User-centered design for surgical innovations: A ventriculostomy case study

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Abstract. A lack of multidisciplinary collaboration during the design phase of surgical innovation development often ignores the people whom we are developing for and therefore omits meaningful and relevant user insights that can potentially be gathered about the context-of-use of a product. To mitigate this issue, we propose a user-centered design approach to developing surgical solutions. End-user involvement during product design has been linked to the development of more useful and usable solutions as it helps create a smooth transition between research, environment, and daily practice. In this paper, we describe the user-centered design process and give an example of how it can be incorporated to enhance the development of surgical innovations. As a case study, we focus on one of the most commonly performed and error-prone neurosurgical procedures, ventriculostomy.

Keywords: UI/UX research · HCI · Design Thinking · User-centered Design · Ventriculostomy · Augmented Reality

1 Introduction

Research in surgical technologies has led to numerous novel hardware and software artifacts, e.g. deep learning methods for surgical video processing, augmented reality for surgical guidance, and robots/devices for minimally invasive surgery. Yet, only some of these innovations have met with success and have been incorporated into daily surgical practice. One reason for this, is the lack of multidisciplinary teams as well as the apparent mismatch between the technological and human needs [9]. Moreover, a lack of interdisciplinary research can result in a focus on either novel hardware use or algorithmic design rather than the needs of the intended end-user (e.g. surgeons)[27]. This has resulted in many proof-of-concept systems that have not been translated into clinical practice [14]. One way to address this is through the application of user-centered design (UCD) practices across areas of surgical innovation. UCD is an iterative design process that focuses primarily on making systems more usable by prioritizing users, their activities, and contexts during each phase of a project.

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When adopting a UCD approach, the first step of any clinical research would be to determine a practical problem or limitation of the end-user. Although perhaps obvious, this is not always possible, especially in academia. Generally, limited access to clinicians, operating rooms, and large cohorts of end users become common challenges. Moreover, trainees taking over existing projects miss out on the opportunity to work closely with clinicians and gaining first-hand experience, not to mention funding that can potentially end prior to rigorous clinical evaluation and validation of a system. These issues can drive researchers to end up solving problems that may not exist or ones that are inconsequential for medical professionals. Contrarily, the active participation of clinicians can ensure clinical relevance and promote feedback within an iterative user-centered design methodology that involves: research, analysis, brainstorming and analyzing ideas, getting feedback, improving a prototype, and testing. To date, however, design has played a limited role in surgical innovation research in academic centres despite the fact that it is well-suited for cross-disciplinary research.

In the following paper, we describe how a UCD approach can benefit surgical innovation projects. We begin with a description of the UCD design process. Then, present what this process could look like for the specific neurosurgical task of ventriculostomy. We conclude with a discussion about the importance of considering human aspects in the design process of clinical innovations, and point out the limitations of our study.

2 User-centered Design

The term 'User-Centered Design' (UCD), coined by Donald Norman in the 1970's [18], is an iterative project-oriented dynamic design process that incorporates multidisciplinary expertise to meet user requirements and expectations while prioritizing ergonomics and product (hardware/software) usability. The adoption of a multidisciplinary collaborative design approach not only broadens a team's perspectives and skills, but also helps target a larger pool of users and puts them at the center of a product's design and development, leading to better outcomes and greater uptake [1]. While different variations of UCD exist, they all consist of three key principles: user involvement from the beginning, empirical measurement of product usage, and iterative design [2]. A typical UCD process has 5 stages: Research, Analysis, Design, Development, and Testing (Figure 1). The 'disseminate' stage was included to account for the academic research model where knowledge transfer of the results is an important step to generate new ideas and future research directives [22].

A variety of **research** methods can be used to gather and leverage user insights to develop compelling user-centric products. Research includes: market research, observations, interviews and self-reported data, designer analysis and use case diagrams which provide a graphical depiction of a user's interaction with current products, etc. Combining findings from multiple sources and methods helps designers corroborate findings by minimizing inadequacies and increasing the validity and reliability of results. Once sufficient data has been

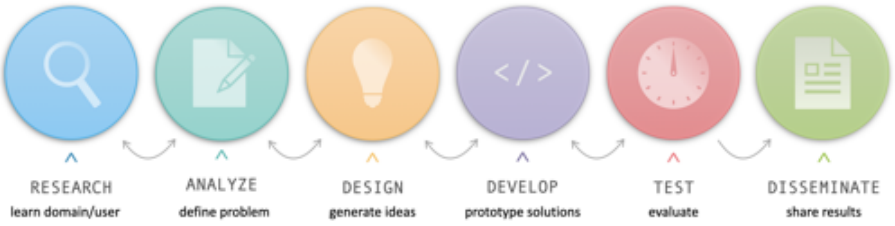

Fig. 1. User centered design is an iterative process with 5 main stages: Research, Analysis, Design, Development, and Testing (Figure 1). We add disseminate at the end of the UCD process to account for the academic research model.

collected, the goals, attitudes and behavioral patterns of the intended user can be deduced and **analyzed**. This helps designers gain a deeper understanding of their users' objectives and information needs, how they perform domain specific tasks and the system specifications required to accommodate these needs that result in concepts and designs that meet user and workflow requirements. After the problem(s) or limitation(s) have been clearly identified, the **design** step is used to generate ideas and tangible designs by incorporating information architecture, creating graphics, and designing user task flows to graphically depict the sequence of events that occur when a user performs a specific task. In order to facilitate the transition from design to **development**, a team must find a balance between design complexity and technical feasibility. Lastly, due to the continuous and dynamic nature of UCD lifecycles, **testing** generally occurs at the end of each design iteration where it serves as a quality check to validate whether the proposed solution successfully addresses specified user requirements and adheres to usability standards. As for evaluations, they are typically performed during the design and development stages and are carried out either heuristically by designers and experts or by end-users via usability testing to reveal and address a combination of different design problems. The former focuses on the compliance of a user interface (UI) with recognized usability principles whereas the latter evaluates the experience (UX) of a product by either testing it with potential users who are asked to perform tasks as they normally would while observers take notes or through the use of metrics to determine usability.

3 Case study

In the following section, we go through a UCD design process in the context of ventriculostomy to illustrate its application as it relates to the development of surgical innovations. Ventriculostomy, one of the most common neurosurgical procedures ($24,380$/year in the US [26]), is an intervention that accesses the cerebrospinal fluid (CSF) pathways when these spaces are either enlarged or filled with blood, resulting in dangerous increases in intracranial pressure (ICP). The technique of ventriculostomy involves drilling a hole through the skull to the

dura mater, and carefully guiding a silicone catheter, the external ventricular drain (EVD), through the brain tissue into one of the ventricles to drain the excess fluid and measure the pressure.

3.1 Research

The research process began with a literature review on the topic of ventriculostomy using Google scholar, the analysis of multimedia sources (videos and images), and a search for commercial ventriculostomy solutions. However, due to the pandemic and the resulting restrictions to emergency rooms (ERs), intensive-care units (ICUs), or operating rooms (ORs), we compensated and opted for alternative source of information, including watching videos of different techniques. After a comprehensive review of the literature (Fig 2), we developed an interactive questionnaire [1] that was sent out to stakeholders.

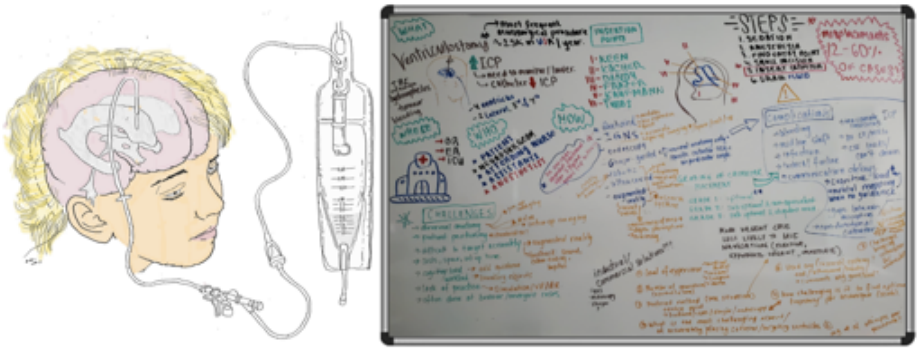

Fig. 2. Left: EVD schematic. **Right:** Whiteboard notes from discussion between HCI/design researchers, medical imaging experts, IGNS developers and engineers.

Procedure: The most common technique for EVD placement is by free-hand insertion. The main steps include: (1) general anesthesia; (2) selecting an entry point (i.e., Keen, Kocher, Dandy, Frazier, Kaufmann, or Tubbs' points, Kocher's frontal point being the most common), (3) local anesthesia, (4) making a small percutaneous incision, (5) drilling a hole through the skull to the dura mater, (6) opening the dura, and (7) guiding the EVD for a distance of about 5 cm, into the ventricles to drain the fluid and monitor the ICP. Whenever possible, pre-operative images, such as computed tomography (CT) or magnetic resonance imaging (MRI) scans, are used to visualize ventricle position, size, displacement, and relevant anatomy. The surgeon relies on external cranial anatomical landmarks to identify the ideal entry point and determine the best trajectory for safe drain placement. Due to cost, time, and equipment constraints, free-hand

[1] https://bit.ly/ucd-ventri

ventriculostomy is routinely the preferred choice [3]. Alternatives to free-hand cannulation include Ghajar guide-assisted cannulation (a physical guide), endoscopic and image-guided neurosurgical (IGNS) systems. Only 3% of neurosurgeons opt for Ghajar guides [13] due to their inability to account for midline shifts (the abnormal degeneration of the brain hemispheres caused by the pressure exerted from the buildup of blood and swelling [23], [19]). Endoscopy is most often used in cases of hydrocephalus[25] and although IGNS systems show promise in determining the safest trajectory to target the ventricles with more precision [5], they are most commonly used in elective settings owing to their expensive, immobile/bulky, time-consuming nature, making them unsuitable for emergency situations [3].

Commercial Solutions: A number of intra-operative neuronavigation systems are available on the market: StealthStation S8 Surgical Navigation System (Medtronic, Minneapolis, USA), VectorVision neuronavigation (BrainLab, Munich, Germany) and Brainsight TMS Navigation, (BrainBox, Cardiff, United Kingdom). As for guiding/mechanical devices, the CODMAN ventriculostomy kit (Integra Lifesciences Corp., New Jersey, USA), and the Ghajar Guide Cranial Drill system (Neurodynamics Inc., New York, USA) are available. As for ultrasound-guidance, the Burr-Hole 8863 (BK Medical Holding Company, Inc., Massachusetts, USA), and the S31KP - Burr-Hole Guidance Transducer (Fujifilm, Massachusetts, USA) or (BK Medical, Denmark) can be used. Ultrasound-guided EVD uses a portable neurosurgical ultrasound scanner with a burr hole transducer as well as a single-use needle guide channel. Robotic-based systems, such as the "Evolution 1" (Universal Robots, Schwerin, Germany) uses a fixed and an articulated mobile platform (Physik Instrumente, Waldbronn, Germany) to assist EVD procedures. The major drawback of ultrasound-guided and robotic guided EVD is the need to enlarge the burr hole more than 13-mm-diameter. Further drawbacks of robot-assisted solutions are cost, configuration, and the extra space required for the hardware.

Research Systems: Many proof of concept systems have emerged in the area of neurosurgery, including mixed reality (augmented and virtual) [4], ultrasound-guided [24], robotic [29], and sonification assisted [20]. Augmented reality (AR) visualization superimpose pre-operative images and surgical plans directly onto the patient thus eliminate the continuous shift in focus between the patient and the IGNS system [15]. AR in ventriculostomy has been used to develop haptic simulation systems for resident students to practice catheter placement[28], interactive mixed-reality-based navigation systems to facilitate the targeting of the ventricles [4] as well as a visualization system using holograms of preoperative CT-generated to guide the procedure [17]. Nevertheless, a number of shortcomings have been linked to AR use, including poor understanding of the depth/visuospatial perception of anatomical data, an inability to provide feedback regarding precision or accuracy of registration, and/or the need to manually hold the AR device [7].

3.2 Analysis

Consistent with the literature, feedback from our survey's participants (from 5 neurosurgeons, 2 residents, 1 IGNS developer) describes the challenges and complications that prevent accurate EVD placement. In urgent settings, where acutely rising ICP mandates immediate ventricular access to stabilize ICP, targeting of the ventricle has been associated with up to 60% misplacement due to human error [21][23]. Based on the results of the questionnaire and reviews, we identified some of the factors that influenced these high rates, such as patient's age (i.e. neonates), abnormal anatomy (i.e. midline shifts, small ventricles), etymology of hydrocephalus (i.e., tumors, intracranial hemorrhage), bedside positioning, neurosurgeon's cognitive load, and lack of training/practice. Complications may included intracranial hemorrhage, midline shift, post-operative infection (i.e., meningitis, ventriculitis), technical/hardware failure (i.e., defective catheter), poor/inaccurate ICP measurements, no access to pre-operative imaging CT/MRI, CSF leakage, subdural CSF collection, seizures, inability to drain CSF, increase of cognitive load (i.e. when no guidance is used), communication delays, and gaps between disciplines [11][25]. All of these factors, in turn, can lead to increases in the length of hospital stays, morbidity and mortality [8].

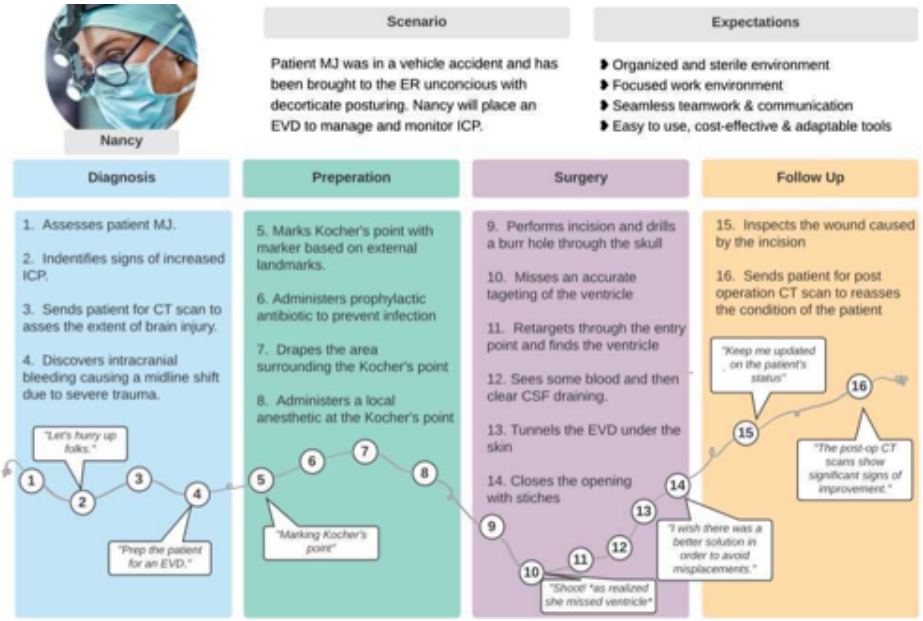

Fig. 3. Journey map of Neurosurgeon Nancy's main goals, frustrations, and specific needs while performing an urgent free-hand ventriculostomy. Dialog boxes express Nancy's thoughts and feelings at every stage of the scenario, and a trajectory line depicts the positive and negative moods.

After assessing the different challenges, we created a journey map [2] to describe a neurosurgeon's objectives, specific needs, and pain-points during ventriculostomy. Specifically, based on the results of our survey, we created the persona (archetype user) "Neurosurgeon Nancy", who works in a Canadian hospital and performs 1-2 EVD placements per week. Despite having access to IGNS systems, she always opts for freehand ventriculostomy as this is what she is most comfortable with. In addition, she has encountered all of the complications that were found in the literature, such as sub-optimal catheter placement, revisions, haemorrhage, and abnormal ventricular anatomy (i.e. midline shifts and small ventricles). Figure 3 outlines the different stages of interaction that Neurosurgeon Nancy goes through as they take place in her actual user environment; the resources, mechanisms or mediums of interaction; and the user's emotional state at each stage of the experience.

3.3 Design

This phase encourages the generation of solutions to improve the user's experience. Often, low-cost/low-effort designs are created (e.g., sketches, wireframes, mockups, and storyboards) in conjunction with risk components/processes that get tested in an experimental setting. Testing becomes an iterative process, aiming to align solutions with the ergonomic preferences and criteria of acceptance.

Based on insights gathered from the questionnaire, primary users and their workflows, the authors of the paper had an ideation session where prospective solutions were identified. The focus was placed on key product design decisions for improving the targeting of the ventricles using a free-hand technique together with pre-operative images. Particular attention was paid to the use of tablets, mobile phones, and wearable devices for augmenting virtual images onto an anatomical space. Haptic feedback is considered as an alert mechanism to prevent damage to tissues/vessels. Other solutions considered included the use of sonification and deep learning to determine optimal trajectories.

Storyboards are visual aids used to communicate ideas of designs in a multidisciplinary team. In the context of product design, design teams use them to model user experiences and interactions with current or future products or services by using them as a medium of communication between team members and stakeholders [10]. They are used to detect a user's emotional engagement when performing a specific task. Figure 4 shows our storyboard, which narrates the flow of events from a normal to a problematic situation occurring in a fictitious ventriculostomy procedure and illustrates our vision of technological utility in clinical practice. In this story, Neurosurgeon Nancy and Resident Rakeem, perform a bedside procedure with the assistance of a mixed-reality solution.

[2] A journey map is a tool used to illustrate the user's workflow, and cognitive load, while they are performing a specific task with the aim of identifying their main objectives and frustrations.

Fig. 4. Storyboard of design solution using augmented reality, deep learning optimal trajectory planning, and sound guidance to perform a bedside ventriculostomy.

3.4 Develop

The final phase in this process is the development of one or more prototypes. The activities associated with this phase include building a feasible prototype and usability testing (described in the next section). Although we did not develop a functional prototype as it is beyond the scope of this paper, we nevertheless took on the task of aligning and validating prospective solutions with the acceptance criteria. To achieve this, we analyzed the results of our survey and found that 60% of the participants agreed that a sub-optimal catheter placement was a major complication of free-hand ventriculostomies. We also considered comments for improving the usability of our proposed solutions, such as "need something fast and accurate used in multiple settings" and "it needs to be introduced early in training and be easy to use and adaptable". We agreed that the introduction of novel technologies during training is essential as it can help facilitate the adoption and integration of technological artifacts into the operating room. Furthermore, we found that 50% of the responses were looking for cost-effective solutions to include in their daily practice. Therefore, based on these findings, we are encouraged to develop low-cost solutions that facilitate the localization of the ventricles with higher accuracy by leveraging intra-operative imaging and augmented reality for educational/training purposes as well as any of the applicable clinical settings (i.e. urgent, elective, emergent case).

We present two mock-ups that we designed based on the ideation session and survey responses. By leveraging the portability, affordability, and interactivity capabilities of tablets, our proposed system extends the MARIN system [16] for the projection of entry point, catheter trajectory and navigation to the target ventricles. Figure 5 (left) illustrates a mock-up of an AR tablet-based solution. With this solution, we combine gestures and anatomical landmarks to perform real-time manual registration between patients and virtual data (i.e. entry point, trajectories, and anatomical models). We envision the tablet being clamped to the patients bedside. Figure 5 (right) depicts a mockup of a mixed-reality solu-

tion using head-mounted displays. More specifically, we will utilize the ergonomic design, gestures, and visual capabilities of HoloLens II (Microsoft, Washington, USA) to enable similar tasks. Since combining sound and visual cues can reduce cognitive load in neurosurgery [20], we will integrate sound and color coding visualizations to assist with depth perception (e.g. changing color of catheter when on optimal trajectory). Haptic feedback is another way to explore depth perception and re-direct navigation.

Fig. 5. Mock-ups of prospective augmented reality prototypes for users to evaluate in terms of design (UI) and usability (UX). **Left:** tablet and **Right:** head-mounted display solutions.

3.5 Test

The testing of a functional prototype is beyond the scope of this paper. However, from the beginning of the UCD process, we defined the requirements that our product will be evaluated against. Based on the results of our research, survey answers, and written and oral exchanges with neurosurgeons, we would consider the requirements of any ventriculostomy innovation: ease of use, easy to set-up, efficient, fast and accurate in multiple settings, adaptable, and cost effective. In addition, we would provide examples of evaluations for functional prototypes against the aforementioned requirements. As for the user study, we would ask participants to complete specific tasks while we observed their experience and document specific system's behaviors. For example, let's consider the following tasks: (1) allow surgeons to test the user interface of HoloLens, (2) perform registration/visualization of pre-operative imaging and anatomy, and (3) navigate to the target ventricle. Ideally, evaluations would be performed in the user's natural setting where the solution would normally be used (e.g. ICU).

Performance evaluations of these tasks would be based on objective and subjective success metrics. In our case study, we would measure, e.g., set-up time, the number of interactions performed, accuracy in catheter placement, and execution time. We would also conduct subjective assessments to measure the robustness of visualization, aesthetics of user-interface, cognitive load, attention, and overall user experience. To achieve this, we would utilize Think Aloud, an

assessment tool where users thoughts and actions are recorded while performing a task; the System Usability Scale (SUS) [6] a subjective assessment tool that measures usability and user satisfaction; and the NASA Task Load Index (TLX) [12], which rates perceived workload while performing a task or immediately afterwards. After testing a number of different prototypes, a clinical trial would generally take place using the finalized system.

4 Discussion

Technology development strategies vary greatly from one project to another. Often the design choices depend on the type of technology (i.e., software or hardware), development tools available, size and skills of the development team, complexity of the project, budget, risks, communication/feedback from stakeholders, and certain assumption about the usage of the final product. With traditional development approaches realizing how end-users will actually engage and interact with the product often comes late in the development cycle. However, modern design methodologies recognize the importance of centering the design and development process around the user. In this paper, we identify the benefits of considering human aspects throughout the design of clinical solutions. We also show that a user-centered approach is valuable when designing and developing technologies in the clinical domain.

There are a number of limitations of this study that deserve to be mentioned. Despite the efforts made to disseminate the survey through different mediums, we only collected responses from people affiliated with medical centers in Canada, US, Mexico, and Guatemala. Therefore, the user and workflow requirements as well as the design decisions proposed in this study are biased towards western nations. Furthermore, to date we have a limited number of responses (8), with zero responses from certain stakeholders (e.g. anesthetists, nurses, and practitioners).

5 Conclusion

Next-generation surgical tools, coupled with advancements in hardware, medical imaging, virtual and augmented reality, and artificial intelligence, are profoundly impacting healthcare with improvements in patient care, quality, and safety of surgical procedures. However, their adoption into clinical workflows and daily practice has been slow, or even disregarded, due to an inadequate understanding of the primary users, usage, ergonomics, and other pragmatic considerations often overlooked during their development.

With this ventriculostomy case study, our aim was to demonstrate the steps needed to drive the development of successful surgical solutions using a user-centered design approach. Furthermore, we highlight the importance of multidisciplinary collaboration and how it can generate efficient, explainable, and usable solutions based on acceptance criteria stipulated by the persons intended to use them. With the user validating the solution at every step of the development cycle, a strong sense of trust can be built before the novelty is accepted

into practice. One key advantage of using an iterative design process is that communication becomes an integral part of the design by making concepts and ideas tangible and thus accessible to all disciplines and users for discussion and evaluation. Such discussion and feedback are necessary for evaluating new technologies and providing evidence of their benefits. We believe that design will eventually take a more prominent role in the development of surgical tools and technologies and will be the driving force behind pushing innovations from laboratory to clinic.

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