Design and Strength Analysis of Laparoscopical Tool for Electrocoagulation Surgery

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Abstract: The goal of this paper was to design a new operating tool for hysteroscopy with better attributes than the currently used tools. The purpose of creating this new tool is to shorten the time of surgery and enable the surgeon to remove larger myomas and polyps. The designed tool may also be used as scissors and is compatible with the currently used hysteroscopes. After the proposed instrument was created it was tested and put through a strength analysis test.

1 INTRODUCTION

Hysteroscopy is an endoscopic examination method that makes it possible to visually examine the uterine cavity, extract a sample of the mucous membrane for further histological examination and even perform surgical treatment in the uterine cavity. The hysteroscope is inserted through the vagina as shown in Figure 1. (Citterbart, 2001)

The purpose of hysteroscopy is to examine the uterine body (myometrium and endometrium) and the cervix. Myometrium examination provides information about the size of the uterus, its shape, uterine malformations and uterine deformities (submucosal lesions), which are defined by their number, localization, consistency and angle of deposition in the uterine wall. (Holub, 1999)

The endometrium is optically checked for its maturation, distribution, vascularization and possible inflammatory processes. (Citterbart, 2001)

The morphology of the cervix is evaluated, from which it is possible to estimate its function and the relationship of the cervix to the uterine cavity.

The uterine cavity may be seen as potential space for optical diagnostics and surgical procedures, although it is narrow, sloping and has a strong myometrium that encloses it. The technical problems of hysteroscopy, surgical hysteroscopy and transcervical surgery are, in addition to the source of light and suitable optics, given above all by adequate and safe uterine cavity distention with appropriate distension media for visual diagnostics and a suitable type of instrumentation. (Holub, 1999)

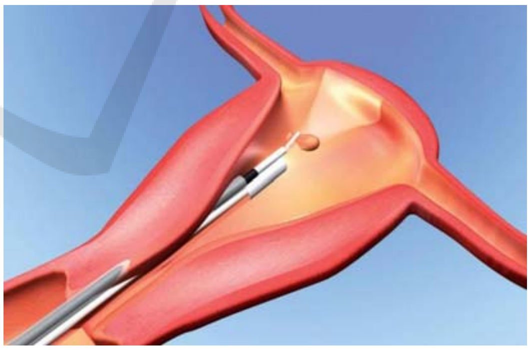

Figure 1: Hysteroscope inserted into the uterus.

2 CURRENT STATE

For examinations and surgical procedures in uterine cavity, panoramic hysteroscopes with 30° wide angle telescopes are used. Less used are contact hysteroscopes and microcolpohysteroscopes. (Holub and Kužel, 2005)

Hysteroscopes can be categorized as:

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- Diagnostic - designed for minor transcervical surgery
- Surgical - designed for more extensive transcervical surgery (resectoscopes)

The panoramic hysteroscope is a modification of a cystoscope. The hysteroscope diameters used are 3 - 4 mm, with a telescope diameter of 4 mm, with an enclosing sheath of 5 or 5.5 mm in diameter. The optical system may provide a direct or oblique viewing angle. The hysteroscope is guided by intense cold light from the extracorporeal source, the hysteroscope's sheath is equipped with valves for control of the inlet and outlet of the distension medium. For therapeutic hysteroscopes (5.5 to 8 mm wide sheaths), flexible or semirigid instruments with a diameter of 5 or 7 Fr (French, with 1 Fr corresponding to 0.33 mm) are introduced via a special channel. The relatively limited transcervical surgery instrumentation includes surgical probes, palpators with various types of endings (sharp, blunt, hook-shaped) cannulae, curettes, pliers and scissors. For hysteroresectoscopes are recommended telescopes with an angle of 12 ° and a diameter of 3 or 4 mm. (Holub and Kužel, 2005)

The hysteroscope instrument with a diameter of 8 or 9 mm (hysteroresectoscope) is supplemented with a ball and a loop for ablation of the endometrium. Instruments of the resectoscope are semirigid. For surgical procedures in the uterine cavity, it is recommended to use semirigid, less flexible instrumentation. Flexible tools are not considered suitable for intrauterine surgery. Flexible hysteroscopes usually do not require dilatation of the cervix for insertion and fixation of the cervix when they are introduced. Their outer diameter is 3.5 - 3.7 mm, their flexibility enables the surgeon to operate in angles up to 100 °. The viewing angle is direct, the angle of view is 90 °, and the depth of the observed field is between 1 and 50 mm. (Holub and Kužel, 2005)

Hamou's microcolpohysteroscope allows panoramic and constant observation with magnification of 1 - 150 times (most frequently used is observation without magnification or with magnification 20 times). It has a diameter of 4 mm and is introduced with a sheath of 5.2 mm diameter. Because of its small diameter it is suitable for hysteroscopic diagnostics and for its special magnification possibilities it is also usable in gynecological oncology. (Kužel, 1996)

In contact hysteroscopes, light reflects into the uterine cavity, allowing intrauterine visualization without uterine cavity expansion and with no light source, except when photographs of the examined tissue are required. Contact hysteroscopy is not widely used because of difficult interpretation of results and limitation of surgical options in the absence of a panoramic view. (Holub and Kužel, 2005)

2.1 Currently Used Hysteroscopy Tool

For ambulatory hysteroscopy one of the most widely used tools is a tool by Johnson & Johnson, specifically from their GYNECARE Gynecological Division, called Gynecare Versascope. The current work was set to improve upon the design of this tool. (Penhaker et al., 2004)

2.1.1 Gynecare Versascope

The hysteroscope is designed to examine the cervical canal and uterine cavity for diagnostic or therapeutic use. The Gynecare Versascope is used to create and maintain the uterine distension and to gain access to the uterine cavity for the hysteroscope. This tool is shown in Figure 2.

Figure 2: Gynecare Versascope hysteroscope.

Characteristic features of the tool:

- Disposable case
- Dimensions are so small that the tool can be inserted without distension into almost every cervix
- Designed to minimize trauma and discomfort
- Slight curvature of 10 ° extends the field of vision and operation
- The working channel is slightly enlarged after insertion so that tools with a diameter of 2 mm can be used
- The rotating part rotates at a 360 ° angle and provides a full peripheral view
- Continuous flow improves vision during therapeutic application

- Conveniently located round clamp ensures good control of distension medium valve
- Deploying the tool into the expandable canal allows for continuous drainage for better visualization during therapeutic interventions.

A monopolar electrode is used for electrocoagulation, which is inserted into the instrument and passes through its body. Its movement can be controlled by the surgeon from the other end. At the same time, an optical system is introduced into the hysteroscope to allow the uterine cavity to be displayed. It is also possible to control the flow of the distension media by a circular clamp which is at the bottom of the tool. The semi-rigid case keeps the tool well-controlled while allowing good manoeuvrability. The non-glossy surface improves visibility on the video. The tools are made of high quality surgical steel that guarantees bending strength and torsion strength. Their average is 5 Fr and 7 Fr. Visible spacing tapes on the case improve the ability to control the depth of tool insertion. (Schmid et al., 2013)

3 DESIGN OF A NEW TOOL FOR HYSTEROSCOPY

The newly designed tool for hysteroscopy was required to have better attributes than the one currently used. It should shorten time of surgery, should be able to remove larger polyps and myomas, should have the ability to be used as scissors and it should be compatible with the currently used hysteroscopes.

3.1 Scissors Mechanism

The monopolar electrode has the disadvantage that it cannot be used as simple scissors and thus make its work more efficient. Therefore, attempting to use hysteroscopy with bipolar electrodes, which would form simple scissors in order to remove tissues (polyps, myomas) and then coagulate tissues with high frequency current. This basic idea led to the first design of a new hysteroscopy operating tool within this work.

The only limiting factor is the maximum tool diameter that is 3 mm. This dimension is determined by the size of the insertion canal on the hysteroscope. For this reason a simple scissors mechanism could not be used. With the small dimensions of the individual rods, the correct functionality of the tool or the pull system could not be guaranteed. As shown in Figure 3, an electrode which was necessary for the use of a high-frequency current was placed at the ends of the individual arms of the scissor mechanism. Figure 3 shows the mechanism in an active coagulation position. For better clarity, the prototype was expanded several times to allow observation by the naked eye. Another option was to use the eccentric length of the individual arms, but this would require even more pulling strings and better precision.

Figure 3: Designed scissors mechanism.

3.2 Joint Mechanism

The greatest emphasis has been put on simplifying the entire design of the tool. Only one rod is used to control the opening of the upper jaw. This mechanism is connected with the control mechanism that the surgeon has in his hand.

The tool is constructed as one fixed unit with one movable part, the above-mentioned upper jaw. Its outer diameter is 3 mm. The length of the entire tool is not yet determined, it will depend on the further development and length required to make the operation convenient. The opening of the jaws is possible by means of a peg.

The front of the tool is bevelled on both jaws to ensure comfortable insertion into the insertion canal on the hysteroscope. A groove is cut at the bottom of the tool to pull the control rod out of the tool body. It is assumed that sufficient flexibility of the control rod is provided for an elastic bend, and this bending will occur repeatedly. This movement results in the opening of the upper jaw, respectively the sliding movement of the rod is converted to a swinging movement of the upper jaw. The jaws are now made up of 9 rows of teeth that are knotted so that the contact area between the jaws is as large as possible. But this number is not final, it is designed only for the prototype, the real tool can have more of these rows, depending on the character of uterine tissue that is supposed to be removed.

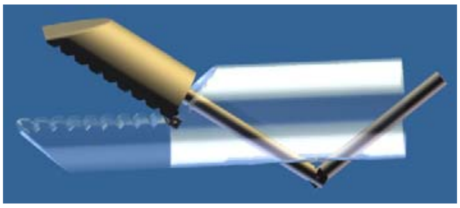

Figure 4: Joint mechanism.

The only possible drawback of the tool is the free space behind the upper moving jaw of the tool. By pulling the tool out of the hysteroscope, the upper jaw may jump around the edge of the insertion channel, making it impossible for the tool to be pulled out after surgery. This problem could be partially avoided by chamfering the back edge of the upper jaws. This proposed mechanism is shown in Figure 4.

3.3 Spring Mechanism

The tool is again constructed as a single fixed unit with a movable part. Its outer diameter is 3 mm. Its length is not yet determined, it will depend on the further development and length required to make the operation convenient. The opening of the jaws is made possible by means of a peg, which is not located in the middle of the tool height, but is located eccentrically. There were two reasons for this change. The first reason was the possibility of a larger jaw opening without the need to increase their length. The second one was structural because of the spring, so that its end could be better anchored in the upper jaw. The front of the tool is bevelled on both jaws to ensure comfortable insertion into the insertion channel on the hysteroscope.

By using the spring as an operating tool control, further simplification of the control would be achieved, however, while meeting the essential requirements, i.e. comfortable and reliable opening of the jaws. A compression spring is used which is connected to the control mechanism the surgeon has in hand. When compressing this spring, the upper jaw will open and the spring jaw closes when the spring is released. This mechanism is shown in Figure 5.

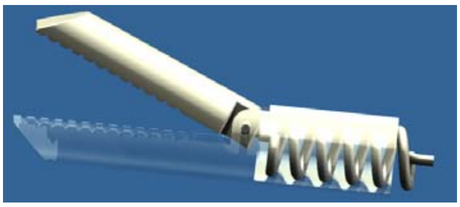

Figure 5: Spring mechanism.

3.3.1 Modified Spring Mechanism

This model does not differ much from the previous one. The main change came in the jaws that formed the series of teeth. At these locations, the groove was cut to a depth of 1 mm throughout the jaw surface and the resulting gap was filled with a conductive surface (electrode) that had the same shape as the jaw contact surfaces. In order to use high-frequency current during coagulation. The electrodes continue through the instrument body to the voltage source.

In addition, it was necessary to wrap the front edges of the tool to avoid injuries during manipulation in the uterine cavity.

The last change concerns the peg, which has been reduced in size so that it is completely hidden in the tool cavity. This proposed mechanism is shown in Figure 6.

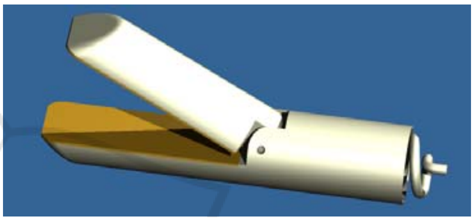

Figure 6: Modified spring mechanism.

3.4 Material Selection

The correct function of the device and its components during the required lifetime is conditioned not only by a suitable choice of the production technology, but also by the proper design and choice of the appropriate structural material from which the component is to be made. The requirements for the function of the structural element directly determine its shape and its lifespan, safety and also its price. (Kratochvíl et al., 2005)

The shape and function of the structural element are limited by the conditions under which the structural element has to function and the material from which it is made. The conditions of operation of the structural element, in particular the stress and deformation, the temperature and the environment, are decisive for the required properties of the material intended for construction.

Appropriate choices are then determined by the technology of manufacturing the components and its price. There is also the issue of the safety factor and it depends, in addition to the chosen strength characteristic, on the importance of the construction element in terms of reliability and lifespan of the whole structure. (Webster, 1998)

Subsequent selection of the appropriate material for the specified design element is carried out using a so-called design index *s*, according to which the correct graph can be selected. For this application the selected graph is Ashby's map. Ashby's maps are divided by different types of loadings of structural elements and other mechanical properties. Design index *s* must be equal or less than the ratio of strength σ_f in MPa to density ρ in Mg/m^3.

$$s \leq \sigma_f / \rho \tag{1}$$

The Ashby's map is best suited for the specified tool, which includes the dependence of the maximum load value (tension) on the maximum density value of the material while maintaining the minimum weight condition. According to Ashby's map, the most appropriate material was selected, which is Carbon Fiber Reinforced Polymer (CFRP). (Kratochvíl et al., 2005)

4 STRENGTH ANALYSIS OF THE DESIGNED TOOL

For strength analysis, it was necessary to determine what strength the jaws of the operating tool would be able to develop. That is why an experiment was made to clarify the magnitude of this strength.

Surgical scissors were used in the experiment. Furthermore, a stand was used to make the whole system stable during work. Two clamps for holding the scissors in the required position and height were placed in a horizontal position. Two conductive steel sheets were glued to the jaws to simulate the coagulation electrodes. However, in order to avoid the passage of the electric current into the scissors, an electric insulator was added between the jaws and the conductive surface. A terminal for the lead cable was created at their outer end. One of these was routed through a clutch that has a special gripping device in order to use common feed wires into the radio frequency wave generator (RF). The second one was connected to a conductive pad that was placed under the scissors' jaws and served as a pickup area for organic fluids, then also connected to the RF wave generator.

First of all, the lower jaw of the scissors has been balanced to eliminate the gravitational force and prevent spontaneous closure. A weight of 20 g was used for this balance. Subsequently, the entire body of the instrument was tested with a multimeter to avoid possible undesired current flow and no high-voltage current injuries. In order to add the weights to the scissors, a holder was used which was attached to the upper grip portion. By successively adding weights of 100 g, 200 g, 500 g, 1000 g the weight value required for sufficient tissue coagulation was determined to be 1200 g. For the first measurement, pork brisket without bone was used as a sample tissue. It has a non-homogeneous structure and it can represent the composition of myomas and polyps in the uterine cavity. All measured values are shown in Table 1. The table consists of dimensions of the tissue sample, the weight needed to compress the tissue to enable proper coagulation, time to complete coagulation and the percentage of fat in the used sample.

Figure 7: Experiment setup.

Table 1: Time and weight needed for tissue coagulation.

Tissue dimensions (mm)	**Weight (kg)**	**Time (s)**	**Fat percentage (%)**
5x14x3	1,2	8	80
5x15x2	1,2	2	30
5x15x2	1,2	5	50 - ideal
5x10x4	1,2	4	100
5x10x4	1,2	6	100
5x10x2	1,2	2	95
5x10x4	1,2	45	100 - tough

5 CONCLUSION

The aim of this work was to design a new electrosurgical tool for hysteroscopy that would replace a set of existing tools used for surgical intervention with current hysteroscopes. The proposed tool should further streamline the performance, ensure greater speed, easier handling and increased safety in use. It also has an ability to be used as simple scissors with electrocoagulation. It enables the surgeon to easily remove larger myomas and polyps in the uterus.

The proposed tool was designed and a prototype was created and tested. Strength analysis was further performed and an experiment was designed to measure the strength needed to clamp the tissue and time for proper coagulation. Pork brisket was used as sample tissue. Depending on the tissue structure, the time needed for coagulation was usually under 8 seconds.

The tool can be used as a replacement for existing tools for hysteroscopes, it enables the surgeon to remove myomas and polyps of various sizes from the uterus cavity and its surroundings.

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