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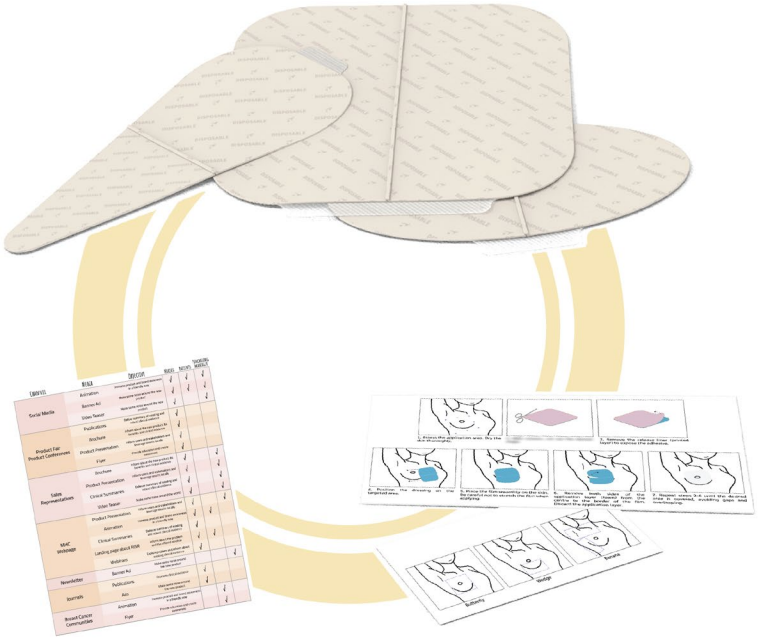

Improvement of protective film for radiation-induced skin reactions

Co-creation product design of Mepitel Film with healthcare professionals

Master's thesis in Industrial Design Engineering

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CHALMERS UNIVERSITY OF TECHNOLOGY
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Master of Science Thesis, IMSX30

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Abstract

Breast cancer is the most commonly occurring cancer among women worldwide and is mainly treated by radiotherapy. The treatment is aggressive and can cause undesired consequences such as radiation-induced skin reactions (RISR), which can inhibit the patient's ongoing treatment, constrain daily activities, and impair quality of life. Mölnlycke Health Care's (MHC) product Mepitel Film is a barrier-forming dressing with clinical evidence to be an effective product for preventing RISR in breast cancer treatment. However, the product is not widely used for this application. This study aimed to understand the usage of Mepitel Film during breast cancer radiotherapy, and together with patients and HCPs, redesign the product to improve the users' interaction and experience with Mepitel Film.

The study consisted of two phases, both with co-creation as a central focus to ensure that deep knowledge about users' needs was gained. The first phase intended to explore and understand RISR and how these can be prevented. An extensive set of data was collected through literature research, interviews with HCPs and workshops with patients. The data was further analysed, and the user needs were identified and defined. It was clear that the main problems with the current Mepitel Film were its challenging application and the fact that its benefits were not widely spread either among HCPs or patients. Personas were created in order to communicate the most important aspects retrieved from the user research. In addition, product goals divided into four categories: properties, awareness, economic and future, were formulated to ensure that the solution fulfilled the users' needs. The personas and product goals were the result of the first phase and acted as a foundation for the next phase of the study.

The second phase aimed to develop solutions that fulfilled the users' needs. Idea generation, including various creative workshops, was conducted, and the conceived ideas were further explored on various breast simulations. The idea generation resulted in two concept refinements that were prototyped and further tested and evaluated together with HCPs. Phase two resulted in a final solution consisting of a three-parted system: a product, application instructions and an awareness plan. The developed product consists of three shapes that facilitate HCPs to apply the dressing on various body curvatures, ensuring the need for fewer modifications. In addition, the developed product features a new application layer, facilitating application procedure and ensuring a more precise application. The application instructions support the HCPs during the application process and guide where the different shapes should be placed on the body. Lastly, the awareness plan aims to ensure that the new product and its benefits will be widely spread among users and stakeholders.

Keywords: *co-creation, breast cancer, radiation-induced skin reactions, barrier-forming dressing, Mepitel Film*

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Gothenburg, Spring 2021.

Alice Karlsson & Júlia Tenuta Martins

Contents

PHASE TWO

1

Introduction

This chapter introduces the background of the topic and presents the aim and objectives of the project. In addition, it presents an explanation of the thesis's disposition and an overview of the design process used throughout the project work.

1.1. Background

Breast cancer is the most commonly occurring cancer in women worldwide, and in 2018 over two million new cases were detected (World Cancer Research Fund International, n.d.). The main treatment for breast cancer is radiotherapy. This can be an aggressive treatment that can cause moderate to severe radiation-induced skin reactions (RISR) in 87% of the patients, which leads to fragile and sensitive skin (Morgan, 2014). These skin reactions can cause pain, discomfort, anxiety, loss of sleep, constraint in daily activities, and impairing life quality. Thus, to heal the damaged skin without disturbance, the skin needs to be protected.

One way to prevent RISR is to use barrier-forming dressings that protect the skin from external friction. The Swedish-based company Mölnlycke Health Care (MHC) has a wide range of medical solutions for hospitals and patients, including dressings. They aim to improve performance in healthcare through innovative solutions. This study was conducted in collaboration with MHC, investigating one of their barrier-forming products, Mepitel Film.

Mepitel Film is originally designed as a protective dressing for wounds and a landing zone for strong adhesives that need to be fixated on the skin. In addition, clinical evidence shows that Mepitel Film is also beneficial for preventing skin reactions during radiotherapy treatment (Herst et al., 2014). Therefore, increased usage of Mepitel Film in breast cancer treatment has the potential to reduce the incidence of severe skin reactions of radiation therapy. Nevertheless, the product is not widely used for this application due to a lack of knowledge about its benefits.

The current version of Mepitel Film is produced in many different sizes, from small versions of 6x7 cm up to bigger ones of 15x20 cm. The product has a paper frame that aims to facilitate the application. However, applying Mepitel Film to the breast is still a challenge for Health Care Professionals (HCPs) because it can be time-consuming and difficult to correctly apply to the breast. For instance, for an experienced radiation therapist, it can take up to 15 minutes to apply the film to the body, which is seen as a problem for busy oncology centres (Herst, 2020). Also, the HCPs usually need to use more than one film to cover the entire radiated area of the breast, and these films have to be precisely applied. They are not allowed to overlap in order to not interfere with the film's properties.

1.2. Aim and objective

The aim of the project is to understand the use and the application of MHC's product Mepitel Film during breast cancer radiotherapy treatment, and together with patients and HCPs, redesign the product in order to improve the users' interaction and experience with Mepitel Film.

The project's objectives are to understand the usage of Mepitel Film within the radiotherapy context. With a co-creation approach, the gathered knowledge will be the base for the redesign and improvement of Mepitel Film.

1.3. Demarcations

The demarcations in the project that help guide and focus on its content are:

- No changes are made to the current technology of Mepitel Film when developing the concepts;
- It is not possible to make substantial changes in the manufacturing process since it has a delicate and sensitive set-up.

1.4. Design Process

The project is divided into two parts, and the design process is built using the double diamond framework (Figure 1). The framework enables the design process to first explore the problem without limitations and then continuously narrow down the ideas. Thus, this process is suitable for investigating complex problems (Design Council, n.d.).

The first part investigates what patients and HCPs use today to protect against skin reactions during radiotherapy. The learnings from the first part are the foundation for the second part, which aims to generate and evaluate product design ideas and build concept prototypes that are further tested and evaluated. Iterations within and between the phases are crucial during the entire process to ensure that the final solution fulfils the users' needs and the project's objectives. Furthermore, the project has a co-creation approach to gain a deeper understanding of the HCPs' and patients' needs.

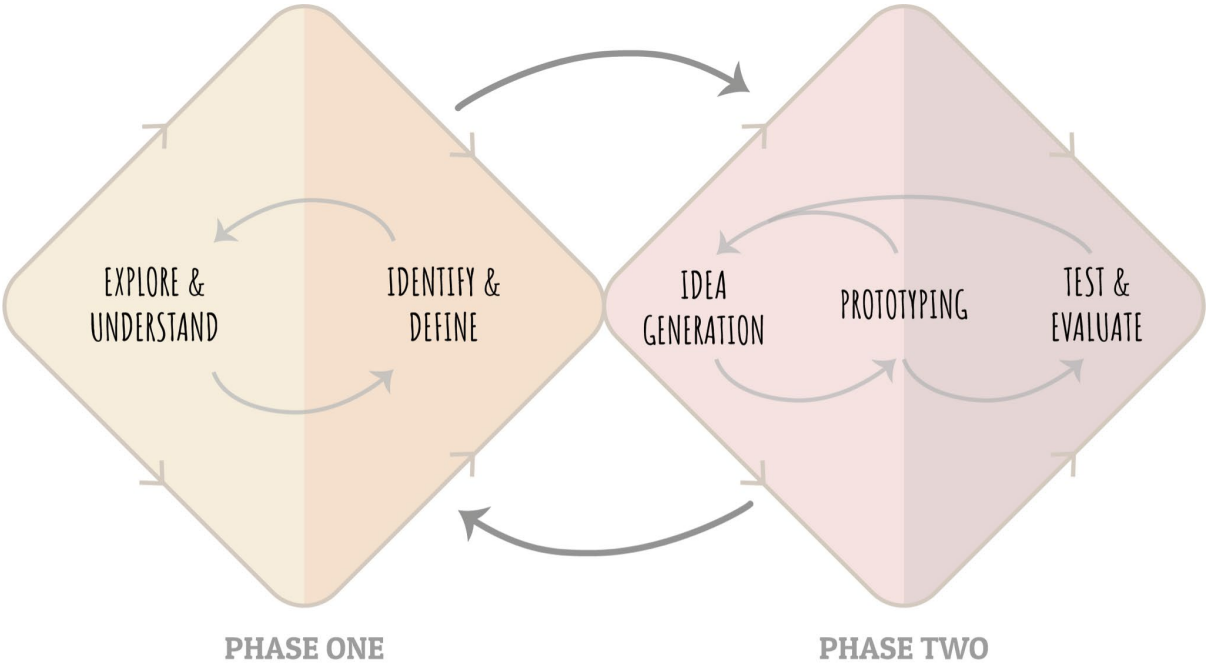


Figure 1. The project's process, divided into two phases

Phase One

In the first phase of the project, the goal is to *explore and understand* the radiotherapy context, the users and the product. This is done by an extensive literature study and user research with the identified user groups. Further, the collected data is analysed in order to *identify and define* the product goals in the next phase of the project.

Phase Two

The second phase focuses on solution development and starts with *idea generation* workshops. The generated ideas are further explored and developed into concepts which later are combined to achieve an optimal solution. The concepts are *prototyped* and *tested and evaluated* by users in order to validate its application and how the users experience it. Finally, the results from the evaluation are used to create the final solution.

2

Theoretical framework

This chapter covers relevant areas of theory related to radiotherapy, skin reactions and the current solution. It also presents relevant concepts for the project development, such as the co-creation approach.

2.1. Radiotherapy

Radiotherapy is the use of ionising radiation in the treatment of diseases, most commonly cancer. In 1898, soon after discovering radium by the Curies, ionising radiation started to be used to treat cancer (IAEA, 2017). Together with surgery and systemic therapies, radiotherapy is one of the three major modalities of cancer treatment.

Radiation interacts with atoms to change them, resulting in electrically charged particles, which may cause biological damage to the irradiated area, such as structural and chemical damages within cells. When the cells' DNA is damaged beyond repair, they stop dividing and die. This effect happens in both healthy and cancerous cells. However, healthy cells are more likely to recover and repopulate faster than cancer cells. For this reason, radiation is delivered in fractions, divided into daily amounts, allowing a certain amount of cell repopulation between the radiation sessions (Morgan, 2014).

In breast cancer treatments, radiotherapy's positive effects have been observed since the beginning of the twentieth century (Rayter & Mansi, 2003). Since then, it occupies a solid place in breast cancer treatment, both for breast-conserving therapy and after mastectomy. Radiotherapy can significantly lower the risk of local and regional recurrence and improve the survival rate (Fischer, Baum, & Luftner-Nagel, 2017; Yee et al., 2021, 2018).

Radiotherapy Scheme

As there are different types of cancer, in different locations of the body, and the response to the treatment can vary from patient to patient, each treatment needs to be individually studied and planned. The steps for planning the radiation treatments are:

(1) Locate the target. It is crucial to irradiate the desired area defined by the physician. If necessary, some accessories can help in aiming the exact spot. Diagnostic methods like tomography, magnetic resonance or positron emission tomography (PET) will help to locate the area.

(2) Plan how to reach the target. Software is used to plan, among other things, the dose distribution, size and shape of the radiation fields, radiation energy and positioning of the beam the incidence of the beam.

(3) Control the treatment. Make sure that the treatment goes as it was planned. Assess if the machine is delivering the right dose, the patient is in the correct position, and the field is accurate.

One example of an accessory that can be used during the treatment is the bolus material. This tissue-equivalent material varies in its composition and thickness, and it is used to increase the skin surface dose and ensure that the area receives adequate amounts of radiation (Wong et al., 2020).

Like any treatment, despite all the care, sometimes side effects during radiotherapy dermatitis can appear, depending on the region being irradiated. If these effects are too intense, the treatment may be interrupted, impairing its overall effectiveness.

2.2. Radiation-induced skin reactions

During breast cancer radiotherapy, most patients develop moderate to severe RISR due to the treatment's aggressiveness (Morgan, 2014; Thompson et al., 2016; Yee et al., 2018). These skin reactions can lead to discomfort, anxiety, loss of sleep, constraint in daily activities, impairing life quality.

Acute skin reactions occur during treatment and begin two or three weeks after the start of radiation. The skin damage happens because the epidermal basal layer cells are destroyed, exposing the dermis. This activates an inflammatory process manifested as erythema (redness), which can evolve to more severe exudative dermatitis reactions (Pires, Segreto, & Segreto, 2008). The diagram in Figure 2 represents the cycle of radiation skin damage.

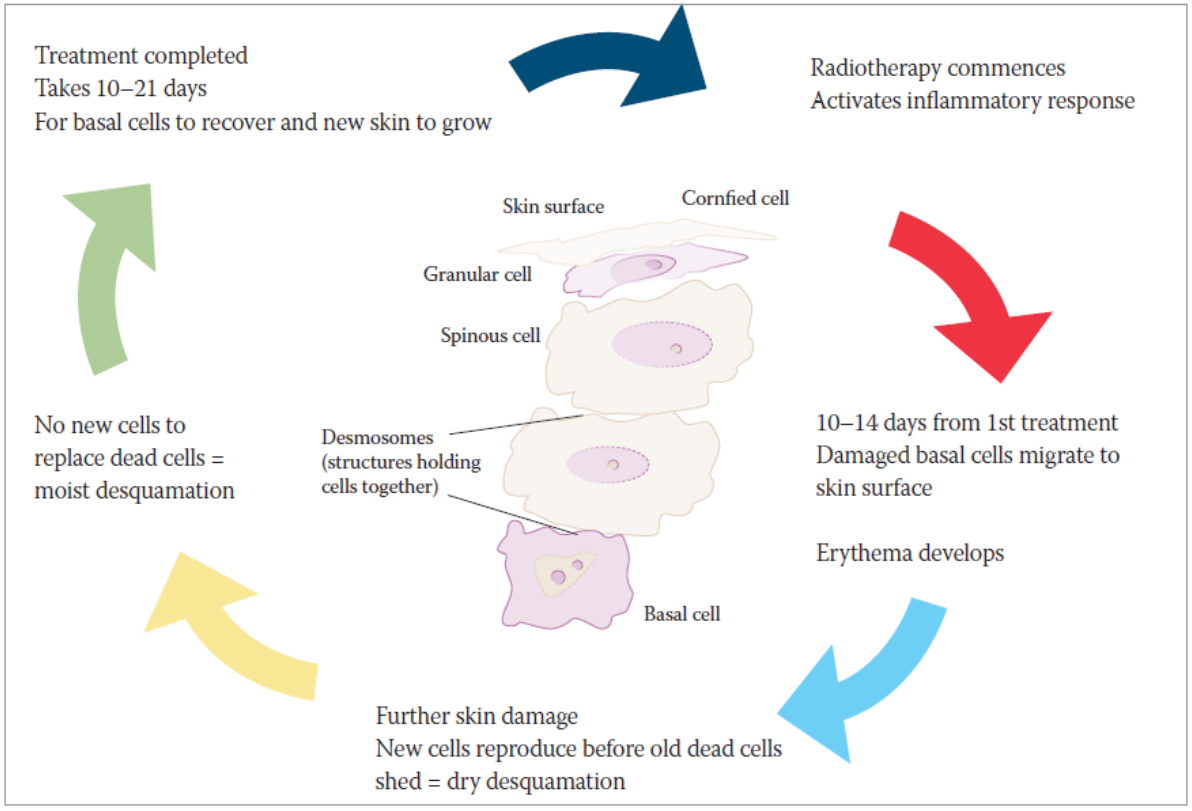


Figure 2. Diagram of radiation skin damage cycle. From "Cycle of radiation skin damage", by Bostock, S. (2016). Improving management of radiotherapy-induced skin reactions: A radiographer's perspective. Wounds UK, 12(3).

To assess the severity of radiotherapy effects, the Radiation Therapy Oncology Group (RTOG) developed, in 1980, the Radiation Morbidity Scoring Criteria. The publication classifies radiotherapy effects starting from 0, where there is no reaction, up to 5, where there is death directly related to radiation. Between these values, the severity of reactions is graded from 1 to 4 (Cox, Stetz, & Pajak, 1995).

Although each patient reacts differently to radiation, there are a few extrinsic and intrinsic factors that seem to aggravate skin reactions in breast cancer treatments. The extrinsic factors are related to the treatment characteristics, such as total dosage, type of equipment, technique,

radiosensitivity of the tissue involved, and fractionation scheme. Intrinsic factors are those patient-related factors and involve age, ethnic origin, smoking, obesity, coexisting chronic diseases, and breast size (Probst, Burke, & Faithfull, 2020).

2.3. Prevention of RISR

Prevention of RISR is important for optimising the treatment, as severe skin reactions can cause delays in the treatment, potentially increasing the risk of recurrence (Yee et al., 2021). Furthermore, moist desquamation is a severe skin reaction that significantly increases the risk of infection (Mayor, 2016). Nonetheless, there are a few basic strategies that seem to be helpful in the prevention and management of RISR, such as keeping the skin clean using water and mild soap, wearing loose clothes and protecting the skin from the sun. Skincare practices aim to keep the skin clean, control pain, provide comfort, avoid friction from clothes and weather, and avoid infections (Mayor, 2016).

As each patient responds individually to the radiation, complete prevention of skin reactions seems unlikely in radiotherapy treatment. However, there is an ambition to minimise the severity of skin reactions, reduce discomfort and prevent further complications (Probst et al., 2020). Many studies have investigated different preventive products and their efficacy to prevent skin reactions from radiotherapy treatment. The different preventive products can be divided into different categories: washing practice, topical steroidal agents, topical nonsteroidal agents, systemic interventions, barrier-forming products and photobiomodulation therapy (PBMT). A detailed description of the preventive product categories currently on the market and their general advantages and disadvantages can be seen in Appendix A.

2.4. Mepitel Film

The investigated product in this project is MHC's Mepitel Film which belongs to the category of barrier-forming solutions (Figure 3). The product is a thin (0,12 mm), transparent and adhesive soft silicone dressing produced in different sizes and has a paper frame for easier application. The product features the Safetac technology developed by MHC in 1989 (Mölnlycke Health Care, n.d.-b). This technology enables the dressing to stick into the intact and dry skin and not on the moist wound. The dressing forms itself to the uneven skin and moulds into the skin pores, which creates a more extensive and less aggressive adhesive area than a dressing without the Safetac technology. Dressings with Safetac technology create a complete seal around wound edges, which prevents maceration by blocking exudate from reaching the surrounding skin (Mölnlycke Health Care, 2019). These characteristics of dressings with Safetac technology enable them not to damage the skin at removal, resulting in less pain during dressing changes and faster wound healing (Mölnlycke Health Care, n.d.-a).

Figure 3. Mepitel Film. Retrieved from "Mepitel Film: Skin protective film dressing'' by Mölnlycke Health Care. (2019).

2.5. Clinical Evidence

Although Mepitel Film was originally designed for wound and skin protection, clinical evidence shows that it is also beneficial for preventing skin reactions during breast cancer radiotherapy treatment. The product has shown positive advantages in reducing RISR and can therefore be used as a prophylactic product. The film is applied to the body before the radiotherapy treatment starts and protects the fragile radiated skin from physical friction (Patries Herst). Thus, its mode of action is solely a mechanical and physical barrier mechanism and does not have any pharmacological effect nor affects the radiation. The film stays in place for several days and can be used continually, not affecting patients' daily activities, such as showers. Furthermore, it has a negligible bolus effect due to its thinness and can thus be left on during the radiation treatment (Herst, 2014).

Herst et al. (2014) conducted a study on 78 breast cancer patients. The study revealed that using Mepitel Film as a preventive product within radiotherapy treatment reduced the overall skin reaction severity by 92%. The trial also showed that Mepitel Film does not entirely protect the patient from skin reactions, but it can prevent severe skin reactions as moist desquamation. 44% of the patients who used Mepitel Film prophylactically in breast cancer radiotherapy treatment developed skin reactions. However, none of them developed into moist desquamation.

In conformity with Herst et al. (2014), Morgan (2014) also investigated the prophylactic use of Mepitel Film in breast cancer radiotherapy treatment. Morgan (2014) conducted a case study among three breast cancer patients undergoing radiotherapy where each patient had significant risk factors for developing skin reactions. The study showed that prophylactic use of Mepitel Film could significantly reduce the severity of RISR, which agrees with the result from Herst et al. (2014) study. Moreover, the Mepitel Film's positive advantages for preventing skin reactions are also presented by Kole et al. (2017), who explains that "Mepitel Film also showed promise as a preventative barrier product for reducing moist desquamation rates".

As presented above, Mepitel Film has shown promising and positive advantages for reducing and preventing RISR. In addition, there is even level one evidence for the efficacy of using Mepitel Film in breast cancer radiotherapy treatment (Wan et al., 2019). However, despite this evidence, the product is not globally adopted, and the major cancer centres do not include the product in their patients' guidelines. Wan et al. (2019) argue that the limited global adoption is related to the lack of well-designed studies and multi-centres trials.

2.6. Co-creation

Design problems are becoming more complex and more significant each day, especially in healthcare. (Ihme, 2018). Thus, designers have been moving closer to the final users to design their solutions (Sanders & Stappers, 2008). Such an approach is known today as co-creation and refers to any act of collective creativity. This, however, is not a new concept. Its origin dates back to the 1980s in Scandinavia when the participatory design movement was emerging. Researchers back then wanted to make sure that different people had their voices heard to create personalised consumer experiences (Lee et al., 2018). A few years later, in the US, the term *collective creativity* was introduced by Elizabeth Sanders. The central premise behind it was that "everybody is the expert in regard to their life and can contribute to the design process" (Lee et al., 2018).

Co-creation enables a large involvement of users, changing their roles from passive to active contributors (Elg, Engström, Witell, & Poksinska, 2012). The users are engaged in the entire process, and thus, their involvement goes beyond interviews and focus groups. The approach empowers a high level of information sharing between users and stakeholders, which results in a rich understanding of the users' world by empowering them to take an active part in the design process (Dickson, Reay, Douglas, & Nakarada-Kordic, 2017). Thus, co-creation places the human at the centre of the design process.

The concept of co-creation, however, is often synonymously used with the term co-design. Sanders & Stappers (2008) define co-design in a broad sense as collaborative creativity between designers and people who are not trained to participate in a design development process. Thus, co-design can be seen as an instance of co-creation. Co-creation connects the people whom the product will impact with designers and researchers (Pirinen, 2016; Sanders & Stappers, 2008). Co-creation activities enable participants to contribute with ideas, participate in discussions and create artefacts that in turn build an understanding of their experiences. In this project, users are mainly engaged in idea generation and evaluation. Thus, the design process embraces a co-creation approach.

Co-creation requires that designers address crucial challenges when dealing with complex problems and maintaining stakeholder relations. These challenges concern whom to involve in the activities, how to make the process available to users and how to structure the environment to support people's collective creativity. In order to facilitate good co-creation workshops, (Lee et al., 2018) presents a Design Choice Framework. The framework emphasises ten design choices divided into four categories that the designer has to consider when selecting the method

used during the co-creation. These choices will have an impact on the outcome of the co-creation sessions. A diagram of the Design Choice Framework can be seen in Figure 4.

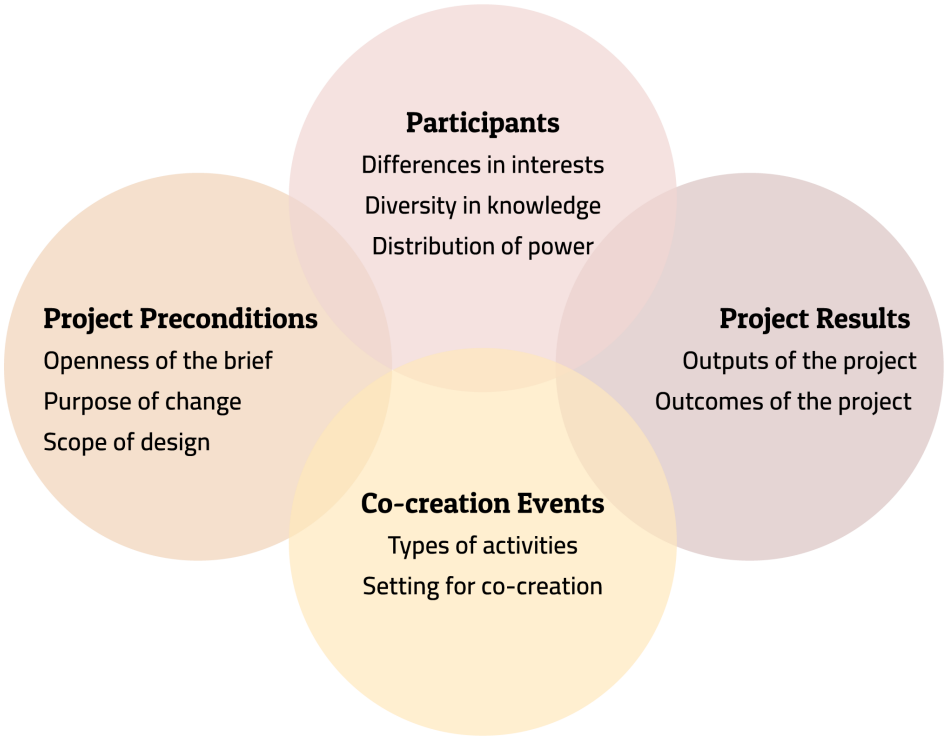
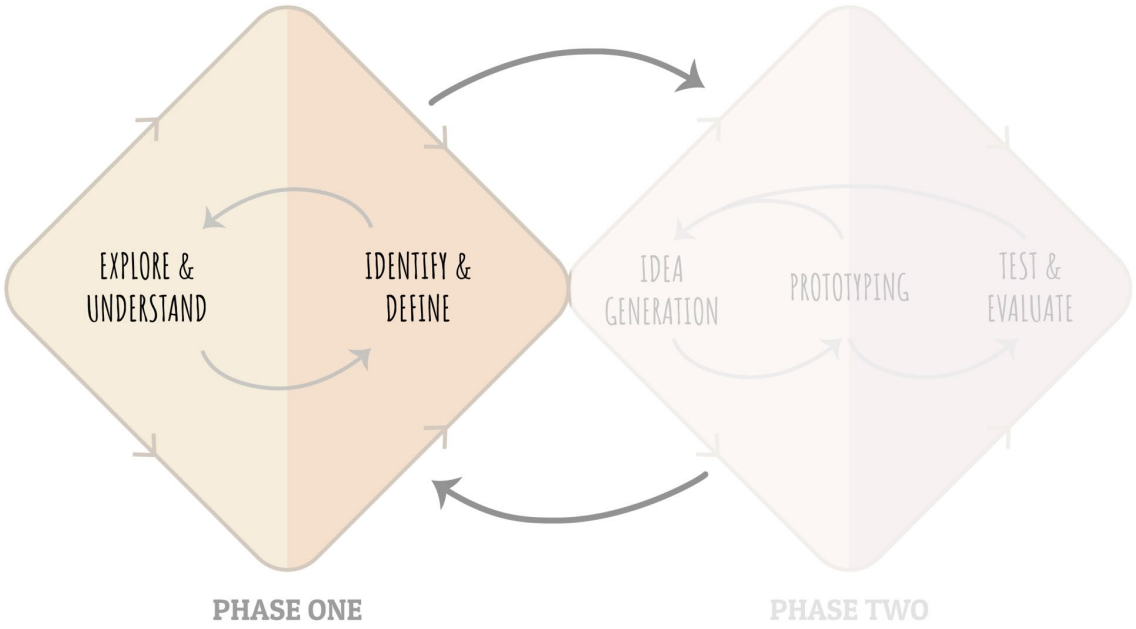


Figure 4. Design choice framework. Adapted from "Ten design choices grouped into four categories'' by Lee, J. J., Jaatinen, M., Salmi, A., Mattelmäki, T., Smeds, R., & Holopainen, M. (2018). Design choices framework for co-creation projects. International Journal of Design.

Project Preconditions set the foundation of the project, framing its scope and purpose. The design choices related to *participants* set who to involve in the co-creation activities, based on essential factors as knowledge and interests. The selection of project preconditions and participants steer the choice of *co-creation events*. The choices from this category determine the achievement of the desired outcomes. The last category, *project result*, considers two levels: outputs and outcomes of the project. The first relates to immediate results, and the latter relates to the further implementation impacts beyond the project.

PHASE ONE

Phase one aimed to generate a deep understanding of Mepitel Film, its usage in the radiotherapy context, and other methods for preventing RISR. This phase provided insights from the two identified user groups and their needs. Through analysis, this phase resulted in personas and product goals that worked as a foundation for the subsequent phase.



3

Method

In this chapter, the method used in the first phase of the project is presented. It encompasses the pre-study, the user research and the data analysis.

3.1. Pre-Study

As part of the Explore and Understand phase of the adopted design process, a pre-study was carried out to build a fundamental knowledge base. The pre-study consisted of literature research and a pilot study. The presented methods aimed to establish an overview of radiotherapy, understand the current procedures adopted in the prevention of RISR, other products offered in the market and Mepitel Film, the core product of the project.

3.1.1. Literature Study

First, the literature study focused on understanding the medical aspects of radiotherapy treatment for breast cancer and how RISR can be prevented. In addition, the methods, treatments schemes and practical aspects of the treatment were investigated. This created the knowledge base that was presented in the theoretical framework. Further, the literature study explored existing preventive products that are on the market today.

The study started with an investigation of MHC encompassing the company's history, their range of products, and Mepitel Film current specifications and how it has been used today in the radiotherapy context. Clinical studies regarding Mepitel Film were reviewed in order to provide a deeper understanding of its usage within breast cancer treatment.

In addition to the papers related to Mepitel Film, several other articles regarding RISR were studied, including the Radiation Dermatitis Guidelines for Radiotherapy Healthcare Professionals. This UK national guidance document promotes equitable and consistent practice across the country, informing policy and standards. The document is based on the research and analysis of more than 33 studies (Probst et al., 2020).

3.1.2. Pilot Study

As a preparation for the user research, a pilot study was carried out. The purpose of this stage was to provide a first glimpse of how patients and HCPs perceived Mepitel Film. To this end, two interviews were conducted. The participants for this pilot study were recruited through MHC's contact. The selected participants were a researcher from Otago University in New Zealand working directly in the research of Mepitel Film for more than ten years and a breast cancer patient who had used MHC's products during her cancer treatment journey.

Both interviews were semi-structured and conducted in a digital format, using the Zoom platform. The formulated questions were different for each interview and targeted specific points to be explored, considering the participants' background. Furthermore, semi-structured spoken interviews allow follow up questions, enabling a deeper understanding of the participants' experiences.

The pilot study also encompassed an exploration of MHC's product range. The company has an extensive assortment of products that utilise Safetac and developed for several different applications in wound care. MHC provided samples of many of these products to allow a better comprehension of what they have already developed. Understanding how the products differ from each other and exploring their strengths and weaknesses enables a broader knowledge of

the companies catalogue and what they have already implemented in the current manufacturing processes.

3.2. User Research

After conducting the pre-study, two user groups were identified: patients and HCPs. The user research aimed to understand these two user groups and how they experienced radiotherapy, RISR and preventive products. The two user groups were investigated separately and in different ways.

The initial plan was to conduct workshops with both patients and HCPs. However, due to COVID-19, it was challenging to reach out to the high demanded HCPs. Thus, the plan had to change, and HCPs were interviewed individually. The individual interviews enabled higher flexibility in time and ensured that as many participants as possible could be interviewed, establishing contacts for further co-creation activities.

3.2.1. Interviews with HCP

The search for HCP to participate in the study was the first step into user research. Suitable HCPs were contacted through MHC's established contacts worldwide and the authors' networking in Brazil and Sweden. They were contacted via email and told in advance the scope of the project and the purpose of the conversation.

In total, seventeen participants were recruited (Table 1). Nine of them were in a written format where the HCP received the questions in a document and then sent back the written answers via mail. The rest of the interviews were conducted digitally via Zoom and took about an hour each.

The interview questions were divided into four main topics encompassing the description of responsibility in the hospital, the radiotherapy journey, the prevention of skin reactions and the experience with Mepitel Film. This division enabled the interviews to go from a broad perspective to a more detailed description of the radiotherapy treatment procedure. This structure aimed to promote a comfortable environment for the participants, encouraging them to share more details of their experiences. In addition, the four topics steered the interviews and ensured that the most important aspects were covered.

Table 1. Interviewed HCPs

Number of participants	Country	Occupation	Interview format
1	Brazil	Nurse/Professor	Digital
1	Brazil	Doctor	Digital
2	Brazil	Nurses	Phone Call / Digital
1	Switzerland	Doctor	Written
8	Czech	Nurses	Written
1	Sweden	Nurse	Digital
1	Belgium	Nurse	Digital
1	New Zealand	Nurse	Digital
1	New Zealand	Researcher	Digital

3.2.2. Workshops with patients

As a part of the co-creation process, two digital workshops were conducted with five patients who had undergone radiotherapy treatment for breast cancer (Table 2). The first workshop was conducted with Swedish patients recruited through breast cancer communities in social media and via local breast cancer organisations. The second was conducted with Brazilian patients that were recruited through personal contacts. The workshops were conducted via Zoom in the participants' native language, Swedish and Portuguese, respectively. The workshops were scheduled for one hour each and used the digital platform Miro as a helping tool. The designer was the facilitator of the workshop, and the sessions were recorded.

Table 2. Participants of the patients' workshop

#	Year of treatment	Country	Workshop
1	2015	Sweden	1
2	2019	Sweden	1
3	2008	Brazil	2
4	2020	Brazil	2
5	2020	Brazil	2

The purpose of the workshops was to gain a deep understanding of how they experienced their treatment, skin reactions and which preventive products they had used. The workshops consisted of two parts. First, the patients created a patient journey and later, there was a group discussion about RISR.

The workshops started with a short presentation of the project, followed by the participants presenting themselves and their cancer experiences before the first collaborative activity of creating a patient journey began.

A template was prepared on the digital tool Miro, a collaborative whiteboard, to facilitate the conduction of the workshop (Figure 5). The template consisted of three phases: before treatment has started, during treatment and after treatment. The participants then described each phase by explaining the duration, actions taken in the phase, which HCP they interacted with, their skin reactions and their overall experience. The patient journey mapped out crucial treatment steps and how they were experienced.

Figure 5. Miro patient journey

The second part of the workshop was a group discussion about RISR. The participants had a shared mind-map with predefined topics as a mediating tool to help keep the discussion in the right course (Figure 6). The group discussion aimed to understand better the patients' knowledge about RISR, how they have experienced and managed these reactions.

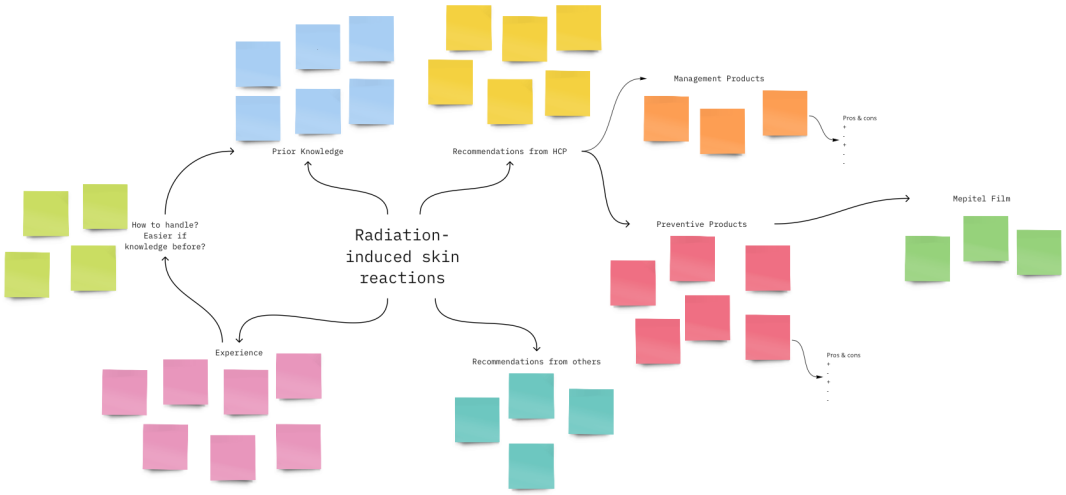


Figure 6. Miro mind map

3.3. Data Analysis

The data from the workshops with patients and the interviews with HCP were analysed through *affinity diagramming* (Pernice, 2018), a method that sorts data into different categories. The data from the two identified user groups, HCPs and patients, were separately analysed in order to enable a comparison between the findings and identify potential differences. Quotes and relevant findings from the user research were written on sticky notes in the digital platform Miro and later clustered into different categories and sub-categories. Each category was later summarised to give a better overview of the main points. An example of an affinity board built on Miro can be seen in Figure 7.

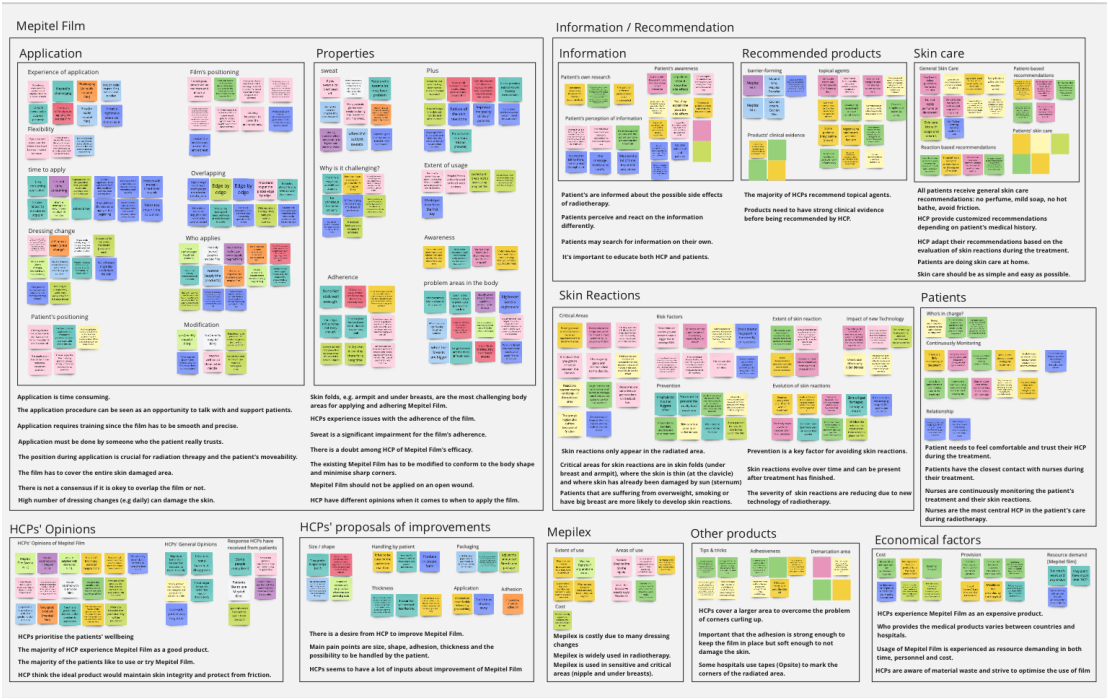


Figure 7. Affinity board in Miro

The results retained from the affinity boards were used as a foundation to create two personas (Selder, 2017). They represent and communicate the goals, motivations and frustrations of the two identified user groups. In addition to the two personas developed from the board, an important stakeholder for the product's success was created. This persona was developed in alliance with the MHC marketing department, which has extensive knowledge and regular contact with these stakeholders. The three personas build a better understanding of the users and stakeholder, providing a holistic view of their behaviours, interests and needs.

Further, the summaries from the affinity boards were once again analysed together with the findings from the pre-study to create product goals that would later be the foundation for developing the concepts. This analysis provided a holistic view of the findings, ensuring that all the main findings from the user research were considered. All findings were merged and reorganised into new categories that were used to structure the product goals that covered the needs of both user groups.

4

Handling RISR

This chapter presents the results from phase one and encompasses the analysed data gathered during the user research in the *explore and understand* stage. The chapter provides an overview of the current barrier-forming products on the market together with the HCPs' and patients' perspectives on RISR.

4.1. Barrier-forming products on the market

Barrier-forming products are one of the many available solutions for preventing skin reactions. They are often thin, transparent and self-adhesive, and offer a protective layer to the skin (Probst et al., 2020). Various companies offer different kinds of barrier-forming products, and all of them protect the skin from RISR in different degrees. A comparison of these products was conducted and is presented in Table 3 in order to have an overview of this product category.

Table 3. Overview of barrier-forming products

Product Name	Manufacturer	Description	Advantages	Disadvantages
Mepitel Film	Mölnlycke Health Care	Thin, transparent, adhesive breathable silicone film dressing with Safetac technology.	- Does not affect the radiation treatment - Significantly reduce the severity of RISR - Promotes moist healing environment	- Limited global adoption - Corners can curl up - Application time: 10-15 minutes for an experienced radiation therapist - Can cause itching
Cavilon Spray No Sting Barrier Film	3M	A polymeric liquid solution that sprays on to the skin and forms a long-lasting transparent film.	- Reduce the risk of moist desquamation - Reduced itchiness - Fast drying - Non-sticky	- Not validated in large studies
Strata XRT	Stratpharma	Self-drying, non-sticky transparent silicone gel that forms a film and lightly bonds to the most superficial skin layer. It is applied daily by the patient	- Reduce the risk of moist desquamation - Helps to promote a moist wound healing environment - Patients can apply it by themselves	- Lack of scientific papers on this product.
Hydrofilm	Hartmann	Transparent and thin polyurethane film dressing, sticking to the surface by a hypoallergenic acrylic adhesive	- Significantly reduced RISR - High wearing comfort - Hardly detectable bolus effect - Favourable cost benefit-ratio	- Shear stress at the edges may occur - Strong adhesive
Mepilex Lite	Mölnlycke Health Care	Thin foam dressing with Safetac technology	- Provide mechanical protection - Decreases skin reaction severity	- Does not affect the moist desquamation rate

All presented products in Table 3 have shown advantages with reducing RISR in breast cancer treatment. Nevertheless, there are also limitations and variations in the outcome of the studies of barrier-forming products. For instance, Herst et al. (2014), Kole, Kole, & Moran (2017) and Schmeel et al. (2018) do agree that the product Cavilon Spray No Sting Barrier Film reduces the risk of moist desquamation. However, its advantages are not validated in large studies. Another example is the product StrataXRT. Chao et al. (2019) present how StrataXRT can reduce RISR, particularly moist desquamation. However, the presented benefits of StrataXRT are challenging to compare with other barrier-forming products due to the lack of scientific papers about StrataXRT.

Another product that has shown great potential in decreasing skin reaction severity is Mepilex Lite, a thin foam dressing that MHC offers. The dressing is 1 mm thick and absorbs exudate, keeping the environment of the wound moist. Due to its comfortability and gentle adherence to the skin, the product is also a protective barrier to sensitive and fragile skin (Mölnlycke Health Care, 2020).

4.2. Patients perspective on RISR

The two activities from the workshop, the patient journey and the mind-map, were fundamental for understanding the patients' perspective of radiotherapy treatment, RISR and preventive products.

Radiotherapy experience

The procedure of the radiotherapy treatment was similar among all patients. However, every patient has a unique treatment plan, and thus, the experience of their treatments differed. All patients expressed the importance of targeting the exact area. They described how the HCPs measured and marked their bodies, a procedure that differed among the hospitals. Some of them used a pen directly on the body, whilst others used a demarcation tape.

In approximately three weeks, the patients went to the hospital five days per week to receive their radiotherapy treatment. Even though the sections were short, in summa, the patients spent a lot of time at the hospital. The participants expressed the importance of a pleasant environment in the radiation room and friendly and helpful personnel. Going through radiotherapy treatment for breast cancer is challenging, sensitive and emotional. Therefore, patients are strongly dependent on the HCPs and the technology in order to have the tumour removed. Thus, it is essential that patients feel comfortable, secure and confident towards the HCP during their treatment.

A common consequence of radiotherapy treatment is skin reactions. However, the patients' experiences of skin reactions differed. Some patients had and still suffered from skin reactions after finished treatment, whilst others had had very mild reactions during their treatment. The patients' skin reactions were only in the radiated area, but they experienced that it was hard to predict exactly where in that area the skin reactions would occur. The patients expressed that their skin was sensitive a long time afterwards. Thus, the patients explained that they continue to take care of their skin after treatment has ended.

Information and recommendation

Although the patients had been treated in different hospitals, all patients described that they had received the same kind of information, e.g. brochures and talking with nurses about radiotherapy treatment and its consequences. However, the detail level of the information differed from patient to patient, and thus, the participants had different experiences of the information received. Some of them felt that it lacked detail in the received information. One of them expressed that *"the consequences of radiotherapy were minimised. It felt like I did not get all the information"*. Whilst other patients experienced that *"I had all the necessary guidance"* and that the HCP *"encouraged me to ask questions"*.

The experience of gathering information differed between patients, as some of them had independently searched for information about radiotherapy treatment. These patients stated that they had had sufficient knowledge about radiotherapy and its consequences. Despite the individual differences in how the patients reacted to the information received, all patients expressed that they wanted to have more information about radiotherapy treatment.

Moreover, a difference between the guidelines and recommendations on preventing and managing skin reactions was identified. The data analysis revealed that patients received dissimilar advice during treatment, depending on the hospital they had been treated. However, general guidelines for all patients were to lubricate their skin with moisturiser and avoid skin damage.

Some of the patients had used the product Mepilex Lite between the radiotherapy sessions in order to protect the skin from external friction. The patients that had used Mepilex Lite were very positive about the product since they liked that they could shape the product freely, apply it by themselves and that the product could be reapplied. Mepilex Lite was experienced as a good product for both prevention and management of skin reactions since it protected the sensitive skin and absorbed some of the exudates. However, all patients who had used Mepilex Lite had had issues with its adherence, especially if Mepilex Lite was used in combination with other products, for instance, management creams. None of the patients had used Mepitel Film during their radiotherapy treatment, and they were not aware that the product existed. However, after hearing about the product during the workshop, some of the patients were positive about the product and its efficacy.

Furthermore, the patients described that the HCPs were not allowed to give recommendations on non-evidence products. Thus, some of the patients had found alternative products on their own, for instance, Aloe-Vera cream. In addition, the patients explained that they had a lot of contact with other patients that were going through or had gone through radiotherapy treatment. They described that it was common that they exchanged information, tips and experiences with each other.

4.3. HCPs perspective on RISR

The individual semi-structured interviews allowed a more profound discussion with each HCP which in turn resulted in a richer understanding of their experiences of RISR.

Dealing with RISR

All HCPs described that skin reactions are a common consequence of radiotherapy, and they claimed that prevention is a key factor for avoiding these. Skin reactions appear only in the radiated area, and they are more likely to happen in skin folds or where the skin is thin. Thus, critical areas are under the breasts, in the armpit and at the clavicle. However, HCPs had different experiences regarding the occurrence of skin reactions. Some HCPs mentioned that skin reactions were very common, whilst others argued that skin reactions as moist desquamation generally do not occur in breast radiation. Nevertheless, the HCPs described that the severity of skin reactions are reducing due to new technology and new treatment techniques.

Moreover, the HCPs described individual differences among the patients' likelihood to develop skin reactions. Patients who are suffering from being overweight, smoking or have big breasts are more likely to develop skin reactions. Furthermore, skin reactions may evolve after treatment has finished.

The HCPs that had used Mepitel Film in radiotherapy treatment had doubts regarding the film's efficiency. Some of them appreciated the product from their first trial whilst others were more sceptical and could not see the benefits. Their opinions also varied regarding when the film should be applied. Some of them applied the film when some reactions had started, whilst others applied it from the start, although the patient did not have any skin reactions. The main issue that the HCPs had with Mepitel Film was the application. The film has to be applied smooth and precise with the patient in the treatment position in order to not interfere with the radiotherapy or the patient's moveability. Thus, the film is applied by HCPs and cannot be applied by patients themselves.

The most challenging areas to apply Mepitel Film are skin folds, for instance, in the armpits or under breasts. However, it is essential to cover these areas since they are also the most prone to develop skin reactions. The opinions varied among the HCPs, and there are different hospital guidelines regarding if it was allowed to overlap the film or not during application. Some of the HCPs claimed that it was possible to overlap twice to make it easier to apply. However, the majority of the HCP applied the film edge by edge. However, all HCPs that have used Mepitel Film agreed that it is important that the film covers the entire skin damaged area in order to ensure good protection.

The importance of a precise and exact application contributed to the HCPs experience of Mepitel Film as a time-consuming product to apply. One of the participants claimed that *"after training it is easy, then it takes about 10 minutes",* which was experienced as a long time for each patient. The HCP described that the film stayed on for several days and that dressing changes are necessary approximately once a week. This was appreciated among the HCPs since every dressing change may further damage the sensitive skin. At the same time, several HCPs

experienced issues with the film's adherence, as not sticky enough. The HCPs described that the film starts to curl up in the edges and corners. However, some of them had found ways to overcome this problem by covering a larger area and trimming the border as it loses from the skin or making the corners more rounded before application. The HCPs described that the issues regarding adherence were most problematic in patients with very dry skin or if the patient sweats a lot.

Information and recommendations

All HCPs emphasised that the patients are informed about the possible side effects of radiotherapy and the potential skin reactions. All patients receive general skin care recommendations, for instance, using mild products with no perfume, not taking hot baths and avoiding friction against the skin. HCPs also provide customised recommendations depending on the patient's medical history. In addition, the patients are visiting the hospital almost daily during their treatment, which enables the HCPs to continuously monitor their skin reactions and provide them with more customised recommendations over time.

The HCP explained that although all patients receive the same kind of information, there may be individual differences regarding how they perceive and react to the information. Some patients have searched for information on their own and have much prior knowledge, whilst others are shocked and thus have difficulties taking in the information. The HCPs described that the information has to be provided carefully and should be seen as *"an educational process with the patient, so they are prepared for the treatment"*.

HCPs explained that the product Mepilex Lite is widely used within the radiotherapy context to manage RISR. The product is mainly used in sensitive and critical areas, such as the nipple or under the breasts. The HCPs claimed that this product could not stay on during the radiotherapy treatment. However, this enabled the patient to apply Mepilex Lite themselves since the application does not need to be precise.

Furthermore, all HCP agreed that the products need solid clinical evidence before recommending them to their patients. Although, there was a variation among the HCPs of which products they recommended to their patients. Some HCP recommended creams with corticosteroids or moisturisers, whilst others recommended chamomile compresses. However, the majority of the HCPs recommended some kind of topical agents.

HCPs expressed that topical agents had disadvantages since it requires that the patient take care of their skin prudently and apply the cream several times per day. Using topical agents requires a high level of compliance and responsibility from the patients, and according to the HCPs, some of the patients struggle with this.

Economic factors

The interviewed HCPs worked in different countries which have different social welfare systems. Thus, there was a significant difference between each country's supplier of medical products. In some countries, the patient has to pay for the product by themselves.

Mepitel Film was experienced as an expensive product by HCPs due to its high cost per package and since it requires resources to apply in the form of time and personnel. HCPs described the usage of Mepitel Film as *"expensive, too much work and requires time that HCP don't have"*. Although the opinions regarding the cost of Mepitel Film varied, other HCPs also experienced the product was expensive, but it was *"cheaper to use Mepitel Film as a prevention than targeting the reactions"*. These opinions were the same regardless of which country the participants were from. Some of the HCPs also argued that the price of Mepitel Film was feasible in comparison to the cost of buying management products such as creams or Mepilex Lite.

5

Takeaways from Phase One

This chapter displays the main takeaways from *Phase One*. All analysed data resulted in three personas and product goals, highlighting the main needs and desires of both identified user groups.

5.1. Personas

The generated personas represent the two identified user groups, and they describe the most crucial aspects retrieved from the user research, encompassing their experiences, frustrations and desires towards the problem. In addition, a persona representing the purchasing manager was created since this stakeholder has an important role in the decision-making process. As the user research did not involve any subject from this area, this last persona was created in collaboration with MHC's marketing department. All three personas acted as a base of inspiration for the concept development and facilitated that the solutions fulfilled users' needs.

Sandra

"We're there for the patients and their family. The patient needs to be part of the team.''

Occupation: Radiotherapy nurse

Age: 42 years old

City: Stockholm, Sweden

Sandra is an experienced radiotherapy nurse and has worked at the local hospital's radiotherapy department for more than ten years. She helps patients going through cancer during their radiotherapy treatments and encounters RISR almost every day. She is really passionate about her work and always strives to be updated about the new developments in the radiotherapy field to ensure the best patient care. Sandra has used different kinds of products for preventing and managing skin reactions but is still not sure which product is the best solution.

Goals

- Ease pain for the patient and make the patient happy
- Nourish a trustworthy relationship with patients
- Ensure patients wellbeing

Motivation

- Find the best treatment for each patient's unique circumstances
- Increase knowledge and understanding within wound care
- Ensure patients satisfaction

Frustrations

- Lack of time and resources
- Different levels of knowledge and expertise among colleagues and stakeholders
- Challenge with patient compliance
- Different opinions among clinicians on how to prevent RISR

Maria

"Sometimes we're feeling insecure since we don't know what is going to happen.''

Occupation: Project Manager

Age: 48 years old

City: Linköping, Sweden

Maria is a successful project manager from Linköping, diagnosed with breast cancer in 2017 and finished her radiotherapy treatment in the middle of 2018. She has an active lifestyle and likes to run in the forest, hang out with her family and cook. Maria suffered from severe skin reactions during her treatment which inhibited her from performing her hobbies and daily routines. Maria tried many products during and after her treatment for managing the skin reactions but had never heard about barrier-forming products. She is an activist in her city's breast cancer community and is always trying to ease up the life of women going through the same thing that she did.

Goals

- Win the fight against breast cancer
- Continue living her life as usual

Motivation

- Feel comfortable and well-treated during radiotherapy
- Go through treatment in the best possible way without severe side effects
- Be healthy

Frustrations

- Lack of information about radiotherapy and its side effects
- Hearing that other patients had different recommendations from another hospital
- Drastic changes in daily activities

Adam

''My goal is to find the right product, to the right price, at the right time.''

Occupation: Purchasing Manager

Age: 36 years old

City: Gothenburg, Sweden

Adam has worked as a purchasing manager at the hospital in Gothenburg for six years. He has continuous contact with med-tech suppliers and always strives to find the best solutions for the best price. In his work life, Adam has to balance the desires of HCPs and his managers, which sometimes he experiences as challenging. At home, he also has to find an appropriate balance between his stressful work and personal life.

Goals

- Get the best possible outcomes for the lowest cost
- Reach KPI's and savings target
- Increase consistency and standardise

Motivation

- Save money for hospital
- Need to save money but also stay compliant
- Retain workforce and ensure employee satisfaction

Frustrations

- Challenging to handle all the different requests
- Clinical staff does not always understand our situation or targets, and we do not always understand them
- Balancing between transactional cost and clinical value

5.2. Product goals

The analysis of all data resulted in product goals that were the foundation of the next phase. It encompassed the most important research findings, defining what was aimed to be achieved in the idea generation phase. The goals were divided into four categories:

- Properties
    - General properties
    - Application
    - Adherence
- Awareness
- Economic
- Future

The category properties embrace most of the goals. For this reason, it was further divided into other three categories: general properties, application and adherence. All product goals were motivated by the analysed data from the literature and user research. The motivation sentences can be seen in the tables presented below for each category.

5.2.1. General properties

General properties embrace the main physical and technical aspects of the product. From these goals, it was possible to set an overview of the main properties that should be achieved in the final solution. Table 4 presents all the goals in this category.

Table 4. General properties goals and motivations

General properties

Goal	Motivation
Encompass the individualisation and uniqueness of treatments	Every treatment is customised for each patient, and every patient has different degrees of skin reactions.
Designed for prophylactic use	Prevention is a key factor for avoiding skin reactions.
Protect the skin from external and internal friction	The mode of action of the Mepitel Film is to provide mechanical protection.
Keep the comfortability of the film	The majority of the patients that have used Mepitel Film perceive it as comfortable.
Can be used by all body sizes and ages	Everyone can get breast cancer. Overweight, bigger breasts and age are risk factors for developing skin reactions.
Do not impact the radiotherapy treatment efficacy and procedure	The treatment has to be performed in a certain manner in order to ensure a successful treatment.
Do not impact the patient's daily activities	The patient needs to feel comfortable while wearing the product. The patients should be able to keep their regular routines of, e.g. showering, exercising, cooking, walking
Avoid overlapping	There is not a consensus if it is okay to overlap the film or not.
Do not be affected by other products used adjacently	Patients do not always apply the film to the entire radiated area. They need to be able to use other products in the non-protected areas
Do not have to be sterile	Mepitel Film should not be applied to an open wound. Since it is only used in closed and dry skin, the product does not have to be sterile

The current product is already fulfilling some goals, but it is important to keep in mind that they are essential factors to the new product development. Such goals are related to the prophylactic use of the product, which according to the user study, is a key factor for avoiding RISR. Therefore, it should be designed as a preventive solution that protects the skin from internal and external friction.

Another critical set of goals is guaranteeing the comfort and well being of patients. Hence, the solution should be comfortable to wear and adaptable to patients of all ages with different body sizes. Also, it should not impair a patient's daily activities, allowing them to live a reasonably normal life, despite the radical treatment they are going through.

As the product is aimed to be used during the radiation treatment, it is of most importance that the solution does not affect the efficacy of the treatment. The possibility of the barrier creating a bolus effect or changing the shape of the breast is of great concern among HCP. If these effects happen, the radiated area could be altered, seriously affecting the efficiency of the treatment. Furthermore, the ideal solution should aim for minimal changes in radiotherapy procedures, such as time to prepare the patient and that the centre still treats the same number of patients per day.

The current solution, Mepitel Film, comes in individual sterilised packages. This procedure, however, is not necessary for this context. The barrier-forming film, when used in dry skin with no open wounds, does not need to be sterile because it will not be used to control bleeding or to absorb any exudation from a wound. This goal is also connected to the economic aspects of the solution since less material will be wasted when using the product, and the sterilising stage of the manufacturing process will not be needed.

5.2.2. Application

The goals related to the application process of the solution are listed in Table 5. They embrace the user's needs for an easier and more straightforward application. The main goal here is to reduce the time of application, a major complaint among HCPs, as it directly affects the treatment procedure. As the user research showed, the time and precision of the application is a matter of habit. Nowadays, it takes about 10-15 minutes for an experienced nurse to apply the film to the patient's body, which is perceived as too long in a busy radiotherapy centre.

Table 5. Application goals and motivations

Application

Goal	Motivation
Reduce application time	It takes now about 10-15 minutes to be applied by a skilled nurse
Enable smooth and precise application	The application requires training since the film application has to be smooth and precise.
Cover the critical areas of the body: under breasts, clavicle and armpit	The severity of skin reactions is reducing due to new technology. However, critical areas will still be prone to suffer from skin reactions.
Minimise the modification needed regardless of where the film is applied on the body	The existing Mepitel Film has to be modified to conform to the body shape.
Enable repositioning	The film is very thin and will entangle if it is repositioned. Application is a matter of habit; novice HCP may not succeed on their first trial.
Have precise and clear application instructions	Good application instructions will facilitate HCP's work. Application instructions will also facilitate if patients have to apply it by themselves.
Enable use and application after finished treatment	Radiation effects can evolve after finished treatment, so patients should be able to apply the solution independently.

The time of application is also related to the precision required to apply the film. It needs to fall as smooth as possible on the skin, without wrinkles or folds, and in the treatment position not to affect the breast shape. For an HCP that does not have much experience with the product, repositioning the film might be necessary. However, it can be a challenge due to the film's low thickness. When removed from the skin in an attempt to reposition it, the film often entangles. Therefore, having the repositioning possibility into the new solution will help HCP to correct possible mistakes, improving the time of application at the same time.

In breast cancer radiotherapy, there are a few areas of the body that are more prone to present severe skin reactions. Areas of the body where there is more friction or the skin is thinner, like

under the breast, the armpit and the clavicle, are part of this group. Therefore, protecting these areas is essential to prevent severe RISR.

Mepitel Film is manufactured in seven different sizes, all rectangles. The current shape, however, makes the application and conformability to the body more complicated, requiring that nurses cut the film in a more appropriate shape before applying it on the skin. For this reason, minimising the necessary modification or streamlining it in the future solution is one of the application goals.

Moreover, skin reactions can still occur two to three weeks after the treatment has finished. Therefore, patients need to keep taking care of the skin to avoid skin reactions in the radiated area. A new solution that can be applied and maintained by the patients after the treatment is over would increase their well-being and comfort, giving them more independence and allowing a faster return to their usual routines.

5.2.3. Adherence

The film's adherence is an essential part of the solution, and the goals related to this category are presented in Table 6. Each time a dressing needs to be changed, the skin is damaged. Even if the dressing has a soft silicon adhesive, the skin is still very sensitive underneath it, and every distress can increase the possibility of developing more severe skin reactions. For this reason, the goals of this category are to minimise the factors that may worsen the adherence of the film and improve the time that it stays attached to the body. The identified factors that worsen the adherence of the film are its shape with sharp corners and edges.

Table 6. Adherence goals and motivations

Adherence

Goal	Motivation
Minimise factors (e.g. shape, edges) that worsens the product's adherence	The solution's adherence is crucial in order to be appreciated.
Improve the time that it stays attached to the body	Less dressing changes are beneficial to avoid skin damage and optimise the use of material.

It is also important to note that if the patient sweats a lot or practices any activities where there is water contact, the film may not be appropriate for this patient. The film has shown decreased adherence when placed in moist skin or over an area that produces a lot of sweat.

5.2.4. Awareness

One interesting finding from the user research was the awareness factor related to both RISR and preventive products. Guidelines differ between centres, not only in different countries but also within the same country. This happens because, alongside the general country's recommendation, centres also set their guidelines based on the results seen in-house. Regarding

preventive products, there is a low spread of the available solutions in the market because of the lack of clinical evidence.

The awareness goals shown in Table 7 are targeting the deficit of available information for HCP and patients. Besides more information about RISR, the knowledge about prophylactic solutions also needs to be increased. Nowadays, the great majority of HCP recommend the use of topical agents to treat the radiated skin and minimise the risk of severe reactions. Although these products are seen as effective in many cases, it is a management measure that requires the compliance and responsibility of the patient.

Table 7. Awareness goals and motivations

Awareness	
Goal	Motivation
Improve awareness of both RISR and the use of prophylactic solutions in radiotherapy	There is a doubt among HCP about Mepitel Film's efficacy. There are individual differences among patients' awareness about RISR and how they perceive and react to information.
Instigate more research to be conducted about the products' efficacy	Studies are poorly designed, and there is a lack of clinical evidence and multi-centre trials
Increase HCP recommendations to use the solution	The majority of HCPs recommend topical agents.
Support HCP to provide patients with sufficient knowledge about RISR	It is important that the patients feel comfortable, secure and confident towards HCPs during their treatment. Patients are exchanging experiences with each other and sharing knowledge, which may lead to misinformation.

5.2.5. Economic

The economic goal of the project is to reduce the total cost and resource when using the solution. Although user research has revealed that Mepitel Film is perceived as an expensive product, the economic goal is not related only to the price. It involves time spent when applying the solution, workforce and material waste (Table 8).

Table 8. Economic goal and motivation

Economic	
Goal	Motivation
The total cost and resources of using the solution should be reduced (e.g. time, personnel, material)	HCPs experience Mepitel Film as an expensive product. The provider of medical products varies between countries and hospitals (e.g. patient, government, hospitals). HCPs are aware of material waste and strive to optimise the use of film.

Morgan (2014) shows in her study that using Mepitel Film has the potential to reduce costs when compared to the use of Mepilex Lite. As Mepitel Film prevents severe skin reactions from developing, usage of the product can reduce wound care management expenditures. The same promising cost-benefit advantages were analysed by Herst et al. (2014), who also argue that usage of Mepitel Film will decrease the overall costs.

Sustainability is an essential economic factor. Mepitel Film is a disposable and non-reusable product, and the project does not aim to change this. However, the product can stick to the body for up to a month, which is long durability compared to similar products on the market (Mölnlycke Health Care, 2019). On the one hand, medical products have ecological and sustainability issues due to the high level of hygienic requirements. On the other hand, these issues can be addressed by considering the usage of material. The improvement and development of the solution should, therefore, aim to optimise the material use and avoid waste in order to ensure a sustainable product.

5.2.6. Future

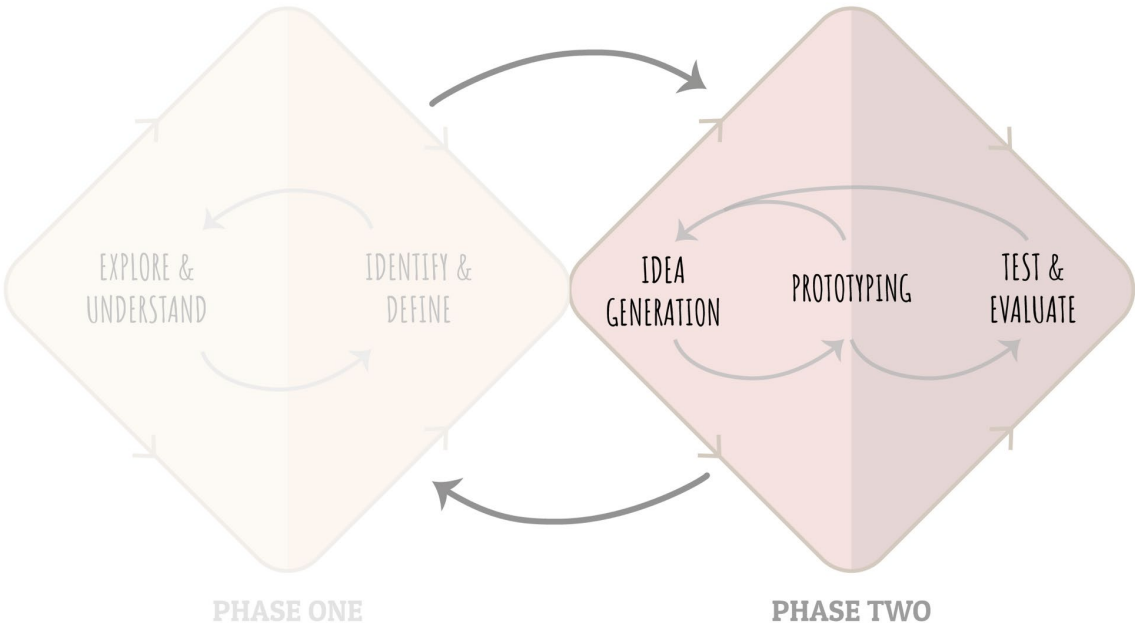
Radiotherapy is a treatment that is in continuous development. There is constant research, and radiotherapy machine companies invest a lot of money in developing new, better technologies. Every year machines, products and equipment improve. Besides technological development, knowledge is increasing, and thus, the qualifications of doctors and medical physicists are also improving. Such advances directly influence the occurrence of RISR, and patients are experiencing fewer skin reactions caused by the radiation. For these reasons, the goal in the future category, presented in Table 9, is to ensure that the solution will be developed parallel with the current technology.

Table 9. Future goal and motivation

Future	
Goal	Motivation
Ensure that the solution is developing in parallel and adapted to the development of the technology	Technology and knowledge in radiotherapy treatment are in constant development, and machines are constantly improved.

PHASE TWO

Phase two aimed to develop a solution that enhanced the usage of Mepitel Film within the radiotherapy context. With a co-creation approach and creative workshops, ideas were generated and further developed into concepts. The most promising ideas were combined and developed into concept refinements that were further evaluated with users.



6

Method

This chapter involved idea generation, form exploration, concept refinement, prototyping and evaluation. The stages were done interactively and together with the users, following the co-creation approach of the project. This phase culminated in a refined final concept.

6.1. Idea generation

The idea generation phase aimed to find possible solutions that improved the usage of Mepitel Film in the radiotherapy context. Due to the co-creation approach, this phase had a large focus on involving users and stakeholders in order to ensure that the solution fulfilled their needs. Thus, the ideation sessions were conducted through creative workshops with

- HCPs
- Personnel at MHC
- MHC's marketing department

The creative workshops had various set-ups. However, all of them encouraged the participants to feel free in their thoughts. They were reminded that all ideas were possible and criticising should be avoided.

6.1.1. Workshop with MHC

An ideation workshop was conducted with MHC personnel to get a more technical perspective of the problem. The workshop was conducted digitally, but half of the group sat together physically at MHC's office, whilst the other half participated via Teams. The workshop was scheduled for an hour.

There were, in total, six people from MHC and two designers that participated in the ideation workshop. The participants had different responsibilities within the company, and thus, they all had various knowledge and perspectives of product development. The heterogeneous group enabled ideas from different departments to be merged, which resulted in a wide range of ideas. A more detailed description of the participants can be seen in Table 10.

Table 10. Participants of MHC's workshop

#	Occupation	Location
1	Technical Category Manager	MHC office
2	Sales representative	Teams
3	Senior Process Designer	MHC office
4	Technical Product Manager	Teams
5	Innovation and Concept Designer	MHC office
6	Project Manager	MHC office
7	M.Sc. Industrial Design Engineering Student	Teams
8	M. Sc. Industrial Design Engineering Student	Teams

The workshop started with a short description of the project's background and the work performed so far. Further, the result from the user research was presented by describing the product goals. The participants were encouraged to ask questions about the goals to ensure that they had understood their content.

After that, the participants were divided into two groups: the first group sat together physically, and the second group participated via Teams. The ideation used the method Brainwriting (Board of Innovation, n.d.) but modified it to adapt the method to the digital circumstances. Thus, the Brainwriting was conducted collaboratively in the groups using the digital platform Miro.

The designers had prepared the Miro board in advance and divided the product goals into three different categories: general, adherence and application (Figure 8). The aim of the workshop with MHC personnel focused on the technical perspective of the product to take advantage of their expertise, skills and knowledge. Consequently, the goals related to awareness, economic and future factors were not included.

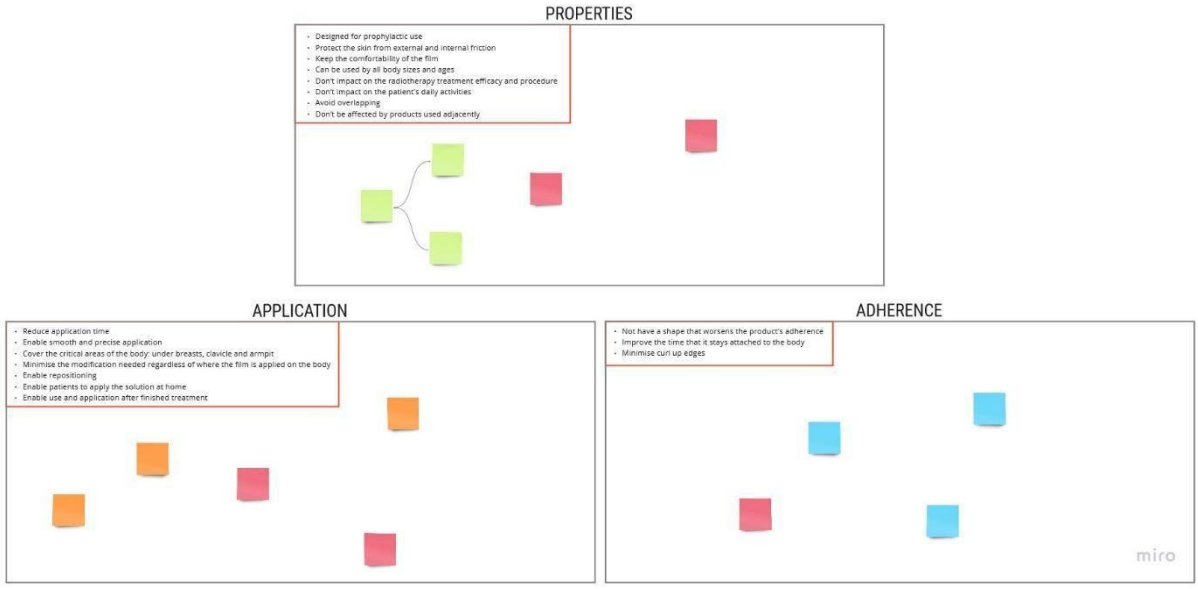


Figure 8. Brainwriting board on Miro

The two groups started with one board each and should only focus on ideate ideas that fulfilled the presented goals on that board. After five minutes, the two groups rotated and took a new board with new product goals. When both groups had ideated on all boards, the brainwriting session was repeated in order to enable the participants to fill in new ideas that might have come up during the first round. The workshop ended with a discussion where the participants could give comments and feedback on both the ideas and the workshop activity.

6.1.2. Workshops with HCP

Two creative workshops with HCPs were conducted in order to increase the knowledge about how HCPs are handling and preventing RISR in their daily work. Both workshops had the same activities and duration of one hour. The digital platform chosen was Zoom, and Miro was used

as a supporting tool. All participants were nurses and had an extensive experience with RISR. However, they had various experiences of Mepitel Film, as shown in Table 11.

Table 11. Participants of HCPs' workshops

#	Occupation	Country	Experience with Mepitel Film
1	Specialist Oncology Nurse	Sweden	Yes
2	Specialist Oncology Nurse	Sweden	Yes
3	Oncology Nursing Professor	Brazil	No
4	Nurse	Brazil	No
5	Specialist Oncology Nurse	Brazil	Yes

The workshop started with a short description of the project, the concept of co-creation and a presentation of the participants. The first activity was a *warm-up activity* where the participants should quickly select an option that they considered as the most ideal for a solution in order to handle RISR between two statements. For instance, "cover the entire radiated area" or "cover only critical areas: under breasts, armpit and clavicle". The statements originated from the product goals, and the purpose of this activity was to get an overview of which product goals the HCPs considered as most important. In addition, the activity instigated discussions and made the participants more comfortable and prepared for further activities.

The next activity of the workshop was called *Dream Scenario*. The designers told them a scenario about a nurse and a patient that suffered from RISR. The scenario had incorporated four discussion topics where the participants discussed how the nurse should act in an ideal scenario according to the circumstances presented in the scenario. The *Dream Scenario* was conducted to increase the knowledge about HCPs reasoning in complex situations, what they consider a time-consuming application and which recommendations they provide to their patients.

The last activity of the workshop was a Brainstorming (Interaction Design Foundation, n.d.) section with the digital platform Miro. Since the participants might have had various experiences generating ideas, it was important to guide them into a creative mindset without limiting their ideas. A key question: *How would be an ideal product to prevent RISR?* was, therefore, presented before the brainstorming activity started. The question aimed to explicitly state the goal with the brainstorming as well as help the participants to come up with ideas by answering a question. Moreover, mediating objects in the form of images and keywords were also displayed during the brainstorming section (Figure 9). These objects aimed to inspire the participants' creativity and to encourage them to think in new ways.

Figure 9. Mediating objects board on Miro

The workshop ended with a short presentation of how the data from the workshop would be helpful for further work. Finally, the participants were encouraged to give potential feedback or ask questions.

6.1.3. Awareness workshops with MHC

One main finding from the user research was the lack of awareness about Mepitel Film and RISR among patients and HCPs. Thus, a workshop together with MHC's marketing department was conducted in order to ideate how the awareness could be increased. The workshop was conducted digitally together with two designers and one representative from the department, the Global Marketing Manager on Acute Wound Care. The workshop consisted of discussions about their current way of building marketing and communication plans and how these could be applied in this context.

All the information gathered from this workshop, together with the personas built in the previous phase, were the foundation for the development of a communication plan — these assets guided how to address the identified problem. The development of the plan focused on three major questions: *Who?*, *How?* and *What?*. The first question focused on deciding which target groups should be reached, the second focused on how to reach these groups, and the last focused on what message that should be communicated and through what media. The result from the awareness workshop is presented in section 8, together with the final concept.

6.1.4. Ideas exploration

The main goal of the ideas exploration stage was to create promising solutions by exploring materials and forms. Based on the ideas generated in the workshops and the product goals, the conceived ideas were translated into different media, such as manual sketching, computer simulations and paper models.

MHC's laboratory was the chosen place to work and further explore the conceived ideas. Several products from MHC's range were provided and used for exploration. A generate-and-explore process (Prats, 2007) was used while performing this step. Concepts were designed, built and tested onto four different kinds of objects simulating the breast: a mannequin body, a

balloon filled with cornstarch, a gel mattress and breast implants. The results were then translated into new concepts in an attempt to improve the solution.

The idea exploration resulted in several concept ideas where each of them fulfilled various product goals in different degrees. The concept ideas were developed at a similar detail level and were represented equally to ensure a fair comparison and judgement. The concept ideas were presented to three product responsible personnel at MHC to receive their feedback on each concept idea's advantages and disadvantages. In addition, the presentation aimed to receive MHC's opinions regarding the feasibility and manufacturability of the concept ideas.

6.2. Development of concept refinement

After the presentation, different concept ideas were combined and merged in order to utilise the main advantages of the different concept ideas. Combining the different concept ideas resulted in two concept refinements that applied the best parts from the concept ideas, each covering a large extent of the product goals.

The two concept refinements were further developed from the concept ideas. This stage was performed in the same way as the idea exploration, through a generate-and-explore process. The main studies for the concepts were the shape and the possible solutions for the application layer.

The shape exploration was conducted exploring paper models together with CAD drawings and tests using Mepilex Lite. The choice to use Mepilex Lite instead of Mepitel Film to perform the tests was due to its ease of handling. The chosen material is thicker and allows the reapplication of the same piece of the product. The tests, as well as in the idea exploration stage, were performed in the available mannequin and breast implants. The layout distribution of the shapes on the sheets was also explored using CAD software to optimise the use of material.

Different settings were explored before arriving at the desirable mix of material, size and shape of the concept refinements, which were later prototyped at MHC's laboratory. Already existing products were put together to build the new solutions. The goal was to produce reliable prototypes of the two concept refinements that would translate the idea in the best way possible for the subsequent evaluation.

A clear set of instructions and guidelines were designed to fit the repurposed target group and complement the solution. In developing the set of instructions for the concept refinements, the first step was to clearly view the steps that needed to be followed to apply the product. This was made by describing the steps as it was going to be performed by an unknowledgeable person. For even more straightforward instructions, the two sets are composed of illustrations developed to help guide the user in applying and positioning the film.

6.3. Test & Evaluation

The two concept refinements were tested and evaluated together with HCPs in two similar evaluation workshops, supported by the co-creation approach. The purpose of the workshops

was to let the HCPs interact with the prototypes and, in turn, receive feedback about their experience. Both workshops were conducted digitally via Zoom, scheduled for an hour and were performed in the participants' native language to ensure that the participants felt as much comfortable as possible. All participants had been part of the previous ideation workshops and were therefore well aware of the project and its purpose. The participants of the workshops are described in Table 12.

Table 12. Participants of evaluation workshops

#	Occupation	Country
1	Specialist Oncology Nurse	Sweden
2	Specialist Oncology Nurse	Sweden
3	Oncology Nursing Professor	Brazil
4	Specialist Oncology Nurse	Brazil
5	Nurse	Brazil

The participants had in advance to the evaluation workshop received material by regular mail. The material consisted of four envelopes containing the items described in Table 13. Envelope 1 to 3 would be used during the evaluation workshop, whilst the fourth envelope could be used for further investigation by themselves outside the workshop. Envelope 1 consisted of the existing Mepitel Film in order to facilitate a comparison of the two concept refinements with the already existing solution. The participants were also provided with balloons to have a round shape to apply the dressings on.

Table 13. Contents of the evaluation kit

Envelope #1	Envelope #2	Envelope #3	Envelope #4
Mepitel Film and balloon	Concept 1 and balloon	Concept 2 and balloon	Two sheets of the base construction of concepts without alterations

The evaluation workshop started with a short introduction about the workshop's purpose and how it would be conducted. The participants received information that the envelopes should be open one by one, perform tasks with the material inside the envelope and later evaluate their experience. The HCPs did not receive any application instructions from the start in order to

assess their initial interaction. They were displayed after Envelope 2 to ensure that the participants used the product correctly and that the evaluation assessed the intended interaction.

The tasks were similar for each envelope, and the participants were asked to:

1. Blow up the balloon.
2. Open the dressing.
3. Plan and tell how to cover the balloon.
4. Modify and cut the dressing (if it was needed).
5. Apply the dressing to the balloon.

The tasks were performed during the workshop in order to enable observation of how the participants interacted with the products as well as catch the conversations they had with each other during interaction with the material. After performing the tasks, their experiences interacting with the material in the envelope were evaluated through a short digital survey. The survey utilised Hesselgren's emotional scale (Hesselgren, 1987) and Likert scale regarding product pleasurability (Jordan, 2003) to identify which emotions were evoked during interaction and the participants overall pleasure, respectively. Further, the workshop continued with repeating the tasks and the short digital survey for envelope 2 and 3. However, the application instructions were not evaluated constantly during the execution of tasks. Instead, the instructions and their guidance were discussed at the end of the workshop.

7

Concepts development

This chapter exposes the findings from *Phase Two,* including ideas generated from workshops, developed concept refinements and results from the evaluation. The chapter provides an overview of each concept idea's advantages and disadvantages, as well as a description of how they were combined to create the two concept refinements. Lastly, the prototyping process and the results from the evaluation workshop are presented.

7.1. Concept ideas

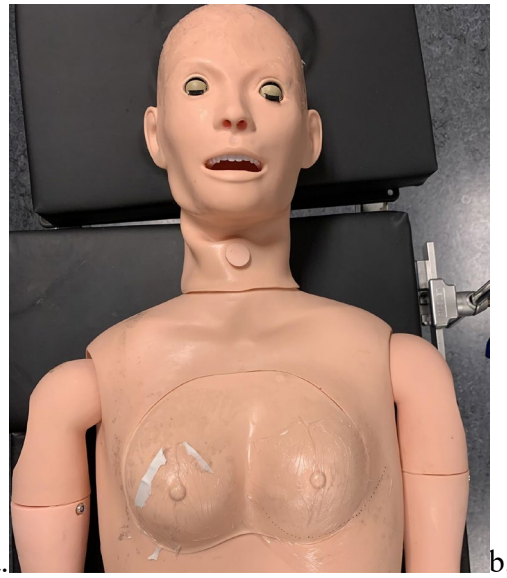
The idea exploration and testing of the product allowed a thorough and holistic understanding of the pain points found during the user research to ensure that the solution covered the most important aspects. One clear pain point to be addressed was the current paper frame used to facilitate the application of the film. The structure indeed helps the applications, but it has its setbacks. For instance, if the HCP cuts the product, the frame is lost since it is only present in the outer border of the film, and the application becomes almost impossible without tangling the film. Furthermore, the stiffness of the paper hinders the film from conforming to the body. So an entire application layer made of paper was not a favourable solution.

Another identified critical point was regarding overlapping the film. It is unclear if the film could be overlapped or not due to differences in opinions whether the overlapping causes the bolus effect. However, during the form exploration, it was verified that some overlapping would help in the positioning of the film since it is challenging and time-consuming to place the films edge by edge.

During the development of the ideas, the models were tested in different kinds of objects simulating breasts. The first structure tested was a mannequin provided by MHC (Figure 10a). Unfortunately, the mannequin's breast did not translate the reality of the woman's body. It was too small and rigid. Therefore, a different breast simulation was built using a balloon filled with corn-starch (Figure 10b). The texture was more similar to the reality, but the continuity of the skin was still missing. However, for the first tests and concepts, both structures were good enough and allowed the ideas to be placed in the breasts to check their feasibility.

On the search for a more suitable application body, a bag filled with a gel-like substance was provided by MHC, a material that is today used as a mattress in hospitals to avoid bedsores and pressure ulcers (Figure 10c). This material resembled more closely the human tissue, and there was continuity between the breast and the neck. The mattress allowed the investigation of the shapes on a less spherical shape, which translated better the reality of a breast. Exploration with the mattress contributed to an understanding of the importance of having multiple shapes in different sizes in order to ensure good coverage. However, it was still hard to shape the material into the format of a breast.

In the attempt of having a more realistic breast model, the Plastic Surgery Department at Sahlgrenska University Hospital in Gothenburg was contacted and resulted in the donation of three different sizes of breast implants (Figure 10d). The models represented a more realistic breast shape and supported to determine the sizes of the forthcoming product.

a.  b. 

c.  d. 

Figure 10. Objects used to simulate breasts: (a) woman's mannequin; (b) balloon with corn-starch; (c) hospital mattress; (d) breast implants

The final idea for the testing body during the exploration stage was purchasing a realistic breast chest made of silicone that is usually used as a costume (Figure 11). This apparatus aimed to test the solution in a more realistic body since testing in actual patients is not allowed. The product, however, only arrived after the form exploration phase, so it was used mainly after the test and evaluation phase.

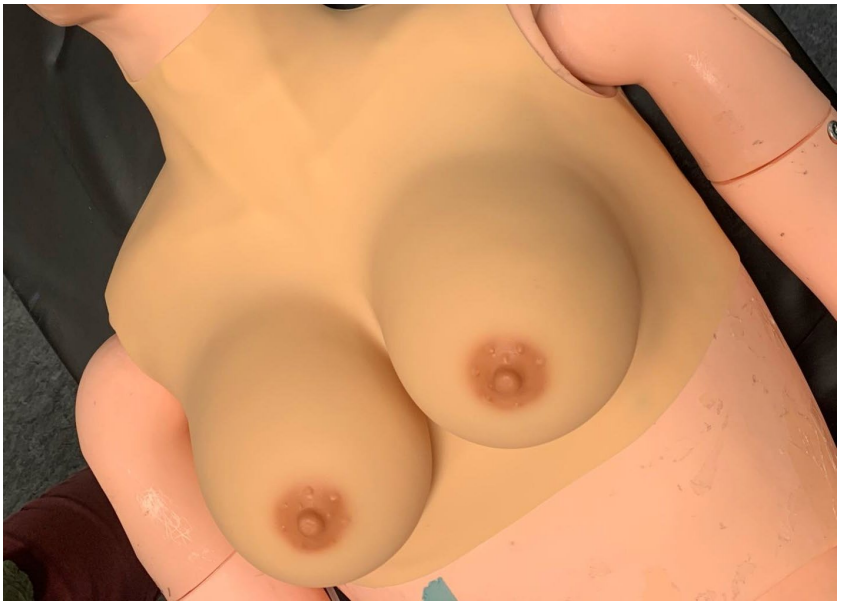
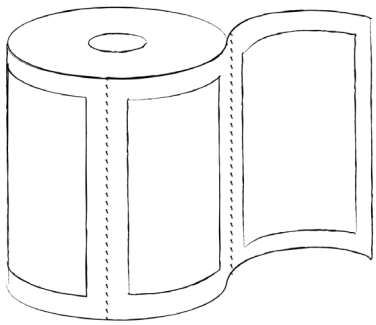


Figure 11. Realistic breast shape mannequin.

The breasts simulations were crucial while exploring the ideas, shapes and sizes. In addition, they contributed to an understanding of the struggle that HCPs go through when applying the product. The idea generation and form exploration culminated in several ideas. Some of them are presented below.

1. Dressing as it is on a roll



What it consists of:

The current product sheets with paper frames are presented in a roll.

How it works:

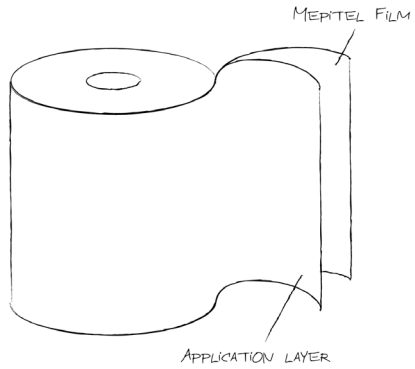
a. A sheet of the product is pulled and detached from the roll;

b. The user modifies the material into the desired shape with a scissor;

c. The realise liner is removed, and the film is applied to the skin;

d. The paper frame is removed from the film.

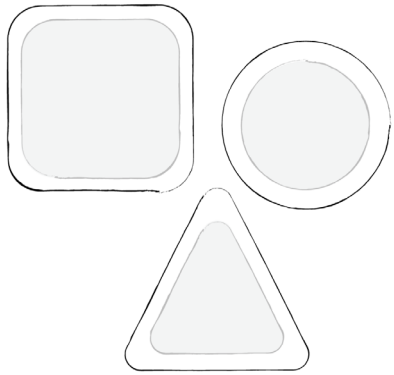
2. Dressing on a roll with application layer



What it consists of:
The film comes as a continuous roll and has an application layer instead of a paper frame to facilitate application.

How it works:
a. The desired amount of film is cut from the roll;
b. The user modifies the material into the desired shape with a scissor;
c. The realise liner is removed, and the film is applied to the skin;
d. The application layer is removed from the film.

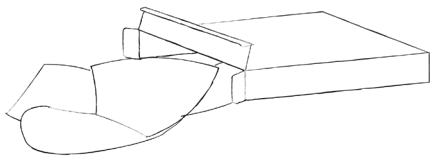
3. Shapes for critical areas



What it consists of:
The film comes in a specific shape that was designed to protect the critical areas of the body: under the breasts, armpit, nipples, clavicle and breast.

How it works:
a. Choose the shape that best fits the body part that should be protected;
b. The realise liner is removed, and the film is applied to the skin;
c. The paper frame is removed from the film.

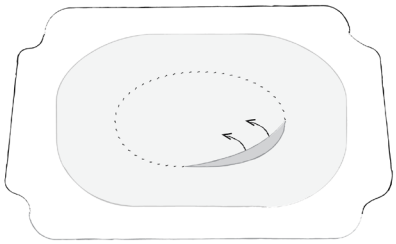
4. Dressing kit



What it consists of:
A box with a kit of the most important shapes to be used during breast cancer radiotherapy. It comes in different sizes to attend to the various body types.

How it works:
a. Choose the shape that best fits the body part that should be protected;
b. The realise liner is removed, and the film is applied to the skin;
c. The paper frame is removed from the film.

5. Perforated shapes

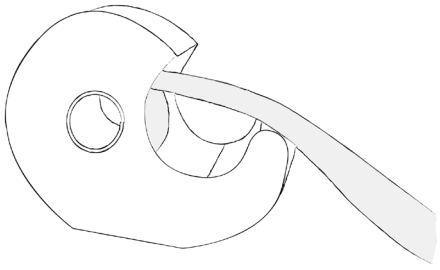


What it consists of:
The product sheet comes with a perforated shape contour that can be detached from the rest of the sheet, eliminating scissors.

How it works:
Option 1:
a. The user detaches the shape from the sheet;
b. The realise liner is removed, and the film is applied to the skin;
c. The paper frame is removed from the film.

Option 2:
a. The realise liner is removed, and the film is applied to the skin;
b. The paper frame is removed from the applied film;
c. The film outside the perforated area is removed from the body, leaving the desired shape on.

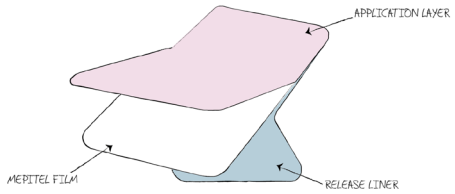
6. Tape



What it consists of:
The product comes as tape, and the user can cut as much as needed. An application layer covers the entire surface of the film. It can be used concomitantly with other products to help their fixation.

How it works:
a. A piece in the desired size is cut;
b. The realise liner is removed, and the film is applied to the skin;
c. The application layer is removed from the film.

7. Application layer



What it consists of:

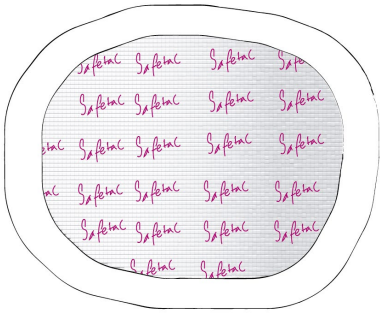
The film's top surface has an application layer that helps in the application process and is removed after the film is applied to the skin. The layer increases the thickness of the film, making it easier to handle the product.

How it works:

a. The realise liner is removed, and the film is applied to the skin;

b. The application layer is removed from the applied film.

8. Round corners



What it consists of:

All the corners of the product are round, helping to minimise the curling-up that might occur after the film is on the skin.

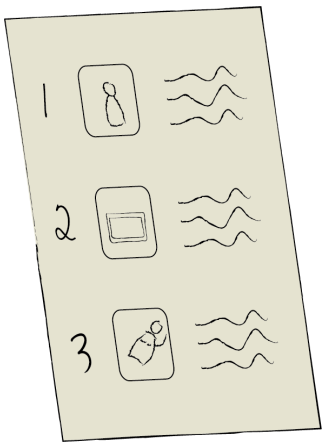
How it works:

a. The product has all of its corners rounded;

b. The realise liner is removed, and the film is applied to the skin;

c. The application layer is removed from the applied film.

9. Application instructions



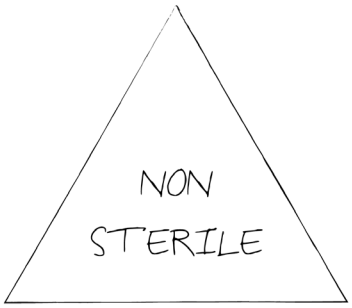
What it consists of:

Clear instructions on how to apply the product on a breast come inside each package. The instructions are easy and straightforward enough so that patients could apply by themselves after the treatment has finished if necessary.

How it works:

a. The user reads and understands the instructions on how to use and apply the product.

10. Non-sterility



What it consists of:
The product is produced as a non-sterile dressing since it is aimed for prophylactic use and is not in direct contact with open wounds.

How it works:
a. Combined with other concept ideas.

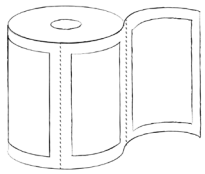
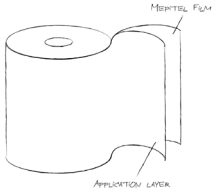
Other improvements involving more technical and material-related aspects of the product were also discussed. As they are out of this project's scope, they have not been further developed but serve as ideas for future implementations that MHC can do. Some of those ideas are described below:

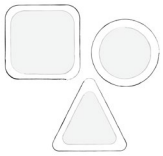
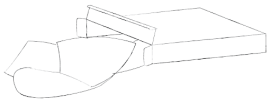
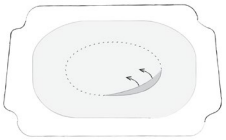
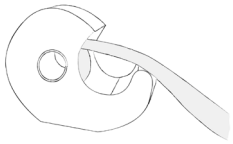
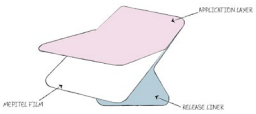
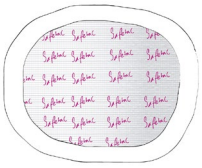
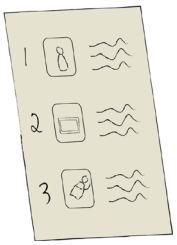
- Increase the thickness of the carrier material
The thickness of the carrier material present in the product should be thickened to facilitate application.

- Active component
The product would have an active component added to its contact layer. The component would help relieve pain and burning that patients might feel, "refreshing" the skin underneath the film.

All concept ideas were presented for MHC. The feedback received was later discussed and analysed, which resulted in a list of advantages and disadvantages for each concept idea, seen in Table 14.

Table 14. Advantages and disadvantages of developed concept ideas

	Concept ideas	Advantages	Disadvantages
	Dressing as it is on a roll	- More available material	- Does not solve the main problems
	Dressing on a roll with application layer	- More freedom of shapes - Reduce waste	- Will be challenging to price

	Shape for critical areas	- HCP already cut the dressings to shapes that better fit the breasts	- Hard to see how the shapes should be applied: can easily turn them in the wrong direction
	Dressing kit	- Good for future commercial - Puts patient in the centre	- More designed for patients than HCP
	Perforated shapes	- Do not need to use scissors	- Losing flexibility of creating which shape you want - Risk that the film is too thin for being perforated
	Tape	- Can fix the problem with bad adherence of Mepilex Lite	- Solve the problem with Mepilex Lite and not Mepitel Film - Can use another product from MHC (Mepitac) for this purpose
	Application layer	- Probably not difficult to add an application layer if the material is similar to one of MHC's already existing materials	- Could be hard to manufacture
	Round corners	- Reduce modifications needed for HCP	- More difficult to combine with other pieces if overlapping is not allowed
	Application instructions	- A given complement to the product - The product was never launched for this context; there is a new target group	- Risk that these are ignored and not read by the users.
	Non-Sterile	- Good if the product is sold targeting use in radiotherapy	- A sterile product can be sold for a higher price

7.2. Concept refinement

Based on the knowledge regarding the advantages and disadvantages of each concept idea, the second step included refinement and combinations of the ideas in order to optimise the solution. This step resulted in two concept refinements. Both of them embraced the idea of replacing the paper frame with a new application layer, as well as designing the dressing in different shapes for different body parts. In addition, the two concept refinements are non-sterile and will contain clear application instructions.

The concept refinements and their further developments are not displayed or described in detail in this report due to intellectual property protection. However, the general description provides sufficient information for the understanding of the concept refinements.

New application layer

The new application layer consists of a thin foam that conforms to the body shape easier than the paper frame. It increases the thickness of the film during the application, which in turn facilitates the application process. Once the film with the application layer is placed on the body, the application layer is removed, leaving only the film on the skin. To facilitate removing the application layer, the foam is split in half and there is a slight overlapping between them.

Shapes for different body parts

Various shapes were explored during the development of concept refinements in order to find shapes that ensured an optimal coverage of the radiated area.

After new testing on the breast simulations, the symmetrical shapes were considered the best since they could be used on both sides of the body. The exploration resulted in three shapes considered optimal for good coverage and were therefore selected to be used on the concept refinements. The three shapes were:

- *Butterfly*
- *Wedge*
- *Banana*

The *butterfly* was designed to cover the breast area. The shape was inspired by sewing patterns for bras and enabled the 2D dressing to conform and fit into a 3D shape. The *wedge* was designed to fit under the breast and had the same curvature as the *butterfly* in order to complement each other. The *banana* can be used for different body parts, such as the armpit, the clavicle or the side of the breast. All shapes had round corners to decrease the risk of curled up edges.

Application instructions

The application instructions start with assessing the targeted area to ensure that the correct shape and size are selected in the subsequent step. First, the release liner should be removed, exposing the film's adhesive that is then positioned and applied on the skin. After the application, the application layer needs to be removed from the centre to the edges to facilitate the removal and avoid the corners of the film lift together with the foam. Finally, the

instructions explain how to proceed with the following pieces of film to cover the entire area, advising to avoid overlapping or gaps between the pieces.

With the application instructions, a guide of suggested placement of different shapes will be provided with the product. Both the application instruction and the guide have a set of illustrations to help visualise the steps and placement suggestions. They are presented in Figure 12.

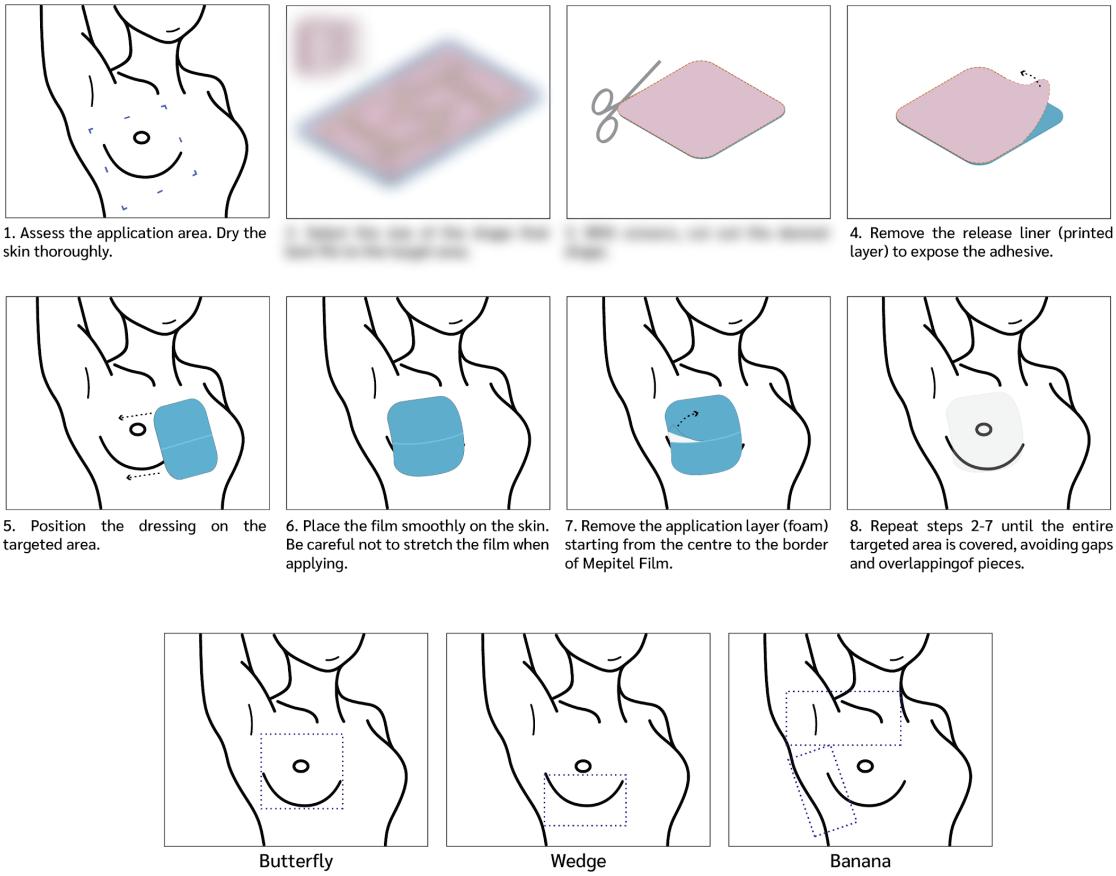


Figure 12. Application instructions (top) and positioning guide (bottom)

7.2.1. Concept refinement one: The roll

The first concept refinement (Figure 13) is a non-sterile roll with three layers of material: the new application layer, Mepitel Film and the release liner. The release liner features a solution that allows the HCP to easily modify the dressing into the three developed shapes: *butterfly*, *wedge* and *banana*. The solution is adaptable to different body sizes, and they are nested to optimise the use of material. Providing the dressing in a roll gives the HCP freedom to choose if they want to use the shapes or not, depending on each patient's unique circumstances.

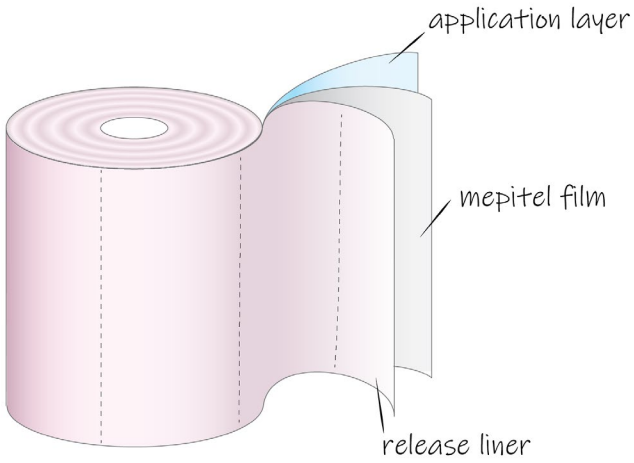


Figure 13. The roll

7.2.2. Concept refinement two: The kit

The second concept refinement (Figure 14) is to provide the dressing into the three developed shapes: *butterfly*, *wedge* and *banana*. The three shapes come in a kit and enable the HCPs to make a good coverage of the radiated area. The kits come in different sizes allowing HCPs to select the size that best fits the patient. This concept refinement also embraces the new application layer, being built in the same way as the other concept refinement. The shapes are ready to use by the HCPs, therefore decreasing the modifications needed.

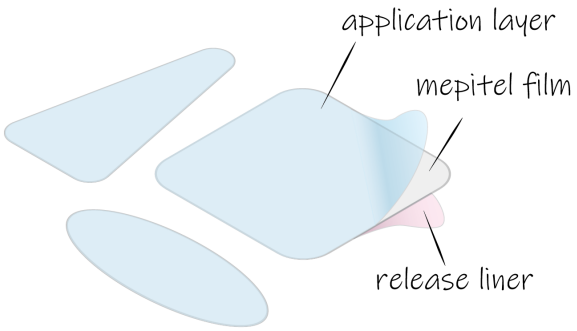


Figure 14. The kit (here represented with random shapes)

7.3. Building the concepts

The two concept refinements were prototyped for the subsequent evaluation phase. As both concepts are composed of the same structure of release liner, Mepitel Film and application layer, the construction of the prototype's base was the same. The prototype's size had to be adapted and scaled-down due to a lack of material in the desired size. Therefore, it was impossible to have all the shapes in only one sheet of the product, nor have it as a roll.

For the first two layers of the concept, the current product was used with the modification of removing the existing paper frame and leaving only the release liner and the film. To these first

two layers, the new foam application layer was applied. The new application layer was manufactured using Mepilex Lite. In the actual product, however, the application layer will be developed and manufactured with a different material, not Mepilex Lite. The process of building the prototype is shown below in Figure 15.

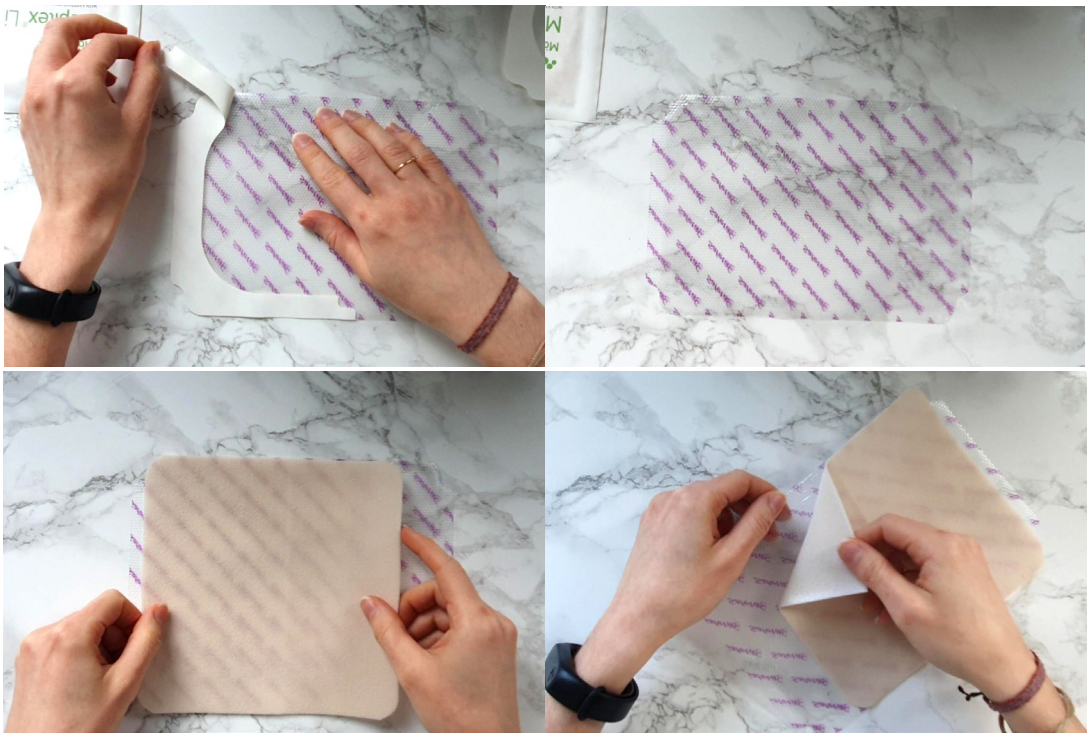


Figure 15. Prototyping process

The final base of the prototype can be seen in Figure 16. The application layer is split and slightly overlapped in the centre to facilitate its removal after the film is applied to the skin. Finally, the solution of three shapes was added to the prototypes.

Figure 16. The final base of the prototype

7.4. Evaluation workshops

The two evaluation workshops provided meaningful insights and feedback on the prototypes. The results are presented below and organised following the workshop structure.

7.4.1. Envelope 1

The content of Envelope 1 was the current presentation of Mepitel Film. This envelope worked as a control test to observe how HCPs usually deal with the product. As the participants handled it, it was possible to notice their difficulties in controlling the thin material, especially when the product is cut and loses the paper frame.

The results of the evaluation questionnaire showed that HCPs had mixed feelings about the current presentation of Mepitel Film. Some of them liked it more and felt confident while interacting with the product, whilst others felt more worried and irritated. None of them was surprised during the interaction. The radar chart in Figure 17 illustrates all the gathered answers about their evoked feelings.

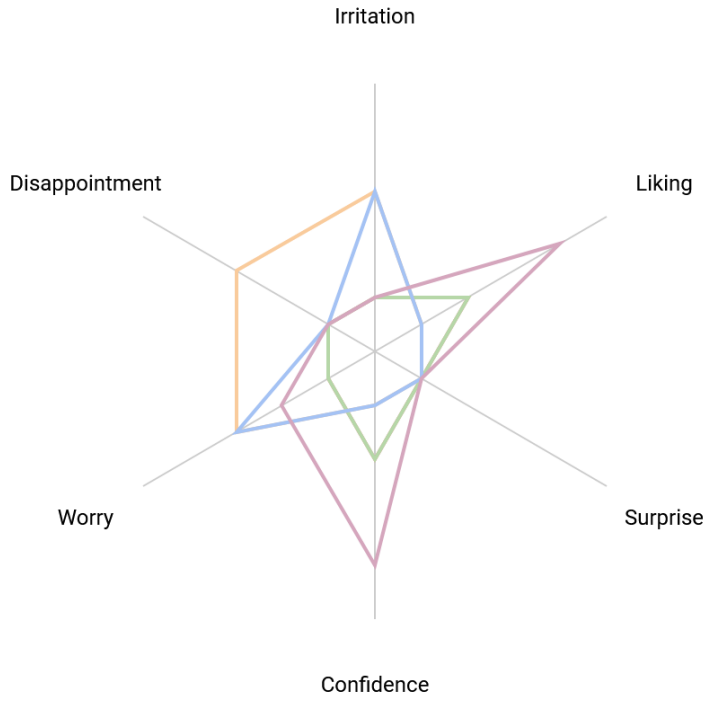


Figure 17. Radar chart of Envelope 1 evoked feelings

The assessment of the product pleasurability (Figure 18) displays the average results from the questionnaire. It indicates that HCPs felt stimulated and considered the product to be easy to apply. Furthermore, they evaluated that the product would not significantly increase their workload. At the same time, HCPs experienced the product interaction as stressful.

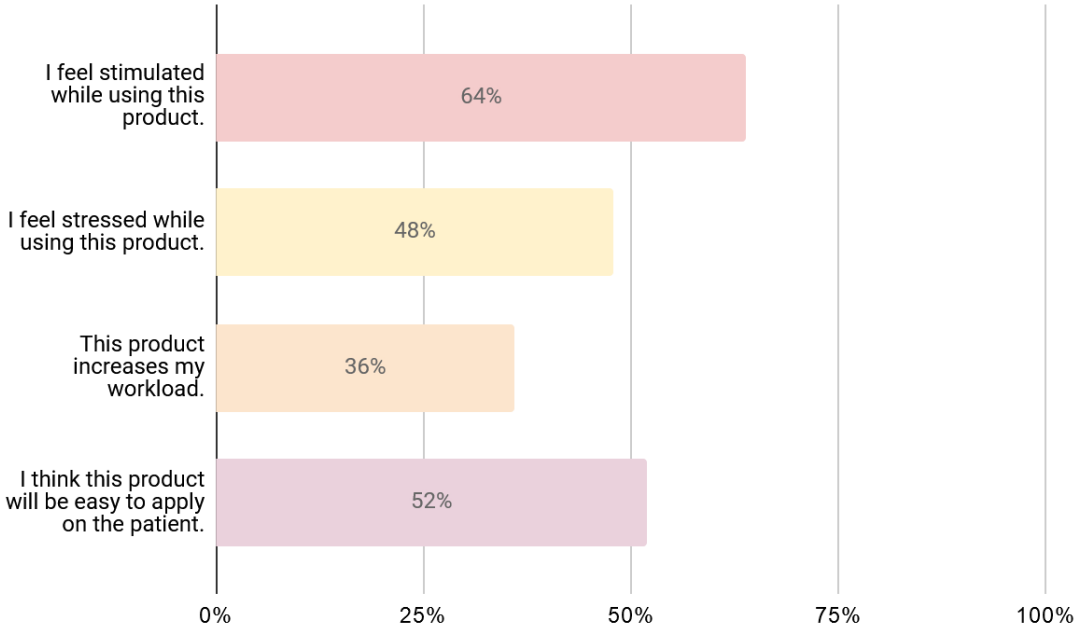


Figure 18. Product pleasurability of Envelope1

7.4.2. Envelope 2

The second envelope contained a whole sheet of concept refinement one. For this solution, participants had to cut through the three-layered material. This action was perceived as easier to perform than with the original Mepitel Film. However, a few participants argued that it takes too much time to cut it before placing it.

After the shape was cut, most participants did not understand how the cut shapes and application procedure worked. Also, they found it hard to remove the application layer from the film. One of them ended up applying only the application layer to the balloon. As this step was performed before showing the application instructions to them, it became clear that this asset is essential for an effective solution.

After the presentation of the instructions, the HCPs appreciated the application layer as it facilitated the positioning of the film. One of them expressed that it was even possible to reposition the film with the application layer, suggesting that one could remove the layer just after making sure that it is in the desired place.

As the radar chart (Figure 19) shows, concept refinement one evoked positive feelings such as liking, surprise and confidence in the HCPs. However, feelings of irritation and worry were also present among some of the participants. Overall, the participants seemed confident while handling the concept.

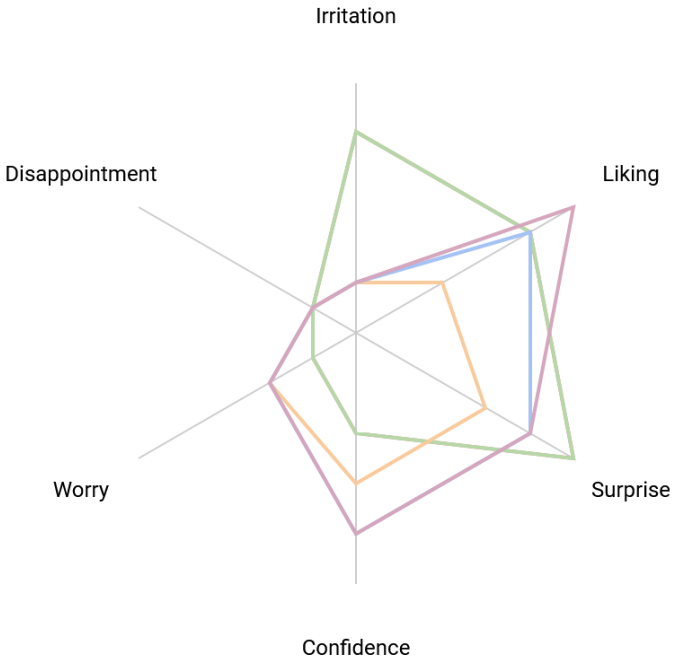


Figure19. Radar chart of Envelope 2 evoked feelings

When analysing the Likert scales (Figure 20), the survey showed that HCPs considered the concept refinement one to be easy to apply and felt stimulated while using it. In addition, the HCPs experienced the product interaction as less stressful than the current Mepitel Film. However, they also assessed that the concept would increase their workload.

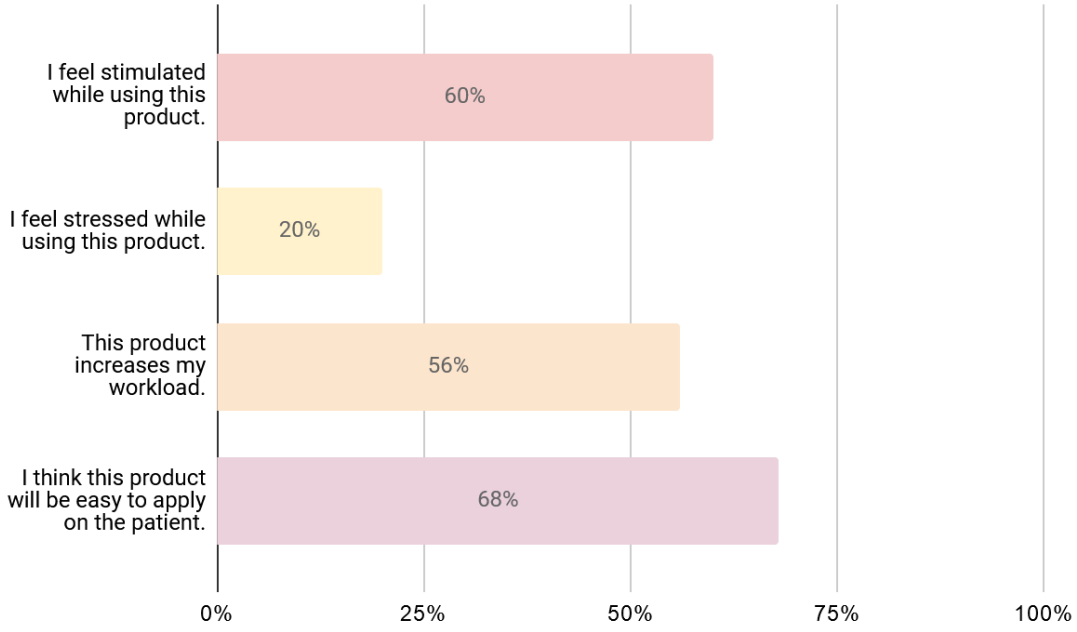


Figure 20. Product pleasurability of Envelope 2

7.4.3. Envelope 3

The evaluation of concept refinement two reinforced that the new application layer was very appreciated among HCPs. They expressed that the foam made the dressing easier to handle and facilitated the application of several dressings without overlapping. In addition, the HCPs experienced that the foam and its division in the middle were beneficial since it decreased the fold and wrinkles that often appear when applying the existing Mepitel Film. As the participants had learnt from the previous envelope how to apply the dressing, the interaction with concept refinement two was experienced as easier. HCPs expressed that *"now I see how it works, the foam actually helps"*, which confirmed the importance of including instructions.

Some of the HCPs considered the *butterfly* as the most optimal shape since it ensured good coverage of the breast. However, other participants expressed that they instead preferred a big sheet to cover the entire breast. One of them had doubts about the joint of the *butterfly* that could fall on the nipple and wondered if that would affect the protection of that fragile area. The *wedge* was appreciated since it was tailored for protecting under the breasts as well as that the shape was smaller than the butterfly and might therefore be a cheaper alternative. Similar opinions were expressed regarding the *banana* and it was appreciated that the shape could be applied to several places on the body.

The HCPs preferred that the dressings were provided in the new shapes and required fewer modifications since it would save time for them. They argued that if the size of the shapes does not fit the patients, they could easily modify it. Some HCPs suggested that the dressing could be provided in kits with various shapes in each box or as a box solely containing one shape. Nevertheless, all participants expressed that some shapes would probably be used more often than others, requiring different amounts of each shape.

The results of the digital survey (Figure 21) showed that concept refinement two evoked positive feelings such as liking, surprise and confidence. Those feelings were the same ones experienced with the previous envelope. Still, in similarity with Envelope 2, the HCPs experienced a low level of disappointment, irritation and worry.

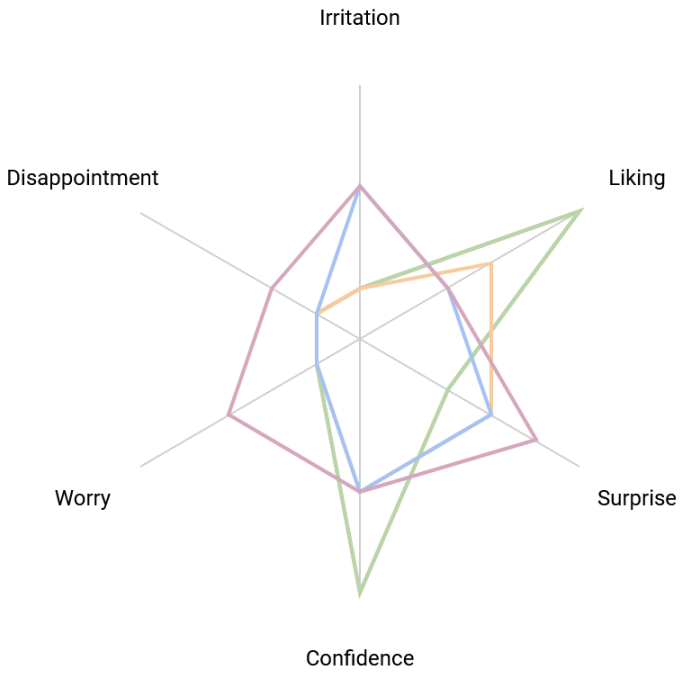


Figure 21. Radar chart of Envelope 3 evoked feelings

The assessment of product pleasurability (Figure 22) demonstrated that the participants felt the same level of stimulation as the previous envelope. Additionally, the ease of application was considered to be similar to Envelope 2. However, the participants felt more stressed during interaction with this concept. On the other hand, it was considered not to increase their workload as much as the concept of Envelope 2.

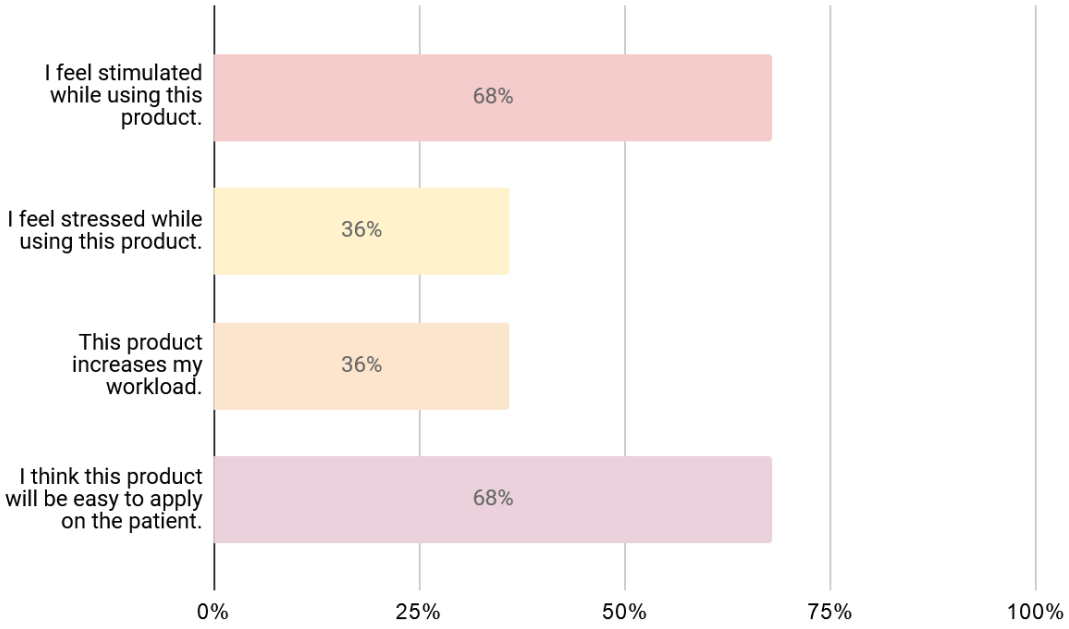


Figure 22. Product pleasurability of Envelope 3

8

Final solution

In this chapter, the final solution is presented. It consists of three parts: the product, the application instructions and the awareness plan. Together the three parts complement each other, forming a system that creates a comprehensive final solution (Figure 23).

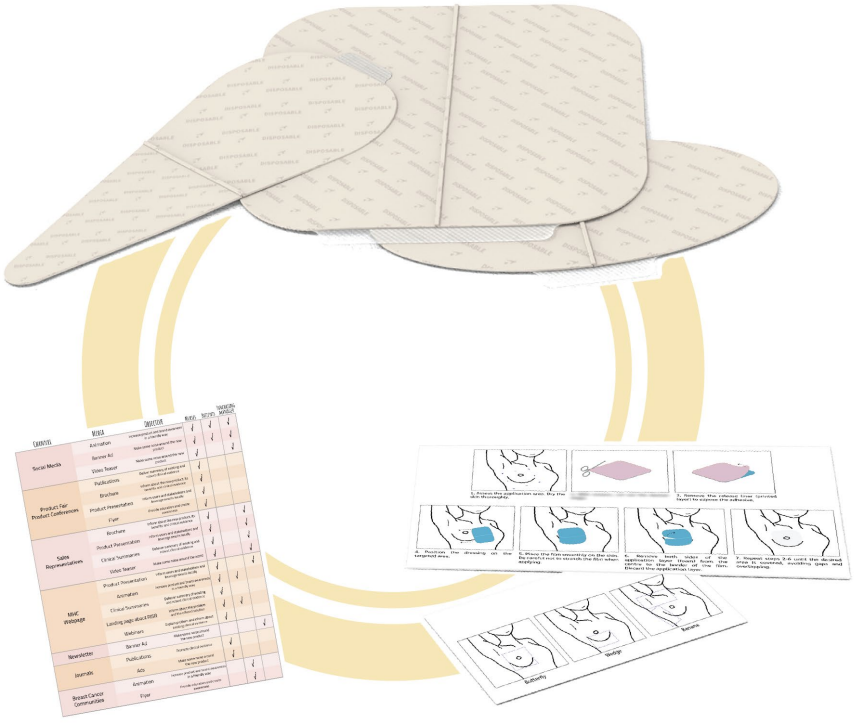


Figure 23. Final solution system

8.1. The product

The product consists of a three-layer dressing composed of a release liner, Mepitel Film and a disposable application layer (Figure 24). The dressing is provided in three shapes: *butterfly, wedge* and *banana.* The shapes are designed and tailored for various body parts, facilitating the coverage.

Figure 24. The application layer

The release liner features a solution that supports the user to modify the dressing to various sizes according to the patient's needs. In addition, it has a tab to facilitate the removal of the liner from the film. After removal of the release liner, the remaining layers of the dressing are applied to the body.

Once the dressing is applied and positioned in a satisfactory way, the application layer is removed. This layer consists of a thin foam that ensures good conformability and facilitates an application without folds and wrinkles. The application layer is split in half and overlaps in the middle helping the user to remove it exposing Mepitel Film. After removal, the foam should be thrown away. A warning printed in its surface stresses to the user that the layer is disposable and needs to be discarded.

Furthermore, each shape comes in its own box to provide the users with the option of purchasing those shapes that they prefer. Although the three designed shapes complement each other, the individual boxes give the HCPs freedom to work with the shapes they want without wasting those shapes they do not appreciate.

8.2. The application instructions

During the evaluation of the concept refinements, the application instructions were confirmed as crucial in order to understand how the product works. Therefore, this part of the final solution is essential to the designed system and supports the HCPs during their interaction with the product.

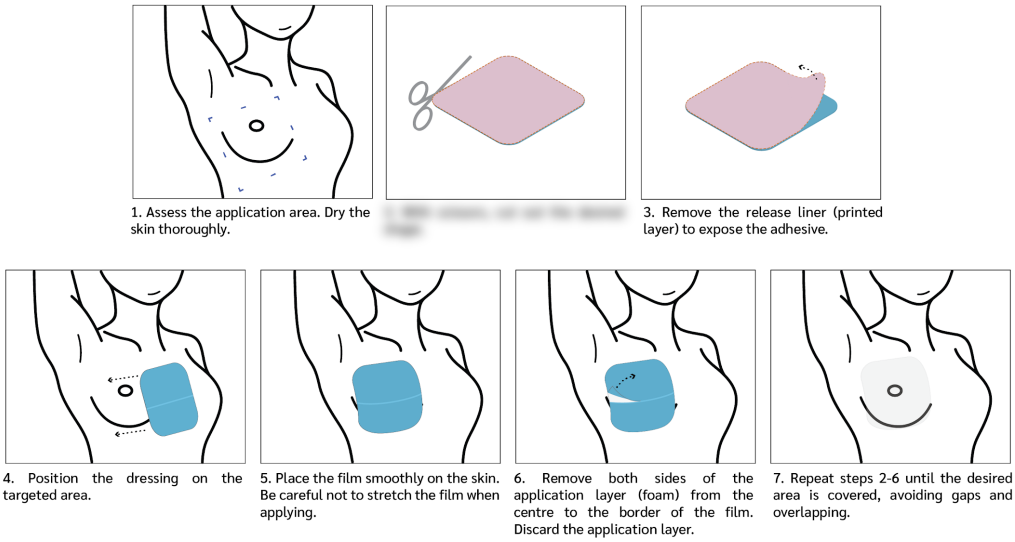


Figure 25. The application instructions

The application instructions in Figure 25 represent the step-by-step guide to applying the product. The use of text and illustrations aid the correct understanding of the solution. The sequence of the instructions described below:

1. Assess the application area. Dry the skin thoroughly.
2. *Omitted information*
3. Remove the release liner (printed layer) to expose the adhesive.
4. Position the dressing on the targeted area.
5. Place the film smoothly on the skin. Be careful not to stretch the film when applying.
6. Remove both sides of the application layer (foam) from the centre to the border of the film. Discard the application layer.
7. Repeat steps 2-7 until the desired area is covered, avoiding gaps and overlapping.

Following these instructions, the prototype of the final solution was applied on the realistic breast chest mannequin in order to test it in a more realistic breast shape and texture. Figure 26 shows the main steps of the application.

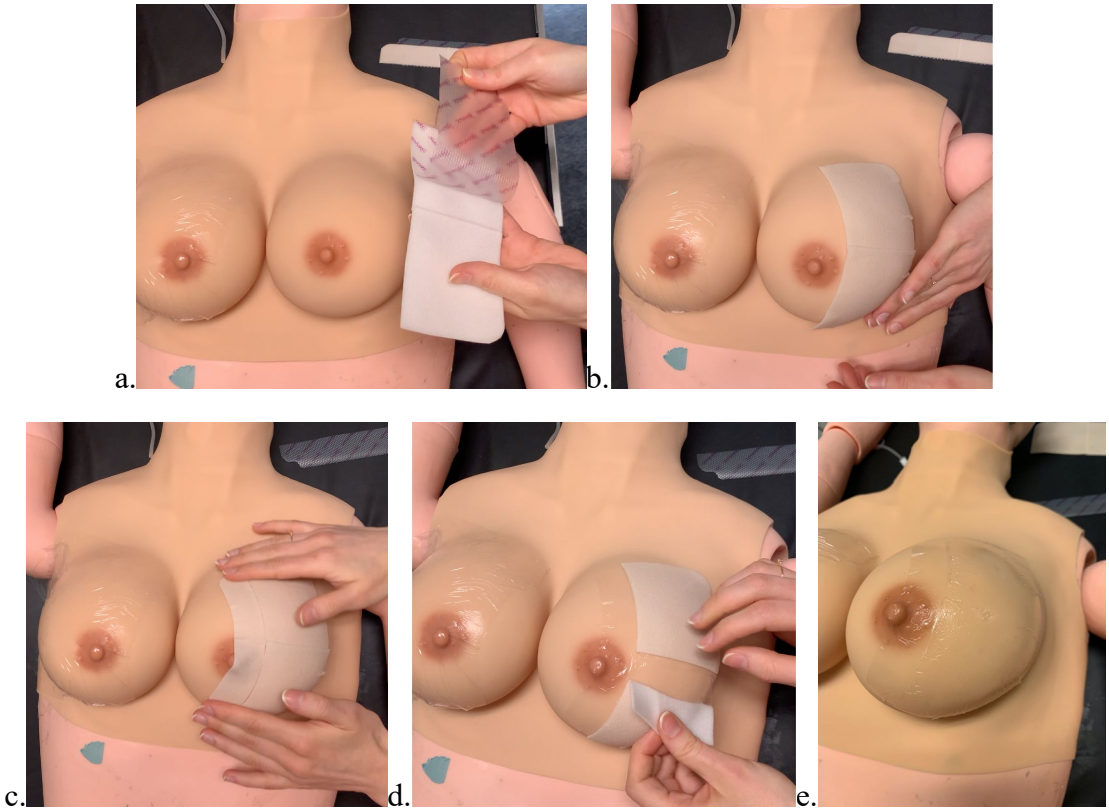


Figure 26. Application of final solution to the realistic mannequin. a. Removal of the release liner, b. application on the breast, c. placement of shapes edge by edge to cover a bigger area, d. Removal of the application layer, e. The final result of applied Mepitel Film.

To complement the application instructions, an application guide with placement suggestions was designed (Figure 27). The guide highlights the suggested designated areas for each shape, helping HCPs to understand the purpose of each shape.

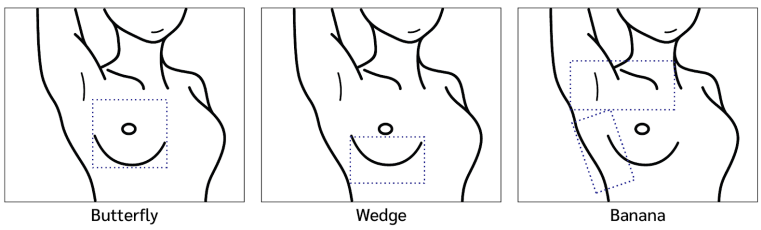


Figure 27. Application guide

8.3. The awareness plan

A communication plan was created to increase awareness about the product and RISR. The plan aims to provide an overview of which channels, media and communicated messages should be used to reach the three target groups: nurses, patients and purchasing managers.

The communicated message is tailored for each target group to ensure effective content that impacts and is of interest for each of them, ensuring that they are reached effectively. Table 15 shows which message should be communicated to each group.

Table 15. Communicated message for each target group

	Nurses	Patients	Purchasing Manager
Communicated Message	Introduce the problem	RISR is a common side effect that inhibit the well-being and takes focus from winning the cancer	The cost benefits with the product
	RISR may affect the course of the treatment		
	RISR impacts the patients' well-being	Should not have to focus on RISR during this challenging and emotional period in life	How the product will save resources in time, material and personnel
	The benefits with the product		

Several channels and media can be used to communicate these messages. As the three target groups are present in various contexts and use different kinds of channels, a unique mix of these is tailored to ensure that the message will be communicated in an effective way and that the awareness of the product increases. The awareness plan is presented in Table 16.

Table 16. Detailed awareness plan

Channel	Media	Objective	Nurses	Patients	Purchasing Manager
Social Media	Animation	Increase product and brand awarness in a friendly way	√	√	√
	Banner Ad	Make some noise around the new product	√	√	√
	Video Teaser	Make some noise around the new product	√		√
Product Fair Product Conferences	Publications	Deliver summary of existing and robust clinical evidence	√		
	Brochure	Inform about the new product, its benefits and clinical evidence	√		
	Product Presentation	Inform users and stakeholders and leverage results locally	√		
	Flyer	Provide education and create awareness	√		
Sales Representatives	Brochure	Inform about the new product, its benefits and clinical evidence	√		√
	Product Presentation	Inform users and stakeholders and leverage results locally	√		√
	Clinical Summaries	Deliever summary of existing and robust clinical evidence	√		√
	Video Teaser	Make some noise around the world	√		√
MHC Webpage	Product Presentation	Inform users and stakeholders and leverage results locally	√		√
	Animation	Increase product and brand awareness in a friendly way	√	√	
	Clinical Summaries	Deliever summary of existing and robust clinical evidence	√		
	Landing page about RISR	Inform about the problem and the offered solution	√	√	
	Webinars	Explain problem and inform about existing clinical evidence	√		
Newsletter	Banner Ad	Make some noise around the new product			√
Journals	Publications	Promote clinical evidence	√		
	Ads	Make some noise around the new product	√		
Breast Cancer Communities	Animation	Increase product and brand awareness in a friendly way		√	
	Flyer	Provide education and create awareness		√	

9

Discussion

In this chapter, the findings of the project are discussed. It includes thoughts and motivations on the methodology and actions taken throughout the study. In addition, it covers proposals for further investigations regarding the process and the product.

9.1. The process

RISR may be a devastating consequence of radiotherapy treatment. The prevention of these is, therefore, considered crucial in order not to inhibit the cancer treatment or the patient's quality of life. Through co-creation, the users contributed to a deeper knowledge about the prevention of RISR and the usage of Mepitel Film in the radiotherapy context.

The double diamond design process was an appropriate process to follow. It enabled the study to diverge and open up without limitations and converge by narrowing and condensing the findings. In addition, the study consisted of two phases which the double diamond process represented well. The iterations between the phases as well as between the activities within each phase were crucial in order to handle the data and knowledge that were continuously gained throughout the process.

The theoretical framework used during the study sustained an essential understanding of the radiotherapy procedure, RISR and an overview of other preventive products. This part of the study was fundamental for further activities since it facilitated understanding the users' language, medical terms and their experiences. Moreover, the pre-study was an important step of phase one since it also contributed to a better understanding of cancer treatment and the usage of Mepitel Film, which in turn facilitated further activities.

On the other hand, it was not possible to conduct the scheduled observations of HCPs due to COVID-19. Observations would have been beneficial to receive a deeper understanding of how the HCPs work and prevent RISR in their daily work, as well as to provide a better insight into the context of the product usage. Instead, HCPs explained in interviews and during the workshops how they interact with various products, their procedures and their work environment. Although the HCPs explanations were very detailed, there is a risk that some critical behaviours or routines were not sufficiently described, which may be important factors to investigate further. Thus, the lack of observations might have affected the outcome of the study.

9.2. Participants

As interaction with users was present during most parts of the project, it was crucial to have a good representation from the two identified user groups. Overall, the number of participants invited to participate in the project was satisfactory, with representatives from different countries and with different backgrounds. This mix provided a holistic view of the problem, embracing their distinct perspectives.

In the last sections of the idea generation workshops with HCPs, the information level reached its peak, and there was too little to be absorbed from the participants. This confirmed that the sample of participants was enough for achieving a good knowledge level. However, broadening even more the representation, including HCPs from other countries, might have been beneficial for the project. Potentially, this might have resulted in a wider perspective of the problems and provided a deeper knowledge to this research.

From the two identified user groups, the HCPs were more present throughout the project. This choice was made because they are the users of the product in the application phase, which was the focal point of the project. Nevertheless, contact with patients at the beginning of the project was essential to understand their experiences and perspective towards the problem. It would have been interesting, though, to have reconnected with them in the evaluation phase, also to hear their ideas and feedback about the developed concepts since they are the ones who wear them.

Besides HCPs and patients, interviews with purchasing managers at the beginning of the process could have added more comprehension about how the decisions are made inside the hospitals and cancer centres. Purchasing managers have an important role in the decision of which products will be purchased. Thus, their know-how would enrich the final solution system, especially in the development of the awareness plan. However, this fact was only identified after the user research was conducted and the lack of awareness was highlighted. Thus, further investigation with such professionals is advised in future research on the product before launching it.

9.3. Co-creation

The choice of utilising a co-creation approach in a project that involves a medical solution is beneficial because the users have a lot of valuable and specific knowledge that is needed for developing such products. This approach deeply involves the users in the design process, minimising the risk of developing a solution that does not meet the established requirements. However, the co-creation activities and which participants to include the need to be planned consciously. For instance, when conducting a digital workshop that requires interaction between all parties, it is easier to mediate the room when fewer people are involved. For this reason, the workshops were developed to be attended by a maximum of four participants.

HCPs were included in different ways during the two phases of the study. The first phase focused on understanding the topic and how it is being handled today. Thus, HCPs were individually interviewed, which ensured that as many professionals as possible could be reached, and in turn, more knowledge could be gained. The second phase aimed at idea generation, so the digital workshops required a group of participants to be assembled to fulfil the goals of the activity adequately.

Co-creation, by its definition, presupposes a higher level of communication and contact among participants. However, in times of the COVID-19 pandemic, the method had to be adapted to the digital environment. On the one hand, it allowed people from different countries to be part of the workshops, enriching the findings and broadening the perspectives about the topic. Reaching out to participants from different cultures, each following a distinct guideline, ensures that the product suits a broader range of the market. On the other hand, the lack of physical workshops hinders the human contact of the activities. For instance, it is harder to perceive body language, sense the mood of the room or encourage informal chatting. If the workshops had been physical, participants might have been more open and dare to talk more freely, which might have provided the study with deeper insights and more implicit knowledge.

Nonetheless, all co-creation activities conducted during this study can be described as successful. For the first stages of the user research, the digital tools Zoom and Miro were very helpful to increase the interactions between the participants and designers during the activities. The act of asking the participants to interact with the screen in fairly simple activities, such as marking the preferred options on the screen, allowed them to feel more integrated into the workshop. Consequently, these interactive activities motivated the participants to feel comfortable discussing with the other parties, creating a feeling that resembled an in-person meeting.

For the evaluation workshops, a creative way to engage the participants had to be designed. Hence, evaluation kits were sent out to the participants and a dynamic workshop was developed. As the packages arrived at them, filled with mysterious envelopes and a handful of candies, curiosity and excitement were engaged. These two feelings were confirmed during the workshops as the participants were eager to know the content of each envelope. The increased level of engagement of the participants is vital to intrigue their participation. Together with the excitement of opening the envelopes, blowing up the balloons to simulate a breast yielded good laughs, helped with the flow of the workshop and lit up the mood of the digital room.

9.4. Evaluation

During the evaluation phase, the concept refinements were investigated with HCPs. Although the evaluation of the concept refinements was fruitful for developing the final solution, they were not evaluated in an authentic radiotherapy context. This displacement and the use of balloons as breasts simulations might have impacted the result. The choice of coherent breast simulation solutions was a challenge since the beginning of the project. Throughout the study, it was hard to find appropriate shapes that represented a realistic breast. Although different solutions were used to simulate a breast, none of them genuinely represented all kinds of breast shapes.

Moreover, further work should focus on evaluating the usage of the final solution in a real context in order to assess its feasibility. However, the final solution features the current technology of Mepitel Film and has focused on improvements for application and awareness. Thus, it is considered to have a significant potential to be feasible in a real context.

9.5. Launching the product

Participants and HCPs from various countries were included in the study. Although their treatment procedures and experiences were very similar, there were some differences in their experiences regarding RISR. The investigated patients and HCPs from Brazil had less experience with RISR than those from Europe. According to the collected data, patients from Europe seem to present more severe RISR than patients from Brazil. Nevertheless, the sample of participants in this study is too small to make compelling conclusions regarding significant differences between countries. However, it would be valuable to investigate further these differences regarding RISR between countries in order to assess if it is worth launching the final solution outside Europe.

Furthermore, launching the product in countries where people sweat more should be carefully considered since Mepitel Film does not adhere sufficiently well to wet skin. This contradicts one of the main advantages of Mepitel Film, that it stays on the body for several days. However, poor adherence due to sweat results in a higher frequency of dressing changes, increasing the material usage and the HCPs' workload. Countries that have a warmer climate and where people sweat more may therefore not be the target countries for launching the final concept.

Another factor that needs to be considered before launching the product is the impact of technological developments. A connection between the kinds of machines used in hospitals and the presence of severe skin reactions was found during the research. With more precise machines, the occurrence of severe skin reactions tends to be reduced over the years. A continuous improvement of the final solution needs to be done over time in order to meet the development of machines and treatment procedures. Thus, the product goal regarding technological development may be an essential factor to consider if the product would sustain competitiveness and effectiveness in the future.

9.6. Economic, societal and ecological aspects

The final solution encompasses a conscious solution that improves economic, societal and ecological aspects. Societal and economic aspects are, for instance, improved by the reduction of application time. The final solution requires less modifications and features a new layer that facilitates the application procedure. The decreased application time might be beneficial for both HCPs and patients. For the HCPs, workload and time spent for each patient are decreased, resulting in more effective work procedures. Whilst for the patients, the time spent in the uncomfortable position required during application is reduced. Thus, a reduction in application time might contribute to a more pleasurable application experience for both HCPs and patients, resulting in improved economic and societal aspects.

Moreover, ecological and economic aspects are also improved. Mepitel Film is a disposable and non-reusable product, and the final solution still adopts these aspects since medical products have high levels of hygienic requirements. However, providing a solution in three predefined shapes results in less material waste. HCPs would not have to make large modifications to the product, avoiding leftover material. This feature is combined with the Mepitel Film's already existing good adherence. The film stays on the body for a longer time than other similar products (Mölnlycke Health Care, 2019), resulting in fewer dressing changes, optimising the material usage. Consequently, it contributes to a more sustainable product that has the potential to reduce expenditure.

Overall, the designed solution is a preventive measure that intends to reduce RISR whilst accurately fulfilling the users' needs. Provided that the solution would be more widely used, the prevention of RISR could increase. A prevention approach could also decrease the workload of HCPs since the occurrence of severe reactions is significantly reduced, resulting in fewer costs with medicine and management dressings (Herst et al., 2014; Morgan, 2014). In addition, prevention may preserve patients from this painful and uncomfortable side effect of radiotherapy. Thus, the final solution has the potential to reduce costs, increase patient's well-being and create value for both user groups.

10

Conclusion

This study investigates how MHC's product Mepitel Film is used in breast cancer radiotherapy and suggests a final solution that has the potential to improve the users' interaction with the product. Although the product has clinical evidence for its efficacy to prevent RISR in breast cancer radiotherapy, the usage of Mepitel Film was limited. The main issues with the existing Mepitel Film were the challenging application procedure as well as the lack of awareness about its benefits.

The final solution was developed through a co-creation approach and consists of a three-part system: the product, application instructions and awareness plan. The main changes were to ease application and raise awareness of the product to increase global adoption. The combination of proposed improvements creates a solution that facilitates the prevention of RISR with Mepitel Film responding to the users' needs more accurately. Thus, the final solution may have the potential to be adopted by more cancer centres and create value for more patients worldwide.

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Appendix

Appendix A - Table of available preventive products in the market

Product Category	Description	Product examples	Advantage	Disadvantage
Washing Practice	Washing the skin gently with mild soap and water.	Dove, Ivory	- According to patients, washing of the irradiated skin is important for their well-being	- Inconsistent evidence between studies
Steroidal topical agents	Topical steroids are the topical forms of corticosteroids with anti-inflammatory actions, and it suppresses the immune response.	Corticosteroids	- Reduce skin reactions	- Insufficient evidence
Non-steroidal topical agent	A topical treatment that contains a non-steroidal anti-inflammatory agent.	Aloe vera, aqueous cream, calendula ointment, Biafine cream, hyaluronidase-based cream, sucralfate, sucralfate derivatives, urea lotion		- Majority of topical agents showed to be ineffective for reduction of incidence or severity of RISR - Inconsistent evidence for being effective in the prophylactic treatment
Systemic interventions	Oral or intravenous substances that act in various modes in the body	Amifostine, oral enzymes, pentoxifylline, supplements		- Lack of evidence
Barrier forming dressings	Offer a protective layer on the skin. The thin layer is often transparent and self-adhesive.	Mepitel Film, Cavilon, StrataXRT, Hydrofilm, silver-leaf nylon	- Decrease skin reaction severity - Protects the skin for several days	- Patients may present intolerance for the product - Limitations in studies - large

				variety of products investigated - Limited positive outcomes presented in some studies
Photobiomodulation therapy (PBMT)	Application of infrared light into the skin in order to stimulate the natural healing process of the skin.	Low-level laser therapy, light-emitting diodes (LED)	- Has been recognised in other areas of radiotherapy toxicity	- Lack of research on long-term effects.

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