EVALUATION OF EFFECTIVENESS OF NEEDLELESS INJECTION TECHNIQUE IN PATIENTS UNDERGOING ORTHODONTIC EXTRACTION- SPLIT MOUTH TECHNIQUE- A CLINICAL TRIAL

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INTRODUCTION

The years between 1750 and 1850 were prominent in the history of western European countries as discovery of anaesthesia made a vast change in their cultural practices within their society.[1] Before the discovery of anaesthesia, pain was presumed as a part of life and people used to think that pain was according to their individual sin & they have to accept it. Thus none made efforts in the society to tackle pain as a suffering of disease or a situation which can be curtailed by medical innovations, devices or scientific techniques. As the society started advancing in commercial, technological and humanity area it made simpler & felt as a need for discovery of anaesthesia by the two dentists named Horace Wells in 1815 to 1848 and William Thomas Green Morton in 1819 to 1868 years.[2,3] Before anaesthesia was founded and used in medical practice, the coca leaf was used by tribal people residing in Negro river region Brazil, where as coca leaf works perfectly for numbness as told by tribal people[4] which was later officially researched & documented by a European researcher.[5] In the 16th century, it was announced that coca leaves when chewed can help alleviate tooth pain

through a report by Jesuit Bernabe Cobo.[6] After this realization of coca leaves advantages in the past, it was followed by the reports of misuse due to unrestrained use of cocaine as it directly affected the central nervous system and gave a good feeling of euphoria.[7] A new class of anaesthesia was then introduced as procaine by chemist Alfred Einhorn. The advantage of procaine was, it exhibited both lipophilic and hydrophobic properties.[7]

The ester linked local anaesthesias comprised of Chloroprocaine, Procaine and Tetracaine while the amino amide local anaesthetics comprised of Mepivacaine, Prilocaine, Etidocaine, Bupivacaine and Lidocaine.[8] Ester and amide type of anaesthesia differ with respect to their structure. Other variations that are reflected are, onset of action, the time duration for which the anaesthetic effect lasts, stability of anaesthesia, shelf life of the solution and allergic reactions associated with them. The advantage of amide type of anaesthesia is that they are stable at high temperatures with a shelf life of around 2 years. The metabolism process is slow and they undergo metabolism in liver. Moreover, the allergic reactions associated with them are also rare. On contrary, ester linked anaesthetics have a short shelf life, cannot withstand heat, get metabolised by glycoprotein named plasma cholinesterase and also reports greater cases of patients with post allergic reaction due to formation of aminobenzoate.[9] As the benefits of amide type of anaesthesia outperforms the ester types, the prior are found to be most commonly used and preferred by health care professionals. In dental practice, bupivacaine and lidocaine have a more frequent use.[10] In order to further enhance their action especially the duration of action, both are available with vasoconstrictor adrenaline. The presence of adrenaline provides clean working field along with longer duration action in small dosage. Besides, both

the types are also available without the presence of adrenaline for their use in patients with hypertension.[9]

Local anaesthesia is defined as "a local state of loss of sensation without loss of consciousness, in a circumscribed area of the body due to a depression of, excitation in nerve endings or an inhibition of the conduction process in peripheral nerves".[11] In ideal cases after any stimulus attack, there is a shift in nerve membrane potential from normal of sodium outflux and potassium influx to increased sodium influx through the membrane. This increased influx of sodium ions which bind to the sodium channels cause depolarization and ultimately pain.[12] There is a two-step mechanism that explains the basic principle by which the local anaesthesia causes loss of pain sensation at the site. The first step elucidates that as soon as the anaesthetic solution is injected in unionised form, it passes through the membrane post which it converts into ionised form and binds to sodium channels i.e., Na^+ on the nerve membrane and averts depolarization thus, gaining the control over pain. The second step includes the expansion of nerve membrane for the passage of local anaesthetic drugs to cause Na+ channel inactivation.[9]

It is such an irony that the discovery of anaesthesia which is intended to ease patient's pain associated with any procedure is itself a reason for agony and fear among significant population. Thus, the biggest challenge for the health care professional remains the administration of local anaesthesia in a way that would cause less possible pain to the patients thereby improving their dental experience and further quality of treatment experienced. Bedi R et al[13] reported trough their study that needle prick fear is one of the most common anxiety inducing pain in dental office. It hampers the mental state and has a negative impact on psychology of patients. The

feeling of needle being penetrated into the mucosa appears to be were fearful and painful. As per the reports by Ali FM et al,[14] 13-14% of patients experience needle phobia. This fear thereby restricts them from going to a dental office to undertake any kind of dental treatment. The fear induced by injection thereby causes deterioration in their oral health[14] and overall general health at long run. Few reported reasons in the literature for this phobia are; past painful dental or medical experience associated with needle[15], heard experience with respect to dental procedures from their near ones like friends, employees and relatives.[16] These reasons threw light in the fact that pain is a word of mouth for those who haven't even experienced it. A multicentric study by Appukuttan DP et al[17] stated that patients with prior history of dental visit and those who have undergone local anaesthesia injection were 3.34 times more likely to avoid the dentists in future. Another study presented that the patients with higher scores on modified dental anxiety were more likely to postpone their dental visits and those with bad past dental experience were found to be more anxious than their counterparts.[18] Thus this fear becomes a hurdle for those with past experience and also for those visiting the dentist for the first time rather avoiding the visit for the same.

Various factors contribute to pain sensation. Major factors are size of the needle, type of anaesthesia used, amount of anaesthesia injected. Other factors which also contribute to pain are site of injection, the duration required for anaesthetic solution to be administered, the experience of a dentist administering the solution and last but not the least is the anxiety level of patient and how the patients perceives pain perception. In terms of solution, the pH of the solution has also been proved to be affecting tissue reaction and thereby pain perception. The acidic medium of solution tends to alleviate pain.[19] Site of injection plays a crucial role in pain perception. Kaufman E et al[20] in

their study provided data on the variation in pain perception by using different injections techniques like infiltration, periodontal ligament injection, mental nerve block and inferior alveolar nerve block. Local infiltration provides least pain and discomfort to the patient but has a significantly higher pain scores when administered in maxillary incisor area. Periodontal area is abundant with free nerve endings while submucosa has few nerve endings. The pressure developed while administering local anaesthesia via periodontal ligament technique creates excessive pressure in the surrounding are thereby increases pain perception to the patients.[21]

Generally, nerve block is less painful compared to local infiltration as it prevents swelling of surrounding soft tissue and its distortion.[22] Maxillary blocks report to be more painful over mandibular blocks. Anterior superior nerve block, middle superior nerve block, infra orbital nerve block, posterior superior nerve blocks are administered on labial or buccal aspect while incisive nerve block and greater palatine nerve blocks are administered from palatal aspect. The tissues of palatal mucosa are tightly attached to underlying periosteum giving a little free space between the palatal tissue and palatal bone. There is no space for the local anesthesia to be deposited and get deposited in a confined area there by creating excessive pressure. Additionally, inbuilt pressure in the stiff tissues causes discomfort and pain to the patients inspite of application of topical anaesthetic gels and sprays.[23] For this reason, the blocks that are injected in palatal mucosa are more painful over the ones injected in buccal mucosa.[24] When the same is compared with buccal nerve blocks or infiltrations, the mucosa expands with the amount of solution deposited thus eliminating the pressure and causing less discomfort and pain to the patient.[23]

Literature throws light of various techniques adopted in order to reduce pain during injection. Buffering of local anaesthetic solution reduces the irritation to the tissues thereby leading to less pain. Smaller the diameter of the needle, lesser will be the distortion of the tissues during the route of needle towards the target site piercing through the tissues. The syringe should be immobilized to avoid unnecessary pain due to movement of the needle. Thus the dentist should place his fingers accordingly to provide stabilization as well as inject solution. Distractions can be used much as vibration to avoid pain sensation to the patients. It has also been proposed that the anaesthetic solution should be injected even during the course of needle into the tissue till it reaches target point. Use of anaesthetic gels and sprays may can help to limit the pain to some extent. The needle should always be advanced slowly into the tissues. The patient should always be asked for their response on pain during the whole procedure of administration of anaesthetic solution so that dentist can make possible changes into the technique while injecting and provide relief to the patients.[25]

Apart from the above techniques, advancement in the devices used for administering local anaesthesia have also developed in past few years. These devices are attached to the syringes. Computer controlled local anaesthetic delivery (CCLAD) system is a technique which allows to inject local anaesthesia with a set speed at a slow and maintained ratio. The devices takes into consideration the anatomical characteristics of the tissue in which it is injected.[26] Comfort Control Syringe, Wand (Milestone Scientific, Livingstone, NJ), Quick Sleeper and iCT (Dentium, Seoul, Korea) are few of the devices adopting this technique.[26] The Wand has been in market from a long time and is recognized for its ease of during the operative procedure because of light weight. Moreover, the circumference of the device is half of that of normal syringe giving a comfortable grasp. On the other hand, the comfort control syringe and

quicksleeper have three time larger size and are also comparable to normal syringe with respect to weight. Another product with Korean manufacture namely DenInjection provides better grip because of its design considering ergonomics.[26] Vibrotactile devices work on gate control theory of pain.[27] Since the theory states that the non-noxious stimuli can block the gates for noxious stimuli and thus control pain, these devices inculcate vibration either machine initiated or mechanically through touch at the site of injection and prevents the pain stimuli reaching the cerebral cortex for creating discomfort.[28] Vibraject, Accupal and Dental Vibe are few of the Vibrotactile devices enlisted in the literature.[27]

Needle free injection is a revolutionary concept accepted lately that allows health care professional to administer anaesthetic solutions as well as drugs and vaccines in a way that causes least possible discomfort to the patients. One such device is Sure Shot that requires a research. The device creates a very thin linear jet of solution that goes beyond the oral tissues and reached the target area to allow its action. Since the device is needleless, it overcomes the accidentally transmitted diseases to the patients as well as dentists with respect to needle prick. The fear associated with needle in many patients also does not become a concern here. Moreover, the cost associated with the needle disposal is significantly reduced. The solution through this device spreads into the deeper layers of mucosa creating sufficient effect much faster than the traditional needle technique anaesthesia. The device can be used efficiently on patients with anxiety, needle phobia, and uncooperative patients. The device has a fine nozzle which acts like a needle and the graduated scale with micro hole of 0.15mm diameter allows the anaesthetic solution to come out in less than 100 milliseconds. The maximum capacity of the device to hold solution is 0.5ml with 0.1 ml used to bend the tissues and avoid trauma during first infusion and 0.3ml during the second

infusion. The nozzle is placed on the attached gingiva and palatal mucosa according to the site of target. Both permanent and deciduous dentition procedure can be done under local anaesthesia using this device.29 Since the device has been introduced very recently, there is paucity of data on its effectiveness compared to other techniques. Considering this, the present study was undertaken to compare the effectiveness of needless injection technique with that of traditional injection technique in patients undergoing orthodontic extraction using a split mouth study design.

AIM AND OBJECTIVES

PRIMARY OBJECTIVE:

To compare the pain perception by needleless injection technique with conventional injection technique while administering local anesthesia for orthodontic extractions.

SECONDARY OBJECTIVE:

To compare pain perception while extraction after administering local anesthesia by needleless injection technique and conventional injection technique.

REVIEW OF LITERATURE

History of local anaesthesia

The general anesthesia, and particularly local anaesthesia, necessitated a cultural shift. The ability to withstand pain (obstetric Pain) was viewed as a mark of masculinity in men. The industrialization, gradual humanization, and democratization of society in Western Europe between 1750 to 1850 established an environment conducive to the development of anesthetics. There was nothing analogous in Asian, Russian, or Islamic countries, where still feudalism existed in various forms. The result of this broad process there was a shift in the cultural, political, religious landscape, affecting a large number of people. [1]

Dentist, were the ones who discovered analgesia, thanks to their daily contact with pain and, as a result, their need to relieve it. People lost their life due to pneumonia, diphtheria, puerperal fever, gangrene, tuberculosis and tetanus along with other illness, thus doctors concentrated on infections over pain. Two dentists, Horace Wells

and William Thomas Green Morton were the first to introduced anaesthesia with nitrous oxide in 1844 and ether in 1846 respectively.

The journey of anaesthesia from cocaine to ropivacaine was described by Ruetsch YA et al in their published article. Around three centuries after Pizzaro's victory in Peru, the Austrian vo Scherzer transported leaves of coca to Europe in 1850 for separation of cocaine from its leaves. Representations of the qualities of the coca leaves encouraged the Austrian Koller to undertake clinical activity under local anaesthesia, by organizing cocaine on the eye, in 1884, as advised by his friend Sigmund Freud. Cocaine was immediately adopted as a local and peripheral anaesthetic in Europe and America. Cocaine's fatal effects were quickly recognized, which resulted in numerous deaths amongst patients and dependent treatment personnel. Until the progress of modern natural science, which resulted in mixing of cocaine in 1891, local anaesthesia was a serious problem. Tropocaine, orthoform, benzocaine , eucaine, tetracaine and Holocaine were among the newer amino ester local anaesthetics that were developed between 1891− 1930. Additionally, amino amide neighborhoods soporifics such as efocaine, lidocaine, procaine, nirvaquine, bupivacaine, articaine, chloroprocaine, etidocaine, cinchocaine, prilocaine, and mepivacaine were developed between 1898−1972. These drugs appeared to be less harmful than cocaine, but they had dissimilar effects on sensory nervous system (CNS) as well as cardiovascular system (CVS). As a pain reliever, bupivacaine has proven to be very intriguing as a result of its extensive history of activity and clinical use.[30]

In 1901, Braun proved epinephrine's "chemical trouniquet" property.[31] Procaine was first produced in Germany by German chemists Einhorn and Uhfelder in 1904-1905. When adrenaline was added, it was discovered that this medication was both effective and safe as a local anaesthetic for the majority of patients. Until the 1950s, physicians

and dentists routinely utilized procaine. Nils Lofgren, a Swedish scientist, created lignocaine, an amine anaesthetic, in 1943. Because it was less allergenic and more effective than procaine, it revolutionized the use of local anaesthetic in dentistry. It was largel accepted by the 1950s.[2]

After being combined in 1957, the availability of bupivacaine in 1965 coincided with static and cumulative indications of CNS and CV effects, causing its use to be limited and the distinct demonstration of unique therapeutic safe CV lethality. Several exploratory experiments led to the identification of this effect, which improved understanding of the activity of local analgesics. The choice of ropivacaine, an unadulterated S-(-) enantiomer, was driven by the distinct demonstration of optically dynamic isomers of the mepivacaine family, whose toxicities was particularly and thoroughly pondered before its presentation available in 1996. Unwanted effects were shown to be limited during the facility's rapid and widespread use of ropivacaine.[3]

Christopher A also wrote an article on the history of local anesthetics. The origins of local anaesthetic may be traced back to 1859, when Niemann isolated cocaine. Koller, an ophthalmologist, was the first to use cocaine for topical anaesthetic in opthalmological medical procedures in 1884. The doctor Halsted administered the first local anesthetic in the oral depression in 1884, when he evaluated wisdom a tooth without pain. Einhorn discovered the combination of procaine, the most common ester type local anaesthetic agent, in 1905. For more than four decades, "procaine" was perhaps the most widely used local anaesthetic because it is amide-derivative of diethylamino acidic. Lidocaine was first introduced in 1948 and it is the widely used sedative in the field of dentistry today, but other amides are also used. Mepivacaine, prilocaine, and bupivacaine were the first local anaesthetics to be used in clinical practice. The scientist Muschaweck combined articane in 1969, and it was approved

as a local sedative in Germany in 1975. In Germany, Austria, Switzerland, France, Poland, and other European countries, Articaine was the most commonly used local sedative.[32]

Pharmacological aspect of local anaesthesia

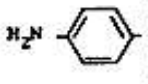
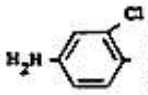
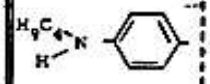
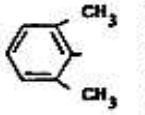
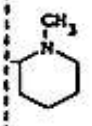
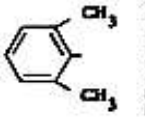
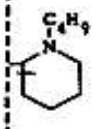
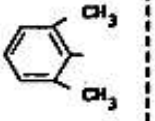
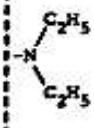
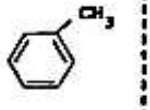
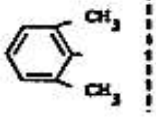
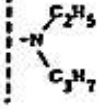
Local anaesthetic medications are pharmacological agents that lead to the loss in sensation perception in a specific location of body. The inhibition of excitement at nerve endings or the blocking of the conduction mechanism in distal nervous tissue causes this limited form of anaesthesia.

Koller revealed the topical anesthetic characteristics of a "cocaine", an alkaloid extracts (Erythroxylin) of leaves of the coca bush, in 1884, and thus regional anaesthesia was born. The 1st injectable drug to be used clinically for the creation of local anesthetic was procaine, which was produced by Einhorn in 1905. Many compounds with comparable chemical structures were created after the launch of procaine. Procaine-like medicines such as tetracaine and chloroprocaine have remained clinically viable local anaesthetic medications to this day.[33] (dos Reis JR A et al)

Lofgren developed lidocaine in 1943, marking the beginning of a new pharmacological class of local anaesthetics. Lidocaine is a diethylamino acetic acid amide chemical, whereas procaine is an ester derivative of para-aminobenzoic acid. Since the discovery of lidocaine, many additional amide compounds have been used as local anaesthetics in clinical practise.[34]

Benjamin G & Covino in 1981, addressed the nature and mechsnisms of local anaesthesia. Local anaesthetic action is usally demonstrated by chemical substances that have the following molecular arrangement(Covino BG)[35] :

Aromatic portion----Intermnediate chain[l] ----Amine portion

AGENT	CHEMICAL CONFIGURATION			PRIMARY ANESTHETIC USE
	Aromatic Lipophilic	Intermediate Chain	Amine Hydrophilic	
A. Esters				
PROCAINE		$COOCH_2CH_2$		Infiltration
CHLOROPROCAINE		$COOCH_2CH_2$		Obstetrical Epidural
TETRACAINE		$COOCH_2CH_2$		Spinal
B. Amides				
MEPIVACAINE		NHCO		Infiltration Peripheral nerve block Surgical epidural
BUPIVACAINE		NHCO		Peripheral nerve blocks Surgical and Obstetrical epidural
LIDOCAINE		$NHCOCH_2$		Infiltration Peripheral nerve blocks Surgical epidural Obstetrical spinal
PRILOCAINE				Infiltration Peripheral nerve blocks Surgical epidural
ETIDOCAINE				Peripheral nerve blocks Surgical epidural

The reported action of duration of local anaesthesia is as follows:

Agent	Relative In Vivo Potency	Approximate Lipid Solubility	Duration (Min)	Approximate Protein Binding
LOW POTENCY — SHORT DURATION				
Procaine	1	< 1	60-90	5
INTERMEDIATE POTENCY/DURATION				
Mepivacaine	2	1	120-240	75
Prilocaine	2	1.5	100-240	55
Lidocaine	2	4	90-200	65
HIGH POTENCY — LONG DURATION				
Bupivacaine	8	30	180-600	95
Tetracaine	8	80	180-600	85
Etidocaine	6	140	180-600	94

Danielsson K et al tested bupivacaine 7.5 mg/ml + epinephrine 5 g/ml, etidocaine 15 mg/ml + epinephrine 5 g/ml, and lidocaine 20 mg/ml + epinephrine 12.5 g/ml for oral infiltration anaesthesia in 1985. Twenty healthy people took part in the experimental, double-blind investigation. One cc of the relevant anaesthetic solution was administered supra-periosteal in the apical region of the upper right lateral incisor. The period of soft tissue numbness was measured as well as the onset, frequency of analgesia, gingival spread, as well as duration of tooth analgesia. The onset of lidocaine was found to be shorter than that of bupivacaine. There was no change in frequency found. Soft-tissue numbness lasted longer with bupivacaine and etidocaine, although tooth analgesia lasted much less with lidocaine.[36]

According to Covino BG (1986), the most important clinical aspects of local anesthetic medicines are potency, onset, duration of action, as well as relative blocking of sensory and motor fibers. These traits are primarily due to the physicochemical characteristics of the particular compounds. In general, lipid solubility dictates a drug's relative intrinsic potency, whereas protein binding affects anesthetic duration and pKa is associated to the onset of action. These qualities are mostly owing to the physicochemical properties of the substances in question. In general, lipid solubility affects the relative intrinsic potency of different medications, whereas protein binding affects the relative intrinsic potency of other pharmaceuticals. In general, there are three types of local anesthetics for peripheral nerve blocking, extradural anaesthesia and infiltration,:1) Procaine and chloroprocaine are low-potency, short-duration agents; 2) Lignocaine, mepivacaine, and prilocaine are moderate-potency, long-duration agents; and 3) Amethocaine, bupivacaine, and etidocaine are high-potency, long-duration agents. The onset of these local anaesthetics varies as well: Amethocaine, Procaine, and bupivacaine have a longer latency period than mepivacaine, lignocaine, prilocaine, and etidocaine.[35]

Sisk AL in (1992) conducted review and reported that Long-acting local anaesthetics have been shown to be helpful for both intraoperative as well as postoperative pain suppression. They are beneficial for long-term dental treatments as well as the prevention of intense pain after a variety of surgical operations. There are possible concerns with the presently available long-acting local anaesthetics for dentistry, despite the fact that they have few adverse effects in the levels commonly used. Bupivacaine has the potential to cause serious cardiac depressive and dysrhythmogenic effects. Although etidocaine has a milder effect also on cardiovascular system, it has been linked to poor intraoperative bleeding management.

Ropivacaine, a newer long-acting local anaesthetic, appears to have advantages over the current long-acting drugs.[37]

Sisk AL in (1992) conducted a review and reported that the combination of a vasoconstrictor to an anesthetic agent have positive effects, including a reduction in local anaesthetic agent's peak plasma concentration, a rise in the duration and quality of anaesthesia, a reduction in minimum anaesthesia concentration required for nerve block, and a reduction in loss of blood during surgical events. The use of a vasoconstrictor in conjunction with a local anaesthetic may also be harmful. According to the literature, the concentrations of vasoconstrictors in the local anaesthetics marketed in the United States for dental usage aren't always ideal for the objectives they're added for. In most circumstances, a lower vasoconstrictor's concentration may accomplish the identical aim as a larger quantity available on the market, with fewer side effects.[38]

MacKenzie TA and Young ER in (1993) reported that the combination of vasoconstrictor with anesthetic agent have numerous positive effects, including a reduction in local anaesthetic agent's peak plasma concentration, a rise in duration and excellence of anaesthesia, a decrease in minimum concentration of anaesthetic required for nerve block as well as a reduction in loss of blood during surgical procedures. The use of a vasoconstrictor in conjunction with a local anaesthetic may also be harmful. According to the literature, the concentrations of vasoconstrictors in the local anaesthetics marketed in the United States for dental usage aren't always ideal for the objectives they're added for. In most circumstances, a lower vasoconstrictor's concentration may accomplish the identical aim as a larger quantity available on the market, with fewer side effects.[39]

Hersh EV et al in (1995) conducted a study to compare in an effort to reduce the period of mandibule soft tissue anaesthesia, researchers compared the duration of soft tissue anaesthesia generated by solutions of 3 % mepivacaine or 4 % prilocaine with out vasoconstrictor in paediatric patients to that of 2% lidocaine with 1:100,000 epinephrine throughout sixty adults. When 3 % mepivacaine or 4 % prilocaine was used instead of two percent lido-epi, there was no difference in the period of soft tissue anaesthesia. When doing mandibular block injections for young children, the authors propose using 2% lido-epi, based on their findings and local anaesthetic dosage considerations.[40]

Becker DE and Reed KL in (2012) reported that in medical as well as dental practise, local anaesthetics have such a long history of safety and efficacy. Because its usage is so common, and side effects are so uncommon, clinicians may neglect most of their pharmaco-therapeutic principles. In their review they discussed about onset of anaesthesia, duration of action, metabolism and elimination of the agent from the body, toxicity associated with local anaesthesia and interaction of these agents with other drugs. The review helped to update essential pharmacology for the various local anaesthetic formulations.[10]

Mumba JM *et al* in (2017) presented a summary of the findings which jotted few points that local anaesthetics prevent pain from being transmitted from nerve endings towards the CNS (Central Nervous System) . Based on the bridging chains between both lipophilic aromatic ring and also the hydrophilic amine group, they are classed as esters or amides chemically. The rapid voltagegated sodium channels are blocked as the principal method of action. The nonionised fraction of the medication cross the lipid membrane of the axoplasm and closes the channel intracellularly to cause this

effect. The period & intensity of the block are determined by the agent's volume and concentration. pKa, lipid solubility, protein binding, pH, and the size of the intermediate chain are all factors that affect the efficacy of local anaesthetics. Adjuncts including such adrenaline, opioids, alpha 2adrenergic agonists (clonidine), and alkalinization can improve efficacy. Toxicity is dependent on the injection site, the vascularity of a site, and the dose injected. Vasoconstrictors may help to minimise toxicity by reducing systemic absorption. Racemic bupivacaine does have the great affinity for sodium channels of all the local anaesthetics drugs in clinical usage and it is the most challenging to treat in the case of systemic toxicity.[41]

Giovannitti JA *et al* in (2013) provided a thorough examination of a pharmacology of local anaesthetics as a class, as well as specific information on the medicines available in dentistry cartridges For healthy adult and paediatric patients, as well as patients with cardiovascular system (CVS) impairments, maximum suggested doses of local anaesthetics and vasoconstrictors are presented. Various consequences and reasons for local anaesthesia failure were examined, as well as present and future advances in local anaesthetic to get an overview of the current local anaesthetic research. In the present oral and maxillofacial surgery model, local anaesthetic remained the basis for pain control in dentistry, especially when paired with moderate-deep anesthesia for invasive & painful operations. Local anaesthetics are also the safest and most efficient pain relievers in medicine and dentistry. Clinicians do have basic clinical framework to improve patient care only if they have a good understanding of pharmacology as well as anatomy. [42]

3. Local anaesthesia implications

Moore KD et al in (1987) reported a study that assessed the anaesthetic efficacy of a periodontal ligament injection with 2 percent lidocaine, 1:100,000 epinephrine, & saline on human mandibular premolars using an electric pulp tester. An injection containing 2% lidocaine with 1:100,000 epinephrine into the periodontal ligament was proven to be effective approach for anaesthetizing mandibular 1st premolars. The period of profound pulpal anaesthesia, on the other hand, was about 10 minutes. The use of sterile saline to inject the periodontal ligament was shown to be ineffective as a method of anaesthetic. This injection technique may also anaesthetize teeth adjacent to and distal to the infiltrated tooth. In clinically healthy teeth, the early needle penetration and anaesthetic solution administration were just mildly uncomfortable. Just after periodontal ligament injection, there was no improvement in tooth mobility 45 minutes later. Three weeks following the injection, there was no clinically visible pulpal or periodontal damage.[43]

Zacharias M et al in (1996) conducted a clinical trial on Patients who had third molar teeth extracted under general anaesthesia had administered a placebo, inj. diclofenac (a nonsteroidal anti-inflammatory medicine) 100 mg, or methadone (an opioid) 10 mg 60 to 90 minutes before surgery, and their pain levels and postoperative medication needs were tracked for three days. During the preoperative period, all patients got local anaesthetic blocks and analgesic medications. During the trial, were there no significant variations in pain scores or medication requirements across the three groups. According to the findings, preoperative usage of nonsteroidal anti-inflammatory medications and opiates may not have a preemptive analgesic benefit in patients who have received appropriate analgesia during surgery . It is possible that continued usage of analgesic medicines during in the postoperative period will be

more beneficial in this regard. Because opiates (methadone) appear to cause more vomiting, they are not recommended for usage in day-care patients.[44]

Ribotsky BM *et al* in (1996) conducted a study to determine the advantages of the effects of mixing 50/50 lidocaine and bupivacaine instead of utilising the two solutions separately on the initiation and termination of local anaesthesia were studied. Twelve volunteers, each offering both feet, were evaluated in a double-blind randomised trial. One foot received a blinded control injection of 1 ml of one of three solutions: 1% plain lidocaine, 0.25 % plain bupivacaine, or a 50-50% combination of 1 % lidocaine and 0.25 % bupivacaine. Sensory blockage was tested with a 5.07 (10 g) "Semmes-Weinstein" monofilament wire, and also the initiation and duration of anaesthesia were documented for each patient. The average onset durations for the 3 solutions were found to be identical, as were the durations of anaesthesia for plain lidocaine as well as the 50/50 mixture. In addition, bupivacaine was found to have a longer duration of anaesthesia than other two solutions. The findings of this pilot investigation suggest that utilising a 50/50 blend of plain lidocaine & plain bupivacaine instead of their separate use had no therapeutic benefit in terms of onset and duration for local blocking.[45]

Daublander M et al in (1997) conducted a study to among 2731 patients receiving dental anesthesia to evaluate the risk factors, the type & dosage of local anaesthetic used, the type and length of treatment, and problems related to local anaesthetic delivery 45.9% of all patients had at least 1 risk factor with their medical history, the most common of which were cardiovascular illnesses and allergies. Complications occurred in 4.5 percent of the cases. It was significantly greater (5.7%) in high-risk patients than in low-risk patients (3.5 percent). The most common side effects (nausea, dizziness, tachycardia, agitation, and tremor) were all temporary and didn't

require treatment. . Furthermore, it was shown that local anaesthetic doses were not rigidly regulated by body weight, particularly in patients with weight less than 50 kg. It was concluded that if patients are regularly assessed for risk factors, local anaesthetic doses are strictly determined, anaesthetics with low epinephrine concentrations are used, and the concept of differentiated dental anaesthesia is applied, dental local anaesthesia can be considered safe and complications can be reduced.[46]

MacMillan CS and Wildsmith AJ in (2000) conducted a study a survey of NHS anaesthetists delivering out-patient anaesthetic for dental treatments in children under the age of ten was conducted. Information on the quality care and common practice in Scotland was sought. Although the anesthesiologists involved in this work had a lot of experience, the monitoring they employed did not satisfy contemporary standards, only with 16% of respondents saying that they used a full number of standard instruments. Although 99 percent had separate recovery facilities and all had accessibility to a defibrillator, 14 and 30 percent, respectively, lacked the skills of dedicated assistance and recovery workers. In up to 71 percent of cases, intravenous access was not acquired routinely after inhalational anaesthetic induction (49 percent , never; 22 percent , sometimes). 88 percent employed central analgesia or local anaesthesia. The duration of the discharge ranged from 10 minutes to 6 hours.[47]

Lee S et al in (2004) conducted a prospective, randomised, blinded trial to compare the anaesthetic efficacy of a computer-assisted Wand Plus injection system to a traditional syringe for the anterior middle superior alveolar (AMSA) injection. The use of a computer-assisted injection(CAI) method was considerably more likely to succeed in pulpal anaesthesia than the traditional syringe technique for all teeth except the central incisor. Successful pulpal anaesthesia ranged from 35 to 58 percent for

computer-assisted injection device, and 20 to 42 percent for the conventional syringe. The initiation of pulpal anaesthesia was delayed with both procedures, and the duration of pulpal anaesthesia decreased consistently over 60 minutes. Although the (AMSA) injection via CAI was more effective than the conventional syringe technique, the, slow onset, decreasing duration of pulpal anaesthesia, low success rates, and above 60 mins did not guarantee predictable pulpal anaesthesia from 2nd premolar to the central incisor.[48]

Kaufman E et al in (2005) conducted a review and reported that Procedures that were not possible under LA were usually done under GA. The decoding of afferent connection of peripheral noxious sensations has produced vital insight that could revolutionise how everyone treats surgical pain in the future. Preemptive peripheral blockage of painful (nociceptive) inputs to the CNS using regional anaesthesia or LA and nsaid analgesics was recommended in animal experiments in the 1980s as a way to reduce postoperative pain. Clinical trials based on this information advise mixing LA with GA, as well as perhaps non-steroidal nsaids with and without narcotics, to lessen postoperative pain severity. When general anaesthetics, coupled with LA can be administered with a lower minimum alveolar concentration and have better recovery characteristics. Preemptive analgesia may decrease postoperative pain that should be used in care delivery, according to growing evidence that combining General anaeshesia and LA may decrease the afferent onslaught of surgery. The evidence for using LA or analgesia with General anasthesia or sedation to assist pain control after surgery was evaluated in this paper.[20]

OZMEN O *et al* in (2013) conducted a studyto see if adding 2% lidocaine to 0.5% bupivacaine, which is utilised in lateral sagittal infraclavicular block, reduces the anasthesia onset time, drug effect time, as well as drug activity when used in upper

extremity surgery, as compared to bupivacaine alone. This study included 120 patients who had been 18–65 years old and planned to have upper extremity surgery and were classified as I–II by the American Society of Anesthesiology. The study's group testing was as follows: The bupivacaine, bupivacaine + lidocaine, and lidocaine groups utilised , 20 mL (20 mg/mL) lidocaine, 10 mL (20 mg/ml) lidocaine +10 mL (5 mg/mL) bupivacaine , and 20 mL (5 mg/mL) bupivacaine respectively. The bupivacaine group's block initiation time was determined to be extremely protracted. The lidocaine and bupivacaine + lidocaine groups developed motor block the fastest. The lidocaine group had the fastest motor block regression, while the bupivacaine + lidocaine group had the slowest. The bupivacaine + lidocaine group and the lidocaine group lost their cold and tactile senses the fastest. The bupivacaine Plus lidocaine group had the quickest loss of pain perception. The bupivacaine + lidocaine group had the longest postoperative analgesia requirement time. There were no significant variances in ratings of satisfaction. In comparison to bupivacaine alone, lidocaine added to bupivacaine dramatically reduced the block onset time and prolonged the postoperative analgesia required time with no adverse effect.[49]

Yadav S et al in (2013) aimed to demonstrate if a single buccal injection of 2 percent lidocaine hydrochloride with 1:200,000 epinephrine might produce palatal anaesthetic in maxillary tooth extraction. Patients who needed their maxillary third molar extracted on either side were enrolled in the clinical investigation. The groups were divided randomly in; group one (study group) contained participants who would receive single injection prior extraction, and group two (control group) included subjects who would receive a single buccal and palatal injection prior extraction. The extraction was completed after 5 minutes. During extraction, all patients was evaluated for Faces Pain Scale and questioned for same on the 100-mm

visual analogue scale(VAS). When maxillary wisdom teeth extraction with palatal infiltration (control group) and without palatal infiltration (study group) were compared using VAS and Faces Pain Scale ratings, the reasult difference was not statistically significant. It was discovered that injecting 2 mL of 2 percent lidocaine hydrochloride with 1:200,000 epinephrine to a buccal vestibular region of the tooth allowed removal of maxillary wisdom teeth without palatal injection.[50]

Balakrishnan K *et al* in (2015) conducted a literature review which discussed bupivacaine's analgesic and anaesthetic properties compared to lignocaine's while surgical extraction of impacted third molars Both bupivacaine as well as lignocaine have advantages and disadvantages, but clinical trials have proven beyond a shadow of a doubt that bupivacaine offers better and longer post-operative analgesia and anaesthesia during minor surgery performed at the chairside, such as surgical extraction of impacted wisdom teeth. As a result, bupivacaine can be used as an anaesthetic solution in combination with adrenaline 1:200,000 during surgical extraction of impacted 3rd molars, as long as the dosage and cardio depressant properties of bupivacaine are considered. More research is under underway.[51]

Dhanrajani P and Chung P in 2016 conducted a study to assess the efficacy and duration of two doses of bupivacaine against adrenaline for post - operative pain in individuals who had four third molars surgically removed under general anaesthesia. Bupivacaine 0.5 percent (n = 30) or 0.25 percent (n = 30) was given to 60 patients underwent surgical extraction of four wisdom teeth. The VAS was used to record the level of pain during the early recovery period, as well as at 2 and 24 hours after surgery. The analgesia effects of both the 0.25 percent and 0.5 percent doses were observed to differ considerably at 30 minutes after surgery, but not at 2 or 24 hours.

The study concluded that bupivacaine 0.5 percent was statistically superior for pain control in the early postoperative period, and there was no statistically significant difference in pain treatment at 2hours and 24hours following surgery.[52]

Agarwal P *et al* in 2017 compared the usage of bupivacaine and lignocaine impacted mandibular wisdom teeth surgical removal This was a randomised, study wherein; 50 individuals with impacted mandibular 3rd molars were allocated into 2 groups at random. In a double-blind study, 0.5 percent Bupivacaine with no vasoconstrictor & 2 percent lignocaine plus 1:80,000 adrenaline was utilised. During surgery, all necessary parameters were recorded, and all patients were given questionnaires to assess the onset of anesthesia, the time of full numbness departure, pain perception, and postoperative analgesic necessity. Bupivacaine was found to have a statistically significant longer duration of action & more painless period postoperatively, as well as a lower pain intensity and lower postoperative analgesic demand. When compared to bupivacaine, its onset of anaesthesia were faster with lignocaine. According to the findings, bupivacaine has greater pain management, a longer duration of anaesthesia, lower postoperative pain, and a lower analgesic demand than lignocaine. It is desirable to use bupivacaine for minor oral surgeries such as the removal of impacted teeth.[53]

Adelusi EA *et al* in 2019 assessed the pain control of 0.5 percent Bupivacaine versus 2 percent Lidocaine. This was a randomised controlled trial that looked at patients who had intra-alveolar tooth extraction. There were 126 participants in each of the two groups: Bupivacaine and Lidocaine. The Numeric Rating Scale was used to assess pain (NRS). The data was examined with SPSS, and statistical significance was set at P0.05. Although post-operative pain was measured between 3 and 12 hours after extraction in the Lidocaine group, there was a considerable improvement, however

in Bupivacaine group, there was essentially no pain for the first 8 to 9 hours. In the Bupivacaine group, there was a considerable reduction in the demand for post-operative analgesics. The Bupivacaine group had significantly higher overall patient satisfaction. According to the findings, bupivacaine appears and provide more effect post-operative pain relief after intra-alveolar tooth extraction.[54]

Halling F et al in 2021 conducted a study to compare use of dental anaesthetics solution in Germany with data from other countries The findings were matched to data on dental local anaesthetic intake published internationally since 2005. Articaine was the first choice local dental anaesthetic agent in Germany, with a market share of over 98 percent. During the period of study, German dental local anaesthetics containing epinephrine 1:200,000 had a market share of 50%, whereas formulation containing epinephrine 1:100,000 had a market share of 40% to 45 percent. Articaine was also the favoured anaesthetic agent in a number of other nations, with market shares ranging from 38 percent to 81 percent, with the significant exceptions in the United Kingdom(UK) and the United States(US), where lidocaine had been the choice of local anaesthetic agent. In a similar fashion to Germany, epinephrine was the primary vasoconstrictor worldwide. The growing number of medically impaired individuals, the increased market share of concentrated epinephrine 1:100,000 were impressive. The use of medicines with lower epinephrine doses (1:200,000) should be given further thought.[55]

Kaul R et al in 2021 conducted a study to assess dentists' attitudes toward infection and and control when treating adolescents and children by evaluating their recommendations for pre- and postoperative antibiotics and analgesics , as well as their use of local anaesthesia (LA) for therapeutic intervention in various clinical scenarios. Over the course of two months, 400 dentists, including general dental

professionals (GDPS) and speciality dentists, were polled. GDPs were found to be overusing antibiotics and analgesics while underusing LA as compared to expert dentists. Antibiotics and analgesics was administered more frequently after surgery than antibiotics and analgesics before surgery. With the exception of LA, that was used equally frequently in both primary and permanent dentition, all methods were employed more frequently in permanent dentition than deciduous dentition. The researchers came to the conclusion that children's reliance on analgesics and antibiotics for infection and pain and control should be reduced, and that the focus should be switched to appropriate final therapy incorporating the use of aseptic methods, LA, and behaviour management strategies.[56]

Alanazi FS et al in 2021 conducted a study to investigate In Saudi Arabia, dental practitioners favour topical and local anaesthetics for youngsters. A total of 274 replies were obtained from The Saudi Arabian dental professionals, with 92.3 percent preferring lidocaine and the majority (57.7%) considering accurate bodyweight when choosing local anaesthesia. The majority of participants (46.3 percent) chose 27 gauge needle for infiltrations and blocks (63.9 percent). The majority of dental practitioners (93.4 percent) favoured short needles for local infiltration, while long needle injections (83.9 percent) were favoured for nerve blocks. The majority of dental practitioners chose benzocaine (68.2%) for topical anaesthetic, while 55.8% of them had no idea what brand of topical anaesthesia they were just using. Prior to the delivery of local anaesthetic, the majority of dental professionals believed that topical anaesthetic was successful, and 83.6 percent of Arabian dental practitioners reported that patients complained about the taste of topical anaesthesia. Regarding the anaesthetics used, there were mixed viewpoints among occupations and genders of dental practitioners. The most generally desired type of local anaesthetic was

lidocaine, while the most commonly chosen type of topical anaesthetic were benzocaine in gel form, according to the dental practitioners' judgments and preferences.[57]

Anxiety and fear among dental patients

Edmondson HD et al in 1972 conducted a research project aimed at determining the biochemical signs of anxiety in dental patients. Urinary metabolites were studied in a group of individuals having dental phobia as well as a matched control population before and after dental treatment. Before therapy, directly following sedation using diazapam 0.2 mg/kg body weight in phobic patients, during initiation of oral anaesthesia effect, and during as well as after surgery, noradrenaline, plasma adrenaline, and free fatty acids were measured. The findings demonstrated that individuals with dental fear had much greater levels of adrenaline than control patients, which were only momentarily reduced by sedation and remained continuously higher after treatment.[58]

Luyk NH et al in 1988 conducted a study By association with dental anxiety anxiety scale (DAS) and state component (A-state) of statetrait anxiety inventory, evaluate the accuracy of visual analogue scale (VAS) in evaluation of shifting levels of dental anxiety (STAI). Forty-five adult patients who were scheduled for a normal dental extraction at an oral surgery clinic took part in the study. Each patient performed the DAS,a 100mm VAS and STAI prior to any treatment. The administration order was chosen at random. Patients were asked to complete DAS, A-State, and VAS, which were all randomly arranged, after the dental extraction was completed under local anaesthetic and soon before discharge. From presurgery to postsurgery, all three

measures show a significant decrease in mean anxiety scores. Both before and after surgery, there were substantial relationships between the three variables.[59]

Willershausen B *et al* in 1999 tested fear of treatment among patients, and the results were matched to clinical data on dental health and oral hygiene behaviours. Sixty-five percent of the patients said they were afraid of dental treatment. Patients who were younger exhibited a higher dread of therapy than those who were older. Noise as well as vibration of drill (56 percent), sight of the needle injection (47 percent), and sitting in treatment chair (42 percent) were all cited by patients as particularly frightening. As a result, the findings of the study clearly advised that more preventive measures to reduce the fear levels of dental treatment.[60]

Kudo M in 2005 conducted a study to understand the association between injection pressure & pain, as well as injection pressure and anxiety, researchers measured injection pressure, anxiety, and pain before injecting a local anaesthetic into the oral mucosa. A 12 mm 30-gauge disposable needle linked to a computer-controlled local anaesthetic delivery system (the Wand) were utilised on twenty-eight healthy men. Injection pressure was monitored three seconds after start of the local anaesthetic injection, pain and anxiety was assessed. The injection pressure was continuously monitored in real time. To reduce anxiety and pain among dental patients, it is recommended that local anaesthetic be given at a low pressure (< 306 mm Hg).[61]

Oosterink FM *et al* in 2008 assessed the differences in connection to level of dental anxiety , gender, age and ethnicity to build a ladder of anxiety-provoking capacities of vast range of dental stimuli. In addition, the study intended to calculate the number of stimulus that should be shown to worried individuals in order to cover all of their dental worries. A questionnaire listing sixty seven potentially anxiety-provoking

stimuli was created and given to 960 adults for the same purpose. Invasive stimulus were shown to be the most anxiety-provoking, while non-invasive stimulus were found to be the least. The fear-inducing potential of dental stimuli differed by ethnicity, gender, age & amount of dental treatment anxiety, but rank order among these stimulus appeared to be unaffected by these variables. Furthermore, only eight (28%) stimuli were detected in the top twenty five most anxiety-provoking objects and circumstances.[62]

Van Wijk AJ and Hogstraten J in 2009 conducted a study to investigate the link between pain and anxiety experienced during a dental injections in a group of 'normal' patients who were ready to undergo invasive dental treatment. A total of 247 patients were studied to see how long and how intense their discomfort was throughout a dental injection. In addition, information on fear of dental pain, dental anxiety, kind of therapy, anaesthetic fluid volume, injection site, and use of surface anaesthetic was gathered. The findings revealed that nervous individuals had higher pain and for a longer period of time than the less anxious patients. Fear about dental pain could explain for 28% of the variation in the period of pain reported. According to the findings, some patients are likely to experience more pain during dental injections and would benefit from additional care and attention from the dentist.[63]

Siddiqui TM *et al* in 2016 conducted a study toTo assist in providing better care to patients, analyse the severity of phobia of needles and evaluate the many dimensions of anxiety of dental injections. 250 adult patients over the age of 18 were chosen from the Baqai Dental College's outpatient Department of Operative Dentistry. A modified version of Milgrom et al structured questionnaire was created. The items were graded on a typical 5-point Likert scale. There was a significant difference in dread of dental injections between male and female individuals, according to the findings. Fear of

cross-infection was discovered to be the most frightening component of dental injection. The patients' least prevalent fears were those related to local anaesthetic, such as insufficient numbness, unpleasant reactions, and difficulty breathing or swallowing. It was determined that dentists must have a better grasp of the nature and depth of their patients' fear of injections in order to improve their knowledge of the influence of fear of dental needles on treatment outcomes and patient reluctance to intervene.[64]

Alternative techniques for administration of anaesthesia

Yesilyurt C *et al* in 2008 conducted a study to compare the Wand with a conventional syringe for determining pain associated with needle insertion during inferior alveolar nerve (IAN) block. 40 patients were included in the study. Wand or sa conventional syringe was used for administration. Pain rating score (PRS) and a visual analogue scale (VAS) were used for analyzing pain. According to the findings, the Wand technique was shown to be less painful than that of the syringes for needle penetration and injection, implying that Wand technique showed significantly lesser pain levels after IAN block injections. For future dental injections, most patients chose the IAN injection technique with the Wand.[65]

Shah M *et al* in 2012 conducted a study to compares a group of ten subjects' pain response to the Wand (®) with the reactivity to typical syringe injections, as well as the size of the area anaesthetized. For the trial, 10 patients were chosen and 20 injections were delivered to them contra laterally, 10 with Wand (®) and the others with a standard aspirating syringe. Each individual had two injections on the palate, one with a Wand (®) (test) and the other with a traditional syringe on the left side (control). Pain perception was measure with VAS. In 2 of 10 subjects, injections with

the Wand (®) were less painful than injection with syringe. Except in two individuals, the amount of the area anaesthetized by both procedures was similar. Wand (®) injections were found to be less uncomfortable; however, mean pain ratings for both groups were mainly below the bothersome level of discomfort.[66]

Langthasa M *et al* in 2012 compared pain perception of children patients during dental clinical procedures using a computerised injection device called a comfort control syringe (CCS) and a traditional injection approach. This study included 50 patients aged 6 to 14 years who required local anaesthetic on both side of dental arch for multiple treatment procedures. The patients acted as their own controls, with CCS on one side of arch and conventional injection technique was utilised on the next appointment. The child's pain response to each of the procedures was assessed using and the faces pain rating scale (FRS) and the visual analogue scale (VAS) right after the injection. The results demonstrated a significant difference on AVS and FRS. No statistically significant difference was found in psychological parameters, implying that the CCS is better over conventional technique for reducing pain perception.[67]

Raslan N and Masri R in 2017 examined the pain levels generated by different types dental anaesthetic injections, as well as the efficacy of the "Dentalvibe" on lowering injection pain. Each of the 40 children in the research took six shots. Groups were; buccal & palatal region infiltration on maxilla and IANB with vibration, and same without vibration. The FLACC and the WongBaker facial pain scales were also used to assess pain. According to the (TR) approach, there were no statistically significant changes in subjective & objective evaluation independent of injection site. Although the (DV) method produced lower pain scores than the standard method in the majority of injection, the difference were also not statistically significant. According to the findings, the Dentalvibe did not lower discomfort or increase kid acceptance.[68]

Ghaderi F and Ahmadbeigi M in 2018 conducted a study to Compare and contrast pain perception in dental injections using Smartject vs. traditional techniques. A randomised single-blind crossovers clinical trial was used in the study. A total of 50 healthy dental students volunteered to take part. On one side (control), they received a topical anaesthetic agent plus injection in the region of maxillary premolar buccal mucosa using traditional technique, whereas on the other side, they received a topical anaesthetic agent plus injection in the upper premolar buccal mucosa using Smartject (experimental). The VAS score between Smartject and the traditional approach was shown to be statistically significant different. The VAS ratings with Smartject and the traditional method were 14.57.3 and 241.21, respectively. According to the findings, needle penetration isn't the primary cause of pain during injections. Pain generation is aided by the inconsistency of fluid pressure caused by injected anaesthetic solution on nerve fibres. As a CCLAD, Smartject can thus be regarded a suitable dental device.[69]

Yamashita Y *et al* in 2020 conducted undertook a clinical trial to see if virtual reality (VR) may help patients relax during impacted third molars teeth extractions under local anaesthetic. For fifty one patients underwent impacted mandibular 3rd molar extraction under local anaesthetic, virtual reality was used to reduce anxiety about the procedure. A questionnaire with a VAS, 5-point Likert scale to assess anxiety, fear and satisfaction before and after treatment were used. Anxiety levels were shown to be lower in VR group, with difference of -13.3, 28.7 mm in anxiety levels assessed by VAS before & after therapy. In the 49 individuals who had not utilised VR, however, it had raised by 4.0 22.3 mm. Furthermore, 92 percent of the VR group claimed that their anxiety had lessened after treatment, according to the post-treatment procedures, particularly extractions and surgical procedures.[70]

Rizzo-Lorenzo A *et al* in 2020 assessed the level of anxiety after learning about the Wand system's operation. Second, pain perception and the necessity for re-anesthesia were evaluated. The experimental group (full description of The Wand) and the control group were assigned to patients at random (no specific information). A supraperiosteal infiltrative method injection of 1.6 mL on buccal side and 0.2 mL on palatal side provided local anaesthetic using The Wand. In comparison to patients who got no information, patients who received a full description of The Wand had no significant reduction in anxiety or perceived discomfort during the anaesthetic act, according to the study. The requirement for re-anesthesia was not linked to anxiety levels, however it was linked to a longer operative time.[71]

Use of Needle-free anaesthesia

Saravia ME & Bush JP in 1991conducted a study on the efficiency of anaesthesia as well as patient preference in paediatric dentistry patients. 34 r youngsters ranging in age from 5 to 15 years were the participants, and 45 dental treatments were performed on them. There was a statistical difference in favour of Syrijet, a tool that provides anaesthetic without the need of a needle. Twenty-five participants said they preferred this strategy. In 36 of the 45 surgeries, the instrument provided full anaesthesia.[72]

Weintraub AM and Leon MPP in 1998 performed a study to determine whether in-vitro reuse of the needleless injection is associated with cross contamination. Another objective was to assess if manufacturer's technique of decontamination is effective. Fluorescein dye, freshly autoclaved injectors, and Streptococcus crista were utilised in the experiment (bacteria found in saliva). The study discovered significant contamination of needleless injectors occurs during in vitro use and contact with contaminated surfaces. Moreover, contamination is transferred over to successive

release locations. The removing the rubber cap that has got exposed, as well as soaking of the injector head in 2% glutaraldehyde followed by sterile water rinse can reduce carryover.[73]

Munshi AK et al. in 2001 evaluated the comfort of administration with the needle-less jet injector for both the doctor and the patient, as well as the effectiveness of anaesthetic provided by the needle-less syringe. In order to compare the efficiency of the needle-less jet injector (Madajet XL), one hundred children of age 3 to 12 years old were treated with it. The ease of administering local anaesthetic with the needle-less jet injector was found to be much more pleasant by both the doctor and the patient. The needle-free jet injector was thought to be much more effective for the procedures performed. The patient's pain perception was greatly reduced by the use of a needle-free jet injector for the treatments performed, and no post-operative problems or side effects were noted after the procedures were completed.[74]

Splinter WM stated in 2002 that jet injection or needleless injection for medication had a fairly limited clinical use in children's healthcare outside of bulk immunizations. Local anaesthetic agents, sedatives (midazolam), and anaesthetic induction agents are among the medications delivered into children using a needle-free technique (ketamine). According to reports, local discomfort is frequently modest, and expenditures are often minimal. The risks connected with this easy and adaptable procedure are thought to be far lower than those linked with alternative approaches like syringe and needle. Additional research was required to corroborate initial claims and determine current and other usage of jet injectors in youngsters.[75]

Dabarakis NN et al. in 2007 evaluated jet injection (Injex) with two different anaesthetic solutions and compared it with conventional injection techniques with the

use of needle. Ten patients received 3%mepivacaine solution through Injex and 22 received 2%lidocaine + epinephrine 1:80,000. The injection of 3% mepivacaine did not lead to pulpal anesthesia in Injex group however, soft tissue anesthesia was effective. Only 14 patients experienced pulp anaesthesia after receiving lidocaine and epinephrine via Injex; all patients in this group experienced soft tissue anaesthesia. Statistically remarkable difference was not present in onset of anaesthesia between Injex and the needle injection technique. However, the needle infiltration group's anaesthesia lasted substantially longer than the Injex injection group's. When using the Injex approach, it was deduced that the anaesthetic solution should be coupled with a vasoconstriction agent.[76]

Arapostathis KN et al. conducted a study in 2010 to investigate children's acceptability and desire towards needleless jet-injection against traditional technique of local infiltration, and to assess the efficacy of anaesthesia. A split-mouth design was used to study 87 nonfearful children who had never had dental anaesthetic before. The initial dental treatment was carried out under traditional infiltration anaesthesia. In a second appointment 1 week later, the same amount of anaesthesia was supplied using the INJEX needleless device, and a second dental surgery was performed. The INJEX approach received more unfavourable feedback. The traditional method was favoured by the majority of the children (73.6 percent). 80.5 percent of the 87 treatment procedures tried after using INJEX required further anaesthetic, compared to 2.3 percent of those attempted after conventional infiltration. When compared to the needleless INJEX, traditional infiltration was much more successful, acceptable, and preferable.[77]

Langthasa M et al. (2012) compared young patients' pain perception while using a computerised injection device comfort control syringe (CCS) and a traditional

injection technique in dental clinic for the procedures. 50 children aged 6−14 years requiring with requirement of anaesthesia for various procedure on both sides. Statistical difference in pain using VAS as well as FRS comparing the computerised and traditional techniques was present. No statistically significant difference was found with respect to physiological data between groups. It was determined that the CCS is better over traditional injection approach to reduce pain.[78]

Makade CS et al. (2014) studied tolerance and choice in adults of needleless jet-injection against standard infiltration, and the efficacy of needleless anaesthetic. The split-mouth design was used to study twenty non-fearful adults who had never had dental anaesthetic before. The initial procedure was carried out under traditional needle infiltration anaesthesia. According to the findings, pressure anaesthetic was approved and favoured by 70% patients over regular needle anaesthesia (20 percent). For the dental treatments, both needle as well as pressure anaesthetic were equally effective. Patients reported significantly reduced discomfort and fear (p0.01) during anaesthetic procedures with pressure anaesthesia. However, needle anaesthetic are more effective for more invasive treatments.[79]

In 2014, Kale TR published a study on needle-free injection technology as well as its uses, merits over needle injections, components, and kinds like liquid injection, powder injection, depot injection, and projectile injection. The article went into detail on a needle-free injection approach that uses pressurised gas to provide force for activation in order to distribute drugs at high speeds through a nozzle. It was possible to gain an assessment of marketed goods, recent trends, and additional needleless medication administration systems. It was concluded that needle-free injection techniuqe is advancing and can make medication administration more convenient, safe and effective.[80]

In 2014, Chong BS et al published a review of different local anaesthesia administration aids, , devices and systems meant to reduce painful injection. Needleless jet-injector systems, vibrating supplementary devices and aids such as Wand Plus, computer controlled local anaesthetic delivery devices, Vibraject , Sleep One and QuickSleeper handpiece, comfort control syringe, anaeject as well as anaeject II, cartri-ace pro were among the alternatives proposed. It was acknowledged that no injection technique was completely painless because the mere concept of going to the dentist and obtaining treatment may enhance the patient's experience of pain. Needleless jet-ijector devices did not relieve pain appreciably and can only achieve a limited level of anaesthesia. Limited studies and a substantial lot of researches on C-LAD devices aided in the development of vibrating devices as well as supplementay aids revealed that they were beneficial in reducing injection pain.[81]

Angelo Z et al. (2018) conducted a review and found that dentists use local anaesthetic (LA) via needle injection to prevent pain. Unfortunately, worry and dread that emerge before to and/or during injection continue to prevent many kids and parents from seeking dental care. Electronic dental anaesthesia, Topical anaesthesia,, jet-injectors, iontophoresis, as well as computerised control local anaesthesia administration systems are the most well-known alternate techniques of administering anaesthetic in dentistry. Despite the fact that these procedures are widely accepted by patients, the authors believe that the effectiveness and practicality of such approaches in general dentistry has limitations.[82]

Tawil SBE and Dokky NAE conducted a study in 2018 to assess pain perception in a group of children dental patients after receiving Jet injection (INJEX). The study involved 58 teeth from 39 children. The youngsters in the research required local anaesthetic for a variety of dental operations. The INJEX needleless device was used

to give anaesthesia after a topical anaesthetic gel was applied. No statistical difference in pain levels between treatment modalities was present. However, when boys and girls were compared, guys had a statistically remarkable higher pain score than that of girls during preparation of cavity only. It was deduced that local anaesthetic utilising INJEX resulted in low pain sensitivity during various dental operations.[83]

Abd Ellatif EM in 2018 conducted a randomised controlled experiment to compare a needle-free injection method to a traditional injection technique for performing anaesthesia in children. The results showed that patients treated with the unnecessary injection system experienced less postoperative discomfort than patients treated with the traditional injection technique. It was concluded that the unnecessary injection system procedure will always be more acceptable by children patients with less postoperative pain than the conventional one.[84]

Gupta R et al. (2018) investigated the anaesthetic effect of mixture of 25 mg/g lignocaine and 25 mg/g prilocaine (EMLA) with needleless jet anaesthesia during scaling and root planing (SRP). The study included 30 participants and probe depths of 5 mm. The visual analogue value difference between control, EMLA, as well as Madajet XL was fairly large. 6.7% of the EMLA group had no pain, 80% with mild and 13.3% with moderate pain on VRS. Madajet XL group; 46.7 percent had no pain, while 53.3 percent experienced minor pain. When no anaesthesia was supplied, 100% patients in the control group felt moderate discomfort. None of them experienced serious pain. The findings indicated that both anaesthetics were capable of producing tissue anaesthesia. In comparison to EMLA, needleless anaesthesia performed relatively well.[85]

Oliveira ACA et al. did a study in 2019 to assess the level of discomfort during anaesthesia administration and to use two anaesthetic methods in the maxilla, calculate the latency time length of pulpal anaesthesia among 41 subjects with class I restorations in 1st maxillary molars. Groups were;1- needleless jet injection metho, 2-carpule syringe and short needle.Eelectrical stimulation threshold (mA) and degree of discomfort were not significantly different between the two methods of anaesthesia. The latency duration was 2 minutes among all subjects. The duration of pulpal anaesthesia did not differ significantly (in minutes) between the two treatments, with the older approach lasting longer. The discomfort felt during anaesthesia was confirmed to be the same for both anaesthetic methods.[86]

In 2020, Theocharidou A performed a research to compare the effectiveness, acceptance, and preference of a needleless jet anaesthetic device with a standard infiltration procedure (Comfort-In). Non-fearful healthy adult volunteers between the ages of 19 and 40 were recruited, as well as maxillary premolars were chosen. Both approaches were used from either side of the same operator on the same day. 63 teeth were treated with traditional local infiltration, while the remaining 63 were treated with Comfort-In. Both approaches had comparable anaesthetic efficacy after 3, 5, 10, and 15 minutes, with the conventional technique being more effective at 20 minutes. Both demonstrated similar acceptance, with the exception of more pain/discomfort following Comfort-In administration. The conventional procedure was preferred significantly more immediate just after session, 24 hours later, and 7 days later. The incidence of ecchymosis and lacerations was reported by 19 volunteers (30.2 percent) in experimental group, while 5 (7.9 percent) using the usual approach (p0.0001). Conventional infiltration was found to be preferable over needleless anaesthesia among non-fearful participants and had fewer side effects.[87]

Christensen C et al. undertook a study in 2020 to test the manufacturer's claims about a revolutionary needleless intraligamentary local anaesthesia injection device (Numbee, BioDent) that can give effective single tooth anaesthesia. A randomised split-mouth design was used, with 15 adult individuals receiving IANB on one side as well as a Numbee injection on opposite side of the same tooth type. There was no notable change in VAS scores for injection pain between both the Numbee and the IANB (p =.078). The IANB had a 46 percent incidence of deep anaesthesia and a 20 percent need for rescue anaesthesia. The Numbee had a 0% incidence of profound anaesthesia and a 60% requirement for rescue anaesthesia. The two techniques were equally preferred by the subjects (50/50). It was determined that the IANB was proven to surpass the Numbee device in terms of achieving profound anaesthesia while requiring less rescue anaesthetic.[88]

In 2020, Menaka EK conducted a study to assess as well as evaluate patient tolerance but also choice for needleless jet injection (MADAJET XL) vs traditional local infiltration (UNOLOK), and effectiveness of needleless anaesthetic. Non-fearful children between the ages of 6 and 12 with no prior experience with local anaesthesia were chosen from either gender. Out of 40 patients, 40 percent felt pain and 42.5 percent felt fear during the administration of local anaesthetic solution, and the operator noted more loss of blood from the injection site with needleless jet anaesthesia when compared to needle infiltration anaesthesia, as well as a greater number of additional anaesthesia required in the case of invasive procedures in 25 percent of the patients. Needless jet anaesthesia was favoured by 57.5 percent of patients over standard infiltration anaesthesia (42.5 percent). It was discovered that patients experienced much less discomfort and fear during non-invasive anaesthetic

treatments when using MADAJET XL. However, needle and syringe anaesthesia will be more effective for more invasive procedures.[89]

In 2021, Hameed MS et al colleagues did a study comparing the clinical efficacy as well as level of patient acceptability of jet injections vs conventional syringe method in patients with symptomatic pulpitis. 70 subjects were randomly allocated to either the needleless pressure injection procedure with the Madajet XL or the traditional syringe technique. During an endodontic operation, a needleless pressure injection approach (Madajet XL) demonstrated to be beneficial in patients having symptomatic irreversible pulpitis.[90]

In 2021, Adami LE et al published a study that demonstrated the clinical effectiveness of mucoadhesive patches of lidocaine and prilocaine hydrochlorides (1:1, 30 mg/patch) with the intention of minimizing infiltrative anaesthesia use for medium-complexity clinical procedures. Biocompatible materials and film casting was used for patched, and they featured drug-release, mucoadhesive, as well as backing layers. A total of 58 adults participated in the trial. The patches were applied to the gingiva of the teeth to be treated. The patch was found to be capable of commencing anaesthesia within a short timespan (5 minutes) as well as attaining the maximum anaesthetic effect within 15 - 25 minutes, lasting at least 50 minutes in most cases. Unwanted side effects were also not documented two hours after administration or during the six-month follow-up. It was determined that the developed anaesthetic patches provide dentistry friendly, patient friendly, needle-free, safe and painless advantages in medium-complex dental operations.[91]

MATERIAL AND METHODS

An interventional study was conducted to evaluate and compare the effectiveness of needleless injection technique (Sure Shot) with conventional injection technique in patients undergoing orthodontic extraction.

STUDY DESIGN:

A split mouth clinical trial

SOURCE OF DATA:

For recruiting patients in the study, the patients reporting to Out Patients Department of Department of Oral and Maxillofacial Surgery, were considered.

STUDY AREA:

The study was conducted in the Department of Oral and Maxillofacial Surgery.

INFORMED CONSENT:

Before conducting the study a written informed consent and procedure to be performed was explained to the patients. Then the patient was asked to sign the consent which gave a brief description about the study. It mentioned to maintain the confidentiality of the patients if their photographs were to be obtained for the study report. **(ANNEXURE-I)**

ELIGIBILITY CRITERIA

Inclusion criteria

1. Patients falling in age group of 14-25 years.
2. Patients with no serious illness or underlying diseases
3. Patients requiring bilateral maxillary premolar extractions for orthodontic purpose

Exclusion criteria

1. Pregnant women.
2. Mentally challenged patients
3. Patients who were known to have allergy to any medication or local anesthetic agent.
4. Patients with known history of systemic diseases as Hypertension, Diabetes Mellitus, HIV, bone disorders, renal disorders, cancer patients,

radiation therapy, infectious diseases and any other systemic disease that could alter the course of study.

5. Patients with gross oral pathology.

6. Patients not willing to give informed consent.

SAMPLE SIZE CALCULATION:

A total of 34 patients visiting OMFS department for extraction of bilateral maxillary premolar for orthodontic purpose, were selected for the present study. The sample size calculation was done using the below formula. Power of the study as kept at 80%, significance was kept at 5% with a confidence interval of 95% the following calculations were made:

$$n = \frac{[DEFF \times Np(1-p)}{[(d^2/Z^2_{1-\grave{u}/2} \times (N-1) + P \times (1-p)}$$

Where,

N=Population size (for finite population)

(p)= Hypothesized % frequency of outcome factor in the population

Confidence limits as % of 100(absolute ± %) (d): 5%

Design effect: 1

Substituting the values in the formula, a sample size of 34 was derived

SAMPLING TECHNIQUE

The patients were selected based on eligibility criteria. Since the study was a split mouth study, the sides were randomly divided randomly into two groups. The randomization for side allocation in Sure Shot needleless technique groups was done by toss of coin.

Group I (n=17): Patients were given Sure Shot needleless injection technique for delivering local anaesthesia (Figure no. 1 A)

Group II (n=17): Patients were given conventional injection technique for delivering local anaesthesia (Figure no. 1 B)

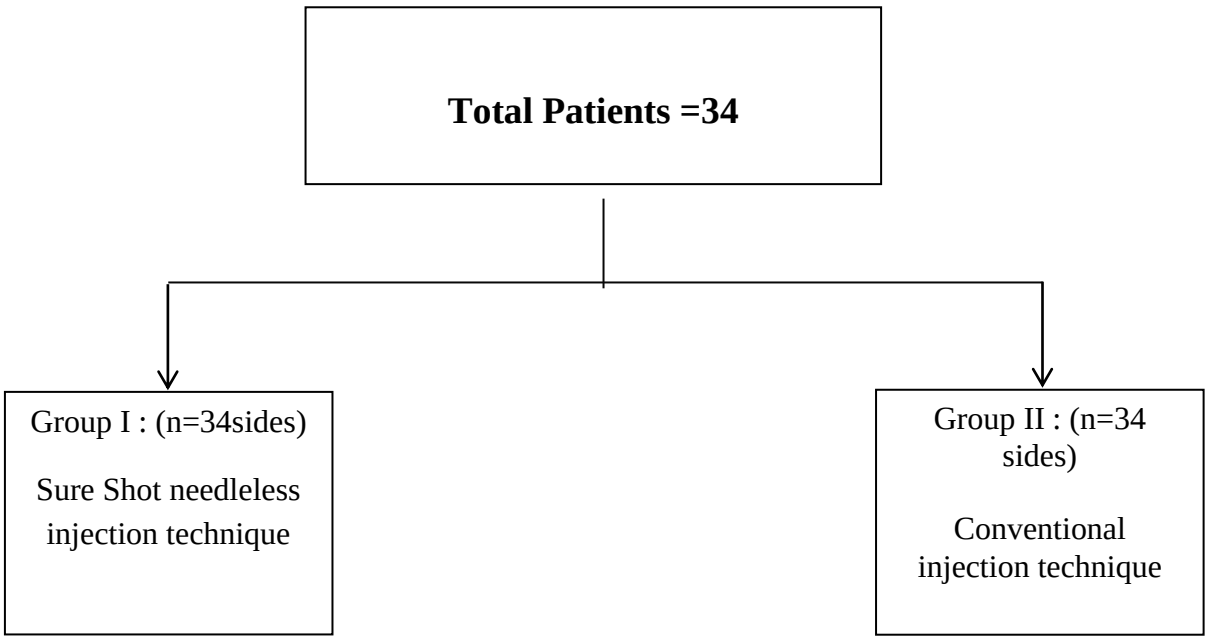


Fig 2 - showing distribution of subjects in the study

RANDOMIZATION

Patients visiting Department of Oral and Maxillofacial Surgery and falling into inclusion criteria of the study were randomized for side allocation for needleless injection technique and the allocation was as below.

Subject	Assigned
Heads	Right
Heads	Right
Heads	Right
Tails	Left
Tails	Left
Heads	Right
Heads	Right
Tails	Left
Tails	Left
Heads	Right
Tails	Left
Tails	Left
Heads	Right
Heads	Right
Tails	Left
Heads	Right
Tails	Left
Heads	Right
Heads	Right
Heads	Right
Heads	Right
Heads	Right
Tails	Left
Heads	Right
Tails	Left
Heads	Right
Heads	Right
Tails	Left
Heads	Right
Heads	Right
Tails	Left
Heads	Right
Tails	Left
Heads	Right

ARMAMENTARIUM REQUIRED (Figure no.3)

- Mouth mask
- Head cap
- Surgical Gloves
- Sterile Cotton
- Kidney tray
- 2 ml short needle syringe
- 2 % lignocaine with 1:2,00,000 epinephrine
- Sure Shot device (Figure no.4,5)
- Standard armamentarium for maxillary premolar orthodontic extractions
- Emergency drug kit

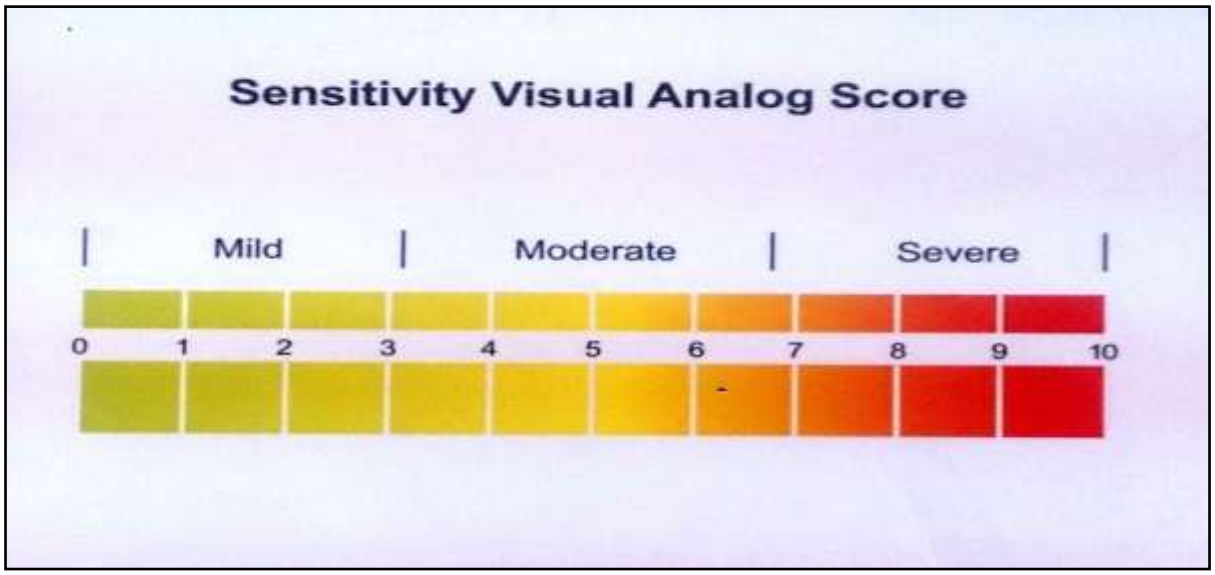
CLINICAL PARAMETERS ASSESSED:

1. Sensitivity Visual Analog Scale
2. Wong-Baker FACES Pain Rating Scale

1. Sensitivity Visual Analog Scale

- The pain VAS scale comprises horizontal or vertical line. The line is 10 centimetres in length. The two extremes represent symptoms are anchored by 2 verbal descriptors.
- The anchores are; “no pain” (score-0) and “pain as bad as it could be” or “worst imaginable pain” (score- 100 or score 10 [depending on the scale unit]).
- Greater pain is indicated by high scores. In postsurgical patients pain intensity is described as none, mild, moderate, or severe on VAS scale.

- The following are the cut points on the pain VAS were kept:
    - Mild pain (0-3 point)
    - Moderate pain (3-7 point)
    - Severe pain (7-10 point)



2. <u>Wong-Baker FACES Pain Rating Scale</u>

- The faces represent no pain (hurt), or some, or a lot of pain.
    - Face 0: it doesn't hurt at all,
    - Face 2: hurts just a little bit,
    - Face 4: hurts a little bit more,
    - Face 6: hurts even more
    - Face 8: hurt a whole lot
    - Face 10: hurts as much as patient can imagine.
- Patient chooses the face according to the pain experience.

CLINICAL PROCEDURE:

- Patients visiting Oral and Maxillofacial Surgery Department for bilateral maxillary orthodontic extractions under the inclusion criteria were divided into two groups-

  Group A – (Study group)

  Sure Shot needleless injection technique for delivering local anaesthesia on one side of maxillary arch

  Group B – (Control Group)

  Conventional injection technique for delivering local anaesthesia on the contralateral side of maxillary arch

- After obtaining written informed consent both the groups were operated by same operator under all aseptic conditions.
- Prior to procedure, self-reported questionnaire with details of age, Gender, address and date of procedure were recorded.
- Under all aseptic precautions, Buccal infiltration and Palatal infiltration was given on one side with Sure Shot needleless injection in Group A patients and

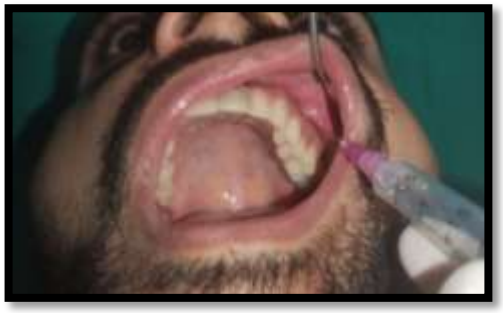
on contralateral side with Conventional injection technique in Group B patients.

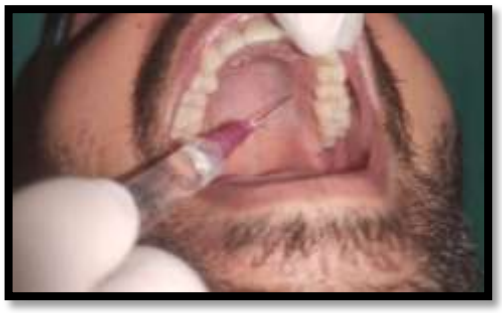
- Keeping the speed of injection same for every patient, local anaesthetic solution, 2% lignocaine containing 2,00,000 epinephrine was deposited for desired nerve block and pain was evaluated while injection and also while extraction.
- Pain on injection was noted for every patient using Visual Analog Scale (VAS). Pain during injection was defined as described by VAS during injecting the solution and not on the needle- prick.
- They were asked to make a note of when they perceive pain at their surgical site.

Color Plate I

Clinical Photographs

Group 'A' **Group 'B'**





(A) **(B)**

Figure no.1- (A) Group A administered with SureShot injection technique and

(B) Group B administered with conventional injection technique

Figure no.2- Armamentarium used in the study

Figure no. 3- SureShot needleless injection

Figure no.4- SureShot needleless injection

STATISTICAL ANALYSIS:

The data regarding responses of the patients on Visual Analog Scale and Won-Baker scale were recorded and transferred onto an Excel Spreadsheet 2010. The data checked for normality using Kolmogorov- Smirnov test.

- For comparing the data between groups for Visual Analog Scale- Unpaired t test
- For comparison the data between groups for Won-Baker Scale- Mann Whitney U test

The significance was set at $p<0.05$.

RESULTS

The present study was conducted to assess the difference between Sure Shot and conventional technique towards pain perception while deposition of anaesthetic solution and extraction of tooth. The pain was measured using VAS and Wong-Baker scale. Unpaired t-test was applied to assess the difference between VAS and Wong-Baker scores. The results obtained are as follows:

Table no.1

The table represents the distribution of patients according to the gender in the present study. A total of 17 males accounting to 50% and 17 females accounting to 50% were present in the study.

Graph no.1

The bar diagram represents the distribution of patients in the study according to gender. The x-axis represents gender and the y-axis represents percentage of

males and females in the study. Number of males and females in the study were same.

Table no.2

The table represents the distribution of patients according to age group. Five patients accounting to 14.7% belonged to 13-15 years age group, thirteen patients accounting to 38.23% belonged to 16-18 years age group, nine patients accounting to 26.47% belonged to 19-21 years of age group and seven patients accounting to 20.58% belonged to 22-24 years of age group. Maximum patients were in the age group of 15-18 years and the least in 13-15 ears age group.

Graph no.2

The bar diagram represents the distribution of patients in the study according to the age groups. The x-axis represents age group and the y-axis represents percentage of patients belonging to each of the age group. The maximum patients were present in 16-18 years age group.

Table no.3

The table represents mean time required for the onset of local anaesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect. The mean time required for onset of local anaesthesia on buccal side was 1.29 minutes with Standard deviation(SD) of 0.24 minutes. The palatal aspect required a mean time of 1.8 minutes with SD of 0.35 minutes. The labial aspect required 1.29 minutes with SD of 0.15 minutes and the lingual aspect required a mean of 1.76 minutes with SD of 0.35 minutes.

Graph no.3

The bar diagram represent mean time of onset for local anesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect. The maximum time of onset was present with palatal aspect and the least with buccal and labial aspect.

Table no.4

The table represents mean duration of local anaesthesia in Sure Shot injection group. The mean duration of local anaesthesia on buccal side was 30.73 minutes with SD of 2.17 minutes. On palatal aspect duration of local anaesthesia was for 21.47 minutes with SD of 3.37 minutes. On labial aspect duration of local anaesthesia was 30.58 minutes with SD of 1.63 minutes and on the lingual it was for 28.97 minutes with SD of 2.69 minutes.

Graph no.4

The bar diagram represent mean duration of local anesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect. The maximum duration of local anaesthesia was present on buccal aspect and the least on palatal aspect.

Table no.5

The table represents mean time required for the onset of local anaesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect. The mean time required for onset of local anaesthesia on buccal side was 1.94 minutes with SD of 0.16 minutes. The palatal aspect required a mean time of 1.9 minutes with SD of 0.22 minutes. The labial aspect required 1.97 minutes with SD of 0.11 minutes and the lingual aspect required a mean of 1.93 minutes with SD of 0.17 minutes.

Graph no.5

The bar diagram represent mean time of onset for local anesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect. The maximum time of onset was present with labial aspect and the least with palatal aspect.

Table no.6

The table represents mean duration of local anaesthesia in Conventional injection group. The mean duration of local anaesthesia on buccal side was 48.08 minutes with SD of 6.94 minutes. On palatal aspect duration of local anaesthesia was for 46.76 minutes with SD of 10.14 minutes. On labial aspect duration of local anaesthesia was 49.55 minutes with SD of 7.91 minutes and on the lingual it was for 48.97 minutes with SD of 8.14 minutes.

Graph no.6

The bar diagram represents mean duration of local anesthesia in conventional injection group on buccal, palatal, labial and lingual aspect. The maximum duration of local anaesthesia was present on labial aspect and the least on palatal aspect.

Table no.7

The table represents difference in the Sure Shot injection and Conventional injection technique groups with respect to time of onset of local anaesthesia on buccal, palatal, labial and lingual aspect. The mean difference in time of onset on buccal aspect was 0.65 minutes with $t=12.83$ and $p<0.0001$. Palatal aspect showed a difference of 0.08 minutes with $t=1.11$ and $p=0.268$. Labial aspect showed a difference of 0.67 minutes with $t=19.76$ and $p<0.0001$ and for lingual aspect the difference was 0.17 with $t=2.67$ and $p=0.009$. Time of onset was significantly less

with Sure Shot injection technique compared to conventional injection technique on buccal, labial and lingual aspect while the palatal aspect showed comparable results.

Graph no.7

The bar diagram represent mean time of onset of local anaesthesia in Sure Shot injection and Conventional injection technique groups. The graph presents less time for onset of local anaesthesia on buccal, palatal, labial and lingual aspect with Sure Shot injection technique group.

Table no.8

The table represents difference in the duration of local anaesthesia between Sure Shot and Conventional injection group on buccal, palatal, labial and lingual aspect. The mean difference in duration of anaesthesia on buccal aspect was 17.35 minutes with $t=13.86$ and $p<0.0001$. Palatal aspect showed a difference of 25.29 minutes with $t=13.79$ and $p<0.0001$. Labial aspect showed a difference of 18.97 minutes with $t=13.68$ and $p<0.0001$ and for lingual aspect the difference was 20 minutes with $t=13.59$ and $p<0.0001$. The duration of local anaesthesia was significantly less for Sure Shot group compared to Conventional injection group.

Graph no.8

The bar diagram represents mean duration of local anaesthesia in Sure Shot injection and Conventional injection technique groups. The graph presents less duration of action of local anaesthesia with Sure Shot group.

Table no.9

The table represents the mean values of Visual Analog Scale (VAS) and Wong-Baker scores for pain perception in conventional injection technique group while

insertion of the needle for administering local anaesthesia. The mean VAS pain score was 7.44 with a minimum of score 5 and maximum of score 6 reported by the patients in this group. The mean Wong-Baker score was 7.82 with minimum of score 6 and maximum of score 10.

Graph no.9

The bar diagram represents mean VAS and Wong-Baker scores in Conventional injection group while insertion of needle. Higher pain scores were reported with Wong-Baker scale.

Table no.10

The table represents the mean values of Visual Analog Scale (VAS) and Wong-Baker scores for pain perception in Sure Shot technique group while deposition of local anaesthesia. The mean VAS pain score was 1.82 with a minimum of score 1 and maximum of score 3 reported by the patients in this group. The mean Wong-Baker score was 1.76 with minimum of score 0 and maximum of score 2.

Graph no.-10

The bar diagram represents mean VAS and Wong-Baker scores in Sure Shot injection group while deposition of local anaesthesia. Higher pain scores were reported with Wong-Baker scale.

Table no.11

The table represents the mean values of Visual Analog Scale (VAS) and Wong-Baker scores for pain perception in Conventional injection technique group while deposition of local anaesthesia. The mean VAS pain score was 7.94 with a minimum of score 6 and maximum of score 9 reported by the patients in this

group. The mean Wong-Baker score was 8.88 with minimum of score 8 and maximum of score 10.

Graph no.11

The bar diagram represents mean VAS and Wong-Baker scores in Conventional injection group while deposition of local anaesthesia. Higher pain scores were reported with Wong-Baker scale.

Table no.12

The table represents the difference in VAS and Wong-Baker score between Sure Shot injection group and Conventional injection group during deposition of local anaesthesia. The mean difference in VAS scores between the groups was 6.11 with $t=38.16$ and $p<0.0001$. The mean difference in Wong-Baker score was 7.11 with $t=34.53$ and $p<0.0001$. The pain was significantly low for Sure Shot injection group compared to Conventional injection group while deposition of local anaesthesia.

Graph no.12

The bar diagram represents mean VAS and Wong-Baker scores in Sure Shot injection group and Conventional injection group during deposition of local anaesthesia. Lower pain scores were reported with Sure Shot injection technique group for both on both VAS and Wong-Baker scale.

Table no.13

The table represents the mean values of Visual Analog Scale (VAS) and Wong-Baker scores for pain perception in Sure Shot injection technique group during extraction. The mean VAS pain score was 6.26 with a minimum of score 5 and

maximum of score 7 reported by the patients in this group. The mean Wong-Baker score was 6.58 with minimum of score 4 and maximum of score 8.

Graph no.13

The bar diagram represents mean VAS and Wong-Baker scores in Sure Shot injection group during tooth extraction. Higher pain scores were reported on Wong-Baker scale.

Table no.14

The table represents the mean values of Visual Analog Scale (VAS) and Wong-Baker scores for pain perception in Conventional injection technique group during extraction. The mean VAS pain score was 4.91 with a minimum of score 4 and maximum of score 7 reported by the patients in this group. The mean Wong-Baker score was 6.58 with minimum of score 4 and maximum of score 6.

Graph no.14

The bar diagram represents mean VAS and Wong-Baker scores in Conventional injection group during tooth extraction. Higher pain scores were reported on VAS scale.

Table no.15

The table represents the difference in VAS and Wong-Baker score between Sure Shot injection group and Conventional injection group during extraction. The mean difference in VAS scores between the groups was 1.35 with $t=6.58$ and $p<0.0001$. The mean difference in Wong-Baker score was 2 with $t=7.86$ and $p<0.0001$. The pain was significantly high for Sure Shot injection group compared to Conventional injection group during tooth extraction.

Graph no.15

The bar diagram represents mean VAS and Wong-Baker scores in Sure Shot injection group and Conventional injection group during tooth extraction. Lower pain scores were reported with Conventional injection technique group on VAS and Wong-Baker scale.

Overall, use of Sure Shot injection technique sowed significant less time for onset of local anaesthesia on buccal, labial and lingual aspect with no significant difference for palatal aspect. With respect to duration of local anaesthesia, it was significantly less for Sure Shot group compared to Conventional injection group. The pain during deposition of local anaesthesia was also found to be significantly low with Sure Shot injection technique compared to conventional injection technique. Only pain during extraction was high with Sure Shot injection technique over conventional injection technique.

DISCUSSION

Various factors influence pain during dental procedures. These include but not limited to gender, the rate of injecting local anaesthesia, force of anaesthetic flow, fear towards the numbness sensation, sharp objects like needles and anxiety within the patient before injecting anaesthesia. The fear associated with dental treatment unfortunately becomes a hurdle towards long term dental and in turn general health for the patients as the patients avoid visiting the dentists and neglect the pain and agony associated with the oral health condition.[20]

There are certain mechanical devices that have been reported to show a positive effect in reducing pain during anaesthetic procedure. These mechanical adjuncts that can be used are classified into intraosseous techniques, vibratactile devices and needleless or jet injections.[92] Other techniques which have been in use are use of warm buffered local anaesthesia, application of topical local anaesthesia before injecting the anaesthesia via needle and administration of conscious sedations through medications like nitrous oxide or benzodiazepine which is a short acting.[93] The intraosseous

devices like X-tip and Stabident by Dentsply Maillefer, Tulsa, OK and Fairfax Dental, Miami, FL are useful in the cases of hot tooth wherein local infiltration or a traditional nerve block does not cause the required numbness around the tooth. These techniques enable intraosseous injection directly into the bone. Both the devices have shown comparable onset of action, increase in heart rate and duration of anaesthesia. The needle is inserted through the attached gingiva and directed towards the bone. The technique has not been in use largely because of the limitation that, the intraosseous devices cannot be used in the patients with periodontal diseases and in the areas interproximal space is minimal.[94] Moreover, these injection have shown less success in providing profound anaesthesia for mandibular 1st molars with a success rate of 75%. Additionally, these devices are invasive and require gingival followed by cortical and alveolar bone perforation.[95]

The needleless jet injection system was dated back to 1866 and was introduced first for immunization and vaccinations. Later the use became evident in dentistry with further modifications in the techniques. This technique provides rapid onset of anaesthesia without the fear of needle stick injury. But they too come with disadvantages of pressure sensation felt by the patient during anaesthesia administration, increase in the chance of hematoma formation, loud noise associated with the device which can be a major disadvantage in case of pediatric patients as it may increase the fear amongst them toward the procedure and equivocal pulpal anaesthesia.[96]

In the present study, the mean time required for onset of local anaesthesia and the duration of local anaesthesia on buccal, palatal, labial as well as lingual aspect was compared between the conventional and Sure Shot injection group. With respect to mean time required for the onset of local anaesthesia, on buccal side it was 1.29

minutes; palatal aspect was 1.8 minutes, labial aspect was 1.29 minutes and the lingual aspect required a mean of 1.76 minutes. On the other hand, Conventional injection group on buccal side demonstrated 1.94 minutes, palatal aspect as 1.9 minutes, labial aspect as 1.97 minutes and the lingual aspect as 1.93 minutes. The time of onset was significantly less for Sure Shot group compared to Conventional injection group for all aspects except palatal aspect. In a study reported by Nikolaos D et al,[76] the conventional injection technique was compared with Injex needleless injection technique. The study did not demonstrate a significant difference in the onset of local anaesthesia between the two groups unlike the present study. It should be noted that the variation in results of the present study from that of Nikolaos D et al[76] study can be due to the use of difference anaesthetic solution. In the present study 2 % lignocaine with 1:2,00,000 epinephrine was used while in the study by Nikolas D et al, mepivacaine 3% in few and lidocaine 2% with epinephrine 1:80,000 in the remaining patients was used in Injex needleless group leading to contrasting results.[76] The results of the present not in agreement with the results obtained by Oliveira ACA et al wherein no significant difference was noted in the latency period of anaesthetic solutions by the two techniques.

Duration of local anaesthesia reported significantly less in Sure Shot group compared to Conventional injection group in the present study for all; buccal, palatal, labial as well as lingual aspect. The results of the present study were in line with the study conducted by Nikolaos D et al.[76] The duration of anaesthesia through conventional injection technique was significantly longer than the needless Injex injection technique. Whereas, in the study by Oliveira ACA et al,[86] which assessed the difference in duration between conventional technique using carpule syringe with that of needleless jet injection technique demonstrated longer duration in conventional

group over needleless group but with no significant difference. The difference in the duration of local anaesthesia between needleless and conventional technique can be attributed to pharmacokinetic process. This process takes place during the tissue diffusion time once the anaesthesia is injected. The diffusion depends on the availability of local anaesthesia in a non ionized form. The greater the concentration of non ionized form the faster would be the diffusion thereby having unimpeded movement of molecules in equilibrium towards the fascicles of nerve.[11]

With respect to pain, the pain in the present study was assessed at the time of insertion of needle in conventional injection technique group. Since the Sure Shot injection technique did not involve needle insertion, this particular pain was not assessed in the intervention group. Additionally, pain during deposition of local anaesthesia and during extraction of tooth was evaluated between the two groups. The results of the present study demonstrated significant difference in pain perception between Sure Shot and Conventional injection group on VAS as well as Wong-Baker pain scale while deposition of local anaesthesia. The pain was significantly low for Sure Shot group compared to Conventional injection group. The results of the present study are in accordance with the study reported by Yildırım S et al[97] wherein pain during deposition of anaesthesia was compared between conventional injection technique with a prior topical anaesthetic application and Comfort-in needless injection technique. The study demonstrated significantly low pain with needless technique over conventional technique with pain perception measured by Wong-Baker PRS scale.

The evidence towards the needleless injection technique was further supported by Makade CS et al[79] wherein a split mouth randomized study demonstrated a significantly less pain among patients injected with needleless jet injection over

classical local infiltration for less invasive dental procedures. The technique had a higher rate of acceptance among the patients over traditional needle technique. The difference between the groups can be attributed to the fact that the needleless injection deposits a small amount of solution in the initial stage which is not the case with conventional technique. Since the amount of anaesthesia deposited is less, the tissue distension is minimal leading to less pain. Thus, during this initial period the optimal diffusion occurs of the anaesthetic solution that blocks the peripheral nerves. As the peripheral nerves get blocked the pain perception is significantly reduced during the further deposition of anaesthetic solution.[11]

The results of the present study were not in accordance with the study reported by Arapostathis KN et al[77] that demonstrated favouring results towards the conventional injection technique over the needleless technique. The patients undergoing dental procedures expressed negative response towards Injex device with a feeling of more annoyance and pain during administration of local anaesthesia. Moreover, because of the pain perception among the needleless injection technique group during procedure even after administering local anaesthesia, the patients required additional solution to be deposited. The author explains that the poor perception towards needleless technique can be attributed to the design of the device and the angulation at which the anaesthesia is deposited. Since the Injex device required a 90 degree angulation whereas the conventional technique do not restrict to such requirements. Thus, in case of lingual aspect the technique was found to be difficult.[98] To addition, Oilveira ACA et al[86] too demonstrated no difference in the pain threshold between the needleless injection technique group over the conventional technique group for dental procedures. Furthermore, preference towards the conventional injection technique was

higher due to more discomfort and pain associated with needleless technique during anaesthesia administration during extraction of intact maxillary premolars.[87]

In the present study, a significant difference was present between Sure Shot and Conventional injection group with respect to VAS and Wong-Baker pain scores during tooth extraction. The pain was significantly more in Sure Shot group compared to Conventional injection group during tooth extraction. The results of the present study were in agreement with Chong BS et al[81] wherein a review reported the effectiveness of various injection techniques. It was established that the needleless jet injection technique do not significantly provide less pain during the dental procedures. Moreover, the depth of anesthesia achieved by this technique was also found to be low compared to the conventional technique. Tawil SBE and Dokky NAE[83] reported no significant difference in pain perception during various dental procedures among patients receiving needleless injection technique. The procedures carried out were, extraction, cavity preparation as well as pulpal procedures.[83]

During the extraction process in one of the split mouth study, the needleless injection technique was not found to be effective for local infiltration and the main reason was pointed towards the depth of action of anaesthesia and the pop sound associate with the device leading to high perception of pain among the patients.[99] Patients experienced significantly less pain with the use of Madajet XL injection technique when compared to classical injection technique. It should be noted that this study provided results with non-invasive procedures. However, for invasive procedures, it was suggested that the classical injection technique with needle would be more effective over needleless injection technique.[89]

Alike results were also reported by few of the studies in the literature. Pain perception was reported to be significantly less with needleless Madajet XL technique among children when compared to the conventional technique. Moreover, the ease of using needleless injection device was also reported to be superior over the conventional technique for both; patients as well as clinicians.[74] Another study by Splinter WM et al[75] reported a limited use of needless injection technique and restricted it towards its use not beyond mass vaccination. Furthermore, the needleless injection technique also provided less postoperative pain and better acceptance compared to the conventional technique.[84]

Needleless injection technique with Sure Shot device provides advantages over the conventional injection technique under many parameters. It is important to note that the pain perception relies on various factors. The dental anxiety of patients, the number of visit to the dental clinic, ages of the patient and to some extent even the gender of the patient. Since the Sure Shot is needleless, the fear associated with the needle among patients is taken care of but considering the extent of action of local anaesthesia through its depth the pain can be found to be significantly more associated with Sure Shot during the actual procedure. Moreover, as supported by other studies, the needleless injection technique does provide benefit in the non-invasive procedure but when it comes to invasive procedure especially extraction of intact teeth the technique may not serve to minimize the pain more effectively compared to the conventional technique. Apart from thi.s, the technique provides benefit in limiting the cross-infections and injuries associated with needle stick injuries to the patients as well as the clinicians. Additionally, it reduced the load of waste disposal to a great extent.

Limitations of the study include,

- The participants were not assessed for their pre-injection dental anxiety and thus there may be few patients who would have perceived greater pain due to anxiety and fear.

Future recommendations,

- Addition of pre-injection apprehension scores can be useful in determining pain perception among anxious patients.
- Studies on larger sample size are recommended.

CONCLUSION

It can be concluded that use of Sure Shot injection technique showed significant less time for onset of local anaesthesia on buccal, labial and lingual aspect with no significant difference for palatal aspect. The duration of local anaesthesia was significantly less for Sure Shot group compared to Conventional injection group. With respect to pain, the pain during deposition of local anaesthesia was also found to be significantly low with Sure Shot injection technique compared to conventional injection technique while during extraction of tooth; the pain was high with Sure Shot injection technique over conventional injection technique.

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TABLES

Table no.1- Distribution of patients with respect to gender

Gender	Frequency	Percentage
Males	17	50
Females	17	50

Table no.2- Distribution of patients with respect to gender

Age	Frequency	Percentage
13-15 years	5	14.7
16-18 years	13	38.23
19-21 years	9	26.47
22-24 years	7	20.58

Table no.3- Mean time required for the onset of local anaesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect

Aspect	N	Minimum	Maximum	Mean	Std. Deviation
Buccal	34	1.00	2.00	1.2912	.24602
Palatal	34	1.15	2.50	1.8221	.35488
Labial	34	1.15	2.00	1.2941	.15991
Lingual	34	1.15	2.15	1.7588	.35043

Table no.4- Mean duration of local anaesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect

Aspect	N	Minimum	Maximum	Mean	Std. Deviation
Buccal	34	25.00	35.00	30.7353	2.17853
Palatal	34	15.00	30.00	21.4706	3.37760
Labial	34	30.00	35.00	30.5882	1.63517
Lingual	34	20.00	30.00	28.9706	2.69101

Table no.5- Mean time required for the onset of local anaesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect

Aspect	N	Minimum	Maximum	Mean	Std. Deviation
Buccal	34	1.50	2.15	1.9456	.16714
Palatal	34	1.40	2.15	1.9029	.22728
Labial	34	1.50	2.00	1.9706	.11942
Lingual	34	1.40	2.00	1.9382	.17235

Table no.6- Mean duration of local anaesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect

Aspect	N	Minimum	Maximum	Mean	Std. Deviation
Buccal	34	30.00	60.00	48.0882	6.96471
Palatal	34	5.00	60.00	46.7647	10.14160
Labial	34	35.00	65.00	49.5588	7.91696
Lingual	34	35.00	65.00	48.9706	8.14447

Table no.7- Difference in the time of onset of local anaesthesia between Sure Shot and Conventional injection group on buccal, palatal, labial and lingual aspect

Aspect	Groups	N	Mean	Mean difference	t-value	Significance (p)
Buccal	Sure Shot	34	1.2912	0.65	12.83	**<0.0001***
	Conventional injection	34	1.9456			
Palatal	Sure Shot	34	1.8221	0.08	1.11	0.268
	Conventional injection	34	1.9029			
Labial	Sure Shot	34	1.2941	0.67	19.76	**<0.0001***
	Conventional injection	34	1.9706			
Lingual	Sure Shot	34	1.7588	0.17	2.67	**0.009***
	Conventional injection	34	1.9382			

*Significance at $p<0.05$

A statistical significant difference is present between Sure Shot and Conventional injection group with respect to time of onset of local anaesthesia for buccal, labial and lingual aspects. The time of onset was significantly less for Sure Shot group compared to Conventional injection group.

Table no.8- Difference in the duration of local anaesthesia between Sure Shot and Conventional injection group on buccal, palatal, labial and lingual aspect

Aspect	Groups	N	Mean	Mean difference	t-value	Significance (p)
Buccal	Sure Shot	34	30.7353	17.35	13.86	**<0.0001***
	Conventional injection	34	48.0882			
Palatal	Sure Shot	34	21.4706	25.29	13.79	**<0.0001***
	Conventional injection	34	46.7647			
Labial	Sure Shot	34	30.5882	18.97	13.68	**<0.0001***
	Conventional injection	34	49.5588			
Lingual	Sure Shot	34	28.9706	20.00	13.59	**<0.0001***
	Conventional injection	34	48.9706			

*Significance at $p<0.05$

A statistical significant difference is present between Sure Shot and Conventional injection group with respect to duration of local anaesthesia for buccal, palatal, labial and lingual aspects. The duration of local anaesthesia was significantly less for Sure Shot group compared to Conventional injection group.

Table no.9- Mean VAS and Wong Baker scores in Conventional injection technique while insertion of needle

Pain scale	N	Minimum	Maximum	Mean	Std. Deviation
VAS	34	5.00	9.00	7.4412	1.05000
Wong Baker	34	6.00	10.00	7.8235	1.24245

Table no.10- Mean VAS and Wong Baker scores in Sure Shot group during deposition of local anaesthesia

Pain scale	N	Minimum	Maximum	Mean	Std. Deviation
VAS	34	1.00	3.00	1.8235	.67288
Wong Baker	34	.00	2.00	1.7647	.65407

Table no.11- Mean VAS and Wong Baker scores in Conventional injection group during deposition of local anaesthesia

Pain scale	N	Minimum	Maximum	Mean	Std. Deviation
VAS	34	6.00	9.00	7.9412	.64860
Wong Baker	34	8.00	10.00	8.8824	1.00799

Table no.12- Difference in VAS and Wong Baker pain scores between Sure Shot group and Conventional injection group during deposition of local anaesthesia

Pain scale	Groups	N	Mean	Mean difference	t-value	Significance (p)
VAS	Sure Shot	34	1.8235	6.11	38.16	**<0.0001***
	Conventional injection	34	7.9412			
Wong Baker	Sure Shot	34	1.7647	7.11	34.53	**<0.0001***
	Conventional injection	34	8.8824			

*Significance at $p<0.05$

A statistical significant difference is present between Sure Shot and Conventional injection group with respect to AVS and Wong-Baker pain scores while deposition of local anaesthesia. The pain was significantly low for Sure Shot group compared to Conventional injection group while deposition of local anaesthesia

Table no. 13- Mean VAS and Wong Baker scores in Sure Shot group during extraction

Pain scale	N	Minimum	Maximum	Mean	Std. Deviation
VAS	34	5.00	7.00	6.2647	.66555
Wong Baker	34	4.00	8.00	6.5882	1.15778

Table no. 14- Mean VAS and Wong Baker scores in Conventional injection group during extraction

Pain scale	N	Minimum	Maximum	Mean	Std. Deviation
VAS	34	3.00	7.00	4.9118	.99598
Wong Baker	34	4.00	6.00	4.5882	.92499

Table no.15- Difference in VAS and Wong Baker pain scores between Sure Shot group and Conventional injection group during tooth extraction

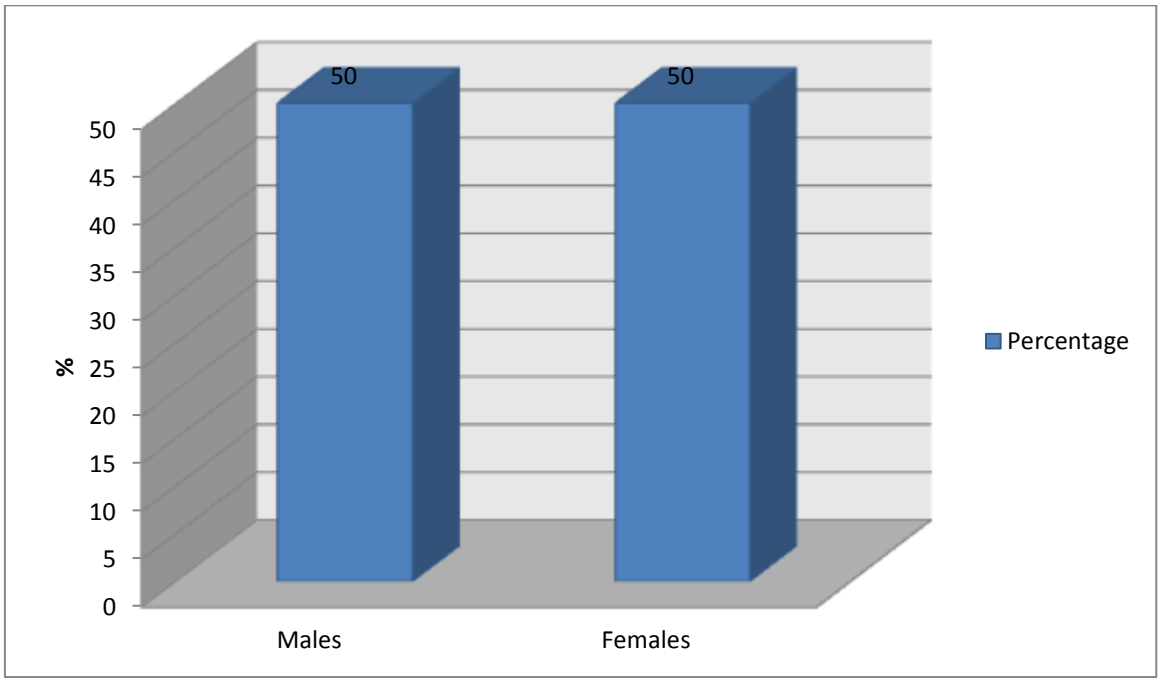
Pain scale	Groups	N	Mean	Mean difference	t-value	Significance (p)
VAS	Sure Shot	34	6.2647	1.35	6.58	**<0.0001***
	Conventional injection	34	4.9118			
Wong Baker	Sure Shot	34	6.5882	2.00	7.86	**<0.0001***
	Conventional injection	34	4.5882			

*Significance at $p<0.05$

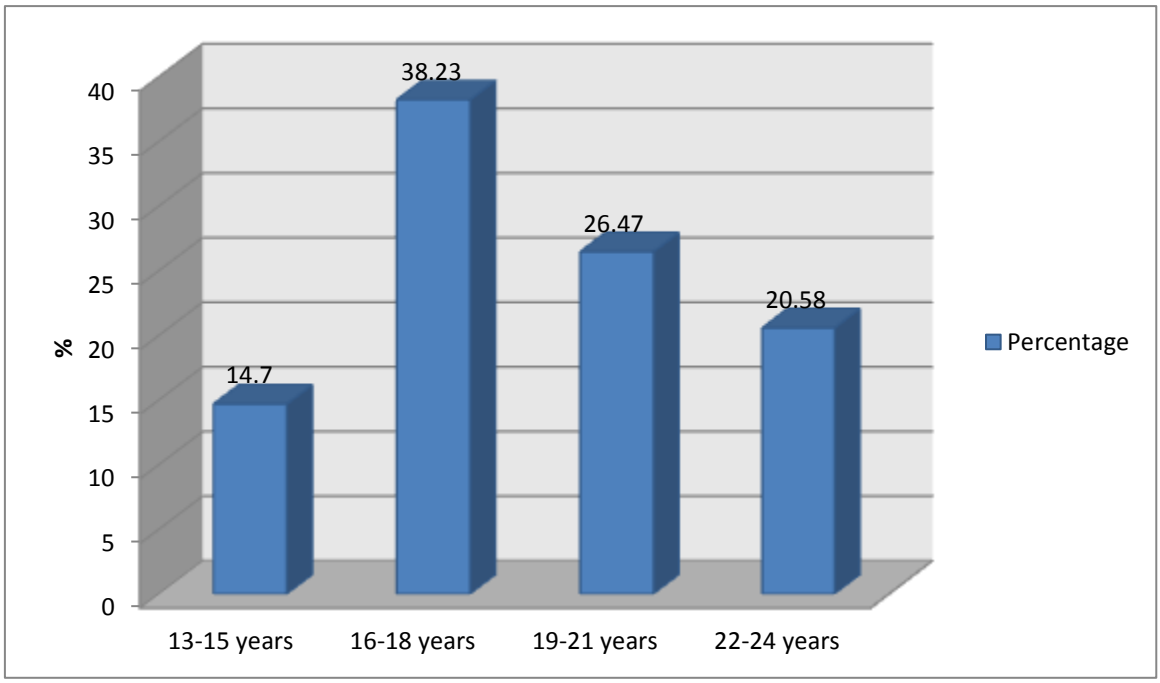
A statistical significant difference is present between Sure Shot and Conventional injection group with respect to VAS and Wong-Baker pain scores during tooth extraction. The pain was significantly more in Sure Shot group compared to Conventional injection group during tooth extraction

GRAPHS

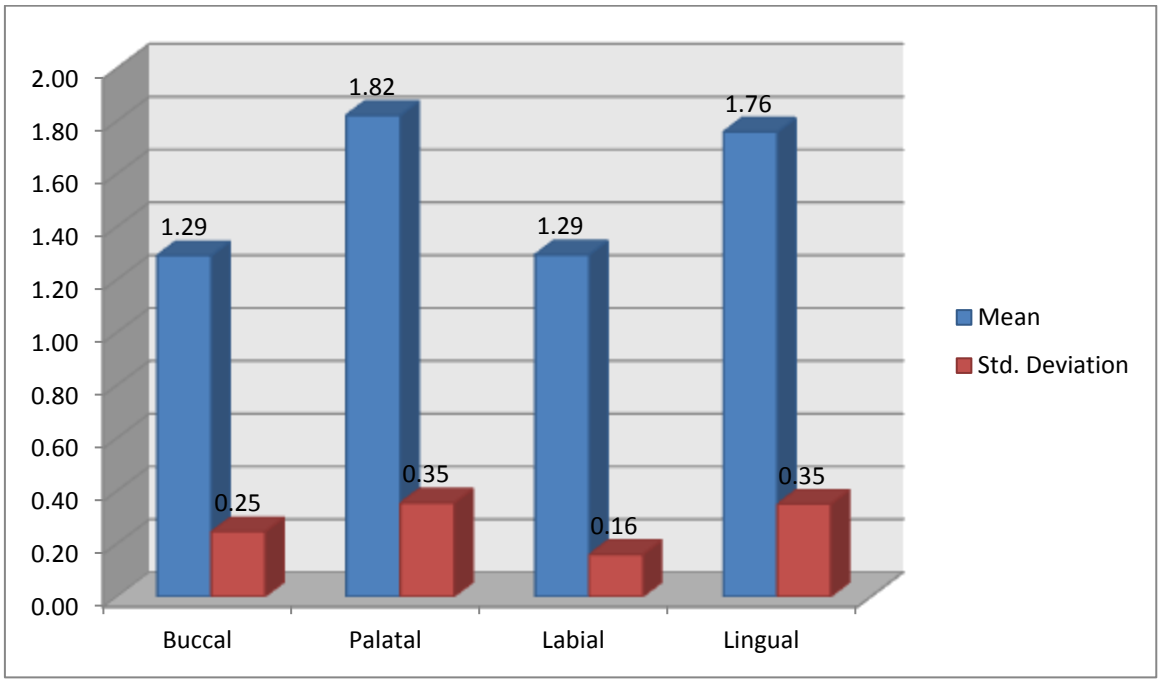
Graph no.1- Bar diagram representing distribution of patients with respect to gender



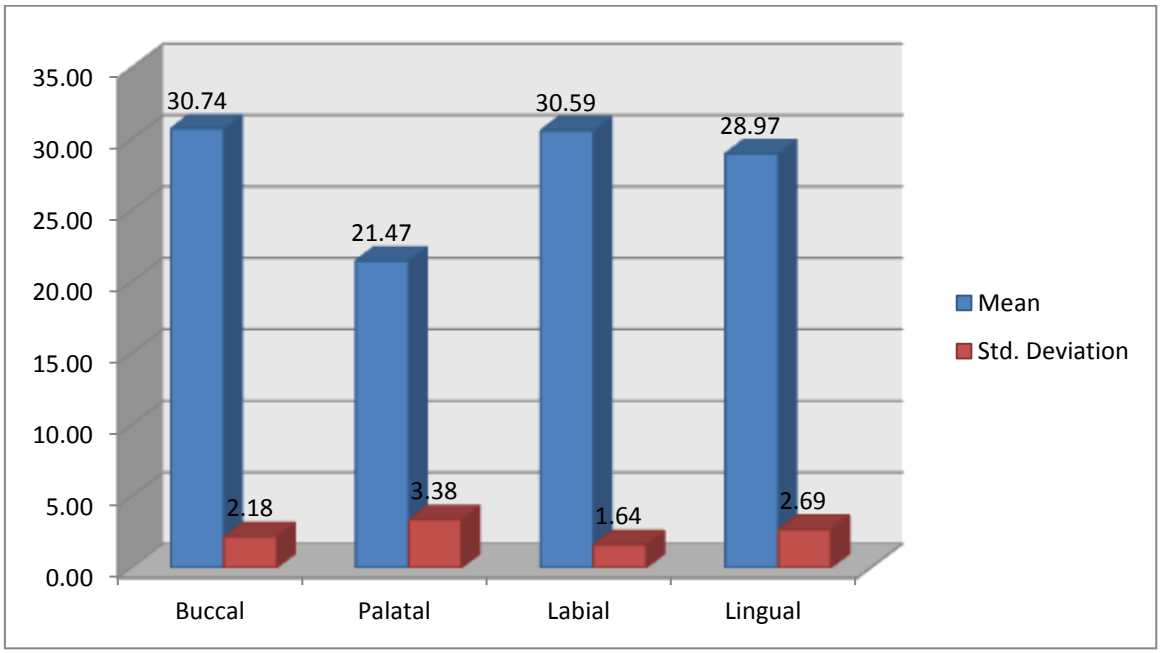
Graph no.2- Bar diagram representing distribution of patients with respect to age



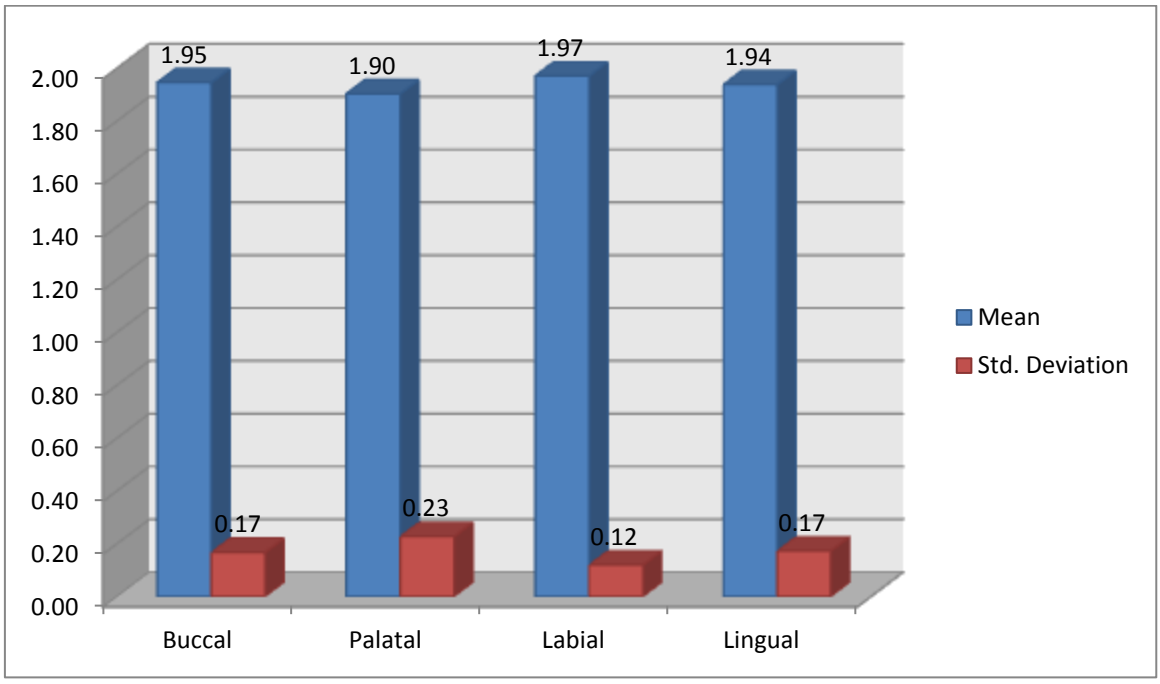
Graph no.3- Bar diagram representing mean time required for the onset of local anaesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect



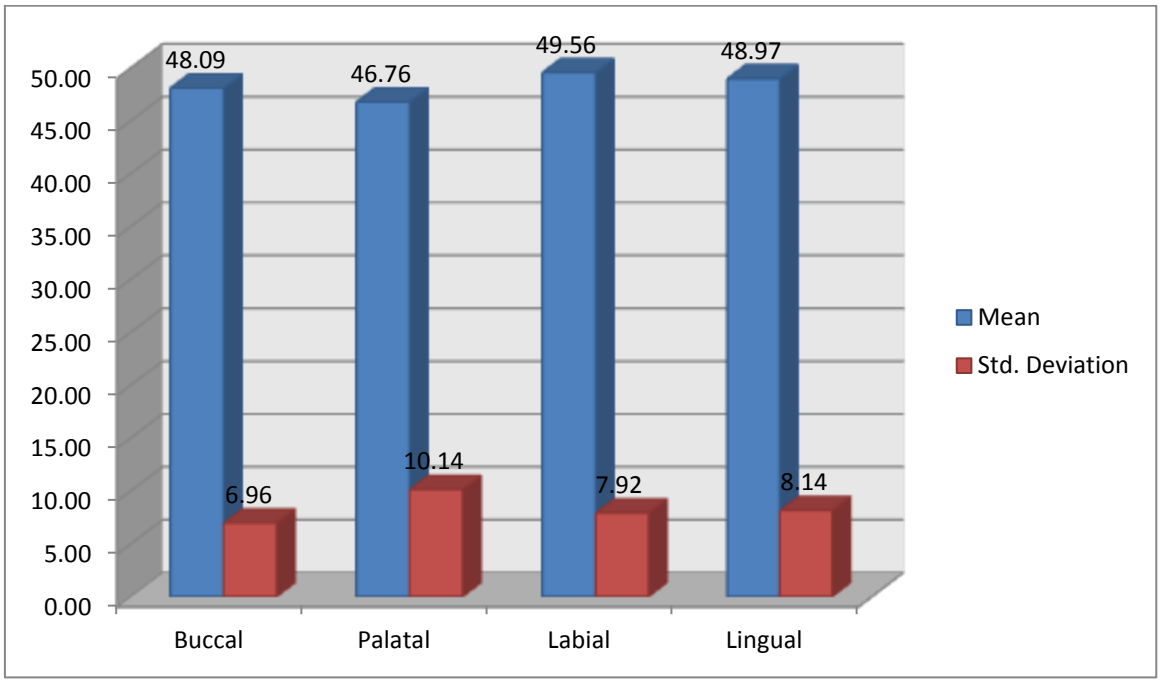
Graph no.4- Bar diagram representing mean duration of local anaesthesia in Sure Shot injection group on buccal, palatal, labial and lingual aspect



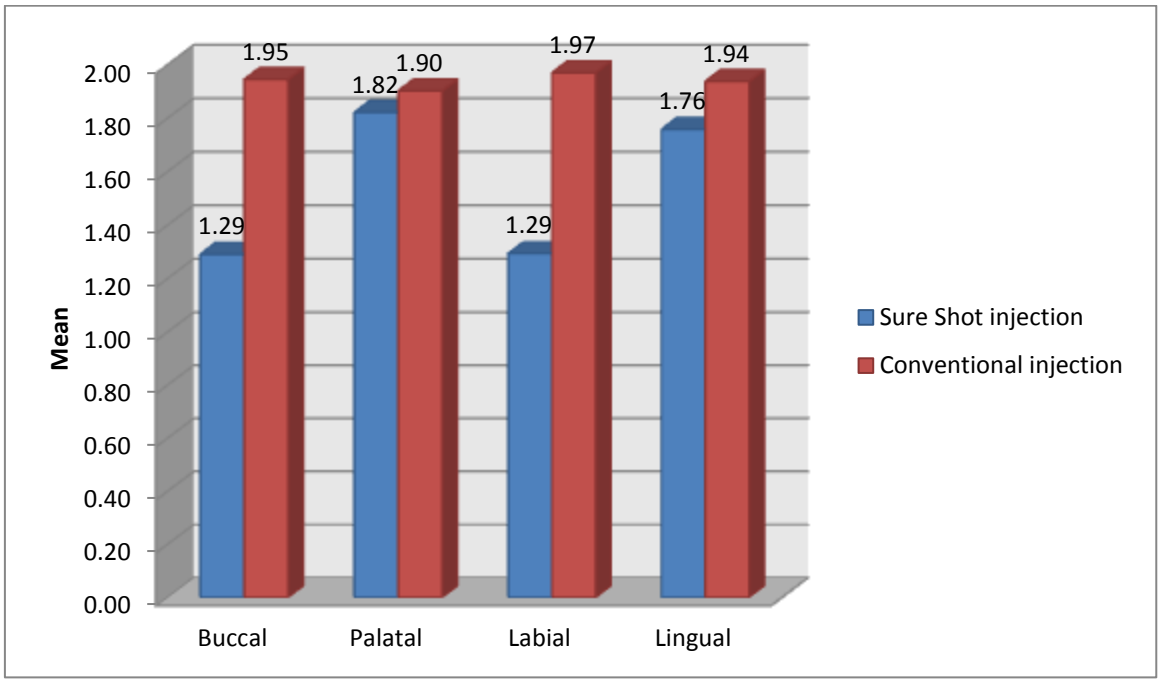
Graph no.5- Bar diagram representing mean time required for the onset of local anaesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect



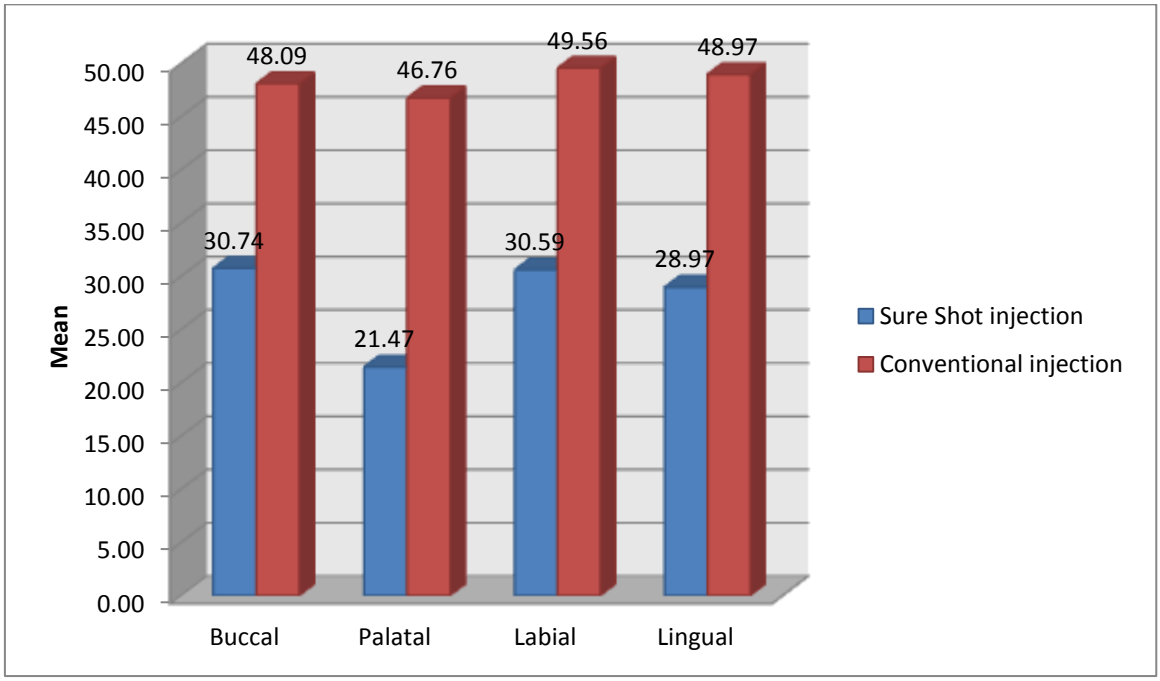
Graph no.6- Bar diagram representing mean duration of local anaesthesia in Conventional injection group on buccal, palatal, labial and lingual aspect



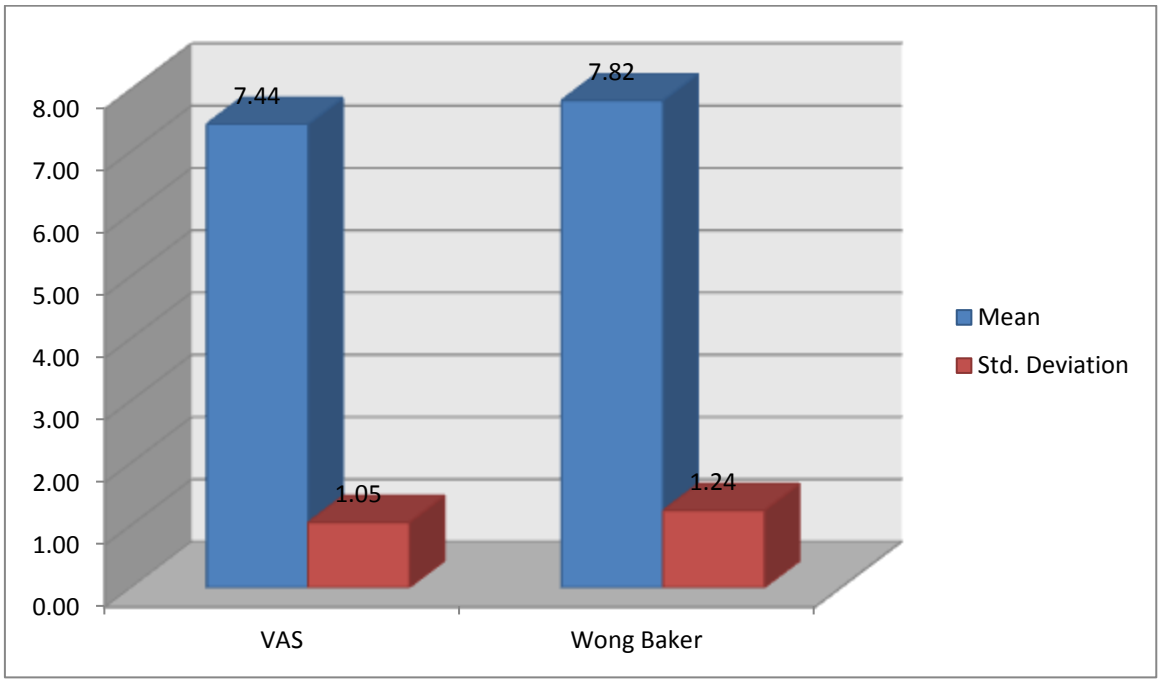
Graph no.7- Bar diagram representing time of onset of local anaesthesia in Sure Shot and Conventional injection group on buccal, palatal, labial and lingual aspect



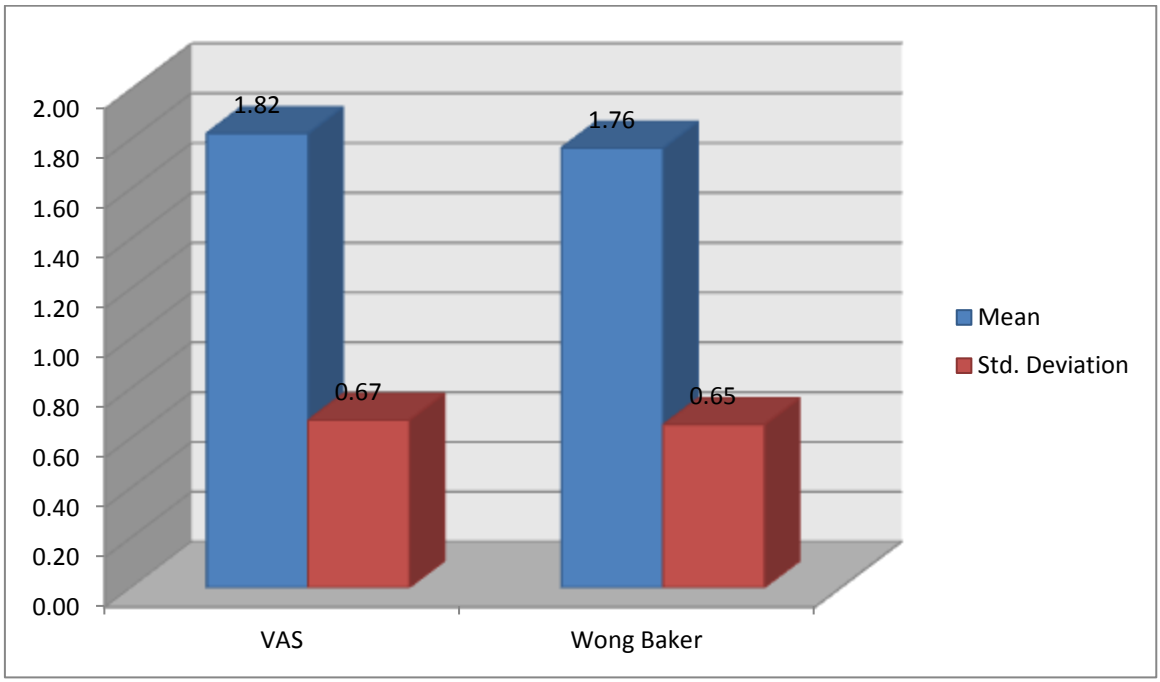
Graph no.8- Bar diagram representing duration of local anaesthesia in Sure Shot and Conventional injection group on buccal, palatal, labial and lingual aspect



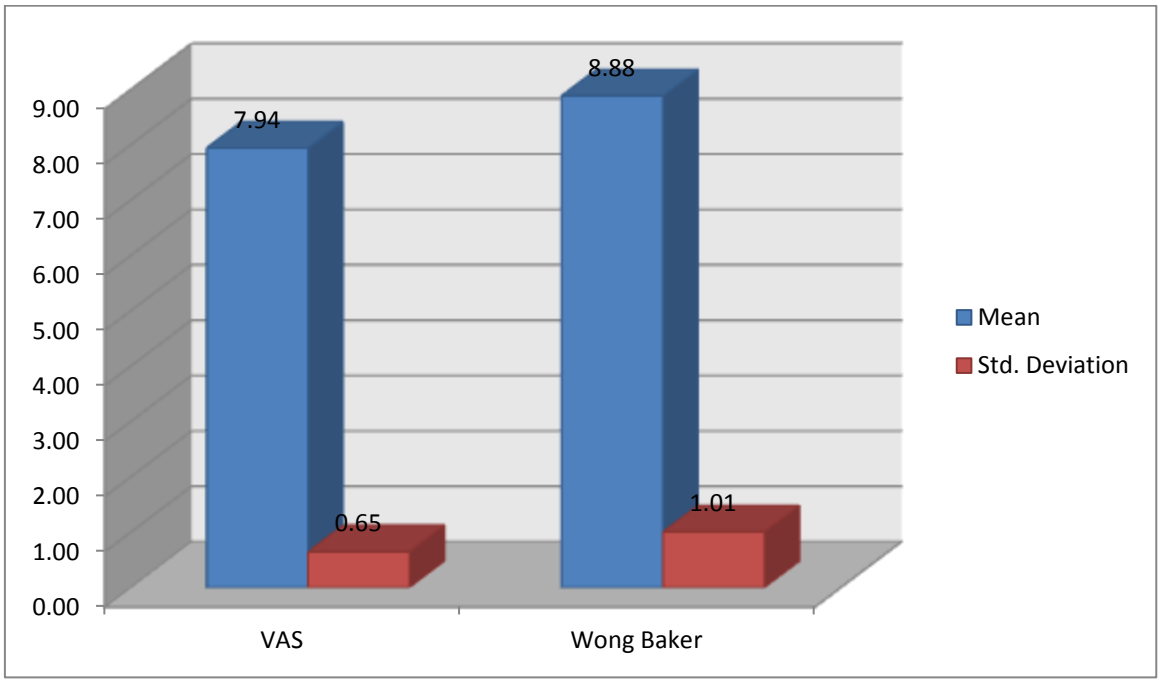
Graph no. 9- Bar diagram representing mean VAS and Wong Baker scores in Conventional injection group while insertion of needle



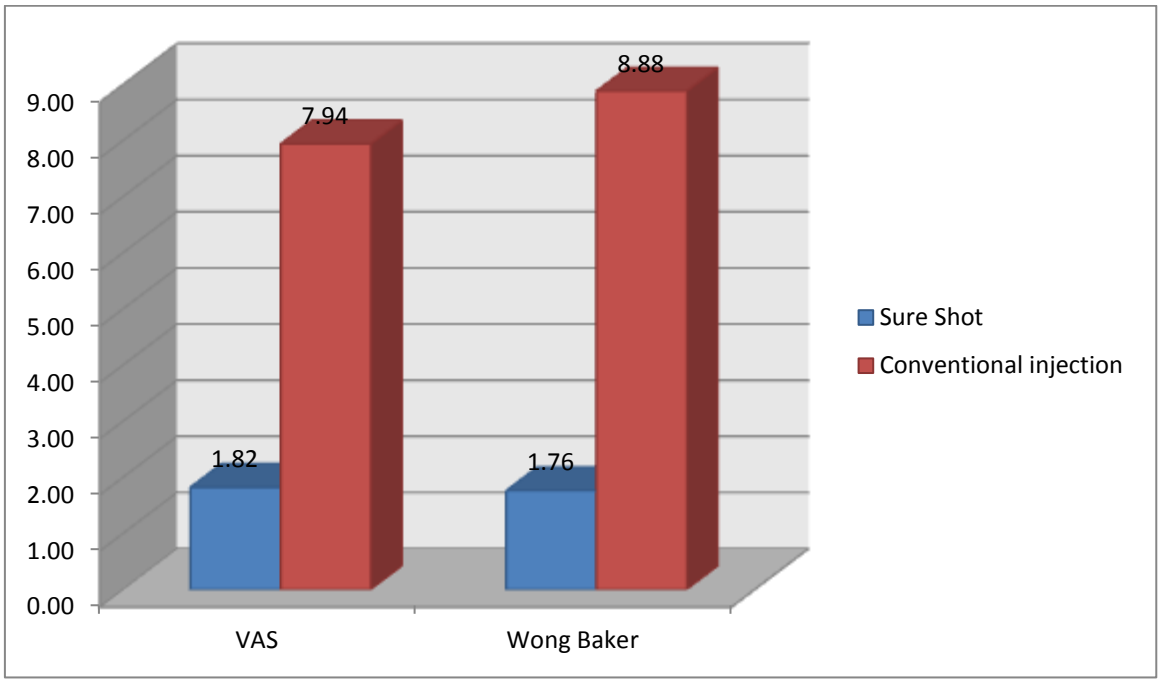
Graph no. 10- Bar diagram representing mean VAS and Wong Baker scores in Sure Shot group during deposition of local anaesthesia



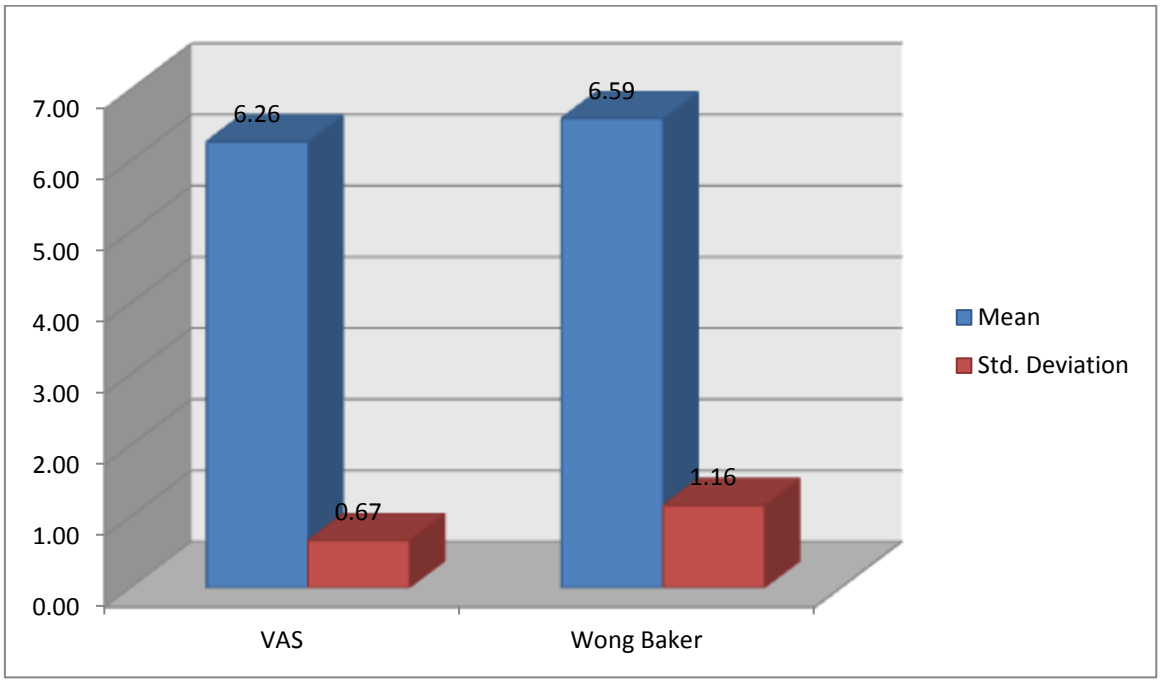
Graph no.11- Bar diagram representing mean VAS and Wong Baker scores in Conventional injection group during deposition of local anaesthesia



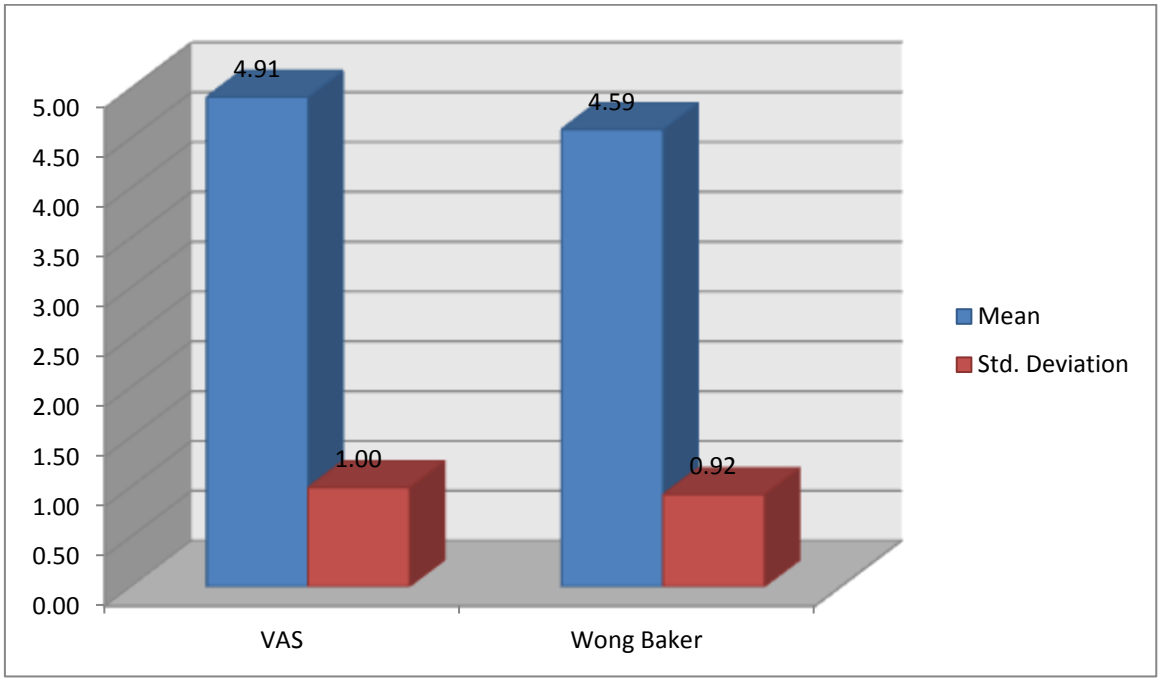
Graph no.12- Bar diagram representing mean VAS and Wong Baker scores in Sure Shot and Conventional injection during deposition of local anaesthesia



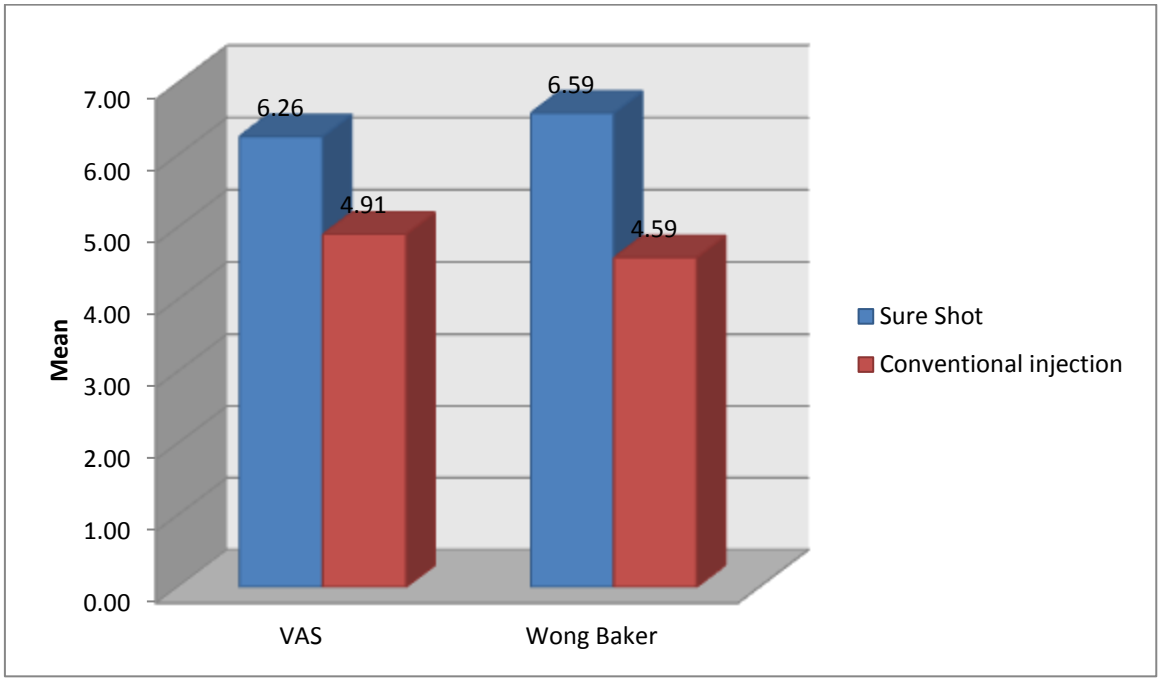
Graph no.13- Bar diagram representing mean VAS and Wong Baker scores in Sure Shot group during tooth extraction



Graph no.14- Bar diagram representing mean VAS and Wong Baker scores in Conventional injection group during tooth extraction



Graph no.15- Bar diagram representing mean VAS and Wong Baker scores in Sure Shot and Conventional injection group during tooth extraction



ANNEXURE I

Consent form

(Confidential)

Informed Consent Form

Evaluation of effectiveness of needleless injection technique in patients undergoing Orthodontic extraction- Split mouth technique- a clinical trial.

NAME: Mr./Master/Mrs./Miss._____

Resident of: _____

_____aged _____ years, exercising my free will/choice, without any pressure/lure of incentive in any form, hereby give my consent for the project to be conducted by **Dr. _____.**

I acknowledge the receipt of "patient's information sheet", and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction.

I agree to undergo this procedure to be taken as part of study

I agree to let my X-rays, photographs, other investigations to be taken as required.

I agree to take part in this project and will not mix any other projects during the period of this trial. I shall report to the dental hospital or other place where called on given appointment dates and time.

I certify that I have read or had read to me the contents of this form.

_____

___Date _____

Patient /legally authorized representative signature

INFORMED CONSENT FORM

(Confidential)

Evaluation of effectiveness of needleless injection technique in patients undergoing Orthodontic extraction- Split mouth technique clinical trial.

I a resident of _____ aged ___ years.

Exercising my free will, without any pressure/lure of incentive in any form, hereby give my consent to be included as subject in the said clinical study.

The doctors have informed me about this research project suitably and sufficiently to my satisfaction. I agree to the treatment modality to be given to me and I am aware of the effects and complications of the said drugs. I agree to allow my photographs to be drawn as required. I agree to take part in this project and will not mix and other projects during the period of this trial. I shall report to the dental hospital or other place where called on given appointment dates and time. I shall inform the doctor on any adverse effect or unusual symptom noticed by me. I shall cooperate with the doctors in all respects. I permit publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed about my right to withdraw from the research project at any given time.

I hereby record my consent for participation in the said trial.

1.				
	Patient's name	Signature	Date	Time
2.				
	Witness	Signature	Date	Time
3.				
	Investigator's name	Signature	Date	Time

(गोपनीय)

माहितीपूर्ण संमती फॉर्म

ऑर्थोडोंटिक अर्क घेणाक्लिनिकल चाचणी -या रुग्णांमध्ये सुई इंजेक्शन तंत्राच्या प्रभावीतेचे मूल्यांकन-, विभाजित-तोंड तंत्र.

नाव: श्री/चि./श्रीमती/कु. ._____

निवासी: _____ वय_____वर्ष.

माझ्या इच्छेच्या / निवडीचा कोणत्याही स्वरूपाचा कोणताही दबाव / प्रोत्साहन न लावता, याद्वारे

डॉ. _____ ने प्रकल्पाचे आयोजन करण्याची माझी मंजुरी देतो/देते.

मी "रुग्णाच्या माहिती पत्रकाची" पावती स्वीकारत आहे आणि डॉक्टरांनी मला या संशोधन प्रकल्पाबद्दल योग्य आणि सूचनेबद्दल माहिती दिली आहे. मी माझ्या मौखिक पोकळीत वापर करण्याची अधिकृती देतो. मी माझ्या एक्स-रे, छायाचित्रे, आवश्यकते नुसार इतर तपासण्या करण्यास सहमत आहे.

मी याप्रकल्पात भाग घेण्यास सहमती देतो आणि या चाचणीच्या काळात कोणतीही इतर योजना एकत्रित करणार नाही. मी डेन्टल हॉस्पिटलमध्ये किंवा इतर ठिकाणी दिलेल्या नियोजित तारखा आणि वेळांचे पालन करीन.

मी प्रमाणित करतो की मी या फॉर्मची माहीती वाचलेली आहे किंवा कोणाकडून वाचवून घेतली आहे.

_____दिनांक_____

_____रुग्ण / कायदेशीर पणे अधिकृत प्रतिनिधी

स्वाक्षरी

(गोपनीय)

माहितीपूर्ण संमती फॉर्म

ऑर्थोडोंटिक अर्क घेणा या-रुग्णांमध्ये सुई इंजेक्शन तंत्राच्या प्रभावीतेचे मूल्यांकनक्लिनिकल चाचणी -, विभाजित-तोंड तंत्र.

.

वैयक्तीक माहिती

रूग्णाचे नाव : दिनांक :
वय/लिंग :
पत्ता :

मोबाईल नंबर :

मी कबूल करतो की डॉक्टरांनी मला या संशोधन प्रकल्पाबद्दल समाधानकारक माहिती दिली आहे. मी माझ्या एक्स-रे, छायाचित्रे, इंप्रेशन आणि आवश्यकतेनुसार अन्य तपासण्या करण्यास सहमत आहे. मी या प्रकल्पात भाग घेण्यास सहमती देतो आणि या चाचणीच्या कालावधीत कोणतेही अन्य प्रकल्प एकत्रित करणार नाही. मला डेन्टल हॉस्पिटल किंवा इतर ठिकाणी दिलेल्या भेटीची तारीख आणि वेळ सांगितली आहे. मी डॉक्टर आणि पॅरामेडिकल कर्मचा-यांना सर्व बाबतीत सहकार्य करेल. या अभ्यासात मी माझ्या सहभागाचे निकाल प्रकाशित करण्यास परवानगी देतो. मला कोणतीही नुकसान भरपाई दिली जाणार नाही. असे करण्यासाठी कोणतेही कारण न देता मला कोणत्याही वेळी या संशोधन प्रकल्पातून बाहेर पडण्याचा अधिकार मिळालेला आहे. मी या अन्वये केलेल्या चाचणीत सहभागासाठी माझी संमती नोंदवित आहे.

१) रूग्णाचे नाव	स्वाक्षरी	तारीख	वेळ
२) साक्षीदाराचे नाव	स्वाक्षरी	तारीख	वेळ
३) डॉक्टरचे नाव	स्वाक्षरी	तारीख	वेळ

MASTER CHART

Pain during Deposition of LA

			Group A				Group B			
Sr.No	**Age**	**Gender**	**Pain on insertion**		**Pain during deposition of LA**		**Pain on insertion**		**Pain during deposition of LA**	
			VAS	Wong Baker	VAS	Wong Baker	VAS	Wong Baker	VAS	Wong Baker
1	14	M	-	-	2	2	8	10	9	10
2	18	F	-	-	3	0	7	8	8	8
3	25	F	-	-	1	2	7	8	8	10
4	20	M	-	-	2	2	`	8	8	10
5	24	F	-	-	1	2	8	8	8	10
6	20	F	-	-	2	2	7	8	7	8
7	23	M	-	-	2	2	7	8	7	8
8	18	F	-	-	3	2	8	8	8	8
9	21	M	-	-	2	0	5	6	8	8
10	23	M	-	-	2	2	6	8	8	8
11	24	F	-	-	2	2	6	8	8	10
12	25	M	-	-	2	2	8	8	8	10
13	18	F	-	-	2	2	7	6	7	8
14	15	M	-	-	3	2	9	10	9	10
15	16	F	-	-	1	2	8	8	8	8
16	22	F	-	-	1	2	8	8	8	8
17	24	F	-	-	2	2	7	6	7	10
18	16	M	-	-	2	2	8	8	8	8
19	15	F	-	-	1	2	9	10	9	10
20	22	M	-	-	2	2	8	8	8	10
21	23	F	-	-	1	2	8	8	8	8
22	14	M	-	-	1	2	9	10	9	10
23	20	M	-	-	1	2	8	8	8	8
24	25	M	-	-	2	2	5	6	7	8
25	22	F	-	-	3	0	8	8	8	10
26	24	M	-	-	2	2	8	8	8	10
27	17	F	-	-	2	2	8	8	8	8
28	21	M	-	-	1	2	7	6	6	8
29	18	F	-	-	1	0	8	8	8	10
30	23	M	-	-	3	2	6	6	8	8
31	19	F	-	-	2	2	7	6	8	8
32	14	M	-	-	2	2	9	10	9	10
33	23	M	-	-	2	2	6	6	8	8
34	25	M	-	-	1	2	7	8	8	8

MASTER CHART

Onset and duration of action of LA

			Group A								Group B							
Sr. No	Age	Gender	ONSET (min)		DURATION (min)		ONSET (min)		DURATION (min)		ONSET (min)		DURATION (min)		ONSET (min)		DURATION (min)	
			BUCCAL	PALATAL	BUCCAL	PALATAL	LABIAL	LINGUAL	LABIAL	LINGUAL	BUCCAL	PALATAL	BUCCAL	PALATAL	LABIAL	LINGUAL	LABIAL	LINGUAL
1	17	M	1.15	2.15	30	20	1.15	2.15	30	25	2	2	40	40	2	1.4	40	40
2	21	M	1.3	2.15	30	20	1.15	2	30	30	2	2	40	40	1.5	2	40	40
3	17	F	1.2	2	25	15	1.5	2.15	30	30	2	1.5	35	35	2	1.5	35	35
4	20	F	2	2.3	30	20	2	2	30	25	2.15	2.15	40	40	2	2	35	35
5	17	M	1.15	2	30	20	1.2	2.15	30	30	2	2	35	35	2	2	35	35
6	19	M	1.5	2.15	30	15	1.3	2	30	30	2	2.15	30	35	2	2	35	35
7	19	M	2	2.5	30	20	1.2	2	35	20	2	2	50	40	2	2	50	40
8	24	M	1.3	2	35	20	1.15	1.2	35	20	1.5	1.5	45	45	1.5	1.5	50	45
9	19	F	1	2	35	20	1.15	2	35	30	2	2	50	50	2	2	50	50
10	17	F	1.4	2	30	15	1.3	2	30	30	2	2	45	45	2	2	45	45
11	23	F	1.2	2	35	20	1.15	1.5	30	30	2	2.1	50	50	2	2	50	45
12	20	F	1.15	2	30	30	1.3	1.5	30	30	2	2	50	5	2	2	50	50
13	17	F	1.3	1.5	30	20	1.4	2	30	30	2	2	45	45	2	2	45	45
14	18	M	1.15	2	30	25	1.2	1.5	30	30	2	1.4	50	50	2	1.5	45	45
15	23	M	2	2	30	20	1.3	2	30	30	2	2	45	45	2	2	45	45
16	18	M	1.2	1.5	30	20	1.5	2	30	30	2	2	50	50	2	2	50	50
17	14	F	1.15	2	30	20	1.2	2	30	30	2	2	50	50	2	2	50	50
18	23	M	1.2	1.5	35	25	1.3	2	30	25	2	2	60	60	2	2	50	50
19	16	M	1.15	1.2	30	20	1.4	2	30	30	1.5	1.5	50	50	2	2	50	50
20	15	M	1.2	1.15	35	25	1.2	2	30	30	2	2	45	45	2	2	60	60
21	13	F	1.5	2.1	30	25	1.4	2	30	30	2	2	55	60	2	2	65	65
22	24	M	1.2	2	30	25	1.2	2	30	30	2	2	50	50	2	2	60	60
23	14	F	1.15	1.5	30	25	1.3	1.5	30	30	2	1.4	50	50	2	2	55	55
24	23	M	1.3	1.5	30	20	1.4	1.15	35	30	1.5	1.5	45	45	2	2	50	50
25	22	M	1.2	2	35	20	1.3	2	30	30	2	2	50	50	2	2	60	60
26	14	F	1.15	2	30	20	1.2	2	30	30	2	2	50	50	2	2	55	55
27	18	F	1.15	2	30	20	1.15	2	30	30	2	2	50	50	2	2	50	50
28	19	F	1.2	1.5	30	25	1.2	1.3	30	30	2	2	55	55	2	2	55	55
29	21	F	1.3	2	30	25	1.3	1.2	30	30	2	2	45	45	2	2	45	45
30	18	M	1.15	1.5	30	25	1.4	1.4	30	30	2	2	50	50	2	2	50	50
31	21	M	1.3	1.3	30	20	1.2	1.2	30	30	1.5	1.5	55	55	2	2	55	55
32	16	F	1.15	1.15	30	25	1.3	1.3	30	30	2	2	60	60	2	2	60	60
33	16	F	1.15	2	30	25	1.3	1.3	30	30	2	2	55	55	2	2	55	55
34	16	F	1.3	1.3	30	20	1.3	1.3	30	30	2	2	60	60	2	2	60	60

MASTER CHART

Pain during Extraction

			Group A		Group B	
Sr.No	**Age**	**Gender**	**Pain during Extraction**		**Pain during extraction**	
			VAS	Wong Baker	VAS	Wong Baker
1	14	M	6	6	4	4
2	18	F	5	6	4	4
3	25	F	6	6	6	6
4	20	M	7	8	6	4
5	24	F	6	6	4	4
6	20	F	7	8	6	6
7	23	M	7	8	4	4
8	18	F	6	6	4	4
9	21	M	6	6	4	4
10	23	M	5	6	4	4
11	24	F	7	8	6	6
12	25	M	6	6	4	4
13	18	F	7	8	6	4
14	15	M	6	6	4	4
15	16	F	7	8	6	6
16	22	F	6	6	5	4
17	24	F	7	8	6	6
18	16	M	5	6	6	4
19	15	F	6	4	4	4
20	22	M	6	6	6	4
21	23	F	6	4	6	4
22	14	M	7	8	7	6
23	20	M	6	6	4	4
24	25	M	6	6	5	4
25	22	F	7	8	5	4
26	24	M	6	6	4	4
27	17	F	7	8	6	6
28	21	M	6	6	5	6
29	18	F	7	8	5	6
30	23	M	5	6	3	4
31	19	F	6	6	5	4
32	14	M	7	8	5	6
33	23	M	6	6	4	4
34	25	M	7	6	4	4