The VeressPLUS™

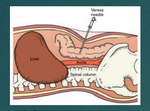
a novel Veress Needle that reduces overshooting after puncturing the abdominal wall

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ROELF R. POSTEMA MD[1], DAVID CEFAI MSC[2], TIM HOREMAN MSC PHD[3]

1. DEPARTMENT OF SURGERY, AMSTERDAM UNIVERSITY MEDICAL CENTERS, AMSTERDAM, THE NETHERLANDS; 2. PROVINCI MEDTECH, NOOTDORP, THE NETHERLANDS; 3. FACULTY OF BIOMECHANICAL ENGINEERING, DELFT UNIVERSITY OF TECHNOLOGY, DELFT, THE NETHERLANDS

1.Background



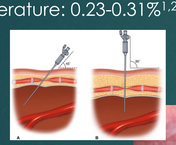
Complications of Laparoscopic Surgery are often associated with initial entry!

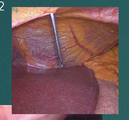
Incidence Veress Needle **injuries** literature: 0.23-0.31%[1,2]

Organ perforation:

Bowel, Liver or Gastric perforation

Vascular injury!







1. Nevler A, Har-Zahav G, Rosin D, Gutman M. Safer trocar insertion for closed laparoscopic access: ex vivo assessment of an improved Veress needle. Surg Endosc 2016;30: 779–782
2. Azevedo JLMC, Azevedo OC, Miyahira SA, Miguel GPS, Becker Jr OM, Hypolito OHM et al. Injuries caused by Veress needle insertion for creation of pneumoperitoneum: a systematic literature review. Surg Endosc 2009;23: 1418-32

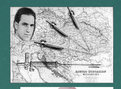
2.Veress Needle

History of the Veress needle: Developed in 1932 by Janos Veress in Hungary.

Use: Closed technique to establish **Pneumoperitoneum** for laparoscopic Surgery

Used **Very Frequently**: 78% [1] by Gynaecologists (81%) and Surgeons (48%) and especially in Bariatric Surgery

Build up of the needle: outer stylet with sharp edge to cut through tissue (abdominal wall); and spring loaded blunt inner stylet which springs out and covers the sharp part when the tissue resistance has fallen away (after entering the abdomen)







1 Molloy, David; Kaloo, Philip D.; Cooper, Michael; Nguyen, Tuan V. (2002). "Laparoscopic entry: A literature review and analysis of techniques and complications of primary port entry". *The Australian and New Zealand Journal of Obstetrics and Gynaecology*. **42** (3): 246–254.

3.Complications!

Why?

The tip of the needle has a very small surface diameter of only 2 mm.

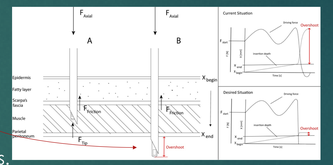
The needle is coupled with the surgeons'arm while *forcing* the needle through the different layers of the abdominal wall.

So, there is kinetic force and momentum of the needle/arm combination left after the needle has entered the abdomen.

This is due to the reaction time of the surgeon to stop the Introduction (time-lag).

During this time there is an "**overshoot**" of the needle in the abdomen (figure).

This **overshoot** can cause **perforations** of tissues and organs.

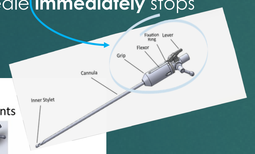


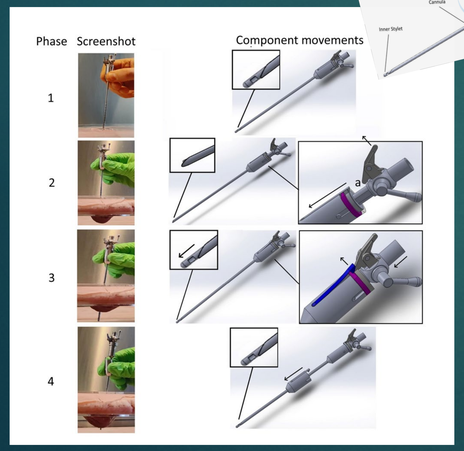
4. VeressPLUS Safety mechanism

The VeressPLUS™ needle

Force Decoupling safety mechanism:

when the needle enters the abdomen, the surgeon's hand/arm is **decoupled** from the needle. The needle **immediately** stops entering!





5. Pre Clinical Studies

The V**+** was evaluated on an **ex vivo porcine abdominal wall** tissue model in a custom setup as a **pilot study**

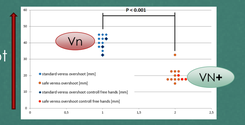
3 participants

2x10 insertions (Vn/V**+**)

60 insertions

50% reduction !

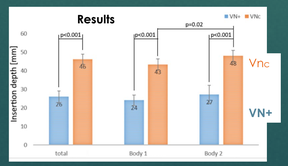
Overshoot



Furthermore, we performed a preclinical study on **human cadavers** in the Anatomy lab of the Faculty of Medicine of the University of Malta, where 18 medically trained participants (novices, intermediates and experts) performed in total 248 insertions in a systematic way on **Thiel embalmed bodies** with the conventional Vn and the V**+**. Insertion depth was measured by recording the graduations on the needle under direct laparoscopic vision.







Conclusion:

A new decoupling safety mechanism, the VeressPLUS™, was integrated successfully in a standard Veress needle that, when tested in a pilot and a preclinical study, showed (very) significantly reduced insertion depths compared to a standard Veress needle.