Paramedic Evaluation of Adult Intraosseous Infusion System

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Abbreviations:
FAST 1 = First Access for Shock and Trauma
IO = intraosseous
IV = intravenous

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Abstract

Introduction: The First Access for Shock and Trauma (FAST 1) Sternal Intraosseous (IO) System is a vascular access device designed as an alternative to peripheral or central intravenous (IV) cannulation for the treatment of critically ill and injured adults. During the development of the device, key objectives included safety, speed of insertion, and ease of use with minimal training. This study evaluated these characteristics.

Methods: Ten experienced paramedics participated in a 90-minute training program for the use of the FAST 1 System at the Paramedic Academy of the Justice Institute of British Columbia. Then, the paramedics used the system in three simulated prehospital scenarios and evaluated the ease of use and compatibility of the training method with current practice using a 10-centimeter (cm) (3.94 inches (in)), visual analog scale.

Results: The duration of the procedure from opening the package to initiation of fluid flow ranged 52–127 seconds (mean = 92 ±32 seconds). Placement accuracy was excellent, with a mean displacement of 2 mm (0.08 in) and 1 mm (0.04 in) in the vertical and horizontal planes, respectively. The paramedics rated the system highly in all areas. They considered the training "straightforward" and "comprehensive". The possibility for interference between the IO system and cervical collars was reported, and several suggestions to remedy this and achieve other improvements were made.

Conclusions: Placement of the FAST 1 is fast, accurate, and easy to use. Paramedics had useful input concerning the design of the product.

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Introduction

Vascular access is a key intervention for the management of critically ill and/or injured patients. However, in cases in which the patient is in circulatory shock (e.g., due to heart failure, drug overdose, or severe hemorrhage), the peripheral blood vessels frequently collapse, and obtaining standard intravenous (IV) access can be difficult. As a result, there may be substantial delays or an inability to administer drugs and fluids.

Intravenous cannulation and infusion of fluids by paramedics in the field remains controversial, particularly for patients who are hypovolemic from trauma-related injuries.[1–5] This is because resuscitation in the field can be hampered by the time and difficulty associated with initiating IV therapy (reported to be as high as 12 minutes for one service),[6–11] the high access failure rates (10–40%), and the small volumes of fluid that typically are administered.[12] In an urban setting, delays caused by repeated and often unsuccessful attempts to initiate IV therapy and stabilize the patient (≥25 minutes) result in higher morbidity and mortality than the "scoop and run" approach.[7,13] Other centers have reported shorter access times and higher success rates, and emphasize the need for physician supervision of paramedic care to ensure appropriate use of the technique.[1,11,14]

Peripheral vascular access can be more difficult in young children than it is in adults. An alternative method of vascular access—IO infusion into the

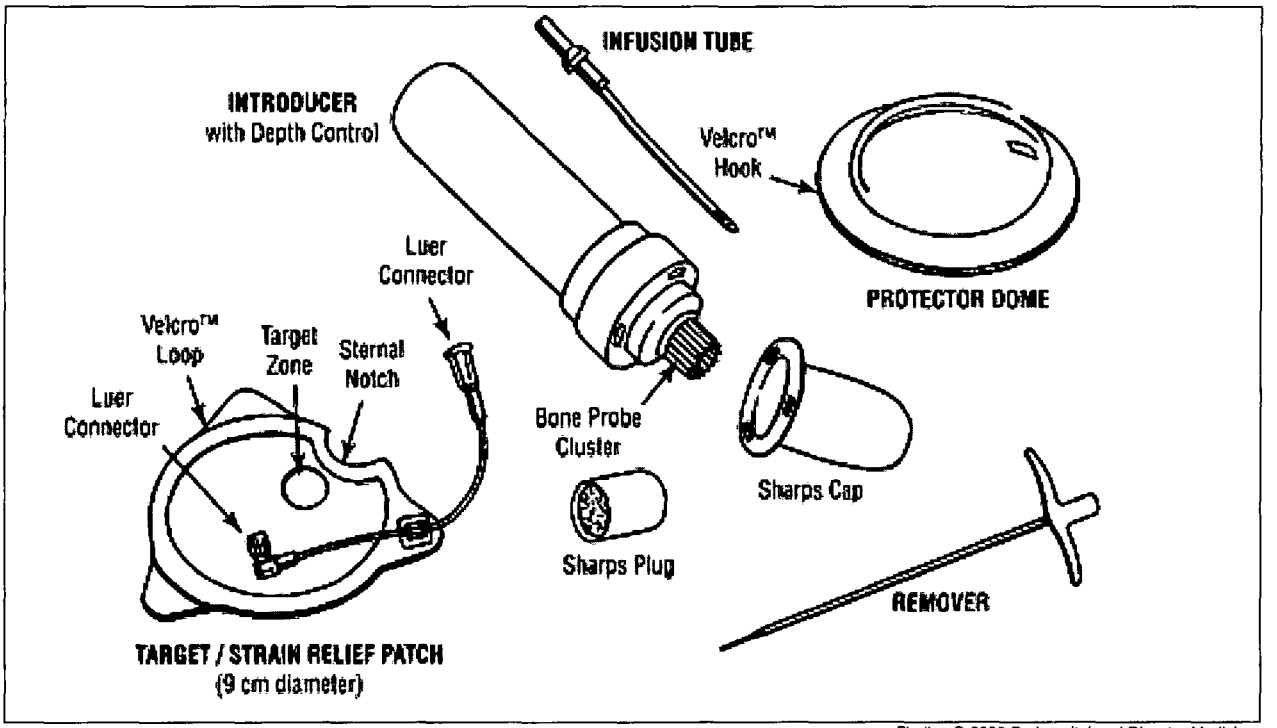

Figure 1—FAST 1 Intraosseous Infusion System

tibia—already is standard practice for the resuscitation of critically ill children <8 years of age.[17–21] Although IO infusion has been used for many years in adults, it is used infrequently for a number of reasons, including the higher success rate of peripheral access in adults and the perceived risk of complications associated with currently available IO access tools.[18,22] However, in military[15] and civilian circles, this stance is changing.[16,23]

There is a need for a faster and more reliable method of vascular access in the prehospital environment, and IO was identified as a promising option. A research and development project was performed to develop a new, sternal IO device that included cadaver research on human sternal anatomy, an iterative prototype development process that focused on ergonomics, and extensive bench testing. Paramedics at the Justice Institute of British Columbia Paramedic Academy and the British Columbia Ambulance Service, as well as US military medical personnel at Fort Detrick, Maryland provided input into the design and testing.

The result of the design process was the First Access for Shock and Trauma (FAST 1) Intraosseous Infusion System (Pyng Medical Corp., Vancouver, British Columbia). The system was designed to offer a safe, fast, reliable, alternative route for the emergency administration of fluids and drugs in the prehospital environment and in the hospital when there is an unacceptable delay in acheiving access.

Methods

The System

The FAST 1 System (Figure 1) consists of five components: (1) the infusion tube; (2) the introducer for placing the infusion tube through the skin into the sternum of the patient; (3) the target/strain relief patch for easily landmarking and penetrating the optimal insertion site on the manubrium; (4) a protector dome; and (5) an infusion tube removal tool.

The introducer has a circle of bone probes designed to detect the anterior cortical bone of the manubrium. The operator places the notched target/strain-relief patch in alignment with the sternal notch. The target zone opening clearly indicates the optimal penetration site. The operator then aligns the bone probes with the target area perpendicular to the plane of the manubrium, and pushes firmly until the bone probes detect the anterior cortical bone. As the operator continues to apply pressure, the bone probes remain at the surface of the bone, while the tip of the infusion tube advances another 5 mm (0.2 in), the precise depth necessary to access the marrow space. As soon as that depth is reached, the introducer automatically releases the infusion tube so that it cannot be pushed farther. The operator pulls straight back on the introducer, exposing the infusion tube and its two-part support sleeve, which falls away. Correct placement is verified by observation of marrow entering the infusion tube. The infusion tube is joined to the tubing on the patch, which is connected to a purged fluid source. Fluid now can flow into the manubrium. Finally, the protector dome is pressed down firmly over the target patch to engage the Velcro™ fastening. The site is clearly visible through the dome, the flexible tube allows skin and tissue movement without disturbing the bone portal, the strain relief function of the patch diverts any stress on the tubing to the skin, and the site requires no further stabilization.

To facilitate training, two simulator systems also were developed. These include: (1) the SimIO (Figure 2), which is identical to the FAST 1 System except that it does not penetrate the skin, so it can be used on volunteers or man-

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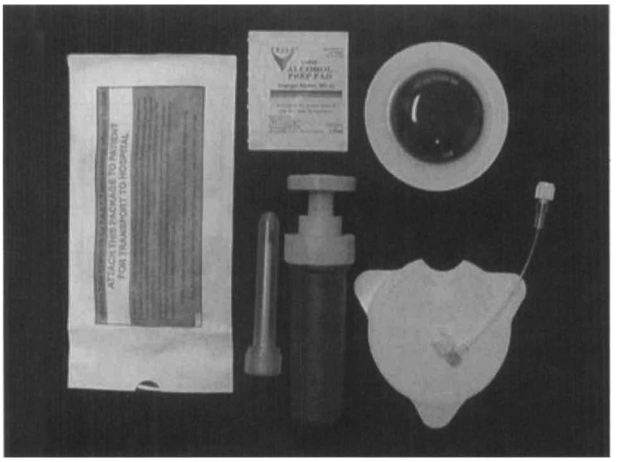

Figure 2—SimIO intraosseous infusion introducer/simulator used for training and simulations

nequins during training; and (2) the Simstern, a simulated sternum that allows caregivers to experience the tactile sensations and forces associated with penetrating the skin, tissue, and bone and to insert the infusion through the cortical bone into the marrow space.

Participants

Ten paramedics from urban and rural stations of the British Columbia Ambulance Service, with training to at least the Emergency Medical Assistant Level-II, participated in the study at the Paramedic Academy of the Justice Institute of British Columbia. Participants were given 90 minutes of instruction in the use of the FAST 1 System using SimIO, Simstern, and the actual device. Prior to commencing the study, participants were required to demonstrate the successful use of the system and the protocol using the simulators.

Study Design

The paramedics were grouped into operator/observer pairs using the simulator system on each other. Each paramedic performed the procedure twice, for a total of 20 trials. The participants were asked to rate the system and the protocol in a non-patient environment. They also were asked to rate the system in common prehospital scenarios, including: (1) trauma; (2) cardiac arrest; (3) seizure; (4) patient transfer involving log-roll lift; (5) patient transfer involving full curl lift; and (6) patient transfer involving fore-and-aft lift. Criteria for evaluation were defined by the Paramedic Academy. Ratings were recorded on visual analog scales (with 0 representing the lowest rating and 10 representing the highest possible rating) and space was provided for subjective comments, which later were coded for content.

Placement accuracy and the time to perform the procedure were measured and recorded. Placement accuracy was measured by having each paramedic locate the site and place the target/strain relief patch on a live volunteer. Using a specially constructed gauge, the patch was marked with the target location for insertion, which is on the midline, 15 mm (0.59 in) below the lower curve of the suprasternal notch. Displacement between the target insertion site and the site identified by each paramedic's patch was measured and vertical and horizontal displacement was recorded.

The time to perform the basic procedure (including the time from opening the package to insertion of the infusion tube, commencement of fluid flow to the "subject", and time to stabilization of the site) was measured in real time using a stopwatch.

The ability of the paramedics to follow the protocol provided during training was assessed by having the observer complete a checklist.

Results

System Ratings

The results of the visual analog rating by the paramedics are summarized in Table 1. The group reported that the skill level required to insert the infusion tube only required the ability to hold the introducer perpendicular to the skin, push it in, and detect automatic release by the depth control mechanism. The only concern expressed by the paramedics was related to use of the IO system in conjunction with cervical spine immobilization devices. Some felt that the target/strain-relief patch was difficult to apply if a C-spine collar already was in place, although the target site itself did not interfere with the collar. The paramedics' comments and discussion at the time of the study indicated that this readily could be overcome by planning and minor adjustments to existing protocols.

Subjective comments are summarized in Table 2. In general, the subjective comments were supportive of the use of the FAST 1 device. Many of the paramedics believed the device was easier to use to gain intravascular access than is the more traditional cannulation of a peripheral vein. The device offered a good alternative to other methods for obtaining intravenous access.

Placement Accuracy

The mean value for device displacement in the vertical orientation was 2.0 ±2.0 (±1 standard deviation (SD)) toward the patient's head and in the horizontal orientation was 1.0 ±3.6 mm left (towards the patient's left side) (Figure 3).

Placement Time

The mean values for the time from opening the package to commencement of flow was 92 ±32 seconds (range 52–127 seconds) and from opening of the package to site stabilization was 96 ±31 seconds (range 58–130 seconds). The mean of the values for the times required for infusion tube placement time was 10.5 ±2.0 seconds.

Insertion Protocol

The paramedics performed the basic simulated insertions with only minor, non-critical deviations from the protocol, such as opening the package earlier than instructed.

Discussion

This study indicates that following simple training, paramedics are able to start IO infusions reliably and with minimal delay using the FAST 1 System in simulated field situations.

Intraosseous infusion using the FAST 1 System has the potential to improve success rates for obtaining vascular access and decrease some of the long delays associated with

		Mean ± Standard Deviation
1.	Did you find the protocol easy to follow on the first attempt?	8.8 ±1.1
2.	Did you find the protocol easier to follow with repeated attempts?	9.7 ±0.4
3.	Were there specific steps that were difficult to follow?	0.0 ±0.0
4.	Do you believe the system will be useful in the paramedic/military environment?	8.9 ±1.2
5.	Is the system designed appropriately for use in the paramedic/military medic environment?	8.7 ±1.4
6.	Do you believe the system is built strongly enough to withstand the forces applied to it during routine uses in the paramedic/military medic environment?	8.4 ±1.5
7.	Did the system meet what you perceive to be acceptable standards of performance when used concurrently with other interventions in the simulated prehospital environment?	9.1 ±0.8
8.	Did the system meet what you perceive to be acceptable standards of performance during patient transfer in the simulated prehospital environment?	8.9 ±1.1
9.	Is the system appropriately designed for ease of use and efficiency?	9.3 ±0.6
10.	Would you wish to use the system in the paramedic/military medic environment?	9.3 ±0.8

Table 1—Visual analog rating of the FAST 1 Intraosseous Infusion System

obtaining peripheral vascular access in the field. Patients who could benefit from rapid vascular access via IO infusion in the prehospital environment include those with peripheral venous collapse due to circulatory shock (e.g., heart failure, drug overdose, severe hemorrhage), or patients with other conditions that make peripheral venous access difficult, including widespread burns, peripheral edema, IV drug abuse, or prolonged IV therapy.[15,24,25] In the emergency department, these patients often require more time-consuming methods for obtaining access (cut downs, external jugular, or central line placement). Using a faster and more reliable means of obtaining intravascular access could enhance the resuscitation and treatment of these patients. To this end, intraosseous devices have been reissued for use by the military.[15]

Prior to the development of the FAST 1 System, significant problems existed with adult IO access methods, and for paramedics in the prehospital environment, peripheral IV access was the only realistic means of gaining vascular access in most adults.

Prior to this study, British Columbia Ambulance Service paramedics had expressed strong reservations about using IO devices. In contrast, the group studied strongly endorsed the FAST 1 System in their quantitative and subjective evaluations.

The FAST 1, which currently is the only device intended for sternal insertion, compared favorably with other IO systems studied by the military. This report contains illustrations of the device and detailed insertion methodology (Figures 1 and 4).[16] Maintaining constant pressure during insertion was identified as important for the FAST 1 and for the Bone Injection Gun (Wais Medical, Kress USA). The paramedics' studies also identified this as an important skill and one able to be mastered through training. The time from the decision to insert to the time of having a stabilized infusion site, was less for the devices not using the sternal site (range 70–90 seconds). However, the mean of the values for the FAST 1 of 114 (±36 seconds) was similar to the mean values of 92 ±32 seconds for all the devices, and all of the devices were inserted in <150 seconds.

The paramedics preferred the IO line to the peripheral lines for procedures like turning or lifting the patient. Peripheral lines often become tangled in clothing or bedding, and unless extreme care is taken to stabilize the site, the lines may be dislodged easily. The central location of the IO line in combination with the strain relief function of the target patch reduced the chance of entanglement or dislodgment. Comparisons between IO access and IV access, via saphenous vein cut down, indicate that success rates are higher for the IO route (92% vs. 69%) and time to initiate flow is shorter (3.9 vs. 7.6 minutes).[26]

The results of these studies justified a subsequent field trial of this IO system,[23] and the data were identified by the Federal Drug Administration as a major factor in expediting its full approval of the FAST 1.

Vascular access via the IO route now is feasible, rapid, technically safe, and more readily accepted.

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Questions	Number of Respondents	Content Coded Exposure
Do you believe the device will be useful in the paramedic/military medic environment?	8	Yes/Yes, extremely simple/Yes with special protocols/excellent second option
	3	Would improve quality of patient care
	2	Easy application makes device useful in remote areas where IV would be difficult to maintain. The more adverse the conditions, the greater the usage
Is the device designed appropriately for use in the paramedic/military medic environment?	6	Yes/Easy, fast. great access and protection, less chance of losing it vs. peripheral IV
	5	Yes with small/minor changes, small protocol adaptions
Do you believe the device is built stongly enough to withstand the forces applied to it during routine use in the paramedic/military medic environment?	6	Yes/absolutely/superior to standard IV/durable/yes with minor adaptions
	3	Less chance of dislodging
	1	Field is always different: wait and see
Did the device meet what you perceive to be acceptable standards of perfomance when used concurrently with other interventions in the simulated prehospital environment?	5	WIth minor modifications of standard protocols
	3	Yes, easier to deal with than peripheral IV
	1	A tradeoff, in some cases, placement caused some interference, in others, placement made life easier
Did the device meet what you perceive to be acceptable standards of performance during patient transfers in the simulated prehospital environment?	5	Yes, even easier/much easier than peripheral IV
	1	No worries of infusuion site, compared to IV with patients' arms
	1	Possible interference when fore-aft lifting heavier patients
Is the device appropriately designed for ease of use and efficiency?	5	Yes/leaps and bounds ahead of peripheral IVs/outstanding/yes as a last attempt for access/very easy, well thought out
	1	Yes, but would need to field test (always different than simulations)
Would you wish to use the device in the paramedic/military medic environment?	6	Yes/hopefully we will see them on car soon/ definitely want this device available as an alternative to IV
	1	Yes, chances of blood contamination would dramatically decrease

Table 2—Content coded responses to subjective questions about the FAST 1 (IV = intravenous)

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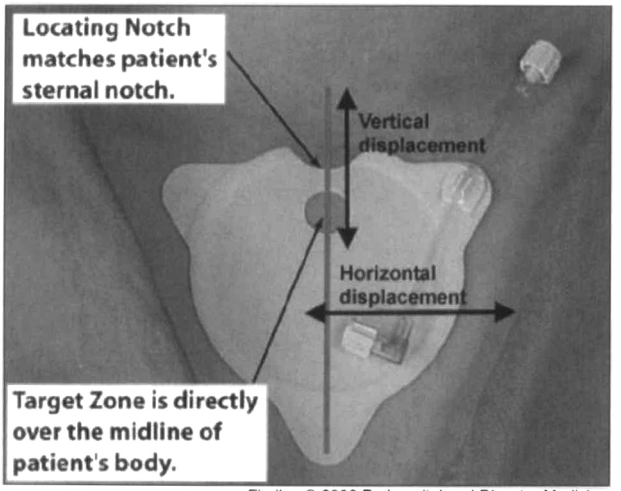

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Figure 3—Placement/displacement of the Target/Strain Relief Patch

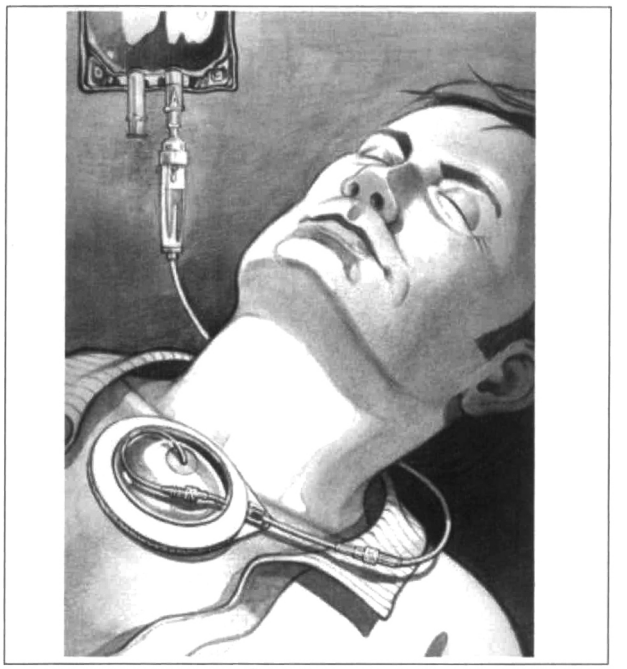

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Figure 4—Placement of the FAST 1 Intraosseous Infusion System

Conclusion

Following a 90-minute training session, 10 paramedics were able to use a prototype adult IO infusion system with high reliability and speed in simulated clinical trials. The FAST 1 was well-received by the paramedics. Their evaluation indicated that the system was easy to operate and compatible with other prehospital care protocols. They gave useful feedback on the effectiveness of training, ease of use, and design. Most paramedics believed that use of the sternal insertion site and strain relief mechanism made the device less likely to interfere with patient transport than was a peripheral IV line. Most also reported that the system was easier to initiate than a peripheral IV, and agreed that they would be confident using the system clinically. The data provided justification to proceed to a multi-center field trial and expedited Food and Drug Administration approval of the device.

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