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Original Contribution

An observational, prospective study comparing tibial and humeral intraosseous access using the EZ-IO☆

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Abstract

Introduction: Intraosseous (IO) access is an alternative to conventional intravenous access. The proximal tibia and proximal humerus have been proposed as suitable sites for IO access.

Methods: A nonrandomized, prospective, observational study comparing flow rates and insertion success with tibial and humeral IO access in adults using the EZ-IO–powered drill device was conducted. The tibia was the first site of insertion, and a second IO was inserted in the humerus if clinically indicated for the same patient.

Results: Twenty-four patients were recruited, with 24 tibial and 11 humeral insertions. All EZ-IO insertions were successful at the first attempt except for 1 tibial insertion that was successful on the second attempt. All insertions were achieved within 20 seconds. Mean ease of IO insertion score (1 = easiest to 10 = most difficult) was 1.1 for both sites. We found tibial flow rates to be significantly faster using a pressure bag (165 mL/min) compared with those achieved without a pressure bag (73 mL/min), with a difference of 92 mL/min (95% confidence interval [CI]: 52, 132). Similarly, humeral flow rates were significantly faster using a pressure bag (153 mL/min) compared with humeral those achieved without pressure bag (84 mL/min), with a difference of 69 mL/min (95% CI: 39, 99). Comparing matched pairs (same patient), there was no significant difference in flow rates between tibial and humeral sites, with or without pressure bag infusion.

Conclusions: Both sites had high-insertion success rates. Flow rates were significantly faster with a pressure bag infusion than without. However, we did not find any significant difference in tibial or humeral flow rates.

1. Introduction

Rapid intravascular access is a vital component of emergency care and resuscitation. Rapidly securing vascular access may be a considerable challenge in the presence of shock or intravascular volume depletion, causing peripheral venous shutdown. Intraosseous (IO) access is an alternative to conventional intravenous access. The proximal tibia [1,2] and, more recently, the proximal humerus have been proposed as suitable sites for IO access [3].

Intraosseous access is established as a safe and effective means to deliver resuscitative fluids and medications in a pediatric population [3-9]. The marrow cavity of long bones provides access to a noncollapsible venous plexus as

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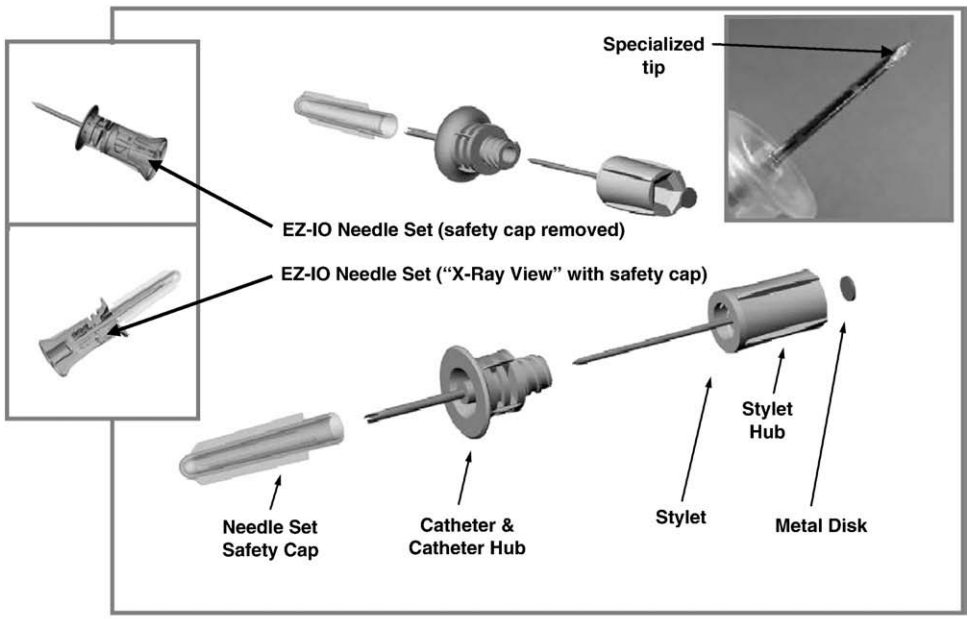
abundant marrow sinusoids drain into large medullary venous channels, which empty into systemic venous circulation via nutrient and emissary veins. This intimate, noncollapsible vascular relationship allows the medullary cavity to be used for the purpose of infusions in emergency situations. Intraosseous access has recently been revived in adults as an alternative when conventional intravenous access may be difficult or impossible [2,10-15]. The standard IO needle has been compared with newer designed needles and, most recently, IO access devices [2,9,10,14,16-18]. Early reports of IO infusion in adults used the sternum [11,19]. However, the proximal tibia is advantageous because it also provides reliable and evident landmarks, has a relatively thin cortex, and is distant from ongoing resuscitative efforts. Likewise, the proximal humerus has been proposed as an alternative insertion site because it is a large long bone, with easily palpated landmarks. However, there have not been any studies comparing the flow rates and relative ease of insertion for these 2 sites.

We carried out a nonrandomized, prospective, observational study comparing infusion flow rates with tibial and humeral IO access in adults using the EZ-IO–powered drill device (Fig. 1). We also compared rates of successful placement, placement time, difficulties in using the device, and adverse events for the 2 sites.

1. EZ-IO driver



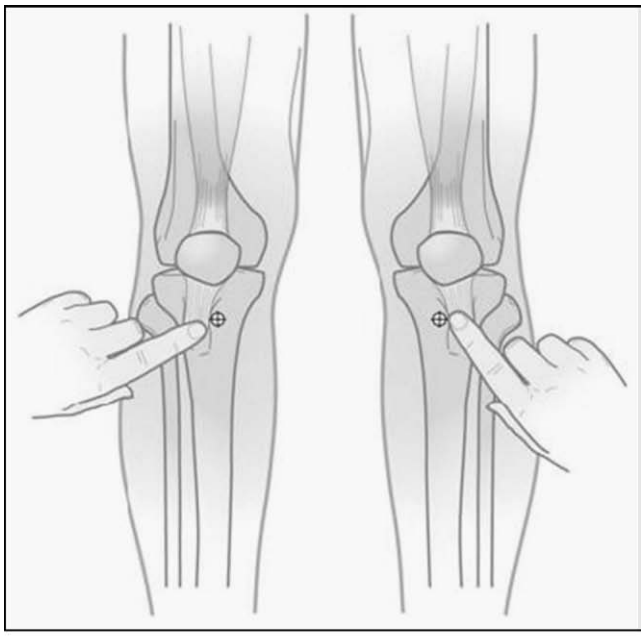
2. EZ-IO needle set which consists of the EZ-IO catheter and the EZ-IO stylet

Fig. 1 Equipment used in this study. Pictures reprinted with permission from Vidacare Corporation.

2. Methods

We conducted a nonrandomized, prospective, observational study comparing flow rates with tibial and humeral IO access in adults using the EZ-IO–powered drill device. This study was approved by the hospital Ethics Committee.

The study population was patients who presented to the Emergency Department of Singapore General Hospital, an urban tertiary hospital. Inclusion criteria were patients who presented to the emergency department with age older than 16 years or >40-kg body weight requiring intravenous fluids or medications and in whom an intravenous line could not be established in 2 attempts or 90 seconds. They also had to be seriously ill or injured, meaning that they had to exhibit 1 or more of the following:



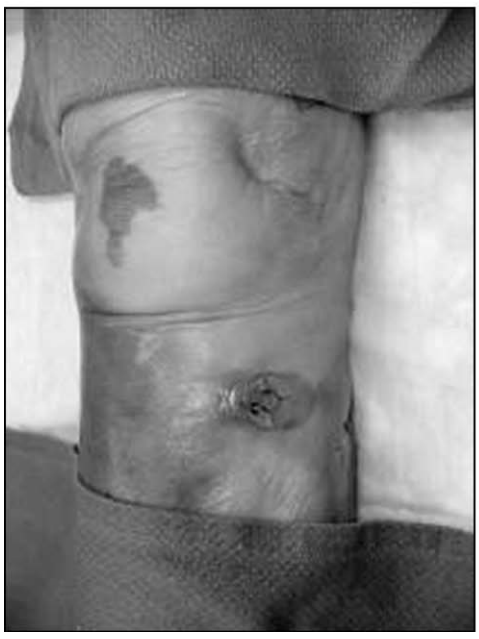


Fig. 2 Location of proximal tibia site for EZ-IO placement. Pictures reprinted with permission from Vidacare Corporation.

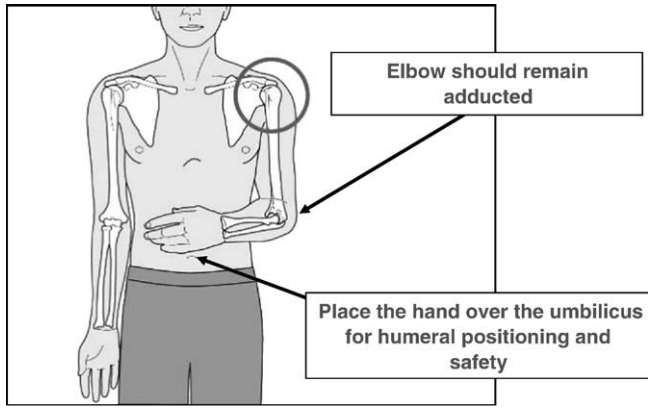


Fig. 3 Location of proximal humeral site for EZ-IO placement. Pictures reprinted with permission from Vidacare Corporation.

a. An altered mental state (Glasgow Coma Score [GCS] of 8 or less)
b. Respiratory compromise (oxygen saturation [Sao_2] 80% after appropriate oxygen therapy, respiratory rate <10 or >40 breaths per minute)
c. Hemodynamic instability (systolic blood pressure of <90 mm Hg) or profound hypovolemia (signs and symptoms of shock)
d. Cardiac arrest (medical or traumatic)

Insertion of an IO needle was contraindicated if there was a fracture of the tibia or femur (consider alternate tibia), similarly for the humerus. Other contraindications included recent surgery in the extremity to be used or previous orthopedic procedure (knee replacement) or IO within 24 hours (consider alternate tibia/humerus), preexisting medical condition (tumor near insertion site or peripheral vascular disease), infection at insertion site (consider alternate tibia/humerus), or significant edema in the extremity to be used. Inability to locate landmarks and excessive tissue at insertion site were also contraindications.

The tibia was the first site of insertion, and a second IO was inserted in the humerus if clinically indicated for the same patient. The correct anatomical site for the proximal tibia is shown in Fig. 2 and the proximal humerus in Figs. 3 and 4. If intravenous saline infusion was started for patients, it was initially without a pressure bag, then with a pressure bag device applied to the infusion.

The EZ-IO is a newly Food and Drug Administration–approved device for adult IO vascular access. It uses a reusable battery-powered driver and a disposable IO needle set. The driver powers the needle into the IO space by rotating it to a preset depth (EZ-IO System Driver model number 9050, Pediatric needle set model 9018, Adult needle set model 9001; Vidacare Corporation, San Antonio, Tex).

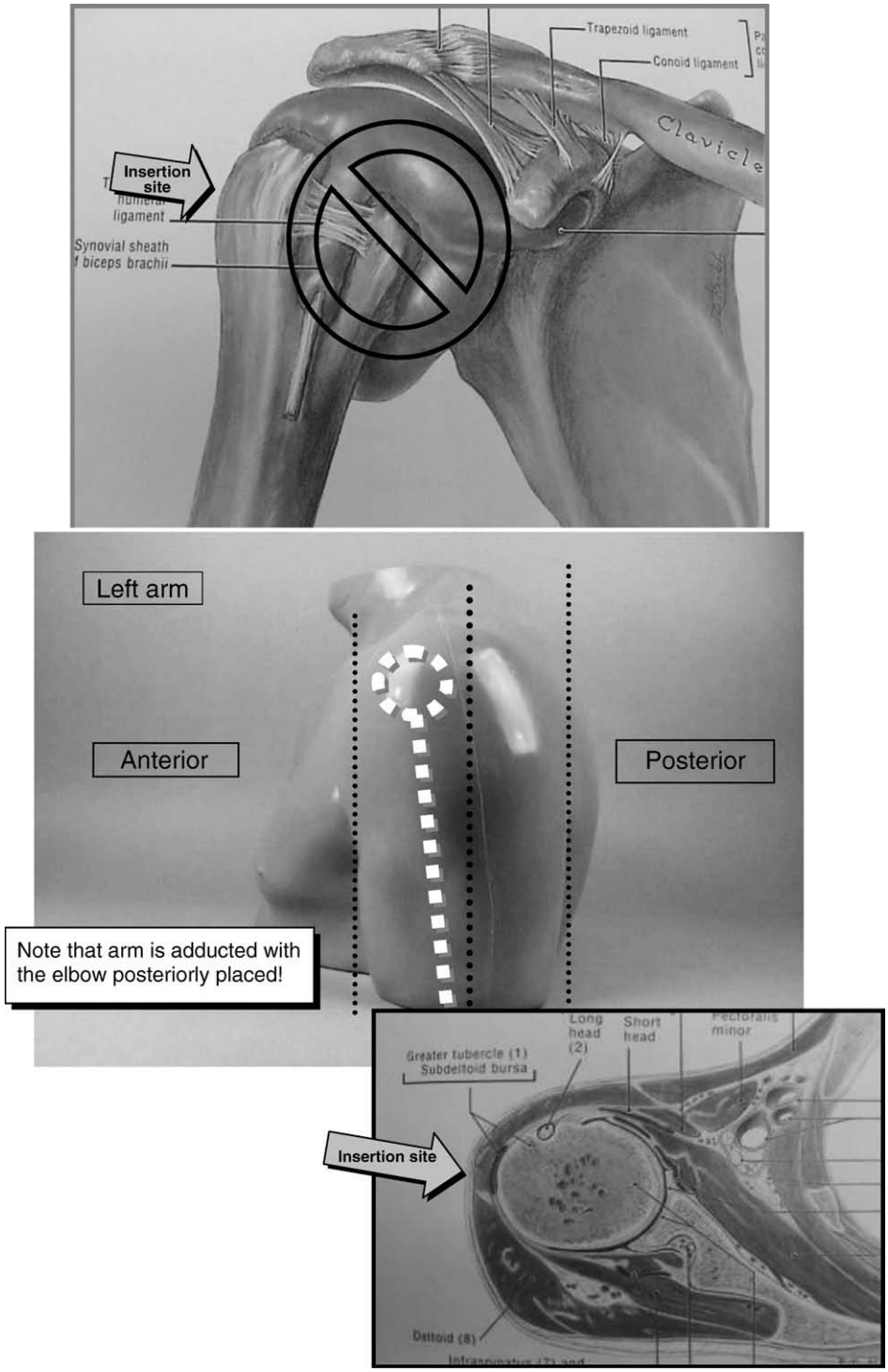


Fig. 4 Lateral view of the location of the proximal humeral site for EZ-IO placement. Pictures reprinted with permission from Vidacare Corporation.

Fig. 1 shows the equipment used including the EZ-IO driver and the EZ-IO needle set, which consists of the EZ-IO catheter and the EZ-IO stylet. This device has 2 types of needles, one suitable for use in adults and another in children for IO vascular access.

The outcomes that were assessed included the success rate of EZ-IO insertion by operators as defined by the ability to place the IO needle, as well as the successful infusion of fluids and drugs. Flow rates using normal saline infusion were measured by an independent nurse observer. Methods of IO needle placement confirmation, estimated total time of insertion, fluids and drugs administered, ease of use and the control and function of the EZ-IO device, any complications, problems encountered in using the device, adverse events to

operator, and types of malfunction of device were evaluated by a questionnaire. Placement time was recorded by the individual operator, from the time the operator placed the needle set into the driver until the time the needle was successfully inserted into the bone. The difficulty of insertion was recorded by the doctor on a 10-cm visual analog scale with 0 representing very easy placement and 10 representing very difficult placement.

Only emergency physicians and medical residents who were trained in the use of the EZ-IO by completing the manufacturer's training program and who were familiar with the protocol were allowed to use the device. The physicians 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 by the manufacturer. This involved locating the insertion site on the plastic bone model, preparing the EZ-IO driver and needle set and inserting the EZ-IO needle set while stabilizing the bone. Thereafter, while stabilizing 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 were subsequently allowed multiple attempts to obtain IO access using the EZ-IO on the plastic bone model.

During actual IO placement, needle placement was confirmed by visualization of blood on the stylet, ability to aspirate bone marrow, firm placement of the needle in the bone, and ability to smoothly deliver a fluid flush. Operators were instructed to give a rapid flush (bolus) of 10 mL saline with a syringe through the EZ-IO, once needle placement was confirmed. Routine use of a pressure bag or pump was recommended for continuous infusions. For conscious patients, a prior flush (bolus) of 20 to 50 mg 2% lidocaine (preservative-free) through the EZ-IO was recommended.

Patients were followed up until hospital discharge for any complications of IO insertion, including needle displacement, fractures, infection of the insertion site, osteomyelitis, fat embolism, extravasation, or compartment syndrome.

Based on a previous pilot study, for the outcome of "comparison of flow rate without pressure bag for tibial versus humeral sites," we expected a tibial rate of 70.0 mL/min, and for the humerus, it was 90.0 mL/min, with an expected difference of 20.0 mL per minute (standard deviation = 30.0). Thus, we estimated a sample size of 20 per group for 80% power.

Data were entered using Microsoft Excel 2002 (version 10) and analyzed using SPSS version 14.0 (SPSS, Chicago, Ill). Frequency tables and descriptive statistics for all covariates were calculated. For parametric distributions, means and SD were reported in the format [mean (SD)], where appropriate. Univariate comparisons using t tests, χ^2 tests, or Fischer exact test were conducted to identify differences in distribution of covariates where appropriate. Ninety-five percent confidence interval (CI) for the differences in flow rates between the tibia and humerus groups was calculated. Matched pairs were used, with the same patient having both tibial and humerus insertions. Statistical significance is set at $P < .05$.

3. Results

From March 1, 2006 to July 30, 2007, 24 patients were recruited, with 24 tibial and 11 humeral insertions. The characteristics of the cases are listed in Table 1. There we no significant differences between tibial and humeral insertions in terms of age, race, sex, GCS at presentation, operator, trauma, or medical etiology. All EZ-IO insertions were successful at the first attempt except for one tibial insertion that was successful on the second attempt. All insertions

Table 1 Characteristics of study participants

	Tibia, n = 24	Humerus, n = 11	*P*
Age, y			.439
16 – 29	8.3	18.2	
30-59	33.3	45.5	
>60	58.3	36.4	
Race			.512
Chinese (%)	68.2	54.5	
Indian (%)	18.2	36.4	
Malay/Others (%)	13.6	9.1	
Male	54.2	54.5	.983
GCS 8-15	65.2	70.0	1.0
GCS <8	34.8	30.0	
Operator			.640
Resident	79.2	90.9	
Attending/Consultant	20.8	9.1	
Trauma	16.7	36.4	.226
EZ-IO placed successfully (%)	100.0	100	1.0
Multiple attempts needed (%)	4.2	0	.38
EZ-IO firmly placed (%)	100	100	–
Good control of needle set (%)	100	100	–
Needle separated from driver easily (%)	100	100	–
Stylet separated from needle easily (%)	100	100	–
Difficulty removing needle from tibia/humerus (%)	4.2	9.1	.627
Easier placement with the EZ-IO than an intravenous cannula (%)	87.5	90.9	1.0
Lignocaine used	87.5	81.8	.897
No flow initially	4.2	0	1.0
Low flow rates	16.7	0	.285
Medication or fluid: cardiac	58.3	45.5	.478
Sedative	0	0	–
Paralytic	0	0	–
NS [a]	79.2	90.9	.640
Glucose	4.2	0	1.0
Other	4.2	0	1.0

[a] A small number of patients did not receive saline infusions because the attending clinician decided that this was not indicated, or they used alternative fluids (eg, colloids).

Table 2 Comparison of flow rates with/without pressure bag

Flow rate	Tibia (mL/min)	Humerus (mL/min)
No pressure bag	73.0 (35.4)	84.4 (37.5)
With pressure bag	165.3 (112.5)	153.2 (65.0)
Difference	−92.3	−68.8
95% CI	−132.2 to −52.3	−99.0 to −38.7

Table 4 Mean placement time of EZ-IO

Placement time (s)	Tibia	Humerus	*P*
1-3	50.0	54.5	.706
4-6	37.5	36.4	
7-10	8.3	0	
11-20	4.2	9.1	

were firmly placed, with good control of the needle set and separation from the driver. In 1 case from each group, some difficulty was reported during needle removal, but this was eventually successful with no complications. Eighty-seven percent of tibial insertions and 90.9% of humeral insertions were reported easier than intravenous cannulation.

Table 2 shows the flow rates of each group with and without pressure bag application. We found tibial flow rates to be significantly faster using a pressure bag (165 mL/min) compared with those achieved without a pressure bag (73 mL/min), with a difference of 92 mL/min (95% CI: 52, 132). Similarly, humeral flow rates were significantly faster using a pressure bag (153 mL/min) compared with those without a pressure bag (84 mL/min), with a difference of 69 mL/min (95% CI: 39, 99). Table 3 shows the comparison of flow rates between tibial and humeral insertions. Comparing matched pairs (same patient), there was no significant difference in flow rates between tibial and humeral sites, with or without pressure bag infusion.

Table 4 shows the mean placement time for each group of insertions. All insertions were within 20 seconds. Table 5 shows the mean "ease of use" score for each group. There was no significant difference between both groups for ease of use and the average pain on insertion, which was rated by the patient.

There were no reported complications such as needle displacement, failure of the drill device to function properly, fractures, infection of the insertion site, osteomyelitis, fat embolism, extravasation, or compartment syndrome.

4. Discussion

In our study, we found that both tibial and humeral sites had high insertion success rates. Intraosseous flow rates were significantly faster with a pressure bag infusion than without. However, we did not find any significant difference in tibial or humeral flow rates.

The IO needle has been previously demonstrated to be a rapid, effective method of alternative vascular access [2,3,9,11,14,18]. We found that the IO needle could be rapidly and safely inserted in both the proximal humerus and proximal tibia by previously inexperienced operators. Previous studies have also shown that emergency drugs and fluids can be rapidly delivered to the systemic circulation, at comparable rates to the intravenous and central venous routes [20,21].

We found that the use of a pressure infusion bag was able to significantly improve fluid flow rates via the IO needle. This is similar to a previous report using pediatric IO needles [22], although we were able to achieve higher flow rates using adult IO needles. We found that the mean flow rates of 165mL/min (tibia) and 153 mL/min (humerus) achieved with a pressure bag was subjectively able to provide the necessary volume resuscitation in our patients, although we did not objectively correlate this with improvement in physiologic parameters. In a pilot study, it seemed that the proximal humerus site was able to give higher flow rates compared with the proximal tibial site. However, we were unable to demonstrate any significant difference in flow rates between the 2 sites.

Various sites have been proposed as suitable for IO insertions, including the proximal tibia [1,2,11], distal tibia [10], sternum [2,10,11,19], radius [15], clavicle [12], proximal humerus, and calcaneum [23]. The ideal insertion site should be a large long bone, with easily identifiable landmarks; superficial; and easy to access percutaneously and proximal, to allow for rapid access of any fluids or medications to the central circulation. In addition, it should be away from vital areas where other resuscitation procedures are ongoing and away from vital structures, which might get inadvertently punctured during insertion. For example, the sternal and clavicular sites present problems when airway

Table 3 Comparison of flow rates between tibia and humerus insertions

Flow rate	Tibia, n = 11	Humerus, n = 11	Difference	95% CI
No pressure bag (mL/min)	71.7 (33.9)	82.5 (37.6)	−10.8	−34.7 to 13.0
With pressure bag (mL/min)	145.4 (70.9)	145.0 (61.4)	0.4	−35.2 to 36.1

For this analysis, we used only matched pairs, meaning we excluded all those patients who did not have both a tibia and humerus insertion.

Table 5 Ease of use score and insertion pain of EZ-IO insertion

	Tibia	Humerus	*P*
Mean ease of use score (cm) (SD)	1.09 (0.68)	1.09 (0.30)	1.0
Average insertion pain (SD)	1.76 (0.83)	2.0 (0)	.726

procedures and cervical immobilization are ongoing in trauma resuscitation. Likewise, the investigators felt that the distal tibia, radius, and calcaneal sites would be relatively distal to the central circulation. Thus, the proximal tibia and proximal humerus sites were chosen for this study. It was felt that the proximal tibia site should be the initial insertion site of choice because the landmarks were obvious, with little soft tissue obstructing the insertion point, and operators would be familiar with the site from pediatric precedents. The proximal humerus was selected as the backup site in the event that intravenous cannulation was still unsuccessful after initial resuscitation. However, we note that the proximal humerus site may not be as intuitively easy to identify. Care has to be taken during insertion to keep the arm in the adducted and internally rotated position (Fig. 3). The insertion site is slightly anterior to the lateral midline of the arm, and care should be taken to avoid the bicipital groove (Fig. 4).

Previously reported complications associated with IO insertions include osteomyelitis [24], extravasation [25], fat embolism [26], compartment syndrome [27], growth plate abnormalities [28], and myonecrosis with hypertonic saline infusion [29]. There were no reported complications with the device in this study, except for 2 cases in which the ward staff reported difficulty removing the needle. However, the needles were both successfully removed once the correct technique was applied. The correct technique involves using a rotating and pulling movement, rather than rocking the needle, which may cause it to break. Also, the needle comes with a Luer lock that can be attached to a syringe to use as a handle for additional traction during removal.

Limitations of the study include the relatively small sample size. We were unable to achieve our targeted sample size for the proximal humerus group because not all these patients had a clinical indication to insert a second IO needle. In many cases, subsequent intravenous cannulation was successful, once initial resuscitation had been initiated through the tibial IO. Thus, our sample size was insufficient to prove equivalence in flow rates between the 2 sites.

Also, the insertion times were not recorded by an independent observer due to the logistic difficulty of having an investigator present at every resuscitation. We also note that insertion times may be longer in a true clinical setting because some time is needed to assemble the driver and needle. However, this time is minimal compared with the actual insertion procedure.

Finally, a small number of patients did not receive saline infusions (see Table 1) because the attending clinician decided that this was not indicated, or they used alternative fluids (eg, colloids). These cases were excluded from the comparison of flow rates.

Nevertheless, we found that the EZ-IO seems to allow medical personnel with little prior experience of adult IO access to be able to achieve successful placement in a fast mean-placement time. The EZ-IO seems to be easy to use with few complications. Both tibial and humeral sites had high-insertion success rates. We recommend the proximal tibial insertion site as the first site of choice for the reasons mentioned previously. However, the proximal humerus seems to be a good alternative site, if tibial placement is contraindicated, or a second IO insertion is clinically indicated. We also recommend routine use of a pressure infusion bag to improve flow rates.

5. Conclusions

Both proximal tibial and humeral sites had high-insertion success rates. Intraosseous flow rates were significantly faster with a pressure bag infusion than without. However, we did not find any significant difference in tibial or humeral flow rates.

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