

ARTICULATING VS CONVENTIONAL LAPAROSCOPIC GRASPING TOOLS - SURGEONS' OPINIONS

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An ergonomically designed articulating laparoscopic prototype tool was developed based on task analyses, evaluation of current tools and surgeon's opinions. A questionnaire was developed to compare the prototype developed to conventional laparoscopic surgical grasping tools. Thirty-eight surgeons evaluated the prototype tool and shared their opinions via a written survey. Surgeons were asked about problems they experience with use of conventional grasper tools and then gave evaluations of the prototype grasper tool. A Wilcoxon Signed Rank Test was used to statistically analyze the questions. Results showed that a significant number of surgeons experience problems in each of fourteen problem areas, including physical (e.g. pain, stiffness and inability to perform precision motions) and cognitive (e.g. mental fatigue) difficulties. The responses had up to a 66% rate of experience by surgeons, with an alarming 29% of surgeons reporting numbness of the fingers or thumb after surgery with conventional tools. When asked to evaluate the prototype grasper, surgeons preferred the articulating prototype grasper to a conventional grasper, felt the prototype would alleviate discomfort caused by conventional tools and would be easier to manipulate.

Keywords: laparoscopy, surgical tools, articulating end effector, ergonomic design

Relevance to Industry

Laparoscopic surgery requires surgeons to perform complex operative procedures using a standardized set of tools. The surgeon performs the operation with surgical tools and video cameras that are inserted into the patient through port sites (trocars). Surgical tools used in laparoscopic surgery are still being developed, and many have been adapted from conventional surgical tools by adding a long (45-52 cm) stylus to fit through the trocar, putting the handle at a right angle to the long axis (shaft) of the tool.

Although the advantages of minimally invasive surgery have been clearly established for the patient, studies have shown that the surgeon is faced with numerous disadvantages caused by poorly designed instrument handles, including the potential of harm to the surgeon due to awkward postures, high repetition and high force exertions and the likelihood of harm to the patient due to poorly designed tools. Thus, there is a crucial need to develop and assess laparoscopic tools that more fully address the needs of laparoscopic surgery and its surgeons.

INTRODUCTION

Laparoscopy is a relatively recent advancement in surgery that requires no major incisions in the patient, allows for quicker healing, reduced post-operative pain and reduced wound complications such as hernia formation and infection. These benefits have made laparoscopy, and other types of minimally invasive surgery, very popular to patients. However, laparoscopy requires more effort from the surgeon than traditional open procedures (Berguer 1998).

Laparoscopic techniques require greater concentration and place greater mental stress on surgeons than open surgery (Berguer et al. 2001b). The tools that laparoscopic surgeons

must use are difficult to use and because of suboptimal design, they may actually be doing harm to the highly trained physician. Additionally, poor laparoscopic tools increase physician fatigue, creating potential for errors that may harm the patient.

Laparoscopic surgery involves making several small incisions for instrument and camera ports, as opposed to open surgery where a large incision is made. The surgeon performs the laparoscopic operation with surgical tools and video cameras that are inserted into the patient through port sites (trocars) which are 3-15mm in diameter and then the area is inflated (insufflated). The surgical tools used in laparoscopic surgery are still being developed and many have been adapted from conventional surgical tools by adding a long (45-52 cm) stylus to fit through the trocar, putting the handle at a right angle to the long axis (shaft) of the tool. Thus, the design of these instruments should be fundamental to the result of the surgery.

Current laparoscopic instruments have been found to be very poorly designed from an ergonomic perspective and it is likely that ergonomics were not considered at all. Berguer et al. (1998) found 8-12% of practicing laparoscopic surgeons frequently experience post operation pain or numbness. This is generally attributable to pressure points on the laparoscopic tool handle. Matern et al. (1999) studied four different handle designs used on laparoscopic tools (shank, pistol, axial, and ring handle) and found that all resulted in either painful pressure spots or caused extreme ulnar deviation.

Physicians report that limited dexterity at the grasper tip can cause them to compensate with excessive, awkward arm motions (Van Veelen et al. 2001b). Articulation at the tip would enhance the capability of the surgeon by increasing the tool's degrees of freedom. An ergonomically designed handle and grasper actuation mechanism would provide a more comfortable, intuitive hand/tool interface. These additional design features would help to increase patient safety by reducing surgeon's fatigue and decreasing the need for complex cognitive planning.

Based on the findings from task analysis, consultation with laparoscopic surgeons, results of a questionnaire (previous work below) (Doné et al. 2004), and several pilot studies, a prototype articulating laparoscopic grasper was developed to include an articulating end effector, an ergonomic handle, and an intuitive hand/tool interface (Figure 1b). In order to assess the design, evaluation of the prototype tool with respect to the current tools must be conducted. This paper investigates the evaluation of the prototype tool by surgeons and comparison with existing tools using a subjective (questionnaire) method.

PREVIOUS WORK – QUESTIONNAIRE 1

Much consultation was done with surgeons before and during the design of the prototype articulating laparoscopic tool. Included in this consultation was a survey evaluating conventional grasper tools, in which 18 laparoscopic surgeons responded to a questionnaire (Doné et al. 2004). The surgeons were queried after a laparoscopic practice session using conventional tools such as those shown in Figure 1a. These training sessions for both expert and student laparoscopic surgeons were held at the University of Nebraska Medical Center. The questionnaire was administered in the anteroom of the OR. Questionnaire 1 is shown in Appendix A. The primary goal of questionnaire 1 was to identify the physical problems that surgeons were experiencing from using conventional laparoscopic tools. The results of the survey were used as the basis for the design of the new prototype articulating laparoscopic tool.

The survey was based on the work of Van Veelen et al. (2001a), Matern et al. (1999), and Berguer et al. (1999). Van Veelen et al. (2001a) evaluated three different types of handles by testing them subjectively (questionnaire) and objectively (video analyses) in order to find out whether his ergonomic guidelines were valid for the evaluation and design of instrument handles. The questionnaire used by Van Veelen et al. (2001a), consisted of six questions focusing on the human/tool interface of laparoscopic tools and asked about the comfort of

different features. Four of those six questions were reworded, for better understanding, and included in questionnaire 1.

Matern et al. (1999) used semiquantitative observations and a questionnaire to evaluate performance and preferences of four different minimally invasive surgical (MIS) or laparoscopic tool handles. The subjects were asked to evaluate several design elements and functions of the handles using a questionnaire. Three of the seven questions were used in questionnaire 1 with different response scales which better identified surgeons' opinions.

Berguer et al. (1999) wanted to assess the prevalence, causes, and consequences of operational difficulties associated with the use of laparoscopic instruments. This was studied by distributing a questionnaire and processing EMG signals quantifying forearm and thumb muscle workload. The questionnaire asked respondents to rate the frequency with which they experienced pain, stiffness, or numbness in several body areas after laparoscopic operations. Most of the list of body parts was adapted with a different response scale, focusing on severity instead of frequency. In addition to these, five more problems were added to the list based on personal observations and curiosities.

The data collected about problems experienced during and after surgeries were statistically analyzed, and also recorded as percentages. A Wilcoxon Signed Rank test determined significant differences from zero (no pain) for each of the problems at the 0.05 level of significance. The hypotheses were:

H_0 : The median is equal to zero.

H_1 : The median is greater than zero.

The alternative hypothesis tests for a median greater than zero was selected since any significant result will indicate a statistically significant (serious) problem experienced by surgeons for each problem.

This test revealed medians statistically larger than zero (no pain) on all but two complaints. "Headaches" were not found to be a significant problem, and because of missing

data (some surgeons did not answer question), “excessive tachycardia/sweating/tremors” could not be tested. The complete list of results can be found in Figure 2. The percentage of respondents who indicated experiencing either slight or substantial problems in these indicated areas during or after use of the conventional grasper tools is also shown in Figure 2, with significant results ranging from 29% to 60% in problem frequency.

The last question on the questionnaire asked surgeons to identify, on a picture of a hand, where they felt pain during or after laparoscopic surgery. Eleven out of eighteen respondents identified painful areas of the hand. Four surgeons indicated experiencing pain on the ulnar side of the wrist. One surgeon indicated experiencing pain on the radial side of the wrist. One surgeon indicated experiencing pain in the entire hand. Three surgeons indicated experiencing numbness of the thumb. One surgeon indicated experiencing soreness on the backs of the fingers (from opening the handle with the finger rings). Two surgeons indicated experiencing pain on the skin surrounding the proximal phalanx of the thumb (also a result of pressure from the thumb ring) (Doné et al. 2004).

PURPOSE

Using the results from the previous survey of surgeons (questionnaire 1) (Doné et al. 2004) mentioned above, along with the results of several other studies (Berguer 1998; Berguer et al. 1999; Berguer et al. 2001a; Cacha 1999; DiMartino et al. 2004; Doné et al. 2003; Matern et al. 2001), and task analysis of laparoscopic surgery, a prototype articulating laparoscopic tool was developed. A new questionnaire (questionnaire 2) was developed for use in evaluating the new prototype and comparing it to conventional laparoscopic grasping tools. The purpose of this paper is to discuss questionnaire 2 and its results in order to assess surgeon’s opinions of the new prototype design.

QUESTIONNAIRE 2

Questionnaire 2 was adapted from questionnaire 1 with improvements based on user feedback and clarification required by subjects when completing questionnaire 1. Questions were simplified and only those providing the most crucial information were included in questionnaire 2. The first page of the questionnaire repeated the most valuable questions from the first questionnaire. The second page asked the surgeon questions about comparing conventional tools and the prototype tool. Surgeons were also asked for their opinion about which of the problems reported from conventional tools may be resolved with use of the prototype tool. The complete second questionnaire is shown in Appendix B.

Questionnaire 2 repeated two questions asked in questionnaire 1. The first question asked for information about problems experienced during or following laparoscopic surgery where they had employed conventional laparoscopic tools. It was asked with, first, the purpose of guiding the respondents to identify and specify their experiences with laparoscopic grasper tools and second, so as to allow follow up asking which of these problems the laparoscopic surgeons believed may be alleviated with the prototype tool design.

METHODS

Subjects

Thirty-eight laparoscopic surgeons from all over the US who were attending advanced laparoscopic training courses at the University of Nebraska Medical Center were surveyed to compare a conventional grasper (Figure 1a) to the prototype articulating laparoscopic tool (Figure 1b). As shown in Figure 1a, the conventional grasper resembles scissors at a right angle to the shaft of the tool, while the prototype design (Figure 1b) features an ergonomic handle with a trackball-like control and a reverse pivot handle. After consenting to participation, each subject was given time to practice with each of the tools and most used a clear model

plastic torso (UNMC house model) to become accustomed to the tools. After the surgeons became acquainted with the tools, they completed the questionnaire.

Experimental Design

Ordinal data were collected throughout this questionnaire; therefore, a Wilcoxon Signed Rank test was used to analyze each hypothesis test. The level of significance for all statistical tests was 0.05. All of the statistical tests were performed using Minitab 14 (Minitab, Inc.).

The null hypothesis for the first portion of the questionnaire was that the surgeon did not experience the problem listed (median = 0) versus the alternative that the surgeon experienced a slight or substantial problem (median >0) for each queried problem. Each problem listed was analyzed separately.

The second question, that of circling painful areas on the hand drawing and rating each from 1 (slight pain) to 4 (numb) was analyzed using descriptive statistics.

The two direct comparison questions (questions three and four) were analyzed first as separate questions by tool. Data on the conventional tool and data on the prototype tool were each compared to see if each had a median greater than zero (positive opinion of that tool). Then the difference was calculated on these questions [(response to prototype) – (response to conventional) by subject] to test if the prototype was preferred over the conventional tool by comparing it to zero (indifferent) versus greater than zero for the median, demonstrating that the prototype was better than the conventional tool.

The section of the questionnaire in which the surgeons were asked if the tool used would relieve the problems commonly associated with laparoscopic surgery (question seven), was analyzed two ways, graphically and statistically (using Wilcoxon Signed Rank test). The surgeons were asked to evaluate if they believed that the prototype would relieve any of the listed problems, if they checked the box that corresponded to the problem indicating that would be relieved it was counted as a yes (1) otherwise it was a no (0) for analysis. The median

frequency for each problem listed was compared to 0 (no relief of the problem) using a Wilcoxon signed rank test.

The questions asking if the articulation would be helpful (question five), if they would try it if commercially available (question 6) and which they would choose to use (question eight) were depicted with descriptive statistics.

Suggestions and comments from last question will be used to keep improving current prototype design, but not statistically analyzed.

RESULTS

When surgeons were asked to indicate on a picture of a hand where they experience pain during or after laparoscopic surgery, 21 out of 38 surgeons indicated experiencing pain on the hand/fingers/wrist. The painful areas circled and rated on the hand drawing by the surgeons are listed on Table 1. The most frequently identified area was the skin surrounded the proximal phalanx of the thumb. Other areas of hand pain were thumb carpometacarpal basal joint. Most surgeons only circled the painful area and did not rate the magnitude of the pain, therefore it was not reported here.

Surgeons were asked about experiences with specific problems, as they were in questionnaire 1. The percentage of surgeons indicating slight or substantial experience with indicated problems (Questionnaire 2) are graphed in Figure 3. An asterisk indicates a statistically significant response at the 0.05 significance level, meaning that the problem is significantly greater than 0 (no pain).

Surgeons were then asked to indicate which, if any, of the problems they believed would be relieved with use of the prototype tool after using it in the clear plastic torso. The results of this series of questions were also graphed and shown on Figure 4, with asterisks above the problems believed to be statistically significantly relieved by the prototype tool (median > 0).

Questions three and four were asked comparing conventional tools to the prototype.

The first of these inquired about the comfort of the tool handle. There was statistical preference towards the comfort of the prototype handle ($p < 0.001$) against the conventional handles (prototype - conventional), as well as when tested separately. A significant number of the respondents said the prototype was either comfortable or extremely comfortable; however, the median response for the conventional tool did not differ from zero (indifferent) ($p = 0.151$) as shown in Figure 5. The second comparison question asked surgeons about their general impression of the tool handles (conventional and prototype). A significant number of surgeons ($p < 0.001$) preferred the prototype tool over conventional tools, based on the general impression. Again, the prototype had a median significantly higher than zero ($p < 0.001$), while the median for the conventional tool did not differ from zero (indifferent) ($p = 0.061$) as shown in Figure 6.

Twelve of the 38 respondents had suggestions for further changes to the prototype tool. Two suggestions referred to reducing the diameter of the shaft from 10 to 5mm which had been planned. Three suggestions referred to the shape/size of the handle, two said to make it smaller, the third to make it larger. Four referred to redesigning the control sphere by 1) adding surface roughness, 2) having a larger ball, 3) making the actuation of the ball like the PlayStation 2 game controller and 4) moving the ball forward (same surgeon who suggested a larger handle size). There were four responses suggesting we add more grasper tip types and cautery. One person wanted the prototype to be of different material and metal alloy; however, the current prototype was formed using stereolithography (DSM Somos® 14120, a low viscosity liquid photopolymer that produces a strong, tough, water-resistant part) and stainless steel. All wanted a prototype that could be tried in vivo.

Thirty-five (92%) of the 38 respondents indicated that the added articulation of the prototype tool would be either somewhat or very useful, three respondents were indifferent.

Thirty-four (89%) of the 38 surgeons said they would be interested in trying the prototype tool

once commercially available and 19 of the 38 surgeons said they would use the prototype tool over the conventional grasping tool.

DISCUSSION

The results of this questionnaire (2) agreed with those of previous studies (Berguer 1998; Berguer et al. 1999; Berguer et al. 2001b, Doné et al. 2004). Laparoscopic surgeons are subjected to pain and discomfort, caused by the tools they use, while performing their jobs. Each of the queried potential problem areas asked about had over a 30% positive response from surgeons, with most over 50%, all significantly greater than zero (no problem). In addition, this study showed an even larger percentage of surgeons with pain or numbness (29%) in the hand as compared to Berguer et al. (1999), who found 8-12%. The prevalence of discomfort/pain is alarming during the use of laparoscopic surgical tools demonstrating a need for ergonomic intervention. The intervention selected was tool redesign.

The statistical results show that surgeons see benefits in improvements from an articulating ergonomic grasper tool prototype. Most surgeons responded that they believe the new design will relieve problems experienced during surgery, the areas targeted prior to design, hand/wrist pain and stiffness, numbness of fingers and/or thumb and awkward manipulation were statistically significant. The perceived reduction of reported discomfort/pain or stiffness in the hand and wrist (believed to reduced by over 50% as shown in Figure 4), finger and thumb numbness (29% in Figure 3) and awkward instrument utilization (50% in Figure 3) is believed to be reduced by 21%, based on the responses shown in Figure 4, by employing the prototype. This demonstrates that the surgeons believed that the ergonomically designed prototype would significantly alleviate problems surgeons currently encounter while using laparoscopic tools. These problems were among the main reasons for the redesign of the tool – to reduce discomfort and allow highly trained surgeons to perform their work tasks easier.

Another reason for the redesign is the addition of the articulation, similar to adding a wrist to the hand/fingers and arm. The subjective assessment of the ergonomically designed articulating grasper shows that the tip articulation is believed to be useful by 92% of the respondents, demonstrating that the redesign effort was successful.

When asked about the comfort of the conventional vs. prototype tool handles, there was significant preference for the prototype tool. Surgeons answered this question immediately after identifying all of the problems they experienced during and after surgery. These results indicate that surgeons are mainly indifferent to the current tool design since they are accustomed to it, but are able to identify numerous side-effects of their use. The responses also indicate that the surgeons believe the prototype tool will be better than current tools, both in terms of alleviating pain, stiffness and in terms comfort. In addition, their impression of the tool was significantly better for the prototype tool.

There are significant resources, both time and money, expended in training a good surgeon and more before they become an expert at laparoscopy. The prevalence of problems created by the current tools is startling and indicates that something must be done to protect the surgeon. Since laparoscopic surgery is a relatively new and rapidly growing field, it is critical that the tools used to perform the surgery be exemplary. The goal of this project was to define the problems that laparoscopic surgeons face, design a tool with an articulation that would also alleviate the identified problems and then evaluate the outcome. The subjective evaluation of the prototype tool demonstrates that good ergonomic analysis and design can improve a standard laparoscopic tool. It further demonstrates that given a choice between current tools and ergonomically designed tools, laparoscopic surgeons will select the more comfortable, more useful tool.

Caveat: The comparison testing performed in this study was done on prototype vs. commercial product and training in a clear torso vs. training in vivo.

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Figure 1:



Figure 1a: An example of a conventional laparoscopic grasper tool



Figure 1b: The ergonomic articulating laparoscopic grasper tool prototype

Figure 2: Percent of surgeons experiencing slight or substantial problems and statistical analysis (Questionnaire 1). Asterisk indicates a statistically significant response at the 0.05 significance level.

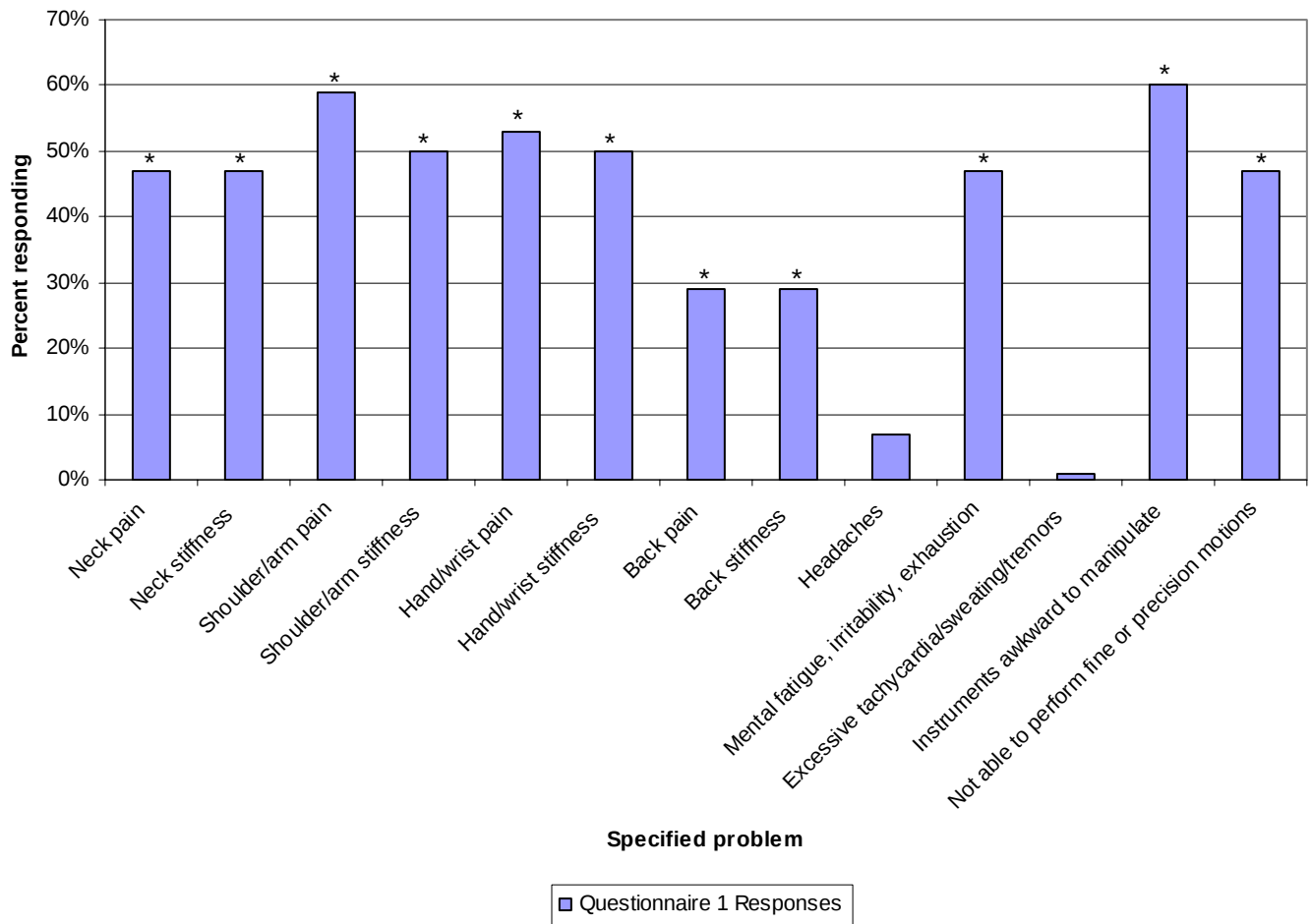


Figure 3. Percent of surgeons experiencing slight or substantial problems and statistical analysis (Questionnaire 2). Asterisk indicates a statistically significant response at the 0.05 significance level.

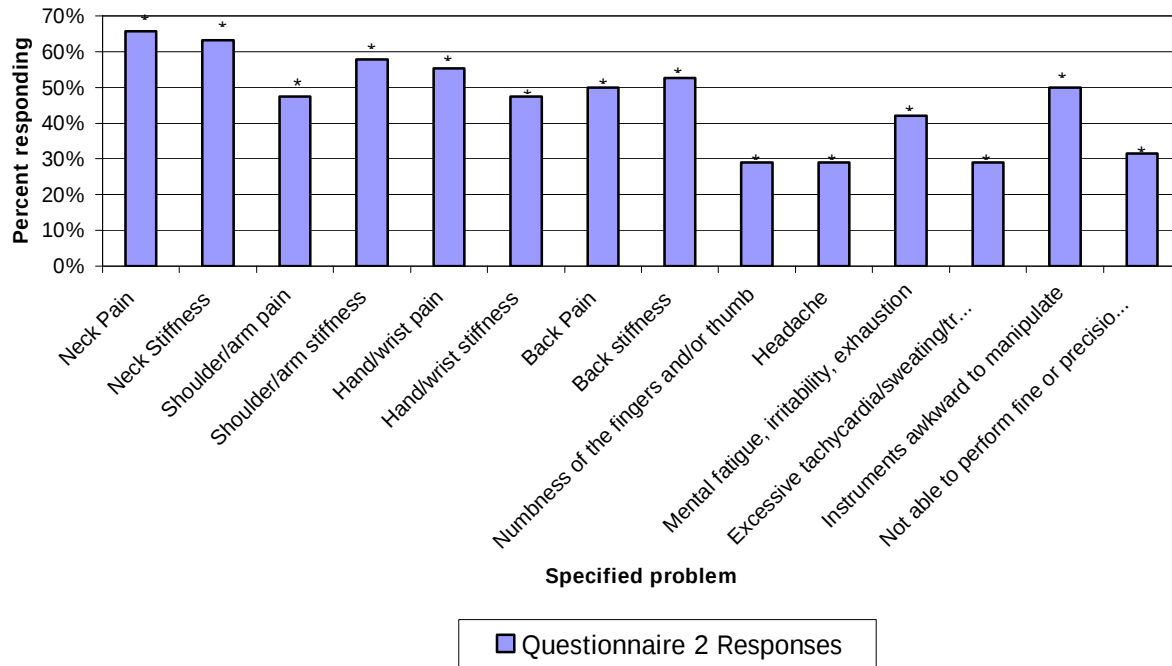


Figure 4: Percentage of surgeons indicating that they believe the prototype would relieve indicated problems (Questionnaire 2). Asterisk indicates a statistically significant response at the 0.05 significance level.

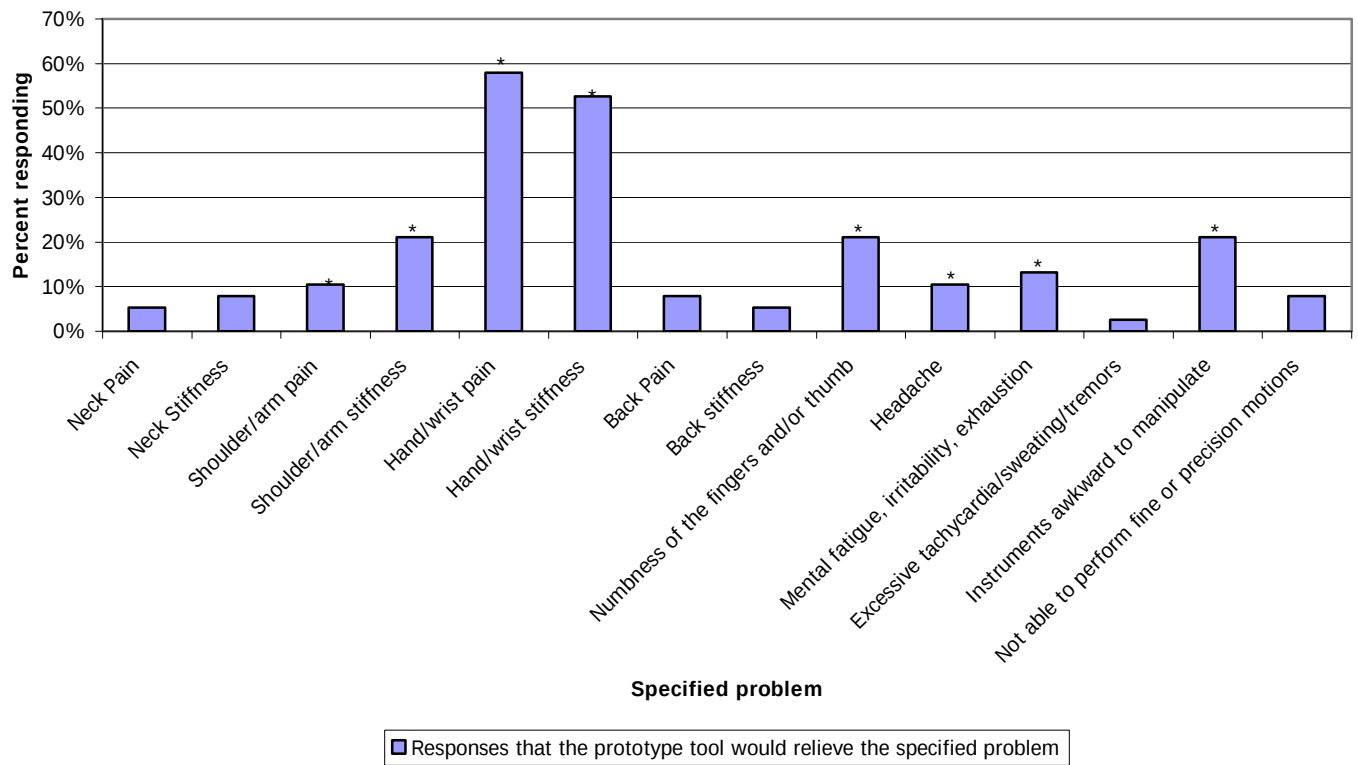


Figure 5: Percent of surgeons indicating how comfortable prototype and conventional tool handle are. (Questionnaire 2)

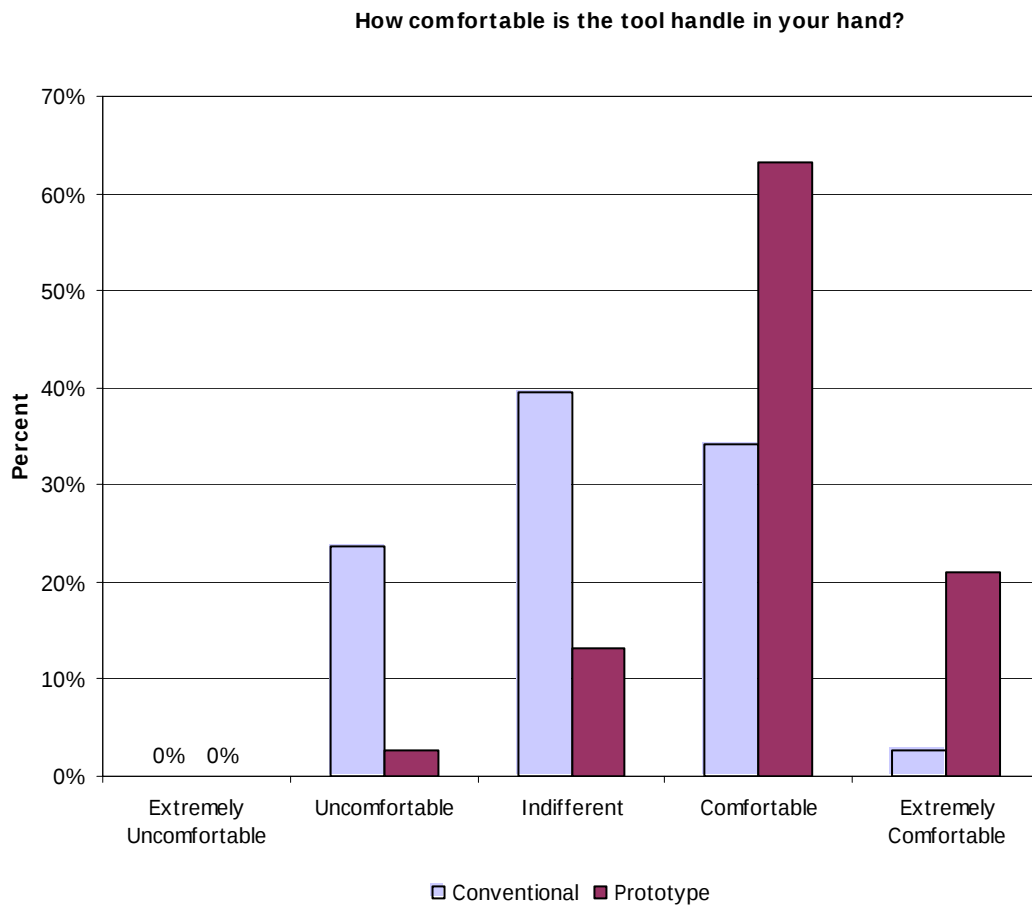


Figure 6: Percent of surgeons indicating general impression of conventional and prototype tool handle. (Questionnaire 2)

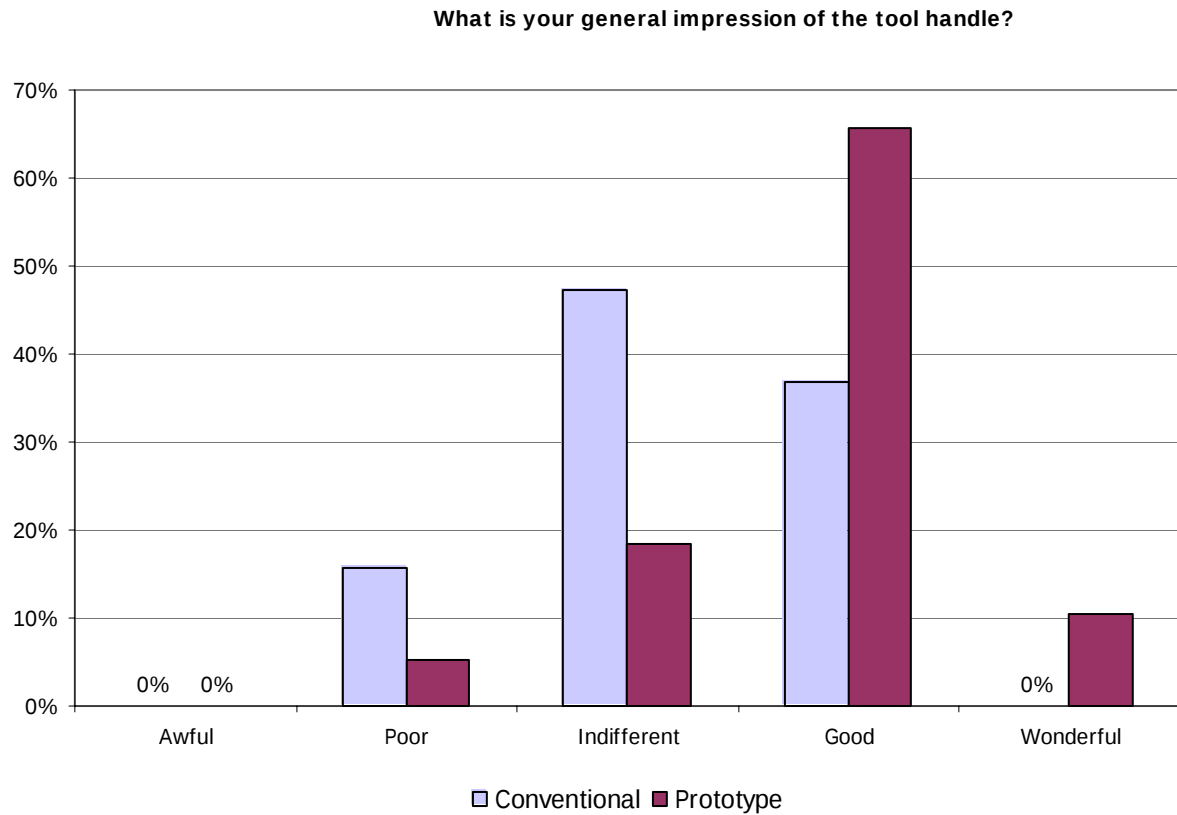


Table 1: Pain experienced on hand/fingers/wrist, frequency. (Questionnaire 2)

# OF SURGEONS	AREA OF PAIN
1	Wrist
1	Numbness of the thumb (digit 1)
3	Palm
3	Skin surrounding the digit 5 metacarpal
8	Skin surrounding the proximal phalanx of the thumb
1	Skin surrounding the distal phalanx of the thumb
2	Skin surrounding the digit 2 distal phalanx
2	Skin surrounding the digit 2 middle phalanx
1	Thumb metacarpophalangeal joint
3	Thumb interphalangeal joint
4	Thumb carpometacarpal basal joint

APPENDIX A Questionnaire 1 (analyzed prior to prototype design)

Grasping tool used _____

Hand used to control tool _____

Is this your dominate hand? ☐ YES ☐ NO

The following questions are adapted from (Van Veelen et al. 2001a), (Matern et al. 1999) and (Berguer 1998). The rating scales have been modified.

1. Regarding the force required to open and close the graspers, what is the experience of comfort/discomfort during use?

0	1	2	3	4
uncomfortable			comfortable	

2. Regarding the rotation function of the instrument tip, what is the experience of comfort/discomfort during use?

0	1	2	3	4
uncomfortable			comfortable	

3. To what extent do the dimensions of the handles agree with your hand dimensions?

0	1	2	3	4
uncomfortable			comfortable	

4. How comfortable is the handle in your hand?

0	1	2	3	4
uncomfortable			comfortable	

5. How precisely can you work with the handle?

0	1	2	3	4
not precisely			very precisely	

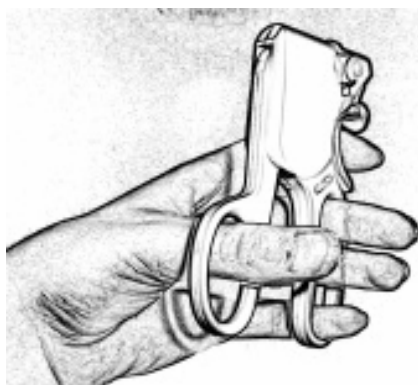
6. What is your general impression of the handle?

0	1	2	3	4
not preferable			preferable	

7. Do you normally experience any of the following problems during or following laparoscopic surgery?

Area/Subject	NO	SLIGHT	SUBSTANTIAL
Neck pain			
Neck stiffness			
Shoulder/arm pain			
Shoulder/arm stiffness			
Hand/wrist pain			
Hand/wrist stiffness			
Back pain			
Back stiffness			
Headache			
Mental fatigue, irritability, exhaustion			
Excessive tachycardia/sweating/tremors			
Instruments awkward to manipulate			
Not able to perform fine or precision motions			

8. Please identify on Drawing 2 where on your hand you feel pain during/after laparoscopic surgery.



Drawing 1



Drawing 2

APPENDIX B Questionnaire 2 Subjective evaluation of the current and prototype tools

Grasping tool used _____

Hand used to control tool ↑ RIGHT ↑ LEFT
Is this your dominant hand? ↑ YES ↑ NO

How many years have you been performing laparoscopic surgery? _____

1. Do you normally experience any of the following problems during or following laparoscopic surgery? (If so, mark slight or substantial)

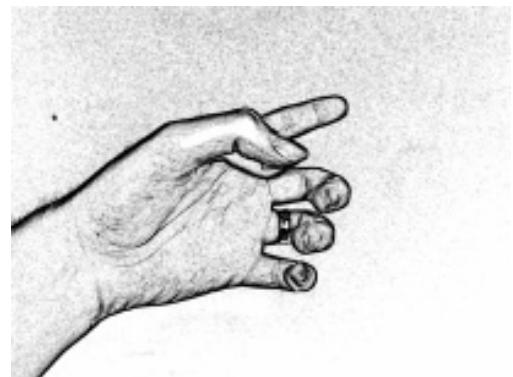
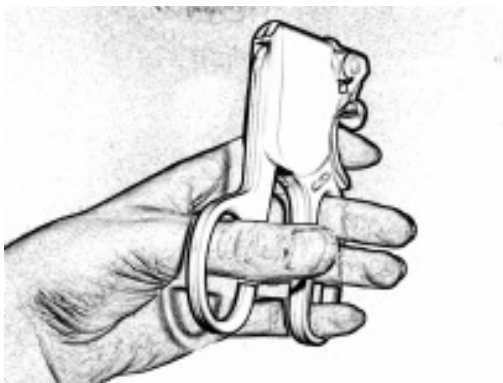
AREA/SUBJECT	SLIGHT	SUBSTANTIAL
Neck pain		
Neck stiffness		
Shoulder/arm pain		
Shoulder/arm stiffness		
Hand/wrist pain		
Hand/wrist stiffness		
Back pain		
Back stiffness		
Numbness of the fingers and/or thumb		
Headache		
Mental fatigue, irritability, exhaustion		
Excessive tachycardia/sweating/tremors		
Instruments awkward to manipulate		
Not able to perform fine or precision motions		

2. Please circle areas of the hand on Drawing 2 where you feel pain during/after laparoscopic surgery and rate the pain 1-3.

1=slight 2=moderate

3=severe

4=numb



Drawing 1

Drawing 2

Please experiment with the prototype tool before answering the following questions.

3. How comfortable is the tool handle in your hand?

Conventional grasping tool	Prototype tool
☐ Extremely uncomfortable	☐ Extremely uncomfortable
☐ Uncomfortable	☐ Uncomfortable
☐ Indifferent	☐ Indifferent
☐ Comfortable	☐ Comfortable
☐ Extremely comfortable	☐ Extremely comfortable

4. What is your general impression of the tool handle?

Conventional grasping tool	Prototype tool
☐ Awful	☐ Awful
☐ Poor	☐ Poor
☐ Indifferent	☐ Indifferent
☐ Good	☐ Good
☐ Wonderful	☐ Wonderful

5. What do you think of the added articulation on the prototype tool?

- ☐ Great – very helpful
☐ Good – somewhat helpful
☐ Indifferent
☐ Not helpful

6. Would you be interested in trying this prototype tool once commercially available?

- ☐ Yes
☐ No
☐ Maybe

7. Do you think the prototype tool would relieve any of the problems you experience with conventional grasping tools? (Please check the areas you believe will be improved with the new design)

☐ Neck pain ☐ Neck stiffness ☐ Shoulder/arm pain ☐ Shoulder/arm stiffness ☐ Hand/wrist pain ☐ Hand/wrist stiffness ☐ Back pain ☐ Back stiffness ☐ Finger and/or thumb numbness ☐ Headache ☐ Mental fatigue, irritability, exhaustion ☐ Excessive tachycardia/sweating/tremors ☐ Instruments awkward to manipulate ☐ Not able to perform fine or precision motions
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8. Given the choice, which tool would you use?

☐ Conventional grasping tool	
☐ Prototype tool	

9. Are there any additional changes you think need to be made to the prototype tool?

- ☐ Yes
☐ No

If yes, what? _____