Comparison of the NIO and EZIO for Resuscitative Vascular Access in the Emergency Department: A Quasi-Experimental, Before-and-After Study

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ABSTRACT

Introduction:

Intraosseous (IO) needle insertion is a key adjunctive procedure in the care of critically ill and injured patients in a variety of settings, including the battlefield. The NIO is a new, fully disposable, single-piece, IO device with potential practical advantages under austere conditions. We sought to compare the efficacy and safety of the NIO to an established, well-studied device, the EZIO, when used for resuscitative vascular access in the emergency department (ED).

Methods:

Retrospective, single-center, quasi-experimental, before-and-after, observational cohort study performed at an urban, tertiary-care hospital ED among adult patients receiving IO access during resuscitation. The before/NIO period lasted from July 1, 2019, to May 31, 2020, and the EZIO/after period from June 1, 2020, to April 30, 2021. Patient demographics, prehospital treatment, ED presentation, characteristics and results of IO insertion(s), potential procedure-associated adverse events, and ED and hospital outcomes were abstracted from the medical record. The primary outcome, rate of first-pass success (FPS), was compared between the NIO and EZIO periods using multivariable regression after adjustment for potential confounding factors.

Results:

We enrolled 63 total patients/66 limbs (mean age 61 ± 18, 51% female), 34 patients/35 limbs during the NIO period and 29 patients/31 limbs during the EZIO period. The most common reason for IO insertion was cardiac arrest (40/63, 63%), followed by respiratory failure, trauma, and sepsis. The majority of IO insertions were performed at the proximal tibia (58/66, 88%) by senior emergency medicine residents or faculty. The overall rate of FPS was 53/66 (80%), 24/35 (69%) with the NIO compared to 29/31 (94%) with the EZIO. After multivariable modeling, the odds of FPS with the NIO vs. the EZIO was 0.19 (95% CI, 0.01–1.5, $P = .16$). Procedure-related adverse events were infrequent in both groups. In-hospital mortality was 45/63 (71%).

Conclusions:

We found that the NIO device was associated with a lower-than-expected rate of FPS compared to the EZIO device, although not significantly different after adjusting for between-group imbalances and considering limitations in the study design. Further, prospective research into the efficacy and safety of the NIO is needed before clinical use can be encouraged.

INTRODUCTION

Intraosseous (IO) needle insertion has become a vital adjunctive procedure for the resuscitation of diverse populations of critically ill and injured patients in a variety of settings, from the emergency department (ED) to the battlefield.[1–4] Whether used as a first-line vascular access modality, such as for out-of-hospital cardiac arrest or military trauma, or as a rescue modality when attempts at intravenous (IV) access have failed, IO cannulae provide rapid, reliable access to the venous system for delivery of critical, time-sensitive interventions.[5–8] To achieve this purpose, IO devices must be practical, safe, and effective, resulting in a high rate of first-pass success (FPS) with insertion.[9–11]

Although multiple commercial IO devices exist for adult resuscitative vascular access, the most utilized device is the EZIO (Teleflex Medical Inc., Research Triangle Park, NC, USA). It employs a separate, reusable, battery-powered driver to facilitate needle insertion and provides different needle lengths for proximal tibial and humeral insertion sites. Clinical experience with the EZIO is vast and FPS rates

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The research findings were not presented at any local, national, or international meetings.

None of the study investigators have affiliations or connections with the company that manufactures and distributes the devices used in the study subjects. No employee of the company was involved in the research nor provided funding for the project.

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are generally high (>85-90%).[3,5,7,12–17] Nevertheless, fully disposable, spring-powered, single-piece devices may have logistical advantages over the EZIO in austere settings. One such newly introduced device, the NIO (Persys Medical Inc., Houston, TX, USA), has been compared against the EZIO in several small, simulation studies with comparably high FPS rates.[18–20] However, to date, no human studies have compared the NIO and EZIO.

We sought to evaluate the efficacy and safety of the NIO compared to the EZIO for resuscitative vascular access in critically ill adult ED patients using a quasi-experimental, before-and-after study. We hypothesized that both the NIO and EZIO would have high rates of FPS and low incidences of adverse events in this setting.

METHODS

Study Design and Setting

Retrospective, single-center, quasi-experimental, before-and-after, observational cohort study performed at an urban, tertiary-care hospital (Einstein Medical Center Philadelphia) ED with ~100,000 annual visits from July 1, 2019, to April 30, 2021. The study was approved by the Einstein Healthcare Network Institutional Review Board and informed consent was waived due to the retrospective, observational nature.

Intraosseous access was performed by emergency medicine resident and faculty physicians for temporary, resuscitative vascular access. Although multiple bony sites for IO insertion exist (e.g., sternum, humerus, femur, tibia, etc.), our institution only utilized the proximal humerus and proximal tibia locations. In the setting of cardiac arrest, IO access was performed before/simultaneous to IV access. In all other critical scenarios, IO access was utilized as a rescue technique after attempts at IV access were performed. Before hospital admission, IV vascular access was established whenever feasible and IO cannula was removed.

Before July 2019, IO access in our department had been performed exclusively with the EZIO device. As part of a quality improvement (QI) initiative starting in January 2019, all emergency physicians were trained in the use of the NIO device. The training involved individualized, hands-on practice with a simulator or cadaver and group lectures on procedural techniques and indications. The training was performed by members of the study team (B.C.D., M.D.E.) who were themselves previously trained by employees of the device manufacturer (Persys Medical Inc., Houston, TX, USA). Upon completion of staff training in July 2019, the NIO device was introduced into clinical use and the EZIO device was completely removed from availability. Reference documents with step-by-step instructions on NIO insertion were continuously available to staff. Additionally, a quick-reference guide was attached to each NIO device placed in the clinical arena with images depicting the appropriate site selection and insertion technique (Fig. 1Y, Z).

The NIO/before period took place from July 1, 2019, to May 31, 2020. During this time, all IO insertions performed as part of standard clinical care were done using the NIO device. Staff was instructed to notify the principal investigator (B.C.D.) after inserting an IO needle and patient enrollment was tracked prospectively as part of the QI initiative. No additional data collection was performed prospectively, however. The EZIO/after period began June 1, 2020, at which time, the EZIO was re-introduced into the clinical arena and the NIO supplies were removed. Staff was notified of the supply change and reminded of the technique and indications of EZIO use through email messaging. The EZIO/after period lasted through April 30, 2021, resulting in the length of both periods being 11 months. During this time, IO use was not tracked prospectively through the QI initiative. Rather, staff documented IO insertion details in the electronic medical record using a newly created, standardized procedure note. The length of the treatment periods was determined by the duration of the QI initiative for the NIO/before period, with the EZIO/after period designed to have the same duration.

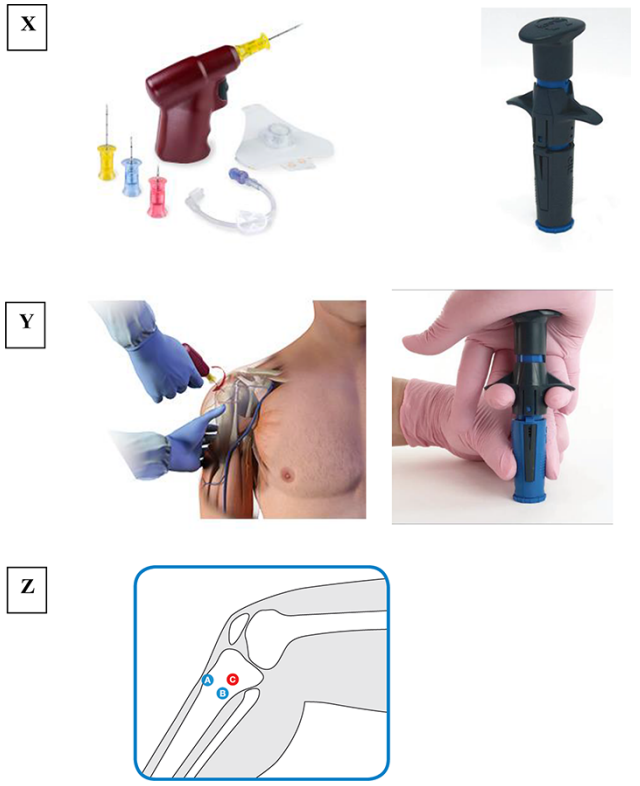

FIGURE 1. X. Intraosseous devices used in the study Arrow® EZIO® (Teleflex Medical Incorporated, Morrisville, NC, USA) – Left NIO® (Persys Medical Incorporated, Houston, TX, USA) – Right. Y. Hand positioning used to deploy the intraosseous devices used in the study. Note the EZIO is deployed with one hand on the driver and one hand holding the limb, while the NIO requires both hands to be holding the device during deployment. Arrow® EZIO® (Teleflex Medical Incorporated, Morrisville, NC, USA) – Left NIO® (Persys Medical Incorporated, Houston, TX, USA) – Right. Z. Needle placement at the proximal tibial insertion site. In the image shown, A indicates the tibial tuberosity. B indicates the site of EZIO insertion, 2 cm medial to the tibial tuberosity. C indicates the site of NIO insertion, 2 cm medial and 1 cm proximal to the tibial tuberosity.

Intraosseous Devices

The adult NIO is a Food and Drug Administration–approved, fully disposable, spring-powered, single-piece, IO needle insertion device. A uniform size (15-gauge × 25 mm long) stainless-steel needle is employed for both proximal tibia and humeral sites (Fig. 1X). The NIO requires two hands controlling the device to properly deploy (Fig. 1Y). Once inserted into the bone marrow, the needle is secured with an adhesive stabilizing dressing and a luer-lock connector is attached to deliver fluid/medication. The proximal tibial insertion site is located 2 cm medial and 1 cm proximal to the tibial tuberosity (Fig. 1Z). The proximal humerus insertion site is located 1 cm superior to the surgical neck on the greater tubercle. The NIO device is also manufactured for pediatric (15-gauge × 14-18 mm needle) and infant IO insertion, but these were not employed in our study.

The adult EZIO is a Food and Drug Administration–approved, partially disposable, two-piece, battery driver-powered IO needle insertion device. Two different needle sizes are utilized: 15-gauge × 25 mm for proximal tibial and 15-gauge × 45 mm for humeral sites (Fig. 1X). The needle is loaded onto the tip of a reusable driver, which powers an intramedullary insertion. The device requires only one hand on the components to perform insertion (Fig. 1Y). Once inserted into the bone marrow, the needle is secured with an adhesive stabilizing dressing and a luer-lock connector is attached to deliver fluid/medication. The proximal tibial insertion site is located 2 cm medial to the tibial tuberosity, slightly different from the NIO device (Fig. 1Z). The proximal humerus insertion site is located 1 cm superior to the surgical neck on the greater tubercle, identical to the NIO device. The EZIO is also manufactured for pediatric/infant IO insertion (15-gauge × 15 mm needle), but these were not employed in our study.

Study Subjects

We enrolled all adult ($\geq$ 18 years old), nonpregnant, patients that underwent IO insertion in the ED from July 1, 2019, to April 30, 2021. Intraosseous needles inserted in the prehospital setting were not included. There were no additional exclusion criteria. For patients that received more than one IO insertion, the details of each IO insertion/each limb were recorded. Subjects from the NIO/before period were identified prospectively as part of the QI initiative, as described above. Subjects from the EZIO/after period were identified retrospectively through a search of the electronic medical record. We were unable to search for the standardized IO procedure note previously created, so the records of all patients presenting to the ED with an emergency severity index triage level 1 (highest acuity) during the EZIO/after period were reviewed individually and patients that received an IO insertion were enrolled.

Data Collection

Study investigators, emergency medicine resident physicians (M.D.E. and M.K.T.), who were trained by the principal investigator (B.C.D.) in methods of chart abstraction and unblinded to the study hypothesis performed medical record review using a standardized data collection form. Each chart was reviewed by one investigator. No duplicative review was performed. The following data elements were collected from the ED record: Demographic information, arrival method, comorbidities, triage vital signs and cardiopulmonary support, IO procedure characteristics (user level of training, site, laterality, and device), occurrence of FPS, method of definitive vascular access obtained, principal diagnosis, disposition, and hospital mortality. Potential adverse events related to IO insertion that occurred in the ED were also recorded (extravasation, dislodgement, site bleeding, and bone fracture).

Definitions

The primary outcome, FPS, was defined as the unobstructed flow of fluid/medication infused through the IO cannula after a single insertion attempt. Laterality was defined based on the patient. Method of definitive vascular access was categorized as peripheral IV, ultrasound-guided peripheral IV, central venous catheter, or none (e.g., if the patient expired with only IO access in place). Adverse events occurring in the ED were abstracted retrospectively if they were recorded in the medical record during the clinical care of the patient; no prestructured surveillance protocol was used.

Statistical Analysis

Continuous variable distributions were assessed for normality using the skewness value (−1 to 1). Normally distributed data are displayed using the mean ± SD. Non-normally distributed data are displayed as median (interquartile range). Categorical variables are presented as counts and percentages. Patient-level data (demographics, comorbidities, vital signs, etc.) was analyzed on a per-patient basis. Data specific to each IO insertion (provider level of training, site, laterality, FPS, etc.) was analyzed on a per-limb basis.

Comparison of the distribution of study variables between the NIO and EZIO periods was performed using Welch's *t*-test, Wilcoxon Rank-Sum test, or Fischer's exact test, as appropriate based upon the data format and normality of distribution. Given the quasi-experimental design and small sample size, we anticipated the possibility of an unequal distribution of covariates potentially associated with FPS between the NIO and EZIO periods. Hence, we analyzed the efficacy of the NIO compared to the EZIO using multivariable logistic regression modeling. Variables associated with FPS in univariate comparison ($P < .1$) were included in the model, along with the treatment period (NIO vs. EZIO). No formal checking of collinearity between variables was performed. The number of variables included in the model conformed

to standard limitations for logistic regression (no more than 1 variable per 10 observations). The primary outcome was assessed using the odds of FPS with the NIO divided by the odds of FPS with the EZIO device, with a 95% CI of the odds ratio (OR).

No formal imputation was performed for missing data. All hypothesis tests were performed using two-sided, alpha = 0.05 boundaries. Data analysis was performed using Microsoft Excel (Microsoft Corporation, Redwood, WA, USA) or R (The R Foundation).

RESULTS

Patient Characteristics

We enrolled 63 total patients (66 limbs), 34 patients (35 limbs) during the NIO period and 29 patients (31 limbs) during the EZIO period. Patient characteristics are displayed in Table I. The population was predominantly African American and overweight–obese and had a significant burden of chronic diseases. Factors affecting limb suitability for IV or IO placement, such as IV drug use, amputation, and contracture deformities, were infrequent. Forty (63%) patients presented in cardiac arrest, some with minimal or no prehospital medical care. Of the remaining 23 (37%) patients that were not in cardiac arrest on presentation, the most common diagnoses were acute respiratory failure, trauma, and sepsis. Patients enrolled during the NIO and EZIO periods were similar in characteristics, with the exception of a significantly greater incidence of end-stage renal disease (ESRD) in the NIO period.

IO Insertion Characteristics

Table II displays the characteristics of the study IO procedures. For both the NIO and EZIO periods, most insertions were performed at the proximal tibia site. The training level of the users differed between the study periods, with the NIO more often inserted by senior residents/faculty compared to the EZIO. Further, the NIO was inserted predominantly on the patient's right side, whereas the EZIO was inserted more commonly on the patient's left.

The overall rate of FPS was 53/66 (80%) and was significantly different between the NIO and EZIO periods (69% vs. 94%, $P = .01$). The overall insertion success rate when including second attempts and beyond was also lower with the NIO than the EZIO (68% vs. 91%, $P = .04$). Adverse events were infrequent throughout, the most common being accidental dislodgement of the IO after successful placement (4/66, 7%). The majority of patients subsequently had a method of IV vascular access placed after IO insertion, with a central venous catheter being most frequently employed.

In-hospital mortality was 71%, with most deaths occurring in the ED in the setting of refractory cardiac arrest. Of those patients that survived to hospital admission, nearly all required intensive care.

Factors Associated With FPS

Table III displays the results of the multivariable analysis of factors associated with FPS. Three variables (history of chronic obstructive pulmonary disease [COPD], history of ESRD, and IO device) were associated with FPS in univariate comparisons. After multivariable modeling, we found the primary outcome of the OR of FPS with the NIO vs. the EZIO to be 0.19 (95% CI, 0.01–1.5, $P = .16$). Neither a history of COPD nor ESRD was significantly associated with FPS in the multivariable analysis.

DISCUSSION

In this small, quasi-experimental study of critically ill adults receiving IO insertion for resuscitative vascular access in the ED, use of the NIO device was associated with a lower-than-expected rate of FPS compared to the EZIO device, although not significantly different after adjustment for potential between-group imbalances. Both devices exhibited a low frequency of adverse events.

With increasing applicability to diverse clinical scenarios, expanding evidence of safety and efficacy, and improving ease-of-use and practicality, IO device demand has risen in recent years and a number of new products have entered the marketplace.[21–23] It is prudent that each new device be rigorously studied and compared to established devices that have already been proven to be safe and effective. We chose the EZIO as the benchmark product in our study, given the body of literature demonstrating its efficacy in a variety of clinical scenarios.[5,17,24] Specific to the frontlines, the EZIO has been successfully employed for primary resuscitative vascular access by service members from multiple countries (the USA and the UK) in varied conflicts (Afghanistan and Iraq).[3,25] Prior studies have demonstrated FPS rates of 85-90% or more with the EZIO, which are essential for a time-sensitive, potentially critical intervention.[7,12,17,26]

Nevertheless, the EZIO device has some potential disadvantages. Specifically, it is not fully disposable and is constructed in two separate parts, the needle and the battery-powered driver. Further, the driver batteries cannot be replaced when they fail; a new driver must be obtained. These practical aspects may be most relevant in austere environments, such as the battlefield, where packaging and simplicity-of-use are paramount. The often-chaotic environment of military medicine and the time-sensitive nature of associated disease states necessitate a simple and reliable mechanism for obtaining IO access. Single-use, fully disposable, one-piece devices, such as the NIO, may be advantageous in such scenarios if they are equally safe and effective as the EZIO.

The NIO has been compared with the EZIO in three simulation-based randomized, controlled trials (RCTs). Szarpak et al. conducted two crossover RCTs in which paramedics performed proximal tibial insertion using both the NIO and EZIO during simulated cardiopulmonary resuscitation in (1) fresh human cadaver and (2) resuscitation manikin

TABLE I. Patient Characteristics

	All patients	NIO	EZIO	*P*
Number of patients	63	34	29	–
Age, years	61 ± 18	62 ± 20	60 ± 15	.62
Female, *n* (%)	32 (51%)	18 (53%)	14 (48%)	.80
Race, *n* (%)	–	–	–	.46
African American	52 (83%)	27 (79%)	25 (86%)	
Caucasian	3 (5%)	3 (9%)	0 (0%)	
Hispanic	3 (5%)	1 (3%)	2 (7%)	
Unknown	5 (8%)	3 (9%)	2 (7%)	
Body mass index, kg/m^2	30 (24–36)	31 (24–34)	26 (23–37)	.68
Comorbidities[b], *n* (%)	–	–	–	–
Seizure disorder	6 (12%)	1 (4%)	5 (21%)	.09
Stroke	10 (20%)	7 (26%)	3 (13%)	.30
Hypertension	43 (84%)	21 (78%)	22 (92%)	.26
Coronary artery disease	15 (29%)	7 (26%)	8 (33%)	.76
Congestive heart failure	16 (31%)	10 (37%)	6 (25%)	.38
COPD	8 (16%)	5 (19%)	3 (13%)	.71
Asthma	6 (12%)	4 (15%)	2 (8%)	.67
ESRD	9 (18%)	8 (30%)	1 (4%)	.03
Cirrhosis	0 (0%)	0 (0%)	0 (0%)	1.0
Diabetes	27 (53%)	14 (52%)	13 (54%)	1.0
Upper extremity abnormality	1 (2%)	1 (4%)	0 (0%)	1.0
Limb amputation	2 (4%)	1 (4%)	1 (4%)	1.0
IV drug use	1 (2%)	1 (4%)	0 (0%)	1.0
Nursing home resident	8 (16%)	4 (15%)	4 (17%)	1.0
Method of arrival, *n* (%)	–	–	–	
Emergency medical services	54 (86%)	30 (88%)	24 (83%)	.23
Self	5 (8%)	1 (3%)	4 (14%)	
Police	4 (6%)	3 (9%)	1 (3%)	
Emergency Severity Index	–	–	–	
1	60 (95%)	31 (91%)	29 (100%)	.50
2	2 (3%)	2 (6%)	0 (0%)	
3	1 (2%)	1 (3%)	0 (0%)	
Presenting vital signs[a]	–	–	–	–
Ongoing cardiac arrest	40 (63%)	20 (59%)	20 (69%)	.44
Mode of respiratory support	–	–	–	.54
ETT/SGA	20 (50%)	12 (60%)	8 (40%)	–
Noninvasive ventilation	1 (3%)	0 (0%)	1 (5%)	–
Bag-mask ventilation	3 (8%)	1 (5%)	2 (10%)	–
None	16 (40%)	7 (35%)	9 (45%)	–
Not in cardiac arrest	23 (37%)	14 (41%)	9 (31%)	.44
Mode of respiratory support[b]	–	–	–	.60
Noninvasive ventilation	4 (19%)	3 (25%)	1 (11%)	
Bag-mask ventilation	6 (29%)	4 (33%)	2 (22%)	
None	11 (52%)	5 (42%)	6 (67%)	–
Temperature, °C	37.0 ± 1.2	36.9 ± 1.0	37.3 ± 1.6	.50
Heart rate, beats/minute	96 ± 31	92 ± 31	108 (101-113)	.22
Systolic blood pressure, mmHg	123 ± 54	139 ± 58	104 (97-121)	.29
Diastolic blood pressure, mmHg	71 ± 28	79 ± 28	61 (55-71)	.21
Mean arterial pressure, mmHg	88 ± 36	99 ± 37	81 (69-88)	.30
Respiratory rate, breaths/min	25 ± 9	24 ± 8	26 ± 11	.78
Pulse oximetry	99 (95-100)	100 (97-100)	95 (90-99)	.05
Fraction of inspired oxygen	1.0	1.0	1.0	.49
Diagnosis, *n* (%)	–	–	–	–
Cardiac arrest[c]	43 (68%)	21 (62%)	22 (76%)	.28
Respiratory failure	16 (25%)	10 (29%)	6 (21%)	.56
Trauma	7 (11%)	5 (15%)	2 (7%)	.44
Sepsis	6 (10%)	4 (12%)	2 (7%)	.68
Nontraumatic hemorrhage	3 (5%)	2 (6%)	1 (3%)	1.0
Dysrhythmia	2 (3%)	2 (6%)	0 (0%)	.50

(continued)

TABLE I. (Continued)

	All patients	NIO	EZIO	*P*
Seizure	2 (3%)	1 (3%)	1 (3%)	1.0
Overdose	1 (2%)	1 (3%)	0 (0%)	1.0
Other	1 (2%)	0 (0%)	1 (3%)	.46

All analyses are performed on a per-patient basis. Data expressed as mean ± SD or median (interquartile range). *P*-value represents the comparison of patients that received IO insertion with the NIO vs. EZIO.

[a]Numerical vital signs (temperature—fraction of inspired oxygen) are only for patients not presenting in cardiac arrest.

[b]Missing data for comorbidities $n = 12$ and mode of respiratory support $n = 2$ patients.

[c]Includes out-of-hospital or in-ED cardiac arrest.

Abbreviations: COPD = chronic obstructive pulmonary disease, CPR = cardiopulmonary resuscitation, ED = emergency department, ESRD = end-stage renal disease, ETT = endotracheal tube, IO = intraosseous, IV = intravenous, SGA = supraglottic airway.

models. In both trials, FPS rates were 97-100% with the NIO and EZIO, but the NIO showed a shorter time to insertion.[18,19] Shina et al. studied novice users (medical students) in a crossover RCT performing IO insertion on a porcine hind leg model and found FPS rates of 88% for the EZIO and 92% for the NIO.[20] Although these studies suggest that both devices are highly effective in simulations, no prior research has compared the efficacy of the NIO with the EZIO in the clinical arena.

In our study comparing the use of the NIO and EZIO for resuscitative vascular access among adult ED patients, we found the rate of FPS with the EZIO to be very high and comparable to prior research but found the rate of FPS with the NIO to be lower than expected. There may be several reasons for these findings. First, our department historically used the EZIO device for IO insertion before the study in which the NIO was temporarily introduced. Despite extensive, individualized training of the staff in the use of the NIO device performed by the study investigators, it is certainly possible that physicians remained less familiar with the NIO insertion procedure and more likely to perform it incorrectly. In particular, the correct positioning of the NIO at the proximal tibial insertion site is slightly different from the EZIO (Fig. 1Z). Although we specifically noted this to our staff and provided point-of-care reminders, leftover behavior from prior EZIO insertions may have resulted in the NIO being placed at the incorrect location and more prone to failure. Second, there were baseline imbalances between the study periods, likely as a result of the small sample size. Patients with ESRD were more common in the NIO group and were also associated with a decreased likelihood of FPS. This novel finding could result from ESRD patients presenting with excessive peripheral edema, resulting in increased depth from the skin to the bone marrow. Additionally, the NIO was more often inserted by more senior providers than the EZIO. However, this would be expected to bias the results "in favor" of the NIO because these providers would be expected to have more overall IO insertion experience.

Nevertheless, there are additional potential reasons the NIO device exhibited a lower-than-expected efficacy that is related to the design of the device itself. First, the NIO uses a spring-based driving mechanism that is independent of the downward force applied by the user onto the limb. By contrast, the EZIO employs a spinning, drill-powered driving mechanism in which the user can apply the additional downward force toward the limb. Thus, it is possible that the driving force created by the EZIO device is stronger than that created by the NIO. This may not manifest in simulated scenarios using manikins/cadavers but reveal itself in more austere clinical environments. This particular situation occurred with a previous IO device employing a spring-powered driving mechanism, the Bone Injection Gun (Persys Medical Inc., Houston, TX, USA), which showed success in comparison to the EZIO in simulated studies but was less effective when applied in various clinical trials.[27–32] Second, as shown in Figure 1Y, the NIO requires the user to place both hands on the device itself during insertion to flatten the base of the device against the patient's limb and simultaneously deploy the trigger mechanism. With the EZIO, the user places their nondominant hand completely on the patient's limb and holds the driver and loaded needle with their dominant hand. Consequently, in tumultuous clinical settings where patients may be moving their limbs, a single user without assistance may more adequately stabilize a patient's extremity when deploying the EZIO compared to the NIO. This may explain our observed predominance of right-sided insertions in the NIO period, in which the presumed mainly right-handed users were more comfortable with the positioning needed to deploy the device on the patient's right lower extremity. Finally, the NIO only utilizes a single-length needle (25 mm) for both proximal tibial and humeral insertions, whereas the EZIO uses a 25-mm needle for proximal tibial and 45-mm needle for humeral locations. In our urban, U.S. population with a significant incidence of obesity, it is possible the 25 mm length is insufficient for humeral insertion in larger patients. Unfortunately, due to the retrospective nature of our study, we were not able to collect data on the exact reason for insertion failure in cases where FPS was not achieved, so we are unable to provide data to directly support or refute these theories.

Our study has a number of important limitations. The sample size was small, resulting in baseline imbalances between treatment groups, wide CIs in our multivariable analysis, and

TABLE II. IO Insertion Characteristics and Outcomes

	All patients	NIO	EZIO	*P*
Number of patients	63	34	29	–
Number of limbs	66	35	31	–
Training level of inserting provider[a]	–	–	–	
PGY1	5 (8%)	1 (3%)	4 (13%)	
PGY2	6 (9%)	1 (3%)	5 (17%)	.02
PGY3	16 (25%)	11 (32%)	5 (17%)	
PGY4	28 (44%)	13 (38%)	15 (50%)	
Faculty	9 (14%)	8 (24%)	1 (3%)	
Limb location	–	–	–	
Proximal tibia	58 (88%)	30 (86%)	28 (90%)	.71
Proximal humerus	8 (12%)	5 (14%)	3 (10%)	
Laterality[a]	–	–	–	
Right	32 (54%)	20 (71%)	12 (39%)	.02
Left	27 (46%)	8 (29%)	19 (61%)	
FPS, *n* (%)	–	–	–	
Yes	53 (80%)	24 (69%)	29 (94%)	
No	13 (20%)	11 (31%)	2 (6%)	.01
Second attempt	5 (38%)	3 (27%)	2 (100%)	
Success	3 (60%)	2 (66%)	1 (50%)	
Failure	2 (40%)	1 (33%)	1 (50%)	
Overall insertion success rate[b], *n*/*N* (%)	56/71 (79%)	26/38 (68%)	30/33 (91%)	.04
Adverse events[c], *n* (%)	–	–	–	–
Extravasation	1 (2%)	1 (4%)	0 (0%)	.46
Bleeding	0 (0%)	0 (0%)	0 (0%)	1.0
Unintended dislodgement	4 (7%)	3 (12%)	1 (3%)	.33
Bone fracture	0 (0%)	0 (0%)	0 (0%)	1.0
Method of definitive vascular access[d], *n* (%)	–	–	–	
Peripheral IV	18 (29%)	11 (32%)	7 (24%)	
Ultrasound-guided peripheral IV	9 (14%)	6 (18%)	3 (10%)	.60
Central venous catheter	27 (43%)	12 (35%)	15 (52%)	
None	9 (14%)	5 (15%)	4 (14%)	
Disposition[d], *n* (%)	–	–	–	
Expired in ED	31 (49%)	16 (47%)	15 (52%)	
Intensive care unit	29 (46%)	15 (44%)	14 (48%)	1.0
Operating room	1 (2%)	1 (3%)	0 (0%)	
Intermediate care unit	1 (2%)	1 (3%)	0 (0%)	
Treated and discharged	1 (2%)	1 (3%)	0 (0%)	
Hospital mortality[d], *n* (%)	45 (71%)	23 (68%)	22 (76%)	.58

Data expressed as mean ± SD or median (interquartile range). All analyses are performed on a per-limb basis among first-pass attempts, unless noted below.
P-value represents the comparison of patients that received IO insertion with the NIO vs. EZIO.
[a]Missing data for training level of inserting provider $n = 2$, laterality $n = 7$.
[b]Overall insertion success is measured on a per-limb basis incorporating all insertion attempts, not just first-pass attempts.
[c]Adverse events were measured only after successful initial insertion of the IO needles.
[d]Measured on a per-patient basis.
Abbreviations: ED = emergency department, FPS = first-pass success, IO = intraosseous, IV = intravenous, PGY = postgraduate year.

an overall potential lack of precision in our results. Correspondingly, we were not able to perform a more robust statistical comparison of the rate of FPS with the NIO compared to the EZIO, such as a noninferiority analysis. The majority of IO insertions were performed at the proximal tibial location, so our findings may not be applicable to scenarios where humeral insertion predominates. This was a single-center study in an urban ED. Although we enrolled a reasonably diverse group of patients, our findings may not be generalizable to other dissimilar clinical scenarios. As mentioned previously, our quasi-experimental design in which the department had been utilizing the EZIO before the brief period of NIO use may have biased the findings against the NIO. Further, we were not able to collect data on the exact reason for device failure, time required for insertion, or user preference due to the retrospective design. We also utilized slightly different methods of subject identification for the two treatment periods, which could have led to unpredictable selection bias. Although our device users were only emergency medicine physicians, they had a wide range of

TABLE III. Factors Associated With FPS

Variable	Univariate OR (95% CI)	Multivariate OR (95% CI)	*P*-value
COPD	0.23 (0.03-1.91)	0.30 (0.04-2.34)	0.23
ESRD	0.14 (0.02-0.99)	0.27 (0.04-1.8)	0.17
NIO device (vs. EZIO)	0.15 (0.02-0.81)	0.19 (0.01-1.5)	0.16

Abbreviations: COPD = chronic obstructive pulmonary disease, ESRD = end-stage renal disease, FPS = first-pass success, OR = odds ratio.

IO experience based on their level of training (postgraduate year 1 [PGY1]—faculty), suggesting the results may apply to other types of operators. Finally, we only compared the NIO against the EZIO, so comparison against other devices requires further investigation.

CONCLUSIONS

We found that the NIO device was associated with a lower-than-expected rate of FPS compared to the EZIO device when used for resuscitative vascular access in the adult ED, although not significantly different after considering between-group imbalances and limitations in the study design. Nevertheless, given that all prior research on the NIO has been under simulated conditions, our findings suggest that further, adequately sized, prospective investigations of the efficacy and safety of the NIO are needed before widespread clinical use can be encouraged. Such trials should take into account the details regarding NIO and EZIO insertion techniques learned from our investigation. Although the NIO exhibits certain hypothetical advantages for use in military casualty care, our results support the continued use of the EZIO for frontline resuscitative vascular access.

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CONFLICT OF INTEREST STATEMENT

None of the authors report any conflicts of interest related to the products utilized in this study.

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