

The Importance of Human Factors Testing in the Design of Surgical Robotic Devices

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Abstract:

Human Factors Testing is vital to the product design life cycle, but it is especially important to complex surgical robot design, owing to the fact that robotic surgical procedures involve both human and robotic interaction. As with any surgery, uncontrolled or unwanted motion is an inherent risk, either by robot or human hand. However, when dealing with humans and surgical robots in the same procedure, the risk can be magnified. One would think we would be more at ease with robotic surgical procedures, when studies show a surgeon's hand is stable to roughly 100 microns, while a surgical robot is stable to roughly 25 microns, however we are reliant on the device design.

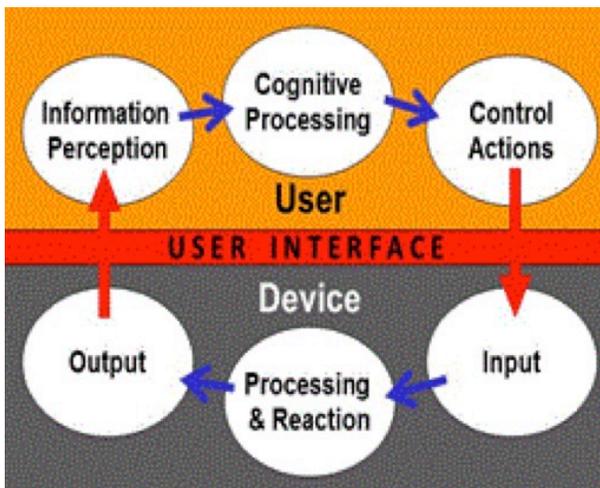
(See <http://www.medicaldesignbriefs.com/component/content/article/25006?start=1>)

In most cases, surgical robots are designed to mimic human hands, yet they still require human interaction to pre-program a surgical procedure, or a surgeon actually controls the surgical robot during the procedure. In either scenario, the devices and interfaces that have been designed properly with a Human Factors approach will be more intuitive and natural for the surgeon to operate, while providing increased precision and safety throughout the procedure. This directly translates into more efficient procedures, cost savings for the hospitals and most importantly, better outcomes for the patient. The ultimate goal is to bring more success to robotic surgical procedures by incorporating human factors testing into device design.

Benefits of Human Factors Testing

In basic terms, a Human Factors (HF) study is a study conducted with representative end users testing the product to assess the adequacy of the device's user interface design to eliminate or mitigate potential use-related hazards. The HF study evaluates: (i) the ability of the user to perform critical tasks, and (ii) the ability of the user to understand the information in the packaging and labeling, such as product labels or instructions for use, that inform the user of actions that are critical to the safe and effective use of the device.

During medical device design, the ultimate goal of the Human Factors Testing is to minimize user-related hazards and risks and then confirm that these efforts were successful and that intended users can use the device safely and effectively.



There are many risks to consider in robotic medical device development, particularly where humans are involved. The Human Factors Testing approach focuses on those risks; the critical interactions between humans and medical devices. Figure 1 at left represents the possible general interactions between a user and a device, the processes performed by each, and the user interface between them. The critical element in these interactions is the device user interface, depicted in the red area.

Figure 1: Device User Interface in Operational Context (adapted from Redmill and Rajan, 1997).

To understand the user/device system, it's important to understand the user's interactions with the device:

- Information Perception: The user perceives information from the device
- Cognitive Processing: The user interprets the information and make decisions about what to do
- Control Actions: The user manipulates the device, its components, and/or its controls. (e.g., modifies a setting, replaces a component, or stops the device)

It's also important to understand the ways that devices receive information and react to the user:

- Input: The device receives input from the user
- Processes and Reacts: The device reacts to the input information
- Output: The device responds and provides feedback to the user about the effects of their actions

It is important to note that Human Factors/Usability Engineering is used to design the user/device interface. The user interface includes all components with which users interact while preparing the device for use (e.g., unpacking, setup, calibration), using the device, or performing maintenance (e.g., cleaning, replacing a battery, making repairs).

Due to the critical interface with humans, there are specific beneficial outcomes of applying Human Factors Engineering testing to medical devices, which include:

- Easier-to-use devices
- Safer connections between device and accessories (e.g., power cords, leads, etc.)
- Easier-to-read controls and displays
- Better user understanding of the device's status and operation
- Better user understanding of the patient's current medical condition
- More effective alarm signals
- Easier device maintenance and repair
- Reduced user reliance on user manuals
- Reduced need for user training and retraining
- Reduced risk of user error
- Reduced risk of adverse events
- Reduced risk of product recalls

See <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/>)

Risks and Benefits of Surgical Robot Medical Devices

As with any surgery, an inherent risk is uncontrolled or unwanted motion, either by the robot or the human hand. Naturally, when dealing with humans and robots in the same procedure, the risk can be magnified. One would think we would be more at ease with robotic surgical procedures, when studies show a surgeon's hand is stable to roughly 100 microns, while a surgical robot is stable to roughly 25 microns, however we are still reliant on the device design. Many medical robots today are built to the strictest of standards in order to guarantee quality control. Overall, assurance of patient safety should always be the top priority in medical device design, which is why Human Factors Testing should be considered during device design.

(See <http://www.medicaldesignbriefs.com/component/content/article/25006?start=1>)

Aside from stability, there are other benefits to patients for using robots in surgeries, such as less invasive procedures, more comfortable experience for the patient, and the ability to perform smaller and more precise movements. There is also the convenience factor; in some cases the surgeon does not even have to be in the same room or same location as the patient, since the physician can see images of the patient and control the robot through a computer. This means that a specialist can operate on a patient who is very far away without either of them having to travel. It can also provide a better work environment for the physician by reducing strain and fatigue. This is especially true for surgeries that can last for hours, which can cause even the best surgeons to experience hand fatigue and tremors. In this case, surgical robots are much more stable and sturdier than humans.

(See <http://www.allaboutroboticsurgery.com/surgicalrobots.html>)

Surgical robots are still considered a relatively new technology and there are very few surgical robot manufacturers in the device development industry. Cost to manufacture is still very high, which in turn makes the cost to purchase prohibitive for many hospitals and healthcare centers. There are still issues with robots vs. humans, as far as latency or the time lapse between the moments when the physician moves the controls and when the robot responds. And there is still a chance for human error if the surgeon incorrectly programs the robot prior to surgery or makes an error in controlling during surgery. The benefits to surgeons include the ability to make needed adjustments during the course of surgery, while a pre-programmed robot cannot.

(See <http://www.allaboutroboticsurgery.com/surgicalrobots.html>)



Example of Surgical Device Design and Development by Proven Process

Proven Process Medical Devices is part of a small niche of companies working in the robotic medical device space. Two PPMD engineers, Benjamin Piecuch and Robert Royce, were named as contributors on a design that was issued a patent by the US Patent Office for a device that remotely controls catheter manipulation. The patent for invention, number 8,740,840, is for a system to remotely control the positioning

of a cardiac catheter within the body of a patient.

(See <http://provenprocess.com/about-proven-process/news-events/ppmd-engineers-granted-us-patent>)

PPMD was challenged by their client to develop a remote catheter manipulation device for cardiac procedures (pictured above) which allows a cardiologist to complete the catheterization procedure outside of the fluoroscopy field. The engineering team met the challenge by designing a device with 3 degrees of catheter control; insertion and withdrawal, rotation, and tip deflection, for cardiac mapping and ablation catheters. The control system was developed without imbedded microprocessors and without software in order to minimize the compliance overhead by eliminating software verification and validation. Proven Process Medical Devices utilized Human Factors Engineering testing during the development of this device to ensure the product was safe and effective.

(See <http://provenprocess.com/Catheter-Manipulation-Device>)

The Future of Surgical Robot Design In Human Factors Hands

There have been many comparisons regarding costs of conventional surgery compared to robot-assisted surgery and although the cost is usually higher with use of robots, the benefits of patient safety and consistent efficacy usually outweigh the cost differential. Plus there are the cost savings that are not always easy to calculate. For example, if robotic surgery cuts down on healing/recovery time, there is money saved in terms of the length of stay in the hospital. If we are ultimately moving to this advanced technology, we need to ensure we are doing all we can to drive costs down, while maximizing patient comfort and safety.

Overall Human Factors contribution is vital to the product design life cycle, but it is especially important to complex surgical robot design. In most cases, surgical robots are designed to mimic human hands, yet they still require human interaction to pre-program a surgical procedure or a human to actually control the surgical robot during the procedure. The intended users of robotic devices should be able to use the device without making user errors that could compromise medical care or patient safety. To effectively do this, there are additional device user factors that should be considered for a device this complex such as physical dexterity, mental and emotional state, level of education, general knowledge of similar devices, knowledge and training specific to the actual device used, and the ability to learn and adapt to new devices.

(See <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/ucm124829.htm>)

The Human Factors Testing approach is expected to increase the effectiveness of robotic technology when deployed, which will give intended users and patients more confidence in the devices. Proven Process Human Factors Engineer, Dino Kasvikis concluded that *“Devices and interfaces that have been designed properly with a Human Factors approach will be more intuitive and natural for the surgeon to operate, while providing increased precision and safety throughout the procedure. This directly translates into more efficient procedures, cost savings for the hospitals, and most importantly, better outcomes for the patient.”*

The ultimate goal of incorporating Human Factors Testing into medical device design is the success and growth of robotic technology for surgical applications along with increasingly better outcomes for patients.

About the Author

Jodi Hutchins of Regulatory Matters Consulting is an Independent Regulatory and Quality Consultant with over 15 years of global medical device registration experience. She held her most recent position for 9 years, as QA/RA Director for a worldwide distributor of medical devices.