Ergonomic Assessment of a Laparoscopic Stapler

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Abstract The laparoscopic stapler is a surgical instrument that automatically creates visceral anastomosis. Although the laparoscopic stapler is widely used, objective ergonomic assessments are lacking. The purpose of this study was to quantitatively assess the force and muscle activities involved during the use of a laparoscopic stapler. The mechanical force needed to create anastomosis in a cattle colon was measured using a tensile tester. Three different loads (150 N, 200 N, and 250 N) were applied individually to compare the anastomosis conditions. The force and muscle activities of the operators of the laparoscopic stapler were also examined. Eleven healthy female subjects (age, 27.4±10.7 years) participated in the study. Force and surface electromyography (EMG) of the flexor digitorum superficialis and flexor digitorum profundus muscles during the use of the laparoscopic stapler were measured and compared to each subject’s maximum grip strength. Approximately 250 N was necessary to operate the laparoscopic stapler appropriately. Although the mean grip strength of the subjects was 27.1±6.8 kg, the mean force applied when they gripped the laparoscopic stapler was 15.1±4.1 kg. Integrated EMG showed no differences between operating the laparoscopic stapler and gripping the hand dynamometer. This study demonstrated that the current design of laparoscopic stapler requires too much force to operate for individuals with small hands and/or low grip strength. In addition, the EMG results indicated that the enormous upper extremity muscular effort is not transmitted efficiently into power to operate the laparoscopic stapler, because of its handle design. Therefore, reconsidering the mechanism of the laparoscopic stapler is crucial to improve the usability of the laparoscopic stapler.

Keywords: laparoscopic stapler, anastomosis, ergonomics, force, electromyography.


1. Introduction

With advances in laparoscopic technology, the surgical procedures used to treat rectal cancer have made remarkable progress over the past few decades. Mechanical anastomosis has successfully shortened the duration of surgery and decreased the amount of bleeding during surgery. In addition, the sphincter preservation anastomosis technique greatly improves of patients’ quality of life, allowing many patients who would have required an artificial sphincter in the past to preserve their own anal sphincter [1]. The circular stapler is a commonly used laparoscopic surgical instrument that automatically creates visceral anastomosis. Yasuno and Sugihara [2] mentioned that development of the circular stapler contributed greatly to the popularization of the sphincter preservation surgery, which is used in approximately 80% of recent colorectal cancer surgeries in Japan. Clearly, appropriate skills for handling these instruments are indispensable for many surgeons. However, numerous studies have reported problems associated with laparoscopic stapler use, including pain, discomfort and numbness in the fingers and/or hands of surgeons [3-6]. For example, van Veelen et al [7] reported that the use of laparoscopic stapler requires too much force, and frequent use of these instruments causes pain and muscle fatigue.

According to Berguer and Hreljac [8], the surgeon’s hand size is a significant factor related to the difficulty in using laparoscopic staplers. They demonstrated that surgeons who used surgical gloves size No. 6.5 (palmar width approximately 83±5 mm) or smaller experienced more difficulty in using laparoscopic staplers. Recently, the Japanese Society of Gastroenterological Surgery (JSGS) conducted the first nationwide survey focusing on user satisfaction and problems associated with using laparoscopic staplers [9]. Many Japanese surgeons with small hands (surgical glove size No. 6.0; palmar width approximately 77±5 mm) were not satisfied with the current design of the laparoscopic staplers, and they were under great stress when using these instruments. In particular, 67% of female surgeons reported that the laparoscopic stapler handle was very large, which had serious problems.

The most important question is whether appropriate
ergonomic assessments were implemented during the development of these instruments. According to Yamaoka et al.[10], one of the key principles to design instruments operating by human hands is that a user with little muscle power can use it easily and the power at the time of operation should not exceed 88 N. Therefore, measuring the muscle power of target user by quantitative methods such as load cell, hand dynamometer and electromyography (EMG) should be indispensable. In a previous study, a questionnaire was conducted to compare the ergonomic efficiency of several types of handles of laparoscopic staplers [11]. However, objective data such as force characteristics and muscle activity during use of the laparoscopic stapler are still lacking. The overall purpose of this study was to develop an improvement plan for the laparoscopic stapler. In order to achieve this goal, the present study aimed to assess the mechanical force and muscle activities involved in laparoscopic stapler use.

2. Methods

2.1 Experiment 1: Mechanical force during the use of laparoscopic stapler

2.1.1 Instrument

This study was performed with a commonly used circular stapler DST-EEA28 (EEA, Covidien, Mansfield, MA, USA) (0.5 kg) (Fig. 1a). The distal end of the EEA consists of 2 staple holders for titanium staples (Fig. 1b). Three procedures are required to operate the EEA; first, staples are pushed out of the staple holder to penetrate the tissue; second, a knife blade removes the extra tissue; third, when anastomosis is complete, the staple is formed a "B" shape (Fig. 1c). The user has to compress the handle fully during operation in order to perform anastomosis successfully.

2.1.2 Measurement

The mechanical force used to perform anastomosis was measured using a tensile tester (Autograph-AGS-J, Shimadzu, Kyoto, Japan). The anastomosis sample was a cattle colon usually sold for food. The thickness (3–4 mm) and stiffness of cattle colons are similar to those of human colon. Before the experiment, fat was removed from the colon to mimic actual surgery. The laparoscopic stapler was fixed by a specially designed jig and the wire of the tensile tester was attached to the distal end of the handle (Fig. 2). Three different loads (150N, 200N, and 250N) were applied individually to compare anastomosis results. Each load was applied 3 times at a tensile speed of 1 mm/sec. The relationship between mechanical force and displacement of the handle lever was analyzed using specific software (TRAPEZIUM, Shimadzu) to measure the force that varies depending on the handle-lever displacement. The anastomosis result was assessed by a surgeon immediately after each load test. The anastomosis samples were dissolved with caustic soda to observe the condition of the staples. We evaluated that the anastomosis was performed successfully when the staple formed a perfect “B” as shown in Fig. 1c.

2.2 Experiment 2: Force and muscle activities involved in the use of a dummy laparoscopic stapler

2.2.1 Subjects

Eleven healthy female subjects aged 27.4±10.7 years participated in the study. All subjects were right-handed and had no history of injury or pain in their dominant upper extremity. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki after obtaining informed consent from each subject. This study was approved by the Tokyo University of Technology Ethics Committee.

2.2.2 Measurements

The force and muscle activities involved in the use of the dummy laparoscopic stapler were examined. Since the laparoscopic stapler is a disposable device that can only be used once, we prepared a dummy stapler for repeat measurements. A strain gauge (N11-FA-03-120, Showa Measuring Inc., Tokyo, Japan) was attached to the dummy’s handle to measure the force (Fig. 3). Surface
electromyography (EMG) was used to identify the muscle force required for the operation of the laparoscopic stapler. Flexor digitorum superficialis (FDS) and flexor digitorum profundus (FDP) muscles were chosen for their relevance in grasping tasks. Surface myography was performed using MyoSystem 1200 (Noraxon, Scottsdale, AZ, USA). Two disposable electrodes, (Vitrode M; Nihon Kohden, Tokyo, Japan) were attached to the skin of the subject’s forearm. Before electrode attachment, the skin over each muscle was cleansed with alcohol and a specific gel to reduce the impedance at the skin-electrode interface. Following the textbook[12], two electrodes were placed on the anterior surface at the proximal 1/3 distance of the forearm to measure FDS, and two electrodes were placed on the posterior surface of the forearm at 4 fingerbreadths distal to the ulna side of the olecranon to measure FDP. The inter-electrode distance was approximately 20 mm. Surgical tape was attached on the electrodes to stabilize the electrodes during measurements. Before data collection, the subjects received instructions about the experimental procedures. Each subject’s hand length and palmar width were measured based on the Martin human body measurement method [13].

First, each subject’s maximum grip strength was measured by a hand dynamometer. EMG of the FDS and FDP were recorded simultaneously. The subject was asked to adjust the width of the hand dynamometer to obtain a comfortable grip, and then to grip it at maximum power for 10 s.

In order to normalize the grip strength between subjects, the maximum force displayed on the hand dynamometer was defined as the MVC force. In addition, the maximum voluntary contraction (MVC EMG) for each muscle was determined from the integrated EMG (IEMG) for a 4-second segment, from 3 seconds after the start of gripping the hand dynamometer.

During measurement, subjects were instructed to remain in a standing position with their arm dropping naturally. The measurement was repeated twice. In order to avoid muscle fatigue, a 5-minute break was set between measurements. Furthermore, EMG was monitored to confirm that fatigue wave was not seen during measurements.

Second, the force and muscle activities when the subjects used the dummy stapler were measured. Each subject gripped the dummy stapler at maximum power for 10 s. In order to mimic the posture during the actual laparoscopic surgery, the subject performed the movement while standing with the dominant arm abducted slightly and elbow flexed at 90 degree, and gripped the distal end of dummy’s handle with the forearm and hand in a neutral position (Fig. 4). To maintain the relative position between the electrodes and muscles, subjects were instructed not to move their arm during measurements while performing isometric contraction. A digital multimeter was used to show subjects the amount of force exerted during measurements. The measurement was repeated twice and a 5-minute break was set between measurements to avoid muscle fatigue.

Lastly, the force and muscle activities involved during the use of an actual laparoscopic staple were measured. Among the subjects, a female (age 20 years, mean grip strength 300 N) was chosen as subject for the test. A strain gauge was attached to the laparoscopic stapler to measure the force. The surface EMG of the FDS and FDP were also recorded. A hard sponge (the thickness and stiffness were similar to a cattle colon) was used to simulate the anastomosis sample.

The peak voltage obtained by the strain gauge was used for force analysis. After the experiment, calibration was conducted with the tensile tester to convert the voltage values into force units (N). Based on the calibration data, the voltage values obtained were converted to N and compared with the subject’s maximum grip strength. The analysis of EMG was as follows. The EMG was filtered with high pass (10 Hz) and low pass (500 Hz) filters. EMG signals were recorded at a sampling rate of 1 kHz. A 4-second segment of EMG data that was most stable (from approximately 3 s after the start of recording) was analyzed. IEMG was the mean value of rectified EMG obtained through full-wave rectification and smoothed with a time constant of 10 ms. Percent MVC for each subject was defined as the value obtained from operating the laparoscopic stapler divided by that obtained from gripping the hand dynamometer.

3. Results

3.1 Experiment 1: Mechanical force during use of the laparoscopic stapler

The results of anastomosis when different levels of mechanical force were applied are shown in Fig. 5. When 250 N was applied, excision and anastomosis of the colon were achieved completely, and the shape of the staplers
formed a perfect “B”. Anastomosis seemed to be possible when 200N was applied, although the shape of some staples was not a perfect “B” (Fig. 6). When 150N was applied, neither excision nor anastomosis was accomplished. Figure 7 shows the relationship between the mechanical force and displacement of the handle lever of the laparoscopic stapler. Adjustment of the slack of the wire and play of the lever is included in the horizontal axis; these values were approximately 20 mm. Three force peaks were identified as the handle width changed (displacement). The initial distance between the handle and lever was approximately 11 cm. Approximately 20 mm was needed to decrease the slack of the wire. The first peak occurred when the distance between the handle and lever was shortened by approximately 25 mm (200 N). The second peak occurred when the distance between the handle and lever was shortened by approximately 30 mm (175 N), and the third peak occurred at a distance of approximately 70 mm (230 N).

3.2 Experiment 2: Force and muscle activities involved in the use of laparoscopic stapler

The mean hand length of subjects was 174.1±10.7 mm (mean±standard deviation) and the mean palmar width was 79.5±3.8 mm. Although the mean grip strength of the subjects was 266±67 N (27.1±6.8 kg), the mean force exerted when the subjects gripped the dummy was 148±40 N (15.1±4.1 kg). Therefore, the force exerted was only 57% of subject’s mean grip strength. A similar result was demonstrated when examining the actual laparoscopic stapler. The mean grip strength was 294 N (30 kg) whereas the mean force exerted during operation was 206 N (21 kg): this was approximately 70% of subject’s mean grip strength. A typical recording of raw EMG signals is shown in Fig. 8. The influence of fatigue was not seen during the analysis interval. The results of IEMG showed no differences between the use of the dummy and hand dynamometer, although large individual differences were observed (Table 1).

4. Discussion

4.1 The force required to complete anastomosis

This study indicated that a force of 250N is needed to accomplish complete anastomosis using the laparoscopic stapler. This is equivalent to the average grip strength of
adult females[14]. The EMG results also indicated that an enormous upper extremity muscular effort is required to use the laparoscopic stapler. In the real surgical operations, surgeons may have to use these instruments under fatigued and stressful situations. Considering these factors, it is reasonable to conclude that the current design of the laparoscopic stapler is not easy to use for surgeons with small hands and/or low grip strength.

4.2 Force characteristics during laparoscopic stapler use
This study identified 3 force peaks when force is applied to operate the laparoscopic stapler. The following is a hypothesis to describe the relationship between force and the mechanism of the laparoscopic stapler. The first peak occurs when the staples are pushed out, and the tips of the staple are needled into the tissues. When this occurs, movement is stopped and the tissues are temporarily fixed. The second peak occurs when the movement of the stainless steel knife is stopped after extra tissue has been excised, and the anvil comes into contact with the knife. The third peak occurs when the staples penetrate the tissues completely and the staples form a “B” shape. After the staples have changed shape, which implies anastomosis is completed, a rapid rise in spring coefficient occurs. This study successfully identified the timing when maximum force is required to anastomose tissues; i.e. when staples penetrate the tissues completely and the staples turn into a “B” shape. Hence, developing a mechanism to transform the staple shape with less force is the key to increase the ease of laparoscopic stapler use.

4.3 Viscosity
Approximately 60 s was needed when mechanical tensile force was exerted to perform anastomosis. However, the subjects only operated the laparoscopic stapler for 5 s. Viscosity coefficient is defined as the ratio of deformation stress and deformation rate. Therefore, the influence of viscosity between the anastomosis sample and the staples and/or knife should be considered. Further experimentation is necessary to evaluate this issue.

4.4 Force exerted during the use of the laparoscopic stapler
The results of this study demonstrated that the force exerted when the subjects used the laparoscopic stapler was much smaller than the subject’s mean grip strength. The initial handle width of the laparoscopic stapler is 11 cm, and the width is shortened to 7 cm when it is fully compressed. In order to perform efficient grip movement, optimum muscle lengths obtained by the most suitable joint angle are necessary. According to the literature, when the most powerful grip is performed, the tip of the thumb should touch the second finger[15].

The handle width of the laparoscopic stapler is approximately 2 times larger than the average grip width of the hand dynamometer (53 mm) which subjects feel most comfortable during gripping. Furthermore, when the laparoscopic stapler is fully compressed (7 cm), the width is still 1.3 times larger than the subject’s average hand dynamometer grip width. Therefore, considering the handle design is important to improve the usability of the laparoscopic stapler.

4.5 Muscle activity during the use of the laparoscopic stapler
The mean integrated EMG were similar between operation of the laparoscopic stapler and the grip strength (MVC) of the subjects. This result implies that the number of excited motor units during gripping of the hand dynamometer and that during operation of the laparoscopic stapler are approximately equal. However, the force exerted during the use of laparoscopic stapler was much smaller than the grip strength of the subjects. This suggests that the design of current laparoscopic stapler does not transmit muscular power efficiently. A limitation of this study was that muscle fatigue was evaluated only by EMG. Therefore, further investigation is necessary to examine the influence of muscle fatigue when using the laparoscopic stapler.

4.6 Conclusion
1. This study showed that approximately 250 N is needed to operate the laparoscopic stapler appropriately.
2. This study demonstrated that the maximum force exerted by female subjects when using the laparoscopic stapler is 150–210 N.
3. The significance of this study is the quantification of the force characteristics when operating the laparoscopic stapler.

References


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