

## An Observational, Prospective Study to Determine the Ease of Vascular Access in Adults Using a Novel Intraosseous Access Device<sup>+</sup>

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### Abstract

**Introduction:** Intraosseous access is an alternative to conventional intravenous access when access is difficult or impossible in the adult population. The EZ-IO™ is a novel intraosseous access device designed for use in adults, utilising a powered driver. **Materials and Methods:** A prospective, observational study involving a convenience sample of 25 medical students, physicians and nursing staff recruited as study subjects to secure intraosseous access using the EZ-IO™ powered drill device, on a bone model. **Results:** Twenty-three (92%) of the 25 study subjects required only 1 attempt at placing the EZ-IO™. There were 24 (96%) successful placements of the EZ-IO™. The average time taken to place the EZ-IO™ was 13.9 seconds. Twenty (87%) of 23 participants reported easier placement with the EZ-IO™ than an intravenous cannula. The average time taken for the physicians, nursing staff and medical students was 3.71 ( $\pm$  SD 1.70) seconds, 7.88 ( $\pm$  SD 4.02) seconds and 33.7 (24.5), respectively. Overall mean difficulty of insertion score (VAS) was 3.1 ( $\pm$  SD 1.9). **Conclusion:** The intraosseous access device evaluated in this study appears to be easy to use with high success rates of insertion with inexperienced participants. There is potential for use in the Emergency Department.

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**Key words:** Emergency department, Intravascular infusion, Resuscitation, Shock

### Introduction

Intravascular access is a vital component of emergency care and resuscitation. There is nothing more frustrating for the emergency physician than the inability to administer fluids or medications just because of the inability to obtain intravascular access. Rapidly securing vascular access will allow for the administration of fluids, pressor agents or other drugs. Insertion of an intravenous cannula may be a considerable challenge in the presence of shock or intravascular volume depletion, causing peripheral shutdown. Although other potential routes to obtain vascular access are available, for example central venous access, they can be time-consuming to establish.

Intraosseous (I/O) access is established as a safe and effective means to deliver resuscitative fluids and medication in a paediatric population.<sup>1-6</sup> The marrow cavity of long bones provide access to a non-collapsible venous plexus as abundant marrow sinusoids drain into large medullary venous channels which empty into systemic venous

circulation via nutrient and emissary veins. This intimate, non-collapsible vascular relationship allows the medullary cavity to be used for the purpose of infusions in emergency situations. Intraosseous access has recently been revived in adults as an alternative when conventional intravenous access may be difficult or impossible.<sup>7-9</sup> Early reports of I/O infusion in adults used the sternum. However, the distal tibia is advantageous because it also provides reliable and evident landmarks, has a relatively thin cortex, and is distant from ongoing resuscitative efforts. Medications and fluids that are infused via the I/O route can gain entry to the central circulation within seconds. The standard I/O needle has been compared with newer designed needles and most recently I/O access devices.<sup>7-9</sup>

We carried out a prospective, observational study to determine the ease of use of a novel I/O device amongst physicians, medical students and nursing staff in the Emergency Department using a bone model. We specifically compared successful insertion rates, insertion times,

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complications and difficulty of insertion scores among the 3 groups.

### Materials and Methods

A prospective, observational study was conducted involving a convenience sample of 25 medical students, physicians and nursing staff recruited as study subjects to secure intraosseous access using the EZ-IO™ powered drill device, on a bone model. This study was conducted under an exemption by the hospital Ethics Committee.

There were 8 physicians (residents), 6 medical students and 11 nursing staff. They had prior experience in intravascular access but none had experience in obtaining I/O access using a standard I/O needle.

A 2-page pilot questionnaire was administered to the group of 25. This questionnaire was developed for use in an on-going validation study for the use of the EZ-IO™ (EZ-IO™ System Driver model number 9050, PD needle set model 9018, AD needle set model 9001. Vidacare Corporation 722 Isom Road, San Antonio, Texas 78216 USA). This is a novel Federal Drug Administration (FDA) approved device which has 2 types of needles suitable for use in both adults and children for I/O vascular access. Successful placement, placement time, difficulties in using the device, adverse events to operator and types of malfunction of device were evaluated by the questionnaire. Placement time was recorded by an independent observer.

Figure 1 is a picture of the equipment used and included the EZ-IO™ driver and the EZ-IO™ needle set which consists of the EZ-IO™ catheter and the EZ-IO™ stylet. The participants were given instructions on the use of the EZ-IO™ and observed a demonstration on its use on a standard plastic bone model of the tibia as provided for by the manufacturer (Fig. 1). This involved locating the

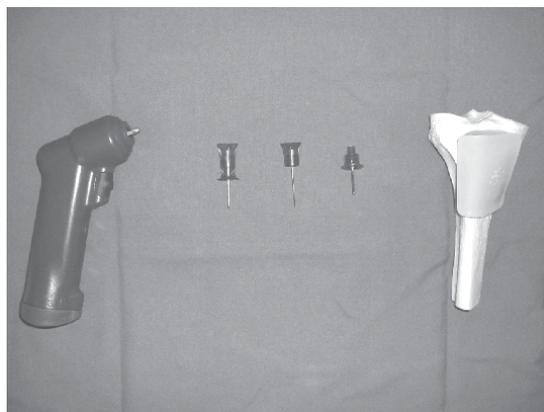


Fig. 1. Equipment used in this study.

Left to right: 1. EZ-IO™ driver 2. EZ-IO™ needle set which consists of the EZ-IO™ catheter and the EZ-IO™ stylet 3. EZ-IO™ stylet 4. EZ-IO™ catheter 5. Plastic bone model of the tibia as provided for by the manufacturer.

insertion site on the plastic bone model, preparing the EZ-IO™ driver and needle set and inserting the EZ-IO™ needle set while stabilising the plastic bone model. Thereafter, while stabilising the catheter hub, the EZ-IO™ driver was removed from the needle set. The stylet was then removed from the needle set.

The study participants subsequently attempted to obtain I/O access using the EZ-IO™ on the same plastic bone model. They were allowed multiple attempts in placement with the aim of ensuring success in placement. Placement times were measured by an independent observer with a stopwatch, from the time the participant placed the needle set into the driver and attempted to insert the needle with the EZ-IO™ into the plastic bone model. The difficulty of insertion was recorded by the participants on a 10-cm visual analog scale (VAS) with 0 representing very easy placement and 10 representing very difficult placement.

Data were entered using Microsoft Excel 2002 (version 10). Analysis was conducted using JMP version 5.1 (SAS Institute, Inc). Frequency tables and descriptive statistics for all covariates were calculated. Parametric distributions, means and standard deviations were reported in the format [mean (SD)], where appropriate. Univariate comparisons using *t*-tests, chi-square tests or Fisher's exact test were conducted to identify differences in distribution of covariates where appropriate. Statistical significance was set at  $P < 0.05$ .

### Results

There were 25 participants in the study and the response rate for the accompanying questionnaire was 100%. The EZ-IO™ insertion characteristics of the operators by groups are listed in Table 1. There were 24 (96%) successful placements of the EZ-IO™ and this was determined by confirming if the needle was firmly placed. Twenty-three (92%) of the 25 study participants required only 1 attempt at placing the EZ-IO™. Of the 2 (1 medical student and 1 physician) of the 25 requiring more than 1 attempt at placing the EZ-IO™, only the medical student was unsuccessful at securing placement of the EZ-IO™. The medical student failed due to unfamiliarity with the equipment and procedure, and hesitating beyond the allocated time given for insertion.

Table 2 shows the "ease of use" characteristics of each group of participants for EZ-IO™ insertion. Two participants were omitted from the analysis as they had not completed this section of the questionnaire. Table 3 lists all the complications experienced by the participants during EZ-IO™ insertion.

Figure 2 summarises data collected from the questionnaire about the subjective comparison of ease between using the EZ-IO™ with using an intravenous cannula when obtaining

Table 1. EZ-IO™ Insertion Characteristics of Participants

	Medical students n = 6	Physicians n = 8	Nursing staff n = 11	P
Multiple attempts needed (%)	1 (16.7)	1 (12.5)	0 (0)	0.41
EZ-IO firmly placed (%)	5 (83.3)	8 (100)	11 (100)	0.19
EZ-IO placed successfully (%)	5 (83.3)	8 (100)	11 (100)	0.19

Table 2. EZ-IO™ Insertion “Ease of Use” Characteristics by Participants

	Medical students (n = 5)	Physicians (n = 8)	Nursing staff (n = 10)	P
Good control of needle set (%)	5 (100)	8 (100)	10 (100)	NA
Needle separated from driver easily (%)	5 (100)	7 (87.5)	10 (100)	0.38
Stylet separated from needle easily (%)	5 (100)	8 (100)	10 (100)	NA
Difficulty removing needle from tibia (%)	3 (60)	1 (12.5)	1 (10)	0.06
Easier placement with the EZ-IO™ than an intravenous cannula (%)	3 (60)	6 (75)	9 (90)	0.40

NA: not applicable

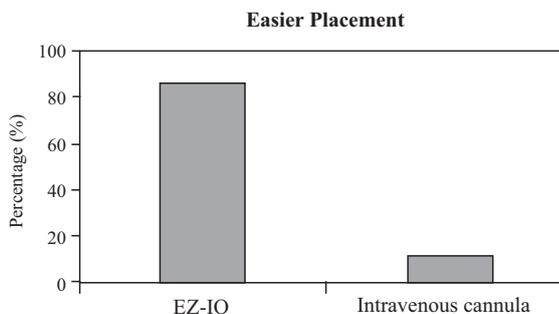


Fig. 2. Percentage of participants who felt EZ-IO™ placement was easier than an intravenous cannula when obtaining vascular access.

vascular access. Of the 5 who reported easier placement with an intravenous cannula, 2 were medical students, 2 were medical officers and 1 was a nursing staff.

Table 4 shows the mean placement time for each group of participants. Table 5 shows the mean difficulty score for each group of participants. The difficulty of insertion score was completed by 24 participants. Overall mean difficulty of insertion score (VAS) was 3.1 (1.9).

## Discussion

In our study, we found a 96% success rate using the EZ-IO™ by our participants. Physicians and nursing staff found it significantly easier to insert the EZ-IO™ than medical students.

There are 2 requirements for an effective medication route during cardiac resuscitations. The first is that it can be quickly placed; the second is that it will deliver medications to the vascular system in an efficient manner.<sup>10</sup> Likewise, rapid intravascular access can be important in trauma and non-trauma, medical emergencies. The I/O needle has been

Table 3. EZ-IO™ Complications Experienced by Participants

	Medical students n = 5	Physicians n = 8	Nursing staff n = 10	P
Puncture wound (%)	0 (0)	0 (0)	0 (0)	NA
Power failure (%)	0 (0)	0 (0)	3 (30)	0.11
Needle breakage (%)	0 (0)	0 (0)	1 (10)	0.51

NA: not applicable

previously demonstrated to be a rapid and effective method of vascular access<sup>11</sup> with a few studies comparing I/O access via a needle or I/O access device.<sup>9,12</sup>

Jun et al showed an 83% success rate with the Jamshidi needle and 76% using the SurFast in an animal model with 42 medical students in their first trial with both needles.<sup>8</sup> Calkins et al showed a 94% success rate for the First Access for Shock and Trauma (FAST, Pyng Medical) model, 94% using the Bone Injection Gun (BIG, Wais Medical, Kress USA Corporation), 97% using the SurFast (Cook Critical Care) and 97% with the Jamshidi needle with 31 military paramedical personnel on a cadaver model.<sup>9</sup> The only study in 19 patients using BIG showed 100% successful placement.<sup>13</sup>

The mean placement time in our study was 13.9 seconds. This appears to be faster than obtaining I/O access via other methods. In Calkins's study, the BIG took a mean placement time of 70 seconds, the FAST took 114 seconds, the SurFast 88 seconds and the Jamshidi needle, 90 seconds.<sup>9</sup> In Halm's cohort of 34 paramedical and paediatric residents, the mean placement times were 56.2 seconds and 25.2 seconds for the Cook and Jamshidi needle respectively.<sup>7</sup>

Table 4. Mean Placement Time of EZ-IO™ by Participants

	Medical students (n = 6)	Physicians (n = 7)	Nursing staff (n = 8)	P
Mean placement time (s) (SD)	33.7 (24.5)	3.71 (1.70)	7.88 (4.02)	0.01
95% confidence interval	22.3, 45.0	-6.77, 14.2	-1.93, 17.7	

Table 5. Mean Difficulty Score of EZ-IO™ Insertion by Participants

	Medical students (n = 6)	Physicians (n = 7)	Nursing staff (n = 11)	P
Mean difficulty score (scale of 1-10) (SD)	5.00 (1.41)	3.00 (2.38)	2.09 (0.70)	0.004
95% confidence interval	3.70, 6.30	1.80, 4.20	1.13, 3.05	

Jun's cohort showed 54 seconds and 33 seconds for the SurFast and Jamshidi needle respectively.<sup>8</sup>

In our study, the overall mean difficulty of insertion score (VAS) was 3.1 and this is comparable to 3.2 for the Jamshidi bone marrow needle in Jun's study.<sup>8</sup> We note that 87% in our study reported easier insertion with the EZ-IO™ as compared to an intravenous cannula.

Limitations of the study include the relatively small sample size. Also the use of a bone model may not adequately simulate the difficulties expected using the device on real patients. Thus insertion times may be longer in a true clinical setting. Another limitation is that potential complications could not be fully assessed given that this study was using a bone model and not live patients. Thus we are unable to comment on possible complications such as pain, infection or bleeding. Further clinical evaluation with clinical endpoints is warranted in future studies.

Nevertheless, we found that the EZ-IO™ appears to allow medical personnel with little prior experience of I/O access or even intravenous access to be able to achieve successful placement in a fast mean placement time. So far, the EZ-IO™ appears to be easy to use and we intend to follow-up with a clinical trial, using the device in the Emergency Department.

## Conclusion

The I/O access device evaluated in this study appears to be easy to use with high success rates of insertion with inexperienced participants. There is potential for use in the Emergency Department.

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