



CLINICAL PAPER

# Comparison of two intraosseous infusion systems for adult emergency medical use<sup>☆</sup>

Thorsten Brenner<sup>a,1</sup>, Michael Bernhard<sup>a,\*,1</sup>, Matthias Helm<sup>b</sup>, Sara Doll<sup>c</sup>, Alfred Völkl<sup>c</sup>, Nicole Ganion<sup>a</sup>, Claudia Friedmann<sup>a</sup>, Marcus Sikinger<sup>a</sup>, Jürgen Knapp<sup>a</sup>, Eike Martin<sup>a</sup>, André Gries<sup>a,d,e</sup>

<sup>a</sup> Department of Anaesthesiology and Emergency Medicine, University of Heidelberg, D-69120 Heidelberg, Germany

<sup>b</sup> Department of Anaesthesiology and Intensive Care, Federal Armed Forces Medical Centre, Ulm, Germany

<sup>c</sup> Institute for Anatomy and Cell Biology, University of Heidelberg, Germany

<sup>d</sup> German Air Rescue, Helicopter unit "Christoph 53", Heidelberg/Mannheim, Germany

<sup>e</sup> Department of Interdisciplinary Emergency Medicine, Hospital of Fulda gAG, Germany

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## KEYWORDS

Intraosseous access;  
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## Summary

**Introduction:** The current guidelines of the European Resuscitation Council (ERC) stipulate that an intraosseous access should be placed if establishing a peripheral venous access for cardiopulmonary resuscitation (CPR) would involve delays. The aim of this study was therefore to compare a manual intraosseous infusion technique (MAN-IO) and a semi-automatic intraosseous infusion system (EZ-IO) using adult human cadavers as a model.

**Materials and methods:** After receiving verbal instruction and giving their written informed consent, the participants of the study were randomized into two groups (group I: MAN-IO, and group II: EZ-IO). In addition to the demographic data, the following were evaluated: (1) Number of attempts required to successfully place the infusion, (2) Insertion time, (3) Occurrence of technical complications and (4) User friendliness.

**Results:** Evaluation protocols from 84 study participants could be evaluated (MAN-IO:  $n = 39$  vs. EZ-IO:  $n = 45$ ). No significant differences were seen in the study participants' characteristics. Insertion times (MW  $\pm$  S.D.) of the respective successful attempts were comparable (MAN-IO:  $33 \pm 28$  s vs. EZ-IO:  $32 \pm 11$  s). When using the EZ-IO, the access was successfully established significantly more often on the first attempt (MAN-IO: 79.5% vs. EZ-IO: 97.8%;  $p < 0.01$ ). The EZ-IO was also found to have more advantages in terms of technical complications (MAN-IO: 15.4% vs. EZ-IO: 0.0%;  $p < 0.01$ ) and user friendliness (school grading system: MAN-IO:  $1.9 \pm 0.7$  vs. EZ-IO:  $1.2 \pm 0.4$ ;  $p < 0.01$ ).

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\* Corresponding author at: Department of Anaesthesiology and Emergency Medicine, University of Heidelberg 110, Im Neuenheimer Feld, D-69120 Heidelberg, Germany. Tel.: +49 6221 56 6351; fax: +49 6221 56 5345.

E-mail address: [Michael.Bernhard@med.uni-heidelberg.de](mailto:Michael.Bernhard@med.uni-heidelberg.de) (M. Bernhard).

<sup>1</sup> Th. Brenner and M. Bernhard contributed equally as first author of this work and in preparing the original research paper.

*Conclusions:* In an adult human cadaver model, the semi-automatic system was proven to be more effective. The EZ-IO gave more successful results, was associated with fewer technical complications, and is user friendlier.

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## Introduction

Clinical studies have shown that an intraosseous access is safe, simple, and effective and is associated with a low rate of complications.<sup>1,2</sup> Although the intraosseous approach is commonly only recommended as an alternative to peripheral venous access in children, it can also be established successfully in adult patients.<sup>3</sup>

Likewise, the current guidelines of the European Resuscitation Council (ERC) stipulate that an intraosseous access should be placed in both pediatric and adult emergency patients if it is difficult or impossible to establish a peripheral venous access for cardiopulmonary resuscitation (CPR).<sup>4,5</sup> Therefore, intraosseous infusion represents the second-choice route of access for administering medications whereas the endotracheal route is only recommended if neither an intravenous nor an intraosseous access can be established.

The development of new devices increases the options available for vascular access through the intraosseous route, particularly for adult patients [e.g., EZ-IO (Vidacare, San Antonio, USA), COOK IO needle (Cook Med. Inc., Bloomington, USA), Bone Injection Gun (WaisMed Ltd., West Hempstead, New York, USA), and F.A.S.T.1™ (PYNG Medical Cooperation, Richmond, BC, Canada)]. Nevertheless, only little experience has been gained so far in establishing an intraosseous access with different intraosseous infusion systems in adult emergency patients.

The aim of this prospective study was therefore to test a classic, manual infusion technique (COOK IO needle) and a new, semi-automatic intraosseous infusion system (EZ-IO) using adult human cadavers as a model. The two systems were compared in terms of insertion times, success rates and the aspect user friendliness.

## Materials and methods

### Study participants

Attendees of the Sixth Invasive Emergency Techniques (INTECH-) seminar in Heidelberg in 2006 voluntarily participated in the study. Before study began, the indications, performance and the potential complications of the two techniques were described in detail as part of the seminar in a 45 min-target-lecture. Thereafter, in a 15 min demonstration an expert showed how to perform the techniques on a human cadaver. By using modern television technology, each participant followed the demonstration on a separate colour monitor in an adjacent seminar room for an optimal view on site. The participants had not been trained on either of the devices before the study began. All participants were verbally informed about the intention of the present study and they gave their written informed consent to take part in the study.

### Material for practice

The human cadavers used for practice and demonstration purposes were prepared before the seminar at the Anatomical Institute by injecting isopropyl alcohol, lysoformin, formalin, glycerin and water into the femoral artery. By using this fixation technique, the bone structure of the cadavers is not changed. However, subcutaneous tissue is far more rigid. Therefore, the intraosseous infusion was placed in the area of the malleolus medialis of the distal tibia. The bone in this area is known to be relatively superficial and only covered by a thin layer of subcutaneous tissue. This excluded any fixation-related difficulties in finding the puncture site and enabled nearly life-like conditions for placing the intraosseous infusion in the cadaver.

### Study design, data collection, and analysis

The study protocol was approved by the local ethical committee. The participants of the Sixth Invasive Emergency Techniques seminar in Heidelberg were divided into two groups according to the randomized, non-blinded, prospective clinical study protocol. Group I employed the manual intraosseous infusion system (MAN-IO) (Cook Med. Inc., Bloomington, USA) (Figure 1), and group II evaluated the semi-automatic intraosseous infusion system (Vidacare, San Antonio, USA) (Figure 2, Table 1).

The manual intraosseous infusion system consists of an infusion cannula (15.5 gauge (G)) with a knob at the end. This manual infusion cannula operates under constant pressure and slight rotary motion until loss-of-resistance is achieved after penetrating the outer layer of the bone and then administers fluid in the marrow space. The semi-automatic system (EZ-IO) consists of a multiple-use, rechargeable battery-powered device with integrated two beveled, hollow drill-tipped needles. The depth of the intraosseous



**Figure 1** Intraosseous puncture using MAN-IO in a human cadaver model.



**Figure 2** Intraosseous puncture using EZ-IO in a human cadaver model.

puncture is not generally determined by means of “loss-of-resistance” in this technique but rather the needle length specifies the individual puncture depth. To establish the intraosseous access in adult patients (>39 kg), the infusion needle is 25 mm long in total and for use in pediatric patients (3–39 kg) 15 mm long in total. The outside diameter (1.8 mm) of the available needles does not differ and is 15 G for both.

The study-relevant data were collected anonymously by using a three-part evaluation form. Part I included the demographic data for the participants (age and sex) and their professional experience (specialty area, function, total professional experience, and experience as emergency physician). Furthermore, each individual’s previous experience in placing an intraosseous access in humans in an

emergency situation was evaluated (number of intraosseous accesses placed up to the time point of the evaluation).

In part II of the evaluation form, data were collected with regard to insertion time in seconds for the given access procedure. This was defined as the time interval between taking the intraosseous infusion system out of the original packaging to actually inserting the needle into the bone and up to problem-free intraosseous administration of 10 ml saline solution as a test dose directly through the needle without using an infusion line extension.

The following were taken as sure signs of a successful intraosseous puncture within the scope of the present study in the adult cadaver:<sup>6–8</sup>

1. A sudden loss of resistance as a clue that the osseous cortex had been penetrated.
2. A stable and springy hold after releasing the stylet from the intraosseous needle.
3. The problem-free injection of saline solution as the safest sign for correct needle position. At this point, no soft tissue swelling around the drilling canal should appear, which represents a direct sign of extravasation.

Furthermore, we recorded the number of attempts each participant needed until the intraosseous access was successfully in place. After an unsuccessful attempt we stopped measuring the time. The next attempt and, as a consequence, also a new time measurement, was started immediately. Each participant was allowed a maximum of three attempts to successfully establish the access; otherwise, the puncture procedure was considered as unsuccessful. In addition, we documented the occurrence of complications in terms of technical failure of the puncture procedure because of device failure (e.g., needle breakage, bent needle, or defective batteries) that ultimately made it impossible to inject the saline solution.

In part III of the evaluation form we rated subjectively the user friendliness according to the grading system used at schools (1 = excellent to 6 = failure).

**Table 1** Product specifications of the investigated intraosseous infusion systems

	MAN-IO	EZ-IO
Manufacturer	Cook Med. Inc., Bloomington, USA	Vidacare, San Antonio, USA
Weight (g)		
Needle	20	5
Device	–	455
Dimensions (cm × cm/G)		
Needle	3.5 × 6.50/15.5	1.8 × 5.8/15
Device	–	14 × 9 × 5
Original packaging	10.5 × 10.5	21 × 15 × 5.7
Price (Euro)		
Needle	57.50	80.00
Device	–	228.00
Durability (years)		
Needle	5	5
Device	–	10
Reusability (yes/no)		
Needle	No	No
Device	–	Yes (up to 1000 insertions)

## Statistical analysis

All study data were entered into an electronic database (Microsoft® Excel 2002, Germany) and evaluated by using SPSS (Version 11.5.1). The results were presented as absolute values, percentages, median with the accompanying quartiles or differences of the quartiles, mean (±standard deviation) and minimal/maximal numerical value. The Kolmogorov–Smirnov test was applied to check for normal distribution. If distribution was found to be normal (age of the participants) the statistical difference between mean ± standard deviation was analyzed using student’s *t*-test. For not normally distributed data, using the Mann–Whitney *U*-test for unlinked random checks, we determined, whether the differences between the respective medians (professional experience and experience as emergency physician, insertion times for each successful attempt) were significantly different. With the help of the chi-squared test, frequency differences among the different characteristics (sex, active emergency physician, not emergency physician, area of specialty, number of attempts, and technical complications) were checked between the two

**Table 2** Insertion times, success rates and technical complications

	MAN-IO (n = 39)	EZ-IO (n = 45)	p
Insertion times			
Successful attempts (s)	33 ± 28; 14–180 (26; 23; 33; 10)	32 ± 11; 15–78 (31; 26; 39; 13)	0.10
Success rates			
First attempt successful (%)	79.5	97.8	<0.01
Second attempt successful (%)	7.7	0.0	0.07
Third attempt successful (%)	0.0	2.2	0.32
No attempt successful (%)	12.8	0.0	<0.02
Technical complications			
Needle bent/broken (%)	15.4	0.0	<0.01

MW ± S.D.; min–max (Median; Q1; Q3; Q3–Q1).

study groups. Furthermore, the chi-squared test was used for comparing the previous individual experience (had performed intraosseous punctures before study participation) and the user friendliness between the two study groups. A value of  $p < 0.05$  was considered to be significant.

## Results

### Demographic data and previous professional experience

Of a total of 98 seminar participants, 84 could be included in the study (85.7%). Fourteen attendees refused to take part in the study (14.3%). According to the study protocol 39 participants were randomized to the manual puncture technique (group I: MAN-IO) and 45 evaluated the semi-automatic infusion system (group II: EZ-IO).

The study participants from both groups were on average 35 years of age and 3/4 were men. About 2/3 of the individuals in both study groups were active emergency physicians, and 1/3 were not. Both study groups comprised of about 60% anesthesiologists, 15% internal medicine specialists, 10% other medical specialties, and 15% paramedics. The members of both groups had an average of 9 years of professional experience with an average of 7 years of emergency medicine for emergency physicians. There were no significant differences in the study participants' characteristics between the groups.

### Individual experience in establishing an intraosseous access

As regards previous individual experience in establishing an intraosseous access, no significant differences were seen between the two groups (MAN-IO:  $0.4 \pm 1.1$  vs. EZ-IO:  $0.4 \pm 1.2$  intraosseous infusions prior to study participation; n.s.). A comparably high number of individuals had never placed an intraosseous infusion before participating in the study (MAN-IO: 85% vs. EZ-IO: 84%; n.s.).

### Insertion times

The time that elapsed before an intraosseous access was successfully established, defined as the time period

between taking the respective intraosseous infusion system out of the original packaging to successfully administering the test dose of 10ml saline solution via the intraosseous infusion needle, and was comparable for the two groups (MAN-IO:  $33 \pm 28$  s vs. EZ-IO:  $32 \pm 11$  s; n.s.) (Table 2).

### Number of attempts

By using the EZ-IO infusion system significantly more successful infusions were established on the first attempt (MAN-IO: 79.5% vs. EZ-IO: 97.8%;  $p < 0.01$ ). One person in the EZ-IO group needed three attempts to successfully establish the intraosseous access. Ultimately, all the study subjects were successful in placing the intraosseous infusion needle using the EZ-IO.

In the MAN-IO group 7.7% of the subjects needed two attempts to successfully establish the intraosseous access whereas 12.8% of the study subjects were not able to carry out the intraosseous puncture procedure even after three attempts (Table 2).

### Technical complications

Establishing an intraosseous access using MAN-IO was associated with technical complications such as bending or breaking an infusion needle such that subsequent intraosseous infusion was impossible in 15.4% of cases (Table 2). In contrast, no such technical complications occurred when using the EZ-IO infusion system (MAN-IO: 15.4% vs. EZ-IO: 0.0%;  $p < 0.01$ ). Concerning the complications of the two techniques, neither penetrating of the posterior wall nor tissue swelling was observed in this study. Only one participant needed three attempts in order to ultimately place the intraosseous needle successfully using EZ-IO. The three attempts were related to a handling problem on the part of this individual in using the semi-automatic EZ-IO system and were not associated with a technical problem of the device.

### User friendliness

In terms of user friendliness the MAN-IO received a subjective score of  $1.9 \pm 0.7$  (school grading system, 1 = excellent

to 6 = failure); however, the EZ-IO received a significantly better score of  $1.2 \pm 0.4$ ; ( $p < 0.01$ ).

## Discussion

The intraosseous approach represents a very fast, technically simple infusion technique that can be highly successfully employed even by inexperienced users. Furthermore, it is associated with a low rate of complications, making it possible to safely administer all medications and infusions normally required in a preclinical emergency setting.<sup>3,9,10–17</sup> Therefore, in the current guidelines for CPR, in children and adults the IO-access is recommended for situations when it is difficult to establish an intravenous access or when there are delays to do this (second-choice method).<sup>5,18</sup> However, compared with pediatric intraosseous infusion, placing an intraosseous catheter in adults requires that a thicker bony cortex be penetrated. Manual catheter insertion, as described in the pediatric literature, may take significantly longer.<sup>19</sup> Therefore, we set out to compare a newly developed battery-powered, semi-automatic device with a traditional manual insertion technique, which still is most commonly employed in EMS.

Concerning the aspects packaging size and weight of the devices, the manual puncture system has advantages over the semi-automatic puncture system. In addition, the manual puncture system is less expensive. However, compared to the intravenous route of access both intraosseous puncture technologies must be considered costly.

Another important factor is related to the expiration date of each device. For both devices, insertion needles are expected to be sterile in the original packaging for about 5 years. Using the EZ-IO, which represents a battery-powered reusable device, the efficiency of the batteries must also be considered. Using the new lithium ion battery pack, the manufacturer guarantees up to 1000 problem-free insertions or a durability of around 10 years. Therefore, the EZ-IO can be considered as a long-lasting device.

Although, an intraosseous access can be placed at various sites, the first-choice puncture site in patients up to the age of 5–6 years is the proximal tibia.<sup>15,20,21</sup> In children older than 6 years and in adults, the distal tibia is the preferred puncture site for intraosseous needles.<sup>22,23</sup>

In the present investigations, the intraosseous infusion systems were evaluated using adult human cadavers and therefore the results can be applied to alive, adult emergency patients with only few limitations. However, due to anatomic differences these results should not be completely transferred to pediatric patients.

In line with other investigations, our results showed that it is simple to establish an intraosseous access.<sup>5,15,18,24–26</sup> By using the manual puncture technique an overall of 87.2% ( $n = 34$ ) of the punctures were successful. However, in five cases (12.8%), the puncture could not be rated as successful even after the third attempt. In comparison to these results, other investigators reported a 80% success rate for the manual technique.<sup>24–26</sup> In contrast, when employing the semi-automatic infusion system, the success rate for the first attempt was 18.3% higher than for the manual technique. Only one participant needed three attempts for successful access but none of the punctures had to be rated as un-

successful after three attempts. Thereby, these findings are in line with other studies demonstrating a 94–97% success rate for the EZ-IO system.<sup>13,27</sup> Furthermore, in an EMS the initial use of the EZ-IO in 125 patients resulted in a success rate of 94%.<sup>12</sup>

Technical complications represent the main reason for the diverging success rates observed between the two insertion techniques. In 15.4% of the cases ( $p < 0.01$ ) the 15.5G-IO infusion needle of the manual system bent and could not be inserted through the outer layer of the bone into the marrow space. In contrast, no comparable problems were observed when the EZ-IO needle was used. Furthermore, other technical problems as insufficient drill power or battery failure were not observed throughout our investigation.<sup>10</sup> This observation might be associated with the use of the new lithium battery package, which provides 10% more torque than the alkaline batteries formerly used.<sup>10</sup>

Owing to the human cadaver the occurrence of other patient-related complications such as hematoma, abscess or osteomyelitis could not be assessed. It should be mentioned at this point, however, that such complications are considered to be rare when using an emergency intraosseous access anyway.<sup>2,25,28</sup>

In case of prolonged or failed intravenous access followed by usage of an intraosseous access device, different time intervals up to the successful IO puncture process have to be considered: At first, the time lost in making multiple and frustrating attempts to place intravenous infusion, and the delay in deciding for the intraosseous access.<sup>19</sup> At second, the time needed from decision making up to the availability of the device at scene. At third, the time needed from opening the original packaging up to the successful IO puncture. By interpreting our findings, it should be mentioned that the described first and second time intervals were not part of the present investigation. However, according to our study and in line with the literature, comparable insertion times of about 30s were observed for both of the infusion systems that we evaluated.<sup>28</sup> Therefore, independent of the technique employed, intraosseous puncture represents an alternative to peripheral venous access that can be performed quickly and promptly. Many published reports have indicated, that intraosseous puncture represents an alternative route of emergency access that is simple to use for nearly everyone: In most studies, a short (<1h) lecture followed by a practical demonstration, and a short hands-on experience have been considered sufficient training.<sup>11,24,29</sup> In accordance to these reports, in the present study, both techniques were rated as “very user friendly” or “user friendly”, whereby the EZ-IO was rated significantly better than the MAN-IO. This can be explained by the fact that with comparable insertion times the success rates achieved with EZ-IO were higher and the system was associated with fewer technical defects.

Nevertheless, in spite of all advantages in these settings, the intraosseous route in general is still a seldom employed option.<sup>20,28,30,31</sup> Especially the use of an intraosseous access in adults, it is still more the exception than the rule.<sup>2,32,33</sup> Furthermore, the changes in the ERC guidelines in favor of intraosseous access have not yet had any effect on the incidence of practically applying this technique. This circumstance is reflected in the present study, which showed that all participating professional groups had to

be designated as completely inexperienced in applying the intraosseous infusion technique. However, the study groups were not homogeneous as both emergency personnel and non-emergency medical personnel and also paramedics were included in each group. We can assume, however, that this does not affect the results of the study in any relevant way as the previous experience of the participants in establishing an intraosseous access was low over all the professional groups and did not differ significantly between groups either.

## Conclusion

Comparing a newly-developed semi-automatic (EZ-IO) and a traditional manual intraosseous infusion system for emergency medical use in an adult human cadaver, the semi-automatic system was proven to be more effective. The EZ-IO gave more successful results, was associated with fewer technical complications, and is user friendlier.

## Conflict of interest

None.

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