Clinical evaluation of the efficacy of anesthesia and patient preference using the needle-less jet syringe in pediatric dental practice

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Most dentists are aware that local anesthetic injections produce the highest incidence of disruptive behavior in children. Both psychological and physiological monitoring of the response of children to dental injection, support empirical observations of clinicians. The needle-free injector delivers local anesthesia without the use of a needle. This is accomplished by delivering the anesthetic solution under high compressive forces. One hundred children between the ages of 3 to 13 years underwent operative procedures using Madajet XL. There was a statistically significant difference in favor of the instrument. The instrument was completely successful in providing anesthesia.
J Clin Pediatr Dent 25(2): 131-136, 2001

INTRODUCTION

One of the most distressing aspects of dentistry for the average dental patient is the fear and anxiety caused by the dental environment, particularly the dental injection, i.e syringe and needle, referred to as "Needle-Phobia" or "Blenophobia".[1-4] The procedure is considered unpleasant from physical, chemical and psychological standpoints.

Epidemiological studies have shown that much of the population does not visit the dentist on a regular basis, primarily because of the fear of the needles.[5, 6] Moreover, the application and induction of local anesthesia has always been a stressful task, both for the clinician and the patient which demand alternative methods that are convenient and effective.

The use of pressure syringes or jet injections as they were termed later, as a therapeutic modality in medicine and dentistry is not new.[7] Since its invention by Hingson and Hughes in 1947, it has been used for a variety of procedures in both the medical and the dental fields.

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Margetis and Quarantillo in 1958 reported the first dental study using the needle-less jet injector.[8] This created a tremendous interest among the dentists, thereby leading to a number of clinical and epidemiological studies on the human and animal subjects.[9-19] Of special interest was the delivery of local anesthetics using this needle-less device.

The needle-less injector, which works on the principle of pressure dynamics, provides an alternative technique for inducing local anesthesia, which is safe and generally well accepted by the patients.[20] It promises to be a viable mode of pain control during various procedures in clinical pedodontics as well.

The objective of the needle-less jet injection is to deliver local anesthesia without subjecting the patient to the unpleasant experience of having to face "the needle" thereby enabling him/her to develop a more positive approach towards the dental treatment by eliminating his/her greatest single fear.[2] As such the aims of the present study were:

1) To clinically evaluate the comfort on administration using the needle-less jet injector both for the clinician and the patient, and
2) To evaluate the effectiveness of anesthesia as delivered by the needle-less syringe both by the clinician and the patient during various clinical procedures.

PATIENT SELECTION

One hundred children between the ages of 3 to12 years were treated using the needle-less injector (Madajet XL), in order to evaluate the efficacy of the needle-less jet injector for various procedures in clinical pedodontics. All the participants in the investigation were the

children attending the pediatric dental clinics at the A. B. Shetty Memorial Institute of Dental Sciences, Derlakatte, Mangalore.

Healthy, cooperative children, receptive to dental treatment and requiring no special intervention such as restraint or conscious sedation were included in the study. Parental consent was obtained prior to the starting of the required procedures. Extractions of the primary teeth, pulp therapy and tooth preparation were performed during this study.

EQUIPMENT / DEVICE (Photograph 1):
Madajet XL needle free injector manufactured by Essenmed Company (Mumbai) was used in the study. It is a jet injection device that delivers the local anaesthetic solution using a mechanical pressure system.

This injector consists of:

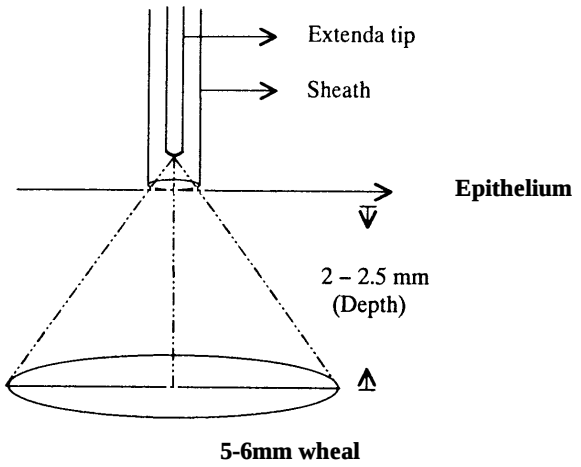
1) A head assembly with glass fill chambers holding up to 4 ml of local anaesthetic solution.
2) The body with cocking lever and discharge button.
3) Extenda-tip and sheath which can be changed between each patient and allows for pinpoint accuracy at the injection site.

The entire assembly is autoclavable.

Principle of working of the needle-less jet injector

Each injection of Madajet XL delivers a volume of anesthetic solution 1/10 of an ml at a depth of 2 to 2.5 mm below the epithelium. At the base of each infiltration a wheal, approximately 6 mm, is formed so that each injection into the tissue forms an inverted cone (Diagram).

The high pressure exerted by the Madajet XL causes the anesthetic solution to infiltrate the tissue in tiny droplet form, which is immediately taken up by the myelin sheath of the nerve. The onset of anesthesia is approximately 1 millisecond.



Procedure

Before the commencement of each procedure, the device (Madajet XL) was shown to the child patient and the popping sound that is generated during the use of the injector was demonstrated. Only after the patient and the parent were satisfied was the treatment initiated. The local anesthetic was delivered as per the instructions of the manufacturer (Figures 2 and 3).

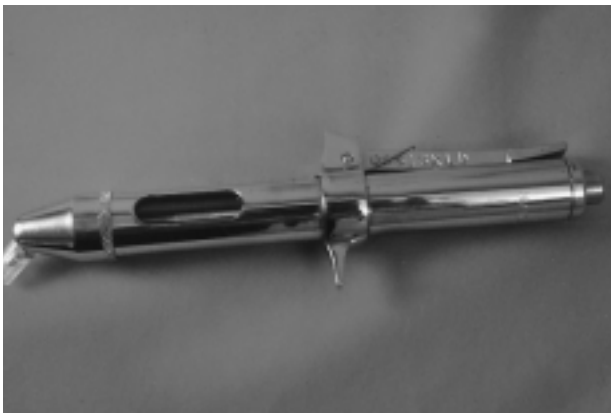


Figure 1. The needle-less jet syringe (Madajet XL) is seen.

Figure 2. The technique of using the Jet Syringe for the Maxilla is demonstrated.

Figure 3. The techinique of using the Jet Syringe for the Mandible is demonstrated.

The effectiveness of the Madajet XL in controlling pain was evaluated by the patient and the clinician individually.

Self-report measures of pain assessment by the patient were done using a Faces Pain Scale[22] and a Pain Thermometer.[23] This was done before, during and after the respective clinical procedure to assess the perception of pain by the child and acceptability of the device.

Comfort of administration of the local anesthetic and efficacy of the anesthesia with the Madajet XL were evaluated by the patient using the Lickerts 5 point continuous scale.[24]

The clinician assessed the reaction of the patient to the Madajet XL, subjectively by interpreting the body language of the child and facial expression and assigning him/her to one of the four groups (Scared, Wary, Interested, Excited) and objectively by recording the changes in the pulse rate manually.

The ease of administration of the local anesthesia using the Madajet XL and efficacy of anesthetic were evaluated using the Lickerts 5 point continuous scale.[24]

Side effects or any other complications occurring with the use of the jet injector were also noted.

Out of the children treated using Madajet XL, 26 required pulpal therapy (including pulpectomy / pulpotomy), 54 required extraction of the primary teeth and 9 required tooth preparation prior to restoration. Eleven required various miscellaneous treatments such as abscess drainage, suturing and rubber dam clamp placement.

The values and scores obtained thus based on the Lickerts scale were analyzed statistically. Ridit Analysis was used to determine any statistically significant differences between the response of the patient and the clinician for perception of comfort on administration and effectiveness of Madajet XL.

OBSERVATIONS AND RESULTS

Table I shows the number of the patients indicating individual scores, based on Faces Pain Scale.

Table II presents the frequency distribution of the evaluation scores along with their calculated mean scores for comfort on administration of Madajet XL. Significant differences were observed between the patients and the clinician's perception for comfort on administration for extraction and pulpal therapy. The clinician perceived it to be more comfortable than the patient.

Table III presents the frequency distribution of the evaluation scores along with the calculated mean scores for effectiveness of Madajet XL. No statistically significant difference was observed between the patient and the clinician's perception for effectiveness of anesthesia.

Table IV shows that number of the patients indicating individual scores based on the pain thermometer.

Table I. Individual patient scores based on Faces Pain Scale

Event/Procedure	Score 1	Score 2	Score 3	Score 4	Score 5	Score 6	Score 7
Extraction (n = 54)					2	38	14
Pulpal Therapy (n = 26)			3			18	5
Tooth Preparation (n = 9)						6	3
Miscellaneous (n=11)						9	2

Summary of success rate for 100 patients according to Faces Pain Scale:
Extraction = 96.3%
Pulpal therapy = 88.5%
Tooth preparation = 100%
Miscellaneous = 100%

Table II. The mean and standard deviation for the clinician and the patient for comfort on administration based on Lickerts scale.

Events	Score 1	Score 2	Score 3	Score 4	Score 5	Mean	SD ±	Significance (Ridit Analysis)
Extraction								
Clinician				6	48	4.889	+ 0.317	6.158
Patient —			4	30	20	4.296	+ 0.603	P<0.001
(n = 54)								VHS
Pulpal Therapy								
Clinician				4	22	4.846	+ 0.368	4.545
Patient			3	15	8	4.192	+ 0.634	P<0.01
(n =26)								HS
Tooth Preparation								
Clinician				3	6	4.667	+ 0.500	0.000
Patient				3	6	4.667	+ 0.500	P > 0.05
(n =9)								NS
Miscellaneous								
Clinician				2	9	4.750	+ 0.444	0.119
Patient				3	8	4.727	+ 0.467	P > 0.05
(n =11)								NS

Total success rate for comfort on administration according to:
Clinician = 100%
Patient = 93%

HS = Highly Significant; VHS Very Highly Significant

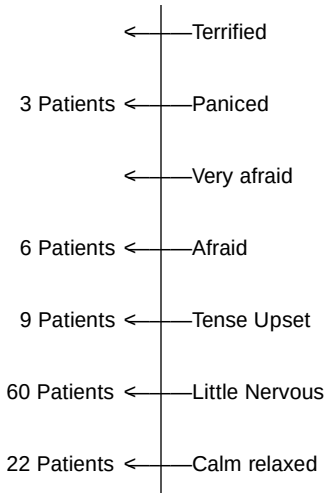
Table III. The mean and standard deviation for effectiveness of anesthesia based on Lickerts scale.

Events	Score 1	Score 2	Score 3	Score 4	Score 5	Mean	SD ±	Significance (Ridit Analysis)
Extraction								
Clinician				6	48	4.859	+ 0.350	1.081
Patient			2	7	45	4.764	+ 0.543	P > 0.05
(n =54)								NS
Pulp Therapy								
Clinician				2	24	4.923	+ 0.272	0.896
Patient				5	21	4.840	+ 0.374	P>0.05
(n =26)								NS
Tooth Prep.								
Clinician				1	8	4.853	+ 0.359	0.093
Patient				2	7	4.837	+ 0.374	P>0.05
(n =9)								NS
Miscellaneous								
Clinician				2	9	4.818	+ 0.405	0.506
Patient				4	7	4.727	+ 0.456	P>0.05
(n = 11)								NS

Total success rate for comfort on administration according to:
Clinician = 100%
Patient = 98%

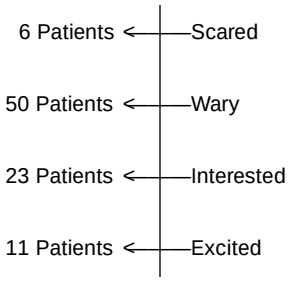
NS = Not Significant

Table IV. The number of the patients indicating individual scores based on the Pain Thermometer.



Total number of patients = 100

Table V. The number of the patients according to their reaction to the instrument. (Madajet XL).



Total number of patients = 100.

Pain control is a challenging task in clinical pediatric dentistry. Conventional pain control techniques, however, deal with only one aspect of pain control, i.e. pharmacological / sensory, the psychological component is often left unsolved. This is especially true of the pediatric pain control where the "fear of the needle" is a major deterrent to quality dental care. It is ironical that to eliminate pain we must momentarily create a painful stimulus.

The needle-less jet injector offers an alternative method of delivering local anesthesia to the pediatric patient, which is non-threatening and generally well accepted by the child patient.[20] Working on the principles of pressure dynamics, it delivers the local anaesthetic into the tissues in a manner that the solution itself acts as a 25 gauge needle, which thereby eliminates the use of the "notorious needle". Thus, the child's main fear is reduced or eliminated.[21] This study was conducted to evaluate the effectiveness of the jet injector in the management of pain during treatment procedures such as pulpal therapy, extraction and tooth preparation prior to restoration in children.

Both, patient and clinician verbal descriptor scales were used to assess the comfort on administration and effectiveness of anesthesia using the needle-less jet injector. Also the pain perceptions of the patient before, during and after each procedure were recorded. Accordingly, both, the patient and the clinician scored the comfort and effectiveness of Madajet XL on completion of the procedure, based on a 5 point continuous Lickert's Scale. Total success rates for comfort on administration with Madajet XL, according to the patient and clinician were 93% and 100% respectively. Similarly, total success rates for effectiveness of anesthesia using Madajet XL according to the patient and clinician were 98% and 100% respectively.

The assessment by the clinician of the comfort of the patient and effectiveness of anesthesia was based on the observation of the facial expressions of the patient and physical response and on the verbal complaints made by the patient during administration of anesthesia and at the time of actual procedure.

The results of the present study showed no statistically significant difference between the perception of comfort by the patient or clinician on administration and effectiveness of anesthesia.

Faces Pain Scale[22] and pain thermometer[23] were used to assess the pain perception of the patient for each individual treatment procedure. Total success rates according to the faces pain scale or extraction, pulp therapy, tooth preparation and miscellaneous clinical procedures, e.g, abscess drainage, rubber dam clamp placement etc., were 96.3%, 88.5% 100% and 100% respectively.

In this respect the results of the present study, that is success rate derived from the pain ratings are in broad agreement with previous work by Bennett,[10] who reported a patient acceptance of 90% using the needle-less anesthesia and operator acceptance of 95%; and with those of Smith *et a1.*,[16] who reported a preference rate of 83% in favor of the jet instrument, and Saravia and Bush, who used the jet injector successfully in 25 of 34 children for a variety of operative procedures.

The advantages of Madajet include, elimination of the pain and fear of the dental injection, less stress for both the patient and the clinician, instantaneous anesthesia, autoclavable, reusable (cost effectiveness).

The results of the present study indicate that, the needle-less jet injector is appropriate for all clinical

procedures on the primary teeth including: extractions, pulpal therapy and tooth preparations prior to restorations. These results corroborate previous findings and confirm the "patient friendly" nature of the injector. It is a promising alternative to other conventional local anaesthetic techniques. Hence the needle-less injector, offers safety and psychological advantages over the conventional modes.

SUMMARY AND CONCLUSION

1. Ease of administration of local anesthetic using the needle-less jet injector was perceived to be significantly comfortable by both, the clinician and the patient.
2. Needle-less jet injector was perceived to be significantly effective for the procedures undertaken, by both, the clinician and the patients.
3. Pain perception of the patient was significantly reduced with the use of needle-less jet injector for the procedures done.
4. There were no post-operative complications or side effects reported after completion of the procedures.

In view of the above it can be concluded that the needle-less jet injector promises to be a viable mode of pain control during various procedures in clinical pediatrics. It appears as a substantial alternative to the other conventional local anesthetic techniques and will be a useful adjunct to the pediatric dentist's armamentarium.

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