Use of a Needleless Injection System for Digital Ring Block Anesthesia

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Digital ring block anesthesia, which is frequently used before surgery for ingrown toenails, is often extremely uncomfortable for patients and can be the most distressing aspect of the procedure. The authors used a novel needleless injection device to induce digital anesthesia before surgery and compared it in terms of patient discomfort and preference with use of a standard needle and syringe for injection in individuals undergoing simultaneous bilateral nail procedures. Use of the needleless device significantly reduced the pain associated with this procedure and was preferred over use of a standard needle and syringe by all individuals. Other potential advantages of a needleless injection system are discussed. (J Am Podiatr Med Assoc 93(1): 23-26, 2003)


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Ingrown toenails have a higher prevalence among younger people, although presentation can be at any age.1, 2 The nail of the great toe is most commonly affected, possibly as a result of inappropriately sized or shaped footwear or a poor nail-cutting technique.3-6 Often, ingrown toenails are considered by the medical profession to be minor cases and relatively unimportant in terms of surgical urgency. However, they can significantly compromise the patient’s quality of life by causing pain, interfering with mobility, impeding the use of normal footwear, and restricting many physical activities. Local infection can aggravate the situation and, if left untreated, may result in a spreading cellulitis, abscess formation, or, less commonly, osteomyelitis of the underlying bone.7

Various treatments have been advocated for ingrown toenails, with prevention focusing on local hygiene and nail-cutting technique. In most cases in which prevention or other more conservative measures have proven ineffective, surgical treatments are necessary. The objective is always removal of the ingrown part of the nail (which may mean removing the whole nail) and obliteration of part, or all, of the associated nail bed. Any infected (granulation) tissue can be removed at the same time. Such procedures can be performed by trained general practitioners, podiatric physicians, or surgeons (often trainees), usually as an ambulatory procedure.

Surgery is performed after anesthetizing the appropriate digit using a “ring block” technique. The two digital nerve branches passing to each toe are blocked with a perineural injection of a local anesthetic such as lidocaine hydrochloride using, for example, a 25-gauge disposable needle (with extreme care taken to use agents without norepinephrine added). As the digital nerves run along both the medial and lateral aspects of each toe, at least one injection of the local anesthetic is needed on each side. Despite the use of small needles, the high sensitivity of this area renders the procedure painful for the patient, regardless of the technique used. This effect becomes highlighted even more in patients with “needle phobias” and younger patients. It is common for the clinician to spend more time administering the anesthetic than performing the surgical procedure.
The authors evaluated a novel needleless injection device (J-Tip, NMP Inc, Irvine, California) used to induce digital ring block anesthesia in patients undergoing simultaneous bilateral ingrown toenail surgery. This new method for providing anesthesia was compared with a traditional needle and syringe, examining effectiveness, patient pain scores, and overall patient satisfaction. Other advantages of using a needleless injection system are also discussed.

**Materials and Methods**

**The J-Tip Needleless Injection Device**

The J-Tip needleless injection device is a novel single-use, disposable device for the delivery of any liquid diagnostic or therapeutic agent directly into the subcutaneous space. It is approved by the US Food and Drug Administration and has the European Union regulatory “CE” mark and has been designed from the outset to be easy to use by all health-care workers and patients themselves, where appropriate. The device is approximately 10 cm long and weighs less than 9 g. Two sizes are available: 0.25-mL capacity and 0.5-mL capacity (with each device allowing variable filling from 0.02 mL upward). Medication delivery is under high pressure (~3,000 psi) created by the release of carbon dioxide gas held in a small cartridge. Drug delivery is achieved at high velocity within a fraction of a second (~0.2 sec). Specifically, the design enables drug delivery that is considered virtually pain-free, with penetration of the tissues to an approximate depth of 5 to 8 mm. Once used, the device cannot be refilled or reused and can be disposed of in an ordinary clinical waste system.

**Patients and Methods**

This study was conducted after being approved by the joint University College London and University College London Hospitals committees on the ethics of human research. Patients attending the Podiatry Clinic at The Middlesex Hospital, London, England, and with bilateral ingrown toenails requiring surgical treatment were asked to participate, provided consent, and enrolled in the study.

All patients underwent surgery on two toenails; the digital ring block anesthetic was administered using a standard needle and syringe in one toenail and the J-Tip needleless injection device in the other toenail. The method of administration of the anesthetic for each digit was determined randomly by a simple coin toss. In all cases, 2 mL of lidocaine hydrochloride 2% (Xylocaine, Astra Zeneca Ltd, Luton, England) was administered to each side of the digit. For the standard method, a 5-mL disposable syringe with a 25-gauge needle was used; for the J-Tip needleless injection system, separate devices were used for each site (the maximum capacity of each device being 0.5 mL). Five minutes after administration, a 29-gauge needle was used to test sensation around and along the entirety of the digit, as a measure of the effectiveness of the anesthesia. Additional anesthesia was given, if required, before surgery (using a standard 5-mL syringe with a 25-gauge needle and an additional 2 mL of lidocaine hydrochloride 2%). The toenail was removed using a standard surgical technique.

As an indication of the severity of pain, patients were asked after the procedure to place a mark along a linear analog scale, with 0 representing “no pain” and 10 representing “the worst pain imaginable.” Patients were subsequently asked to fill out a questionnaire, answering the following questions:

1) Did you feel any discomfort during the surgical procedure? (Yes/No)
2) How easily was the injection administered—the J-Tip device compared with the standard needle and syringe? (Easier/Same/More Difficult)
3) Was a supplement to either injection method required to establish adequate anesthesia? Before the procedure? (Yes/No) During the procedure? (Yes/No)
4) If you were given the choice, would you elect to use the J-Tip device in preference to the standard needle and syringe? (Yes/No) If no, then why not?

Analog pain scores were recorded by measuring (in centimeters using a standard ruler) the distance from the “0” point that the mark was placed along the line by patients. Answers to the questionnaires were summarized.

**Statistics**

Comparisons of pain scores between the standard needle and syringe and the J-Tip device in experimental groups were made using the Mann-Whitney U test for unpaired results (two-tailed). Answers to the questions posed are summarized by number responding either positively (Yes) or negatively (No) or stating a preference for each question (as appropriate) divided by the total number of patients.

**Results**

Twelve subjects were enrolled in the study, all of whom underwent surgery for the simultaneous removal of bilateral ingrown toenails. Six subjects were women and six were men, with a median age of 35.5 years (range, 17 to 74 years). For each subject,
digital ring block anesthesia was administered using the standard needle and syringe method for removal of one toenail and using the J-Tip needleless injection device for removal of the other toenail.

Use of the J-Tip needleless injection device was associated with a significant reduction in overall pain experienced by patients undergoing digital ring block anesthesia before toenail removal. The median pain score for the J-Tip–injected toe was 2 (range, 2 to 3), and for the standard needle and syringe–injected toe was 8 (range, 6 to 9) \( P < .001 \).

The responses on the patient questionnaires further emphasized the benefit of using the J-Tip device in this setting. All 12 patients answered that 1) they felt no discomfort with use of the J-Tip device and considerable discomfort with use of the standard needle and syringe; 2) injection with the J-Tip device was easier than with the standard needle and syringe; and 3) if given the choice, their preference for anesthetic would be the J-Tip device rather than the standard needle and syringe.

One drawback of the J-Tip device, however, was that additional anesthetic administration (3 mL of lidocaine hydrochloride 2%) was required for all patients to achieve adequate anesthesia at the tip of the toe. However, although this additional anesthetic was administered using a standard needle and syringe, little or no pain was encountered at this stage owing to the previously induced anesthesia. Although the total volume of local anesthetic used to produce anesthesia was higher with the J-Tip device, as all patients needed supplementation with the conventional method, the total volume used (6 to 9 mL of lidocaine hydrochloride 2%) was always well below the maximum permitted dose. Although not measured precisely, it was noted that the time to achieve adequate anesthesia was slightly longer when using the standard needle and syringe method.

## Discussion

Ring blocking is an effective method of inducing digital anesthesia to allow toenail surgery to be performed. Traditionally, a ring block is formed by obliterating conduction from the two digital nerves of the appropriate digit via a perineural injection of a suitable (plain) local anesthetic agent. To date, ring block has always been achieved by means of a standard needle and syringe. However, this technique requires a degree of specialized training and can be very uncomfortable for the patient and, on occasion, hazardous for the administrator. Administration other than to the perineural space could endanger the viability of the nerve or could cause a systemic reaction if accidental intravessel administration occurred. Needling down onto the periosteum is often painful, and any discomfort may be magnified in the minds of those who have a needle phobia or who are younger. Needle-stick injuries before, during, or after the procedure are common.

The aim of this study was to explore use of the J-Tip needleless injection device in achieving ring block anesthesia when performing toenail surgery. For this, 12 patients requiring simultaneous bilateral toenail surgery were recruited. The results demonstrate that use of the J-Tip device significantly improved the procedure for the patient. However, there were difficulties. First, the effective area anesthetized often excluded the most distal part of the digit. Consequently, supplementation of local anesthetic agent was usually required. However, as patients experienced no pain when injected further, the procedure overall was more comfortable for the patient and technically easier when using the J-Tip device. When the traditional needle and syringe method was used, all patients reported significant pain. In some cases, increased pain resulted in patients forcibly withdrawing their foot from the operating field, promoting needle-stick injuries and causing significant delays. All patients preferred use of the J-Tip device for this procedure. Second, the local anatomy along each toe often resulted in an inadequate “seal” of the J-Tip device’s orifice to the surrounding tissues, with subsequent leakage when fired and, hence, an inability to propel the entire volume of anesthetic agent into the underlying tissues.

Use of the J-Tip needleless injection device seems to be safe and relatively easy for inducing ring block anesthesia. Use of the device ensured a virtually pain-free induction of anesthesia initially, contributing to less morbidity. The absence of a needle should be particularly reassuring for younger and needle-phobic patients.

The J-Tip device has several potential advantages over more traditional methods. It requires no specialized training, and medical or nonmedical staff can safely administer a variety of liquid therapeutic or diagnostic agents. Administration of the liquid agent is performed by holding the device perpendicular to the skin of the area to be anesthetized. Then, by pushing firmly against the underlying tissue to achieve a good seal, the safety clip is withdrawn and the trigger that releases the carbon dioxide from its containing chamber is pressed. The loaded liquid is released under high pressure, at high velocity, through a micro-orifice at the tip of the device. The liquid is delivered in an aerosol form subcutaneously to a depth of 5 to 8 mm, fanning out on maximum penetration to a width...
of 8 to 10 mm. Once the liquid passes through the epidermal and dermal layers of the skin, the energy used to propel the medication is mostly spent, making disruption or penetration of the liquid into an adjacent blood vessel nearly impossible. The empty device can then be disposed of in an ordinary clinical waste container, as the absence of a needle makes a special needle-disposal system unnecessary. The correct use of the device, although relatively simple, is subject to certain conditions. It is imperative for the administrator to achieve a good seal between the device and the underlying skin. Failure to do so results in leakage of the highly pressurized liquid, mainly into the air. Thus the device is less likely to be effective in areas where bone prominences are not covered with a sufficient thickness of subcutaneous tissue.

The device, initially developed for patient self-administration of insulin, has been used successfully to administer low-molecular-weight heparin for deep venous thrombosis prophylaxis, radioactive 99mTc-labeled colloidal albumin for the detection of sentinel node malignancy, and local anesthetics before venous cannulation.

**Conclusion**

The J-Tip device 1) should help eliminate the anxiety associated with needles by some individuals, 2) has been designed such that no specialized skills are required to use it, 3) is virtually painless in use, 4) is unlikely to accidentally deliver medication intravenously, and 5) eliminates the chance of needle-stick injury for health-care workers and lessens the potential for cross-infection, as no needles are used either in drawing up the medication or in its delivery.

The higher cost of the device, per unit, compared with a conventional needle and syringe may represent a drawback. Furthermore, the limited volume capacity of the device (maximum, 0.5 mL) may dictate the use of multiple J-Tips for each patient, further increasing the cost. However, with new guidelines for clinical governance, the safety and quality of care associated with use of this device should help outweigh such arguments.

**References**