

Efficacy of the Computer-Controlled Injection System STA™, the Ligmaject, and the dental syringe for intraligamentary anesthesia in restorative patients

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Abstract

Objective: The purpose of this investigation was to evaluate the efficacy of the STA™ Intraligamentary Injection, including the duration of anesthesia, and discomfort during and after the injection, when compared to an Intraligamentary Injection administered with the Ligmaject and the dental syringe. **Materials and methods:** Sixty patients in need of restorative treatment were selected and randomly divided into three groups of 20 subjects each. Each subject received an intraligamentary injection. Each tooth (lower bicuspid) was blindly tested with an electric pulp tester at 10-minute cycles for 60 minutes. Anesthetic success was defined as no response to the maximum output of the pulp tester (80 reading). **Results:** 100% of patients of Group 1 (STA™) showed complete anesthetic effect after 10 minutes, and no additional injections were needed. Only 2 patients reported low pain after 24 hours. The patients anesthetized with the dental syringe (Group 2) showed complete anesthetic effect after 40 minutes, and, in 7 patients, an additional injection was needed. Furthermore, 7 patients reported pain after 24 hours (4 medium and 3 low pain). In Group 3 (Ligmaject system) all patients experienced anesthesia after 40 minutes, an additional injection was needed for 1 patient and 4 patients reported low pain and 1 medium pain after 24 hours. In accordance with the Cox regression analysis, the use of the STA™ System resulted in a significantly shorter time to the onset of anesthesia in comparison with the use of a dental syringe ($p < 0.05$). The STA™ System was also more effective than Ligmaject. However, this difference was not statistically significant ($p > 0.05$). Although the Ligmaject induced anesthesia quicker than the dental syringe, this difference was not found to be significant from a statistical viewpoint ($p > 0.05$). **Conclusion:** Within the limitation of this clinical study, the STA™ System resulted in more predictable, reliable, and comfortable anesthesia than the two other tested systems.

Introduction

The intraligamentary or periodontal ligament (PDL) injection technique uses a standard dental syringe^{1,2} and many clinicians have described several difficulties related to it. These include positioning the needle within the desired location,³⁻⁵ controlling the placement of the needle throughout the administration phase of anesthesia,⁶ increased pain perception reported by dental patients due to high syringe pressure and consequent tissue damage.⁷⁻¹⁰ Other concerns centre around the correct amount of anesthesia to be delivered,¹¹ the duration of the effect of the anesthesia,¹² and the type of anesthetic that can be injected.¹³

The STA™-System (Single Tooth Anesthesia System, Milestone Scientific, Inc., Livingston, NJ) was developed in 2006 as an evolution of the Wand System and incorporated DPS (Dynamic Pressure Sensing) technology, specifically engineered for dental applications.¹⁴ The STA provides a continuous monitoring of real-time pressure during all phases of an injection. It can limit the maximum pressure used as well as detect a loss of pressure from leakage during an injection.^{15,16} Furthermore, greater anesthesia dosage can be delivered by the STA than with a conventional syringe while performing a PDL injection.

The recommended dosage of anesthetic solution ranges from 0.5 mL (single tooth) to 0.9 mL (multi-rooted teeth) when using 4% concentration of articaine hydrochloride.¹³

The aim of this study was to evaluate the efficacy of the STA Intraligamentary Injection, including the duration of anesthesia and discomfort experienced during and after the injection, when compared to an Intraligamentary

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Table 1. Statistical analysis of efficacy of anesthesia data

Cox regression analysis demonstrated that the use of STA™ System resulted in a significantly shorter time to onset of anesthesia in comparison with the use of a dental syringe ($p < 0.05$). STA™ System was also more effective than Ligmaject. However, this difference was not statistically significant ($p > 0.05$). Although Ligmaject induced anesthesia quicker than the dental syringe, this difference was not found to be significant from a statistical viewpoint ($p > 0.05$).

		1'	10'	20'	30'	40'	Significance $p < 0.05$	Additional injections	Significance $p < 0.05$	1 day
Effective anesthesia	STA™ System	9	20	20	20	20	A	0	a	2 low pain (VAS 1-3)
	Dental Syringe	2	13	15	17	20	B	Needed in 7 patients	b	4 medium pain (VAS 4-6) 3 low pain (VAS 1-3)
	Ligmajet	5	17	19	19	20	AB	Needed in 1 patient	a	1 medium pain (VAS 4-6) 4 low pain (VAS 1-3)

Injection administered with the Ligmaject and dental syringe.

The null hypothesis was that no difference can be found independently from the type of delivering system used.

Materials and Methods

The study was approved by the Ethical Committee of the University of Siena; All patients gave written informed consent after being informed about all the procedures and possible discomfort.

Sixty patients were recruited from the Research Center for Dental Health clinic (affiliated with the University of Siena) and selected according to the following criteria:

1. Patients between 20-50 years of age.
2. Patient who have had a complete physical examination in the past 12 months; present with good health and have no contraindications to local anesthesia.
3. Patients who are not taking any medications that would alter pain perception.
4. Female patients who are not pregnant.
5. Patients without any neurogenic pain disorders.
6. Patients in need of restorative treatment on vital teeth (lower bicuspid)

All patients received restorative treatment according to their treatment plan.

The patients were randomly divided into three groups of twenty each according to their therapeutic needs. The groups received intraligamentary anesthesia using the following systems:

Group 1: The STA™ system.

Group 2: A dental syringe.

Group 3: The Ligmaject system.

The injection was performed using 4% Articaine with epinephrine 1:200,000 (Berlin et al., 2005).

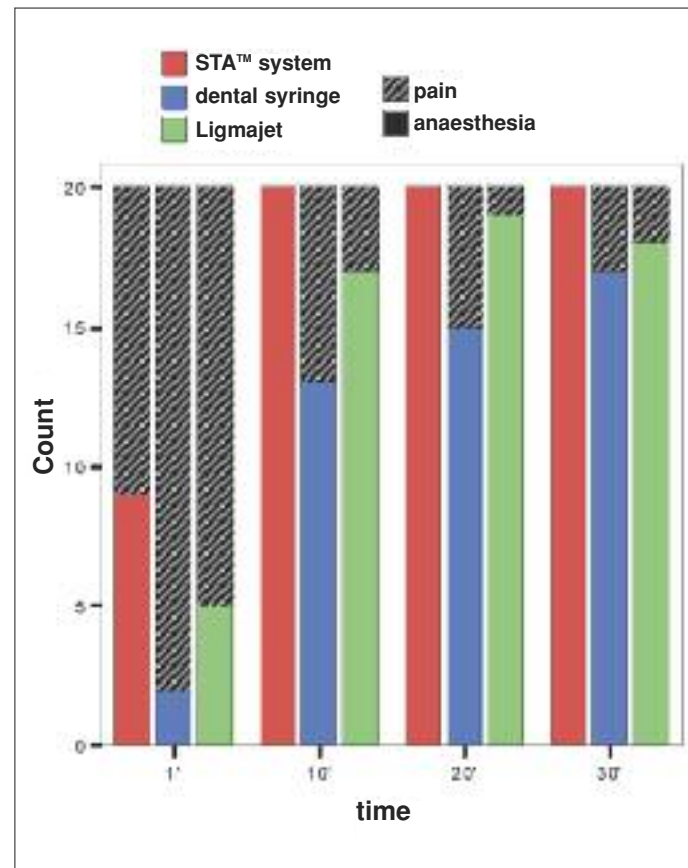
The STA™ was in operation while the injections using the syringe and the Ligmaject were administered. Subjects were therefore unable to distinguish between the three techniques, using sound as an indicator.

A counter-balanced chart was made for the right and left injection sides of each subject. The type of injection and number of subjects who experienced anesthetic success were recorded.

All subjects were contacted telephonically the day after receiving the injection, and if post-operative pain was reported, were recalled for a patient interview and examination to evaluate discomfort at the injection site and pain during chewing.

Comfort During Injection

A preordered VAS scale (from 0 to 10; 0=no pain/sensitivity

Table 2. Relationship between the three different systems, pain and anaesthesia

1-3= low pain; 4-6= medium pain; 7-9= high pain; 10=extremely high pain) was used on account of intraligamentary injections causing different degrees of pain during the injection.

The clinical evaluations were done at baseline in each patient: before commencement to evaluate whether sensitivity is already present, and at recall after 24 hours if post-operative discomfort was present.

Furthermore, efficacy of anesthesia was evaluated after 1 minute, 10 minutes, 20 minutes, 30 minutes and 40 minutes and any additional injection required was recorded. Efficacy of anesthesia was evaluated with a pulp tester and the evaluation consisted of the presence or lack of sensitivity, without using a VAS scale.

Statistical Analysis

Cox regression analysis was used to evaluate the effectiveness of the effect of the anesthesia on the three groups. The Chi-Square test Statistical analysis was used to evaluate the need for additional injection data and the pain intensity data at 1-day recall.

Results

Successful pulpal anesthesia was obtained in 100% of patients of Group 1 (STA™) after 10 minutes and no additional injections were needed. Only 2 patients reported low pain after 24 hours (Tables 1-5).

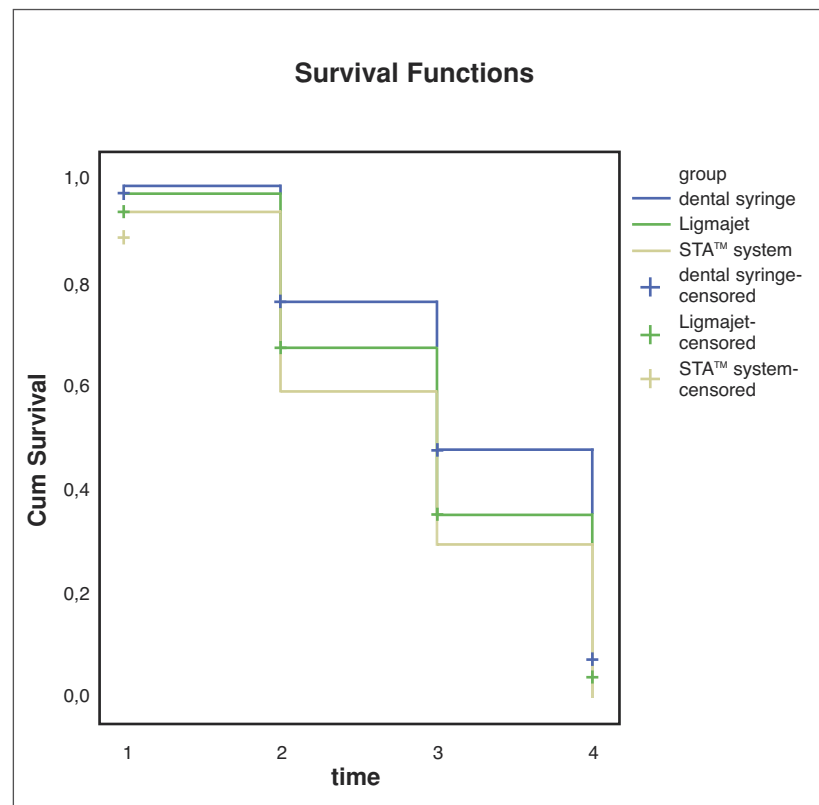
The patients anesthetized with a dental syringe (Group 2) experienced complete anesthetic effect after 40 minutes with an additional injection needed for 7 patients. In addition, 7 patients reported pain after 24 hours (4 medium and 3 low pain) (Tables 1-5)

In Group 3 (Ligmajet system) all patients experienced anesthesia after 40 minutes with 1 patient requiring an additional injection. After 24 hours, 4 patients reported low pain and 1 medium pain. (Tables 1-5)

In accordance with Cox regression analysis, the use of the STA™ System resulted in a significantly shorter time for the complete onset of anesthesia in comparison with the use of a dental syringe ($p < 0.05$). The STA™ System was also more effective than the Ligmajet. However, this difference was not statistically significant ($p > 0.05$). Although the Ligmajet induced anesthesia quicker than the dental syringe, this

Table 3. Survival Functions

Legend: time 1=1'; 2=10'; 3=20', 4=30'.



difference was not found to be significant from a statistical viewpoint ($p>0.05$).

Discussion

The results of this clinical study revealed the STA™ System to be highly effective. The length of time needed to produce an anesthetic effect was no more than 10 minutes in all patients, while a longer period was needed when using either the traditional dental syringe or the Ligmajet: in Group 2 only 13 patients experienced any effect after 10 minutes compared with 17 patients when the Ligmajet was used. It is pointed out that 10 minutes is the clinically accepted period to wait for the effect of anesthesia, while a longer duration is usually considered by both the dentist and the patient as too long. However, to ensure that the anesthesia was effective in Groups 2 and 3, a 40-minute wait was required.

Another important aspect to note was that additional injections were needed in 7 patients (Group 2) and 1 patient (Group 3) respectively, but were unnecessary when using the STA™ System.

After a post-operative follow-up period of 24 hours, each participant was asked to rate their residual

discomfort on a visual analogue scale of 0-10. Post operative pain at 24 hours was almost absent in Group 1 (only 2 patients reported it at a low score) while 7 patients and 5 patients respectively in Groups 2 and Group 3 reported residual pain.

The use of a PDL injection during restorative dental procedures allows for a quick onset of anesthesia - usually immediately - as well as profound anesthesia for an adequate length of time in which to perform most routine procedures. In addition, PDL injection techniques could serve as adjuncts to routine injections to alleviate difficult patient discomfort and pain.

The results of this study confirm those already reported by others on the efficacy of computerized local injection techniques.¹⁷⁻¹⁹

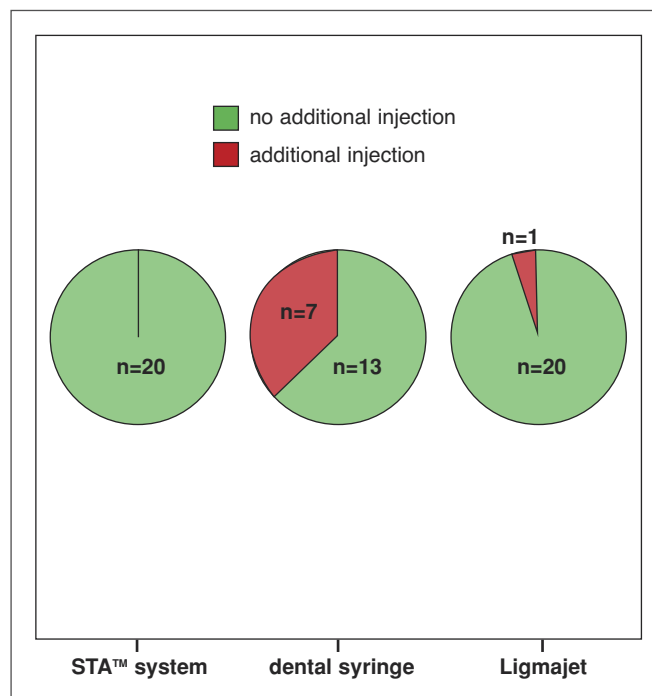
Although statistical analysis showed no significant differences between STA™ System and Ligmajet, the wide clinical evaluation of the results favours the STA™ System as a quicker and more reliable PDL procedure.

References

1. Fischer G. Local anesthesia in dentistry. 4th ed. Philadelphia: Lee & Febiger, 1933.

Table 4. Statistical analysis of need for additional injection data

The Chi-Square test demonstrated that the different techniques had a statistically influence on the possible need for additional injections after the first shot. When using a dental syringe, the need for additional injections was significantly more frequent than with the use of STA™ System and Ligmajet ($p < 0.05$).



2. Hochman MN. Single-tooth anesthesia: pressure sensing technology provides innovative advancement in the field of dental local anesthesia. *Compendium*, 2007;28:186-93.

3. Malamed SE. The periodontal ligament (PDL) injection: an alternative to inferior alveolar nerve block. *Oral Surg Oral Med Oral Pathol* 1982; 53:117-21.

4. Meechan JG. Intraligamentary anaesthesia. *J Dent* 1992; 20:325-32.

5. Smith GN, Walton RE. Periodontal ligament injection: distribution of injection solutions. *Oral Surg Oral Med Oral Pathol* 1983; 55:232-8.

6. Pashley EL, Nelson R, Pashley DH. Pressures created by dental injections. *J Dent Res* 1981; 60: 1742-8

7. Per tot WJ, Dejou J. Bone and root resorption. Effects of the force developed during periodontal ligament injections in dogs. *Oral Surg Oral Med Oral Pathol* 1992; 74:357-65.

8. Brannstrom M, Nordenvall KJ, Hedstrom KG. Periodontal tissue changes after intraligamentary anesthesia. *ASCD J Dent Child*. 1982; 49: 417-23.

9. Galili D, Kaufman E, Garfunkel AA. Intraligamentary anesthesia-a histological study. *Int J Oral Surg* 1984; 13: 511-6.

10. Albers DD, Ellinger RF. Histological effects of highpressure intraligamental injections on the periodontal ligament. *Quintessence Int* 1998; 19: 361-3.

11. Dower JS, Barniv ZM. Periodontal ligament injection: review and recommended technique. *Gen Dent* 2004; 52: 537-42.

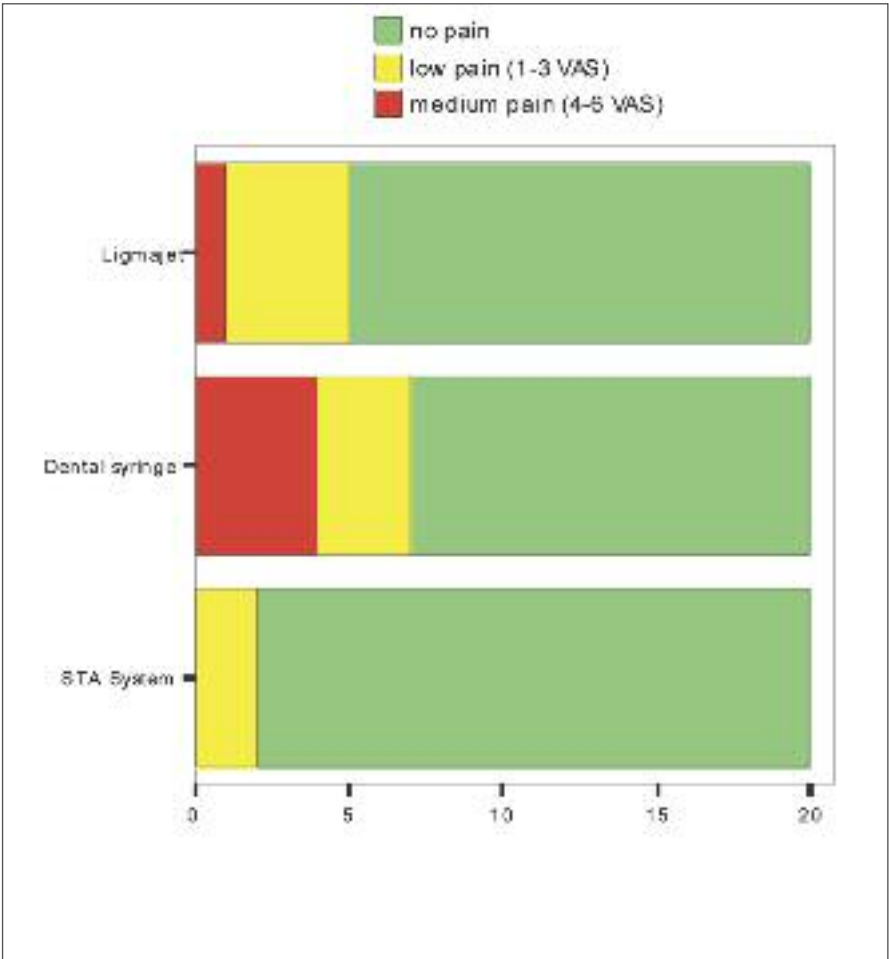
12. Schleider JR, Reader A, Beck M. The periodontal ligament injection: a comparison of 2% lidocaine, 3% mepivacaine, and 1:100,000 epinephrine to 2% lidocaine with 1:100,000 epinephrine in human mandibular premolars. *J Endodont* 1988; 14: 397-404.

13. Berlin J, Nusstein J, Reader A. Efficacy of articaine and lidocaine in a primary intraligamentary injection administered with a computer-controlled local anesthesia delivery system. *Oral Surg Oral Med Oral Pathol Radiol Endod* 2005; 99: 361-6.

14. Ghelber O, Gebhard R, Adebayo G. Utilization of the CompuFlo in determining the pressure of the epidural space: a pilot study. *Anesth Analg* 2005; 100:S189.

Table 5. Statistical analysis of need for additional injection data

The Chi-Square test demonstrated that there were not statistically significant differences among the three techniques with regard to the intensity of pain that persisted one day after the procedure ($p>0.05$).



15. Hochman M. Inventor; Drug infusion device with tissue identification using pressure sensing. US Patent Pending 10/827 969, May, 2004.

16. Hochman M. Inventor; Computer controlled drug delivery system with dynamic pressure sensing. US Patent Pending 11/614 417, June, 2006.

17. Nicholson JW, Berry TG, Summitt JB. Pain perception and utility: a comparison of the syringe and computerized local injection techniques. *Gen Dent* 2001; 49: 167-73.

18. Ashkenazi M, Blumer S, Eli J. Effectiveness of computerized delivery of intrasulcular anesthetic in primary molars. *J Am Dent assoc* 2005; 136: 1418-25.

19. Versloot J, Veerkamp JS, Hoogstraten J. Computerized anesthesia delivery system vs traditional syringe: comparing pain and pain-related behavior in children. *Eur J Oral Sci* 2005; 113: 488-93.

20. Hochman MN, Friedman MJ, Williams W. Interstitial tissue pressure associated with dental injections: a clinical study. *Quintessence Int.* 2006; 37: 469-76.