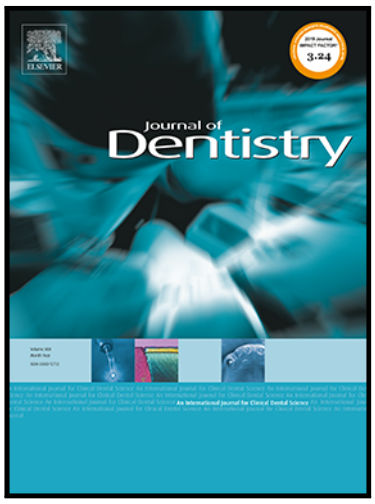

Jet injection needle-free dental anaesthesia: Initial findings

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PII: S0300-5712(22)00221-4
DOI: https://doi.org/10.1016/j.jdent.2022.104165
Reference: JJOD 104165

To appear in: *Journal of Dentistry*

Received date: 13 March 2022
Revised date: 10 May 2022
Accepted date: 13 May 2022

Please cite this article as: Paul A. Brunton , Mitten McLean , Senthilkumar Vedagiri , James McKeage , Bryan Ruddy , Kate Weatherly , David White , Andrew Taberner , Carolina Loch , Jet injection needle-free dental anaesthesia: Initial findings, *Journal of Dentistry* (2022), doi: https://doi.org/10.1016/j.jdent.2022.104165

Jet injection needle-free dental anaesthesia: Initial findings

Short title: Needle-free dental anaesthesia

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Acknowledgements

Thanks are extended to research participants for their time and interest in the study. Dental assistants Jean Legros and Diane Gavegan are thanked for their help during clinical procedures.

Funding

This work was supported by the MedTech Centre of Research Excellence (Project number 3715995).

Conflict of Interest Statement

AJT is a co-founder and minority shareholder in jet-injection company Portal Instruments Inc (https://www.portalinstruments.com).

Abstract

OBJECTIVES: We evaluated patient preference and reported levels of anxiety and discomfort of participants treated with a new needle-free electric motor-driven device vs. conventional local anaesthetic for dental extractions in a proof-of-principle study. Healing and response of gingival tissues to injection were also evaluated at 1, 3- and 7-days post-procedure.

METHODS: After informed consent, eight participants who required bilateral maxillary extractions were included in the trial. The side and order of placement for the needle-free and conventional anaesthetic were randomized. The same operator delivered anaesthesia and ensured teeth were anaesthetized on both sides. Another operator, unaware of order and type of anaesthesia placed, performed the extractions.

RESULTS: Participant's average discomfort scores were low for both techniques, and lower for the needle-free injection at all timepoints. Needle-free local anaesthesia was the preferred technique by most participants at most timepoints. The average volume

of anaesthetic dispensed was similar between techniques. Successful anaesthesia with the needle-free device was achieved in 6 out of 8 participants. Healing of the extraction sockets and adjacent oral mucosa progressed normally for all participants, with no evidence of infection, trauma or hematoma in the injection sites of the test and conventional sides.

CONCLUSIONS: The needle-free local anaesthetic technique investigated achieved sufficient anaesthesia for tooth extractions in the maxilla in 75% of the subjects. A larger clinical trial is needed to further validate the technique tested and to investigate whether needle-free local anaesthesia can be successfully applied to the provision of restorative therapy.

Clinical Significance: The results of this study can be used by clinicians treating patients who suffer from dental anxiety and needle-phobia.

Keywords: Local Anesthesia; Tooth extraction; Patient preference; Needles.

Introduction

Dental anxiety or fear of dental procedures is a significant barrier to accessing regular dental care, affecting about 9% of the global population [1, 2]. Dental anxiety and needle-phobia have contributed to more patients avoiding dental treatment and missing regular check-ups, generating poor oral health outcomes and associated negative impacts on general health. Dental anxiety often arises from negative past experiences with dental treatment, with local anesthetic delivery by injection playing an important role in generating anxiety [1, 3, 4]. This is relevant because delivery of local anesthetic can make dental treatment painless and comfortable for patients; it is, however, the greatest cause of dental-related anxiety for those who have a needle phobia. Patients often fear more the sight of a needle during local anesthetic delivery than the treatment itself [5].

Needle-free jet injection delivers local anaesthetic as a high-speed stream about the diameter of human hair, and it is considered a promising way to possibly

overcome needle-phobia and dental anxiety. The high-speed stream is formed by pressurizing the fluid which is typically done by releasing a compressed spring. Jet injectors have been adapted for dental use since the ‘70s, with systems such as Syrijet (Keystone Industries, USA) and Panjet (Wright Health Group Ltd, UK) promoting successful anaesthesia of the target tissue and improved patient comfort [6, 7].

More recent jet injection systems such as Madajet (Mada Medical Products, USA) [8], Injex (INJEX Pharma AG, Germany) [9], and Comfort-in (Mika Medical Co, South Korea) [4, 10] have been used in dentistry for local anaesthetic delivery. Despite differences in methodology, jet injection systems used, type of anaesthetic, target teeth and dental procedures performed, these previous studies have demonstrated a wide range of responses in terms of device efficacy and patience acceptance and preference. These spring-driven jet injection systems have also been deemed noisy and cumbersome by patients and clinicians. A recent study using a spring powered jet injector found that 57% of participants were troubled by the noise produced by the device [5].

Recently, alternatives to spring driven jet injection systems have been explored for dental anaesthetic procedures, including jet injectors driven by compressed air [11, 12] and controllable electric motors [13]. The motor driven systems have the advantages of being quiet, gentle and electronically-controllable, which can allow the delivery of liquid doses to a range of depths in the tissue [14-16]. Recent developments for dental use also involved using an extended wand to facilitate device placement in the mouth [13]. This motor driven injector allowed the operator to manipulate the jet speed between or during injections, in order to target different tissues with varied properties [13].

A previous ex vivo study using two Thiel-embalmed human cadaver heads showed the successful delivery of dental anaesthetic to the desired locations with the

motor driven jet injector [13]. In this previous study, anaesthetic delivery was visualised through CBCT imaging. This trial also showed negligible pressure loss along the extended wand. Given the successful delivery in ex vivo human tissue, it was important to conduct a pilot clinical trial to validate the new injection system for dental local anaesthesia in the clinical setting. This study aims to evaluate patient preference, reported levels of anxiety and discomfort, and to assess the response of gingival tissues of participants treated with the needle-free device and a conventional dental local anaesthetic for dental extractions.

Materials and Methods

The injector being tested in this pilot clinical study is shown in Fig. 1 and is described in detail in McKeage et al (2021) [13]. This injector was driven by an electric motor that actuated a piston within a 0.3 mL stainless steel ampoule (3.57 mm diameter, 30 mm stroke length). A slender tube was attached to the front of the ampoule to allow the device to reach into the mouth. A 200 µm diameter orifice (O'Keefe Controls Co.) at the distal end of this tube was the outlet through which the fluid jet was formed.

FIGURE 1

This study received ethical approval from Northern A Health and Disability Ethics Committee, approval number 20/NTA/186. The study is registered on the Australian and New Zealand Clinical Trials Database (Reference number ACTRN12621000490875). In addition, Māori consultation was undertaken under the XXXXXXX Research consultation committee.

Participants, who met the following inclusion criteria:

1. older than 18 years of age;
2. required bilateral extractions in the maxilla;

3. with no major co-occurring health conditions that may affected a participant ability to participate in the study;
4. no known history of dental anxiety;

were recruited from the XXXXXX at the XXXXXXX, New Zealand.

Potential participants were approached and given details of the study, including a participant's information sheet. At a subsequent appointment, eight participants agreed to participate in the study and written informed consent was obtained.

Topical anaesthesia (Zap topical anesthetic gel, Germiphene, Canada; Benzocaine USP 18% w/w and Tetracaine Hydrochloride USP 2% w/w) was applied to the buccal mucosa adjacent to the teeth to be extracted. The test intervention, which was local anaesthesia delivered by the needle-free injection device, and the control intervention, which was conventional local anaesthesia delivered with syringe and needle, were randomly allocated to the right or left side of the maxilla along with which anaesthetic procedure was performed first. Randomisation was ensured through sealed envelopes chosen at random by the participant, and all participants received both the control and test interventions. Random allocation ensured equal representation of which side was anaesthetised first and by what technique. The local anesthetic Articaine HCl (Articaine hydrochloride 4% 88 mg with adrenaline 1:100,000 22 micrograms) was given by the same operator from the same batch number (B25911AA EXP 2021 07) for the entire study.

An accepted standard test was used to ensure the teeth were anaesthetised prior to extraction. This involved probing the periodontium, at pressure, using a Williams probe. Additional local anaesthetic was given if needed as per the random allocation. If local anaesthesia was still not obtained after the second dose further local anaesthetic was delivered using the control technique only. Another dentist, who was part of the research team and unaware of which anaesthetic technique had been used,

performed the extractions as per the treatment plan. Standard post-operative instructions were given to participants.

The volume of anaesthetic delivered to achieve anaesthesia via the two methods were measured. After the local anaesthesia had been provided, the participants' levels of anxiety were measured using the Corah Dental Anxiety Scale (DAS) [17] and Index of Dental Anxiety and Fear (IDAF-4C) [18]. High dental anxiety was defined as a score of 13 or more in DAS and 3 or more in IDAF-4C (following [19]). The response of the gingival tissues to both anaesthetic delivery modes (i.e., whether the healing was progressing normally) was evaluated through analyses of clinical photographs at 1-, 3- and 7-days post-procedure. In addition, the participants' level of discomfort was assessed using a numerical scale (1- no discomfort at all – 10- extreme discomfort) at 1-, 3- and 7-days post-procedure.

Results

Demographic characteristics of study participants

Eight participants who needed bilateral extractions as part of their treatment plan took part in this pilot clinical trial. Five male and three female participants, aged 33 to 59 years (average age 46.4 years) met the eligibility criteria and were invited to participate. Most participants were of NZ European descent (63%), followed by Māori (25%) and Asian (12.5%).

Evaluation of dental anxiety

Participants' average DAS score was 10 (range 5-20). Five out of 8 participants had a score of less than 13, thus being classified as not being dentally anxious. One participant was classified as having high dental anxiety (score of 20). Participants IDAF-4C scores averaged 1.24 (range 0.63-2.19) and scores below 3 indicated low dental anxiety.

Patient's discomfort and preferred technique

Average discomfort scores were low for both techniques (needle-free 1.38 – 2.13; conventional 1.75 - 2.38), and lower for the needle-free injection at all timepoints (Fig. 2). Discomfort scores were higher at baseline, decreased at 1-day post-procedure for both techniques, and remained the same (needle-free) or decreased at 3- and 7-days (conventional).

FIGURE 2

The test needle-free local anaesthesia technique was the preferred technique by most participants at all timepoints, except at 7-days post extraction procedure (Fig. 3). A similar number of participants preferred the conventional technique or neither. One participant preferred either technique at all time points.

FIGURE 3

Participants reported on which parts of the procedure they considered uncomfortable. One participant mentioned the noise produced by the needle-free device as uncomfortable at baseline and 1-day post-procedure. For one participant, the delivery of anaesthetic using a needle (conventional technique) was uncomfortable at all time points. Additional uncomfortable aspects reported included the topping up of anaesthetic needle for a few patients, and the mirrors inside the mouth needed for clinical photography.

Volume of anaesthetic dispensed and Clinical performance

The average volume of anaesthetic dispensed was similar between the needle-free (1.41 mL; range 1.1-2.3 mL) and conventional techniques (1.44 mL; range 1-1.9 mL). Successful anaesthesia with the needle-free device was achieved for 6 out of the 8 participants. For two participants, extra anaesthetic had to be dispensed using the conventional technique due to an inability to achieve anaesthesia with the needle-free device despite two attempts with the technique. Following anaesthesia, teeth

were successfully extracted in both the test and conventional sides. Healing of the extraction sockets and adjacent oral mucosa progressed normally for all participants, as evident in clinical photographs (Fig. 4). There was no evidence of infection, trauma or hematoma in the injection sites of the test and conventional sides.

FIGURE 4

Discussion

Fear of dental treatment, and specifically the provision of local anaesthesia with a syringe and needle, are significant barriers for many in accessing dental care [3, 20]. Therefore, the possibility of providing effective needle-free anaesthesia could help reduce dental anxiety and possibly improve regular access to dental treatment for individuals who do not routinely access dental care due to fear of dental treatment [21]. This would be highly beneficial, as regular dental attendance allows for more preventive and minimal treatments, which can reduce an individual's burden of disease rather than sporadic attendance driven by pain where usually conditions will have progressed such that significant intervention is required, such as root canal therapy or dental extractions [22].

Whilst this trial was conducted with a small number of participants, the results are promising in that six out of eight patients had a successful pain-free extraction when local anaesthetic was delivered by the test device. In two cases, further local anaesthetic was required using a conventional technique. The reasons why successful anaesthesia wasn't achieved in these two cases are unclear and could be related to anatomical positioning of the teeth or infection at the extraction site. A larger study of more subjects would be needed to determine why the technique might not be successful for some individuals.

Previous studies on the efficacy of needle-free devices for the delivery of dental local anaesthesia, and patient's acceptance and preference, have shown mixed results. Theocharidou et al. (2021) [10] tested the efficacy, acceptance and patient's preference of conventional infiltration vs the Comfort-In needle-free jet anaesthetic device. They performed pulp vitality and soft tissue pain reaction tests on premolars, without subsequent dental procedures. Although both techniques showed similar effectiveness, conventional infiltration was preferred by most participants. A study testing children's acceptance and preference for INJEX needle jet injection compared with classical local infiltration reported more negative experiences for the needle-free method, and most children preferred traditional local infiltration [9]. In another study, one hundred children between the ages of 3 to 13 underwent operative procedures using Madajet XL. There was a statistically significant difference in patience preference in favor of the instrument, which was successful in providing anesthesia [8]. In a study on the effectiveness of the INJEX needle-free injection for infiltrative anesthesia for tooth extraction with 28 adult patients, participants reported significantly higher pain or discomfort scores for the INJEX device, and researchers suggested this method was not effective for local infiltrative anesthesia for extractions [5]. Oliveira et al. (2019) [4] measured the degree of pain during anesthesia, latency time and duration of pulpal anesthesia for participants requiring class I restorations. They observed no statistical difference in the basal electrical stimulation threshold and degree of pain between conventional and needle-free anesthesia; however traditional infiltration anesthesia resulted in a longer anesthetic duration compared with needle-free jet injection.

In this study, the subjects were followed for seven days to gather further feedback on the levels of discomfort and preferred anaesthetic technique, but also to check on the healing of the sockets and bleeding/laceration of the injection site.

Healing was uneventful and bleeding/laceration were minimal or negligible, irrespective of the anaesthetic technique used. In a previous published clinical trial, Gao et al. (2021) [12] suggested perpendicular needle-free injection induced a high risk of bleeding and laceration compared to oblique angles, which was not observed here. Generally, the needle-free technique was preferred by participants in this study, with some making mention of the noise when the device is activated as an uncomfortable part of the procedure. In previous studies with other devices, the “pop” sound generated when the INJEX® device was pressed, and the inadequate anesthesia supply, deemed this device ineffective for local infiltrative anesthesia for tooth extractions [5]. The noise generated from the device tested here did not, however, detract from the generalized preference for the needle-free technique, which again is promising.

In this study, the amount of local anaesthetic delivered by each technique was similar; however, it became obvious during the trial that the wand/tip of the needle-free injector might need some modification to prevent leakage of local anaesthetic when the device is activated. It was also observed that the angle at which the wand/tip contacts the palatal mucosa is crucial to prevent leakage, coupled with a smaller increment of local anaesthesia being delivered by the device. Previous studies using high-speed videos showed that perpendicular needle-free jet injection induced significantly more ‘regurgitation’ of anaesthetic than oblique injection, which was also confirmed in a cadaveric study [12]. This suggests the angle of injection and adaptation of the wand/tip should be considered. Therefore, it is likely that the device tested here might achieve local anaesthesia with a lower dose of local anaesthetic. Further research is needed with a larger number of participants to further test the device in terms of dose delivery and possible new designs for the wand/tip.

In this trial, anaesthesia was delivered on both buccal and palatal sides. Palatal delivery was somewhat more difficult, as observed with leakage of anaesthetic and issues with the angle at which the wand/tip contacted the palatal mucosa. To overcome this, palatal injections were done in small 0.1 mL increments to avoid regurgitation of anaesthetic due to denser nature of the palatal mucosa and bone, while buccal injections used roughly the whole ampoule volume (0.3 mL). This suggests tissues in buccal and palatal areas would have different jet speed and volume requirements for successful delivery, and as such only a controllable technology such as the one tested here would have the ability to alter the injection characteristics for different target tissues.

The use of the device for restorative therapy and use in the mandible for extractions and restorative work are areas for future research. However, it can be assumed that if an extraction can be achieved with the test device, restorative therapy in the maxilla should not be problematic.

Conclusion

Within the limitations of the study, it can be concluded that the needle-free local anaesthetic technique investigated achieved sufficient anaesthesia for tooth extractions in the maxilla in 75% of the subjects. Further research such as a larger clinical trial is needed to further validate the technique tested and also to investigate whether needle-free local anaesthesia can be successfully applied to the provision of restorative therapy. This proof-of-principle pilot study described a technological innovation which could reduce or eliminate dental anxiety due to needle-phobia, a common barrier to care for a significant proportion of the general population which could improve their access to routine dentistry.

CRediT author statement

Brunton, PA – Conceptualization; Investigation; Writing - Review & Editing; Supervision; Funding acquisition.
McLean, M - Investigation; Methodology; Writing - Review & Editing; Resources.
Vendagiri, S - Investigation; Methodology; Writing - Review & Editing; Project administration; Resources.
McKeage, J - Conceptualization; Methodology; Investigation; Writing - Review & Editing; Funding acquisition.
Ruddy, B - Conceptualization; Methodology; Writing - Review & Editing; Funding acquisition.
Weatherly, K - Conceptualization; Methodology; Investigation; Writing - Review & Editing.
White, D - Conceptualization; Writing - Review & Editing; Funding acquisition.
Taberner, A - Conceptualization; Methodology; Writing - Review & Editing; Supervision; Funding acquisition.
Loch, C - Conceptualization; Investigation; Formal analysis; Writing - Original Draft; Supervision; Project administration; Funding acquisition.

Declaration of interests

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

AJT is a co-founder and minority shareholder in jet-injection company Portal Instruments Inc (https://www.portalinstruments.com).

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Legends

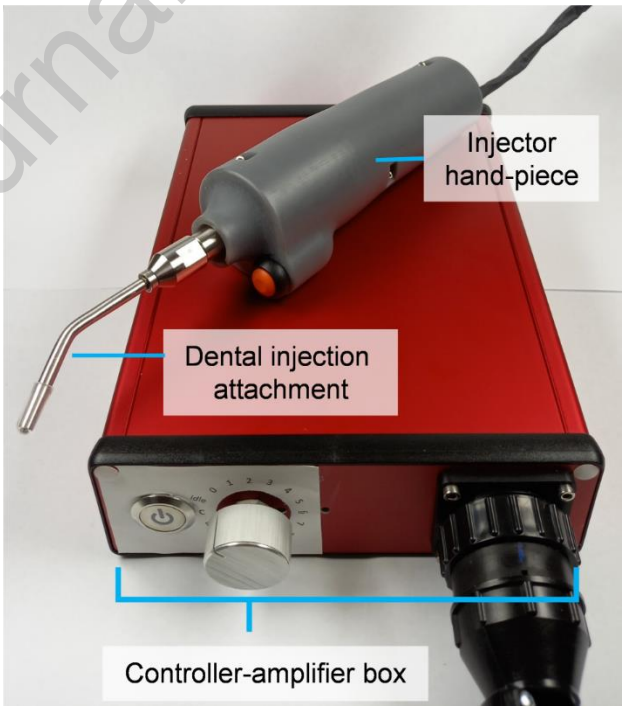

Figure 1 – Needle-free jet injector driven by an electric motor.

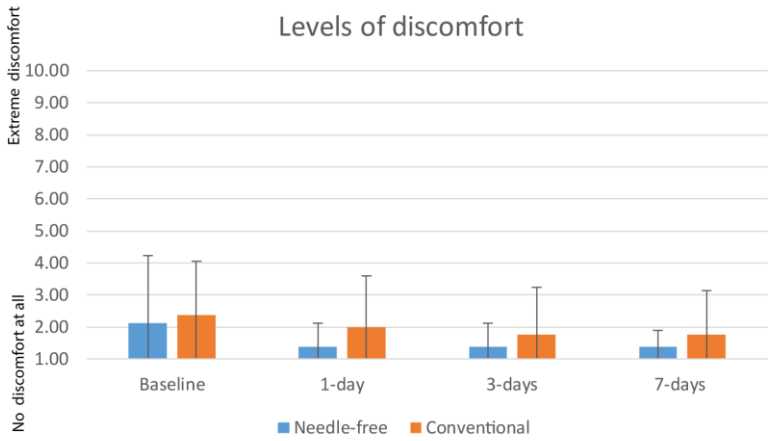

Figure 2- Average (± SD) self-reported levels of discomfort scores (1: no discomfort at all – 10: extreme discomfort) with needle-free and conventional anaesthetic techniques at baseline, 1-, 3- and 7-days post-extraction procedure.

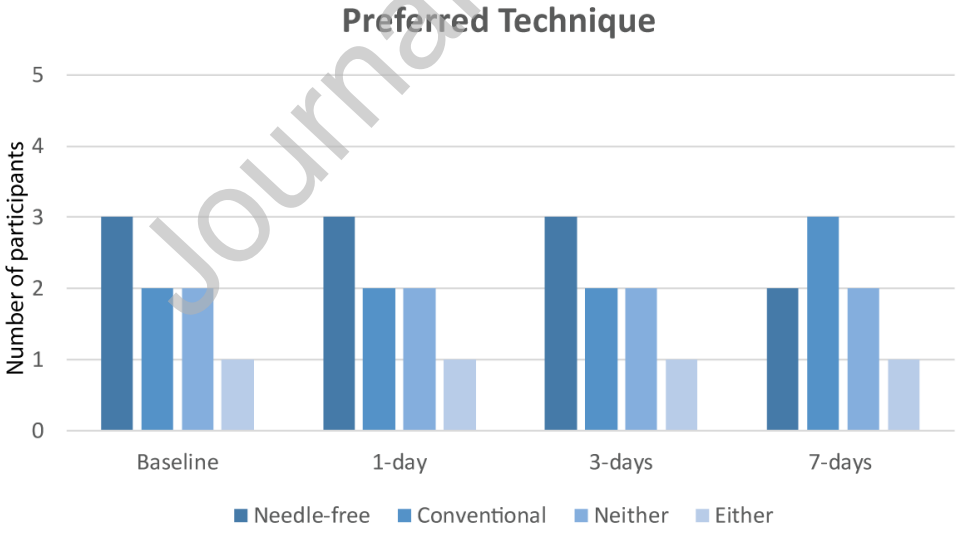

Figure 3 – Preferred anaesthetic technique by number of participants at baseline, 1-, 3- and 7-days post-extraction procedure.

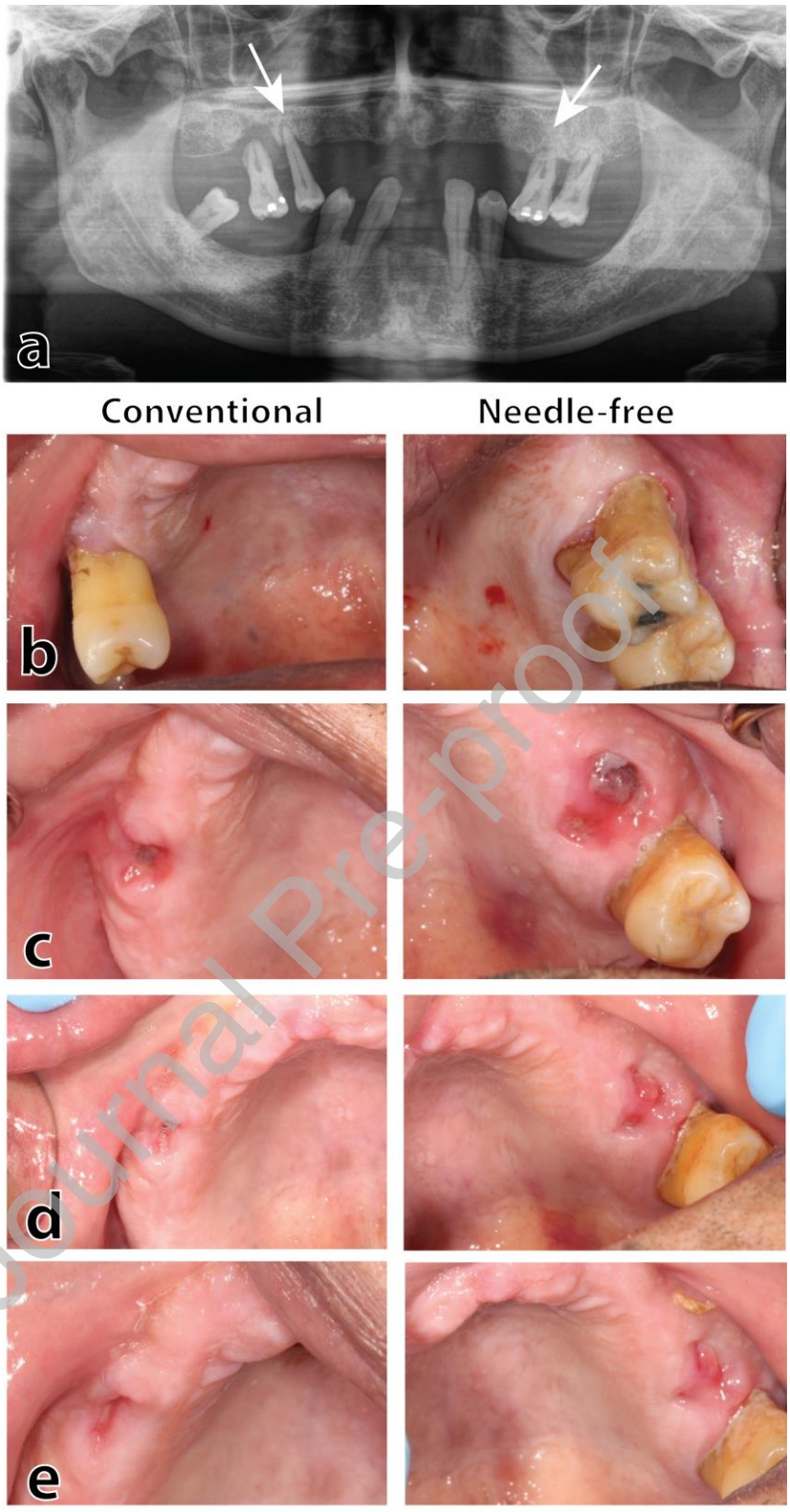

Figure 4 – a) OPG of participant showing teeth to be extracted. Conventional and needle-free sides at different timepoints: b) baseline. c) 1-day. d) 3-days. e) 7-days.