Proving the proof of concept; developing new methods and knowledge to evaluate products supporting cancer therapy

REED, Heath <http://orcid.org/0000-0003-2615-3315>

CASE STUDY:
Proving the proof of concept; developing new methods and knowledge to evaluate products supporting cancer therapy

Heath Reed
Art and Design Research Centre, Sheffield Hallam University, Sheffield, UK

Abstract

This article illuminates through a case study, SuPPORT 4 All (Support, Positioning and Organ stabilisation during breast cancer Radiation Therapy / S4A). It describes how three-dimensional design research assesses, assimilates and is applied to define product requirements in a cross-disciplinary research team, activity occurring concurrently, yet also informing the act of designing the eventual products themselves. The study describes how a multidisciplinary research and development team, more specifically the design researchers within it, developed a range of holistic knowledge sets to establish critical criteria to validate physical outcomes. The study illustrates the methods used and developed to elicit the scale of the challenge and discusses the validity of these methods and technologies when wide-ranging design specifications may not exist at project outset.

Keywords – Research design, new knowledge, innovation, applied research, cross disciplinary, radiation therapy, prototyping.

Introduction

The terms proof of concept (PoC) or proof of principle (PoP) are widely used in the fields of product design to describe objects, devices or technologies that demonstrate the feasibility of how a thing may look or function. In the context of product design their primary purpose is to verify performance so that evaluations can take place that confirm the viability of a proposition, idea or concept in support of a new product development opportunity. Three broad categories of proof of concept exist; things that "look" like the design intent, things that perform like the design intent and things that both look and function as per the design *intent*.

With respect to the term *intent*, the descriptors "demonstrate", "evaluate", "verify", and "feasibility" suggest that at project commencement some form of compliance criteria or metrics knowledge exist by which the measure of success or failure of a new PoP proposal can be determined. Or that there is in existence some form of technical or use requirement specification that can be applied to emerging concepts. But what happens when we do not know what these success criteria are? An unmet need may have been identified but how do we use design research to ascertain what the parameters from user acceptance issues to technical success of a new device or system might be?

Through this case study, we identify key values developed by a "proving the proof of concept" methodology to new product development.

Context

Many successful designs in the health domain can be shown to address unmet needs, be cost effective, function well and be accepted and adopted by users. Therefore a successful design

encapsulates and embodies broad and holistic criteria. Will it work? Can it be manufactured? Will it be cost effective? Will people accept or want to use it?

When we set out to address new and less well understood problems there can often be little knowledge or understanding by the development team of the challenges to be addressed. For a clinician, a firm understanding of a critical manufacture process may be missing. For the user, how a particular feature may have clinical advantage may not be appreciated, and for the designer the specifics of a particular medical condition or procedure may not be known. Domains for new product development in health are obviously very broad, from orthotics to cancer treatment and from hardware to system design. Therefore unless the design researchers specialize in one or two interrelated areas, for example oncology and device design, the designers are rarely expert or experienced in any one particular clinical field. There are accepted deficiencies of knowledge in terms of what technical, cost or user acceptance "metrics" may be called on to make positive or negative judgments about a proposed device or system PoP/PoC solution.

This case study illuminates the use of three-dimensional design methodologies in an investigative context to help determine the viability of particular design responses. It illustrates a number of facets of value which are not exhaustive nor mutually exclusive. These are the result of a series of experiments including the development of prototypes, rigs, test equipment, or creating "devices" that assist exploration in developing new knowledge and better outcomes.

Problem area and challenges

The SuPPORT 4 All (S4A) project focuses on the development and provision of technology in the form of a garment that assists in the positioning of a patient's breast tissue during the course of cancer radiotherapy. The project was funded by the National Institute for Health Research (NIHR) Invention for Innovation (i4i) programme.

Radiotherapy is used in an adjuvant[1] context following surgical removal of the tumour following a breast cancer diagnosis. The purpose of using radiation therapy is to avoid local recurrence of the tumour within the breast. Accuracy of radiotherapy plays a key role in ensuring positive outcomes for patients with a breast cancer diagnosis, good cosmesis and limited side effects in normal tissue close to the breast. While there have been advancements in recent years in technical precision and treatment within the radiotherapy clinic (hardware, equipment, methods), the breast itself can be said to remain "mobile". As such, variations in patient set-up as a result of tissue mobility during radiotherapy can negatively impact on treatment accuracy. In this project, a repeatable method of both stabilizing and positioning mobile breast tissue was sought. Whereas stabilization is key to treatment accuracy, positioning is key to ensuring the affected breast is in the correct location to be treated and the unaffected breast is positioned out of the treatment field. The project further investigated and aimed to address issues of patient dignity during treatment as people undergoing this therapy are regularly required to do so naked from the waist up.

The primary aim of the project is the design of PoP prototype garments that could be tested at increasing levels of complexity in iterative steps. These range from "lab based" experiments ("lab" as in the use of test rigs and early non-human experimentation in controlled settings), to in-CT[2] scanner on "phantoms"[3], before testing in a human patient study or Clinical Feasibility Study (CFS). For reasons of safety, ethics, and governance, the design team was unable to physically test, first hand, and explore early physical design concepts on people. The goals at each stage were to validate that

the emerging designs and PoP garments were in fact capable of immobilizing, stabilizing, and positioning, in a repeatable manner, so that the radiotherapy could be delivered more accurately and safely and offer the patient a more dignified experience. As stated, the key focus of this project was the design of the bra itself but knowledge needed to be built and assimilated by the team in order to establish relevant design criteria. For example, how might we actually test for accuracy success? How might we understand the effect of our proposals on radiation dosimetry[4] within the supported breast? How do we build knowledge about human anthropometrics of the target groups, of the appropriate garment materials, features, garment construction and manufacture?

An earlier, pre-NIHR i4i funded phase, investigation had been conducted by members of the team and the broad, core principles of a proposed enabling technology for a S4A radiotherapy bra was identified. Early low-level design concepts were proposed in response to criteria known at the time, and the clinical and healthcare experts in the team had a deep and rich understanding of those anatomical, procedural, and medical physical issues. The design team (the individuals primarily tasked with finding and enabling solutions), however, did not. By some means that disciplinary specific knowledge, at least partially, needed to be learned and understood by the design team.

The team, comprising end users, clinical oncologists, medical physicists, dosimetrists, therapy radiographers, Patient and Public Involvement (PPI) experts, garment manufacture partners (Panache Lingerie Ltd.), and design researchers agreed that devices and systems needed to be developed to help both understand and test PoP bra designs as they advanced.

Addressing the Challenges

The team knew that a device was required to test candidate bra designs prior to conducting a human study, to capture data about performance. In medical physics “phantoms” are used for these purposes but most available phantom products are made from a mix of “stiff” or “rigid” materials of various densities and as such are hard, “non-mobile” structures. As previously noted, one of the predeterminers of the research was ensuring that the breast could be positioned in a way that the cancer treatment beam did not intersect with internal organs such as the heart and lungs or other organs at risk (OAR).

As this phase of the project involved understanding the effect of PoP devices on mobile breast tissues, how the breast might be positioned and re-positioned, and its relationship to OAR, it was determined that conventional “rigid” female phantom torso products could not be used for this purpose. Therefore, a “hybrid rigid mobile phantom” (HRMP) was proposed. The design researchers set about the definition, specification and the detailed design and construction of a HRMP phantom. The device, developed iteratively, finally consisted of an off the shelf, rigid male phantom torso containing conventionally simulated internal organs and physiological structures and of generic adult human anatomy (heart, lungs, bone structures etc.) that could be viewed via normal imaging procedures (i.e. CT and x-ray). The male phantom was then enhanced and encapsulated by, and with, custom-made, mobile, female body forms (simulated breasts). The HRMP became affectionately known as “Barbra”.

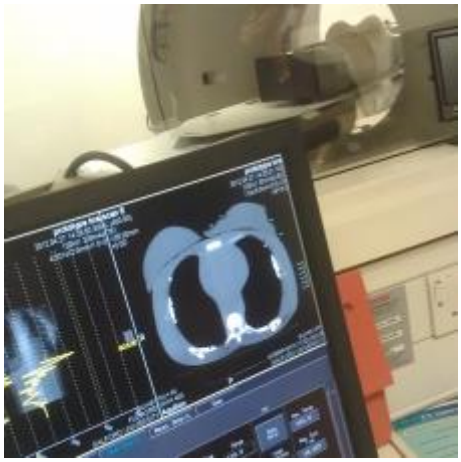

Figure 1. Example of a CT scan showing section through mid-chest.

An example of a CT scan (foreground) of the effect of an early PoP bra prototype on a simulated breast is shown in Figure 1. This imaging “slice”, at mid-chest, shows the proximity of the heart and lung (organs at risk - OAR) tissue in relation to a patient's left breast. In the background the hybrid phantom can be seen in situ within the CT scanner.

The team developed specific material combinations and production techniques that replicated as closely as possible target breast shape and size, and simulated degrees of breast tissue mobility, generally as a product of target patient age. The phantom needed to act like normal breast tissue in terms of mobility but under CT imaging be viewed as close as possible to tissue in terms of greyscale i.e. it had to be sufficiently radio-opaque or radio translucent to replicate as closely as possible the real scenario, thus allowing subsequent radiation dosimetry planning. This added an additional challenge to the phantom build. Just as a product design itself evolves through a series of design iterations, this “proving” system evolved through a number of development versions. Shown in Figure 2. this is an early stage example of the HRMP. It was constructed from liquid filled, shaped, thin walled rubber breast forms that were then attached to the rigid male phantom torso.

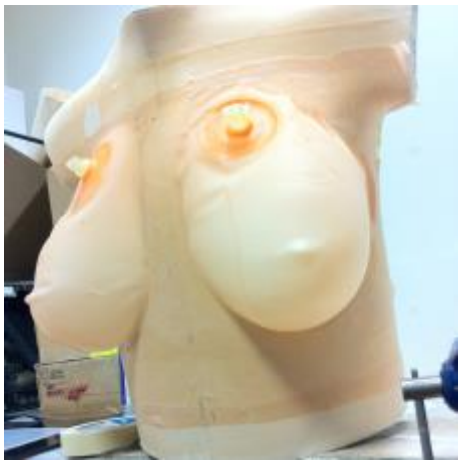

Figure 2. Example of an earlier iteration of the “hybrid rigid mobile phantom” (HRMP “Barbra”).

Following refinement of the HRMP “proving” device PoP bra garments could be CT scanned in situ on the hybrid phantom and data sets in the form of CT images and numerical data produced for PoP bra performance analysis. In this way the effect of bra prototypes on breast tissue, in terms of optimal positioning (optimal positioning of the breast being critical to dosimetry) and re-positioning the breast could be tested. Ensuring the PoP design did this while avoiding or minimizing the radiation dose received by OAR could be better understood by the multidisciplinary team.

Figure 3. The refined hybrid phantom (HRMP) device being prepared for a CT scan

Value of approaches

Alongside the clinically biased bra performance data that was produced, the design, development, and construction of the hybrid phantom by the research team proved a highly valuable means of embedding knowledge about other requirements of the proposed interventions.

For the HRMP to be created, the designers were required to draw on a number of sources to build knowledge about human factor considerations, form and “material” constitution and performance. Knowledge was developed about human anatomy, in particular about female anatomy in a predominately male design team, awareness about bra size, comfort, fit and construction and about the variety of breast shapes and body anatomies the eventual design needed to cater for. This exploratory work led to a better understanding of human breast tissue mobility and integrity as a product of patient age. For example, in the final phantom design the team developed specific material combinations and production techniques that, as closely as possible, replicated both the target breast shape and size as well as simulating degrees of breast tissue mobility.

By way of example only, in one PoP bra version tested (illustrated in Figure 4.) a “hard” tissue transition from the lower rib cage to lower breast tissue was observed. The team determined that, besides any associated comfort concerns, such features may negatively impact on radiation dosimetry. A modification to the next iteration of the PoP bra design included features to “smooth” the tissue transition.

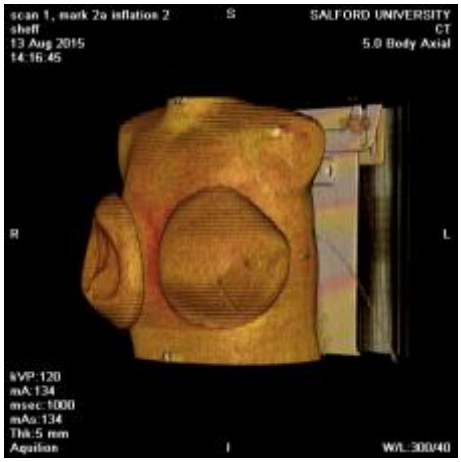

Figure 4. Example of 3D composite image using CT data showing the result of a PoP prototype bra in situ on the hybrid phantom.

At this stage the team were able to see for the first time the effect on simulated breast tissue shape resulting from PoP bra prototypes. This had not been possible prior to 3D CT composite imaging as the PoP bra prototypes were not able to be constructed from optically transparent materials so the research team could not visually observe the effects of the PoP bras directly. Ultimately, it is radiation dosimetry that dictates the success of the bra design but the process of HRMP definition, design and construction produced key insights into how the physical design may be modified to optimize treatment.

Benefits of engaging in these ways included building a more granulated understanding of the processes, techniques, and expertise involved in delivering radiotherapy. The use of CT systems to plan radiotherapy “boundaries”, treatment pathways and, last but not least, the technical challenges all inform the eventual product design.

Conclusions

The S4A hybrid phantom work allowed the product development team to get up close and “hands on”, albeit in a simulated sense, with the physicality of breast tissue factors, “material” behaviour and also to learn about the challenges of positioning the breast where the designer researchers were unable to experiment on and with real people. Of course, the design task in this project is the development of the garment itself but the design and development of such “proving” devices and systems helped the team to identify design features and to prioritize their importance.

Although just one area of enquiry of the entire project, the phantom work enabled the building of knowledge – both for the design researchers and wider team. This was essential because it enabled the designers and the broader team to recognize new design opportunities and to invent new product features. The example shows how design research has developed techniques and methods to uncover different types of insight. This “new to the designer” knowledge became a part of the tacit understandings of the S4A device requirements which are embedded in the final PoP pre-production prototype outcomes.

The example further shows that the product specification can grow and evolve in parallel with the design of things, but that to achieve this, design needs to be engaged in activity “around” the

intended product; activity that seeks to “prove the proof of concept”; because it informs the product designers who are tasked with designing the eventual end product. The activity further informs clinical oncologists, therapy radiographers, dosimetrist and physicists of the potential benefits of bra based approaches on the accuracy and effectives of treatment. The case study broadly illustrates collaborative, multidisciplinary research during and in parallel to the new product design process but a specific aspect of focus in this context is the use of “proving the proof of concept” design approaches that enable understandings to be built in the entire team about what is both acceptable and achievable in terms of product performance. At the time of writing the hybrid phantom device itself and the methods used to create it appropriately for CT scanning investigations are new to clinical practice.

The methods and approaches described here take the idea of praxis (Praxis; the process by which a theory, lesson, or skill is enacted, practiced, embodied, or realized) as explorer / investigator, discoverer and definer, as well as problem resolver. Applying design in these ways can ensure more holistic considerations are made towards greater acceptance of outcomes because they lead to a closing of the gap between what does not exist yet (the proposed new product idea) and the broader identification (usually by non-design disciplines) of the unmet need.

It is argued that objects such as these help cut through the many difficulties of multidisciplinary working; difficulties of depth of knowledge, method, discipline semantics and experience. The act of designing and making experiments to test hypothesis further embeds knowledge in the designers and clinicians about the condition and the needs of the users.

Design can be highly capable of directing and supporting such challenges through its creative approaches, skills and methods. But these kinds of projects can be highly challenging. For them to succeed, productive multi-disciplinary teams need to be assembled and each team member is required to actively learn from the other disciplines as mutually as is possible. In designing for health, and when meeting currently unmet need with currently unknown solutions, individuals must be able to both convey and understand the other disciplines’ challenges, methods and language to greater or lesser extents.

Funding
This report is independent research funded by the National Institute for Health Research (Invention for Innovation (i4i), Support, Positioning and Organ Stabilisation during Breast Cancer Radiation Therapy: SuPPORT 4 All Bra II-LA-0214-20001). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Acknowledgments
The author and S4A project team gratefully acknowledge Professor Peter Hogg and the Medical Imaging, Radiography team at the Centre for Health Sciences Research, University of Salford, Manchester, the Health Care Practitioners and consulted patients who kindly gave their time and insights. Sheffield Teaching Hospitals NHS Foundation Trust, Panache Lingerie Ltd. the projects industrial partners, the S4A project team including Professor Heidi Probst, Principal Investigator, and Mr Andrew Stanton, the projects Creative and Technical Design Research Assistant responsible for the HRMP phantom construction design.

Address for correspondence

Heath Reed
Art & Design Research Centre
Sheffield Hallam University
Cantor Building
153 Arundel Street
Sheffield S1 2NU

H.Reed@shu.ac.uk
0114 225 6762

Biography

Heath Reed works with the Art and Design Research Centre (ADRC) and Lab4Living (L4L) as Senior Research Fellow based at Sheffield Hallam University (SHU). He has worked in the creative industries for many years and since the mid-1990s has focused on three-dimensional design and the role it can play in bringing about product innovation. Heath is the recipient of a number of design awards, named inventor on a portfolio of intellectual property, is Principal and Co-investigator researching, designing, delivering, and directing a range public and commercially funded new product research.

---

[1] adjuvant - applied after initial treatment for cancer, especially to suppress secondary tumour formation.

[2] CT – "Computed Tomography" is a type of X-ray used to produce detailed images of internal organs and their positions.

[3] "Phantoms" are body mannequins (or individual body parts) made from materials that simulate varying tissue properties that can be CT scanned.

[4] Dosimetry is the measurement of the absorbed dose delivered by radiation.