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Universiteit Gent

Prof. Wilfried De Neve – *promotor*
Vakgroep Radiotherapie en Experimenteel Kankeronderzoek
Universiteit Gent

Prof. Jan Detand – *promotor*
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Universiteit Gent

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Vakgroep Radiotherapie en Experimenteel Kankeronderzoek
Universiteit Gent

Prof. Patrick Segers
Vakgroep Elektronica en Informatiesystemen
Universiteit Gent

Dankwoord

Toen ik afstudeerde als industrieel ingenieur: Industrieel Ontwerpen, kreeg ik de prachtige kans om verder te werken op mijn master thesis: *"De Optimalisatie van de Buikligpositie Tijdens Borstradiotherapie."*. Dit sprak mij enorm aan omdat ik mij kon verdiepen in twee verschillende werelden.

Het ene luik van het doctoraat is medisch georiënteerd en focust zich vooral op de medische resultaten, anatomie en comfort van de patiënt. Dit viel onder de vakgroep: *Radiotherapie en experimenteel kankeronderzoek*. Ik kon mij verder verdiepen in radiotherapie, borstkankerbehandeling, anatomie van de mens, patiënten opvolgen en bevragen, behandelingen meevolgen en samenwerken met het medische team.

Het andere luik van het doctoraat focust zich eerder op het functioneel en efficiënt ontwikkeling van medische prototypes en validatie. Dit viel onder de vakgroep: *Industriële Systemen en Productontwerp*. Hier kon ik mij verder verdiepen in het uitvoeren van gebruikerstesten, medical device development, gebruik van composieten en vele andere moderne technologieën voor de ontwikkeling van prototypes.

Doordat deze twee werelden een zeer verschillende aanpak van werken hebben, maakte dit het doctoraat juist zo interessant. Ik zocht een gulden middenweg tussen de twee onderzoeksgroepen en werkte aan een project dat mij enorm veel voldoening gegeven heeft. Ik leerde met andere onderzoekers en bedrijven samenwerken en deed ervaring op in zowel de academische, technologische en medische wereld. Voor deze reden wil ik graag iedereen bedanken met wie ik de afgelopen 4 jaar heb kunnen samenwerken.

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Op naar een volgend avontuur!

Bert Boute
Kortrijk, oktober 2018

CONTENTS

LIST OF ACRONYMS

3D	Three-Dimensional.
ABS	Acrylonitrile Butadiene Styrene.
BMI	Body-Mass Index.
CAD	Computer Aided Design.
CAM	Computer Aided Manufacturing.
CBCT	Cone-beam CT.
CDRH	Centre for Devices and Radiological Health.
CNC	Computer Numeric Control.
COG	Centre Of Gravity.
CT	Computed Tomography.
DIBH	Deep Inspiration Breath-hold.
DVH	Dose-Volume Histogram.
EC	Ethics Committee.
FAGG	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten.
FBD	Free Body Diagram.
FDA	Food and Drug Administration.
FDM	Fused Deposition Modeling.
FE	Finite Element.
FoS	Factor of Safety.
GHTF	Global Harmonisation Task Force.

HCI	Human Computer Interaction.
Hi-Fi	High Fidelity.
IP	Intellectual Property.
LINAC	Linear Particle Accelerator.
LNI	Lymph Node Irradiation.
Lo-Fi	Low Fidelity.
MD	Medical Device.
MDD	Medical Device Development.
MDF	Medium-Density Fibreboard.
MI	Mammaria Interna.
MRI	Magnetic Resonance Imaging.
NB	Notified Body.
NRS	Numerical Rating Scale.
OAR	Organs at Risk.
PA	Polyamide.
PC	Polycarbonate.
PI	Pain Intensity.
PMMA	Polymethyl Methacrylate.
PS	polystyrene.
PU	Polyurethane.
PVC	Polyvinyl Chloride.
QoL	Quality of Life.
RF	Radio-Frequency.
RIM	Resin Infusion Moulding.
SME	Small and Medium Enterprises.
TNM	Tumor, Node, Metastasis.
TV	Target Volume.
UCD	User-centred Design.

UX	User Experience.
VAS	Visual Analogue Scale.
VRS	Verbal Rating Scale.
WBI	Whole Breast Irradiation.
X-Ray	Röntgen Radiation.

Samenvatting

Van alle gediagnostiseerde kankers over de hele wereld, zijn 12% van de gevallen borstkanker bij vrouwen. In Europa is dit buiten huidkanker, de meest gediagnostiseerde kanker met 362 000 gevallen in 2012. In 2015 werden in België 10 378 vrouwen geregistreerd met borstkanker. De kans dat een Belgische vrouw voor haar 75ste borstkanker krijgt is een op negen. Gelukkig is in ons land het sterftecijfer voor borstkanker de laatste decennia gedaald met ongeveer 10%.

Meerdere studies tonen aan dat de borstkankerbehandeling met adjuvante radiotherapie in de buikligpositie verschillende voordelen heeft in vergelijking met de ruglig positie: een meer homogene dosis verdeling in de te behandelen borst; het beter sparen van vitale organen zoals longen, hart en slokdarm; reductie van acute toxiciteit en verlagen van het risico op geïnduceerde longkanker of hartschade. Echter zijn de huidige commercieel verkrijgbare devices voor buiklig (verder prone breastboards genoemd) ontoereikend en hebben verschillende gebreken. De prone breastboards hebben niet de mogelijkheid voor de bestraling van de regionale lymfeklieren (hiervoor worden nu ruglig devices gebruikt), er is gelimiteerde bewegingsvrijheid van de gantry voor interessante bundelrichtingen, er is dikwijls pijn of discomfort en een verlaagde set-up precisie wordt vaak geregistreerd.

Het UZ Gent kwam daarom met de vraag om een nieuw device te ontwikkelen welke geschikt was voor het comfortabel behandelen van zowel de borst als lymfeklieren in buiklig. Dit met een verhoogde precisie, bundel access en betere medische resultaten, in vergelijking met de ruglig behandeling. Anderzijds is het ontwikkelen van medische apparatuur een complexe procedure waar rekening moet gehouden worden met zaken zoals: eisen en wensen van verschillende stakeholders, protocollen, wetten, ethische aspecten en gebruikerscomfort. Met als gevolg dat de klassieke aanpak voor het ontwerpen van medische devices vaak niet voldoet.

Hieruit volgend werd het onderzoeksproject opgericht naar *"De Ontwikkeling van een Nieuwe Patiëntpositie en Device voor de Radiotherapiebestraling in Buiklig van Borst- en Regionale Lymfeklieren"*.

Dit project onderzocht enerzijds vanuit een medisch perspectief de mogelijkheid tot het comfortabel en effectief bestralen van zowel borst- als regionale lymfeklieren in de buikligpositie; en anderzijds vanuit een industrieel ontwerp perspectief hoe we functionele en efficiënte medische prototypes kunnen ontwikkelen, welke gebruikt kunnen worden voor klinische studies en validatie.

Een van de meest gebruikte aanpakken voor het ontwikkelen van medische devices is *Evidence-Based Medicine*. Dit richt zich voornamelijk op de functionele en meetbare data die verkregen zijn uit gecontroleerde testen. Niet functionele en minder meetbare data zoals patiëntcomfort en welzijn zijn vaak minder belangrijk. Sinds enkele jaren begint er erkenning te komen dat medische zorg enkel vanuit een biomedisch perspectief niet voldoende is. Er moet een meer *"patient-centred"* aanpak komen die dus ook rekening houdt vanuit het perspectief van de patiënt zelf. Doormiddel van een meer user-centred en co-design georiënteerde aanpak, zou dit kunnen opgelost worden. Echter worden gebruikers bij de ontwikkeling van vele medische devices pas relatief laat betrokken in het proces en worden gebruikerstesten tijdens de ontwikkelingsfase vaak beperkt tot het uiterst noodzakelijke. Dit kan zijn omdat medische apparaten vaak *"technology driven"* zijn en strenge tijds- en financiële beperkingen hebben. Met als gevolg verkiezen veel bedrijven liever snelle winst boven een niche product dat nog niet volledig bewezen is, efficient is of terugbetaald kan worden aan de patiënt.

Via ons eigen ontwikkeld framework voor het ontwerpen van medische prototypes wilden we daarom aantonen dat het mogelijk is om aan de hand van verschillende iteraties (zowel klein als groot) efficiënte en medisch effectieve prototypes te maken, welke al heel snel konden getest worden met de gebruikers. Op deze manier konden we vroeg in het ontwerpproces verschillende aspecten testen en valideren.

De ontwikkeling van de devices is onderverdeeld in 5 fasen, gaande van *Preliminary Research (ofwel Phase 0)* tot en met *Phase IV*.

Tijdens de Preliminary Research (Phase 0), exploreerden we verschillende concepten en onderzochten mogelijke patiëntposities. Hieruit kozen we een lichte, asymmetrische draagstructuur met prone crawl patiëntpositie: een positie waarbij de patiënt een fase vanuit het crawl zwemmen nabootst: de arm aan de ipsilaterale kant is naast de patiënt gepositioneerd en de contralaterale arm is boven het hoofd gepositioneerd. Om een goed bereik van bundels te hebben voor regionale lymfeklierbestraling, mag de schouder aan de te bestralen kant niet ondersteund zijn. In Phase I (hoofdstuk 7) hebben we deze positie verder uitgewerkt en getest met zeer eenvoudige prototypes. Zo konden we snel het patiëntcomfort evalueren en het potentieel van de prone crawl positie aantonen. Tijdens Phase II (hoofdstuk 8) werd het patiëntcomfort verder geoptimaliseerd alsook de modulariteit en instelbaarheid voor verschillende patiënttypes en de introductie van de vloerlaser voor patiëntpositionering. Dit is een lineaire laser die vanaf de grond een lijn projecteert op de borst. Aan de hand van deze laser konden we de set-up precisie en positioneren van de patiënt verbeteren. Om de devices uitgebreid te kunnen testen, werden in Phase III (hoofdstuk 9) vier volledig functionele devices ontwikkeld: twee linkszijdige en twee rechtszijdige. Alsook werden nieuwe concepten voor hoofdsteunen en armsteunen geëxploreerd, geproduceerd en getest ter verbetering van comfort en medische resultaten. Uiteindelijk werden

in Phase IV (hoofdstuk 10) twaalf devices ontwikkeld voor een geplande studie met 390 patiënten verdeeld over drie ziekenhuizen.

Tijdens iedere fase werden verschillende testen uitgevoerd ter validatie. Er werden gebruikerstesten, comfort evaluaties, feasibility trials, kadaverstudies en in silico behandelingen uitgevoerd.

Door de iteratieve aanpak en toepassing van het framework hebben we succesvol de nieuwe prone crawl positie en device kunnen ontwikkelen. Hiermee konden we aantonen dat de behandeling van zowel borst als lymfeklieren op onze device beter is in vergelijking met de commercieel beschikbare devices. We hebben verbeterde setup precisie, betere dosis verdeling voor de borst, het beter sparen van vitale organen en sterke verbetering van het comfort verwezenlijkt. Er wordt momenteel verder gewerkt aan de optimalisatie van de device + integratie van nieuwe functies zoals MRI compatibiliteit, productie optimalisatie en de integratie van een niet-invasieve ventilator voor de verlengde breath-hold techniek (zie future work).

Summary

Of all worldwide annual diagnosed cancers, 12% is female breast cancer. In Europe, this is the most commonly diagnosed cancer (excluded from skin cancer) with 362 000 cases in 2012. During 2015, there were 10.378 cases of female breast cancer registered in Belgium. As a result, there is a chance of one out of nine that a female Belgian woman will be diagnosed with breast cancer before the age of 75. Luckily, the mortality rate has decreased with approximately 10% over the last decade.

Several studies provide evidence that prone radiotherapy treatment for breast cancer has several advantages in comparison with the supine position treatment: better dose distribution for the to be treated breast, better sparing of vital organs such as lung, heart and thyroid, less acute toxicity, less risk of radiation-induced cardiac toxicity and of lung cancer induction. However, commercially available prone devices are inadequate and the patient set-up is associated with a complicated procedure, reduced precision, discomfort and pain. Furthermore, prone radiotherapy is especially challenging in patients requiring both breast and regional lymph node irradiation because of unfavourable anatomy caused by bilateral arm elevation and restricted choice of desirable beam paths.

Based on the above reasons, the Ghent university hospital felt the need for the development of new patient support device which could treat both breast and regional lymph nodes in prone position, be comfortable, have improved set-up precision, better access for favourable beam paths, and overall improved medical results in comparison with the supine treatment technique. On the other hand, the development of medical devices is a complex procedure which must take into account all the requirements and wishes of each stakeholder, protocols which need to be followed, laws, ethical aspects, user comfort and technical aspects. With the result that the classic approach for medical device development is inadequate.

Based on these findings, the research project was set up on *"Development of a New Prone Patient Support Device for Radiation Therapy of Breast and Regional Lymph Nodes"*.

Since this project was hosted by two research groups, we investigated two research aspects. One aspect originated from the department of radiotherapy and experimental cancer research and investigated the possibility for effective and comfortable treatment of both breast and regional lymph nodes in prone position. The second aspect originated from

the department of industrial systems and product design and investigated how we can develop functional and efficient medical prototypes, which can be used form clinical studies and validation.

One of the most common research approaches within healthcare and medical device development in the western world is evidence-based medicine. It focuses mainly on functional data and measurable variables. Non-functional requirements and less measurable aspects such a patient wellbeing and comfort, tend to be less important. During the last years, healthcare professionals and administrators are recognising the importance of a patient-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. By means of a more user-centred and a co-design approach, this could be solved. Nonetheless, during current medical device development, users are in general relatively late integrated into the design process and user-tests during the development phase are limited. This may be because medical devices are frequently *"technology driven"*. In addition, strong time and financial constraints often apply. Consequently, most companies look for short term cash with relative low risks, instead of investing into a product for a niche market or when insufficient clinical evidence, cost-effectiveness or reimbursement could be demonstrated.

We developed a new framework which can be used as a guidance for developing medical device prototypes. With this framework, we wanted to prove that it is possible to perform several iterations and produce efficient prototypes which are medical effective and could be used for user testing. In this way we were able test and validate several aspects early in the design process.

The development process of the devices is divided in five phases, going from *Preliminary Research (Phase 0)* to *Phase IV*.

Starting with the Preliminary Research (Phase 0), we explored several device concepts and investigated possible patient positions. Based upon this, we opted for a thin asymmetric support structure with a prone crawl patient position. The patient resembles a phase of the crawl swimming position with the ipsilateral arm positioned next to the body and the contralateral arm positioned above the head. To be able to have adequate beam access for lymph node irradiation, the ipsilateral shoulder should not be supported. In Phase I (chapter 7), we further refined the patient position and tested this with basic prototypes so we could evaluate patient comfort and prove the potential benefits of the prone crawl position. During Phase II (chapter 8), patient comfort was further optimised and adjustability for different body types was improved. We introduced a floor laser for patient positioning. This linear laser projects a line onto the breast and chest, which improves set-up precision. To be able to test the prototypes more in depth, we developed four fully functional devices during phase III (chapter 9). Two left sided and two right sided devices were developed. In addition, new concepts for arm and head support were explored and tested to improve patient comfort and beam accessibility. During the fourth and last phase of this dissertation (chapter 10), twelve fully optimised devices were produced and will be used for a planned study with 390 patients, divided over three hospitals.

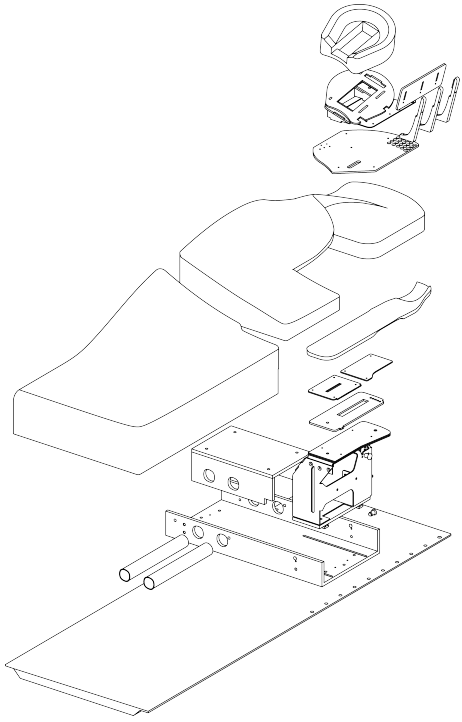
During each phase several tests were executed for comfort evaluation, position optimi-

sation and validation of medical results. We performed user test, clinical trials, cadaver studies and in silico treatments.

By means of an iterative approach and application of our framework, we were able to successfully develop a new prone crawl patient position and device for radiation therapy of both breast and regional lymph nodes. Based upon the performed clinical trials, we can conclude that the prone crawl breast couch delivers better results in comparison with commercially available devices. We achieved better set-up precision, better sparing of vital organs and a strong improvement of patient comfort. Currently, we are working on a new version which further optimises the device and integrates new functions such as MRI compatibility and the integration of a non-invasive ventilator for the prolonged breath-hold techniques (see future work).

Chapter 1

Technical Specifications



Exploded view of the latest prototype iteration

In this chapter we describe different anatomical terminologies, planes and orientations for readers who are unfamiliar with medical jargon. Secondly, we describe the technical specifications of the breast couch and illustrate every component of the device. At last, we specify every prototype iteration and visualise the final prototype which was produced during the author's work. This chapter can be seen a reference for terminology, prototypes and part names.

1.1 ANATOMICAL TERMINOLOGY

During this work, several anatomical terms referring to the human body were used. In order to better understand these terms, a short overview of the human anatomical planes, orientations and terms is presented. The anatomical position of the human form is based upon a standardised position: standing upright, eyes looking forward, arms at the sides of the body with palms turned out. When referring to a specific side of the body, it is from the patient's point of view.

1.1.1 ANATOMICAL ORIENTATIONS

- **Lateral**: toward the sides of the body
- **Contralateral**: at the opposite side of a certain structure (Right is the contralateral side of Left)
- **Ipsilateral**: at the same side of a certain structure
- **Medial**: Toward the midline (median plane) of the body
- **Cranial**: Head end of body
- **Caudal**: Tail end of body
- **Anterior or ventral**: Toward the front of the body
- **Posterior or dorsal**: Toward the back of the body
- **Superior or supra**: A part above another part
- **Inferior or sub**: A part below another part
- **Proximal**: Close to the point of attachment to the body
- **Distal**: Remote from the point of attachment to the body
- **Internal**: On the inside of the body
- **External**: On the outside of the body
- **locoregional**: Restricted to a localised region of the body

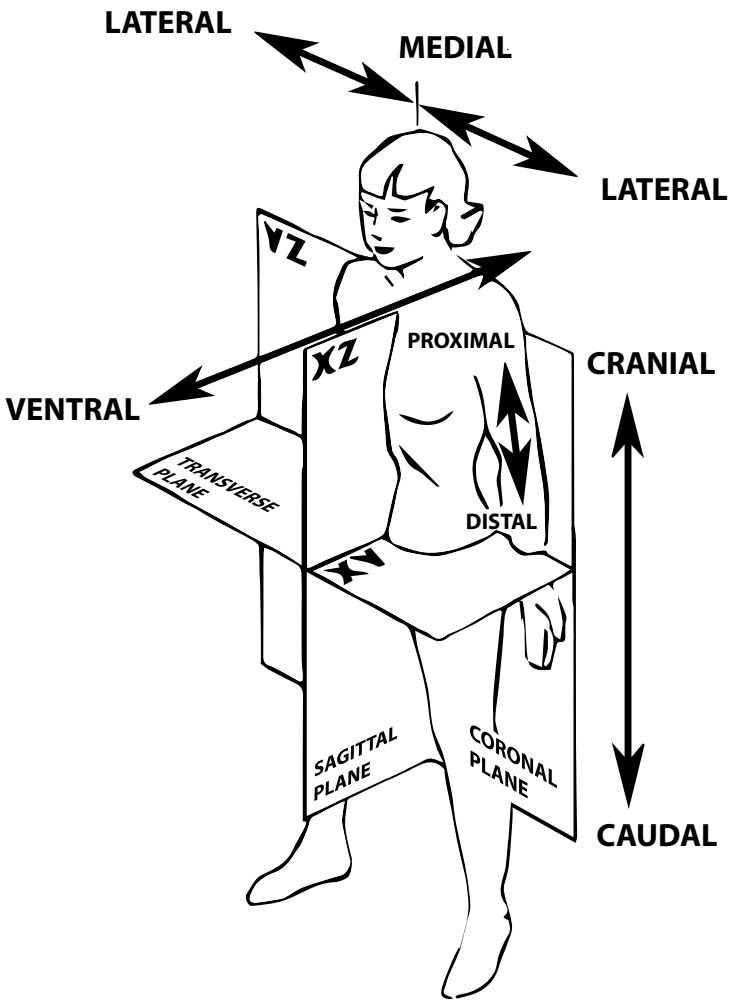


Fig. 1.1 Human anatomical planes and its orientations.

1.1.2 ANATOMICAL PLANES

- The **sagittal plane** divides the body into a left and right part
- The **coronal plane** runs perpendicular to the sagittal plane and divides the body into anterior and posterior parts
- The **transverse or horizontal plane** divides the body into upper and lower parts (or cross-section)

1.1.3 MEDICAL TERMS

- **Clavicule**: collarbone
- **Oesophagus**: food pipe
- **Thorax**: chest
- **Sternum**: breastbone
- **Humerus**: upper arm bone
- **Thyroid**: endocrine gland in the neck
- **Cervical vertebrae**: the vertebrae of the neck
- **Thoracic vertebrae**: middle segment of the vertebral column
- **Abdomen**: belly or stomach
- **Mastectomy**: removal of the whole breast
- **Lumpectomy**: removal of the breast tumour (and some healthy tissue around it)
- **Flex**: contraction of muscle or decreasing the angle between two bones, such as bending the elbow
- **Extension**: increasing the angle between two bones, such a straightening the elbow

1.2 EXPLODED VIEW BREAST COUCH

As can be seen on the exploded view of the last breast couch prototype version (fig. 1.2), it comprises of several parts. Throughout the iteration phases, the names of the main parts remained the same and are listed below:

- The **head support**
- The **leg support shell**
- The **pedestal** serves as a support for the upper shell and connects it to the Polycarbonate (PC) baseplate (by means of the carbon fibre tubes)
- The **baseplate** serves as a multifunctional connection platform
- The **carbon fibre tubes** connect the pedestal to the baseplate
- The **LINAC couch table** is the table of the treatment machine
- The **Q-fix head support** is a commercial available head support

- The **indexed head support baseplate** enables different adjustments for the head module
- The **upper shell** supports the patient's upper body
- The **arm support** supports the ipsilateral arm
- The **arm support baseplate** enables craniocaudal movement of the arm support blade
- The **indexed arm support plate** enables laterolateral movement of the arm support blade
- The **arm module baseplate** serves as a universal connection platform for different arm support blades
- The **arm module** itself supports the hip and is connected to the baseplate

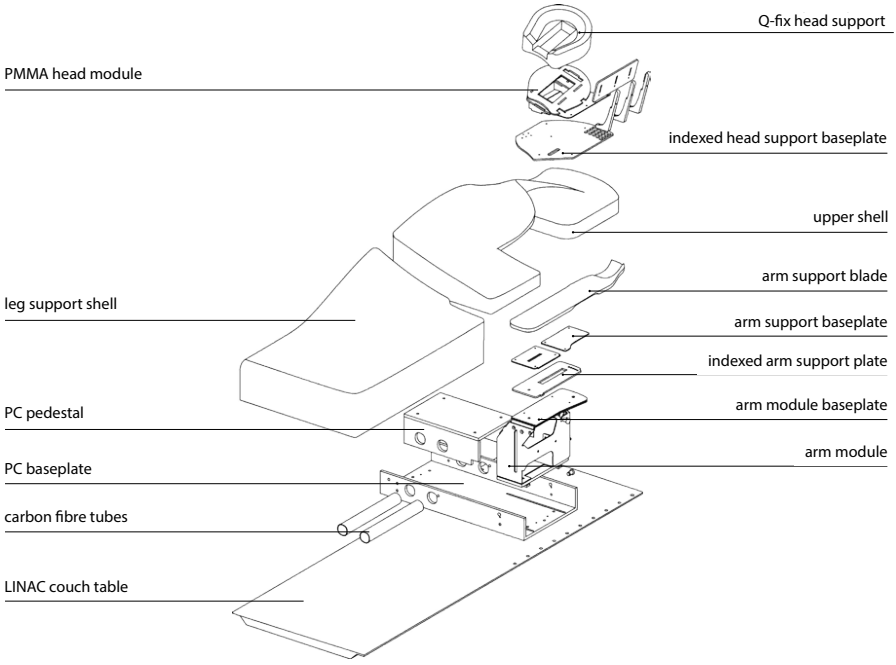


Fig. 1.2 Exploded view of the last breast couch prototype (BC3-R).

1.3 DIMENSIONS

We define the main dimensions of the breast couch. Figure 1.3 illustrates the bottom view of the assembly. The close-up illustrates the different holes in the baseplate which can be

used for connection of the breast couch to different treatment tables.

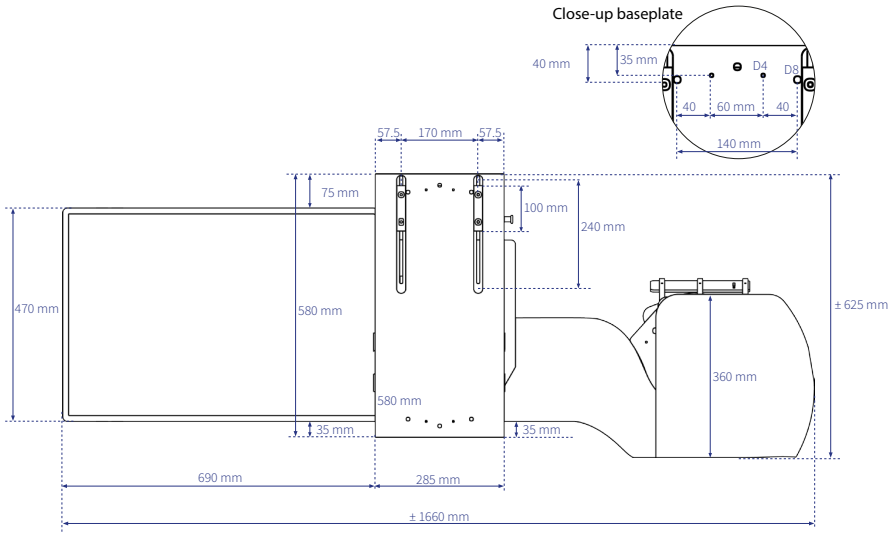


Fig. 1.3 Bottom view breast couch BC3-R.

1.4 PROTOTYPE ITERATIONS

Two different support device prototypes can be specified: breast boards and breast couches (in detail explained in section 2.2.1).

- **A breast board (BB)** is a table-top support device, resting completely on the table.
- **A breast couch (BC)** is a support device where the part supporting the patient's upper body region is hanging over the treatment table (see fig. 1.5). This setup has the advantage of better beam access for favourable bundles since there is no restriction of the table couch structure underneath the upper breast couch region.

As can be seen in figure 1.4, eight breast board iterations were performed during Phase I. Inferior materials and basic techniques were used.

In Phase II, we produced three iterations (two breast boards and one breast couch) with basic tools and materials, but more advanced prototypes were produced.

During Phase III, one prototype iteration was performed and four prototype devices were produced (two left sided and two right sided). By means of a fibreglass mould system, we could produce identical prototypes. More advanced materials and techniques were used.

Phase IV prototypes were full carbon fibre prototypes, produced with High Fidelity (Hi-Fi) materials and techniques. thirteen prototypes were produced (one proof of concept, followed by six left sided and six right sided breast couches).

	CHAPTER	PROTOTYPE	QUANTITY	MATERIAL	TECHNIQUE
2014-2015	PHASE I	ITERATION: 1.1 (BBV1) - 1.8 (BBV8)	8 (1.1 - 1.8)	RECYCLED MATERIALS, WOOD, PU-FOAM, POLYESTER + FIBREGLASS	HAND TOOLS, BASIC TECHNIQUES, THERMOFORMING, HAND LAY-UP COMPOSITE
2016	PHASE II	ITERATION: 2.1 - 2.2 (BBV9-10) 2.3 (BC1-R)	3 (2.1, 2.2, 2.3)	WOOD, PU-FOAM SHEET METAL, CLAY EPOXY + FIBREGLASS, ABS	HAND TOOLS, SHEET METAL BENDING, BASIC TECHNIQUES, LASER-CUTTING, CLAY MODELING
2017	PHASE III	ITERATION: 3.1 (BC2-L + BC2-R)	4 (2xBC2-L, 2xBC2-R)	EPOXY + FIBREGLASS, CARBON FIBRE TUBES, SHEET METAL, PMMA, PC, PLA	VACUUM BAGGING, RIM CNC-SHEET METAL BENDING, LASER-CUTTING, 3D-PRINTING
2018	PHASE IV	ITERATION: 4.1 (BC2.5) 4.2 (BC3-L + BC3-R)	13 (1xBC2.5) (6xBC3-L, 6xBC3-R)	EPOXY + CARBON FIBRE, SHEET METAL, PA, PMMA, PC	RIM, CNC-SHEET METAL BENDING, LASER-CUTTING, FIBRE REINFORCED 3D-PRINTING
2019	PHASE V	FUTURE WORK: BC4	/	EPOXY + CARBON FIBRE, NON-FERROUS METALS	/

Fig. 1.4 Overview of every prototype iteration during each phase. Quantity produced, main materials and used techniques are specified.

Fig. 1.5 Final breast couch iteration BC3-L, positioned on the LINAC table.

Chapter 2

Introduction

Breast couch version BC3

In this chapter we explain the principles of breast cancer and the different treatment techniques, we sketch the background of the research project and state of the art of prone breast boards. Subsequently we describe the research objective and explain its translation into design goals. Lastly, the thesis layout is clarified.

2.1 BACKGROUND

Designing a medical device is a complex process: different stakeholders such as doctors, therapists, nurses, patients, physicists and physicians are integrated in the process. New technologies and treatment methods are explored and need to be validated to prove their advantages over the standard and trusted methods. In addition, existing protocols need to be followed, new ones need to be defined and medical results and patient comfort must meet the stakeholders' needs. Over the years, new technologies and materials have been invented, methodologies improved, norms and values changed and the requirements of the stakeholders have evolved.

In the past, medical device development was mainly evidence based and the patients did not have a significant role in the process (Martin, Norris, et al., 2010). The main goal was a *"functional"* device which could be used for treatment (Sackett, 1997; Sackett et al., 1996). Less functional aspects such as patient comfort, emotions and ethics were not brought up. Later on these *"less functional"* aspects became more and more important. Designers were integrated in the process as a result of which medical devices became more appealing and had an improved User Experience (UX) due to assessing patient comfort and emotional impact (Grocott et al., 2007).

PROJECT BACKGROUND

The initial application of this research project originated from the Ghent University Hospital. Based on the state of the art of current treatment techniques, they wanted to develop a new prone patient support device for radiotherapy treatment which enables them to treat both breast and regional lymph nodes on the same device, with improved medical results and patient comfort. Commercially available devices are inadequate, and the current Medical Device Development (MDD) process does not fulfil the needs of the applicant. From an industrial design engineering perspective, we noticed the potential and need for development. From there on, the call was established.

The main purpose of this project was the development of a patient support device for better breast and regional lymph node radiotherapy in prone position. Secondly, by developing a medical device in a research environment, we wanted to demonstrate that through iterative prototyping cycles, a user-centred and co-design approach and cost efficient prototyping techniques, functional products can be produced, used for testing and validation of the medical device itself.

This research project was a single case-based research, spread over 4 years.

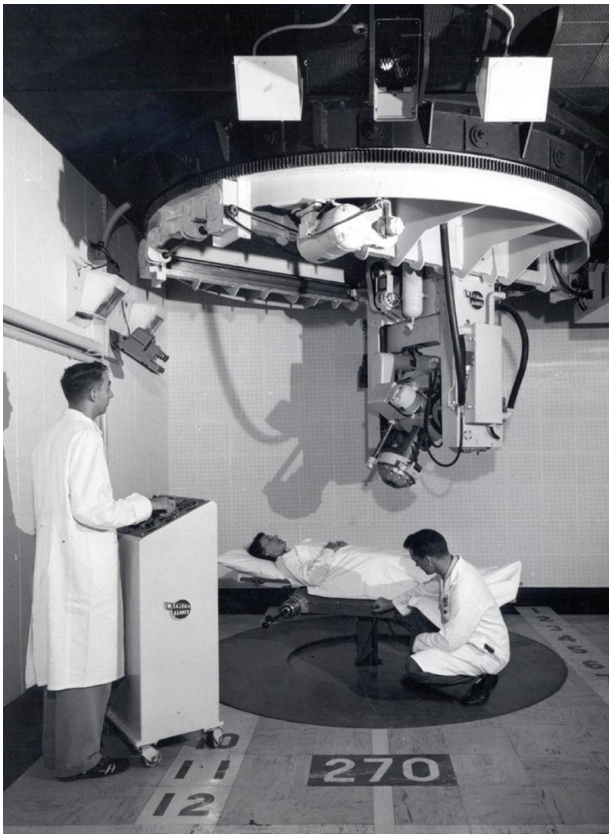


Fig. 2.1 A radiotherapy treatment device from 1955 which looks like a deadly weapon from an old horror movie [1].

2.2 BREAST CANCER

12% of all new cancers diagnosed worldwide each year are female breast cancers [2]. In Europe, breast cancer is the most commonly diagnosed cancer [362 000 cases in 2012 [3] (excluded from skin cancer)] and the third highest cause of cancer death (Ferlay et al., 2007).

In Belgium (2015), there were 67 087 cases of cancer registered (excluded from skin can-

[1] AP/Oak Ridge Associated Universities
[2] World Cancer Research Fund – `https://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/breast-cancer-statistics/`
[3] World Health Organisation – `http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx/`

cer) of which 10.378 cases of breast cancer [4]. There is a chance that one out of nine women will be diagnosed with breast cancer before the age of 75. Luckily, the mortality rate has decreased with approximately 10% over the last decade.

STAGES

The Tumor, Node, Metastasis (TNM) Classification of Malignant Tumours is an internationally accepted system used to determine the disease stage. The disease stage allows to estimate prognosis and guide therapy. Combinations of $T(0-4)$, $N(0-3)$ and $M(0-1)$ are grouped into stage categories (Sobin et al., 2009).

Breast cancer is categorised on a scale from 0 to IV, going from a non-invasive cancer which remains in its site of origin (stage 0); to an invasive cancer that spreads to other organs beyond the breast and regional lymph nodes (stage IV) (American Cancer Society, 2017).

The target group during this research project was the treatment of breast cancer patients with lymph node metastasis. This means that there is cancer in the breast and it has also spread to one or multiple nodes in the breast regional lymph nodes (fig. 2.2). The target group is situated between breast cancer stage I and III.

METASTASIS

Cancer metastasis is the spread of a cancerous tumour from the initial location to other locations outside the breast. In many patients, metastasis formation is a stepwise process. The first step is metastasis to the regional lymph nodes (fig.2.2). The second step is metastasis to other organs such as lungs, liver, bone or brains.

LYMPH NODE METASTASIS

As being a part of our immune system, our body has a network of lymph vessels and nodes (fig. 2.2) which produces and stores white blood cells (lymphocytes) that help fight diseases and infections.

Patients with breast cancer that has spread to the lymph nodes but not beyond are the target group of our research.

When breast cancer cells are found in the lymph nodes it may be treated with various combination treatments including: surgery, chemotherapy, hormone therapy, immune therapy and lymph node radiotherapy (further called Lymph Node Irradiation (LNI)).

TREATMENT METHODS

Surgery can be considered as the primary treatment method for early-stage breast cancer (both whole breast removal or a small part of the breast). The goal of surgery is the complete removal of the tumour with a cancer-free margin to reduce the risk of (local) recurrences and prevent progression of the tumour.

[4] `http://www.kankerregister.org/`
[5] Cancer Research UK / Wikimedia Commons.

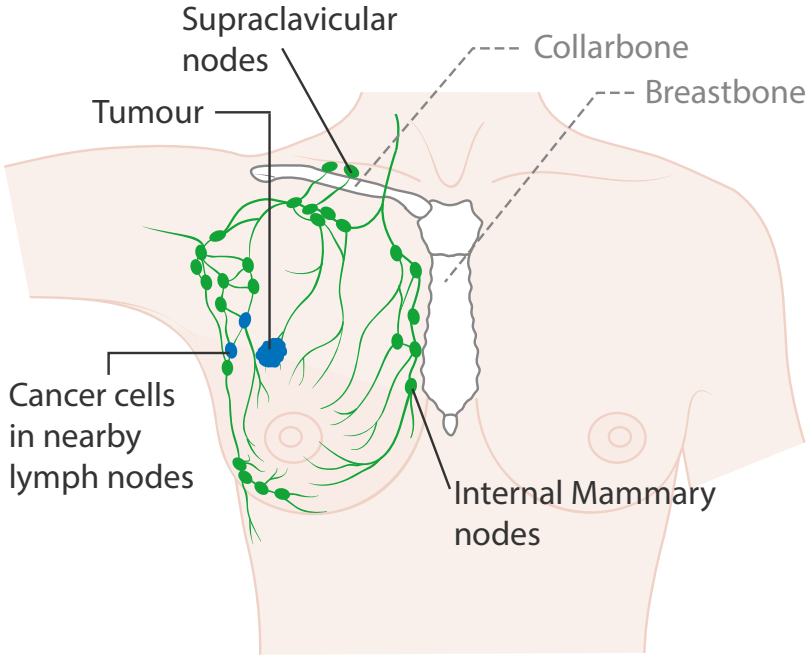


Fig. 2.2 A stage IB breast cancer. Breast lymph node system (green) and cancer cells (blue) [5].

Radiotherapy is an adjuvant treatment technique used to eliminate cancer cells that are left behind after surgery. The full radiotherapy procedure is explained in detail in chapter 4.

Chemotherapy is the treatment procedure of cancer which uses one or more anti-cancer drugs, which kill cancer cells. Since chemotherapy flows through your body in the bloodstream, it can treat cancer cells anywhere in the body (a systemic therapy). Chemotherapy may be given with a curative intent, controlling and prolonging intent or palliative reason. It mainly targets rapidly dividing cells such as cancer cells, but also affects blood cells, oral mucosa, stomach, intestines and hair growth.

Hormones like oestrogen may accelerate the growth of breast cancer. Medication that counteracts the unwanted effects of hormones on breast cancer are used in hormone therapy. Hormone therapy is very often used for breast cancer treatment (as adjuvant therapy), ofter together with radiotherapy.

Targeted therapy is done by blocking the growth of cells that have specific targeted mutant proteins that are essential for cancer cell survival. Due to this targeted approach, not every rapidly dividing cell is affected in the host's body, which is less harmful for healthy cells

and thus beneficial for later recovery.

Immune therapy works by stimulating the host's immune system to fight cancer cells. In breast cancer, immune therapy is still in its research phase.

FOLLOW UP

After finishing breast cancer treatment, patients are followed up for several years. Depending on the received treatment method (or combination of methods), the surgeon, gynaecologist and oncologist will perform follow-ups. Since almost every cancer treatment can have side-effects, it is very important to go to all follow-ups to maintain good health and manage potential side-effects. Some may last only a few days, while others only show up after several years.

The first two years, breast cancer patients are followed up every three months. After two years, follow-up is every six months. Eventually, after four years, an annual follow-up is performed.

2.2.1 BREAST BOARD

A breast board is a patient support and positioning device that is used for the radiotherapy treatment of breast and regional lymph node cancer. The device immobilises and aids the patient for better positioning and treatment. Two different types of device setups can be distinguished; a supine breast board and a prone breast board.

SUPINE BREAST BOARD

On a supine breast board, patients are treated in supine position. The patient is lying on their back with (most of the time) both arms positioned overhead (fig. 2.3). The head can be positioned straight or turned to the opposite side of the to-be-treated breast. This results in an easy device set-up and comfortable patient positioning.

Fig. 2.3 MammoRx Supine Patient Position System by Orfit [6].

Fig. 2.4 Prone breast board. Adopted from Ohio State University Medical Center [7].

[6] MammoRx Supine Patient Position Systems – `https://www.orfit.com/radiation-oncology/products/`

[7] Prone breast board – `https://medicalxpress.com/news/2014-10-experts-body-position-breast-cancer.`

PRONE BREAST BOARD

On a prone breast board, patients are positioned in prone position, where the breast is hanging through or under the treatment device. The gravitational force causes the breast to hang freely with no deformation and results in interesting access for treatment (fig. 2.4 and 2.5). The smaller breast width decreases radiological path lengths, which is beneficial for dose distribution and reduction of high-dose regions (Veldeman, Speleers, et al., 2010).

2.3 CURRENT SETUP

Recent studies provide evidence behind a shift from supine to prone radiotherapy for breast cancer: less acute toxicity, less risk of radiation-induced cardiac toxicity and of lung cancer induction (Monten et al., 2015; Mulliez, Veldeman, Speleers, et al., 2015; Mulliez, Veldeman, Van Greveling, et al., 2013). However, the prone patient set-up is associated with a complicated procedure, reduced precision, discomfort and pain (Huppert et al., 2011; Mulliez, Veldeman, Speleers, et al., 2015; Veldeman, Speleers, et al., 2010). Recent studies even registered incidents of chest wall pain and rib fracture (Kirby et al., 2010; Veldeman, Speleers, et al., 2010). Furthermore, prone radiotherapy is especially challenging in patients requiring both Whole Breast Irradiation (WBI) and regional LNI because of unfavourable anatomy caused by bilateral arm elevation and restricted choice of desirable beam directions to the lymph node regions by components of the patient support system obstructing favourable beam paths (Huppert et al., 2011).

The current commercially available prone breast boards (Qfix™, Varian Pivotal™, Klarity and AIO™) may be suited for WBI+LNI but the typical prone position with bilateral arm elevation (fig. 2.4) creates an unfavourable anatomy for LNI and the device support structure for shoulder and arm restricts the use of anterior beam paths for LNI.

The AIO™ Orfit[8] prone breast board is used as our standard prone position treatment device for WBI (fig 2.5). Unfortunately, discomfort is often reported and caused by stretching of the ipsilateral arm. This is especially the case for patients who underwent axillary dissection.

Our aim was to investigate a new prone patient position and develop prototypes which are suitable for both WBI and LNI, analyse them and iterate to improve patient comfort, medical performance and reproducibility.

UZ GENT

At our radiotherapy centre of the Ghent University Hospital, we yearly treat ±500 patients with breast cancer. For patients who underwent whole breast removal (mastectomy), the supine position is used (±100 patients), all other patients who underwent breast-conserving surgery (lumpectomy) are treated in prone position (±400 patients).

html/

[8] AIO™ Solution, All-In-One Patient Positioning System – https://www.orfit.com/radiation-oncology/products/the-aio-solution/

For patients who underwent lumpectomy, 300 of them are treated for breast cancer (WBI); while the other 100 are treated for both breast- and lymph node cancer (WBI+ LNI). Patients for WBI are treated in prone position as standard, while patients for WBI+LNI are included into our clinical trials comparing prone vs supine position treatment.

For patients eligible for prone treatment, 10% could not be properly positioned onto the AIO™ Orfit breast board. Consequently, they needed to be repositioned and treated in supine position. This was caused by following reasons: patient mobility (age, arthritis, former surgery, and others), restricted arm movement caused by breast and/or lymph node dissection, a too large Body-Mass Index (BMI) and pain or pressure points that affect patient position reproducibility.

Note: *While treating patients on our new prone crawl breast couch, only less than 5% could not be properly positioned and needed to be repositioned in supine position.*

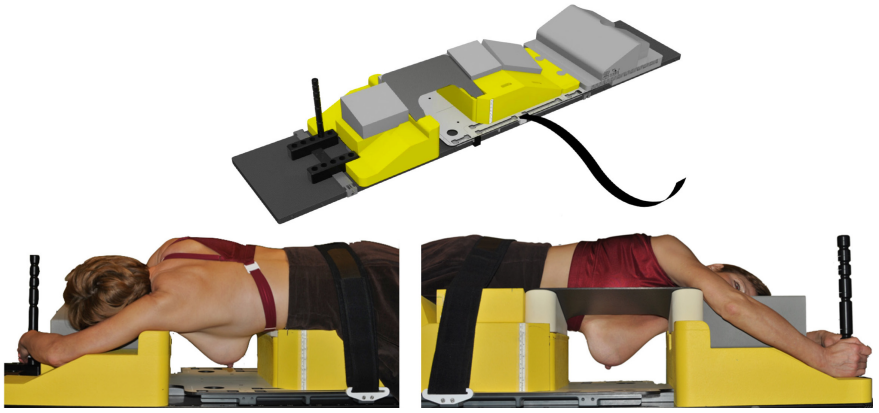


Fig. 2.5 AIO™ Orfit breast board device used as standard for prone treatment, adopted from (Mulliez, Veldeman, Van Greveling, et al., 2013).

2.3.1 MEDICAL PERFORMANCE

The standard prone position setup for treatment at our centre has several limitations; the anatomy of the breast board itself causes stretching of both arms (bilateral arm elevation); the supporting foam structure under shoulders, arm and head region limits the possibility for visual patient position confirmation and obstructs the range of favourable beam paths; The shape of the wedge causes artefacts on Computed Tomography (CT)-images and its flat shape causes pressure points resulting in local pain in the non-treated breast, thorax and sternum region. The anatomy of the patient, supporting foam structure, and table top version restricts the possibility of LNI.

2.3.2 PATIENT COMFORT

As can be seen in figure 2.6, discomfort was often recorded. Several patients reported: pain- and pressure points in both arms, shoulders, sternum and neck, uncomfortable position, pinched veins, bruises and the feeling of *"sliding off"* the breast board (caused by incline of whole device, and are therefore in an unstable position). There was even one case of a patient who had a bruised rib, caused by the hard, carbon fibre wedge on the AIO™ breast board. In some cases, the treatment was interrupted: halfway during their treatment sessions, the patients reported unbearable pain or bruises and needed to be further treated onto the supine breast board. Consequently, this required repositioning, simulation and replanning of the patient.

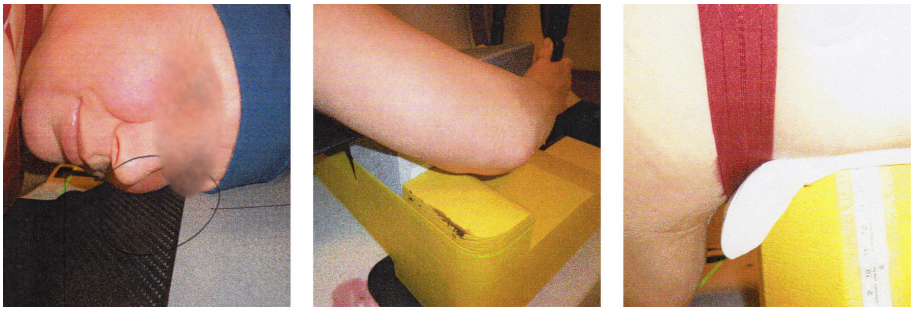


Fig. 2.6 Patient on AIO breast board. Left: head partially resting onto the carbon fibre wedge. Middle: arm uneven supported causing pressure points. Right: soft napkins are placed on the sharp edge at the thoracic wall.

2.3.3 NURSES

Some nurses reported difficulties of properly positioning patients in a comfortable position onto the AIO™ breast board. This was often caused by pain & pressure points. Painful pressure points were reduced by placing soft napkins underneath painful support areas (fig. 2.6-right). Secondly, inadequate immobilisation of the patient resulted in decreased position accuracy and thus more commonly patient repositioning during treatment. For 10% of the patients, the medical team was unable to properly position them onto the AIO™ device. Subsequently, they needed to position them on a supine treatment device. This results in inefficient patient handling and possible patient flow delays.

2.4 RESEARCH OBJECTIVE AND DESIGN GOALS

2.4.1 MEDICAL ORIENTED

Lymph node radiotherapy has not yet been effective in prone position. Especially setup precision, beam access, dose distribution and patient comfort are challenging in prone position. For this research project, the emphasis lies on defining the right patient position, patient support device design and treatment protocol in order to achieve an effective treatment for both breast and regional lymph nodes, in prone position. This will be compared with the standard supine and prone position treatments. Therefore, we hypothesise the following medical oriented research question:

- *Can we developing a new prone patient support device which is a comfortable and effective treatment technique for both breast- and regional lymph node radiation therapy?*

2.4.2 DESIGN ORIENTED

MDD is often restricted by protocols, complex parameters, Intellectual Property (IP), time and money constraints. Therefore, prototype production, iterations and user interactions are often reduced to a minimum. By the use of the correct prototyping techniques, iterative prototyping and co-design, we want to demonstrate that functional prototypes can be efficiently produced and used for clinical testing and validation. Herby we establish a design-oriented research objective:

- *How can we produce functional and efficient medical prototypes, which can be used for validation and clinical trials?*

2.4.3 DESIGN GOALS

To be able to translate the research objectives into more practical working points, we established several design goals. These goals can be seen as a more pragmatic approach and interpreted as a practical translation of the research objectives. When all the design goals are fulfilled, the research objectives should be as well. The design goals, both medical and design oriented, will be used as a guide to validate intermediate results during every iteration phase, user test or evaluation of medical results.

MEDICAL ORIENTED

- *New prone position* (G_1) – At the end of this work, the prototype design should be able to produce a feasible prone position which is a suitable patient position

for treatment. Different patient positions need to be explored, evaluated and optimised. Patient positions should to be tested with various patients, volunteers or Thiel embalmed bodies.

- *Prone lymph node irradiation* (G_2) – Patients on commercially available devices for prone breast irradiation are typically positioned with both arms elevated above the head. The structure of head- and arm support often obstructs favourable anterior beam paths for LNI (Huppert et al., 2011). Nonetheless, a prone setup for radiotherapy has several advantages in comparison with supine (Kirby et al., 2010; Mulliez, Speleers, et al., 2013; Mulliez, Veldeman, Van Greveling, et al., 2013). Therefore, it should be interesting to irradiate the lymph node region in prone position. Unobstructed beam access for favourable beam paths should be evaluated and prototypes made to test the patient position, region deformation and support surface.

- *Reproducibility* (G_3) – Reproducibility is an important factor during radiotherapy. Especially in prone position this can be challenging (Lymberis et al., 2012; Veldeman, Speleers, et al., 2010). Therefore, the prototype and new patient position should ensure reproducible results with high accuracy. To be able to do this, the device should be adjustable, indexed and position errors should be less than in supine treatment.

- *Beam Accessibility* (G_4) – Proper beam accessibility is very important for homogeneous beam distribution, sparing of vital organs and healthy tissue. This is both favourable for WBI and LNI, and should be better than the available devices.

- *Patient Comfort* (G_5) – Patient comfort during radiotherapy needs to be taken into account. Especially prone treatment is often reported to be less comfortable than supine treatment. Additionally, since the major part of the patients are elder women, arthritis, arthrosis or other mobility limiting phenomena are a frequent occurring. To be able to ensure a comfortable position for every patient, the patient's limited range of motion should be taken into account. Furthermore, the device should be adjustable for every body size or measure. The patients' comfort need to be better in comparison with the commercially available devices. this will need to be evaluated and used for further iterations.

DESIGN ORIENTED

- *Safety* (G_6) – Since we want to have as much as possible beam access range, no support structure underneath the to-be-treated breast and node region is desired. The device should be thin, stiff and strong. The device should meet the required safety measures, Factor of Safety (FoS) and protocols to prevent possible failure of mechanisms, fixations or materials and patients falling off the device during positioning or treatment.

A support device for radiotherapy is a surface-contacting device to intact skin surface only with limited exposure whose cumulative single, multiple or repeated use or contact is up to 24 h. The upper surfaces of the crawl breast couch, leg- and arm support as well as the headrest may be in contact with the skin of the patient during the 15 fractions of each 10-15 minutes of CT-simulation or treatment. The biosafety of used materials which come in contact with the patient should therefore be investigated. Hygiene such as sterility and washability should also be looked in.

- *Modular* (G_7) – Since further insights will be gathered during- and after this project, the device should be modular built for further component upgrades, different support or fixation systems, adapter systems for treatment systems in other centrums, integration of sensors or Magnetic Resonance Imaging (MRI) compatibility.

- *Iterative Cycles* (G_8) – Medical device development is a complex process and by applying iterative design cycles throughout each phase, we want to show that it is possible to find a proper end solution by solving every sub-problem, and thus achieve good medical end results.

- *Efficiency: Cost + Time* (G_9) – By selection the correct prototyping technique, material choice and user test during each iteration, we want to demonstrate that it is possible to produce functional prototypes which can be used for clinical trials and deliver good medical results.

The numbering of the goals (G_1 to G_9), will be used to refer to a specific goal throughout this work.

2.5 THESIS LAYOUT/READERS'S GUIDE

This thesis consists of 11 chapters including technical specifications and general introduction. Five phases of the development process of the prone crawl device are described in this thesis: *preliminary research (phase 0), phase I, phase II, phase III* and *phase IV*. *phase V* of the development process can be considered future work and is further explained in chapter 11.

The reader can encounter some repetition amongst different thesis chapters. The author finds that this better explains each chapter individually and will be more convenient to read. He hopes the reader will understand this. Some data of published articles are rewritten and integrated into this thesis. This data is copyright protected to the journal publisher.

- **CHAPTER 1** defines the different anatomical terms, planes and orientations that were used. We describe the technical specifications of breast couch BC3 and illustrate every component of the device. The full development of the device is explained along this work.

- **CHAPTER 2** explains the principles of breast cancer and the different treatment techniques, we sketch the background of the research project and state of the art of prone breast boards. Subsequently we describe the research objective and explain its translation into the design goals. Lastly, the thesis layout is clarified.

- **CHAPTER 3** reports the current research approach and its issues within healthcare. We briefly explore the standard product development process and the medical device development process. We describe the research approaches that were applied for this project, the role of prototyping and the different stakeholders. Lastly, the different development phases during this project are described.

- **CHAPTER 4** details the preliminary research that has been performed during this research project. We explain the radiotherapy treatment process, benchmarks, concept exploration and selection. A part of this phase was performed during the author's master thesis project called *"Optimisation of the prone patient position for breast radiation therapy"*.

- **CHAPTER 5** defines the realisation and application of the framework that was used during this research project. The framework can be used as a guide for prototype development of medical devices.

- **CHAPTER 6** gives in-depth details on the evolution of the patient's pain & comfort assessment during this research project, the background of end-user comfort is described and the used pain intensity measurement tool and it drawbacks during the first phase are explained. In addition, we classify a new pain intensity measurement system.

- **CHAPTER 7** describes the first iteration phase, basic parameters and fundamentals of the device were determined to obtain and validate a comfortable prone crawl patient position. Low fidelity prototypes were produced with inferior materials and basic skills. A proof of concept was established and user tests were executed on a small scale.

- **CHAPTER 8** describes the second phase, prototypes were produced with more durable materials and advanced techniques since prototypes needed to be functional and ready for clinical trials. The purpose of phase II was further optimisation of: the patient support surface, patient comfort, usability and improving setup accuracy.

- **CHAPTER 9** describes the third development phase. Fully functional prototypes were produced with high fidelity materials and techniques. Four prototypes (two left- and two right sided) were produced and used for a validation trial with real treatments. The purpose of phase III prototypes was to validate: medical performance, the fully indexed system, the new floor laser alignment system and breath-hold feasibility.

- **CHAPTER 10** describes the fourth phase. Fully functional and optimised prototypes were produced and used for a large clinical trial, involving multiple hospitals. A series of twelve devices was produced. This chapter can be considered as the current (ongoing) phase of this research project.

- **CHAPTER 11** concludes this work. The aim of this dissertation was to develop a new patient support device for prone radiotherapy of breast and regional lymph nodes. By developing a new framework for medical prototype development, we were able to efficiently perform several prototype iterations. Eventually, we establish a new prone crawl patient position, which was reported to be both comfortable and deliver good medical results. Finally, we describe the future perspective of this research project.

2.6 LIST OF PUBLICATIONS

JOURNAL ARTICLES

B. Boute, W. De Neve, B. Speleers, A. Van Greveling, C. Monten, T. Van Hoof, J. Van de Velde, L. Paelinck, W. De Gersem, T. Vercauteren, J. Detand, and L. Veldeman (2017). "Potential benefits of crawl position for prone radiation therapy in breast cancer". In: *Journal of Applied Clinical Medical Physics* 18.4, pp. 200–205

B. Boute, L. Veldeman, B. Speleers, A. Van Greveling, T. Van Hoof, J. Van de Velde, T. Vercauteren, W. De Neve, and J. Detand (2018). "The relation between patient discomfort and uncompensated forces of a patient support device for breast and regional lymph node radiotherapy". In: *Applied Ergonomics* 72, pp. 48–57

P. Deseyne, B. Speleers, W. D. Neve, B. Boute, L. Paelinck, T. T. V. Hoof, J. V. D. Velde, A. V. Greveling, C. Monten, G. Post, H. Depypere, L. Veldeman, W. De Neve, B. Boute, L. Paelinck, T. T. V. Hoof, J. Van de Velde, A. Van Greveling, C. Monten, G. Post, H. Depypere, and L. Veldeman (2017). "Whole breast and regional nodal irradiation in prone versus supine position in left sided breast cancer". In: *Radiation Oncology* 12.1, pp. 1–12

CONFERENCE CONTRIBUTION

B. Boute, W. De Neve, and J. Detand (2017). "The prototyping process of a patient support device for radiotherapy of breast and regional lymph nodes in prone position". In: *Proceedings of the Fourth Conference on Design4Health*. Ed. by K. Seemann and D. Barron. Melbourne, Victoria, Australia: Sheffield Hallam University jointly with Swinburne University of Technology

B. Boute (2014a). "Design of a breastboard for prone breast radiotherapy". In: *15th FEA Research symposium*, pp. 24–24

A. Debyser, B. Boute, and J. Detand (2017). "The Design of a Bistable Composite Connection Method Applied on the Low Volume Production of a Breast Board Table Connection". In: *MATEC Web of Conferences*. Ed. by J. Detand, D. Ruxu, J. Self, and J. Gunsing. Vol. 104

L. Paelinck, B. Boute, L. Veldeman, C. De Wagter, B. Speleers, A. Van Greveling, G. Post, and W. De Neve (2017). "EP-1487: Dosimetric aspects in the development of a crawl positioning device for prone breast radiotherapy". In: *Radiotherapy and Oncology* 123, S796

P. Deseyne, G. Post, A. Van Greveling, B. Speleers, K. Vandecasteele, L. Paelinck, B. Boute, H. Depypere, C. Mbah, W. De Neve, and L. Veldeman (2018). "OC-0191: Improved

set-up accuracy for adjuv ant whole breast irradiation in the prone-crawl position". In: *Radiotherapy and Oncology* 127.April, S102–S103

PATENT

J. Shang, G. Li, R. Singh, Q. Gu, K. M. Nairn, T. J. Bastow, N. Medhekar, C. M. Doherty, A. J. Hill, J. Z. Liu, and P. A. Webley (2012). "Discriminative separation of gases by a "molecular trapdoor" mechanism in chabazite zeolites." In: *Journal of the American Chemical Society* 134.46, pp. 19246–53

SOCIAL MEDIA

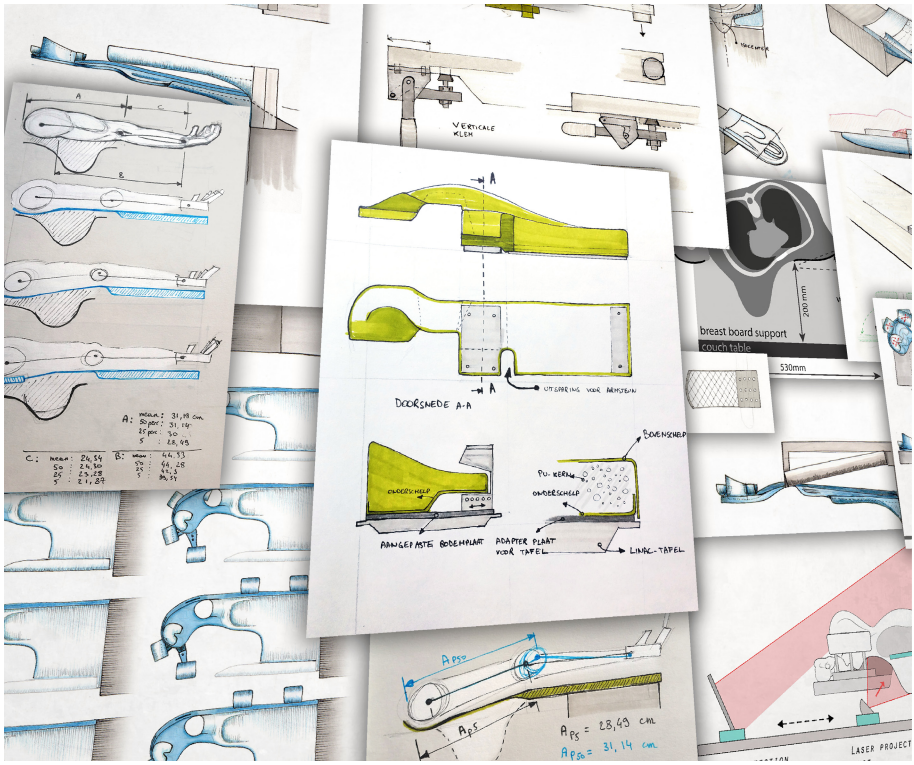
K. op tegen Kanker (2018). *bestraling in Buiklig*. URL: https://www.facebook.com/komoptegenkanker/videos/1698271783568677/?hc_ref=ARQhgCi_-zfWFiz223qpM-fGhUOHTWTmOpXZOdJF-E_d_1Lgs35SC9ggXiUnS7d1BX4

B. Boute(2018). "*Display at 200 years Ghent University Anniversary.*"

Één (2018). *Iedereen tegen kanker 2018*. URL: https://www.vrt.be/vrtnu/a-z/iedereen-tegen-kanker/2018/iedereen-tegen-kanker-s2018.ch.1ae702e8-2183-4e40-96d3-7a076ef7defe/

Chapter 3

Research Approach



Concept explorations and different idea sketches

In this chapter we describe the current research approach and its issues within healthcare. We briefly explore the standard product development and medical device development process. We describe the research approaches that were applied during this project, the value of prototyping and the role of every stakeholder. Lastly, the different development phases during this project are described.

3.1 EVIDENCE BASED MEDICINE

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 instead of the non-functional requirements and less measurable aspects such a patient wellbeing and comfort (Mullaney et al., 2012). Healthcare professionals and administrators are recognising the importance of a patient 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 (Edvardsson et al., 2006; Edvardsson et al., 2008; Mullaney et al., 2012).

3.2 RESEARCH THROUGH DESIGN

Although research through design is manly used in Human Computer Interaction (HCI), the term originated in design (Soegaard et al., 2013). In contrary to a company who designs commercially successful things, the intent of research through design is to generate knowledge for the research and practice communities through designing the things right and not to make profit or commercially viable products (J. Zimmerman et al., 2007). It can be used to identify opportunities for new technologies or improvements of current technologies (J. Zimmerman et al., 2007). Research through design takes advantage of the unique insights which are gained through design practice to bring a better understanding to complex issues (Godin et al., 2014).

When using research through design, the designer/researcher creates new products, technologies, experiments or processes and uses this data to perform research on. This approach was mainly applied throughout this research project.

3.3 CO-DESIGN

In a classic (and simplified) design process (see figure 3.1), the user can be seen as a passive object of study, the researcher can add knowledge from theories or research and gathers data and knowledge through observation and interviews. The designer or design team passively receives knowledge from reports and adds technology, creative thinking and design methodologies; which are needed to generate ideas, concepts, prototypes and so forth (Sanders et al., 2008).

Co-design can be seen as a design process where every stakeholder is involved in the process. As Sanders et al. (2008) states:

"The person who will eventually be served through the design process is given the position of 'expert of his/her experience', and plays a large role in knowledge development, idea generation and concept development. In generating insights, the researcher supports the 'expert of his/her experience' by providing tools for ideation and expression. The designer and the researcher collaborate on the tools for ideation because design skills are very important in the development of the tools. The designer and researcher may, in fact, be the same person."

During co-design, the role of the *"user"* gets mixed up: they can play a co-creating role and even become a co-designer; but this is not always true. It depends on the expertise, passion, creativity and motivation of the *"user"*. People can be creative but not all people can be a designer (Sanders et al., 2008). Additionally, the context, and phase during the design process can affect the stakeholder's participation.

Applied to this research project, the involvement of each stakeholder varied during each phase. Although most stakeholders are in a constant and strong interaction loop, the involvement of the *"users"* altered during the process and needs some explanation: early in the process patients' comfort and position was the main focus. Some co-design was performed with the users (here volunteers and ex-patients): they were interviewed, surveys were filled and they actively participated during user tests. Later on, medical aspects such as beam accessibility, treatment optimisation and so on. became the main focus and no more co-design with volunteers or patients was executed. In general, co-design was mainly performed between the designer and the medical team (fig. 3.3). At the end, the process focus eventually shifted to prototype optimisation, structural and usability improvements.

3.4 USER-CENTRED DESIGN

Many authors have stated that the application of a User-centred Design (UCD) approach in medical device development has added value, and provides guidance on the theory behind it (Grocott et al., 2007; Sawyer et al., 1996). Although there are a number of possible reasons why designers wait with consulting of the users. As Martin et al. (2012) states: *"Currently, users are generally not brought into the development process until after the*

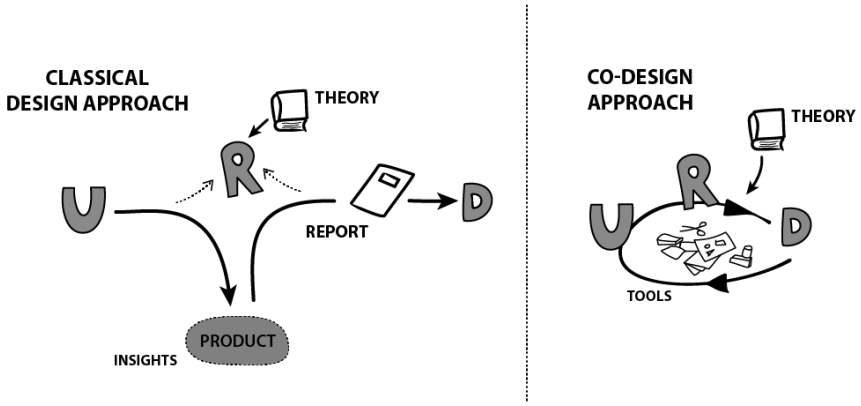


Fig. 3.1 Classical design approach (on the left), and a co-design process where user, researcher and designer are collaborating. Adopted from (Sanders et al., 2008).

design brief for a new product has been produced. This may be because medical devices are frequently technology driven rather than resulting from an identified un-met need". Two other notable reasons are time and financial constraints (Martin, Clark, et al., 2012).

Therefore, to enable incorporation of new features to prototypes with greater ease and lower cost, identification of user needs and co-operation of the user is important for the development process of new medical devices, and it should happen in an early stage of the design process (Martin, Murphy, et al., 2006). An example of a medical device with a UCD approach and multidisciplinary team is the development of a laparoscopic instrument (Loring et al., 2010).

Applied to this research project, a UCD approach was mainly used in the early stages: *exploration, defining fundamentals, proof of concepts and comfort optimisation*. During the preliminary phase, patients were surveyed and interviewed, staff was interviewed, observations were performed and comfort was analysed. In phase I, small user tests, interviews and pain and comfort analysis were executed. As can be seen in figure 3.2, a small user test was performed on an early prototype (Phase I). Patient position and comfort was evaluated and possible adjustments were directly made on site for direct feedback. Throughout the next phases, prototypes, user tests and user comfort gradually improved. This resulted in a diminishing need for involving every stakeholder during each user test.

3.5 MAIN STAKEHOLDERS

The three main stakeholders during this research project construct a triangle where each of them is interacting with each other. Combined, they represent the iterative development cycle with the *Activity, Context* and *Prototype* as central focus (figure 3.3). It is important

Fig. 3.2 Example of a small user test during an early prototype iteration (Phase I). Several team members (nurse, patient, physician, physicist and designer) are testing, evaluating and modifying new patient positions.

to notice that the three key roles have significantly different needs, skillsets and knowledge. Additionally, this can change during the development process. Together they all contribute to a good interworking and co-creation of problem solving, exploring new possibilities and solutions.

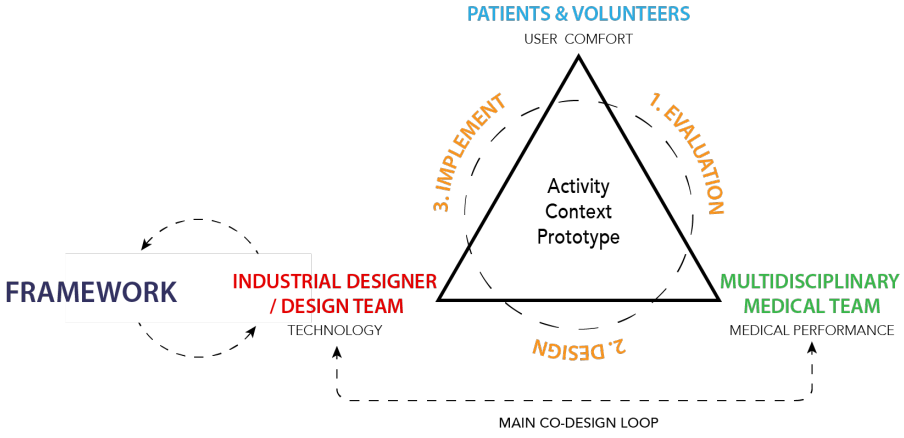


Fig. 3.3 Triangle between the main key roles of this research project. The realisation of the framework evolved parallel and was interconnected with the designer. Co-design was mainly performed between the designer and medical staff. Adapted from (De Couvreur et al., 2011).

3.5.1 MULTIDISCIPLINARY MEDICAL TEAM

The multidisciplinary medical team can be seen as the most versatile group and consists of several different profiles: nurses, physicians, biomedical engineers, radiation oncologist, anatomy experts, etc. We describe the three main profiles of the medical team.

- ***Nurses*** – Both medical and radiotherapy nurses are closely related to the patients. They introduce and guide the patients through the treatment process, perform patient positioning, execute simulation and treatment sessions and perform patient follow-ups. Additionally, they handle, transport, configure and clean the different patient support devices.

- ***Physicians*** – The physicians supervise initial patient positioning and treatments, perform treatment plannings, supervise clinical trials and user tests, analyse medical treatment results and execute treatments of special patient cases.

- ***Radiation oncologist*** – The radiation oncologists and physicists test, plan and simulate different experimental treatment techniques, bundle directions and patient setups. They perform planning for in-silico treatments, patient treatments or cadaver studies. material related properties, such as beam build-up effect and radiolucency, are also analysed by the physicists.

MEDICAL PERFORMANCE

Together, the medical team executes the whole treatment procedure. During the development process, it is there task to evaluate and survey the quality of treatment, medical results and insights. Their main focus is the medical performance of the device and medical results.

3.5.2 INDUSTRIAL DESIGNER/DESIGN TEAM

As an industrial designer, it is his role to act as a *"bridge person"* between the different domains. In this case medicine, healthcare and (industrial) design. To be able to work efficient on the project, he needs to understand the fundamentals of radiotherapy, cancer treatment, planning, patient handling and so on. But does not need to be able to execute specialised medical tasks. On the other hand, he needs to be able to perform research, develop prototypes, have knowledge of several production methods, follow design strategies, execute user tests and analyse results, but does not need to be a statistics or material properties expert. Since it is a multidisciplinary team, the designer, and every other stakeholder, can always rely on the expertise of other specialised profiles.

In addition, the designer is also a researcher and is investigating the applied framework to the project (see chapter 5). The development of the framework itself evolved during this project and is applied through the designer onto the other stakeholders (fig. 3.3).

TECHNOLOGY

The industrial designer (or design team) can be seen as the *"technology facilitator"* between stakeholders. It is the designer's task to translate the patient-user values and feedback to the medical team and vice versa (De Couvreur et al., 2011). His main job is to explore and ideate new technologies & approaches, use and create tools & prototypes which fulfils both patient's and medical team's needs.

3.5.3 PATIENTS & VOLUNTEERS

- ***Volunteers*** – Volunteers who perform user tests and comfort evaluation are often ex-patients or staff. They contribute to new patient position explorations, comfort evaluation, etc. We involve them early into the design process and try to evaluate their user experience after every iteration, since this has added value (Martin, Clark, et al., 2012).

- ***Patients*** – All studies, which involved simulations or treatments of patients, were approved by the local ethics board (reference number: EC UZG 2014/1250, Belgian Registration Number: B670201422932). They were properly introduced and guided throughout the whole treatment process. Patients participated in CT-imaging for treatment simulations, comparative radiotherapy treatments (half of the sessions on standard prone device, other half on the new prototypes) and full treatments.

  they contribute to patient position evaluation, perform pain and comfort assessments, beam access analysis and setup precisions analysis.

- ***Thiel Bodies*** – A Thiel body (or cadaver, which imitates the natural look and feel of a living body) cannot actively participate to comfort analysis and may be rather seen as tool than a user. Nonetheless, since Thiel bodies have the same flexibility and feel of a normal female body, we were able to utilise them as human surrogates and use them for physical analysis of internal body forces (through CT-imaging), Free Body Diagram (FBD)-analysis and surface optimization (see chapter 7). They were several times used to position, CT-scan and analyse different patient positions (since CT-scanning is harmful for living volunteers). Therefore, they contributed to user comfort.

- ***Phantom body*** – For some cases we used a breast + thorax phantom for analysis of CT-image artefacts.

USER COMFORT

User comfort is evaluated by multiple users: patients, volunteers, ex-patients and staff. The patient position (and user comfort) was optimised through trial and error because standard anthropometric data was insufficient and inaccurate for our case: the complex asymmetric shaped patient position could not be linked to standard anthropometric data. Therefore, user comfort was several times evaluated with multiple volunteers who had different anatomy and body sizes. Spinal orientation and head position, was analysed through CT-image analysis of both patients and Thiel bodies.

3.6 DEVELOPMENT PROCESS

3.6.1 PRODUCT DEVELOPMENT PROCESS

Similar to the model of Cooper (1983) and Sanders et al. (2008), a typical product development process can be divided in specific stages (fig.3.4):

1. **EXPLORATION**
   In this stage, the problem is defined and invention discovered. Different ideas are generated and further exploration is done. This is also called the fuzzy front end since these activities are located before defining specific product requirements. It is a chaotic nature where every possibility is possible. It is often unknown wether the deliverable will be a product, service or interface (Sanders et al., 2008). At the end of this phase, the deliverables and design criteria are defined.

2. **CONCEPTUALISATION**
   Further research and detailed investigation is performed. Based on the defined design criteria, different concepts are developed and further explored.

3. **PROTOTYPE DEVELOPMENT & BUSINESS ANALYSIS**
   First prototypes are developed, tested and iterated. Business analysis and possible market value are evaluated.

4. **PRODUCT DEVELOPMENT & VALIDATION**
   A pre-market product is developed: technical specifications are defined, testing and validation of the product is performed. Later-on the first product itself is produced.

5. **MARKET LAUNCH & PRODUCTION**
   The product is launched, together with marketing, distribution and sales plan. The product itself is (mass) produced.

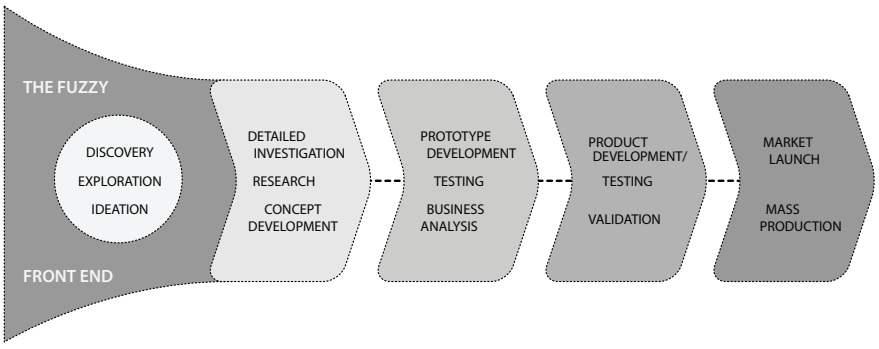


Fig. 3.4 typical product development process. Based on Sanders et al. (2008).

3.6.2 DEFINITION OF A MEDICAL DEVICE

According to the European Medical Device Directive (93/42/EEC)[1], a medical device can be defined as any instrument, apparatus, implant, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Control of conception.

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Richard, 2001).

Since it would be unfeasible to subject all medical devices to the same conformity (a life depending or hazardous device needs other conformities in comparison with an ankle brace), they are classified, tested, regulated and analysed before they are allowed on the market.

The classification of medical devices is a *'risk based'* system based on the vulnerability of the human body taking account of the potential risks associated with the devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, e.g. duration of contact with the body, degree of invasiveness and local vs. systemic effect. These criteria can then be applied to a vast range of different medical devices and technologies. These are referred to as the *'classification rules'* and are set out in Annex IX of Directive 93/42/EEC. They correspond, to a large extent, to the classification rules established by the Global Harmonisation Task Force (GHTF) in the guidance document GHTF/SG1/N15:2006 (Commission et al., 2010; Lalis, 2006).

The classification can be divided in four categories, dependant on the potential risks of the device.

- **Class I** devices have the lowest potential risk. Such devices can be for example surgical retractors, tongue depressors, medical thermometers, disposable gloves and so forth.

- **Class IIa** devices have low to moderate potential risk and can be, among others, hypodermic needles and suction equipment.

[1]OJ L 169, 12.7.1993, p. 1–
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:1993:169:FULL&from=HR

- **Class IIb** devices have moderate to high potential risk and can be lung ventilators, bone fixation plates or others.
- **Class III** devices have the highest potential risk and need to undergo extensive testing and analysis before they can be on the market. These devices can be, among others, heart valves, implantable defibrillator and DNA probes.

"Approximately 30% of all types of medical devices are in Class I. Class I devices do not support or sustain human life and do not present a potentially unreasonable risk of illness or injury. About 60% of devices are in Class IIa and IIb. They may involve some degree of risk and are subject to federally defined performance standards (such as Röntgen Radiation (X-Ray) devices) Finally, all devices that are life supporting or sustaining, that are of substantial importance in preventing impairment of health, or that have a potential for causing risk of injury or illness are in Class III. Approximately 10% of medical devices are in Class III" (Gelijns, 1989).

BREAST BOARD

A patient support device for breast radiotherapy is defined as a **Class I** medical device and falls under non-invasive devices, rule 4: *a non-invasive device which either do not touch the patient or contact intact skin only* (Lalis, 2006) (G_6).

3.6.3 MEDICAL DEVICE DEVELOPMENT PROCESS

MDD can be seen as a multidisciplinary approach between engineering, marketing, biomedicine, medicine, industrial design, technology and anatomy. The development stages are similar to a standard product development process, but extra preconditions apply to each stage:

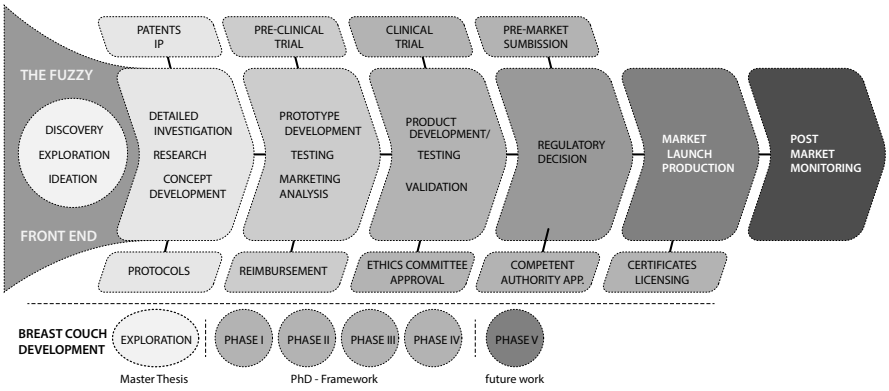


Fig. 3.5 Typical medical device development process from discovery and ideation to product launch and post market monitoring [2]. Breast couch development phases underneath.

[2]based on the MDD processes of: Food and Drug Administration & Starfish Medical and Victoria Burt.

1. EXPLORATION

the exploration stage of a medical device is very similar to the product development process: problem definition, exploration, discovery of the invention and ideation. At the end of this stage, the design criteria are defined.

2. CONCEPTUALISATION

During the conceptualisation, extensive research, detailed investigation, design criteria and first concepts developed. During concept development, it is important that certain protocols need to be taken into account. This can be related to the users or patients, treatment methods, mechanical, software or others.

Secondly, a form of IP protection is favourable (patents, copyrights, trademarks, trade secrets). For this project, a patent application has been filed. This needs to be submitted before publishing anything to the public. It protects your invention, treatment technique, material or software. Furthermore, patents can be beneficial for companies: during the early development stages (finding investors or funds, IP protection, etc.) or end stages (production, exclusive dealing right, licensing and so on). On the other hand, there is reason for concern that strong patent protection my hinder rather than stimulate technological and economic progress (Mazzoleni et al., 1998).

3. PROTOTYPE DEVELOPMENT & BUSINESS ANALYSIS

During the prototype development and business analysis stage, first prototypes are developed and iterated, business analysis and possible market value are evaluated. During this stage it is important whether or not your device can later-on be reimbursed, since this can affect your production and material choices. At the end of this stage, first pre-clinical trials will be performed, which need to have local ethics committee approval.

4. PRODUCT DEVELOPMENT & VALIDATION

During this stage, clinical trials are performed, a first trial product is developed, technical specifications are defined, production techniques clarified, testing and validation of the product is performed. At the end of this stage, a fully working product is delivered and ready for premarket submission. Before clinical trials, the device needs to be registered and approved by the Belgian competent authority: Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG).

5. REGULATORY DECISION

Based on the premarket submission, a regulatory decision is made by a Notified Body (NB), whether or not your medical device is eligible for production and CE-approval or other certificates. Work, production, instructions and manufacturing need to be documented and submitted, safety manuals described, technical drawings and build of materials defined, storage description, etc.

6. MARKET LAUNCH & PRODUCTION

Your product is ready to be launched, full product manufacturing is performed and quality assurance followed up.

7. **POST MARKET MONITORING**
   During post market monitoring, Long-term clinical studies and data analysis are performed, product safety is monitored, unexpected product malfunctions and errors are analysed. Through post market surveillance, products can be further upgraded, refined, confirmed or denied.

REGULATIONS

In comparison with the traditional product development process (fig.3.4), the MDD-process (fig.3.5) is far more complex: the team needs to assess new technologies, ethics, meet several protocols, strict regulatory approvals, pre-clinical tests, clinical tests, certificates and reimbursement.

the British Medical Journal's journalist Deborah Cohen criticises the current development system as a *"fragmented, poorly regulated, market driven system, with financial incentives to prioritise manufacturers' interests over those of patients, and with no requirement for clinical evaluation of a device's safety or effectiveness"* (Godlee, 2012).

As Krucoff et al. (2012) states, there have been several initiatives to help streamline the process regulatory approval of drugs and devices. In the latest initiative, the Food and Drug Administration (2011) Centre for Devices and Radiological Health (CDRH) launched the Medical Device Innovation Initiative which facilitates speed to market of transformative technologies.

"The regulatory process affects a significant portion of the device development pathway and should accommodate the iterative, cyclical nature of device design and development (Food and Drug Administration, 2011)."

Nonetheless these efforts, MDD has reached a crisis stage, especially in the United States (Krucoff et al., 2012).

The safety concerns from the public, lawmakers, regulatory and reimbursement agencies, as well as intense medical–legal influence resulted in a risk-averse environment and led to the requirement for in-depth preclinical data before a clinical feasibility pilot study can begin. As well the uncertainty about the amount of clinical trial evidence that will led to regulatory approval and reimbursement. This risk of ultimate failing, resulted in small companies moving to friendlier, offshore countries (Simonton, 2012). Due to the risk of challenging regulatory and reimbursement processes and approvals, venture capital has dramatically exited this space. It was often the traditional source for early financial support for individual inventors and small companies (Salemi, 2012).

Although (Food and Drug Administration, 2011) states that: *"A large portion of a device's total product life cycle is occupied by product development from concept to marketing. The pathway to successful device development is cyclical and iterative as ideas are prototyped, tested, improved, re-tested, optimized and finalized. The device development pathway is a continuum with feedback loops and device modifications."*

Krucoff et al. (2012) still criticises this: *"To revitalize device innovation, we must first recognize that it is a highly interconnected "ecosystem," wherein regulatory and reimbursement processes, clinical trial infrastructure, public expectations, and investment decisions dynamically interact."*

INDUSTRY AS A PARTNER?

Large and well-established companies such as Siemens and Phillips have strong reputations for applying good human factors approaches. Therefore, it is likely that there is a good user-centred and ergonomics practice being carried out. Nonetheless, in Belgium, MDD is ofter undertaken by Small and Medium Enterprises (SME)s such as engineering firms, subcontracting and university spin-offs. They are less likely to have access to proper in-house expertise in this area (Martin, Craven, et al., 2005).

The problem with most companies is that they look for short-term cash. Additionally, it is very difficult to seduce a big company with a product for a niche market or when insufficient clinical evidence, clinical acceptance, cost-effectiveness or reimbursement could be demonstrated (Sharma et al., 2018). At the end, the idea needs to seduce the whole company and be profitable.

On the other hand, SMEs are open for innovation in order to be competitive, but the risk of innovation is sometimes too difficult or too high to handle (Courvoisier, 2016).

FROM AN ACADEMIC RESEARCH POINT OF VIEW

We chose not to work with an industrial partner. Through this method, we were able to obtain several research funds and prolong the R&D-phase as much as possible before going into production. This enabled us to extensively perform user tests, produce prototypes, improve performance of the device and ensure that every stakeholder's need is fulfilled (G_9).

through the research funding programs, we were able to obtain some grands of different institutions:

- A part of this research project was financed through Cancer Plan Action 29 by the Federal Public Service of Health, Food Chain Safety and Environment, Belgium (*KPC-29-008*).
- A part of this project was funded by a Career Catalyst Grant from Susan G. Komen ($Grant377841$).
- Prototype research was funded by *StarTT 241* grant of the Industrial Research Fund, Ghent University thanks to management by Lieve Nuytinck, Bimetra, Clinical Research Centre, Ghent University.
- Anatomy experiments were funded by Foundation against Cancer, grant 2012 — 200.
- Staff (doctoral students, physicians, nurses) was funded by grants of Think-Pink, Emmanuel van der Schueren of Kom op tegen Kanker and Kom op tegen Kanker.

When the desired outcomes of the user tests and clinical trials are obtained, an industrial partner will be needed for valorisation an industrialisation of the device. A patent application was performed for IP-protection and production. This will guarantee the company an exclusive right to produce and deal the device.

3.7 PROTOTYPING

Many designers corroborate the value of prototypes in the design process(Schrage, 2013; E. Zimmerman, 2003) and as explained in section 3.2, by means of prototyping, testing and evaluating, we are able to feed our research. Through different kinds of prototypes (functional, aesthetic, form, structural), we are able to filter our needs, and test our desired things. (Lim et al., 2008). During each iteration, new prototypes, adjustments and tests are performed, which feed each feedback loop. As Lim et al. (2008) states: *"A primary strength of a prototype is in its incompleteness. It is the incompleteness that makes it possible to examine an idea's qualities without building a copy of the final design"*.

The skill of designing a correct prototype so that it can filter the qualities of interest that the designer wants, relies on the competence involved in prototyping (Lim et al., 2008). This means that a good prototype can be very incomplete but still filters the qualities and aspects that the designer and researcher wants to examine or explore (Lim et al., 2008) (G_9).

3.8 ITERATIVE CYCLES

In MDD-companies, teams still tend to have only clinical and engineering backgrounds. This culture often results narrow cost- and time constrained development processes. As mentioned previously, the emphasis lies on functional data, is mainly technologically driven and research is evidence based (Sackett, 1997; Sackett et al., 1996). The traditional followed product development cycle follows a linear *"top-down"* process (fig.3.6). It is widely used and most people think, the more complex your problem is, the more you should follow this structure in a orderly flow (Conklin, 2005). This *"waterfall"* structure (illustrated as the linear method in fig.3.6) lets you follow the instructions, protocols and manuals to acquire your solution. You start from the first problem at the top *"flow"* down, step by step, towards the solution.

As Conklin (2005) discusses, these linear processes work for tame problems which are well-defined and have a clear problem definition and boundary. However, as De Couvreur et al. (2011) state for assistive devices in well-being and rehabilitation, these linear processes do not apply to the development of medical (patient support) devices: there is a constant interplay between patient (*comfort, user experience*), medical staff (*medical performance*) and the design team (*technology*). When you have a solution for a specific problem, you cannot wait until the end of the development process to test user comfort or validate med-

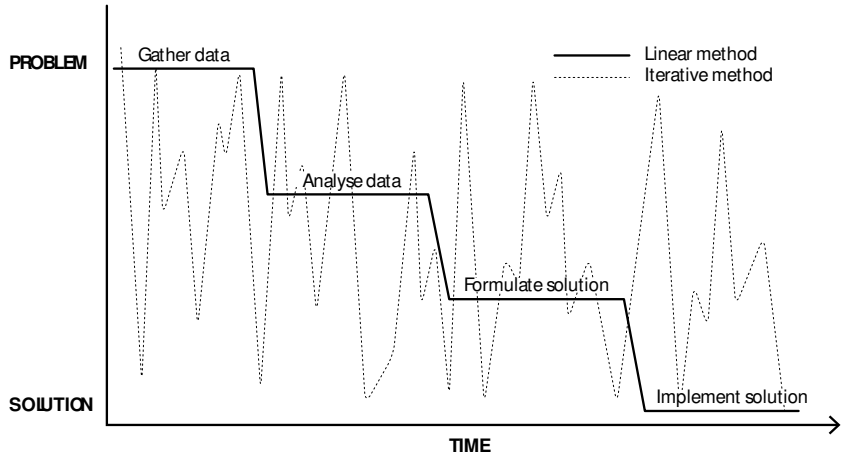


Fig. 3.6 Product development cycle. Adopted from (Conklin, 2005).

ical performance. therefore, during each iteration phase, a constant in interplay between every key player and finding/solving problems is important.

Pugh's model of controlled convergence (1991), can be described as an alternating process between concept divergence (concept generation, finding solutions) and concept-controlled convergence (selecting the best solution) which drastically converges to the final product or solution. This is similar to Conklin's iterative method of solving wicked problems whereas the beginning of each divergent phase of Pugh's model can be compared to a problem phase during Conklin's iterative method and a convergent phase can be compared to a solution phase.

This iterative development process of constantly diverging (exploring solutions) and converging (selection the right solution) was the base of the prototype development phases (G_8). Subproblems were analysed and iterations were constructed, resulting in fast user tests, direct feedback and the ability for small adjustments, without affecting the whole prototype.

3.9 DEVELOPMENT PHASES

When using an iterative approach, the distinct development phases during a typical MDD-process (investigation - prototype development - product development - ...), shown in figure 3.5, should not be seen as separate phases but a continuum, cyclical pathway with several feedback loops and iterations (Food and Drug Administration, 2011). Several steps in the development process overlap, run simultaneously, need to be repeated, retested or improved.

During every phase we developed each time completely new prototypes. This was needed since each phase have their specific functions and requirements for certain user tests, medical tests and so on. Within each phase, several prototype iterations were executed: these can vary from small usability modifications (as can be seen in phase IV), to each iteration being almost an entirely new prototype (phase I iterations).

The preliminary research phase was the transition from the authors master thesis to this research project. In this work, phase I to IV were completed (fig.3.5). User tests of phase IV were not yet completed at the time of submitting this dissertation. Phase V is described in future work.

- **IDEATION** and some preliminary research was performed by the medical team of Prof. Wilfried De Neve. During this phase, the idea of a potential new prone device for both WBI and LNI was born.

- **PRELIMINARY RESEARCH** can be considered as the discovery phase and exploration of several concepts. Followed by further research, detailed investigation and concept development. This phase was partially conducted during the author's master thesis.

- **PHASE I** is the realisation of the invention itself. Based on the framework (later explained in chapter 5), several prototypes were developed. They were tested with volunteers, cadavers and in silico simulations were performed.

- **PHASE II** Functional prototypes with more advanced materials and prototyping techniques were produced, pre-clinical trials and in silico tests were performed.

- **PHASE III** Fully functional prototypes were produced with Hi-Fi materials and techniques. Optimisation of sub-parts was performed and high accuracy and reproducibility was required for clinical trials and real content testing.

- **PHASE IV** Fully optimised and functional prototype were produced in Hi-Fi materials. A small series was produced for large scale testing.

- **PHASE V** future work: pre-market ready prototypes.

	PHASE	FOCUS	APPROACH	DESIGN METHOD	TEST METHOD	TEST RESULT
2014	PRELIMINARY RESERACH	DEFINING FUNDAMENTALS UNDERSTANDING THE PROJECT	CLASSIC PRODUCT DEVELOPMENT PROCESS, USER-CENTERED, CO-DESIGN	STATE-OF-THE-ART RESEARCH, BENCHMARKS, EXPLORATION	EX-PATIENT SURVEYS STAFF INTERVIEWS OBSERVATION	/
2014-2015	PHASE I	PATIENT POSITION FUNDAMENTALS, PROOF OF CONCEPT, USER COMFORT	FRAMEWORK USER CENTERED DESIGN CO-DESIGN	PROOF OF CONCEPT PROTOTYPES PAIN & COMFORT OPTIMISATION THROUGH FBD ANALYSIS	SMALL USER TESTS, VOLUNTEERS AND THIEL BODY CT-SCANS, SURVEYS, INTERVIEWS, LABO TESTING	3X9 VOLUNTEERS 2 THIEL BODIES 5 TREATMENT SIMULATIONS COMFORT EVALUATIONS
2016	PHASE II	PATIENT POSITION TESTING, BEAM ACCESS EVALUATION, TREATMENT PLANNING	FRAMEWORK CO-DESIGN	FUNCTIONAL PROTOTYPES ADVANCED MATERIAL- AND PROTOTYPE TECHNIQUES	PRE-CLINICAL TRIALS IN SILICO TREATMENTS THIEL BODY SCANNING	10 PATIENT TREATMENTS COMPARATIVE TRIAL COMFORT EVALUATIONS
2017	PHASE III	REPRODUCIBILITY AND ACCURACY OPTIMISATION	FRAMEWORK CO-DESIGN	HIGH FIDELITY PROTOTYPING TECHNIQUES, SMALL SERIES	CLINICAL TRIALS REAL CONTEXT TESTING	40 PATIENT TREATMENTS AND COMFORT EVALUATIONS
2018	PHASE IV	MEDICAL RESULTS, PRECISION AND PRODUCTION OPTIMSATION, ACCURACY, SCALABILITY	FRAMEWORK CO-DESIGN	HIGH FIDELITY PROTOTYPING TECHNIQUES, SMALL SERIES	MULTI-HOSPITAL BIG CLINICAL TRIAL	400 PATIENT TREATMENTS 3 HOSPITALS INVOLVED
2019	PHASE V	MRI COMPATIBLE BREATH-HOLD COMPATIBLE	FRAMEWORK CO-DESIGN	FUTURE WORK	FUTURE WORK	FUTURE WORK

Fig. 3.7 Overview of different phases during this thesis.

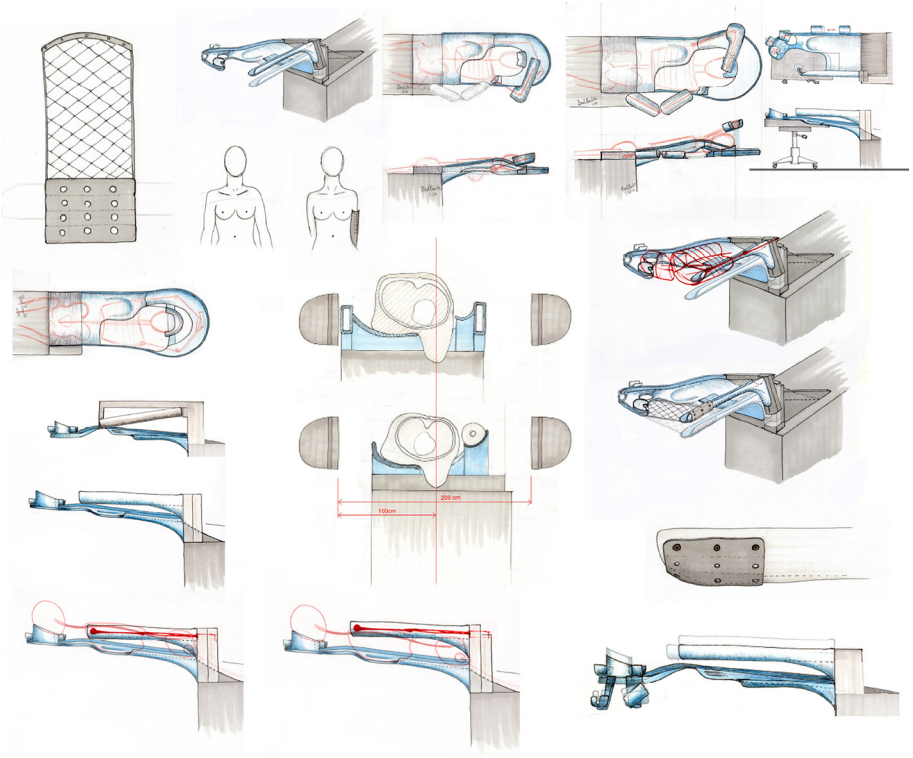
3.10 CONCLUSION

This chapter has described the research approach and design methodology used throughout this work. We described the use of a research through design approach and state the advantages of applying co-creation and user centred design. Through iterative cycles and performing several user tests, we were able evaluate the stakeholders needs. We sketched the architecture of a medical device development process and described its complexity and regulatory issues.

By performing pure academic research without an industry partner, we were able to prolong the R&D phase over several years. Subsequently, we made sure we had a working and comfortable device, which has good medical performance and was extensively tested before commercialisation. Even though we did not work with an industrial partner, we think it can be beneficial to involve the industry early in the project because of the financial support and expertise of the market.

Chapter 4

Preliminary Research



Patient position explorations

In this chapter, we describe the preliminary research that has been performed during this research project. We explain the radiotherapy treatment process, benchmarks, concept explorations and selection. A part of this phase was performed during the author's master thesis project called "Optimisation of the prone patient position for breast radiation therapy".

4.1 RADIOTHERAPY PROCEDURE

Radiotherapy is a treatment method for cancer which uses high energy X-Ray beams to destroy cancer cells. They are carefully measured and focussed on the area with affected tissue to destroy any cancer cells that may be left behind after breast surgery. Apart from radiotherapy killing mainly cancer cells, healthy tissue is also affected. Luckily most of the healthy tissue is able to recover over time.

Local radiotherapy after partial breast removal (lumpectomy) and axillary node dissection diminishes the recurrence risk at 10 years by $21,2\%$ in women with pathologically confirmed lymph node involvement. This reduces recurrences by about a third when compared to lumpectomy and axillary dissection alone, translating in a $8,5\%$ breast cancer specific survival benefit at 15 years (Darby et al., 2011).

The procedure of breast or lymph node radiotherapy can be divided into three main stages: fixation & imaging (or radiotherapy simulation); treatment planning and treatment execution. Mullaney et al. (2012) visualises the radiotherapy process in a very understandable way.

4.1.1 SIMULATION

The first phase of the radiotherapy treatment starts with the CT-simulation of the patient. In this phase, the patient is introduced to the whole treatment procedure. The medical staff explain the function of the breast board, positioning and fixation, imaging and treatment procedure. To prevent the risk of contralateral breast irradiation, a unilateral breast holder (Van de Velde, Schellebelle, Belgium) is fitted. this prevents the tendency of the non-treated breast to move towards the to-be-treated breast (Veldeman, Speleers, et al., 2010). The patient is then positioned and fixated onto the device. When the desired position is acquired, the transition between thorax and to-be-treated breast is marked with fine copper marking wire (fig. 4.1)(Veldeman, Speleers, et al., 2010). Subsequently CT-images are taken. A CT-scanner produces a detailed 3D model of the patient through X-Ray imaging. This model enables the team to precisely define the target region while saving as much a possible healthy tissue.

After locating the centre of the target area, a treatment-isocenter is defined. This isocenter is projected onto the patient by means of an automatic laser projection system. The projected isocenter is marked with a semi-permanent marker onto the patient. These

markings will later be used for reference during patient positioning. The simulation phase takes approximately 30 minutes of which the patients are positioned on the breast board for 15 to 20 minutes.

Fig. 4.1 Patient after CT-simulation, positioned on an early breast board prototype. Marking wire, laser lines and isocenter marking are visible on the to be treated breast.

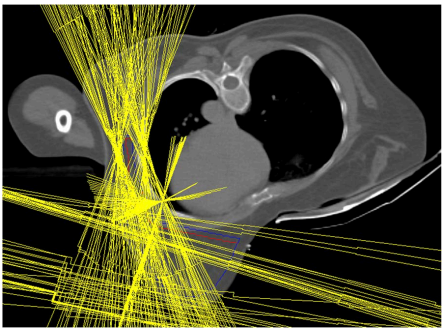


Fig. 4.2 Illustration of a coplanar beam plan. The yellow lines indicate multiple beam apertures. OAR such as arm, lung and heart are avoided.

4.1.2 BREATH-HOLD

Deep Inspiration Breath-hold (DIBH) is a technique where the patient takes a deep, but still comfortable, breath and holds this during a part of the radiotherapy treatment session ($\pm$15 seconds). With this technique you fill the lungs with air and move the heart further away from the to-be-treated breast. The use of DIBH has proven to be advantageous for patients requiring left-side breast irradiation. With DIBH you are able to significantly reduce lung and heart irradiation in both prone- and supine position (Mulliez, Van de Velde, et al., 2015; Mulliez, Veldeman, Speleers, et al., 2015; Remouchamps et al., 2003). In the case of DIBH, the simulation session is extended since patients need to practise the DIBH. Once a stable DIBH is acquired, CT imaging can be performed. Subsequently, a shallow breathing CT-image is taken for later comparison.

4.1.3 PLANNING

During treatment planning, there are several persons involved: oncologists, therapeutic radiographers and radiation physicists. Planning of the treatment starts with the patient's CT-images which are used for the contouring of organs, tumour and breast region. After contouring, the target volume is defined and beam directions for treatment are planned and calculated (fig. 4.2-right).

A commonly used X-Ray dose objective (or dose prescription) is $\pm 40 Gy$ (Gray) for the target volume (Deseyne, Speleers, et al., 2017; Mulliez, Veldeman, Speleers, et al., 2015). The dose constraints define the maximum amount of dose that OAR can receive.

Subsequently, the whole treatment is simulated and beam paths, attack angle and intensity of the X-Ray beams are further optimised to achieve a homogeneous beam distribution and spare as much as possible healthy tissue and organs.

4.1.4 RADIOTHERAPY TREATMENT

The radiotherapy treatment is mainly executed in 15 to 20 consecutive sessions (or fractions) of each 15 to 20 minutes, each time one session a day. Radiotherapy treatment for breast cancer is performed externally: the treatment machine (or Linear Particle Accelerator (LINAC)) is positioned near the patient (without touching it) and moves around the to be treated regions to irradiate smaller fraction from different angles. This enables a better total dose distribution while sparing of vital organs or healthy tissue.

By means of laser projection, the previously marked isocenter during simulation can be aligned with the LINAC's isocenter. When the patient position matches the laser projection, a Cone-beam CT (CBCT)-image is taken and an overlay of the CT-images during simulation is compared for positioning error analysis. Additionally, minor patient position adjustments can be performed. When the patient is within the desired position tolerance, the treatment procedure is executed. The arm (gantry) of the LINAC can rotate 360° around the patient to acquire the desired beam angles for irradiation (fig. 4.3).

Fig. 4.3 Patient positioned on a LINAC treatment device[1].

Large randomised trials confirm that moderate fractions (15 fractions) are at least equivalent in tumour control and toxicity although the total dose is lower than the traditional $50Gy$ in 25 fractions. There is now even a tendency towards even lower dose objectives

[1] Photo derived from The Sir Bobby Robson foundation
`http://sirbobbyrobsonfoundation.org.uk/`

with shorter fractions: a further acceleration to 5 fractions (Yarnold, 2011). In our latest clinical trial (see chapter: 10), we will treat patients in five fraction with a total dose prescription of $\pm 28Gy$.

4.2 BENCHMARKS

There are several commercially prone breast boards available. Unfortunately, none of them completely fulfils the requirements our medical staff: the ability for both WBI+LNI in prone position, a slight patient roll for improved beam access and wide beam access for breast & lymph node region.

Most of the available benchmarks do have a resemblance with our prone crawl breast board, but patients are typically positioned with both arms elevated. This position deforms the lymph node region and creates unfavourable anatomy for LNI. Additionally, the device's support structure for upper arm and shoulder always restricts the use of anterior beam paths for LNI.

Fig. 4.4 Different prone breast board devices. Starting from top left to right: Klarity, Sagittilt, Kvue Access 360, Qfix Access, Civco New Horizon, Orbital ClearVue.

- **KLARITY**
  The Klarity Prone Breast System[2] is a tabletop prone breast board system which is

[2]Klarity Prone Breast System–
`http://www.klaritymedical.com/prone-breast-system`

suitable for WBI but not for LNI. The customisable contralateral indexing may be interesting, although soft support surfaces (such as the cushion for the contralateral breast) decreases precision and reproducibility. Due to the support structure of the device, beam accessibility is restricted and patient roll is unavailable.

- **SAGITTILT**
  The Sagittilt Prone Breast Solution[3] is a tabletop breast board model which has the ability of patient roll along the sagittal axis. This rotation enables the breast to hang further away from heart and lung. Nonetheless some therapists reported patient immobilisation issues when the device was rotated. Consequently, the device was further used without patient roll. Additionally, the bilateral arm position, treatment table and arm/head support structure obstruct favourable beams for LNI.

- **KVUE™ ACCESS 360™**
  The Qfix Kvue Access 360 Prone Breast insert[4] is a breast couch system whereas the device is connected to the treatment table. The upper part (torso/head region) is overhanging, resulting in a wider range of possible bream access. The lymph node region is partially supported by a radiolucent carbon fibre mesh structure. Although WBI+LNI could be possible, the patient position with bilateral arm elevation and very limited lymph node access, restricts the use of favourable beam paths for LNI. Additionally, the flat patient orientation restricts the to be treated breast to hang sufficiently through the device.

- **QFIX ACCESS™**
  The Qfix Access™ Prone Breast Device[5] is the tabletop version of the Access 360 Prone Breast couch. Favourable beam paths are further decreased caused by table and support structure under the arm-and head region.

- **CIVCO NEW HORIZON™**
  The Civco New Horizon™ [6] tabletop prone breast board is a light and compact device that looks rather comfortable. The support structure and position of the contralateral breast partially restricts favourable beam paths close to the thoracic wall. LNI is not possible.

- **AIO™ ORFIT**
  The All-in-one Patient Positioning System by Orfit is already partially described in 2.3.1. This device is quite similar to the Civco New Horizon™. The patient is positioned with a distinct 15° of roll. In contrary to the Civco device, the contralateral breast support follows the roll and is closely positioned to the thorax. This results in an improved beam access for paths close to the thoracic wall.

[3]Sagittilt Prone Breast Solution–
`https://www.orfit.com/radiation-oncology/products/sagittilt/`
[4]Kvue™ Access 360™–
`http://www.qfix.com/qfix-products/breast-and-torso.asp?CID=4&PLID=77`
[5]Qfix Access™ Prone Breast Device–
`http://www.qfix.com/qfix-products/breast-and-torso.asp?CID=4&PLID=76`
[6]Civco New Horizon™ –
`http://civcort.com/ro/breast-positioning/breastboards/`

- **ORBITAL CLEARVUE™**
  The Orbital ClearVue™ prone position breast radiotherapy system is an elevated tabletop model which enlarges beam direction range since the support structure is reduced to some vertical support pillars. The flat patient orientation prevents the breast to satisfactory hang through the device.

4.2.1 PROPERTIES

We scored each benchmark on five property specifications and compared it with our desired prone breast couch device. Each aspect could be scored from 0 to 3 going from the property being unavailable, to the most ideal property specification respectively:

- The possibility for LNI.
- Patient roll, which is favourable for beam access.
- General beam accessibility.
- Adjustability, for patient comfort and positioning.
- The ability of full gantry rotation: device hanging over the table (called breast couch), resulting in a 360° beam access.

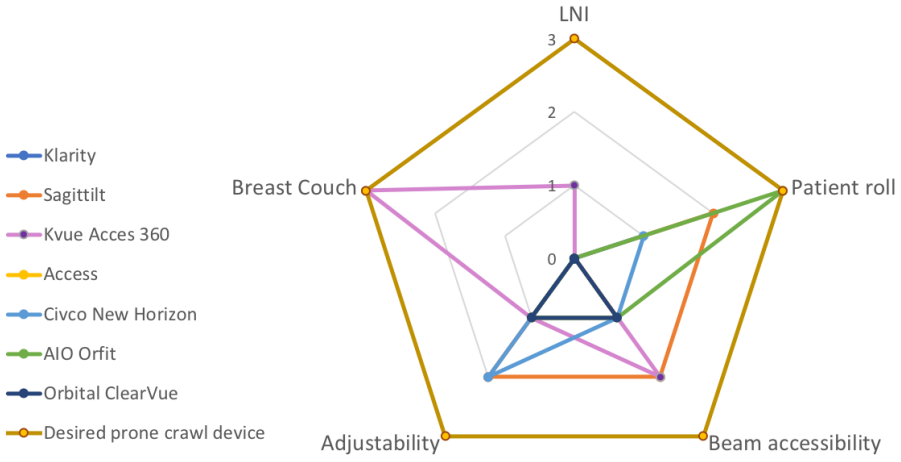


Fig. 4.5 Radar plot of different properties of all breast board benchmarks and the desired prone device.

4.3 CONCEPT EXPLORATION

Based on benchmark research, literature review, findings and ideas of the medical team, a concept exploration was performed. Three main concepts were compiled: rotation C-arms, a fixed symmetric frame and an asymmetric frame. A more in depth concept exploration can be found in the authors master thesis called *"Optimisation of the prone patient position for breast radiation therapy"* (Boute, 2014b).

ROTATING C-ARMS

Derived from a preliminary idea from the medical staff, a concept with rotating C-arms was explored (fig. 4.6-middle): during patient positioning, the C-arms (green bars in fig. 4.6) are open and rotated downwards. Once the patient is properly positioned, the C-arms rotate upwards and are located above the patient.

This concept provides an enlarged beam access under the patient. The rotating C-arms result in a slim design once closed. Some drawbacks may be: complexity and handling of the device, production and stability (C-arm which are loaded during rotation).

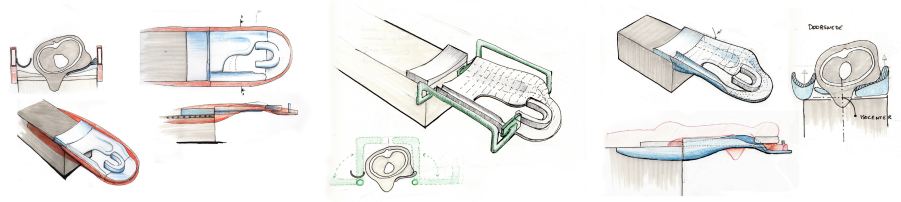


Fig. 4.6 Concept exploration. Left: fixed symmetric frame concept. Middle: rotating C-arm concept. Right: asymmetric frame concept.

FIXED SYMMETRIC FRAME

This concept has a fixed symmetric support frame (red frame in fig. 4.6-left) with inlets for right- or left sided breast board support inserts.

The biggest advantage of this concept is the use of a single and rigid support frame with different inserts. This results in high modularity (could even be used for other patient support devices). The symmetric design would be light and easy to use. On the other hand, the fixed symmetric frame could cause for restricted patient movability or beam access and the width of the device could interfere with the gantry's path. Additionally, the frame should be firmly fixated to the treatment table or pedestal.

ASYMMETRIC FRAME

The last concept is a fully asymmetric frame. Two devices will be needed for treatment (left + right sided). The idea of this concept is a monocoque support structure for the upper body.

This will enable us to gain superior beam access. The monocoque structure will result in a light and slim device with better ergonomic patient support due to the asymmetric design. Some drawbacks may be: several devices needed (left-right-medium-large), less modularity due to the monocoque shell.

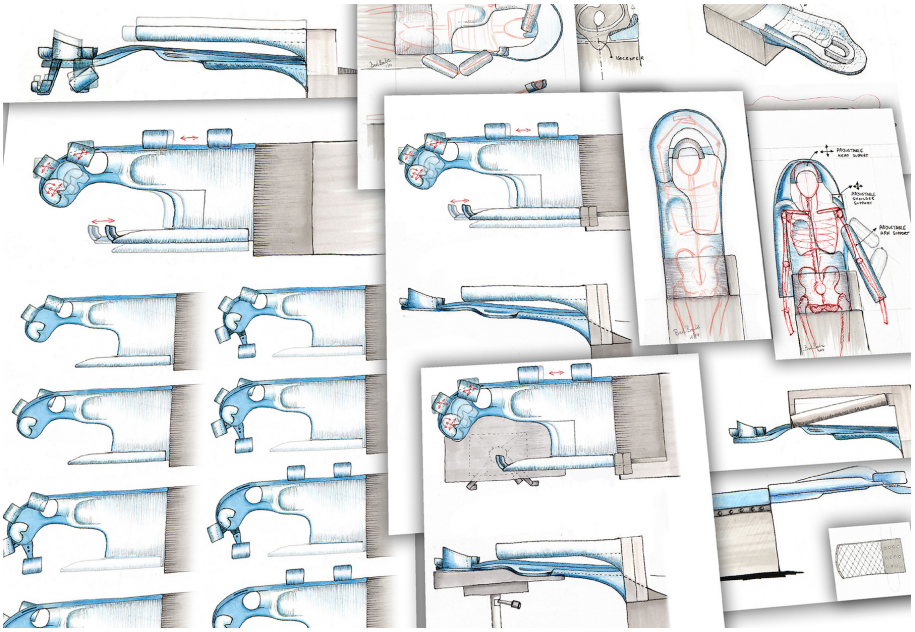


Fig. 4.7 Collage of the refinement of the asymmetric breast couch concept. Exploration of different arm supports, position studies.

4.4 CONCEPT REFINEMENT

Despite less modularity and a minimum of two different breast board devices needed for treatment (left-side and right-side), we decided that the asymmetric frame was the preferred concept. The most prominent advantage of this concept is the slim and light design, resulting in superior beam access. Due to different body anatomies, further investigation is needed wether or not different sizes of the device will be needed.

As can be seen in figure 4.7, some further refinement of the concept was performed: different arm positions were explored, patient's anatomy and gantry's range of motion were analysed. Patient positioning and fixation add-ons were studied.

ASYMMETRIC BREAST COUCH CONCEPT

The refinement of the asymmetric frame concept resulted in an unsupported breast, shoulder and upper chest region at the to-be-treated side (fig. 4.8). This enables anterior beam access for breast and LNI. An adjustable ipsilateral arm support (fig. 4.8-(2)), which can

move in anteroposterior, laterolateral and craniocaudal direction should initiate patient roll and enable proper positioning. The head support (1) should be adjustable and contralateral arm can be supported above the head or next to the body (3).

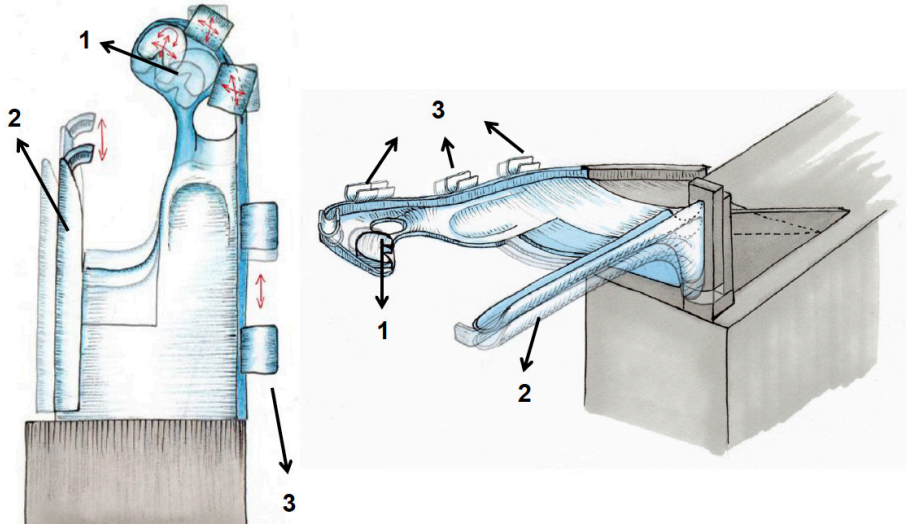


Fig. 4.8 Asymmetric breast couch concept. 1) Adjustable head support. 2) Adjustable arm support. 3) Different arm supports for contralateral arm.

4.5 CONCEPT TESTING

WEDGE REGION

In parallel with the concept exploration, discomfort and the image artefact issue with the AIO breast board wedge was investigated. On the AIO device, the part which supports the contralateral breast (so called wedge) is flat, very uncomfortable and causes imaging artefacts: a darkening in the image, coplanar with the wedge (fig. 4.10-Left). Pain was experienced at sternum and contralateral breast.

A new support surface was designed and shaped from a hard foam Polyurethane (PU) block. Derived from this PU model, a thin polystyrene (PS) shell was thermoformed, which was positioned onto the AIO breast board and tested (fig. 4.9).

By transforming the wedge into a non-planar surface, the image artefact could be resolved. Additionally, the concave shape at the contralateral breast region improves patient comfort. The right CT-image in figure 4.10 presents the new wedge concept which better follows the breast's shape and resolved image artefacts.

Fig. 4.9 Test set-up of new contralateral breast support on the AIO breast board.

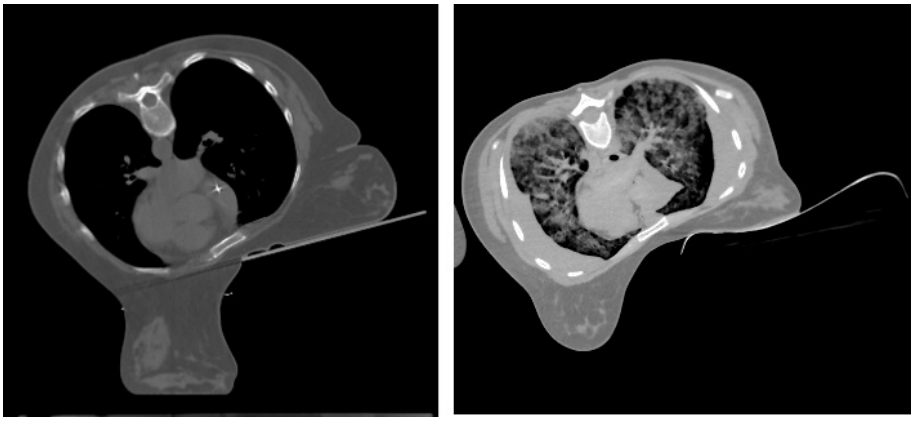


Fig. 4.10 Comparison of anatomic wedge support for contralateral breast. Left: AIO wedge with hard edge at sternum and image artefact. Right: wedge prototype with improved anatomy and no image artefacts.

4.6 CONCLUSION

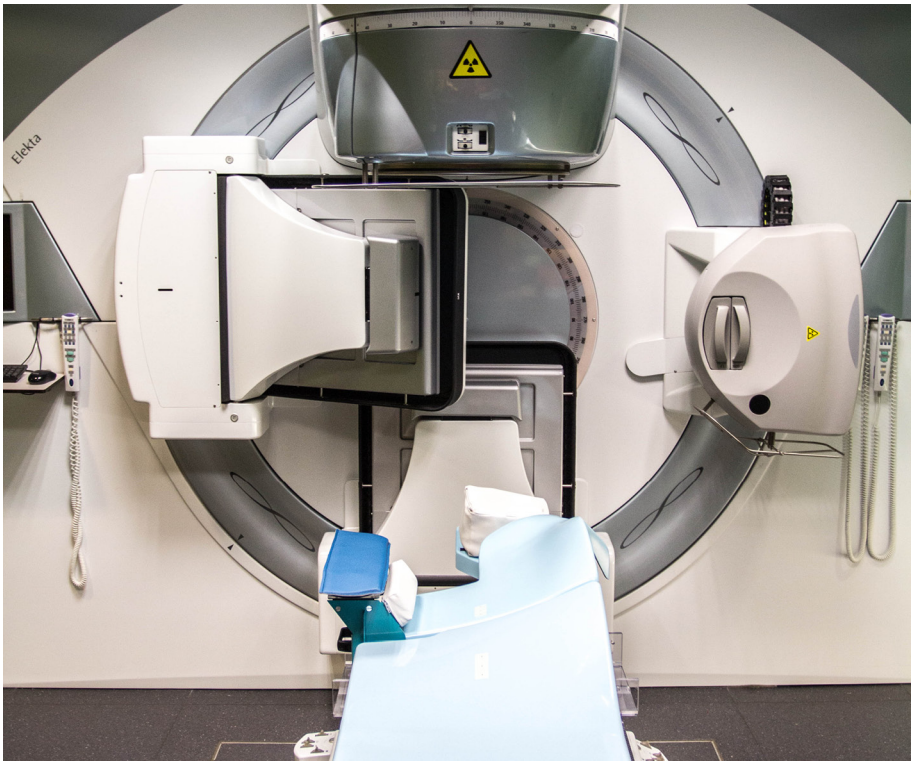
This chapter describes the preliminary research that has been executed during this research project a part was performed during the author's master thesis. Continuing on the breast cancer management that has been explained in the introduction, the different steps during the radiotherapy treatment procedure are now described in depth. We described the different commercially available breast board devices and its drawbacks. Subsequently, a concept exploration was performed. After some refinement, the asymmetric breast couch concept was the preferred choice: a thin and light structure for easy handling and superior beam access for both WBI and LNI. A new contralateral breast support was explored and showed promising results for later integration into the asymmetric concept.

Based upon this preliminary research, the feasibility of the project could be evaluated. Consequently, applications for research funds were applied. This resulted in a prototype research fund by *StarTT 241* (started during the authors master thesis). Additional funds for staff and clinical trials were applied during the author's doctoral research period (see chapter 3.6.3).

During this phase, the framework, which is explained in the following chapter, was not yet applied. A more typical product development process was followed: problem and objective definition (explained in introduction), background research, questionnaires, benchmark research, concept exploration, selection and refinement and eventually concept testing (which is more in depth explained in chapter 7: Phase I).

Chapter 5

Framework



Breast couch version BC2 on the treatment machine

In this chapter we describe the realisation and application of the framework that was used during this research project. The framework can be used as a guide for prototype development of medical devices.

5.1 DEFINITION

There are several structures which can be used as a guide or tool during the development process of products, software or projects. Some structures are very well defined and should be followed step by step, while other structures are very loose and act more as guideline.

There is no general definition of each structure. Consequently, based on several descriptions, we recapitulate our own definition[1] [2] (Ishak et al., 2005; Patten et al., 2017):

- **APPROACH**
  An approach can be considered as the loosest structure. It can refer to any way of development: a methodology, a strategy, a guideline, based on a theory, perspective or other things. It is therefore hard to define its specific meaning and perhaps should not be called a structure.
- **FRAMEWORK**
  A framework serves as a support or guide during the development process. It provides a raw structure, method or tools required, but its loose structure leaves room for inclusion of other tools, methods or practices.
- **METHODOLOGY**
  A further developed and tested framework can be considered as a model or methodology. During a methodology, a systematic analysis set of principles is defined. It can be used for comprehending which method (or set of methods) is suitable to specific cases.
- **THEORY**
  A fully developed and tested methodology can become a theory. Theories are developed to explain, predict and master the whole process. It has a fixed set of instructions, parameters and a more predictable outcome.

During the development of the breast board, we wanted to establish a new framework which was suitable for the prototyping development process of medical devices. More in particular, we wanted to map the relation between the process context and parameters; choice of prototyping materials and techniques; and prototype testing and validation during each iteration cycle.

[1] Business Dictionary – `http://www.businessdictionary.com/`
[2] Oxford Dictionary – `https://en.oxforddictionaries.com/`

5.2 EXISTING FRAMEWORKS

No applicable frameworks for Medical Device (MD) prototype development were found in literature. If a framework was found, it was mainly a regulatory, software or business-oriented framework.

Most of the practical frameworks (and other structures) are originated from software development and social science. In addition, several frameworks of mechatronic projects are also interesting since mechatronic systems are multidisciplinary devices and require specific approaches to design and optimise them (Casner, Houssin, et al., 2015). These approaches could also be used or adopted for medical prototype development. Some commonly used frameworks are:

WATERFALL FRAMEWORK

The waterfall framework (which is explained as the linear method in chapter 3, section 3.8) can be considered as the *"traditional"* approach: a linear top down structure. Every stage during the development process is well defined and each stage is normally finished before proceeding to the next stage. The advantages of this framework are: predefined requirements and expectations of every stakeholder, a more easily follow up of the process and straight forward workflow. On the other hand, changes of the stakeholders' needs, interim evaluations, and implementation of additional functions can be challenging.

AGILE FRAMEWORK

Agile development can be seen as an iterative and team-based development approach structure where the requirements, approach and solutions rapidly evolve through each iterative cycle (so called *"sprints"*in software development). Each sprint has a predefined duration, requirements and scope. At the end of every sprint, it is reviewed and evaluated by the team and every other stakeholder. This results in a high level of flexibility and involvement of every stakeholder. Some advantages of this framework are: several opportunities for interim evaluation and adjustments, great involvement of stakeholders, reduced costs and time to market (Version One, 2009). Besides that, some disadvantages may be: high demand of participation in the project (both stakeholders as team), the high level of iterative cycles may result in a decrease of overall end quality of the product.

V-MODEL FRAMEWORK

The V-model may be considered as an extension or improvement of the waterfall framework and can be seen as a verification and validation model. It describes on the left side of the V-formation the requirements, specifications and activities that need to be performed. On the right side, it reflects the integration, verification and validation of the process (Pritchard, 2006).

In contrary to the waterfall, and moving linear, the V-model returns back upwards after the development stage. It illustrates the relation between the process requirements, specifications and selection; and the testing, validation and verification of it. Once at the bottom of the V-model, phase verification and validation start. As a stage on a certain horizontal

level of the V-model is validated with the other side, you are able to go to the next stage of validation and further in the development phase (Mc Hugh et al., 2013). In the case of a problem during verification or validation on a certain stage, the the opposite side of the V-model must be revisited and if necessary reiterated (Mc Hugh et al., 2013). Some advantages of this framework are: ease of use and more concrete workflow, evaluation and verification during each phase. Some disadvantages may be: rigid structure, less flexibility.

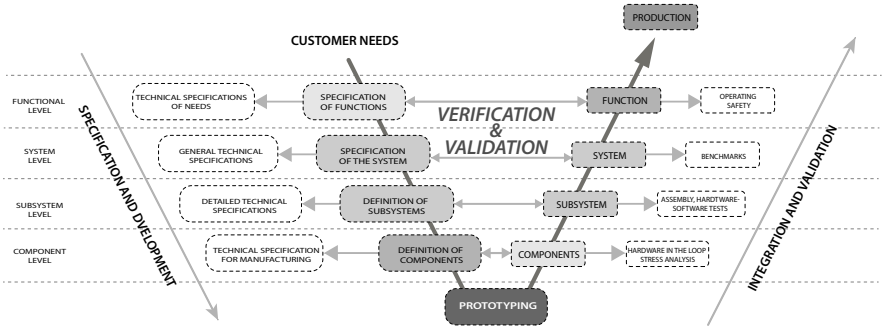


Fig. 5.1 Example of a V-model framework for designing mechatronic systems. Adopted form (Casner, Renaud, et al., 2012).

Medical device development is often developed in accordance with the regulatory requirements of the region where the product is being marketed (Mc Hugh et al., 2013). Hence, the V-model is often used due to its partially linear structure, implementation, testing and validation phases (Mc Hugh et al., 2013; McCaffery, Donnelly, et al., 2004). In addition, the V-model appears to be the most suitable framework regarding regulatory requirement (McCaffery, McFall, et al., 2005).

5.3 A NEW FRAMEWORK

When developing medical devices, you are often restricted by protocols, ethics, regulatory requirements, moral questions and material restrictions (Martin, Murphy, et al., 2006).

During this research project, a new framework for medical device development was established to better define, develop and validate medical prototypes. It has it roots derived from the general iterative product development approach (*prototype, make, test* and *iterate*) (Detand et al., 2009). The architectural structure can be considered as a hybrid model: an Agile V-model (or AV-model).

The V-structure serves as a defined structure for protocol and parameter validation during each iteration cycle, while the agile approach is more oriented towards the general approach and multiple iteration cycles that are performed, involvement of stakeholders through co-creation and flexibility during each phase.

During each iteration, several fundamental steps needed to be undertaken: What will be developed and achieved during each iteration phase; what are the requirements and protocols; which techniques and approach will be used; how will the prototype development be executed; which user tests will be performed and how can we validate it.

Therefore, we divide each iteration cycle into three stages:

- **Process Analysis**
- **Process & Prototype Parameters**
- **Process Selection & Execution**

Figure 5.2 illustrates the framework. The left side represents the specification stages with the design input, the right side represents the integration and validation stages of the process. The bottom of the V-model represents the development phase (Balaji, 2012). The outcome of the right side provides feedback loops and verification to the design input. Note that each iteration cycle can have a different output: it can be more medical, technical or user oriented.

When every stage is verified through it feedback loops (**make, test & evaluate**), the iteration phase is completed. The output is examined and used as input for a new iteration phase.

In the case of undesired prototype results, a user test failure or unsatisfactory medical results; the specific stage during the framework should be redone until the required results are achieved.

5.3.1 PROCESS ANALYSIS

During the process analysis, the current process is inspected and mainly *"what"*-questions are investigated: what is the current process, what do we want to investigate, what do we want to improve, what do we want to measure, what are the protocols, what prototypes do we need, what are the fundamental parameters, what tests do we want to perform, etc.

APPLICATION

How the process is analysed, can be done on several ways:

- **INVESTIGATION OF THE STAKEHOLDERS**
  Defining the ideas, needs and wishes of the stakeholders can be done through observations, follow-ups, interviews, co-creation sessions, surveys, etc.

- **ANALYSIS OF EXISTING PROCESSES AND SYSTEMS**
  To be able to get a better understanding of the current process or system, field research can be performed, existing processes or systems can be researched and analysed.

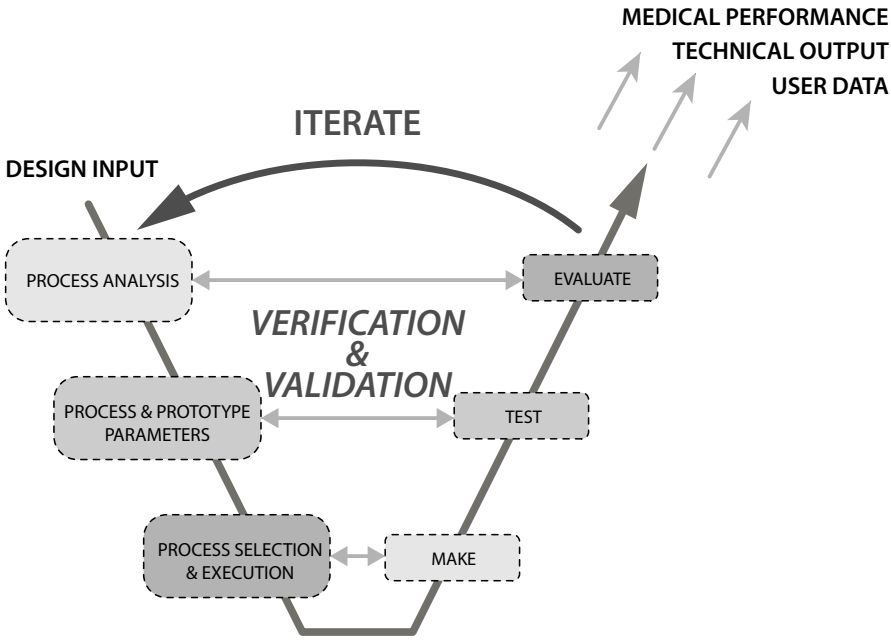


Fig. 5.2 Iterative prototyping framework for medical device development.

- **USER ANALYSIS**
  What does the user want or need? This can be done through user-research, surveys, interviews, follow-ups and others.

5.3.2 PROCESS AND PROTOTYPE PARAMETERS

Defining the correct parameters of both process and prototype during the iteration phase, is important to find the best suitable prototyping process. It will directly affect the outcome and result in better verification of each stage. These parameters can be related to following aspects:

- **PURPOSE**
  What will be the purpose of the prototypes: they can be used for visual representation, proof of concept, ergonomic testing, functional testing, structural testing and so on.
- **DEDUCTION**
  Sometimes parameters can be derived from similar processes or products. When designing a new version of an existing device (or based on), these parameters can be predefined from previous experiences, machine restrictions, existing devices or boundaries.

- **TIME**
  The amount of time that you are allowed or want to invest in your prototype will be directly related to the process selection in the next stage: it is of great importance to keep in mind that this can be a big constraint.

- **QUANTITY**
  How many prototypes need to be produced? One-of-a-kind or a small serie? Do they need to be reproducible?

- **QUALITY**
  Which quality, finishing or precision is desired?

- **MATERIAL**
  Which material is needed? Can low-fi/rapid prototyping material be used or is the same material as for the final product preferred? Is it biocompatible? Can it be sterilised? Is it recyclable? etc.

- **TEST**
  Do we want to test it with the end user, volunteers, in silico testing, etc..

APPLICATION
All these parameters and design choices are somehow related to each other and the change of a specific parameters will likely affect another (or several). It is therefore important to know which parameters are significant during the next process selection and execution stage.

Defining the right process and prototype parameters can be done through elaborating above aspects and interpretation of: preliminary research, interviews, investigations, wishes and needs.

5.3.3 PROCESS SELECTION AND EXECUTION

Based on the defined parameters from the previous stage, the correct prototyping process is selected and executed. Most of the techniques used, are standard prototyping techniques for product development (Hallgrimsson, 2012). Some techniques which were used during this research project are:

- **HAND-SCULPTING**
  Different techniques with hand tools can be used for the sculpting of early stage prototypes to more advanced ones: hard PU-foam, or wood can be sculpted using grates, files or sandpaper. Clay sculpting can be used for adding material onto prototypes(Yamada, 2006).

- **MACHINING**
  The principal machining processes can be considered turning, drilling and milling.

By means of removing material, you are able to shape a wide array of materials with high accuracy [3].

- **DIGITAL MANUFACTURING**
  Digital manufacturing is the fabrication process with computers or coming from digital files, directly to the product. They offer fast iterations possibilities, high accuracy and have the ability to produce complex models (Gershenfeld, 2012). Lasercutting, Three-Dimensional (3D)-printing and Computer Numeric Control (CNC)-milling are all digital manufacturing techniques which were used during this project [3].

  Several parts were 3D-printed on a MarkForged MarkTwo™ [4] 3D-printer. This is a mid-range Fused Deposition Modeling (FDM) 3D-printer which enables continuous fibre reinforcement: it can print with a continuous fibre reinforced Polyamide (PA) filament (fibreglass, carbon fibre or aramid), which results in significantly improved strength, in comparison with standard 3D printed parts. We used fibreglass reinforced PA parts which enabled us to produce low volume custom parts with high strength, accuracy and low cost. All these parts are both X-Ray and MRI compatible since they are metal free. Furthermore, they have excellent structural properties and are easy to reproduce.

- **COMPOSITE LAMINATES**
  Composites are highly popular and have a long history going form construction sites (concrete with reinforced metal) to nano-technology (carbon nanotubes). It is often used as prototyping technique and is relative easy to work with (Detand et al., 2009). A composite is a material made from two (or more) material with totally different physical properties. The combined material results in improved properties. Therefore a composite can become lighter, stronger or less expensive in comparison with the conventional materials [3] (R. F. Gibson, 1994).

  Fibre reinforced plastics are comprised of a polymer matrix reinforced with fibres (such as a fibreglass and polyester laminate) (Edwards, 1998). Fibreglass and carbon fibre laminates are widely used in automotive, healthcare, sports, space and maritime sectors.

- **MOULD MAKING**
  Moulds can be used for copying a specific design, production of small series which require higher precision, etc. Moulds can be produced in metal, wood, plaster, silicone or composites [3].

  Composite moulds are relatively cheap and easy to manufacture (Detand et al., 2009). Series up to 100+ parts per mould can be produced. they are easy to produce and have good tolerances (Summerscales et al., 2005). The produced products from the moulds can be (but is not limited) in plastic, silicone or composite laminates

[3] Design for Low Volume Production – `http://designforlowvolumeproduction.blogspot.com/p/technology-sheets.html`
[4] Markforged, Inc. – `https://markforged.com/`

(using hand lay-up-, vacuum bagging-, Resin Infusion Moulding (RIM)- or other techniques).

APPLICATION

Prototype process selection is dependent on the process parameters (as explained in 5.3.2) and the skill set of the designer/design team: a certain techniques can be fast and high efficient, but requiring high skills or experience. When executing this technique without experience, the outcome may be a time-consuming process with low efficiency and poor end-results. It is therefore the task of the designer to select and execute the correct prototyping process, according to the process parameters and his own skillset.

The designer is not necessary the producer of the prototypes (but preferably is). In the case of not producing the prototypes by his own, it is his task to have knowledge of the different prototyping and development techniques and knowing when to use them.

5.4 RESULTS

As explained previously, each stage can be looped back and validated through a **make, test & evaluate** stage (fig. 5.2):

- **Make <-> Process Selection**: The prototype, product or service is executed and validated if the correct technique was used.
- **Test <-> Process Parameters**: The prototype is tested and user tests are executed. What are the results? Did we meet the predefined protocols and parameters? Do we have the desired quality?
- **Evaluate <-> Process Analysis**: Evaluation of the test is performed: Was the test useful, what are the pro's and contra's, are the results significant? Are the test results as predicted? What are the expected and unexpected outcomes?

When each question during every feedback loop is fulfilled, the verification and validation of the iteration phase is completed. The outcome, which can be focused to a specific (or several) key role such as medical staff, design team or patient (see section 3.5), is consolidated into the next iteration phase.

5.4.1 APPLICATION

Since every phase of the product development process *(concept-, prototype-, product development and production)* has different wishes, needs, protocols, parameters, execution

[3]Design for Low Volume Production –
`http://designforlowvolumeproduction.blogspot.com/p/technology-sheets.html`

methods and outcomes; the framework could also be applied on the other phases during the development process:

- **CONCEPT DEVELOPMENT**
  During the analysis of the process, it is important to broach the fundamental requirements and sketch the current problem.

  The parameters can define which kind of concept is desired. What are the wishes and needs for it? What is the goal?

  While selecting and executing the prototype process, questions can be asked such as: how will I generate concepts, should I execute surveys, organise brainstorm- and co-creation sessions, who will I integrate during the exploration phase, ... Mood boards, renders, drawings, sketches and other methods can be used to generate and visualise ideas.

- **PROTOTYPE DEVELOPMENT**
  The main goal of this framework was the creation of a practical structure for prototype development during MDD and is thus already explained along this chapter. A more detailed explanation of each phase can be found in section 5.4.2.

- **PRODUCT DEVELOPMENT**
  When applying this framework to the product development phase, production analysis, parameters and execution (production techniques) can be analysed. Some question may be: how we want to develop it, what is the batch size, which production techniques will be used or which regulations are needed.

  Different parameters could be quality, quantity, durability or expected precision.

- **(MASS) PRODUCTION**
  Applied on (mass)production, questions arise such as: scalability, distribution, recycling, marketing and follow-up.

5.4.2 BREAST BOARD

When retrospecting the development process of the breast coach during this thesis, the framework fundamentals were established during the first phase and gradually optimised and applied throughout the next phases of this project:

PHASE I

Process Analysis: In the first phase, we wanted to verify the prone crawl technique and position, test different arm- positions and supports. Additionally, we wanted to analyse pain and comfort evaluation.

	PHASE	FRAMEWORK	ACHIEVEMENTS
2014	PRELIMINARY RESEARCH	-	-
2014-2015	PHASE I	ESTABLISHING FUNDAMENTALS	POSITION FUNDAMENTALS, PROOF OF CONCEPT, USER COMFORT TESTS
2016	PHASE II	OPTIMISATION	FUNCTIONAL PROTOTYPES, PRE-CLINICAL TRIAL, IN-SILICO TESTS
2017	PHASE III	UTILISATION	FULLY FUNCTIONAL PROTOTYPES, CLINICAL TRIAL, OPTIMISATION, REAL CONTEXT
2018	PHASE IV	UTILISATION	OPTIMISED PROTOTYPES, SMALL SERIES, LARGE SCALE CLINICAL TESTING
2019	PHASE V	UTILISATION	PRE-MARKET PRODUCTION, OPTIMISED FOR INDUSTRIALISATION, ANALYSIS

Fig. 5.3 Overview of the framework, applied on the different phases during this thesis.

Process and Prototype Parameters: To be able to test the patient position and comfort, we needed to construct a proof of concept prototype. In order to be able to execute fast user tests, we needed simple prototypes that could be easily modified on the spot.

Selection and Execution: By using simple prototyping techniques, basic skills and inferior materials, fast prototypes iteration were produced. User tests with small groups and in silico treatments, enabled us to verify early in the design process the advantages of the prone crawl position, possible beam access and validate the patient position & comfort.

PHASE II

Process Analysis: In the second phase we wanted a functional prototype which could be tested and used for the first clinical trials. Therefore, we needed improved accuracy, optimised patient comfort and improved favourable beam paths.

Process and Prototype Parameters: To be able to test beam accessibility, prototypes needed to be reproducible, thin and lightweight. We also required a stronger and structural prototype which was suitable for comfort testing, pre-clinical trials and in silico treatment.

Selection and Execution: By producing a mould and resin infusing fibreglass prototypes and using Hi-Fi materials and skills, we could produce functional prototypes. By designing a sheet metal arm support, we could achieve a strong and accurate arm module, which is suitable for structural tests. By indexing every adjustable part (arm support, hip support) we could measure and evaluate different patient positions. Pain and comfort evaluations were executed for comfort optimisation. With in-context testing, i.e. on the real treatment machine, we could better evaluate patient- and usability comfort.

PHASE III

Process Analysis: During the third phase we wanted fully functional prototypes which could be used for bigger clinical trials. We wanted to test the prototypes in the real environment and use them as for real treatment.

Process and Prototype Parameters: To be able to execute the clinical trial, we needed four prototypes: two identical left-sided and two identical left-sided (mirrored from the left-sided). Therefore, every prototype needed to be reproducible, identical and fully functional. to be able to compare the study results, patient positioning, accuracy and product error needed to be equal for the whole set of prototypes.

Selection and Execution: To be able to have 4 reproducible prototypes, the design was 3D scanned, digitised and optimised in a CAD-CAM environment. Left- and right-sided PU moulds were CNC-milled. Prototypes consisted of fibreglass and epoxy resin. Through the RIM techniques, prototypes could be produced with high precision and consistency. Arm modules were manufactured by sheet metal fabrication. Pain and comfort was evaluated for comfort optimisation. During treatment, patient position and setup precision were analysed and compared.

PHASE IV

Process Analysis: Fourth phase prototypes were used for a big clinical trial: inclusion of more than 380 patients over three treatment institutions. With this study, we want to compare breast retraction between prone crawl and supine WBI+LNI. Additional objectives are: toxicity, cosmesis, Quality of Life (QoL), dosimetric analysis.

Process and Prototype Parameters: Since multiple hospitals are involved, the prototypes need to be modular constructed so they would fit for various table connections. Every device needs to be identical to be able to compare data. The devices need to be regulated and approved.

Selection and Execution: We developed a small series of twelve devices. The head- and arm support was further optimised, which resulted in improved patient position and comfort. FAGG applications was submitted and accepted, each prototype is labelled and their function, handling, storage and production method described.

PHASE V

The fifth development phase is not covered in this dissertation and can be considered future work. A potential application of the framework could be:

Process Analysis: We want optimised prototypes for industrial production, MRI compatible device and integration of a patient ventilator for DIBH.

Process and Prototype Parameters: Weight and strength optimisation, usability improvements, cost optimisation, patient experience and DIBH analysis.

Selection and Execution: new CNC milled moulds, mounting inserts, cutting gauge, gluing gauge, assembly gauge. Standardisation, outsourcing of parts, etc.

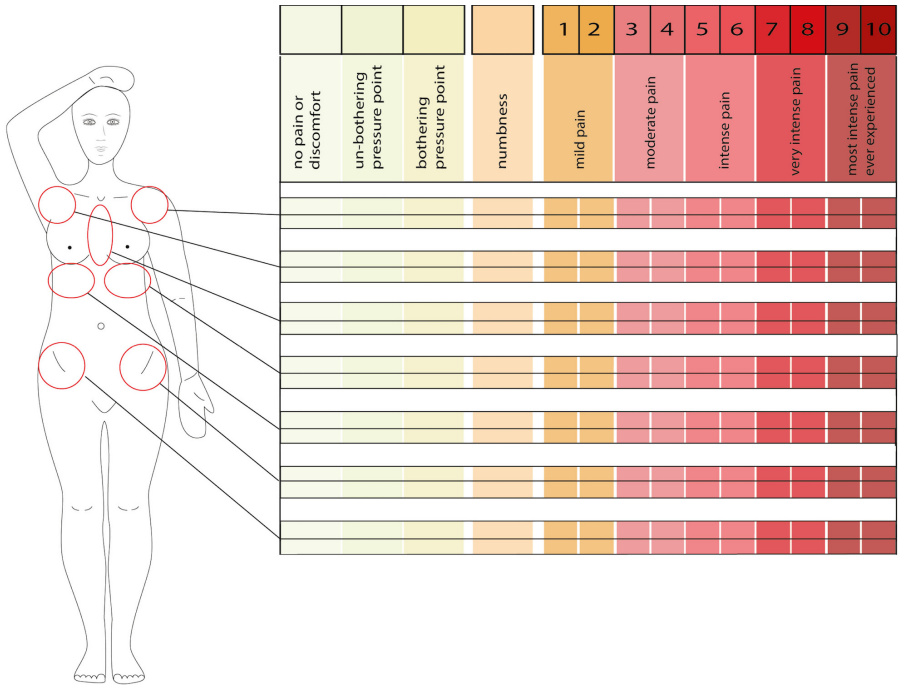
5.5 CONCLUSION

In this chapter we described the different structures which can be used for product development and explained some commonly used frameworks. We developed a new framework which can be used as a guidance for medical prototype development (G_9). We chose to use a V-model based framework due to the complexity of the project, regulations and protocols. The framework is divided in three stages: *process analysis, process & prototype parameters and process selection & and execution*. Following the principles of a V-model, each stage is validated and verified before proceeding to a new iteration cycle *(make, test evaluate)*(G_6). Due to multiple iteration cycles, co-creation and flexibility of the project; a more agile approach is applied for the overall project. We can therefore consider our framework a hybrid model: an agile V-model.

This framework was established and evolved throughout this research project. It was applied for the construction of the prone breast couch and its iterations. During each development phase in this work, it was successfully used and further optimised. Its main purpose is to serve as a support or guidance during the prototype development process of medical devices but can also be used for the prototype development of products or other phases during the product development process. It is not yet a finished structure and is open for inclusion of other tools, practices or methods.

Chapter 6

Pain & Comfort Evaluation



Final pain assessment scale

In this chapter we describe the evolution of the patient's pain- and comfort assessment during this research project, the background of end-user comfort is described and the used pain intensity measurement tool and it drawbacks during the first phase are explained. In addition, we classify a new pain intensity measurement system.

6.1 BACKGROUND

6.1.1 END USER COMFORT

End-user comfort is well addressed in ergonomics literature for commercial products. One of the most researched is sitting comfort of different seats (De Looze et al., 2003). Little published work exists on end user comfort and ergonomic aspects of medical device development (Martin, Norris, et al., 2010). If research was done, it was about patient safety and ergonomics (Clarkson et al., 2004; Martin, Norris, et al., 2010), user comfort for medical staff (instruments) (Loring et al., 2010; Xiao, 2014), patient comfort during operations (M. P. Jensen, Chen, et al., 2002) and medicine handling and dispensing (Dong et al., 2009). One of the possible reasons why there is not much published research about the development of medical devices is the understandable reluctance of companies to disclose commercially sensitive information about the development process (Martin, Clark, et al., 2012).

6.1.2 WHAT IS COMFORT?

There is no widely accepted definition of comfort. Webster's third International Dictionary of the English Language (Unabridged, 1981) defines comfort as a state or feeling of having relief, encouragement and enjoyment. Slater (1985) defines comfort as a pleasant state of physiological, psychological and physical harmony between a human being and its environment. L.G. (1980) stresses comfort is a state of a person involving a sense of subjective wellbeing, in reaction to an environment or situation. However, some issues are not under debate (De Looze et al., 2003): (1) comfort is a construct of a subjectively-defined personal nature; (2) comfort is affected by factors of a various nature (physical, physiological, psychological); and (3) comfort is a reaction to the environment.

The current debate in literature is about the difference between comfort and discomfort. It has been specified as two different states (Hertzberg, 1972; P., 1969), as opposites on a continuous scale (C. Jensen et al., 1992; Vergara et al., 2000; Wilder et al., 1994) and as two separate entities by different factors (Zhang et al., 1996). In the case of medical device development, we could say feelings of discomfort like pain, tiredness, soreness and numbness could be associated with physical factors while comfort could be associated with feelings of relaxation and well-being (Zhang et al., 1996).

6.1.3 FACTORS OF DISCOMFORT

There are several factors which influence comfort and discomfort. As Zhang et al. (1996) conclude for sitting, physical factors such as ache, blood circulation cut off, cramped and sore muscles, blisters, fatigue, pressure points, stiffness and unsupported areas. underlie discomfort, while comfort is related to descriptors such as: calm, content, luxurious, pleasant, supported andm warm.

Some additional factors which can influence comfort and discomfort for patients using or lying on medical devices include but are not limited to:

- **TREATMENT TIME:** the time value or duration of the treatment and time a patient lies on the device or is immobilised (E. B. Lerner et al., 2000). A patient could experience no pain or discomfort in the first radiotherapy session while after several sessions the patient could experience severe pain and discomfort and, in worst case, the treatment could be interrupted.

- **FIXATION & IMMOBILISATION:** patient immobilisation done by fixation can result in pain or discomfort caused by hard support areas, tensioned belts or local pressure areas (Cordell et al., 1995; E. B. Lerner et al., 2000; E. Lerner et al., 1996).

- **PATIENT MOBILITY:** some elderly patients have painful joints and mobility issues caused by arthrosis, arthritis or other conditions (Petersson, 1986). Also, some patients underwent breast surgery or lymph node removal, which can result in restricted movement possibilities.

- **MATERIAL PROPERTIES:** material properties can be related to both comfort and discomfort. A surface can have a high or low friction finishing, anti-slip, soft or hard touch feeling, warm or cold feeling (E. Lerner et al., 1996).

- **DESIGN OF THE MEDICAL DEVICE ITSELF:** shape elements of the device can gratefully affect patients comfort: wrong anatomical proportions, partial body supports and uneven pressure distribution (Cordell et al., 1995). De Looze et al. (2003) and Zhang et al. (1996) concluded that the correlation between pressure distribution and discomfort appears to be most clear objective measure, in particularly for car seats.

- **PATIENT'S FREE BODY DIAGRAM:** the patient's FBD can also be related to the design of the medical device: pressure points, partial body support or uneven distribution could result in uncompensated internal body forces which could cause stress or strain in other body regions. Consequently, this could influence the patient's position, stability or comfort experience.

6.2 PAIN AND COMFORT EVALUATION

Patient comfort is an important user aspect during this development process of a support device since each patient is treated between 15 and 25 successive treatment sessions of each 10 to 20 minutes (Veldeman, De Gersem, et al., 2012). This results in being positioned up to 500 minutes on the device itself. During treatment, symptoms of pain, sore muscles, bruises, pinched veins and discomfort can appear over time (Huppert et al., 2011; Veldeman, Speleers, et al., 2010).

The Visual Analogue Scale (VAS), Verbal Rating Scale (VRS) and Numerical Rating Scale (NRS) are among the most common Pain Intensity (PI) measurement systems used by clinicians and researchers. There is an extensive literature regarding the reliability and validity of each of these systems across many populations (Chanques et al., 2010; M. P. Jensen, Chen, et al., 2002; M. P. Jensen, Karoly, et al., 1986).

6.2.1 PHASE I - INITIAL PAIN ASSESSMENT

During phase I, we composed a survey consisting of six questions related to specific regions on the female body where they may experience pain: *neck, right shoulder, left shoulder, thorax, right arm, left arm*. Each region could be rated on a NRS from 0 to 10 going from no pain to an unbearable pain experienced respectively. NRSs are considered to be the most versatile and commonly used scales for pain intensity assessments (Hjermstad et al., 2011). Question 7 was related to patient stability: they could report if they had a feeling of *"rolling or sliding off"* the device. Additionally, they were able mark regions on a sketch of a female body with an *X* for experiencing pain or an *O* for experiencing discomfort (see figure 6.1).

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INDUSTRIAL DESIGN CENTER

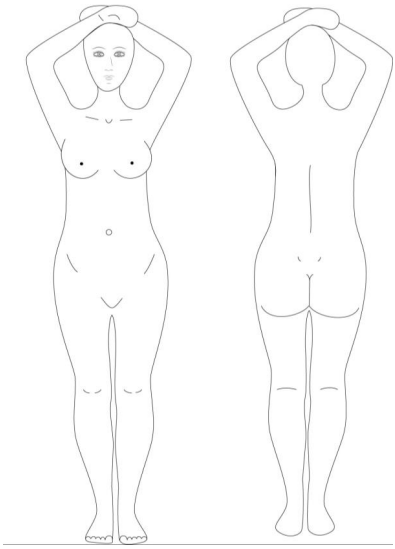
Breast board evaluation form

Patiënt nr:
Length:
weight:

Please fill in your pain experience after lying on the device for at least 10 minutes.
Mark with an X

	No	yes, (1= few; 10 = unbearable pain)									
	0	1	2	3	4	5	6	7	8	9	10
Did you experience pain or discomfort in the neck?											
Did you experience pain or discomfort in the right shoulder?											
Did you experience pain or discomfort in the left shoulder?											
Did you experience pain or discomfort in the right arm?											
Did you experience pain or discomfort in the left arm?											
Did you experience pain or discomfort in the thorax?											
Did you have the feeling of rolling off the table?											

Where did you experience pain (mark with X) or discomfort (mark with O).



Remarks:

Thank you for your cooperation.

Fig. 6.1 Pain and comfort form for AIO Orfit breast board and Phase I prototypes.

6.2.1.1 RESULTS

VISUAL REPRESENTATION

After each pain and comfort assessment, data was gathered and pain scores were visually plotted onto a female body representation (figure 6.2). Each blue circle represents a registered pain case. The radius is proportional to the pain intensity (1 to 10). Number of overlapping circles, and thus colour intensity, indicates the amount of pain registrations at this specific location. Grey circles on the pain scale were unused grades.

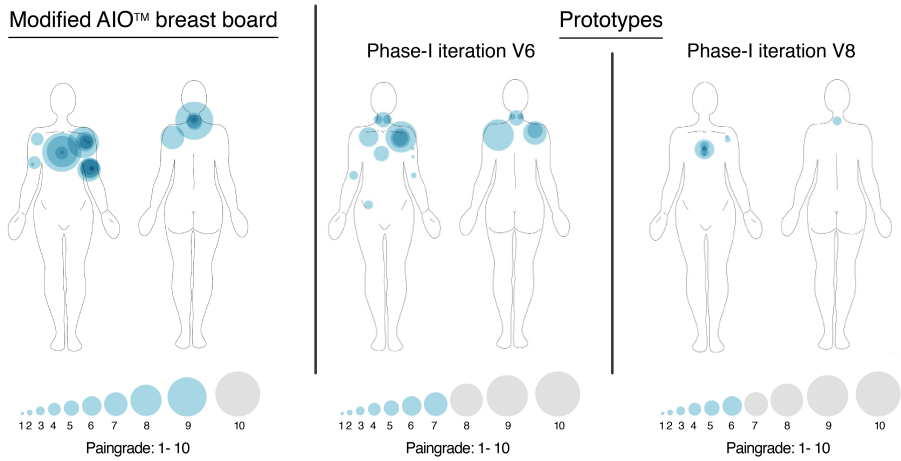


Fig. 6.2 Visual representation of pain and comfort scored on the modified AIO™ Orfit breast board, iteration V6 and V8 breast board prototype.

When evaluating pain and comfort for the AIO™ Orfit breast board and phase I prototypes (V6 and V8), the use of a standard NRS was effective: pain grades going from 1 up to 9 (AIO™) were reported, resulting in an evenly distributed pain assessment. Although when interviewing patients, they often reported that it was difficult to give an objective pain score and tended to downplay the experienced pain. Results of phase I comfort evaluation are further described in chapter 7, section 7.3.5. As can be seen for iteration V8 in figure 6.2, the amount of registered pain cases and intensity has been drastically decreased. This indicates that pain assessments of next device iterations will be more shifted towards the left side of the scale.

6.2.2 PHASE II - EXPLORATION

During phase II, prototype iterations became better and more advanced, resulting in improved comfort, and thus decreased pain intensity experiences. To be able to have usable data (for comfort and patient position optimisation), we wanted a more homogeneous distributed result. Following this, some alternative PI measurement systems were explored.

We tested three different pain and comfort evaluation forms with 22 volunteers. At the end of every user test, they could select their preferred rating system:

- ***Standard NRS-system*** – A standard numeric rating system is widely used. The volunteers can give a number going from 1 to 10. A score from 1-4 can be seen as mild pain, 5-6 as moderate pain and 7-10 as severe pain. The problem which emerges here is that the people do not know this comparison and find it sometimes hard to compare their pain to with just a number.
- ***VAS-system*** – Since some people find it difficult to rate pain with a number, a visual rating system could be beneficial: the person marks an x on the line, which represents their pain intensity. The distance to the x-mark is measured and represents the pain intensity. In practice, this is more challenging since there is only a line with on the left- and right side the words *"no pain"* and *"unbearable pain"* respectively. everything in-between is a blind zone, and difficult to judge.
- ***Combined Metric Scale*** – A combined metric scale (fig. 6.3) can be seen as a VAS with multiple descriptive cues (derived from categorical pain scales). This enables people to rate their pain intensity with greater clarity, using verbal descriptors (Averbuch et al., 2004).

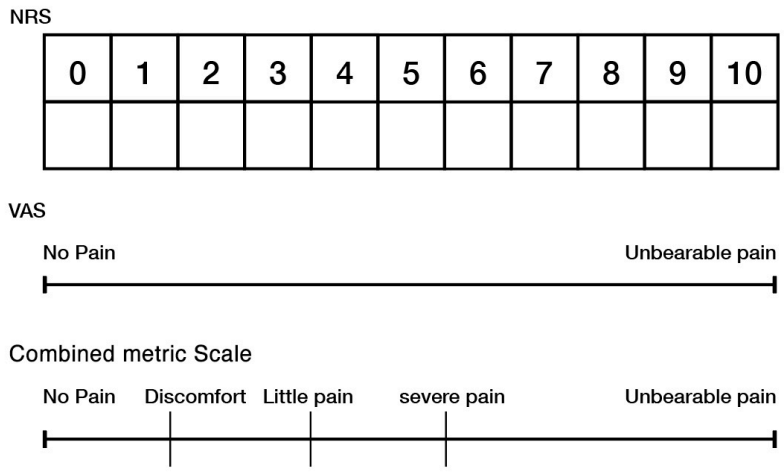


Fig. 6.3 Three different pain scales which could be selected: NRS, VAS and Combined metric scale.

6.2.2.1 RESULTS

Volunteers could rate eight different body regions + evaluate their feelings of stability and stress while being positioned. Out of 22 volunteers, 11 preferred the standard NRS system.

In general, all 22 volunteers reported for all 3 evaluation forms low pain scores: pain reports were more shifted towards the left side (near no pain) and often no *"pain"* was registered. Nonetheless patients still reported factors of discomfort. As before, they often reported that it was difficult to rate an objective pain score and tended to downplay their experienced pain since *"the new prototype is already way less painful than the old one"*.

	pain or discomfort regions							
volunteer	Neck	Head	R-shoulder	L-shoulder	R-arm	L-arm	Sternum	hip region
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	3	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	3	0
7	0	4	0	0	4	0	4	4
8	0	1	0	0	7	0	5	0
9	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	1
11	0	0	0	0	0	0	0	0
avg	0,00	0,45	0,00	0,00	1,00	0,00	1,36	0,45

Fig. 6.4 Pain and comfort evaluation using the NRS 10 system for prototype iteration 2.3. Almost all pain regions scored very low.

To be able to measure and evaluate the patient's experience on a more objective way, we wanted to build a new PI measurement system which enables us to evaluate both pain and discomfort.

6.2.3 PHASE III - A NEW SYSTEM

Since standard numeric, categorical or visual PI measurement system did not deliver the desired results, we wanted to establish a more visual system with explanatory words, visual represented pain regions and being able to evaluate discomfort. Following this, we developed a new PI measurement system (fig.6.5), which can be seen as a hybrid model of previously mentioned systems. The system comprises two parts:

- The first part consists of four descriptors related to discomfort. They are located on the left side of figure 6.5: *no pain or discomfort; non-interfering pressure point; interfering pressure point; and numbness*. They can be seen as feelings of discomfort but no physical pain. they are measured on a VRS and are more qualitative oriented.

- The second part consists of five explanatory descriptor related to conventional PI measurements (right side of figure 6.5) : *little-, moderate-,strong-,very strong- and unbearable pain*. They can be seen as feelings of physical pain. In addition, they are rated on a NRS going from 1 to 10 and can thus afterwards be measured more quantitative.

The pain & comfort assessment form is designed in colour, which adds a more visual feedback and feeling to the pain and discomfort descriptors.

Eleven possible pain areas are visualised on a sketch of a female body and can be evaluated: *neck, thorax(left-right), sternum, back, left- and right hip, left- right upper arm and left- right lower arm*. Furthermore, patients have the possibility to specify additional pain regions by choice.

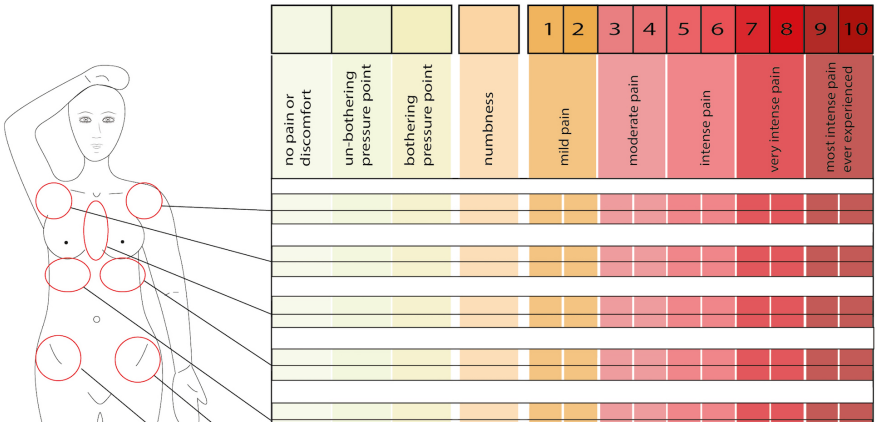


Fig. 6.5 Section of the hybrid pain evaluation measurement system. Left side: visual indication of the pain areas. Left side of the scale(unnumbered): VRS for feelings of discomfort. Right side: NRS with explanatory words for feelings of pain.

6.2.3.1 RESULTS

The new system enabled us to evaluate pressure/tension scores (related to discomfort) and pain scores, for the eleven different regions. Patients were able to score both discomfort and pain on the same PI measurement system. A more in depth description of the results can be found in chapter 9: Phase III.

VISUAL REPRESENTATION

The visual representation of the new PI measurement system is divided in two parts: a visualisation of the discomfort factors such as pressure points, tension and numbness (blue circles), and a visualisation of the experienced pain (red circles).

In order to have a correct interpretation of the results, both representations should be viewed side by side because when pain diminishes, pressure or discomfort could increase. This could result in a decrease in discomfort scored (blue) while scored pain is increased (red).

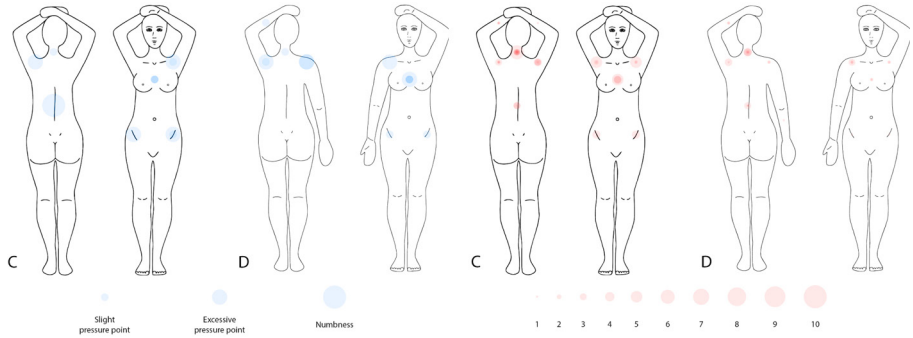


Fig. 6.6 Visual representation of discomfort assessment (blue) and pain intensity assessment (red), viewed side by side.

6.3 CONCLUSION

Proper pain evaluation can be challenging. Especially when the experienced pain is low and more factors of discomfort rather than pain are experienced. Subsequently, the currently available pain assessment systems did not work as desired during our user tests. In order to be able to properly evaluate pain and discomfort, we developed a new PI measurement systems which is better suited for our user tests during this project.

By developing a new *"hybrid"* PI measurement system we were able to record both discomfort and pain intensity with the same system. The visual indications of pain regions onto the female body sketch, together with the colour coded scale, enables users to better evaluate PI with greater clarity and in a more coherent way (G_5).

Through visual representation of both discomfort (*pressure points and numbness, blue circles*) and pain evaluation (*1-10, red circles*) we were able to present them in a clear and understandable way.

A more in depth investigating and testing of different PI measurement systems could be beneficial, but would require more time, research exploration, testing and evaluation. The new system was evaluated with 50+ patients during this work and proved to be sufficient for this project (G_9).

Based upon previous findings, we could say that most PI measurement systems are generally oriented towards a more intense pain evaluation rather than discomfort, pressure points, numb feeling or other less linear measurable discomfort factors. Hence, when only minor pain or discomfort is experienced, these PI measurement systems usually lead to superficial insights.

During phase I, we used a standard NRS. This worked well, and delivered the expected results (see section: 7.3). Due to the patient comfort improvements of phase II prototypes (and diminishing of high pain reports), pain & comfort scores were shifted more to the

left of the scale and not evenly distributed, resulting in less usable data. To be able to better evaluate pain & comfort, we developed the new PI measurement system, with the result that pain & comfort evaluations of the BC1 prototype during phase II were more evenly distributed and delivered interesting results for both discomfort and pain evaluation (see section: 9.2.2). During phase III, we also used the new measurement system. The results confirm that the scale is usable for both discomfort and pain evaluation.

Chapter 7

Phase I

Breast couch version BBV8

During the first iteration phase, basic parameters and fundamentals of the device were determined to obtain and validate a comfortable prone crawl patient position. Low fidelity prototypes were produced with inferior materials and basic skills. A proof of concept was established and user tests were executed on a small scale.

7.1 FUNDAMENTALS

The fundamental parameters for the prone crawl prototypes (fig. 7.2 & 7.1) were derived from preliminary research and experience of the Civco New Horizon and AIO™ breast board (Mulliez, Veldeman, Van Greveling, et al., 2013; Veldeman, Speleers, et al., 2010):

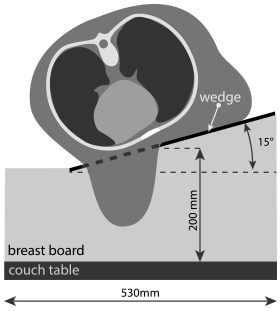


Fig. 7.1 Schematic section view of a right sided breast patient on the AIO™ Orfit breast board with the fundamental parameters described.

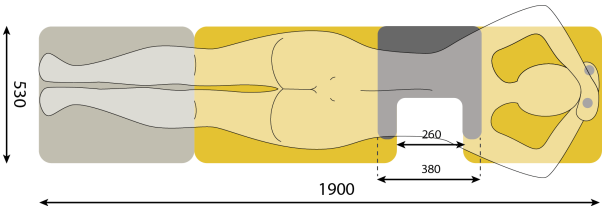


Fig. 7.2 Schematic view of a right sided breast patient on the AIO™ Orfit breast board with the fundamental parameters described.

- Maximum length and width of the device for a full range of motion of the gantry and treatment table without collision.
- Contralateral supporting wedge, cut-out size and position for the to-be-treated breast.
- Size of head-, shoulder-, hip- and leg support.
- The typical inclined wedge for the contralateral breast, which slopes downwards to the centre of the breast board, causing a slight roll of the thorax ($15° - 20°$) to a prone-lateral rather than a prone position.
- The use of a unilateral breast holder to improve patient positioning and sparing of the contralateral breast.
- Difference in left-right height of pelvis- and thorax part of the breast board, which emphasises patient roll.

- Elevation of the whole set-up above the couch table, which enables a comfortable flex in the pelvis and assures sufficient space for the treated breast to hang through the device, without touching the couch table.
- The leg support creating flex in the knees, which stabilises the pelvis region and allows ankles to be elevated and rest freely.

7.1.1 BEAM ACCESS RANGE

The usual range of possible beam orientations for WBI on the AIO™ breast board is mostly limited to a laterolateral tangential beam path orientation (fig.7.3). The beams were mostly planned with coplanar tangential beams. Gantry angles were slightly more than 180° apart to eliminate beam divergence at the breast–chest wall (Mulliez, Speleers, et al., 2013; Veldeman, Speleers, et al., 2010). For the new prone crawl breast board concept, a larger range of beam orientations for both WBI and LNI will be available (fig. 7.4).

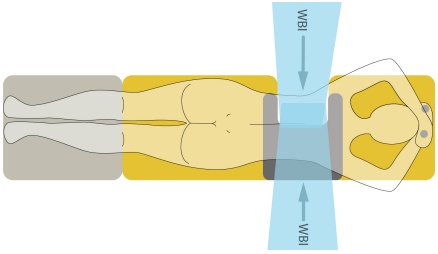


Fig. 7.3 Beam access range for WBI on the AIO™ breast board.

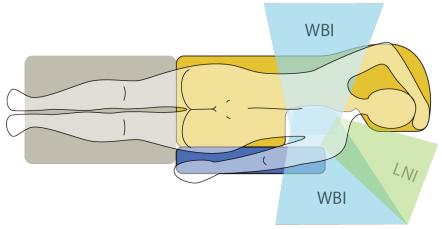


Fig. 7.4 Expected beam access range for WBI+LNI on the prone crawl concept.

BENCHMARKS

The use of standard opposed tangential fields were reported for Klarity, Kvue Access 360 and Qfix Access (Kim et al., 2016). Although table rotations are possible for the access 360 breast board, large-angle superior-oblique beam paths are not achievable since the arms of the patient obstructs these fields (Huppert et al., 2011).

7.1.2 BIO-COMPATIBILITY

Cured fibreglass composites are highly inert materials and commonly used in medical devices that have contact with patient skin as well as in daily life for a wide variety of devices (furniture, sports equipment, car components, recreational materials). It was commonly used for patient support devices in radiotherapy, radiology, surgery and other medical disciplines but is now more replaced by the lighter and stiffer carbon fibre composites.

Both polyester and epoxy resin are highly inert once cured. No academic literature has been found of cases reporting skin contact allergies (G_6).

In case of soft cushioning, standard materials such as Polyvinyl Chloride (PVC) artificial leather (Skai®) and PU foam padding will be used. These materials are commonly used for furniture, cushioning, etc, and are considered safe for our application (G_6).

7.2 ITERATIONS

7.2.1 ITERATION 1.1-1.5

METHOD

First breast board iterations version 1 to version 5 (further called BBV1 to BBV5) of phase-I were raw and Low Fidelity (Lo-Fi) prototypes (fig. 7.5). Inferior materials were used, which enabled rapid prototype generation:

- Recycled medical products, recovered from older breast boards and other medical devices were adapted and used for arm- and head supports.
- Wood such as beams, Medium-Density Fibreboard (MDF) and multiplex boards were used for the initial support structure.
- We used PU hard foam blocks, which were hand-sculpted for the establishment of 3D-surfaces and more complex organic shapes such as the contralateral breast- and hip support regions.

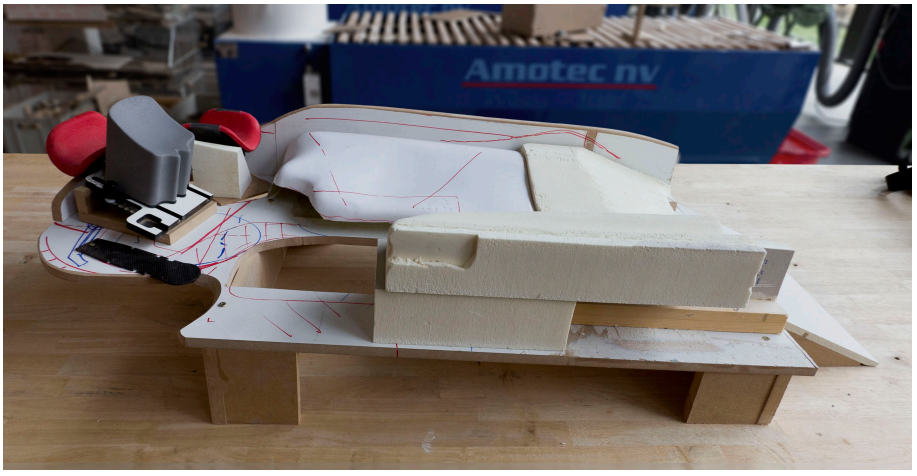


Fig. 7.5 Breast board prototype iteration 4 (BBV4) produced with recycled medical parts, wood and foam structures and the new thermoformed contralateral wedge (white PS shell in the middle).

Using basic skills and tools such as sawing, drilling, sanding, gluing and other shape modification and fixation methods, fast iterations could be established without much time or money efforts. The goal of these prototypes was to explore: the new prone patient position, support of the contralateral breast region and test different arm- and head positions.

RESULTS

The newly shaped wedge, which follows the contour of the contralateral breast resulted in improved patient positioning (fig. 7.5). The inclined wedge seems to support the contralateral breast more evenly and initiates a $15° - 20°$ thorax roll, which is beneficial for beam accessibility.

The fundamental parameters were verified: the patient should resemble a crawl swimming position with the ipsilateral arm positioned alongside the body and the contralateral arm preferably above the head (fig. 7.6). An approximate $20cm$ device elevation for flex in knees and stabilising of pelvis would be desirable. To enable full gantry rotation, the width of the device should be $\pm 530mm$.

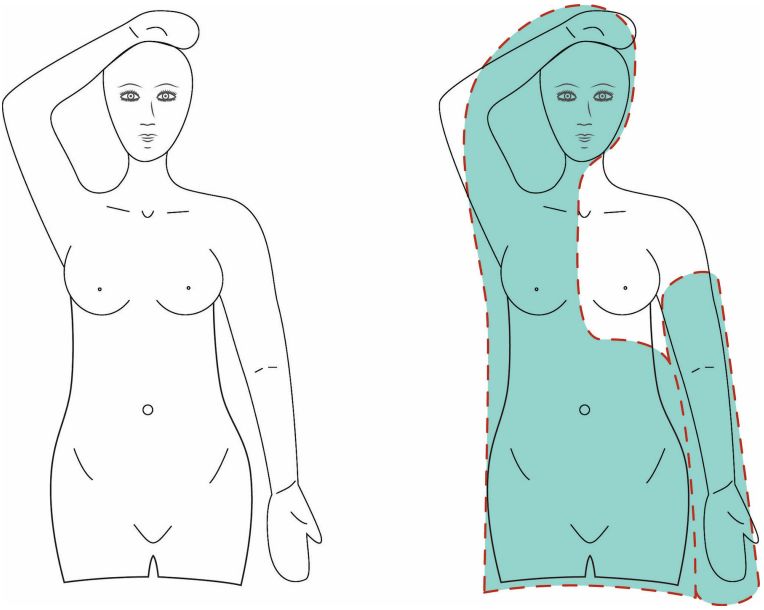


Fig. 7.6 Proposed patient crawl position and support area (green). The treated breast and lymph node region are unsupported, resulting in superior beam access.

7.2.2 ITERATION 1.6

METHOD

The sixth iteration (BBV6) was based on the same structure of iteration BBV5. It was developed for the establishment of a suitable prone crawl patient position. Specific prone crawl arm- and head positions were tested, a (primitive) adjustable hip support module was installed and served as a lateral support for the abdomen and pelvis region. The ipsilateral arm support was mounted onto the hip support. The arm was positioned in a gutter shaped support next to the body for a natural position of shoulder and lymph node region, resulting in favourable access for LNI (fig.7.8). The contralateral arm position was further

explored and remodelled by hand shaping PU-foam: the prototype has now an upward contralateral-axilla support, which evenly supports the shoulder region (fig. 7.7). The concave shaped upper surface of the wedge supports the contralateral breast. The medial edge of the wedge is rounded for a better pressure distribution at the sternum.

Fig. 7.7 Front view of iteration BBV6, laminated with fibreglass and polyester resin for added strength.

Fig. 7.8 Iteration BBV6 with the new gutter shaped contralateral arm support and the wedge's concave contralateral breast region.

Since structural strength was needed for user-testing of the prototype, the whole PU-foam shaped breast board prototype was laminated with chopped strand fibreglass mats and polyester resin using the wet layup technique. This low-cost and relatively easy technique enables the designer to create strong and structural prototypes with fairly low effort and time since no moulds or advanced tools are needed (Edwards, 1998). The polyester surface can be sanded, cut and drilled with basic tools. In addition, add-ons can be laminated onto the surface. As can be seen in figure 7.8, each separate polyester layer has a different colour (red and white), this enables you to compare how much material is removed while sanding and smoothing the prototype surface.

RESULTS

Test results showed that the contralateral arm and axilla support still did not provide enough support. For some patients, the contralateral shoulder and arm was pulled medially. The gutter shaped arm support restricted patients' arm mobility and the shoulder region on the to-be-treated side was also a common pain issue. The range of motion and positioning of the adjustable hip support was reported sufficient. Comfort experience was in general improved. Only pressure points and pain were experienced in neck and both shoulder regions. The medial edge of the wedge induced sometimes painful pressure onto the sternum.

7.2.3 ITERATION 1.7 & 1.8

METHOD

Based on CT-scans, pain & comfort analysis of iteration BBV6 (see section 7.3.5) and findings of the medical staff, a new support surface for the contralateral axilla and arm was developed:

Transverse CT-slices of female Thiel-embalmed cadavers (further called Thiel bodies) (Crop et al., 2012; Thiel, 1992), spaced by approximately $5cm$ in craniocaudal direction, were analysed and digitally edited (fig. 7.9). In-between the edited slices, surface shapes were interpolated. The new upper surface of the prototype was re-drawn on the transverse images according to knowledge gained during previous iterations. These CT-slices of Thiel-bodies were used to relate the re-drawn prototype surface to human anatomy.

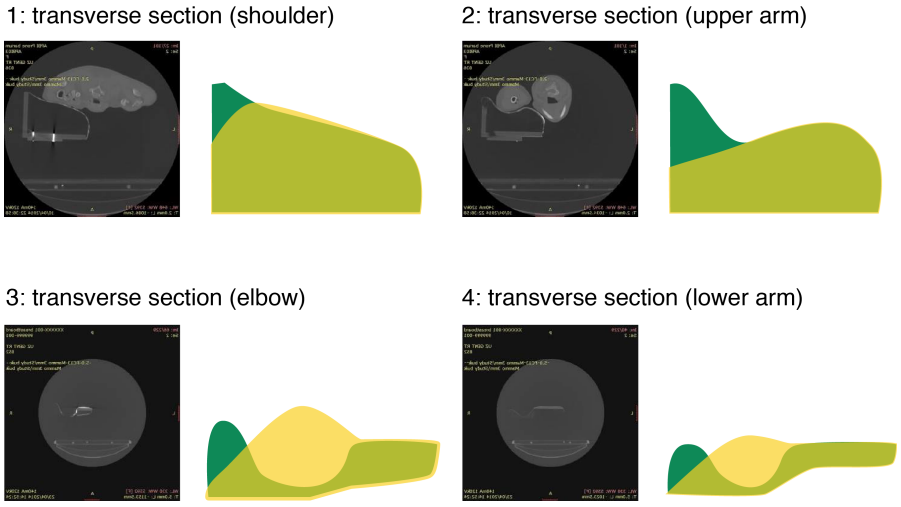


Fig. 7.9 Transverse sections of CT-scanned Thiel bodies on prototype iteration BBV6. Green: representation of prototype BBV6 section silhouette. Yellow: suggested new support area for axilla- and contralateral arm region.

The green area in figure 7.9 represents the transverse section of prototype iteration BBV6. The yellow area represents the new suggested patient support surface. A new upper contralateral arm support was redesigned to an inverted wing (i.e. surface cranking downwards in lateral and cranial directions) (fig.7.9, tile 2 & 3). This evenly supports the contralateral axilla and arm and forces the shoulder to slide over the axilla support (fig.7.9, tile 1). The whole prototype was sanded after laminating and coated with a polyester topcoat to ensure a smooth finish for user testing (fig. 7.10). The contralateral arm support was adjustable in width and height.

RESULTS

By reshaping the ipsilateral arm support into a flat surface, the arm could be more freely positioned by flexing the elbow. Additionally, this inverted wing design counteracts the tendency of rolling off the device and thus provides a more stable position by counteracting lateral and downward movement.

The upper body partially rests onto the ipsilateral arm support alongside the body. This support can be both anteroposterior and laterolateral positioned for adjusting patient roll and adapting to different body types. The arm-hip module provides support for abdomen and pelvis region. This design physically eliminates the possibility for patients to roll off

the device.

Fig. 7.10 Breast board iteration BBV8, ready for user-testing

7.3 PATIENT COMFORT OPTIMISATION

The next part of this chapter is based on the published article called: *"The relation between patient discomfort and uncompensated forces of a patient support device for breast and regional lymph node radiotherapy."*. The first author is Bert Boute and it has been published in *Applied Ergonomics*[1] (Boute, Veldeman, et al., 2018). Some paragraphs are copied, while others are edited from the article.

Comfort optimisation was done through FBD analysis of volunteers and Thiel bodies, positioned on the AIO™ breast board and prototype iteration BBV6 and BBV8. Through CT-images, we analysed uncompensated internal body forces. Subsequently, we developed new prototypes which were able to compensate these internal forces and achieve a force neutral- and comfortable patient position.

[1] Journal of Applied Ergonomics – `https://www.journals.elsevier.com/applied-ergonomics/`

7.3.1 PARTICIPANTS

Nine female volunteers [ex-patients (who had been treated previously in prone position) and staff] with wide anatomical variation were selected [weight: $48 - 100kg$; length: $146 - 184cm$; Breast size: small to large (not recorded)]. They all participated during every user test, treatment position optimisation, and pain and comfort evaluation. All volunteers were familiar with the AIO™ breast board.

7.3.2 APPARATUS

The device used for the first part of the volunteer study was the modified AIO™ prone breast board for WBI. This device is a tabletop model and is more in depth described in chapter 2.

Devices used for the second part of the volunteer study were prone crawl breast board prototypes. The two major iterations of phase I (BBV6 and BBV8) were used. Intermediate iterations were used for the establishment of the prone crawl position and local improvements such as arm, breast, hip and head support. For each support region, patient position and shape of the breast board were analysed and redesigned in order to counteract suspected uncompensated forces, leading to discomfort, instability and internal body strain.

7.3.3 PROCEDURE

Each breast board device (AIO™ and prototypes) was placed on top of the CT-simulator couch blade. Volunteers on the AIO™ breast board were positioned in prone position with both arms elevated. Two handles were installed above the head for better stabilisation. A slight roll of $15°$ of the torso ensured better treatment accessibility. Volunteers on the prototypes were positioned in prone crawl position, with the arm at the treated side (ipsilateral) alongside the body. The ipsilateral shoulder and chest was unsupported, resulting in the possibility for regional lymph node irradiation. The contralateral arm was positioned above the head resembling a phase of a crawl swimming movement. The whole patient was tilted with a roll of $15°$ i.e., treated side of the patient is positioned lower than the contralateral side. The ipsilateral breast is hanging through the device which is suspended over the table, resulting in excellent radiotherapeutic anatomy and beam access for WBI + LNI (Boute, De Neve, Speleers, et al., 2017; Deseyne, Speleers, et al., 2017). Volunteers were asked to lie immobile for at least 10 minutes.

After each session, volunteers were asked to fill in a survey considering pain and comfort evaluation. Six regions could be rated: *neck, right shoulder, left shoulder, thorax, right arm, left arm*. A NRS from 0 to 10 going from no pain to an unbearable pain experienced respectively was used. NRSs are considered to be the most versatile and commonly used scales for pain intensity assessments (see chapter 6: Pain & Comfort Evaluation).

7.3.4 DATA ANALYSIS

Transverse CT-images of female patients (positioned on AIO™, BBV6 and BBV8 breast board prototypes) spaced with approximately $5mm$ in craniocaudal direction, were used for data analysis. Additional CT-images of female Thiel bodies were used for further device improvements. Derived from patient CT-images, simplified CT-illustrations were sketched (figure 7.11-right) and the Centre Of Gravity (COG) was defined using CAD simulation software. A mass density of $0,3g/cm^3$ and $1g/cm^3$ was used for lung and rest of the body respectively. FBD-forces in complex support regions (*head/upper arms; shoulders/neck; breast; abdomen/pelvis*) were empirically derived from CT-images and transferred onto the CT-illustrations. Interacting-, uncompensated forces and moment of forces were defined. Figure 7.11 illustrates this process.

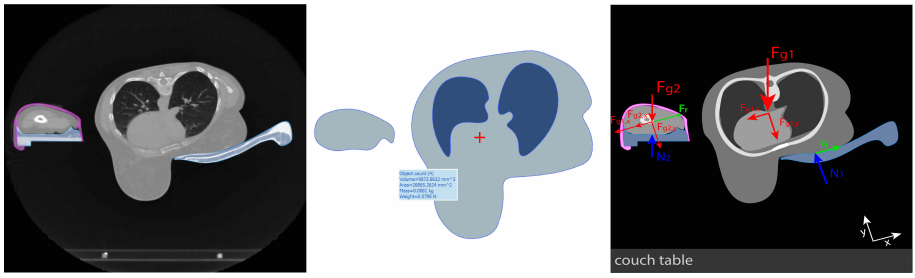


Fig. 7.11 process of the simplified patient FBD and its COG determination: Left: transverse section of CT-scanned patient with contoured patient support device and fixation strap. Middle: CAD-simulation of COG (red cross) with dark blue area as lung region ($0.3g/cm^3$) and light blue area for rest of the body ($1g/cm^3$). 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 each volunteer, pain and comfort scores were visualised on a sketch, representing the female body (fig. 7.12). Each circle represents a painful region reported by a volunteer. Size of the circles represent pain scores, going from 1 as smallest circle, to 10 as largest circle. The colour intensity represents multiple pain reports in the same region.

Results of pain and comfort evaluation from the first study were analysed and compared with their FBD sections. Subsequently, this data was used for the next prototype iteration to optimise patient position & comfort and acquire a force-neutral FBD in every body region. Data from prototype iteration BBV6 was used for the adjustments made on next prototypes. Data from prototype iteration BBV8 was analysed and used for comparison between a comfortable patient position and an inner force-neutral patient's FBD.

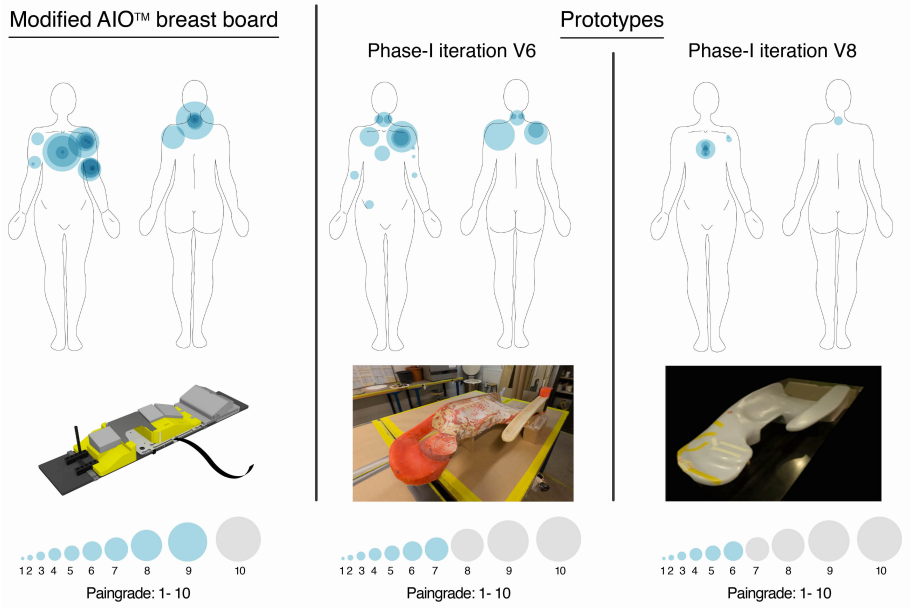


Fig. 7.12 Visual representation of pain and comfort scored on the modified AIO™ Orfit breast board, iteration BBV6 and BBV8 breast board, using a NRS. Blue circles represent pain or discomfort; radius is the pain grade from 1 to 10, grey circles on pain scale were unrecorded grades; number of overlapping circles, and thus colour intensity, indicates the amount of people experiencing pain at this location. Each time 9 patients were evaluated.

7.3.5 RESULTS

7.3.5.1 MODIFIED AIO™ ORFIT BREAST BOARD

PAIN AND COMFORT ANALYSIS

High discomfort was reported in both upper arms and axilla (fig. 7.12-left), especially on the treated breast side (fig. 7.13-A). The arm support did not evenly support the arm and caused pressure points (fig. 7.13-top, region between section 1 and 2). Soft napkins were often placed on the arm supports to distribute pressure. Pain at the antero-medial side of the ipsilateral upper arm was caused by arm elevation. Volunteers had to apply a counter-force with the same arm to maintain a stable position (handgrip visible on figure 7.13). Pain was frequently reported at the neck region, caused by an uncomfortable head-position and support. Repeatedly pain was reported at the sternum near the medial edge of the wedge, supporting the contralateral breast. An uncomfortable feeling of rolling off the device and being in an unstable position was often reported since no lateral side support for torso, hip or leg was available on the device.

FBD UPPER ARMS, SHOULDERS AND NECK REGION

Poor arm support surface (fig. 7.13-top) results in partial support of upper arms and shoulders ((fig. 7.13-1). Figure 7.13-2 displays the unsupported contralateral axilla. Most of the forces are thus loaded on the ipsilateral axilla- and arm support. The sharp edge of the foam wedge results in a concentrated load on the upper arm. Since no lateral support is available, patients tend to slide off the device. This was partially compensated by grabbing the handlebars, which results in a stressed arm position. Neck strain and an uncomfortable head position was often reported.

FBD BREAST REGION

The FBD at the breast region (fig. 7.13-3) consists of following forces: partial gravity force of the patient weight (F_{g1}), normal force (N_1) perpendicular to the support surface, and friction force (F_f) between wedge and breast. F_f is rather small since the wedge has a smooth surface and the contralateral breast is supported with a soft fabric unilateral breast holder (Van de Velde, Schellebelle, Belgium) used to retract the contralateral breast away from the treated breast. The y-component ($F_{g1,y}$) is compensated by N_1. The X-component ($F_{g1,x}$) is marginally compensated by the F_f . Since the COG is located left from the wedge and no lateral support is present, a constant moment of force occurs and tends to roll the patient downwards off the device. This moment of force is compensated in other body regions such as shoulder-neck region or abdomen-pelvis region.

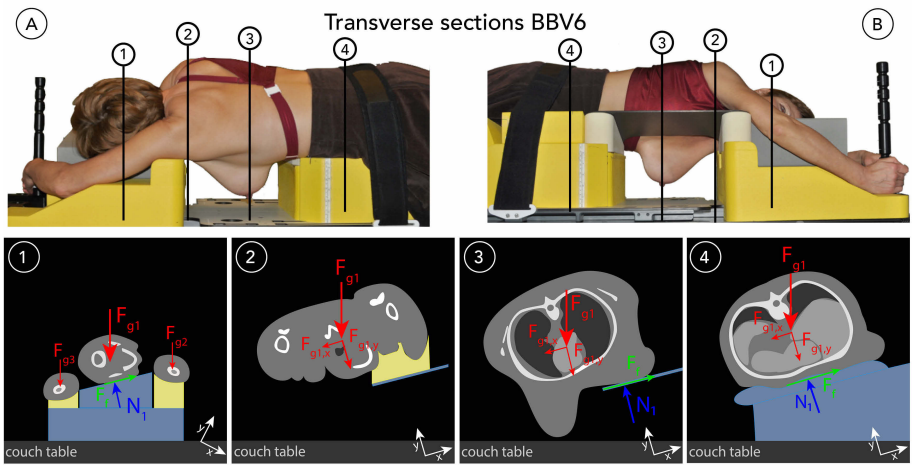


Fig. 7.13 patient position on the AIO™ breast board with transverse section regions marked. Image modified from (Mulliez, Veldeman, Van Greveling, et al., 2013). Transverse body sections of: 1) neck and upper arm region. 2) shoulder region 3) breast region and 4) abdomen and pelvis region. Yellow areas represent unsupported body regions; blue areas the patient support device.

FBD ABDOMEN AND PELVIS REGION

The device supports the whole abdomen region (fig. 7.13-4). $F_{g1,y}$ is fully compensated by $N1$. $F_{g1,x}$ is partially compensated by F_f. A constant moment of force occurs and

tends to roll the patient downwards off the device. This moment of force, together with the uncompensated moment from the breast region, causes internal body torque and needs to be partially compensated by pelvis and legs; resulting in a constant internal body tension and consequently stressed position. The belt for hip fixation cannot be properly fastened and provides inadequate support since latero-lateral movement is still possible.

7.3.5.2 BREAST BOARD PROTOTYPE V6

PAIN AND COMFORT ANALYSIS

As predicted from previous iteration tests, the sixth prototype iteration had an overall improvement of pain and comfort scoring in comparison with the AIO™ breast board (fig. 7.12-middle). Uneven support of the contralateral arm resulted in some discomfort. Due to partial axilla support, moderate pain was reported. The ipsilateral arm support scored better on pain and comfort evaluation in comparison with the AIO™ breast board. Pain at ipsilateral shoulder was reported since the cranial part of the arm support did not evenly support the shoulder. Sternal pressure was reduced by the ipsilateral arm- and shoulder support. The concave shaped wedge resulted in a better support of the contralateral breast. No pain or discomfort was reported in abdomen and pelvis region. Moderate pain was reported in neck region due to a too high head support.

FBD CONTRALATERAL ARM, SHOULDERS AND NECK REGION

In the shoulder region, $F_{g1,y}$ is fully compensated by N_1 (fig. 7.14-2). $F_{g1,x}$ is partially compensated by F_f. Since the COG is located left from the shoulder support and no lateral support is present, a constant moment of force occurs. This is partially compensated by the weight of the contralateral arm (fig. 7.14-1) and new position of the ipsilateral arm (fig. 7.14-3). Some stress and torsion were reported in the neck due to uneven contralateral arm- and axilla support. The arm could not be properly positioned and thus immobilised, resulting in a bigger pressure load on ipsilateral arm and shoulder. The hard surface of the arm support resulted in a concentrated load.

FBD BREAST REGION

The moment of force, which caused rolling off the device is fully compensated by the arm support at the ipsilateral side. Upper body weight is now divided over F_{g1} and F_{g2}. F_{g2} consists of the arm weight and partial upper body weight. $F_{g1,x}$ is compensated by F_f and F_r. $F_{g1,y}$ is compensated by N_1.

FBD ABDOMEN AND PELVIS REGION

The moment of force at the pelvis region, which caused the patient to roll off the device, is fully compensated by the lateral hip support. F_{g1x} is fully compensated by F_r. The smooth surface of the breast board results in minor friction between patient and device. This is advantageous for patient re-positioning.

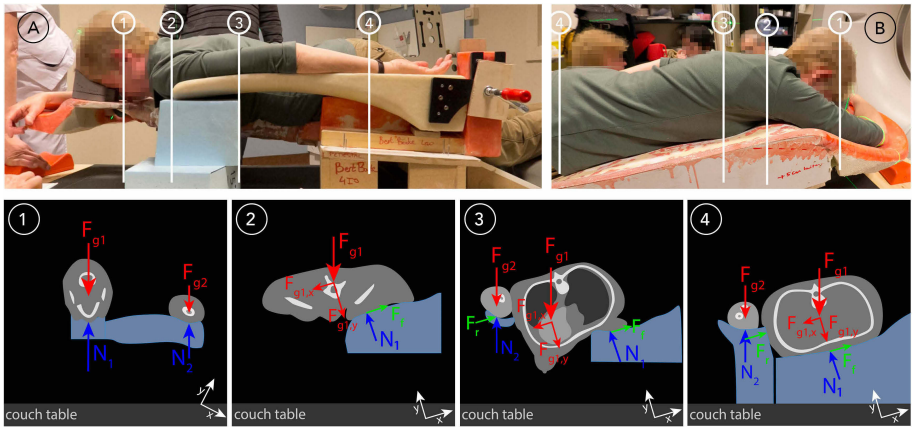


Fig. 7.14 patient position on the sixth breast board prototype with transverse section regions marked. Transverse body sections of 1) neck and upper right arm region 2) shoulder region 3) breast- and upper left arm region 4) abdomen pelvis and lower left arm region. Yellow areas represent unsupported body regions; blue areas the patient support device.

7.3.5.3 BREAST BOARD PROTOTYPE V8

PAIN AND COMFORT ANALYSIS

No pain and discomfort were reported for contralateral arm and shoulder (fig. 7.12-right). Contralateral axilla and upper arm were more evenly supported. The shoulder sliding over the axilla support, was reported to be comfortable. Comfort of the ipsilateral arm was improved. Minor pain was reported at the sternum. This sternal pressure can be related to hard support surface and an inadequate support of the contralateral breast.

FBD CONTRALATERAL ARM, SHOULDERS AND NECK REGION

$F_{g2,x}$ acts as a downwards-right force which causes the contralateral arm to slide downwards over the axilla support, resulting in a latero-lateral immobilisation of the shoulder region (fig. 7.15-2). The head is positioned downwards, resulting in minimised stress in neck region (fig. 7.15-1). Although no pain was reported at the contralateral axilla and arm, the yellow area in figure 7.15-2 indicates that the axilla was not fully supported. The force F_{g1} in shoulder region needs to be compensated by arms, neck or abdomen region. In the long term, this could result in strain or pressure points.

FBD BREAST REGION

Y-component ($F_{g1,y}$) of the gravity force in figure 7.15-3 is compensated by N_1 since the concave curved wedge more evenly distributes pressure. X-component ($F_{g1,x}$) is marginally compensated by friction force F_f. The main compensation of $F_{g1,x}$ is caused by F_r of the arm support. F_r eliminates the possibility of rolling off the device, caused by the moment of force. N_2 of the arm support in figure 7.15-3 compensates F_{g2}, which

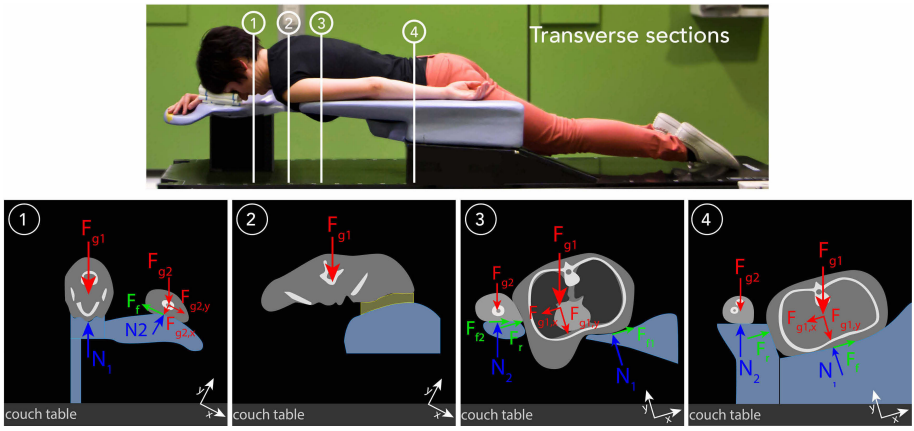


Fig. 7.15 patient position on the eighth breast board prototype with transverse section regions marked. Transverse body sections of 1) neck and upper arm region 2) shoulder region 3) breast region and 4) abdomen and pelvis region. Yellow areas represent unsupported body regions; blue areas the patient support device.

is composed by the weight of the contralateral arm and partial body weight (transferred from shoulder region).

FBD ABDOMEN AND PELVIS REGION

The lateral hip support fully immobilises the abdomen and pelvis region. Reaction force F_r fully compensates possible roll-off caused by $F_{g1,x}$ (fig. 7.15-4).

7.3.6 STUDY DISCUSSION

After searching separate keywords such as: *discomfort, user comfort, medical devices, FBD, identifying factors, patient immobilisation, radiotherapy, postural loading, revalidation, etc.* Only published research was found concerning discomfort and postural loading at the joints (Boussenna et al., 1982), identifying factors of comfort using hand tools (Kong et al., 2012; Kuijt-Evers et al., 2004) identifying factors of comfort and discomfort in sitting (Cordell et al., 1995; De Looze et al., 2003), postural load (Chung et al., 2005; Vergara et al., 2000) and muscle fatigue during truck driving (Wilder et al., 1994). No directly relevant published research was found on the relation between discomfort and uncompensated internal forces affecting patient comfort and medical performance. Especially for radiotherapy devices no data was found. Therefore, the aim of this study was to find a relation between uncomfortable patient positions (on medical devices) and the patient's FBD. One of the possible reasons why there is not much published research about MDD is the understandable reluctance of companies to disclose commercially sensitive information about the development process (Martin, Clark, et al., 2012).

7.3.6.1 SUCCESS OF THE STUDY

The first part of the study analysed the relation between the FBD and discomfort on the modified AIO™ breast board. FBD analysis demonstrates that uncompensated forces are related to pain and comfort scores. Pain reported in the neck area can be related to an opposite rotation ($80° - 90°$) of the cervical vertebrae and upper thoracic vertebrae. This head rotation is rather extreme since mean axial cervical range of motion for female persons between the age of 50 and 65 is $140,8°$ (SD of $18,4°$, $n = 60$) (Roy et al., 1996). Shoulders and upper arms need to compensate the unstable upper body position to prevent it from rolling off the device, which results in muscle contraction of arms and firmly gripping the handholds to maintain a stable position. Pain reported at the sternum can be related to the whole weight of the torso resting on the wedge. The flat wedge surface unevenly supports the breast and consequently causes a pressure peak at the medial edge. Since the torso is not supported on the ipsilateral side, other sections such as shoulders and hips need to compensate this roll effect, resulting in strain and torque.

Prototype BBV6 was the establishment of a prone crawl position prototype which counter-acted most moments of force and uncompensated forces. The ipsilateral arm support counteracts the moment of rolling off the device and serves as a lateral support for the torso. The hip support (caudal part of the arm support) immobilises abdomen and pelvis region. Although every internal body force was compensated, discomfort was still reported. Sub-optimal support surface areas resulted in partial body support and as De Looze et al. (2003) states, uneven pressure distribution resulted in discomfort and local pain points.

With prototype iteration BBV8, we were able to counter-act all uncompensated forces. Except for minimal pain reported at sternum and ipsilateral arm, all pain points were eliminated. This was done through support surface optimization: better pressure distribution, improved support surface contact, local foam sheet application and adjustable support modules. Most people reported this iteration as comfortable.

By Thiel soft-fix embalming, the skin and muscles remain flexible and allow the limbs to be moved in a natural way (Crop et al., 2012; Thiel, 1992). In addition, no internal body- or muscle strain is possible. This was favourable for replicating a *"relaxed"* an *"natural"* body position. When analysing CT-images of Thiel Bodies, we noticed that they were very similar to patient CT-images. Subsequently these images could be used for additional position analysis.

By analysing CT-images of specific body regions of each time one subject with average body proportions, we were able to derive a general simplified FBD. Uncompensated forces could be specified and directly related to pain and comfort analyses of every volunteer. Based on transverse CT-image- and FBD analysis, we were able to improve the prototype design and reduce overall discomfort. These results demonstrate that further prototype iterations could be executed with a general FBD analysis of one subject. A similar method approach could be advantageous in other research projects.

7.3.6.2 STUDY LIMITATIONS

This study was conducted with nine volunteers for pain and comfort evaluation, each time one patient was CT-scanned on the AIO™, BBV6 and BBV8 device for the establishment of the FBD's. Since ethics committee allowed us to only scan one patient per prototype, additional Thiel bodies were used for extra CT-scanning. These scans were used for internal body anatomy analysis and prototype optimisation.

Bigger sample sizes (more in particular for CT-imaging) could be advantageous but are harder to obtain ethics approval, especially early during the development phase of medical devices. In addition, this could be counter-productive and unpractical since first prototype iterations evolved rapidly. During further iterations (with more advanced prototypes), bigger sample sizes were used (Boute, De Neve, Speleers, et al., 2017).

Since patients were only positioned for approximately 10 minutes (instead of 15minutes for a real treatment), a comparative study was performed where ten patients received half of their WBI treatment sessions on the crawl breast board prototype and the other half on the AIO™ device (Boute, De Neve, Speleers, et al., 2017). In general, the prone crawl device scored best.

7.3.6.3 IMMOBILISATION

Positioning and immobilisation of patients is extremely important during radiation therapy (Rosenthal et al., 1993). The sole focus of a fixation device is to provide each time reproducible patient positioning throughout the duration of patient treatment sessions. Immobilisation can be defined as the act of limiting movement through fixation of a body part in order to facilitate treatment, and thus, cure the disease (Mullaney et al., 2012). When a patient is not properly immobilised, or not positioned in a natural and reproducible position, the patient can be at risk of having a reduced cure probability due to complete or partially missing of the target volume. Also increased accidental dosing of OAR can result in adverse side effects (Mullaney et al., 2012).

7.3.6.4 OTHER FACTORS OF DISCOMFORT

The time when a patient lies on the device or is immobilised during treatment, can influence discomfort (E. B. Lerner et al., 2000). A patient could experience no pain or discomfort in the first radiotherapy session, while after several sessions the patient could experience severe pain, discomfort and in worst case the treatment could be aborted. Patient immobilisation done by fixation can result in pain or discomfort caused by hard support areas, tensioned belts or local pressure areas (Grocott et al., 2007; Mulliez, Veldeman, Van Greveling, et al., 2013; Rosenthal et al., 1993). Patient mobility: some elder patients have painful joints and mobility issues caused by arthrosis, arthritis or other conditions (Petersson, 1986). Additionally, some patients underwent breast surgery or lumpectomy, which can result in restricted movement possibilities and pain. Material properties can be

related to both comfort and discomfort. A surface can have a high or low friction finishing, anti-slip, soft/hard (E. Lerner et al., 1996).

7.4 FEASIBILITY TRIAL

We included five left sided breast cancer patients and simulated them in both standard supine position (Civco Posirest™-2 breast board [2]) and in prone crawl position (on prototype BBV8). For each patient, a treatment plan was made in prone- and supine position for WBI + LNI. We plotted and compared dose volume histograms for breast and lymph node region, lungs, heart, thyroid and contra lateral breast. Dose distributions were visualised and compared. The medium prescribed dose for breast irradiation was $40Gy$ (Deseyne, Speleers, et al., 2017).

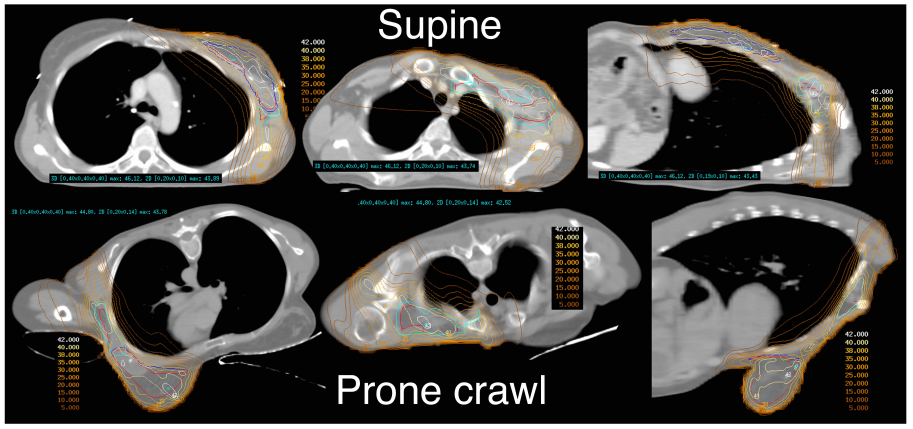


Fig. 7.16 Comparison of dose distribution in the breast region (left and right row) and lymph region (middle and right row) between supine and the new prone crawl position. Isolines represent the received treatment dose in Gray (Gy).

RESULTS

As can be seen in figure 7.16, the plan (example of one patient) in prone crawl position yields better dose homogeneity for the breast region and lymph node targets, i.e. iso lines closer to each other, bigger area receiving a medium of $40Gy$ and lower over-dosed regions.

Additionally, in prone crawl position, doses reduction to all OAR was achieved in comparison with the supine position. As can be seen in figure 7.17, the dotted lines represent the prone crawl treatment while the full lines represent the supine position. A certain amount of relative volume (vertical axis) can be related to the amount of received dose (horizontal axis). When looking at the Dose-Volume Histogram (DVH), all dotted lines (crawl position) are lower than the full lines (supine), resulting in less dose received and thus

[2] Civco Posirest™-2 – `https://civcort.com/ro/breast-positioning/breastboards/posirest2-B4.htm/`

better sparing of OAR. Doses were significantly reduced ($P < 0.05$) in prone position for: ipsilateral lung, contralateral lung, contralateral breast, thyroid, oesophagus and skin. There were no significant differences for heart and humeral head doses (Deseyne, Speleers, et al., 2017).

When looking at the received dose for the target volume (red), a slightly steeper transition is visible for the crawl position. This results in a more homogeneous dose distribution for the to-be-treated area.

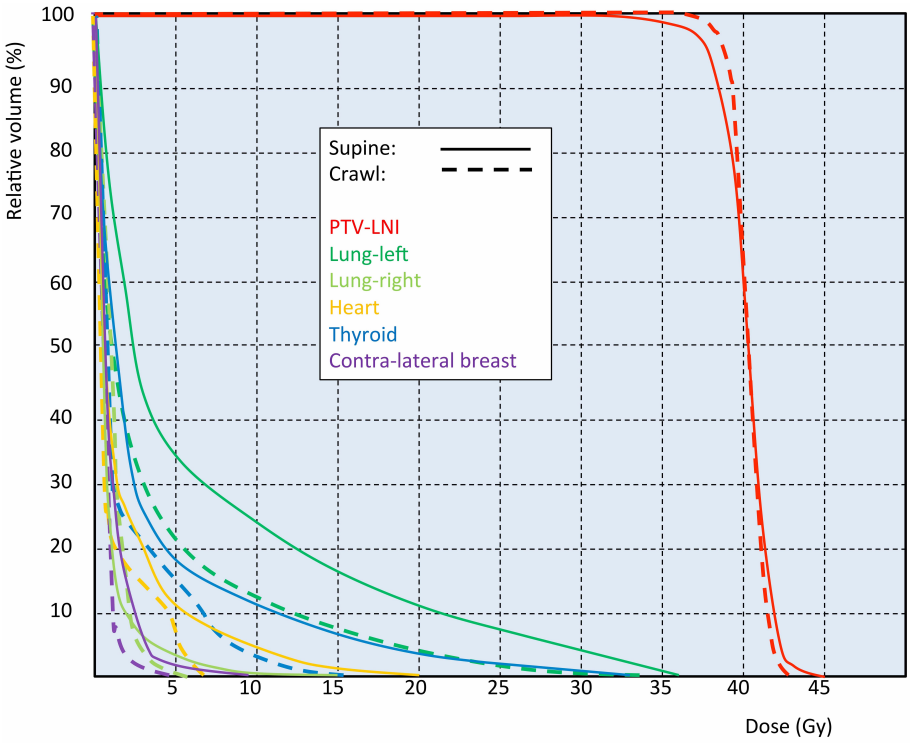


Fig. 7.17 Comparative dose volume histogram of one patient for breasts, OARs and planning dose (red) between the prone crawl and supine position.

7.5 CONCLUSION

Through iterative prototyping with basic materials and techniques, performing small user tests and pain & comfort evaluations, we were able to explore different patient positions (G_1) without large time or money investments (G_9). Subsequently, we defined the fundamentals of the support device and eventually established a new patient position, which was both reported to be comfortable (G_5) and suitable for WBI and LNI (G_2): the prone crawl position (G_1).

When performing FBD analysis of patients and Thiel bodies through CT-images, we were able to identify uncompensated internal body forces and relate this to discomfort. When counterbalancing these uncompensated internal body forces, we were able to achieve a force-neutral patient position. This resulted in good patient positioning and eliminated discomfort (G_5). This workflow could be potentially beneficial for the development of other medical devices.

A feasibility trial of five patients delivered promising results for good breast and nodal target coverage with better sparing of OAR such as ipsilateral lung, thyroid, contralateral breast, contralateral lung and oesophagus, in comparison with the supine treatment position (G_1,G_2,G_4). There was no difference in heart and humeral head doses.

The head and neck support of breast board prototype BBV8 are still an issue. Frontal support resulted in a rather unstable head position, in some cases even neck pain. The inverted wing support of BBV8 resulted often in an uneven support of the patient's contralateral axilla and upper arm. This will be addressed during the next chapter of this work (Phase II).

Chapter 8

Phase II

Breast couch version BC1 during CT-simulation

In the second phase, prototypes were produced with more durable materials and advanced techniques since prototypes needed to be functional and ready for clinical trials. The purpose of phase II was further optimisation of: the patient support surface, patient comfort, usability and improving set-up accuracy.

8.1 ITERATIONS

8.2 ITERATION 2.1

Derived from breast board iteration 1.8 (BBV8), a quick copy was produced using a ”disposable mould” i.e., a thin and inexpensive fibreglass mould which should only be used once or twice. This mould enabled us to produce a prototype with a thin wedge region for the contralateral breast, which was needed for patient position testing and beam access evaluation.

8.2.1 PATIENT POSITION

Hip, elbow and wrist position registration during pain & comfort evaluation of breast board iteration 1.8 were used for defining the average patient joint positions. These positions were used for further surface optimisation and prototype development in phase III.

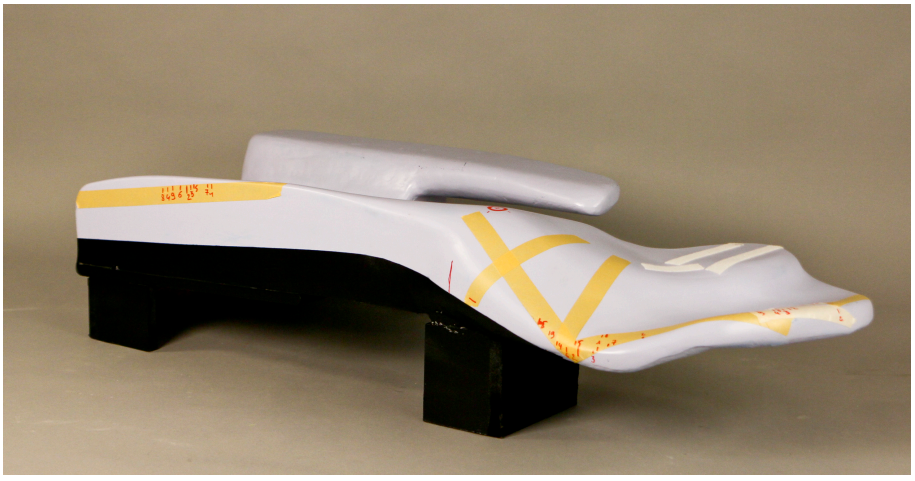


Fig. 8.1 Measured hip-, elbow and wrist positions during pain & comfort evaluation of prototype iteration 1.8 (BBV8).

8.2.2 PRODUCTION

The produced prototype was a hand laminated fibreglass composite piece and was built as follows: the top layer of the shell consists of an epoxy gelcoat serving as a protective layer for the fibreglass and acts as a smooth surface for the patient side. Additionally, this can afterwards be sanded, painted or repaired. Secondly, several twill weave fibreglass mats were applied, impregnated with epoxy resin by hand lamination and compressed through the vacuum bagging technique (fig. 8.2-middle). This inexpensive and easy technique enables the designer to produce complex pieces with better specifications and higher fibre to matrix ratio, in comparison with the standard hand lay-up technique. For core material, a closed cell $10mm$ PVC sheet was precisely cut and glued to match the shell's 3D shape. A wooden plate was inserted for later connection to the base-module (fig. 8.2-right). To complete the sandwich structure, another set of fibreglass twill mats was applied, laminated and vacuum bagged.

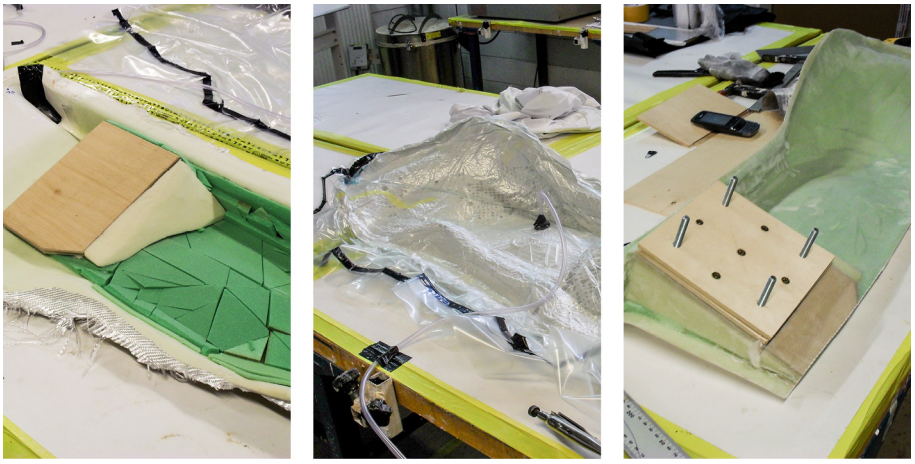


Fig. 8.2 production of prototype iteration 2.1. Left: insertion of the closed cell PVC core; Middle: application of the vacuum bagging technique; Right: finished composite shell with wooden baseplate installed.

8.2.3 SURFACE OPTIMISATION

SYNTHETIC CLAY

Synthetic clay modelling, is an excellent tool for making cheap and fast adjustments. It is widely used in the automotive styling sector (Yamada, 2006), product development, sculpting and by animation artists. Traditional (or natural) clay is a mineral, which is a mixture of organic and metallic particles. This material holds a lot of water. When it dries, it becomes more stiff and sturdy but also becomes brittle. Due to water evaporation, the model shrinks and small cracks may appear.

Synthetic clay is oil-based and does not evaporate. Therefore, it stays malleable for a long

time and can be reused several times. By heating or cooling, the oil in the clay changes the viscosity and influences malleability. Warm clay ($\pm 70°C$) can be easily modelled; while cooler, room temperature clay is much harder and can be easily modified using scraping and rasping tools.

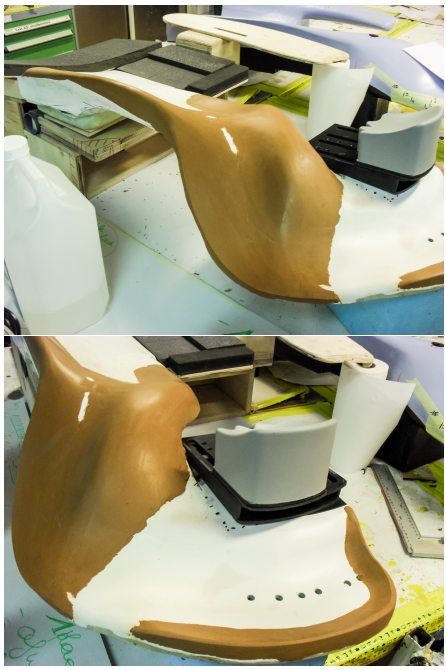


Fig. 8.3 Synthetic clay was used for remodelling the support surface of the contralateral arm support

OPTIMISATION

Pain at the contralateral shoulder was related to arm elevation. During previous iterations, extreme elevation with the elbow close to the head was scored uncomfortable and painful at the shoulder and upper forearm. Less elevation, allowing the elbow to move away from the head, was more desirable.

The upper contralateral breast region, contralateral arm- and axilla support was remodelled to an anhedral sweep-forward wing design using clay modelling techniques (fig 8.3). By remodelling the prototype surface with synthetic clay, we could fast and easily add or remove material on a non-destructive way to achieve the desired design. Therefore, small volunteer tests for surface optimisation could be performed on a fast rate.

Contralateral shoulder comfort was improved on the phase-II prototypes since the contralateral arm rests more evenly on the anhedral sweep-forward surface. At the contralateral shoulder, the anhedral design creates a saddle from which the top supports the contralateral mid-clavicular region. The contralateral arm rests on the lateral slope of the saddle and the hand holds the cranial edge of the head support part. The position of the

contralateral arm on the lateral slope of the saddle counteracts the tendency of the unsupported ipsilateral clavicular and axillary region to slide into the aperture of the device and thus results in a more stable patient position.

8.2.4 HEAD POSITION EXPLORATION

Since the previous iteration phase focused more on the prone crawl position exploration and upper body position, the head support region was still unexplored. Derived from previous iterations and the AIO™ Orfit device, several reports of discomfort were registered for the head and neck region: pressure on forehead, stress in neck region, inability of head rotation (due to limited mobility), pressure on nose and chin, etc.

To be able to achieve a comfortable position, and solve the above problems, several head support systems were explored and tested (fig. 8.4). As can be seen in figure 8.5, each head support function is listed, going from H_1 to H_7. Prototypes with multiple functions can be described as H_1,H_2; which means that the head support prototype has a frontal support (H_1) and can move in cranio-caudal direction (H_2).

Fig. 8.4 4 different head support prototypes: top-left: H_1,H_2,H_4; top-right: H_1,H_2,H_4,H_5; bottom-left: H_1,H_2,H_3,H_4,H_5; bottom-right: H_6.

- *Frontal Support (H_1)* - The idea of a frontal support on the forehead was to achieve a more natural position for the spine, i.e. face looking forward.

- *Craniocaudal Movement (H_2)* - Since we want the breast to be positioned in the concave support area, and the axilla onto the saddle-like support area of the device, difference in head-to-breast length needed to be compensated by the head support. To be able to do this, the possibility of a cranio-caudal adjustment was introduced.

- *Chin Support (H_3)* - To gain more stability and reduce pressure on the forehead, a chin support was tested. This was beneficial for comfort and stability but slightly prevented torso roll, which was undesired.
- *Head Extension (H_4)* - By means of a slight extension of the cervical vertebrae, i.e. head looking upwards, we were able to initiate a subtle shoulder retraction, i.e. thorax coming more forward. As a result, this facilitated better torso roll.
- *Head Tilt (H_5)* - To be able to have better access to the lymph node region, the possibility of tilting the head towards the contralateral arm was introduced.
- *Sloped Cushion (H_6)* - The sloped cushion, rolling down towards the contralateral arm, was tested to produce a stable head position and facilitate patient roll.
- *Massage Pillow (H_7)* - With the O-shaped massage pillow, we aimed for improved comfort and stability.

HEAD SUPPORT & COMBINATION	FUNCTION	BEAM ACCESS	STABILITY	COMFORT	ROLL	TOTAL
H1+H2	FRONTAL SUPPORT CRANIO-CAUDAL	0	0	0	0	0
H1+H2+ H3	H1+H2+ CHIN SUPPORT	0	+	+	-	+
H1+H2+ H4	H1+H2+ EXTENSION	0	0	0	+	+
H1+H2+ H3+H4	H1+H2+H3+ EXTENSION	0	+	+	+	+++
H1+H2+ H4+H5	H1+H2+H4+ TILT	++	0	-	+	++
H1+H2+ H3+H4+H5	H1+H2+H3+ H4+TILT	++	+	-	+	+++
H6	SLOPED CUSHION (HIGH AND LOW)	+	++	-	++	++++
H7	MASSAGE PILLOW	0	+	+	0	++

Fig. 8.5 evaluation of different head supports and their combinations.

As can be seen in figure 8.5, the head support with sloped cushion (H_6), had the best overall score. Although the frontal head support (whether or not with additional functions) had strong potential regarding beam access and patient roll, discomfort and instability were often reported: some volunteers reported pain: on nose and forehead (H_1, H_4), neck region (H_4, H_5, H_6) and instability. This was partially solved by indexing the head support, but required multiple adjustments for each volunteer, which was complex and counterproductive at the time.

CONCLUSION

Most of the head supports offered good beam access (G_4) but lacked stability and comfort (G_5). Achieving a correct, stable and comfortable head position was often challenging. Therefore, for the user tests we opted to use the sloped cushion (H_6) with two different

heights (50 and $100mm$). This will be easy to use, stable and ensures a good patient roll (G_1). To be able to better score on every aspect, a more in-depth exploration will be needed (and is performed during phase III).

8.3 ITERATION 2.2

Throughout iteration phase II, the support surface for contralateral breast region was further improved, a new and adjustable arm- and hip module was installed and patient CT-scans were performed and analysed.

8.3.1 HIP- AND ARM MODULE

To be able to fully test different arm positions with a more accurate positioning, an adjustable hip- and arm support module was developed (fig. 8.6). With this arm support, we were able to define the fundamentals of the arm support module and arm support blade. The arm support module consists out of two parts: a hip module and a arm support blade. The hip module is a sheet metal $S235JR$ piece with an integrated cushion for soft lateral support at the level of abdomen and pelvis. The hip module can move on the anchorage component in laterolateral direction. The arm support blade is mounted on the hip module by a mechanism that allows changing pitch, yaw and craniocaudal positioning.

Fig. 8.6 First fully adjustable hip- and arm module. The hip module is adjustable in laterolateral direction; the arm module in craniocaudal, anteroposterior and laterolateral position.

8.3.2 SURFACE OPTIMISATION

The contralateral breast region was enhanced by reshaping the support area to a more concave shape: this resulted in less pressure on the breast and a more even pressure distribution. Surface of contralateral lower arm was enhanced by hand-shaping PU-foam and laminating it with polyester resin and fibreglass for structural strength. The head support was enlarged and made planar for easy placement of different head support systems.

8.3.3 LEG SUPPORT

The new leg support was elevated $15cm$ above the table couch. This resulted in the ability for the feet to hang freely in a natural position. The slight flex in hip and knees enabled the patients to be positioned in a more stable and ergonomic way (fig: 8.9). The soft padding ensured comfortable positioning.

8.4 ITERATION 2.3 - BC1-R

During iteration 2.3, the prototype evolved from a breast board (i.e. table-top support device, resting completely onto the table) to a breast couch (i.e. support device hanging partially over the table). This breast couch setup has the advantage of better beam access for favourable bundles since there is no restriction of the table couch structure underneath the breast couch. A sub-frame was installed for support of the overhanging part and an indexed and fully adjustable sheet metal arm support was put in place. The breast couch iterations will now be named as BC1-R: Breast Couch iteration 1, Right-sided.

Left sided patients need to be CT-scanned at least twice (once for DIBH and once for shallow breathing). An additional third CT-scan for prototype testing and in silico treatment could be harmful for the patients. Consequently, we switched from left sided breast couch prototypes to right sided prototypes. To be able to produce a right sided breast couch, we needed to mirror the prototype.

8.4.1 VIRTUALISATION

Since mirroring a physical prototype is to this day still not (yet) possible, we needed to make the transfer from the physical world to the virtual world of prototyping. This is commonly known as a big challenge, which consumes a significant amount of working hours, required different skills and can be highly problematic (D'Adderio, 2001; I. Gibson et al., 2002). During physical prototyping, you can easily make adjustments with hand tools, with approximated measurements, in context or during user tests. Whereas in the digital world of virtual prototyping (such as a CAD environment), every shape, material or object is defined by parameters or dimensions. Additionally, it is less convenient to make

adjustments on the fly during user tests. On the other hand, with the proper skillset, you have unlimited possibilities for digital prototyping concerning, different iterations, shape, material, technique and so on. And this with high accuracy, adjustability and at no cost (material or prototyping).

A DIGITAL MODEL

To be able to produce a digital 3D model of the prone crawl prototype, we needed to copy the physical model by means of 3D-scanning a previous prototype iteration (2.2). This was done through CT-scanning the whole device on the medical CT-scanner at our hospital. Sagittal slices with $5mm$ spacing were used for scanning.

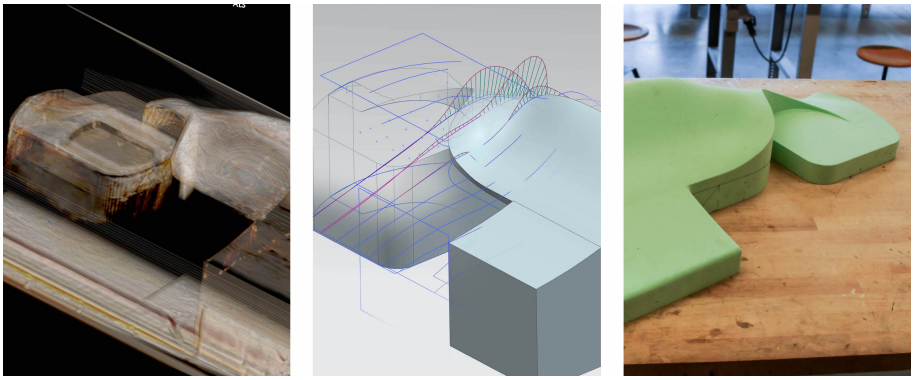


Fig. 8.7 Digitising process of BC1-L. Left: Generated 3D point cloud through CT scanning BC1-L; Middle: Surface modelling and optimising support surface in a CAD-CAM environment; Right: Mirrored, CNC-milled high density PU foam prototype.

Derived from this CT-scan, a point-cloud was generated and imported into a CAD-Computer Aided Manufacturing (CAM) software environment (fig. 8.7-Left). Secondly, the point-cloud was interpreted and translated to a 3D model. This was done through drawing approximate splines, which follow the point-cloud as close as possible (fig. 8.7-Middle). With this method of reverse engineering, we could copy and digitise most crucial areas of the prototype (upper body, and especially breast region). The process of reverse engineering and creating a 3D-model from a physical model, does not correspond to an automated process of translation but requires substantial skills, creative and integrative efforts of the designer or engineer (D'Adderio, 2001). Further digital surface optimisation was performed to achieve high quality surfaces and generate a proper 3D CAD-model.

Finally, through CAM, the 3D model was CNC milled out of a hard, high density PU-foam block and used for the production of the pre-moulds (or plug) (fig. 8.7-Right).

8.4.2 MOULD SYSTEM

In order to be able to perform clinical trials with multiple breast couch prototypes with the same dimensions and tolerances, a mould system was needed to produce identical prototypes.

PRE MOULD

A plug acts as an exact copy of the prototype (CNC-milled PU-foam in this case) and is used for the production of a fibreglass mould. The plug is reinforced with a thin layer of fibreglass and topcoat finishing. This topcoat can afterwards be sanded and polished for a high-gloss finish. After polishing, a release agent is applied which prevents the plug from sticking to the mould.

MOULD

The mould consists of a thick fibreglass and polyester resin structure which has the inverted shape of the model. By using a mould system, multiple composite parts can be produced using RIM or other techniques. Depending on the complexity of the part, fibreglass moulds can have a lifetime up to 500 parts per mould but, due to the complexity of the breast couch shell (vertical walls, size, surface), a production quantity of ± 50 will be more realistic.

8.4.3 THIN SHELL STRUCTURE

To be able to create a thin, strong and durable shell, a fibreglass sandwich structures was produced. First, an epoxy gelcoat was applied into the mould, which serves as a protective layer. The second layer consists of several woven fibreglass mats which were, after vacuum bagging the dry fibreglass mats, impregnated with epoxy resin based on the Resin Infusion Moulding (RIM) technique. This method has superior structural- and strength/to weight ratio specifications in comparison with the hand lay-up vacuum bagging (Williams et al., 1996). Subsequently an aramid honeycomb structure was fitted for structural improvements and finally a second layer of several woven fibreglass mats were applied and impregnated with epoxy resin to finalise the composite sandwich structure.

8.4.4 INDEXED HIP- AND ARM MODULE

In order to fully test the hip- and arm module, a new fully adjustable sheet metal module was developed with an enlarged range of motion for better defining the optimal positions (see fig.8.9). The whole module can slide underneath the abdomen support, resulting in a laterolateral movement range of up to $8cm$ for the hip support.

Sheet metal production is an inexpensive technique which enables the designer to produce custom works (low production quantities) at a low cost, which are strong, precise and can be complex shaped. Prototyping of such parts in a non-metal material would be expensive

Fig. 8.8 New breast board with aramid honeycomb core, positioned on the CT-simulation table. The thin shell structure results in enlarged beam access range.

and a time-consuming task. Future arm modules will be produced in composite material, plastic or aluminium for weight reduction and MRI compatibility.

Since tangential bundles close to the arm and pectoralis are very favourable, we wanted the arm support blade to be *"as thin and slim"* as possible. The support blade is fabricated in fibreglass composite material through the RIM technique and an infusion compatible Lantor Soric® core. This resulted in a $8mm$ thick support blade at the upper arm region (fig.8.9). The arm support was structural tested and capable of resisting a $700N$ force at the far end (shoulder region), without permanent deformation or visible delamination.

Fig. 8.9 Prototype iteration 2.3 with: thin fibreglass upper shell, indexed sheet metal hip module, adjustable fibreglass arm support, elevated leg support with slight flex in hip- and knees for improved comfort, flat head support region for different head modules.

8.4.5 FLAT SURFACE FOR HEAD SUPPORT

During this iteration, we used the sloped head support module H_6, since this scored best from previous user test (see iteration 2.1). The flat head support region serves as a general platform for different kind of head modules, which could later on be tested.

8.4.6 FLOOR LASER

The currently used method for prone breast radiotherapy can be less accurate in comparison with the supine method (Veldeman, Speleers, et al., 2010). Although our prone crawl breast board device has already better setup precision in comparison with the supine position, we wanted to further improve this by the introduction of a floor laser alignment system.

A conventional laser alignment system (green lasers in fig. 8.10) has modules installed only on the walls and ceilings of the treatment room. This enables projection of sagittal, transverse and coronal laser lines. Since there is no laser module installed on the floor, frontal sagittal laser lines (for prone patient positions) are impossible.

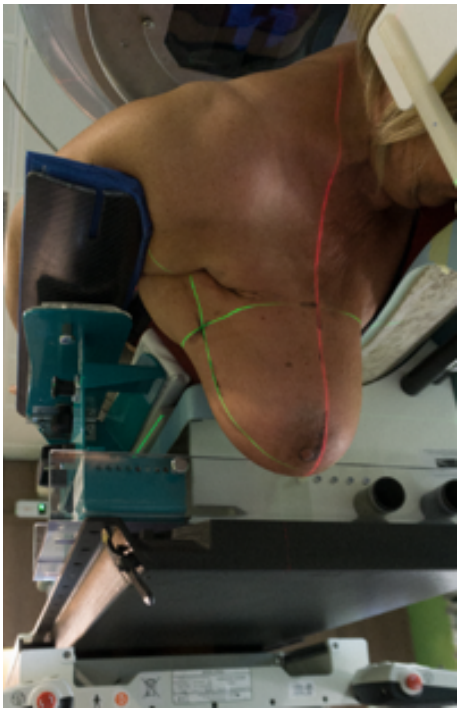


Fig. 8.10 Red: new sagittal floor laser projection; Green: conventional laser projection system.

8.4.6.1 CT SIMULATION

Due to the construction of the CT simulation table, we used a breast board instead of a breast couch for simulation. Due to this construction, there is only limited space between the breast board and table. Hence, it is not (yet) possible to use the standard floor laser projection system. Subsequently, the floor laser system is only used for positioning on the LINAC machine.

PROCEDURE

Patients are positioned for CT-simulation and scanned. When the isocenter is defined during CT-analysis, the standard laser projection system (mounted on walls and ceiling) projects this isocenter onto the patient's skin. Eventually, the projected lines are marked on the skin with a semi-permanent marker.

8.4.6.2 LINAC

Breast couches for treatment are connected over the treatment table and allow for floor laser projection. We installed a linear laser that is positioned on the floor and projects a sagittal line onto the front of the patients breast and thorax (fig. 8.10). This enables the staff to mark additional sagittal lines on breast and lymph node region, which results in improved laterolateral position accuracy.

PROCEDURE

During the patients' first treatment session, they are positioned according to the previously drawn isocenter lines during CT-simulation. Additionally, for final positioning, a CBCT image is taken and used to quantify patients' shifts in anteroposterior, laterolateral and craniocaudal directions in comparison with the CT images, taken during simulation. When the patient is correctly positioned with both systems, the new sagittal floor laser projection is marked onto the body. Succeeding treatment sessions, the additional sagittal lines can be used for more accurate patient alignment during isocenter positioning, subsequently this is followed by a CBCT for patient shift analysis.

FUTURE

To further improve patient position accuracy and treatment workflow, a floor laser system during CT-simulation would be favourable. Since the CT table restricts the possibility for a normal floor laser. A new system needs to be developed: a small laser projection unit which can be mounted on the CT tabletop. The sagittal ceiling laser position will need to be registered by a laser detection unit (mechanical or electronic), and projected onto the breast region by a laser projection unit (fig. 8.12).

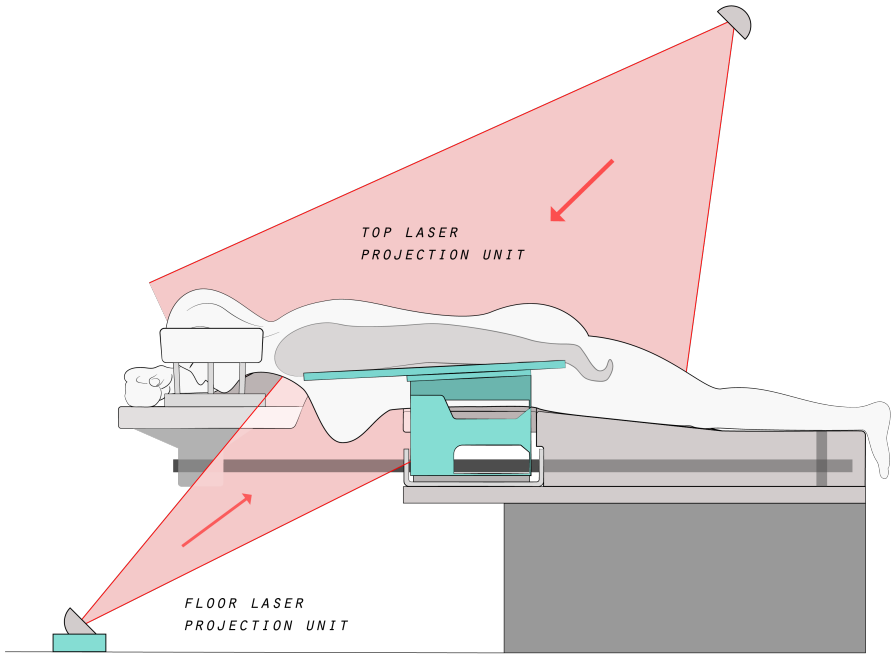


Fig. 8.11 Breast couch with sagittal floor laser setup, which can be installed in or on the floor.

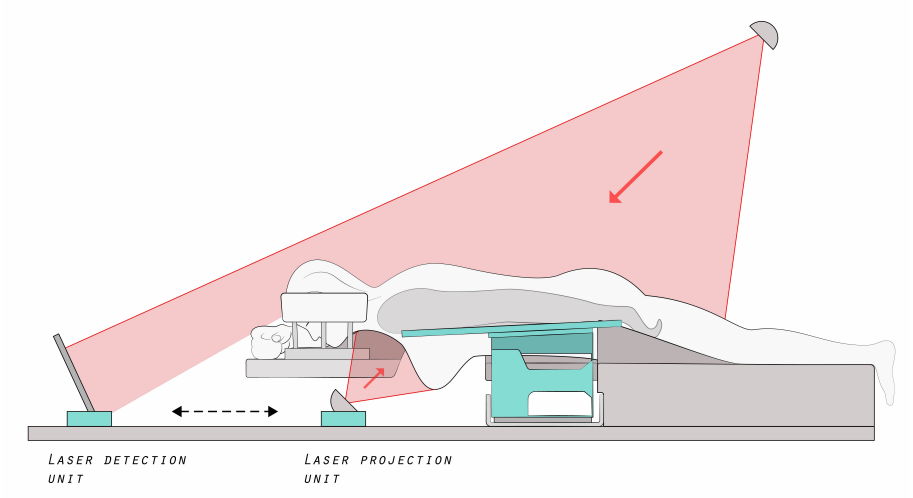


Fig. 8.12 Floor laser system concept for tabletop breast boards (CT-simulation).

8.5 USER TEST

During phase II, two different user tests were performed: a volunteer study for position and comfort evaluation; and a randomised crossover trial, comparing the AIO™ Orfit prone breast board and the new prone crawl breast couch (BC1). In parallel with the crossover trial, pain & comfort evaluations were performed.

8.5.1 VOLUNTEER STUDY

During each prototype iteration, small volunteer studies were performed for patient position improvements, support surface optimisation, adjustability improvements, beam access enhancements, head modules and pain & comfort evaluation. Several volunteers (patients, ex-patients and staff) with a wide anatomical variation were asked to lie on the device and evaluate the prototypes.

8.5.2 RANDOMISED CROSSOVER TRIAL

The next part of this chapter is based on the published article called: *"Potential benefits of crawl position for prone radiation therapy in breast cancer."*. The first author is Bert Boute and it has been published in *Journal of Applied Clinical Medical Physics*[1] (Boute, De Neve, Speleers, et al., 2017).

The goal of the randomised crossover trial was to investigate the prone crawl position for patients requiring both WBI and LNI, and comparing its setup precision, beam access and dosimetry with the standard prone AIO™ Orfit breast board (Boute, De Neve, Speleers, et al., 2017).

We included ten patients (45 year or older, right-sided breast carcinoma, suitable for adjuvant radiotherapy after lumpectomy for breast cancer) who received half or their treatment sessions on the crawl breast couch (BC1) and the other half on the standard prone device (AIO™).

RESULTS

By using the floor laser system on the BC1 prototype, the random set-up error in the laterolateral direction was less than $3mm$ (for nine of ten patients) and was $4mm$ for the $10th$ patient (Boute, De Neve, Speleers, et al., 2017).

For the AIO™, we registered nine of ten patients with a random set-up error of more than $3mm$ ($> 5mm$ in 5 patients; $> 8mm$ in 3 patients). The difference was significant

[1] Journal of Applied Clinical Medical Physics – `https://aapm.onlinelibrary.wiley.com/journal/15269914/`

($P = 0.013$, paired student's-T test). As for anteroposterior and craniocaudal directions, random set-up errors were equal for the crawl breast couch and AIO™.

There was also a significantly decreased random error spread on the BC1, which means that there is less day-to-day variation between and within patients. In the future, this could allow for smaller planning area margins, which reduce radiation of OAR and the need for daily CBCT to evaluate random errors in patient positioning.

As for set-up time, there was no significant difference registered between the two support devices.

On the BC1 breast couch, beam directions in the coronal and near-sagittal planes have access to the breast or regional lymph nodes without traversing device components. On the AIO™ this is unattainable.

The overall dosimetry for Target Volume (TV)s and OARs of the BC1 was improved in comparison with the AIO™. The spider charts in figure 8.13 show the DVH parameters for OARs for the AIO in red, and the BC1 in blue. Each spider plot shows individual patient data for each OAR. As can be seen in figure 8.13, almost all received doses on the OARs is lower for the BC1, i.e. area in blue lines smaller than area in red lines. Due to the improved dosimetry for the heart, lungs and contralateral breast, the reducing of stochastic effects in these organs is possible.

8.5.3 COMFORT EVALUATION

During phase III user tests, the new hybrid PI-measurement system was used. We divided the visualisation of the PI measurement scale in two: a graphical representation for pressure and discomfort evaluation and a graphical representation with a NRS for pain evaluation. Note that, to be able to have a correct interpretation, both representations should be viewed side by side because when pain diminishes, pressure or discomfort could increase. This could result in a decrease in discomfort scored (blue) while scored pain is increased (red).

At simulation during the randomised crossover trial, there was only one patient who felt tense on the crawl couch, she also experienced this on the AIO™ breast board. After treatment, none of the patients experienced tension, sensation of sliding down the wedge or tension on the prone crawl couch.

Looking at discomfort (fig. 8.14), We see a decrease in pressure for both devices comparing evaluation during simulation and after treatment (A>C and B>D). When comparing the AIO™ device with the BC1 prototype, BC1 scored best during both simulation and after treatment.

Looking at the pain evaluation for the AIO™ device (fig. 8.15), We see an increase in pain intensity cases after treatment. Pain was frequently reported at: the sternum near the edge

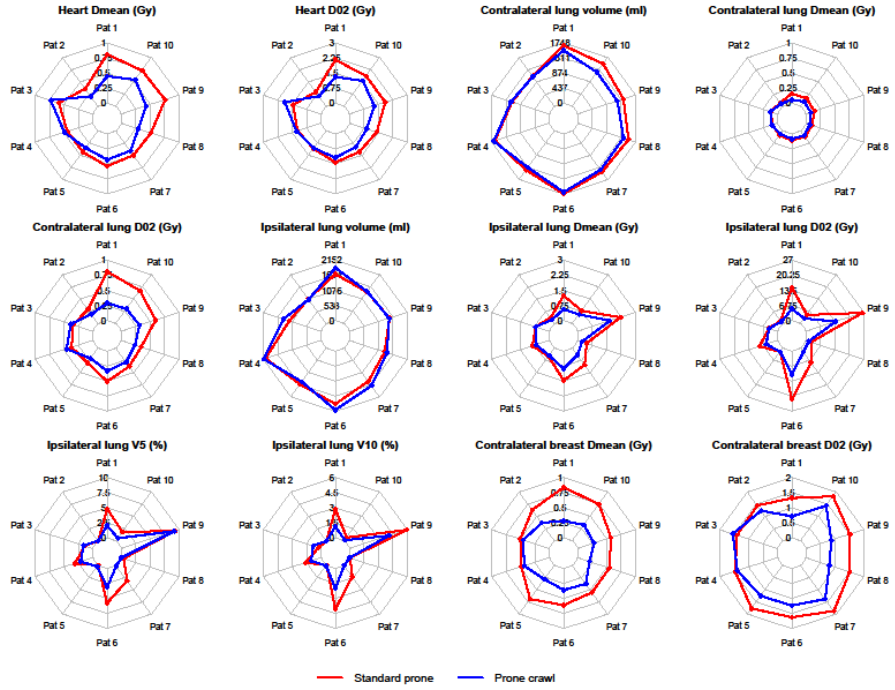


Fig. 8.13 Spider charts of statistically different DVH parameters between standard prone (AIO™) and prone crawl prototype (BC1).

of the surface supporting the non-treated breast; at the ipsilateral shoulder; at both upper arms and at the neck. Some patients reported tension or sensation of sliding down.

For the BC1 prototype, we see only a small increase in registered pain evaluations and no increase in pain intensity. Pain was registered at the sternum and minor pain was reported at the cranial edge of the arm support (ipsilateral side). Neck pain was mild or absent (Boute, De Neve, Speleers, et al., 2017).

When comparing the AIO™ device with the BC1 prototype, BC1 scored best during both simulation and after treatment. Nine out of ten patients preferred the BC1 over the AIO breast board.

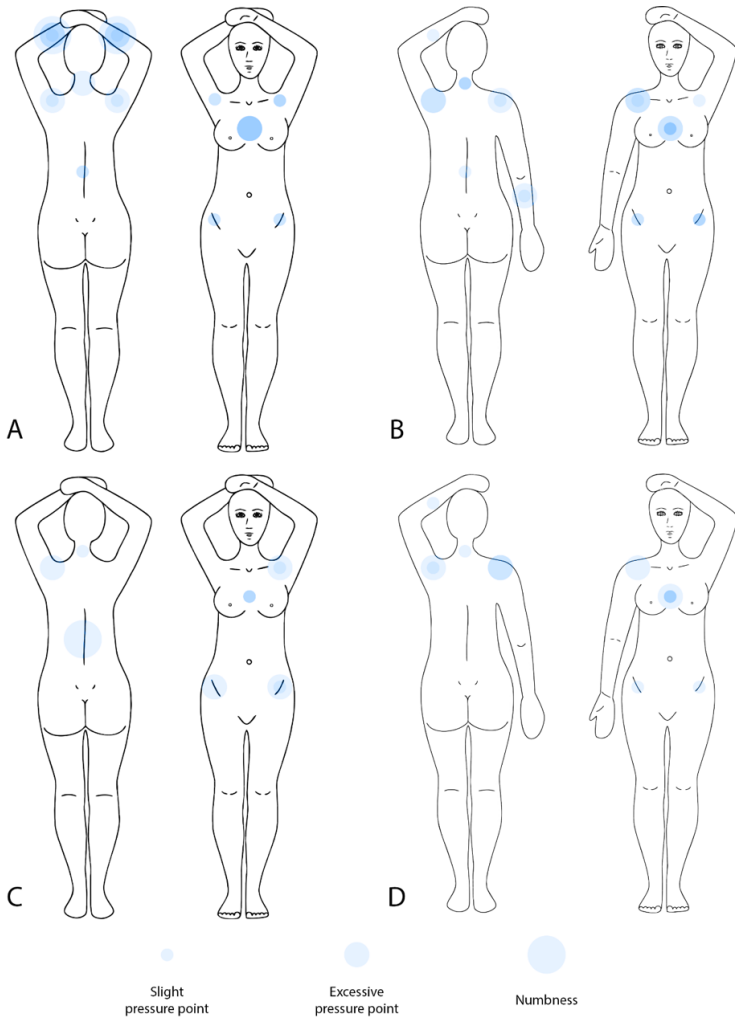


Fig. 8.14 Discomfort scores by individual patients, to be viewed side by side with Figure 8.15. Different circle sizes indicated different pressure/discomfort scores per patient. Overlapping circles intensify the circle colour. A: AIO™ prone breast board at simulation B: Breast couch BC1 at simulation C: AIO™ prone breast board after treatment D: Breast couch BC1 after treatment.

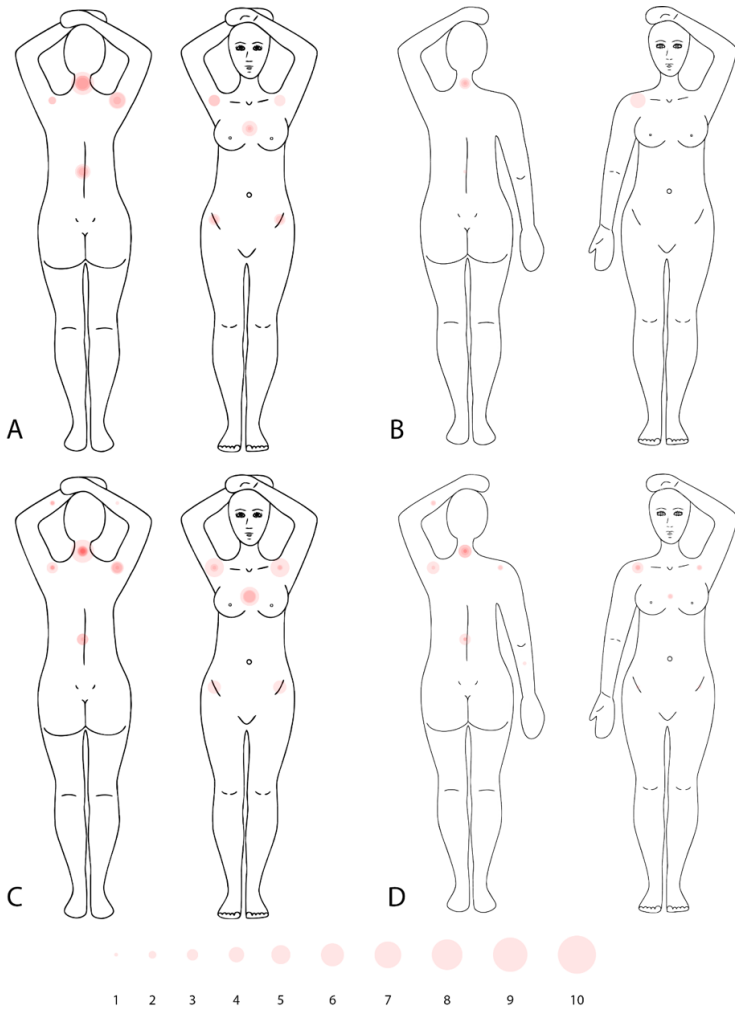


Fig. 8.15 Pain scores by individual patients, to be viewed side by side with Figure 8.14. Different circle sizes indicated different pain scores per patient. Overlapping circles intensify the circle colour. A: AIO™ prone breast board at simulation B: Breast couch BC1 at simulation C: AIO™ prone breast board after treatment D: Breast couch BC1 after treatment

8.6 CONCLUSION

Through digitising the prototype, we were able to freely optimise and modify the breast couch in a CAD environment (G_9). Additionally, we were able to produce a mirrored prototype, which was used for further testing. With the introduction of the mould system, we were able to easily produce multiple composite shells, with the desired technical specifications, strength and tolerances (G_6, G_9).

By optimising the overall patient support surface, developing a fully adjustable hip- & arm module and exploring new head supports, we were able to improve the overall patient position, set-up accuracy and patient comfort (G_1, G_3, G_5, G_7). The short iterative prototyping cycles with small user tests enabled us to improve the overall construction, range of motion for patient positioning and favourable beam access (G_4, G_6, G_8).

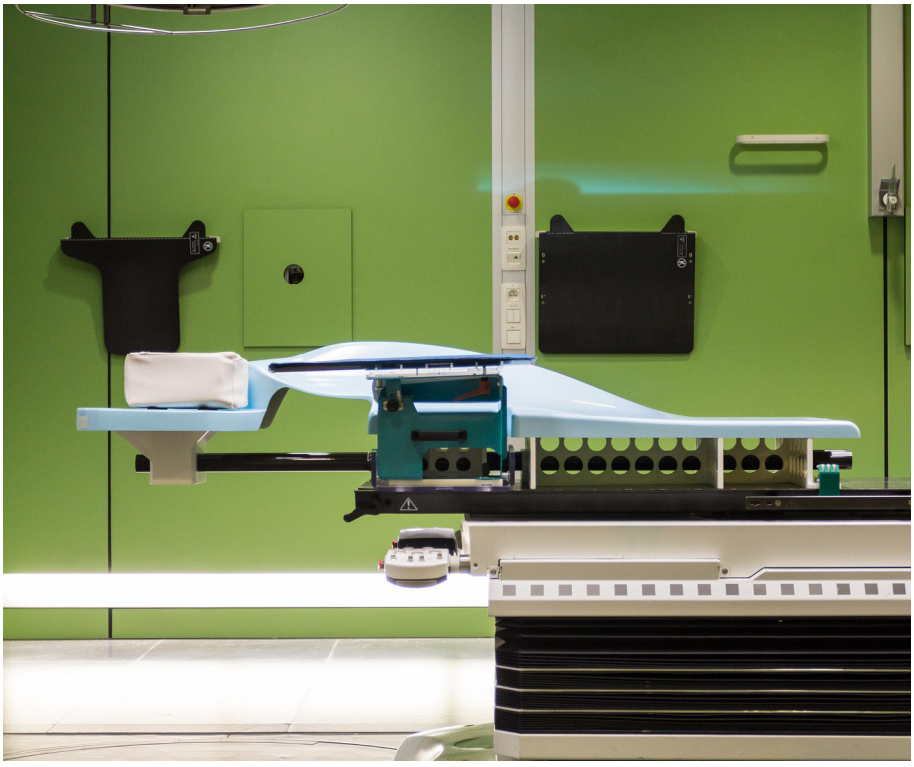
The anhedral shaped support surface for the contralateral arm resulted in an evenly distributed contact area and better support. The saddle shaped support of the contralateral axilla resulted in a locking of the axilla and arm, which improved stability and comfort. Finally, the new arm-, hip- and head support resulted in better patient adjustability (G_5).

The crossover trial demonstrates that in comparison with the standard prone position (AIO™), the prone crawl position improves position accuracy, matching set-up errors that are seen in supine positioning without adding to treatment times, improved beam access range and better dosimetry for vital organs such as heart, lung and contralateral breast, which can possible reduce stochastic effects in these organs (G_1, G_3, G_4, G_5, G_6).

Although an overall improvement of comfort and medical performance was achieved, some aspects still need to be improved for future iterations: the arm support module needs to be more modular and have a wider range of motion to better suite every body type (G_1, G_7); the head support cushion needs to be further tested for comfort evaluation (G_5); the composite shell and support construction needs to be thinner and lighter for improved beam access and usability (G_4).

Chapter 9

Phase III



Breast couch version BC2, positioned on the treatment machine

During the third development phase, fully functional prototypes were produced with Hi-Fi materials and techniques. Four prototypes (two left- and two right sided) were produced and used for a validation trial with real treatments. The purpose of phase III prototypes was to validate: medical performance, the fully indexed system, the new floor laser alignment system and breath-hold feasibility.

9.1 ITERATION 3.1 - BC2

In order to perform bigger clinical trials ($n = 40$) and be able to produce multiple breast couch prototypes with the same dimensions and tolerances, a mould system was required. We produced a small series of two right-sided and two left-sided breast couches, used for clinical testing. Since the mould system of BC1-R could be reused. Only a new left sided system was produced. Additionally, a new leg module was introduced, the arm module was finalised and the head support was tested.

Upper shells (upper body support) for BC2-left and right, were produced by the same method of BC1: a RIM, epoxy and fibreglass sandwich structure with aramid honeycomb core material. Starting from this phase, all composite parts (upper- and leg shells) were produced in co-operation with MAT2 [1].

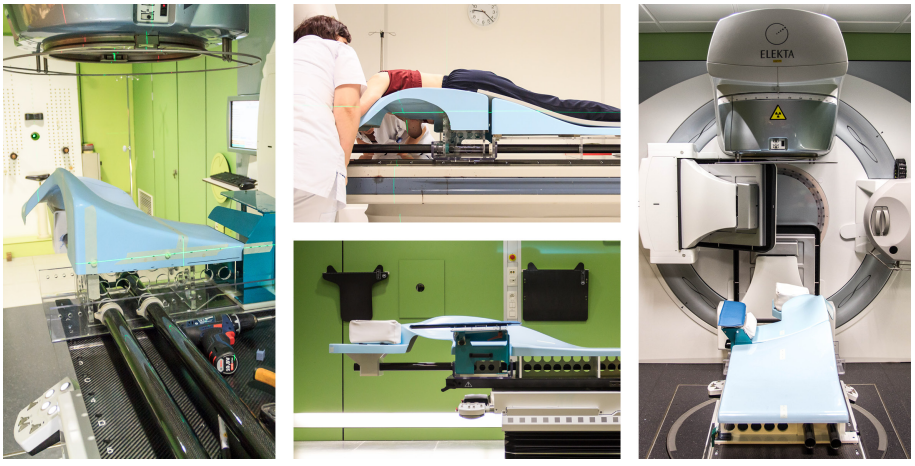


Fig. 9.1 Different stages during the development process of BC2. Left: Assembly and testing on LINAC, Middle: Top, first patient simulation; Down, arm module and carbon fibre arm support blade on LINAC, Right: final BC2 prototype on LINAC.

[1] MAT2 - Composites & Sports – `http://www.mat2composites.com/`

9.1.1 LEG MODULE

Derived from the BC1 leg support (fig. 9.2), a new leg support module was developed. The fundamentals were: light flex in hip and knee for improved positioning, a $10-15cm$ elevation for a comfortable foot position (hanging off the leg support).

A sloped and soft foam leg support module was developed which ensured slight flex in knee and hip. This leg support (9.2-3) resulted in a comfortable patient positioning but the medical staff reported sometimes a decreased position accuracy due to the soft cushioning. Furthermore, the flat support cushion in the hip region prevented in some cases proper patient roll.

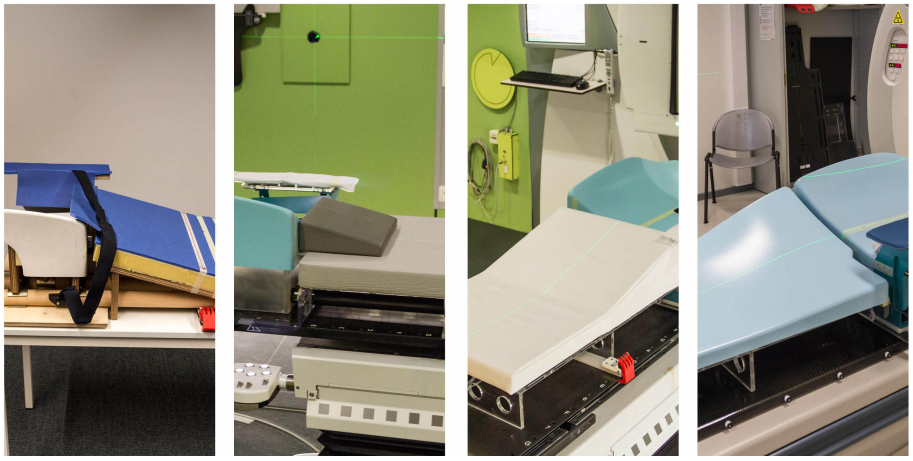


Fig. 9.2 Different iterations of the leg modules. Left to right: BC1 module, exploration for BC2, BC2 flat soft foam test module, BC2 hard fibreglass composite leg module with patient roll.

To be able to have a better overall patient roll, the hips should also be positioned on a down-sloped plane. Consequently, a skewed leg support with a roll of $15°$ was developed (fig. 9.2-right). Basic parameters were derived from the previous leg support (slight flex, elevation, dimensions). This was developed through CAD-modelling. The composite leg support shells were produced with the same mould system as the BC2 upper shells. The leg support shell consisted of a RIM epoxy & twill weave fibreglass sandwich structure. This was infused through a $5mm$ thick 3D|CORE™ PET 100 core.

This hardshell support resulted in better patient positioning and good patient roll (initiated from the hips). If additional comfort is required, a thin foam padding can be installed.

9.1.2 BASEPLATE

A baseplate was produced (fig. 9.3), serving as a multifunctional connection platform on the breast couches. It consists of a $10mm$ thick PC plate, which was thermoformed into

a transverse U-shaped base. Several holes in the baseplate enabled connection for the arm modules, fixation of the carbon bars, fixation of leg modules and connections to tables couches (for simulation and treatment machine).

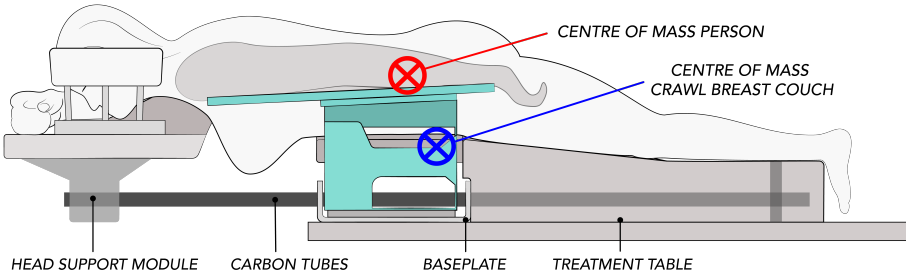


Fig. 9.3 Patient on BC2 with centre of mass defined.

As can be seen in figure 9.3, an external frame consisting of two carbon fibre tubes (twill weave, $\varnothing\ 40/37mm$) that spans between the cranial and caudal part of the body support components was installed. With this frame, we were able to produce breast couches which have improved mechanical strength and are self-supporting: the weight of the lower body, leg module and baseplate is counterbalancing the weight of the overhanging part of the breast couch. A head support module was installed underneath the cranial part of the breast couch, which was connected to the carbon fibre tubes (fig. 9.3).

However, the two carbon fibre tubes may hinder beam paths for patients with pendulous breasts. Consequently, we conducted a study which investigated the influence of these carbon tubes on the build-up dose and beam attenuation (Paelinck et al., 2017). Based upon this study, we can conclude that measurements showed that the carbon fibre bars have no clinically relevant effect on the build-up dose. Possible attenuation by the bars could be calculated and compensated using Pinnacle software (Paelinck et al., 2017).

9.1.3 ARM MODULE

During iteration BC1, the arm module adjustments could be positioned through sliding (and reading the position from a scale). This resulted in difficult positioning due to *"sliding the module just on the right number"*. To solve this problem, a fully indexed arm module was introduced which allowed only a predefined amount of fixed positions. The arm module was made of $3mm\ S235JR$ sheet metal, which was powder coated for a clean and washable finish (G_6).

ARM SUPPORT BLADE

A flat, universal baseplate was installed on the sheet metal arm module (fig. 9.4-2). This enabled us to test different arm support blades onto the same baseplate. The hip module can move (indexed) on the baseplate in laterolateral direction (fig. 9.4-1). The arm support

Fig. 9.4 Sheet metal arm module with indexed positioning: 1) latero-lateral adjustment for arm module on baseplate; 2) arm support blade resting on the arm module baseplate; 3) cranio-caudal adjustment of arm support blade; 4) pitch adjustment.

blade is mounted on the indexed hip module, which allows changing pitch (frontal-distal, fig. 9.4-4), yaw (laterolateral, fig. 9.4-2) and craniocaudal position (fig. 9.4-3).

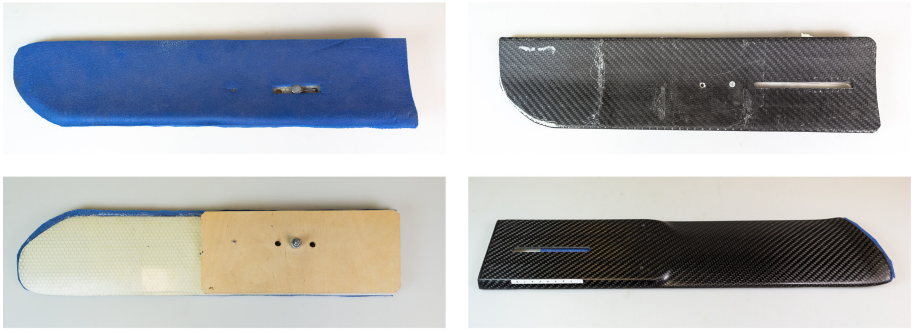


Fig. 9.5 Evolution of different arm support blades, used on BC2. 1) First fibreglass arm support blade. 2) Arm support blade with primitive wooden adapter plate. 3) First carbon fibre arm support with PMMA adapter for adjustability. 4) Enhanced carbon fibre support blade with integrated adapter plate.

We evolved from a fibreglass arm support with wooden adapter plate for cranio-caudal adjustability (fig. 9.5-left), to a full carbon arm support with an integrated adapter plate (slot for cranio-caudal adjustability) (bottom-right). The arm support blade consisted of a carbon fibre sandwich laminate, which is infused through a RIM compatible Lantor Soric® core. This resulted in a thin ($5mm$) and stiff support blade, which was favourable for beam access and patient positioning. A soft cushion was installed for comfort improvement (fig. 9.6).

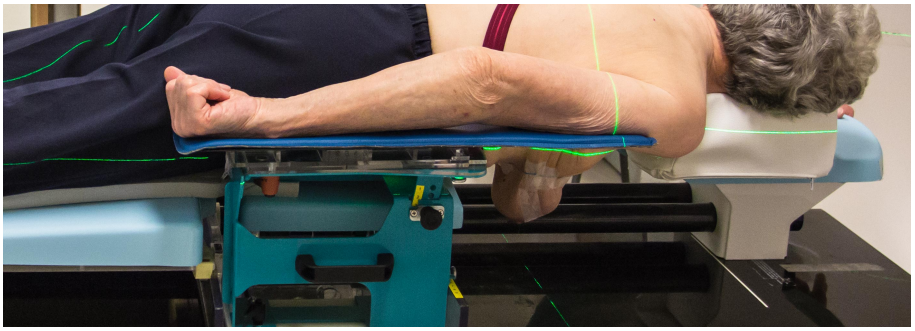


Fig. 9.6 Breast board on CT-simulation table. Arm module with carbon fibre arm support blade and high head support cushion.

9.1.4 HEAD SUPPORT

Derived from the phase II head support analysis, we produced two head supports: sloped pillows -$H_6$with different heights ($50mm$ and $100mm$, high pillow visible in fig. 9.6). The possibility of a more posterior or anterior head position enabled us to better align the head with the cervical and thoracic vertebrae. All head support pillows were fabricated by Mousse Shop [2].

9.1.5 TABLE FIXATION

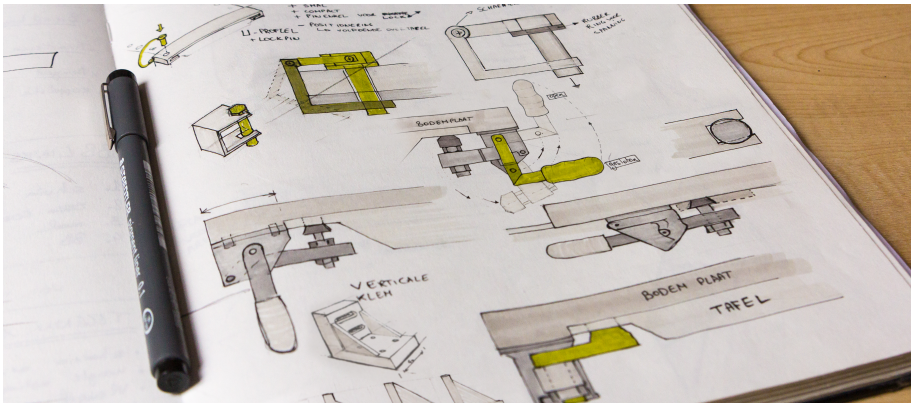


Fig. 9.7 Exploration of different fixation mechanisms, which can be used on the LINAC treatment table.

[2]Mousse Shop –
`https://www.mousseshop.be/`

Since the device is now considered a breast couch and hanging over the treatment table, a connection or fixation with the treatment table is needed. An exploration was performed and some concepts were prototyped and tested (fig. 9.7).

9.1.5.1 SIMULATION

Due to the table construction of the CT simulation machine (Toshiba Aquillion CT scanner [3]), it does not allow us to install the breast couch with the upper part hanging over the table. The breast couch device is therefore installed as a breast board and positioned on top of the table. Consequently, fixation is only needed for latero-lateral and cranio-caudal alignment of the breast board.

9.1.5.2 LINAC

EXPLORATION

For a breast couch, the device is fixed on the caudal part of an I-Beam EVO treatment table of an Elekta [4] Synergy LINAC. With the cranial part of the treatment table being removed, no parts of the I-beam EVO treatment table are below the patient's torso.

Although the centre of mass is located above the treatment table (fig. 9.3), a fixation is installed as a safety mechanism for proper positioning and preventing of tipping over (caused by an external force).

PROTOTYPING

Several fixation systems were explored and tested for usability, positioning, user feedback, and strength. Standard clamps (fig. 9.7-left) were modified to fit underneath the I-Beam EVO treatment table and clamp the breast couch, we tested lock-pin systems, clip-on systems and dead-point locking systems (fig. 9.7-Middle and right). Unfortunately, these were often reported to be bulky, require high forces to open or close, hinder breast couch placement (from storage cart to treatment table) or may damage the treatment table.

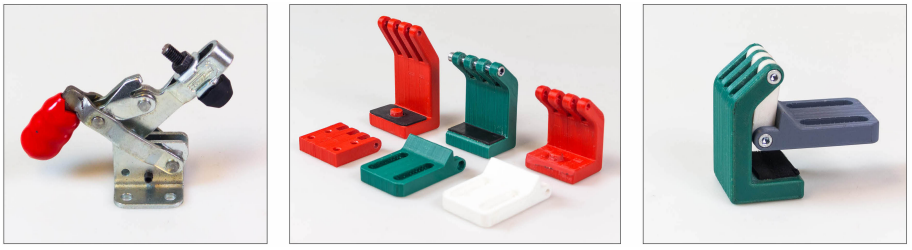


Fig. 9.8 Different fixation prototypes for BC2. Left: modified clamp, Middle: Exploration of different clamping systems, Right: Final assembled clamping system.

[3]Toshiba Medical Systems, Tokyo, Japan
[4]Elekta, Crawley, West-Sussex, UK

Eventually, a rotating slider lock was used which fixates the breast couch by rotating a handle underneath the treatment table (fig. 9.9-right). In addition, minor laterolateral adjustments ($5mm$) could be performed for calibrating the breast couch. The fixation prevents the breast couch from tipping over, enables laterolateral alignment and delivers visual feedback to the nurses when the device is properly positioned and locked.

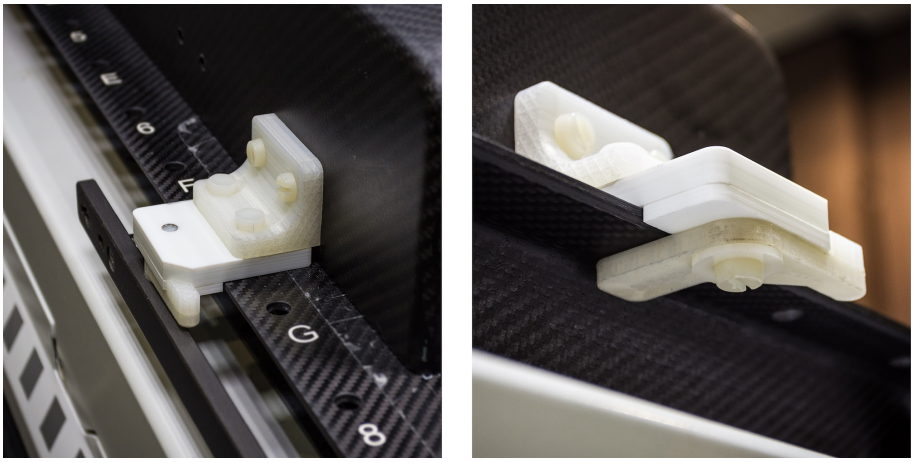


Fig. 9.9 A fibreglass reinforced 3D-printed and laser-cut module for the Linac table-fixation.

9.1.6 BIO-COMPATIBILITY

In order to comply with the FAGG, documentation of every material which comes in contact with the patients is required. As described in chapter 7, no academic literature has been found regarding skin contact allergies (or similar cases) for cured polyester and epoxy resins, fibreglass or carbon fibre. The used materials for phase III prototypes which come in contact with the patients, are listed below:

Crawl breast upper shell and leg support	Fibre	Epoxy
Name of the material (generic and trademark)	Woven Glass 2/2 Twill 280g/m2	High Performance IN2 epoxy infusion resin
Supplier	Easy Composites Ltd.	Easy Composites Ltd.
Supplier product code and grade	GF-22-280-100	EP-IN2-S-1
Quality or standard adhered	E-glass	/

Table 9.1 Material description and characterisation for crawl breast upper shell and leg support shell.

The headrest consists of two components:

Arm support blade	Fibre	Epoxy
Name of the material (generic and trademark)	Woven carbon fibre 2/2 twill 12K 650g/m2 - Grafil 34-700	High Performance IN2 epoxy infusion resin
Supplier	Easy Composites Ltd.	Easy Composites Ltd.
Supplier product code and grade	CF-22-650-100	EP-IN2-S-1
Quality or standard adhered	ISO 9001:2008 - FM 56416	/

Table 9.2 Material description and characterisation for the arm support blade.

Arm support foam	Material
Name of the material	Polyethylene Gelert foam
Supplier	Sport-direct
Supplier product code and grade	782165
Quality or standard adhered	/

Table 9.3 Material description and characterisation of arm support foam padding.

Head support unit	Sloped pillow
Name of the material	PVC-artificial leather - Skai®
Supplier	Konrad Hornschuch AG
Supplier product code and grade	/
Quality or standard adhered	/

Table 9.4 Material description and characterisation for the head support unit.

9.2 USER TEST

During phase III, two different user tests were performed: a validation trial with both left- and right sided patients, validating setup precision, treatment time, comfort, dosimetry and the feasibility of breath-hold.

9.2.1 VALIDATION TRIAL

The validation trial consisted of 40 patients requiring adjuvant WBI and were treated on the crawl breast couch BC2. Twenty left-sided and twenty right-sided breast patients were included. All the left-sided patients were treated with the DIBH technique (Deseyne, Post, et al., 2018).

For each treatment fraction, a CBCT was performed to analyse the patients' shifts in anteroposterior (AP), laterolateral (LL) and craniocaudal (CC) directions after being positioned with the isocenter laser lines. Data were then compared to published results for prone positioning in the literature (Deseyne, Post, et al., 2018).

RESULTS

We completed the validation trial but not all data has already been processed. Based on a preliminary data analysis we can present some results below.

In short, the data shows that the margins calculated for positioning on the crawl couch (BC2) are amongst the lowest reported for WBI in prone position compared to published literature results, especially for the AP and LL axes, due to the new floor laser system (Deseyne, Post, et al., 2018). These findings illustrate the crawl couch's ability to minimise the existing positioning inaccuracies in prone positioning. This reproducibility and accuracy is imperative in order to proceed to implementation of LNI in prone position (Deseyne, Post, et al., 2018).

For the twenty patients with left-sided breast carcinoma, the DIBH technique proved to be feasible and reproducible for breast-only radiotherapy.

9.2.2 COMFORT EVALUATION

We used the new hybrid PI-measurement system for pain & comfort evaluation during the validation trial. The visualisation of the PI measurement scale was divided in two: a graphical representation for pressure and discomfort evaluation and a graphical representation with a 11-NRS for pain evaluation. Note that, to be able to have a correct interpretation, both representations should be viewed side by side because when pain diminishes, pressure or discomfort could increase. This could result in a decrease in discomfort scored (blue) while scored pain is increased (red).

Looking at the overal discomfort scores at the end of their treatment (fig. 9.10-B), we see a slight increase of both intensity and registered cases, in comparison with the start. The highest discomfort was located at the ipsilateral shoulder region with 8 registered cases at the start, and 10 at the end of their treatment.

When analysing the experienced pain (fig. 9.11), we see an overall decrease in both registered cases as pain intensity. We noticed that the neck and ipsilateral shoulder region had the highest pain scores. During the start of their treatment, 16 patients registered the neck region to be painful (with a max score of 6) and 11 patients registered the ipsilateral shoulder to be painful (max score 5). At the end of their treatment sessions, 15 patients reported the neck region painful (max score 6) and 10 patients reported the ipsilateral shoulder to be painful (max score 5).

Comfort evaluations indicate that both neck and ipsilateral shoulder regions deliver in-

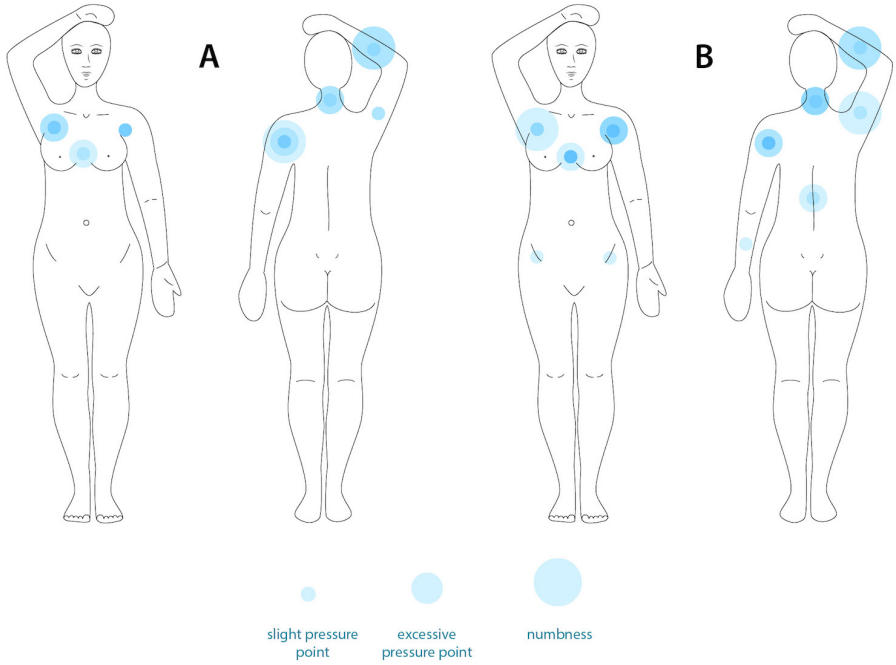


Fig. 9.10 Discomfort scored by 40 patients, to be viewed side by side with Figure 9.11. Different circle sizes indicated different pressure/discomfort scores per patient. Overlapping circles intensify the circle colour. A: scores at the start of their treatment B: scores at the end of their treatment.

adequate and uneven support. Pain at the neck region can be related to the sloped head support pillow. This delivered insufficient support and improper head positioning. In addition, the medical staff reported issues with precise alignment of the head and reproducibility. Besides, the head and pillow were sometimes restricting favourable beam paths for LNI, due to a too medial head orientation. Pain at the ipsilateral shoulder can be related to the hard cranial edge of the arm support blade (fig. 9.6). The medical staff reported issues that proper ipsilateral arm positioning sometimes restricted adequate patient roll.

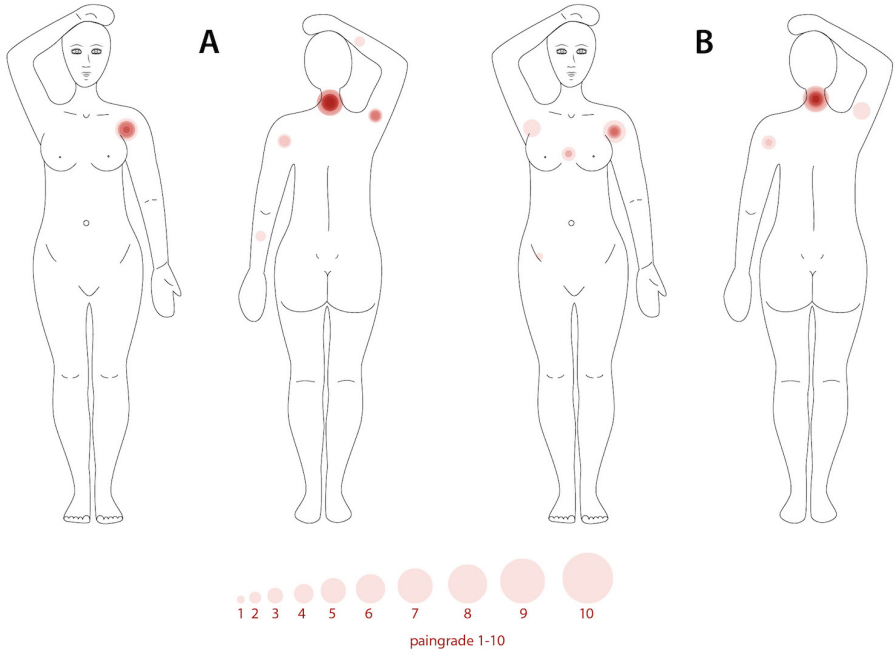


Fig. 9.11 Pain scored by 40 patients, to be viewed side by side with Figure 9.10. Different circle sizes indicated different pain scores per patient. Overlapping circles intensify the circle colour. A: scores at the start of their treatment B: scores at the end of their treatment.

9.3 CONCLUSION

During phase III, only one full prototype iteration was performed: the establishment of the second breast couch version: BC2-R and BC2-L. We produced four prototypes: two left-sided and two right-sided (for simulation and treatment). These devices were fully functional and structural conform (G_6). They were used for treatment simulations, a validation trial and comfort evaluation (G_1, G_2,G_4, G_5). Furthermore, smaller sub iterations of the arm support, head support and floor laser were executed for prototype optimisation and adjustability(G_7, G_8, G_9). The device was produced with materials which were reported to be skin friendly and easy to wash and disinfect (G_6). In general, we are now converging in the process, but for sub parts new iteration cycles (with diverging and converging phases) were executed (G_8).

The validation trial demonstrates that BC2 is very suitable for prone crawl position WBI and allows for good coverage, better setup precision and improved reproducibility (G_1, G_3). This improved accuracy is crucial for later LNI implementation in prone position (G_2). The DIBH technique proved to be feasible and reproducible for left-sided WBI-only radiotherapy (G_3).

Derived from the comfort evaluation we can conclude that the sloped head support pillows were insufficient: the head support positions need to be indexed, more comfortable and further contralateral positioned for better LNI access. The arm support blade was reported to be painful en delivered insufficient support. An exploration and redesign of both head and arm support blade are needed for Phase IV.

In general, we optimised the breast couch for treatment planning (medical performance) and patient comfort. We performed a validation trial which reported the advantages, accuracy improvements and DIBH feasibility of the prone crawl device.

Chapter 10

Phase IV

Close-up of the new head support on breast couch BC3

During the fourth phase, fully functional and optimised prototypes were produced and used for a large clinical trial. A series of twelve devices was produced. This chapter can be considered as the current (ongoing) phase of this research project.

10.1 ITERATION 4.1 - BC2.5

INTERNAL FRAME

The breast couch BC2.5, with internal frame can be considered as the first exploration of a fully self-supporting breast couch: an overhanging breast couch with no external frame supporting the breast couch. The overhanging part of the breast couch is now supported by an internal frame, which is installed in the upper shell of the breast couch. This enlarges the range of motion for the gantry and beam access.

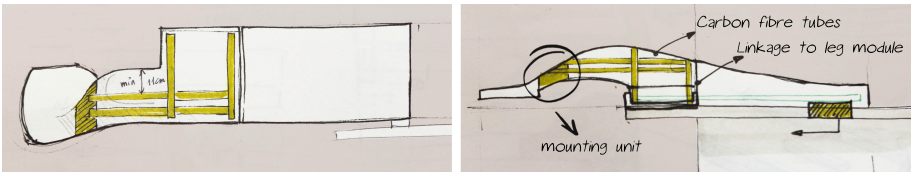


Fig. 10.1 Internal frame concept.

10.1.1 SMALL BARS HIGH

The idea of this concept was to reuse the prototypes of phase III and upgrade them by installing an internal frame. This would result in only some small modifications needed. By inserting a mounting unit in the contralateral axilla region and two carbon fibre tubes (twill weave, $\varnothing$ $30/26mm$) high in the upper shell of the breast couch, we wanted to achieve improved stiffness and a self-supporting breast couch. As can be seen on the left image of figure 10.2, the carbon bars are positioned higher than the lowest point of the contralateral breast support region, i.e. horizontal treatment bundles are now possible. Additionally, there will be no support unit underneath the head region needed.

LOAD TESTING

We tested this set-up with a load of $100N$ on the head position and $500N$ on the contralateral axilla support. Although the carbon fibre tubes were stiff enough (loaded with $500N$), torsion was noticed at the contralateral axilla region. When loaded with $100N$ at the head support (point X on fig. 10.3), there was a displacement of: $5mm$ at the wedge region (D), the medial versus lateral side of the head support area had a displacement difference of $9mm$ ($A - B$) and the cranial side of the head support had a displacement of $14mm$ (B).

Fig. 10.2 Internal frame prototype with two carbon fibre tubes installed in the upper breast couch shell.

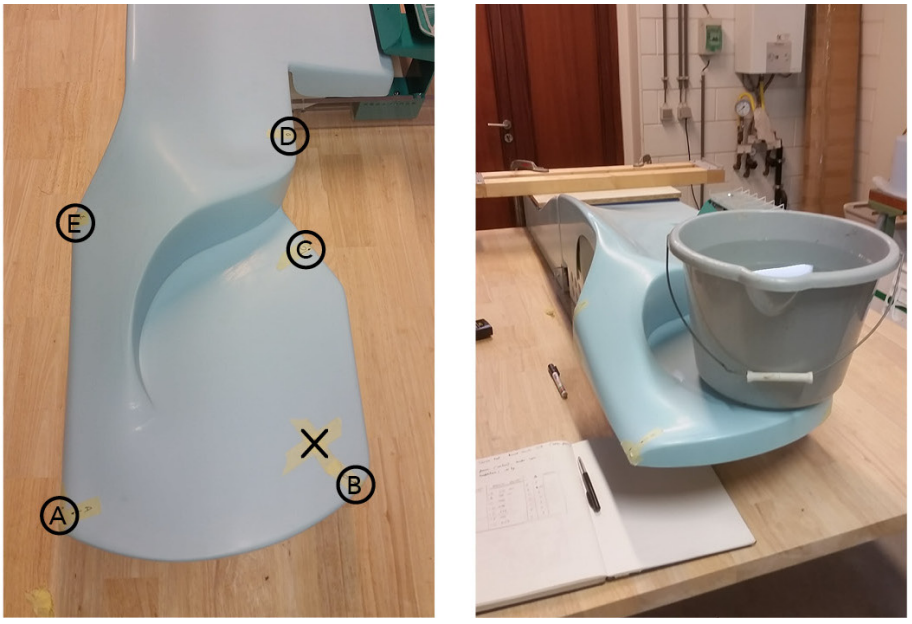


Fig. 10.3 Load testing of intern frame. A load of 100N was applied at point X.

10.1.2 SMALL BARS HIGH + PARTIAL PU CORE

Since there was too much torsion at the axilla region, we wanted to reinforce the shell by inserting a PU hard foam core in the cranial part (fig. 10.4). This would enlarge the stiffness and enable a better fixation of the upper carbon tubes.

By producing a partial mould, we were able to seal the cranial part of the upper shell (fig. 10.4-Left). A 2K PU-foam with a density of $70 kg/m^3$ was used as core material. A 3D printed tube insert was installed for proper fixation of the carbon tubes with the PU core.

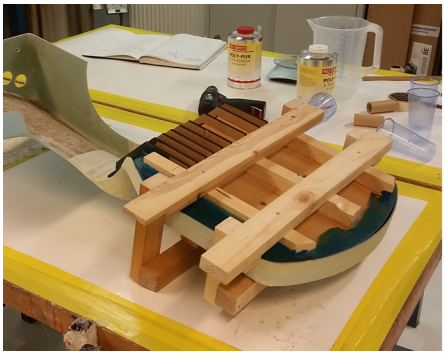



Fig. 10.4 Left: Partial mould installed on BC2.5. Right: Demoulded PU hard foam core with 3D printed tube fixation insert.

10.1.2.1 STRUCTURAL STRENGTH TESTING

CALCULATION

Since the breast couch is in a natural equilibrium, structural strength calculation is limited to the device itself, and independent from structural strength of the couch table of the LINAC or CT simulator. The forces exerted by the patient on the device are mainly gravitational forces. An estimated 40% of a person's mass is resting on the overhanging part of the breast couch after being positioned in crawl position on the device. The weight distribution on the breast couch upper shell and arm support blade is approximately $2/3^{rd}$ and $1/3^{rd}$ respectively. However, a larger downforce on upper shell of arm support blade may occur when the patient positions herself and leans more on one side to manoeuvre towards the desired position. We assume that in worst case, up to 40% of the person's mass may rest on the shell or arm support, i.e. leaning completely on one side of the device.

The maximum downforce F on either side is given by:

$$F = 0.4 * M * g = 274.4$$

where M is the mass of the person and g the gravitational constant $9.8m/s^2$. The downforce on one side for an average person of $70kg$ would be $274.4N$.

Figure 10.5 illustrates the FBD for a single carbon fibre tube that gives additional structural strength to the breast couch shell. When climbing on the device, the maximum exerted force can be considered at the contralateral axilla region (hand straight below shoulder). This position is approximated by the position of F in figure 10.5, with a length of $35cm$ (a) overhanging. The length of b is $21cm$.

The downforce F_d exerted by the connection between the carbon fibre tube and base plate is:

$$F_d = F * a/b$$

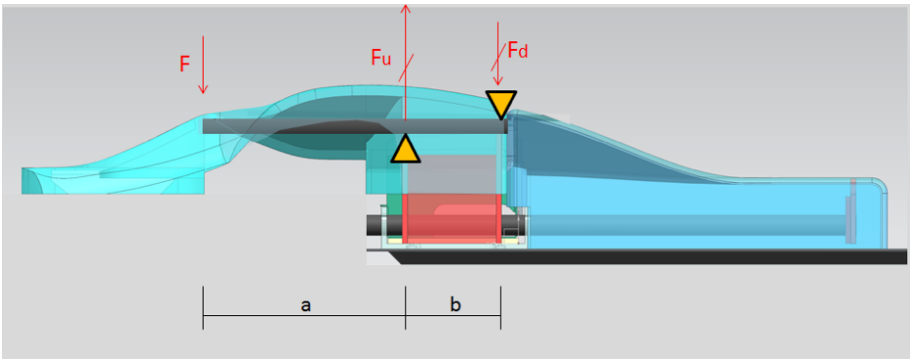


Fig. 10.5 FBD of downforce exerted by a load F on a single carbon fibre tube. Position of connections of the tube to vertical elements of the base plate are indicated by yellow triangles. Connections cause reactive upward and downward forces F_u and F_d, respectively.

Neglecting the weight of the carbon fibre tube, the upward force F_u is:

$$F_u = F + F_d = F(1 + a/b)$$

In a $3 - point$ flexural strength test, similar to the set-up in figure 10.5, fracture would occur at the location of F_u. The carbon fibre tube (twill weave, $\varnothing\ 30/26mm$) was tested with a force of $800N$ at F resulting in a displacement of $11mm$ and no damage. For a $70kg$ person F_u would be

$$F_u = 0.4 * 70 * 9.81(1 + 35/21) = 731.7N$$

The peak strain exerted by a $70kg$ person would be $1/3^{th}$ of the tested load force on a single frame tube. For a $100kg$ person, the peak strain would be less than half of tested load force. Additionally, the inner frame consists of two parallel carbon fibre tubes, resulting in a FoS of 4 or more for a 100kg person. Furthermore, the structural strength of the breast couch shell itself was not integrated in the calculation. Hence, the FoS would be even higher. The two parallel carbon fibre tubes were connected to the PC baseplate with a carbon fibre reinforced 3D printed piece. Additionally, the breast couch upper shell is fixated to the leg shell and can be considered rigid.

LOAD TESTING

We performed the same load test as with the small bars high: a load of $100N$ on the head position and $500N$ on the contralateral axilla support. Torsion was still noticed but is now shifted towards the wedge region. No torsion was noticed at the axilla region. When loaded with $100N$ at the head support (point X on fig. 10.3), there was a displacement of: $2mm$ at the wedge region (D), the medial versus lateral side of the head support area had a displacement difference of $4mm$ ($A - B$) and the cranial side of the head support had a displacement of $8mm$ (B).

10.1.2.2 CONCLUSION

By installing the internal frame and PU-foam core, we were able to enlarge the overall stiffness, reduce torsion of the breast couch and achieve a self-supporting device. Nevertheless, installing the PU foam core was challenging: difficult sealing of the mould, installing of the tube fixation and uniform foaming of the core. Torsion may be reduced on the head and shoulder region but is now shifted towards the breast region (wedge). Since we want this region to be as stiff as possible (for position accuracy), a new solution is needed.

Although the prototype may be strong enough (G_6), when positioning on the device, the structure felt *"wobbly and unstable"*, which is undesirable for patient comfort (G_5). Additionally, the production procedure was complex and difficult to reproduce (G_3, G_9).

Some possible solutions may be:

- Better fixation of carbon tubes (to prevent displacement towards each other).
- Use of bigger oval, triangle or triangle-round tubes. This would reduce torsion without decrease of beam access.
- Application of a double shell with full PU-core.
- Installation of a truss-like carbon fibre structure, replacing the full PU-core.
- Full unibody concept: a new monocoque structure with leg + upper shell combined, with core/sandwich structure.

10.1.3 HEAD SUPPORT

Derived from phase III, the new head support module should be improved on following aspects:

- Indexed positioning system for accurate immobilisation and reproducible positions.
- Improved comfort and head position alignment.
- The possibility for a more contralateral head positioning for better LNI beam access.

To be able to better score on every desired function of the head support module, a more in-depth investigation and anatomical study was performed. Based upon findings of the radiation oncologists and physicians, following functions were desirable:

- ***Frontal Support*** ***(H_1)*** - Face looking forward to achieve a more natural position.
- ***Craniocaudal Movement*** ***(H_2)*** - Craniocaudal adjustment of the head support.
- ***Head Extension*** ***(H_4)*** -For better torso roll and lower positioning.
- ***Head Tilt*** ***(H_5)*** - Tilting the head towards the contralateral arm for better access to the lymph node region.

10.1.3.1 ANATOMICAL ANALYSIS

We performed a small FBD analysis which explored the desired functions:

FRONTAL SUPPORT

To be able to have a natural position when the head is frontally positioned, we want the cervical vertebrae to be inline with the thoracic vertebrae (fig. 10.7). Since the whole body has a roll of 15 to 20°, the head should also have that same roll (fig. 10.6).

When the patient was positioned in a frontal way + slight head roll, we noticed that the head is still able to *"roll off"* to the treated breast side due to the uncompensated force $F_{g1,x}$. This causes an unstable head position. To counteract this force and solve this problem, a lateral head support needs to be installed. This will prevent the head from rolling towards the treated side.

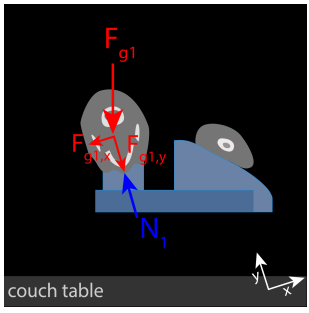


Fig. 10.6 Section view of head position for BC3. Due to the head roll of 15°, $F_{g1,x}$ is unsupported.

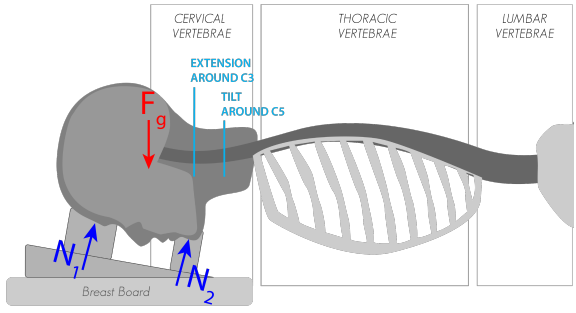


Fig. 10.7 Sagittal section view of a female body. A frontal head support with 10 degrees of extension is installed. A gentle extension and tilt only occurs in the cervical region.

HEAD EXTENSION

By means of a $10° - 20°$ head extension, we can achieve a slight extension of the cervical vertebrae and initiate a subtle shoulder retraction (fig. 10.7). This facilitates a better torso roll.

When positioning patients with a slight head extension, it is important to make sure that the extension is not too extreme and the bending radius of the vertebrae is large enough, i.e. a smooth transition between the thoracic- and cervical vertebrae. Too much head extension, together with a too high or too low head support, could cause strain, neck discomfort or position difficulties. to prevent the head and cervical vertebrae from sag and strain, a support at the chin region should be installed. Force N_2 neutralises the head position (fig. 10.7).

HEAD TILT

If a head tilt is introduced, it is important to note that there should be a smooth transition between the head and thoracic vertebrae. The initiated tilt should therefore start in the middle of the cervical vertebrae (fig. 10.7).

To be able to achieve a comfortable position, a natural orientation of the head and cervical vertebrae is thus desired. Due to the roll of both torso and head, it is now easier and more comfortable to perform additional head tilt towards the contralateral arm.

ANTHROPOMETRY

To be able to produce a uniform head support which fits most of the patients, a small anatomical analysis was performed. We used the anthropometric data of a $P_{97,5}$ female adult [1], to develop the first head support prototypes (fig. 10.8 & 10.9)

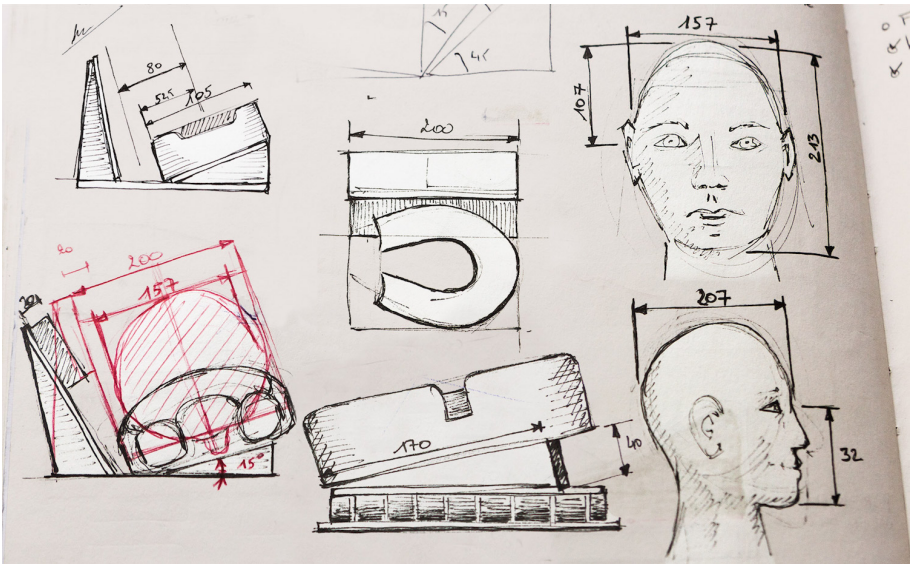


Fig. 10.8 Anatomical study of a $P_{97,5}$ female head position.

10.1.3.2 PROTOTYPES

As can be seen in figure 10.9, derived from the anthropometric data, a laser-cut plywood support module was developed. By means of an indexed head support plate, we were able to adjust the support module in craniocaudal direction ($4cm$) and adjust head tilt. We acquired a 15° head roll and tested different head extensions (0°,10° and 20°). We explored three different frontal head supports which could be mounted onto the plywood support module (fig. 10.9): an Orfit prone head support with adjustable chin cushion [2] ; an Orfit prone head support with adjustable forehead cushion; and a U-shaped Q-fix

[1] Body dimensions of the Belgian population, 2005 –
`http://www.dinbelg.be/DINBelg%202005%20anthropometry%20table.PDF`
[2] Orfit Product Brochure -
`https://www.orfit.com/app/uploads/ORFIT-RADIATION-ONCOLOGY-full-brochure-51000E.pdf`

Prone Headrest™ [3].

Both Orfit prone head supports were reported to be less comfortable than the Q-fix head support: volunteers often reported instability and pressure at forehead and chin.

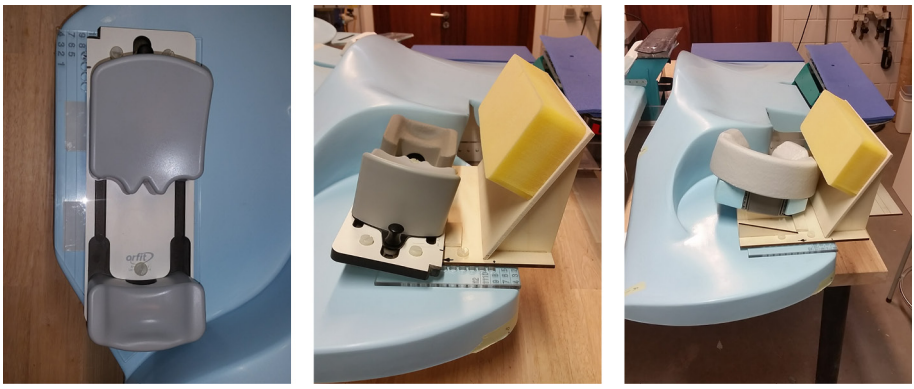


Fig. 10.9 Different concepts of head support prototypes. Left: Frontal module with Orfit head support. Middle: frontal support with roll and lateral support. Right: Oval support (Q-fix) with roll, lateral support and extension.

USER TEST

We tested the different head supports (fig. 10.9) with volunteers (medical staff and colleagues) and concluded that the set-up with Q-fix Prone Headrest was reported to be most comfortable. Through a $0°$ to $15°$ head tilt, we were able to acquire better beam access. The $15°$ roll resulted in a comfortable head position and the $10°$ head extension provided the best balance between patient position (beam accessibility) and comfort.

FINAL PROTOTYPE

The final head support module (fig. 10.10) is produced from laser-cut Polymethyl Methacrylate (PMMA) sheets, which are connected through chemical welding. The lateral supports (4) are produced in 3D-printed fibreglass reinforced PA and screwed onto the module and a lateral cushion is installed for comfort. The head module connects to the cranial flat surface of the upper body support component by means of an indexed PMMA plate (1). Using laser-cutting, a matrix of indexed holes (2) ($1A$ to $4A$ cranio-caudal, $15mm$ increments; $1A$ to $1D$, tilt movement of the head, increments of $5°$) and a slit are cut out the indexed plate. The flat lower side of the head support module (3) connects to the slit using a bolt which can travel in craniocaudal direction. The head support module is positioned on the indexed plate and locked at one of the indexed positions by a deadlock cylinder inserted in one of the holes (5).

[3] Q-fix, Avondale, PA, USA – `http://www.qfix.com/qfix-products/breast-and-torso.asp`

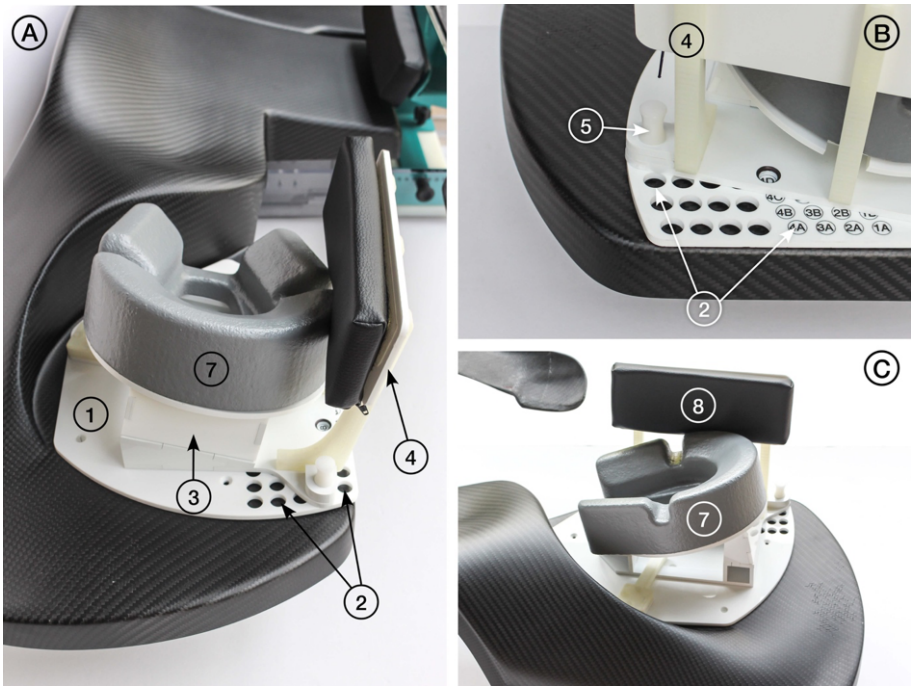


Fig. 10.10 Final head support prototype for BC3. A: 1) Indexed base plate. 2) position holes. 3) Wedged head support module. 4) Lateral support of the head. 7)Q-fix Prone Headrest™. B: 5) Deadlock pin. 2) Detailed view of the indexed holes. C: Full assembly with: 7) Q-fix Prone Headrest™. 8) Soft foam pad mounted on the lateral support.

10.2 ITERATION 4.2 - BC3

10.2.1 DOUBLE SHELL STRUCTURE

We analysed the possible solutions for structural improvements and concluded that a double shell structure with PU core would be the best solution: by using a double shell, we will be able produce a thinner section at the breast region. The custom made lower shell will generate superior stiffness, strength and beam access, in comparison with an internal frame or truss like structure. In addition, a double shell structure + core serves as a big composite sandwich structure, which eliminates the need for the integration of an aramid honeycomb core (or other core material) in each shell (fig. 10.11). This reduces cost, production time and weight.

The full unibody concept (upper shell and leg support combined) would have even better specifications (both structural and production oriented) but requires a completely new mould system, which is time and cost consuming. For the double shell concept, only an additional mould for the lower shell is needed. The full unibody concept is further

explained in chapter 11: Discussion and future work.

We evolved from a fibreglass breast couch to a full carbon fibre set-up. This has several reasons: lighter set-up, higher stiffness and better mechanical properties. Furthermore, unlike the fibreglass pieces, we did not use a gelcoat. This reduces production time and moreover, the overall structure became lighter and thinner. To be able to apply a clean finish and protect the carbon shells, we used a 2K matt varnish instead.

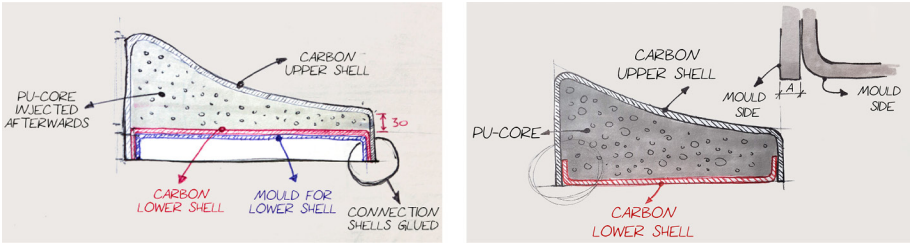


Fig. 10.11 Left: section view of the first double shell structure with PU-core. Right: section view of second version.

10.2.1.1 LOWER SHELL

The lower shell was designed in CAD-CAM software to match the upper shell. Equal to the mould production of Phase III prototypes, a PU plug was CNC milled and used for the mould system production.

A special wave-like surface was design at the contralateral breast region of the lower shell (fig.10.12). This eliminates CT-image artefacts caused by dense planar surfaces (see chapter: 4- preliminary research). Furthermore, this surface design improves the structural properties. When assembling, the lower shell will slide into the upper shell and be glued together with a high performance structural 2K epoxy adhesion (Permabond® ET500) (fig. 10.11). Afterwards, a core material will be installed by injecting a 2K, closed cell hard PU foam with a density of $70 kg/m^3$. The flat surface at the abdomen region will have bolt inserts, enabling easy assembling to the pedestal and baseplate. The vertical wall (between leg shell and upper shell) will have metal nut inserts, for connecting the leg support shell.

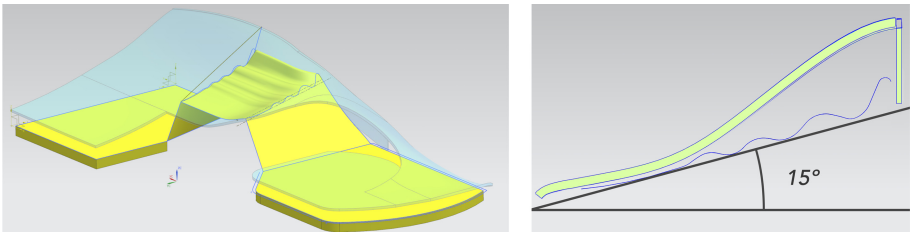


Fig. 10.12 Left) digital prototype of proposed lower shell for BC3. Right) section of wedge region.

With the introduction of this double shell structure, we now have an improvement of $15°$ beam access in the sagittal plane at the breast region (fig. 10.12).

DISCUSSION

While assembling the first version of the upper and lower shell, we encountered several problems. When using the RIM technique, a one-sided mould is used. This results in a high-quality finish at the mould side, but a more variable finish at the other side. Due to layer build-up and resin flow, the thickness of the shell can vary significantly. We noticed shell thickness differences up to $1.5mm$, especially at curvy surfaces or corners. As a result, the final shell thickness varied between $1,5mm - 3mm$.

As can be seen in figure 10.12-left, the upper shell and the first version of the lower shell were connected to each other with their rough sides. Consequently, shell thickness variation of both shells needed to be taken into account, resulting in a possible thickness variation of up to $3mm$. Since we used a glue gauge for connection the two shells, the lower shell did not fit always as desired. To be able to solve this, sanding and trimming of the shell's edges was often needed to properly fit. This was an inefficient and time-consuming task.

When evolving to the second version of the lower shell (fi. 10.12-right), only one shell thickness variation needed to be taken into account: we connected the rough side of the upper shell to the mould side of the lower shell. This resulted in a possible thickness variation of only $1.5mm$, which was beneficial for the final tolerances and reduced manual labour time (sanding and fitting).

Some possible solutions for further improving final tolerances and reducing assembly time, may be the use of a double-sided mould system. Through this method, a constant shell thickness and a double sided finished surface can be acquired (further discussed in future work, chapter 11).

10.2.1.2 STRUCTURAL STRENGTH TESTING

FINITE ELEMENT ANALYSIS

We explored the possibility of a Finite Element (FE) analysis of the device and concluded that it would be very difficult for several reasons. Although FE-models, mechanical properties of resins, core materials and fibres can be found, no standard model for the produced composite material itself exists and is therefore difficult to define.

- First, the mechanical properties of the composite used for the breast board is unknown. This could be defined through analysis of a test sample, but since the composite structure is not uniform (deformation of fibres and uneven distributed matrix material) this would be challenging and probably inaccurate.
- Secondly, the lay-up of the composite is complex: several fibre mat orientations were used ($0°$-$90°$ $12K$ $650g/m^2$ and biaxial $300g/m^2$), several layer thicknesses

were applied and different core materials were inserted.

- Lastly, if we were able to define every parameter and perform a FE-analysis, it would require high computing power and the calculated results versus measured results would probably be far off and unreliable due to calculation tolerance and difficulty of composite build-up (González et al., 2012).

LOAD TESTING

Based on previous findings, we can conclude that a structural strength test by means of a physical load testing would be a more practical approach. The test set-up is based upon the BC2.5's setup:

40% of a person's mass rests on the extending parts after being installed in crawl position on BC3. The weight distribution across both parts is approximately $1/3^{rd}$ for the arm support blade and $2/3^{rd}$ for the body support extending side. The largest downforce occurs while positioning:

The Maximum downforce F on a single extending part is 40% of the person's weight: $274.4N$.

The approximate location of this force F is shown in figures 10.13.

In laboratory measurements, a force $F = 274N$ caused a downward displacement of $3mm$ at point A, the most cranial edge of the body support component of BC3.

When increasing F progressively to $1000N$, a further downward displacement of A was noticed. ($10mm$ at $1000N$) without sign of collapse or impending fracture anywhere in BC3. Point A returned to its original position after removing the load, suggesting elastic bending of BC3 at loads exceeding the anticipated clinical peak loads by a factor > 3.

The left yellow triangle in figure 10.13 indicates the position of the reactive force F_u from the elevation platform of the anchorage element to the lower surface of the inferior shell of the body support element. The right yellow triangle indicates the position of fixation device in the laboratory that provided the reactive force F_d.

The reactive force of the platform for a load F is highest at position Fu in figure 10.13 For the F-position, a has a length of $35cm$. The length of b is $85cm$.

Neglecting the weight of BC3, the upward force F_u is

$F_u = F + F_d = F(1 + a/b)$

For a $70kg$ person: $F_u = 0.4 * 70 * 9.8(1 + 35/85) = 387N$

For a 120 kg person: $F_u = 0.4 * 120 * 9.8(1 + 35/85) = 664N$

BC3 has been loaded with $2kN$ of sand bags directly above the platform position F_u, resulting in $< 2mm$ deformation followed by elastic recovery. Hence, the peak strain

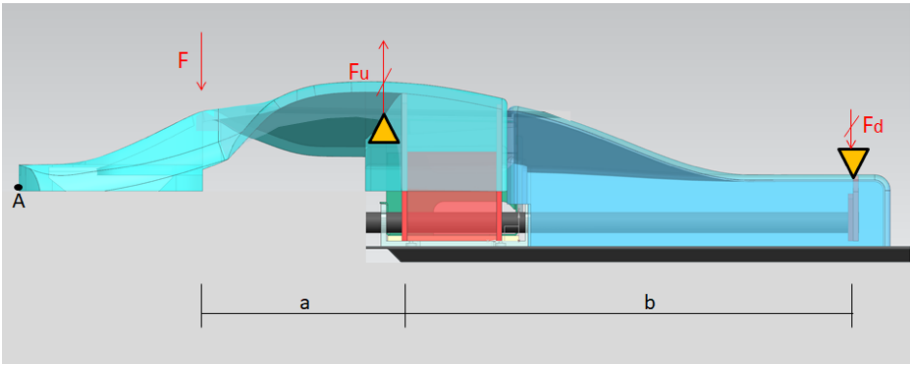


Fig. 10.13 FBD of downforce exerted by a load F on BC3. The left yellow triangle indicates the position of the reactive force from the elevation platform on the base plate to the lower surface of the inner shell of the body support element. F_u is the reactive upward force. The right yellow triangle indicates the position of fixation device in the laboratory that provided the reactive force F_d.

exerted by a $120kg$ person would be less than $1/3th$ of the load range tested in the laboratory.

10.2.1.3 CONCLUSION

During testing, minimal displacement and torsion was noticed on the overall structure. With a FoS of 3 for a $120kg$ person, the device can be considered strong enough. The double shell structure enables us to produce light and strong sandwich structures with a wide beam access range and thin wedge region. Due to the lower shell, the breast couch has now a flat and smooth lower surface and is easy to install to the pedestal and leg support.

10.2.2 ARM SUPPORT

10.2.2.1 CURRENT ARM SUPPORT

We noticed that the arm support used during previous iterations had some drawbacks for both comfort and anatomical position: the cranial edge of the support caused sometimes discomfort at the upper arm (fig. 10.14-Left); in some cases, the medical staff reported difficulties positioning the ipsilateral arm: natural pronation and light flex of the elbow caused an uneven support on the blade, causing high pressure at the edge of the blade (fig. 10.14-Middle); positioning the arm straight onto the support blade was not always possible due to the patient's mobility or surgery (fig. 10.14-Right).

With the current arm support blade, there is a lot of movement possible on the craniocaudal axis (elevation or depression of the shoulder blades). This can cause different

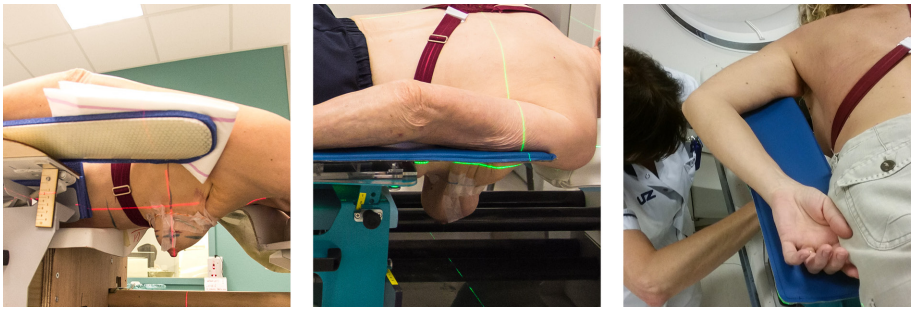


Fig. 10.14 Drawbacks of the arm support on BC2. Left) Soft napkin underneath the upper arm for pressure relief; Middle) the upper arm and elbow is not fully supported, causing higher pressure at the edge of the support blade; Right) Light flex of the elbow due to restricted mobility.

deformations during treatment sessions of the lymph node region. Finally, lateral positioning of the arm is not defined: during each individual session, the shoulder + humerus can be more lateral or medial positioned and elbow can be more flexed or be straight.

10.2.2.2 EXPLORATION NEW ARM SUPPORT

When analysing the arm support, a concave support at the shoulder region would be beneficial for a more evenly support + immobilisation of the shoulder. A lateral shoulder support could also limit the laterolateral movement, which improves positioning precision. Since light flex was previously observed, the same anatomy could by applied on the arm support blade design.

We explored and tested several concepts (fig. 10.15): a flat support blade with concave shoulder cut-out; a blade with $10°$ and $20°$ downslope for the upper arm; $10°$ and $20°$ downslope + $10°$ abduction for upper arm; concave shoulder support, foam shoulder support, foam support with cut-out for humerus head and full- and partial air pillow shoulder support.

Derived from testing, a support blade with $10°$ of downslope and $10°$ abduction of upper arm (light flex and pronation arm), resulted in the best support (fig. 10.16-up). We chose to design the arm support for P_5 patients [4] (top shoulder to elbow: $28,49cm$, see fig. 10.16). Patients with P_{50} have only an upper arm length increase of $2,7cm$. With a downslope of only $10°$, this will be no problem during positioning.

Shoulder support 3 and 5 were reported to be comfortable (fig. 10.16). Especially the support with big air pillow, supporting both front and cranial part of the shoulder (5), was reported to be very comfortable. As can be seen on figure 10.17, the shoulder, upper and lower arm is evenly supported. The new arm support provides high access to the

[4] P_5: 5^{th} percentile, only 5% of the observed people have shorter dimensions. – `https://multisite.eos.ncsu.edu/`

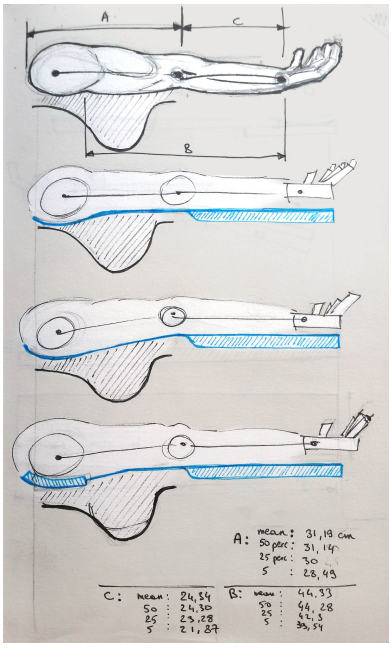


Fig. 10.15 Different arm support blade concepts for BC3. Top to bottom: analysis of arm dimensions; flat blade with shoulder cut-out; down-sloped support blade; partial down-sloped support blade.

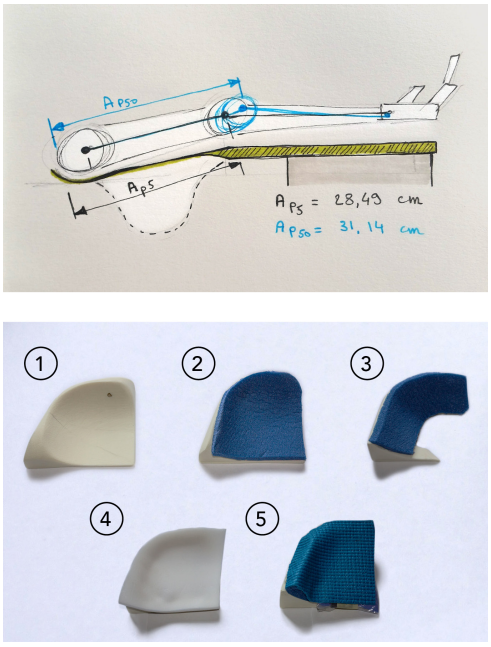


Fig. 10.16 Up) proposed arm support blade. Down) different shoulder support modules: 1) hard foam. 2) full concave soft foam. 3) foam support with humerus head cut-out. 4) shoulder support with small air pillow. 5) shoulder support with big air pillow (also supporting cranial side of shoulder).

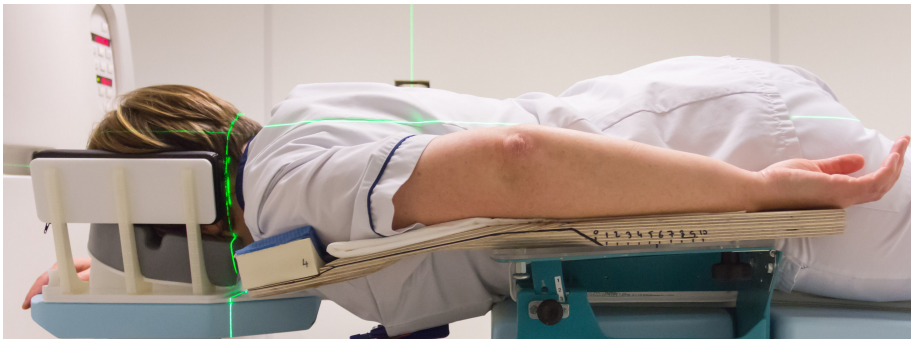


Fig. 10.17 Testing the proposed arm support with shoulder support 5.

lateral side of the breast. By positioning the shoulder in the concave support, cranial and lateral movement is restricted, which enhances fixation.

We CNC-milled a mould and produced carbon fibre arm support blades with a thickness of $5mm$, resulting in maximum beam access and optimal strength. A lateral and cranial

foam padding (blue) + air pillow for humerus head is installed for equal pressure distribution of the shoulder. The slit enables a craniocaudal adjustability of $8cm$. Later on, a washable fabric cover was installed for hygienic purpose.

Fig. 10.18 Carbon fibre arm support blade and air pillow for BC3 prototypes.

10.2.2.3 STRENGTH TESTING

When a patient positions herself on the device, they typically use the most cranial part of the arm support as a hand rest position. This is indicated by the vector F in figure. 10.19. When the hand is positioned at F, the length to F_u is $25cm(a)$. The length of b is $24cm$. The downforce F_d exerted by the connection between the arm support blade and the arm support model at the caudal side is:

$$F_d = F * a/b$$

Neglecting the weight of the arm support blade itself, the upward force F_u is:

$$F_u = F + F_d = F(1 + a/b)$$

For a $70kg$ person F_u would be:

$$F_u = 0.4 * 70 * 9.8(1 + 25/24) = 560.2N$$

A fibreglass arm support blade from Phase II (sandwich lay-up of 4 layers (each $280g/m^2$), $3mm$ thick Lantor Coremat® core and another 4 layers ($280g/m^2$) broke at $F = 690N$ ($12.5mm$ displacement at $390N$).

A carbon fibre arm support blade using a composite sandwich lay-up of 3 layers with a density of $400g/m^2$, Lantor Coremat® $3mm$ and another 3 layers ($400g/m^2$) did not break at $F = 690N$ ($6.5mm$ displacement at $390N$).

A sandwich lay-up of 1 layer twill weave ($650g/m^2$), 1 biaxial layer ($300g/m^2$), Lantor Soric®($2mm$), 1 biaxial layer ($300g/m^2$), 1 layer twill weave ($650g/m^2$), 3D PET core

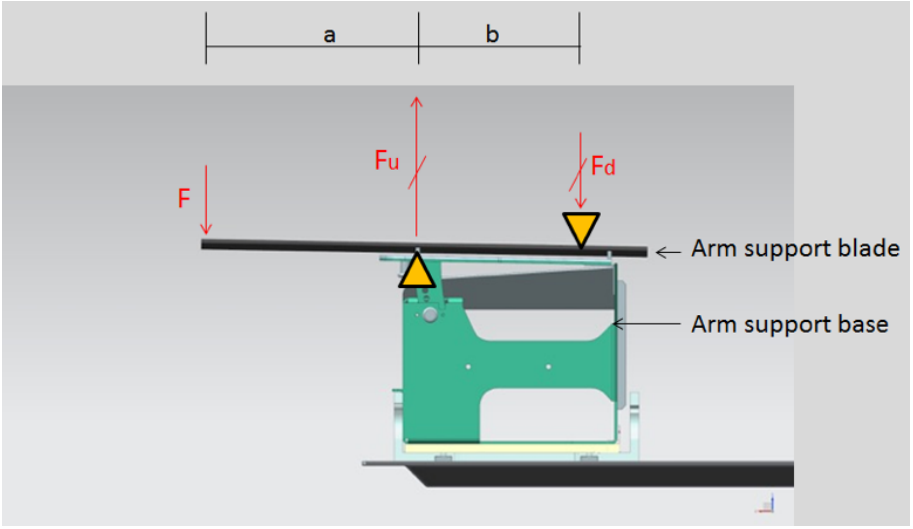


Fig. 10.19 FBD of downforce exerted by a load F on the arm support blade in its most cranial position. Position of connections of the arm support blade to the arm module causing reactive upward and downward forces F_u and F_d, respectively, at the locations indicated by yellow triangles.

$(5mm)$ and 1 layer twill weave $(650g/m^2)$ is used for the new arm support blade of prototype BC3. This is even stronger with no risk of breaking at:

$$F_u = 690(1 + 25/24) = 1,437.5N$$

Hence, a FoS of at least 2.5 is guaranteed for a $70kg$ person regarding the arm support blade. Hence, for a $100kg$ person, a FoS of 2.0 for the arm support component may be a conservative estimate.

CONCLUSION

With the new arm support blade design, we were able to produce a support which was reported to be both comfortable and had good medical results: the carbon fibre blade has a FoS of 2 for a 100kg person, the concave shaped shoulder support (with air cushion) enables for good positioning and comfort and the new shape of the blade enables for better beam access from the contralateral side.

10.2.3 BIO COMPATIBILITY

Both upper and leg support shells are now fabricated in carbon fibre + epoxy resin (same specifications as the arm support in Phase III).

The new headrest consists of two components that have contact with the patients' skin:

1. The Q-fix Prone Headrest™ (a commercially available head support).
2. A soft pad that gives lateral support to the head of the patient which consists of a foam core covered with PVC artificial leather (Skai®).

Head support unit	1) Frontal Prone Headreast	2) Lateral Support
Name of the material (generic and trademark)	Q-fix Prone Headreast™	PVC-artificial leather - Skai®
Supplier	Q-fix, Avondale, PA, USA	Konrad Hornschuch AG
Supplier product code and grade	RT-4544KV-06	/
Quality or standard adhered	/	/

Table 10.1 Material description and characterisation for the head support unit.

10.2.4 SMALL SERIES

During this phase, we produced twelve breast couch devices which will be distributed over three different hospitals (University Hospital Ghent, Jules Bordet Institute Brussels, Sainte-Elisabeth Hospital Namur)

To be able to fit the breast couch on different treatment table couch models, we developed a universal baseplate with several connection possibilities which fit on each table (Ghent, Brussels, Namur).

We developed sets of four devices at a time (two identical left-sided and two identical right-sided). To be able to produce identical devices with the same properties, the whole production process was documented, different gauges were used for drilling of holes, trimming edges, and gluing upper and lower shell to each other.

Fig. 10.20 A set of upper body support shells and leg support shells finished with a matt varnish.

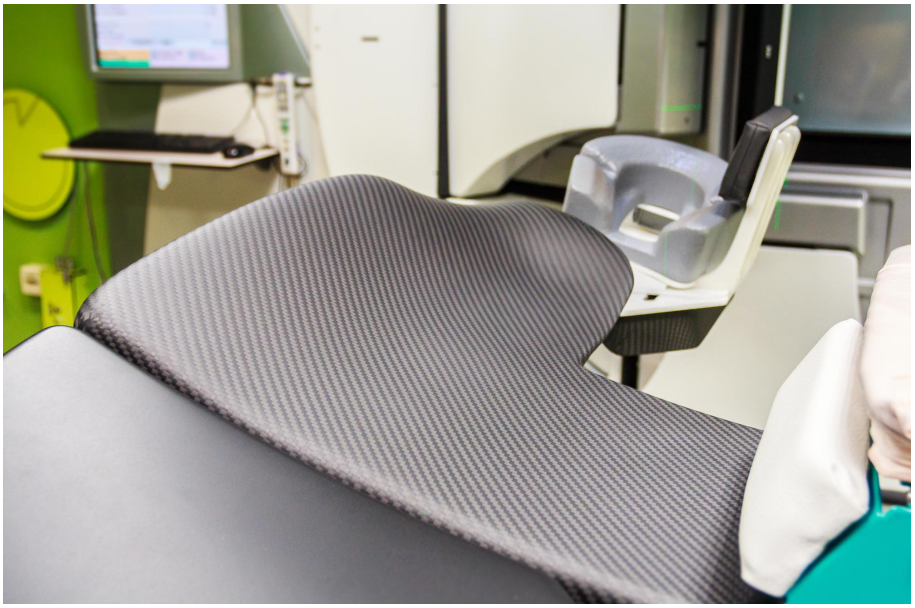


Fig. 10.21 Close-up of finished carbon fibre breast couch BC3, ready for testing.

10.3 USER TESTS

At the time of writing this dissertation, only volunteer tests concerning comfort and positioning (head support and arm support blade) were completed. A big clinical trial (10.3.1) is planned but has yet to be completed.

10.3.1 MULTI HOSPITAL CLINICAL TRIAL

During this trial, we will perform WBI + LNI comparing prone crawl versus supine position treatment in a randomised study with 5 an 15 fractions.

This randomised trial will consist of a 2 x 2 full factorial design comparing the accelerated schedule in 5 fractions (median dose to breast: $28.5Gy$) with the standard moderate hypofractionation scheme of 15 fractions (median dose to breast: $40.05Gy$). Patients will be assigned to be treated in the prone or supine position, in 15 or 5 fractions. The effects of both interventions (prone position and acceleration) will be investigated separately. The primary endpoint will be breast retraction (volume loss) 2 years after radiotherapy. To be able to have significant results, a sample size of 388 patients is needed. 97 patients in each arm will be included in the trial. they are referred for WBI + LNI.

PRIMARY OBJECTIVES

- To compare the rate of breast retraction between prone crawl and supine WBI+LNI.
- To compare the rate of breast retraction between moderate hypofractionation (15 fractions) and acceleration (5 fractions).

SECONDARY OBJECTIVES

- Analysis of acute toxicities.
- Analysis of late toxicities other than breast retraction.
- Analysis of cosmesis.
- Analysis of quality of life.
- Analysis of locoregional and distant tumour control.
- Evaluation of the necessary treatment slots for all treatment arms.
- Dosimetrical analysis of target volumes and organs at risk.

Specific for the intervention *'treatment position'*:

- To evaluate the difference in setup accuracy between prone crawl and supine WBI+LNI.

Specific for the intervention *'fractionation scheme'*:

- To compare treatment cost between moderate hypofractionation and acceleration.

10.4 CONCLUSION

With the introduction of a carbon fibre double shell structure, we were able to produce thinner and stronger devices with improved stiffness (G_6). This reduced overall device weight, improved medical performance due to improved beam access range and reduced production time due to more efficient manufacturing techniques (G_2, G_4, G_9). The new lower shell enabled us to more easily assemble the upper body shell to the device's baseplate and leg support shell, which enhances assembly time and reduced complexity (G_9).

By means of a small FBD analysis and anatomical observation, we were able to produce a new head support module which enabled us to properly position and immobilise the head further away from the to-be-treated side without compromising patient comfort (G_2, G_4, G_8). The indexed head position allows sufficient adjustability for different patient body types and lengths: $35mm$ craniocaudal movement and $15°$ tilt adjustability. A fixed extension of $10°$ was adequate (G_3, G_5, G_7).

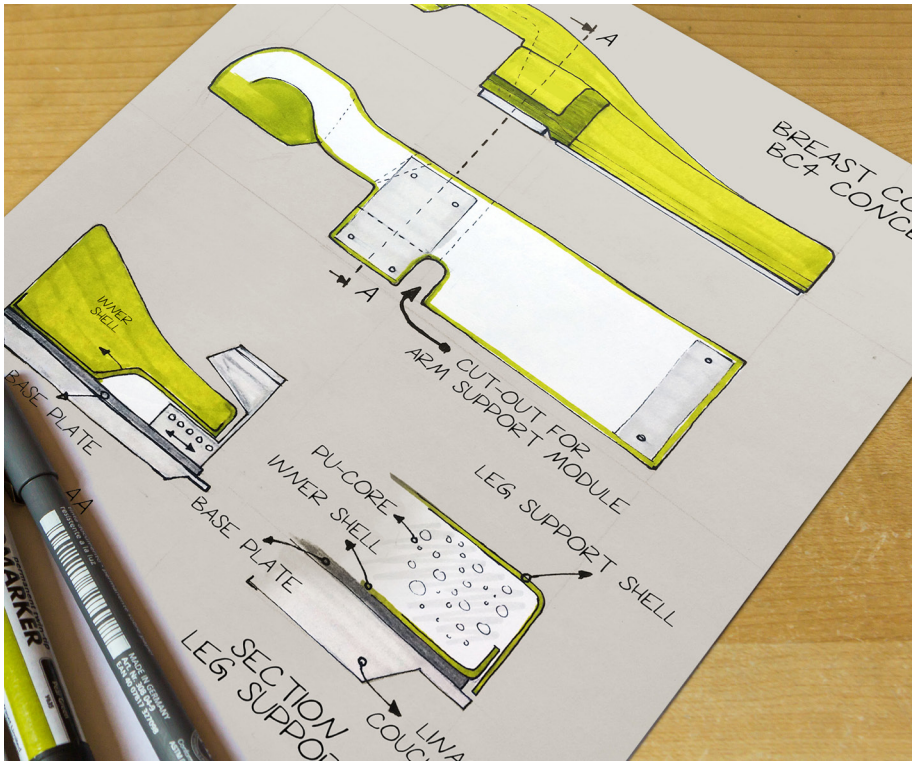
Structural load tests were performed on every carbon fibre part. Based upon these results, we can conclude that the device is strong enough for further testing. The overall FoS of the device is >2.5 for a person of 100kg. According to the Food and Drug Administration (FDA), this can be considered a safe medical device [5](G_6).

With the new arm support blade design, we were able to solve the discomfort issues reported on the previous iterations (G_5). We were able to better distribute the support surface and improve immobilisation of the shoulder and upper arm region. This enhances patient set-up precision and beam access form the contralateral side (G_3, G_4).

[5] Food and Drug Administration, USA –
`https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071154.htm`

Chapter 11

Discussion & Future Work



Concept exploration of a potential breast couch BC4

The aim of this dissertation was to develop a new patient support device for prone radiotherapy of breast and regional lymph nodes. By developing a new framework for medical prototype development, we were able to efficiently perform several prototype iterations. Eventually, we established a new prone crawl patient position, which was reported to be both comfortable and deliver good medical results.

11.1 RESEARCH OBJECTIVE

By developing a new prone crawl support device, we were able to treat both breast and regional lymph nodes on the same device, improve set-up precision, deliver more homogeneous dose distribution and better spare vital organs, in comparison with commercially available devices for prone and supine treatment.

Developing medical devices is often challenging, money and time consuming. By means applying our framework during each prototype iterations, co-creation with the medical team and a UCD approach, we were able to produce functional prototypes in an efficient way which could be used for several clinical trials and validation.

With the realisation of this new prone crawl patient position and support device, we can say that it fulfils all predetermined design goals from chapter 2:

MEDICAL ORIENTED

- *New prone position* (G_1) – We explored different prone patient positions and concluded that the prone crawl position with the arm at the non- treated side above the head and the arm at the treated side along the body, has the best overall performance for both patient comfort and medical results (Boute, 2014b; Boute, Veldeman, et al., 2018).

- *Prone lymph node irradiation* (G_2) – By means of several in silico treatments, Thiel body studies and clinical trials, we provided evidence that both breast and lymph node irradiation are possible on our new prone crawl breast couch, and it has several advantages in comparison with the standard prone and supine treatment technique (Boute, De Neve, Speleers, et al., 2017; Deseyne, Speleers, et al., 2017)

- *Reproducibility* (G_3) – Through a fully indexed patient positioning system, we are able to better immobilise and reproduce patient positions. With the aid of a sagittal floor laser alignment system, we are able to achieve higher set-up precision in comparison with the standard prone and supine devices (Boute, De Neve, Speleers, et al., 2017; Deseyne, Post, et al., 2018).

- *Beam Accessibility* (G_4) – We drastically improved beam accessibility for both breast and lymph node region: the contralateral breast is supported by a thin wedge structure which enables us to better treat the breast and Mammaria Interna (MI) lymph

nodes, the ipsilateral chest and shoulder region is unsupported, resulting in improved access for i.a. the supraclavicular lymph nodes. The rotated head position toward the contralateral elbow, enables us to use beams in a more craniocaudal direction. Improved beam access results in a more homogeneous dose distribution and better sparing of vital organs (Boute, De Neve, Speleers, et al., 2017; Deseyne, Post, et al., 2018; Deseyne, Speleers, et al., 2017).

DESIGN ORIENTED

- *Comfort* (G_5) – We analysed discomfort and patient experience on the standard prone device and used this as a reference for further development. With the realisation of a new PI measurement tool, we were able to better evaluate the patient pain and comfort experience during user testing of every prototype. By means of FBD analysis, Thiel body studies and pain & comfort assessments, we were able to develop a comfortable prone crawl support device. We are able to properly immobilise the patient and still achieve a comfortable position. Finally, no tension or stress was reported (Boute, De Neve, Speleers, et al., 2017; Boute, Veldeman, et al., 2018).

- *Safety* (G_6) – Using resin infused carbon fibre composite sandwich structures, we were able to establish strong, light and stiff breast couch devices and arm support blades, which were reliable and usable for treatment. The breast couch is a self-supporting device, meaning that the device's overhanging part is in equilibrium with the supported part, i.e. no external forces are needed to fixate the device. The installed fixation clamps are an additional safety feature in case an external force is applied on the breast couch, i.e. accidentally hitting or leaning onto the device by another person. All composite parts are tested for structural loading and have a safety factor of > 2 for a patient of $100kg$.

- *Modular* (G_7) – We built a modular system which is easy to upgrade and modify. As can be seen through the different design phases, all new arm support blades can be easily fitted onto the arm- and hip support module. Different head support units were developed, which all fitted onto the same head support index plate.

- *Iterative Cycles* (G_8) – We went through several iterative cycles for both full prototype iterations and sub parts. Through this iterative approach, we were able produce a high number of prototypes: 13 iterations resulted in 30+ prototypes produced. This enabled us to find better solution through co-design with the medical team and perform user tests, comfort evaluations, in silico treatments and Thiel body studies already early in the development process (Boute, De Neve, and Detand, 2017). This was beneficial and resulted in early validation of the prone crawl set-up (Boute, De Neve, Speleers, et al., 2017; Boute, Veldeman, et al., 2018; Deseyne, Speleers, et al., 2017).

  A disadvantage of this approach resulted in the various ethics approval applications which needed to be filed for each prototype iteration (Ethics Committee (EC) and FAGG). This resulted sometimes in a cost and time consuming process.

- *Efficiency: Cost + Time* (G_9) – By following the established framework during each iteration phase, we were able to efficiently select the correct prototyping technique, material and context for testing (Boute, De Neve, and Detand, 2017). See table 1.4 for an overview of the used techniques and materials during each iteration.

  We used several (low cost) digital prototyping techniques such as 3D printing and laser cutting which enabled us to develop prototypes, perform user tests and evaluate the results on a time and cost-efficient way.

  Even with very basic prototypes (Phase I), we were able to analyse treatment results by means of in-silico treatments and cadaver studies. This enabled us to gain fundamental insights and validate results early into de development process (Boute, De Neve, Speleers, et al., 2017).

11.2 FRAMEWORK

The framework was established during the first development phase (Phase I) of this project. We generated a structure for medical device prototyping which questioned three aspects: what is the process and how will we approach it **(process analysis)**, defining the correct parameters during this iteration **(process and prototype parameters)**, selecting and executing the right prototype process **(process selection and execution)**.

By using a hybrid V-model structure (AV-model) during each iteration cycle, we were able to more easily validate and verify the selected prototyping process, parameters, stakeholders' needs and generated output data. The framework resulted in different output focusses, depending on the process analysis (or design input). Some output results were: patient comfort and user experience, medical performance, technical output and user data.

We have employed a practical approach during this research project, which can be related to our educational background in industrial design engineering. This can also be noticed in the framework. It has it roots derived from our general product development approach, which is taught in our educational program: **observe**, produce physical **prototype**s, **test**, **evaluate** and **iterate**.

Finally, due to the nature of this research project, the framework was applied on only one case, the breast couch research project. Following this, we do not state that this structure should be considered as a standard or the best workflow but think that it can provide useful guidance for efficient process analysis, prototype generation and validation during medical device development.

As can be seen in figure 11.1, the framework will be used and further developed during Max Schoepen's PhD. Future PhDs or master theses can be used for validation of the framework with other cases.

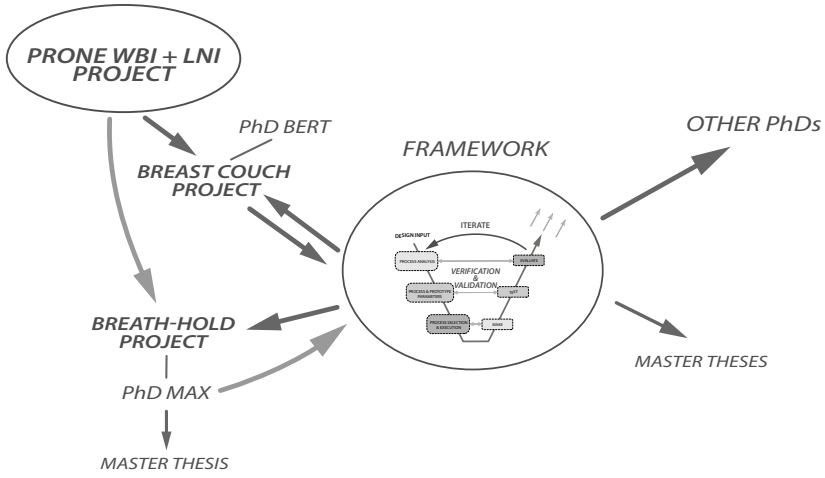


Fig. 11.1 Future vision of framework: application of framework on several master theses and PhDs.

11.3 PRODUCTION

Due to the breast couch's class I classification of a medical device, prototype production was relatively easy. We were able to use a wide variety of materials and production techniques.

When developing medical devices with a higher classification, certain additional protocols need to be followed. This can be specified materials, material certifications, production in clean rooms, special tolerances, etc.

We used several low volume prototyping techniques such as laser cutting, 3D printing, milling, composite fabrication and sheet metal production. Some components, such as the head support unit for example, were produced by laser cutting PMMA plates and connecting them by means of chemical welding. This enabled us to rapidly produce prototypes with a good finishing. Unfortunately, PMMA is rather brittle and not suitable for impact forces (hitting or falling of the module). Other production techniques and materials such as ABS, PVC, PC, etc, may be suited but need further investigation.

Prone crawl breast couches will probably never be mass produced like other medical devices (such as consumables, medical hand tools, wheel chairs, etc.) Furthermore, new product (or part) upgrades are likely to be executed. Consequently, it is important to analyse the currently used production methods and evaluate whether or not they are suitable concerning desired production cost, time, accuracy and quantity.

11.4 MEDICAL DEVICE DEVELOPMENT

FROM AN ACADEMIC RESEARCH POINT OF VIEW

When developing medical devices, the involvement of an industrial partner is often favourable and applicable. Nonetheless, it was difficult for us to find a suitable partner for this project. Furthermore, they often have strict time and financial constraints (Martin, Clark, et al., 2012). By not working with an industrial partner, we were able to obtain several research funds and prolong the R&D-phase as much as needed. This enabled us to extensively perform user tests, improve medical performance and ensure that every stakeholder's need is fulfilled.

The author's PhD research, which lasted 4 years, is part of the research project about the development of a new prone patient position for breast and lymph node irradiation. Through several research funds, we were able to appoint some employees onto this project: PhD candidates, post docs, medical staff and physicians. Other research funds were used for prototype development and user testing.

FROM A CLASSIC COMPANY APPROACH

Retrospecting from an industrial point of view, appointing several employees up to 4 years for R&D would be very expensive or even impossible for SMEs. Furthermore, constructing and analysing satisfactory clinical trials is a complex and time consuming procedure due to proper patient recruitments and the multidisciplinary approach. In addition, due to its experimental origin of the project and niche market, investing in research projects which may not be successful or unprofitable after some years, can be considered as high risk for companies.

11.5 FUTURE WORK

In this section, we describe the next steps of this research project that will be performed (Phase V). Some parts need to be redesigned in order to be MRI compatible and additional functions such as an active breathing ventilator will be installed for prolonged deep inspiration breath hold sessions.

We used the same mould system for the upper shell and leg support shell since phase III prototype. During phase IV, some degradation of the moulds occurred and some repairs were needed: we noticed some moulds starting leaking. An extra layer of fibreglass and polyester was applied to seal the micro cracks and leaks. Secondly, due to the shell's complex shape, high pulling and levering forces were used during demoulding of the pieces. This resulted sometimes in damaging of the gelcoat (chipped off edges).

In addition, to prevent deformation, the shell is positioned into the mould system when

the upper shell and inner shell are glued together. Consequently, due to the improved stiffness, demoulding becomes more challenging and mould damage is more likely.

The development of the baseplate originates from phase III prototypes and is rather bulky and heavy. No major redesigns were performed during phase IV prototypes since some baseplates from phase III were used and modified for phase IV production. This is similar to the sheet metal arm support module: no major improvements were performed between phase III and IV.

11.5.1 FULL UNIBODY DESIGN

During the fifth phase, a redesign may be performed to establish a full unibody design which combines both upper- and leg support shells into one shell (fig. 11.2). The inner shell could also be redesigned: as can be seen in section view of figure 11.2, the pedestal (PC part that connects upper body shell to the baseplate) could be removed and integrated into the inner shell. In addition, the baseplate itself could be flattened and reduced in size. With the introduction of the unibody shell, several improvements could be achieved:

- *Reduced complexity* – Only one upper shell and one under shell will be produced: no more connection and alignments between different shells are needed. Demoulding and fibre lay-up will be less challenging due to a less complex mould (less deep corners and vertical side walls). Furthermore, no more U-shaped baseplate with pedestal and carbon fibre tubes will be needed.
- *Reduced production time* – Production time will be reduced for both shell production, assembly and alignment/calibration at the treatment machine: less parts need to be assembled and aligned, the fibre lay-up will be easier to apply and infuse.
- *Reduced cost* – Besides the production of a new mould system, overall costs will be reduced due to less material needed for shell production, decreased production time, alignment and calibration time (man-hours).
- *Improved structural properties* – The overall strength of the shell can be improved since upper and leg support shell are one: no more mechanical connections are needed since carbon tubes, pedestal and baseplate are integrated into the shell. Weight will be reduced since less material and components are needed.

11.5.1.1 NEW MOULD SYSTEM

As already discussed in section 10.2.1, composite shells which are produced by the RIM technique, have a smooth, high quality finish on the mould's side but a rough finish with looser tolerances on the other side. As a result, the shell thicknesses of the different composite pieces can thus very. This can be a problem for later assembling or connection of different pieces.

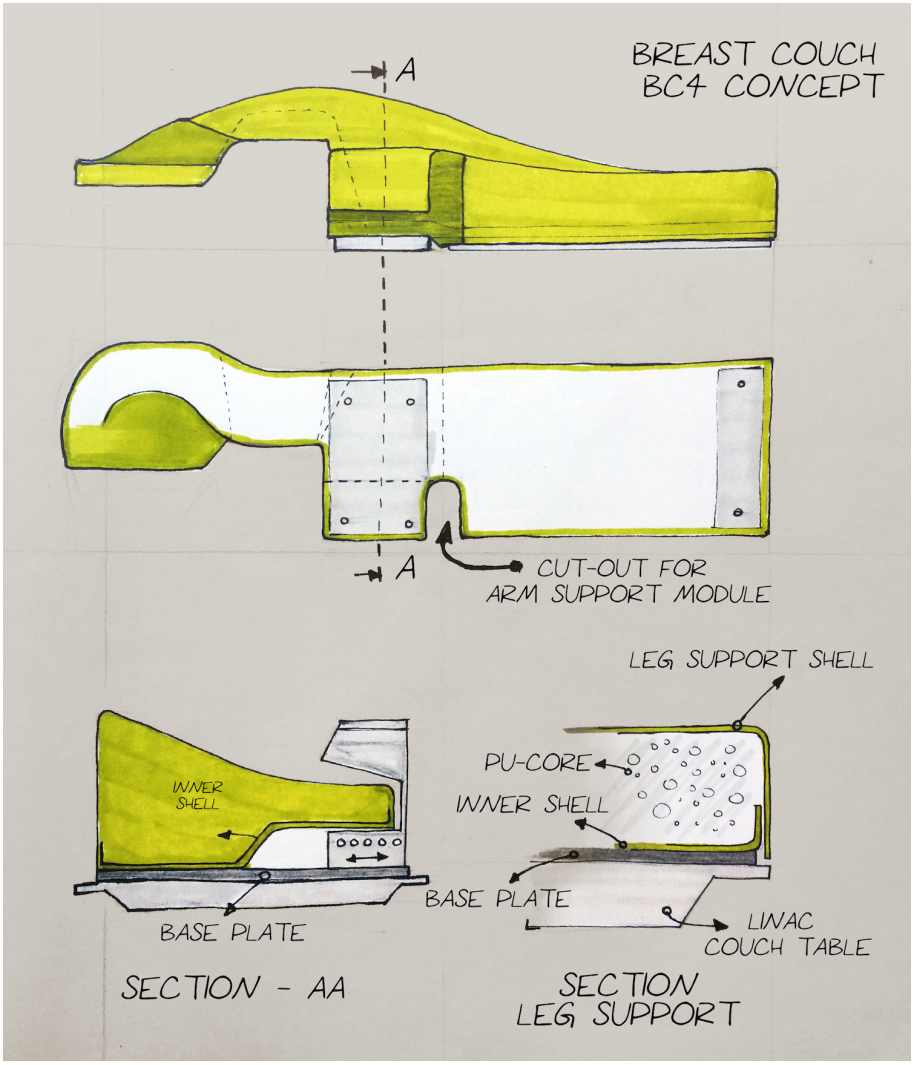


Fig. 11.2 Breast couch BC4 concept. Top: full unibody of upper shell with cut-out for arm support module. Middle: top view of unibody. Bottom: section views of abdomen region with new baseplate (left), and leg support shell (right).

By using a double sided (or closed) mould system, we are able to produce a two sided high quality finish composite part with a consistent shell thickness (Bai, 2013; Mazumdar, 2001). Some production techniques which may be used are resin transfusion moulding (RTM) or compression RTM (Bai, 2013). This would improve final tolerances, reproducibility, reduce assembly costs (trimming, fitting, gluing) and improve overall mechanical performance. On the other hand, some drawbacks may be: expensive mould system production, complex procedure and expensive production cycles.

11.5.2 MRI COMPATIBILITY

To be able to produce a MRI compatible breast couch, no ferrous or iron-containing materials may be used. Suitable metals for MRI are: titanium, cobalt chromium, copper and some stainless steel alloys which are non-magnetic.

A second point of concern is Radio-Frequency (RF) shielding: every conductive material has the possibility of electromagnetic shielding. Due to its conductive properties of carbon fibre composites, it can cause severe RF shielding artefacts (Jafar et al., 2016).

For the production of a MRI compatible breast couch, all carbon fibre composite parts will need to be interchanged with fibreglass parts. The sheet metal steel arm support will need to be redesigned and produced in a composite material, no ferrous metal or combination of them.

11.5.3 DEEP INSPIRATION BREATH-HOLD

As previously explained in Preliminary research (chapter 4), moderate deep inspiration breath-hold (DIBH) is advantageous for better sparing of heart and lung doses for left sided breast treatments.

During one treatment session, patients perform several breath-holds of each time $\pm 20s$. Although the patients trained the DIBH technique in advance, DIBH quality, time, and lung capacity, were often reported to be different between each DIBH itself.

Moreover, patients with metastasis are forced to perform several breath-holds of up to $20s$. This forms a mental and physical barrier for most patients.

NIV SYSTEM

Following a novel deep inspiration breath-hold technique, patients are ventilated with oxygen-enriched air using a non-invasive breathing mask and a mechanical ventilator. With this forced form of hyperventilation, CO^2-levels drop and patients gain the ability to perform breath-holds of several minutes. With this technique, a single, high quality, deep inspiration breath-hold during the whole treatment session could be sufficient. This can improve accuracy, patient comfort and treatment time.

Colleague, and PhD candidate, Max Schoepen will further investigate the integration of the face mask and ventilation system in the future breast couches. The design will be challenging on both technical and ergonomic level: radiotherapy compatible materials, usability, patient monitoring, comfort and patient experience. In addition, he will also further develop the breast couch itself (future work).

11.6 COMMERCIALISATION

When a final prototype is produced and clinical trial validations are completed, a pre-market submission can be performed. Since the breast couch is a *class I* medical device, only a *"self-declaration"* needs to be submitted to a Competent Authority in order to be able to be marketed throughout the *EU*.

Nevertheless, development and commercialisation of products or services in a university environment is often challenging. Some possible solutions to successfully valorise and industrialise this project can be: by a university spin-off, through outsourcing, licensing or IP selling. All these aspects are not covered in this dissertation and need yet to be further investigated during the fifth development phase. UGent TechTransfer manages the IP of the university and drives the use of IP through the creation of spin-offs and licensing. They are arranging a research collaboration with the industry and will further support us.

Furthermore, to be able to proper use the prone breast couch devices and treatment techniques after commercialisation, centres need to be informed, medical staff must be trained and monitored, maintenance and calibration must be instructed, devices need to be followed-up and so on.

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