

SHORT TERM SCIENTIFIC MISSION (STSM) SCIENTIFIC REPORT

This report is submitted for approval by the STSM applicant to the STSM coordinator

Action number: CA18117

STSM title: Development of a safer Veress needle for abdominal laparoscopic surgery

STSM start and end date: 9/4/2022 to 14/4/2022

Grantee name: Christian Camenzuli

PURPOSE OF THE STSM:

The main treatment modality for patients suffering from rare gynaecological cancer is the surgical excision of the tumour (if the stage and the patient's co-morbidities allow). Laparoscopic surgery is the gold standard approach and this requires the development of a pneumoperitoneum. The veress needle has been used for a long time however the dangers of organ injury on insertion of the device has always been a major concern. This is particularly the case in rare gynaecological cancers which have a higher risk of altering the pelvic and abdominal anatomy and therefore increasing the risk of intra-abdominal organ injury during insertion. The scope of this STSM was to continue working on developing an adaptation to make the veress needle safer. The work of this has been already started through a collaboration between the University of Malta and TU Delft University in the Netherlands. This mission focused on further strengthening the collaboration and fine tune the device through discussions, presentations, hands-on testing and drafting of 2 publications.

DESCRIPTION OF WORK CARRIED OUT DURING THE STSM

The work carried out during this mission can be summarised as follows:

- Saturday 9th April 2022: After arrival, afternoon meetings with students of TU Delft were carried out on campus. These students are actively engaged in the development of this device and similar devices in order to make laparoscopy surgery for patients suffering from gynaecological cancers safer even in the hands of relatively inexperienced surgical trainees.
- Sunday 12th April 2022: Meeting with Mr David Cefai, who is the director of the SME by the name of ProVinci Medtech (<https://provincimed.tech/>). Discussions were held on how the innovative design of the novel Veress needle which can reduce overshooting after puncturing the abdominal wall can be tested with a view of carrying out more finetuning.
- Monday 11th April 2022: Meeting with on campus PhD student who is contributing with further refining the device with a view to bringing it closer to being ready for clinical trials. During this day, we analysed the data obtained from the last cadaveric experiments carried out earlier in Malta. We also analysed the results obtained from the pan-European survey on the use of the Veress needle. Additionally we also assessed the new modifications carried out to the design of the novel Veress needle which was based on the feedback given by the experts and novices during the previous experiments. We addressed concerns regarding the process for sterilising the device as well as issues with the handling. The evaluation was carried out on simulators.
- Tuesday 12th April 2022: This day involved multiple meetings with Professor Tim Horeman, his team and university administration at TU Delft. During these meetings, the capabilities of the team at TU Delft, both technical and experience, to contribute to the development and fine-tuning of the device, were explored. In addition these meetings helped to consolidate the collaboration between the two Universities (ie TU Delft and University of Malta) with the aim of signing a

memorandum of understanding in the near future. This would make further research and development of biomechanical devices to make laparoscopic surgery safer easier to co-ordinate.

- Wednesday 13th April 2022: This day was dedicated to the writing of the scientific papers that we plan to submit for publication soon. This project, will hopefully see the publication of a number of academic papers and during this visit we specifically worked on two of these papers. In addition we explored the application of other devices which are being developed at TU Delft University in the context of laparoscopic surgery for rare gynaecological cancers.
- Thursday 14th April 2022: Wrap up meeting and flight back to Malta.

DESCRIPTION OF THE MAIN RESULTS OBTAINED

The outcomes of this short mission can be summarised as follows:

1. Fine tuning of the novel Veress needle based on the background of the feedback from previous cadaveric evaluation. This device is now in the final stages before entering the market, with cadaveric assesement already showing improved safety profile particuarly in non-expert hands. The new version developed during this mission will be trialed again in cadavers at the University of Malta, before the device enters the clinical trial phase;
2. Writing of scientific papers for publication in peer-reviewed journals. The two papers written during this mission are now going to be circulated with the rest of the group prior to submission;
3. Re-inforcing the collabrative efforts between the University of Malta and TU Delft.inorder to continue working together, particularly in the development of novel devices inorder to make laparoscopic surgery safer, especially in the case of rare gynaecological cancers, where the anatomy may be challenging and unpredictable.

FUTURE COLLABORATIONS (if applicable)

The devices, including the novel Veress needle, which have been fine tuned during this visit and which have been tested on simulators, will now need to be tested on Thiel embalmed cadavers at the Department of Anatomy, Faculty of Medicine and Surgery, University of Malta. This will happen in the next few weeks through a delegation of the main stakeholders from TU Delft, including PhD student/s coming for a mission in the labs at the University of Malta. In this way the new data can be used to work on the next publications and to take the new device to market.

In addition, the strengthening of the collaborating teams from both univeristies that happened through this short term scientific mission, is the begining of a long and fruitful collaboration that will pave the way for the development of further devices to help make laparoscopic surgery safer for the gynaeoncology patients and other patients needing minimally invasive surgery, as well as for the surgeon.