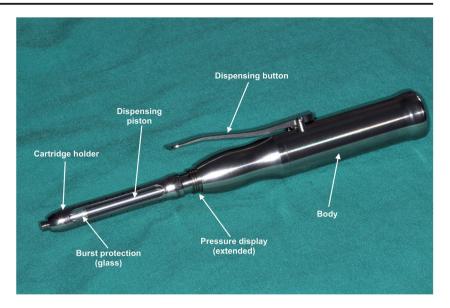
#### **Primary objectives**

Anesthetic success rate

Only when patients experienced no pain during the treatment was the anesthetic technique assessed to be successful. Figure 2 shows the anesthetic success rate, which was a 100% (53/53) in the case of IANB, whereas successful P-INF was only achieved in 35% (17/48).



Fig. 1 Pressure syringe (Biofeedject®) (SMJM Inject GmbH, Aachen, Germany). Components marked by white



Anesthetic efficacy and subjective experience of pain

All patients rated the respective anesthetic technique for its efficacy when full local numbness subjectively occurred after the injection using a NRS (Fig. 3). For P-INF, 27/48 patients (56%) rated the anesthetic efficacy as nonsufficient whereas only 11/53 patients (20%) did in the case of IANB. Based on the patients' ratings, it revealed that IANB was the favored technique as it provided full/sufficient anesthesia more often than P-INF (80 vs. 44%; P < 0.001).

Once adequate numbness was achieved, no significant differences in the patients' subjective rating of pain during the treatment or unpleasant treatment were revealed, whereas significantly more patients [53/101 (52%)] experienced greater pain of injection when getting treated with IANB (P=0.039; Fig. 4). For pain of injection, the mean NRS score of P-INF was 1.85  $\pm$  1.59 and for IANB a mean of 2.62  $\pm$  2.08 was evaluated.

**Table 1** The allocation of the removed teeth and all analyzed parameters

Tooth	Treated number (n)	Procedure		Method	
		Extraction (n)	Surgical extraction (n)	P-INF	IANB
35	3	3	0	1	2
36	7	6	1	3	4
37	2	1	1	0	2
38	36	1	35	17	19
45	2	2	0	1	1
46	6	5	1	3	3
47	4	3	1	3	1
48	41	3	38	20	21
Total	101	24	77	48	53

# Secondary objectives

Amount of used solution and number of second injections

Concerning the amount of used volume (mL) of the local anesthetic solution (Ultracain DS<sup>®</sup>) during the procedures, it turned out that significantly less volume was needed in cases of successful P-INF when compared with that of IANB (1.379 mL  $\pm$  0.15 vs. 1.747 mL  $\pm$  0.132; P < 0.001). Second injections were always performed with IANB and were significantly more often required when using P-INF (n = 33/48 vs. n = 22/53; P = 0.006). Hence, second injections were not included in the total amount of used anesthetic solution.

Duration of local numbness

A follow-up at the first day after surgery showed a mean duration of local numbness up to  $3.57 \pm 1.72$  h for P-INF



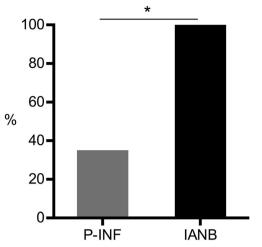


Fig. 2 Bar chart indicating the success rates (%) of block anesthesia of the inferior alveolar nerve (IANB) and local pressure infiltration anesthesia (P-INF) administered with Biofeedject<sup>®</sup> pressure syringe system. The asterisk indicates statistical significance

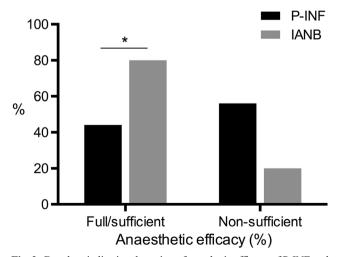
(Biofeedject<sup>®</sup>) and  $3.59 \pm 1.51$  h for IANB. Hence, no relevant difference could be observed.

## Onset of action

Regarding the duration until onset of anesthetic action (min), the findings at hand revealed that both methods performed equally (P-INF mean =  $8.65 \text{ min} \pm 3.84 \text{ vs.}$  IANB mean  $8.62 \text{ min} \pm 4.27$ , respectively).

## **Discussion**

A common clinical problem faced by different professional groups (dentists, oral surgeons, and maxillofacial surgeons) is the difficulty of achieving profound local anesthesia in patients undergoing dental treatments such as a simple or



**Fig. 3** Bar chart indicating the rating of anesthetic efficacy of P-INF and IANB. The asterisk indicates statistical significance

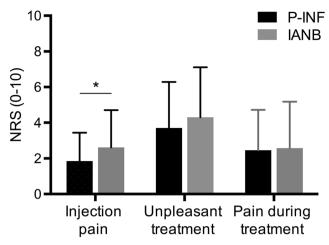


Fig. 4 Pain during treatment, unpleasant treatment, and injection pain rated with a numeric rating scale (NRS) for inferior alveolar nerve block anesthesia (IANB) and local infiltration anesthesia with a pressure syringe system [Biofeedject® (P-INF)]. The asterisk indicates statistical significance

surgical tooth extraction in the posterior region of the mandible [32–34]. It is well known that the patients' satisfaction as well as their anticipation of pain may compromise the dental treatment [1, 4, 34]; hence, adequate anesthesia is essential to develop a more positive attitude of the patient toward dental procedures. The main difficulty in the posterior mandible is related to the thickness of the cortical bone [30, 35]. In this context, IANB is considered as the standard anesthetic technique [6] regardless of its higher risk for complications. PDL seems to be a viable alternative to IANB in cases of circumscribed treatments without involvement of the surrounding soft tissue. Nevertheless, PDL has some inherent disadvantages such as bacteremia and the technique itself needing considerable experience. Therefore, the aim of this study was to compare IANB with a special infiltration technique (P-INF) for extraction of teeth in the posterior mandibular with regard to the patients' individual pain perceptions.

Although IANB is described as the standard method for local anesthesia, it is associated with complications including vessel and nerve damages as well as a significant failure rate [30, 36]. This outcome is typically attributed to its susceptibility to anatomical variations in the mandibular foramen beside the fact that the numbers of accessory innervations have to be anesthetized [37, 38]. Hence, practitioners and scientists have been searching for safer alternatives for IANB over the past few years. In this context, infiltration anesthesia (INF) was often described to meet the requirements of easier and safer administration together with equal qualities of anesthetic effects [31, 37, 39]. The successful use of primary infiltration anesthesia for treatments in the mandibular deciduous and permanent dentition was reported in several studies [28, 37, 40]. The study of Corbett et al. showed significant benefits in adding buccal and lingual infiltration extra to the inferior



alveolar nerve block [29], whereas that of Foster et al. did not [6].

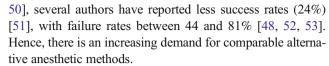
However, to our knowledge, no clinical trial compared the anesthetic efficiency of this particular type of pressure-controlled INF administration with that of the IANB. According to the manufacturers' home page, the used pressure syringe system provides adequate local anesthesia for simple tooth extraction, surgical tooth extraction, implantation, and other procedures in the posterior mandible. Its application is claimed to reduce the required volume of anesthetic solution and perform faster onset of action relating to a faster treatment. In accordance with others, the present study showed that significant less volume of anesthetic solution was required when performing P-INF compared to IANB (P < 0.001) [37].

In contrast to other studies [37] addressing the patients' subjective pain perceptions, the present study demonstrated that applying P-INF was significant less painful than IANB (P = 0.039; Fig. 4). Regarding unpleasant as well as painful treatment, the results at hand indicated that both techniques were equal (Fig. 4). Concerning the onset of anesthetic action, P-INF and IANB seemed to act similar which is not surprising since the probing technique only tests for surface sensitivity. For complete pulpal anesthesia, a time-delayed onset can be expected for P-INF since the anesthetic agent has to diffuse to its neural target whereas a faster onset, most likely caused by the anesthetic agent placed near its neural target structure at the mandibular foramen, in the case of IANB was demonstrated [37, 41]. Moreover, high inter- and intra-individual differences of response to articaine in the time of onset have been documented [42].

In order to ensure comparable conditions, a solution of 4% articaine and epinephrine (1:200,000) was used in both techniques. Articaine is frequently used and its allergic and toxic potential is low [42, 43]. In comparison to other local anesthetic agents, articaine excels at its ability to penetrate bone more easily due to its chemical structure [17, 44]. It is also possible for the anesthetic agent to diffuse through the accessory foramina of the mandible, into the medullary bone [19, 45–47].

Evaluating the anesthetic efficacy (full/sufficient) as the primary objective, the study at hand revealed that 80% of the patients treated by IANB rated the method to be fully sufficient, in contrast to only 44% of patients treated by P-INF (Biofeedject®) (Fig. 3) which is in accordance to a study performing INF with a conventional syringe [48]. The greater need for second injections in the case of P-INF is consistent with the patients' rating of the anesthetic efficacy. Regarding complete pulpal anesthesia, the idea of an advanced anesthetic effect by respective mesial and distal administration each into the lingual and vestibular sites of the adjacent gingiva only (Biofeedject®) is questionable.

Although Yang et al. found IANB to be successful in up to 96% of treatments in the molar region of the mandible [49,



In the study at hand, P-INF (Biofeedject<sup>®</sup>) was significantly less successful in patients undergoing tooth extraction in the posterior mandible when compared to the IANB anesthesia. This would be in accordance with the national survey of Devine M. et al. since it was shown that the majority of the respondents (oral surgeons) uses block anesthesia for tooth extraction in the mandibular molar region [54]. This is in contrast with other studies in which INF and IANB were found to be equal concerning anesthetic efficacy in cases of tooth extraction in the mandibular molar region using 4% articaine with 1:100,000 epinephrine [17, 37].

The literature clearly indicates that INF can provide profound anesthesia in cases of dental treatment in the posterior mandible when administered properly and in addition with the use of 4% articaine and 1:100,000 epinephrine [17, 55–57]. This would be in accordance with the present results revealing no significant difference between the two techniques in the perception of pain during the treatment, once complete pulpal numbness has occurred. Similar results were described by Bataineh et al. in a recent study [58].

There are some limitations to this study. One of the drawbacks using P-INF as the main anesthetic technique in comparison to IANB anesthesia is the fact that lip numbness cannot serve as a reliable sign of infiltration anesthesia technique's success due to the anatomical situation. Prior to the treatment, local numbness was tested with a probe on the tooth itself and the surrounding soft tissue only. The use of an electric pulp tester would have provided more objective findings. Thus, a longer latency time between administration and therapy start in addition to the use of a higher concentrated anesthetic solution (1:100,000) could potentially increase the success rate of P-INF since the anesthetic agent would have had more time penetrating the bone to its neural target. This would underline the CBCT-based findings of Flanagan who determined a cortical bone wall thickness of 2-3 mm as threshold to achieve sufficient anesthesia in the posterior mandible region [30]. Higher success rates of P-INF also could potentially be achieved by using larger volumes of anesthetic solution. In this context, El-Kohley et al. found INF to achieve profound anesthesia in up to 93% of cases by using 3.6 mL of 4% articaine solution (1:100,000) for extraction of the mandibular molars [31].

# Conclusion

Taken together, even if Biofeedject<sup>®</sup> represents an innovative technique of local infiltration anesthesia, the results at hand clearly suggest that the IANB should be favored over P-INF as



the suitable anesthetic technique to achieve profound local anesthesia in simple or surgical tooth extraction in the mandibular molar region.

**Author Contributions** All the authors of this manuscript had substantial contribution to the conception and design or acquisition, analysis, and interpretation of data; all revised it critically for important intellectual content and did the final approval of the version to be published. All authors read and approved the final manuscript. D.G.E. Thiem (daniel.thiem@med.uni-rostock.de) takes responsibility for the integrity of the work as a whole, from inception to finished article.

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#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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