NIO Adult White Paper

French Army Evaluation of the “NIO Adult” Intraosseous infusion device

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<td>11 March 2015</td>
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The PerSys Medical Group
Abstract

The NIO (New Intra Osseous infusion) device was recently developed by Waismed Ltd., the developer and manufacturer of the Bone Injection Gun (B.I.G.) intraosseous (I.O.) device. As part of a market study, the French Army conducted an evaluation using the NIO Adult Intraosseous device. The participants in this evaluation were French military medical staff who are users of the B.I.G. I.O. devices and have been conducting I.O. procedures and using the B.I.G. devices for several years. The objective of the trial was to evaluate the participants’ satisfaction, primarily focusing on three usage elements: 1. Packaging, 2. Implementation, 3. Preferred choice of intraosseous device. The results showed: 79.2% satisfaction of product packaging and 100% satisfaction of product implementation. 100% of the participants are willing to convert to the NIO Adult as their preferred choice of I.O. device. Conclusion: All the participants succeeded on their first attempt to use the sterile NIO Adult device and succeeded in finding the correct anatomical insertion site on the proximal tibia on the mannequin leg. The results of this evaluation show that the NIO Adult intraosseous device was met with positive reviews and can serve as the French army's intraosseous device of choice.

1. Background

Army Physicians, Nurses, Paramedics and Medics may face difficulties in medical emergencies, when needing to obtain Intravenous (I.V.) vascular access administer drugs or fluids. In addition, in a battle zone, I.V. access may require excessive time due to environmental conditions. I.O. vascular access is a rapid efficient way of administering drugs and fluids by medical professionals.

I.O. vascular access is considered to be a safe and efficient procedure. I.O. infusion maybe appropriate for in critically ill or injured patients of all ages. The same types of fluids and medications and dosages that are delivered via the I.V. route can be delivered via the I.O. route.

Waismed Ltd. manufactures semi-automatic, spring loaded I.O. devices. Waismed Ltd. developed the B.I.G. (Bone Injection Gun) in 1996 (see Fig. 1) and has recently (in 2014) developed a new and upgraded semi-automatic, spring loaded Intraosseous device called the NIO Adult (see Fig. 2).
The NIO Adult is a simple, automatic Intraosseous (I.O.) device, which is ready to use for safe, quick and easy vascular access. The NIO Adult is used in emergency situations, when vascular access is needed for fluid and drug administration. The NIO Adult is small, light, and easy to use in even the most demanding situations. The NIO Adult is designed to be easily injected into either the tibia or the humerus in all clinical settings.

The B.I.G. and the NIO Adult are both sterile, single use devices. When activated, a spring-loaded needle is released, and the needle enters the bone’s medullary cavity. The user then removes the trocar needle leaving a cannula inside the bone’s medullary cavity, and this cannula can then be used by a caregiver to infuse fluids, drugs, or blood, which then flow to the central vascular circulation system.

Although both the B.I.G. Adult and NIO Adult are semi-automated spring loaded devices, their technical specifications differ, as shown in Table 1 below:

<table>
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<tr>
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<th>Safety steps required to release the needle</th>
<th>Integrated Needle stabilizer</th>
<th>Needle mechanical stopper</th>
<th>Force of the spring kgf</th>
</tr>
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<tbody>
<tr>
<td>B.I.G. (Adult)</td>
<td>One (1)</td>
<td>No. The safety latch can serve as a needle stabilizer</td>
<td>No</td>
<td>19.7±1.8</td>
</tr>
<tr>
<td>NIO (Adult)</td>
<td>Two (2)</td>
<td>Yes</td>
<td>Yes</td>
<td>26±2.6</td>
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</table>

Waismed Ltd. has expertise and experience in developing and manufacturing I.O. devices and has acquired substantial global feedback from vast usage of the B.I.G. devices in order to develop the next generation in I.O. devices: the NIO Adult. There are some technical differences between the B.I.G. and the NIO Adult. Firstly, the NIO Adult contains a dual safety mechanism which provides additional...
safety for users and patients. Secondly, the NIO Adult device can only be triggered when a safety latch is rotated to “open”, and then, simultaneously, the device is pressed against the patient’s limb while pulling up a trigger. Thirdly, the dual step safety mechanism can prevent an unintentional activation of the device and this differs from the B.I.G., which has a one-step safety latch. Fourthly, the NIO Adult includes an innovative needle stabilizer (i.e., needle fixator and needle stopper). With the B.I.G. the safety latch/clip is then used to fixate the needle, and this is done manually. With the NIO Adult, the needle fixator is released during the needle activation and is automatic. Finally, the spring in the B.I.G. Adult device has a loaded spring force of 19.7±1.8kgf, whereas the NIO Adult device has a loaded spring force of 26±2.6kgf. The increased spring force helps to ensure the needle’s penetration into the bone’s medullary cavity.

2. Purpose

2.1. To evaluate the use of the NIO Adult by B.I.G. users at the French army.
2.2. To compare the B.I.G. Adult and the NIO Adult, to understand which is the preferred device of choice.

3. Method

In January 2014, the French army conducted an evaluation of the NIO Adult device. The trial was performed in Citera De Lyon, the French army’s Lyon Military Training Centre in Lyon, France. The evaluation was led and supervised by Dr. Jean-Yves Martinez. Before the trial was performed, a Waismed Ltd. representative conducted comprehensive training for the trial participants and supervision that included a presentation, training session and a hands-on session using both the NIO Adult training device and the NIO Adult sterile device.

The NIO Adult devices were activated on mannequin legs that simulate the adult human leg. Ten NIO Adult sterile devices were used in the evaluation, and the 8 participants comprised of one physician, two nurses, and five medics.

The participants were asked to test the NIO Adult device and evaluate it as follows:
1. Packaging – package volume, weight and durability.
2. Implementation - intuitive usage, speed of usage, safety and ergonomic.
3. The will to convert to the NIO Adult device as their I.O. device of choice

After testing the NIO Adult device, the participants answered a questionnaire and were asked to rank their personal usage experience as either bad, satisfied or very satisfied. At the end of the questionnaire, the participants were asked which I.O. device they preferred to use, the NIO Adult or the B.I.G. Adult.
4. Results

The results of the evaluation are divided into three different sections:
- Packaging
- Implementation
- NIO Adult vs. B.I.G. Adult – I.O. device of choice

Graph 1 Results - Packaging

User Satisfaction

Packaging: 79% of the participants were satisfied with the NIO Adult’s packaging. The main issue was the volume of the packaging. 37.5% of the participants marked the package volume as “bad”. Furthermore, 100% of the participants were satisfied with the weight of the package, although the NIO Adult is slightly heavier than the B.I.G. Adult by 20 grams.
Graph 2 Results - Implementation

User Satisfaction

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Speed</th>
<th>Intuitive</th>
<th>Safety</th>
<th>Ergonomic</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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**Implementation**: 100% of the participants were satisfied by the NIO Adult's implementation (being intuitive, fast, safe and ergonomic). All of the participants mentioned that the device is both safe to use and easy to operate. There were some comments made by the participants regarding the use of the NIO Adult, including "It is simpler and more intuitive, and easier to implement with stable catheter and regarding the safety mechanism, more intuitive with less risk of error and more reassuring with the system "unlock" feature".

NIO Adult vs. B.I.G. Adult: 100% of the participants were more interested in the NIO Adult as their I.O. device of choice.

All of the participants succeeded in their first attempt to use the sterile NIO Adult device, and in finding the correct anatomical insertion site on the proximal tibia on the mannequin leg. There were no safety hazards nor performance problems reported during the evaluation.

5. **Conclusion**

The NIO Adult is a simple, automatic intraosseous (I.O.) device, which is ready to use for safe, quick and easy vascular access. The NIO Adult is used in emergency situations, when vascular access is needed for fluid and drug administration. The NIO Adult is small, light, and easy to use in even the most demanding situations. The NIO Adult is designed to be easily injected into either the tibia or the humerus in all clinical settings.

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All the trial participants succeeded in their first attempt to use the sterile NIO Adult device and found the correct anatomical insertion site on the proximal tibia on the mannequin leg. The results of this evaluation show that the NIO Adult intraosseous device was met with positive reviews and can serve as the French army’s intraosseous device of choice.