The Artisential® Articulated Laparoscopic Forceps: A Dry Lab Study to Examine Dexterity and Learning Effects in Operators of Different Levels of Laparoscopic Experience

IBRAHIM DARWICH, MD[1]
SENIOR CONSULTANT

CHRISTEL WEISS, PHD, DIPL.-MATH.[2]
HEAD OF THE DEPARTMENT OF MEDICAL STATISTICS AND BIOMATHEMATICS

MOHAMMAD ABUASSI, MD[1]
RESIDENT

DIETMAR STEPHAN, MD[1]
PROFESSOR OF GASTROENTROLOGICAL SURGERY

FRANK WILLEKE, MD, PHD[1]
PROFESSOR FOR VISCERAL-, VASCULAR- AND GENERAL SURGERY

[1]DEPARTMENT OF SURGERY, ST. MARIENKRANKENHAUS SIEGEN, SIEGEN, GERMANY
[2]DEPARTMENT OF MEDICAL STATISTICS AND BIOMATHEMATICS, MEDICAL FACULTY MANNHEIM, HEIDELBERG UNIVERSITY, THEODOR-KUTZER-UFER, MANNHEIM, GERMANY

ABSTRACT

Purpose: The advantages of articulation became known with the advent of robotic surgery. This dry lab study examines the dexterity and learning effect of a new articulated laparoscopic instrument called ArtiSential®.

Methods: A peg board task was designed. Three groups of volunteers with varying levels of laparoscopic expertise were organized to perform the task: expert, intermediate and novice. The participants performed the task using an articulated and a straight instrument, once before a 30-minutes training session und once afterwards. The times required for performing the task were recorded. The performances were analyzed and compared between the groups as well as between the straight and the articulated instrument.

Results: The experts were significantly quicker than the novices with both instruments before the 30-minutes training session ($p = 0.0317$ for each instrument). No significant time difference was found between the three groups after the 30-minutes training session. The time reduction to achieve the peg transfer routine with the articulated instrument was significantly greater in the novice and intermediate group ($p = 0.0159$ for each

instrument). No significant difference in time reduction was observed between the groups with the straight instrument. Irrespective of the user, the articulated device was quicker than the straight one after 8 hours of training (p = 0.0039).

Conclusion: The ArtiSential® articulated device can improve dexterity. A significantly greater learning effect was observed in the novice and intermediate groups in comparison with experts. A plateau in the learning curve was observed after a few hours of training.

INTRODUCTION

Since the advent of modern laparoscopic surgery by the German gynecologist, Kurt Semm, in the late 70's [1,2], the general design of laparoscopic instruments has remained basically unchanged [3]. A classical laparoscopic instrument consists of a straight shaft with a jaw-like tip at its distal end capable of opening and closing as well as axial rotation with the help of a knob present at the level of the handle grip. Once the instrument is driven into the patient's abdomen via a port, the laparoscopic surgeon utilizes the so-called "fulcrum effect" to manipulate the instrument. This basically means that the tip of the instruments moves inversely with respect to the handle, resulting in a relevant reduction in the degrees of freedom compared with the movement capacity of the human hand [4]. Advances in video imaging and growing experience have encouraged laparoscopic surgeons to try to perform nearly every procedure laparoscopically despite reduced dexterity [5]. Limited access in confined anatomic regions like the pelvis or the mediastinum pushed classical laparoscopy to its limits. This paved the way for innovation directed at introducing articulation capabilities at the level of the tip of the laparoscopic instrument [6]. The advantages of robotic surgery brought about by the da Vinci® surgical system (Intuitive Surgical, Inc., Sunnyvale, CA) were soon realized in terms of increased dexterity and degrees of freedom as well as elimination of the fulcrum effect [7]. Yet the very high acquisition, running and maintenance costs of the da Vinci® surgical robot triggered an interest in developing "wristed" instruments for conventional laparoscopy. The search for cost-effective laparoscopic instruments that offer similar advantages with regard to increasing the degrees of freedom and improving dexterity started. Several purely mechanical or partly motorized products have been developed or even introduced to the market, yet none of these products have so far managed to play a relevant role in laparoscopic surgery as presented in a review of such instruments by Anderson et al. 2016 [8]. The authors of this review attributed the lack of success of these different instruments, amongst other things, to steep learning curves, unmatured and still early stages of development and the lack of consensus on optimal design.

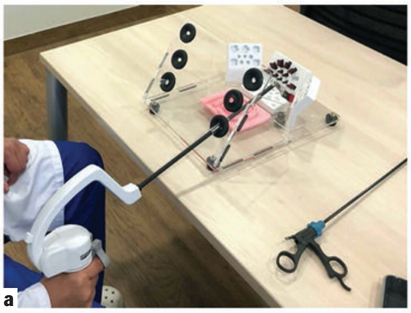

Figure 1a. The designed peg transfer routine.

Figure 1b. The designed peg transfer routine.

In 2019 a new multi-degree of freedom articulated single-use laparoscopic instrument was introduced under the name ArtiSential® by LIVSMED, Seongnam, Republic of Korea. The end effector of this instrument utilizes two joints to perform a 360-degree wristed capability much similar to that of the da Vinci® surgical system [9]. LIVSMED offers a complete lineup of ArtiSential® instruments in different sizes and shaft lengths including dissectors, graspers, needle holders, scissors, spatulas, hooks and clip applicators. Both modes of cautery, monopolar and bipolar, are available.

In a dry lab study, we designed a peg transfer routine to compare the level of dexterity as well as the learning effect between ArtiSential® and a classical straight laparoscopic instrument in three different groups of volunteers: expert laparoscopic surgeons, intermediate laparoscopic surgeons (surgery residents) and laparoscopy-naive medical students.

The rationale behind recruiting novice participants is that these never performed laparoscopies before and are thus unfamiliar with the fulcrum effect. It was therefore assumed that these novices would tend to have a flatter learning curve with an articulated laparoscopic instrument that simulates the movement of the hand rather than with a straight instrument. Furthermore, a comparison of their performance to that of expert or intermediate laparoscopic surgeons who are quite used and adapted to the fulcrum effect becomes of utmost interest.

MATERIALS AND METHODS

DESIGN OF THE SIMULATION TASK

A peg transfer routine was determined for the peg boards of the ArtiSential® training kit provided by LIVSMED. The tilted design of the upright peg boards in this training kit is aimed to increase the difficulty of peg placement which is why it was selected for use in this study. The routine consisted of transferring a total of 12 constant pegs of different sizes and shapes from a frontal facing, slightly tilted and upright positioned board to another lower horizontally positioned board. The routine continued by transferring 10 pieces out of the pegs in the horizontally positioned board to an upright positioned slightly tilted board on the right-hand side of the participant (Fig. 1a and b). The routine was done single-handedly with the right arm (all study participants were right-handed).

The peg transfer routine as well as the mechanism of function of the articulated laparoscopic instrument were explained to each participant in a short tutorial of 10 minutes. The mechanism of function of the straight laparoscopic instrument was additionally explained to the laparoscopy naive participants. The participants were not allowed to physically inspect the instruments or perform any peg transferring before or during the tutorial to ensure that no practicing of the routine took place before the first trial.

After the tutorial, the peg transfer routine was performed by each participant, once with the articulated instrument and once with the straight instrument. The time required to complete the routine was recorded by two neutral reviewers for each instrument.

Every participant received afterwards two 30-minutes training sessions to independently practice the routine for each instrument respectively.

The peg transfer routine was then repeated with both instruments and the time required to complete the routine was recorded by two neutral reviewers for each device.

After that and in order to examine the full capabilities and the learning curve of ArtiSential®, the expert and the novice with the quickest time scores were allowed to exercise the peg transfer routine with both instruments, straight and articulated, for a total of 8 hours (4 hours for each instrument). Then both had to perform the peg transfer routine 5 times in a row for each of the instruments, straight and articulated. The time required to complete the routine was recorded by two neutral reviewers each time.

CLASSICAL STRAIGHT LAPAROSCOPY INSTRUMENT

A classical monopolar grasping laparoscopic device was utilized for the peg transfer routine to be performed with a straight instrument (ERAGON-modular 5 mm insulated atraumatic grasping forceps, 20 mm double action, Richard Wolf Instruments, Vernon Hills, IL, USA). This device has a rigid insulated 5 mm shaft and an atraumatic double action 20 mm jaw at the tip. The axial rotation of the tip is secured by a rotational knob fitted between the handle and the shaft. The handle has no locking mechanism (Fig. 2 a).

ARTISENTIAL® ARTICULATED LAPAROSCOPIC INSTRUMENT

An ArtiSential® Bipolar Fenestrated Forceps (LIVSMED, Seongnam, Republic of Korea) was utilized for the peg transfer routine to be performed with an articulated laparoscopic instrument (Fig. 2 b). The ArtiSential® devices are both FDA cleared as well as CE Mark approved.

The tip of this device has two components with two joints. During simultaneous maximal flexion of both joints, the shaft and the two components of the tip are situated in three geometrical planes that are perfectly perpendicular to one another (Fig. 3). The device utilizes a system of pulleys which allows the tip to move in a complete hemispherical space. The handle design allows an up-and-down rotational movement in the vertical plane as well as a right-and-left rotational movement in the horizontal plane. The thumb and the index finger are inserted into two trigger-like controllers that secure the open-close mechanism of the jaw. The direction of movement of the hand or indeed that of the thumb and the index finger matches the movement of the tip (Fig. 4). When an axial rotation of the forearm is added while operating the device, seven degrees of freedom become available: in-out, rotation, pitch, yaw, wristed pitch, wristed yaw and grasp (Fig. 4 and Fig. 5).

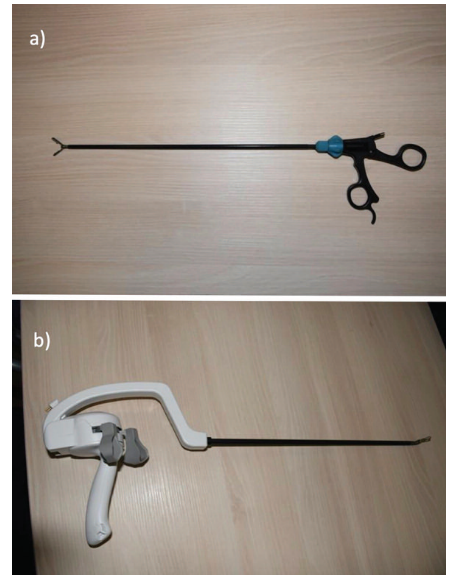

Figure 2. a) The ERAGONmodular grasping forceps, 20 mm double action, Richard Wolf Instruments, Vernon Hills, IL, USA. b) Artisential® Bipolar Fenestrated Forceps (LIVSMED, Seongnam, Republic of Korea)

STUDY PARTICIPANTS

Three groups of participants were invited to take part in this dry lab study: Five expert laparoscopic surgeons with a minimum of 500 laparoscopic procedures, including complex upper and lower GI-tract surgeries, five intermediate surgeons (residents in general surgery) with an experience of 10-20 Laparoscopic cases and five laparoscopy naive medical students. None of the participants had any experience with hand held articulated laparoscopic devices. Furthermore, none of the participants had earlier experience with the da Vinci® robot. The participants had

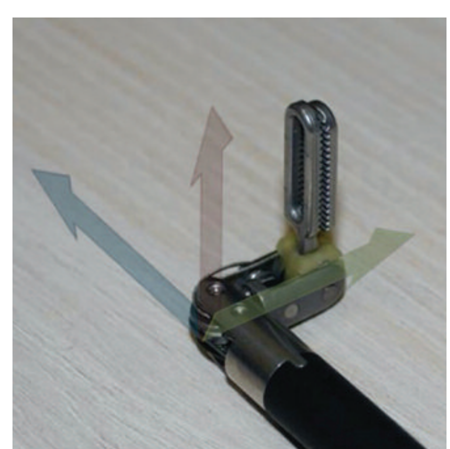

Figure 3. Maximal flexion of the end effector of the Artisential® bipolar fenestrated grasper

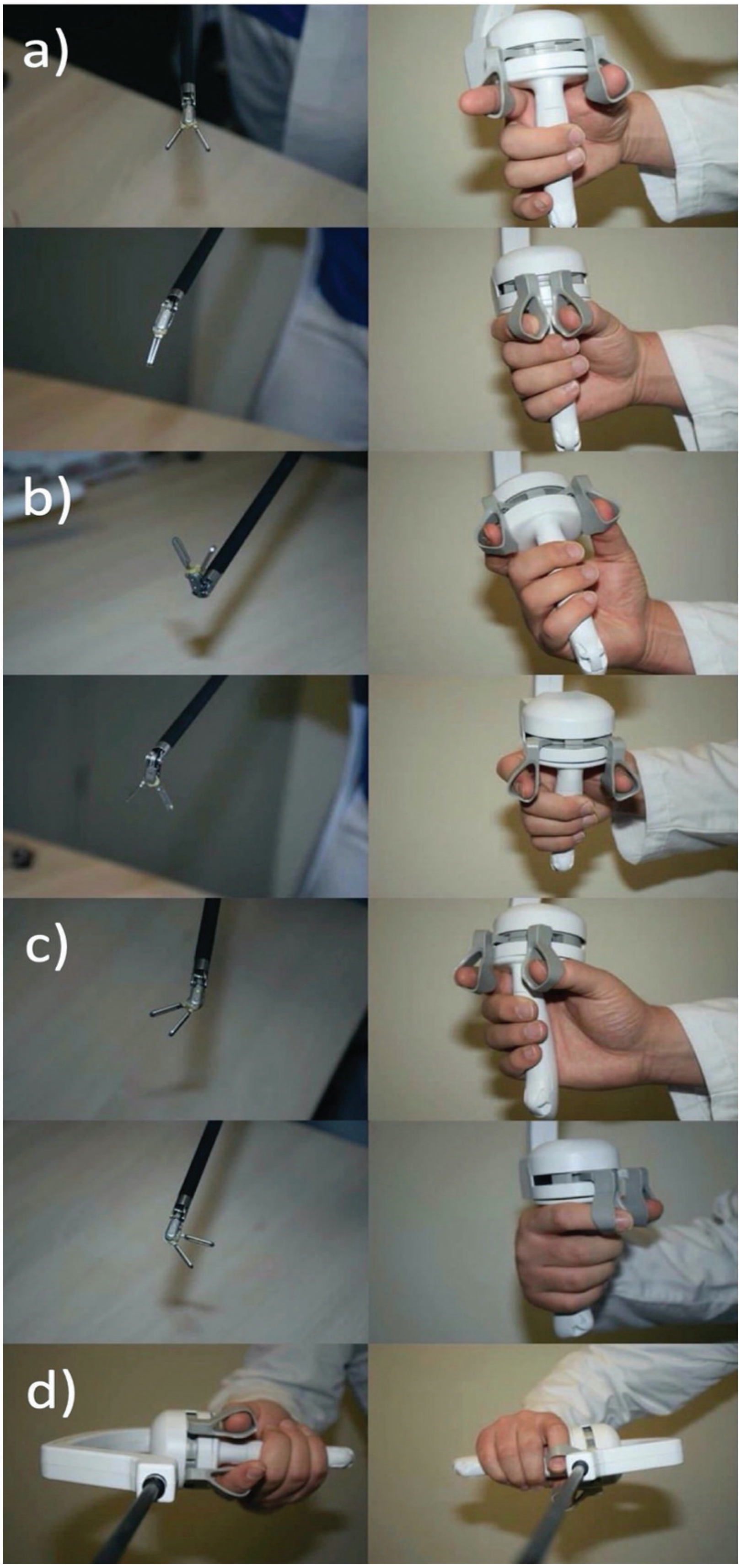

Figure 4. The movement of the end effector matches The movement of the thumb and index finger. This sequence shows the mechanism of: a) open-close, b) up-down, c) right-left and d) axial rotation of the forearm

no access to the articulated device beforehand and did not have any information about the device to be tested. The participants performed the peg transfer routine and the 30-minutes practice for each instrument independently and without external help or outside interference at any time.

All participants gave written consent to take part in the study.

The dry lab study protocol was approved by the committee of doctoral studies of the Medical Faculty Mannheim but did not require formal approval by the ethics committee after consultation.

STATISTICAL WORKUP

Required times are presented by mean value and standard deviation together with the range.

For the comparison between 3 or 2 independent groups, Kruskal-Wallis test or Mann-Whitney U test has been used, respectively. Post hoc tests have only been performed if the result of the Kruskal Wallis test has been significant. Wilcoxon test for two paired samples has been performed in order to evaluate the differences between "before" and "after training session".

In general, the result of a statistical test has been considered as significant for $p < 0.05$. Because of the rather small samples sizes, exact p values have been calculated. As the study is regarded as an explorative study, no adjustment for multiple testing was performed.

RESULTS

BEFORE THE 30-MINUTES TRAINING SESSION

The mean times achieved by all groups, the mean time reduction after the 30-minutes training session and the results of statistical analysis are shown in Tables 1 and 2 respectively.

In general, before the 30-minutes training statistically significant differences have been detected for both instruments, straight and articulated ($p = 0.0409$ and $p = 0.0333$, respectively). The experts were significantly quicker than the novices ($p = 0.0317$ for each instrument). The experts also tended to be quicker than the intermediates, this did not reach statistical significance however ($p = 0.0556$ for each instrument). No statistically significant difference was found in this regard between the intermediates and the novices (straight $p = 0.7937$, articulated $p = 0.4206$).

AFTER THE 30-MINUTES TRAINING SESSION

No statistical time difference was found between the three groups to achieve the peg board task with both instruments, straight and articulated, after the 30-minutes training session ($p = 0.7012$ and $p = 0.1613$, respectively).

TIME REDUCTION AFTER THE TRAINING SESSION

The experts were able to reduce their mean time to achieve the peg board task by 1.5% with the straight and by 45.4% with the articulated instrument after the 30-minutes training session. The intermediates reduced these same times by 25.8% and 72.4% whereas the novices reduced these by 47.1% and 70.7% respectively.

The mean time reduction achieved by novices and intermediates with the articulated instrument was significantly greater than that achieved by the experts ($p = 0.0159$ for each comparison Novice-Expert and Intermediate-Expert). No significant difference in time reduction has been observed between novices and intermediates ($p = 0.5476$).

The mean time reduction which had been achieved with the straight instrument, did not differ significantly among groups ($p = 0.1613$).

COMPARISON OF THE QUICKEST EXPERT WITH THE QUICKEST NOVICE

The mean times achieved to perform the peg board task after an 8-hours training session did not differ significantly between the quickest expert and the quickest novice (Articulated $p = 0.4841$; Straight $p = 0.3095$). The mean times achieved are presented in Table 3. On the other hand, the drill times achieved by both the quickest expert and the quickest novice with the articulated instruments (Table 4) where significantly quicker than those achieved with the straight instrument ($p = 0.0039$). Furthermore, a flatter learning curve was observed with the articulated instrument in both, the quickest expert and the quickest novice, demonstrating more homogeneity of times (Fig. 6 and Fig. 7).

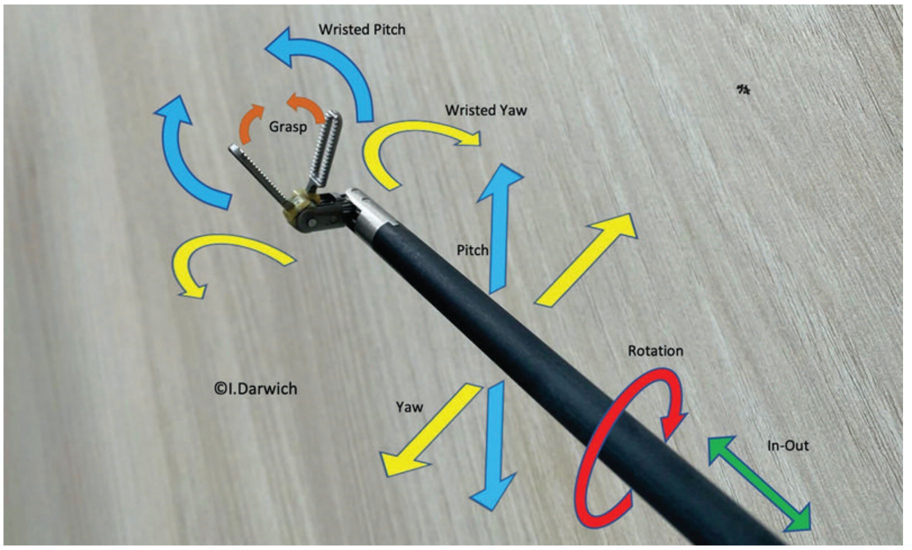

Figure 5. Illustration showing the seven degrees of freedom: in-out, rotation, pitch, yaw, wristed pitch, wristed yaw, grasp.

Table I
Results of the participants before and after the 30-minutes training session with both instruments

Participants	Straight Instrument	Articulated Instrument
Experts		
Mean time before training session (minutes)	6.50 min (SD 2.20) (Range: 4.0 min – 10.0 min)	12.84 min (SD 3.55) (Range: 9.20 min – 15.9 min)
Mean time after training session (minutes)	6.40 min (SD 2.42) (Range: 4.70 min – 10.60 min)	7.18 min (SD 2.87) (Range: 3.90 min – 10.0 min)
Time reduction (%)	1.5 %	45 %
Intermediates		
Mean time before training session (minutes)	11.26 min (SD 4.51) (Range: 6.50 min – 18.0 min)	35.72 min (SD 22.43) (Range: 10.80 min – 69.80 min)
Mean time after training session (minutes)	8.36 min (SD 3.40) (Range: 5.10 min – 14.10 min)	9.86 min (SD 5.57) (Range: 3,70 min – 15.50 min)
Time reduction (%)	25.8 %	72.4 %
Novices		
Mean time before training session (minutes)	10.86 min (SD 5.50) (Range: 6.80 min – 20.20 min)	23.04 min (SD 4.80) (Range: 15.50 min – 28.10 min)
Mean time after training session (minutes)	5.74 min (SD 1.17) (Range: 4.30 min – 7.0 min)	6.74 min (SD 3.84) (Range: 2.90 min – 13.20 min)
Time reduction (%)	47.1 %	70.7 %

SD standard deviation

DISCUSSION

In this dry lab study, we examined the ArtiSential® laparoscopic forceps in terms of dexterity and the learning effect. To do this, we designed a peg transfer routine to be done with the ArtiSential® forceps as well as with a classical straight laparoscopic instrument. Three teams of varying experience in laparoscopy performed the routine: experts, intermediates and novices. We compared their performances in terms of the time to achieve the peg board task and compared their ability to reduce these times after training sessions.

The results of this study confirmed a significantly quicker learning effect in the novice and intermediate groups, using the articulated laparoscopic instrument,

Table II
Results of the participants before and after the 30-minutes training session with both instruments

Instrument	Task time	Kruskal-Wallis-Test	Novices-Experts	Novices-Intermediates	Experts-Intermediates
Straight	Before training session	p= 0.0409	p= 0.0317	p= 0.7937	p= 0.0556
	After training session	p= 0.1613	---	---	---
	Time reduction	p= 0.1836	---	---	---
Articulated	Before training session	p= 0.0333	p= 0.0317	p= 0.4206	p= 0.0556
	After training session	p= 0.7012	---	---	---
	Time reduction	p= 0.0081	p= 0.0159	p= 0.5476	p= 0.0159

Table III
Comparison of the results of the quickest expert and the quickest novice after an 8-hours training session

Participants	Straight Instrument	Articulated Instrument
Quickest Expert Mean time after 8-hours training session (minutes)	3.22 min (SD 1.17) (range: 1.90 min – 4.90 min)	1.36 min (SD 0.21) (range: 1.20 min – 1.70 min)
Quickest Novice Mean time after 8-hours training session (minutes)	2.36 min (SD 0.73) (range: 1.30 min – 3.30 min)	1.22 min (SD 0.16) (range 1.0 min – 1.40 min)
Expert-Novice Comparison	p = 0.3095	p = 0.4841

SD standard deviation

Table IV
Task times by both the quickest novice and quickest expert and comparison of their times according to instrument type

Instrument	(n)	Mean (min)	SD	p value
Straight	10	2.80	1.0	p = 0.0039
Articulated	10	1.30	0.20	

n number of drills, min minutes, SD standard deviation

in comparison with the experts. No such observation was made with the classical straight instrument. Furthermore, a few hours of training with the articulated instrument proved to be sufficient to reach a plateau in the learning curve in both, the quickest novice and quickest expert.

COMPARISON OF THE GROUPS AND THE LEARNING EFFECT

The mean time required by the novices to achieve the peg transfer routine after the 30-minutes training session (Table 1) appeared to be somewhat quicker than that achieved by the experts with both instruments, straight (5,74 min) and articulated (6,74 min). However, group comparison did not attain statistical significance for either instruments (straight p = 0.1613; articulated p = 0.7012).

On the other hand, the mean time reduction achieved by the novices (70.7%) and intermediates (72.4%) with the articulated instrument was significantly greater (p = 0.0159 for each instrument) than that achieved by the experts (45.4%). Whereas the time reduction achieved with the straight instrument by both, novices and intermediates, was not significantly greater than that of the experts (Table 2).

This result backs up the assumption that laparoscopy-naive subjects as well as those with little experience in laparoscopy might be less influenced by the "fulcrum effect". In other words, novices and intermediates seem to be quicker than laparoscopy experts in coping with an articulated end effector whose motion simulates that of the operator hand or fingers.

Focusing on the quickest expert and the quickest novice after 8-hours training, no significant difference was found in the mean performance of the two (Table 3). Both managed yet to achieve a dramatic reduction of the mean times for the task.

The quickest novice achieved a time record in this study of 1.00 minute with the articulated instrument in one of the 5 drills. The fastest time achieved by the quickest expert with the articulated instrument was 1.2 minutes. The articulated instrument was also significantly quicker in performing the drills than the straight one, when all drills performed by the two quickest were compared (p = 0.0039). It was also obvious that once a plateau was reached in the learning curve, relatively constant times were registered with the articulated instrument to achieve the peg board task. This appears to be due to the ability to orient the peg with the flexible jaw for it to exactly fit inside the respective position on the board. This came in contrast to the performance times achieved with the straight instrument, which appeared to be more scattered on the graph. A possible explanation for this observation is that the placement of the peg on the board depended on the "chance" of that peg being in the right position in the fixed jaw of the instrument so as to fit inside the respective board opening (Fig. 6 and Fig. 7).

In a concluding assessment, this study

shows that a few hours of dry lab training may suffice to understand the mechanism of operation of the ArtiSential® fully articulated laparoscopic device and to achieve a good command of its control. Furthermore, the results after the 30-minutes training session back up the assumption that a laparoscopy-naive or a laparoscopy-intermediate user of this device would be able to learn its mechanism of operation faster than an expert laparoscopist who is heavily used to the "fulcrum effect". Further training for a few hours would also lead to a plateau in the learning curve which seems to be similar in both, the expert and the novice user. The articulated instrument appears in the hand of an operator after a few hours of training, regardless of the level of expertise in laparoscopy, to be quicker in performing a standardized dry lab task than a straight instrument.

THE BACKGROUND OF THE UTILIZED METHODS OF ASSESSMENT

The number of cases needed to reach a plateau in the learning curve of laparoscopic surgery remains controversial [10]. A study by Tekkis et al. 2005 suggested that surgeons with more than 100 cases were more likely to attempt performing difficult cases laparoscopically as those with a lower number of cases [11]. The participants in our study were defined as experts if they had performed a minimum of 500 laparoscopic cases. This head start in terms of experience was evident in the better performance delivered by the expert group with both instruments before the training session.

Furthermore, the idea of recruiting novices to compare the performance of a novel surgical technology with a conventional one has been implemented in the past [12]. This aims at investigating the level of intuitiveness and ease of operating a technological device. The greater learning effect delivered by the novices in this study with the articulated instrument in comparison with the experts seems to support the rationale of adopting such a method of investigation.

The design of a peg transfer routine to be performed before and after a time-limited training session in order to compare between the groups, relied on evidence from the literature favoring a Criterion-based training of laparoscopic skills [13]. Further evidence exists also for the validity of utilizing box-trainers for simulating and transferring laparoscopic skills [14]. The LIVSMED training kit, utilized in this study, consisted of upright and slightly tilted peg boards which add a margin of difficulty that is directed at testing the abilities of an articulated instrument. However, and to the best of our knowledge, there is no evidence in the literature validating this kind or indeed any other specific kinds of box-trainers.

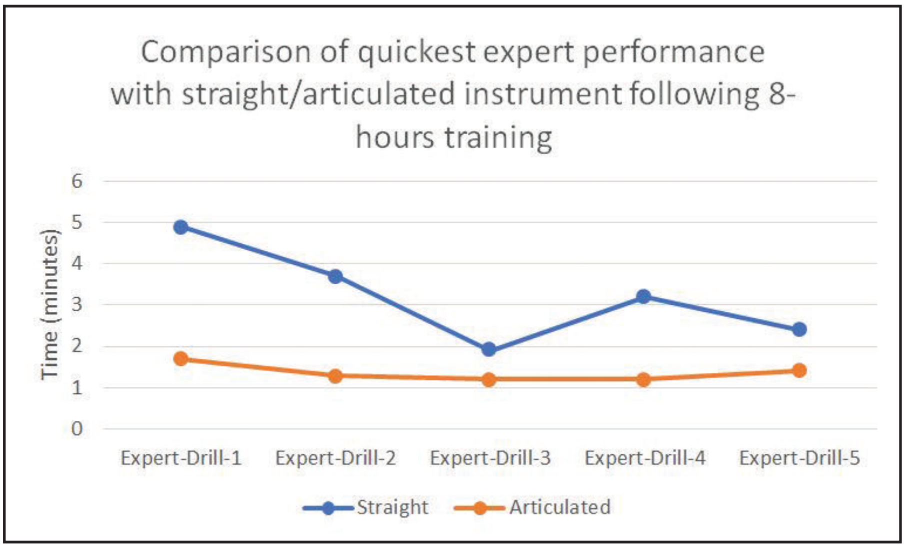

Figure 6. A graph summarizing the times achieved by the quickest expert to perform the peg transfer routine with the straight and articulated instrument following the 8-hours training session.

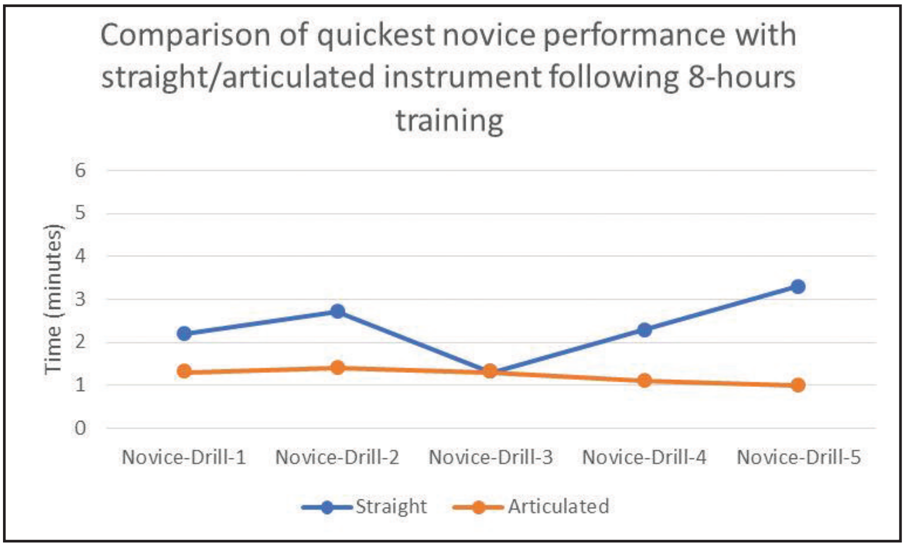

Figure 7. A graph summarizing the times achieved by the quickest novice to perform the peg transfer routine with the straight and articulated instrument following the 8-hours training session.

IMPLICATIONS FOR THE FUTURE

Laparoscopy has become the gold standard of interventional surgery, not only due to less complications, less blood loss, less pain, shorter length of stay and better cosmesis, but also because of its non-inferiority to open surgery when it comes to clinical and oncologic outcomes [15]. Yet the advent of laparoscopic surgery came at the expense of reduced ergonomics and dexterity which inevitably paved the way for accepting the high costs of robotics despite conflicting evidence of a clear clinical benefit [16-18]. Realizing the advantages of Articulation and the ever-growing interest in bringing more flexibility, ergonomics and dexterity to surgical robots [19], it was only a matter of time before a similar interest would arise in the development of hand-held fully articulated laparoscopic instruments [8,20].

In 2019, the ArtiSential® fully articulated laparoscopic instruments were introduced by LIVSMED, Seongnam, Republic of Korea. A few publications, mostly case reports and small case series, recently appeared describing the intraoperative use of these instruments in different laparoscopic procedures in the upper and lower gastrointestinal tract as well as the thorax [21-25]. Yet little information has been available about the mechanism of operating these devices and indeed the level of surgical dexterity they provide.

The ArtiSential® has however been suggested as the first multi-degree of freedom hand-held laparoscopic instrument able to achieve tasks that used to solely belong to the "sovereign" domain of the da vinci® robot. A dry lab study published by Min et al. in 2019 demonstrated that ArtiSential® was able to perform difficult suturing tasks just as good as the da vinci® surgical robot [9].

The first surgical procedures with the ArtiSential® fully articulated laparoscopic devices have already been performed in our surgical department and we will be publishing our data in this regard shortly [26].

LIMITATIONS OF THIS STUDY

This study has limitations. First, exact p values have been calculated without adjustment for multiple testing because of the small sample sizes in this rather explorative study. Second, the training kit provided by LIVSMED is specifically designed with tilted boards to add a margin of difficulty that intends to illustrate the superiority of the articulated instrument. This probably resulted in bias in terms of comparison with the straight instrument. Third, the training kit did not utilize a scope and a monitor and depended on direct vision. This obviously simulated laparoscopy to a much lesser extent. In addition, the results and interpretations obtained in this dry lab setting might not correspond well to the quite different haptic expected in wet lab situations. Fourth, this study was designed to measure time only as a criterion of comparison between the groups. Other criterions such as precision and proficiency in performing the task were not examined. This of course can be the subject of future studies.

THE COST FACTOR

The high costs of robotic surgery constitute a well-known hurdle for every healthcare provider looking to acquire this technology [27]. The ability to introduce on-demand articulation to laparoscopic surgery without the need of engaging a robot is probably what instruments such as ArtiSential® are capable of. A designated list price for the single-use ArtiSential® device is still not available in Germany due to a still lacking authorized dealer up until the time of submitting this manuscript for peer review. We expect however the price of an instrument to be in the upper three-digit range according to our conversations with potential candidates for an authorized dealership. Childers et al., 2018 revealed a cost per procedure of $3658, including the cost of instruments and accessories as well as the cost of purchasing and maintaining the surgical robotic system [28]. Hence, an important cost advantage is to be expected with the use of ArtiSential® devices in that regard.

CONCLUSION

The ArtiSential® fully articulated laparoscopic device can be a useful instrument in improving dexterity. Furthermore, a significantly greater learning effect was observed in the novice and the intermediate groups in comparison with the laparoscopy experts. A plateau in the learning curve was equally observed after a few hours of training by the quickest expert and the quickest novice. STI

ACKNOWLEDGEMENTS

This work is dedicated to Marc Kloeckner-Lang, an enthusiastic laparoscopic surgeon who died all too young in spring 2020.

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