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The relation between patient discomfort and uncompensated forces of a patient support device for breast and regional lymph node radiotherapy

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ABSTRACT

Although many authors stated that a user-centred design approach in medical device development has added values, the most common research approach within healthcare is evidence-based medicine, which tend to focus on functional data rather than patient wellbeing and comfort. End user comfort is well addressed in literature for commercial products such as seats and hand tools but no data was found for medical devices.

A commercial patient support device for breast radiotherapy was analysed and a relation was found between discomfort and uncompensated internal body forces. Derived from CT-images, simplified patient free-body diagrams were analysed and pain and comfort evaluated. Subsequently, a new patient position was established and prototypes were developed. Patient comfort- and prototype optimization was done through iterative prototyping. With this approach, we were able to compensate all internal body forces and establish a force neutral patient free-body diagram. This resulted in comfortable patient positioning and favourable medical results.

1. Introduction

Currently, the two major concerns in medical device development (MDD) are improvement of patient safety and medical performance (Scanlon et al., 2006; Balka et al., 2006; Peters and Peters, 2007; Mullaney et al., 2012). Medical device tests are usually focused on functional data and conducted under technical vision and not in the real environment in which the devices will be used. However, non-functional data such as user emotions and usability aspects have not yet been fully covered (Tanure et al., 2015).

One of the most common research approaches within healthcare in the western world is evidence-based medicine. It has been defined as an approach to healthcare that "integrates individual clinical expertise with the best available external clinical evidence from systematic research in order to ensure the best prediction of outcomes in medical treatment" (Sackett, 1997; Sackett et al., 1996). The strong emphasis on clinical research in evidence-based medicine results in high level of importance upon functional data and measurable variables. Subsequently, they tend to distance themselves more from less quantitative (and functional) measurable aspects (such as patient wellbeing and comfort) (Mullaney et al., 2012). Healthcare professionals and administrators are recognizing the importance of a user centred care approach and that medical care delivered solely from a biomedical perspective is unable to produce an acceptable level of care, from a patient perspective (Mullaney et al., 2012; Edvardsson et al., 2006, 2008).

1.1. Comfort

End user comfort is well addressed in ergonomics literature for commercial products. One of the most researched is sitting comfort (De Looze et al., 2003). Little published work exists on end user comfort of medical devices (Martin et al., 2010; Sawyer et al., 1996). If research was conducted, topics such as patient safety and ergonomics (Martin et al., 2010; Clarkson et al., 2004), user comfort for medical staff (instruments) (Loring and Lemieux, 2010; Xiao, 2014), patient comfort during operations (Jensen et al., 2002) and medicine handling and dispensing (Dong and Vanns, 2009) were broached.

There are several factors which influence discomfort. As Zhang et al. (Cordell et al., 1995) conclude for sitting, physical factors such as ache, blood circulation cut-off, cramped and sore muscles, stiffness, etc. underlie discomfort. Additionally, shape elements of the device can also

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Fig. 1. Process of the simplified patient FBD and its centre of gravity (COG) determination: Left: transverse section of CT-scanned patient with contoured patient support device and fixation strap. Middle: CAD-simulation of COG (red cross) with dark blue area as lung region (0.3 g/cm^3) and light blue area for rest of the body (1 g/cm^3). Right: derived CT-illustration with simplified FBD. Blue areas represent the patient support device, purple area represents the arm fixation strap. Red vectors represent gravity forces, blue vectors represent normal forces and green vectors represent reaction and friction forces. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

affect patient discomfort: wrong anatomical proportions, partially body support and uneven pressure distribution (Cordell et al., 1995).

In the case of MDD we could say feelings of discomfort can be associated with physical factors while comfort can be associated with feelings of relaxation and well-being (Zhang et al., 1996). Some additional factors which can influence comfort and discomfort for patients using or lying on medical devices are: treatment time, fixation and patient immobilization, patient mobility, material properties and the design of the medical device itself.

This paper focuses on the design of the medical device itself and the relation between uncompensated internal forces in the patient free-body diagram (FBD) and discomfort.

1.2. Breast board

Devices used for this study are so called breast boards (Fig. 3). A breast board is a patient support device for breast (and lymph node) radiotherapy. Prone position breast radiotherapy has several advantages in comparison with supine position (Monten et al., 2015; Mulliez et al., 2015; Soegaard and Dam, 2013). However, it is challenging for patients requiring whole breast irradiation (WBI) and lymph node irradiation (LNI). Our aim was to investigate a new, comfortable patient position and device which is suited for both WBI and LNI.

1.3. Objective

The objectives of this study were: (1) to specify pain- and pressure points on the currently used breast board (AIO™ Orfit) and compare

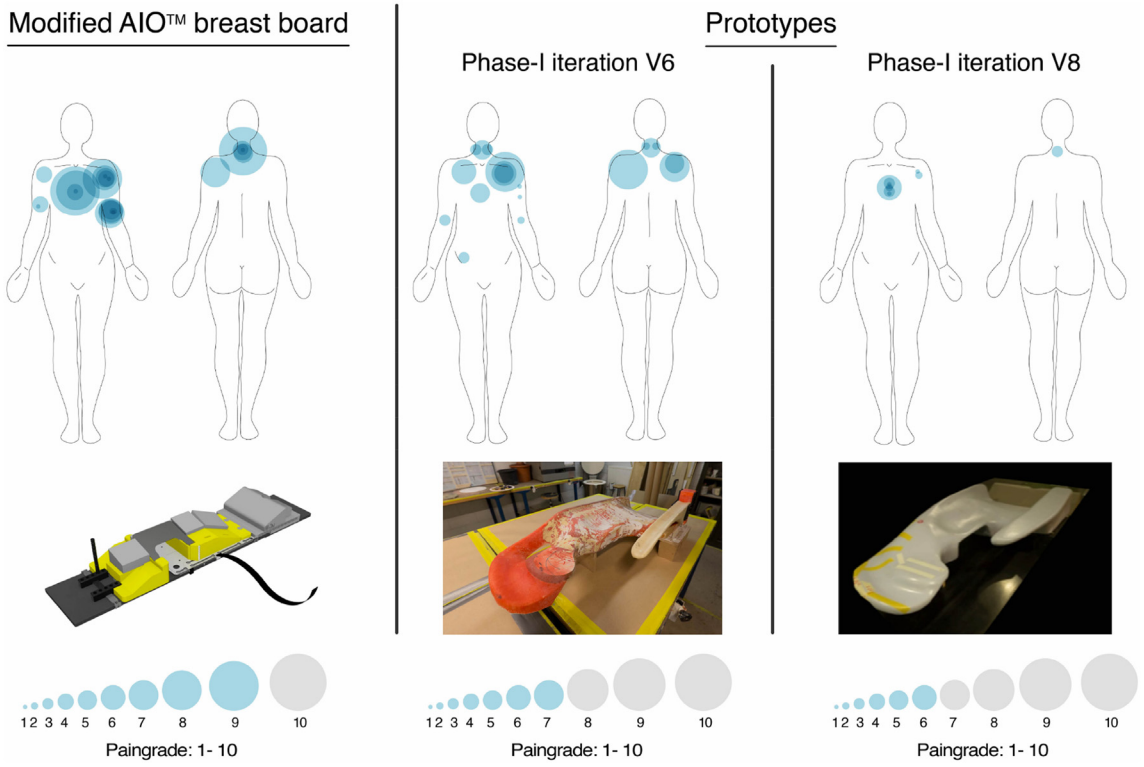

Fig. 2. Visual representation of the pain and comfort scored on the modified AIO™ Orfit breast board, iteration V6 and V8 breast board. Blue circles represent pain or discomfort; radius is the pain grade from 1 to 10, grey circles on pain scale were unused grades; number of overlapping circles, and thus colour intensity, indicates the amount of people experiencing pain at this location. Each time 9 patients were evaluated. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)