User Research Improves Laparoscopic Instruments

BY BETH LORING & ERIN-ANNE LEMIEUX

Improved ergonomics, comfort, and usability for surgeons result from the work of teams representing a broad range of user-centered product design expertise.

LAPAROSCOPIC SURGERY, A TYPE OF MINIMALLY invasive surgery, is a technique in which operations in the abdomen are performed through small incisions rather than the larger incisions that are needed in traditional surgical procedures. The laparoscopic approach minimizes postoperative pain, speeds recovery times, and has become the preferred method for many abdominal surgeries.

Unfortunately, the long-handled instruments surgeons use in laparoscopic procedures often leave much to be desired in terms of ergonomics, comfort, and usability. This case study describes the user-centered redesign of a laparoscopic instrument handle for Cardinal Health (www.cardinalhealth.com). A multidisciplinary team of industrial designers, engineers, and researchers developed a new handle that addresses the ergonomic shortcomings and enables surgeons to perform procedures with greater comfort and efficiency. The product has been so successful in the marketplace that Cardinal Health projects an 80% increase in sales over the life of the product.

User-Centered Design Process

Common laparoscopic instruments include dissectors, graspers, clamps, and scissors (among others) in a variety of handle, shaft, and jaw configurations. However, most include two-ring scissor-type handles set at an angle to the long shaft of the instrument and incorporate additional controls, such as rotation knobs and ratchets, for fine manipulation of the end effectors within the patient's abdomen.

Cardinal Health had purchased the Snowden Pencer line of laparoscopic instruments, which included two similar handle designs (see Figure 1). Although these handles were popular with surgeons, Cardinal Health wanted to develop a next-generation product that would stand out in the marketplace and better meet users' needs. As part of this initiative, they chose Farm, a medical product development firm (www.farmpd.com), to help redesign the product, which became the Cardinal Diamond Line™ laparoscopic handle, shown in Figure 2.

The design team followed a user-centered design process that involved surgeons throughout the development effort, as required by international and U.S. standards for the design of medical devices (American National Standards Institute, 2001; International Electrotechnical Commission, 2007; U.S. Food and Drug Administration, 2007). Our research and evaluation activities included the following:

- Surgical observations
- Interviews with surgeons, including rating and ranking exercises
- Data analysis leading to specific design requirements
- Development of a range of design concepts
- Iterative user testing and refinement
- Selection and refinement of the final design

This project involved a multidisciplinary team of five Farm employees as well as a group of sales, marketing, and engineering staff from Cardinal Health. The formative research activities (Steps 1 through 3) took about 5 months, and the remaining activities took an additional 12 months.

Figure 1. Original Snowden Pencer handles.

Figure 2. Redesigned Diamond Line handle.

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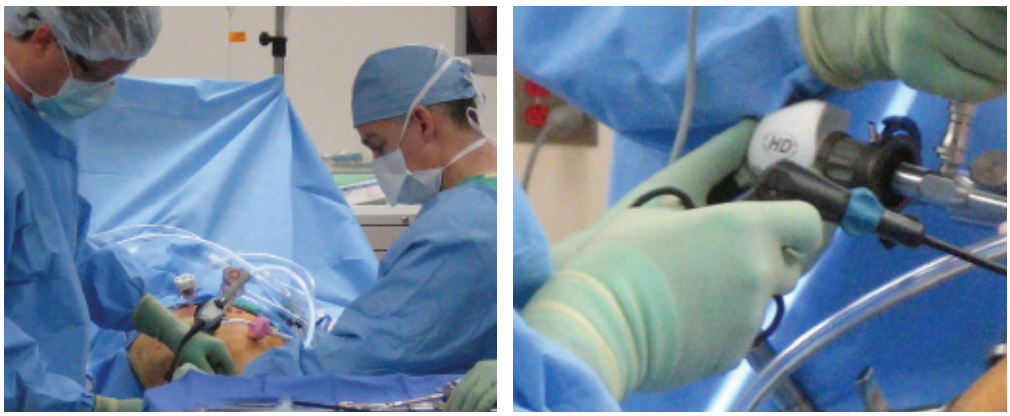

Figure 3. Documentation of grip style and variation.

Surgical Observations

The research team conducted 24 field observations and interviews with surgeons at 14 hospitals around the United States. These surgeons – whose specialties included general surgery, laparoscopic surgery, gynecology, and bariatrics – were recruited by Cardinal Health. The surgeons varied in their level of experience, from residents to fellows, and practiced at different types of facilities (surgical centers, small community hospitals, and large teaching hospitals). Four female and 20 male surgeons participated.

Before going into the field, we conducted phone interviews with each of the surgeons to gain a better understanding of laparoscopic procedures and the handle design attributes that were considered most important. The phone interviews also prompted the surgeons to think about the instrument handles ahead of our visits, something few had done because their focus is primarily on the patient and the function of the end effectors inside the body.

At the hospitals, we observed surgeons performing laparoscopic procedures in the operating room (OR). We then interviewed them outside the OR, typically in their offices. We observed a variety of procedures, including hernia repair, gastric bypass, splenectomy, and fundoplication. Each site visit took about a half day.

While in the OR, the team took notes, photos, and video and, in some cases, queried the surgeons as they worked. For the most part, surgeons readily gave permission for this data capture, although one did decline to be photographed or videotaped. On some occasions, the surgical support staff expressed concerns about patient confidentiality, until we assured them that we would not capture any patient-identifying images or video. We explained that we would focus primarily on the surgeon's stance, hand positions, and manipulation of instruments.

In addition, we gathered data on the following:

- Workflow within the sterile field
- Function-specific activities (lead surgeon versus assistant or scrub nurse)
- Peripheral instrument relationships
- Grip style and variation (see Figure 3)
- Actuation of the rotation knob and ratchet

We observed that many surgeons, particularly shorter ones, had to hold their arms up at awkward angles for extended periods, causing neck and shoulder pain as well as fatigue. We also learned that many of the instrument handles caused pressure points resulting in hand numbness and pain. In the extreme, these problems even prevented surgeons from practicing medicine.

Interviews and Ranking Exercises

Following the OR observations, we interviewed the surgeons. First, we conducted an exercise in which they ranked the importance of seven design attributes identified in the phone interviews as being important (comfort, grip, safety, actuation, ratchet, rotation knob, and weight and balance) by sorting note cards in order from highest to lowest importance. We then asked them to rate the Snowden Pencer handles on a scale of 1 (poor) to 6 (excellent) for each attribute while we recorded their responses and comments.

Next, we opened a case containing eight competing instruments and conducted a Pugh decision matrix analysis, in which the surgeons rated each instrument by indicating whether they thought it was "better than" (+1), "the same as" (0), or "worse than" (-1) the Snowden Pencer instrument on each attribute.

Finally, we asked the surgeons to demonstrate the positive and negative aspects of the Snowden Pencer and competing instruments while we videotaped them and took photos (see Figure 4).

FEATURE AT A GLANCE: This case study describes the user-centered redesign of a laparoscopic instrument handle for Cardinal Health. A multidisciplinary team designed a new handle that addressed multiple ergonomic shortcomings and enabled surgeons to perform procedures with greater comfort, safety, and efficiency. Improvements included a flexible grip to allow palming or use of finger rings; broad, contoured surfaces that provided comfort and avoided pressure points; a larger rotation knob with ribs to aid grip, especially with wet gloves; and a tapered shape to accommodate a wide range of finger lengths and grip styles.

KEYWORDS: ergonomics, medical device, surgical instrument, user research, industrial design, user testing

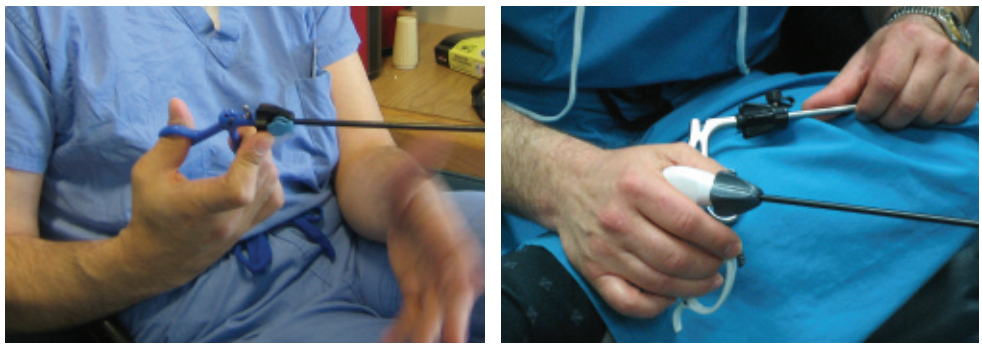

Figure 4. Surgeons demonstrate likes and dislikes with various instruments.

Data Analysis

When the field research was complete, the team analyzed the written notes, videos, photos, and data from the rating and ranking exercises. Analysis of the video recordings revealed a wide variety of grip styles; some surgeons used both rings and some used one ring while "palming" the device. Surgeons with smaller hands — particularly women — had difficulty because the rings were too large. This is consistent with publications reporting that most surgical devices are designed for males (Wiklund, Rudnick, & Liberatore, 2006).

Analysis of the rating and ranking data uncovered an interesting mismatch: Although surgeons rated the attributes of comfort, grip, and actuation as most important, the Snowden Pencer device rated relatively low on those attributes and higher on the less important attributes (see Figure 5). This indicated that the team should focus most on improving comfort, grip, and actuation.

The results of the Pugh analysis were used to identify the strengths and weaknesses of the competing devices, as shown in Figure 6. The negative numbers indicate where competing devices were considered inferior to Snowden Pencer, and the positive numbers indicate where they were considered superior to Snowden Pencer. For example, instrument E's rotation knob was preferred among surgeons.

Design Requirements

The data analysis resulted in a list of key design requirements for the redesign of the instrument handle:

- *Comfort:* Select the most ergonomic wrist angle through user testing. Enlarge the rings and contour them to fit various hand sizes. Distribute the pressure by providing broader contact surfaces and incorporating softer materials. Provide removable rubber inserts for surgeons with small hands.
- *Grip:* Accommodate a range of grip styles, allowing surgeons to reposition their thumb and fingers as needed. Provide ribs or texture for thumb actuation while palming the instrument. Provide a "pinky rest."
- *Actuation:* Ensure that actuation is easy and intuitive. Maintain the perception of quality of the Snowden Pencer brand by creating a robust and smooth actuation mechanism.
- *Ratchet:* Relocate the release button. Improve the robustness of the teeth. Add a defeat feature for times when ratcheting is not needed. Reduce the force required to engage and release.

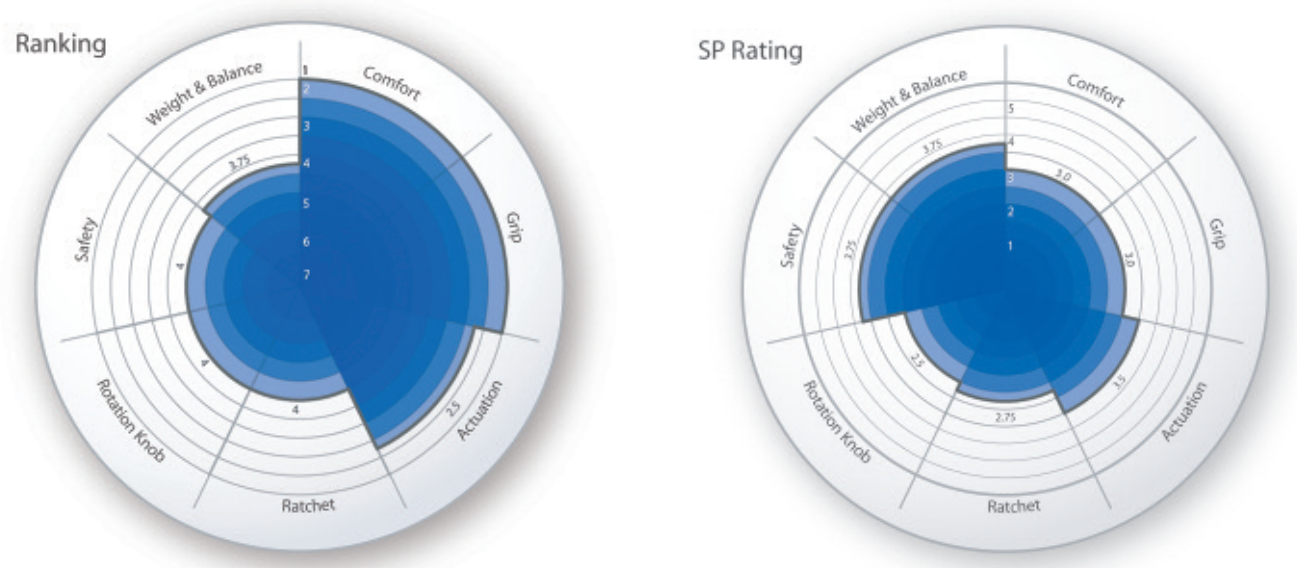

Figure 5. Results of the ranking and rating exercises.

Attributes	Competitive Instruments A	B	C	D	E	F	G	H
Comfort	2	1	5	-3	7	6	-12	-6
Grip	-4	-8	4	-8	0	0	-8	-5
Actuation	-1	0	0	-4	1	-5	-8	4
Ratchet	-1	-2	-3	n/a	n/a	-5	-10	1
Rotation Knob	-11	3	1	9	10	2	-2	7
Safety	-2	-5	0	-4	0	2	-6	-2
Weight & Balance	-3	-3	0	0	2	2	-10	-1

Figure 6. Results of the Pugh analysis.

- *Rotation knob:* Increase the size to make it easier to turn. Provide longer finger channels that can be felt through surgical gloves. Position the knob so that surgeons with smaller hands can reach it. Provide softer, easier detents when turning.
- *Safety:* Eliminate any pinch points. Avoid exposed metal.
- *Weight and balance:* Maintain a perception of quality through careful selection of weight and materials. Ensure that the handle is balanced in the hand. Minimize bulk.
- *Brand attributes:* Maintain the recognizable Snowden Pencer blue handle color.

Concept Development, Iterative User Testing, and Refinement

The multidisciplinary team brainstormed design solutions and created a wide range of sketches. The most promising sketches were then refined, and the industrial designers created 3-D models that explored variations on features such as angles, ring positions, and grip surfaces (see Figures 7 and 8).

After conducting an internal evaluation of six hand-carved models, we narrowed the concepts and created three refined hand-carved and painted models, presenting various options for addressing the ergonomic, comfort, and usability aspects of the handle.

Next, the team returned to the field, where we tested the three models with a subset of surgeons who had participated in the field research. We gathered feedback in a series of one-on-one interviews, during which we had users hold and manipulate each of the models. We also asked users to rate each of the models on five adjusted design attributes (comfort, grip, actuation, rotation knob, and bulk and size). We were not able to evaluate safety or weight and balance because these models were constructed of foam. Instead, we replaced weight and balance factors with bulk and size, which users could evaluate using the foam models. These models did not yet have ratchet mechanisms, so that attribute was not evaluated. The three models and their resulting ratings are shown in Figure 9.

REVEAL Project Studies Technologies to Support Laparoscopic Surgery

A multidisciplinary team of researchers at the University of Kentucky's Center for Visualization and Virtual Environments (www.vis.uky.edu) and the University of Maryland Medical Center's Department of General Surgery have been working together since 2004 to promote the development of new visualization technologies to support surgical performance during laparoscopic surgery. The REVEAL (Reconstruction, Enhancement, Visualization, and Ergonomic Assessment for Laparoscopy) project evolved from an initial collaboration of general surgeons and computer scientists to include specialists in both physical and cognitive ergonomics, as it became apparent that the design and arrangement of displays could have a significant impact on the mental workload and physical stresses experienced by surgeons. Gyusung Lee, Jacob Seagull, Cindy Lio, Martina Klein, and Melody Carswell are among the HF/E professionals who have been involved in the project.

As a part of its Center for Visualization series, the Research Channel produced and aired a program on the REVEAL project. View the 28-minute video at www.researchchannel.org/prog/displayevent.aspx?rID=16793&fID=345.

— *Melody Carswell, Past* EID *Editor*

Figure 7. Design option showing the traditional grip style with contoured rings and pinky rest.

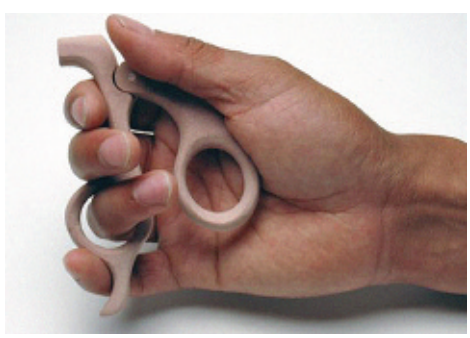

Figure 8. The same design option showing accommodation of the palming grip style with a smooth, broad surface that fits in the palm comfortably.

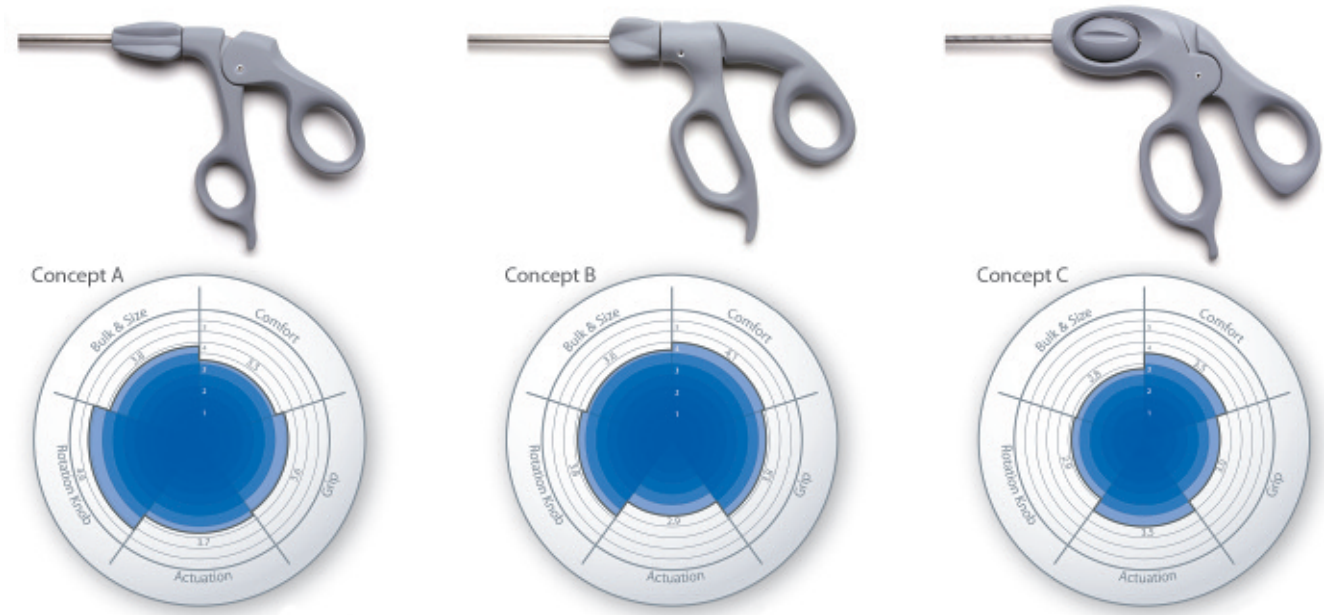

Figure 9. The three models tested with users, with their attribute ratings.

To determine the preferred angle for the handle, we built a test device that allowed surgeons to "dial in" the angle they preferred (see Figure 10). They then tried using the models in a trainer, a box in which they could simulate the movement of the instruments within the patient's abdomen.

Overall, Concept A was preferred, but with the addition of a double finger ring. Using this feedback, we refined the chosen concept and conducted three additional iterations of modeling and testing with surgeons over nearly six months. We improved the placement and size of the finger and thumb rings, the location of the pinky rest, and the size, angle, and placement of the thumb rest.

The resulting works-like and looks-like model was well received, except for the ratchet mechanism (see Figures 11 and 12). This prompted us to design and test additional options for the ratchet.

The Final Design

Following the iterative design process, we selected a final design, and the team moved into mechanical engineering and design for manufacturing. The final laparoscopic handle had key features that met the design requirements, as shown in Figure 13, including these:

- Flexible grip to allow palming or use of finger rings
- Broad, contoured surfaces that provided comfort and avoided pressure points whether palming or using the rings
- A new ratchet that was easier to set and release, offered auditory feedback, and included a quick lock/release button so surgeons could lock the end effector if needed and then easily unlock (defeat) it to use without the ratchet feature
- A larger rotation knob with ribs to aid grip, especially with wet gloves, and a long, tapered shape to accommodate a wide range of finger lengths and grip styles
- A removable rubber ring insert to accommodate surgeons with small hands.

The improved ergonomics of the Cardinal Diamond Line™ handle allow surgeons to perform minimally invasive procedures more comfortably, safely, and efficiently. In addition, the product's outstanding success in the marketplace proves that doctors value these features.

Figure 10. Mockup for selecting preferred angle.

Figure 11. Works-like and looks-like model.

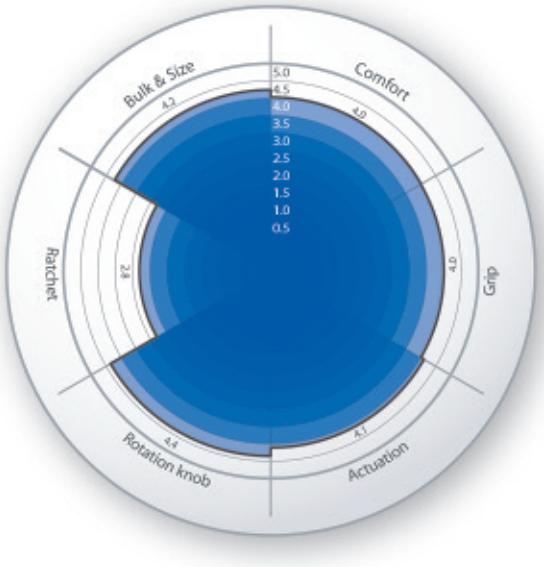

Figure 12. Attribute ratings for the model.

This case study illustrates the importance of following a user-centered development process, as required by national and international regulations, when designing medical instrumentation. We were fortunate that Cardinal Health strongly supported this process and provided access to surgeons at numerous points during the design effort. Although some manufacturers still don't understand the value of human factors and user research, forward-thinking companies are moving beyond the letter of the law, following good design processes and reaping financial rewards.

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Figure 13. Final design with features explained.