Jeff
Kapec
Contributing
Writer

FEATURE

Scrubbing in for Good Design

Operating room observations are key to innovative design of implants and devices.

In designing medical products for orthopedic surgery, the most direct path from concept to finished product runs directly through the operating room. In fact, it runs through many operating rooms because designers can't get the deep insights into the physical and interactive forces that impact how a device will be used with just one observation. That's because every surgeon, scrub nurse, and operating room layout creates a unique environment with differing physical parameters and interpersonal dynamics.

The author in the clinical setting. Designers need to understand individual orthopedic operating room environments because each has its own physical parameters and interpersonal dynamics. Photo courtesy of Tanaka Kapec Design Group.

In creating a new medical device, designers need to understand the complex set of forces that exist in a wide range of operating room environments. And to do this, there is no substitute for firsthand observation in the setting where a device or implant will be used. If they delegate the observation to an engineer or marketer, the designer won't see the dynamic interactions, patterns, and surgeon preferences that contribute to a successful design. This is due, in part, to the notable difference between the perspective of a designer and an engineer.

Designers are taught to think abstractly about form, in three dimensions, differently than engineers. The designer will have undergone many years of visual training that provide a unique skill set to observe and then to use that critical vision in the creative process. While the person responsible for marketing will often have a great depth of knowledge of the procedure and surgeons who perform it, he or she, too, will have a different skill set.

What's So Special About Orthopedic Surgery?

Clinical observation by designers is critical for creating orthopedic devices and implants because of the nature of the orthopedic surgical process. Orthopedic surgery is unique for the following reasons:

- **It's a mechanical process.** Orthopedic surgery goes beyond the soft tissue into the patient's skeletal structure, leading to procedures that are mechanical in nature. This explains why many orthopedic surgeons studied engineering before they entered medical school.
- **It's equipment intensive.** The presence of numerous drills, shaping instruments, impacters, mallets and other unique pieces of equipment in orthopedic surgery creates the need for many sterilization trays. This complex physical setup must be taken into consideration by the designer.
- **The context matters.** The

mechanical nature of the process and the complexity of the physical setup mean that any new device or implant must easily integrate into a complex context. In other words, there are a lot of moving parts in orthopedic surgery that make the addition or replacement of a device more of a challenge than in surgeries that work principally on soft tissue.

What Designers Should Look for in the OR

At Tanaka Kapec, we have been designing devices and implants for orthopedic companies and surgeons for more than 30 years. In the more than 300 surgeries we have observed, it has become apparent that investing extra time early in the design process to observe numerous surgeries is the best way to create breakthrough products.

In the operating room, the designer must observe and interpret the pressures being put on the surgeon, the way a device will be used and the level of support he or she will receive during a case.

In the design of hip implant instrumentation, we observed a number of surgeries, two of which were studies in contrast. In one surgical center, the surgeon had extraordinary talent and was working with a hand-picked, highly experienced staff. The surgery flowed like a 90-minute choreographed dance with the scrub nurse handing the surgeon the next instrument before being asked. A few weeks later, we observed a similar hip replacement procedure at a different hospital that is well-known, but not focused, on that procedure. This surgery, which took three hours, was anything but a choreographed dance. Instead, it was characterized by a slow, plodding, labored process, from start to finish.

Both teams used the same instruments and implants, and in both cases the patients did not present unusual anatomical problems. This example illustrates the need for designers to understand a wide range of styles and techniques and create universal products that meet the need of every surgeon. Without firsthand observation of these two surgeons and numerous others, it would have been less likely the final product would have served the needs of two such drastically different techniques. Before a designer dons scrubs, he or she should establish an observation strategy and checklist of questions.

• **Surgeon's style of operation.** Because the surgeon's style of operation is critical, it's important for an industrial designer to develop a series of questions to guide the observation. Does he or she work fast or slowly? Is the surgeon pattern-based or interactive at each turning point? How is his or her sense of spatial relationships? Does he or she respond actively to subtle tactile and audible sensory input? (For example, does the surgeon listen intently when they hit and tap a part of the body?) Is he or she inventive, capable of conceiving of design-like ideas for reconstruction on the spot?

• **The operating room culture.** Given that the scrub nurse is the principal transition point between the sterile field and the rest of the room, his or her personal style also has a significant bearing on how a new piece of equipment will integrate into an operating room. Is he or she autocratic or collaborative? Does he or she stick steadfastly to established procedures or adopt a more flexible approach based on the situation?

It's important to know whether the operating room support team is dedicated to a surgeon or compiled on a case-by-case basis. Do support personnel respond as a highly coordinated team to the challenges that arise, or do they act as a journeyman and think only about their specific responsibility? Is everyone uptight and serious, or is there levity when it's appropriate? Another subtle insight into the surgeon and the team as they work together is whether or not music is played and which type of music it is.

• **The culture of the hospital.** How a hospital operates affects how the orthopedic surgery operates. Is the operating room running at capacity from morning to late afternoon? If so, there will be lots of stress on the support team charged with transitioning the room from one operation to the next, and this has a bearing on what will constitute good design.

• **Physical space in the operating room.** Is the room cramped or spacious? When it's cramped, equipment will be stacked. The space available will, in part, determine the flow of the operation. How are the sterile fields and backup tables organized? Is the room well equipped?

• **The type of surgery.** Will the device be used in an emergency trauma situation, a regularly scheduled procedure or both? Orthopedic surgical devices must be designed to accommodate dynamic environments and surgical processes. In one surgery we observed at Brigham and Women's Hospital in Boston, Mass., the orthopedic surgeon and a team were quickly assembled to treat a car accident victim whose existing implant shattered her femur during the impact. In this situation, we were able to observe the significant impact of factors that might at first seem innocuous, such as how the sterilization trays are organized or how the instrument is placed on the sterile field.

What Do You Do With All That Data?

With so many variables, we have found that on many projects it is necessary to observe as many as 10 surgeries with different surgeons, in different facilities. Once this data is collected, the designer's focus turns to a series of more analytical and creative steps.

• **Organize the data.** Design-related data collected in the clinical observation phase is organized into the following categories:

• **Functional targets.** What are the primary and secondary functions that must be addressed? What are the key dependent relationships between the primary functional requirements? What are the invisible functional targets that have more to do with context of behaviors, sensory feedback and the operating room environment? What are the subordinate functional targets that come into play before or after the device is engaged in the sterile field?

• **Space limitations for the device.** Based on the OR observation, the designer must understand the range of space limitations that will be imposed on the device before and after its use in the procedure.

• **Anatomic characteristics of the patient.** Every patient has a different build and set of proportional relationships that must be addressed by the surgeon, so the implant and the corresponding instruments must be designed with this variability in mind.

• **Surgical styles.** What are the ranges of surgical styles that must be accommodated? Most orthopedic devices can't be custom built, so they must take into account the anatomic characteristics of many patients and the varied working styles of the surgeons who will use the device. A surgeon may behave differently with a device when he or she knows a designer is observing. As with most people, when someone else is watching, the surgeon will tend to be more formal in his behavior. It's like a golfer who is careful to swing the club properly when the pro is watching, but who reverts to his bad habits when he's on his own.

• **Visibility requirements.** What are the visibility requirements? Will the device potentially obstruct a surgeon's visibility? Will it be used in minimally invasive procedures and, if so, how will that impact the design?

• **Weight and balance.** How important is the weight and balance of the device? What is the impact of balance on handling and precision?

• **Sales rep interpretation.** A good sales rep will also have his or her observations/opinions about how various surgeons work with the implants and procedures, and a good designer will take these into consideration.

• **Analyze the data.** A key task of the orthopedic device designer is to put the abstract relationships of force, size, overall function and other characteristics into perspective, and use the information to create a device that complements the surgical technique. This process includes analyzing the kinesthetics, tactical, and spatial information gathered in the clinical environment and incorporating it into the design concepts. Things like hand grips and body pressure are important considerations because they are critical for enabling the surgeon to maintain control and precision when using the device.

• **Develop a second-level design brief.** In our processes, we use the dynamic information that is observed and recorded in the surgical operating room to develop a second-level design brief, which runs parallel to the technical design specification.

We build on the data analysis to visualize new concepts that can be translated into meaningful functional attributes for a new design. Rather than being linear, the process involves taking a design spec and conceptualizing solutions that are, in effect, either left or right of the center line. The process includes a dialog among design team members who, in the end, coalesce around a palette of ideas.

• **Develop multiple design concepts** that contrast and compare the multiple attributes that must be accommodated in the final design.

• **Replicate the anatomical setting.** The design process often involves replicating the anatomical setting, using photographs taken during live surgeries. It's another step in truly understanding the nuances of how a device will work.

• **Develop 3-D models.** We generally develop a range (three to 20 or more) of 3-D, hand-fabricated models for a device. We then meet with the surgeons to talk with them about the spatial relationships and give them a chance to feel the instrument and provide verbal feedback. Stereolith-ography models are developed based on key preferences we received from the form studies, which have subsequently been interpreted as CAD models.

• **Go back into the OR with a prototype.** In many situations, we go back into the operating room to observe how the prototype is used by a number of surgeons.

In designing orthopedic devices, static implants, like plates and dynamic implants such as knees and hips, the insights gained through first-hand observation in the operating room can't be gained any other way.

Orthopedic device design must take into account a complex set of spatial relationships, functional needs, physical kinesthetics and user patterns and preferences. With this complexity and with the functionality of the design often a life-and-death matter, there is too much at stake for the designer to delegate his or her responsibility for first-hand observation.

By donning scrubs and investing sufficient time early in the design process to observe multiple surgeries, the industrial designer can create new products that are more innovative and effective. ❖

Jeffrey Kapec is a principal and executive vice president of Tanaka Kapec Design Group, Inc. From 1980 to present, Kapec has worked on design and product development programs in the following areas: surgical instruments, medical diagnostic equipment, pharmaceutical packaging, drug delivery systems, technical instruments, office equipment, office furniture design and consumer products. He has been awarded more than 30 utility and design national and international patents in advanced technology, surgical instruments, and mechanical design. Kapec has logged hundreds of hours viewing and recording surgical procedures with some of the most renowned surgeons.