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Evaluation of a new pediatric intraosseous needle insertion device for low-resource settings

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Abstract

Background and Purpose: The Near Needle Holder (NNH) (Near Manufacturing, Camrose, Alberta, Canada) is a reusable tool to introduce a standard hollow needle for pediatric intraosseous (IO) infusion. We compared the NNH to the Cook Dieckmann (Cook Critical Care, Bloomington, IN) manual IO needle in a simulation setting.

Methods: Study subjects were 32 physicians, nurses, and medical students participating in a trauma course in Guyana. After watching a training video and practicing under supervision, subjects were observed inserting each device into a pediatric leg model using a randomized crossover design. Outcome measures were time to successful insertion, technical complications, ease of use, and safety of each device.

Results: The mean time for IO insertion (32 ± 13 seconds) was similar for both devices (P = .92). Subjects rated the NNH device equivalent in ease of use to the Cook IO needle but slightly lower in perceived safety to the user.

Conclusions: After training, all subjects successfully inserted the NNH IO device in a simulation environment, and most rated it as easy to use and safe. The NNH is a significant advance because IO needles are often not available in emergency departments in developing countries. Further studies are needed to evaluate clinical effectiveness of the NNH.

Rapid vascular access is an essential component of the management of children in shock. An intraosseous (IO) needle can be inserted within minutes for emergency vascular access when intravenous attempts have failed.

Mechanical and manual IO insertion devices are commercially available. Mechanical devices are not as well suited to low-resource settings because of their increased cost and reliance on battery power. For this reason, the Near Needle Holder (NNH) was developed as a low-cost and reusable method of introducing a standard hollow-bore needle into the marrow of the tibia (Fig. 1). It has been used in Southeast Asia, demonstrated at the Bethune Round Table on International Surgery (Calgary, 2010), and is now

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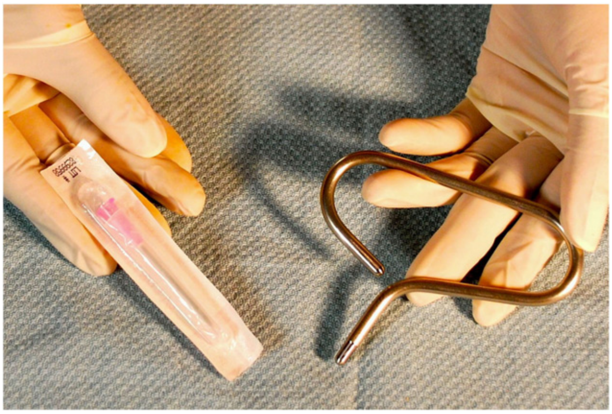

Fig. 1 Near Needle Holder.

commercially available (Near Manufacturing, Camrose, Alberta, Canada; www.nearperfection.com).

The primary objective of this study was to compare the insertion success and user's perceptions of the NNH to the single-use modified Dieckmann needle (Cook Critical Care, Bloomington, IN) [1]. A secondary objective was to evaluate the instructional video produced for the IO training module.

1. Methods

All participants, local and visiting faculty taking part in a Canadian Network for International Surgery Trauma Team Training update course in Georgetown, Guyana, in November 2010 were invited to take part in the study. Institutional Research Ethics Board approval was obtained in both Canada and Guyana. After obtaining written consent, each study subject completed a background data sheet detailing their type of medical training, specialty, postgraduate experience, number of IO lines placed, and IO device currently in use in their facility.

1.1. Instructional video

A 5-minute instructional video demonstrating the IO needle insertion technique with both devices was produced in Guyana. A compact, Canon FS300 video camera (Canon Canada Inc, Mississauga, Ontario) was used to film the simulated procedure, and footage was edited using iMovie '09 for Macintosh (Apple Inc., Cupertino, CA). Study participants watched the video twice before completing a 6-item, multiple-choice quiz to assess knowledge about IO insertion. Additional questions were asked to ascertain the participant's perceived value of the video as a training tool, using a 7-point Likert scale.

1.2. Intraosseous evaluation

The 2 devices compared in this study were the 18-gauge modified Dieckmann pediatric IO needle by Cook Critical Care (referred to as the Cook needle) and the NNH used with a 1-inch 18-gauge needle. After watching the instructional video twice, participants were given 5 minutes to practice inserting both devices on a plastic pediatric leg model. Feedback was provided on insertion technique by the primary investigators. Once subjects were comfortable and competent inserting both devices, participants were asked to demonstrate needle insertion using correct technique and confirm correct placement of the needle by aspirating simulated bone marrow. Because the purpose of the study was to evaluate the devices, participants were not evaluated on their insertion technique. A randomized crossover design was used. Computer-generated block randomization determined which device was used first by each participant. After inserting the first device, participants crossed over to insert the second device. Tape was applied across the proximal tibia of the leg model, and the desired needle insertion site was marked with a dot. This tape was replaced between subjects. The designated needle insertion site was used to prevent reinserting needles in the same hole, which would compromise the integrity of the model.

An independent observer recorded the time taken for successful insertion of each device, defined by aspiration of simulated bone marrow. Technical complications were noted. Participants then completed a written evaluation on the ease of use and safety of each needle using a 7-point Likert scale.

1.3. Data analysis

Descriptive statistics were calculated to summarize the participants' demographic data and quiz scores. A paired *t* test with 95% confidence intervals was used to compare mean time for successful insertion of each device. Fisher's Exact test was used to compare the rate of technical complications and Likert scores on the participant evaluations. Two-sided *P* values less than .05 were considered significant.

2. Results

Thirty-two subjects evaluated the IO devices and completed the instructional video evaluation. The group's type of medical training, medical subspecialty, and prior experience with IO devices are summarized in Table 1.

2.1. Intraosseous evaluation

All participants successfully inserted both IO needles on the first attempt. The mean time for successful insertion was the same for both devices (NNH, 32 ± 13.2 seconds; Cook, 32 ± 12.3 seconds), with a mean difference of 0.25 seconds ($P = .92$; 95% confidence interval, −4.97 to 5.57). The rate of technical complications was nearly identical for both devices (Cook, 11/32; NNH, 12/32; *P*, not significant; Fig. 2). Both

Table 1 Demographic and background data of study participants (N = 32)

		n (%)
Level of medical training	Course instructor	3 (9)
	Physician	19 (59)
	Nurse	5 (16)
	Medical student	5 (16)
Previous IO experience	None	16 (50.0)
	≤5 insertions	11 (34.4)
	6-10 insertions	3 (9.4)
	11-20 insertions	1 (3.1)
	≥21 insertions	1 (3.1)
IO device currently available at facility	Angiocatheter	9 (28.1)
	18-gauge needle	9 (28.1)
	Cook IO device	5 (15.6)
	Nothing	3 (9.4)
	Do not know	6 (18.7)

needles tended to plunge into the marrow with sudden loss of resistance as the needle passed through the bone cortex, risking penetration of the posterior cortex. One participant found that the Cook IO needle bent. The main difficulties with the NNH were difficulty removing the handle from the hollow-bore needle, occlusion of the needle with a bone plug, and alteration of the position of the needle during removal of handle. Although the above complications of insertion had the potential to impact needle insertion success, all participants were able to aspirate bone marrow, confirming correct needle location in the medullary cavity.

Subjects agreed that both devices were easy to use (Cook, 30/31; NNH, 25/31; P = .15). Twice as many subjects thought the NNH posed a safety risk to themselves (Cook, 4/32; NNH, 8/32; P = .34), although most agreed that the NNH was safe to use and an improvement over the current equipment available. (Fig. 3). Some reported that they had previously been inserting a hollow-bore needle manually for IO infusion, and all participants felt that a device for IO insertion should be introduced at their facility. Additional comments made about each device are listed in Table 2.

2.2. Instructional video

Concept, scriptwriting, filming, and editing took approximately 40 hours to complete. The mean postvideo quiz score was 83% (5% ± 0.9%). The most common question answered incorrectly (8/32) was the location of needle insertion on the medial side of the tibial tuberosity. Eighty-eight percent of trainees agreed or strongly agreed that the video was a useful clinical tool, and 85% agreed or strongly agreed that it should be included in future training courses (Fig. 4).

3. Discussion

Intraosseous access uses the medullary cavity of long bones to gain parenteral access for fluid and drug administration [2]. Venous sinusoids in the bone marrow drain into medullary venous channels that drain into the systemic venous system via nutrient and emissary veins [3]. Pharmacokinetic studies have shown that fluids and medication delivered via the IO route reach the systemic circulation as quickly as those administered intravenously [4]. Unlike peripheral veins that collapse during shock, intramedullary vessels are held open by the rigid, non-collapsible bony wall [5]. The most commonly used sites are the distal femur, proximal tibia, and distal tibia. Alternate

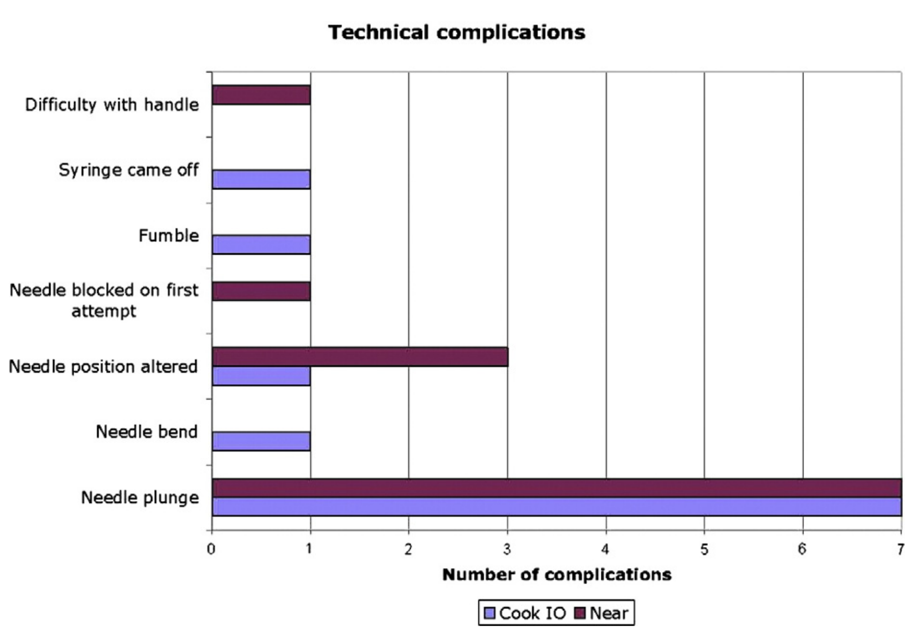

Fig. 2 Technical complications encountered with the NNH vs the Cook device (N = 32).

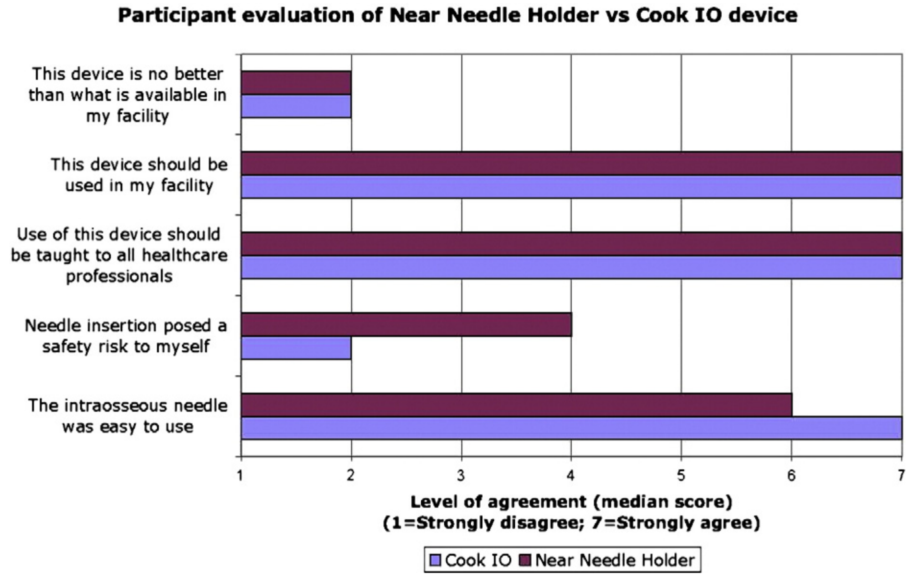

Fig. 3 Participant evaluation of the NNH vs Cook device (N = 32).

venous access techniques such as central line placement and venous cutdown have poor success rates in critically ill children [6] and are time consuming [7]. Studies have demonstrated that IO use can decrease the time needed to obtain vascular access in pediatric patients in cardiac arrest [6,8] and that the success of vascular access in this patient population is higher for IO access (83%) than for saphenous venous cutdown (81%), subclavian central line (77%), and percutaneous peripheral (17%) [9]. Although typically used in the emergency and critical care settings, IO access can also be used in the perioperative setting [10]. Historically, IO use was recommended only in children younger than 6 years; however, its use in infants, pediatric, and adult patients has been supported by recent literature, as well as guidelines for cardiopulmonary resuscitation and trauma [11-13]. Evidence shows that paramedics and flight nurses can be taught IO insertion techniques [14] and can successfully establish IO access in the prehospital setting [15-18].

Available IO needle devices can be classified as either manual or mechanical. Current commercially available single-use manual IO devices include the threaded Sur-Fast needle (Cook Medical Inc., Bloomington, IN) and modified Dieckmann needle [1] and the Jamshidi needle (Baxter Healthcare Corp, McGaw Park, Ill). All have central removable trocars that prevent occlusion with bone on insertion. Mechanical IO devices include 2 spring-loaded devices, the Bone Injection Gun (BIG) (PerSys Medical, Houston, TX) and the First Access for Shock and Trauma 1 (FAST1) (Pyng Medical Corporation, Richmond, Canada), and 1 powered drill, the EZ-IO (Vidacare Corporation, Shavano Park, TX). The BIG and EZ-IO are marketed for adult and pediatric use, whereas the FAST1 is only marketed for establishing vascular access via the sternum in adults. Numerous studies have been compared insertion success, time for insertion, complication rates, and user-friendliness of manual and mechanical IO devices in nonclinical and clinical settings [19-25].

The NNH was developed as an alternative manual device to insert IO needles. Anecdotally, hollow-bore needles have been inserted into the tibia directly by hand for IO infusion in some low-resource settings. This was the stimulus to develop a safe, inexpensive, sterilizable, and reusable device to insert hollow bore needles for IO infusion. Although the NNH does satisfy these requirements, the disadvantages of this device include the lack of a central trocar to prevent occlusion by bone plugs, the need for a supply of hollow-bore needles, and the need for an instrument to stabilize the needle hub during

Table 2 Summary of participant comments regarding safety and ease of insertion of the Cook device and NNH

	Cook	NNH
Pro	"seems to take shorter time, less steps, quicker, faster, safer"	"...good experience, the first time using such an instrument"
	"easy and self-explanatory, everything in one package, easy to stock/find/use in a hurry"	"cheaper but slightly more difficult to use, good choice in resource poor setting"
	"fast and secure, easier to remove and to place"	"we do not have a device currently in use, Near needle would be great to use in my facility"
Con	"was faster but got bent faster"	"...less control of the needle because needle holder is too...far from the needle itself..."
	"because of present resource constraints I think the Near needle is a better option in my facility"	"too many steps to goal, need to triple check insertion, felt unsafe"

Fig. 4 Participant evaluation of the video as a training tool.

removal of the handle. The estimated price of $20 for the NNH is less costly than commercially available devices (Jamshidi, $96; Cook, $42; FAST, $165; BIG, $70; EZ-IO, $380 for power driver, battery, and 1 IO needle) [26].

The locally produced training video used to teach IO needle insertion technique was effective and well received by study participants. However, 25% of participants did not identify the medial side of the tibia as the correct location, and this has led to a revision of the training video to highlight that point. This underscores the importance of evaluating training videos to ensure that students learn what is intended. Instructional videos teaching basic life support skills and simple surgical techniques have shown skill acquisition and participant confidence level comparable with conventional instructor-led courses [27,28]. The potential for cost savings, ease of delivery, and ongoing access to refresher viewings make this learning method an attractive choice, especially when dealing with large geographical distances and low-resource settings. Telesimulation is an additional training tool that can be used to overcome large distances [29] but suffers from similar disadvantages as traditional face-to-face teaching in that the timing of teaching is inflexible and skills may be practiced incorrectly if correct technique is not reinforced between teaching sessions. Combining telesimulation with training videos may be the optimal modality for teaching procedural skills over distances. Further research is required in this area.

This study suffers from several limitations. Although the efficacy of the NNH was demonstrated in a simulation environment, further evaluation is required to determine clinical effectiveness. In addition, although designed to be a single-use device, the Cook device was reused in this study. This may have been a factor in the case of the Cook needle bending during insertion. Finally, comparing the NNH with the current practice of handheld hollow-bore needle insertion may have been more clinically relevant because it is unlikely that the costly, single-use Cook IO device would be used in Guyana.

All subjects successfully used the NNH IO insertion device in a simulation environment, and most rated it as easy to use and safe. The advantages of the NNH over other commercially available devices are its reusability (sterilization is required) and lower cost, making it particularly attractive in low-resource settings. Further studies are needed to evaluate the safety and effectiveness of the NNH in the clinical setting.

The on-site production of a context-specific training video for simple surgical procedures using inexpensive audiovisual equipment is a useful and viable educational practice. The instructional video that was produced as part of this study effectively conveyed instructions and was well received by learners. Video-based instruction methods may be a cost-effective tool in future training scenarios, when combined with direct instruction or telementoring.

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