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C-CLAD

COMPUTER - CONTROLLED LOCAL ANESTHETIC DELIVERY

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Clinical Summary

Milestone Scientific hosted the Computer-Controlled Local Anesthetic Delivery (C-CLAD) Symposium at The Ritz-Carlton, Amelia Island, Florida.

Stanley Malamed, DDS, Professor of Anesthesia and Medicine at the University of Southern California, Los Angeles, served as Chairman of the Symposium.

The goals of the event were:

- to reinforce the science and clinical studies on C-CLAD;
- to reaffirm the technology's practical chair-side application in clinical settings; and
- to build a consensus of acceptance of C-CLAD and its many benefits among an expanded breadth of industry experts.

The following is a summary report of the C-CLAD Symposium, including clinical presentations, quotes and conclusions.



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Computer-controlled local anesthetic delivery system (C-CLAD)

A computer-driven arrangement of software, hardware and dental implements used to administer anesthetic injections in which the amount of drug and injection speed are predetermined by a software-driven motor. The injection itself is manually applied.

Mosby's Dental Dictionary, 2nd edition. © 2008 Elsevier, Inc.

The History of C-CLAD

Mark Hochman, DDS

During the late 1880's, noted physicians Sigmund Freud, Carl Koller and William Halstead were each pursuing a common area of clinical research: the development of the drug Benzoylmethyl Ecognine, more commonly known as cocaine, for medicinal use and its application as the first local anesthetic.

While Freud and Koller were the first to notice the anesthetic effects of cocaine, it was Halstead who introduced cocaine as a local anesthetic in dentistry. Using a hypodermic syringe, he demonstrated that an interstitial injection of aqueous cocaine resulted in an effective inferior alveolar nerve block; that a small amount of anesthetic injected into the trunk of a sensory nerve resulted in a numbing of pain in all of that nerve's branches. This discovery ushered in a new era of local pain management for both dentistry and medicine.

The hypodermic syringe used by Halstead in his research was a simple mechanical device developed in 1853 by French surgeon Charles Gabriel Pravaz. It consisted of a hollow-bore needle connected to a chamber with a sealed plunger. Remarkably, the basic design, mechanics and manual operation of the Pravaz syringe in use over 150 years ago is almost identical to the medical and dental syringes used today.

So, what have we learned about this delivery system? What does the clinical data reveal about its common use? Aside from all its noted benefits, we know – and there have been numerous dental studies and consumer surveys documenting this – that the dental syringe invokes fear in patients. In fact, it is estimated that nearly one in 20 adults will avoid, cancel or fail to appear for dental appointments because of their fear of dental injections.

In 1997, a new and innovative drug delivery system was introduced to the field of dentistry by **Milestone Scientific Inc.** Originally branded *The Wand*[®], this system was later renamed the *CompuDent*[®]/*Wand* System and represented the world's first Computer-Controlled Local Anesthetic Delivery (C-CLAD) system. In a matter of only a few years, this new technology has helped redefine our perception of how local anesthesia can and should be achieved.

This novel system afforded us the ability to control the rate of delivery of the local anesthetic solution with a precise, computer-controlled injection. In addition, it introduced the exciting concept of using a handpiece that weighs less than ten grams, thus allowing the user to hold it in a pen-like fashion and enabling superior tactile control and greater dexterity than with alternative injection technologies. Moreover, this new drug delivery system represented a monumental advancement for subcutaneous injections and has radically improved the outcome and experience for millions of patients over the past decade, thereby helping to mitigate the 'fear factor' that has become so closely linked to the dental visit.

With this new technology, several new injections not previously reported in dentistry were introduced. The anterior middle superior alveolar (AMSA) nerve block, first published in 1997 by Dr. Friedman and Dr. Hochman, is a technique that is now taught in dental schools around the world. It is a contemporary technique to achieve maxillary anesthesia of multiple teeth from a single palatal injection. In addition, Drs. Friedman and Hochman introduced a second injection called the palatal approach-anterior superior alveolar (P-ASA) nerve block, in which dental and soft tissue anesthesia of the central and lateral incisors is achieved by a single palatal injection. This is the first dental injection that allows practitioners to anesthetize multiple maxillary teeth across the midline during the administration of a local anesthetic. A third innovation related to this new delivery system is a technique to improve the success rate of the infra-alveolar nerve block by reducing or eliminating needle deflection. This injection technique uses bi-rotational insertion that can be performed using *The Wand* handpiece. Holding *The Wand* handpiece with a pen-like grasp and being able to rotate the needle while translating forward has been clinically proven to eliminate deflection during penetration. One study at Boston University has shown a reduction in missed blocks and earlier onset of anesthesia due to the increased accuracy of this technique.





Anterior Middle Superior Alveolar (AMSA)



Palatal Approach-Anterior Superior Alveolar (P-ASA)

In 2001, Milestone's ongoing research and development efforts in fluid dynamics helped them to identify a method for measuring the precise quantity of the exit pressure of fluids at the tip of the needle during subcutaneous drug administration. This led to the Company's next breakthrough in C-CLAD technology: *CompuFlo*.

Specifically, the *CompuFlo* technology is a computer-controlled injection delivery system that uses *Dynamic Pressure Sensing*® (DPS) for painless delivery and aspiration of medicants. DPS triggers visual and audible in-tissue pressure feedback that helps to: 1) identify tissue types for the healthcare provider; 2) recognize when certain types of tissue have been penetrated; and 3) ensure that the injection of medicants occurs at the precise location necessary. The Hermann Memorial Hospital at the University of Texas was the first to publish a scientific article relating to a medical application of this disruptive technology. *CompuFlo* underwent several pilot studies involving the administration of epidural injections and succeeded in identifying false positives of anesthetization. Epidural administration is just one of many medical and extra-medical applications identified for *CompuFlo*'s use.

In 2007, Milestone applied *CompuFlo* in dentistry to address an important challenge - achieving single tooth anesthesia. It is widely known that dentistry performed today is largely on individual teeth in which nerve block anesthesia is not necessary. Milestone's most advanced application of C-CLAD technology, aptly named the *STA Single Tooth Anesthesia System*, or *STA System*, allows dentists to receive real-time feedback for the first time, indicating when they are in the right location when performing single tooth anesthesia.

Often referred to as a "blind injection," the traditional periodontal intraligamentary (PDL) injection uses high pressure within a localized tissue area; the typical outcome is anesthesia of only short duration due to the fact that only a small volume of drug can be administered under such high pressure. It has been shown both histologically, as well as clinically, that over-pressurization of the area can lead to tissue pathologies. The *STA System* has changed all of this.

The *STA*'s predecessors, *The Wand* and the *CompuDent* systems, represented a material improvement over the antiquated 150-year dental syringe. These instruments empowered dental practitioners to give much more comfortable injections with materially lower pressure during administration; allowing placement of a much larger volume of drug; achieving longer duration of anesthesia; minimizing tissue reactions; and resulting in a safer, more positive patient experience.

With the introduction of the *STA System*, dental practitioners can now achieve all of these objectives and more, including single tooth anesthesia, as well as all currently administered dental injections, with resulting superior outcomes.

Milestone's commitment to advancing the science of computer-controlled injection technology has earned the Company global distinction as an industry pioneer and innovator in the fields of dentistry and medicine.



Dr. Mark Hochman is a multi-trained specialist in Periodontics, Implant Dentistry and Orthodontics. He is currently an Associate Clinical Professor at New York University College of Dentistry. He is a team member of the New York Center for Specialized Dentistry, as well as a member of an interdisciplinary team practice composed of specialists providing comprehensive dental care in New York City. Dr. Hochman has served as Director of Clinical Affairs and Director of Research and Development for Milestone Scientific Inc. since 1999. He is recognized as a world authority on advanced drug delivery systems in dentistry and medicine. A contributor to the dental literature on a variety of topics, Dr. Hochman invented and participated in the development of much of the C-CLAD technology currently available from Milestone, including the STA System.

Injection Advances and Challenges

Stanley F. Malamed, DDS



Dr. Malamed was born and raised in the Bronx, New York, graduating from New York University College of Dentistry in 1969. He then completed a dental internship and residency in Anesthesiology at Montefiore Hospital and Medical Center in the Bronx, New York before serving for two years in the U.S. Army Dental Corps at Ft. Knox, Kentucky. In 1973, Dr. Malamed joined the faculty of the University of Southern California School of Dentistry in Los Angeles, where today he is Professor of Anesthesia & Medicine. He is a Diplomate of the American Dental Board and recipient of the Heidebrink Award (1996) from the American Dental Society of Anesthesiology as well as the Horace Wells Award from the International Federation of Dental Anesthesia Societies (1997).

Dr. Malamed has authored more than 135 scientific papers and 17 chapters in various medical and dental journals and textbooks in the areas of physical evaluation, emergency medicine, local anesthesia, sedation and general anesthesia. In addition, he is the author of three widely used textbooks, published by CV, Mosby: *Handbook of Medical Emergencies in the Dental Office* (6th Ed. 2007); *Handbook of Local Anesthesia* (5th Ed. 2004); and *Sedation—A guide to Patient Management* (4th Ed. 2003); and two interactive DVD's: *Emergency Medicine* (2nd Ed., 2008) and *Malamed's Local Anesthetic Technique DVD* (2004).

The C-CLAD system represents a significant change in the manner in which a local anesthetic injection is administered.

Many doctors have found that as a result of the unique characteristics of C-CLAD, most traditional dental injection techniques can be performed with greater predictability and with less discomfort.

Excerpts from *Handbook of Local Anesthesia, Ed. 5*—Stanley F. Malamed, DDS; Copyright 2004, Mosby, Inc.

The renaissance of local anesthesia began in 1973. Until that time, while new drugs such as mepivacaine and prilocaine had been introduced, little had changed in terms of local anesthetic techniques since the publication of Leonard Monheim's textbook on local anesthesia in 1948. The rebirth of interest in local anesthesia and the development of new delivery techniques began in 1973 following the publication of an article by Dr. George Gow-Gates in which he described a new approach to mandibular anesthesia. His objective was to find an alternative to the inferior alveolar nerve block technique that would improve upon its 80% to 85% success rate. Realizing that mandibular blocks typically failed due to poor positioning of the injection (often too low relative to the position of the mandibular nerve), Dr. Gow-Gates pioneered a new technique utilizing a superior injection site that achieved greater success rates. Since its introduction, this technique has been taught in every dental school in the United States, and has given way to other innovative techniques being investigated and introduced to dentistry. These have included Akinosi-Vazirani (the closed-mouth mandibular block), the periodontal intraligamentary (PDL) injection, and the intraosseous injection. The continued interest in and development of new techniques ultimately led to computer-controlled local anesthesia delivery (C-CLAD).

"With the computer-controlled STA System, clinicians have the ability to develop new injection techniques and to offer improved pain control."

With the computer-controlled *STA System*, clinicians have the ability to develop new injection techniques and to offer improved pain control. Moreover, it is now possible to anesthetize single teeth for procedures without a patient experiencing residual anesthesia of the tongue and/or lips. Similarly, new techniques developed following the introduction of C-CLAD—notably the AMSA and P-ASA—provide profound local anesthesia at the desired treatment site(s) without unwanted or residual soft-tissue anesthesia.

The renaissance in interest in local anesthesia has resulted in developments directly attributable to the introduction of the *STA System*, together with the innovative injection techniques made possible with this new C-CLAD technology. The *STA System* addresses one of the great challenges of dentistry by providing an effective, safe solution to single tooth anesthesia.

How dentists are judged by their patients

1. A dentist who gives a painless injection
2. A dentist who does not hurt
3. Staff who are...kind, professional, caring, warm and helpful
4. Runs on time
5. "Doctor, that was the most thorough dental exam I've ever had."
6. Dentists who listen, allow questions, treat dumb questions with dignity
7. Patients are happy with the results
8. Prompt emergency service
9. Prompt new-patient examination appointment
10. High standard of sterilization



Computerized Delivery of Local Anesthesia

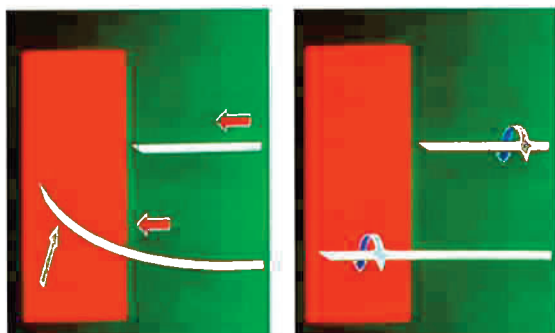
J. Mel Hawkins, DDS, BScD(AN), FADSA, DADBA

“The STA System offers enhanced predictability, injection accuracy, operator confidence and patient comfort.”

Computer-controlled local anesthetic delivery (C-CLAD) in dentistry has advanced the science of local anesthesia. Injection techniques with C-CLAD have included use of the original *Wand* unit launched in 1997, the *Comfort Control Syringe*, the *Quick Sleeper* and, most recently, the *STA System*.

As observed clinically and as reported in the literature, traditional injections can be associated with pain related to the rate of injection of the anesthetic solution and perhaps also to the acidity of the anesthetic solution. It should be noted, however, that needle gauge and temperature of the anesthetic solution do not impact whether or not a patient experiences pain. Nonetheless, there are several disadvantages associated with traditional injection techniques – particularly the mandibular block injection, which presents a long delay before onset of the anesthesia, as well as a demonstrated lack of predictability. Failure to achieve local anesthesia largely occurs due to tissue vector forces, which deflect the needle along the injection path. In addition to these issues, mandibular blocks are associated with pain during injection; collateral numbing of the cheek, lip and tongue; and post-operative pain.

Tissue vector forces



Use of the *STA System* offers several clinical and patient care advantages over traditional injection techniques. Foremost is the fact that it provides for

a precise method for administering local anesthesia at the site of a single tooth, avoiding the need to give a mandibular block. It also has an injection time of one minute for single-rooted teeth and two minutes for multi-rooted teeth; and provides immediate onset of profound anesthesia using a 4% articaine hydrochloride local anesthetic solution with 1:200,000 epinephrine. As a result, there is no waiting time – the dental procedure can be started immediately.

C-CLAD Advantages

| | |
|------------------------------------|---------------------------------|
| Controlled pressure/volume ratio | Operator confidence |
| Injection time of 1-2 minutes | Decreased pain during injection |
| Immediate, profound anesthesia | Reduced post-operative pain |
| PDL and/or intraosseous injections | Practice builder |

Additionally, the ergonomically designed feather-weight *STA* handpiece gives the operator unsurpassed tactile control, which also helps during the administration of local anesthesia. Furthermore, injection pressures using the *STA System* are greatly reduced compared to those that occur when using a traditional technique. In addition, less local anesthetic is required, resulting in patients experiencing reduced postoperative pain. The intraligamentary (PDL) injection can be the sole, primary injection for local anesthesia using the *STA System*, with the achievement of consistently profound, painless and immediate anesthesia.

In conclusion, the *STA System* offers enhanced predictability, injection accuracy, operator confidence and patient comfort.



Dr. Mel Hawkins has 35 years of private practice, clinical and teaching experience. He has developed and directs a full day hands-on version of this program throughout North America. His venues include several state meetings, ADA meetings and private office tutorials.



Physiologic and Clinical Characteristics of PDL Anesthesia Delivered by a High Pressure Syringe and a Computerized Device

Malka Ashkenazi, DDS

“Use of C-CLAD with the STA System is non-stressful and results in lower pain. The efficacy is high, using fewer injection sites and less anesthesia compared to intraligamentary injections.”

The effectiveness of intraligamentary anesthesia has been demonstrated by three studies that collectively involved 474 primary and permanent teeth in children and adults, ranging from 79% for vital pulpotomy to 95% extractions with consistently higher effectiveness rates across all studies for extractions. By comparison, computer-controlled local anesthesia delivery (C-CLAD) using an intrasulcular injection technique with the STA System has been found to be 89% effective in a study of 159 first and second primary molars for which this technique was applied. This anesthesia was obtained using 0.9mL of anesthetic solution per root that was injected mesiolingually, mesiobuccally, distolingually and distobuccally.

Dr. Ashkenazi and her colleagues are currently conducting studies on single tooth anesthesia using C-CLAD technology. Based on preliminary data, its effectiveness in the study was 98% for first and second primary molars (N=131) and 79% for permanent molars and premolars (N=29), using only a quarter or one-third of a carpule per root administered lingually. It was also found that the effectiveness of single tooth anesthesia is related neither to the age of the patient nor to the location of the treated teeth.

Other areas of investigation have included the incidence of anesthesia in adjacent teeth, the role of vasoconstrictors, the potential impact of the use of single tooth anesthesia on developing tooth buds, and the presence or absence of pain during and following use of C-CLAD techniques.

Anesthesia of Adjacent Teeth

Using an intraligamentary injection technique with an anesthetic solution containing 2% lidocaine with epinephrine has been reported to anesthetize 45% and 78% of teeth mesial and distal to injection sites, respectively. In contrast, the effectiveness of anesthesia of adjacent teeth using C-CLAD with the STA System has been demonstrated to be in the range of 88% to 86% for primary school molars and first permanent molars adjacent to teeth receiving single tooth anesthesia.

The Use of Vasoconstrictors

It is well known from the literature that effectiveness of the intraligamentary injection technique is related to the use of vasoconstrictors, with reported efficacy in the permanent dentition of 81% to 87% with the use of vasoconstrictors, but just 8% to 42% without their use.

Dr. Ashkenazi and Dr. Ram have studied the use of mepivacaine without vasoconstrictors, finding a 39.5% efficacy rate for anesthesia of primary molars in 48 children. They have concluded that a vasoconstrictor is required for efficacy of both intraligamentary and single tooth anesthesia.

In approximately 10% of subjects in one group, the pulse rate increased by between 31 and 58 beats per minute during the administration of local anesthesia; while in another group, roughly 15% experienced increases of around 21 to 30 beats per minute.

Efficacy of anesthesia

| Treatment | CDS-IS - % | STA - % |
|------------------|--------------|--------------|
| Restoration | 97 (93/96) | 91 (92/102) |
| Pre-formed crown | 92 (24/26) | 92 (12/13) |
| Extraction | 63 (10/16) | 91 (10/11) |
| Pulpal therapy | 71 (15/21) | 71 (5/7) |
| Total | 89 (142/159) | 90 (119/133) |

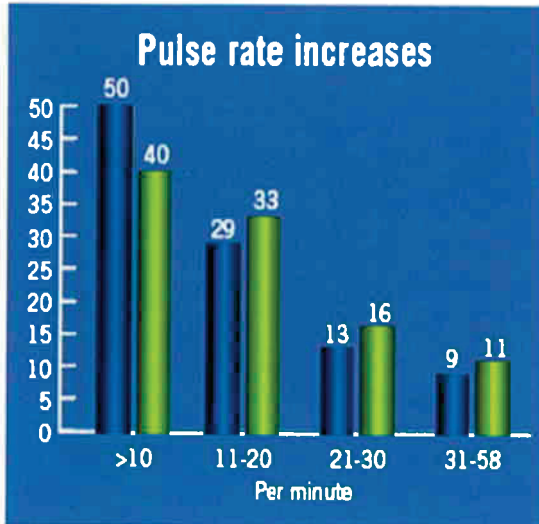
Comparative effectiveness: Study vs. meta-analysis

| Treatment | IS-CMA and STA | Infiltration | HP-IL |
|----------------|----------------|----------------|--------------|
| Restoration | 93% (237) | 65-95 % (120) | 85 % (193) |
| Extraction | 74% (27) | 75% (4) | 95% (22) |
| Pulpal therapy | 71% (28) | 47-61.5 % (28) | 79-81% (120) |
| Total | 89% (292) | 74% (152) | 84 % (335) |



Pulse rate changes with infiltration and intrasulcular techniques

| Pulse rate | With epinephrine | | Without epinephrine | |
|---------------------|------------------|------------|---------------------|-------------|
| | CDS-IMF | CDS-IS | CDS-IMF | CDS-IS |
| Basic pulse | 95.3±11.8 | 95.7±13.8 | 95.6±11.9 | 91.4±13.5 |
| During injection | 101.4±13.9 | 101.6±11.8 | 96.8±13.0 | 94.3±14.0 |
| Mean increase | 5.1% | 5.6% | 4.8% | 5.0% |
| Range of increase | -11 to +45 | -5 to +58 | -10 to 12 | -10 to 20 |
| Range of % increase | -10% to 52% | -5% to 69% | -10% to 13% | -11% to 22% |



Interestingly, changing the site of the intrasulcular injection resulted in an almost immediate decrease in the pulse rate, suggesting that the increase in pulse rates experienced at the first site had possibly been due to injection of the anesthetic solution into small blood vessels at the site. No statistical correlation was found between changes in pulse rates and age, gender, or the presence or absence of a vasoconstrictor in the local anesthetic solution administered.

The Developing Tooth Bud

In a new study on intrasulcular injections of 76 first and 90 second primary molars in 78 subjects, Dr. Ashkenazi, Dr. Blumer and Dr. Eli concluded that intrasulcular anesthesia does not induce damage to the underlying dental bud. One child in the test group presented later with hypomineralization of the first permanent lower premolar, and two children in the control group presented with hypoplastic enamel defects in the permanent control premolars. This was in contrast to an earlier study on monkeys in 1984, in which Brännström found that administering high pressure intraligamentary injections for primary molars was capable of damaging the underlying developing tooth buds if an anesthetic containing a vasoconstrictor was used.

Lack of Pain with STA

Studies have produced conflicting reports on the presence of pain during high pressure intraligamentary injections, possibly due to differences in technique. In addition, the use of traditional intraligamentary injections have been reported to result in post-injection discomfort in 88% of subjects. In one study, pain was experienced by some subjects for up to 48 hours after the anesthetic had been administered. Use of C-CLAD with the *STA System*, however, has been reported to be relatively non-stressful and to result in less or no pain.

Dr. Ashkenazi reported that over more than eight years of clinical use, she had only two patients who complained of discomfort with use of *The Wand/STA System*.



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Dr. Malka Ashkenazi graduated dental studies at the Hebrew University in Jerusalem in 1979. In 1987, she completed her specialization in pediatric dentistry at Tel Aviv University, followed by three years of postdoctoral education in Houston, TX. Between 1999 and 2000, she studied medical hypnosis at Tel Aviv University. Dr. Ashkenazi has been a clinical instructor and lecturer for dental students and post-graduate students in pediatric dentistry since then. She is a mentor for students completing their DMD theses and for basic research by postgraduate students. Dr. Ashkenazi serves as a member of the Committee of Receipt of Specialization to the post graduate program, and since 1993 has been a member of the National Examinations Committee for Specializations in the fields of pediatric dentistry and orthodontics. In 2007, she was distinguished as a Senior Lecturer in pediatric dentistry. Since 2004, she has served as Chairperson of the Inspection Committee of the Israel Society of Pediatric Dentistry. She has delivered abstracts at many international conferences and serves as a reviewer in several international journals on pediatric dentistry.

Efficacy of the Computer-Controlled STA System, the Ligmaject and the Dental Syringe for Intraligamentary Anesthesia in Restorative Patients

Marco Ferrari, MD, DDS, PhD

"The results of this clinical evaluation demonstrate that the STA System provides quicker onset of anesthesia, enables more comfortable administration of local anesthetic and offers a more reliable intraligamentary injection technique."

The STA System, an evolution of the original Wand system, incorporates dynamic pressure sensing (DPS) technology that provides continuous monitoring of real-time pressure during all phases of an intraligamentary injection, thereby limiting the maximum pressure that is applied. In addition, the DPS technology detects any loss of pressure during the injection, enabling delivery of a larger amount of anesthetic during intraligamentary injections than is possible with a conventional syringe.

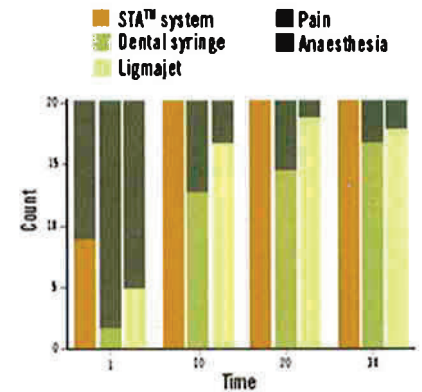
The null hypothesis for Dr. Ferrari's study, which evaluated the efficacy of the STA System for intraligamentary anesthesia as compared to either the Ligmaject or the traditional dental syringe, was that there would be no differences in efficacy for these three devices.

Sixty healthy patients, ages 20 to 50, with lower premolars that required dental treatment were recruited into a study and randomized into the three test groups for each test device. Following clinical evaluation at baseline, all patients received 4% articaine with 1:100,000 and 1:200,000 epinephrine. The efficacies of anesthesia and discomfort during injection (using the VAS analog scale) were then measured. All patients were also contacted the following day in order to obtain their self-reported assessment of post-injection pain.

In the STA System group, effective and profound anesthesia was obtained within ten minutes of the injection and none of the patients required a second injection. In contrast, in the group receiving injections using the traditional dental syringe, effective anesthesia was obtained in all patients after 40 minutes, with 35% requiring additional injections to obtain effective and profound anesthesia. In the Ligmaject group, effective anesthesia in all patients again took 40 minutes, with one patient requiring an additional injection.

The onset of anesthesia using the STA System was consistently faster than with the handheld syringe and the Ligmaject. With respect to postoperative pain after 24 hours, two patients in the STA System group reported low pain, while seven patients in the traditional dental syringe group and five patients in the Ligmaject group reported low to medium pain.

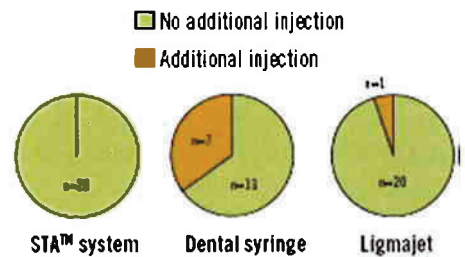
Speed of onset and efficacy of anesthesia



Difficulties with intraligamentary injections

- Position of the needle
- Controlling the location of the needle during administration
- High pressure syringe increases the perception of pain perception
- Amount of anesthetic to be delivered
- Duration of anesthesia

Post-injection pain experience



Dr. Marco Ferrari graduated in Medicine and Surgery from the University of Pisa, and earned his degree in Dentistry at the University of Siena and his PhD in Dental Materials at ACTA in Amsterdam. He is currently Dean of the School of Dental Medicine, Director of the Dental Materials and Fixed Prosthodontics Department and Director of the International School of Doctorate on Biotechnology at the University of Siena; Research Professor, Department of Restorative Dentistry and Fixed Prosthodontics, Tufts University, Boston; Adjunct Professor, Department of Fixed Prosthodontics, University of Rochester, USA; and Visiting Professor, Department of Prosthodontics, Xi'an University, China. Dr. Ferrari is also a member of the Editorial Boards of the *Journal of Dental Research*, *Journal of Dentistry*, *American Journal of Dentistry*, *International Journal of Prosthodontics* and *Journal of Adhesive Dentistry*; and he is the Editor of *International Dentistry South Africa*. In addition, Dr. Ferrari is President-elect of the Academy of Dental Materials, Past-President of the European Federation of Conservative Dentistry, and Secretary of the Italian Conference of Dental Schools. He has published more than 250 articles in international journals. At the Symposium, Dr. Stanley Malamed presented Dr. Ferrari's study.



STA—The Dental School Perspective

Ira Lamster, DDS, MMSc



Dr. Ira Lamster received his DDS from the State University of New York at Stony Brook (1977), his MMSc from Harvard University (1980), and a Certificate of Special Training in Periodontology from the Harvard School of Dental Medicine (1980). Currently, Dr. Lamster is dean and professor of dentistry at Columbia University, College of Dental Medicine.

Dentistry is a technology-based profession, so it is important that dental schools do embrace new technology. One of the advantages for the part-time volunteers that we rely on to help teach students is that they can learn about the new technologies that we introduce at the dental school. Current technologies that are taught as part of the curriculum or as continuing education courses include diagnostic tests and use of Cone Beam and *iCAT*® devices. New technologies being introduced include tissue-cutting lasers and use of the *STA System*. It should be acknowledged that introducing new technology into the pre-doctoral curriculum can be difficult, since in most schools the curriculum remains four years in length while the knowledge base to be covered during that time is ever increasing.

In assessing students, dental schools and the accrediting agency look for competency, which can be measured on a scale with five levels, starting with a novice with only book knowledge. Competency is expected of students after the four-year curriculum is completed; a good guide for measuring competency is Miller's pyramid. At the lowest level of the pyramid is knowledge (knows); followed by competence (knows how), performance (shows how) and action (does).

An example question is: How do a traditional syringe and the *STA System* work? Using Miller's pyramid, this is placed in the context of clinical cases with decision making on when each device would be used and which cases would be most appropriate.

Technology, such as the *STA System*, has a place in dental schools today, for there is nothing of more concern to patients than the appearance of the dental syringe. Therefore, it needs to be determined when the *STA System* should be introduced to the point of competency. In introducing the *STA*, it is most important to find a champion and advocate, who will probably be the faculty member responsible for the anesthesia and pain-control course. The technology must be introduced as an evidence-based learning module, with information provided in a clear and usable form. It is important in this regard that a partnership exists between the Company and the dental school, and that the dental school is involved in post-marketing evaluation to gather information on clinician and patient experiences. Dental students are the practitioners of the future who will be adopting this technology once they go into practice; so it is important that they learn about it in dental school.



Treating with Connection

Cynthia K. Brattesani, DDS

"Every dental school in the country should be teaching students how to use the *STA System* to provide painless injections and reduce patient anxiety."

Success in practice can be attributed to the dentist's connection with patients, to which the *STA System* – or its predecessor *The Wand* – can contribute, as it helps to reduce the anxiety experienced by patients. The number one and two fears in dentistry are the drill and the injection, with the injection being the greatest fear. Every dental school in the country should be teaching students how to use the *STA System* to provide painless injections and reduce patient anxiety.

Survey comments regarding the *STA System* injection experience have included the following: "I was afraid to come to the dentist, but not anymore!"; "I did not even feel the shot!"; "The treatment visit was a very pleasurable experience." The public demands things that are faster, look better, work better, last longer and taste good. The *STA System* is on top of that list and provides patients with a better experience.



Dr. Cynthia Brattesani is a 1989 graduate of the University of California, San Francisco, School of Dentistry. She has served as President of the San Francisco Dental Society and as a council chair of the ADA. She lectures nationally on use of technology in the dental office.

Dentists' Stress in the Workplace

Monika Daublaender, MD, DDS



Dr. Monika Daublaender is a consultant oral surgeon and lecturer in oral surgery and pain management at the University Medical Centre in Mainz (Germany). After studying medicine and dentistry in Germany and Switzerland and receiving her medical and dental degrees, she qualified as an oral and maxillofacial surgeon in 1988 and 1990 and later completed specialty training in pain management in 2000. She was bestowed the Scientist Award by the German Society of Dental, Oral and Craniomandibular Sciences in 2000. Dr. Daublaender is President of the German Association for Dental Anaesthesia and past President of the EFAAD. She has published approximately 80 scientific papers and participated in numerous national and international meetings.

“Single tooth anesthesia is a major improvement in injection technique, reducing discomfort for patients and stress for dentists.”

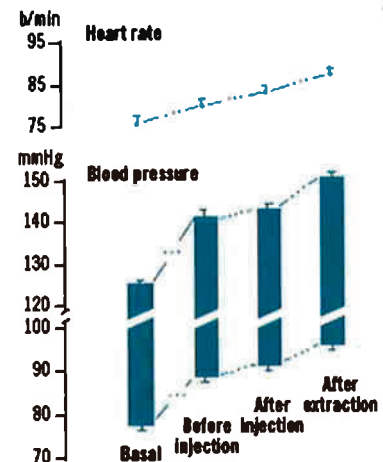
Workplace stress is the harmful physical and emotional response that occurs when there is a poor match between job demands and the capabilities, resources or needs of the worker. While we usually think of other professions when we focus on workplace stress, it has been shown that dental professionals are subject to workplace stress, as well. A British survey in 2004, involving almost 2,500 general dentists (70.4% male, 29.6% female), found that workplace stress was significant and that there were two main components to workplace stressors – occurrences such as running behind schedule and the patients themselves. Patients, especially anxious ones, are the single greatest workplace stressor for dentists.

Dr. Daublaender reported on a study by Italian researchers in which monitoring of the dentists' vital signs during patient injections and extractions demonstrated an increase in blood pressure from baseline to injection and from injection to extraction. In addition, she reported that the patients' level of anxiety, rather than the difficulty of the procedure, had the greatest influence on the dentists' stress.

In a separate study by Simon et al, 18.8% of 711 responding dentists reported that the administration of local anesthetics was stressful enough to have caused them to have reconsidered dentistry as a career at some point; only 2% of respondents did not perceive any problem or stress related to giving local anesthesia. It has also been found that the type of injection influences the level of stress dentists experience.

The inferior block resulted in greater stress, most likely due to the difficulty of obtaining anesthesia with this technique;

Changes in cardiovascular parameters of the dentist during injections and extractions



Borea G, Montebugno L, Braiato A. The effects of patient anxiety on the cardiovascular stress of dentists. *Quintessence International* 1989;20(11):853-7.

also the anterior infiltration and periodontal ligament (intra-ligamentary) injections were reported as being more stressful, probably due to the potential for pain associated with these injections. The immediate and short-term effects of this stress on the dentist include tension, anger and concerns about the injection site or loss of a patient because an injection was not painless. The longer term physical and psychological impacts include frustration, anxiety, high blood pressure, fatigue, insomnia, irritability and depression.

Dr. Daublaender further reported on a project that she and Dr. Malamed began approximately four years ago with the objective of obtaining insights into dentists' perceptions on giving injections and patient expectations. While approximately 86% to 88% of respondents reported feeling secure when giving local anesthesia,



the results showed substantial differences between United States dentists and German dentists with respect to the perceived influence of the injection on their relationships with patients – 96% of American dentists versus 86% of German dentists thought this influenced the relationship.

Patients judge the quality of a dentist by how painful the injection is. While patients expect some discomfort or pain during an injection, and most dentists recognize this, dentists perceive their patients are overreacting and being unrealistic, because most dentists believe they give painless injections. The intraligamentary injection has been rated as the most painful injection technique; therefore the ability to provide single tooth anesthesia painlessly using C-CLAD technology painlessly is a major improvement.

Dr. Daublaender also reported on the *Task Force Monitor*®, a device used to assess dentists' stress by real-time measurement of the heart rate, continuous beat-to-beat blood pressure (systolic, diastolic, mean) and stroke volume of the heart. The device will also monitor autonomic functions, auto-regulation of blood pressure, heart rate, blood pressure variability and baroreceptor reflex sensitivity. A study was performed in which the dentist treated patients by giving them three injections and the *Task Force Monitor* was used to measure the dentist's stress levels and vital signs. The series of injections was infiltration, inferior alveolar block, palatal injection, or PDL, with either a handheld syringe or C-CLAD system. In this ongoing study, it has already been determined that a dentist's stress does indeed increase when administering injections.



Stressors in the dental environment

| | |
|---|-------|
| Running behind schedule | 68.4% |
| Coping with difficult, uncooperative patients | 64.8% |
| Working under constant time pressure | 64.4% |
| Medical emergency of a patient in the surgery | 60.8% |
| Dissatisfied patients | 52.2% |
| Treating extremely nervous patients | 47.4% |
| Seeing more patients than you want to | 46.4% |
| Working quickly to see as many patients as possible | 45.2% |
| The piecework system of payment | 43.4% |

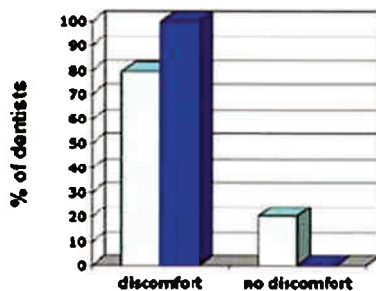
Myers HI, Myers LB. *It's difficult being a dentist: stress and health in the general dental practitioner. British Dental Journal: 197:89-93*

Patients that stress the dentist during injections?

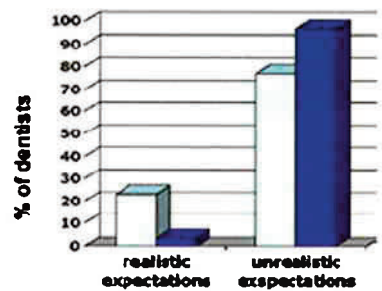
| | |
|---|------|
| Anxious patients | 67 % |
| Children per se | 7 % |
| Difficult children | 5 % |
| Medically compromised patients | 6 % |
| Esteemed person, family friend, new patient | 4 % |
| Female patients | 4 % |

Dower, Jr. JS, Simon JF, Peltier B, Chambers D, *Patients who make a dentist most anxious about giving injections. CDA Journal 1995, Sept. 35 - 40*

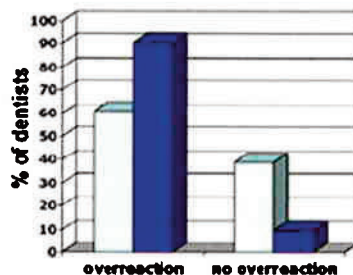
Patient expectations when receiving an injection



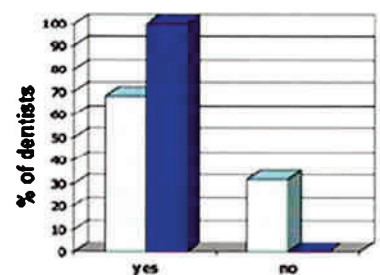
Patient expectations towards pain during injections



Patient reactions to the discomfort during injection



Do you think you can give painless injections?



Simon JF, Peltier B, Chambers D, Dower J
 Dentists troubled by administration of anaesthetic injections:
 Long term stresses and effects. *Quintessence Int.* 1994; 25(9):641-6.



"The STA System gives patients confidence and comfort during procedures. It helps energize your practice and the dental profession as a whole by attracting patients with anesthesia issues. The STA is the best stimulus package available for dentists."

The STA System helps build the dental practice and increases the confidence of both dentist and patient. Dr. Nylaan reported on his experiences with the STA System, including those within a small segment of patients that previously required procedures performed without anesthesia, because of the need to avoid post-operative complications.

Using the STA System, it is possible to provide painless dentistry for nearly all patients. In fact, a 90% to 95% success rate can be achieved with fewer postoperative problems.

Patient satisfaction with the STA is high due to a number of factors, including lack of numbness of the gums or lips post-operatively and

Reliable, predictable anesthesia

Fewer post-operative problems

No trismus or risk of hematomas

Less risk of needle breakage

No risk of intravenous injection

No pain at the injection site

STA — Compassionate Care in the 21st Century

Bryan Nylaan, DDS, PC



lack of fear of accidentally biting themselves as a result of residual soft-tissue anesthesia.

As an example of the benefits of the STA System, Dr. Nylaan shared his experience with Catherine, an 11-year old patient with severe spina bifida and a thoracic cavity so severely compressed that her physician determined she would not live to see her 12th birthday without corrective spinal surgery. The spinal surgeon had mandated a healthy mouth with no infection as a prerequisite for surgery. Through use of the STA System, Catherine was so relaxed that it was possible to extract seven over-retained teeth in one visit. After spinal surgery, Catherine gained eight inches of height in one day, and her life was saved.



Dr. Bryan Nylaan received his DDS from the University of Michigan. He is a member of the Michigan Dental Association, Chicago Dental Society and American Dental Association.

The Magic STA for Tots and Teens

Fred S. Margolis, DDS, FICD, FACD, FADI

"My patients do not feel post-operative numbness using the STA System, do not experience discomfort after the injection, and may not realize that they even had an injection."

Dr. Margolis reported on a number of his cases involving use of the STA System on pediatric patients, emphasizing the positive reactions these patients had to the painless injection experience made possible with the STA. In one case, a patient presented with an abscess as a result of a failed pulpotomy. After use of the STA buccally and lingually, the patient felt no numbness or pain after the extraction. In another patient, four upper incisors required Class III restorations, and after just one palatal anterior superior injection with the STA System, the teeth were prepared and restored.

Dr. Margolis noted that children display better behavior when they receive periodontal ligament anesthesia with the STA System (or *The Wand*) versus conventional infiltration anesthesia — no more collateral numbing, which discourages children from biting their lip and tongue; and no more calls from upset parents after hours or on weekends. You can even break the handpiece down so that it's out of sight while administering the injection. Kids love the non-threatening STA handpiece, especially when compared with the traditional syringe. They do not experience post-operative numbness using the STA System, do not experience discomfort after the injection, and may not realize that they even had an injection.



Dr. Fred Margolis received his BS and DDS from Ohio State University and his certificate in pediatric dentistry from the University of Illinois College of Dentistry. He is a clinical instructor at Loyola University's Oral Health Center and an adjunct clinical assistant professor at the University of Illinois College of Dentistry.





STA Single Tooth Anesthesia System™ (STA System)

In early 2007, Milestone Scientific introduced the *STA Single Tooth Anesthesia System™* (*STA System*) that incorporates the 'pressure force feedback' elements of Milestone's patented *CompuFlo®* with *Dynamic Pressure Sensing (DPS™)* technology, and consists of a computer-controlled drive unit about the size of a cable modem (5" L x 2"W x 5" H), and a separate single-use disposable handpiece/needle assembly. The core technology utilizes an electro-mechanical motor regulated by a central processor unit (CPU) functioning in concert with a force/pressure transducer. Traditional syringe techniques utilized in routine intraligamentary injections are hampered by the blind nature of the injection, the extreme pressures generated in local tissues during the procedure, and the

relatively small volume of anesthesia able to be reliably delivered. These factors have resulted in reduced duration of anesthesia, unnecessary collateral anesthesia and increased pain associated with tissue damage.

The *STA System* takes the guesswork out of the administration of anesthetic by providing real-time visual and audible feedback via the *CompuFlo* with *DPS* technology. During an injection with the *STA System*, *CompuFlo* with *DPS* continuously monitors the exit pressure of the anesthetic in real-time during all phases of administration. In addition to its general use for all dental injections, the *STA System* is uniquely capable of predictably and more comfortably administering "Single Tooth Anesthesia" into the Periodontal Intraligamentary (PDL) space, something never before possible using conventional techniques. This injection results in the patient having no collateral numbness and no pain along with instant, predictable anesthesia. The benefits of administering injections with the *STA* instrument are significant for the patient, the dentist and the business of dentistry.

Consensus Statements Derived from the C-CLAD Symposium

"Administering an intraligamentary injection, or any other injection, with the *STA System* is the safest, most effective and comfortable way to perform single tooth anesthesia."

"The *STA System* is a proven technology that allows you to build a successful dental practice."

"The *STA System* provides an effective method to deliver anesthesia for all dental injections in a less stressful manner for both the patient and the doctor."

For more information, please visit www.STAis4U.com or www.milestonescientific.com.

