Pain perception and utility: A comparison of the syringe and computerized local injection techniques

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A Clinical Comparison of Pain Perception And Injection Efficacy/Ease Using A Syringe *vs.* Computerized "Wand" Local Injection Technique

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Abstract

Context - Despite continued advances in anesthetic devices, agents, techniques, scientific and behavioral research, and the training and education of dentists, complete and predictable control of pain and anxiety associated with the injection for local anesthesia is not always an absolute certainty. Literature review reports that 20 to 23% of the population is highly anxious or even phobic about dental treatment.
Objective - We compared both patient and operator subjective response to the manual syringe injection (SI) and the computerized Wand anesthetic delivery system (WI) for the two predominate injections used in general dentistry, a maxillary supraperiosteal infiltration injection and a lower inferior alveolar mandibular block injection.
Study Design/Population - Thirty subjects received two injections of each type on one side of the mouth at each of two separate sessions. At the second visit, injections were performed on the opposite side of the mouth. Type of injection and location were altered so that all patients received both infiltration and mandibular block injections on each side of the mouth with both traditional and Wand devices. No other dental treatment or examination was performed so that any patient anxiety and response could be attributed solely to the effect of the respective local injections.
Main Outcome Measure - Each of the two dentists administering the local injections provided a subjective evaluation of the patient's pre-injection anxiety and comfort during injection. The dentists also rated both of

the two injection systems as to their ease of use and their preference the type of anesthetic delivery. Patients rated personal discomfort during injection (for each device), perception of discomfort after each visit (for each device), assessment of own apprehension prior to each injection (for each visit), and preference for device for future injection.
Results – In all areas of pain perception, the Wand was rated as having less pain and less discomfort/soreness, less anxiety/apprehension, and was rated easier to use (when analyzed using any of the study measures).
Conclusions – Successful and painless local injections have greater import than patient compliance and practice efficacy. Development of devices that can reduce fear/anxiety due to injection is imperative. The wand device, when compared to the syringe, for two major dental injections, has been shown to meet these criteria.

Keywords. Injection, wand, local anesthesia, pain, perception, patient anxiety

1.0 Introduction. The public and professional acceptance of contemporary dental treatment is indebted to the refinement of the hypodermic syringe and to the introduction of first Novocain and subsequently of Lydocaine amide as anesthetic agents in the early twentieth century [1]. However, in spite of continued advances in anesthetic devices, agents, techniques, scientific and behavioral research, and the training and education of dentists, complete and predictable control of pain and anxiety associated with the injection for local anesthesia is not always an absolute certainty. Incidents of discomfort or pain associated with local anesthesia may result in far greater and protracted problems than loss of time, efficiency, or confidence with one appointment. A literature recent review reports that 20 to 23% of the population are highly anxious or even phobic about dental treatment [2]. When interviewed, most individuals recount an episode or preconception of painful dental treatment associated with the injection or else they classify the needle or syringe as the predominant fear provoking stimuli [3]. Many of these affected individuals, as a consequence of these fears, will delay or avoid dental treatment, or endure else they will endure subsequent treatment with great physical and psychological distress.

A variety of measures and devices have been suggested or employed in order to ensure the success or comfort of the needle injection or even to provide an alternative to it. The augmentation of sedative-hypnotic and relaxing drugs such as nitrous oxide, barbiturates, and tranquilizers is well documented and well accepted [4]. New anesthetic agents are available, capable of providing extended anesthesia, enhanced diffusion, or rapid onset [5]. Recent anesthetic devices of interest include electronic devices for transcutaneous electronic nerve stimulation (DEA: 3M Dental Products, St. Paul), needleless injection systems (Madajet: Mada Equipment Co., Caristadt, NJ), intraosseous injection systems (Stabident: Fairfax Dent Inc, Miami), and a cutaneous deliver bioadhesive patch (DentiPatch: Noven Pharmaceuticals, Lincoln Park, NJ) [6].

Several generally accepted dental intervention measures, thought to alleviate the occasional discomfort associated with the basic syringe-needle technique, are highly suspect. One example of such a misconception is that of needle diameter *vs.* pain perception. In fact, within the range of standard selection, smaller diameter gauge needles are not inherently less painful, less traumatic, or less perceptible to the patient [7]. Another misconception is that discomfort with injections is associated with anesthetic drugs that are at room temperature when injected rather than when pre-warmed to body temperature [8]. According to textbooks and leading authorities, a major cause of burning and painful

sensations with local injection, assuming a sharp, defect-free needle, is depositing the anesthetic too rapidly or with too much force [9]. A minimum of sixty seconds to administer an anesthetic cartridge is usually recommended as the *de facto* standard in order to prevent tissue damage or serious reaction. However, a recent survey reports that the average time spent injecting is 20 seconds [10]. With the variance in distensibility of oral soft tissues, dentists may have to adjust thumb pressure against the syringe plunger to accommodate injection pressures from nominal to as much as 660 psi [11]. A new, recently introduced anesthetic delivery device - the Wand (Milestone Scientific, Lockport, IL) - purports to address these problems while offering numerous other advantages and safeguards over the standard manual syringe delivery system. The Wand is a computer controlled, anesthetic delivery, device that delivers a constant flow rate of local anesthetic regardless of the location, density and resiliency of the soft tissues at the injection site.

(FIGURE OF WAND DEVICE HERE) Figure 1

The wand device has been previously demonstrated successfully to fifty blindfolded dentists [12]. Contralateral palatal injections by the Wand were subjectively compared to manual syringe injections. To record the intensity of pain, subjects responded to a five-step verbal description from "none" to "severe" and marked on a linear visual analogue scale, VAS, in order to convert the subjective descriptions to an analog scale. The computerized injection was reported to be two- to three times less painful [12]. In another assessment [13], 80 patients were asked to record a five-step level of anxiety to the sequential stages of a theoretical dental visit, starting with making the appointment, through anesthetic injection, and finally to a perception that "numbness was inadequate" and required augmentation. Patients then received a Wand injection identical to the injection required by the theoretical dental visit. They scored the same questions immediately post-operatively and again within two weeks. The authors concluded that the lower anxiety scores after exposure to the Wand delivery system demonstrated successful desensitization. They infer that anxious patients, prone to avoid or delay dental treatment, may benefit from the positive experience and availability of an alternative, "precision-metered" anesthetic delivery system [13]. In addition, dentists could benefit from the use of the Wand if can be shown that the small trial results can be extended generally. Malamed [14] suggests that dentists might well wish to use the Wand if a significant number of their patients are reporting mild to moderate discomfort with routine local injections [14].

2.0 Study Design

2.1 Population. In this study, we compared both patient and operator subjective response to the manual syringe injection (SI) and the computerized Wand anesthetic delivery system (WI) for the two predominant injections used in general dentistry, a maxillary supraperiosteal infiltration injection and a lower inferior alveolar mandibular block injection.

Thirty subjects (n = 30), were selected from applicants responding to a solicitation for participation in the study, received (m = 2) two injections of each type on one side of the mouth at each of two separate sessions. Selection criteria were as follows: (1) participants must be adults self-assessed as being in good health, (2) not pregnant nor likely to become

pregnant during the study period, and (3) having schedules permitting two clinical appointments and a follow-up survey. The patients ranged in age from 23 to 54 with a median age of 35; 26 of the 30 subjects were female. At the first appointment, patients received a printed explanation of the study, consent forms, and medical/dental history forms. The attending dentist reviewed with the patient the medical history and purpose of the study. Estimates of the amount of previous dentistry (based upon observation of the oral cavity by the administering dentist), "none, some, much" were recorded but were not analyzed. Patients were given a brief explanation of the Wand device and forewarned to expect a series of both slow and rapid audible "beeps" from the device during anesthetic administration.

At the second visit, injections were performed on the opposite side of the mouth. The type and location of the injections was altered so that all patients received both infiltration and mandibular block injections on each side of the mouth with both traditional and Wand devices. No other dental treatment or examination was performed so that any patient anxiety and response would be assumed to be due solely to the effect of the respective local injections. Two (p = 2) dentists administered the local injections and provided a subjective evaluation of the patients pre-injection anxiety and comfort during injection. The dentists also rated the two, injection systems ease of use and their respective preference for type of anesthetic delivery.

2.2 Study Assignment and Injection Protocol. Patients were randomly assigned to either of two dentists (senior faculty members of the dental school) to administer the injections. The same dentist gave the injections, for both clinical sessions, to the same patient. For the first session, a randomized table was prepared to indicate the side of the mouth, left or right, to be anesthetized and the type of injection, SI or WI, to be used for each location, maxillary or mandibular. Each patient received an injection with both a manual syringe and a Wand at each appointment. On the designated side, the maxillary lateral incisor was anesthetized with a supraperiosteal infiltration injection penetrating the muco-buccal fold at the estimated location of the root apex. The other injection, on the same side was an inferior alveolar nerve block using standard positioning technique. For the second visit, the side of the mouth, and anesthetic delivery system for the two locations were reversed. Therefore, each patient in the study received both SI and WI for a maxillary infiltration and also for a mandibular nerve block.

Prior to anesthesia, both the maxillary lateral and the mandibular cuspid were first tested for viability using a refrigerant spray applied with a cotton applicator to register a timed response to a cold stimulus. Mucosa at the penetration site was dried with gauze and desensitized with a topical anesthetic (Hurricane® Beautlich L.P. Waukegan IL) applied for approximately 30 seconds. A 30 gauge needle and 3% Mepivicaine (Carbocaine) without vasoconstrictor were used for all injections. Approximately 0.9 ml of anesthetic was used for maxillary infiltration and 0.9 –1.4 ml for mandibular blocks. Immediately after aspiration, which is identified, when using the Wand instrument, by a series of rapid audible beeps, two timers were started to register onset times of soft and pulpal anesthesia. Soft tissue anesthesia was confirmed by probing of the soft-tissue. When onset of soft tissue anesthesia was noted, refrigerant was applied to the reference tooth every minute

until insensitivity confirmed onset of pulpal anesthesia. In the few circumstances where pulpal anesthesia was not confirmed, the injection was repeated and the timer restarted.

(PHOTO OF INJECTION WAND BEING HELD) Figure 2

2.3 Assessment of Discomfort/Apprehension and Ease of Use. Immediately following each injection, a recording assistant asked the patient to give a subjective assessment of discomfort associated with the injection. A modification of a linear visual analogue scale, VAS, was used to convert the intensity of pain to an analogue scale. The patient was asked to rate the experience with a number from zero (representing no discomfort) to 10 (representing the most severe pain conceivable). Immediately following the clinical appointment, the clinician marked a similar 0 – 10 scale for both SI and WI injections to record his perception of patient apprehension prior to each injection and the patient discomfort during the injection. In addition, the operator recorded his overall impression of ease of use and profoundness of anesthesia as better with SI or WI, no difference, or uncertain.

At the beginning of the second visit, and at the survey interview occurring within one week after the second appointment, the recording assistant asked the patients to rank - using the same 0-10 scale - their perception of post-operative soreness for both the SI and WI injections prior appointment. Additionally, the patients were asked to assess (rate) their apprehension/nervousness prior to both SI and WI injections for both the first and the second appointments. Finally, patients were asked to rate their preference for future SI and WI injections as either slight, moderate or strong or else indicate no preference. Table [1] lists the questions and when each was asked:

Patient's discomfort during administration with SI and with WI (after injection) Patient's perception of discomfort/soreness after injection with SI and with WI (post-operative) Patient's assessment of own apprehension prior to first injection with SI and with WI (post-operative) Patient's assessment of own apprehension prior to second injection with SI and with WI (post-operative) Patient's preference for future injection (after-study interview)
Operator's perception of patient's apprehension prior to SI and prior to WI (after appointment) Operator's perception of patient's discomfort during administration with SI and with WI (after appointment) Operator's perception of ease of use for SI vs. WI (after appointment) Operator's perception of profoundness of anesthesia for SI vs. WI (after appointment)
Time after injection to soft tissue and to pulpal anesthesia for SI and for WI

Table 1: Summary of questions and categories regarding injections

3.0 Statistical Data Analysis: All statistical analyses were performed using *BMDP* (Biomedical Data Processing Package, Los Angeles, CA); *Minitab* (State College, PA); *JMP* (SAS Institute, Cary, NC); and *StatView* (SAS Institute, Cary, NC). Where applicable, demographic data were statistically evaluated for normality using the cumulative normal distribution function, Anderson-Darling, and Kologorov-Smirnov normality tests. Basic descriptive statistics, statistical visualizations, regression analyses, ANOVAs, and distribution-free statistics were performed using *BMDP* and *Minitab*. Graphics were developed using *Minitab*, *JMP* and *SigmaPlot* (Jandel Scientific, SAS Institute, Cary, NC).

4.0 Results.

4.1 Anesthesia. Both delivery systems had key components and techniques in common, the needle, type of anesthetic drug, and basic positioning and administration technique for each site. Therefore several categories of inquiry did not show any differences between the control SI and experimental WI devices. The differences, rather, reflect, the differences inherent with the location and anatomic differences of a maxillary infiltration verses an inferior alveolar block. For example, the longer time for onset of soft tissue and pulpal anesthesia for the mandibular block compared to the infiltration injections were expected. There was no significant difference between onset times or for perception of profoundness of anesthesia between SI and WI for the same locations.

4.2 Patient Perception of Pain and Discomfort.

4.2.1 General Patient Perception of Pain and Discomfort. It is a well-known fact that assessment of pain is extremely difficult to perform. Numerous methodologies exist for this task and it is beyond the scope of this paper to the review the literature in this area. Assessment of the patient's perception of pain and discomfort may be examined at a number of levels. In this study, we considered the following: (1) pain perception related to prior dental experiences (as assessed by the amount of previous dental work), (2) correlation of pain remembered from visit 1 and carried over to visit 2 (as assessed by association of patient's perception of pain and discomfort at visit 2 with that of visit 1) as well as pain from visit two assessed at the third visit, (3) pain perception based upon location of injection (maxillary *vs.* mandibular), (4) pain perception based upon final device preference, and (5) complex interactions of the aforementioned assessment variables. We begin our discussion by examining the overall assessment of pain.

4.2.2 Overall Results as Assessed by Final Device Preference. One way to examine the perceived pain is to use the "comfort level" of the patient and to examine the "patient preference" for mode of anesthetic delivery at the end of the study as the proxy variable for that comfort level. Of the twenty-one patients (70%) who indicated a preference for one system or the other (n = 9 left the preference item blank), twice as many preferred the Wand (n = 14) over the syringe (n = 7). What is interesting is that, of the 7 individuals expressing a preference for the syringe, n = 3 indicated that they had a moderate preference and n = 4 indicated that they had a strong preference for the syringe over the wand (none indicated that they had a slight preference). On the other hand, when examining the strength of preference associated with the Wand, we see that n = 2 had a slight preference for the Wand over the syringe, while n = 6 had a moderate and n = 6 had a strong preference for the Wand over the syringe (Table [2]).

Preference Strength	Syringe	Wand
No preference	0	0
Slight preference	0	2
Moderate preference	3	6
Strong preference	4	6
Column total	7	14

Table 2: Patient preference for syringe *vs.* Wand at the completion of the study

4.2.3. Reports of Post-Operative Discomfort/Soreness as a Measure of Pain. An alternative proxy for pain is the "patient post-operative discomfort" memory level associated with the two injection devices. When the patients were asked to report their perception of discomfort/soreness after the first visit there was a clear distinction between the two anesthetic delivery mechanisms:

Syringe Pain	Count	Cum. Count	Percent	Cum. Percent	Wand Pain	Count	Cum. Count	Percent	Cum. Percent
0	13	13	43.33	43.33	0	19	19	63.33	63.33
1	1	14	3.33	46.67	1	5	24	16.67	80.00
2	3	17	10.00	56.67	2	2	26	6.67	86.67
3	8	25	26.67	83.33	3	1	27	3.33	90.00
4	0	25	0	83.33	4	1	28	3.33	93.33
5	1	26	3.33	86.67	5	0	28	0	93.33
6	2	28	6.67	93.33	6	1	29	3.33	96.67
7	0	28	0	96.67	7	0	29	0	96.67
8	0	28	0	96.67	8	0	29	0	96.67
9	1	29	3.33	96.67	9	0	29	0	96.67
10	1	30	3.33	100.00	10	1	30	3.33	100.00

Table 3: Patient post-operative discomfort memory, reported after first visit injections for syringe and Wand. We have shaded the table according to the four groupings (no pain, slight pain, moderate pain, and severe pain).

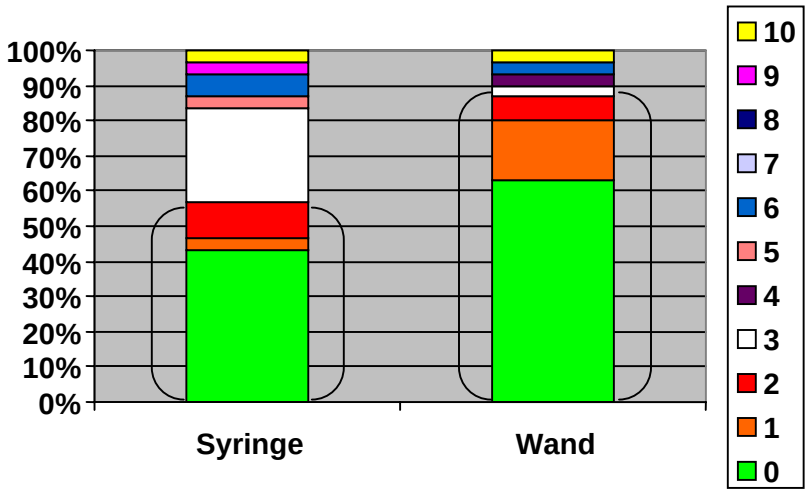


Figure 3: Summary of the 30 patients' memory of post-operative pain and discomfort after the first clinical visit. Observe that the Wand has a significantly greater number of both no and lower level pain and discomfort remembered. Bracketed elements correspond to none-to-mild responses for each group. Table [3] illustrates the numeric values for this figure.

It is clear, from viewing the statistics in Table [3] above, that there is a difference between the pain reports, post-operatively after the first visit. Note that, 43% of the syringe reports indicated no pain *vs.* 63% of the Wand reports indicating no pain. In addition, if we examine the combination of no pain and slight pain, we see that the syringe users reported 57% in this category *vs.* 87% for the Wand. In addition, if we examine the number of moderate (30% syringe *vs*. 7% Wand) and severe (13% syringe *vs.* 7% Wand) post-operative responses for each device, we see that 43% of the clients reported a moderate to severe post-operative syringe response against 14% of the clients reporting the same for the

Wand. When we examine the Visit 3 results (Patients were asked to remember the discomfort and soreness from Visit 2), we obtain the following tabular information:

Syringe Pain	Count	Cum. Count	Percent	Cum. Percent	Wand Pain	Count	Cum. Count	Percent	Cum. Percent
0	14	14	46.67	46.67	0	18	18	60.00	60.00
1	1	15	3.33	50.00	1	5	23	16.67	76.67
2	2	17	6.67	56.67	2	3	26	10.00	86.67
3	8	25	26.67	83.33	3	1	27	3.33	90.00
4	0	25	0	83.33	4	1	28	3.33	93.33
5	1	26	3.33	86.67	5	0	28	0	93.33
6	2	28	6.67	93.33	6	1	29	3.33	96.67
7	0	28	0	96.67	7	0	29	0	96.67
8	0	28	0	96.67	8	0	29	0	96.67
9	1	29	3.33	96.67	9	0	29	0	96.67
10	1	30	3.33	100.00	10	1	30	3.33	100.00

Table 4: Patient post-operative discomfort memory, reported after second visit injections for syringe and Wand

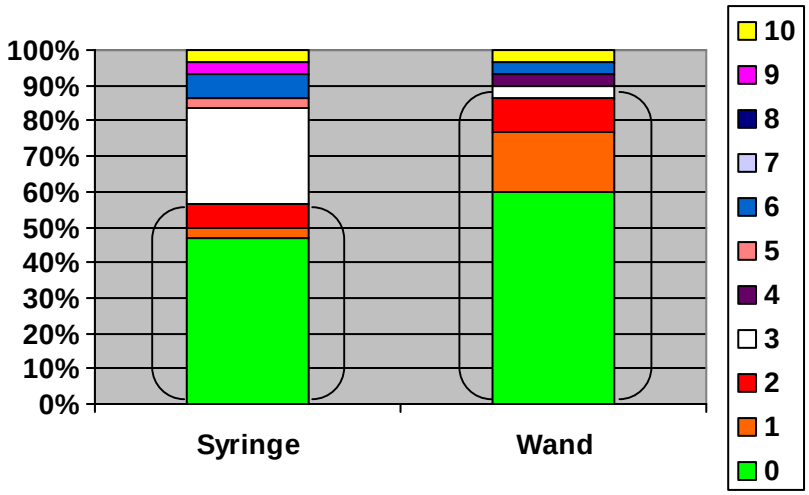


Figure 4: Patient post-operative discomfort memory, reported after first visit injections for syringe and Wand. Observe that the Wand has a significantly greater number of both no and lower level pain and discomfort remembered. Bracketed elements correspond to none-to-mild responses for each group. Table [4] illustrates the numeric values for this figure.

After the 2nd visit, It is clear, from viewing the statistics in Table [4] above, that there is a difference between the pain reports, post-operatively after the second visit. Note that, 47% of the syringe reports indicated no pain *vs.* 60% of the Wand reports indicating no pain. In addition, if we look at the combination of no pain and slight pain, we see that the syringe users reported 57% in this category *vs.* 87% for the Wand. If we examine the number of moderate (30% syringe *vs.* 7% Wand) and severe (13% syringe *vs.* 7% Wand) post-operative responses for each device, we see that 43% of the clients reported a moderate to severe post-operative syringe response against 14% of the clients reporting the same for the Wand. We summarize the overall self-assessed discomfort in Table [5] and illustrate it in Figure [5] below.

Degree of patient's self-assessed discomfort after given visit	Visit 1		Visit 2	
	Syringe	Wand	Syringe	Wand
No pain	43%	63%	47%	60%
Slight pain	16%	23%	10%	27%
Moderate pain	30%	7%	30%	7%
Severe Pain	13%	7%	13%	7%

Table 5: Degree of patient's self-assessed discomfort after each visit, for each anesthetic delivery device (all tests of proportion difference significant at $p < 0.05$).

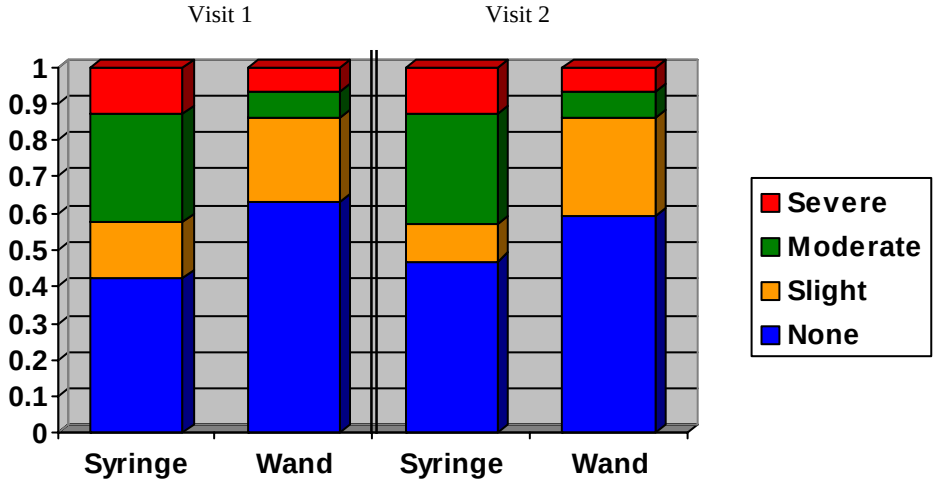


Figure 5: Illustration of degree of patient's self-assessed discomfort after first and second dental visits. The two columns to the left of the double line represent Visit 1 and the two to the right represent Visit 2. Data for this Figure may be found in Table [5].

Examining Figure [5], it is easy to see that the Wand has a greater proportion of individuals reporting none and/or slight responses when compared to the syringe. In summary, both by final preference of injection device as well as by self-assessed discomfort, the patients in the study found the Wand device preferable to the syringe injection.

4.2.4 Patient Perception of Discomfort During Injection. Patients were asked to assess their perception of discomfort experienced during the administration of the injection via both the wand and the syringe, after each visit. In the first of the following two tables, we illustrate the data for the patient perception of discomfort experienced during the administration of the injection, for the syringe and the wand, for the first visit:

Syringe	Count	Cum Count	Percent	Cum Percent	Wand	Count	Cum Count	Percent	Cum Percent
0	5	5	16.67	16.67	0	5	5	16.67	16.67
1	4	9	13.33	30.00	1	10	15	33.33	50.00
2	7	16	23.33	53.33	2	6	21	20.00	70.00
3	6	22	20.00	73.33	3	1	22	3.33	73.33
4	2	24	6.67	80.00	4	3	25	10.00	83.33
5	3	27	10.00	90.00	5	3	28	10.00	93.33
6	1	28	3.33	93.33	6	0	28	0.00	93.33
7	0	28	0.00	93.33	7	2	30	6.67	100.00

8	1	29	3.33	96.67	8	0	30	0	100.00
9	1	30	3.33	100.00	9	0	30	0	100.00
10	0	30	0	100.00	10	0	30	0	100.00

Table 6: Patient report of perception of discomfort experienced during the administration of the anesthesia by syringe and wand for Visit 1.

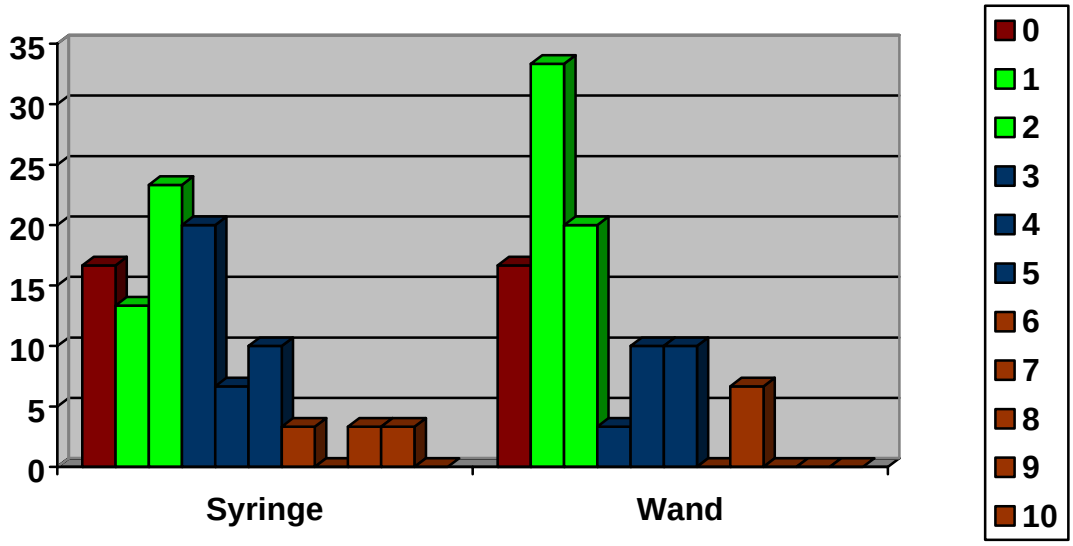


Figure 6: Illustration of the patients perception of discomfort experienced during the administration of the injection via the syringe and the Wand after the first visit. Data is given in Table [6] above.

Figure [6] is somewhat difficult to assess. If we combine ratings, as we did previously, we can construct the following rating Table [7] for the patient's perception of discomfort experienced during anesthetic administration, by device, after the first visit.

Degree of patient's self-assessed discomfort after given visit	Visit 1	
	Syringe	Wand
No pain	16.67%	16.67%
Slight pain	36.67%	53.33%
Moderate pain	36.67%	23.33%
Severe Pain	10.00%	6.67%

Table 7:Degree of patient's self-assessed discomfort after each visit, for each anesthetic delivery device (all tests of proportion difference significant at $p < 0.05$).

This data is illustrated in Figure [7] below. It is immediately clear that, patients experienced a far greater degree of increased levels of pain with the syringe, during visit 1, than they did with the Wand. In particular, it is clear that, while they clearly had the same degree of no pain, the Wand significantly greater slight pain percentage than did the syringe and less greater percentages of higher degrees of pain (moderate and severe).

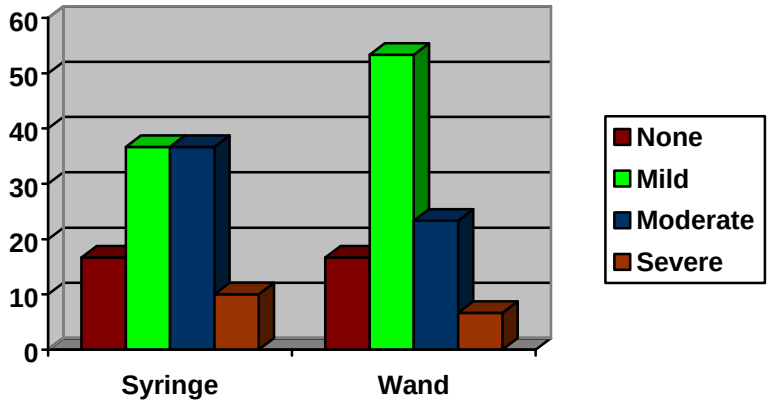


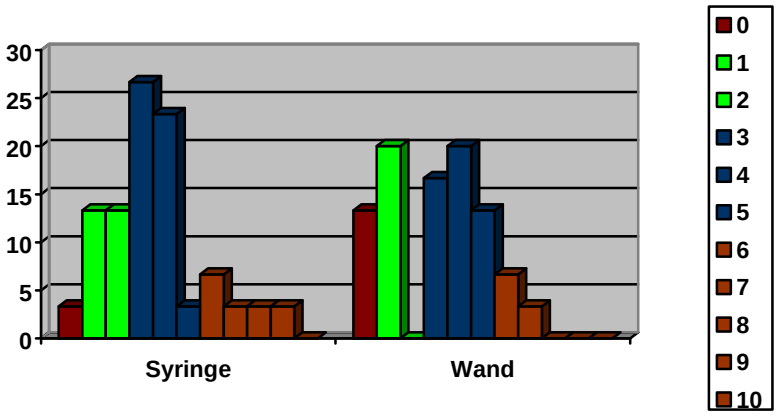
Figure 7: Illustration of the data presented in Table [7] above.

We can repeat the same analysis for Visit 2. The results of this analysis are summarized in Table [8] below and the following figures.

Syringe	Count	Cum Count	Percent	Cum Percent	Wand	Count	Cum Count	Percent	Cum Percent
0	1	1	3.33	3.33	0	4	4	13.33	13.33
1	4	5	13.33	16.67	1	6	10	20.00	33.33
2	4	9	13.33	30.00	2	5	15	16.67	50.00
3	8	17	26.67	56.67	3	6	21	20.00	70.00
4	7	24	23.33	80.00	4	5	25	13.33	83.33
5	1	25	3.33	83.33	5	2	27	6.67	90.00
6	2	27	6.67	90.00	6	2	29	6.67	96.67
7	1	28	3.33	93.33	7	1	30	3.33	100.00
8	1	29	3.33	96.67	8	0	30	0	100.00
9	1	30	3.33	100.00	9	0	30	0	100.00
10	0	30	0	100.00	10	0	30	0	100.00

Table 8 Patient report of perception of discomfort experienced during the administration of the anesthesia by syringe and wand for Visit 2.

If we combine ratings, as we did previously, we can construct the following rating Table [9]



for the patient's perception of discomfort experienced during anesthetic administration, by device, after the second visit.

Degree of patient's self-assessed discomfort after given visit	Visit 2	
	Syringe	Wand
No pain	3.33%	13.33%
Slight pain	26.67%	36.67%
Moderate pain	33.33%	26.67%
Severe Pain	10.00%	3.33%

Table 9: Degree of patient's self-assessed discomfort after each visit, for each anesthetic delivery device (all tests of proportion difference significant at $p < 0.05$).

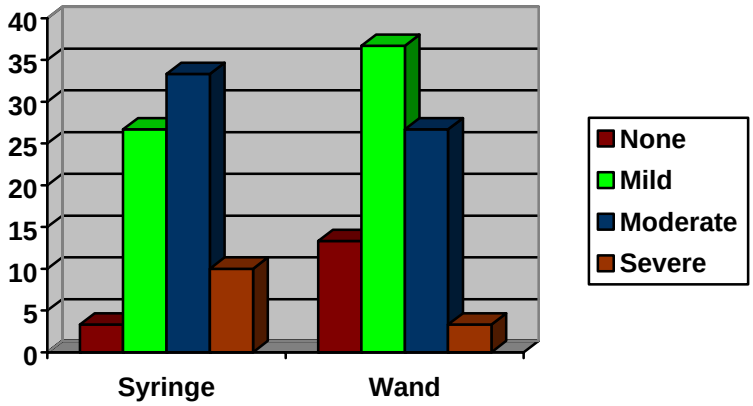


Figure 8: Illustration of the degree of patient's self-assessed discomfort after visit 2, for each anesthetic delivery device.

It is again clear that, during the injection process at Visit 2, the Wand was perceived as less painful. In both cases, the Wand did lose a small percentage of patients who voted it as not being painful at all. There are a number of potential explanations for this phenomenon. First, since each patient was subjected to a syringe injection and the order of the injection was not randomized, it is possible that the pain from the syringe injection could be confounding Wand injection pain if the syringe injection was given before the Wand injection. Additionally, it is possible that prior memory of other injections, in the prior visit, could be additionally confusing the patient's judgement of the degree of discomfort perceived during the visit 2 injections. It is further possible that altered perception of the Wand device itself, subsequent to the first visit injection, could potentially alter the discomfort perception. For example, if the patient knew that the goal of the study was to ascertain the relative pain of the two devices, it is possible that that knowledge of the study goal could confound the patient's judgement once the patient had experienced the first Wand injection, thereby potentially biasing the patient's judgement of the second injection discomfort.

4.2.5. Assessment of Patient Perceived Pain via Measures of Apprehension/Anxiety. A third mechanism for assessing the patient perceived pain is to examine the self-reports of patient apprehension/anxiety. In the first of the following two tables, we illustrate the data for the patient apprehension/anxiety for the syringe and the Wand, prior to the first injection with the device.

Syringe	Count	Cum Count	Percent	Cum Percent	Wand	Count	Cum Count	Percent	Cum Percent
0	2	3	10.00	10.00	0	4	4	13.33	13.33
1	7	10	23.33	33.33	1	5	9	16.67	30.00
2	5	15	16.67	50	2	6	15	20.00	50.00
3	5	20	16.67	66.67	3	6	21	20.00	70.00
4	3	23	10.00	76.67	4	5	26	16.67	86.67
5	3	26	10.00	86.67	5	1	27	3.33	90.00
6	1	27	3.33	90.00	6	2	29	6.67	96.67
7	2	29	6.67	96.67	7	1	30	3.33	100.00
8	1	30	3.33	100.00	8	0	30	0	100.00
9	0	30	0	100.00	9	0	30	0	100.00
10	0	30	0	100.00	10	0	30	0	100.00

Table 10

Figure [9] illustrates the data in the preceding Table [10]. In the following figure, we have grouped the data in the previous figure into three major

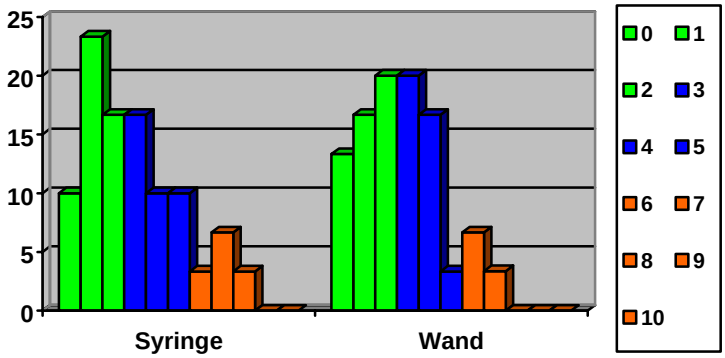


Figure 9

categories of pain: none-mild, moderate, and severe. We can immediately see that more people rated themselves as extremely apprehensive about the syringe. Despite the fact that the Wand was explained to the patients, there was still a signficant number of patients who found it anxiety inducing.

In the following table, we illustrate the patient assessment of their own apprehension prior to the second injection with each of the two devices:

Syringe	Count	Cum Count	Percent	Cum Percent	Wand	Count	Cum Count	Percent	Cum Percent
0	7	7	23.33	23.33	0	12	12	40.00	40.00
1	7	14	23.33	46.67	1	9	21	30	70
2	5	19	16.67	63.33	2	2	23	6.67	76.67
3	6	25	20	83.33	3	4	27	13.33	90.00

4	4	29	13.33	96.67	4	2	29	6.67	96.67
5	0	29	0	96.67	5	1	30	3.33	100.00
6	0	29	0	96.67	6	0	30	0	100.00
7	0	29	0	96.67	7	0	30	0	100.00
8	0	29	0	96.67	8	0	30	0	100.00
9	1	30	3.33	100.00	9	0	30	0	100.00
10	0	30	0	100.00	10	0	30	0	100.00

Table 11

Figure [10] below illustrates the data associated with Table [11]. Notice

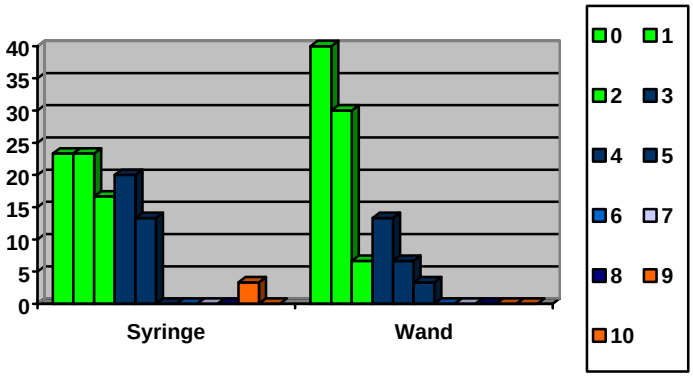


Figure 10

When we group the data into our three "pain" groups, as before, it is clear that the Wand nervousness/apprehension has decreased significantly.

It is immediately clear that the nervousness/anxiety associated with the "unknown" Wand device decreased significantly after the first injection using the Wand. In addition, we can see that, while there was still some high anxiety associated with the syringe use, there was

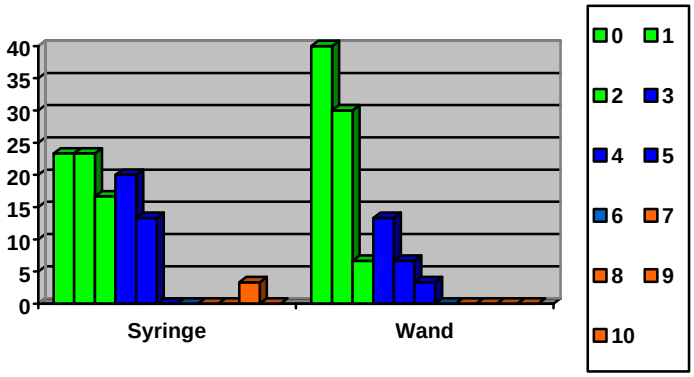


Figure 9

none for the Wand.

4.2.6. Patient Perceived Pain Based Upon Injection Location. The mandibular and maxillary injections differ in the technique and type of anesthesia, a regional block *vs*. a localized infiltration, the anatomical nature of the tissues, and the basic techniques for positioning and placement of the needle and anesthetic. The advantage of the Wand is greater with the maxillary lateral incisor injection and less defined with the mandibular

block injection. The data was examined to see whether or not either of the two injection locations, maxillary infiltration (Table 12) and mandibular block (Table 13) was significantly more comfortable for either the syringe or the Wand.

We begin with the data from the first visit. This is illustrated in the following two tables.

	Maxillary Infiltration – SI						Maxillary Infiltration - WI				
	pain	count	cum ct	percent	cum %		pain	count	cum ct	percent	cum %
Min	0	3	3	10.00	10.00	Min	0	3	3	10.0	10.0
	1	1	4	3.33	13.33		1	9	12	30.0	40.0
	2	1	5	3.33	16.67		2	1	13	3.33	43.33
Mod	3	3	8	10.00	26.67	Mod	3	1	14	3.33	46.67
	4	1	9	3.33	30.00		4	2	16	6.67	53.33
	5	2	11	6.67	36.67		5	2	18	6.67	60.00
Severe	6	1	12	3.33	40.00	Severe	6	0	18	0	60.00
	7	0	12	0.00	40.00		7	0	18	0	60.00
	8	1	13	3.33	43.33		8	0	18	0	60.00
	9	0	13	0.00	43.33		9	0	18	0	60.00

Table 12: Patient pain response for maxillary infiltration injection, SI vs. WI (Visit 1)

	Mandibular Block – SI						Mandibular Block - WI				
	pain	count	cum ct	percent	cum %		pain	count	cum ct	percent	cum %
Min	0	2	2	6.7	6.7	Min	0	2	2	6.67	6.67
	1	3	5	10.00	16.7		1	1	3	3.33	10.0
	2	6	11	20.00	36.7		2	5	8	16.67	26.67
Mod	3	3	14	10.00	46.7	Mod	3	0	8	0	26.67
	4	1	15	3.33	50.0		4	1	9	3.33	30.00
	5	1	16	3.33	53.33		5	1	10	3.33	33.33
Severe	6	0	16	0.00	53.33	Severe	6	0	10	0	33.33
	7	0	16	0.00	53.33		7	2	12	6.67	40.00
	8	0	16	0.00	53.33		8	0	12	0	40.00
	9	1	17	3.33	56.67		9	0	12	0	40.00

Table 13: Patient pain response for mandibular block injection, SI vs. WI (Visit 1)

In response to the maxillary infiltration, it is clear that the maxillary infiltration was significantly less painful with the Wand than with the syringe. In response to a maxillary infiltration with the syringe administration, only 5 patients (16.67%) rated the discomfort in the minimal category. However, with the Wand administration, 13 patients (43.33%) rated the experience as minimal discomfort. This is a statistically significant difference ($p < 0.05$). The mandibular block experience was slightly different (10%) and was marginally statistically significant ($p < 0.06$), the differences in the minor discomfort (and moderate and severe categories), is not statistically significant. The modest advantage in the numbers of patients reporting minimal discomfort with the Wand system is also reflected in the their reported preferences for future injections (Table5).

The second visit data by injection site look as follows. This is illustrated in the following two tables.

	Maxillary Infiltration – SI						Maxillary Infiltration - WI				
	pain	count	cum ct	percent	cum %		pain	count	cum ct	percent	cum %
Min	0	1	1	3.33	3.33	Min	0	2	2	6.67	6.67
	1	3	4	10.00	13.33		1	3	5	10.00	16.67
	2	3	7	10.00	23.33		2	1	6	3.33	20.00
Mod	3	4	11	13.33	36.67	Mod	3	1	7	3.33	23.33
	4	4	15	13.33	50.00		4	2	9	6.67	30.00
	5	0	15	0.00	50.00		5	1	10	3.33	33.33
Severe	6	2	17	6.67	56.67	Severe	6	1	11	3.33	36.67
	7	1	18	3.33	60.00		7	1	12	3.33	40.00
	8	0	18	0.00	60.00		8	0	12	0	40.00
	9	9	27	0.00	60.00		9	0	12	0	40.00

Table 14: Patient pain response for maxillary infiltration injection, SI vs. WI (Visit 2)

	Mandibular Block – SI						Mandibular Block - WI				
	pain	count	cum ct	percent	cum %		pain	count	cum ct	percent	cum %
Min	0	0	0	0.00	0.00	Min	0	2	2	6.67	6.67
	1	1	1	3.33	3.33		1	3	5	10.00	16.67
	2	1	2	3.33	6.67		2	4	9	13.33	30.00
Mod	3	4	6	13.33	20.00	Mod	3	5	14	16.67	46.67
	4	3	9	10.00	30.00		4	2	16	6.67	53.33
	5	1	10	3.33	33.33		5	1	17	3.33	56.67
Severe	6	0	10	0.00	33.33	Severe	6	1	18	3.33	60.00
	7	0	10	0.00	33.33		7	0	18	0	60.00
	8	1	11	3.33	36.67		8	0	18	0	60.00
	9	1	12	3.33	40.00		9	0	18	0	60.00

Table 15: Patient pain response for mandibular block injection, SI vs. WI (Visit 2)

4.4 Confounding of Pain Perception and Assessment. As we indicated at the beginning of this session, it is possible that pain perception could easily be confounded by a number of variables including the "level of pain experience" at the prior visit, having the clinician assess the pain when seeing the patient's pain assessment, and prior dental experience to name a few factors.

4.5 Dental Practitioner Preference/Ease of Use. Both dentists displayed a definite learning curve with the Wand system, as reflected by their assessment of ease of use following each appointment: either better for SI, better for WI. or no difference. Although both dentists were experienced, neither had any previous exposure or practice with the Wand system except for watching a training videotape and a few practice injections on each other. As a preliminary measure to evaluate the protocol, the first six patients were scheduled for both appointments and survey before scheduling the first appointment for the remaining patients in the study. For this "mini-trial" group, the total "ease of use rating" over the 12 appointments (2 appointments/patient × 6 patients) for ease of use was as

follows: "better with syringe" = 0, "better with Wand" = 5, "no difference" = 7. With practice, the totals for the remaining 26 patients were "better with syringe" = 1, "better with Wand" = 44, and "no difference" = 7. [JERRY, THESE NUMBERS DO NOT MAKE SENSE. WE HAD ONLY 30 PEOPLE IN THE STUDY. HOW IS IT THAT YOUR NUMBERS MAKE IT LOOK AS THOUGH THERE ARE 32 PATIENTS? EITHER THIS IS CORRECT OR YOUR STATEMENT ABOUT HAVING 30 IS INCORRECT (SEE STUDY PROTOCOL SECTION)]

	Better With Syringe	Better With Wand	No Difference
First 6 patients	0	5	7
Next 26 patients	1	44	7
Total 32 patients	1	49	14

Table [**]: "Ease of use" data for the first 6 patients (both visits combined) followed by the "ease of use" data for the next 26 patients (both visits combined).

In the following Table [**], it is clear that we can see that the administering dentists definitely displayed a learning curve behavior and that, with time and practice, there was an increased preference for the Wand device. The first column of the table illustrates the total number of injections that the administering dentist would have completed at the end of that phase of the study for each device. Since both dentists gave the equal numbers of injections for both devices, the injection number is identical for both the syringe and the Wand.

	Injection Number	Better With Syringe	Better With Wand	No Difference
After just the first 6 patients (both visits)	12	0 (0%)	5 (42%)	7 (58%)
After all first visits complete	60	1 (3%)	21 (70%)	8 (27%)
After all second visits complete	120	0 (0%)	24 (80%)	6 (20%)

Table [**]: Combined "ease of use" ratings for the first 6 patients (both visits combined), first/second visits of all of the study patients. The first column gives the total per device number of injections that the administering dentist would have completed at the end of that phase of the study.

It is clear from the illustration below that the learning curve preference for the Wand was fairly rapid for both clinicians.

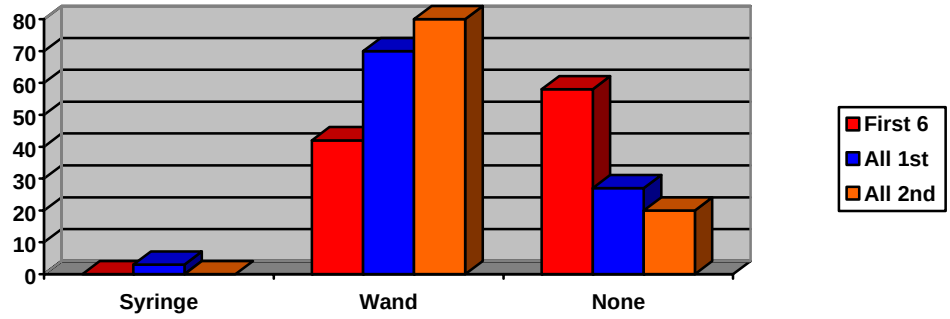


Figure 10: Combined "ease of use" data for the first six patients (both visits combined), for all 30 patients (just the first visits), and for all 30 patients (both the first and the second visits)

It is also reasonable to examine whether or not the ease of use varied as a function of the site of injection. Table [****] illustrates this data.

Injection Site	**Maxillary Block**			**Mandibular Block**		
	Better With Syringe	Better With Wand	No Difference	Better With Syringe	Better With Wand	No Difference
After all first visits complete	1 (3%)	1 (3%)	21 (70%)	21 (70%)	8 (27%)	8 (27%)
After all second visits complete	0 (0%)	0 (0%)	24 (80%)	24 (80%)	6 (20%)	6 (20%)

Table [**]: Combined "ease of use" ratings for the first 6 patients (both visits combined), first/second visits of all of the study patients. The first column gives the total per device number of injections that the administering dentist would have completed at the end of that phase of the study.

5.0 Conclusions/Discussion. The results of this study indicate that by all measures of pain assessment available in this study, the Wand system was more comfortable, less anxiety causing, and the clear anesthetic delivery instrument of choice when compared to the manual syringe system of anesthetic delivery. This conclusion is based upon a number of different ways of examining the "patient perceived pain."

The perception of treatment discomfort, whether direct or conditioned, may result in increased anxiety, fear, and behavior patterns detrimental to personal dental health and well being [15,18]. Projected from general population studies, one to two out of every ten patients in a dental waiting room may be unduly anxious about receiving a local injection. This sizable population of high anxiety patients is correlated with relatively poorer oral health, more caries, and less regular visits for dental treatment [15 – 18]. There is a general consensus that fear of the injection or specifically to the needle is a prominent focus of patient's anxiety and fear [19]. Although the causal factors, for fear of local injections are varied and complex, almost three-fourths of affected patients, when interviewed, report a past dental treatment experience that was painful or traumatic [20].

Successful and painless local injections may have even greater import than patient compliance and practice efficiency. Studies of life-threatening medical emergencies occurring during dental treatment indicate that 55% of such emergencies occurred, due to psychogenic stress or excessive anesthetic uptake within the cardiovascular system, during or within 5 minutes of the local injection [21]. Attention to local injection technique is therefore important to the reputation and practice success of the dentist and also to the comfort and safety of the patient [22].

The Wand device delivers a computer-controlled pressure and volume (flow rate) of anesthetic regardless of the location, density and resiliency of the soft tissues at the injection site. Traditional injections, such as palatal nerve blocks and periodontal ligament injections, often avoided because of discomfort, pressure or stress to both patient and operator, are claimed possible with predictable comfort. A micro-processor controlled piston activates the plunger of a standard 1.8 ml anesthetic cartridge to force the anesthetic through narrow flexible and disposable micro-tubing attached to a terminal plastic "pen style" luerlock handle that is threaded with a standard needle. A variable delivery rate (high or low speed) and aspiration are automatically performed with a foot controller.

Elimination of the traditional metal syringe barrel and thumb ring offers several advantages. First, no costly and repetitious sterilization maintenance of the syringe is required. Second, the thin plastic handle allows a precise pen grasp and does not impart a metallic hard or cold impact to the oral tissues upon contact. Third and ideally, improved tactile feedback, visibility, and automated aspiration allow the dentist to concentrate on the needle positioning and patient interaction required for effective and painless local anesthesia. Fourth and most importantly, the computer controlled anesthetic delivery system is advertised to prevents tissue distension, to eliminate heavy hand pressure required for perfusion of dense tissue, and to automate delivery timing to overcome a tendency to inject too quickly.

No doubt the selection of the types and locations of the injections studied in this clinical trial had a pivotal effect on the comparison of the two systems. The manufacturer especially advocates the Wand for injections into dense, non-resilient tissues such as the attached mucosa of the palate for greater palatine or nasopalatine nerve blocks or into the periodontal ligament space for an intraligamental or PDL injection. As cited before, the Hochmann study reported a comparative advantage of two-three times that of the syringe when blindfolded dentist volunteers received palatal injections by both systems [13]. However, these injections are infrequently required. The authors of this study elected to compare location and types of local anesthetic injections that are commonly and routinely used in general dentistry, thereby studying the greater general applicability of the Wand device. In addition, in order to make the study more clinically relevant as well as applicable, the authors used a population of university employees rather than dentists as subjects. Although the advantages of a single blind protocol using blindfolds and similar audible signals for both delivery systems is apparent, the authors felt that this would unduly distort and exaggerate the fear, apprehension, and response of a typical patient volunteer, making the study less relevant and less generally applicable.

The clinical appointments proceeded normally with few unexpected events. Of the sixty inferior alveolar blocks given, seven required re-administration of anesthetic to produce confirmation of pulpal anesthesia [HOW MANY WERE SYRINGE, HOW MANY WAND?]. Due to the anatomical variation and depth of the needle penetration, Malamed's textbook postulates a success rate for the lower inferior alveolar nerve block of about 80%, equivalent in this study to 12 missed mandibular blocks [23]. A simple binomial test of proportions shows that this reduction is statistically significant $p < 0.05$. Conversely, the operators were surprised that two maxillary infiltration injections were missed and required re-application of anesthesia. One of these lateral incisors continued to respond to a cold test. Of the 120 injections, patients rated thirteen (10.8%) from 6 to 9 which the authors arbitrarily categorized as "severe" discomfort. The maxillary infiltration was the site for 7 of these responses (Table 3) and the mandibular block for 6 (Table 4). Both dentists were experienced, diligent, and took pride in their ability to administer a "painless" injection and were not hurried or rushed as compared to busy private practitioners. The authors are not aware of other published studies that affirm this surprising percentage of discomfort with routine injections. If the percentage is representative, it would support the epidemiological prevalence of substantial populations who are consciously or even subconsciously apprehensive of future dental treatment. There is general agreement that females are most affected by the anxiety and fear of injections [24 – 26]. Though not by design, the patients in this study were almost exclusively in this group. Consequently, a follow-up trial, focussing on sex and ethnic balance is deemed appropriate for further analysis of the pain problem.

Over the period of this clinical trial, both dentists and the dental assistant came to prefer the Wand system. However, there were a few annoyances associated with its use. By far, the greatest irritant was with the prolonged aspiration cycle that lasted approximately 15 seconds before the administration of the anesthetic drug could commence, this in comparison to the traditional syringe where the momentary reverse direction on the thumb ring only takes a few seconds. With the Wand, the long (≈54 inches) length of the microtubing between the computer activated device holding the cartridge and the needle dictates extended time to reverse the flow to the point of visual confirmation. In addition, there is a transition from a slow beeping tone marking the regulated delivery of anesthetic to a rapid series of beeps denoting the length of the aspiration cycle. Unless the patient is forewarned, the transition can be mistaken for an "alarm" or a malfunction potentially inducing additional fear and subsequent enhanced pain in potentially fear-prone and pain-prone patients.

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There was also no significant difference with the operator's assessment of patient pre-injection anxiety and the patient's self-report of prior anxiety for SI and WI. Likewise, there was no significant difference with either injection system between the patient rating of discomfort and the operator's assessment of patient discomfort from vocal or by involuntary reactions to stress. However, the operators may have been influenced in hearing the patient's numerical rating of discomfort before marking their own assessment following the clinical appointment.

Statistical evaluation of subjective responses, especially with the complex and emotional nature of pain, must be treated with caution. The presentation of means and averages and even types of statistical tests derived from this type of response is often misapplied and misleading. The constraints of such data, which is neither discrete nor continuous, is addressed more completely in the Discussion section that follows. The authors believe that an inspection and comparison of the frequency table or their derived graphs may serve more accurately than statistical derivations.

To illustrate, a standard frequency table distribution is presented (Table 2) for patient ratings of discomfort for all injections given with a manual syringe (SI) and with the Wand (WI) for both visits combined. The authors arbitrarily assigned categories of minimum (Min) for slight/no pain for responses of 0-2; moderate pain (mod), 3-5, and severe pain, 6-9. No patient rated any injection a "10", the worst pain imaginable.

	Patient Pain – SI						Patient Pain - WI				
	pain	count	cum ct	percent	cum %		pain	count	cum ct	percent	cum %
Min	0	6	6	10.0	10.0	Min	0	9	9	15.0	15.0
	1	8	14	13.3	23.3		1	16	25	26.7	41.7
	2	11	25	18.3	41.7		2	11	36	18.3	60.0
Mod	3	14	39	23.3	65.0	Mod	3	7	43	11.7	71.7
	4	9	48	15.0	80.0		4	7	50	11.7	83.4
	5	4	52	6.7	86.7		5	5	55	8.3	91.7
Severe	6	3	55	5.0	91.7	Severe	6	2	57	3.3	95.0
	7	1	56	1.7	93.4		7	3	60	5.0	100.0
	8	2	58	3.3	96.7		8				
	9	2	60	3.3	100.0		9				

Table 2. Patient discomfort ratings for all SI vs. WI. * percentage is rounded to nearest one-tenth.

Although there is not a significant statistical difference between overall patient ratings of the two injections, a strong tendency that the Wand injection is more comfortable is apparent from the Table 2. The Wand system injection was rated as minimal discomfort by 36 patients (60%) compared to only 25 (41.7%) for the manual syringe injection. Also, 8 patients rated the syringe method as inducing "severe" discomfort vs. only 5 patients (8.3%) for the Wand. Four patients (6.7%) rated the syringe injection higher than 7 but no patients rated the Wand higher than a 7.