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DESIGN OF AN ERGONOMIC ELECTROSURGERY SMOKE EVACUATOR: A CASE STUDY FOR DESIGN OF MEDICAL TECHNOLOGIES

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INTRODUCTION

In the medical technology field the knowledge required is multi-disciplinary and the needs are complex. The design of a medical technology is constrained by many factors including regulatory, economic, environmental, sustainability, manufacturability, ethical, and socio-political elements [1]. The adoption of a new medical device relies heavily on its ability to fit into the multifaceted medical environment and satisfy the users' needs. These needs are often overlooked in the traditional design process, which focuses on the functional requirements of the device and user input is often sought in later stages of the design [2].

User centred design principles are becoming apparent in medical device regulations, emphasizing their importance to the field. The US Food and Drug Administration (FDA) requires developers to apply human factors principles throughout the design process in order to "identify, understand and address use-related hazards" [3]. We believe that it is essential that the device be designed to meet contextual needs such as environmental and user based needs, as much as functional requirements.

This paper outlines many of the eccentricities of innovating in the medical technology field in contrast to other fields. The approach being proposed here will be demonstrated through the design and evaluation of the first generation prototype of an electrosurgery smoke evacuation device as summarized in Figure 1. This device was designed as part of a term project for the Engineers in Scrubs (EiS) graduate program at the University of British Columbia (UBC), an emerging biomedical technology innovation program.

Details on market analysis, the medical device approval process and commercialization of a new device are very specific to the device itself, only a brief introduction to these topics will be covered in this paper. However, insuring the safety and efficacy of the new device and abiding by the standards set out by regulatory bodies are of great importance to medical device innovation.

DESIGN PROCESS

The design process begins with needs finding, the main focus of which is to observe and analyze clinicians in their work environment in order to fully understand current clinical practices and identify existing technology gaps. Needs finding is followed by needs screening, which includes more observation, research and communication with stakeholders to validate the chosen focus. By the end of this phase, the innovator should have established a deep, clear and unbiased understanding of the needs. Multi-disciplinary teams and clinical immersion during needs finding and screening can ensure that a truly significant clinical need is identified [4].

Once the need is fully defined, the concept generation and selection can begin. The key to idea generation in the medical technology field is to eliminate biases in the concept proposing process by incorporating members from multiple disciplines. Finally, by comparing the concepts with the needs statement, the innovators can start to evaluate ideas and a

few promising concepts are explored further. This may lead to iteration due to new ideas, needs or requirements.

1. Needs finding

NEEDS IDENTIFICATION: There are many different ways to identify a need in the medical technology field including consultation with medical professionals, clinical observation and clinical research.

The need for our project was identified during a seminar involving seven surgeons from the vascular surgery department at Vancouver General Hospital (VGH) and the students enrolled in the UBC EiS program. The team of surgeons presented ongoing problems in their field. From this list of problems, through discussion and preliminary research, we identified the need for a better smoke evacuation system for electrosurgery. Our team consisted of four EiS students, an engineering design mentor and a cardiovascular surgeon as the clinical mentor.

OBSERVATION: By clinical observation, innovators can identify needs or technology gaps and glean more important insights for potential improvements in the medical technology field. In the observation process, thinking from stakeholders' perspectives and maintaining an open mind are essential.

Since the need presented in this paper was identified by stakeholders' descriptions, it was important to conduct observations in order to fully understand and characterize the need present in an unbiased manner. Observations were made in surgery in order to understand current clinical practices and techniques. Two videos were provided to the team by the clinical mentor demonstrating the electrosurgery process in animal testing with and without smoke evacuation. These videos allowed us to view the effect of smoke evacuation in a more controlled environment. From these observations, we identified that the main issue with the current generic design of smoke evacuation systems (a vacuum tube connected to a suction device) is that it was not designed to integrate fully with the electrosurgical device. It interfered with the surgeon's ability to perform and eventually was not utilized in the operating room.

NEEDS STATEMENT: Creating the needs statement is the process of translating a problem into solution-independent key points that should be met by the design concept.

Based on observations and preliminary research, each team member identified a preliminary set of needs and formulated a needs statement. From the individual needs statements a list of key points was extracted: intent of design, ergonomics of the design, cost and risk to OR personnel. The final needs

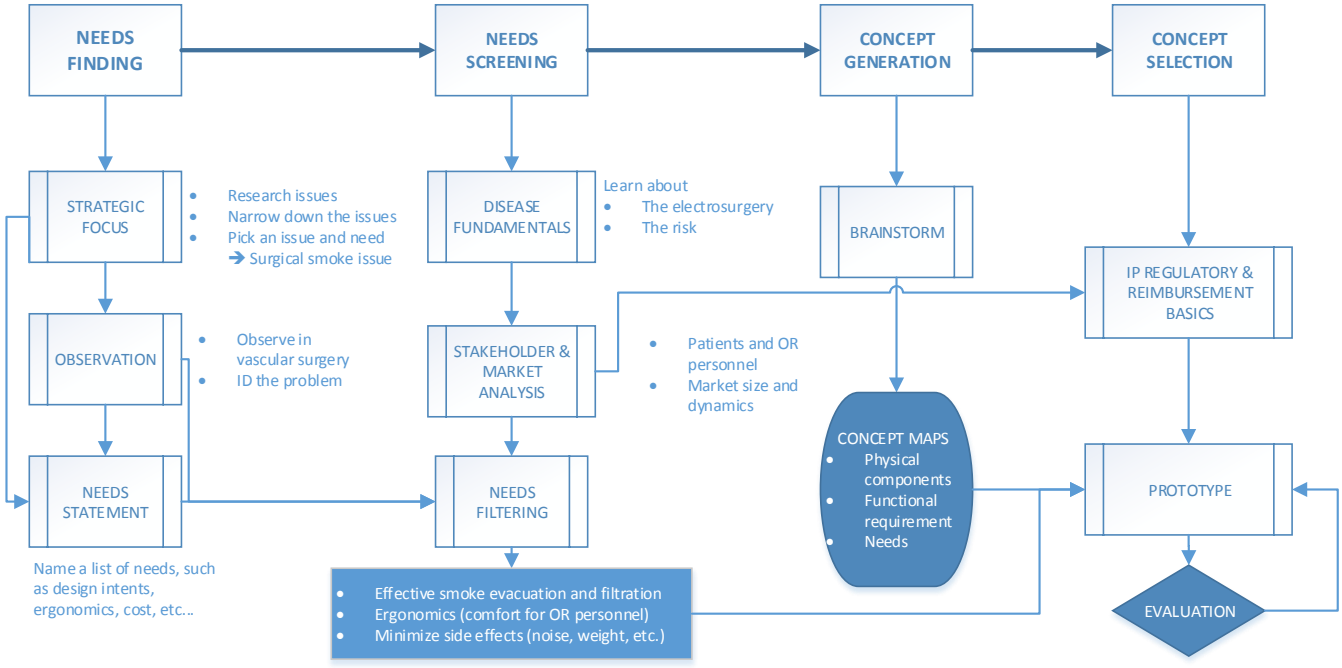

Figure 1: Electrosurgery smoke evacuator design process overview

statement was developed by combining all the key points listed above: "*We aim to remove 95% of surgical smoke in order to reduce the risk of surgical smoke exposure to the OR personnel by designing a device intended to work with the current electrosurgery units in a way that does not affect a surgeon's performance.*"

This paper is focused on the ergonomics of the device. The device is currently undergoing rigorous functional testing as part of its second iteration in order to address other aspects of the needs statement.

2. Needs screening

DISEASE FUNDAMENTALS: Fundamental knowledge of the clinical relevance of the need and current and emerging technologies can guide the design conceptualization, market analysis, regulatory approval process and intellectual property protection.

In this project, the disease fundamentals study focused on four questions: What is the electrosurgery process? Why do we need smoke evacuation? How do the current smoke evacuators work? And why don't surgeons use these current devices?

STAKEHOLDER & MARKET ANALYSES: Stakeholder analysis should include a systematic examination of all the interactions between all parties involved in financing and delivering care and the device itself. Market analysis should include information on market size, market dynamics, and market needs. These analyses are closely related to each step in device development.

For our stakeholder analysis, both cycle of care and flow of money analyses were used to identify stakeholders involved in the everyday use of the device as well as those who finance it. OR personnel at risk from inhaling the surgical smoke produced by electrosurgery were identified as the primary stakeholders.

Our market analysis involved research on the current electrosurgery smoke evacuator being used at VGH and other technologies available in the market to evacuate smoke in electrosurgery as well as laparoscopic surgery, such as Eschmann® smoke evacuation system, Conmed® Surgical Smoke Solution and CooperSurgical® smoke evacuation systems.

3. Concept generation and selection

CONCEPT MAP: Concepts are generated through a series of brainstorming and ideation sessions. These concepts are then grouped together to create a visual map. Ideas can be grouped in different ways or categories which may lead to a different visual representation of these same concepts. Concept maps can help bring out synergies, gaps or biases in the set of concepts generated. Figure 2(A) shows the concept map that summarizes this project based on physical components and their functional requirements. The smoke evacuator

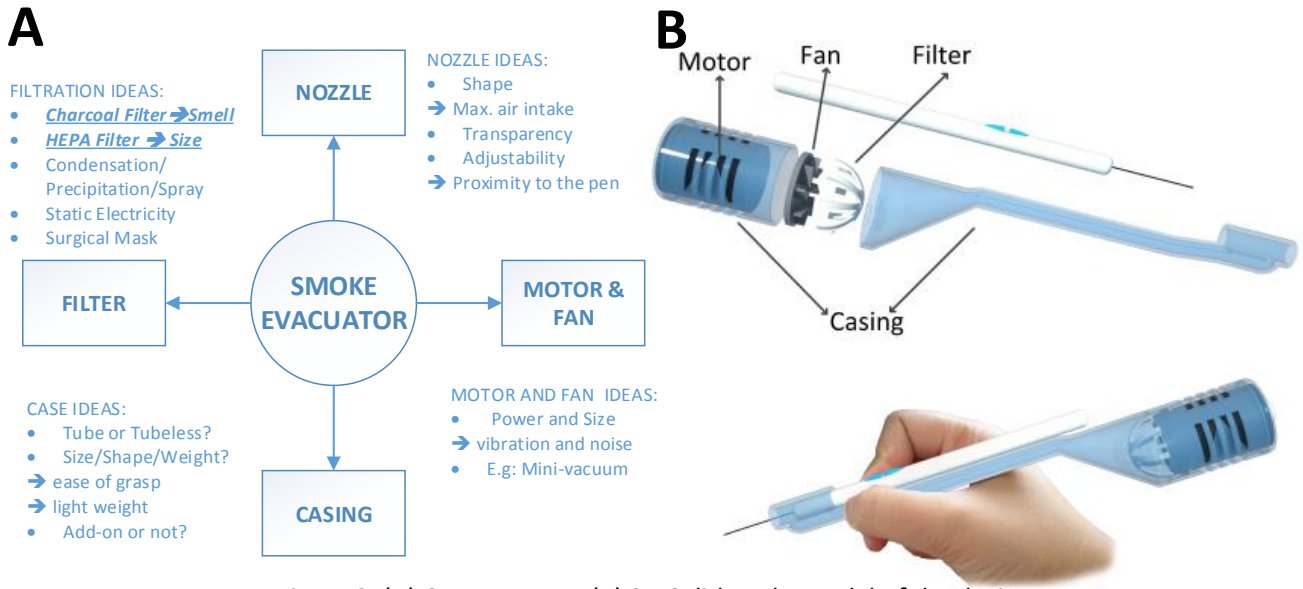

Figure 2: (A) Concept Map; (B) 3D SolidWorks model of the design

was dissected into four parts: nozzle, filter, motor/fan and casing. This map helps outline the functions of each individual part while still keeping an open mind to how they fit together to create the final device.

CONCEPT SCREENING AND SELECTION: This step in the design process compares the concepts in the concept map to the requirements. This is done to screen the concepts in order to pursue a limited number of promising ideas. Prototypes are then developed in order to evaluate these concepts. Lastly, the innovator should be able to select concepts for the final design of the device.

For each physical component, we proposed a series of concepts that were evaluated based on the design criteria and the needs statement. Figure 2(B) illustrates the 3D model of the final prototype after the concept generation and selection process.

The shape of the casing was designed to conform to the electrosurgery pen as well as the surgeon's grip. The motor/fan and filter units were integrated into the evacuator design rather than being a separate unit off-site to minimize interference with the surgeon's performance. The relative positions of each physical component were determined based on ergonomics principles. Prototypes of the device were developed by fixating the motor and fan at different positions on the electrosurgery device. Comfort, weight and usability were evaluated for each configuration and the end-heavy configuration was chosen based on evaluations from two users.

We ran tests to evaluate the suction capability of four different nozzle shapes and different motor/fan units. For these tests, surgical smoke was produced and evacuated by different prototypes of the device. Video footage analysis of the tests demonstrated that a straight nozzle minimizes the amount of smoke escaping from the tip of the electrosurgery pen (5-10 percent depending on the orientation of the device). The motor/fan units need to remain small and lightweight. A 5V DC motor satisfied these requirements and also provided enough power to filter the smoke.

Based on manufacturer specifications, a HEPA filter (Flanders®) was chosen to eliminate molecules in the size range of the harmful molecules present in the smoke [5]. This was combined with a charcoal filter which successfully removed the unpleasant odor of the surgical smoke.

The first generation prototype of the device was made by combining the selected concepts. The overall clip-on design considers ergonomics and human factors and is able to remove and filter the majority of the created surgical smoke.

CONCLUSION

This paper demonstrated the first iteration of the medical technology innovation process through a case study. A second iteration of the design has been developed as a capstone design project in UBC Department of Mechanical Engineering and is being tested with surgeons for ergonomics and filtration ability. A medical technology design process can lead to a successful product by investing in a more rigorous needs finding process, including the end user in the design team, and by iterating the ideas and concepts to reach a functional solution that will fit in the context of the problem.

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