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Ergonomic Problems Originating in the Use of High-Frequency and Ultrasonic Medical Devices

A.-M. von Saucken (geb. Seyffert)[1], S. Donner[2], M. Kraft[3]
[1] Fachgebiet Medizintechnik, Technische Universität Berlin, Germany, aseyffert@zmms.tu-berlin.de
[2] Graduiertenkolleg prometei, ZMMS, Technische Universität Berlin, Berlin, Germany
Beuth Hochschule für Technik Berlin, Hypatia-Programm, Berlin, Germany
[3] Fachgebiet Medizintechnik, Technische Universität Berlin, Germany

Abstract

High-frequency and ultrasonic medical devices are widely used in laparoscopic surgical procedures. Using these devices can result in ergonomic problems. Two studies were performed: in a questionnaire surgeons were asked to evaluate laparoscopic surgical instruments. Based on the resulting 74 data sets it was possible to define various improvements to the design of instruments. In a subsequent field study 70 surgical procedures were observed to comprise user caused problems in the interaction with medical devices.

1 Introduction

Laparoscopic surgery has benefits for the patient such as smaller wounds, faster recovery, and therefore shorter hospital stays [1]. To perform laparoscopic surgery, however, specialized medical devices and instruments are needed. As a result, surgeons have to cope with limited visual information and mobility because the abdominal wall remains closed with the exception of small holes, where surgical instruments are inserted [1]. In addition, the control monitor will require permanent attention as instruments are placed *in situ*.

One of the main tasks of surgery in general is the separation and the connection / fusion of vessels and tissue. Traditionally, scalpels have been used to cut and for centuries sewing technologies have been used to close wounds. From a medical point of view, a correctly-sewed fissure is still one of the best ways to connect tissue and to close vessels. Sewing is a highly flexible technology which can be well adapted to the medical situation. In laparoscopic procedures, however, sewing has not been established as the first choice because laparoscopic sewing is extremely difficult due to the limited space inside the abdomen [2]. Furthermore, as a result of the complexity of the task, it takes much longer to connect tissue by laparoscopic sewing than with other technologies such as with clip applicators, staplers, high-frequency (HF), and ultrasonic (US) devices. Although other technologies can be used to cut (like water jet and cryo technologies) and to fuse tissue (like gluing), HF and US are commonly used.

1.1 High-Frequency (HF) Surgery

HF devices are used in laparoscopic surgery to coagulate vessels and to cut tissue. One general advantage of the HF technology is the possibility of forceless cutting, thus allowing clean cuts. In addition, bleeding is reduced due to the thermal effect on the tissue.

If a high-frequency ac voltage (with frequencies between 300 kHz and 3 MHz) is applied to human tissue, a current will flow whereby its height is dependent on the electrical impedance of the tissue. The impedance in turn is influenced by temperature, field intensity, applied energy, and the conductivity of the tissue, which can vary locally. Cutting is achieved when the energy density is high enough and an electric arc is visible. A low energy density and a slow temperature rise will enable coagulation [3].

HF instruments are operated by the surgeon him- or herself, using foot-pedals or controls on the instrument handle. Another possibility is the operation by oral commands of the surgeon. In this case, an assistant surgeon or a nurse will turn the current on and off from outside the sterile area. From there, controls allow the adjustment of the HF device, e.g. by choosing special programs containing settings for coagulation or dissection (see image below).

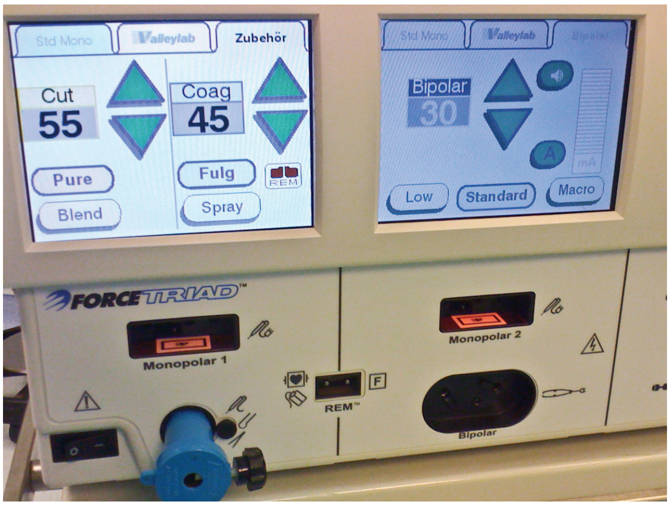

Image 1 Example of a graphical user interface to adjust the settings of high-frequency devices.

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For some time now ergonomic issues regarding the operation of HF devices have been reported. Known problems concern foot-pedals where high risks of mistakes are inherent [5]. In general, when operating HF devices, two buttons or pedals are used: a blue one to coagulate, a yellow one to dissect. During a surgical procedure, however, the surgeon has no sight of foot-pedals and even controls on the instrument handle are hard to recognize in a dark operating room. Apart from an acoustic signal, there is no possibility to ascertain whether the current is set to “on” or “off”. In addition, wires on the floor pose a constant threat of tripping (see image 2).

Image 2 Foot-pedals in a MIC operating room shot 2010.

For HF technologies, always two electrodes are needed to close the electric circuit whereby the human tissue is placed in between. While both electrodes are of the same size in the bipolar modus, monopolar devices consist of a very small electrode on the tip of the instrument and a very large separate electrode fastened to the patient, e.g. on the patient’s thigh. Therefore, many differences between monopolar and bipolar devices are the result, both for the surgeon and for the patient.
Having only one of the two electrodes on the instrument, the monopolar HF instruments can in general be operated with a higher precision [3]. A typical monopolar HF instrument is the monopolar hook used to dissect e.g. gallbladder and liver in a laparoscopic cholecystectomy. The hook is very thin and allows an accurate handling. In bipolar devices the instrument has both electrodes on the tip, which makes the handling more difficult. Often, bipolar instruments are combined with graspers.
From the surgeon’s point of view, monopolar devices are better to handle. However, there is a higher risk of injuries to the patient because the neutral electrode is located on another part of the patient and the current will flow from the surgeon’s instrument tip to the neutral electrode. The current won’t take the shortest way but the line of least resistance which can include highly sensitive structures and organs of the patient [3]. Therefore, the surgeon has to remember that by using the monopolar HF instrument he closes a circuit from the instrument tip to the neutral electrode on the patient. In addition, the patient can be harmed when the neutral electrode is not fastened accurately. If the whole area of the large neutral electrode is not fastened properly, burnings are possible when the local energy density gets too high in the connected area. The amount of energy needed is higher for monopolar devices because the distance between the electrodes is larger.

1.2 Ultrasonic Devices

Ultrasonic (US) devices use a frequency between 20 and 60 kHz to create either dissection or coagulation or both, depending on the used frequency [4]. Compared to HF technologies, ultrasonic has, among others, the advantage of minimal thermal tissue damage, less sticking to the tissue, and less smoke formation. In addition, no electrical energy will flow through the patient. At maximum power, ultrasonic dissectors can cause tissue damage due to the cavitational effect which is magnified by the vibrating energy and the thermal spread. Like HF devices, ultrasonic instruments are operated by controls on the instrument handle or by foot pedals. Ultrasonic instruments, mostly one way instruments, are still quite expensive compared to HF devices.

2 Methods

Two studies were performed to evaluate the ergonomic problems originating in the use of HF and ultrasonic medical devices. In the first study, surgeons in Germany, Austria and Switzerland were asked in 2009/2010 to evaluate laparoscopic surgical instruments in a questionnaire (see also [6]). As many instrument groups as possible were included like trocars, graspers, endoscopes, as well as cutting and closing devices. Personal information was considered only when necessary, e.g. the surgeon’s medical department as well as their level of pain due to the working conditions while conducting minimally invasive surgery (MIS).
In the second study, 70 surgical procedures in six hospitals were logged and analyzed in 2010, among them cholecystectomies, hernia operations, appendectomies, cyst removals and other standard laparoscopic procedures. The information recorded in the journals included the used devices, the amount, position and location of the involved personnel, trocar positioning, workflow of the operation (duration, used instruments, description of the tasks etc.), pa-

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tient peculiarities, and a description of the operating room (OR). Afterwards, the journals were digitalized and analyzed in order to define similarities, aberrations, and ergonomic issues.

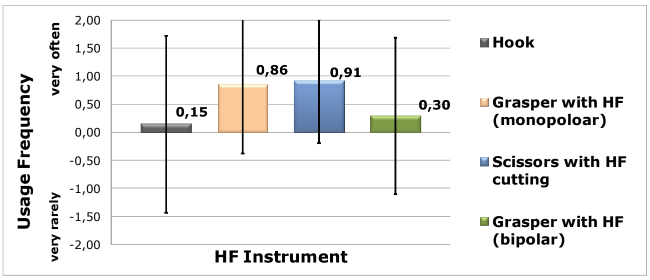
3 Results

3.1 Results of the Questionnaire

43 out of 74 (58 percent) surgeons replied in the questionnaire that they often mistook the HF foot pedal controls for coagulation and dissection. In rare cases (four out of 74, five percent) nurses had to operate the pedal controls pursuant to oral commands given by the surgeon. 58 percent (43 out of 74) would have preferred a control integrated in the instrument handle over foot-pedals given similar costs. 66 surgeons (89 percent) were right-handed, five (7 percent) left-handed, three didn't answer that question. Nevertheless, only 46 (62 percent) preferred operating foot-pedals with their right foot (left foot preference: eight (eleven percent), alternating use of right and left foot: 17 (23 percent), not specified: three). Over 75% of the surgeons (56 out of 74) reported that due to the use of HF devices, tissue was sticking to the tip of the instrument (not specified: seven).

To seal blood vessels, most surgeons (28, 38 percent) would have preferred clips, closely followed by bipoloar HF surgery (24, 32 percent). US was the preferred technology of eight surgeons (11 percent), five (seven percent) would change their preference according to the medical situation. Ligasure® was the first choice for two surgeons (three percent) as was sewing (not specified: five).

In addition, the participants of the study were asked to state their usage frequency of four HF devices (hook, grasper with monopolar / bipolar HF and scissors with HF cutting) and rate them. For both, a scale between -2 (used very rarely or rather rated very poorly) and +2 (used very often or rather rated very good) was used (see image 3).



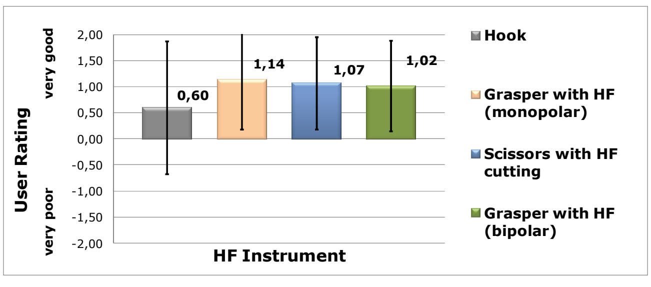


Image 3 Frequency (upper chart) and User Rating (lower chart) of four HF devices (Hook, Grasper with monopolar/bipolar HF and scissors with HF cutting).

3.2 Results of the Field Study

In all 70 live procedures, 53 out of 400 occurred incidents (13 percent) were caused by interaction with HF/US devices and instruments whereby 38 (72 percent) were problems of use and 15 (28 percent) equipment malfunctions. From the 53 incidents, ten (19 percent) were directly linked to the use of foot pedals, e.g. mistaking of pedals and stumbling over wires on the floor. The study showed that 20 percent (14 out of 70) of the surgeons used monopolar instruments exclusively, 44 percent (31 out of 70) preferred bipolar instruments exclusively and almost 13 percent (nine out of 70) used only ultrasonic techniques. Seven percent (five out of 70) used a combination of bipolar and ultrasonic, while almost 16 percent (eleven out of 70) used a combination of these technologies (monopolar and bipolar HF: 14 percent (10); monopolar HF and ultrasonic: one percent (1); bipolar HF and ultrasonic: seven percent (5)). All ergonomic problems pertain the complete OR team. Often, more than one person was taking part. Out of the 53 reported HF incidents, in twelve (23 percent) the operating surgeon was involved and in 15 (28 percent) the nurse outside the sterile area. One (two percent) incident concerned the assisting surgeon and two (four percent) the nurse in the sterile area.

An often-observed – apart from the foot pedal problem – was a short complete blackout of the HF system due to missing or falsely attached wires, or controls that had been wrongly set. These incidents hampered the workflow of the operation and in a few cases endangered the patient.

4 Conclusion

Although bipoloar HF devices are safer for the patient, monopolar technologies are still prevalent. Due to their easier handling, monopolar devices are more often used and also better rated. Already in 1995, Neumann had presented a quasi-bipolar instrument, thus combining the advantages of both HF technologies while avoiding the respective disadvantages [3]. That particular approach was though never realized in instruments that are most commonly used. Bipolar HF technologies may be advantageous for the patient, but monopolar HF surgery will more often than not be preferred unless bipolar HF technologies can be used with more precision. Partially, ultrasonic devices can be an alternative to HF technologies but ultrasonic instruments do result in higher costs for the whole procedure. Ultrasonic is only rarely used, even though the technology definitely has advantages compared with monopolar and bipolar HF surgery.

HF and ultrasonic devices alike are frequently operated by foot-pedals. Both studies have shown that the risk of mistaking the pedals is quite high, thus posing a potential danger for the patient.

The wire between the instrument and the foot-pedals can cause members of the OR team to trip themselves up, especially if the surgeon needs a pedestal to compensate for the different body heights of team-members (see image 4).

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Image 4 Foot-pedals on a pedestal in another OR, 2010.

As van Veelen stated, using foot-pedals can also cause an imbalance to the user because the weight is mainly shifted onto one foot [5]. By way of contrast, in an automobile, the area where the pedals are located is limited and the pedals themselves can be identified more easily. Also in a car, the driver is sitting, while in an OR the situation is quite different. In an OR, the surgeon is standing in front of a table, and while the general position of the surgeon won't change dramatically during the operation, small posture changes will indeed be necessary to avoid muscle cramps. These small changes are however sufficient to lose track of the foot-pedals, especially since HF and ultrasonic devices are not used in one go. Therefore the use of foot-pedals may be interrupted several times, and each time it is, the foot-pedals can get lost on the floor.

As a conclusion, it would be far better to use the instrument handles for purposes of control. When developing new devices, foot-pedals should be avoided whenever possible. The vast majority of surgeons themselves prefer hand controls over foot-pedals. The foot-pedal problem gets even worse when taking into account that HF and ultrasonic devices are operated by different foot-pedals. Now surgeons who choose to use both technologies have to cope with not only with one, but two pedal sets. If, however, foot-pedals are used, it would be advisable to put them in a specific location, maybe even linking them with the OR table. Since the positioning of the OR team depends mainly on the operation being performed, there would have to be a set of options to attach the foot-pedals in a way that is easily remembered. In conclusion, the movement of loose foot-pedals is a problem and should be avoided or at least reduced, if at all possible.

In a few cases, nurses, were asked to operate the HF device or to set controls by themselves. Generally, it is strictly regulated what actions a nurse is allowed to perform on the patient. In the OR however, these regulations are extended, thus putting more pressure on the nurses. In addition, the patient is also endangered when a nurse has to follow a vocal command of the surgeon. There will always be a small delay between the giving and the following of the command. If a rapid action is necessary, it can't be done immediately. Apart from the instruments themselves, there is the problem that almost every electrical medical device has a different plug, graphical user interface(s), and navigation concept(s). Some of these errors that were reported in the second study resulted in an incorrect operation of control screens. A solution to this problem may be a greater degree of instrument (and user interface) standardization, thus avoiding the confusion brought about by the large diversity of handling devices.

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