

Single-Tooth Anesthesia: Pressure-Sensing Technology Provides Innovative Advancement in the Field of Dental Local Anesthesia

Abstract

This article will review standard techniques for intraligamentary injection and describe the technology and technique behind a new single-tooth anesthesia system. This system and technique represents a technological advancement and a greater understanding of intraligamentary anesthesia.

Today's most common method of injecting dental anesthetic, the dental syringe,^{1,2} debuted in the late 1800s when William Halstead introduced the first pain management techniques to medicine and dentistry.³ Halstead demonstrated that a subcutaneous injection of aqueous cocaine injected adjacent to the trunk of a sensory nerve resulted in the numbing of pain in all of that nerve's branches. Although many important developments in dental local anesthesia have occurred since that time regarding the formulation and pharmacokinetics of anesthetic drugs, very few meaningful improvements have been made with respect to the syringe itself.

In 1997, a new concept of drug delivery was introduced to the dental profession: computer-controlled local anesthetic delivery systems (CCLADS).^{4,5} The original CCLADS product was called The Wand^a and has since been renamed The Wand/Compudent System. This delivery system consists of a computer-controlled drive unit and a separate single-use disposable handpiece/needle assembly. Several other CCLADS followed, including Comfort Control Syringe^b, QuickSleeper^c, and Anaject^d.

In 1998, a fundamental change was introduced to drug delivery systems with the development of dynamic pressure sensing (DPS) technology, which enabled fluid pressure and flow rate at the needle tip to be precisely controlled and monitored in real-time during all phases of the injection process.⁶ DPS technology is unique in that it allows a clinician to easily and accurately identify specific tissue types, at the needle position, based on tissue compliance. This pressure-regulated CCLADS represents a second-generation device compared with the first-generation devices described above. Applying this new concept to dental injections enables the clinician to perform an easier, faster, and more reliable dental injection technique.

The Advent of the PDL Technique

In the early 1900s, Guido, Fischer, and Cassamani were the first to describe the intraligamentary or peri-

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^a Milestone Scientific Inc, Livingston, NJ, 07039; www.milestonescientific.com

^b Dentsply International, York, PA 17405; www.dentsply.com

^c Dental Hi Tech, France; www.dentalhitech.com

^d J Morita Nashika Line, Japan – distributed by Septodont, Inc.



Figure 1—The standard periodontal ligament (PDL) technique uses a “blind” approach and placement of the needle into the PDL. The traditional technique relies on subjective “feel” of the operator.

odontal ligament (PDL) injection technique,^{7,8} which uses a standard dental syringe and consists of “blind” placement of a hollow-bore metal needle into the gingival sulcus, followed by advancing the needle into the PDL located between the root surface (cementum) and the bony socket of a tooth⁹⁻¹⁴ (Figure 1). The technique is understood today as a nontrephinating intraosseous injection.

Critical to the technique was the placement of the needle tip within or at the entrance to the PDL, followed by the application of high pressure (typically between 600 psi to 1200 psi) to deliver anesthetic into dense oral tissue.^{15,16} The total recommended volume of anesthetic solution was 0.2 mL to 0.4 mL using this method. However, both components of the technique have pitfalls.

For example, for the past century, many clinical authors have described the difficulties of positioning the needle within the desired location because of the usual lack of direct visualization and absence of identifiable anatomic landmarks. The result has been a “blind” approach to needle placement.⁹⁻¹⁴ In addition, maintaining correct needle placement throughout the administration phase of anesthesia is difficult to achieve and confirm.^{12,15}

While the application of maximum hand pressure on the dental syringe is necessary to forcibly move anesthetic solution through the dense tissue, unusually high syringe pressures can cause tissue damage as evidenced by histologic, animal, and human studies.¹⁵⁻¹⁹ This tissue damage also results in increased pain perception reported by dental patients.²⁰⁻²²

Another concern is that traditional syringes do not allow the clinician to confirm that the correct amount of anesthetic has been delivered, because both blockage or leakage during injection can occur.²³ This can result in insufficient duration of anesthesia.

Two studies reported a 10- to 20-minute duration of effective pulpal anesthesia for the PDL technique when tested.^{20,24} That research used a variety of local anesthetics with varying concentrations of vasoconstrictors. When performed with greater volume, the PDL technique demonstrated a longer effective working time correlated with a larger dosage administered.²⁵ Inadequate anesthetic

solution volumes result in limited duration of anesthesia.

In summary, traditional techniques and technologies used in routine intraligamentary injections are hampered by the blind nature of injection, the extreme pressures generated in local tissue during the procedure, and the relatively small volume of anesthetic that can be reliably delivered. These factors have resulted in a reduced duration of anesthesia, increased pain, and the associated tissue damage previously noted.

Leveraging Technology to Overcome PDL Pitfalls

In mid 2006, Milestone Scientific, Inc obtained Food and Drug Administration (FDA) clearance to market a medical device (CompuFlo System) that regulated exit pressure and accepted all standard syringes. This system was available exclusively for medical applications.

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While a variety of applications for medical use have been identified, the epidural regional anesthesia has been one of the first to be clinically tested. Published scientific abstracts demonstrate that this technology allows for the identification of the epidural space with a high degree of accuracy and at a level previously unobtainable. In 2 separate studies, Ghelber and colleagues reported a 100% success rate for the identification of the epidural space.^{26,27} In addition, the use of this device has shown a markedly improved and simplified training of physicians in performing epidural injections.²⁷

In 2006, a second device (STA-System [Single Tooth Anesthesia System] Milestone Scientific, Inc. Livingston, NJ, www.STAis4U.com) was developed that incorporated DPS technology and was specifically engineered for dental applications.^{6,28,29} This system has since obtained FDA clearance for dental use.

The system functions similarly to the medical unit by providing continuous monitoring of the exit pressure in real-time during all phases of drug administration. The dental system also has the ability to limit the maximum pressure used and will detect a loss of pressure from leakage during an injection. The device is the only CCLADS to provide real-time DPS technology, enabling clinicians to perform a predictable and highly successful single-tooth anesthesia technique.

At the core of the device lies an electromechanical motor regulated by a central microprocessor unit functioning in concert with a force/pressure transducer. A series of force/pressure transducers detect system resistances, allowing a mathematical algorithm to calculate instantaneous real-time measurements of the fluid “exit pressure.”⁶ The measured pressure data become a feedback signal,

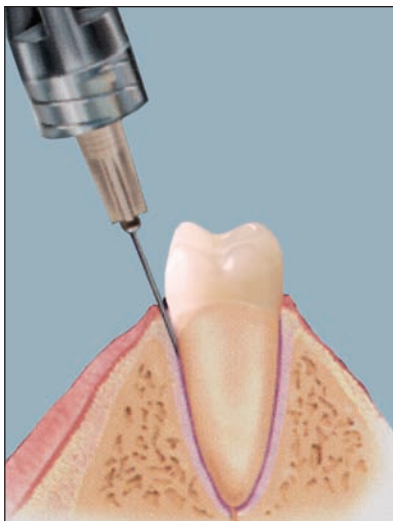


Figure 2—The STA-intraligamentary injection uses the STA-System real-time dynamic pressure-sensing technology to guide the needle to the PDL. Accurate and objective feedback is provided to the operator.

which is then converted into an audible sound, as well as a visual display so that the user is continuously aware of the tissue density. The concept of real-time DPS and display is unique to this device and technology.

Fundamentals of the STA-Intraligamentary Injection

The STA-intraligamentary injection requires the needle tip to be physically guided to the PDL (Figure 2). This is achieved using real-time DPS technology and acknowledging that tissue in the body is comprised of varying densities.

For example, the PDL possesses an interstitial pressure range that is unique to the surrounding tissue, namely bone and attached and unattached gingival tissue. Once the needle tip is located in the optimal location, the system provides confirmation (in the form of audible tones, visual display, and spoken alerts) that the needle tip has arrived and has not moved outside the targeted tissue during administration. In addition to location confirmation, the system provides pressure-sensing feedback to inform the clinician that no blockage of the needle from obstruction or tissue clogging has occurred.

Dynamic pressure sensing also alerts the user if leakage occurs, which can be a result of poor needle placement, insufficient hand pressure on the handpiece, or internal leakage of the cartridge or tubing. The technology is designed to inform the clinician if a potential loss of pressure has occurred as a result of any of the undesirable scenarios described above.

Greater anesthetic dosage can be administered using the new technology than with conventional syringe-based intraligamentary injection techniques. This is because of the moderate pressures applied and the computer-controlled rate of flow during administration. The volume of anesthetic solution is not limited via the (nontrephinating, intraosseous) intraligamentary route performed with the injection. Therefore, the recommended dosage of

anesthetic solution ranges from 0.9 mL (for single-rooted teeth) to < 1.8 mL (for multi-rooted teeth) when using a 2% concentration local anesthetic solution. When using a 4% concentration such as articaine hydrochloride, half the dosage is recommended (eg, 0.5 mL for single-rooted teeth to 0.9 mL for multi-rooted teeth).

The clinician should understand that the volume of anesthetic is related to the duration of anesthesia, and plan according to individual procedural needs. The typical duration of anesthesia exceeds the time required to perform routine dental care when an appropriate volume is administered. Re-dosing during treatment is possible with this technique.

The ability to accurately identify specific tissue types based on real-time measurements of tissue resistance (eg, tissue compliance, interstitial tissue pressure) is unique and a critical aspect of DPS technology. Pressure measurements of different tissue density types are related to the physical compliance of specific tissues during fluid injection, the ratio of increase of volume to the simultaneous increase in fluid pressure. The DPS capability of this system has been published in the medical and dental literature.

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Ghelber and colleagues have demonstrated the ability to differentiate between specific tissue types during a subcutaneous injection based on pressure.²⁶ In addition, Hochman and colleagues performed 200 dental injections that identified 3 specific tissue type categories that were based on interstitial pressure measurements in the intraoral cavity: the periodontal ligament tissue, the attached gingiva, and the unattached gingiva mucosa.³⁰

Performing the STA-Intraligamentary Injection

The STA-System is comprised of a lightweight, portable drive unit and a separate single-use disposable handpiece assembly attachment (STA-Wand). The drive unit is powered by a standard AC electrical connection. The handpiece consists of a handle, microbore tubing, and an anesthetic cartridge holder that accepts any standard dental anesthetic cartridge and any standard medical needle. The injection is typically performed using a 30-gauge or 27-gauge half-inch luer-lock needle.

The drive unit operates in 3 basic modes of drug delivery rates:

- STA: 1-speed mode (0.005 mL/sec)
- Normal: 2-speed mode (0.005 mL/sec and 0.03 mL/sec)
- Turbo: 3-speed mode (0.005 mL/sec, 0.03 mL/sec, and 0.06 mL/sec)

All injection rates are controlled by the clinician using a foot-control connected to the drive unit, and



Figures 3A - 3C—The STA-System real-time feedback is an audible and a visual pressure sensing scale. The visual scale is displayed on the front panel, composed of a series of LED lights—orange, yellow, and green. The orange lights indicate minimal pressure (Figure 3A), the yellow indicate mild to moderate pressure (Figure 3B), and the green indicate moderate pressure (Figure 3C), indicative of the PDL tissue.

only the STA 1-speed mode should be used when performing this intraligamentary injection.

As the needle is introduced through the tissue, the system provides continuous audible and visual feedback to the clinician. The system has a visual pressure sensing scale composed of a series of LED lights (orange, yellow, and green)(Figures 3A-3C). The orange lights indicate minimal pressure, the yellow indicate mild to moderate pressure, and the green indicate moderate pressure indicative of the PDL tissue. It is important to note that because of slight variations in patient tissue density, the PDL tissue also may be identified at pressures of the yellow LED high-range as well.

Through auditory feedback, the clinician is aware of correct needle-to-intraligamentary position being maintained during the injection. The auditory feedback is comprised of a series of sounds with a pressure-sensing scale composed of ascending tones to guide the clinician. When the clinician hears the ascending sequence, this indicates that the pressure is rising. When the periodontal ligament is identified, the letters “PDL” will be spoken indicating that the correct needle position has been achieved. Maintaining a consistent level of moderate pressure throughout the injection process is necessary for success. The audible and visual feedback provides this important information to the user.

Clinical use of the system has found that it is common to reposition the needle to find the optimum position within the intraligamentary tissues, enabling a clinician to develop a high degree of predictability and accuracy when performing the injection, and transforming the “blind” syringe approach into a scientific method for locating the correct needle-to-intraligamentary position.

The clinician may find that slight movements of either the clinician’s hand or patient’s head can result in a rapid loss of pressure that would typically not be detected using a dental syringe. During the injection, the clinician is kept informed of the correct needle to intraligamentary position. The real-time feedback of this system also informs the clinician of the proper hand pressure to be applied. Heavy or

forceful pushing on the handpiece can block the flow of anesthetic solution, which will be detected by the system and an “over-pressure” condition will occur, exceeding the maximum pressure programmed in the unit. This is common; the unit will sound an auditory and visual alert and the clinician can restart the injection. It might be necessary to reposition or move the needle to a new location.

If inadequate hand pressure is applied when establishing a needle-to-intraligamentary relationship, a proper seal between the needle and the intraligamentary tissue cannot be established. This leads to insufficient pressure or leakage of the anesthetic solution into the patient’s mouth. The DPS technology will detect this before it can be visually seen by the clinician, preventing

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the typical bitter taste of leaking anesthetic.

The clinician should use his or her own judgment as to the anesthetic drug selection and volumes used. The following information serves only as a guideline, and clinicians are advised to refer to the appropriate drug manufacturers for specific recommendations. In addition, clinicians are advised to review the current dental literature and dental textbooks for guidance on recommended dosages and drug recommendations.

When using 2% lidocaine hydrochloride or other local anesthetics formulated with a 2% concentration, the following recommendations are made:

- A drug volume of 0.9 mL is recommended for single rooted teeth.
- A drug volume of <1.8 mL is recommended for multi-rooted teeth.

When using 4% articaine hydrochloride or other local anesthetics formulated with a 4% concentration, the following recommendations are made: (Note: It is strongly recommended when using 4% articaine hydrochloride that a 1:200,000 vasoconstrictor concentration be used.)

- A drug volume of 0.5 mL is recommended for single-rooted teeth.
- A drug volume of 0.9 mL is recommended for multi-rooted teeth.
- The use of 2% local anesthetics containing a vasoconstrictor concentration of 1:50,000 parts is not recommended for administration of an intraligamentary injection.
- The use of 4% local anesthetics containing a vasoconstrictor concentration of 1:100,000 parts is not recommended for administration of an intraligamentary injection.

The clinician may find that slight movements of either the clinician's hand or patient's head can result in a rapid loss of pressure that would typically not be detected using a dental syringe.

Depending on the local anesthetic solution selected, the injection can take 1 to 2 minutes to administer for a single-rooted tooth, and 1½ to 3½ minutes for a molar.

One of the advantages of using 4% articaine hydrochloride 1:200,000 vasoconstrictor solution is that it will require half the time to perform the injection compared with 2% concentration anesthetics (eg, lidocaine hydrochloride). This is because the current recommendation suggests approximately half the volume to be administered when using a 4% concentration.

An additional advantage was reported by Berlin and colleagues.²⁵ The research team conducted a well-controlled randomized study demonstrating an increase of more than 10% in success rates when using 4% articaine with a CCLADS to perform an intraligamentary injection.

Documented Patient and Operator Preference of Single Tooth Anesthesia

Reports in the dental literature consistently find a patient preference with intraligamentary injection using CCLADS compared with the inferior alveolar block injection and/or buccal infiltration.³¹⁻³⁶ Most notable is the significant reduction in pain-induced disruptive behavior among pediatric patients.³¹⁻³⁶ This is worthy of special note because reducing disruptive behavior in children will result in a lifelong benefit to these dental patients.

Operator preference to perform the PDL injection also has been well documented.^{10,23,34,37} This preference may be related to immediate onset of anesthesia, the ability to perform dentistry bilaterally in the mandible in a single visit, and high patient acceptance because of a lack of numbness of the tongue, lip, and cheek. There also is an operator preference attributed to the safety of the intraligamentary injection when compared with the risks of deep tissue injections (eg, potential of transient or permanent lingual paresthesia).

Summary

The STA-intraligamentary injection provides a unique, single-tooth injection technique that provides a level of safety, comfort, and predictability previously unattainable. The system provides the clinician with multiple benefits that cannot be achieved using the standard dental syringe, the pistol-grip high-pressure syringe, or other CCLADS:

1. It enables a predictable intraligamentary injection to be performed as a primary injection with associated rapid onset and increased duration of anesthesia.
2. An objective means of determining tissue compliance and thereby enabling rapid acquisition of the PDL.
3. Objective, continuous, real-time pressure feedback data ensuring that the prescribed moderate pressure range is maintained within the injected tissue.
4. Objective, real-time information as to the occlusion of a needle and/or the loss of pressure resulting from intraoral anesthetic solution leakage.

This system with DPS technology is the only CCLADS with the ability to provide important clinical feedback in real-time, thus allowing adjustments and confirmations to be made as determined by the clinician.

However, it should be understood that the procedure still requires users to have an in-depth knowledge of basic anatomy, basic technique, and a full understanding of local dental anesthesia. The PDL injection, performed with this system, eliminates previous subjectivity regarding correct needle position and leads to a high level of confidence and success in single-tooth dental anesthesia.

Disclosure

Dr Hochman is the inventor of the STA-System and is a consultant to Milestone Scientific, Inc.

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