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Comparative Study of the Use of Different Sizes of an Ergonomic Instrument Handle for Laparoscopic Surgery

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Abstract: Previous studies have shown that the handle design of laparoscopic instruments is crucial to surgical performance and surgeon's ergonomics. In this study, four different sizes of an ergonomic laparoscopic handle design were tested in a blind and randomized fashion with twelve surgeons. They performed three laparoscopic tasks in order to analyze the influence of handle size. Execution time, wrist posture, and finger and palm pressure were evaluated during the performance of each task. The results show a significant reduction in the time required to complete the eye-manual coordination task using the appropriate handle. The incorrectly sized handle resulted in a rise in palm pressure and a reduction in the force exerted by the thumb during the transfer task. In the hand-eye coordination task, the use of the right handle size led to an increase in middle finger pressure. In general, surgeons had an ergonomically adequate wrist flexion in all tasks and an acceptable radio-ulnar deviation during the transfer task using the ergonomic instrument handle. Surgeons found it comfortable the use of the ergonomic handle. Therefore, the use of an appropriately sized instrument handle allows surgeons to improve ergonomics and surgical performance during the laparoscopic practice.

Keywords: laparoscopy; instrument handle; ergonomics; hand pressure; wrist posture; parametric design

1. Introduction

Laparoscopic surgery has become a standard procedure instead of open approach for many surgical interventions and it is widely used in health services around the world. This rising interest in laparoscopy is based on several benefits, such as better surgical outcomes for patients and resource optimization for healthcare services [1]. Furthermore, this surgical technique has constantly evolved over the past few years, mainly due to training efforts of surgeons [2–4] and technological advances of surgical equipment [5]. However, there are some important technical limitations that should be addressed in order to increase both performance and wellbeing of surgeons: reduced freedom of movements due to the fixed location of the surgical ports, the need for high precision through long instruments, loss of tactile feedback (no direct touch of intracorporeal anatomical structures), and the use of bidimensional vision instead of real stereoscopic (3D) vision. The combination of these features of laparoscopy makes it difficult for surgeons to achieve hand-eye coordination, depth

perception and performance of certain intracorporeal maneuvers, resulting in prolonged forced postures and the consequent impairment of surgeons' performance and precision and the potential onset of musculoskeletal disorders [6]. In order to overcome some of these problems, ergonomic criteria should be applied to both patients and surgeons [7,8]. In this respect, an important field of application of ergonomics for surgeons is the improvement of surgical equipment and tools, as well as its adaptation to the surgeon's needs. The design of ergonomically better surgical tools would reduce the surgeon's muscle fatigue and other associated diseases [9], with the potential improvement of the surgical performance [7]. This results in enhanced patient safety and surgical results.

In view of the above, an ergonomic laparoscopic instrument handle has been designed and developed in previous studies [10,11]. This new surgical tool follows the design criteria for universal objects named "Design for All" criteria [12]. These criteria were included in the Universal Design guide that enumerates the seven principles of a universal design [13]. One of these principles is to facilitate "flexibility in use" so that most people could use the designed products [14,15]. In this regard, hand tools must meet these design criteria in order to overcome obstacles such as age, gender, psychomotor skills or laterality.

An important challenge to be dealt with is to ensure a consistent tool design, both in shape and dimensions, for a specific functionality [16]. Stoklasek et al. demonstrated the onset of pain and discomfort after long use of hand tools with a poor ergonomic design that eventually led to fingers' numbness and, in some cases, paresthesia [17]. Additionally, anthropometric dimensions of hand tools is another fundamental design aspect. Hand size is a critical factor for precision tools, specifically in laparoscopic instruments [18]. Surgeons with small or large hands often have problems gripping laparoscopic tools, mainly because of the size or shape of the instrument handle. For this reason, they sometimes have to grip these instrument handles in a different way to that the designers intended [18]. It is important to note that laparoscopic surgical tools are commonly sold in a standard size [19–21].

Specifically, the opening and closing mechanisms of surgical instruments present complications for surgeons with large and small hands. Surgeons with small hands often have difficulties in using instruments with a bigger size than the ideal one, mainly for instruments with a power grip [16]. For this reason, several studies have focused on addressing this problem by analyzing the opening and closing system of laparoscopic instruments [22], force applied during its use [23], hand and fingers kinematics [24,25], and EMG activity during the laparoscopic practice [26–28]. Changes in the handle design of laparoscopic instruments have been shown to affect localized muscle fatigue, mainly in the muscle groups of the surgeons' forearms [6,29–31].

Therefore, the objective of this work is to carry out a blind study to analyze the effects of different sizes of the ergonomic design of a laparoscopic handle on the surgeon's ergonomics and surgical performance. This will be done by comparing the use of a handle that is the appropriate size for the surgeon's hand with one that is the wrong size. The study will be carried out during the performance of various basic training tasks for laparoscopic surgery.

2. Materials and Methods

2.1. Description of the New Hhandle Design

Figure 1 shows a functional prototype of the patented laparoscopic instrument handle (EP10382362) used to carry out this study. This intellectual property resulted from the ERGOLAP project (Obtaining Criteria for Ergonomic Design of Laparoscopic Surgery Instruments. DPI2007-65902-C03-03) developed by the University of Extremadura (UEx), Jesús Usón Minimally Invasive Surgery Centre (JUMISC) and Institute of Biomechanics of Valencia (IBV). This novel instrument handle design is mainly characterized by a power grip that keeps the precision of movements. The parameters of the laparoscopic instrument handle design in relation to the anthropometry of the surgeon's hand are described in [10,11]. This design provides the surgeon with a neutral posture of the wrist thanks to

the wide contact surface between the palm and the handle, promoting the reduction in fatigue and possible associated musculoskeletal disorders.

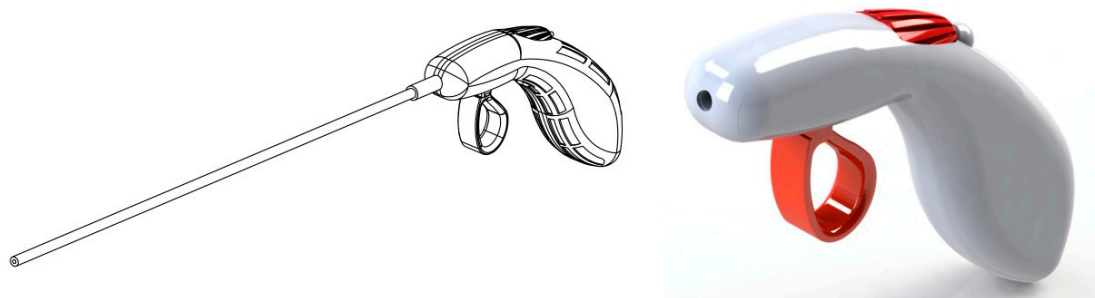


Figure 1. Design of the laparoscopic instrument handle (patent EP2471473A1) developed in the ERGOLAP project.

Additionally, the parametric 3D CAD design allowed us to easily scale the model to fit different hand sizes in an ergonomic way using the Palm Length Measured (PLM) [11]. Therefore, four different sizes (XS, S, M and L) (Figure 2) were 3D printed for this study following the specifications defined in previous studies [10,11].

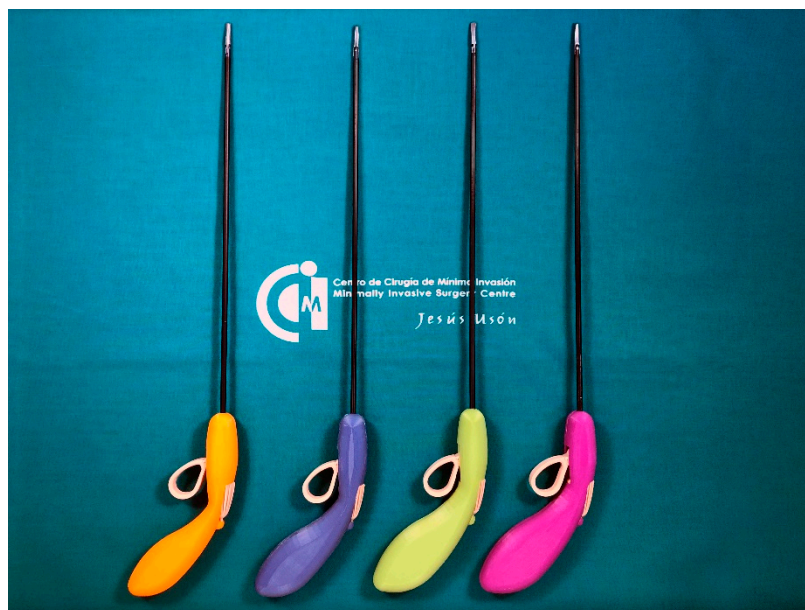


Figure 2. Prototypes of the handles for laparoscopic instruments developed. The sizes of the handles, from left to right, are XS, S, M and L.

2.2. Development of the Prototypes

As described above, the four instrument handles were 3D printed with PLA using a Prusa Original MK3 MMUS2.5 (Prusa Research s.r.o., Prague, Czech Republic), together with the triggers to control the opening and closing of the instrument tip and the wheels to rotate it. In order to obtain fully functional prototypes, these components were mounted on the internal mechanism of a standard laparoscopic forceps. This allows surgeons to test these new handle designs during the execution of conventional laparoscopic tasks.

2.3. Participants

Twelve surgeons participated in this study. Two surgeons were left-handed. All participants performed the tasks using the new design of the instrument handle with their dominant hand and a conventional laparoscopic instrument with their non-dominant hand. Four participants were novice surgeons (<10 laparoscopic procedures performed), 5 had an intermediate level of experience in laparoscopic surgery (between 10 and 100 laparoscopic procedures) and 3 were experienced surgeons (>100 laparoscopic procedures).

2.4. Tasks

At the beginning of the study, the size category (XS, S, M and L) of each participant's hand was identified using a template. Each task was performed using both an instrument handle with the correct size for the surgeon and a handle with a difference of two sizes (wrong size) in a blind and randomized fashion. The type of laparoscopic instrument used with both the left and right hands to perform the activities was grasping forceps. For this study, participants were asked to perform three different basic laparoscopic tasks on a physical simulator (SIMULAP®; CCMIJU, Cáceres, Spain) with a 10-mm, 30-degree rigid laparoscope (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) as the vision system (Figure 3). The height of the table and monitor were adapted to the comfort needs of each participant and the laparoscopic camera was fixed to prevent movements during the execution of the tasks. Surgeons were given a brief explanation of how to operate the controls on the new instrument handle (trigger and wheel). Since the study was randomized, participants received no training period with the instrument in order to prevent them from being familiar with a specific handle size and thus avoid possible bias.

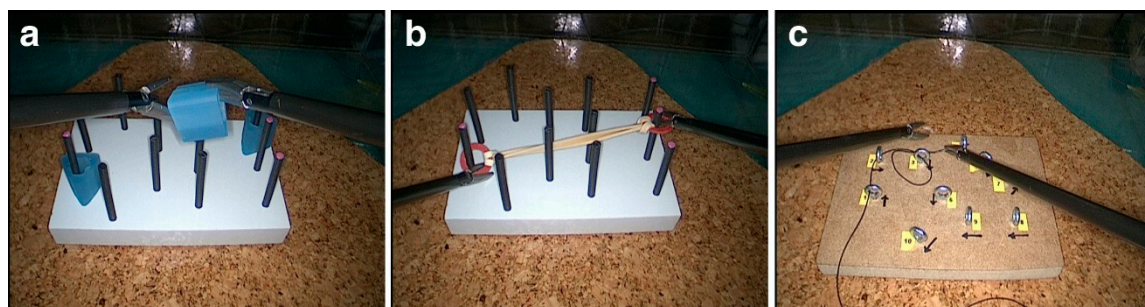


Figure 3. Tasks: (a) Hand-eye coordination, (b) coordinated traction and (c) transfer task (labyrinth).

2.4.1. Hand-Eye Coordination

To perform this task, participants were asked to grasp three colored objects from one side of the pegboard with their closest hand, transfer the object mid-air to their opposite hand, and place the object on a peg on the other side of the pegboard (Figure 3a). Once all three objects had been transferred, the process was reversed.

2.4.2. Coordinated Traction

This task required the placement of an elastic band from a peg placed on one side of the pegboard to three other pegs on the other side, sequentially (Figure 3b). The starting peg was on the opposite side of the participant's dominant hand.

2.4.3. Transfer Task (Labyrinth)

Participants were asked to transfer a straight needle through a circuit of rings, distributed at different angles (Figure 3c). The needle was driven through the rings using the dominant hand and with the support of the non-dominant hand. The order of the rings and orientation of the needle driving were indicated with numbers and arrows on the pegboard, respectively.

2.5. Assessment

The execution time was recorded for each trial. In addition, ergonomic aspects of using the new instrument handle design during the execution of each task, such as wrist posture and pressure exerted on the instrument handle, were analyzed (Figure 4).



Figure 4. Setup of the study. A surgeon is performing the transfer task using an instrument handle with a size L.

2.5.1. Hand Pressure

To measure the fingers and hand pressure while using the instrument handle, the FingerTPS™ (Pressure Profile Systems, Inc., Hawthorne, CA, USA) wearable and wireless system was employed. In this study, a set of five sensors to record the pressure exerted by the surgeon's distal phalanges of the thumb and index, middle and ring fingers, as well as the palm, were used. The system was calibrated for each participant.

2.5.2. Wrist Posture

The flexion-extension and radio-ulnar deviation of the wrist were recorded using a dual-axis electrogoniometer (Biopac Systems, Inc., Goleta, CA, USA) attached to the surgeon's hand and forearm using medical adhesive tape. In order to measure both axes simultaneously, two DA100C amplifiers (Biopac Systems, Inc.) were used. This device was calibrated at the beginning of the study. The risk level of the wrist posture was determined by means of a modified version of the RULA (Rapid Upper Limb Assessment) method as described in [32]. Risk values were defined according to the wrist angle, with wrist flexion-extension and radio-ulnar deviation angles between -15° and 15° being considered ergonomically acceptable.

2.5.3. Subjective Assessment

At the end of each task, the participants were asked to complete a questionnaire to evaluate, using a visual scale from 1 to 10, the comfort of performing the task with each instrument handle used.

2.6. Statistical Analysis

For statistical analysis, the Wilcoxon signed rank test was used to compare the surgeons' performance and ergonomic data of both study groups (right and wrong instrument handle size).

All statistical analyses were carried out using R version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria). The results are shown as mean and standard deviation. For all tests, $p < 0.05$ was considered statistically significant.

3. Results

3.1. Execution Time

The surgeons required significantly less time to complete the hand-eye coordination task using the adequate size of instrument handle (Figure 5). The execution time was similar for the other tasks, regardless of the type of instrument handle used.

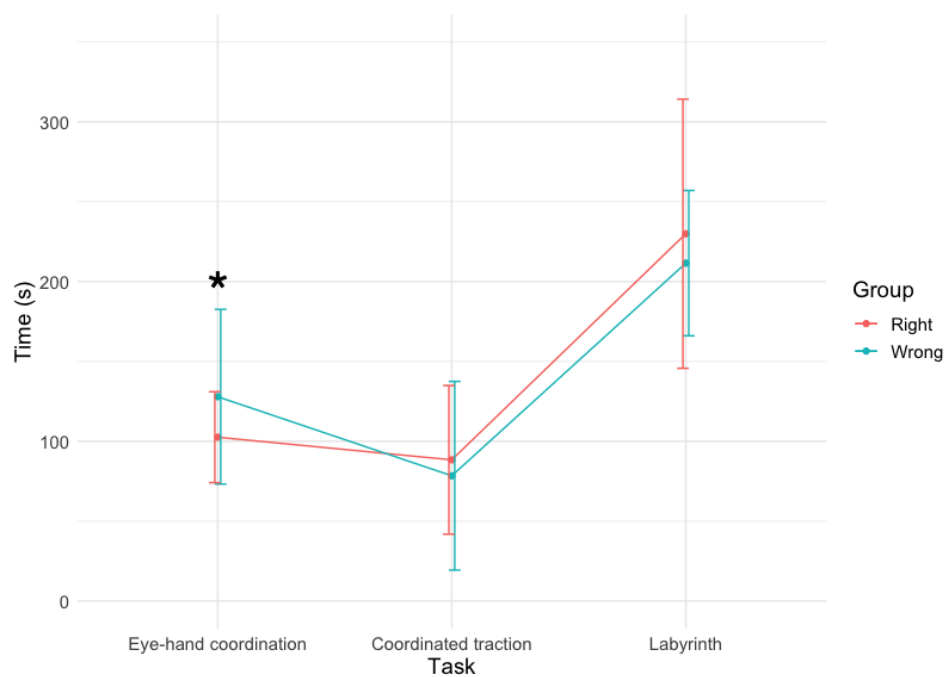


Figure 5. Execution time of the three laparoscopic tasks using the right and wrong instrument handle size. * $p < 0.05$.

3.2. Hand Pressure

There was a remarkable increase in palmar pressure on the wrong size instrument handle for the coordinated traction and transfer tasks compared to the right size handle, being statistically significant for the latter task (Figure 6). Using the right size of instrument handle led surgeons to apply more pressure with the thumb and middle fingers during the transfer and hand-eye coordination tasks, respectively, when compared to the use of the wrong size handle.

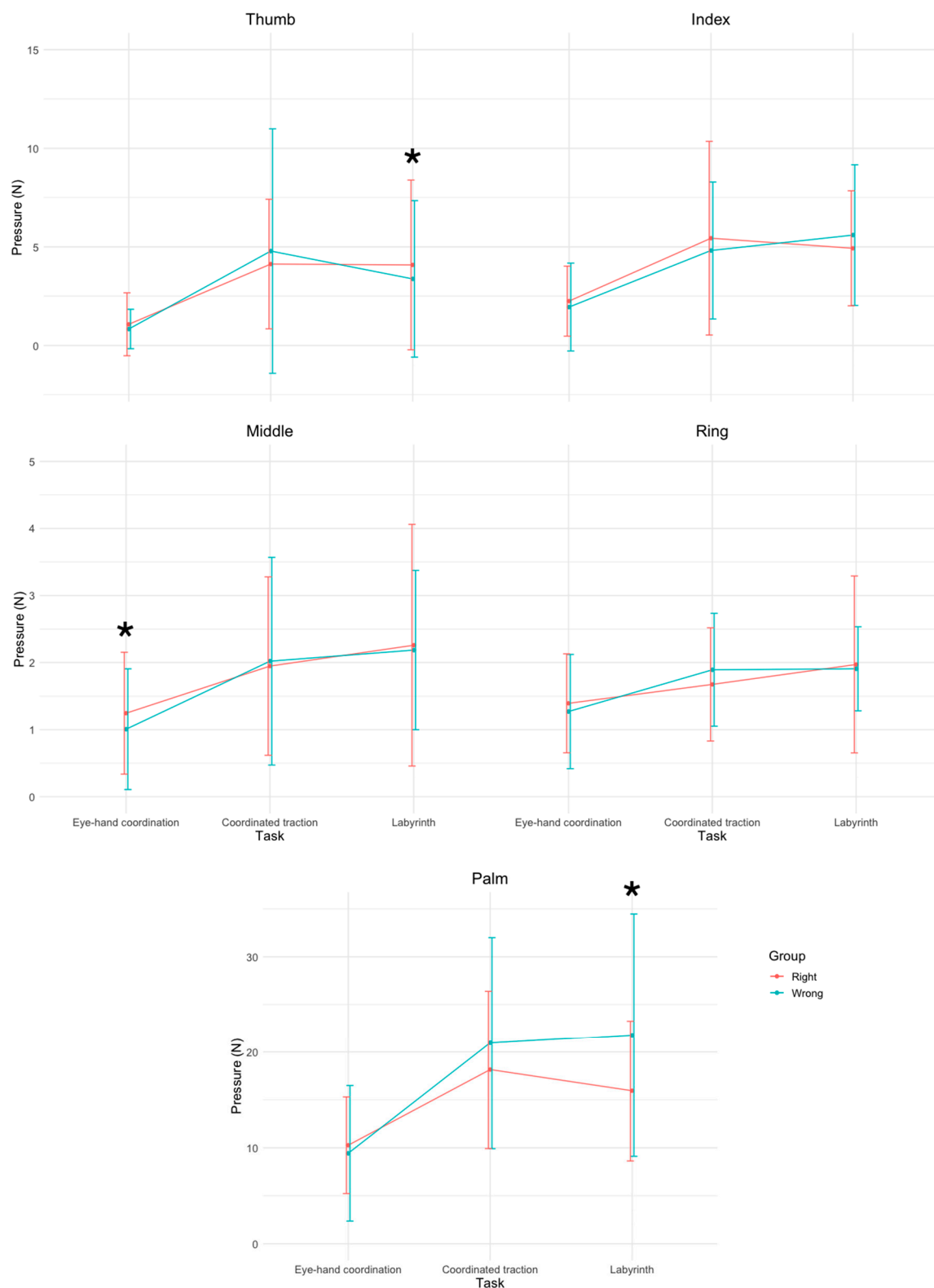


Figure 6. Pressure exerted by the surgeons' fingers (thumb, index, middle and ring fingers) and palm during the laparoscopic tasks using the right and wrong instrument handle size. The range of pressure values (y axis) has been adapted to each data set. * $p < 0.05$.

3.3. Wrist Posture

No statistically significant differences in wrist posture with each instrument handle were shown for any of the laparoscopic tasks (Figures 7 and 8). Regarding the wrist radio-ulnar deviation, the surgeons only obtained an ergonomically acceptable wrist posture, according to the criteria of RULA method, during the transfer task and for both sizes of instrument handle. In the case of wrist flexion-extension, both groups of handles led to an adequate posture of the wrist for all the tasks.

3.4. Subjective Assessment

The results from the questionnaires show that there were no statistically significant differences in the comfort of using the two different sizes of instrument handle for the three performed tasks (Figure 9).

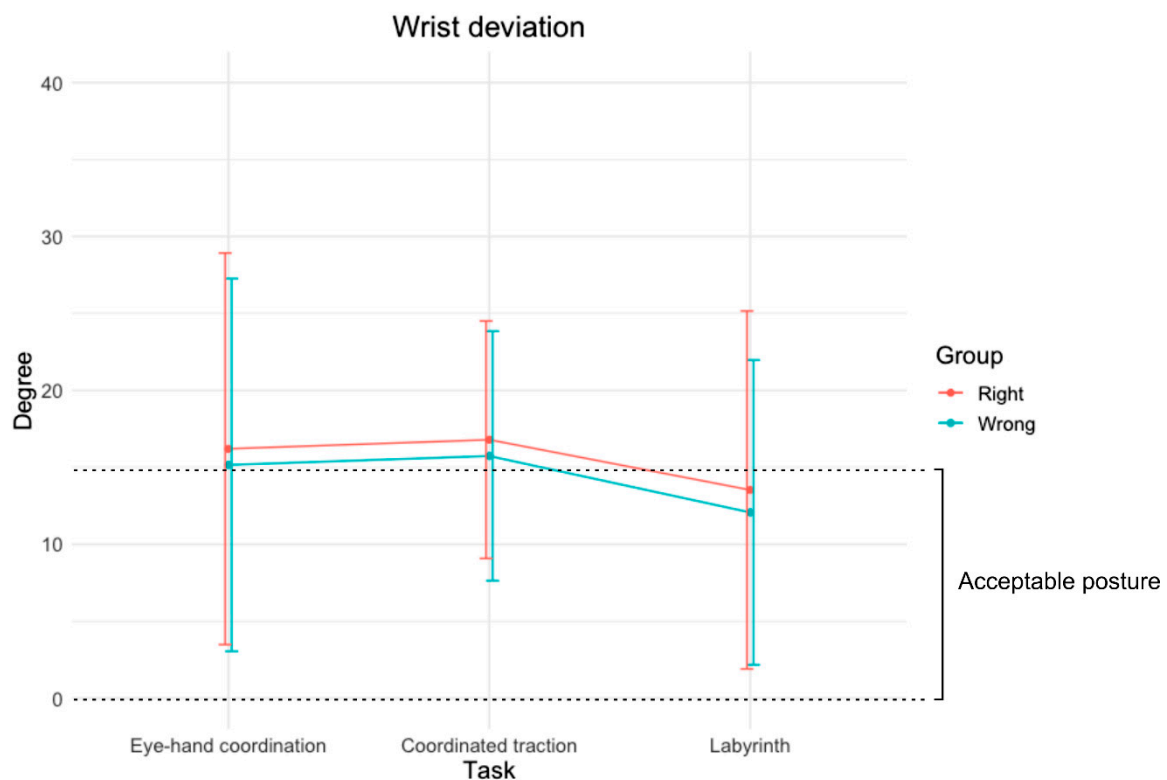


Figure 7. Radio-ulnar deviation of the surgeons' wrist during the laparoscopic tasks using the right and wrong size of instrument handle. The graph indicates the acceptable posture of the wrist according to RULA method.

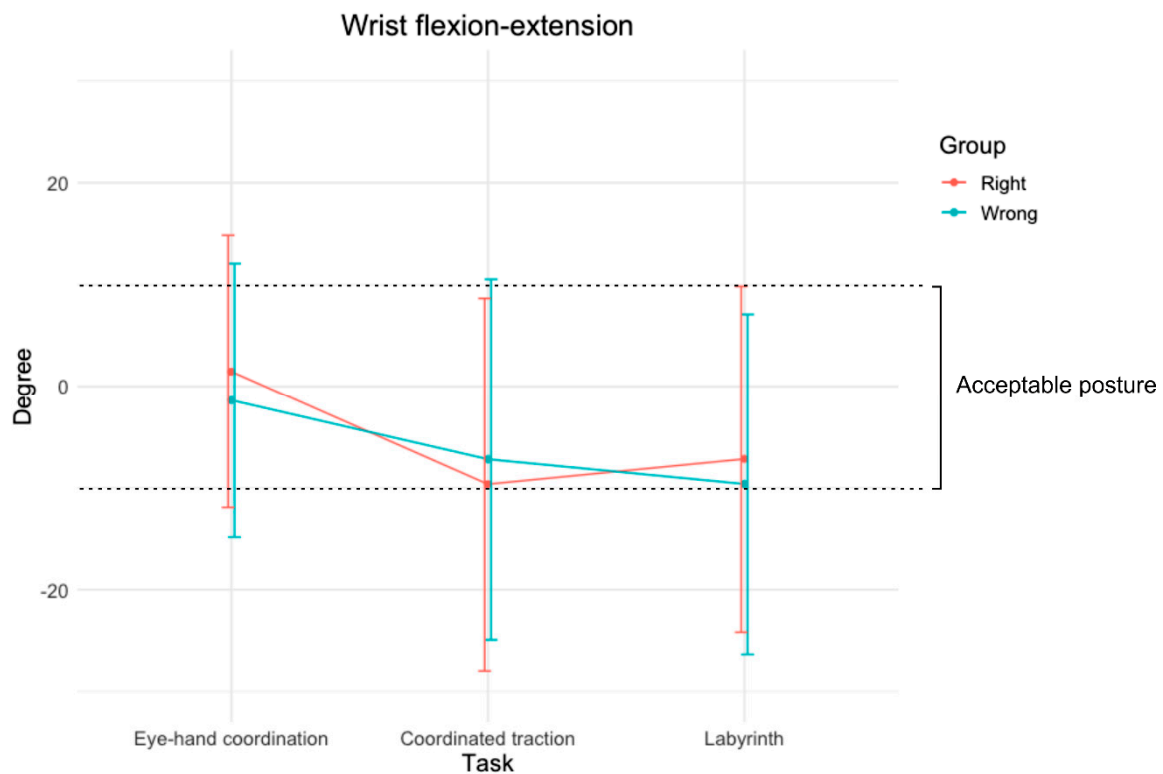


Figure 8. Flexion-extension of the surgeons' wrist during the laparoscopic tasks using the right and wrong size of instrument handle. The graph indicates the acceptable posture of the wrist according to RULA method.

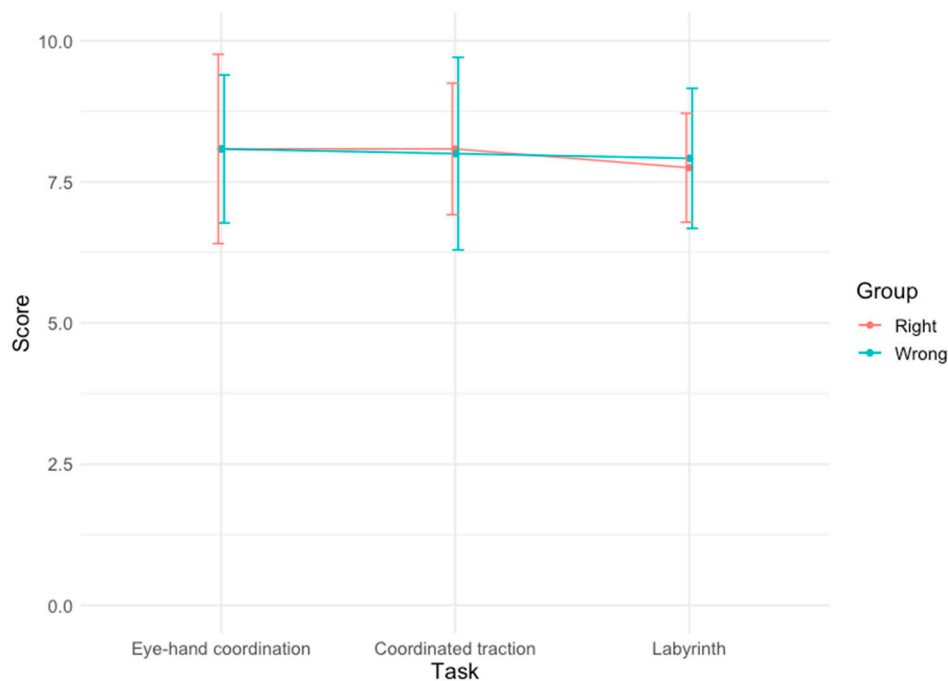


Figure 9. Results of the surgeons' evaluation regarding the comfort of performing each task using the two types of instrument handles.

4. Discussion

There are several studies in the scientific literature that confirm the need to improve the comfort and ergonomic criteria of instruments for laparoscopic surgery. The instrument handle is an essential part

of laparoscopic instruments, whose inappropriate design can have a detrimental effect on the surgeon's efficiency and wellbeing [33]. The rate of work-related musculoskeletal disorders in laparoscopy are from 73% to 100%, with poor instrument handle design being one of the main risk factors [34,35]. In a survey by Santos-Carreras et al., they assessed the acceptance of different surgical instrument handle designs and they reported that conventional laparoscopic instrument handles such as the axial handle scored lowest in terms of comfort [36]. Other studies also indicated that axial handles require significantly more muscle activity than the other common types of instrument handle [37]. In this study, we have analyzed the relationship between the surgeons' ergonomics and performance and different sizes of a novel laparoscopic instrument handle design [11]. The results verify that the use of different instrument handle sizes has consequences on the surgeon's grip pressure and surgical skills.

It seems that the use of an adequate size of instrument handle helps hand-eye coordination and bimanual dexterity in the development of laparoscopic tasks, reducing the execution time, as shown by the results of this study. Tung et al. also presented an innovative laparoscopic handle design with a pistol grip attempting to address some of the ergonomic limitations in laparoscopic surgery [38]. Although the validation of this handle design was mainly subjective, they reported significantly shorter execution times in performing cutting and peg transfer tasks when compared to a conventional laparoscopic tool. However, execution time may not be a very meaningful assessment parameter in the case of the coordinated traction task. This task requires participants to exert a high degree of traction with the instruments and, therefore, to firmly the instrument handle. Due to the metal material of the rings, they sometimes slipped off the instrument tip, thus increasing the time required to complete the task, despite the surgeon's skills.

Regarding the pressure exerted by the surgeon's fingers and palm using the instrument handle, the palm exerted the highest amount of pressure on the handle when compared to the rest of the anatomical sites analyzed. This result was also reported by Rossi et al. using a power grip configuration [39]. In the case of the fingers, the thumb and index finger applied a greater amount of pressure than the middle and ring fingers. This may be because of the primary use of the thumb to control the wheel to rotate the instrument tip and the index finger to operate the trigger that opens and closes it. It should be noted that the use of an inappropriate handle size, especially in more complex tasks such as the transfer task (labyrinth), led to a significant increase in the pressure on the palm. It seems that this substantial increase in palmar pressure was accompanied by a reduction in the pressure exerted by the thumb when controlling the instrument wheel. Therefore, instead of distributing the force exerted by the fingers and the palm in a more balanced way, in this case it was mainly focused on the surgeon's palmar area. In a power grip configuration, like the one we have in our design, the handle should be held by the partially bent fingers and the palm, exerting a counter pressure with the thumb lying near the plane of the palm. Excessive strain and repetitive hand actions associated with power gripping contribute to trauma and localized fatigue [39].

The instrument handle design presented in this study allowed for an ergonomically acceptable wrist flexion-extension posture during the laparoscopic practice. This posture was also maintained for all the different handle sizes evaluated in the study. Other studies, using commercially available instruments [40] and prototypes of instrument handles [41,42], also reported that a pistol handle configuration provides an ergonomically adequate wrist flexion, providing a significantly better wrist posture than using a conventional laparoscopic tool. The results of the presented study are consistent with those presented in a previous study in which we evaluated another ergonomic power grip handle for a handheld robotic laparoscopic instrument [43]. The ergonomic analysis showed that, after training, the use of the robotic instrument resulted in an ergonomically acceptable flexion-extension of the wrist, in contrast to the posture acquired by using the conventional needle holder with axial handle. In addition, in another study we analyzed the surgeon's wrist flexion-extension posture when handling conventional instruments for laparoscopic surgery, including axial, curved, and ringed handles [44]. The results showed that, for all instruments, most surgeons have ergonomically unfavorable angles of wrist flexion, which were prone to possible musculoskeletal disorders. One of the first ergonomic

studies of laparoscopic instrument handles by Matern et al. also warned of ergonomic deficiencies in wrist flexion when using ring handles and excessive radial deviation in axial handles [45]. In the case of the wrist radio-ulnar deviation, we observed the most notable improvements using the ergonomic instrument handle during the execution of the transfer task. These results reinforce the ergonomic benefits to the surgeon of using the presented handle design for laparoscopic practice.

The general design of the handle has been positively evaluated by the participants of this study with regard to the comfort of use, without showing significant differences between the groups of handle sizes. Perhaps in this study we have been conservative and a difference of only two sizes is not enough to appreciate noticeable changes in the use of the presented instrument handle design. For future studies, we will seek to compare designs with larger size differences, which could be also a very common situation in surgical practice, mainly between female and male surgeons.

This study presents some limitations of which we are aware of. Although there are other studies in the same field with a similar or smaller number of subjects [37,40], the number of participants in this study is restricted. In further studies, we will increase the study population in order to obtain more representative results and allow comparison by experience levels in laparoscopic surgery. The skills acquired by experienced surgeons in handling laparoscopic instruments may be an influential factor in their ergonomics when using different sizes of instrument handles. On the other hand, in this study we only analyzed the instrument handles with laparoscopic grasping forceps. Future work will be carried out on the use of this handle design for other laparoscopic instruments, such as a needle holder, and thus analyze the experience of surgeons in more complex tasks as intracorporeal suturing.

5. Conclusions

The results of this study show that the ergonomic design of the instrument handle improves the surgeon's ergonomics and comfort during laparoscopic practice, promoting a more neutral operating wrist posture. The use of an adequate size of the instrument handle allows for improved surgical performance, surgeons required less time to complete the eye-hand coordination task than using the incorrect size, and ergonomics by reducing the contact pressure on the surgeon's palm during the transfer task.

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