# N.I.O Human Cadaver Studies

# Summary of Clinical study on human cadavers
# Device Performance and Validation Tests

Study sites:

Lima September 2012

Georgia October 2012

Lima March 2013

New York Institute of Technology College of Osteopathic Medicine

## 1. Background

This paper summarizes the human cadaver's studies done with the NIO device during 2012 and 2013 as part of the validation tests of the device.

The purpose of this document is to summarize the main conclusions drawn following each study and the subsequent development and correction process.

This paper summarizes the following studies:

- NIO A.V Protocol.10 - 2012 Sep 28 Lima Cadaver lab, at the Central Morgue of Lima.
- NIO A.V Protocol.11 - 2012 Oct 05 GA USA Cadaver lab, at Georgia Health Sciences University.
- NIO A.V Protocol.13 - 2013 Mar15 Lima Cadaver lab, at the Central Morgue of Lima.
- A study that was conducted by Avram Flamm, OMSII, and Bennett Futterman, MD at the New York Institute of Technology College of Osteopathic Medicine. To this day, an article on the study was not published.

## 2. Tests Acceptance criteria:

2.1. The insertion depth of the needle is as pre-adjusted ± 10%mm at each insertion site:

2.1.1. At Proximal tibia and Humeral Head 25± 3mm

2.2. No structural deformations are visually seen on the needle.

2.3. The needle mechanical stopper (Needle stabilizer) provides less than 3 mm of over penetration.

2.4. X-RAY Images of the limbs show no skeletal deformations or fractures due to the insertion.

2.5. Successful operation of the device is if all mention hereafter has accrued:

2.5.1. The trigger mechanism operated and the needle with the needle stabilizer easily released.

2.5.2. The device succeeds to operate in inserting the needle into the bone.

2.5.3. It was possible to separate the trocar from cannula using manual vertical force and twisting.

2.5.4. Administration of fluids was declared successful, fluids flushed in and no extravagation of fluids is noticeable.

2.6. For the secondary study on Proximal Tibia and for the study performed in NY, the success rate was assesses by successful operation of the device as described in section 3.5 and successful fluid administration.

## 3. NIO Users

3.1. On both studies conducted in Lima, the users were the company engineer and another two persons related to sells and marketing of the product.

3.2. The study conducted in GA, USA was performed by 12 different users with Para/Medical education, most of them were medical students.

3.3. The study conducted at the New York Institute of Technology College of Osteopathic Medicine was performed by Avram Flamm, OMSII, and Bennett Futterman, MD.

## 4. Study subjects

4.1. The overall studies were conducted on 55 adult human cadavers both women and men.

4.2. The studies conducted in Lima Peru were performed in the Central morgue of Lima on 17 fresh human adult cadavers. Subject's age was 20-80 years old, both women and men. Specifically, there were 2 subjects in there 80’s, 3 subjects in there 70’s, 2 subject in there 60’s, 1 subject in his 50’s, 2 subjects in there 40’s, 3 subjects in there 30’s and 4 subjects in there 20’s.

4.3. The study conducted in Georgia USA was performed in Georgia Health Sciences University on 12 embalmed and preserved human adult cadavers. Subject's age was 50-90 years old, both women and men. Specifically, there was 1 subject in his 90’s, 3 subjects in there 80’s, 6 subjects in there 70’s, 1 subject in his 60’s and 1 subject in his 50’s.

4.4. In the above studies, for each subject, 8 insertion locations were reviewed according to the exclusion criteria: Proximal Tibia, Humeral Head for right and left body side.

4.5. The study conducted at the New York Institute of Technology College of Osteopathic Medicine was performed on 26 embalmed and preserved human adult cadavers. The

IO needle was inserted at the humerus, iliac crest and tibia sites, bilaterally for a total of 6 insertions per cadaver.

## 5. Exclusion Criteria

5.1. Subjects with systemic skeletal diseases (Osteoporosis, etc…)

5.2. Subjects malformations on the insertion site

5.3. Subjects with surgical scars in the insertion area

5.4. Subjects age below 12 years old

## 6. Results

The following results summary relates to the three cadaver studies excluding the study in NY:

6.1. **Proximal tibia insertion site:**

6.1.1. There were 53 successful attempts out of 58, consequently, the study had a 91.4% success rate.

6.1.2. All 5 failures accrued in the usability study conducted in GA USA, all were due to user errors to insert the NIO to soft tissue or to a very wrong location so the device was pulled out. In all failed attempts, the user identified by himself that the device was not inserted into the correct insertion site.

6.1.3. In all successful attempts, the needle penetrate to the required penetration depth and the procedure of fluid administration was successful.

6.2. **Humeral head insertion site:**

6.2.1. There were 54 successful attempts out of 58, consequently, the study had a 93.1% success rate.

6.2.2. All 4 failures accrued in the usability study conducted in GA USA, all were due to user errors to insert the NIO to soft tissue so the device was pulled out. In all failed attempts, the user identified by himself that the device was not inserted into the correct insertion site.

6.2.3. In one attempt the needle failed to meet the required penetration depth. The measured penetration depth was 21.9mm where the minimal allowed range is 22mm.

6.2.4. In all successful attempts and in particular the one that failed to meet the required penetration depth, the procedure of fluid administration was successful.

6.3. **The Usability study in GA USA demonstrated:**

6.3.1. The average time of procedure for using the NIO was 18.3 seconds for the Proximal tibia and Humeral head. The average time on the Proximal Tibia was 13.6 seconds and for humeral head, it was 23 seconds.

6.3.2. The average user graded the ease of use of the NIO was 8.5 where the average grading for the Proximal Tibia location was 9.1 and for Humeral Head location, it was 7.9.

6.4. **"Wrong" location on proximal tibia:**

6.4.1. Out of 41attempts to activate the device on different “wrong” locations, 35 cases succeeded, i.e. success rate of 85.4%.

6.4.2. The study was performed on a total of 12 cadavers, aged 20-93 years old, both female and male. Specifically, there was 1 subject in his 90's, 2 subjects in there 80’s, 4 subjects in there 70’s, 2 subject in there 60’s, 1 subjects in his 40’s, 1 subjects in his 30’s and 1 subjects in his 20’s.

6.4.3. All the cadavers used for this study, were first used for injecting the NIO to the correct location in the proximal tibia. In all cases the attempt to the insertion site was successful.

6.4.4. Out of 6 failures, 2 were in the same cadaver, a make 35 years old, 3 in another cadaver, a male 73 years old and another one in a male cadaver 75 years old.

6.4.5. It is important to emphasis that the NIO should be used in the correct insertion site, according to the IFU. However, the study demonstrate that even when being installed distal to the Medical guidelines acceptable location (due to user error), the NIO still has high success rate.

6.5. **Bone fractures:**

6.5.1. The study conducted in Lima Peru included x-ray images pre and post to each insertion. All the attempts were x-rayed including the insertions to a "wrong" location in the proximal tibia (i.e more than one attempt on the same limb and in some cases even up to 5 attempts to same limb).

6.5.2. The x-ray images were analyzed by an orthopedic. The full results are summarized and discussed on bone fractures study result "NIO-A.V.Report.09 Occurrence of fractures in bones".

6.5.3. No fractures were observed in any of the x-ray images post operation that were incurred as a result of the NIO activation. Even in cases were the X-RAY image was taken after the numerous insertions, bone fractures did not occurred.

6.6. **NY study at the New York Institute of Technology College of Osteopathic Medicine:**

6.6.1. Utilizing a cadaver model, the NIO device was used in the tibia, humerus and iliac crest and compared first attempt success rates for vascular access**.**

6.6.2. The NIO devices were inserted in 26 cadavers with a total of 127 attempts.

6.6.3. 12 of the cadavers were male and 14 female.

6.6.4. The average age of the cadavers was 79 years at death.

6.6.5. The first attempt success rate for inserting an NIO in the tibia was 98%, Humerus 91%, and Iliac crest 77%.

6.7. Table 1 summaries each study results, based on successful fluid administration on the different insertion site, separated according to the study location:

| Insertion site | Study location and date | Total insertions | Needle penetrate to desired depth | Saline injection Succeed | % Success | Remarks |
|---|---|---|---|---|---|---|
| Proximal Tibia | 2012 Sep 28 Lima | 12 | 12 | 12 | 100.00% | |
| | 2012 Oct 05 GA USA | 29 | 24 | 24 | 82.76% | 5 Failures were due to user errors to insert the NIO to soft tissue or very wrong location |
| | 2013 March 15-17 Lima | 17 | 17 | 17 | 100.00% | |
| | Total | 58 | 53 | 53 | 91.38% | |
| | NY Study | NA | NA | | 98.00% | estimation |
| | 2012 Sep 28 Lima | 12 | 12 | 12 | 100.00% | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Humeral Head** | 2012 Oct 05 GA USA | 27 | 23 | 23 | 85.19% | 4 Failures were due to user errors to insert the NIO to soft tissue |
| | 2013 March 15-17 Lima | 19 | 18 | 19 | 100.00% | In one case the needle penetrate to 21.9 mm |
| | Total | 58 | 53 | 54 | 93.10% | |

Table 1

6.8. Table 3 summaries all the attempts made to different location distal to the correct penetration site on proximal tibia. The marking "0" and "Ped. location" was previously defined in section 2.3. Other insertion location are marked according to their distal distance from the correct insertion site:

| Insertion site | Total insertions | Saline injection Succeed | Saline injection failed | % Success |
|---|---|---|---|---|
| 0 cm | 16 | 14 | 2 | 87.50% |
| Ped. Location | 16 | 14 | 2 | 87.50% |
| 3 cm | 1 | 0 | 1 | 0.00% |
| 4 cm | 5 | 4 | 1 | 80.00% |
| 5.5 cm | 2 | 2 | 0 | 100.00% |
| 8.6 cm | 1 | 1 | 0 | 100.00% |
| Total insertions | 41 | 35 | 6 | 85.37% |

Table 2

6.9. Figure 2 present the success rate for the different “wrong” locations:

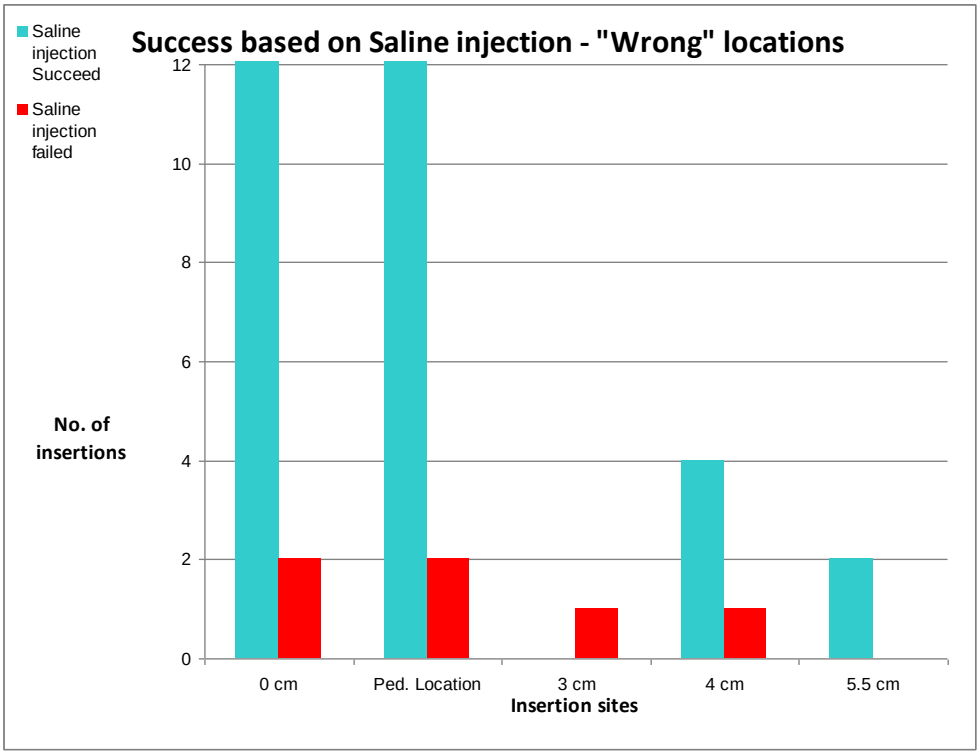


Figure 3

## 7. Discussion

7.1. Nearly 390 NIO devices were used for these studies. 263 for the internal cadaver studies in Lima Peru and GA USA and 127 for the study in NY USA.

7.2. In all cases that were x-rayed post insertion, there were no bone fractures due to the insertion. More than that, in some cases, after the needle was injected to the proximal, more additional insertions were made to a "wrong location" on the same limb. Even in these cases there was no evidence to bone fracture on the limb due to injection.

7.3. The trigger mechanism operated as required.

7.4. Results of the usability study showed that the average procedure time for using the NIO was 18.3 seconds for the Proximal tibia and Humeral head.

7.5. The average user graded the ease of use of the NIO was 8.5.

7.6. In all cases there were no structural deformations seen on the needle as bent or broken needle.

7.7. The results of the study demonstrate the efficiency of the NIO device when applied to the proximal tibia or humeral head insertion sites, i.e. Over 90% success rate in fluid

administration or specifically 91.4% in proximal tibia and 93.1% in Humeral Head insertion sites.

7.8. The accuracy and effectiveness of the device when used on the proximal tibia insertion site have been demonstrated when the NIO was used as indicated (at the correct injection site) as well as at a deviation distal to the correct injection site. The NIO showed 91.4% success rate at the correct injection site (58 cases) and 85.4% success rate distal to the correct injection site (35 cases).

7.9. Despite the Humeral head is known as an anatomical point that is difficult to locate, 54 out of 58 insertion were successful, with a success rate of 93.1%.

## 8. Conclusion

The results of the human cadaver study validate the accuracy and efficiency of the NIO device when used on the proximal tibia or humeral head insertion sites.

Following 58 attempts to the proximal tibia and 58 to the humeral head, the NIO has been proven to have 91.4% success rate in the Proximal Tibia and 93.1% success rate in the humorous. The study in NY showed higher success rate of 98% in proximal tibia and 91% in Humeral head. The usability study showed that the average procedure time was 18.3 seconds and the average user graded the ease of use of the NIO was 8.5, where 10 is very easy

The accuracy and effectiveness of the device when used on the proximal tibia insertion site have been demonstrated when the NIO was used as indicated (at the correct injection site) as well as at a deviation distal to the correct injection site. The NIO showed 91.4% success rate at the correct injection site (58 cases) and 85.4% success rate distal to the correct injection site (35 cases).

The results support a conclusion that the NIO is tolerant to common user errors related to the correct insertion site on the proximal tibia. If a user (by mistake) penetrated to the "pediatric location" or to distal locations on the Tibia or as far as 5 cm distal to the Medical guidelines acceptable location, it is possible to assume that there is a high success rate for penetrating into the bone.