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Portable Cricothyrotomy Medical Simulator: Can design help save lives in an emergency?

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Abstract
In 2012, the Masters of Design (Industrial Design) program at the University of South Australia was approached by Dr Michal Wozniak of Adelaide University Medical School, one of Australia's premier medical educational institutions, to develop an affordable, portable, Cricothyrotomy Task Trainer, in order to facilitate the medical simulation of the Cricothyrotomy procedure, to allow prospective doctors and nurses as well as existing medical professionals, to practice and become competent in this form of surgery. The Cricothyrotomy is an emergency procedure that facilitates the insertion of an air-tube through the cricothyroid membrane, in the event of an upper-airway blockage, which is commonly the result of facial trauma typically found in vehicle crash situations. This technique is often thought of as the procedure of last resort, as the patient can no longer breath and they are about to expire. Practice with a Cricothyrotomy simulator will normally be the last opportunity a student has to develop skills in the procedure, before they may be required perform the technique on a living human being.

In the field of medical training, there is a need for cost-effective and well-designed medical simulators, which allow trainee doctors and nurses as well as other groups of medical professionals, to practice various lifesaving procedures. An iterative research, design, prototype and test, methodology was employed in order to materialise:

- *An anatomically accurate medical simulator that allows the cricothyrotomy process to be taught and practiced, permitting students to locate and find all relevant anatomical landmarks, execute the procedure using the same tools that would be required in an actual blocked-airway situation, and to receive the same anatomical feedback on the execution of the task, as they would expect to receive from an actual human.*
- *A simulated experience which would accurately reflect the operational challenges and patient variation that would be expected in a real life or death situation.*

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- *Modular solution, allowing the simulator to be adapted to simulate different patient scenarios (for example, an overweight person versus somebody of normal weight).*
- *The ability to have the cricothyrotomy procedure performed on the simulator to a high degree of accuracy. This involves an individual making an incision at a precise point on the neck, located primarily by touch and feel.*

A commercialisation agreement was negotiated and signed between the University of South Australia's technology transfer company, ITEK, and VBM, a medical simulation company based in Germany. The product has since been tooled for manufacture and is now commercially available. The "Crico Trainer" was also a finalist in the 2014 James Dyson Awards and the Hills Young Australian Design Awards 2014.

Keywords: medical simulation, industrial design, digital fabrication, prototype, exploratory test, assessment test, validation test, immersion, realism

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Introduction

The profession of Industrial Design is experiencing significant change. Designers now face problems which involve complex systems, which require new forms of interaction. The advent of social networking, mass customisation, advanced manufacturing and online design tools, are resulting in new methods of communication and engagement, which are changing the environment and skills required by Industrial Designers. Globalised trends in manufacturing have resulted in the transfer of manufacturing from first world economies, to lower cost manufacturing regions. These changes have had had a profound effect on the role of Industrial Design and hence the ways in which it Industrial Designers are educated. No longer can an Industrial Designer simply step outside the design office onto the factory shop floor, in order to witness and resolve a Design for Manufacturing (DFM) issue first hand. An Industrial Designer's DFM education in the past would have been supplemented through this type of no-the-job interaction, but now the factory manufacturing a particular product may be many thousands of kilometres away. Iterative prototype fabrication and testing can to some extent provide students with the opportunity to explore detailed manufacturing issues first hand.

Medical simulations are imitations of real-world situations which aim to provide realistic, immersive, situational training that mirrors the medical practice environment of the real world. The ultimate goal of the procedure is to engage the participant in a training scenario to the point where it feels genuine and in order to accomplish this, the level of realism must be high. Student opinions of simulation realism have been discussed in several studies and have invariably been described as being significant to information retention (Devitt *et al*, 2001; Feingold *et al*, 2004; Reznek *et al,* 2003). Knowledge is best retained when the information cues are embedded within the simulation scenario. Offering information to a student in a situation that is bare of appropriate indicators and cues, makes the recollection of correct information more difficult.

Medical simulation based training complemented with realistic medical task simulators and scenario cues, permits the student to translate both information and cues, therefore increasing the probability of effective recall when the condition is represented in a real life situation. Collins and Harden (1998) stated, "The more realistic the patient representation, the more likely will the examination assess what the student will do in practice".

While simulator-based medical educational experiences are generally highly regarded, students and lecturers frequently mention the lack of clinical-realism and feedback from many task trainers as a significant limitation. When a high degree of clinical-realism is achieved, the immersive effect on the simulation participant can be high J. A. Gordon (2004). Tulving and Thomson (1973) stated that information is best retained when the cues for the information are embedded within the simulation scenario. Offering information to a student in a situation that is bare of appropriate indicators, makes recollection of correct information more difficult. High fidelity task trainers are therefore an effective pedagogical approach to medical education.

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For many learning situations, especially for teaching particular tasks and skills, it may be only necessary to simulate individual elements of a patient or task. Task trainers therefore only aim to provide the key aspects of a procedure which is being learned. While they do not aim to simulate a high-fidelity patient simulator, they are a cost effective way to allow students to develop the skills required for specific medical procedures.

The Design Problem

The cricothyrotomy procedure permits patient oxygenation during an upper-airway blockage, often resulting from a massive facial trauma commonly experienced in unrestrained vehicle crash situations. The procedure is not regularly performed due to participant uncertainly with the procedure. Medical practitioners and paramedics however need to be sufficiently proficient to confidently undertake the technique, to allow it to be performed correctly in an emergency situation. This is often the procedure of last resort, where incubation has failed and it allows the direction of oxygen directly to the patient's trachea and is undertaken normally when the patient is about to expire. There was therefore a need to develop a task training device which was able to; faithfully simulate a cricothyrotomy procedure by providing authentic feedback as is found in a human analogue; allow the procedure to be repeated a number of times with minimal maintenance between each use; be simple to store and maintain; adaptable to represent worst-case-scenarios in patient anthropometrics and it should be affordable, making the simulator accessible to the widest audience possible.

Cricothyrotomy Procedure

A cricothyrotomy is in general terms, a lifesaving procedure where an opening is made through the skin on the neck of a patient just below the Adam's Apple and a second deeper incision made through the cricothyroid membrane with a tube being inserted through this opening, in order to create an airway through which a patient can breathe. A needle cricothyrotomy is a similar procedure, but instead of making a scalpel type incision through the skin and cricothyroid membrane, a large "over-the-needle" catheter is inserted. Therefore, the key functionality required from the task trainer is:

- The ability to identify the incision position on the skin at a specific point on the neck of a patient below the Adam's Apple, which is located primarily by touch.
- The cannula and needle should then be inserted through the patient's Adam's Apple.
- The Needle should be removed leaving the cannula in place.
- A thin guide-wire is then inserted through the cannula down into the patient's windpipe.
- The cannula is removed leaving the guide-wire in place.
- A scalpel is used to make small incision at base of guide-wire.

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- A Melker Cricothyrotomy Kit is then threaded onto the guide wire and inserted into windpipe.
- The guide-wire is finally removed leaving the Melker kit in place allowing the patient to breath.

The product should accurately reflect the physiological variables that are encountered in an actual medical crisis, allowing the task trainer to be adapted to mimic a variety of different patient analogues, such as an overweight person as opposed somebody of moderate weight.

The Proposed Product

The product vision for the design and development of an anatomically accurate medical simulator which allows the Cricothyrotomy procedure to be taught and practiced, allowing students to locate all relevant anatomical landmarks, execute the procedure using the same tools that they would use in a real situation and to receive the same types of patient feedback on the execution of the task, as would be expected while performing the procedure on a real patient.

Requirements

- The procedure will be performed with the actual medical instruments required to successfully accomplish the task.
- The product must be easily maintained (cleaned and consumable parts replaced)
- The product must be affordable.
- The product must be easily packed away and stored for long periods of time without deterioration when not in use.
- Modular, to allow disassembly for transport and the replacement of damaged components.

Realism

- The simulator needs to closely resemble the anatomy of a human neck.
- Physically, the product should have a high degree of realism specifically in the neck region, and possibly mimic the lower facial structure which may restrict access to the neck in an emergency.
- The simulator may be adaptable to replicate different medical indicators such as an ashen, pale appearance or use interchangeable simulated soft tissues to alter the diameter of the neck, restricting clear access to the cricothyroid cartilage.

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- Every effort should be made for the simulator to 'feel' human, not only in skin texture, but also to the extent that a user can feel the rigid structures of the throat below a movable, elastic and flexible skin.

Cleaning and Maintenance

- The product must be easy to store and maintain
- Any detachable or consumable items must be replaced easily, quickly and economically.
- If the simulator is required to be cleaned, this should be achievable with minimal effort, without requiring specialist technical knowledge.

Technical Challenges

- Tissue consistency and anatomical accuracy are important considerations.
- As the procedure involves puncturing the skin of the simulator, it is likely that the material simulating the apparatus skin may need to be replaced over time.
- The product must therefore be able to undergo the procedure at least 50 times with minimal maintenance between each use.
- A method for removing and replacing damaged 'skin' will also need to be considered.

Commercial Goals

- Design a medical simulator that theoretically can be produced in low numbers for less than existing competitive products on the market.
- Consider efficient use of materials and processes and so reduce unnecessary production costs.
- Ensure that consumable materials such as the simulator's skin are equally economical to replace.

Methodology

The design exercise was undertaken over one and a half academic years, and the approach was structured within a Stage Gate new product development process focusing on problem research, concept development, prototype development and testing, product finalization, documentation

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and commercialisation. Each of the design process phases consisted of smaller sub-stages that allowed for detailed user experience research to be undertaken, observing users within a medical simulation environment and seeking expert advice on the many iterative prototypes that were developed, from educators within Adelaide University Medical School and clinicians at the Royal Adelaide Hospital.

The process also involved close concurrent collaboration with business through the University of South Australia's technology transfer company ITEK and technology providers through the use of digital fabrication technologies as described in Figure 1.

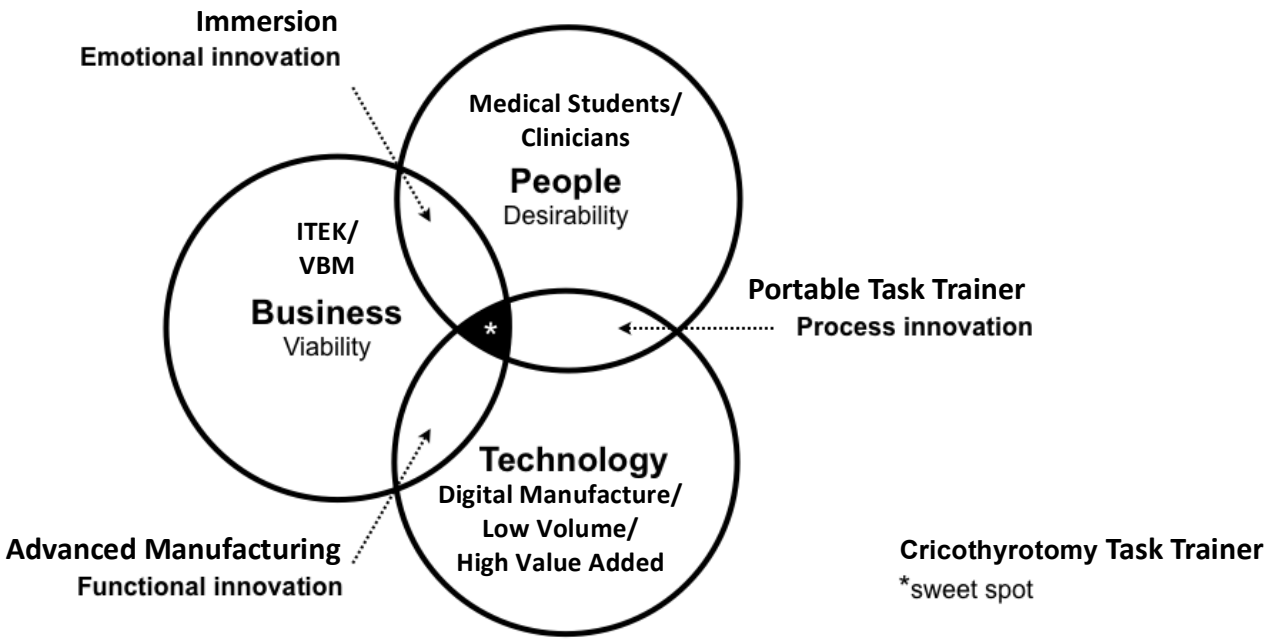

Figure 1: User Centred Design Approach

Effective product design and development methods centre on the ways in which R&D activities can be successfully planned, managed and executed. The process can be viewed as an arrangement of synchronized activities and decisions which progress the product development process from initial problem identification, through to a final detailed problem solution (Walker, 2014). The process of design is fundamentally an iterative methodology, which includes the expression of the problem which is to be solved, researching, collecting and analysing information, the application of creative thinking approaches, and the exploration of potential problem solutions through prototyping and testing and finally applying an optimised solution. During the product development process, it is essential to differentiate between different categories of prototype and test that can be applied at different stages of new product development. This process

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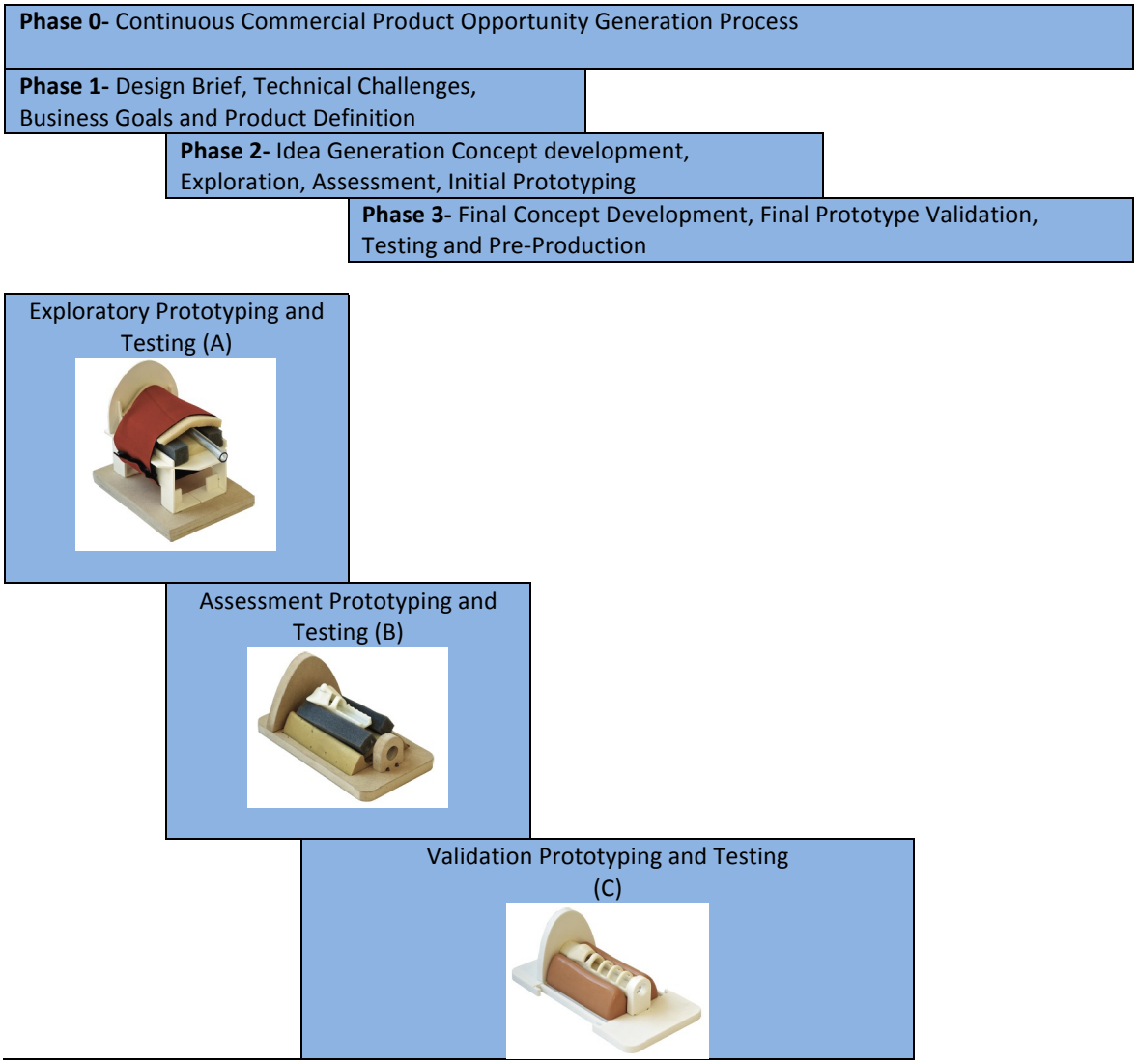
assists designers consider the intent of each prototype developed. Alternative prototyping and test methods have different purposes, methods and categories of simulation:

- Exploratory prototyping and testing
- Assessment prototyping and testing
- Validation prototyping and testing
- Comparison prototyping and testing

A typical new product development method will normally, consist of multiple phases, as detailed in Figure 2. The process is normally represented diagrammatically with overlapping phases, to illustrate the iterative character of the product development process (Cooper, 2005).



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Comparison Testing (D)	

Figure 2: Exploratory, Assessment and Validation Simulator Prototyping Stages

It is vitally important that prototypes are continually evaluated and screened against usability metrics, to ensure that only concepts which meet user expectations, advance to the next phase. Over the entire design process, in excess of 10 iterative functional prototypes were simulated, constructed, tested and evaluated by students and clinicians, leading to the final simulator design which was adopted for manufacture by VBM, as shown in Figure 3.

Figure 3: Final Student Design and Final Manufactured Simulators

Summary

Iterative design, prototype building, testing and evaluation using digital technologies can provide industrial designer students with the ability to thoroughly evaluate complex interactive designs and explore many alternative design concepts with experts in the field as shown in Figure 4, before the final commitment to a particular production proposal.

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Figure 4: Prototype Evaluation Process

More importantly, it can help replace the loss of first hand manufacturing experiences resulting from the transfer of manufacturing away from first world economies. Iterative prototyping fabrication and testing can provide Industrial Design students with the opportunity to explore detailed manufacturing issues first hand.

Cricothyrotomy Simulator Development Team

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VBM: VMB is a manufacturer of high quality medical products and medical simulators.

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