A Comparison of Injection Pain and Postoperative Pain of Two Intraosseous Anesthetic Techniques

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The purpose of this prospective, randomized, blinded study was to compare injection pain and postoperative pain of an apical primary X-Tip™ intraosseous technique to a coronal primary Stabident intraosseous technique in mandibular first molars. Using a repeated-measures design, 41 subjects randomly received 2 primary intraosseous injections at 2 separate appointments. Using a site distal to the mandibular first molar for both injections, the subjects received 1.8 mL of 2% lidocaine with 1 : 100,000 epinephrine administered with the X-Tip™ system using an apical location in alveolar mucosa or 1.8 mL of 2% lidocaine with 1 : 100,000 epinephrine administered with the Stabident system using a coronal location in attached gingiva. The pain of infiltration, perforation, needle insertion, solution deposition, mock or actual guide sleeve removal and postoperative pain were recorded on a Heft-Parker visual analogue scale (VAS) scale for the 2 intraosseous systems. The results demonstrated that the apical primary X-Tip™ intraosseous technique was not statistically different ($P > .05$) from the coronal primary Stabident technique regarding pain ratings of infiltration, perforation, needle insertion, solution deposition, mock or actual guide sleeve removal and postoperative pain (at the time subjective anesthesia wore off). However, on postoperative days 1 through 3, significantly ($P < .05$) more males experienced postoperative pain with the X-Tip™ system than with the Stabident system.

Key Words: Intraosseous; X-Tip™; Stabident; Anesthesia; Pain.

The intraosseous injection (IO) allows placement of a local anesthetic directly into the cancellous bone adjacent to the tooth to be anesthetized. Currently, there is an intraosseous injection system marketed under the name Stabident (Fairfax Dental Inc, Miami, Fla). This system is comprised of a slow-speed handpiece driven perforator, a solid 27-gauge wire with a beveled end, that when activated drills a small hole through the cortical plate (Figure 1). The anesthetic solution is delivered to cancellous bone through the 27-gauge ultrashort injector needle placed into the hole made by the perforator. Injection pain and postoperative pain of the Stabident system have been evaluated as a primary injection. Replogle et al[1] and Coggins et al[2] reported 0–7% of subjects had moderate pain and none had severe pain with a primary Stabident perforation at the mandibular first molar site. Replogle et al[1] and Coggins et al[2] also reported 2–15% of subjects had moderate pain and 0–2% had severe pain with anesthetic solution deposition at the mandibular first molar site. Postoperative pain, at the time subjective numbness wore off, has been reported by various authors[1–6] to range from 2–16% moderate pain with a 0–3% incidence of severe pain. The postoperative pain ratings decreased over the next 3 postoperative days.[1–6] Swelling and purulence at the Stabident IO injection sites have been reported less than 5% of the time.[1–6]

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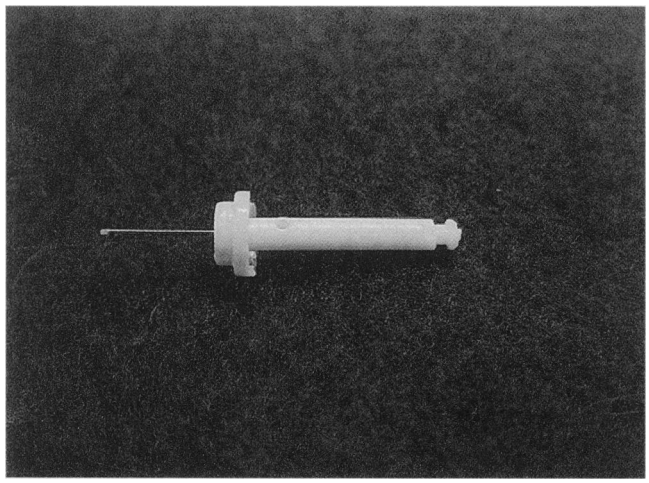

Figure 1. The Stabident perforator, a solid 27-gauge wire with a beveled end, which is placed in a slow-speed handpiece.

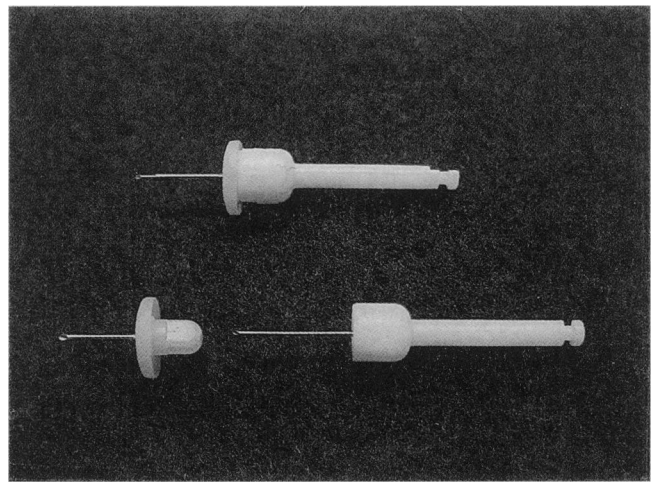

Figure 2. The X-tip™ anesthesia delivery system consists of an X-tip™ (top) that separates into 2 parts: the drill (a special hollow needle) and guide sleeve component (bottom).

All of the above studies used the Stabident system. Currently, a second intraosseous system is on the market. The X-Tip™ anesthesia delivery system (X-Tip™ Technologies, Lakewood, NJ) consists of an X-Tip™ that separates into 2 parts: the drill and guide sleeve component (Figure 2). The drill (a special hollow needle) leads the guide sleeve through the cortical plate, whereupon it is separated and withdrawn. The remaining guide sleeve is designed to accept a 27-gauge needle to inject the anesthetic solution. The guide sleeve is removed after the intraosseous injection is complete.

Both the Stabident and X-Tip™ intraosseous systems instruct the user to locate the perforation site in attached gingiva.[7,8] However, because the guide sleeve remains in place with the X-Tip™ system, we felt it could be used in alveolar mucosa at an apical location. Occasionally, the Stabident system fails or cannot be used at the coronal location due to periodontal disease (deep pockets) or lack of interproximal space (roots are too close together). Would the alternative X-Tip™ system, used in an apical location, result in similar pain ratings and postoperative discomfort as the Stabident system? There are no scientific studies on the X-Tip™ system regarding injection pain or postoperative pain.

The purpose of this prospective, randomized blinded study was to compare injection pain and postoperative pain of an apical primary X-Tip™ intraosseous technique to a coronal primary Stabident intraosseous technique in mandibular first molars.

MATERIALS AND METHODS

Forty-one adult subjects, 24 men and 17 women, participated in this study. The subjects were in good health and were not taking any medications that would alter pain perception. The Ohio State University Human Subjects Review Committee approved the study and written informed consent was obtained from each subject.

Twenty-four mandibular left and 17 right sides were tested, with the first molar chosen as the tooth to receive the IO injections. Clinical examinations indicated that all teeth were free of caries, large restorations, and periodontal disease, and that none had a history of trauma or sensitivity.

Two appointments at least 2 weeks apart were scheduled for each of the 41 subjects. Longer intervals than 2 weeks were scheduled if the subject reported postoperative problems with the first IO injection. With a repeated-measures design, each subject randomly received either the Stabident IO injection or the X-Tip™ IO injection at 2 separate appointments. Assigned random numbers determined the order of IO system administration. The principal investigator gave all IO injections.

The IO injection with the Stabident system was given in the following manner. With the subjects in a reclining position, the area of perforation was determined by the horizontal line of the buccal gingival margins of the first and second molars and a vertical line that passed through the interdental papilla on the distal aspect of the first molar. A point approximately 2 mm below the intersection of these lines was selected as the perforation site if the site was in attached gingiva. If this point was in alveolar mucosa (2 subjects), the injection site was moved just above the junction of the attached gingiva and alveolar mucosa. The alveolar mucosal soft tissue, adjacent to the determined perforation site, was

anesthetized with a supraperiosteal infiltration injection of 0.6 mL of 2% lidocaine with 1 : 100,000 epinephrine (Xylocaine, AstraZeneca, Wilmington, Del) deposited through a 30-gauge needle attached to an aspirating syringe. Five minutes after the infiltration injection, pressure was applied at the determined perforation site with a periodontal probe. If the subject felt pain, an additional 0.3 mL of 2% lidocaine with 1 : 100,000 epinephrine was administered (2 subjects). The pain of needle insertion and solution deposition of the additional infiltration injection was not recorded for these 2 subjects. The cortical bone was perforated with the Stabident perforator (a bevel-ended solid wire attached to a plastic hub) in a contra-angle, slow-speed handpiece. The perforator was placed through the gingiva and was oriented perpendicular to the cortical plate. With the point gently resting against bone, the handpiece was activated, at full speed, while pushing the perforator, with light pressure, against bone and then slightly withdrawing the perforator and then pushing it again against bone. This action was continued until a "break through" feeling was observed or the perforator was placed to length. The handpiece was always activated while the perforator was within bone to prevent lodging or breakage that might occur if the perforator was allowed to stop rotating. An easy perforation was defined as a perforation that could be completed in less than 5 seconds using only light pressure. A difficult perforation was defined as a perforation that required moderate pressure and/or took longer than 5 seconds to penetrate the cortical bone. Before inserting the 27-gauge ultrashort Stabident needle through the perforation, the needle was bent at the hub to a 45-degree angle to allow for ease of insertion. The area of perforation was blotted with a sterile cotton roll to control hemorrhage and identify the perforation site (a small dot of hemorrhage on the blanched gingiva). The standard syringe was held in a pen-gripping fashion, and the needle was inserted into the perforation site and 1.8 mL of 2% lidocaine with 1 : 100,000 epinephrine was delivered over a 1-minute time period. If back-pressure (defined as greater than light finger pressure on the syringe handle to deliver the solution) was encountered on solution deposition, the needle was rotated approximately a quarter turn and deposition was reattempted. If this was not successful, the needle was removed and checked for blockage. When blocked (4 subjects), a new needle was used. If not blocked, the site was reperforated (1 subject) with a new perforator and the injection completed. The pain of the reperforation was not recorded for this 1 subject. At completion of the deposition of solution, a mock guide sleeve removal was performed so all treatment procedures would seem identical to the subject. The mock guide sleeve removal was accomplished by mimicking the procedure to remove the X-Tip™ guide sleeve. The operator retracted the subject's cheek, placed the tip of the hemostat in contact with the anesthetized gingiva, and moved the hemostat back and forth for 3–5 seconds.

The IO injection with the X-Tip™ system was given in the following manner. With the subjects in a reclining position, the area of perforation was determined to be in alveolar mucosa at a site distal to the mandibular first molar. The perforation site was approximately 3–7 mm inferior to the Stabident perforation site without extending below the coronal aspect of the buccal shelf. The alveolar mucosal soft tissue, adjacent to the determined perforation site, was anesthetized with a supraperiosteal infiltration of 0.6 mL of 2% lidocaine with 1 : 100,000 epinephrine deposited through a 30-gauge needle attached to an aspirating syringe. Five minutes after the infiltration injection, pressure was applied at the determined perforation site with a periodontal probe. If the subject felt pain, an additional 0.3 mL of 2% lidocaine with 1 : 100,000 epinephrine was administered (5 subjects). The pain of needle insertion and solution deposition of the additional infiltration injection was not recorded for these 5 subjects. The guide sleeve of the X-Tip™ system was secured against the drill via finger pressure as the red protective covering was withdrawn. The alveolar mucosa was pulled taut, using the fingers of the other hand, to minimize engaging the mucosal tissue during rotation of the perforator. The perforator was pushed through the alveolar mucosa until the X-Tip™ contacted bone. Holding the drill at a 90-degree angle to the bone, the slow-speed handpiece was activated, at full speed, while pushing the perforator, with light pressure, against bone and then slightly withdrawing the perforator and then pushing it again against bone. This action was continued until a "break through" feeling was observed or the perforator was placed to length. The handpiece was always activated while the perforator was within bone to prevent lodging or breakage that might occur if the perforator was allowed to stop rotating. An easy or hard perforation was defined as outlined for the Stabident perforation. The drill was then withdrawn from the guide sleeve, leaving the guide sleeve in place. Before inserting the 27-gauge short X-Tip™ needle (21 mm) into the guide sleeve, the needle was bent at the hub to a 60–80° angle to allow for ease of insertion. The standard syringe was held in a pen-gripping fashion, and the needle was inserted into the guide sleeve to its hub and 1.8 mL of 2% lidocaine with 1 : 100,000 epinephrine was delivered over a 1-minute time period. If back-pressure (defined as greater than light finger pressure on the syringe handle to deliver the solution) was encountered on solution deposition, the needle was rotated approximately a quarter turn and

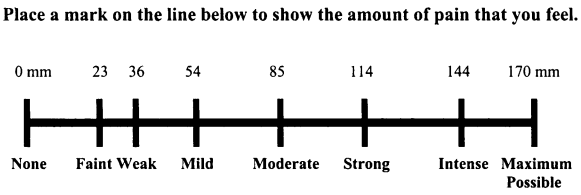

Figure 3. Heft-Parker visual analogue scale (VAS) used for assessment of pain. The millimeter demarcations were not shown on the patients' VAS scale.

deposition was reattempted. If this was not successful, the needle was removed and checked for blockage. No needles were blocked. Due to the backflow of the anesthetic solution into the oral cavity in 1 subject, the guide sleeve was removed using a hemostat and the site was reperforated with a new perforator and the injection completed. The pain of the reperforation was not recorded for this 1 subject. Upon completion of deposition of solution, the guide sleeve was removed using a hemostat. For both the Stabident and X-Tip™ techniques, each subject was instructed to close his/her eyes during all injections and during the actual or mock guide sleeve removal to blind the techniques.

The subjects were instructed to rate the pain of the infiltration, IO injections, and mock or actual guide sleeve removal. The pain rating was done on a Heft-Parker visual analogue scale (VAS)[9] (Figure 3). The scale consisted of a 170-mm line with various descriptive terms. The subjects placed a mark on the scale where it best described their pain level. The VAS was divided into 4 categories. No pain corresponded with 0 mm. Mild pain was defined as greater than 0 mm and less than or equal to 54 mm. Mild pain included the descriptors of faint, weak, and mild pain. Moderate pain was defined as greater than 54 mm and less than 114 mm. Severe pain was defined as equal to or greater than 114 mm. Severe pain included the descriptors of strong, intense, and maximum possible.

A postinjection written questionnaire asked the subjects to rate the pain and any side effects in the area of the IO injection at the time initial numbness wore off and in the morning for 3 days following the appointment. The subjects used the same VAS for the pain ratings as was used for the pain of the intraosseous injection.

The data were statistically analyzed. Comparisons of the pain ratings (IO and postoperative) were assessed using multiple Wilcoxon matched-pairs, signed-ranks tests. All *P*-values were adjusted using the step-down Bonferroni method of Holm. Postoperative sequelae of the 2 techniques were compared using the McNemar test. Comparisons were considered significant at $P < .05$.

RESULTS

Forty-one adult subjects, 24 men and 17 women, from age 19 to 43 years with an average age of 26 years, participated. Because we studied a young adult population, the results of this study may not apply to children or the elderly.

The pain ratings for the infiltration injections are presented in Table 1. The majority of needle insertion pain ratings were in the mild category, with no significant differences ($P > .05$) for females, males, or between the techniques. Anesthetic solution deposition resulted in a 22–27% incidence of moderate pain, with 1 report of severe pain. There were no significant differences ($P > .05$) for females, males, or between the techniques.

The pain ratings for the intraosseous injections are presented in Table 2. Perforation resulted in a 24–25% incidence of moderate pain, with 1 report of severe pain. There were no significant differences ($P > .05$) for females, males, or between the techniques. Needle insertion resulted in a 5–10% incidence of moderate pain, with 1 report of severe pain. There were no significant differences ($P > .05$) for females, males, or between the techniques. Anesthetic solution deposition resulted in a 22–32% incidence of moderate pain, with 1 report of severe pain. There were no significant differences ($P > .05$) for females, males, or between the techniques. The majority of the pain ratings for guide sleeve removal, for the X-Tip™ system, were in the none to mild categories. There were no significant differences ($P > .05$) between the actual guide sleeve removal and mock guide sleeve removal.

The postinjection pain ratings for the IO injections are presented in Table 3. At the time subjective anesthesia wore off, postinjection pain ratings were similar for the Stabident and X-Tip™ systems, with no statistical differences for females, males, or between the techniques. The incidence of moderate pain was 7–15%, with no reports of severe pain. At postoperative days 1–3, significantly ($P < .05$) more males experienced postoperative pain with the X-Tip™ system than with the Stabident system. There was a 25% incidence of moderate to severe postoperative pain on day 1 (with decreasing incidence over the next 2 days), with the X-Tip™ system in males.

Postoperative sequelae of the intraosseous injections are presented in Table 4. There was a 5–20% incidence of swelling and a 5–15% incidence of soreness to chewing. There were no significant differences ($P > .05$) between the 2 techniques.

DISCUSSION

For the Stabident and X-Tip™ techniques, needle insertion for the infiltration injection, into alveolar mucosa,

Table 1. Percentages and Pain Ratings of the Infiltration Injections

		*Pain Ratings**					
	N	*None (0 mm)*	*Mild (1–54 mm)*	*Moderate (55–113 mm)*	*Severe (>114 mm)*	*Mean (SD)*	*P-Value†*
Stabident: infiltration							
Needle insertion	41	4 (10%)	33 (80%)	4 (10%)	0 (0%)	34 (±25)	
Females	17	1 (6%)	15 (88%)	1 (6%)	0 (0%)	31 (±23)	
Males	24	3 (12%)	18 (75%)	3 (12%)	0 (0%)	35 (±26)	
X-Tip™: infiltration							
Needle insertion	41	3 (7%)	37 (90%)	1 (2%)	0 (0%)	28 (±19)	1.000
Females	17	0 (0%)	17 (100%)	0 (0%)	0 (0%)	27 (±16)	1.000
Males	24	3 (12%)	20 (83%)	1 (5%)	0 (0%)	29 (±22)	.858
Stabident: infiltration							
Solution deposition	41	2 (5%)	27 (66%)	11 (27%)	1 (2%)	48 (±32)	
Females	17	0 (0%)	12 (71%)	5 (29%)	0 (0%)	48 (±30)	
Males	24	2 (8%)	15 (62%)	6 (25%)	1 (4%)	48 (±34)	
X-Tip™: infiltration							
Solution deposition	41	6 (15%)	26 (63%)	9 (22%)	0 (0%)	39 (±30)	.465
Females	17	1 (6%)	13 (76%)	3 (18%)	0 (0%)	37 (±26)	1.000
Males	24	5 (21%)	13 (54%)	6 (25%)	0 (0%)	40 (±32)	.750

* Heft Parker visual analogue scale (VAS) ratings.
† There were no significant differences ($P > .05$) between the 2 techniques.

resulted in mild pain ratings, with 2–10% of the subjects reporting moderate pain and no reports of severe pain (Table 1). The mean VAS ratings were 34 for the Stabident technique and 28 for the X-Tip™ technique, which would be in the range of weak pain (Figure 3). There was no significant difference ($P > .05$) between the X-Tip™ and Stabident techniques. This would be expected because the technique and location of needle insertion was identical regardless of the IO system utilized. Coggins et al[2] reported a 20% incidence of moderate pain and no reports of severe pain with needle insertion, into the attached gingiva, for the infiltration injection of the mandibular first molar. Replogle et al[1] reported only a 2% incidence of moderate pain with infiltration, into attached gingiva, of the mandibular first molar. Generally, the results of the current study and the studies by Replogle et al[1] and Coggins et al[2] would indicate that needle insertion, either into attached gingiva or alveolar mucosa, may result in a 2–20% incidence of moderate pain. No topical anesthetic was applied in this study, although it is recommended by the Stabident and X-Tip™ manuals.[7,8] Topical anesthetic was not applied to the mucosal injection site because we wanted to measure the pain of the infiltration injection. The use of topical anesthetic has been advocated as an aid in reducing the pain of needle insertion. While Rosivack et al[10] demonstrated the effectiveness of topical anesthetic, Gill and Orr[11] and Kincheloe et al[12] showed no significant pain reduction with the use of topical anesthetic. Martin et al[13] found that if the patient thought they were receiving topical, whether they did or not, pain ratings were lower. Therefore, the most important aspect of using topical anesthetic may not be its clinical effectiveness but rather the psychological effect on the patient who feels the practitioner is doing everything possible to prevent pain.[13]

For both IO techniques, solution deposition for the infiltration injection resulted in a higher incidence of pain than needle insertion, with 22–27% of the subjects reporting moderate pain and 0–2% reporting severe pain (Table 1). The mean VAS ratings were 48 for the Stabident technique and 39 for the X-Tip™ technique, which would be in the weak to mild range (Figure 3). There were no significant differences ($P > .05$) between the 2 techniques. Once again, this would be expected because solution deposition was identical for the 2 techniques. Replogle et al[1] and Coggins et al[2] reported a low incidence of moderate pain (2%) and no reports of severe pain with solution deposition, into the attached gingiva, at the mandibular first molar site. The fewer reports of moderate and severe pain in these studies may relate to the volume of anesthetic solution injected. The previous studies used 0.1 mL of anesthetic solution whereas the current study used 0.6 mL. We elected to give 0.6 mL of anesthetic solution because of the need to anesthetize either the coronal Stabident perforation site or the apical X-Tip™ site at each appointment. Another factor for differences in pain between the studies would be the site of solution deposition—the alveolar mucosa versus attached gingiva. Perhaps the alveolar

Table 2. Percentages and Pain Ratings of the Intraosseous Injections

		Pain Ratings*					
	N	*None (0 mm)*	*Mild (1–54 mm)*	*Moderate (55–113 mm)*	*Severe (>114 mm)*	*Mean (SD)*	*P-Value†*
Stabident							
Perforation	41	8 (20%)	22 (54%)	10 (24%)	1 (2%)	39 (±38)	
Females	17	2 (12%)	9 (53%)	5 (29%)	1 (6%)	48 (±45)	
Males	24	6 (25%)	13 (54%)	5 (21%)	0 (0%)	33 (±32)	
X-Tip™							
Perforation	41	6 (15%)	25 (61%)	10 (25%)	0 (0%)	39 (±37)	1.000
Females	17	2 (12%)	11 (65%)	4 (24%)	0 (0%)	37 (±37)	1.000
Males	24	4 (17%)	14 (58%)	6 (25%)	0 (0%)	40 (±38)	1.000
Stabident							
Needle insertion	41	7 (17%)	29 (71%)	4 (10%)	1 (2%)	28 (±34)	
Females	17	5 (29%)	10 (59%)	1 (6%)	1 (6%)	25 (±36)	
Males	24	2 (8%)	19 (79%)	3 (12%)	0 (0%)	30 (±32)	
X-Tip™							
Needle insertion	41	10 (24%)	29 (71%)	2 (5%)	0 (0%)	15 (±21)	.482
Females	17	1 (6%)	16 (94%)	0 (0%)	0 (0%)	18 (±19)	1.000
Males	24	9 (38%)	13 (54%)	2 (8%)	0 (0%)	14 (±22)	.161
Stabident							
Solution deposition	41	3 (7%)	24 (58%)	13 (32%)	1 (2%)	50 (±40)	
Females	17	1 (6%)	11 (65%)	5 (29%)	0 (0%)	52 (±41)	
Males	24	2 (8%)	13 (54%)	8 (33%)	1 (4%)	49 (±40)	
X-Tip™							
Solution deposition	41	2 (5%)	29 (71%)	9 (22%)	1 (2%)	46 (±35)	1.000
Females	17	1 (6%)	12 (71%)	4 (24%)	0 (0%)	45 (±31)	1.000
Males	24	1 (4%)	17 (71%)	5 (21%)	1 (4%)	46 (±38)	1.000
Stabident (mock removal)							
Sleeve removal	41	16 (39%)	24 (58%)	1 (2%)	0 (0%)	9 (±16)	
Females	17	8 (47%)	9 (53%)	0 (0%)	0 (0%)	8 (±15)	
Males	24	12 (50%)	11 (46%)	1 (4%)	0 (0%)	10 (±17)	
X-Tip™							
Sleeve removal	41	19 (46%)	21 (51%)	1 (2%)	0 (0%)	8 (±13)	1.000
Females	17	7 (41%)	10 (59%)	0 (0%)	0 (0%)	5 (±7)	1.000
Males	24	12 (50%)	11 (46%)	1 (4%)	0 (0%)	10 (±16)	1.000

* Heft Parker visual analogue scale (VAS) ratings.
† There were no significant differences ($P > .05$) between the 2 techniques.

mucosal site would result in more moderate pain than the attached gingival site. However, it is unknown how much the site contributed to the pain of injection versus the volume of solution. Generally, we can state that solution deposition of 0.6 mL of 2% lidocaine with 1 : 100,000 epinephrine for infiltration in alveolar mucosa, for the mandibular first molar, could result in moderate pain being experienced about 25% of the time. The potential for severe pain is small.

Perforation pain ratings were similar for the Stabident and X-Tip™ systems, with no statistical differences between the 2 techniques (Table 2). The mean VAS ratings were 39 for the Stabident technique and 39 for the X-Tip™ technique—which would be in the weak to mild range (Figure 3). Moderate pain was reported in approximately 25% of the subjects, with 1 (2%) report of severe pain (Table 2). Replogle et al[1] and Coggins et al[2] reported 0–7% of subjects had moderate pain and none had severe pain with a primary Stabident perforation at the mandibular first molar site. The differences between the current study and those of Replogle et al[1] and Coggins et al[2] may relate to operator technique or differences in patient population. Because there was no difference in perforation pain with the X-Tip™ and Stabident systems, we can speculate that the site of perforation (coronal or apical) was not a factor in the pain of perforation. Generally, the results of the current study and the studies by Replogle et al[1] and Coggins et al[2] would indicate that there is a potential for moderate perforation pain in 7–25% of patients and a small potential

Table 3. Summary of Pain Ratings for Postinjection Survey With the Intraosseous Injection

		*Pain Ratings**				
	N	*None (0 mm)*	*Mild (1–54 mm)*	*Moderate (55–113 mm)*	*Severe (≥114 mm)*	*Mean (SD)*	*P-Value‡*
Stabident						
Day 0†	41	15 (37%)	23 (56%)	3 (7%)	0 (0%)	19 (±24)	
Females	17	7 (41%)	9 (53%)	1 (6%)	0 (0%)	16 (±24)	
Males	24	8 (33%)	14 (0%)	2 (8%)	0 (0%)	20 (±24)	
X-Tip™							
Day 0†	41	9 (22%)	26 (63%)	6 (15%)	0 (0%)	31 (±33)	1.000
Females	17	5 (29%)	9 (53%)	3 (18%)	0 (0%)	30 (±36)	1.000
Males	24	4 (17%)	17 (71%)	3 (12%)	0 (0%)	32 (±30)	1.000
Stabident							
Day 1	41	14 (34%)	25 (61%)	1 (2%)	1 (2%)	22 (±29)	
Females	17	7 (41%)	8 (47%)	1 (6%)	1 (6%)	29 (±39)	
Males	24	7 (29%)	17 (71%)	0 (0%)	0 (0%)	17 (±29)	
X-Tip™							
Day 1	41	7 (17%)	24 (58%)	8 (20%)	2 (5%)	37 (±40)	.305
Females	17	5 (29%)	9 (53%)	3 (18%)	0 (0%)	28 (±35)	1.000
Males	24	2 (8%)	15 (62%)	5 (21%)	2 (8%)	44 (±43)	.020‡
Stabident							
Day 2	41	25 (61%)	14 (34%)	1 (2%)	1 (2%)	12 (±26)	
Females	17	9 (53%)	7 (41%)	0 (0%)	1 (6%)	19 (±33)	
Males	24	16 (67%)	7 (29%)	1 (4%)	0 (0%)	7 (±18)	
X-Tip™							
Day 2	41	15 (37%)	19 (46%)	7 (17%)	0 (0%)	27 (±37)	.185
Females	17	9 (53%)	7 (41%)	1 (6%)	0 (0%)	17 (±28)	1.000
Males	24	6 (25%)	12 (50%)	6 (25%)	0 (0%)	35 (±42)	.022‡
Stabident							
Day 3	41	31 (76%)	9 (22%)	0 (0%)	1 (2%)	6 (±23)	
Females	17	13 (76%)	3 (18%)	0 (0%)	1 (6%)	11 (±33)	
Males	24	18 (75%)	6 (25%)	0 (0%)	0 (0%)	3 (±11)	
X-Tip™							
Day 3	41	17 (42%)	19 (46%)	5 (12%)	0 (0%)	19 (±31)	.076
Females	17	10 (59%)	6 (35%)	1 (6%)	0 (0%)	11 (±25)	1.000
Males	24	7 (29%)	13 (54%)	4 (17%)	0 (0%)	24 (±35)	.009‡

* Heft Parker visual analogue scale (VAS) ratings.
† Ratings at the time anesthesia wore off.
‡ There was a statistically significant difference ($P < .05$) between the 2 techniques.

Table 4. Postoperative Sequelae of the Intraosseous Injections

Technique	*Swelling Without Exudate*	*Swelling With Exudate*	*Soreness to Chewing*
Stabident	2/41 (5%) 1 male, 1 female	0/41 (0%)	2/41 (5%) 1 male, 1 female
X-Tip™	8/41 (20%) 7 males, 1 female	1/41 (2%) 1 male	6/41 (15%) 4 males, 2 females
P-value*	.070	1.00	.289

* There were no significant differences ($P > .05$) between the 2 techniques.

for severe pain when either system is used as a primary technique in the mandibular first molar.

The Stabident system uses a solid core perforator with a beveled end. The X-Tip™ perforator system has a drill and guide sleeve component. The outer guide sleeve component has a beveled end that is approximately 1–2 mm short of the needle drill. When unpackaged, the distance between the drill needle and guide sleeve component varies between 1 and 2 mm depending on the bevel of the guide sleeve. Both components rotate together when the handpiece is activated but it is unknown which component does the bulk of the cutting or whether they both contribute equally. Regardless, the X-Tip™ perforator component is larger in diameter than the Stabident perforator. We measured 25 Stabident perforators and 25 X-Tip™ perforators (drill and guide sleeve components). The average diameter was found to be 0.42 mm for the Stabident perforator and 0.63 mm for the X-Tip™ perforator. However, in terms of the pain of perforation, the larger diameter of the X-Tip™ system did not contribute to more pain with perforation (Table 2).

Insertion of the IO needle, into either the guide sleeve (X-Tip™) or bone (Stabident), resulted in pain ratings that were similar for the Stabident and X-Tip™ systems, with no statistical differences between the 2 techniques (Table 2). The mean VAS ratings were 28 for the Stabident technique and 15 for the X-Tip™ technique—which would be less than weak pain (Figure 3). Moderate pain was reported in 5–10% of the subjects, with 1 (2%) report of severe pain (Table 2). Replogle et al[1] and Coggins et al[2] reported 2–8% of subjects had moderate pain and none had severe pain with needle insertion into bone, using a primary Stabident technique, at the mandibular first molar site. Clinically, insertion of the IO needle either directly into coronal bone (Stabident system) or into the guide sleeve component (X-Tip™ system) may result in moderate pain being experienced 2–10% of the time. The potential for severe pain is small.

For the X-Tip™ system used in the current study, insertion of the 21-mm needle into the 13-mm-long guide sleeve would result in 8 mm of the needle protruding into bone. Therefore, contact with cancellous bone would occur with both the Stabident needle insertion and X-Tip™ needle insertion.

Solution deposition pain ratings were similar for the Stabident and X-Tip™ systems, with no statistical differences between the 2 techniques (Table 2). The mean VAS ratings were 50 for the Stabident technique and 46 for the X-Tip™ technique—which would be in the weak to mild range (Figure 3). Moderate pain was reported 22–32% of the time and severe pain was reported in 2% of the subjects (Table 2). A majority of subjects either told the principal investigator who gave the injections, or noted on the VAS, that most of the pain experienced during IO deposition occurred during the initial few seconds. Replogle et al[1] and Coggins et al,[2] using a primary Stabident technique, reported 2–15% of subjects had moderate pain and 2% had severe pain with solution deposition at the mandibular first molar site. The differences between the current study and those of Replogle et al[1] and Coggins et al[2] may relate to operator technique or differences in patient population. Generally, the results of the current study and the studies by Replogle et al[1] and Coggins et al[2] would indicate that there is a potential for moderate solution deposition pain in 2–32% of patients when either system is used as a primary technique in the mandibular first molar. The potential for severe pain is small.

Guide sleeve removal pain ratings were similar for the mock guide sleeve removal (Stabident system) and the actual guide sleeve removal (X-Tip™ system), with no statistical differences between the 2 techniques (Table 2). The mean VAS ratings were 9 for the mock guide sleeve removal (Stabident technique) and 8 for the X-Tip™ technique—which would be less than faint pain (Figure 3). Moderate pain was reported 2% of the time and there were no reports of severe pain (Table 2). Because the guide sleeve removal procedure for the Stabident technique was a mock procedure and no statistical differences were shown between techniques, guide sleeve removal for the X-Tip™ was not considered to be a painful procedure.

With respect to postoperative pain, the 2 subjects who were reperforated (1 Stabident and 1 X-Tip™) could have had a small effect on postoperative pain. However, it is very unlikely that the administration of an additional 0.3 mL of anesthetic solution for the infiltration would have had an effect on postoperative pain.

Postinjection pain ratings, at the time subjective numbness wore off, were similar for the Stabident and X-Tip™ systems, with no statistical differences between the 2 techniques (Table 3). The mean VAS ratings were 18 for the Stabident technique and 31 for the X-Tip™ technique—which would be in the faint to weak pain range (Figure 3). The incidence of moderate pain was 7–15%, with no reports of severe pain (Table 3). Various authors[1–6] have reported that 2–16% of subjects had moderate pain and 0–3% had severe pain at the time subjective numbness wore off after receiving Stabident IO injections. Therefore, the incidence of moderate pain is similar between the previous studies and the current study. Clinically, with both the X-Tip™ and Stabident IO systems, the likelihood of having moderate pain at the time subjective numbness wears off is 16% or less. The potential for severe pain is small.

For the Stabident IO injections, postinjection pain was rated as none to mild, on the first morning, in 95%

of the IO injections, with 2% reporting moderate or severe pain (Table 3). Generally, the pain ratings decreased over the next 2 days, with only a couple reports of moderate and severe pain (Table 3). Stabident postinjection pain ratings, on the first morning, have been reported by a number of authors[1–6] as 0–10% moderate pain and 0–5% severe pain. For postoperative day 2, moderate pain has been reported as 0–10%, with no reports of severe pain.[1–6] For postoperative day 3, moderate pain decreased to 0–5%, with no reports of severe pain.[1–6] The results of the previous studies are similar to the current study. Therefore, the Stabident IO injection has a 0–10% potential for moderate postinjection pain, on the first morning, with decreasing moderate pain ratings over the next 2 days. The potential for severe pain is less than 5%.

For the X-Tip™ IO injections, postinjection pain was rated as none to mild, on the first morning in 75% of the IO injections, with 25% reporting moderate or severe pain (Table 3). For postoperative day 2, moderate pain was reported as 17%, with no reports of severe pain. For postoperative day 3, moderate pain decreased to 12%, with no reports of severe pain. Statistical analysis showed that males experienced significantly more postoperative pain, starting on the first morning and continuing through day 3, with the X-Tip™ system than with the Stabident system (Table 3). The 25% incidence of moderate to severe postoperative pain on day 1 (with decreasing incidence over the next 2 days) with the X-Tip™ system in males would indicate that male patients should be informed that they may experience moderate to severe pain a quarter of the time when the X-Tip™ system is used in an apical location. Patients may have to take analgesic medication to help with their postoperative pain.

Why did males have significantly more postoperative pain with the X-Tip™ IO injection? Reviews by Unruh[14] and Miaskowski[15] have indicated that there are differences between males and females regarding clinical pain experiences. Unruh[14], in reviewing research articles examining sex differences in clinical pain experiences, reported that females generally have higher levels of pain, have pain more frequently, and have a longer duration of pain than do males. However, in the current study, males experienced more moderate levels of pain and had pain more frequently than females. Therefore, we can speculate that the results of this study are not necessarily related to sex issues but to other factors or combinations of factors. One factor was the apical location of the X-Tip™ perforation. Kingsmill and Boyde[16] studied mineralization density of human mandibular bone and reported that the lowest density occurred in the anterior alveolar crest while one of the highest densities was found buccally in the posterior mandible. Therefore, the apical site of the X-Tip™ perforation, as was used in the current study, would probably be a higher mineralized site than the coronal site of the Stabident perforation. In concert with the perforation site would be the male bone density. Kingsmill and Boyde[16] found women had lower mandibular bone mineral content than men. Therefore, if the apical cortical bone in the posterior mandible in males is denser and more mineralized than the crestal bone, the apical perforation process may cause greater frictional heat generation. Another factor, as mentioned previously, was that the X-Tip™ perforating system diameter is larger than the Stabident perforator. Therefore, the greater surface area of the X-Tip™ system may generate more frictional heat in the osseous tissues during perforation. A controlled histological study is needed to confirm the factor of X-Tip™ perforator diameter and the role it plays in damage to osseous tissues. Additionally, the effects of the X-Tip™ perforation on postoperative pain, when used in a coronal location, are not known.

There was 1 Stabident subject reporting severe postoperative pain at day 1 through day 3. The perforation for this individual was rated as easy. The moderate ratings for day 1 and day 2 were from 2 separate subjects and their perforations were rated as hard. The 10 X-Tip™ subjects reporting moderate to severe postoperative pain at day 1 were the same subjects who accounted for all the moderate to severe ratings over the next 2 days. Eight perforations for these individuals were rated as easy and 2 were rated as hard. It is difficult to explain the moderate to severe postoperative pain ratings based solely on the difficulty of perforation because the majority of the perforations were rated as easy. Perhaps the factors for more postoperative pain in males, as discussed previously, would account for bone damage and still be associated with an easy perforation.

Although no animal study has investigated the effects of the Stabident or X-Tip™ IO injection systems on gingiva and bone, various authors[1–6] have reported postoperative swelling and purulence at Stabident IO injection sites. Generally, the incidence in these studies[1–6] has been less than 5%. These changes are likely related to gingival or bone trauma during perforation. In the current study, 2 subjects (5%) reported postinjection swelling, with no exudate, with the Stabident technique (Table 4). All resolved by the third day. Clinically the chance is less than 5% that swelling or exudate will occur postoperatively with the Stabident system.

Swelling (with no exudate) with the X-Tip™ technique occurred 20% (8 of 41) of the time (Table 4). One subject (2%) had purulent exudate associated with the swelling. Four of the 9 swellings resolved by the third postoperative day. Five of the subjects did not resolve until 1–2 weeks. Eight of 9 subjects who reported swellings

were male and their postoperative pain ratings were higher than the male subjects without swellings. Although the swelling was not statistically significant ($P = .07$) when compared with the Stabident system, clinically, the X-Tip™ system may have a higher incidence of postoperative swelling.

Five to 15% of the subjects reported the first molar "felt high" when chewing for a few days (Table 4). There was no statistical difference between the 2 techniques. Other studies[1–6] using the Stabident technique reported an incidence of 0–13%. This feeling is most likely an increased awareness to biting that results from soreness in the area caused by damage from perforation or inflammation of the bone. Clinically, with both the X-Tip™ and Stabident IO systems, the likelihood of patients reporting that their teeth would be sore to chewing would be 15% or less.

In conclusion, the apical primary X-Tip™ intraosseous technique achieved similar pain ratings for infiltration, perforation, needle insertion, solution deposition, mock or actual guide sleeve removal, and postoperative pain (at the time subjective anesthesia wore off) as the coronal primary Stabident technique. However, on postoperative days 1–3, significantly more males experienced postoperative pain with the X-Tip™ system than with the Stabident system.

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