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Design of Mini-Grasper Inserted By Hypodermic Needle

Robin Najmaoui[1], Sorin Cimpean[2]

[1]Polytechnic School Brussels, [2]Saint Pierre University Hospital Brussels

Abstract

The tendency of the surgical world is to perform minimal-invasive surgeries and to reduce the traumatic effects of surgical act on the abdominal wall. We designed an instrument that can be that allows a transparietal intraabdominal placement using a hypodermic needle giving the possibility to perform a suture or grasping gestures. This new tool could also be used as a mini-grasper in case of limited dissection or for the suspension of the gallbladder during laparoscopic cholecystectomy. This design would allow for one-hand use but would need practice since the unwilling activation of the mechanism would cause the clamp to retract. Furthermore, this new medical device could offer to the surgical world the possibility to manipulate internal structures without the need of prior insertion of a trocar. This could allow a reduction in the number of incisions, thereby increasing patient postoperative comfort.

Background

The tendency of the surgical world is to perform minimal-invasive surgeries and to reduce the traumatic effects of surgical act on the abdominal wall. The treatment of abdominal diastasis will be used as a starting point to design an instrument capable of manipulating intraabdominal organs and performing transparietal sutures without the insertion of additional trocars and with less traumatic injury.

In order to achieve this goal, several tools will be studied in detail. Various improvements will then be proposed in order to meet surgical needs, such as an optimization of the ergonomics and a reduction of the potential traumatic character which is a considerable problem of the existing instruments.

For this purpose, several conceptual solutions will be described and compared before choosing the best solution that will be subject to 3D modeling. The development of the device being completed, various improvements are suggested in order to anticipate the possibility of inconclusive tests.

Identification of the surgical problem

Diastasis Recti Abdominis Muscle (DRAM) [1] is a progressive pathology mainly affecting women or patients who experience a rapid loss of body mass. It is characterized by a complete or partial separation of the rectus muscles [2] [3], which can pose aesthetic and functional problems. In most of the cases this pathology can be treated by specific physiotherapy. However, in large diastasis, or refractory to the conservative treatment, surgery may be necessary.

The surgery can be performed by laparotomy or by laparoscopy. The laparotomy technique consists in suturing the aponeurosis and approximating the rectus muscles in order to reduce the diastasis. A large incision is performed in the lower abdomen or on the midline. This is very invasive for the patient, and can increase the risk of postoperative complications. [4] In order to improve patient comfort, a minimally invasive laparoscopic method was developed [5]. This procedure consists of subcutaneous dissection, aponeurosis suture and muscle approximation (Figure 1) which can reduce the severity of potential postoperative complications. The sutures and abdominal wall are then reinforced by the placement of a non-resorbable mesh. (Figure 2)

We designed an instrument that allows a transparietal intraabdominal placement using a hypodermic needle, giving the possibility to perform grasping gestures and sutures. This new tool could also be used as a mini-grasper in case of limited dissection or for the suspension of the gallbladder during laparoscopic cholecystectomy.

Objective

The aim of this article is to propose a new tool based on what already exists on the market. In addition to allow percutaneous sutures in a more secure manner, this instrument could also give a grasping capacity, allowing the apprehension of various tissues. This instrument is designed to reduce the traumatic nature of a trocar in cases where a supplementary grasper is needed.

Suturing instruments

Suture aid instruments were developed with the aim of facilitating and systematizing the suturing of trocar insertion sites. [8] Several existing devices operate on this same principle, such as the Carter Thomason Close Sure System [9], the Easy Close ™ or Omni Close ™ [6] (Unimax) visible on (Figure 3). Some instruments penetrate the tissues thanks to their sharp head whereas the insertion is facilitated by a hypodermic needle for others. For the suture a simple hook or a rudimentary grasper is used to retrieve the suture thread.

Numerous changes are introduced in the tool discussed in this article, such as the improvement of the ergonomic. Indeed, the actual instruments are designed to be used with 3 fingers while they should be able to be handled with 2 fingers only without risk of slipping, even when wearing wet gloves. In addition, to have suitable handling, the length of the needle must be increased as well as the opening of the jaws. Finally, the potential tissue trauma must be minimal, contrary to some actual instruments for which the grasper is composed of the two ends of a metal wire. The different solutions chosen for the design are described in the following section.

Conceptual solutions

Handle design

The use of closed circles for the places of insertion of the user's fingers could significantly increase the support and prevent slipping. However, this system decreases the maneuverability of the instrument. We propose as a solution to increase the size and the curvature of the grips on the body of the object as shown on (Figure 4).

Jaws design

The challenge will be to increase the grasping capacity of the instrument while maintaining its simplicity and reducing tissue trauma. To determine the best way to achieve these results, several ideas were compared.

The traumatic nature of the instruments using bended metal wires is eliminated in the first concept. Unfortunately, the grip capacity is also drastically reduced. This can be resolved by the slight insertion of the upper part in the opening of the lower portion when closed, as shown in the second design. However, the tip could pierce a hole in the tissue, damaging its integrity. Hence the third concept of pliers where the upper part, by the fold of the end of the wire, presents a more rounded shape. Finally, the fourth concept would provide an improved grasp capacity given the complementarity of the jaws but would increase the complexity of the tool.

Having compared the various solutions in terms of simplicity, handling, grasping capacity and safety, the third concept has been deemed most promising.

Implementation of the design

The working principle of the device is as follows: initially, the jaws are hidden within the needle. Once the button of the mechanism is activated, the clamp, formed of a metal wire and hitherto compressed in the instrument, comes out by adopting an open position which is its natural form. A spring allows the structures to be replaced in their original positions when the button is released.

A total of 7 different components where identified. The hypodermic needle, which allows percutaneous access and carries the forceps, is composed of a 210mm long 12-gauge metallic tube. One end will be beveled at an angle of 30° whereas the other end will be inserted 5mm into the "body" of the instrument (Figure5). The latter is made of plastic and presents two lateral protrusions for the placement of the fingers. At the upper end, a threading is made in order to fix the locking piece (prevents the ejection of the internal device due to the spring when screwed in place). This thread is cut in two places and a notch is present on the inside of the part in order to block the rotation of the activation button and avoid the wrong positioning of the clamp attached to it through the support tube. This piece is a 240mm long 18-gauge metallic tube. A 15mm portion of it will be inserted into the "button" while the clamp will be inserted in its other end. This clamp is made by bending a metal wire (Figure 6). Finally, the mechanism is able to operate due to the action of a spring.

Assembly

The different parts of the medical device having been produced, it is necessary to proceed with the assembly:

1- Insertion and fixation of the support tube into the activation button. 2- Introduction through the locking part and the spring. 3- Integration of the clamp within the support tube and fixation by pressure points to the latter. 4- Fixation of the needle in the body of the instrument. 5- Insertion of the grouping of step 3 into the body using its notches as guides for the protrusions of the activation button. 6- Screwing of the locking piece while keeping the spring slightly compressed. The final assembly is illustrated in Figure 7.

Potential improvements

Even though tissue piercing is made unlikely with the designed grasper, the withdrawal of the latter within the hypodermic needle could result in the tearing of the grasped tissue. In order to avoid this trauma while optimizing the produced force, various solutions can be considered. The first one uses an adjustable screw to prevent the complete retraction of the jaws inside the needle. The modifications of the design are illustrated in Figure 8. The rotation of the activation button sets the gap between the transition part (yellow) and the adjustment part (red), which are not able to rotate. The first one then defines the maximum opening of the clamp whereas the latter determines the minimum opening of the device. Unfortunately, this design makes the use of both hands mandatory for the adjustments and the free rotation of the activation button might reduce the ease of operation of the instrument.

A second solution is the implementation of the working principle of retractable pens in the device. This would allow for two different stable positions. The first one corresponds to a closed state whereas the pliers stay slightly outside of the needle in the second one. The transition is caused by a full compression of the button. This design would allow for one-hand use but would need practice since the unwilling activation of the mechanism would cause the clamp to retract.

Conclusion

DRAM is a pathology which can have serious consequences in the absence of preventive treatment. Classical surgical interventions are either very traumatic or very complex to perform, the development of new minimally-invasive techniques and instruments can prove to be very relevant. Following researches in the current literature and the establishment of specifications, it was possible, by a conceptual study, to determine the most suitable tool and potential improvements. Furthermore, this new medical device could offer the surgical world the possibility to manipulate internal structures without the need of prior insertion of a trocar. This could allow a reduction in the number of incisions, thereby increasing patient postoperative comfort. More detailed studies of the device as well as its realization could therefore allow for a promising instrument for minimally invasive surgery in the future.

Conflict of interest

The authors have no conflict of interest to declare.

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Figures:

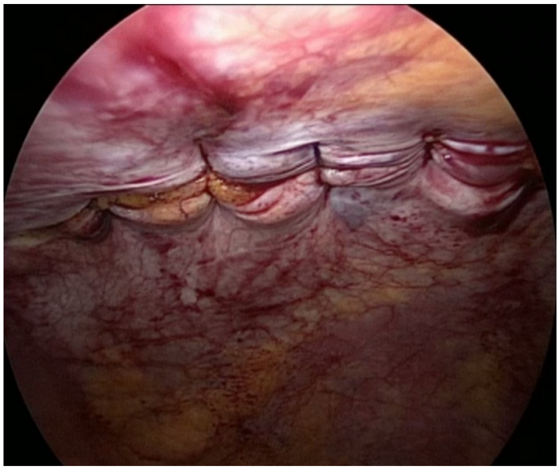

Figure 1. Aponeurosis suture and muscle approximation

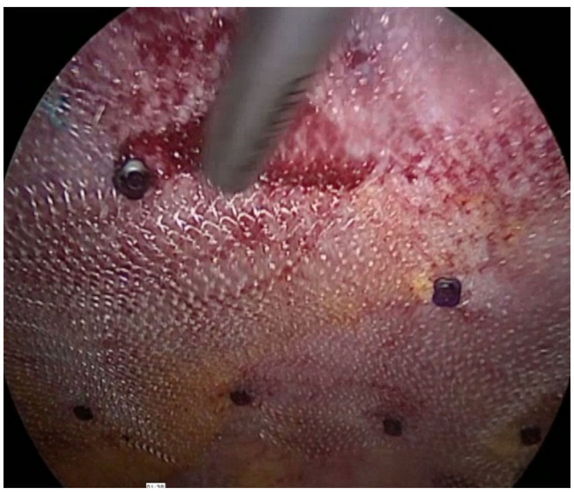

Figure 2. Placement of a non-resorbable mesh.

Figure 3: Examples of existing suturing instruments

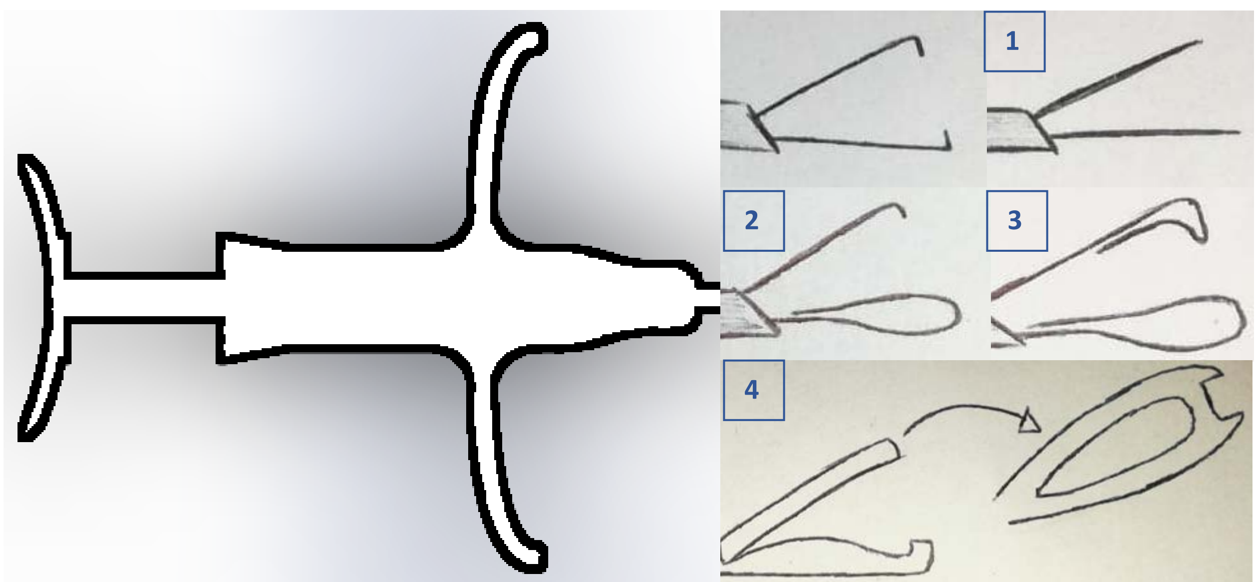

Figure 4: Potential designs for the handle (left) and the jaws (right) of the instrument

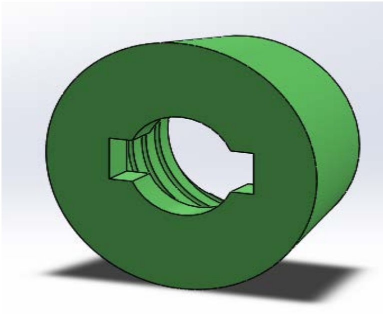
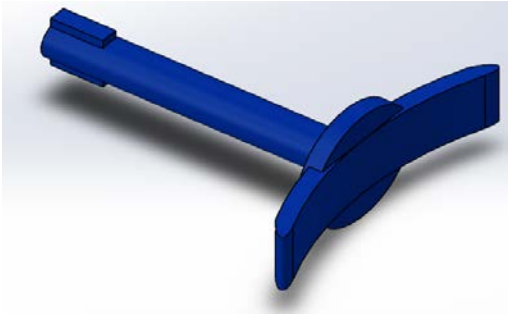

Figure 5: CAD of the locking piece (left) and the activation button (right)

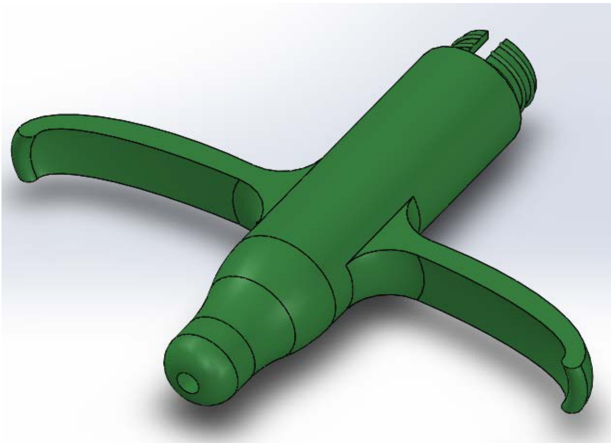
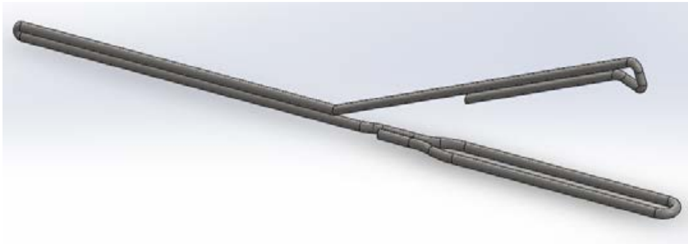

Figure 6: CAD of the body of the instrument (left) and the clamp (right)

Figure 7: CAD of the assembled instrument

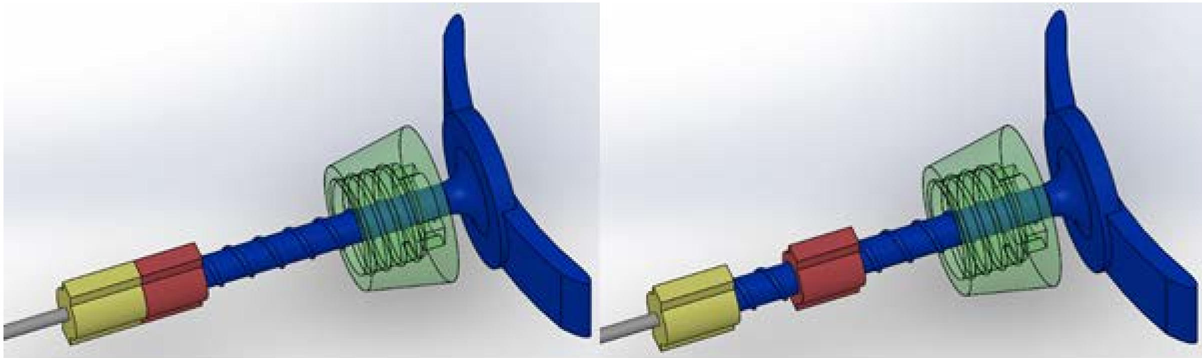

Figure 8: Implementation of the adjustable screw solution