Computerized Local Anesthetic Delivery vs. Traditional Syringe Technique

SUBJECTIVE PAIN RESPONSE

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■ ABSTRACT ■

A study was designed to determine if there are changes in the perception of pain when the flow rate and pressure of an injected anesthetic are precisely controlled. Fifty dentists were given contralateral palatal injections. One side was injected with the Wand Injector, a new delivery system that uses a microprocessor and an electric motor to precisely regulate flow rate during administration. The control side was injected using a standard manual syringe, in which flow rate and pressure are operator-dependent and cannot be controlled accurately.

The subjects used two subjective scales to describe their perceived pain experience. When their responses were analyzed the Wand Injector was found to be two- to three-times less painful than the manual injection. The results were statistically significant ($p<.001$). The authors conclude that there is an optimal flow rate of anesthetic solution at which the perception of pain during an injection is minimized.

The perception of pain during the administration of an intraoral injection of local anesthesia can be attributed primarily to: 1. tissue puncture; 2. fluid pressure; 3. the flow rate of the drug administered. Other factors that may influence the perception of pain are the temperature of the drug and the tactile control of the needle. If these variables could be controlled precisely we could alter the perception of pain during an intraoral injection.

It is our hypothesis that there is a range of optimal flow rates at which pain perception can be minimized. Currently the most widely used method of injection is the metallic aspirating cartridge syringe system. With this system, flow rate and fluid pressure are operator-dependent and cannot be controlled precisely. A new computerized delivery system, planned for introduction into the dental market, can precisely control the flow rate and modulate fluid pressure by the use of a microprocessor and an electronically controlled motor. This new

system also allows for a pen-like grasp hold that appears to result in an enhanced tactile sense.

The objective of this clinical study is to determine if the computer anesthetic administration, by injecting at an optimal flow rate and controlled fluid pressure, influences the perception of pain in test subjects when compared with a conventional local anesthetic delivery system.

Methods and Materials

The Wand Injector (WI) (*Milestone Scientific, Inc.*) is a microprocessor-driven injection device that delivers a controlled infusion of anesthetic solution. The WI uses the standard 1.8 ml. dental anesthetic glass cartridge. The microprocessor monitors and varies the infusion pressure while maintaining a defined flow rate. An electronically driven plunger contacts the rubber stopper in the cartridge and expells the anesthetic solution at the precisely regulated rate. Sterile tubing connects the cartridge receptor to a pen-like, hand-held instrument that is attached to a standard dental needle, together forming a disposable syringe assembly *(Figure 1)*. The WI will automatically aspirate during drug administration to insure that intravascular placement has not occurred. The WI is an FDA market-approved instrument.

A total of 50 dentists participated in this clinical study. Participants had to be between 18 and 65 years of age, in good general health and have no contraindications to local anesthetics. Pregnant females were not eligible for the study. The study subjects volunteered to participate. Verbal informed consent was obtained prior to the clinical study.

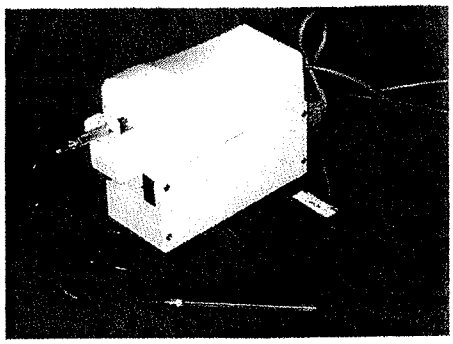


Figure 1. *Wand system prototype working model consists of control unit, disposable injector and foot control.*

Subjects were blindfolded during the study. Each subject received two injections in one appointment. Subjects served as their own control. The test injection was a computer-regulated injection, the Wand Injector. The control injection was performed with a metallic, breech-loading, aspirating syringe *(Cook-Waite Carpule Aspirator®)*. An audible tone was produced by the WI during both injections so that subjects were unable to distinguish between the two techniques by sound. Injections were given palatally on teeth numbers 04 and 13, 10 mm. from the free gingival margin. A table of random numbers determined which injection was received first.

All patients received mepivacaine 3% without a vasoconstrictor (carbocaine HCL 3%, *Cook-Waite Labs®*), at a temperature of 70° Fahrenheit (21° C). A volume of 0.45 ml. was administered in each using a 30-gauge needle (*Monojet Corp.®*) for both injections.

The Wand Injector was calibrated to have a fixed plunger travel at the rate of 1/200inch/sec. The microprocessor was programmed to vary the solution pressure in response to tissue resistance encountered while maintaining a fixed flow rate established by plunger travel rate.

FIGURE 2

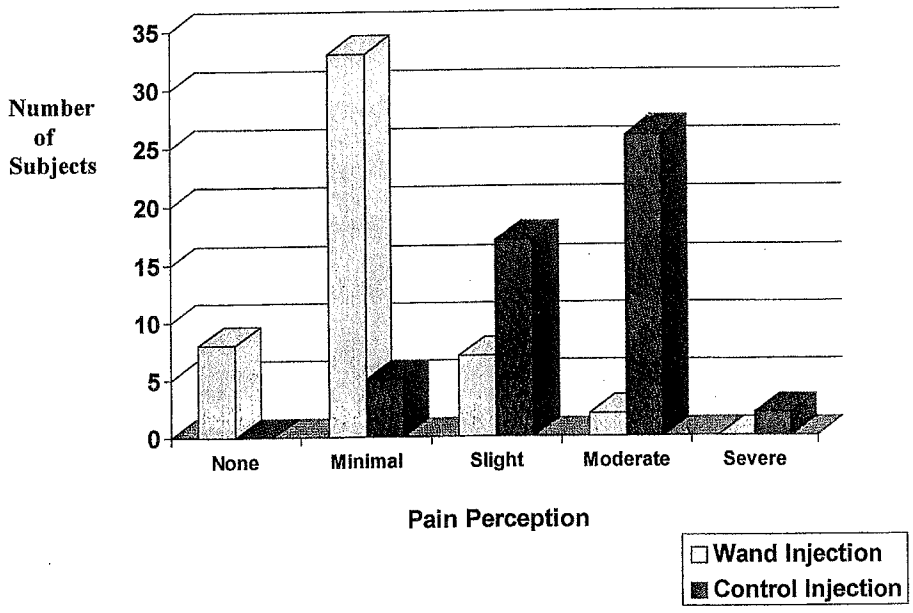
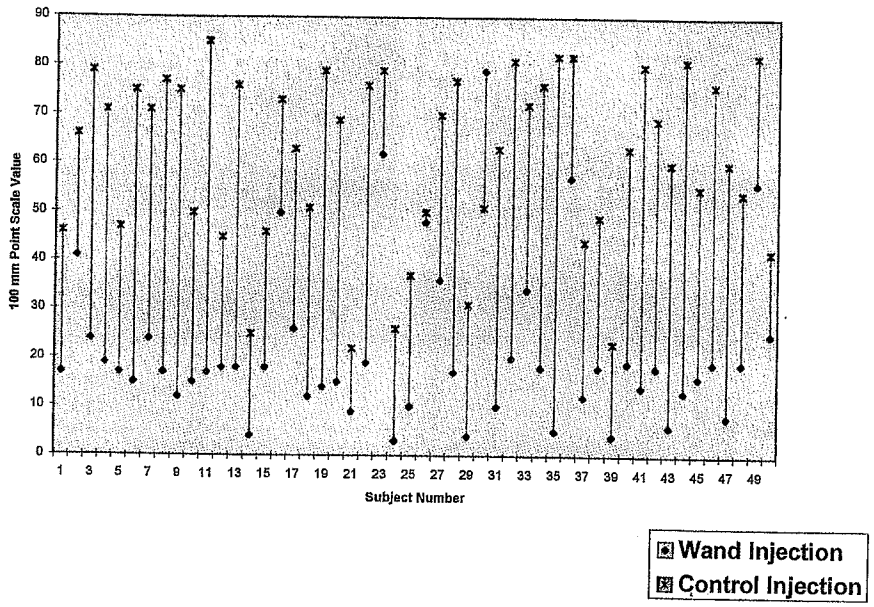


FIGURE 3



The WI was designed so that head pressure varies between zero and 25 pounds. The system cannot exceed 25 pounds of pressure, thereby preventing the glass cartridge from breaking or the needle assembly from rupturing. With the conventional delivery system, 0.45 ml. was administered over 25 seconds; care was taken to use "light" force with the hand-held syringe.

Immediately following the injections subjects responded to a verbal scale and a visual analog scale, or VAS, to assess the intensity of pain they experienced. A five-point verbal scale—0=none, 1=minimal, 2=slight, 3=moderate, 4=severe—was scored. The VAS is a 100 mm.-long horizontal scale that converts five subjective responses into a measurable analog scale. 0=none was on the far left, at 0 mm., and 4=severe was scored on the far right at 100 mm. Analysis of data was performed by the Wilcoxon Matched Pairs Signed Rank Test.

The tip of a dental explorer, applied with positive pressure on the palatal tissue 10 mm. from the free gingival margin on teeth numbers 04 and 13, was used to assess anesthesia. Post-administration testing was done at one-minute intervals until a lack of response to sharpness was obtained for three consecutive readings. Two dentist investigators administered the injections using a standardized technique. The doctors were instructed to make needle contact with periosteum three seconds after penetration of soft tissue.

Post-administration testing was done at one-minute intervals until a lack of response to sharpness was obtained for three consecutive readings.

Results

Forty-eight of the 50 subjects said the Wand Injector was more comfortable than the conventional syringe technique ($p<.001$). One subject found them to be equivalent, and one found the WI less comfortable *(Table 1)*. The mean and median for the WI for the five-point verbal scale was 1.02 and 1.0 respectively. The mean and median for the five-point verbal scale for the conventional syringe technique was 2.5 and 3.0 respectively. Results of the Wilcoxon Matched Pairs Signed Rank Test indicate the difference between the WI and the manual injection ratings is statistically significant ($p<.001$).

Bar graphs of the 5-point verbal scale for both the WI and control technique are shown side by side *(Figure 2)*. The following is observed:

Eighty-two percent of the "pain" responses to the WI were either "No Pain" or "Minimal Pain" perceived, while only 10 percent of the control subjects choose these two catagories.

Fifty-six percent of the "pain" responses to the control technique were either "Moderate" or "Severe," while only four percent of the WI subjects chose to describe it as "Moderate" and zero percent found it to be "Severe."

Plots of each subject's responses to the VAS to both the WI and conventional syringe technique are found in Figure 3. Of interest is the finding that different pain thresholds can be identified for each subject. Sub-

jects that started at a higher perceived pain level for the manual injection technique consistently demonstrated a higher perceived pain level for the WI.

Fifteen subjects made unsolicited comments that the manual palatal injection was reasonably comfortable, even though they found the WI preferable. Soft tissue anesthesia was tested by pricking the palatal tissue with an explorer, using positive pressure. Both the manual injection and the WI anesthetized soft tissue within two minutes on all subjects. The WI was as effective in achieving anesthesia as the conventional syringe method, but was consistently found to be less painful.

TABLE 1

	WAND		NORMAL	
Subject #	5 point scale	100mm scale	5point scale	100mm scale
1	1	17	2	46
2	2	41	3	66
3	1	24	3	79
4	1	19	3	71
5	1	17	2	47
6	1	15	3	75
7	1	24	3	71
8	1	17	3	77
9	1	12	3	75
10	1	15	2	50
11	1	17	3	85
12	1	18	2	45
13	1	18	3	76
14	0	4	1	25
15	1	18	2	46
16	2	50	3	73
17	1	26	3	63
18	1	12	2	51
19	1	14	3	79
20	1	15	3	69
21	0	9	1	22
22	1	19	3	76
23	2	62	3	79
24	0	3	1	26
25	1	10	2	37
26	2	48	2	50
27	2	36	3	70
28	1	17	3	77
29	0	4	1	31
30	3	79	2	51
31	1	10	3	63
32	1	20	4	81
33	1	34	3	72
34	1	18	3	76
35	0	5	3	82
36	2	57	3	82
37	1	12	2	44
38	1	18	2	49
39	0	4	1	23
40	1	19	2	63
41	1	14	3	80
42	1	18	3	69
43	0	6	2	60
44	1	13	3	81
45	1	16	2	55
46	1	19	3	76
47	0	8	2	60
48	1	19	2	54
49	2	56	4	82
50	1	25	2	42
mean	1.02	21.42	2.5	61.64
median	1	17.5	3	67.5
mode	1	18	3	76
st dev	0.622372	16.22557	0.735402	17.90765

Discussion

The results of this study demonstrate a statistically significant reduction in the perception of injection pain when comparing a computer-administered local anesthetic with the conventional local delivery as performed on dentists.

Because of the characteristics of the palatal tissues this injection was deemed to be among the most painful of dental injections, and indeed is considered by many dentists to be one of the most traumatic techniques used in dentistry. Even so, 96 percent of participants indicated they considered the WI administration to be a "None" to "Slight" pain experience.

The results support the concept that an optimal flow rate of administration of local anesthetic exists. Optimal flow rate can be defined as the rate of administration of fluids into soft tissues via a needle at which minimal or no discomfort is felt. It is our contention that this is not a single specific rate but a range of rates. To date the ability of any operator to quantify the rate of delivery of local anesthetic has been impossible. The rate used in this study, 1/200 inch/sec. of plunger travel for the dental cartridge, is within the range of an optimal flow rate.

The WI is unique in that it can maintain optimal flow rate precisely during the administration of local anesthetic. The plunger travel is preset in the software of the instrument at 1/200 inch/sec. A microprocessor with a feedback loop maintains this rate even when different tissue resistances are encountered. The pressure produced during the injection can vary in order to maintain the desired flow rate. The ability to separate flow rate from pressure is a unique feature of the WI.

The conventional syringe system directly links flow rate to the pressure at which the local anesthetic is injected. It is not possible to separate these two

properties during manual administration. It is also not possible to maintain a particular flow rate when different resistances are encountered during manual administration.

Another benefit of the WI system over conventional delivery systems is improved tactile sensation. The pen-like grasp hold enables the operator to maintain a more gentle and controlled manipulation of the needle. Minimal force is required during administration. The majority of procedures in dentistry requiring refined eye-hand coordination are performed with a pen-like grasp hold.

The use of a microprocessor with feed back loop methodology enables the WI to precisely correct for resistance changes while maintaining the optimal flow rate, resulting in a reduction of pain during injection. In addition it is now possible to generate high levels of pressure at an optimal flow rate. This has lead us to additional findings in the administration of local anesthesia.

During clinical use of the WI several interesting observations were made that need more research. We found the WI capable of producing comfortable periodontal ligament injections, which produce pulpal anesthesia. Because high pressure can be produced while still maintaining an optimal flow rate, patients receiving a PDL injection perceive minimal discomfort. This preliminary finding requires additional study.

We were also able to obtain pulpal anesthesia of multiple maxillary teeth from a single palatal injection administered approximately 15 mm. perpendicular to the contact point of the premolars on the palate. It has been speculated that the WI's ability to produce high pressure at a low flow rate allows the anesthetic to diffuse through the cortical and medullary bone to anesthetize a segment of the anterior middle superior alveolar nerve plexus. This is another preliminary finding requiring future research.

Prior to participating in this study many of the dentists believed they gave "a painless injection."

Conclusion

The discovery of a group of chemicals with the ability to block transmission of nerve impulses dates back to the 1800s. The anesthetic cartridge and syringe was introduced by Cook in 1920. Its daily use, combined with a high degree of safety and predictability, has lead to a complacency regarding dental local anesthesia. In fact, prior to participating in this study many of the dentists indicated that they believed they truly gave "a painless injection." It is this attitude that contributes to the lack of development of more innovative methods of administering local anesthetic.

Fear of dentistry by our patients is well documented in the dental literature. In a study that asked subjects to rank 25 dental situations from most fearful to least fearful the image of a dentist holding a syringe and needle ranked as the fourth most fearful experience. Also well documented is the fact that up to 14 percent of the U.S. population totally avoids dentistry because of fear. Given these facts and perceptions, an instrument representing a significant improvement in anesthetic delivery should prove to be a great benefit to dentistry.

The use of local anesthetics has been part of the dental armamentarium for more than 75 years. This traditional delivery system is highly effective and has proven to be safe. The inclusion of computer-controlled administration offers the benefits of the past system with new enhancements that were previously unobtainable. This is the first study to demonstrate that an optimal flow rate does exist in the administration of local anesthetics.❑

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Tax Tips for Dentists

Stuart A. Sinclair, CPA

I know how to make the purchase of a new pain-free laser drill painless.

First, take a disabled access tax credit on one-half of $10,000, which will net you $5000 in cash tax savings.

Second, take a section 179 deduction of $18,000, which could net you close to another $9,000 of tax savings. Depreciate the remaining $17,000 over five years for a deduction of $3400 per year to save another $1700 per year for five years.

To recap, assuming a $40,000 painless laser drill, you now have saved $22,500 in income taxes, meaning that your net cost to have this tremendous competitive advantage over other dentists is only $17,500.

I have assumed that you are in a 50 percent total tax bracket. If you are in a lower tax bracket, your savings will be proportionately smaller.

Treat your patients to no pain and your practice will gain.

Mr. Sinclair's office is located in Plainview, on Long Island. He counsels on business and personal taxes, specializing in dental finances.