

**Comparative evaluation of 4%Articaine and 2% Lignocaine for primary mandibular molar extractions in 5-10 years old children - A randomized control study**

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**Abstract**

The purpose of this study was to compare clinical efficacy of 4% Articaine HCl (with adrenaline: 1:100000) and 2% Lignocaine HCl (with adrenaline: 1:80000) for primary mandibular molar extractions in children. A randomized control study.

**Material and method:** .A total of 60 children requiring primary mandibular molar extraction received buccal and lingual infiltration using either 4% articaine HCl (with adrenaline: 1:100000) and IANB by 2% lidocaine HCl (with adrenaline: 1:80000), with 30 children in each group. Parameters which were evaluated and compared were, the pain during injection and during extraction (efficacy) [wong-baker facial pain scale (WBS) and

objectively by FLACC], onset of anesthesia [sec] and duration of post-operative anesthesia [sec]. The heart rate [HR] and the blood pressure [BP] values were assessed objectively as an indirect measure of physiological pain perception. The student unpaired t-test was used for comparing mean pain scores, heart rate and blood pressure in both the groups.

**Result:** Buccal and lingual infiltration with articaine was sufficient for achieving lingual and buccal anesthesia in all the children receiving it. The mean WBS & FLACC value was found to be higher in lidocaine group and was statistically significant. There was a significant difference between 4% articaine and 2% lidocaine in terms of onset of subjective and objective symptoms and onset of soft

tissue anesthesia.

**Conclusion:** Mandibular primary molar extraction procedure can be successfully accomplished by 4 % articaine (with 1:100,000 adrenaline) buccal and lingual infiltration bypassing the traditional IANB of lignocaine.

**Keywords:** Articaine, Lignocaine, Mandibular Infiltration Anesthesia, Tooth Extraction.

### Introduction

Local anesthesia (LA) is the cornerstone of clinical dentistry. As early as 19th century, local anaesthetic solutions have been used for dental procedures for management of pain during treatment<sup>(1)</sup>. Successful local anesthesia plays a cardinal role in painless dental treatment. It is ironic that local anesthesia allows virtually pain-free treatment, yet is associated with many anxious thoughts and misconceptions in young patients<sup>(2)</sup>. Nerve blocks, like the greater palatine nerve block and the inferior alveolar nerve block, are considered typically to be more painful compared to infiltration<sup>(2)</sup>. Unpleasant treatment experience during LA administration negatively influence the child's behavior towards dental treatment defeating the primary objective of LA i.e. painless dentistry.<sup>(2)</sup>

Infiltration anesthesia has been used successfully to treat maxillary teeth but mandibular infiltration has been routinely avoided in treating mandibular molars due to its questionable effectiveness, likely arising due to a thickness of a buccal cortical plate, which does not allow adequate dissemination of commonly used LA lignocaine<sup>(4)</sup>.

Thus, the key area of interest in the use of local analgesia for children is whether it is possible to do away with the use of an inferior dental block (IANB) and use infiltration instead<sup>(4)</sup>. Due to limited solubility of lignocaine it is not the anesthetic drug of choice for infiltration technique. This lead to search for a suitable anesthetic agent for infiltration.

**Rusching and colleagues in 1969**<sup>(4,5)</sup> introduced an amide anesthetic, articaine which is an amide local anesthetic, 4-methyl-3[2-(propylamino) propionamido]-2 thiophenecarboxylic acid, methyl ester hydrochloride it was introduced to clinical practice in 1976. In April 2000, the U.S. Food and Drug Administration granted approval for the sale of 4 percent articaine with 1:100,000 epinephrine in the United States under the name of Septocaine (Septodont). It is characterized by increased liposolubility and presence of thiophene ring which proves to be effective in producing profound anesthesia. With the development of articaine which contains a thiophene ring making it more potent and more lipid soluble thus enhancing its diffusion through both hard and soft tissue, mandibular infiltration anesthesia in molar region has become a possibility<sup>(2-4)</sup>.

Literature also suggests that use of articaine for maxillary pulpal and soft tissue anesthesia is effective<sup>(6)</sup>. Data regarding the efficacy of articaine infiltration for primary mandibular molar extractions is sparse. Hence, the present study was planned to compare the clinical efficacy of 4% Articaine HCl (with adrenaline: 1:100000) and 2% Lignocaine HCl (with adrenaline: 1:80000) for primary mandibular molar extractions in children.

### Material and method

Study was reviewed and approved by institutional ethical committee V S P M dental college and research Centre, Nagpur, Maharashtra, India. This randomized control study was carried out in the department of pediatric and preventive dentistry of the respective college. Sample size for the study was calculated based on results of previous studies. The minimum number of subjects was n = 60 (30 in each group) a dropout of 20% was also taken into consideration. A total of 60 children were selected from the outpatient department of pediatric dentistry by

using a convenience sampling procedure based on following selection criteria: Healthy children in age group 5-10 years, children cooperative enough to follow the instructor's directions. (Frankl's definitely positive and positive), children having at least one primary mandibular molar indicated for extraction under local anesthesia, children whose parents/caretakers sign the consent letter of participation and children who gave assent for treatment were included in study. Children with active infection at the site of injection and children with known history of allergy to any local anaesthetic agent were excluded from the study. Case history was recorded and a preoperative radiograph was taken before extraction. The procedure and possible discomforts or risks after administering either lidocaine or articaine were fully explained to the accompanying guardian, and their written informed consents were obtained before beginning the procedure. Parents of the children selected for the study were explained the purpose and methodology of the study in local vernacular language and a signed informed consent was obtained.<sup>(1)</sup>

The children were randomly divided into two groups based on simple (unrestricted) randomization by envelope method. 30 sealed envelopes were prepared, containing one card each having the names of either of the two local anaesthetic drug, accordingly 30 envelopes of Group 1 and 30 envelopes of Group 2 were prepared<sup>(7)</sup>. For equal gender wise distribution in each group, 2 blocks prepared by thoroughly shuffling 15 envelopes of Group 1 and 15 envelopes of Group 2. The series of envelopes thus formed were numbered from 1- 30 in each block. For male patient envelope was drawn from block 1 and for female patient envelope was drawn from block 2 sequentially by investigator 1 in first visit.

In first visit, children in both group underwent non-invasive treatment like fluoride application or oral

prophylaxis to get them acclimatized to the dental environment and also confirm their cooperative behavior. Wong-Baker FACES Pain Rating Scale (FPS) was introduced and explained to the children. During the second visit, each child received a single anaesthetic dose by respective group protocol, Group 1(2% Lignocaine HCl IANB) and Group 2 (4% Articaine HCl buccal & lingual infiltration) for the tooth to be extracted.

For Group 1 (2% Lignocaine HCl IANB)(Lignospan, Septodont), standard Inferior alveolar nerve block was performed with 1.5 ml of lignocaine using the conventional technique as described in Handbook of Local Anesthesia<sup>(2)</sup>. A long buccal nerve injection (0.3 ml) also was administered in all subjects receiving IANB. Rate of injection was approximately 1.5 mL/minute.<sup>3</sup> For Group 2 (4% Articaine HCl buccal & lingual infiltration) (Septanest, Septodont) 1.5 mL was administered in depth of the mucobuccal fold opposite to the mandibular molar<sup>(8)</sup>. For the lingual soft tissue anesthesia, 0.3 mL of the same anesthetic was deposited for lingual infiltration by advancing needle through interdental papillae on both mesial and distal aspects of tooth being extracted<sup>(2)</sup>. Both anesthetic drugs were administered by self-aspirating needle (Septodont fusion syringe) & 30 gauge short needle (septobject, septodont). The lowest effective dose of anesthesia was administered as submucosal infiltration and/or nerve block. Up to one cartridge of lidocaine (maximum dose: 7 mg/kg body weight) and articaine (maximum dose: 7 mg/kg body weight) was administered. After confirming all signs & symptoms of profound LA, extraction procedure was carried out following the standard protocol.

Complete procedure was videotaped & recording was done from a fixed distance from the dental chair with a video recorder such as to provide complete visual of child. The recording started from the moment the child

sat in the dental chair during second visit and ended when the extraction procedure was completed. All local anesthesia and extractions procedure were performed by an investigator 1 in all patients.

During second visit, parameters recorded were pain on injection, onset of anesthesia (measured in seconds), duration of anesthesia (measured in minutes), efficacy of anesthesia, heart rate (HR) and blood pressure (BP). The pain experienced by patient during the administration of the injections was recorded by investigator 2, asking child to select the facial expression that best represented by his/her experience of pain /discomfort by Wong-Baker FACES Pain Rating Scale (WB) and objectively by investigator 2, watching videotape of injection procedure from patient sitting on chair till the end of LA procedure by using the Faces, Legs, Activity, Cry, and Consolability (FLACC) scale.

The time of onset was evaluated, objectively by operator by the presence /absence of pain to prick of sharp dental probe applied on gingival margin on the attached gingiva buccal to the tooth to be tested. For duration of Anesthesia (Measured in Minutes), parents were instructed to ask the child and to record the time when the feeling of numbness disappeared (offset time). They were asked by phone after 1, 2 or more hours to report it and were also asked about the occurrence of adverse effects.

Profoundness (efficacy) of Anesthesia assessed subjectively by Wong-Baker FACES Pain Rating Scale (FPS) and objectively by investigator 2 watching videotape of procedure from end of LA procedure till end of extraction by using the Faces, Legs, Activity, Cry, and Consolability (FLACC) scale HR & BP were recorded by investigator 2 by using a digital sphygmomanometer and finger pulse oximeter<sup>(9)</sup>. Heart Rate & Blood Pressure readings were taken, 2 minute prior to administration of LA, 2 minutes after LA administration, during extraction

2 readings were taken.

First 10 videos were reassessed by investigator 2 & rated separately for evaluations of injection pain and profoundness of anesthesia during procedures to establish intra-rater reliability. All data (Subjective and objective measurement) was recorded in the customized case record proforma.

## Result

The descriptive statistics for demographic characteristics of age for the patients in the two treatment groups 2% Lignocaine HCL (with adrenaline: 1:80000) IANB and 4% Articaine HCL (with adrenaline: 1:100000) Buccal and Lingual infiltration given in **table 1** the mean age of patient in group 1 was  $8.06 \pm 1.55$  years and group 2 was  $8.11 \pm 1.46$ . . By using chi-square test, statistically no significant difference was found in ages of the patients of two groups ( $\chi^2$ -value=2.75,  $p=0.59$ ).

On comparison of Wong Baker Scale Score for the pain on injection during administration of LA in both groups [**table 2**]. Mean for pain on injection in patients of group 1(2% lignocaine) was  $2.93 \pm 2.39$  and in group 2(4% articaine) it was  $1.60 \pm 1.61$ . Statistically significant difference was found in the mean value of pain on injection in patients of two groups ( $t=2.53$ ,  $p=0.013$ ). FLACC scale score was assessed by investigator 2 for the pain experienced by the patient during administration of anesthesia. On comparison of FLACC score [**table 3**] for group 1 (2% lidocaine) was  $2.66 \pm 1.42$  and in group 2 (4% articaine) it was  $1.40 \pm 1.19$ . Statistically significant difference was found in the mean value of pain on injection in patients of two groups ( $t=3.73$ ,  $p=0.0001$ ).

On comparing time of onset of anesthesia in two groups given in **table 4**, Mean time of onset in patients of group 1(2% lignocaine) was  $165(2 \text{ min } 45 \text{ sec}) \pm 42.24$  and in group 2(4% articaine) it was  $138(2 \text{ min } 18 \text{ sec}) \pm 43.58$ . Statistically significant difference was found in the

meantime of onset in patients of two groups ( $t=2.04$ ,  $p=0.045$ ).

Duration of anesthesia when compared between two groups [table 5]. Mean duration of pain in patients of group 1 was  $130.66\pm 20.83$  and in group 2 it was  $123.76\pm 7.75$ . Statistically no significant difference was found in mean duration of pain in patients of two groups ( $t=1.70$ ,  $p=0.094$ ).

When Wong Baker scale score for the pain experienced by the patient during extraction procedure (efficacy of anesthesia) was compared [table 6] it was observed to be less with buccal & lingual infiltration of articaine as compared to the IANB lignocaine which was statistically significant. Mean pain during extraction in patients of group 1 (2% lignocaine) was  $5.40\pm 3.11$  and in group 2 (4% articaine) it was  $2.20\pm 2.36$  ( $t=4.47$ ,  $p=0.0001$ ). The investigator 2 assessed the pain experienced by the patient during extraction (efficacy of anesthesia) by FLACC scale and observed it to be less with articaine group as compared to the lignocaine group, which was found to be statistically significant [table 7] Mean pain during extraction in patients of group 1 (2% lignocaine) was  $3.93\pm 1.98$  and in group 2 (4% articaine) it was  $2.30\pm 1.57$  ( $t=3.53$ ,  $p=0.001$ ).

**During extraction,** Mean SBP in patients of group 1 (2% lignocaine) was  $114.26\pm 10.95$  and in group 2 (4% articaine) it was  $104.33\pm 9.08$  ( $t=3.82$ ,  $p=0.0001$ ) and mean DBP in patients of group 1 (2% lignocaine) was  $77.93\pm 7.63$  and in group 2 (4% articaine) it was  $69.63\pm 7.63$  ( $t=4.21$ ,  $p=0.0001$ ), statistically significant difference was found in systolic and diastolic blood pressure in patients of two groups during extraction. [Table 9]

## Discussion

Pain control is an essential part of any dental treatment especially in children. To assess child's pain effectively, it

is important to measure more than one dimension of the pain experience. Because pain is highly individual and multidimensional phenomena, subjective as well as objective assessment is important. Hence a composite measure<sup>(11)</sup>, which includes self-report, observational or behavioral and physiological assessments is desirable. Use of local anesthetics to control a patient's pain is one of the essential factors for successful dental treatment<sup>(12)</sup>.

A number of studies have shown the superiority of 4% articaine to 2% lidocaine when used as buccal infiltration of the mandibular first molar in adults<sup>(13)</sup>. Additional studies compared the depth of pulpal anesthesia in the mandibular molars obtained after buccal infiltration by articaine to that obtained after the inferior alveolar nerve block (IANB) with 2% lidocaine and found a similar success rate for both of them<sup>(14-16)</sup>. Moreover, other studies clearly demonstrated that articaine by buccal infiltration in the mucobuccal fold of the first mandibular molar can provide more successful anesthesia to mandibular teeth when administered alone or as a supplement to the IANB with lidocaine or articaine.

Age group of 5-10 years, was selected for the study, as suggested by Bansal et al (2017)<sup>(17)</sup> who observed extraction due to over retention was maximum in the over age of 11 years. According to Sherman et al. & Wandner et al. (2012)<sup>(19)</sup> the age and gender of patients were reported to be the possible factors influencing the perception of pain. Bataineh et al (2016)<sup>(8)</sup> observed in their study that pain perceptions of male and female patients extraction-related pain was significantly higher in female than in male ( $p = 0.01$ ). To avoid gender bias in the present study equal number of male and female were included.

In the present study, statistically significant difference in pain on injection between two groups was observed. Wong Baker Scale Score noted for the pain on injection

during administration of LA in both groups. These results are in accordance with Chopra et al (2016)<sup>(20)</sup> and Sharaf et al (2016)<sup>(23)</sup> where they found by using VAS scale, inferior alveolar nerve block be more painful than local infiltration.

In the present study, on comparing time of onset of anesthesia in two groups, statistically significant difference was found in the meantime of onset in patients of two groups. The results found in our study are similar to the results observed in the study done by Jung et al (2008)<sup>(24)</sup> who found buccal infiltration with articaine have faster onset when compared to IANB with lignocaine. On comparing articaine infiltration with lignocaine IANB. The faster onset of articaine anesthesia is found not only because of its high lipophilicity, but also due to the 4% concentration hour of articaine in solution because of which its ability to diffuse through nerve membranes, soft tissues and bone is enhanced.

Wong Baker Scale score for the pain experienced by the patient during extraction procedure was compared it was found to be statistically significant. On comparison of FLACC score, it was found to be statistically significant. . It is in accordance with the Kolli et al (2017)<sup>(18)</sup> this study, articaine buccal infiltration showed better success than lignocaine buccal infiltration, which can be explained by the fact that articaine is one of a kind among amide local anesthetic due to the presence of thiophene ring, which makes it more lipid soluble. Due to which diffusion of articaine is better through soft tissues than other anesthetics, subsequently accomplishing higher intraneural concentration, more broad longitudinal spreading and way better conduction blockade. Hasse et al (2012)<sup>(27)</sup> found that a lower concentration of articaine (a thiophene derivative) was sufficient to block an action potential when compared with other amide anesthetics.

In present study, duration of anesthesia when compared between two groups, statistically no significant difference was found between two groups. These results are similar to study done by Kambalimath et al (2013)<sup>(26)</sup> where no significant difference in duration of anesthesia between lignocaine and articaine group. Articaine stands better in this respect though statistically it is not significant. In contrast, Haas et al (2008)<sup>(27)</sup>, Vahatalo et al (1993)<sup>(28)</sup> and Costa et al (2005)<sup>(12)</sup> stated that 4 % Articaine with 1:100,000 epinephrine infiltration had longest duration of anesthesia as compared to lignocaine .

Heart rates of the participating patients were measured through a pulse oximeter device at 3 intervals where statistically no significant difference was found between at baseline, after administration of LA and during extraction. In contrast Mittal et al (2015)<sup>(22)</sup> and Kambalimath et al (2013)<sup>(26)</sup> reported a slight increase in heart rate from baseline values in both their lidocaine as well as articaine groups.

Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) of the participating patients were measured through sphygmomanometer device at 3 intervals. Statistically no significant difference was observed in SBP and DBP, at baseline score and after administration of LA.

These results were in accordance with rathi et al (2019)<sup>(11)</sup>, where the mean systolic and diastolic blood pressure recorded during the intervention was raised from the baseline values in both the groups, which could be attributed to painful stimulation and manipulation of tissue for extraction. The mean systolic and diastolic blood pressure value of the articaine group recorded during intervention was less than the lidocaine group which may be due to effective analgesia in articaine group. Kambalimath et al (2013)<sup>(26)</sup> reported the change in the systolic and diastolic blood pressure after administration

of the local anesthetic agent as compared with the base line value in both the groups.

### Conclusion

#### From the present study it can be concluded that

1. Buccal and lingual infiltration of 4% articaine (with 1:100,000 adrenaline) effectively provided adequate buccal and lingual soft tissue anesthesia for primary mandibular molar in the children aged 5-10 years...
2. Mandibular primary molar extraction procedure can be successfully accomplished by 4 % articaine (with 1:100,000 adrenaline) buccal and lingual infiltration bypassing the traditional IANB of lignocaine.
3. 4% Articaine (1:100000 adrenaline) infiltration shows promising substitute for painful lignocaine IANB in children.

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**Legend Tables and Figures**

Table 1: Age wise distribution of in two groups

Age Group	Group 1	Group 2	$\chi^2$ -value
5.1-6 yrs	5(16.7%)	3(10%)	2.75 p=0.59,NS
6.1- 7 yrs	3(10%)	4(13.3%)	
7.1-8 yrs	3(10%)	3(10%)	
8.1-9 yrs	7(23.3%)	12(40%)	
9.1-10 yrs	12(40%)	8(26.7%)	
Total	30(100%)	30(100%)	
Mean±SD	8.06±1.55	8.11±1.46	
Range	5.08-10.00	5.10-9.98	

Table 2: Comparison of Wong-Baker Scale score for pain on injection between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1 (2% lignocaine)	30	2.93	2.39	0.43	2.53 p=0.013,S
Group 2 (4% articaine)	30	1.60	1.61	0.29	

Table 3: Comparison of FLACC Scale score for pain on injection between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1 (2% lignocaine)	30	2.66	1.42	0.25	3.73 p=0.0001,S
Group 2 (4% articaine)	30	1.40	1.19	0.21	

Table 4: Comparison of time of onset for local anesthetic solutions between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1	30	165	42.24	7.71	2.43 p=0.018,S
Group 2	30	138	43.58	7.95	

Table 5: Comparison of duration of anesthesia between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1	30	130.66	20.83	3.80	1.70 p=0.094,NS
Group 2	30	123.76	7.75	1.41	

Table 6: Comparison of Wong Baker Scale score for pain during extraction between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1 (2% lignocaine)	30	5.40	3.11	0.56	4.47 p=0.0001,S
Group 2 (4% articaine)	30	2.20	2.36	0.43	

Table 7: Comparison of FLACC Scale score for pain during extraction between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Group 1 (2% lignocaine)	30	3.93	1.98	0.36	3.53 p=0.001,S
Group 2 (4% articaine)	30	2.30	1.57	0.28	

Table 8: Comparison of Heart Rate in Two Groups at three intervals during treatment

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Baseline	Group 1 (2% lignocaine)	30	96.06	15.90	2.90	1.34 p=0.18,NS
	Group 2 (4% articaine)	30	101.46	15.19	2.77	
After LA	Group 1 (2% lignocaine)	30	110.06	20.57	3.75	1.43 p=0.15,NS
	Group 2 (4% articaine)	30	102.66	19.42	3.54	
During Extraction	Group 1 (2% lignocaine)	30	107.75	18.81	3.43	0.67 p=0.50,NS
	Group 2 (4% articaine)	30	104.63	16.67	3.04	

Table 9: Comparison of Systolic Blood Pressure SBP in two groups at three intervals during treatment

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Baseline	Group 1(2% lignocaine)	30	102.66	16.36	2.98	0.42
	Group 2(4% articaine)	30	104.26	12.45	2.27	p=0.67,NS
After LA	Group 1(2% lignocaine)	30	107.76	11.76	2.14	0.92
	Group 2(4% articaine)	30	104.83	12.71	2.32	p=0.35,NS
During Extraction	Group 1(2% lignocaine)	30	114.26	10.95	1.99	3.82
	Group 2(4% articaine)	30	104.33	9.08	1.65	p=0.0001,S

Colour Plate No 1



Fig 1: Disposable Gloves, Head Cap And Facemask



Fig 2. Diagnostic Instruments

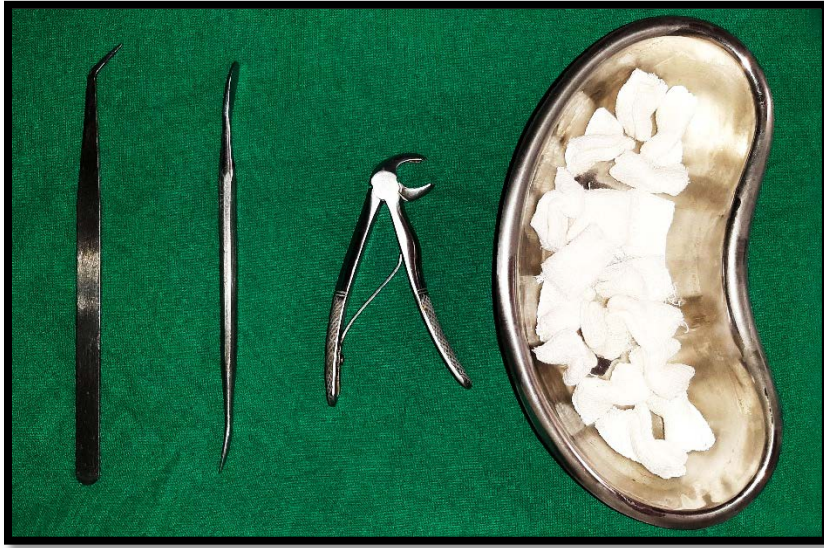


Fig 3: Instruments For Extraction Procedure



Fig 4 : Articaine With Adrenaline 1/100,000 (Septanest )



Fig 5 : Lignocaine With Adrenaline 1/100,000 (*Lignospan*)

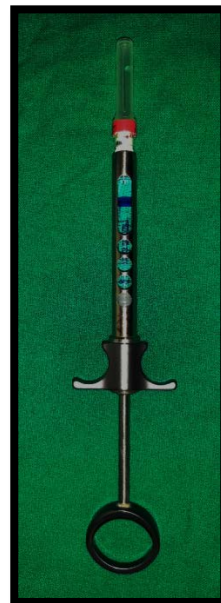


Fig 6 : Septodont Fusion Syringe With 30 Gauge Long Needle



Fig 7 : Digital BP Apparatus



Fig 8 : Pulse Oximeter



Fig 9 : Patient Position



Fig 10



Fig 11

Fig 10 & Fig 11 Intra-Operative