A design to enable electromagnetic tracking on laparoscopic sealers for surgical navigation

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This thesis is written for the surgical oncology department of the Antoni van Leeuwenhoek Hospital. The hospital is specialized in oncology: the diagnosis and personalized treatment of cancer. It is part of the Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital (NKI-AVL). The hospital is constantly investigating the improvement of current treatments and the discovery of new treatments. It is a hospital with many different disciplines (AvL, 2018). A patient undergoes often a combination of several treatments, for example radiotherapy and surgery.

One of the expertized disciplines is surgical oncology. Within this department research about 'image-guided interventions' is performed. One of the research teams focusses on whether surgical navigation is feasible or beneficial during tumor removal surgeries in the abdomen. This technique can be compared with the navigation of a car, which needs to go from point A to B. The surgeon can observe the exact location on a screen in the operating room. Now, this technique is used during open surgeries. Unfortunately, using this technique during laparoscopic surgeries is not possible due to the lack of space in the abdomen. An integration between the navigation technique and the used 'Ligasure Maryland Jaw' surgical instrument during laparoscopic surgeries is desired. The following research question will be answered:

"What is a safe, user-friendly and accurate way to integrate the surgical instrument LigaSure™ Maryland Jaw and the Aurora 6DOF Cable Tool sensor, with a connection solution which supports laparoscopic surgical navigation?"

Approach

The study is divided into four stages: [1] Analysis, [2] Concept Development, [3] Detailing, [4] Prototyping. First, several analyses are performed to understand the context in the hospital, the technique itself, possible materials and product opportunities. The stakeholder analysis gave insights about who could affect the design and how and with whom the design should be evaluated. The material of the product must be biocompatible and must be cleaned & sterilized multiple times. The analysis showed that Dental SG, a resin which can be 3D printed by a Formlabs printer, is the best option.

Product Development

Requirements are derived from the analysis phase. With these criteria, several concepts can be made. The main goal of this assignment is to get the sensor as close as possible to the tip. Therefore, a long Sleeve around the shaft of the Maryland is designed. The design consists of three main components: [1] Sleeve, [2] Fixator on instrument, [3] Sensor integration in design. For each main component, several sub-concepts are considered. Through product tests and feedback sessions with the primary stakeholders, a total design is derived. With a Multi-criteria Decision Analysis, the best design is chosen and further improved in the detailing phase. The final design (Figure 1) is user-friendly and easy to use. The sensor can be placed very easily in the design since the design has easy accessibility. This due to the special two-parted system, unique shaped sensor cover and hand-tight cable gland fixator. Next, to the slide system, a bolt is implemented into the design. The two-parted Sleeve can be connected to each other by a slide system. To block any rotational movements, an addition bolt is implemented in the design.

During the prototyping phase, tests about the ease of use and strength are performed. Vertical and rotational forces were being tested on the prototype. Movements of the sensor in the design are not allowed. Due to any movements of the design, the accuracy of the navigation technique cannot be assured. In vertical direction, the movements are fixed. However, in rotational direction, the design can still rotate when applying forces.

Conclusion

It is nonetheless a promising improvement of laparoscopic surgeries and the navigation technique. The results of the design are promising and the surgical oncology departments want to start with clinical tests of the product. However, the clamping mechanism of the design is not strong enough in rotational direction. So, the rotational movements need to be fixated on different laparoscopic and should be tested in future studies. When this is done, the design is easy to integrate into the operating room, on the laparoscopic instrument and with the surgical navigation technique.

Figure 1: Integration of the final design on the Ligasure Maryland Jaw.