

# Clinical Evaluation of Efficiency, Acceptance & Preference Between Needleless Jet Injector Anesthesia (MADAJET XL) & Classical Needle Infiltration For Dental Procedures in Pediatric Patients

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## Abstract


**Objectives:** To evaluate and compare pain perception during administration of anaesthetic solution, effectiveness and preference between needle-less jet injector and conventional infiltration technique in children.

**Materials & Methods:** Sixty-five patients with mean age of 8.33 years (SD 1.58, range 6-12) were anaesthetized by needle-less jet injector and conventional needle infiltration technique in two separate appointments for invasive/noninvasive dental procedures. Pain during administration and during treatment was evaluated by Likert and Wong Baker Faces Pain Rating scale. Patients gave their preference between two anaesthetic techniques for next course of treatment in third visit. Effectiveness of each anaesthetic technique was assessed by evaluating presence and absence of pain while probing gingivae, during use of high and low speed handpiece, during extraction and pulp extirpation.

**Results:** Pain perception during administration of anaesthesia was significantly less by needle-less jet injector than conventional infiltration technique ( $P < 0.05$ ) and there was no significant difference in effectiveness during treatment procedures ( $p > 0.05$ ). Postoperative complications viz. bleeding and bad taste during administration of anaesthetic solution was higher for jet injector (60% and 33.84% respectively) than conventional infiltration (21.53% & 12.31%). A total 81.5% of subjects preferred jet injectors over conventional infiltration technique.

**Conclusion:** Needle-less jet injector was perceived to be significantly less painful and preferred means of anaesthetic drug administration over conventional needle infiltration. It provided adequate anaesthesia in maxillary and mandibular teeth during all the procedures, but it was less effective in mandibular molars for invasive procedures. Thus it is suggested that needle-less jet injector can be used as supplementary to conventional infiltration technique.

**Keywords:** Local anaesthesia, needle-less local anaesthesia, jet injector, local infiltration, Pediatric dental patients.

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## Introduction

Pain is one of the most commonly experienced and vaguely described emotions during dental treatment. A child experiencing pain exhibits higher resistance to treatment due to which behavior guidance becomes a major concern. This renders it important; to reduce the pain and discomfort to minimum at each dental visit. The most widely used method for pain control is to block pathway of pain impulses by depositing anaesthetic agent in proximity to nerve. Various methods and techniques have been developed over the years, to deposit anaesthetic solution in desired anatomical area; most common in practice is, needle connected to a syringe since several decades.

Various epidemiological studies have revealed that dental fear is prevalent at all age groups and genders worldwide.<sup>[1],[2]</sup> One of the

primary identified reasons is fear of injections, which most pediatric patients exhibit during treatment. Hence it is a challenge for the Pediatric dentist to deliver painless dental care and at the same time instill positive attitude in the child towards dentistry.

A step in this direction is application of techniques by which the anaesthetic solution is introduced into the tissue without use of needle. Recently the needle-less jet injectors have proved to be a valuable asset to the armamentarium of Pediatric dentists. It forces a high-velocity spray of anesthetic solution under high pressure into oral mucosa and infiltrates the tissue in tiny droplet form, which is immediately taken up by myelin sheath of the nerve.

John F. Roberts introduced the jet injection syringe in (1933).<sup>[3]</sup> It was popularized in clinical use in 1947, since then it has been used

in various medical procedures like for insulin delivery, regional and digital blocks, incision of abscess, vasectomy, cryosurgery aspiration biopsy of lymph nodes, repair of laceration, curettage and cyst excision.<sup>[4]</sup> In 1973, Santangelo, Mott and Stevenson reported that 83% leukemic patients preferred jet injectors over conventional needle for anesthesia during lumbar puncture and bone marrow aspiration.<sup>[5]</sup> Although Jet injector has attracted a number of dental practitioners since last five decades,<sup>[6]</sup> the current opinion advocates its use only for surface anesthesia, supplementary to the standard infiltration technique.<sup>[7]</sup> Therefore; the present study compares pain perception during administration of anaesthetic solution and effectiveness, using the needleless injector and conventional technique in children.

**Materials & Methods**

Subjects were selected from outpatient department of Pedodontics and Preventive dentistry. It was a prospective study with split mouth design in which 65 subjects aged between 6-12 years of both the genders were included after gaining approval from the Institutional Ethical Committee. A thorough medical history was obtained. The entire procedure with all the possible complications were explained to parents and a prior written informed parental consent was obtained before any procedure.

Healthy subjects having at least two primary teeth, one in each contra lateral side of mouth in same dental archreceptive to similar dental procedures. Children showing positive/definitely positive behavior according to Frankl's behavior rating scale were included in the study. Fearful subjects, negative and definitely negative, previous experience of dental injections, primary teeth with periapical pathology and permanent teeth were excluded from the study.

Extraction (grade-I, II mobility and root stumps), pulp therapy and restoration (class I, II) were performed during the course of study. Selection of arch side to receive an infiltration by jet injector or needle infiltration and visit was done randomly for each subject. Before commencement of any procedure, the device (Madajet XL)( Fig 1) was shown to the subject and the popping sound that is generated during use of the injector was

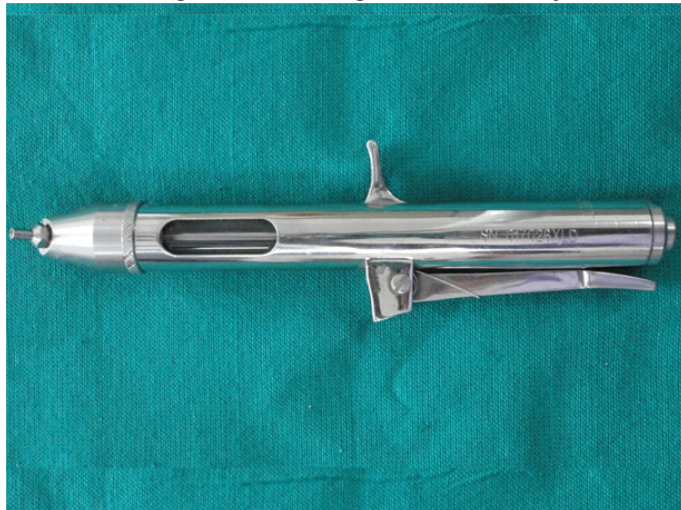


Figure 1: Needle-less Jet injector (Madajet XL)

demonstrated. Each injection of Madajet XL delivers a volume of anesthetic solution 1/10 of an ml. For buccal and lingual/ palatal infiltration total 0.4 ml of 2% lignocaine HCl, with 1:80,000 epinephrine was used as injectable anaesthetic solution by conventional needle ( 24 gauze) (0.3 ml solution on buccal and 0.1 ml on lingual/palatal side) and by needle-less injector (three simultaneous shots on buccal and two on lingual/palatal side) (Fig 2). Before administration of local anaesthesia, topical anaesthetic agent lidocaine 15% was applied over the mucosa.

All procedures and assessments were done by single operator. In both appointments pain perception during administration of anaesthesia and effectiveness in controlling pain was evaluated by two pain rating scales;

a) Wong Baker faces pain rating scale<sup>[8]</sup>: (unidirectional self-reported pain rating scale)



It comprises of 6 faces of different expressions, representing different levels of pain. The child was asked to choose the face that best describes his/ her own pain.

a) Likert scale<sup>[9]</sup>: (operator based scale of pain assessment) It is a unidimensional 5 point scale grounded on the intimate understanding of the subject matter. Assessment by clinician was based on facial expressions, physical response (bodily movement) and on the verbal complaints made by the subjects in reaction to both techniques used.

**Score Criteria**

- 1 Hurt worst
- 2 Hurt even more
- 3 Hurt little more
- 4 Hurt little
- 5 No hurt



Figure 2: A-Buccal infiltration by needle-less jet injector B-Palatal infiltration by needle-less jet injector C-Buccal infiltration by conventional technique D- Palatal infiltration by conventional technique

**Score 1 (Hurt worst)** - Was assigned, when the patient's response to effectiveness of anesthesia was negative, accompanied with extreme agitation, flaying of extremities, moving the head and crying.

**Score 2 (Hurt even more)** -Was assigned, when the patients showed orofacial muscle contractions expressing pain, and did not allow the treatment to be done. Some patients verbally conveyed pain by crying

**Score 3 (Hurt little more)**-Was assigned, when the patients got the treatment done although with constant whining.

**Score 4 (Hurt little)** - Was assigned when the patients shows occasional instances of slight discomfort.

**Score 5 (No hurt)** - Was assigned when the patients showing no indication of pain or discomfort.

Any complication (bleeding, bad taste) during administration of anaesthesia was also recorded. The subjects were asked to give their preference for anaesthetic techniques (needle-less jet injector/conventional method) on third appointment. The interval of time between appointments was dependent upon type of treatment but was not more than 3-4 days.

Data were analyzed using the SPSS 16.0 edition software. Paired t-test was performed to compare pain during administration of anaesthetic solution using needle-less jet injector/conventional needle infiltration and during treatment.

## Results

The sample consisted of 65 subjects including both genders, out of which 39 (60%) were males and 26 (40%) were females. Subjects were aged between 6-12 years (mean age 8.33±1.58). Extractions (41.5%) were performed in maximum subjects followed by restorations (36.9%), and pulpectomies in (21.5%) subjects.

(I) Distribution of subjects according to preference of anaesthetic technique 81.5% preferred needle-less jet injector over conventional infiltration technique of anaesthesia for next course of treatment.

### A. Age-wise preference

Preference for needle-less jet injector was highest among 8-9 years of age group, 85.7% subjects preferred needle-less jet injector over conventional infiltration technique. 80.9% preferred needle-less jet injector in 6-7 year age group and 75% preferred needle-less jet injector in ≥10 year age group. There were no statistically significant (p=0.62) association found between age and preference of anaesthetic technique. (Table-1)

### B. Gender-wise preference

82.1% of females preferred needle-less jet injector than males (81.1%), but statistically no significant (p=0.91) association was found between gender and preference for anaesthetic techniques. (Table-1)

Age in years	No. (n=65)	Male	Female
6-7	21, (32.3%)	17	4
8-9	28, (43.1%)	14	14
≥10	16, (24.6%)	6	10
Mean±SD (8.33±1.58)		37 (60%)	28 (40%)

**Table 1:** Age and gender-wise distribution of subjects

(II) Comparative evaluation of pain perception during administration of anaesthesia

A statistically significant (p=0.0001) difference was found in pain perception during administration of anesthesia between needle-less jet injector and conventional needle infiltration by both Likert scale and Wong Baker faces pain rating scale. Needle-less jet injector was significantly less painful than conventional needle infiltration. (Table-2)

Type of scale	Needle-less jet injector (Mean±SD)	Conventional infiltration technique (Mean±SD)	p-value <sup>1</sup>
Likert scale	4.22±0.69	2.48±0.94	0.0001*
Wong Baker scale	1.32±0.74	2.98±1.25	0.0001*

<sup>1</sup>Paired t-test, \*Significant

**Table 2:** Comparative evaluation of pain perception between needle-less jet injector & conventional infiltration technique during administration of anesthesia.

(III) Comparative evaluation of effectiveness of needle-less jet injector and conventional needle infiltration

Our assessment of pain (Likert scale) was higher in subjects anaesthetized by conventional infiltration technique than in needle-less jet injector but it was not statistically significant (p=0.60)

Patients' perception of pain in Wong Baker faces pain rating scale was higher in needle-less jet injector than conventional infiltration technique during treatment but it was not statistically significant (p=0.48) (Table-3).

Type of scale	Needle-less jet injector (Mean±SD)	Conventional infiltration technique (Mean±SD)	p-value <sup>1</sup>
Likert scale	4.22±0.99	4.17±0.90	0.60
Wong Baker scale	1.42±1.03	1.33±0.89	0.48

<sup>1</sup>Paired t-test

**Table 3 :** Comparative evaluation of effectiveness between needle-less jet injector & conventional infiltration technique during treatment.



(IV) Comparative evaluation of effectiveness of anaesthesia delivered by needle-less jet injector and conventional infiltration technique during various procedures of primary anterior and posterior teeth including both the arches:

**a. Extractions**

Bilateral extractions were performed in 27 (41.5%) subjects out of which 12 (44.4%) pairs of teeth were anterior and 15 (55.5%) were posterior including both arches. 25 (92.59%) pairs of teeth were successfully extracted but during extraction of 2 (7.41%) mandibular root stumps profound anaesthesia was not accomplished by needle-less jet injector.

Pain assessed by operator (Likert scale) and pain perceived by patient (Wong Baker Faces Pain Rating Scale) during extraction, was more in needle-less jet injector than conventional infiltration technique but the difference was not statistically significant. (Table-4)

**b. Restoration**

Restorations were successfully completed in all 24 (36.9%) subjects bilaterally, out of which 9 (37.5%) were done on anteriors and 15 (62.5%) on posteriors. Pain assessed by operator (Likert scale) during restoration was more for conventional infiltration technique, but the difference was not statistically significant (p=0.32). Pain perceived by patient (Wong Baker faces pain rating scale) during restoration was more in needle-less jet injector, but the difference was not statistically significant (p=0.46). (Table-4)

Treatment modality/ Type of scale	Needle-less jet injector (Mean±SD)	Conventional infiltration technique (Mean±SD)	p-value <sup>1</sup>	Failure rate
<b>Extraction</b>				2 (7.41%)
Likert scale	3.72±1.06	3.80±1.11	0.60	
Wong Baker scale	1.76±1.05	1.60±1.04	0.46	
<b>Restoration</b>				0
Likert scale	4.38±0.64	4.33±0.63	0.32	
Wong Baker scale	1.08±0.83	1.17±0.76	0.16	
<b>Pulp therapy</b>				3 (21.42%)
Likert scale	4.45±1.21	4.64±0.50	0.65	
Wong Baker scale	1.36±1.20	1.09±0.70	0.53	

<sup>1</sup> Paired t-test

**Table 4:** Comparative evaluation of effectiveness of anaesthesia delivered by needle-less jet injector & conventional infiltration technique during various procedures.

**c. Pulpectomies**

Pulpectomies were performed in 14 (21.5%) subjects bilaterally, out of which 3 (21.4%) were done on anterior teeth and 11 (78.5%) in posterior teeth including both arches. However profound anaesthesia was not achieved in 3 mandibular molars which were additionally anaesthetized by conventional

infiltration technique. Thus comparison of effectiveness for pulpectomy was presented for 11 subjects. There was no statistically significant difference in Likert scale (p=0.65) and Wong Baker faces pain rating scale (p=0.53) during pulp therapy between conventional infiltration technique and needle-less jet injector. (Table-4)

(V) Success rate of anaesthesia by needle-less jet injector and conventional infiltration technique

Conventional infiltration technique provided profound anaesthesia during all procedures in all subjects (success rate 100%). Whereas success rate of needle-less jet injector was found to be 92.30% as 5 subjects required additional anaesthesia by conventional infiltration technique to complete the procedure. (Table-5)

Type of anaesthetic method	Success rate	Failure rate
Needle-less jet injector	92.30%	7.69%
Conventional infiltration technique	100%	0%

**Table 5:** Comparative evaluation of success rates (Successful anesthesia) between needle-less jet injector and conventional method.

(VI) Complications of needle-less jet injector and conventional needle infiltration during administration of anaesthetic solution

Bleeding from oral mucosa with needle-less jet injector was found in 60% subjects and 21.53% with conventional infiltration anesthesia. Bad taste was reported by 33.84% subjects with needle-less jet injector and 12.31% by conventional infiltration technique. The incidence of bleeding and bad taste were associated more with needle-less jet injector but the difference in complications using both the techniques, was not statistically significant (p=0.18) (Table 6)

Type of Complications*	Needle-less jet injector (n=65)		Conventional (n=65)	
	No.	%	No.	%
Bleeding	39	60%	14	21.53%
Bad taste	22	33.84%	8	12.31%
Total	41	63.08%	18	27.69%

**Table 6:** Distribution of type of complications during administration of anaesthetic solution

## Discussion

Pain control is one of the most important aspects of paediatric dentistry; and local anesthesia remains backbone of pain control in dentistry. Children are often distressed by mere sight of needle than by ensuing dental treatment. Every pediatric dentist's ultimate goal is a happy child walking out of the operatory with a positive dental attitude even after an invasive procedure. Pain during administration of anaesthesia possibly owes to tissue damage caused by needle penetration and pressure of anaesthetic solution into the tissue.<sup>[9]</sup> It has been suggested that finer the needle and slower the delivery of anaesthetic solution, lesser is the pain caused.<sup>[10]</sup> A necessity to eliminate needle-phobia was intensely felt by researchers, and research aiming towards this goal commenced and rested in 1947, when Hingson et al<sup>[6]</sup> used needle-less delivery system, Since jet injector devices use a small volume of anaesthetic solution (0.1 ml) in each shot, it produces less tissue expansion (Aberge et al 1978),<sup>[11]</sup> and gradual reduction in pressure causes deposition of the solution in layers, with initial deposition occurring in deeper layer which is less painful followed by deposition in superficial layer (Margetis et al 1985)<sup>[12]</sup> and (Bennett et al 1971).<sup>[13]</sup>

The present study was aimed to assess the effectiveness of anaesthesia and pain during treatment by using both, subject and clinician based pain rating scales. The difference between pain perception by patient and operator was non-significant, suggesting similar efficacy for both techniques (Table-2).<sup>[14,7,12,13,14]</sup> Oulis et al (1996)<sup>[15]</sup> and yonchak et al (2001)<sup>[16]</sup> have explained that the anaesthetic solution diffuses through the cortical plates in both jaw bones and anesthetizes the pulpal nerves up to equal depth by both methods.

In the present study, infiltration by conventional technique provided adequate anaesthesia during all procedures (restorations, extractions and pulpectomies) with 100% success. However, needle-less jet injector failed to provide adequate anaesthesia in 5 subjects (7.69%), thus additional anaesthesia was administered through conventional needle infiltration technique to complete the procedure. All the failures were associated with mandibular molars during pulp tissue management and extractions, whereas restorations were successfully performed in all the subjects (Table-4).

Saravia et al (1991)<sup>[14]</sup> found success rate as high as 80%, while Munshi et al (2001)<sup>[1]</sup> and Makade et al (2014)<sup>[7]</sup> observed that total success rates for effectiveness of anesthesia using Madajet according to patient and clinician was 98% and 100% respectively. Conflicting results were reported by Arapostathis et al (2010),<sup>[17]</sup> they found that 70 of 87 (80.5%) cases required additional anaesthesia. Oulis et al (1996)<sup>[15]</sup> and Yonchak et al (2001)<sup>[16]</sup> explained that cortical plate of maxillary bone is more porous than mandible, thus diffusion of anaesthetic solution is questionable in mandibular posterior region. Meechan et al (2011)<sup>[18]</sup> stated that there are holes present in the body of the mandible like mental foramen and multiple minor perforations, which could permit diffusion of solution into cancellous space. These multiple minor perforations are present especially on

lingual aspect of mandibular anterior, this could possibly explain successful completion of all the procedures in anterior mandibular by needle less jet injector infiltration and higher percentage of failure in mandibular posterior region. Arapostathis et al (2010)<sup>[17]</sup> found higher percentage of failure in their study as it was based on adult mandible which is less porous due to mineralization of the bone with age.

In present study, bleeding from oral mucosa and bad taste due to leakage of anaesthetic solution into oral cavity was significantly higher with needle-less jet injector (60% and 33.84% respectively) than conventional needle infiltration (21.53% and 12.31% respectively). According to Makade et al (2014)<sup>[7]</sup> and Arapostathis et al (2010)<sup>[17]</sup>, significantly more bleeding from mucosa at the injection site was noted with jet injector (Madajet and Injex respectively) than conventional infiltration technique. However, Makade et al (2014)<sup>[7]</sup> reported no significant difference in bad taste with both the techniques. Our findings were in contrast to Dabrakis et al (2007)<sup>[3]</sup> they reported limited bleeding at the injection site in 14.6% of patients. Margetis et al (1958)<sup>[12]</sup> suggested that bleeding from mucosa immediately after anesthesia was due to extremely fast delivery of anaesthetic solution through jet injectors and leakage of anaesthetic solution due to improper positioning of head assembly accounted for bad taste. Hence in our study jet injector was firmly placed over mucosa during infiltration of anaesthetic solution although it was difficult to achieve because of scalloped bone adjacent to root apices, thus we were not able to eliminate this complication entirely.

The subjects were recalled to give their preferences for anaesthetic techniques (needle-less jet injector/conventional infiltration technique) on third appointment. 81.5% subjects preferred needle-less jet injector over conventional needle infiltration. This might be due to less threatening appearance of needle-less jet injector, significantly less pain was perceived by the subjects during anaesthetic administration as compared to conventional infiltration technique. Our findings were in agreement with Saravia et al (1991)<sup>[14]</sup> they found 75% patients' preferred for needle-less jet injector. Munshi et al (2001)<sup>[1]</sup> reported 93% patients' acceptance for pressure anesthesia.

The results (pain perception & effectiveness) of the present study were antagonistic to the study by Arapostathis et al (2010)<sup>[17]</sup>; they reported negative experiences with jet injector as 73% children preferred the conventional infiltration technique. Similarly, Dabarakis et al (2007)<sup>[3]</sup> in their study found that only 17.6% patients preferred jet injector; whereas 52.8% preferred classical injection technique. In both the studies, authors reported higher incidence of failure rate with needle-less jet injector (Injex) and pain during treatment was found to be higher with Injex. It is possible that some children might have bad experience with jet injectors, which might influence their responses to the needleless devices (Injex). The anaesthetic device used in their study was Injex, in which the anaesthetic delivering segment forms a 90° angle with the main body contrary to Madajet.<sup>[14,7]</sup> Madajet delivery segment forms a 45° angulation with gingiva

producing better and easy positioning with complete contact with gingiva creating less pressure during administration resulting in less leakage and less bad taste compared to other pressure anaesthetic.<sup>[7]</sup>

Based on the findings of present study, age and gender werenot significantly related to preference of anaesthetic technique. This was in accordance with Schmidt et al (1966)<sup>[19]</sup> and Arapostathis et al (2010),<sup>[17]</sup> they also observed no age difference in preferences. Saravia et al (1991)<sup>[14]</sup> and Arapostathis et al (2010)<sup>[17]</sup> also reported no gender differences for preference. In present study 18.4% of children preferred conventional needle infiltration over jet injector, which was higher in older age group children (preference was 25% in  $\geq 10$ -year age group). This might be due to anxiety on introduction of a new technique and the distressing popping sound that comes with activation of needleless injector. Majstorovic et al (2004)<sup>[20]</sup> also found that needle phobia progressively decreases with increasing age.

Needle-less jet injectors can be a valuable tool in managing needle phobic children in order to provide effective and efficient treatment and instill a positive dental attitude for future. The present study may help in establishing role of needle-less jet injector in managing fearful & anxious paediatric population. However, further investigations with larger sample size are recommended to assess effectiveness in mandibular molars.

### Conclusions

Needle-less jet injector was found to be less painful during administration of anaesthesia than conventional needle infiltration in our study. It effectively anaesthetized mandibular anteriors and maxillary teeth for all the procedures and was less effective for invasive procedures like pulpectomy and extractions for mandibular molars. Needle-less jet injectors can be a valuable tool in managing needle phobic children and instills a positive dental attitude for future.

The perpetuation of conventional techniques of LA administration needs to be reconsidered and modified to enhance the quality of care provided in the modern era of dentistry. The present study may help in establishing role of needle-less jet injector in managing fearful & anxious paediatric dental population.

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