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Pre-clinical evaluation of the new veress needle + mechanism on thiel-embalmed bodies: a controlled crossover study – Experimental research

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Background: Veress needles (VN) are commonly used in establishing pneumoperitoneum in laparoscopic surgery. Previously, a VN with a new safety mechanism 'VeressPLUS' needle (VN+) was developed to reduce the amount of overshoot.

Methods: Eighteen participants (novices, intermediates, and experts) performed in total of 248 insertions in a systematic way on Thiel-embalmed bodies with wide and small bore versions of the conventional VN (VNC) and the VN+. Insertion depth was measured by recording the graduations on the needle under direct laparoscopic vision.

Results: Participants graded the bodies and the procedures as lifelike. Overall, a significant reduction ($P < 0.001$) in average insertion depth was found for the VN+ compared to the VNC of 26.0 SD16 mm versus 46.2 SD15 mm. The insertion depth difference in the novice group was higher compared to the intermediates and experts ($P < 0.001$). The average insertion depth for both needle types was less ($P < 0.001$) for female participants compared to male.

Conclusion: This study indicated that the VN+ significantly reduced the insertion depth in all tested conditions. Whether the difference between female and male performance can be linked to differences in muscle control or arm mass should be further investigated. Useful technical information was gathered from this study to further improve the VN+.

Keywords: entry technique, laparoscopy, safety mechanism, veress needle

Introduction

In laparoscopic surgery, a pneumoperitoneum is created by the introduction of CO₂ to give a distention of the abdomen to be able to view and get access to the intra-abdominal structures. Besides being a standard in gynecological laparoscopy, the Veress needle (VN) is also used frequently in general surgery, gaining in popularity especially in bariatric surgery. In a large nationwide survey from the Scandinavian Obesity Surgery Registry, the VN

HIGHLIGHTS

- Veress needles are commonly used to create pneumoperitoneum in laparoscopic surgery.
- A new VeressPLUS Needle (VN+) safety mechanism was tested on cadavers.
- Eighteen subjects from novices to experts participated.
- A significant reduction in average needle insertion depth was found for the new VeressPLUS Needle.
- In all cases, female participants had lower average insertion depths than male.

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was used to establish pneumoperitoneum in 59% of 17445 bariatric operations and the investigators even noticed an increase in the use of the VN during the course of the study^[1]. Kosuta^[2] concluded that the VN is easier and also relatively safe in this group of patients, whereas an open introduction in the obese patient is technically more demanding.

The VN is designed to prevent accidental injury by consisting of two parts: a blunt inner stylet and a sharp outer tip. The working principle of the Veress mechanism dictates that the blunt tip protector shoots forward after the reaction force on the needle (generated by the abdominal wall during insertion) very quickly drops to zero. This is illustrated in Figure 1. As the surgeon has to use a high force to puncture and overcome the resistance of the abdominal wall and because of the mass of his or her arm, a lot of potential energy is present. After the immediate loss of resistance on the tip of the VN, this potential energy will accelerate the VN further into the abdomen only until it is stopped by the surgeon^[3,4]. This phenomenon is called 'overshooting' and due to

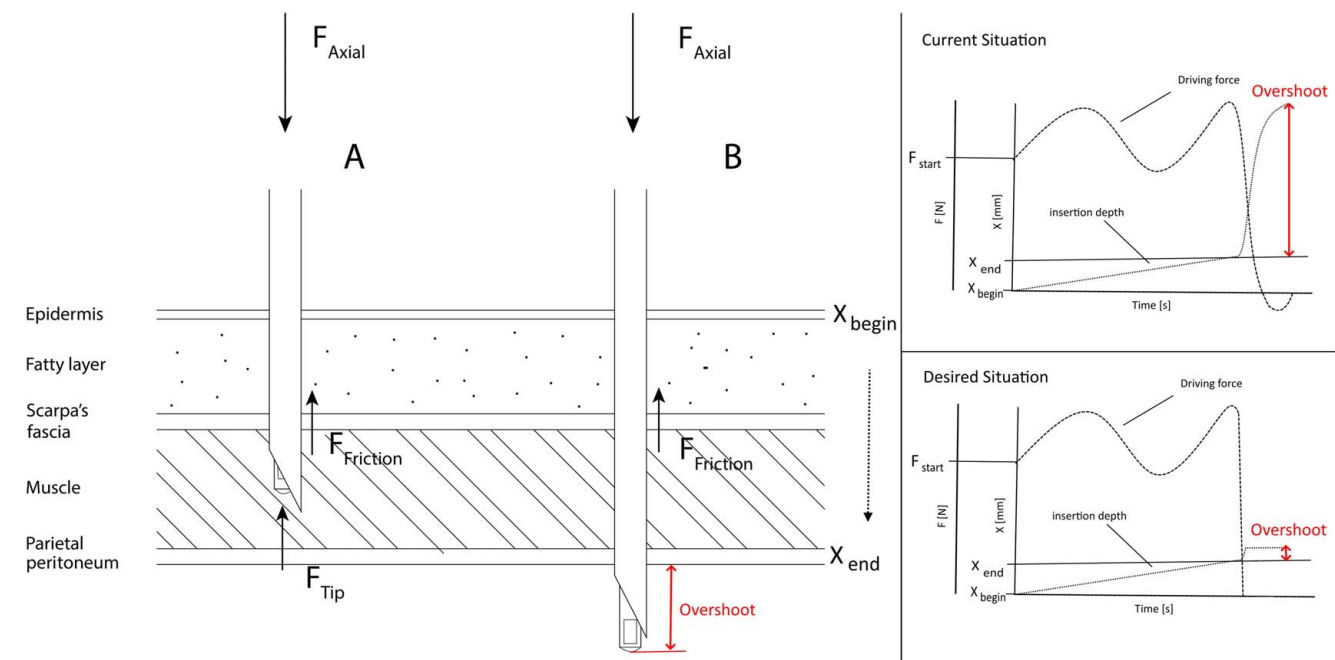


Figure 1. Working principle of the Veress needle and visual presentation of the overshoot in the current situation and the desired situation.

the relatively slow reaction of the human control system^[5,6], overshooting cannot totally be prevented (Fig. 1). Even if a surgeon is able to react fast, the indented tissue layers that were pressed inward by the tip of the VN will move toward their original position as soon as the tip punctures the peritoneum, exposing even more of the needle inside the abdominal cavity. Mainly because of the diversity of all these drawbacks, minimization of VN overshooting requires a relatively long learning curve.

To that purpose, the 'VeressPLUS' needle (VN+) was developed by integrating a new safety mechanism into a conventional VN (Fig. 2). This safety mechanism immediately removes the driving force as soon as the tip enters the cavity, thereby reducing potential overshoot. The mechanism works by preventing the puncturing acceleration of the tip of the VN by immediately decoupling the surgeon's hand from the VN after entering the abdomen (Fig. 3 image 4). A construction was designed which disconnects the grip-part (which has the surgeon's fingers on it) from the VN at exactly the same moment when the blunt inner stylet of the VN springs forward, thereby immediately removing the (kinetic) force from the VN. In a previous study, the VN+ was evaluated in a benchtop setup covered with an isolated porcine abdominal wall, showing a significant reduction in overshoot of more than 50%^[7].

The primary objective of this new study was to verify the added value of using the VN+ with a safety mechanism compared to a conventional VN (VNC) in a more representative preclinical setting. Therefore, Thiel-embalmed human cadavers^[8] were used to compare the overshoot between the new and conventional needle design. Tissues of Thiel-embalmed bodies have good representative mechanical properties, which are relevant when testing instrument technology that relies on differences in stiffness, reaction force, and friction when interacting with tissues^[9].

The secondary objective was to determine the presence of other influencing factors such as the needle diameter, type of body, wear, user experience level, and user gender. Finally, a design analysis was done based on the collected user feedback, and improvements were suggested.

Methods

Test setup

In total, two Thiel-embalmed bodies were used over three days. The first body was a 72-year-old male with no previous laparotomy or abdominal scars, who had died of myocardial infarction (length: 170 cm; bodyweight: 70 kg). The second body was a male of 65 years without abdominal scars. The cause of death had been a hospital-acquired pneumonia and pulmonary embolism secondary to metastatic pancreatic cancer (length 186 cm; bodyweight: 80 kg).

The setup of the experiments can be seen in Figure 4. An HD Aesculap laparoscopy tower setup (Aesculap) was used with a 10 mm 30° scope, which was inserted through a balloon trocar (Medtronic Netherlands) in the abdomen just below the umbilicus. Intra-abdominal pressure was stabilized using CO₂ to 4 mmHg. This pressure-level was as low as possible to allow for unambiguous visualization of the insertions but almost equaling normal abdominal pressure. Two different needle types were used, a thin bore needle with a diameter of 2 mm and a length of 145 mm and a wide bore with 2.8 mm diameter and 145 mm length.

Questionnaire

We used a questionnaire, which consisted of questions about sex, age, and previous experience. A 1 to 5 Likert scale (with 1 being the worst and 5 being the best) was used to score the 'life-likeness'

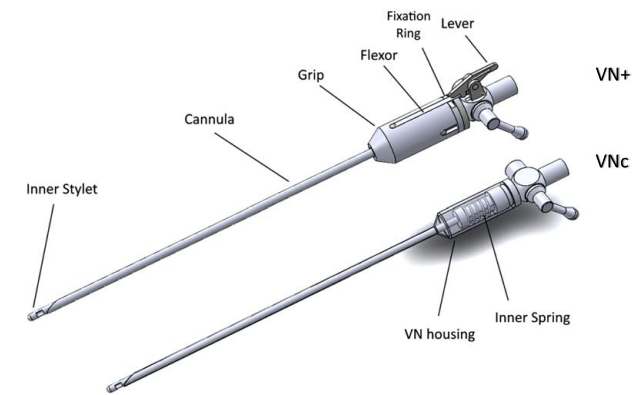


Figure 2. parts, build up of- and difference between the VN+ and VNc.

of the Thiel-embalmed bodies, the realism of the procedure, the safety of the VN + procedure, and the difficulty of using the new needle design (Supplemental File 1, Supplemental Digital Content 1, <http://links.lww.com/MS9/A70>).

Participants

Eighteen participants were included in this study, four were classified as expert (defined as 50 + VNc placements), four as intermediates (between five and 50 placements), and ten as novices (less than five placements). Table 1 shows the demographics of the participants.

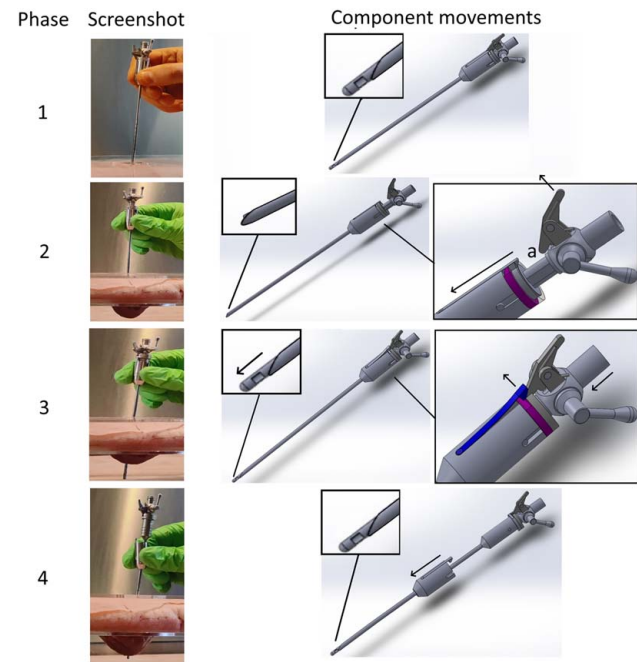


Figure 3. VN+ parts and test setup that shows the principle of the new VN+ mechanism. (A) The needle is hold at the grip during insertion. (B) during insertion the grip is connected to the needle and force is transferred towards the tip of the leened. (C) as soon as the tip penetrates the abdominal cavity the grip dislodges from the needle housing. (D) the dislodged grip travels towards the abdominal wall due to residential inertia of the arm and hand while the needle remains in place.

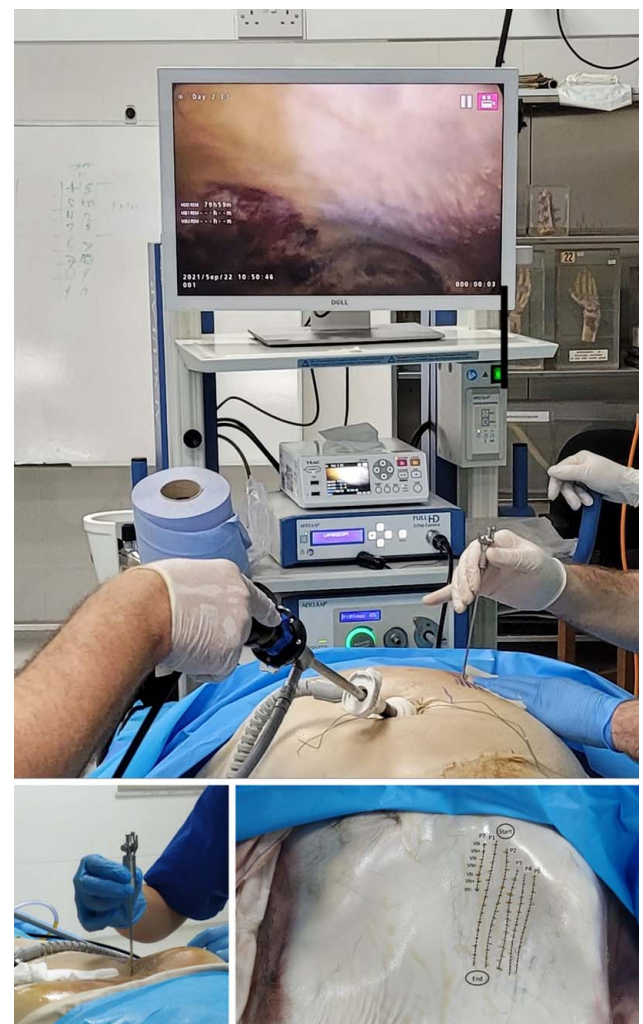


Figure 4. Test-setup with Thiel embalmed bodies and laparoscope for intra-abdominal vision. Below Left, hand position on the grip of the needle. Below Right, trajectory followed in the abdomen from start to end.

Protocol

After completing the first part of the questionnaire, the participants were instructed and explained how the mechanism works. During the instruction phase, they were allowed to try the needle on a dedicated area, away from the intended research area, until they were able to manage their grip and found their best insertion strategies (Fig. 4 left below). To minimize the risk of hitting organs upon entering the abdominal cavity, certain areas are dedicated for VN placement such as Palmer's point in the left upper quadrant of the abdomen^[10]. In order to use the bodies as efficiently as possible whilst offering a similar experience in terms of abdominal composition to all participants, the whole upper part of the abdomen was used for the insertions, which were done in an alternating fashion (with and without the safety mechanism) for 12 punctures (2 × 6) from cranial to caudal (Fig. 4 right below) so a 'fresh' part (with no defect or lesion) of the abdominal wall was used for each attempt. The participants were with their backs to the video monitor so they were blinded to what was happening inside the abdomen. Insertion of the VN+ was successful when

Table 1
Demographics and background data of all participants

General	Value
Male/Female	14/4
Age [mean SD]	34 SD 9 years
Experience with Veress needle [mean SD]	38 SD80 procedures
Left/Right handed	1/17

the mechanism fully unlocked. If not, the attempt was noted as an unsuccessful trial, the cause was determined and the insertion data was removed. After the hands-on part, the participants were asked to fill out the last part of the questionnaire with questions about the quality of the bodies and procedures based on their personal experiences and the difficulty of using the VN+ device. It is important to note that the VN+ dislodge action is not influenced by the amount of insertion force but only by the position of the inner stylet.

Data comparison and statistical analysis

Video footage was used by the three observers to determine the insertion depth, indicated by the number of markings engraved on the part of the needle surface inside the abdomen. The true insertion depth was calculated in Excel based on the known distance between each marking. After the participants completed the tests, any differences in maximum insertion depth between the VNc and VN+ groups were determined with a nonparametric Mann–Whitney test (SPSS v16) as the normality tests conducted on all data indicated that the data was not normally distributed in the VN+ group. Additionally, group comparisons were made as can be seen in Table 2 between the wide bore versus the small bore needles, sex, the used body, and participant experience level. A *P*-value less than 0.05 was considered a significant difference. The participant data statistical analysis between conditions and groups can be found in (Supplemental File 2, Supplemental Digital Content 2, <http://links.lww.com/MS9/A71> & 3, Supplemental Digital Content 3, <http://links.lww.com/MS9/A72>). The potential learning curve was established based on a

Table 2
Group comparisons between the wide bore versus the small bore needles, sex, the used body, and participant experience level when using the VNc or the VN+.

Statistical comparison (nonparametric) VNc				
group 1	size	group 2	size	Significance level (<i>P</i>)
Male	84	Female	24	0.002
Wide bore	72	Small bore	36	0.009
Body 1	51	Body 2	51	not significant
Expert	32	Intermediate	32	0.004
Intermediate	32	Novice	80	0.041
Expert	32	Novice	80	0.002
Statistical comparison (nonparametric) VN+				
group 1	size	group 2	size	Significance level (<i>P</i>)
Male	84	Female	24	0.002
Wide bore	72	Small bore	36	not significant
Body 1	51	Body 2	51	not significant
Expert	32	Intermediate	32	not significant
Intermediate	32	Novice	80	not significant
Expert	32	Novice	80	not significant

regression analysis executed on the averaged outcomes per trial including all trial data. The potential influence of wear was established based on a regression analysis conducted on 12 separately executed trials with the wide bore needles (Supplemental File 4, Supplemental Digital Content 4, <http://links.lww.com/MS9/A73>). Wear is defined as the diminishing sharpness of the bevel of the VN after each attempt. For the regression analysis a *P*-value less than 0.05 was considered significantly different.

Design analysis

Both questionnaire data and observation were clustered and used to suggest design improvements if needed.

Results

In total, six participants used the small bore VN+ system and 12 used the wide bore VN+ system. For the data analysis, a total of 216 insertions were measured and recorded coming from 18 participants that each did 12 insertions. Six of these 12 insertions were done with the VNc and six with the VN+. In total, 38 training insertions were done by all participants before the measurements were started. These training trials were not used in the data assessment. On average, 3.4 training insertions were needed during the instruction phase before the VN+ system was used without failure. Registered failures during training were finger contact with the decoupling mechanism that prevented proper functioning and preliminary decoupling of the VN+ needle.

The first two columns in Figure 5 show how all participants scored the quality of the bodies and procedure based on their personal experiences, and the second two columns show the difficulty and safety of the VN+.

Figure 6 shows the data of the participants with significance levels found between the conditions VNc and VN+ (Data set 1) and Table 2 indicates significant differences between different sex, different needle size, experience level, and different bodies for both the standard VNc and modified VN+ (data set 2). The SPSS output of the statistical analysis of both data sets can be found in (Supplemental File 2, Supplemental Digital Content 2, <http://links.lww.com/MS9/A71>). Figure 6 A shows the learning curve plots, which illustrate that in our study there is no learning curve for using either of the two devices. In Figure 6 B and Table 2 it can be seen that there is a significant increase in insertion depth while using the wide bore VNc compared to the small bore VNc, but this is not the case with the VN+. From the graph, it can also be clearly seen that with both the wide and the small bore VN the insertion depth is significantly lower with the VN+ as compared to the VNc. Figure 6 C and Table 2 show that there was a significant difference in insertion depth between the two bodies but only when the VNc was used. When using the VN+ the insertion depth was comparably low. Figure 6 D shows a significant reduction in insertion depth again between the VNc and the VN+ for either participant gender but for the average insertion depth for both the VNc and the VN+ this was significantly lower for female participants compared to male participants (Table 2). Figure 6 E and Table 2 illustrate that there is a significant difference in insertion depth between novices and experts and intermediates but not between experts and intermediates. There was no difference in the significant reduction of insertion depth

SCORING QUESTIONS

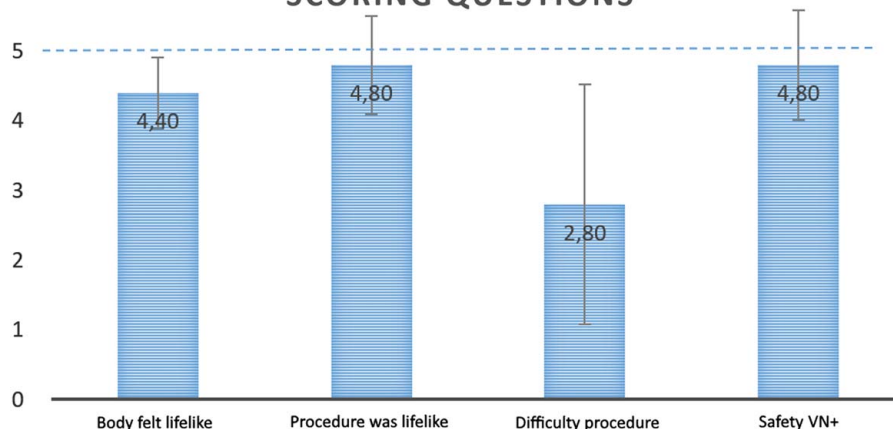


Figure 5. Participants scores for the quality of the Thiel bodies and procedure, and for the difficulty and safety of using the new VN+.

between all groups when using the VN+ compared to the VNc. With the VN+ the much lower insertion depth is independent of expertise level. Figure 6 F shows that in our study there is no potential learning curves related to wear and tear during use of the needles (Supplemental File 3, Supplemental Digital Content 3, <http://links.lww.com/MS9/A72> & 4, Supplemental Digital Content 4, <http://links.lww.com/MS9/A73>).

User feedback on design

Feedback of the users for improvement of the system can be divided into 'mechanism' related (44%), 'grip' related (44%), and 'others' (4%). The mechanism related feedback remarks mostly mentioned the reliability of the system. In some cases, it failed to unlock when undesired interaction took place between the fingers and parts of the mechanism. In other cases, it failed when the sleeve was not properly moved towards the incision, because of the presence of an excessive external torque on the interface. The grip-related remarks indicate that the interface was sometimes slippery; there was not much space to accommodate the fingers and therefore it was not easy to prevent contact with parts of the mechanism. In two cases, it was suggested to extend the grip of the mechanism toward the location of the tip of the needle. In the 'other' category it was mentioned that a large bore needle is preferred for faster insufflation. Another remark was that the needles became blunt and should be sharpened and two remarks were made about how the new VN+ method reduced the feeling of transitioning through the abdominal wall layers.

Discussion

In all cases, participants were positively surprised after working with the new VN+. Good instructions and some training trials were needed for the participants before the system mechanics were fully understood. Performance only improved as participants understood that it was important not to touch the moving parts and to apply the needle force as good as possible towards the incision. All users rated the Thiel-embalmed bodies and procedures very high, indicating that the

properties of the tissues are considered to be lifelike enough to provide a very good training and practice environment. Especially for procedures and technology that rely on proper tissue-machine interaction, Thiel bodies are desired above other preparation methods or in-vitro setups^[11]. Of course, the clinically most ideal situation would be to test the VN+ on patients but the step before that in our view is using- and fine-tuning it on the most 'lifelike' cadaver model.

The performance with Thiel-embalmed human cadavers is comparable with the results from the in-vitro experiments^[7]. However, the data also indicate that participants need to learn how to hold the needle in a proper way for the mechanism to fully dislodge as the first attempts often went wrong. The absence of a learning effect; however, does indicate that when the system is operated properly, the insertion depth is determined by the VN+ safety mechanism and not by the gained experience, which is also illustrated by the absence of an effect of the experience level of the surgeon on the insertion depth. This being said, the failures that were noted after the first trials could be interpreted as a learning curve. After the technical issues have been solved it is advisable to investigate the learning effects again to ensure that the failed trials did not hide any potential steep learning effects.

The data comparison suggests that the diameter of the needle plays a more important role when using VNc than VN+ as using the latter one showed no significant differences between groups. Traditionally, having a thicker needle means that more force is needed to drive it through the abdominal wall, increasing the risk on overshoot. If this increase of risk is reduced due to the use of a safety mechanism, it could mean that even thicker bores can be used. A wider bore needle is advantageous because of the fact that it enables faster insufflation, reducing operating time. If possible, it is interesting to relate the VN+ driving force and insertion speed profile to the insertion depth in further studies.

In addition, having two different bodies does seem to result in a different averaged insertion depth when using VNc, something that was not observed for the VN+. This indicates that differences in the anatomic layers that normally influence the human control system are not relevant when using the

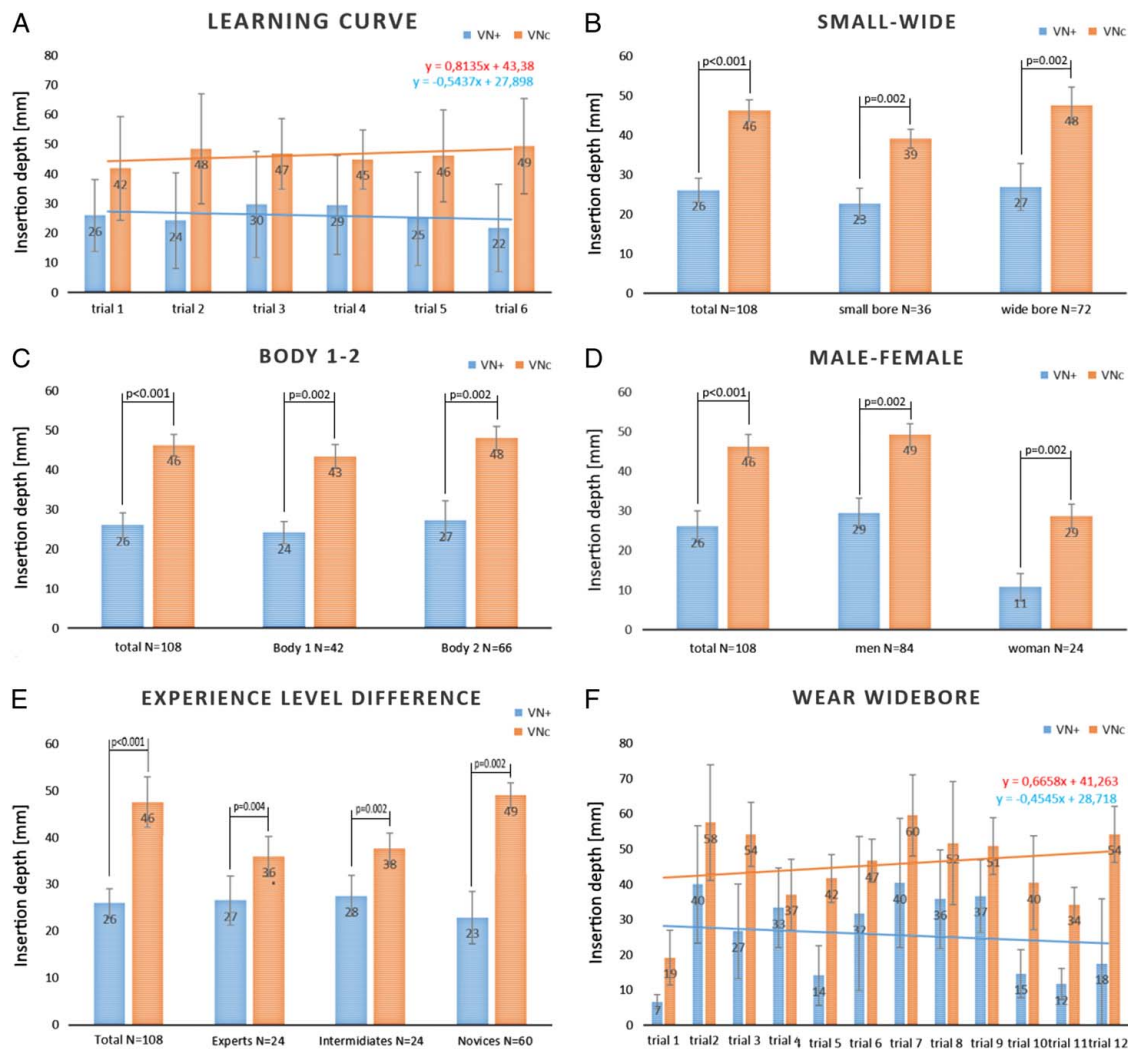


Figure 6. Insertion depth using VNc and VN+ with STD. (A) Depth data for six consecutive trials of 18 participants, with linear regression lines. (B) Insertion depth for wide bore and small bore with VNc and VN+. Total group data is added for reference. (C) Insertion depth data for the two different bodies. Total group data is added for reference. (D) Insertion depth for the two different genders. Total group data is added for reference. (E) Insertion depth between VN and VN+ for the three different experience levels. The total group data is added for reference. (F) Insertion depth data of 12 trials executed with the wide bore VN+ and VN needles with regression lines.

safety mechanism of the VN+. This should be further explored on bodies with more distinguished differences in BMI and anatomy.

When looking at the influence of the experience level on the overall insertion depth, we see that although a significant difference was found for all groups, a larger effect was found in the novice group compared to the intermediates and experts. This suggests that less-trained surgeons can benefit the most from this additional safety system. Presumably because they have not developed the fine motor controls that the more experienced surgeons have gained over years of practice.

An interesting finding is that there was a significant difference between male and female participants: with an average insertion depth of 2.1 and 5.7 mm for the women versus 5.9 and 9.9 mm for the men when using the VN+ and VNc, respectively. Additionally, a significant difference of P less than 0.001 was found for each needle type between men and women. It could well be that women are more likely to use less

force or have better control capabilities compared to men in line with the results of Hsin Yi^[12] who showed that females made fewer errors and used less force in several laparoscopic exercises using the da Vinci master slave robotic system and Lou^[13], who showed that female medical students exhibited a significantly better performance to males, especially in training complicated surgical procedures. Another explanation can be that men are more prone to take risks whereas women are more careful^[14]. Whether this finding can also be related to less muscle strength or lower arm mass should be further investigated^[15]. In a follow up clinical evaluation study we will also record the hand size of the participants because this could also play a part in the difference between men and women in this study.

The design analysis based on the collected user feedback for the final objective suggests that the system needs to be more reliable. We concluded that the most important way to achieve that is to alter the design in such a way that all moving parts

from the needle will be shielded in order to prevent the contact between lever and pins from hampering the unlocking mechanism. When using the system, it became evident that the needle needs to be really sharp to prevent abdominal wall layers from being pushed into the abdominal cavity instead of having a clean cut through each layer. Especially when the insertion point is further away from the ribs, it can be argued that a blunt tip more likely presses the tissues further down than needed, resulting in contact between the peritoneum and organs, which could lead to complications. Although wear influences were not present in our study, the tissue tip interaction observations strongly suggest to keep the needles well maintained and sharp at all times. The feedback from all participants that had experience with the VNc suggested that the needle should not be held at the grip-part, as intended by the manufacturer, but at the cannula level. Therefore, we will adjust the design by changing the interface through adding a thin over-tube around the cannula that is connected to the grip. To prevent the cannula and inner stylet from moving inward due to gravity or from undesired contact between the dislodged grip and needle components, it could be beneficial to increase friction between the cannula and tissue by adding ridges or a profile around the cannula tip. When the design is updated the researchers will try not to compromise on the elegance and simplicity of the design.

In a number of insertions, the VN+ needle moved further inward, despite unlocking, due to contact between the dislodged housing and the needle components. Analysis of these cases sometimes shows a distorted uncoupling of the safety mechanism and sometimes a too slow movement of the inner stylet. The first indicates that the hand position and force direction play an important role, whereas the latter shows that it is very important to clean the mechanism well after use as dirt gets stuck between the stylet and needle, thereby influencing performance. In order to prevent participants from aiming force incorrectly toward the incision, whereby undesired contact occurs between the dislodged housing and the rest of the needle, design improvements are needed which will increase the distance between parts as soon as the system uncouples. The impact of these improvements together with proper user training should be investigated in a future study. A safe implementation of the system is needed to truly investigate the added value for different types of users.

Study limitations

The use of two sizes of needles, although interesting, clouded the design of the study a little. In future research, it is advisable to include less of these variables to keep the study results 'cleaner'. Only male bodies were used for the experiments in this study. As the tissue layer thickness of the female abdominal wall can be different from that of males, the influence on the VN+ should be investigated in future studies.

Conclusion

In line with preliminary in-vitro results, this study, conducted on lifelike Thiel-embalmed bodies, indicated that the VN+ significantly reduced the insertion depth in all tested conditions. With this system, the insertion depth now only depends on the transition from the abdominal wall to the intra-abdominal cavity, independent from the surgeon's skills or experience level.

Whether the difference between female and male performance may be linked to differences in muscle strength and/or arm mass or other factors should be further investigated.

During this study, we used a comprehensive questionnaire, which, together with discussion with participants, provided us with very useful physical and technical feedback, enabling us to further improve the design of the VN+ device in the near future.

Ethical approval

The Medical Ethical Committee of the Faculty of medicine and Surgery of the University of Malta has given approval under number: FRECMDs-2021-134.

Consent

All participants have signed an informed consent form.

Sources of funding

NA.

Conflicts of interest disclosure

Roelf R. Postema, Jenny Dankelman, Christian Camenzuli, Jean Calleja-Agius, Sem Hardon, Frank-Willem Jansen, and Tim Horeman-Franse have no conflicts of interest or financial ties to disclose, David Cefai has a patent pending on the VN+.

Data availability statement

All data are securely stored at the Delft University of Technology Servers. They are available upon request to the corresponding author.

Provenance and peer review

Not commissioned, externally peer reviewed.

Acknowledgments

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