Operating Room Observation Key to Innovative Implant Design

In designing implantable medical devices, 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 deep insight into the physical and interactive forces that impact how a device will be used with merely one observation. It takes several observations because every surgeon, scrub nurse and operating room layout creates a unique environment with differing physical parameters and interpersonal dynamics.

In creating a new medical device, designers must understand the complex set of forces that exist in a variety of operating room environments. And there is no substitute for first-hand observation in the setting where a device or implant will be used. If the observation is delegated 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 differ from engineers in that they are taught to think three-dimensionally about form. The designer will have undergone many years of visual training that provides 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 also will have a different skill set. This column will examine the design of an orthopedic device.

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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;
- **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;
- **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.

Observing the Orthopedic OR

In the more than 300 surgeries we have observed as a company, 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 the case.

We observed a number of hip implant procedures, two of which were studies in contrast. At one surgical center, the physician worked 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 procedure at a different but well-known hospital that does not focus on hip replacements. This surgery took three hours and was anything but a choreographed dance. Instead, it was a slow, plodding, labored process from start to finish. Both teams used the same instruments

and the same 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.

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 quickly or slowly? Is the surgeon pattern-based or interactive at each turning point? How is his sense of spatial relationships? Does he respond actively to subtle tactile and audible sensory input?

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/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 whether the team is chosen 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? Whether or not music is played and the type of music preferred provides another subtle insight into the surgeon and the team as they work together.

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.

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 back-up tables organized?

The type of surgery. Will the device be used in an emergency trauma situation, a regularly scheduled procedure or both? 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 on impact. In this situation, we observed 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 to Do With All That Data

With so many variables, we have found that many projects require the observation of as many as 10 surgeries with different physicians 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 are related to behaviors, sensory feedback, and the operating room environment?

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

• **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.

• **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 representative also will have observations/opinions about how various surgeons work with the implants and procedures. A good designer will take these observations 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. Issues such as handgrips and body pressure are important considerations because they are critical for enabling the surgeon to maintain control and precision when using the device.

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• **Develop second-level design brief.** In our processes, we use the information 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 compare and contrast 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.

• **Develop three-dimensional models.** We generally develop a range (three to 20 or more) 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.

• **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 various 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. ❖

Jeffrey Kapec is principal and executive vice president of Tanaka Kapec Design Group, a consulting design firm that integrates industrial design and mechanical engineering into a cohesive fabric of innovative design options for clients. In its more than 30-year history, the company has learned that firsthand visual observation is essential for advanced design, which makes for the "wow" factor in the minds of clients and their customers.