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Visual Mapping of Clinical Procedures Using Ethnographic Techniques in Medical Device Design

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1. Introduction

Medical device users have a symbiotic relationship with their tools. They are adaptable and highly resourceful when targeted towards reaching their clinical goal. As a result, the ability to make sound decisions regarding the user device interface and subsequent device design requires a fundamental understanding of how device users work, how they are trained, and increasing tacit knowledge as gained through experience. This chapter presents a case study on the design of a novel catheter user interface utilizing ethnographic techniques with emphasis on contextual inquiry to determine and define design opportunity and subsequent design requirements. Integral to the project, a visual mapping of ethnographic information was generated and used to both inform the design team about the context of complex procedures to guide design decisions as well as an alternative use as a training tool for novice device users. This guide demonstrates visual ethnographic information and has been successfully used by both product development teams and in the Mayfield Clinic Endovascular 101 course material. This course targets young inexperienced practitioners and serves as an introduction to a complex type of clinical procedure.

Active use of video ethnography combines a richer sense of understanding and mandates a level of collaboration with all parties involved (Spencer). The priorities between each participating group had to be negotiated and renegotiated throughout the study to determine critical elements and assess which aspects were required to be highlighted. This transparent approach provided a rich foundation for new device design opportunity identification and collaborative mapping. This further elicited data from personal memories and experiences to form a collective intelligence as historical record and advanced training materials. By focusing the research team on answering "so what?" the technical aspects of practice are uncovered and the requirements of device design in this arena were determined.

2. Visual research, mapping and ethnography

Visual research methods provide a deeper and subtler exploration of social contexts and relationships are recognized allowing us to see the everyday with new eyes (Spencer). In using photographic techniques in conjunction with ethnography the captured images are used to highlight the truthfulness of appearance and/or the explicitness of performance. In medical device design (or product development in general) objects can seem to have a social life of their own and are links to a complex system of production through consumption and exchange. This in turn has value of identity, monetary and social gain (Spencer). The goal of conducting this type of research is to inform a design team about the lifecycle of a device, the devices used in conjunction with a target device and evaluate the relationship the device has with the user as an extension of the user's body. By designing tools as extensions of a user, design teams practice user-centered design and proven human factors principles.

Ethnographic research has been formally conducted for the medical device development industry for the past 10 years (Wilcox). These research techniques are widely used to generate and define opportunity gaps and/or unmet user needs. This method affords a rich experiential understanding of user behaviour that when documented in a usable visual manner can inform design teams in regards to the social interactions and overall flow of user-device-procedure in terms of Whom? Did what? With what? Why? User challenges? Mitigations? As well as identify subsequent design implications. Most interesting to note in using ethnography in medical device design is the discovery that users (surgeons, in general) do not perceive high stress with a negative connotation. In fact, it is this challenge with which they thrive and we as patients benefit. Using the techniques described below, it is possible for a design team to uncover those aspects of a procedure or device design that should be changed based on preferences and those that must be addressed in order for the practice to advance.

2.1 Methodology: Contextual inquiry

For clinical procedure background, interventional radiology generally involves the treatment of human disease by therapeutic alteration of internal anatomy and physiology using devices that are deployed and controlled from remote percutaneous access sites with indirect visual feedback provided by trans-corporeal imaging systems that include ultrasound, fluoroscopy, computerized tomography and more recently magnetic resonance imaging. In many interventional radiology procedures, the blood vessels (arteries and veins) are used as conduits for navigation of surgical instruments to the treatment site. Oftentimes the blood vessel itself is the treatment target, and so the vessel serves as the surgical workspace. In interventional neuroradiology practice, endovascular procedures involve maneuvering fine wires and coaxial tubes called catheters, most often from the groin region to the arteries that nourish the brain. To accomplish this, interventional radiologists (users) rely upon image guidance (fluoroscopy) which demands of them numerous mental models, cognitive loads and physical interactions during any given procedure. Specifically, they rely upon their personal dexterity and tactile sensitivity in manipulating the catheters, with very few assistance tools, and must be infinitely familiar with anatomical structures for navigation throughout the body. They rely heavily on tacit knowledge for an expedient procedure. While there are a host of standards applicable to device design in general (AAMI/ANSI HE 75) there are no design standards nor ergonomic recommendations available to improve the interaction of catheters with their operators. This has been identified as a weakness within the industry as is a target research area for the application of ergonomics to device design.

Since physicians have no other choice but to use the devices currently available, the ability to recognize inefficiencies due to poor ergonomic device design is often overlooked. In contrast, all medical devices are subject to challenging requirements vis a vis clinical efficacy and safety. As a result of this dichotomy there is an opinion of acceptance since the clinical efficacy and safety is obviously most important. The methodology presented highlights challenge areas as uncovered during this research.

In conjunction with the University Hospital and Department of Neurosurgery (Cincinnati, OH), 24 diagnostic cerebral angiogram cases were observed and documented via the developed multi-channel video system. Todd A. Abruzzo, M.D. and/or Andrew J. Ringer, M.D. served as the attending surgeon for each case, and in some cases provided instruction to one of five fellows with a ranging degree of experience - first year fellowship experience to final year fellowship experience. Prior to collecting data, IRB approval and patient consent was requested and granted. The diagnostic angiogram cases were documented and characterized using a system of careful notetaking, photography and videography units within the surgical theatre (as shown in Figure 1; numerical figures represent data recording locations). Clinicians provided study members with literature review of training manuals prior to beginning the data collection series and were interviewed throughout the study to confirm findings.

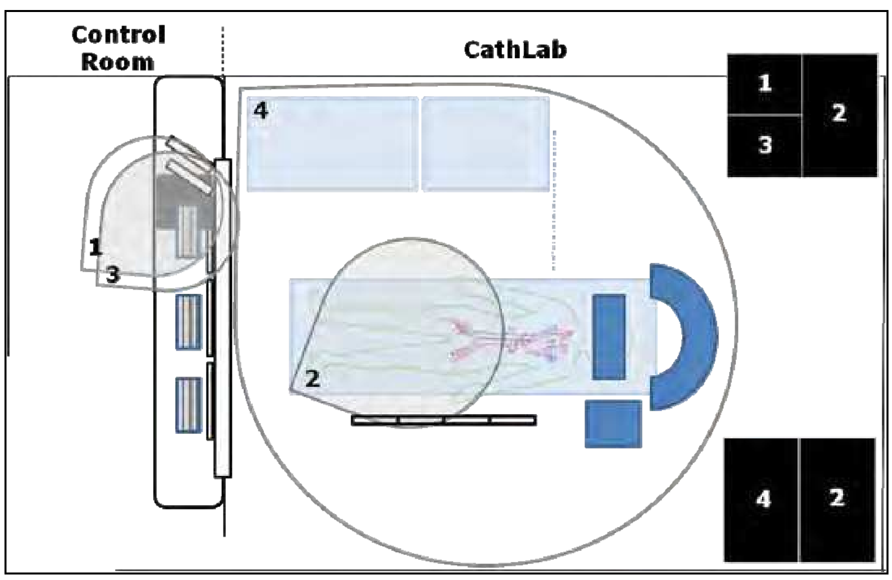

Fig. 1. Surgical Theatre Set-Up

All study participants were observed conducting diagnostic cerebral angiograms and interviewed in-depth. During the interviews participants were asked to describe each step of performing a diagnostic angiogram. In the case of the participants who were currently being trained to accomplish these procedures, they were asked to highlight the differences between the attending physicians. In completing this interview highlighting preferences, a further depth of understanding by the research team was achieved while avoiding any judgement and with the recognition that all techniques represent valid approaches much like the methods and means of "skinning a cat."

An additional technique of using visual metaphors in imagery was used to determine user preferences around a particular step in the procedure. Participants were provided a set of image stickers to which they would adhere the image which best reflects their opinion regarding each step they identified in the procedure. Once all steps had correlating images the research team asked the participant to interpret the selection. This interpretation of visual language can create vivid and authentic personal narratives (Spencer) and in this case determined the emotive context of the procedure. This technique has been adopted and practiced within the medical device industry in companies such as Johnson and Johnson and several industrial design consulting offices.

2.1.1 Data analysis and procedure map development

Multichannel video was edited into a 4 channel display allowing the research team to capture both the distal working end (internal to the patients body) as well as hand-eye motions of the use (outside the patients body). Video analysis determined ultimate measures and key stages of the clinical procedure. An initial map was developed explaining each step in the procedure with descriptive detail.

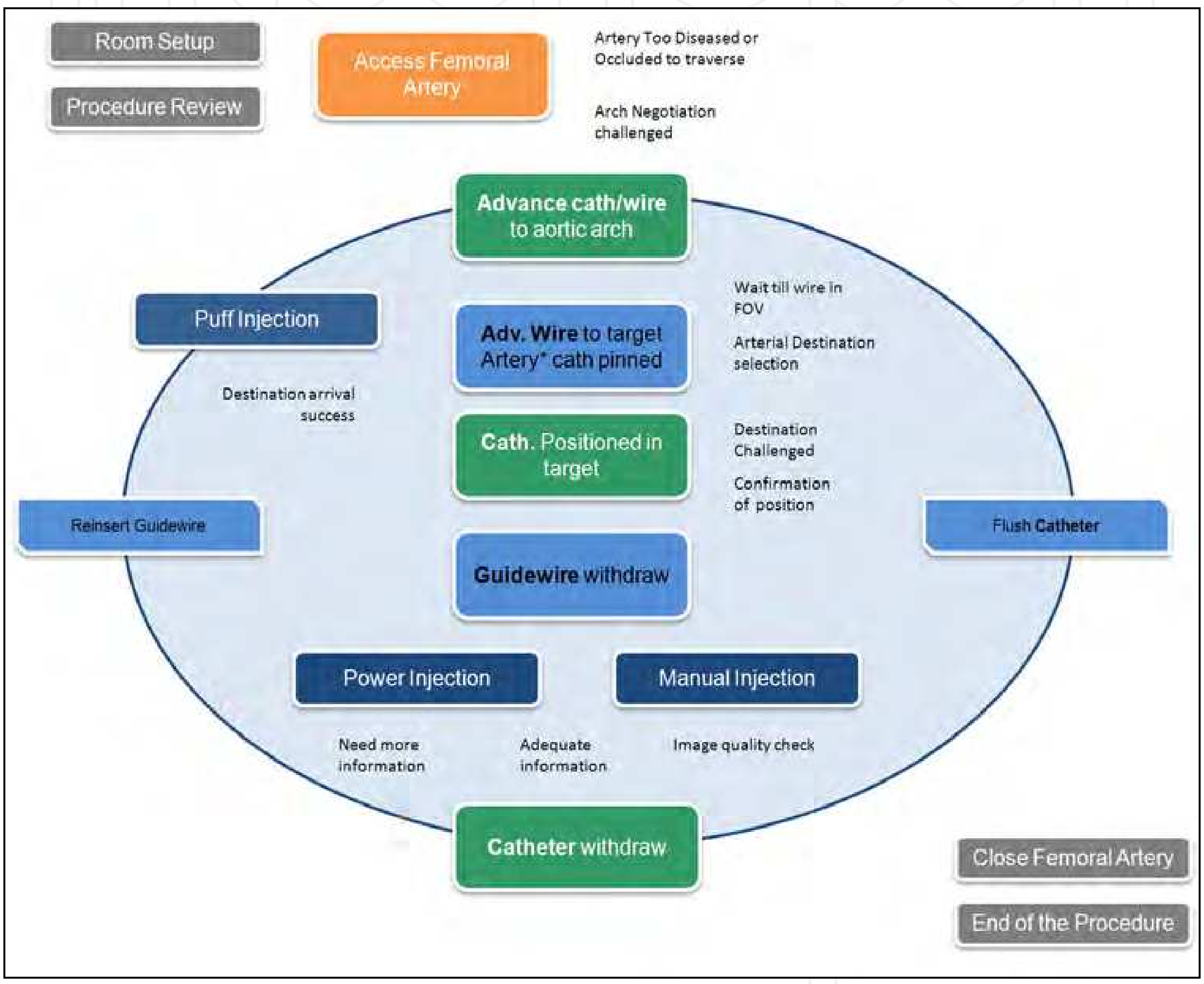

Fig. 2. Basic Procedure Flow (Procedural steps vary somewhat depending on user preference)

2.1.2 Interpreting results for design

Many aspects of ethnography determine aspects of a user group which while important in understanding the users behaviours; beliefs and culture do not directly correlate to design directives. For example, the users reliance on visual cues to complete the procedure operate on the most basic level of human perception, yet there is a great deal we do not understand about the complex process of recognition and its attribution of meaning (Spencer). Since we are unable to instrument the practicing clinicians this researched solely focused on hand movements specifically to identify which actions of the hand resulted into what behaviors of the catheter at the distal end (farthest most end inserted into the body).

Virtually all catheters are round in cross-section and vary in their durometer (stiffness) throughout their overall length, getting increasingly more flexible towards the distal end and stiffer at the interaction point. The only input a user can have is to either push or pull the catheter and to torque it at a preferred rate to improve the likelihood of directing it to a desired location. As the ethnographic research indicated, a critical component of successful navigation with the catheter technology to the clinical region of interest is efficient and effective guidance of the catheter and guidewire assembly. However, becoming effective and efficient in advancement requires many years of experience. A contributing factor of the difficult learning curve is due to the lack of users awareness in respect to the input torque. The current technology does not provide a haptic or cognitive load that the user can interpret and assess during the advancement phase.

Through root cause analysis these tasks can be simplified in the context of the overall clinical procedure. Emphasis is placed on verifying translation into design criteria with users as design interpretation could be incorrect and negatively impact the design solution. To improve interaction the design team developed the following set of criteris for an improved catheter interface design:

- Stiffness at the proximal end (user interaction point) must be equal to or better than current devices.
- Center lumen of the catheter must remain tubular in order to conform with compatible guidewire for proper advancement
- Feedback of torque between index and thumb must be increased (perceptually) by users with gloved hands
- Manufacturing techniques of extrusion must be considered without significant increase in cost of manufacture

Since the ideal surgical instrument is a contiguous extension of the haptic unit (the hand) that enables an expanded range of effector actions and environmental effects, the design team looked for comparative technologies and/or actions with the same conditions as motivations. For example, in sewing while tying a knot the user simply wraps the thread around their thumb/finger then rotates to achieve an intertwining. In this example, the amount of rotations of the thread work advantageously to tie a better know while the user has little idea exactly how many times the threads are interwoven. In reality, there is an interface between the hand and the surgical instrument creating a barrier that introduce variable levels of interference and impedance between the cognitive process and the intended task. The challenge put forth by the design criteria is to somehow improve knowledge of a condition which is given little thought while maintaining the positive elements of current catheter design.

The proposed design solution is to modify the section of interaction as indicated in figure 3 below. The area of opportunity is approximately 20 inches from the proximal end.

In this area of the catheter there is no tissue interaction per se rather this section is largely for manipulation and has a strengthened inner core which improves device manipulation. In maintaining our design criteria and allowing an open brainstorm session the following cross-sections were determined to be possibilities as shown in figure 4.

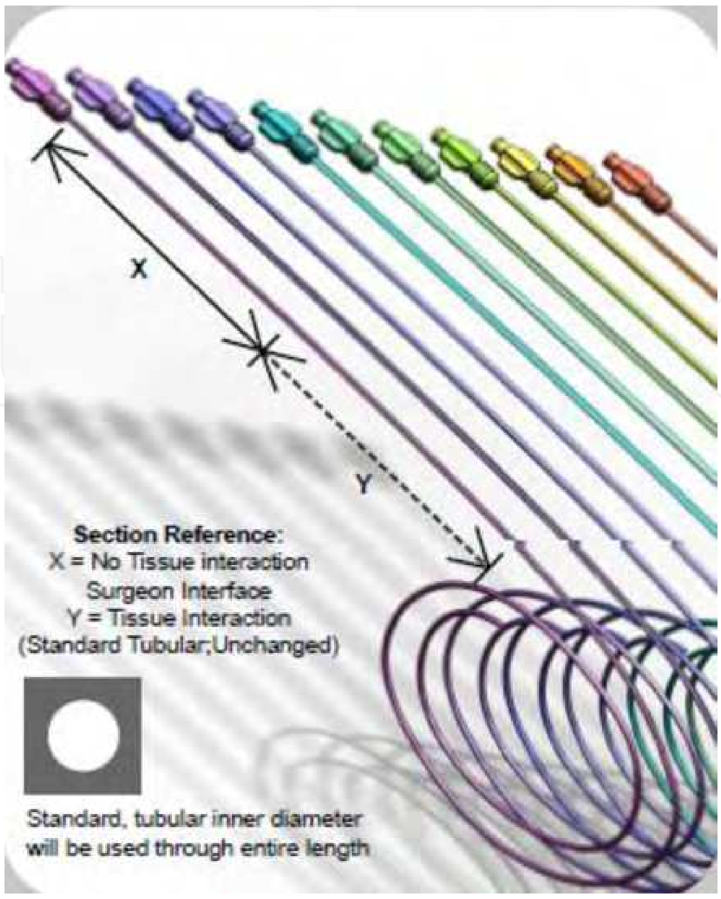

Fig. 3. Catheter Interaction Area 1

Fig. 4. Variable Interface Geometry 1

While each of these concepts are viable options only a few were modelled for design verification and usability testing. Again, the design team referred back to the original ethnographic results to set up concept verification testing. In using a glass model of the vascular system, users were asked to use the concept catheter as well as the existing catheter to navigate the aortic arch to the innominate artery. The objective of the study was to collect torque, rotation, and time metrics during simulated use to characterize operating profiles for both current state of the art and catheter interface devices. The method used was to instruct users to navigate concept design through simulated vascular model until the catheter distal end-effector has passed a designated line within the right subclavian. Note: the users conduct the test twice per sample. An example of the results from this study are shown in Figures 5 and 6. Our conclusion is that the revised catheter interface may provide a more controlled and defined work path as shown by decreased change in amplitude oscillation for rotation and torque profiles.

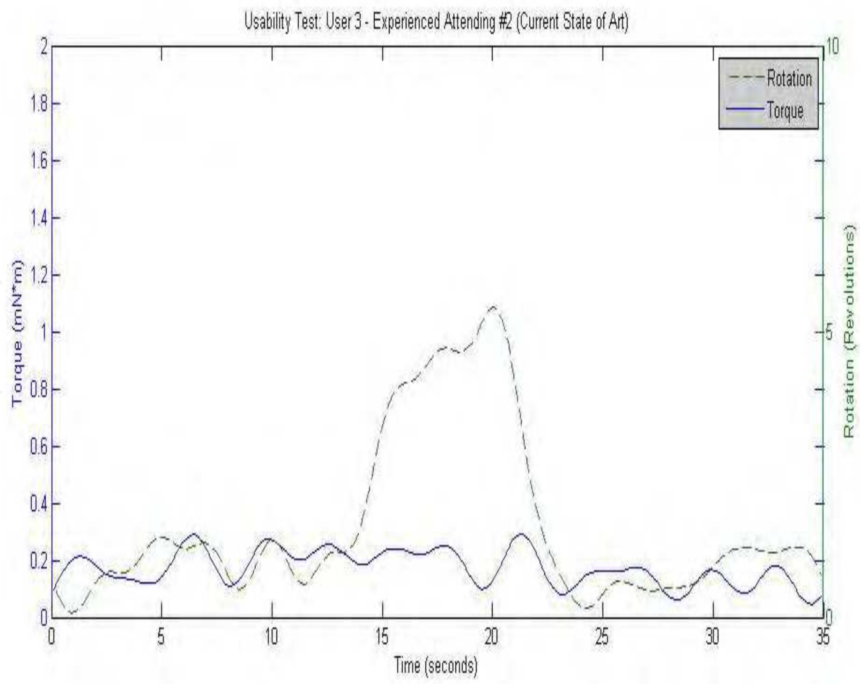

Fig. 5. Current Catheter Design 1

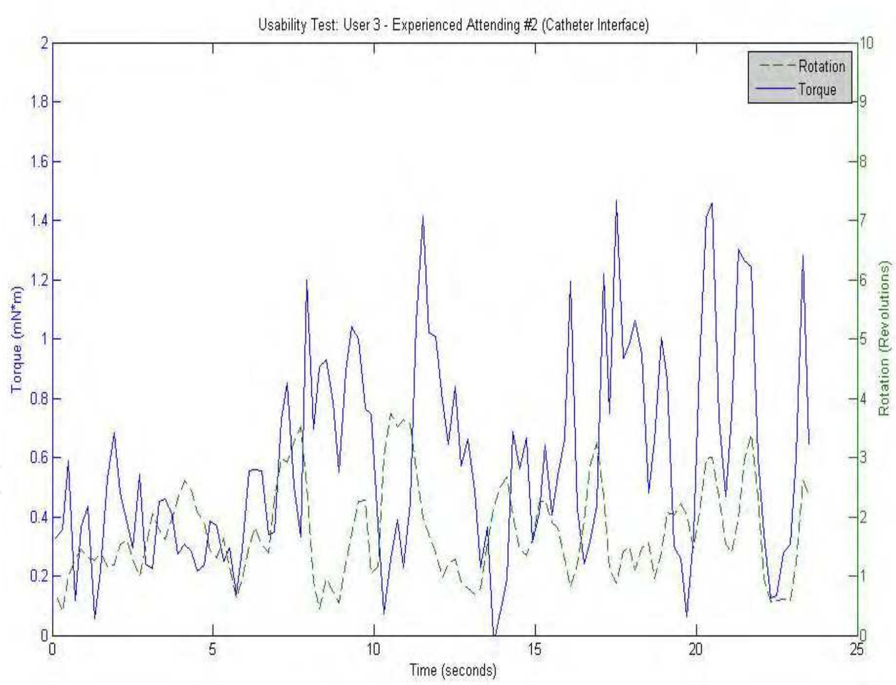

Fig. 6. Conceptual Catheter Design 1

Ethnography provided the foundation of the design proposal and subsequent verification testing. As a result of the collective efforts across various disciplines it was determined that a "D' shaped cross-section produced at the proximal interaction length of the catheter is the optimum design configuration to improve haptic feedback of potential energy and prevent redundancy. Figure 7 below depicts the optimum design.

Fig. 7. Ideal Catheter Cross-section 1

2.1.3 Interpreting results for training

The procedural map (Fig.8) results of this ethnographic study were re-tooled as guidance to introduce the steps, tools, anticipated challenges-mitigations, and user variances to inform and educate new users who are about to perform diagnostic cerebral angiography.

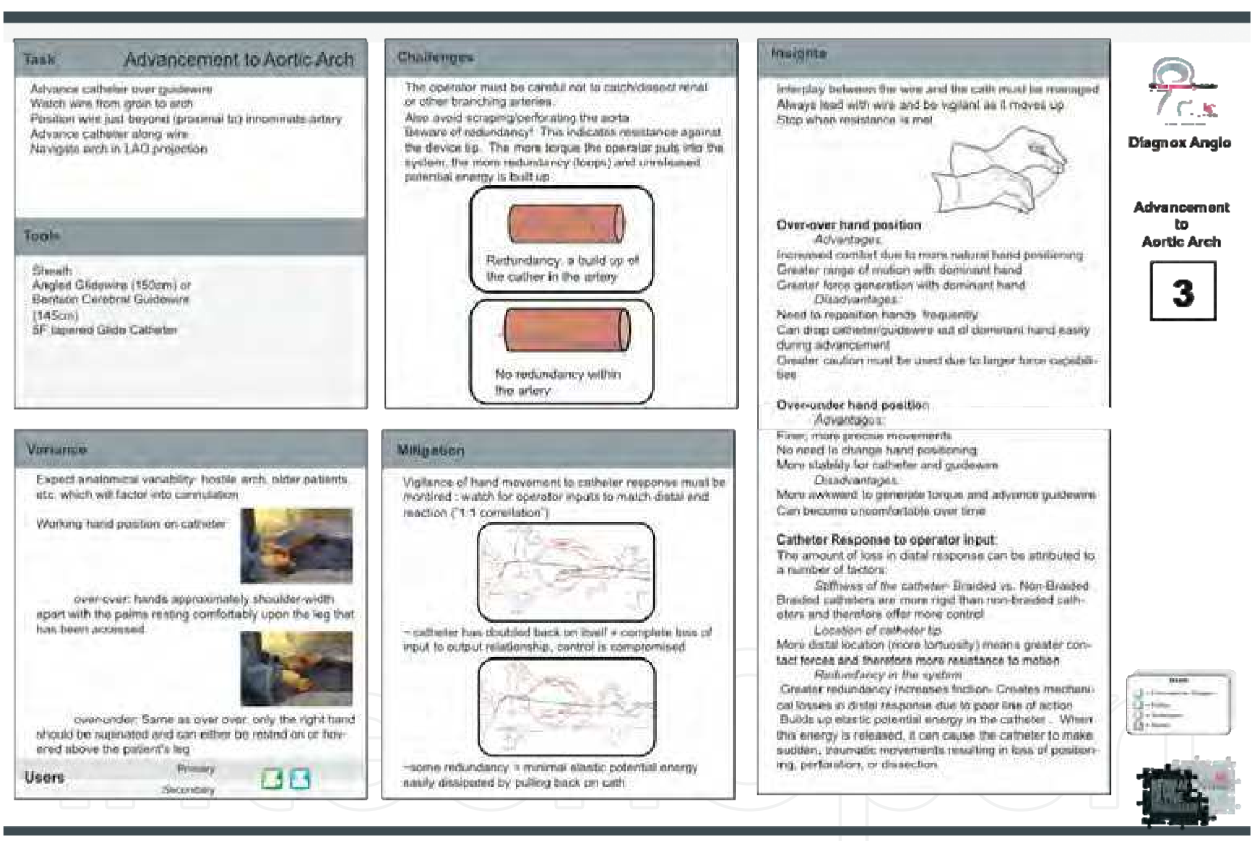

Fig. 8. Training Procedure Map Example

This type of procedural medicine is highly dependent upon technical performance, adherence to accepted protocol may be of paramount importance. The safe and effective performance of medical procedures requires a complete understanding of the technical steps required, mastery of performance of those steps and their performance is the proper sequence. Omitting or altering even a single step may have significant consequences. The two physician authors (AJR, TA) have participated in the performance and teaching of cerebral angiography for many years and direct an introductory course on its performance for trainees from around the country. Cerebral angiography is a common medical procedure with a low tolerance for complications

(<1%) and wide applicability across multiple services and institutions. Standardization of the performance and reporting of the procedure aids in communication across these services and institutions. The procedural diagram has helped in this endeavor in two fundamental ways. First, the careful and complete analysis of each and every step of the procedure allows novice usersto assess and improve the efficiency of each step and to eliminate errors. Review of the diagram helped to identify the most variable and time consuming steps of the procedure and to consider improvements in those steps. Since the goal of the course and training are to produce physicians who are safe and effective performers, identifying the "weak links" is invaluable. Second, the procedure diagram is a visual and interactive teaching tool for our trainees. Following the sequence of steps and the alternatives in a clear and visual diagram makes understanding of each step and the procedure as a whole easier.

As discussed in “Doing Visual research” unlike traditional research methods ethical questions of confidentiality and anonymity were prevalent during this study. Inherent to visual research are the blurring of boundaries between participation and observation. Since this research was conducted in analysis of a complex medical procedure, participation by all levels of clinical leadership were required to attain a depth of understanding.

This study was IRB approved and followed best practices with regard to human subject research. However, due to the visual nature it is impossible to adequately anonymize all of the visual data (DVR). In review and data analysis it is possible to identify performance challenges and best practices based on individual preferences. For example, the design research team noted differences in the number of support personnel required and the subsequent job functions as part of the entire system. Since our results could have the potential negative impact and influence willing participation, this detail was reviewed as superfluous and discarded. Additionally, timed performance to complete the procedure was diligently managed at the onset of the study. This measure proved counter productive as there is an inherent reliance of visual perception by the clinical practitioner to determine what steps are required next based upon the patient’s vascular anatomy. Since we ‘read’ images in front of our eyes through the pictures we have in our heads (DVR), individual interpretations depended on previous knowledge and prior codes developed over time. As a result there is a bias in experience and overall technique.

As discussed earlier, observation and interference gets blurred in visual research anonymity is compromised despite best practices as mandated by IRB protocols. In this research effort this was very true. This affects perceived performance or lack thereof and what the team views as a measure. Another example noted during this study was the variance on amount of interim hand cleaning throughout the procedure. In order to better understand the significance or lack thereof the research team questioned the attending physicians. Once cued into this variability, they in turn became more cognizant. Thus we observed and by highlighting the difference we now unintentionally interfered albeit in a positive direction.

3. Conclusion

Surgical or catheter based interventions are complex procedures. The current combination of experience and tools that the physicians have, afford them enough control to turn their intentions into actions. However, there are numerous barriers between the user intentions and how they translate these into actions. These barriers happen simultaneously and are haptic feedback, environmental conditions, and visual discrimination.

The use of visual mapping techniques of clinical procedures within ethnography can be a powerful tool to determine unmet user needs as well as other areas of improvement in the context of use. In essence by collecting the data and designing the data to meet the needs of multiple stakeholders, in this case a product development design team as well as clinical training, an increased depth of overall understanding is achieved. Mapping assures communication of research findings across various disciplines working in product development and confirms design assumptions with users. Compensatory user strategies are uncovered in the clinical context and a clearer understanding for potential error can be analysed for root cause. The re-purposing of an ethnographic procedural map for training purposes facilitates rapid access to organized procedural flow and serves a reference tool for novice users. The in-depth discussion and use of visualizations affords immediate cautions to ill-advised conditions and subsequent strategies of avoidance.

4. Acknowledgment

This research is sponsored by NSF Grant #IIP-0652208 and industry members of the NSF MIMTeC I/U CRC. We would like to thank the University Hospital, the Mayfield Clinic and the following Medical Device Innovation and Entrepreneurship Students: Mike Wirtz, MS BME, Steve Nelson, BS ID, and Joe Strelnick BS BME, As well as previous Clinical Fellows Drs. Usman Khan and Andrew Grande.

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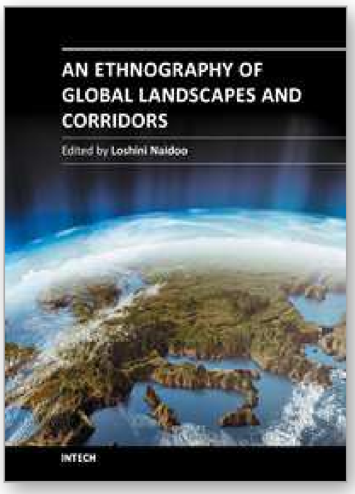

An Ethnography of Global Landscapes and Corridors
Edited by Dr. Loshini Naidoo

ISBN 978-953-51-0254-0
Hard cover, 270 pages
Publisher InTech
Published online 09, March, 2012
Published in print edition March, 2012

The chapters presented in this book draw on ethnography as a methodology in a variety of disciplines, including education, management, design, marketing, ecology and scientific contexts, illustrating the value of a qualitative approach to research design. The chapters discuss the use of traditional ethnographic methods, such as immersion, observation and interview, as well as innovative ethnographical methods which have been influenced by the new digital culture. The latter challenges notions of identity, field and traditional culture such that people are able to represent themselves in the research process rather than be represented. New approaches to ethnography also examine the use and implication of images in representation as well as critically examining the role and impact of the researcher in the process.