

Interstitial tissue pressure associated with dental injections: A clinical study

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Objectives: The purpose was to measure the interstitial fluid pressure generated from tissue resistance during administration of local anesthetic solution at 4 anatomic locations within the oral cavity and to determine whether differences in soft tissue density affect interstitial fluid pressure when anesthetic solution is administered at a fixed flow rate.

Method and Materials: A computer-controlled local anesthetic delivery device (CompuFlo, Milestone Scientific) that records and stores pressure data during a subcutaneous injection was used. Subjects consisted of adult patients seeking routine dental care that required local anesthesia. A total of 200 injections were administered and fluid pressure readings recorded. Injections were divided into 4 groups of 50: group 1—intraligamentary injections (FDL); group 2—palatal injection, anterior middle superior alveolar nerve block; group 3—supraperiosteal buccal infiltrations, and group 4—inferior alveolar nerve blocks. For all injections 1 cartridge (1.8 ml) of lidocaine containing 1:100,000 concentration of epinephrine was administered at a fixed flow rate of 0.005 ml/sec.

Results: One way analysis of variance (ANOVA) revealed that the data were statistically significant ($P < .001$), with corresponding mean values as follows: group 1, 293.98 psi; group 2, 68.16 psi; group 3, 11.50 psi, and group 4, 9.76 psi (F-ratio of 2371.933). Groups 1 and 2 were different from all other groups; groups 3 and 4 were not statistically different from each other. **Conclusion:** Interstitial resistance to fluid pressure can be measured during administration of 4 different local anesthetic injections used in dentistry. Based on fluid pressure and tissue resistance characteristics, a soft tissue density classification was defined. (*Quintessence Int* 2006;37:469-476)

Key words: computer-controlled drug delivery system, computer-controlled local anesthetic delivery system, dental injection pressure, local anesthesia, local anesthetic technique, tissue pressure

The standard routes of drug administration into the body are inhalation, enteral, and par-

enteral.^{1,2} Practitioners select a route that is congruous with the specific target as well as the physical characteristics of the drug being administered. Local anesthetic drugs are formulated as aqueous solutions and allow for placement into subcutaneous anatomic locations. Halstead performed the first local anesthesia nerve block a century ago and identified an appropriate drug delivery system: the syringe and hollow-bore needle.³ Following Halstead, numerous important pharmacologic advancements have been made to local anesthetics, resulting in safer and more effective drugs.^{1,2} In sharp contrast, far fewer meaningful modifications have been made to the drug delivery system (ie, the syringe and hollow-bore needle) over this same time span.^{2,5}

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Date of Submission: July 21, 2004

Date of Acceptance: November 21, 2005



Fig 1 CompuFlo, a fluid-pressure computer-controlled local anesthetic delivery system.

Syringe-based drug delivery systems have evolved out of the need to economically and conveniently store and deliver drugs. Since the 1940s, the glass anesthetic cartridge has served as a practical means to providing a premixed drug to be used in conjunction with a metallic, breech-loading, aspirating syringe.^{1,2} A traditional dental syringe can be more appropriately referred to as a *hand-driven dental syringe*. It is not ergonomically designed to allow precise manual control of fluid flow, nor does it allow hydrodynamic elements of the system to be altered. To address these deficiencies, an innovative dental device for the administration of local anesthetic was developed by Spinello.³ In 1997, after modifications to the original design were made, it became commercially available from Milestone Scientific as the Wand.⁴ It has since been renamed the CompuDent/Wand System from Milestone Scientific.⁵ In 2001 an additional device named Comfort Control Syringe (CCS) was introduced by Dentply International into the dental market.⁶ These computer-controlled local anesthetic delivery systems (CCLADS) represent a dramatic shift in administration by enabling the precise control of a flow rate during all dental injections.

In 1998, Hochman initiated research on a novel computer-controlled device capable of advanced fluid dynamics not previously reported.⁷ This system was developed to

precisely control and measure the fluid pressure at the needle tip within tissue in real time. This unique drug delivery system was designed to allow injections to be performed while simultaneously monitoring the pressure and precisely controlling flow rate. The core technology is based on a series of mathematical algorithms functioning in concert with a pressure transducer, enabling instantaneous real-time measurements of the fluid "exit pressure."⁸ The pressure data are electronically processed and become a feedback signal that regulates the entire injection process. This fluid-pressure computer-controlled delivery system is referred to as CompuFlo (Milestone Scientific) (Fig 1). The system differs from all previous CCLADS because it is designed to accept a wide variety of disposable medical syringes as well as a dental anesthetic cartridge.

A CCLADS represents a new category of advanced subcutaneous drug delivery systems. These include the Wand, CompuDent, CompuMed (Milestone Scientific), Comfort Control Syringe, QuickSleeper (Dental Hi-Tech), and Anaject (Nashika). The CompuFlo system represents a second-generation CCLADS with additional capability of detecting pressure and electronically responding through feedback-loop circuitry. It is anticipated that additional systems will be developed as further interest grows in this new generation of drug delivery systems.

It has been universally accepted in dental textbooks on local anesthesia that an injection administered "slowly" is both the safest and most comfortable means of delivering local anesthetic drugs.⁹⁻¹¹ Definitions and quantifications of "slow injection" have been offered by various authors. One textbook defines a slow rate of delivery as being between 0.5 mL/min and 1.0 mL/min (0.008 mL/sec and 0.017 mL/sec, respectively).⁹ In Malamed's widely used textbook he advises clinicians to use an even slower rate of delivery when injecting into tissues of low elasticity, such as the palate.^{10,12,13} Dental injections are routinely administered into tissue types of various densities without an understanding of how different tissues, densities and in situ resistance influence the outcome of these injections.

Palatal injections are well recognized to be the most uncomfortable of all injections in the oral cavity.^{12,13,32} This is due, in part, to the highly innervated and densely packed connective tissue stroma of the palate. In contrast, injections administered into loose alveolar connective tissue, such as those found in a supraperiosteal buccal infiltration, produce subjective pain responses that are much less than those in the palate.^{12,13} In addition, pain and tissue damage have been associated with unintentional trauma during dental injections.¹³⁻¹⁷ Although largely unreported at this time, the above phenomenon could also be expected to relate, first, to the relative elasticity found within different tissue types and, second (and perhaps more importantly), to the uncontrolled and relatively undefined pressures associated with dental local anesthetic injections.

The objective of this study was to measure and record the pressures during dental injections while using a defined fixed flow rate. This was performed on 4 different tissue types in the oral cavity during administration of local anesthetic solution. Data were recorded using the pressure computer-controlled local anesthetic delivery system.

METHOD AND MATERIALS

Data were collected from randomly selected adult patients seeking routine dental care. Pregnant women were excluded from the study. Past medical histories were reviewed and recorded. The data on each patient were recorded from a single initial injection administered during a given treatment session. Fluid pressure was recorded during delivery of 4 dental injection techniques: group 1, intraligamentary injection (aka periodontal ligament injection) (PDL); group 2, the palatal injection (PI), anterior middle superior alveolar nerve block; group 3, the supraperiosteal buccal infiltration (SBI); and group 4, the inferior alveolar nerve block (IANB).

A full cartridge (1.8 mL) of xylocaine 1:100,000 with epinephrine (Astra USA) was administered. Fifty separate recordings were made for each injection technique. A fixed

flow rate of 0.005 mL/sec was set as the given flow rate for all injections (the same flow rate currently programmed into the CompuDent/Wand system). This is currently recommended by the manufacturer (Milestone Scientific) and approved for dental use by the FDA in tissues that were included in this study. Faster flow rates of delivery are available but have not been recommended for use in all 4 tissues tested in this study; therefore, a single flow rate was used. The pressure-CCLADS unit used in this study (CompuFlo) automatically documented the maximum pressure produced during each injection delivered. Patients were seen again 1 week later, for recording of any adverse clinical response to the injection.

The pressure-CCLADS provided an instantaneous and continuous reading of pressure (in pounds per square inch), flow rate, and volume during the delivery of each injection. The system was pre-programmed to compensate for a wide variety of variables while maintaining an accurate reading of interstitial pressure. Settings and specifications for specific needle length and gauge were selected from the pre-programmed database within the system. The programmed database allows for specific settings and specifications related to all the disposable components used, ie, syringe size, delivery tubing, and needles. In addition, drug characteristics of viscosity, temperature, and specific weight were also stored in the selectable database of the pressure-CCLADS. Collectively, all of these elements become known as an *injection configuration* within the pressure-CCLADS software database. The strict control of these parameters ensured accurate and meaningful measurements during each injection.

RESULTS

The data were analyzed using a 1-way analysis of variance (ANOVA). The pressure means measured in pounds per square inch (psi) were as follows: 293.08 (PDL), 68.16 (PI), 11.50 (SBI), and 9.76 (IANB), with a F-ratio of 2371.933. The data were statistically

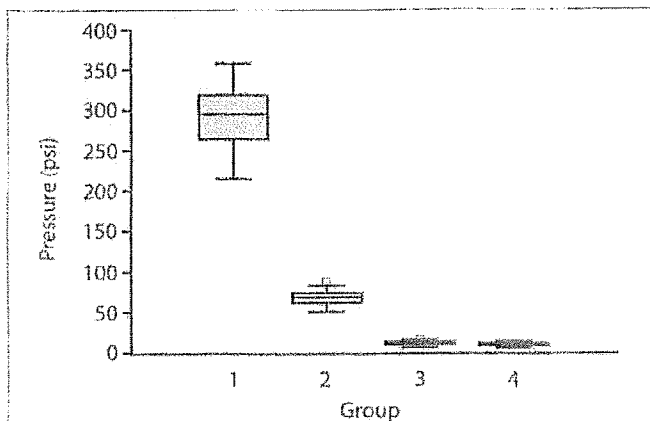


Fig 2 Box and whisker graph showing the 3 distinct ranges of pressure demonstrated by the 4 injection groups. Group 1, intraligament injection; group 2, palatal injection; group 3, supraperiosteal injection; and group 4, inferior alveolar block injection.

significant ($P < .001$). A Student-Newman-Keuls post hoc test was run at a $P < .05$ level of significance. Group 1 (PDL) was found to be different from all other groups. Group 2 (PI) was found to be different from all other groups. Group 3 (SBI) was found to be different from groups 1 and 2. Group 4 (IANB) was found to be different from groups 1 and 2. Groups 3 and 4 were not found to be statistically different from each other. This analysis of data identified 3 distinct groups based on an ANOVA analysis with Student-Newman-Keuls test for pairwise comparisons (Fig 2).

At the 1-week postinjection appointment, no adverse clinical signs or symptoms occurring directly from the injections were reported. However, 2 patients reported moderate indirect postanesthesia discomfort related to lip biting while anesthetized.

DISCUSSION

Previous authors have investigated the clinical implications of interstitial pressure during dental injections.^{18,19} Rood reported on his pressure measurements of the inferior alveolar block injection.¹⁸ Utilizing a fluid pressure gauge interconnected to a traditional syringe, he demonstrated pressure readings between

0.20 and 8.99 psi.¹⁸ Pashley and coworkers measured pressures for the PDL injection and reported values ranging between 329 and 659 psi.¹⁹ Walmsley and coworkers reported the inability of the operator to accurately control the fluid pressure using either a traditional syringe or high-pressure syringe system.²⁰ In addition, they reported that the clinician's gender had a measurable effect on the pressure generated during an injection with either syringe type. On average, male operators tended to generate higher fluid pressure in comparison to female operators. Pressures ranged between 236 and 308 psi for the traditional syringe and between 427 and 756 psi for the high-pressure syringe.²¹

The current research demonstrates that using advanced computer technology, subcutaneous interstitial pressures could be accurately measured and recorded in real time. It was determined that a given range of pressures could be identified for specific tissue types using a fixed flow rate of 0.005 ml/sec. This rate of flow was specifically selected because it represents one of several flow rates available in dentistry from a commercial product. The single flow rate of 0.005 ml/sec was exclusively studied to conform to the recommendations of the manufacturer. It is conceivable that more meaningful data may have been elicited if additional flow rates were included in this study; ie, would a slower flow rate produce lower pressures or a faster flow rate produce higher pressures in all 4 tissues tested? These are valid and important questions that should be answered in the future.

This study demonstrated that interstitial pressure generated from the tissue resistance encountered could be correlated to the tissue density type for a particular anatomic location. One can speculate that differences in tissue resistance will result in a redistribution of the drug over a given area. As an increase in the volume of fluid occurs within an area of the tissue, the cellular matrix will either absorb and/or redistribute the incoming noncompressible fluid. In response to pressure within the tissue space, a particular level of pressure is either maintained or increased during this accommodation phase of the injection. If the tissue's cellular compo-

Table 1 Classification of soft tissue density

Type	Definition	Example of tissue type	Injections performed in this tissue type	Interstitial tissue pressure and resistance
Type 1	Low-density tissues, comprised of loosely organized connective tissue matrix interposed with adipose tissue, intercellular fluids, and small volumes of organized collagen fibers.	Subcutaneous connective tissues of the maxillary buccal mucosa and infratemporal fossa	Buccal infiltration Inferior alveolar nerve block	Low pressures, low resistance
Type 2	Moderate-density tissues, comprised of a combination of densely packed collagen fiber bundles interposed with a small amount of glandular tissues and/or adipose tissue. Relatively small amounts of intercellular fluids are found in these tissues. A moderate degree of collagen organization is found in tissues of this type.	Attached palatal gingiva Attached gingival tissues Muscle tissues of the oral cavity	Palatal injections Injections into attached gingiva	Moderate pressures, moderate resistance
Type 3	High-density tissue composed of predominately dense, highly organized collagen fiber matrices.	Periodontal ligament Muscle tendon attachments	Periodontal ligament injection	High pressures, high resistance

sition is such that it is comprised of densely packed collagen fibers, the injected fluid will be more physically constrained within a tissue matrix at the local site. Localized containment of fluid within a dense tissue matrix leads to rapid elevation of interstitial pressure due to the inability to redistribute the fluid over a greater area of tissue. In contrast, tissue composed of a loosely organized cellular matrix can more efficiently accommodate the fluid by distributing it over a greater area, resulting in the maintenance of lower pressure within the tissue. The density of the tissue type and the resistance encountered will therefore play a key role in the redistribution, which will substantially control the interstitial pressure within that tissue type.

Applying the physics formula for pressure enables us to understand interstitial pressure and drug distribution within a tissue space:

$$\text{Pressure} = \frac{F}{A}$$

where *F* is force and *A* is area. Highly organized, densely packed collagen fibers, such as those found in certain oral tissues, including the periodontal ligament and gingival hard palate (where fluids are contained within a smaller area), reduce the ability for diffu-

sion of injected fluid. This reduced ability for denser tissues to allow rapid redistribution of the drug results in higher internal pressure and greater resistance during injections. In contrast, loosely organized tissues with a connective stroma composed of a collagen matrix interposed with interstitial fluid and adipose tissues, such as those found in the mucobuccal fold and infratemporal fossa, result in lower interstitial pressure and resistance, as a consequence of the drug being spread through a larger tissue area.

From this observation, a conjecture can be made leading to a correlation that tissue density may affect the injection process and outcome. The density classification of soft tissue is presented in Table 1 to aid the clinician toward a greater awareness of tissue types and injection dynamics (ie, flow rate, pressure, and time).

An understanding of the interrelationship between soft tissue density, fluid pressure, volume, and flow rate helps to explain certain clinical observations. For example, when the PDL injection is administered with a hand-driven manual syringe, only a small portion of the fluid volume (0.2 mL) can be administered. In contrast, when the same injection is administered with a CCLADS, a greater volume (1.8 mL) can be administered. These



quantitative differences may be explained when a specific flow rate, tissue type, and injection fluid dynamics are considered.

The biologic effects of excess pressure within tissues like the periodontal ligament have been investigated. Various authors have commented on the impact of high-pressure injections in what are now understood to be high-density (type 3) tissues.^{22,23} Histologic reports have conclusively demonstrated that both reversible and irreversible tissue damage can result.²⁴⁻²⁶ Systems are available today to precisely control pressure. The pressure-CCLADS ensures that appropriate pressure is being maintained at the specified flow rate (ie, 0.005 mL/sec) by using an electro-mechanical motor regulated by microprocessor technology. In the PDL injection, this type of newer delivery system actually can maintain reduced pressure, promoting larger drug-volume delivery while minimizing pain and the risk of tissue damage.²⁷

In contrast, a conventional hand-driven syringe relies on the human neuromuscular skeletal system (the thumb) of the operator, who instinctively responds to overcome tissue resistance, ie, "back pressure," by applying greater hand force to the syringe plunger. This typically results in escalating pressure within the dense interstitial tissue. When attempts are made to use less force on a manual syringe plunger, the operator may not be delivering significant pressure or volume of drug over time. The inability to gauge the fluid flow and pressure when using standard handheld syringes is the result of insufficient tactile feedback.²⁸ It is the inability to precisely control both flow rate and pressure during drug administration that makes a hand-driven traditional syringe imprecise when compared to a contemporary electro-mechanical system technology. The ability to control both the pressure and the flow rate with a CCLADS has been shown to reduce the negative sequela typically associated with injections into high-density tissues of the oral cavity while simultaneously increasing effectiveness.^{29,30,31}

Palatal injection techniques are described as the most painful of all intraoral injections.^{32,33} These techniques can now be more fully appreciated based on the understand-

ing of flow rate and the knowledge of soft tissue density and its associated fluid pressure. The interstitial pressure produced in the palatal tissues when using a CCLADS with a 0.005 mL/sec flow rate results in different fluid dynamics than those obtained with the hand-driven traditional syringe. Moderate to severe pain consequent to administration of even small volumes of local anesthetic solution with a hand-driven traditional syringe are well documented in the literature.³⁴⁻³⁶ By contrast, Friedman and Hochman reported the delivery of a volume of 1.8 mL of anesthetic at a single palatal site, resulting in "minimal or no pain" when using a CCLADS device at a fixed flow rate with controlled pressure.³⁷ These differences related to the palatal injection techniques can now be appreciated in the new context of soft tissue density and the ability to control the fluid dynamics of flow rate and, more importantly, pressure.

Regardless of the ability of the operator, the mechanical limitations of the hand-driven standard syringe are such that the barrier to the administration of a sufficient volume of solution into certain tissues necessary for effective pulpal anesthesia while simultaneously minimizing the subjective pain perception of most patients is very difficult to overcome. In addition, a traditional syringe was not designed to precisely control parameters of rate and pressure over time. Even though guidelines exist in dental anesthesia textbooks for the delivery of local anesthetic solution, they are rarely adhered to in clinical practice.³⁸

The advantages of using a CCLADS are as follows: (1) it allows precise flow rates to be established and maintained, (2) it enables an accurately controlled pressure limit during the administration process, and (3) it eliminates operator subjectivity in relation to "back pressure" response associated with a hand-driven traditional syringe system.

The advantages found when using a pressure-CCLADS also include the ability to: (1) collect clinical data and document local drug delivery during subcutaneous injections, (2) identify specific interstitial pressure readings for specific tissue types (ie, tissue density), (3) continuously monitor and control pressure during the injection, and (4) utilize "pres-

sure" to determine the correct needle position within this specified tissue. The concept of measuring and monitoring pressure to determine location and tissue type have been reviewed in the medical literature.³⁶⁻³⁷

Medical researchers have already used interstitial tissue pressure measurements for a variety of medical applications. Ghelber and coworkers at the University of Texas Medical School at Houston have completed 2 pilot studies using the CompuFlo technology system for epidural injections. They demonstrated the ability to reliably identify pressure characteristics of the different tissues as well as the epidural space in all cases treated.³⁶⁻³⁷ Lechner and coworkers have demonstrated the use of pressure measurements to help identify the epidural space as well. In a clinical study including 60 patients, a success rate of 100% accuracy was achieved with their experimental equipment.³⁸ Derby and coworkers created a new diagnostic classification based on pressure-controlled discography of the spine.³⁹ The clinical parameter of pressure and pain provocation during lumbar discography provided a predictor to surgical and nonsurgical outcomes. These research teams performed their studies using experimental equipment that mimic the capabilities of the pressure-OCLADS technology. The device used in this study represents a new generation of advanced subcutaneous drug delivery systems that will enable clinicians to use the clinical parameter of interstitial tissue pressure in a variety of new applications in the practice of medicine.

Further research is needed to determine whether using this type of technology in dentistry will yield benefits for the patient and clinician. An ongoing preliminary investigation has demonstrated the ability to allow a more precise needle placement during PDL injections using this technology. Initial findings suggest that by utilizing pressure data during the administration of the PDL injection, the predictability of success for single-tooth anesthesia may be improved.

CONCLUSION

This study demonstrates a new injection technology that provides interstitial pressure readings in real time. Three specific tissue categories have been defined based on tissue density, cellular composition, and pressure characteristics. The ability to monitor and control the flow rate and pressure during a dental injection sets the stage for a new perspective on dental local anesthesia. Further research should be conducted to determine how interstitial pressure and tissue resistance information might be utilized to improve the predictability and comfort of local anesthesia in dentistry.

ACKNOWLEDGMENTS

The authors would like to thank Dr Eugene Hittleman, Associate Professor and Director of Behavior Science Programs at New York University College of Dentistry for his generous effort in providing the data analysis and interpretation of the statistical findings.

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