Master Thesis Industrial Design Engineering

BEYOND THE POUCH: CO-DESIGNING A TEMPORARY POUCH-FREE SOLUTION WITH INTESTINAL OSTOMATES

A mixed-methods study mapping the needs, wishes, and lived experiences of intestinal ostomates

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Abstract

Despite significant innovation in pouch-based systems, many ostomates report ongoing physical, psychological, and social challenges that impact quality of life. Therefore, this thesis explores the feasibility of temporary pouch-free periods. These pouch-free periods are defined as controlled intervals during which individuals with an intestinal stoma, manage waste output without continuous use of a pouch. Pouch-free periods are not intended to replace traditional pouching systems, but rather aims to offer greater flexibility and autonomy in context based situations. To investigate this under explored topic, a mixed-methods approach is employed, combining a literature review, a questionnaire, and co-design sessions. Through this method, key user needs and requirements are discovered, validated and built upon. The outcomes are used in the development of an early-stage product concept. Furthermore, the results underscore the value of user involvement in the development of medical devices and highlight the potential of pouch-free options to complement existing care. This research contributes to the growing field of human-centred design in healthcare by proposing future-oriented directions in ostomy innovation not bounded by typical pouch use.

Acknowledgments

This thesis marks the culmination of my master's study, and would not have been possible without the support, guidance and contributions of many individuals.

First and foremost, I would like to express my sincere gratitude to my supervisors, ir. Hanneke Reuvekamp and dr. Dave Matthews. Their guidance and constructive feedback helped tremendously in keeping a red thread throughout this thesis.

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To all of you, thank you.

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Chapter 1: Introduction

The introduction chapter begins by providing background information on living with an ostomy. Furthermore, the problem statement, research objective, scope, research questions, and methodological approach are discussed. To conclude an overview of the thesis structure is provided.

1.1 Overview

The healthcare system's demand for patient-centred care solutions is growing (O'Hare, 2018). Patient-centred care emphasizes care that is respectful of and responsive to individual patient preferences, needs, and values. This approach moves beyond clinical outcomes to prioritize autonomy, emotional well-being, and quality of life. In the context of ostomy care patient-centred principles are essential to ensure care aligns with the realities of lived experience(Fix et al., 2017; Kwame and Petrucka, 2021). Thus highlighting the need of integrating the clinical and personal dimensions. Ostomy surgery is often an life-saving procedure, yet it imposes significant lifestyle adjustments for the individuals who undergo it (Krouse et al., 2009). Throughout this thesis, individuals living with an intestinal bowel stoma will be referred to as ostomates. These adjustments may affect physical health, daily routines, psychological well-being, and social participation (Alenezi et al., 2021;Xi et al., 2022). Currently, approximately 38,000 people live with an ostomy, with 7000 new procedures performed each year (Stomavereniging, 2023), in the Netherlands. For many of these ostomates the adaptation to the stoma does not stop at medical management. It often consists of ongoing navigation of daily life on multiple levels.

Pouching systems are the golden standard in ostomy care (Quigley et al., 2021; Rolfsen et al., 2024). Most ostomates view these medical devices as reliable. While the stoma alters physiology, it is the dependence on an external pouch that often leads to difficulties in daily life. These experiences are highly individual, as some mention being well-adapted to their new life while others express unmet needs or frustrations (Vasiljev et al., 2024). Understanding these diverse experiences, needs, and wishes is key to identifying opportunities for improving ostomy care.

A concept explored in this thesis is that of temporary pouch-free periods. Such a period can be defined as controlled intervals during which ostomates can manage waste output without relying on a pouch. While it is not intended to replace the standard pouching systems, this approach may offer additional options to the current way of using. This area is currently under explored in both research and product development. This highlights an opportunity for further exploration.
To guide this exploration the experiences and needs of ostomates with an intestinal stoma, as well as their perspectives on temporary pouch-free periods are investigated. A mixed-method approach combining a literature review, questionnaire, and co-design workshops is used to identify and map key themes in user experience and inform conceptual design directions. By integrating clinical effectiveness with personal perspectives, this study aims to contribute to more user-informed innovation in ostomy care.

1.2 Context of the Research

The gastrointestinal tract is an internal system responsible for digestion, nutrient absorption, and waste elimination (Tabibian, 2023; Perrin, 2023). Under normal conditions it is enclosed within the body, food enters through the mouth and waste exits through the anus. When this system is disrupted due to disease, injury, or surgical intervention, an artificial opening is created as an alternative route for waste to exist the body (Perrin, 2023; Abdalla et al., 2016; Parini et al., 2023). This procedure is known as an ostomy, in which the artificial opening called a stoma is created on the abdominal wall(Ambe et al., 2018). Although there are different types of ostomies, the focus of this research is on intestinal ostomies, which divert waste from either the small or large intestine. The stoma itself has no muscle control, making the discharge of waste is involuntary. This continuous output requires the use of an ostomy pouch to prevent leakages and protect the skin from waste contact (Gilpin et al., 2024).

Intestinal ostomies are typically divided into ileostomies and colostomies(Gilpin et al., 2024). An ileostomy diverts waste from the small intestine, resulting generally in continuous and liquid output (Babakhanlou et al., 2022; D'Ambrosio et al., 2022). In contrast, a colostomy diverts waste from the large intestine, which tends to produce a firmer and more predictable output (Ambe et al., 2018; Pine et al., 2019). These physiological differences are important to consider, as they influence user needs and design considerations in ostomy care.
Living with a stoma may involve adjustments across physical, psychological, and social domains. These adjustments can include skin irritation, leakage, changes in body image, and reduced

participation in public or physical activities (Ber, 2021; Jeppesen et al., 2022; Lapitan et al., 2024; Kovoor et al., 2023; Xi et al., 2022). Although some ostomates report positive adaptation, others express unmet needs related to autonomy, comfort, and confidence in daily life(Petersén & Carlsson, 2021). While pouch systems remain the golden standard in stoma care and are clinically effective, their continuous use can impact overall well-being (Kang & Choudhary, 2022; Ayaz-Alkaya, 2018). This suggests that standard ostomy care does not reflect the full range of lived experiences (Aibibula et al., 2022; Ayaz-Alkaya, 2018; Yuan et al., 2018). As a result the existing challenges can diminish quality of life for many individuals (Alenezi et al., 2021). Throughout this thesis, the combination of physical, psychological, and social challenges will be referred to collectively as challenges. When the combined impact across these domains is discussed more holistically, the term well-being will be used.

Designing effective solutions for complex healthcare challenges requires a method that prioritizes user involvement from the earliest stages. Such method is co-design, which is part of a participatory design approach. In this method the end-users engage as co-creators in the design process (Mattelmäki, 2008). By doing so co-design allows for a deeper understanding of user needs and challenges, this is possible because participants are positioned as contributors who shape design outcomes with their lived experiences(Liem & Sanders, 2011). In the context of ostomy care, co-design is valuable as ostomates get the chance to directly influence the design of a product that impacts their daily lives (Masterson et al., 2024).

1.3 Research Rationale, Objective, and Scope

1.3.1 Research Problem

Currently, there is a lot of innovation in ostomy materials, yet the focus is primarily on improving the pouch design and accessories (Gilpin et al., 2024; Virgin-Elliston et al., 2023). Even though these innovations have improved user experience, they still remain within the paradigm of continuous pouch use. A potential opportunity is identified in the concept of temporary pouch-free periods. A temporary pouch-free period is defined as controlled intervals during which ostomates can manage waste output without relying on a pouch. This concept should not be viewed as a replacement to pouch systems, as not all ostomates seek an alternative to continuous pouch use. It is explored as an additional alternative to help ostomates regain a sense of control, reduce discomfort, or increase the participation in preferred activities. Alternative approaches such as these pouch-free concepts are beginning to surface for both colostomates and ileostomates (Barbosa et al., 2024). Nonetheless, the ones that exist often face limitations in usability, market readiness or user acceptance.

This thesis positions the research problem within the lack of diverse and user informed alternatives in ostomy care. These existing developments are ongoing, yet there is limited publicly available evidence that these processes have integrated the lived experiences, preferences, and expectations of ostomates. How ostomates perceive the idea of temporary pouch-free periods is unclear. Moreover, there is a lack of information about the needs and concerns associated with such periods and how lived experiences of ostomates can inform the design requirements. Another aspect not widely reported is the technical and medical feasibility of such periods. These concept remain underexamined in both academic research and participatory design practice. This absence of user-informed research highlights a significant gap in ostomy care beyond pouch-based systems.

1.3.3 Research Aim and Objectives

The aim of this thesis is to investigate the potential of temporary pouch-free periods for intestinal ostomies by identifying the medical, technical, and human-centred design considerations. Addressing this also requires broader insights into the lived experiences of ostomates. Thus, the research will also focus on mapping the broader needs, preferences, and challenges faced. While the development of a finalized pouch-free design is not the goal, the study will explore conceptual designs in support of future innovations in ostomy care. With the exploration of an user-informed alternative, this thesis contributes to shifting ostomy care beyond the pouch.

The following research objectives guide the achievement of this aim
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- **Collect and analyse quantitative and qualitative data** on the experiences, needs, and wishes of ostomates through an online questionnaire and co-design workshops.
- **Identify medical, technical, and material considerations** of temporary pouch-free periods through a literature review.
- **Facilitate co-design workshops** in which ostomates co-develop and evaluate early product ideas.
- **Synthesize the findings** into a set of design requirements and user-need maps.
- **Develop and communicate a conceptual design** direction that support temporary pouch-free periods to inform future innovations

1.3.4 Research Scope

This study focuses on finding out whether temporary pouch-free periods could work for people with ileostomies and colostomies, despite their physical differences. By focusing on intestinal ostomies, this research aims to better understand the specific challenges involved in managing digestive waste (Corona & Adams, 2022; Corona & Adams, 2024).
Urostomies, which redirect urine, are not part of this research. They involve different issues, both technically and medically (Rachid et al., 2020). Including urostomies would make the study too broad.

The thesis focuses on understanding what ostomates experience and need, while also exploring how temporary pouch-free solutions could function in this context. This results in guidelines and conceptual directions, rather than a tangible working prototype. Setting this scope allows for in-depth exploration of the experiences of intestinal ostomates. It provides a foundation for future research and design with the potential to improve quality of life through alternatives to continuous pouch use.

1.4 Research Questions

This thesis explores the potential of temporary pouch-free periods for intestinal ostomates. This is done through a combination of methods, leading to the main research question below.

MAIN RESEARCH QUESTION

What are the key needs and expectations of intestinal ostomates regarding temporary ostomy pouch-free periods, and what medical and technical considerations are relevant to addressing these needs?

In parallel the following design challenge is formulated to guide the conceptual design process.

MAIN DESIGN CHALLENGE

Develop a conceptual product solution that aligns with the key needs and expectations of intestinal ostomates, enabling temporary pouch-free periods.

To address the main research question and design challenge, this research reviews existing literature to examine challenges faced by ostomates. Besides this, it looks at how these challenges are represented in existing research and product development. Furthermore, the medical and technical considerations of temporary pouch-free periods are explored. As well as the role of emerging materials and technologies. These inform the first sub-questions:

A. What challenges do ostomates face in current pouch-based care, and how are these reflected in product solutions?
B. What medical and technical considerations are relevant to the feasibility and safety of temporary pouch-free periods?
C. What emerging materials or technologies could support the development of pouch-free solutions?

Sub-question A is partially answered through the literature review but further built upon through a questionnaire and co-design sessions. This combined approach enhances the academic insights with lived user experiences.

The aim was to understand the lived experiences of ostomates, building on the challenges discovered by the literature review. Alongside the experience, the current needs and preferences regarding ostomy care and their perspectives on temporary pouch-free periods are explored from an user perspective. These insights inform the mapping of experiences, needs, and preferences, and guide the co-creation and early development of concepts. The following sub questions are answered:

D. What are the key needs and wishes of ostomates regarding ostomy care?
E. How do ostomates perceive and experience the idea of a temporary pouch-free period?

The findings will be synthesized into design criteria and user needs based on the previous co-created design directions. The synthesis will help in exploring what would be required for the practical implementation of pouch-free period in future care. This leads to the final sub-question:

F. What design and user requirements must be considered to support the potential implementation of temporary pouch-free periods in ostomy care?

1.5 Methodological Approach

This thesis follows a mixed-method approach, combining a literature review, a questionnaire, and co-design sessions(Creswell & Creswell, 2017). First, a literature review is conducted to gain insights into ostomy care, and ostomy materials. This is followed by a questionnaire with both quantitative and qualitative questions to explore the experiences, needs, and preferences of ostomates. Following this, co-design sessions are conducted to validate earlier findings, uncover lived experiences, and collaboratively explore potential design directions. Each method informed the following phase to gain a deeper understanding of the experiences of ostomates. This research design captures both broad statistical trends, as well as in depth user insights. Triangulation is used to enhance the validity and reliability of the results. The data from the literature review, survey, and co-design outcomes are cross verified. This is done to mitigate biases inherent from single-method approaches (Fetters et al., 2013; O'cathain et al., 2016).

Figure 1.6a portrays the methodological overview of this thesis. The overview consists of three consecutive phases. Phase 1 focuses on understanding the broader context of designing for ostomy care through a literature review and a questionnaire. Phase 2 builds on this context through the lived experiences and the collaborative development of early concept directions. Lastly, Phase 3 synthesizes findings into validated user needs and design requirements, and covers the conceptual development of the pouch-free solution. The specific details of each method will be presented within the corresponding chapters.

This study was approved by the Ethical Committee of the University of Twente (reference number: 240750), and all participants gave informed consent. For a full description of the ethical procedures and data handling, see Appendix A1.

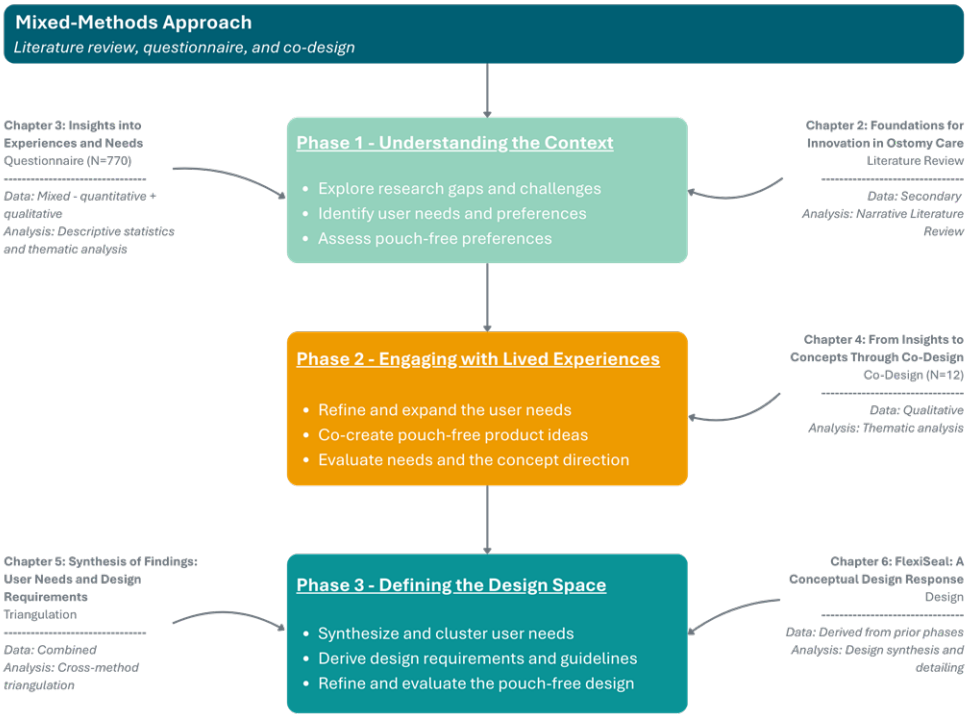


Figure 1.6a Methodological overview of this thesis

1.6 Thesis Structure

CHAPTER 1: INTRODUCTION
The introduction sets the stage for this research, providing the context, motivation, and relevance of the study. It introduces the problem, research objectives, scope, and research questions. The methodological overview is also discussed, along with an outline of the thesis structure.

CHAPTER 2: FOUNDATIONS FOR INNOVATION IN OSTOMY CARE
This chapter reviews existing literature on ostomy care, focusing on current challenges, solutions, and innovations. It identifies gaps in knowledge, particularly regarding temporary pouch-free periods, and positions the study within the broader field of healthcare design.

CHAPTER 3: INSIGHTS INTO EXPERIENCES AND NEEDS
This chapter focuses on the questionnaire conducted to gain insights into the needs, challenges, and preferences of ostomates. Regarding general ostomy care and temporary pouch-free periods. This chapter presents the key results and insights and discusses how these inform the co-design workshops.

CHAPTER 4: FROM INSIGHTS TO CONCEPTS THROUGH CO-DESIGN
This chapter outlines the co-design process with ostomates. This includes the session structures, key outcomes, and user insights. It shows how co-design deepened earlier findings and informed the development of concept directions, refined user needs and design requirements.

CHAPTER 5: SYNTHESIS OF FINDINGS: USER NEEDS AND DESIGN REQUIREMENTS
Chapter 5 synthesizes all findings from the mixed method approach. The results from the literature review, questionnaire, and co-design workshops will be interpreted to identify and map key user needs, lived experiences and design requirements. Lastly, the chapter concludes by outlining how these insights inform the following design phase.

CHAPTER 6: FLEXISEAL: A CONCEPTUAL DESIGN RESPONSE
This chapter presents the final conceptual design. It will cover design guidelines, the design process, and feedback integration. Further on, the technical aspects of the design will be discussed and the use scenario's will be explained. Lastly, the concept is evaluated against the design requirements.

CHAPTER 7: DISCUSSION AND CONCLUSION
This chapter discusses the research findings, it highlights broader implications for ostomy care, and reflects on methodological and conceptual limitations. It concludes by revisiting the research objectives and questions, and considers the significance of co-designed approaches in advancing pouch-free innovation. A preview of key recommendations is included, with a full set presented in Chapter 8.

CHAPTER 8: RECOMMENDATIONS
The final chapter offers key recommendations for ostomy device innovation, with a specific focus on pouch-free solutions. In addition, it highlights improvements in general ostomy care. The recommendations address user needs, clinical safety, and opportunities for innovation and support in daily life.

Chapter 2: Foundations for Innovation in Ostomy Care

This chapter begins with an overview of ostomy care, including basic anatomy, ostomy types, challenges experienced by ostomates, and opportunities in ostomy care. Existing pouching systems and their limitations are reviewed, followed by emerging innovations in the field. Lastly, this chapter introduces the medical and technical considerations that inform the design of pouch-free solutions. Within this chapter the focus is on answering the following sub questions: What challenges do ostomates face in current pouch-based care, and how are these reflected in product solutions, What medical and technical considerations are relevant to the feasibility and safety of temporary pouch-free periods, and What emerging materials or technologies could support the development of pouch-free solutions?

2.1 Methodology

The research process began with a systematic literature review to collect information on ostomy care and materials. A literature review is not only a summary of existing knowledge, but also a systematic means to identify current knowledge gaps in the current state of research (Snyder, 2019). This literature review lays the foundation for the study by identifying key challenges and knowledge gaps in ostomy care, particularly regarding pouch-free periods. These insights informed the questionnaire design and guided the overall research direction. Besides this it also contributes to methodological triangulation, strengthening the study's validity.

2.1.1 Systematic search strategy

Databases searched for articles consisted of Google Scholar, PubMed, and FindUT. FindUT is the academic search engine of the University of Twente. Inclusion criteria were English-language studies from 2015 onward (2015-2025). This time frame is used to ensure that outdated research was not included. Exceptions to this time frame were articles covering subjects which were not outdated, for example Sanders (2008) explaining co-design and for the ostomy devices timeline. The focus of the search was on intestinal ostomies and human-centered outcomes. Over 100 sources are reviewed and synthesized in the literature review. All references were managed with Scribbr.

A combination of keywords such as "ostomy care," "stoma challenges," "ostomy patient experience," "co-design in healthcare," and "ostomy quality of life'' are used for the search.

2.1.2 Analysis approach

Throughout the review notes were taken to summarize what is known, and where contradictions or gaps exist. While the review did not follow a formal PRISMA protocol, it employed a systematic approach by documenting search strategies, databases and inclusion criteria. Recurring themes were identified, and gaps about addressing the challenges from a user perspective in ostomy care became apparent. This review provided a robust foundation for this thesis, aligning with recommendations for flexible yet rigorous literature synthesis (Grant & Booth, 2009).

2.2 Overview of Ostomy Care

2.2.1 Medical Background and Indications

An ostomy is a surgical procedure to create a stoma. The stoma is an artificial opening, in the case of intestinal stomas, on the abdominal wall to reroute bodily waste(Ambe et al., 2018; Choudhary & Kaur, 2020). This surgery is applied when the gastrointestinal tract is compromised because of medical conditions or trauma. The procedure is often life-saving and in the medical context used for conditions such as colorectal cancer, inflammatory bowel disease(IBD), ulcerative colitis, and diverticulitis among others(Carvalho et al., 2015; Hendren et al., 2015). The stoma is in this case an alternative exit point for fecal matter, which is used to bypass the damaged or diseased sections of the gastrointestinal system. This waste matter is then collected with a pouch system for hygiene and comfort purposes(Kang & Choudhary, 2022). The primary aim of this procedure is to preserve life(Choudhary & Kaur, 2020). By restoring the body's ability to eliminate waste effectively survival rates among patients are improved and the quality of life can be significantly increased(Gilpin et al., 2024).

Furthermore, ostomies can be temporary or permanent(Hendren et al., 2015; Ambe et al., 2018). This depends on the medical condition and the prognosis of the patient. When the gastrointestinal tract needs time to heal, a temporary ostomy is chosen. When restorative surgery is not possible a permanent ostomy is required. This can happen when there is extensive tissue damage or

malignancy progression. (Gaćkowska et al., 2021). This differences has influence on the quality of life of patients, and their ability to adapt to the ostomy. To get a better understanding of how ostomies work, a deeper understanding of the gastrointestinal tract is needed.

A crucial aspect of the digestive system of the body is the intestinal tract. Within this tract digestion, nutrient absorption, and waste elimination takes place(Tabibian, 2023; Perrin, 2023). By understanding how this system works, it will become clearer how the different types of stomas can be managed. Within the mouth and stomach, the process of digestion starts. Food is broken down into smaller particles with the help of gastric acids and enzymes. These particles pass into the small intestine, which is responsible for absorbing nutrients, vitamins, and minerals. The absorption of these is essential for the functioning of the body. The ileum, the final part of the small intestine, will transfer the unabsorbed waste to the colon(Corona & Adams, 2022). The colon is another term for the large intestine. At this point in the digestive tract, the waste contains a lot of water.

The primary function of the colon is to reabsorb water and electrolytes. The waste has a more solid form, which is vital for the body to maintain hydration and electrolyte levels. Lastly, the rectum acts as a storage reservoir, before the waste is eliminated through the anus(Corona & Adams, 2024). This is a healthy gastrointestinal system. When something happens to disrupt this system, be it injury or illness, this leads to risks such as bowel obstruction, infection, and nutritional deficiencies(Perrin, 2023). In this case, an ostomy can be chosen to preserve the patient's ability to maintain a relatively normal lifestyle. Because within this tract the sequence can be disrupted at different points, there are different types of ostomies. As this thesis focuses on ileostomies and colostomies, the extent of these will be discussed.

2.2.2 Intestinal Ostomy Types and Stoma Variations

INTESTINAL OSTOMIES

The classification of ostomies is based on their anatomical location and surgical purpose(Ambe et al., 2018). The functional output depends on the location within the digestive tract, when an ostomy is placed higher in the tract the output is more liquid and enzymatic. Whereas when the ostomy is placed lower the output is more formed stool(Gilpin et al., 2024; Hedrick et al. 2023). Figure 2.2.2a shows the common places of stoma placement. The distinction between these type of ostomies makes the care plans highly individualized. This individualization is apparent in the choice of appropriate pouching systems and patient education(Liu et al., 2023). Table 2.2.2a outlines the primary differences between ileostomies and colostomies.

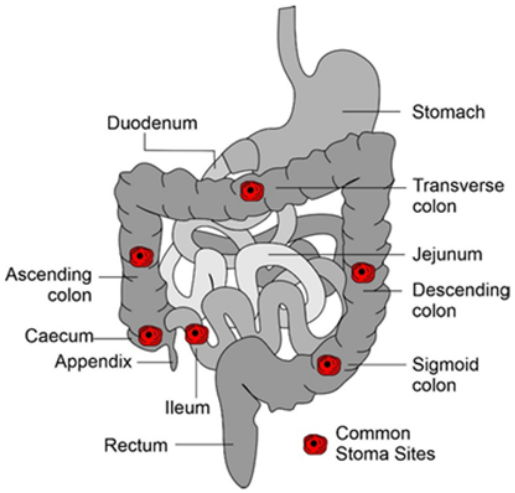


Figure 2.2.2a Common sites of stoma placement (Figure from Gilpin et al., 2024)

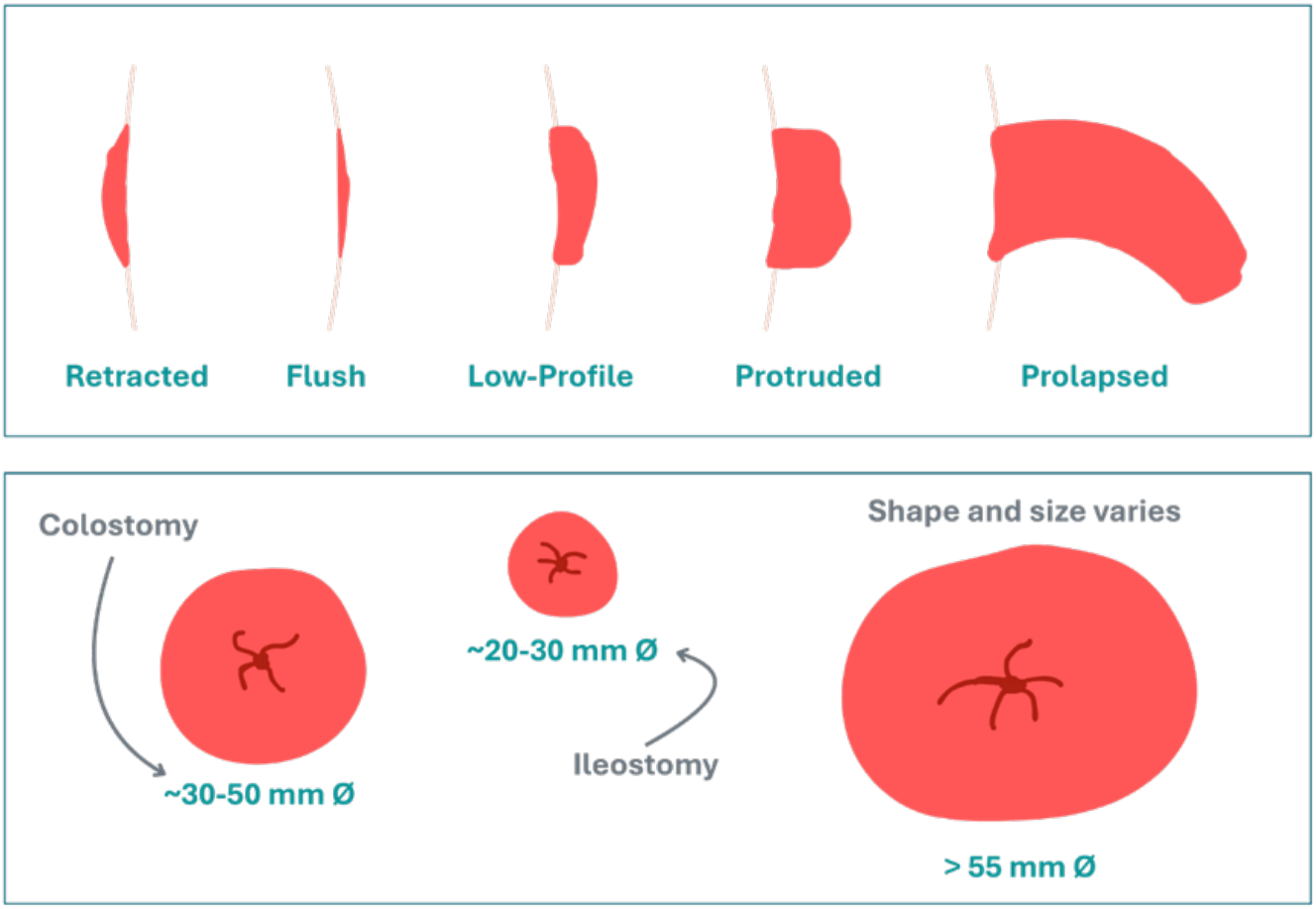
Table 2.2.2a Functional and management differences between ileostomies and colostomies. (Corona, M., & Adams, L., 2022;2024; Santos et al., 2024; Mithany et al., 2023; Hedrick et al. 2023; Gilpin et al., 2024; Ostomy Expanded Version, 2019)

Parameter	Ileostomy	Colostomy
Stoma Location	Ileum (end of small intestine)	Colon (ascending, transverse, descending, or sigmoid)
Output Consistency	Liquid, enzymatic, continuous	Liquid (ascending) to solid (descending/sigmoid)
Daily Output Volume	500–1000 mL (normal); >1500 mL = high-output	200–700 mL (descending/sigmoid); varies widely
Emptying Frequency	Multiple times per day	Typically once per day (per 24 hours)
Skin Protection	High need; frequent leaks and irritation due to enzymatic output	Moderate to low; varies with stool form and pouch fit
Device Needs	Drainable, high-capacity, secure seal	Filtered, typically closed-end; irrigation (sigmoid colostomates)
Typical Challenges	Leakage, skin irritation, active stoma, short wear time, high-output risk	Pancaking, ballooning, gas management, odor concerns

STOMA VARIATIONS

A stoma bud's appearance depends on the surgical technique, segment of the intestine used, and individual patient factors. The stoma bud is the part of the stoma that protrudes from the skin. A well-functioning stoma is typically slightly protruded above the skin's surface. This facilitates proper pouch adhesion, leading to reduced leakage and fewer peristomal skin complications. Stoma height plays an important role in preventing complications. A mature Ileostomy should ideally protrude 2-2.5 centimeters, whereas a mature colostomy should protrude 1-1.5 centimeters. In addition to height, stoma size and shape vary widely, ranging typically from ~20 mm to over 55 mm in diameter (Stomavereniging, 2023b). Notably, stomas are dynamic structures that can change in size and shape over time, especially, in the weeks following the surgery(Parini et al., 2023). Figure 2.2.2b illustrates the diversity in stoma protrusion height (top panel) and diameter and shape (bottom panel). The figure portrays typical diameter and shape ranges for an ileostomy and colostomy, however is important to note that what is considered typical or normal is individual. Irregular or asymmetric stomas are especially difficult to manage with standardized products. These anatomical differences influence appliance fit, sealing success, and risk of leakage(Krogsgaard et al., 2023). Understanding these variations is essential for individualized ostomy care.

Figure 2.2.2b Variation in stoma protrusion, diameter, and shape. (Cronin, 2023; Corona & Adams, 2022; Krishnamurty et al., 2017; Maeda, 2022)



2.2.3 Pouch Systems

The most commonly used management system for stomas is a pouch system, sometimes also called an appliance. These systems are designed to collect waste from the stoma and protect the surrounding skin from irritation(Gilpin et al., 2024; Calara et al., 2017). Besides this, the pouch systems provide comfort and discretion for ostomates. The correct management of a stoma relies heavily on the proper selection and use of a pouching system. Because this care and selection is highly personalized, Wound, Ostomy, and Continence (WOC) nurses often assess individual patient needs and provide tailored recommendations. This section will cover the basics of pouching systems.

A critical component of a pouching system is a skin barrier, also referred to as a baseplate or wafer. The baseplate is an adhesive layer, which forms the critical interface between the stoma and the collection pouch(Vestergaard et al., 2024). It adheres directly to the skin around the stoma. This creates a seal to protect the peristomal skin from enzymatic or microbial waste output. Different materials and shapes are available to meet individual requirements(Colwell et al., 2022). Another key element is the collection pouch. This pouch attaches to the baseplate and the waste is collected within. Pouches are available as closed or drainable systems. Drainable systems are often used with higher or more liquid outputs, and closed systems are more often employed for the more formed output (Corona & Adams, 2022; Corona & Adams, 2024). Most pouches also have a flatus filter to minimize odor and ballooning of the pouch caused by trapped flatus(Gilpin et al., 2024). The following Figure 2.2.3a shows the basics of the pouching system.

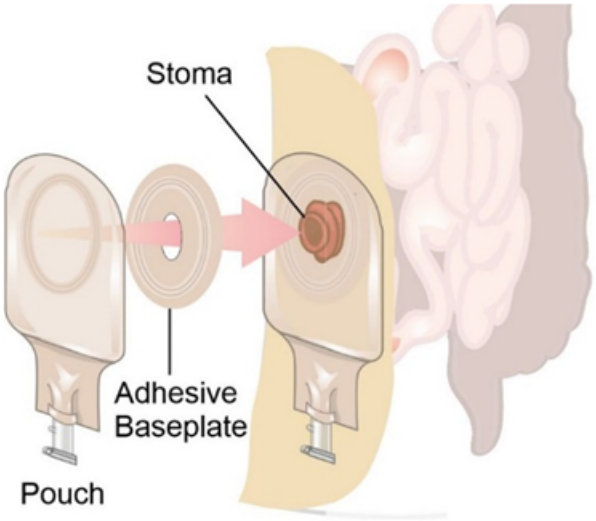


Figure 2.2.3a Pouching system basics. (Figure from Gilpin et al., 2024)

There are also many accessories such as deodorizing filters, support belts, and barrier rings or pastes which can provide additional security and comfort(Morss-Walton et al., 2021). However, according to some WOC nurses the use of accessories should be approached with caution. Relying too heavily on supplementary aids may add unnecessary complexity. This aligns with the ‘less is more’ principle by prioritizing proper application and optimization of basic materials(Reuvekamp et al., 2020). The proper use of pouching systems forms the foundation of effective stoma care, understanding daily stoma routines will be explored in the following section.

2.2.4 Living with a Stoma

This section explores the common practices in ostomy care. Subjects that will be discussed are the daily care routines, the role of healthcare professionals, autonomy, and quality of life.

DAILY CARE AND SELF-MANAGEMENT

After an ostomy surgery, the daily care routines of ostomates change enormously. Routines are necessary for maintaining hygiene and preventing complications, and also for promoting confidence and independence (Elnaim et al., 2024). Changing the pouching systems is a fundamental aspect of daily care, not following the care practices can lead to issues such as detachment or leakage (Corona & Adams, 2022; Corona & Adams, 2024). The frequency of emptying varies depending on the type of pouch, type of ostomy, and the output consistency(Stichting Stomaatje, 2024). Moreover, finding the correct material can be an overwhelming experience for many ostomates. This process often consists of trial and error (Reuvekamp et al., 2020), where the lack of professional guidance worsens the problem (Hollister & Stomavereniging, 2024). The absence of individual recommendations can delay the selection of the right pouching system, and contribute to ongoing challenges (Aibibula et al., 2022). Establishing a routine and using the correct pouching system is essential in ostomy management.

Although ostomates often establish these routines, daily care is also shaped by environmental and material limitations. Managing a stoma outside the home can be intimidating. Often due to the absence of appropriate restrooms, which may result in anxiety or reduced participation (Aibibula et al., 2022).While traveling or taking part in outside activities this limitation can restrict the users' mobility and independence. Another limitations is that ostomates must also carry ostomy materials when away from home, and can require them to be always prepared and alert for unexpected situations(United Ostomy Associations of America, 2023). Daily management can also be influenced by compromised discretion, because of visible pouch profiles. This can complicate clothing choice and body image(Aibibula et al., 2022).
Another crucial aspect in regaining daily life is ostomy education (Harris et al., 2020). The integration of practical care routines, personalized material selection, and addressing systemic limitations ensure effective daily ostomy management. However, these aspects do not exist in isolation and are embedded within a broader framework of professional care and long-term support (Jin et al., 2021; Liu et al., 2023). The next section explores the role of WOC nurses in this framework.

ROLE OF WOC NURSES AND CLINICAL SUPPORT

Wound, ostomy, and continence (WOC) nurses play an important role in supporting ostomates. This role encompasses the pre-and postoperative phases, covering aspects like stoma siting, education, and emotional support (Heerschap & Duff, 2021; Matsubara & Hirohata, 2024). WOC nurses help new ostomates with choosing the right material, and help them adapt through the process. Such support is crucial in the early stages for building autonomy and confidence in managing the stoma (Danielsen & Rosenberg, 2014).

In the Netherlands, function-oriented prescribing (functiegericht voorschrijven) is the standard framework for prescribing ostomy materials. This is a patient-centred model that makes sure materials are tailored to individual preference, lifestyle, and clinical needs (Stomavereniging, 2023b). Another valuable aspect of this method is that it relies on shared decision making between the ostomates and care professionals. In turn, this helps promoting efficient use of resources and minimizing unnecessary accessories (V&VN, n.d.). The 'less is more' principle reflects the aforementioned framework, the use of basic materials often resolve common issues like skin irritation or leakage (Reuvekamp et al., 2020).

Nevertheless, many ostomates still report gaps in follow-up support. Especially ones with ongoing complications, nearly half of those indicate insufficient care according to a questionnaire conducted in the Netherlands (Hollister & Stomavereniging, 2024). In addition, this minimal approach fails to address more complex or evolving needs. This highlights the importance of responsive and individualized care strategies.

AUTONOMY

Autonomy is a critical factor of ostomy care, and in this context refers to an individual's ability to independently manage their stoma, make informed health decisions, and maintain control over their daily life(Poletto & Da Silva, 2013). It supports emotional stability and restores a sense of control, this reduces anxiety in social and personal contexts (Hardiman et al., 2016). Well-being can be improved with competency and confidence in care routines.

With sufficient education, social support and individual adaptation individuals can reach autonomy. First, it is important to educate ostomates about self-care, such as intervention on pouch systems or troubleshooting techniques (Kang & Choudhary, 2024). When these interventions are tailored to individual needs, they are more effective (Liu et al., 2023). Next to professional support, autonomy can also be strengthened through peer networks and emerging technologies (Keng et al., 2021). Digital platforms and wearable feedback tools can help normalize care, and peer-led groups may reduce anxiety and help with building self-efficacy (Van Der Storm et al., 2024; Wang et al., 2022). Rosa et al. (2017) builds on this concept by discovering that self-care is a big component of autonomy, but this is often hindered by fear and insecurity. Autonomy grows when ostomates are supported in self-care routines and managing their materials effectively (Corona & Adams, 2022; 2024).

QUALITY OF LIFE

Autonomy in ostomy care is not only about encouraging independence, but also the cornerstone of holistic well-being. It closely intersects with Quality of Life (QoL), which encompasses physical, emotional, and social well-being (Diniz et al., 2021). According to the WHO(WHOQOL, 2012), QoL is defines as ''an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." For ostomates, QoL is not only shaped by physical health, but also body image, emotional resilience, and social participation(Li et al., 2022; Alenezi et al., 2021; Goldstine et al., 2019).

Survey data from the Netherlands (Hollister & Stomavereniging, 2024) indicates and average QoL score of 7.7 out of 10 among ostomates. Those without complications and with over ten years of experience reported notably higher scores. This suggests the importance of time, adaptation, and effective management. On the contrary, ostomates with frequent issues reported a one-point lower average on QoL, highlighting the link between complication burden and well-being. Complications can negatively affect all dimensions of well-being, including physical, psychological, and social. These dimensions are interconnected, as physical discomfort can diminish emotional well-being, while both may hinder social engagement and the sense of normalcy. Psychological adaptation often requires a shift in self-perception and confidence. Whereas, stigma (either perceived or internalized) can impact the social dimension. These effects are highly individual in which long-term adjustments and ongoing self-management are required (Alenezi et al., 2021).

Improving QoL requires a multifaceted approach, addressing the physical, psychological, and social challenges. Key areas include professional support, peer networks, and better materials. Furthermore, WOC nurses play a central role through follow-ups, personalized advice, and education (Li et al., 2022). Besides this, peer support can help reduce isolation and build coping strategies (Goldstine et al., 2019). Survey results (Hollister & Stomavereniging, 2024) highlight a strong need for continued professional involvement and show that gaps in follow-up care and public accommodations remain. Education about using the correct pouching system, or proper use can already improve QoL. However, innovative approaches to ostomy management also offer promising improvements. This starts with improvements on existing material. Even so, insights from the survey (2024) underscore the need for product innovation. Ostomates expressed desires for flatter and more discreet designs, skin friendly adhesives, and larger or less labor-intensive pouches among others.

RESILIENCE AND NEW FOUND HEALTH FREEDOM

As ostomy surgery is a life-saving procedure, thus it is not appropriate to focus only on the challenges. Ostomies can alleviate life-threatening conditions, which can significantly enhance the QoL as well(Gilpin et al., 2024). Looking at experience stories from de Stomavereniging(Stomavereniging, 2023b), it becomes clear that positivity and the emphasis on possibilities are highlighted in ostomy world. Within the context of this thesis it is important to look at both sides of the spectrum to really understand the experience of ostomates.

The experiences shared on the Stomaverening website (Stomavereniging, 2023b) really underscores the potential of ostomy surgery in enabling individuals to reclaim their lives. One ostomate describes himself as a ‘positive person with a stoma’, discussing and emphasizing how a stoma helped him regain his vitality. Another ostomate explains how having a stoma helped her return to her passion of diving, before she could not travel and visit diving locations anymore. This really shows how life with a stoma can open unexpected and rewarding opportunities. These narratives demonstrate resilience and adaptability, which should be taken into account when designing for ostomates.

Modern innovations also picked up on the resilience and adaptability, and decided to focus on further contributing to more independent and fulfilling lifestyle for ostomates. For example, the OriVa Port (The Gutsy Port | James Dyson Award, 2023), discussed further in Section 2.3, exemplifies a shift toward treating ostomy devices as integrated extensions of the self, enabling pouch-free periods and enhanced control. These shifts in the golden standard of ostomy care are promising.

2.3 Evolution of Ostomy Devices

It is valuable to understand the evolution of ostomy devices for the contextualization of persistent challenges and emerging opportunities in ostomy care. This subchapter provides a structured overview of the development of these devices. Figure 2.3 portrays the chronological timeline of major innovations in ostomy care technologies. The timeline includes key developments in pouching systems, baseplates, filter integration, and current emerging technologies. Accessories, like belts, powders, and pastes, do play an important role in ostomy care as well. However, they are not included in the timeline to maintain focus on core system innovations.

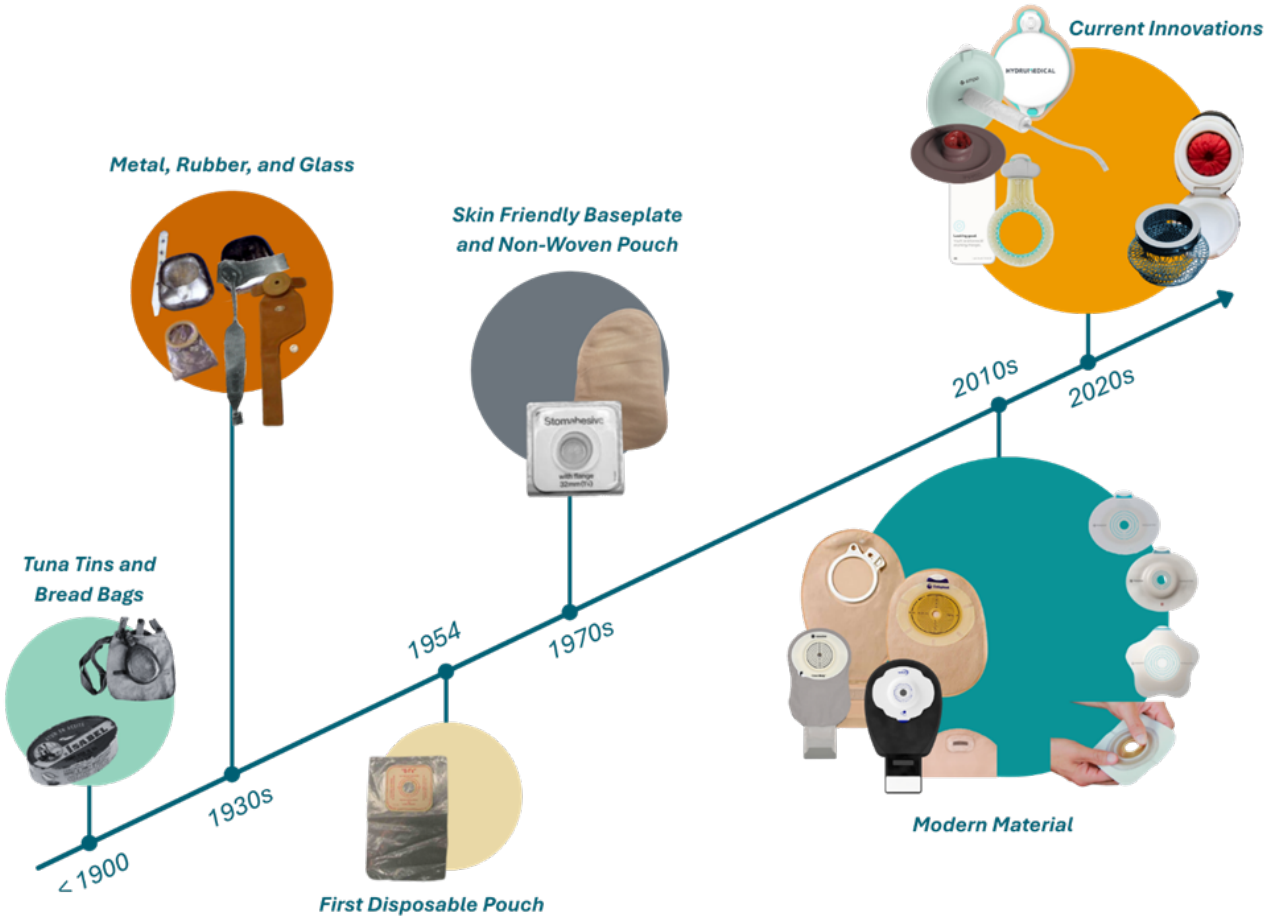


Figure 2.3 Timeline of key innovations in ostomy care, focusing on pouching systems, baseplates, filters, and emerging pouch-free or smart technologies (Pictures adapted from Stichting Stomaatje, 2024b; Pelican Healthcare, 2021; Böhning; AMPA Medical | Ostomy Care; TIES INFORMATION – OstomySecure; Coloplast; Odapt ;Hydrumedical; Convatec; Welland (n.d.))

Historically, ostomy surgery was dubbed a 'secret surgery' and reserved as a last resort (Wasserman & McGee, 2017). This point of view was mirrored in waste collection methods, which were almost non-existent till the early 20th century. Ostomates were forced to use makeshift devices such as rags, tuna tins, glass bottles, or bread bags held in place by straps (Pelican Healthcare, 2021). These failed in odour containment and skin protection, leading to social isolation. Around 1935, the first rubber pouches, secured to the skin with cement or a belt, appeared in Germany (Stichting Stomaatje, 2024b).

A major turning point occurred in the 1950s, when Danish nurse Elise Sørensen collaborated with Aage Louis-Hansen to develop the first disposable, adhesive ostomy pouch. Although discreet and airtight, the zinc oxide adhesive caused skin irritation. Another limitation was the noise and transparency of the pouches (Stichting Stomaatje, 2024b; Martin, 2019). Furtheron, the professionalization of stoma care was marked by the introduction of skin-friendly adhesives like Stomahesive® (1972) (Martin, 2019) and the rise of specialized nursing (Davidson & Fischer, 2020). By the 1980s two–piece systems, convex baseplates, odor-proof films, and integrated filters emerged to further refine ostomy care (Davidson & Fischer, 2020; Stichting Stomaatje, 2024b). After 2010 the ostomy pouching technology had evolved into the form recognizable today.

2.3.1 Contemporary Ostomy Devices

Current ostomy systems reflect decades of iterative development. The developments primarily focus on improving skin compatibility, leakage protection and discretion. The optimization of these aspects is ongoing and can be seen in the current pouching systems in use. These are available in a variety of designs, closed or drainable, transparent or opaque, and either one-piece or two-piece configurations (Gilpin et al., 2024; Lehur et al., 2019). This modularity allows for tailored and individual ostomy care. Figure 2.3.1a portrays a variety of the most common ostomy pouching systems.

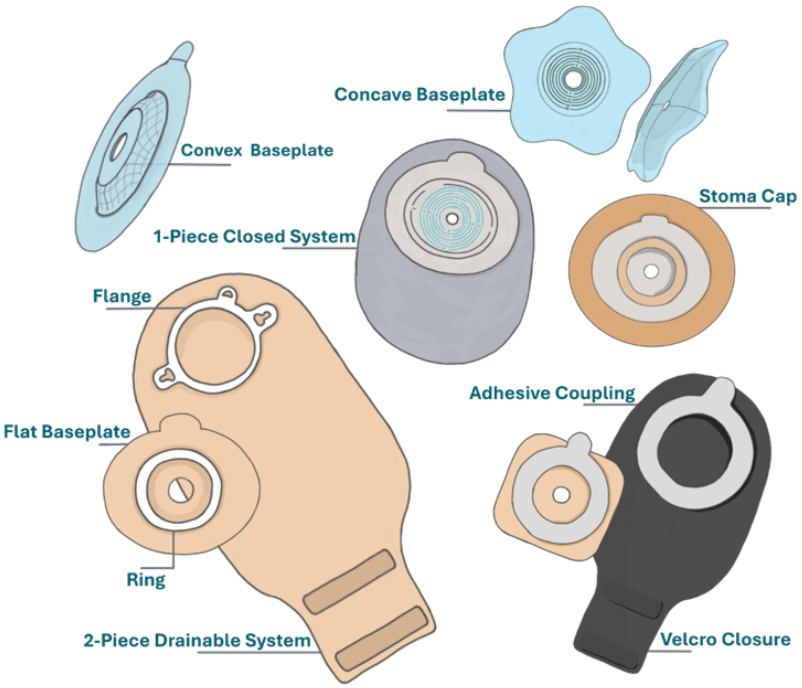


Figure 2.3.1a Most common pouching systems

Ostomy systems are commonly divided into one-piece and two-piece designs (Morss-Walton et al., 2021; Corona & Adams, 2022, 2024). In one-piece systems, the pouch and baseplate are combined into a single unit, making them easier to apply and less noticeable under clothing. In contrast, two-piece systems allow users to change the pouch without removing the baseplate. A mechanical coupling (flange and ring) or a retentive adhesive system is employed to achieve this. While a mechanical coupling provides user friendly pouch changes, they are less flexible and bulkier (Corona & Adams, 2024). Pouching systems also vary in how they are emptied. Closed systems are discarded after one time use, and drainable system can be emptied through a resealable opening.

POUCHES

The pouch is the central component of current collection systems. Modern pouches are primarily composed of multilayer thermoplastic films, to find a balance between odor impermeability, flexibility, and mechanical strength. Figure 2.3.1b illustrates the schematic cross-section of the layered components. The inner film is gas permeable, often made from Polyvinyl alcohol (PVA). The outer impermeable film makes sure the odour molecules are led through the filter. This functionality is achieved by spotwelds to create distinct internal compartments. For the impermeable layer the following thermoplastics, or their composites can be used. (PE) is often used for flexibility and sealability, and polypropylene (PP) for mechanical durability. While Ethylene vinyl alcohol (EVOH) has an excellent odour barrier. The outermost non-woven textile layer, consisting of spunbonded Polypropylene (PP) reduces glare, rustling noise, and the plastic feel of the pouch. (Gilpin et al., 2024).

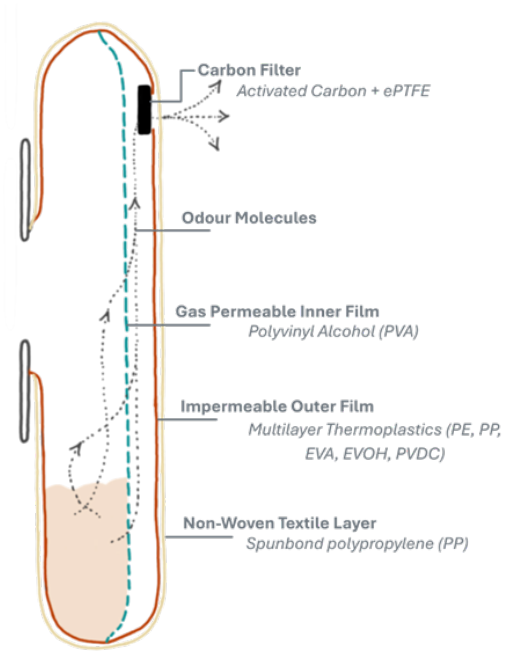


Figure 2.3.1b Cross-section pouch layers. Adapted from Gilpin et al. (2024)

Pouches are produced in a wide variety of sizes and shapes. This wide variety is due to different anatomical variations, differences in output consistency, and individual lifestyle preferences (Virgin-Elliston et al., 2023). Often the pouches are introduced in mini, midi and maxi sizes, though specific volumes vary across product lines. Standard pouches hold typically between 300 and 700 milliliters. Larger capacity pouches are available for high-output stomas, as well as stoma caps (10 mililiters) for ostomates who irrigate. (Coloplast, n.d.; Hollister, n.d.; Convatec, n.d.; Welland, n.d.). In addition to these size and shape differences, the color of a pouch plays an

important role in visual discretion. Transparent pouches are often employed immediately after the operative phase, allowing ostomates visual output feedback. While opaque pouches, often in beige, grey, or black, are available for long-term use (Gilpin et al., 2024).
Ostomy pouch design continues to evolve through targeted improvements. These include improvements for comfort, functionality, and discretion. For instance, ConvaTec's Esteem Body™ (Convatec, n.d.) line consists of an 8-shaped pouch to reduce sagging during wear and is covered in a water-repellent textile. Such developments highlight the ongoing refinement of pouch materials and form to better meet user needs. Another notable improvement is research into biodegradable liners, to lessen the environmental impact of plastic pouches. These flushable liners are made from water-soluble polymers, often not suitable for more liquid and enzymatic outputs. A fully biodegradable pouch is elusive at this point due to the challenge of balancing mechanical performance and hydrolytic decomposition (Gilpin et al., 2024).

BASEPLATES

The baseplate is the adhesive interface between the pouch and the peristomal skin. Currently, the baseplates are available in flat, convex, and concave forms to accommodate different anatomies (Gilpin et al., 2024). Figure 2.3.1c shows three different baseplates from the SenSura Mio line of Coloplast (n.d.). The exact shape and material composition changes from manufacturer to manufacturer. Flat variants are suitable for protruding stomas and even surfaces, whereas convex models apply gentle pressure to improve sealing around flush or recessed stomas. During the last few years the flower shaped convex model has been developed, to adapt to more body compositions, specifically hernias or bulges.

Figure 2.3.1c Flat, convex, and concave baseplate from the SenSura Mio line (Coloplast, n.d.)

The baseplate surrounds the stoma, thus opening types vary within baseplates. Pre-cut baseplates fit around round and stable stomas and can be bought in a variety of sizes. Another option is the cut-to-fit, this allows for manual adjustments and can be seen in Figure 2.3.1c. An innovation in these openings is the moldable type, these barriers conform dynamically to the stoma's shape. This reduces the risk of cutting errors, mechanical trauma, and peristomal skin complications (Szewczyk et al., 2014).

Most baseplates use hydrocolloid adhesives, often composed from carboxymethylcellulose, pectin, gelatin, and polyisobutylene, layered under a PE or PU film. These baseplates provide a combination of adhesion, absorption, and skin compatibility (Gilpin et al., 2024). Although these offer good adhesion and moderate moisture absorption, they degrade with perspiration and enzymatic exposure. Hydrocolloids can swell in high-output cases as well, leading to detachment. Frequently removing the baseplate increases the risk of medical adhesive-related skin injury (MARSI) (Swift et al., 2020).

Recent innovations address these limitations, especially in terms of material engineering. In the ATTRACT trial by Sætre et al. (2023) skin-protection technology is added to a baseplate. The digestive enzymes in the stomal effluent are immobilized through adsorption, preventing them

from reaching and damaging the peristomal skin. The composition of this technology is not discussed. Another direction is integrating dermatologically active compounds into the hydrocolloid layers, like ceramides and Manuka honey (Gilpin et al., 2024). The long-term clinical efficacy remains under evaluation, yet their inclusion reflects the trend toward skin-protective design. Furthermore, the SROT project (Hansen, 2020) discusses the importance of moisture dynamics for adhesive performance. This project discusses a dual-adhesive system, with a perspiration absorbing hydrocolloid center and structural adhesive rim. Hydrogel based adhesives are also promising, a chitosan-based hydrogel is developed at MIT. This hydrogel forms watertight and skin-conformal bonds via polymer chain interlocking, providing a strong adhesion and soft mechanical properties (Pan et al., 2020). A distinct line of material innovation is silicones being reengineered into a breathable and skin-compatible alternative to hydrocolloids. Micro-porous silicones made from a hydrophobic matrix and hydrophilic additives enable vapor transmission and maintain a moisture barrier. This is unlike the hydrocolloids which swell or degrade under perspiration, leading to high risk of maceration and MARSI. A peel-force test has shown that silicone adhesives also allow for atraumatic removal and extended wear time (Swift et al., 2021). Baseplate designs are shifting from static adhesives towards more adaptive and skin-friendly systems.

FILTERS

An integral aspect of pouch systems is the flatus filter. The functionality is the venting of intestinal gas to prevent ballooning while also reducing odour. Typically, these filters are integrated into the pouch, and contain activated carbon (as fibers, foam, or particles) enclosed below a gas permeable membrane. The activated carbon adsorbs malodorous compounds like hydrogen sulfide through physical adsorption within its porous structure. Materials used for this membrane are expanded polytetrafluoroethylene (ePTFE) or ultra-high molecular weight polyethylene (UHMW-PE). This membrane protects the filter from fecal contamination and saturation (Gilpin et al., 2024).

However, contact with stoma output or water can block gas transport, leading to ballooning and compromising baseplate adhesion. To mitigate this risk, manufacturers have introduced different physical barriers to shield the filter. For example a pleated membrane to create gas paths, pre-separated membranes to increase the surface area for gas exchange, or even the use of replaceable external filters with manual vents. These external filters and manual vents can control gas release but may affect odor control. (Gilpin et al., 2024). Virgin-Elliston et al. (2023) proposed a different approach a 360° filter placed close to the stoma inlet and away from direct effluent stream. This significantly reduced ballooning via circumferential gas separation and an increased diffusion area. Despite these developments, flatus filters remain a technically demanding component. Future improvements must continue to optimize the interplay between gas permeability, odor adsorption, and liquid resistance under dynamic use conditions.
Ostomy pouch designs have improved significantly, yet there are still limitations in the environmental, anatomical, and material areas. These persistent limitations highlight the need for further research and innovation. Particularly in integrating more adaptive materials, reducing skin burden, and enhancing discretion without sacrificing safety. The following section will investigate current research and innovations.

2.3.2 Emerging Innovations

Current pouch systems have seen improvements over the recent years, in parallel with this there are a growing number of emerging solutions trying to disrupt the status quo of ostomy management. These innovations include additions to existing systems like smart technologies, or custom-fitted baseplates. However, pouch-free approaches or continence control–oriented solutions, have gained increasing attention. This section highlights these developments that reflect the shift toward more individualized, discreet, and responsive ostomy care.

SMART OSTOMY DEVICES

Smart or digital ostomy care systems have potential in mitigating leakage-related stress. The Heylo™ system, developed by Coloplast, is a CE-marked leakage notification device that monitors moisture beneath the baseplate using sensor rings and transmits alerts via a smartphone app (Barbosa et al., 2024). This system is already available in the UK markets, and clinical studies have been done to validate the working principle. These trials demonstrated significant reductions in leakage incidents, improved emotional well-being, and better self-care practices (Brady et al., 2024). A similar product is the Ostom-i Alert (Barbosa et al., 2024). This device helps users to track pouch fill levels via a Bluetooth sensor and smartphone application. With this overfilling of the pouch is prevented, together with the associated leakage risk.

CUSTOMIZABLE MATERIALS

An emerging and valuable tool for producing personalized ostomy products for a better anatomical fit is the use of 3D printing. A review by Soh et al. (2023) identified the potential of 3D printing in creating personalized appliances, surgical planning tools, and educational stoma models . Despite current use being limited to pilot studies and experimental setups, 3D printing enables anatomically precise fittings. This can enhance peristomal skin integrity and user satisfaction. One product called Odapt (Home | Odapt, n.d.), offers a reusable 3D-printed silicone baseplate. This baseplate can be customized via a smartphone scan. Silicone is chosen for its biocompatibility, flexibility, and reusability. They mention that adhesion happens with silicone gels, however the product is still in development.

CONTINENCE CONTROL DEVICES

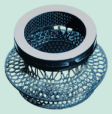
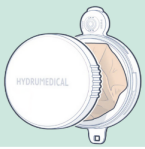
Numerous continence control devices have been in development, which aimed to reduce physical problems and improve the quality of life of ostomates. However, most remain experimental or are no longer marketed. Important to note is the availability of limited public information on their status. Figure 2.3.2a portrays six devices of continence control devices, which will be reflected on in the section.

Figure 2.3.2a Overview of six discontinued or experimental continence control devices, illustrating the diversity of design strategies in historical and early-stage pouch-free ostomy solutions. (Pictures adapted from Mediq, n.d.; Barbosa et al., 2024; Lehur et al., 2019; Karke, 2024; Sierra et al., 2020)

The Conseal™ Plug (Mediq, n.d.; Dourado et al., 2024) and Vitala™ CCD (Dourado et al., 2024) offered short-term continence for colostomates but are no longer commercially available, reasons for withdrawal were not disclosed.These could be used for 8-12 hours without leakage. SphinX and the StomaLife Valve (Karke, 2024) (both patented) explored internal or semi-implantable continence solutions but lack clinical data and face unclear regulatory or technical pathways. The AOS-C2001-B (Lehur et al., 2019) demonstrated promising outcomes in pilot trials but was limited by anatomical eligibility and single-use design. This product was designed for users with a left-sided colostomy and formed or semi-formed stool. The Sierra et al. (2020) prototype proposed an internally retained, 3D-printed collection bag with external sealing. The device remains in early-stage evaluation and has not entered clinical practice. The SphinX, the Conseal™ Plug, and StomaLife Valve are considered invasive devices, as they are used internally. The concepts discussed are innovative, but also illuminate recurring design, clinical and commercial challenges. In some cases, limited market potential or lack of profitability may have contributed to their discontinuation, although such decisions are rarely disclosed by manufacturers.

Building on the insights and limitations of earlier concepts, several continence control concepts are now under active development. These new concepts reflect a renewed emphasis on usability, discretion, and safety. This is supported by the advances in materials science and human-centered engineering. Table 2.3.2a portrays these concepts, with their status, target users, materials, advantages and limitations.

Table 2.3.2a Overview of continence control devices currently in development. Pictures used from (AMPA Medical | Ostomy Care, n.d.; Böhning, 2023; Hydrumedical, n.d.; Barbosa et al., 2024; TIES INFORMATION – OstomySecure, n.d.)

Device	Status	Users	Working Principle	Materials	Advantages	Limitations
TIES® 	In development; Expecting CE-mark in 2027 Undergoing multicenter clinical studies.	Adults with permanent ileostomies (new or existing).	A surgically placed titanium implant forms a sealed transcutaneous stoma interface with a sliding lid for controlled, appliance-free drainage.	Titanium implant (3D-printed, porous), plastic lid, polymer seals.	No skin contact, no adhesives, less leakage, supports continence and active lifestyle, improved QoL.	Invasive, unknown long-term outcomes, requires frequent emptying by sensation.
OriVa Port™ 	Advanced prototype; provisional patent; fundraising for efficacy testing.	Colostomy and Ileostomy users.	A custom lid-and-valve system (artificial sphincter), consisting of an O-ring and reusable wafer. The hinged lid opens manually for drainage.	HDPE housing, silicone wafer, hydrocolloid adhesive, hydrophobic nylon.	Discreet, control over output, flexible and reusable, optional pressure feedback, not invasive.	No clinical data, frequent emptying, no odor filter, sealing reliability and long-term wear performance unverified.
InterPoc™ 	In development (ongoing product refinement).	Ileostomy users	Expanding internal insert retains effluent; removed via string into discard sleeve. External cap with odor-sealing membrane.	Not disclosed.	Discreet, improved mobility, integrated odor film, reduced skin contact and leakage risk.	Single-use (replace every 4–6 hours), no long-term clinical data, limited output capacity, use of pouch like cap.
HYDRUSTOMA® C3 	In development (available soon), clinical trial completed.	Colostomy Users	Two-piece disposable system (Plate + Capsule/Bag) with silicone valve for gas release, the pouch remains folded under a twist cap and is deployed only during emptying.	PE, hydrocolloid, silicone valve, EVA/PVDC, non-woven PE	Degassing valve, discreet design, skin-friendly hydrocolloid, day/night bag options.	No clinical data, discarded after use, limited to ≤40 mm stomas.

The TIES® (Barbosa et al., 2024; TIES INFORMATION OstomySecure, n.d.) is a surgically placed titanium implant for ileostomates. After healing a lid is used on the implant, which can be opened for controlled output release. At this point there are ongoing clinical trials, and the company website mentions a positive effect on skin problems and quality of life. Although it is promising, the device is invasive and relies on user sensation for emptying. It is mentioned that users might need to empty 2-10 times a day. The internal part of the implant acts as a small reservoir as well. Concerns about long-term usability and safety are raised, and clinical data has not been published yet.

The OriVa Port™ (Böhning, 2023) is in the prototyping phase and mimics an artificial sphincter through a lid and valve system. This design is non-invasive, and emptying is user-controlled. The device is reusable and can be used for temporary periods without a pouch. The design is customizable for different individuals and can be used by colostomates and ileostomates. In the development of the OriVa Port users and healthcare professionals are included. Performance consistency and sealing reliability remain unverified currently.

Moreover, the InterPoc™ (AMPA Medical | Ostomy Care, n.d.) is a minimally invasive internal insert for ileostomates. It is designed for short wear intervals of 4-6 hours, and a discard sleeve is integrated to make removal hygienic. While its discreet form and reduced odor are advantageous, the single-use nature and low capacity might limit its applicability for daily use.

Lastly, HYDRUSTOMA® C3 (Hydrumedical, n.d.) offers a concealed pouch for colostomates. It consists of a baseplate with a capsule cover. The baseplate contains a silicone gas release mechanism. Within the capsule a pouch is folded and becomes visible only with manual emptying. The capsule will be discarded after each use, while the baseplate can stay on the skin for longer. Though the design emphasizes hygiene and wearability, it has yet to be introduced on the market and is constrained by anatomical compatibility (≤40 mm stomas).

Collectively, these devices illustrate the field's transition toward user-controlled continence solutions using biocompatible polymers, hydrocolloid adhesives, and engineered seals. At this point long-term data collection, medical device regulation, output handling, and integration into everyday routines remain critical hurdles to their adoption. Despite these advancements many ostomates still experience challenges related to fit, odour, leakage, and emotional burden. Understanding this progression not only contextualizes current design choices but also underscores the need for interdisciplinary approaches.

2.4 Challenges in Ostomy Care

Ostomy care covers a complex interplay of physical, psychological, and social challenges. These dimensions are often categorized separately, however there are closely linked. Physical complications such as leakage or skin irritation can lead to emotional distress, and this can in turn cause social withdrawal or reduced participation. This dynamic shows that worsened well-being rarely stems from a single cause. In the following sections the challenges are addressed separately to provide structure, yet the dynamic between them is central to understanding the broader impact on quality of life

2.4.1 Physical Challenges

Physical complications are among the most frequently reported issues in ostomy care and have a major impact on quality of life. Correct appliance choice should minimize discomfort, yet literature and Dutch survey data highlight that it is not as simple. Many ostomates still continue to experience persisted challenges. Table 2.4.1a provides an overview of the most common physical issues, including skin complications, leakage, discomfort, pancaking, hernias, prolapse, ballooning, odor, and sound. The prevalence of these challenges is underscored by national data collected in recent years.

Table 2.4.1a An overview of the most common physical challenges faced by ostomates, including their causes, prevalence, and typical management strategies

Challenge	Description	Cause	Prevalence	Management
Peristomal Skin Complications	Inflammation or breakdown of skin surrounding the stoma	Output exposure, poor fit, skin stripping	50%[1]–75%[2] of those with complications	Proper fit, correct adhesives, improved barrier materials
Leakage	Uncontrolled output escaping from the pouching system	Poor fit, high-output stoma, body contour changes	63%[2] -87%[1] of those with complications	Convex appliances, customized fittings
Pain and Discomfort	Physical discomfort during routine wear or movement	Prolonged wear, friction, adhesive tension	30.3%[1]of those with complications	Ergonomic pouch design, flexible barriers
Pancaking	Stool collects near stoma, not falling into pouch	Thick stool, negative pressure in pouch	43.2%[1] of those with complications	Lubrication, dietary change, filter blocking
Parastomal Hernia	Intestinal bulge through the abdominal wall near the stoma	Aging, obesity, chronic cough	21%[1]–50%[3] of those with complications	Hernia belts, physical activity, surgery
Prolapse	Stoma protrudes excessively	Weak muscles, pressure	7%[3] - 14%[1] of those with complications	Sugar to reduce swelling, surgical consideration
Ballooning	Accumulation of gas in pouch causing discomfort	Inadequate filters	35%[2] - 91%[4] of those with complications	Improved filters, dietary management
Odor	Unpleasant smell from pouch or leakage	Inadequate filters	12%[2] of those with complications	Odor-neutralizers, dietary adjustments, improved filters
Sound	Audible noise from gas or pouch movement	Gas, pouch material, movement	7%[2] of those with complications	Improved filters, sound-dampening materials

Reuvekamp et al. (2020)[1] Hollister & Stomavereniging (2024)[2] Tsujinaka et al. (2020)[3] Virgin-Elliston et al. (2023)[4]

In 2020 (Reuvekamp et al., 2020) and 2024 (Hollister & Stomavereniging, 2024) surveys were conducted among Dutch ostomates, in which the complications were highlighted as well. The survey conducted by Reuvekamp et al. (2020) had 199 responses, with 155 ostomates indicating they struggled with physical problems. The collaborative survey from de Stomavereniging and Hollister (2024) included more participants, 1357 respondents. From these respondents 1 in 3 struggled with complications, portraying the significant impact of physical complications among ostomates. The studies report varying frequencies of the same challenges among the respondents. This variance could stem from different survey methodologies, sample sizes, or advancements in ostomy care practices.

Skin complications stand out as the most frequently reported challenges in both literature and the conducted surveys. Skin issues, including mechanical trauma and fungal infections, are especially common and typically linked to output exposure or poor adhesive fit(Stelton, 2019; Morss-Walton et al., 2021). Furthermore, leakage is the number one physical problem experienced by ostomates, and 44% of the ostomates are concerned about leakages occurring(Elnaim et al., 2024; Aibibula et al., 2022). Leakage is worsened by body contour changes or high-output stomas. Similarly, pain and discomfort arise from prolonged pouch wear and movement-related friction (Summa et al., 2021; Coloplast, 2024). Pancaking, predominantly affecting colostomates, on the other hand complicates output flow and increases leakage risk (Davis & Colwell, 2024). Long-term complications include parastomal hernias and stoma prolapse, both of which interfere with appliance fit and comfort (Tsujinaka et al., 2020). Even seemingly minor problems, like ballooning or pouch-related noise(Virgin-Elliston et al., 2023; Stichting Stomaatje, 2024), can have substantial emotional and social consequences. This is because of filters loosing effectiveness when saturated (Stichting Stomaatje, 2024). Newer designs show promise for reducing ballooning (Virgin-Elliston et al., 2023), though they have limited impact on odor. Despite such material

innovations many of these complications persist. Physical issues do not occur in isolation, but they frequently contribute to psychological distress that further complicates daily life.

2.4.2 Psychological Challenges

The psychological challenges related to living with an ostomy are significant. These challenges extend beyond physical well-being and include aspects such as alterations in body image, self-esteem, and mental well-being. How ostomates emotionally adapt to life with a stoma varies widely among individuals. This section examines the psychological struggles faced by ostomates and the importance of psychological support. The survey conducted by the Stomavereniging and Hollister (2024) does not focus on psychological challenges, while the survey from 2020 (Reuvekamp et al., 2020) mentions mental issues experienced by 38.7% of the respondents.

BODY IMAGE AND SELF-ESTEEM

The disruption of body image is the most frequently reported psychological challenge (Ayaz-Alkaya, 2018). Ostomates often struggle with feelings of disfigurement, self-disgust, and reduced attractiveness (Jin et al., 2020). This burden further increases feelings of shame and impacts the willingness to engage in social activities (Tan et al., 2024). Within the context of body image, many ostomates report a feeling of being ‘different’ or ‘unattractive’, affecting confidence and self-esteem. Impacted confidence and self-esteem can hinder the ability to engage in social and intimate relationships as well (Jin et al., 2020; Petersén & Carlsson, 2021; Ayaz-Alkaya, 2018; Kang & Choudhary, 2022). Jin et al. (2020) emphasize ‘personal disgust’ as a key concept, where aversion to one’s own body impedes both adaptation and self-care.

ANXIETY AND DEPRESSION

High levels of anxiety and depression are common among ostomates. Studies report that up to 50% of ostomates experience above-normal levels of anxiety, and 16% report mild to moderate depression (Ayaz-Alkaya, 2018; Elnaim et al., 2024). Anxiety is often rooted in the physical challenges, such as leakage, odor, and the visibility of the pouch. The loss of control over bodily functions and the extensive adaptation required to integrate ostomy care into daily life further worsens the mental burden (Ayaz-Alkaya, 2018). Ostomates reported that these factors contributed to heightened alertness and an inability to trust their bodies, leading to mental fatigue and increased anxiety and depression (Petersén & Carlsson, 2021).

STIGMA AND SHAME

Stigma, both external and internalized, significantly impairs psychological adjustment (Ayaz-Alkaya, 2018; Jin et al., 2020). Cultural attitudes towards ostomies can increase these issues, especially in societies where ostomies are poorly understood or accepted (Da Silva et al., 2021). Even subtle social reactions can reinforce feelings of otherness and trigger self-isolation (Petersén & Carlsson, 2021). Cultural rejection and financial insecurity further amplify shame and self-blame (Yuan et al., 2018; Da Silva et al., 2021). This shame often manifests in social withdrawal and decreased autonomy (Tan et al., 2024; Kang & Choudhary, 2022).

PSYCHOLOGICAL SUPPORT AND COPING MECHANISMS

To improve the outcomes for ostomates it is important to employ psychological support. Psychological support comes in many forms. Peer groups foster self-acceptance and reduce isolation (Goldstine et al., 2019), while counseling helps process emotions and build resilience (Aibibula et al., 2022). Tailored education can build on this by strengthening mental preparedness (Choudhary & Kaur, 2020). Further on, continued care from WOC nurses also contribute to improved self-image and care confidence (Mørkhagen & Nortvedt, 2023). Lastly, family and professional support further reduce stress and help counter societal stigma (Yuan et al., 2018).

2.4.3 Social Challenges

Many social challenges are a result of the earlier discussed physical and psychological challenges. Nevertheless, these social barriers have a significant impact on various aspects of ostomates' lives.

SOCIAL ACTIVITIES

The avoidance of social events is a common among ostomates. This avoidance is driven by practical challenges, such as managing the stoma in public spaces and the lack of suitable facilities. Fear of judgement and anxiety about complications, such as leakage or odour, further discourage participation as well(Kang & Choudhary, 2022; Ayaz-Alkaya, 2018). Within this physical activities are similarly avoided, which contributes to inactivity and fear of exercise (Russell, 2017). The lack of knowledge about suitable activities can worsen this inactivity, highlighting the importance of education once more. Next to this, the societal attitudes and cultural stigma around ostomies play a role in intensifying isolation in ostomates (Yuan et al., 2018). In some cases, self-isolation occurs as ostomates avoid situations where their stoma might be noticeable, leading to reduced social contact and emotional strain (Alenezi et al., 2021).

INTIMACY AND RELATIONSHIPS

The effect of the physical and psychological implications can be seen in intimate relationships as well. Sexual problems among ostomates are a persisting problem. This includes impotence, frigidity, and dyspareunia. These problems are most of the time connected to body image issues, and low self-esteem(Ayaz-Alkaya, 2018). Young male ileostomates in particular report anxiety about partner perceptions, needing to plan intimacy and struggling with spontaneity (Petersén et al., 2021). Another notable result is that adjustment concerning sexuality and intimacy had the lowest adjustment scores a year after ostomy surgery. Women more often focused on not feeling attractive being naked, and used different strategies to hide their stoma. These challenges extend beyond initial fears of rejection according to literature. Self-disgust and internalized stigma are found to be critical factors that negatively influence romantic and sexual relationships(Jin et al., 2020). Peer support groups have proven essential in rebuilding confidence and addressing these issues (Mørkhagen & Nortvedt, 2023; Goldstine et al., 2019).

WORKPLACE AND EMPLOYMENT ISSUES

Having a place to work and socializing with colleagues plays an important role in stopping self-isolation. Many ostomates report leaving employment due to fears of discrimination or insufficient workplace facilities. This limits professional growth and economic participation (Choudhary & Kaur, 2020). Cultural and societal perceptions of ostomies worsen these difficulties(Yuan et al., 2018), as some individuals conceal their condition to avoid judgment (Petersén & Carlsson, 2021). A stark gender disparity is found in the workplace Despite these barriers, coping strategies are adopted to helps individuals adjust to their new reality. Adopting coping strategies can help with rebuilding confidence and resuming professional activities. However, one ostomate was afraid of noises coming from her stoma during her teaching job. Her coping strategy was eating one egg for the whole day. Coping strategies like this underscore the need for tailored education, innovation in materials, and stigma reduction(Petersén & Carlsson, 2021).

2.5 Design Considerations and Regulatory Context

The concept of temporary pouch-free ostomy solutions offer an alternative to continues pouch wear. However, within the literature, there are few detailed accounts of how pouch-free concepts have been technically realized. Besides this, limited information is available on why earlier products were unsuccessful or discontinued. This leads to a significant lack of information how such periods can be realized in the context of design implications and regulatory context. This chapter looks at existing literature to understand core constraints and enablers for pouch-free periods. This is done by discussing medical, regulatory, technical and material criteria.

2.5.1 Medical and Physiological Considerations

The key aspects influencing feasibility of a pouch-free solution are the physiological and biomechanical boundaries related to temporary occlusion of the stoma. These aspects include parameters such as effluent volume and consistency, internal pressures, skin mechanics, and stoma geometry, all of which are summarised in Table 2.5.1a.

Table 2.5.1a Relevant medical and physiological criteria for design

Criteria	Explanation	Parameter	Source
Output Volume	Total amount of stool/effluent expelled per day, key considerations for containment, sealing, and skin protection	Ileostomy: 500–1000 mL/day (high: >1.5 L/day); Colostomy: 200–700 mL/day	(Hedrick et al. 2023; Ostomy Expanded Version, 2019)
Bristol Stool Form Scale (BSFS)	Stool consistency is classified from hard lumps to watery discharge. This variability presents key considerations for containment, sealing, and skin protection	Ileostomy: BSFS 6–7 (loose to watery stool) Colostomy: BSFS 3–7 (formed to liquid stool)	(Izard, 2021)
Flatus Volume	Total volume of intestinal gas expelled per day, relevant for pressure management, odor control, and venting	0.17–4.9 mL/min; 25–100 mL per event	(Modesto et al., 2021)
Ischemic Pressure Limit	Sustained pressure above this threshold may impair capillary blood flow, leading to tissue damage	<30 mmHg (below capillary pressure)	(Tennyson et al., 2016)
Stoma Geometry	Shape and size impact sealing and retention, varies greatly among individuals	Protrusion: <5 mm to >30 mm, Typical diameter ranges ~10 mm to > 50 mm	(Cronin, 2023; Krishnamurty et al., 2017)
Intra-Abdominal Pressure (IAP)	Pressure inside the abdominal cavity affecting wall tension, excessive surges from movement, containment or straining can cause pain or tissue damage	Rest: 5–7 mmHg, Jumping: up to 170 mmHg	(Addington et al., 2008)
Intraluminal Pressure (ILP)	Pressure inside the gut lumen (colon/ileum) driving output via stoma, relevant for containment and pain threshold	normally: 5–20 mmHg, pain threshold: ~30–45 mmHg	(Bouin et al., 2002; (J. Chen et al., 2017)
Moisture Vapor Transmission Rate Skin	High moisture load reduces adhesion, risks MASD, and challenges breathability	> 200 - 300 g/m^2 /24 h (sweating ~ 1200 g/m^2 /h)	(Nuutila & Eriksson, 2020; Smith & Havenith, 2010)
Skin Displacement	Refers to lateral or vertical movement of skin due to postural changes or motion, relevant for seal stability and adhesive flexibility	Up to 30 mm (conservative upper bound from kinesiology taping data)	(Chen et al., 2017)
Skin Strain	Relative percentage deformation of skin due to body movement, relevant for stress distribution and flexibility of device interfaces	Abdominal skin strain can reach up to 29%	(Rupani et al., 2025)
Elastic Modulus Skin (In Vivo)	Young's modulus of skin, indicating resistance to deformation. Varies widely across studies; key for material matching to avoid shear, pressure points, and poor conformity.	Tensile: 4.6–20 MPa Torsion: 0.42–1.12 MPa Suction: 0.13–0.26 MPa	(Hendriks, 2005)

Output characteristics, such as volume and form(Izard, 2021; Moshkowitz et al., 2013), influence requirements related to drainage, sealing and venting(Hedrick et al. 2023; Ostomy Expanded Version, 2019). In addition, stoma geometry and size are fundamental to design as they determine the required fit, sealing surface, and mechanical interface needed (Cronin, 2023; Krishnamurty et al., 2017). Next to this, the internal pressures within the abdomen (intra-abdominal) and within the intestine (intraluminal) are of great importance. Pressure rises due to movement, strain or peristalsis can affect stoma occlusion and seal (Addington et al., 2008; Bouin et al., 2002; J. Chen et al., 2017). Yet, when the occlusion leads to higher pressures than tolerable this can be unsafe. Staying far below maximum pressure tolerances is a must.

Maintaining skin and stoma integrity is equally critical. Excessive pressure on the skin or stoma risks ischemia(Tennyson et al., 2016). While movement induced displacement and strain on the skin-device interface needs to be taken into account as well to ensure a safe occlusion (Chen et al., 2017; Rupani et al., 2025). Additionally, moisture management of the design relates to skin health. This can be addressed by the use of adequate Moisture Vapor Transmission Rate (MVTR). Literature mentions that the MVTR of the skin-device interface should be minimally higher than that of the skin to avoid Medical Adhesive Related Skin Injury (MARSI) (Nuutila & Eriksson, 2020; Smith & Havenith, 2010).

Furthermore, compliance with the skin's biomechanical response is essential to ensure a safe product. Values reported on skin biomechanics in literature are not consistent, as these depend on the test characteristics and skin samples. The values reported in Table 2.5.1a are guideline ranges. Designing skin-design interfaces that approximate these values, especially under moist and compliant conditions, is key to optimizing seal conformity and reducing interface stress(Chen et al., 2017; (Rupani et al., 2025; Hendriks, 2005). The Young's modulus of skin defined under the suction test (Hendriks, 2005) can proof valuable for ostomy products, as it reflects how skin stretches under non-invasive loads, like baseplate attachment. While medical and physiological considerations define what a device must achieve in practice, regulatory criteria formalize these requirements to ensure consistent safety, efficacy, and compliance across clinical contexts.

2.5.2 Regulatory and Safety Considerations

Ostomy products are classified as medical devices, which means that all temporary pouch-free ostomy devices must comply with the European Medical Device Regulation (Medical Device Regulation (MDR) 2017/745, 2017) and applicable ISO/EN standards. Complying with the regulation ensures clinical safety, performance, and marketability within the European Union (Ogrodnik, 2020).

Under MDR 2017/745, medical devices are classified based on risk, duration of use, and anatomical interaction. Pouch systems are classified Class I under this system, however a pouch-free solution with internal components can be classified as Class IIa (Rule 5 of Annex VIII). This classification reflects moderate risk and requires Notified Body oversight for conformity assessment and CE marking. Meeting MDR requirements is done by compiling a technical documentation file. This file consists of the following: A General Safety and Performance Requirements (GSPR) checklist, A Clinical Evaluation Report, A Risk Management File (per ISO 14971), Evidence of biological safety (ISO 10993), Sterilization validation (e.g., ISO 11137), and Usability and performance data (e.g., ISO 62366-1, ISO 8670-2). Design verification and validation must follow clear principles of traceability. This process is documented in a Design Traceability Matrix(ISO 13485/MDR Annex II), which links user needs to technical requirements, applicable standards, and test outcomes.

In addition, a certified quality management system (EN ISO 13485) must oversee design, production, and documentation to ensure consistent quality. Once on the market, the device must be supported by a robust Post-Market Surveillance (PMS) plan. All regulatory pathways begin with a clear definition of the device's intended use. This refers to the specific medical purpose, target user group, and clinical context for which the product is designed and marketed. It

determines how, where, and by whom the device is used. Intended use helps with guiding regulatory classification and informs the selection of applicable standards, testing requirements, and risk mitigation strategies(Ogrodnik, 2020). Relevant ISO standards have been selected based on the specific functional and clinical risks of the device and are summarized in Table 2.5.2a.

Table 2.5.2a Relevant ISO standards to pouch-free design, information gathered from NEN Connect

Standard	Scope	Relevance	Deliverables
ISO 10993-1:2018	Biological evaluation – Test planning	Framework for selecting biological tests based on contact and use duration	Biological Evaluation Plan
ISO 10993-5:2009	Biocompatibility – Cytotoxicity	Ensures materials do not harm cells in contact with skin or mucosa	In vitro cytotoxicity tests
ISO 10993-10:2021	Biocompatibility – Irritation and Sensitization	Evaluates potential for irritation or allergic response, critical for adhesives and skin-contact materials	Skin irritation and sensitization assays
ISO 10993-17:2023	Toxicological risk assessment of leachables	Determines safe exposure levels for any leachable substances from materials	Tolerable Exposure (TE) and risk assessment
ISO 10993-18:2020	Chemical characterization of materials	Identifies material composition and extractables as input to toxicological evaluation	Chemical analysis (e.g., GC-MS, LC-MS)
ISO 11137-1:2015	Sterilization – Radiation	Applies to components requiring radiation sterilization	Validation of dose delivery and sterility assurance level (SAL 10^{-6})
ISO 8670-2:1996	Ostomy devices – Mechanical integrity testing	Critical for evaluating leakage, flange retention, and mechanical safety	Leak resistance, coupling strength, durability tests
ISO 14971:2019	Risk management for medical devices	Mandatory process for identifying, evaluating, and mitigating hazards during design	Full Risk Management File
EN ISO 13485:2016	Quality management system for medical devices	Required for CE marking and regulatory compliance	Design domentation, audit trail, traceability
ISO 62366-1:2015	Usability engineering – Human factors	Ensures user can safely and effectively handle, insert, and remove the device	Usability validation with representative users
IEC 60601-1:2020	Electrical safety of medical equipment	Relevant if sensors or feedback electronics are added	Electrical insulation, leakage current, mechanical safety tests

2.5.3 Technical Considerations

Achieving pouch-free products necessitates considering technical constraints as well. As outlined in Table 2.5.3a, several technical criteria are critical for the design. However, it is notable that the numerical thresholds often act as guidelines. This is because different material and test methods provide different values in literature. Gas management depends on microporous filters that allow odor-free venting while preventing liquid escape (Modesto et al., 2021; Gilpin et al., 2024). Sealing mechanisms must maintain containment under both static and movement-induced pressure variations (F. Chen et al., 2015; Carrington et al., 2017). Wear time is limited by factors such as skin moisture, adhesion breakdown, and pressure load. The wear time mentioned comes from clinical tests of continence devices discussed by Dourado et al. (2024). In this paper, functional continence pressure is discussed as the intraluminal pressure range that typically indicates the presence of fecal matter. This value serves as a valuable guideline for designing devices that prevent leakage without exceeding mucosal perfusion limits. Moroveover, insertion geometry must ensure comfort and safety, especially when internal components are used (Daurelle et al., 2015; Monty, 2016; Hanuka et al., 2009).

The amount of parts that a device has introduces cleaning challenges and increases the risk of contamination (Torres et al., 2021; Kremer et al., 2023). This shows that cleaning an medical device is essential. Thus the device must withstand repeated cleaning with household disinfectants without deforming or degrading (ISO 17664-1, 2021; MDR 2017/745).
Finally, a fallback functionality is vital in the case of failure or unsafe pressure ranges. Users must be able to quickly detach the device. This aligns with ISO 14971:2019, which emphasises risk mitigation through redundancy.

Table 2.5.3a Necessary technical criteria to consider in designing

Criteria	Explanation	Parameter	Source
Filter Pore Size	Gas release without liquid leakage to reduce pressure buildup, odour, and sound	0.2 to 0.5 µm	(Modesto et al., 2021; Gilpin et al., 2024)
Containment and Sealing	Ability to contain output and resist leakage under physiological pressures	Pressure: Typically 4–14 mmHg, Pressure during movement or strain: ≤ 180 mmHg	(F. Chen et al., 2015; Carrington et al., 2017)
Maximum Wear Time	Wear time is constrained by skin moisture, effluent, adhesion breakdown, and medical safety	≤12 h for temporary occlusion stoma	(Dourado et al., 2024)
Functional Continence Pressure	Experimental (plug) continence devices achieve occlusion at this pressure range without causing ischemia	10–15 mmHg	(Dourado et al., 2024)
Insertion Geometry	Shape and surface must allow comfortable and safe insertion (potential internal componenets). Shape/size varies patents provide guidelines	Shape: Cone or rounded tip for easy insertion Insertion length: 20-60 mm	(Daurelle et al., 2016; Monty, 2016; Hanuka et al., 2009)
Assembly Complexity	Fewer parts and steps reduce user error and contamination risk, exact numerical values of parts not widely reported	Devices with internal components, hinges, or lumens are harder to clean and more prone to residual contamination	(Torres et al., 2021; Kremer et al., 2023)
Use Cycle (Single vs. Reusable)	Determines robustness, material selection, and hygiene needs. The number of reuses must be validated and specified in the instructions for use	Reusable parts for ≥ 100 cycles if applicable (Dependent on material choice)	(Medical Device Regulation (MDR) 2017/745, 2017)
Cleaning	Reusable parts must allow safe, effective cleaning. Manufacturers of reusable medical devices provide validated cleaning instructions to ensure safe reuse	Compatible with 70% alcohol/soap, no swelling (Household supplies)	(ISO 17664-1; Medical Device Regulation (MDR) 2017/745, 2017)
Fallback Functionality	Emergency compatibility with standard pouches and/or fail safe mechanism for reliability	Allows immediate transition to standard 1- or 2-piece ostomy system without additional tools or adhesives	(ISO 14971:2019; Medical Device Regulation (MDR) 2017/745, 2017)

2.5.4 Material Considerations

Lastly, the material selection for temporary pouch-free devices should balance mechanical reliability, skin safety, chemical safety, and environmental responsibility. Table 2.5.4a summarizes the most important criteria material should adhere to. An important aspect is preventing medical adhesive-related skin injuries (MARSI), materials must maintain a secure seal without causing redness, skin tears, or irritation during removal (Patra et al., 2024). The product should also tolerate temperature fluctuations without deforming or degrading, especially under body heat or humid storage conditions (Podstawski et al., 2024). One aspect which is noteworthy to discuss are key mechanical properties, like tensile strength, adhesive peel strength, and shear strength. These make sure the device maintains adhesion under movement and pressure. The exact values that the material should adhere to depends on the material chosen, but also on the test done to gather the numerical values. Thus exact values differ widely in literature. Ensuring comfort at the skin interface and offering the necessary structural support leads to choosing the correct hardness score of materials (Zhao et al., 2015).

Biocompatibility is non-negotiable under MDR and for safety. Materials that contact skin or mucosa must be proven non-irritant and non-toxic. Also any surfaces exposed to stool must resist enzymatic breakdown and microbial colonization especially in the case of ostomy products. If the product is not reusable and biodegradable elements are used, they need to safely break down after use without affecting in-wear reliability(Medical Device Regulation (MDR) 2017/745, 2017).

Equally important is how materials respond to the movements of the body. Materials must stretch, should be able to compress, and shift with skin movements. If this is not possible it can lead to discomfort or seal failure. Thus matching the skin's biomechanical behaviour helps maintain performance during daily activity (Chen et al., 2017; Rupeni et al., 2025; Hendriks, 2005).

Table 2.5.4a Important material criteria for pouch-free devices

Criteria	Explanation	Parameter	Source
Medical Adhesive-Related Skin Injury (MARSI)	Adhesive use must not cause erythema, vesicles, bullae, erosions, or skin tears	No skin damage persisting ≥30 min post-removal (MARSI threshold)	(Patra et al., 2024)
Thermal Compatibility	Resist thermal stress without deformation, degradation, or functional loss under extreme temperatures (storage and sauna use)	−10 °C to +120 °C	(Podstawski et al., 2024)
Hardness	Materials must balance comfort and structural function; soft for skin contact, firm for mechanical stability	Baseplate: Shore A 10–25 Plug: Shore A 20–40 Rigid Shell: Shore D 60–75	(Zhao et al., 2015)
Biocompatibility	Materials must not cause sensitization, irritation, or cytotoxic effects	ISO 10993-1, -5, -10 compliance	(ISO 10993-1, 2018; ISO 10993-10, 2021)
Biodegradability	Disposable parts must degrade safely after use; biodegradables should meet compostability standards if applied	The test is considered as valid if the degree of biodegradation of the reference material is more than 70% after 45 days	14855-2:2018
Biological and Chemical Resistance	Surfaces must resist bacterial adhesion, biofilm formation, and enzymatic degradation	Non-absorbent, disinfectable, stable in fecal pH	(ISO 17664-1:2021, ISO 11737-1:2018)
Skin Biomechanic Matching	Materials must deform compatibly with skin during movement and posture changes to maintain seating and prevent discomfort. Requires tuning for displacement, strain, and modulus	Accommodates up to 30 mm skin displacement and 29% strain; Elastic modulus matching: 4.6–20 MPa (tensile), 0.42–1.12 MPa (torsion), 0.13–0.26 MPa (suction)	(Chen et al., 2017; Rupani et al., 2025; Hendriks, 2005)

2.6 Applying Co-Design in Ostomy Care

Designing effective solutions for complex healthcare challenges requires a method that prioritizes user involvement from the earliest stages. Co-design is part of a participatory design approach, in which end-users engage as co-creators in the design process. This differs from traditional user-centered design, in this field the users are more passive subjects which are being studied(Mattelmäki, 2008). Co-design allows for a deeper understanding of user needs and challenges, this is possible because participants are positioned as contributors who shape design outcomes with their lived experiences(Liem & Sanders, 2011). Under the umbrella of co design many tools have been developed to help non-designers with articulating their needs, wishes, and lived experiences. The articulation of these aspects is not only through words, but also through visual, tactile, and interactive methods.This following subchapter will explain what co-design is and how this can be employed in the context om ostomy car. (Sanders & Stappers, 2008; Zamenopoulos & Alexiou, 2018).

2.6.1 Principles of Co-Design

Co-design emphasizes the active role of users throughout the design process. However, it also extends beyond direct user-designer collaboration by facilitating dialogue among various stakeholders. These stakeholders include professionals, organizational actors, and expert networks. Through iterative collaboration the diverse perspectives can improve the quality of both research and design. Ultimately, this process contributes to more user-appropriate outcomes and greater satisfaction among end users (Sanders & Stappers, 2008; Lee et al., 2018).
Sanders et al. (2008) define co-design to be the collective creativity applied across the whole design process. This collective creativity comes from designers, but also from people not trained in design. Figure 2.6.1a shows the co-design process. The fuzzy front end is a critical phase where the scope and problem statement will be discussed. This is done by looking at the context and the technological opportunities. Co-design enhances the early, uncertain phase of innovation (the fuzzy front end) by involving users in idea generation. Yet, it is equally important to include them in later decision-making moments to ensure their continued influence on outcomes.

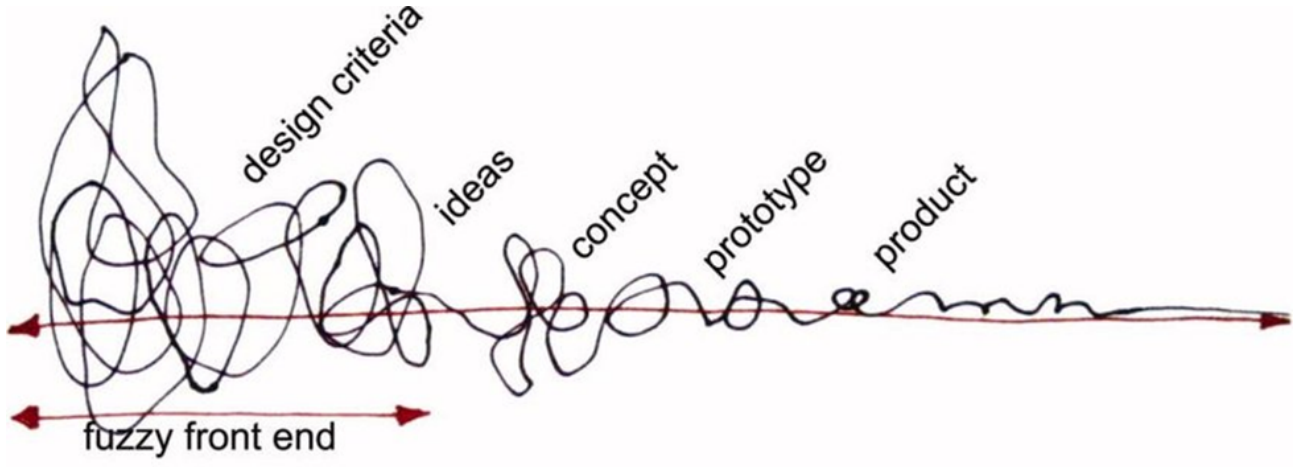


Figure 2.6.1a Co-design process (Sanders & Stappers, 2008)

Core values within co-design are mutual learning, shared power, and creative collaboration. Participants are seen as experts in their own lived experience, which is an idea rooted in participatory design (Williams et al., 2021).

The shift towards co-design challenges traditional user-centred hierarchies. This is because co-design fosters a more balanced exchange between participants and professionals. Not only are

participants experts in their lived experiences, they also contribute their embodied and unspoken knowledge. This type of knowledge is often difficult to articulate, but it is crucial for uncovering real needs (Sanders, 2002). The real needs can be uncovered by using expressive methods, and providing thoughtful facilitation. It is important to remember that within co-design the input of participants should have a genuine impact on decisions, which can help tokenism and support collaboration(Sanders & Stappers, 2008; Moll et al., 2020). As mentioned above, facilitations plays an centra role in achieving this. Facilitators should create an inclusive and respectful setting. Besides this, they are responsible for managing group dynamics, bridging the gap between technical language and personal experience, and adjusting activities to accommodate cognitive, emotional, or physical differences among participants (Allam et al., 2021). In this way, facilitation becomes a foundation of meaningful co-design, ensuring the process remains inclusive and empowering throughout.

METHODS AND TOOLS

Uncovering meaningful insights in co-design means understanding the user's context. Context refers to the social, emotional, physical, and practical dimensions of life. These dimensions shape how people experience a product or service. Uncovering the context can be done through context mapping. This is a tool which helps explore these factors by inviting participants to reflect on their daily routines, emotions, and interactions. Through tools such as timelines, emotion cards, and narrative prompts, context mapping reveals tacit knowledge and hidden needs. Tacit knowledge is often overlooked in conventional interviews or observations. Context mapping helps the participants to get sensitized to co-designing and making them familiar with subjects the co-design workshops will cover (Stappers & Sanders, 2003). Building on this foundation, generative techniques are often used in context mapping exercises to access what participants know, feel, or imagine. These methods encourage creative expression through the use of collages, storyboards, diaries, and model-building. These activities are different as they help translate abstract experiences into tangible artifacts (Sanders, 2000; Sanders & Stappers, 2008). After the context mapping the co-design workshops take place.

Most co-design takes place in workshop settings, where small groups engage in collaborative activities such as storytelling, persona development, experience mapping, card sorting, sketching, and low-fidelity prototyping among others(Bird et al., 2021; Lee et al., 2018). These sessions are designed to be inclusive and interactive, while also fostering mutual learning and shared exploration. There is no rule or method for choosing co-design activities. As the selection depends on the research goals and on what is appropriate and accessible for the participants involved.

Notably, co-design has also evolved to accommodate online and remote formats. Tools like digital diaries (Chambers et al., 2021), postal kits (Langley et al., 2021), and phone-based co-design sessions (Allam et al., 2021) have shown that participatory design can remain inclusive even when in-person interaction is not possible. The possibility of online co-design sessions can be useful in the healthcare setting, because particpants may have varying physical, emotional, or cognitive needs. This again highlights an need for flexible and responsive approach to co-design.

2.6.3 Co-Design in Ostomy Care

In the context of ostomy care, co-design is valuable as ostomates get the chance to directly influence the design of a product that impacts their daily lives (Masterson et al., 2024). It is of great importance to start the inclusion already in the beginning phase, called the fuzzy front end of design (Mattelmäki, 2008). Within this phase, the problem definition becomes clearer by mapping out needs and wishes. Besides this, initial design directions are also discussed. This is critical to the design process, as early involvement results in designs that are more likely to address user needs and usability challenges. Early involvement also creates a deeper engagement and more meaningful contributions of ostomates to the design process.

The co-design workshops will serve as a platform for ostomates to contribute their insights, co-develop ideas, and validate concepts (Sanders & Stappers, 2008; Sumner et al., 2024). Using participatory design in the medical field helps to create solutions that better fit the real needs and experiences of patients. This approach leads to greater design acceptance and improves overall patient well-being (Masterson et al., 2024). Although co-designed interventions don not always lead to dramatic clinical improvements. They are often seen as more relevant, usable, and acceptable to the users. This is because in healthcare the emotions, daily routines and personal contexts matters as much as medical outcomes. Thus designing with and the user is valuable (Ospina-Pinillos et al., 2018).

An important aspect to co-design are the facilitators. Especially in the healthcare setting more sensitive issues are covered. Thus the job of the facilitator is to ensure psychological safety and support inclusive participation (Moll et al., 2020). Ethical co-design also demands transparency, equitable power-sharing, and careful attention to representation and accessibility (Williams et al., 2021; Coulentianos et al., 2020).

Co-design has already demonstrated its value in various domains such as diabetes, Parkinson's disease, and dementia. In these domains the interventions must fit to the emotional and social realities of everyday life (Rines et al., 2022). These cases show how participatory methods can uncover latent needs and improve the emotional acceptance of healthcare solutions.
In ostomy care literature on co-design remains underexplored. Despite the deeply embodied aspect of living with a stoma, there are few peer-reviewed studies focusing on co-design for ostomy products. A notable exception is the co-produced "ostomy communication guide," in whisch patients helped identify key social challenges and evaluate prototypes (Harrison et al., 2024). Grey literature also suggests promising directions. Kittscha (2023) conducted participatory workshops on psychosocial support, and Llobet Leca (2022) co-developed a customized 3D-printed wafer through iterative sessions. These examples indicate the feasibility and value of co-design in this field, even if academic documentation is still limited. It also empowers participants by validating their experiences and turning them into sources of design value (McLister et al., 2023). In this thesis, co-design is not merely a methodological choice but a practical requirement to develop a pouch-free device that resonates with the lived reality of ostomates.

2.7 Key Insights

This literature review shows that ostomy care is influenced by interconnected physical, psychological, and social challenges. Despite advances in pouching systems, many needs are still insufficiently addressed. Emerging technologies and temporary pouch-free concepts offer potential but face critical medical, technical, and biomechanical constraints. Human-centred, participatory design is positioned as essential to bridge the gap between technical feasibility and lived experience. These findings directly informed the design of the questionnaire, focusing on ostomates' experiences, challenges, and attitudes toward pouch-free solutions.

Key insights informing the next chapter:

- Physical complications (e.g., leakage, skin irritation) persist and are closely linked to emotional distress and social limitations.
- Standard pouching systems often fail to fully accommodate autonomy, discretion, and individual anatomical variation, despite improvements.
- Psychological resilience and quality of life are influenced by autonomy, material suitability, and environmental support.
- Temporary pouch-free periods are promising but must respect human biomechanical limits and ensure safe sealing, skin health, and removal.
- Emerging solutions highlight a shift toward dynamic, human-controlled management, yet real-world evidence remains limited.
- Human-centred, participatory methods are crucial to uncover latent needs and support meaningful, acceptable innovation.

Chapter 3: Insights into Ostomy Experiences and Needs

This chapter presents the results and interpretations of the questionnaire study conducted among ostomates. It includes both quantitative and qualitative findings, covering three main areas: lived experiences within ostomy care, preferences for products and accessories, and perceptions of temporary pouch-free periods. Responses are analysed statistically and thematically to extract key user needs, design considerations, and relevant contextual insights. These results directly inform the co-design phase and the formulation of user needs and requirements. The following research sub questions will be partially answered within this chapter, What challenges do ostomates face in current pouch-based care, and how are these reflected in product solutions, What are the key needs and wishes of ostomates regarding ostomy care, and How do ostomates perceive and experience the idea of a temporary pouch-free period?

3.1 Methodology

After identifying gaps in the literature review, a structured questionnaire is used to capture the experiences of ostomates in daily life, needs and wishes for ostomy care, and interest in pouch-free periods. The questionnaire is chosen for its ability to systematically collect data within large sample sizes efficiently. The questions consisted of closed-ended and open-ended questions, ensuring both breadth and depth of data (Aocns, 2015; Fowler, 2013). The questions at the end were used as a recruitment strategy for the following co-design phase. A pilot-test of the survey is conducted to make sure it was fitting to the target group. The survey was available through Microsoft Forms in English and Dutch to ensure not to exclude English speaking participants. While the questionnaire itself was developed in collaboration with another master's student, the recruitment and analysis were conducted independently.

3.1.1 Recruitment strategy

The target population for the questionnaire were adult individuals living with intestinal ostomies. Inclusion criteria were an age above 18 years old, having a colostomy or ileostomy for any medical reason, the ability to read English or Dutch, and being knowledgeable with online surveys. Exclusion criteria consisted of individuals with urostomies, persons under 18 years old, and those who did not or could not give consent. No other strict restrictions were put on the participants as the questionnaire is used to capture a broad, and diverse sample of ostomates. The dataset consists of 770 responses, after an exclusion of 39 responses. Exclusions were based on the lack of informed consent, having an age below 18 years, and the classification as medical professional or other. The exclusion based on the role of a respondent was necessary due to a low number of responses within these categories. As a result, the target group was narrowed and refined to focus exclusively on ostomates.

Initially a convenience sampling is used for the recruitment of participants. Convenience sampling is a method in which participants are selected based on their accessibility and willingness to participate. This approach enabled the recruitment of motivated ostomates willing to share experiences and engage in co-design activities (Etikan, 2016). The platforms through which participants were recruited consisted of online communities, patient organizations, and national associations. An important aspect to recruitment was the collaboration with organizations such as the Stomavereniging, Stomaatje, and Chron & Colitis. Besides this, networking is was used through LinkedIn and stoma-related events such as the Stoma Day in Oegstgeest to reach more participants. A link to the survey was posted on these platforms or shared through e-mail newsletters. Furthermore, snowball sampling (Heckathorn & Cameron, 2017) was used to expand the participant pool with existing social networks. Respondents were encouraged to share the questionnaire link with other ostomates in their network.

3.1.2 Questionnaire Development

The questions were developed specifically for this study, tailored to the research objectives rather than adapted from existing validated questionnaires. While this may limit direct comparability to other studies, it ensured the questions were highly relevant to the specific goals of understanding ostomates' needs and exploring periods without an ostomy pouch. The questionnaire was designed to take 10-15 minutes to complete.

The questionnaire was pilot-tested (Taherdoost, 2016) by de Stomavereniging, resulting in adjustments to vague wording for better clarity and understanding. A mix of closed-ended and open-ended questions are selected to cater to this population. Closed-ended questions provided clear and structured response options, while open-ended questions provided the needed depth to understand the closed-ended questions (Fowler, 2013). The questions were made up in English

and in Dutch to ensure the accessibility for the target group. The questions for ostomates can be found in Appendix B1.
Another aspect in the development of the questionnaire is the collaborative approach taken to design the questions. This is done together with a colleague master student A. Brilliant, who is conducting a complementary thesis research. This joint effort ensured that ostomates would not be overwhelmed with two similar questionnaires going around. However, this also meant that not all information in the questionnaire will be relevant for this thesis and only the relevant data will be discussed in this chapter. That said the complete raw data set can be found in Appendix B2.

3.1.3 Data collection

Participants could complete the questionnaire anonymously online. The first question asked for the language preference, immediately after the participants were shown an information and consent page. This page explained the studies purpose, assured confidentiality, and stated that the proceeding implied consent.

The survey platform Microsoft Forms is used to collect all responses, as Microsoft is in line with GDPR privacy regulations (Microsoft, 2024). No personal identifiers were collected within the questionnaire itself, however at the end participants could voluntarily give their e-mail address if they were interested in the co-design sessions. Responses were automatically recorded in the Microsoft Forms database. After a 1-month data collection period, the questionnaire was closed and the data exported as Excel file to a local hard drive.

Prior to analysis the data underwent pre-processing, the open questions were checked for identifiable information. This was either anonymized or pseudonymized, for example a name of a hospital and surgeon doing the operation. English responses were translated into Dutch. Translation of the closed-ended questions followed the Dutch question options. The open-ended questions were translated carefully to preserve meaning. Appendix B3 presents the data cleaning log.

The final cleaned data set with 770 responses was then imported into IBM SPSS for the statical analysis, and ATLAS.ti for the thematic analysis.

3.1.4 Data analysis

For a comprehensive analysis of the data a combination of statistical analysis and thematic analysis are used. Using both analysis methods quantitative trends can be integrated with qualitative depth. Statistical analysis is essential for identifying patterns, distributions and relationships within the dataset. These insights are objective and reproducible (Theisens, 2023). Descriptive statistics such as frequencies and percentages are used to create an overview of the experiences of ostomates. Inferential techniques such as chi-square tests (McHugh, 2013) helped determine associations between variables. The use of statistical methods improves the generalizability of the results. Ensuring that the reported trends are not only due to chance but reflect patterns in the target population (Bryman, 2016).

To determine the appropriate statistical tests, normality tests were conducted. There was a non-normal distribution of data (Norman, 2010). Thus, while reporting results the median and interquartile ranges are used instead of means and standard deviations. Inferential statistics were used to identify patterns and subgroup differences. Furthermore, Chi-square tests were employed to examine the associations between categorial variables. The sample size was sufficiently large, and assumptions of the chi-square tests were met to ensure validity. Additionally, sensitivity analyses were conducted to confirm that larger subgroups did not disproportionately drive any significance reported (McHugh, 2013).

In contrast, a thematic analysis provides rich and contextualized interpretations. From the data collected with the open-ended questions a deeper understanding of subjective experiences, motivations and concerns can be reported (Braun & Clarke, 2006). A thematic analysis is valuable in health research. Because individual narratives offer more insight than numerical data alone (Nowell et al., 2017). Thematic analysis ensures that the personal and heterogenous experiences of ostomates are not overlooked (Clarke & Braun, 2016).

The thematic analysis is done following the six-phase framework by Braun and Clarke (2006). First, the data was read to ensure familiarization. Each open question is analyzed separately at first, to ensure a structured review because of the large sample size.The analysis followed a mixed inductive–deductive approach. Initial codes were generated inductively, which ensured that coding remained close to the data. However, as the analysis progressed, it became evident that many resulting themes aligned with the structured domains of the questionnaire. These domains consisted of the challenges, material experiences, and the perceptions of pouch-free periods. This alignment reflects a deductive component, as the questionnaire was intentionally designed to explore these areas.

The codes and subthemes are reviewed consecutively to accurately represent the data. Each subtheme is then defined and named per question. Afterwards a broader analysis is done by looking at all questions together and finding main themes. Furthermore, a co-occurrence analysis was conducted in Atlas.ti to see how often subthemes appeared together. This analysis reveals relationships between concepts, thus it helped identify which aspects were most frequently linked in the ostomy experience. Building on this, the whole thematic network is visualized. Lastly, the analysis is reported with extracts from the data to illustrate the discovered themes.

3.2 Participant Characteristics

3.2.1 Demographic Overview

To provide a context for the analysis of these results the demographic composition is essential. This section covers the characteristics of age, gender, and preferred language. With this information the representativeness of the sample is discussed.

The summary of the demographic composition can be found in Table 3.2.1a. Here it becomes clear that the age distribution is skewed towards older participants. The majority (57.0%) of the respondents belong to the 65+ group. The 41-55 and 61-65 age groups account for 13.8% and 12.2% of the respondents respectively. While younger participants, 18-30 years old, make up only 3.3% of the sample. This limited representation of younger ostomates should be considered within age-related differences of the analysis.

The gender distribution is more balanced, the sample consists of 54.3% female and 45.3% male respondents. A small proportion (0.4%) did not want to disclose their gender. The near balance of this distribution ensures that both male and female experiences are well represented. Most participants (94.4%) completed the survey in Dutch, 5.6% chose English.
Understanding this sample composition is important for further analysis. Because of the demographic imbalances, sensitivity analyses were conducted to ensure that the conclusions drawn from the data were not heavily influenced.

Table 3.2.1a Demographic characteristics of the sample

Category	Variable	Frequency(N)	Percentage(%)
Age Distribution	18-30	26	3.3%
	31-40	34	4.5%
	41-55	106	13.8%
	56-60	71	9.2%
	61-65	94	12.2%
	65+	439	57.0%
Gender Distribution	Male	349	45.3%
	Female	418	54.3%
	Prefer not to say	3	0.4%
Preferred Language	Dutch	727	94.4%
	English	43	5.6%

3.2.2 Stoma Characteristics

Besides demographic characteristics, it is important to look at ostomy related characteristics. This section covers stoma type, duration since surgery, reasons for stoma formation, and surgical context. Additionally, the demographic variations within these characteristics are examined. Looking at the results the majority of respondents have a colostomy, the stoma type split can be seen in Figure 3.2.2a. Within these respondents 73.1% of the participants have had their stoma for more than 2.5 years.

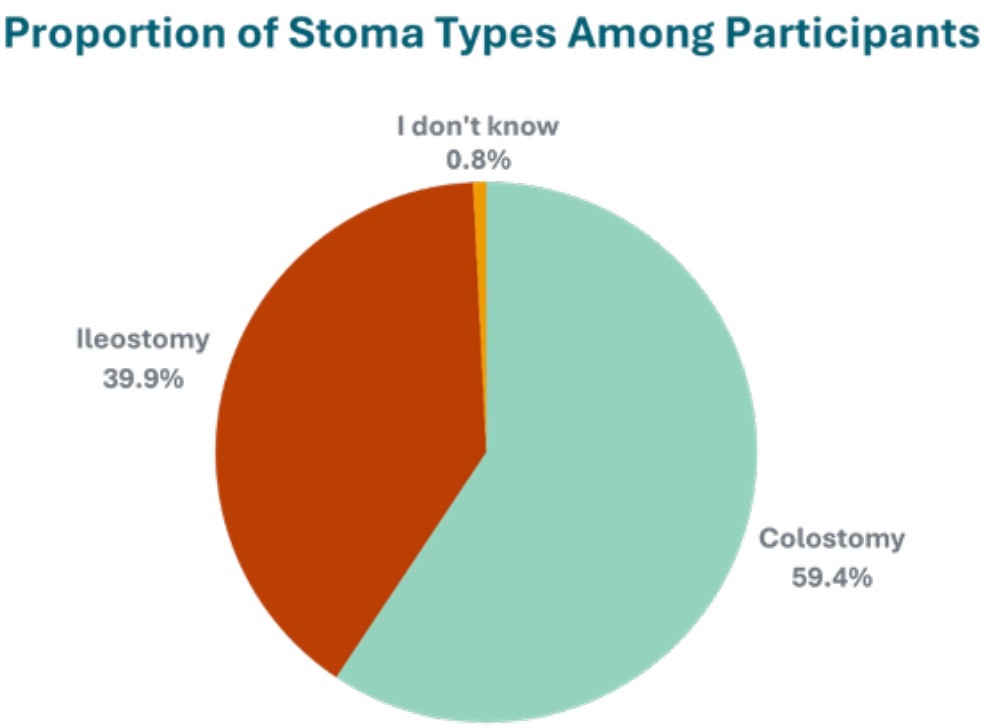


Figure 3.2.2a Stoma Type

Some demographic variations were evident in stoma type. The distribution of stoma type across the age groups shows a clear trend. As age increases the proportion of colostomies increases. Among the 18-30 age group 15.4% has a colostomy, while this is 69.2 % among the 65+ age group. This trend among all age categories can be seen in Figure 3.2.2b. No substantial gender-based differences were observed in stoma type or reason for stoma formation.

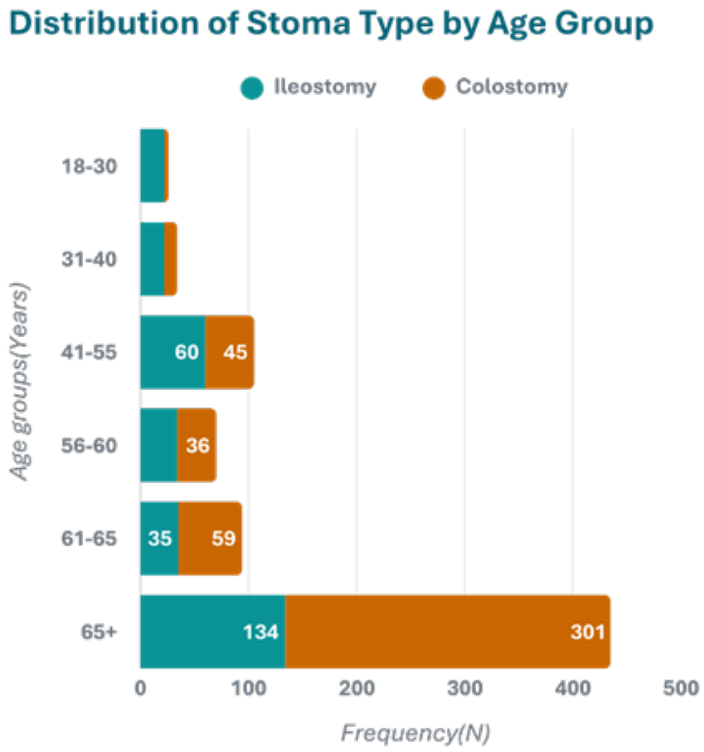


Figure 3.2.2b Distribution of stoma type by age group

Furthermore, the most common reason for stoma formation was oncological disease (48.7%), followed by inflammatory bowel disease(29.1%). Figure 3.2.2c portrays the other reasons for ostomy surgery. The option 'other' is also significant, the most common reasons named were a combination of questionnaire options and obstipation. Within this sample the majority of ostomates (63.1%) had a planned ostomy surgery.

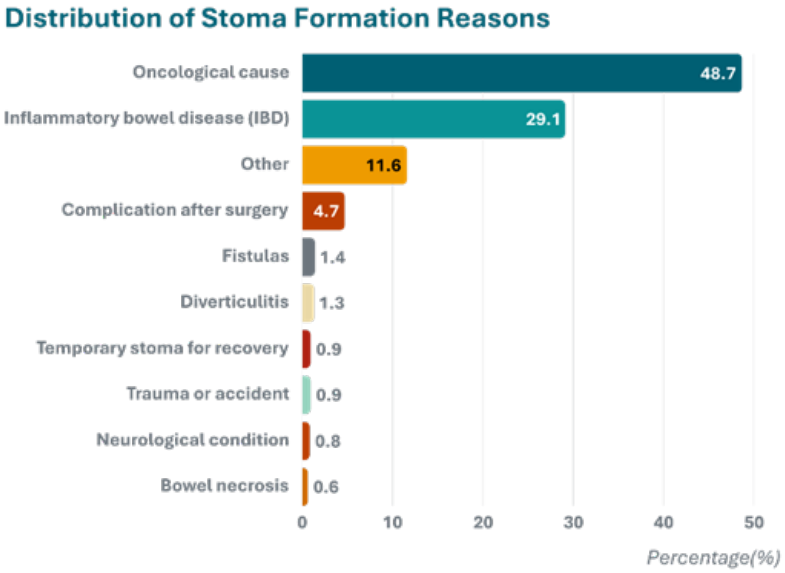


Figure 3.2.2c Reasons for stoma formation

3.3 Thematic Network and Definitions

Because the thematic network serves as a foundation for the integrated synthesis of the findings, it is important to present the network first. Within the thematic network the structure and relationships between themes and subthemes is visualized.

3.3.1 Thematic Network

This thematic network is presented in Figure 3.3.1a. It serves as a framework for understanding the complex interactions between physical, psychological, social, and material aspects of ostomy care. This visual map reinforces the multidimensional nature of the experiences of ostomates. Within the core of the network is the central node, Experiences and Needs of Ostomates. From this node six primary themes emerge, all in a different colour. Each of these themes branch out into corresponding subthemes. The subthemes are colour coded in the same colour as the main theme. The subthemes linked to each theme are connected via grey lines, reflecting their hierarchical relationships.

In addition, purple arrows in the network visualize co-occurrence relationships between subthemes. These were identified through a co-occurrence analysis which highlights when subthemes from different themes frequently appear together in the same individual responses. Co-occurrence suggests that participants experienced these aspects not as isolated challenges, but as intertwined dimensions of daily life with a stoma.

Daily Routine and Lifestyle Adjustments co-occurred 188 times with Psychological Adjustment and Acceptance. This indicates that changes to hygiene, diet, or daily planning often have an emotional or cognitive impact, such as requiring mental adaptation or coping strategies. Similarly, Self-Image and Embodiment co-occurred 140 times with Social Confidence and Public Presence, reflecting how internal perceptions of the body influenced social interactions, public comfort, and perceived stigma.

These intersections highlight that the ostomy experience is rarely one-dimensional. Physical routines, psychological adaptation, and social presence often co-exist in participants' narratives, emphasizing the need for integrated and context-sensitive design solutions.

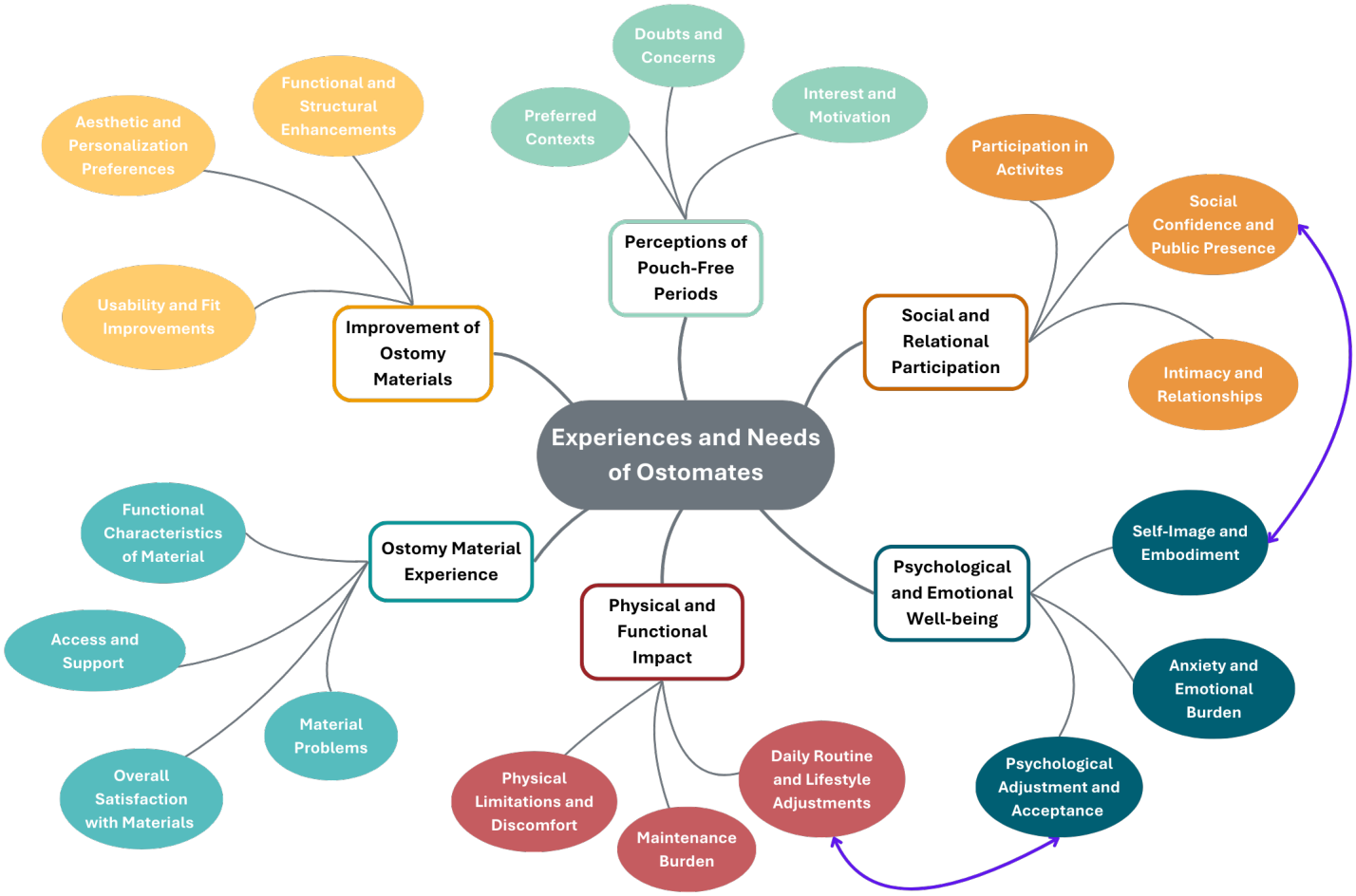


Figure 3.3.1a Thematic Network Questionnaire

3.3.2 Theme Definitions

Understanding the definitions of the themes and subthemes facilitates the interpretation of the integrated findings presented in the following sections. These definitions are summarised in Table 3.3.2a.

Table 3.3.2a Theme and subtheme definitions

Theme	Definition	Subtheme
Physical and Functional Impact	Describes how the stoma physically affects the body, imposes limitations on movement and daily functioning, and creates a sustained need for planning and maintenance	**Physical Limitations and Discomfort:** Describes bodily restrictions and discomfort resulting from the stoma and ostomy material
		Daily Routine and Lifestyle Adjustments: Covers changes in daily habits, hygiene, and planning due to stoma care
		Maintenance Burden: Refers to the time, effort, and vigilance required for ongoing stoma management
Psychological and Emotional Well-being	Encompasses the emotional responses associated with living with a stoma, including adaptation processes, ongoing anxieties, and impacts on self-perception and identity	**Psychological Adjustment and Acceptance:** Captures mental adaptation and acceptance of life with a stoma
		Anxiety and Emotional Burden: Describes emotional strain linked to stoma-related worries and uncertainty
		Self-Image and Embodiment: Concerns changes in body perception, confidence, and self-consciousness
Social and Relational Participation	Explores how ostomates navigate public, social, and intimate contexts, and how the stoma influences their confidence, spontaneity, and interpersonal relationships	**Participation in Activities:** Relates to the ability to engage in social, recreational, or public activities
		Social Confidence and Public Presence: Reflects self-assurance and comfort in public or group settings
		Intimacy and Relationships: Addresses the stoma's influence on romantic and physical closeness
Ostomy Material Experience	Covers the subjective experiences with ostomy products, ranging from satisfaction and performance to accessibility, usability, and material-related challenges	**Overall Satisfaction with Materials:** Expresses general contentment with current ostomy products
		Material Problems: Identifies recurring product-related issues or failures
		Functional Characteristics of Materials: Covers product performance aspects like adhesion and comfort
		Support and Access: Relates to access to information, supplies, and professional guidance
Improvement of Ostomy Materials	Represents user-driven suggestions for improving the function, comfort, personalization, and usability of current ostomy devices and accessories	**Functional and Structural Enhancements:** Describes user-suggested improvements to product design and function
		Aesthetic and Personalization Preferences: Refers to visual or stylistic preferences for stoma products
		Usability and Fit Improvements: Focuses on ease of use and adaptation to different body types
Perceptions of Pouch-Free Periods	Examines user motivations, perceived risks, and preferred scenarios for temporary pouch-free solutions as an alternative to standard pouch-based care	**Interest and Motivation:** Explores reasons for wanting to try pouch-free periods
		Concerns and Perceived Risks: Captures hesitations regarding feasibility, hygiene, or safety
		Preferred Contexts and Duration: Describes ideal settings and timeframes for pouch-free use

3. 4 Integrated Thematic Findings

For the exploration of the experiences, needs, preferences of ostomates both closed-ended and open-ended questionnaire responses are integrated. Statistical patterns from the data are combined with thematic depth, which allows a comprehensive interpretation of challenges, material experiences, and perceptions surrounding pouch-free periods. The results are structured around the six main themes. These themes aligned with the predefined domains of the questionnaire discussed in the methodology.

Before analysing specific thematic dimensions of the experience of ostomates, it is important to understand how ostomates subjectively assess the overall impact of living with a stoma. This general question captures perceptions that may cover the physical, emotional, social, and practical domains. Presenting this data first provides essential context for interpreting the more detailed findings that follow. Besides this, the impact score highlights the diversity in experience. The reported impact scores serve as a baseline reference for the following breakdown across the six main themes.

The impact of a stoma on daily life varies among respondents, while some report minimal disruptions, others mention significant impact. Within the questionnaire respondents were asked to rate how much having a stoma affects their daily lives. This impact is rated on a five-point scale (1 = no impact, 5 = extreme impact). Figure 3.4a shows the boxplot for the impact score among participants. Most respondents reported experiencing some level of impact, 45.7% selected a score of 2. Only 2.7% reported extreme impact, and 8.6% reported no impact at all. Next to these percentages the boxplot allows for a summary of variability, skewness, and individual differences. Because the data is not normally distributed, the median and IQR are reported rather than the mean and standard deviation to provide a more accurate reflection of central tendency and spread, avoiding distortion from extreme values. The median score is 2, indicating that half of respondents reported a mild or lower impact. The interquartile range (IQR) spans from 2 to 3, meaning that 50% of responses fall within this range. A small number of outliers at score 5 demonstrate that some individuals experience a much higher impact. These cases, though less common, signal that stoma-related challenges can be deeply disruptive for some.

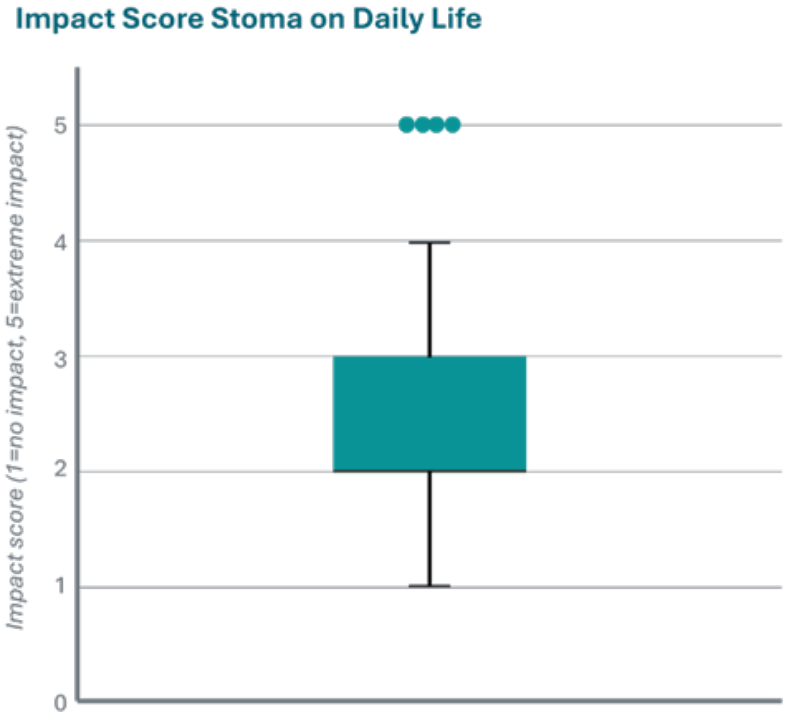


Figure 3.4a Boxplot of Self-Reported Stoma Impact on Daily Life

It is important to note that even a moderate self-reported impact score may reflect ongoing challenges and can affect well-being. This can be seen in the reporting of overall challenges, as even the respondent with lower impact scores mentioned existing challenges and interest in temporary pouch-free periods. The relatively low impact scores do not lessen the relevance of this study, it highlights the complexity of ostomy experiences and the continued need for human-centred solutions that address diverse and evolving user needs.

3.4.1 Physical and Functional Impact

This section explores how living with a stoma physically affects the body, daily functioning, and the burden of routine maintenance. Physical and Functional Impact was a reoccurring primary theme. Challenges reported covered lack of control over output, physical discomfort, and mobility restrictions. A need for extensive lifestyle adjustments was also significant among responses, yet this adjustment was not always seen as negative. This highlights the contradictions that some ostomates experience these difficulties as burdens, while others discuss regaining a newfound health, despite physical and functional limitations. The following section is structured according to three subthemes: Physical Limitations and Discomfort, Daily Routine and Lifestyle Adjustments, and Maintenance Burden.

PHYSICAL LIMITATIONS AND DISCOMFORT

Challenges were categorized into physical, psychological, and social challenges. The answer options consisted of Yes, No, I have experienced it in the past. A significant portion of the respondents reported experiencing challenges. This part will cover the physical challenges, these were the most prevalent, as 37.3% mentioned that they are currently experiencing physical problems. Figure 3.4.1a presents the distribution of participants based on whether they currently experience, have previously experienced, or have never experienced physical challenges.

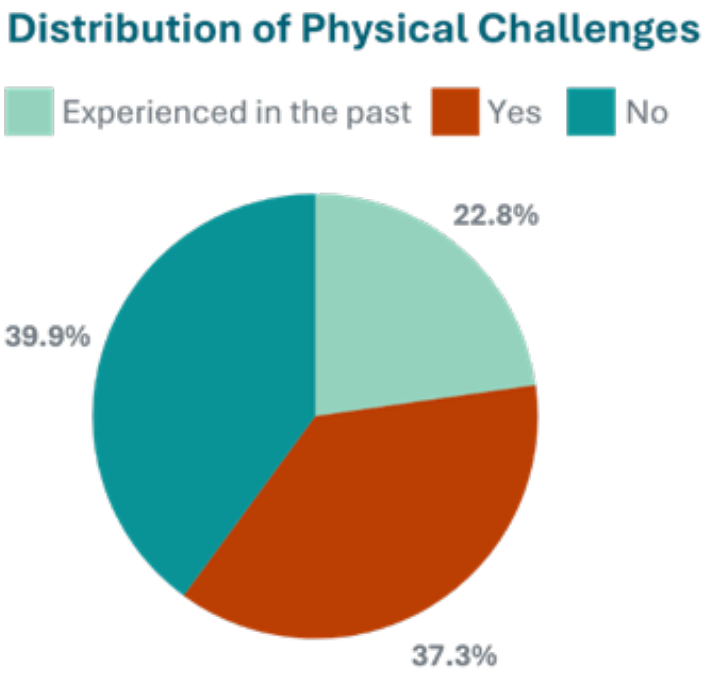


Figure 3.4.1a Distribution of participants by current, past, or no experience of physical challenges

To understand which physical challenges were the most prevalent, participants were asked which specific challenges they encountered. Multiple responses were allowed per participant for these specific challenges. As a result, the percentages in Table 3.4.1a. reflect the percentage of cases experiencing each challenge, rather than the proportion of the total respondents. Acknowledging that individuals experience multiple concurrent difficulties. The most occurring responses are bold and have a different colour in the table. This table presents the specific challenges in the physical, psychological, and social domains. Among physical challenges, leakage (85.3%), skin problems (62.2%), and pancaking (40.6%) were the most prevalent.

Furthermore, key associations between participant characteristics and the prevalence of challenges are revealed through cross-tabulations and chi-square analyses. Some characteristics showed significant relationships, and for these, sensitivity analysis is employed to ensure the robustness of the associations. Ileostomates were more likely to report ongoing physical challenges (44.1%) than colostomates (32.4%). The chi-square test showed that this association is highly significant ($\chi^2 = 35.456$, $p < 0.001$), which indicates that within this sample, physical challenges are significantly more prevalent among ileostomates compared to colostomates. This difference is likely related to the nature of ileostomy output, which can increase the risk of skin irritation, leakage, and adhesive failure as discussed in Chapter 2. Building on this, ileostomates mentioned higher rates of skin problems (67.0% vs. 57.0%, $p = 0.028$) and stoma fistulas (76.9% vs. 23.1%, $p = 0.040$). On the other hand, colostomates were significantly more likely to experience pancaking (64.7% vs. 35.3%, $p < 0.001$) and parastomal hernias (60.8% vs. 39.2%, $p = 0.005$). However, the generalizability of this finding should be interpreted with caution due to the use of convenience sampling for participant recruitment.

Tabel 3.4.1a Specific challenges experienced by ostomates, and its percentage of cases

Category	Challenge Type	Percent of Cases(%)
Physical Challenges (N=463)	**Skin problems**	**62.2**
	Leakage	**85.3**
	Pain	18.8
	Bleeding	15.6
	Prolapse	14.5
	Pancaking	**40.6**
	Necrosis	3.0
	Parastomal hernia	31.1
	Stoma fistulas	2.8
	Other	5.0
Psychologial Challenges (N=215)	**Shame**	**56.3**
	Difficulty with acceptance	**61.9**
	Difficulty asking for help	22.3
	Other	19.5
Social Challenges (N=214)	Avoiding social gatherings	32.7
	Fear of public leakage	**62.1**
	Concerns about intimacy and relationships	44.4
	Negative reactions of others	14.5
	Physical activity difficulties	**57.9**
	Concerns about public toilets	48.6
	Concerns about traveling	**51.4**
	Difficulty of clothing choices	42.5
	Difficulty of stoma care	23.8
	Other	8.4

The qualitative data builds on the aforementioned descriptive statistics as the respondents described limited mobility, reasons for physical challenges, and discomfort associated with daily functioning not covered fully in the closed-ended options. One respondent noted: "*There are some things I just can't do anymore, I can never lift more than 10 kg. It makes work difficult, and I can't pick up my grandchild, so I can't babysit.*" Highlighting the influence of physical limitations on one's life. Besides this, another respondent explained the effect of wrong material choice on the physical challenges experienced. This can be seen in the following quote, "*The first six years I had a lot of trouble due to poorly fitting materials, daily pain and leakage. Over the past nine years, the materials have fit increasingly better, so I've had fewer problems.*"

DAILY ROUTINE AND LIFESTYLE ADJUSTMENTS

Although not all respondents framed their stoma as physically challenging, many described having to make continuous adaptations in their daily routines. These included careful planning around toilet access, carrying supplies, managing diet, and waking up earlier for care routines. The frequency of these experiences was reflected in the high tag count (436x) for this subtheme.

Several quotes illustrate the pervasiveness of this planning burden: *“Never do anything spontaneously again, always having to consider your stoma.”* and *“You are busy 24/7 checking pouch fullness, emptying it, dealing with pain, monitoring mucus and blood production.”*

Such adjustments often led to restricted spontaneity, especially during travel or social events. As one participant stated: *“I can no longer travel spontaneously! I need to make sure I have enough supplies, extra luggage, and check where I can access a restroom for changing.”* The effect of these experiences imposed by functional limitations carry on to the other domains, once more emphasizing the interrelations between themes.

MAINTENANCE BURDEN

The third subtheme covers the time and effort required to maintain stoma hygiene and function. Respondents often described stoma care as a continual task that required vigilance, time, and physical energy. While not always interpreted as negative, the cumulative burden was evident in statements such as: *“With a stoma, you are never truly done; you must always be prepared to change the pouch at any time and place.”* The necessity of frequent changes, skin care routines, monitoring for leakage, and adjusting adhesives were reported as tiring or disruptive, especially during work or at night. Diet also played a role in maintenance, with some respondents needing to monitor food intake to manage stool consistency and avoid complications.

Contradictions

Furthermore, contradictions became apparent within this theme. While some ostomates report physical and functional restrictions, others mention that they are completely adapted. Those often mention they do everything they did before having a stoma, "*I do everything I did before. My next step is to start exercising again, preferably boxing.*"

Another contradiction worthwhile to mention is that some ostomates experience more freedom because of their stoma, while the stoma makes others dependent. A quote showing this freedom is the following, "*My stoma gave me my life back; I can now enjoy and be active again.*" The impact of a stoma on daily life varies a lot too, continuous impact is reported often. However, many respondents also noted that the impact was minimal, "*I’m completely used to my stoma and barely notice it in my daily life.*" How this impact is perceived depends on if the ostomates can adjust to the daily routines, mobility, and physical challenges encountered. Having limitations and challenges in the context of stoma care influences how well ostomates can adapt and accept their life with a stoma.

3.4.2 Psychological and Emotional Well-Being

This section explores the psychological and emotional dimensions of living with a stoma. In the questionnaire for the specific psychological challenges options shame, difficulty accepting the stoma, and difficulty asking for help were covered. The thematic analysis provided an extending view on these options. These covered aspects such as fear of leakage, self-consciousness, and continuous vigilance. The quantitative findings indicate that 15.8% of respondents currently experience psychological challenges, the distribution can be seen in Figure 3.4.2a. From the respondents experiencing psychological challenges, difficulty accepting the stoma (61.9%) was the most prevalent (Table 3.4.1a). However, it is important to note that when looking at all responses the subtheme of Psychological Adjustment and Acceptance was more prevalent. This suggests that adaptation is a central psychological process for many ostomates, not only those who classify their experience as emotionally challenging. Thus, the subtheme of Psychological Adjustment and Acceptance remains highly relevant to understanding the broader emotional landscape.

Figure 3.4.2a Distribution of participants by current, past, or no experience of psychological challenges

PSYCHOLOGICAL ADJUSTMENT AND ACCEPTANCE

The majority of respondents mentioned that they accepted their stoma and integrated it in daily life. One respondent mentioned that they can do anything with the stoma they did before having one, "*I do everything I would have done without a stoma.*" Many recognized the necessity of an ostomy procedure for their survival. Even though it is not ideal there is acceptance, "*I accepted my stoma immediately it saved my life. It's not ideal, but I can live with it.*" These quotes reflect the subtheme of psychological adjustment, where the stoma is no longer seen as a disruption but part of everyday life.

ANXIETY AND EMOTIONAL BURDEN

Despite the widespread acceptance, some respondents experience ongoing anxiety and worry. Most anxiety is about leakage, noise, smell, and the availability of public restrooms "*I'm afraid of leaks, so whenever I notice any smell, I immediately check my stoma.*" Especially when they are in a social setting, "*When I go on day trips, I'm often anxious about being somewhere without a nearby restroom.*"

SELF-IMAGE AND EMBODIMENT

Self-Image and Embodiment were often reported as challenges, which were not earlier discussed in the closed-ended questions. Respondents dealt with a worse self-image in social or public settings, "Better continence, but worse self-image embarrassment about intimacy." The visibility and noise of the pouch system was also an issue relating to ostomates perception of self-image. "The pouch itself is bulky and often visible under clothing. The material makes a crinkling sound, which makes me self-conscious."

CONTRADICTIONS

The varied responses while reported the effect on psychological and emotional well-being provided contradictions within the data. The most apparent one is about the differences in gratitude and burden. Where some ostomates view the stoma as a life-saving solutions, which provides them with more freedom. Others experience constant constraint and burden. The constant worry can be seen in this quote: "*From an active life to constantly thinking about something you have no control over.*"

This effect on well-being can also be seen in the differences between routine and constant adjustments. When the stoma is part of one's daily routine, ostomates report a higher acceptance and freedom. If adaptation and acceptance is difficult, due to challenges for example, constant adjustments are needed according to the respondents. The following response portrays this constant burden, "*I still have a hard time adjusting. I'm constantly wondering if it's okay.*" With this it also becomes clear that there are contradictions between perceived freedom and restrictions.

Some report that they can do anything, and do not have to think about the stoma. While others mentioned that they can do nothing. Neutral or pragmatic views were also apparent these mentioned that they can do everything they wanted, yet they always must take their stoma into consideration.

3.4.3 Social and Relational Participation

This section explores how having a stoma affects social life, recreational engagement, and intimate relationships. Social challenges were experienced by 21.7% of the respondents, the distribution among participants can be seen in Figure 3.4.3a. The following themes were among the most nuanced in the survey data, revealing a range of participation barriers as well as contrasting narratives of regained freedom.

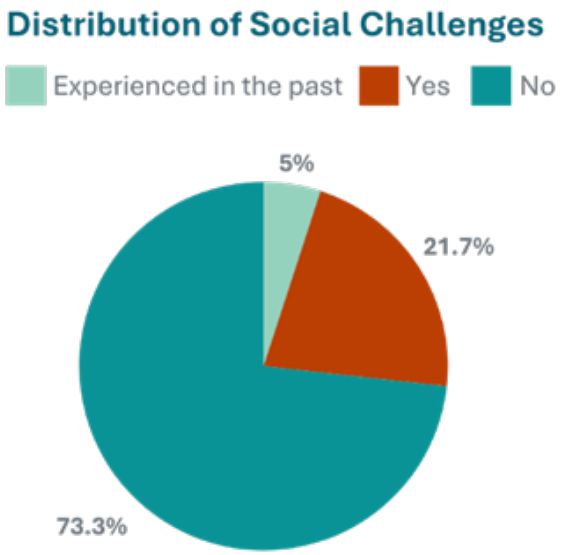


Figure 3.4.3a Distribution of participants by current, past, or no experience of social challenges

PARTICIPATION IN ACTIVITIES

The most common areas in which the respondents reported being restricted in were social, recreational and sport activities. Reported activity limitations often stemmed from fear of leakage, difficulty accessing restrooms, or the noticeability of the stoma or pouch. The participation in these activities is influenced by different areas of stoma care. Physical challenges including pain and chronic fatigue, among others, limit participation. Potential leaks and the constant need to monitor their stoma did influence participation heavily as well: "*During sports, I'm always worried about leaks.*" Going on vacation or to the beach proved to be difficult as well, "*Going to the beach or on vacation is difficult when you always have to search for a restroom.*" Next to this, some respondents were heavily affected by the noticeability of the stoma or appliance, one participant even mentioned not to swim in public anymore: "*I can live with it well, but the bulge on my abdomen affects how I wear clothes, and I don't swim in public.*"

SOCIAL CONFIDENCE AND PUBLIC PRESENCE

How an ostomate feels about their self, or how society perceives them did heavily influence social integration and participation. When an individual is at ease with their stoma and does feel confident in social settings there is more participation. Others remain highly aware of the stoma's presence, especially when noise, odour, or pouch visibility might draw attention. Next to this, the quantitative findings highlight that fear of leakage(62.1%) is the most prevalent social barrier, see Tabel 3.4.1a. Some individuals even completely avoid social settings because of this, "*I avoid large gatherings unless I can explain that I have a stoma and that it sometimes makes noise.*"

INTIMACY AND RELATIONSHIPS

A widely reported impact was on romantic relationships. Some mentioned feeling restricted in intimate moments due to the physical presence of the pouch, others focused more on a heightened self-consciousness. Constantly thinking about the stoma is a reoccurring response, also in the following response, "*Intimacy has never been the same. I'm always thinking about my stoma and any noises it might make.*"

CONTRADICTIONS

A stoma can be seen as a social restriction, or as a possibility for newfound freedom. Some feel restricted in participation of social, recreational and sport activities. Others made clear that a stoma was enabling them live life more fully, "*With my stoma, I can do anything sports, going out, working, traveling. In short, living a normal life.*"

Accepting the stoma and being open about it were coping mechanisms for ostomates, who do not feel restricted. A contradiction between openness and privacy is seen in the responses, one respondent summarized this in the following response "*Acceptance and openness are key! If you are honest about it, you can lead a normal life.*" Others mention that they do not talk about their stoma and only go to gatherings if they feel safe to explain that they have a stoma.

3.4.4 Ostomy Material Experience

For innovation it is important to evaluate current devices in use. This theme focuses on the experiences ostomates have regarding their material. Quantitative findings indicate that the majority of respondents (640 out of 760) expressed satisfaction with their current ostomy materials. These users described their systems as comfortable, reliable, and easy to use. Satisfaction was frequently related to reduced worries about leakage or skin issues. This contributed to a sense of peace of mind for many ostomates. To uncover if the pouching system only is sufficient for the ostomates, the questionnaire covered the use of accessories and DIY adaptations to material.

More than half of the respondents (57.0%) mentioned the use of market available ostomy accessories. This high rate of accessory use contrasts with the conservative 'less is more' philosophy often advocated by WOC nurses. It is often emphasized that minimal product use should reduce skin complications, simplify routines, and lower costs. Next to this, respondents also reported the use of DIY materials or adaptations as solutions for physical challenges. From the 770 respondents 28.6% used DIY materials or adaptations to existing materials. Figure 3.4.4a portrays the distribution of specific accessories used. The percentages are the percent of cases, as the question type allowed for multiple answers. Skin protecting wipes and sprays, barrier rings, and support belts were the most frequently used ones.

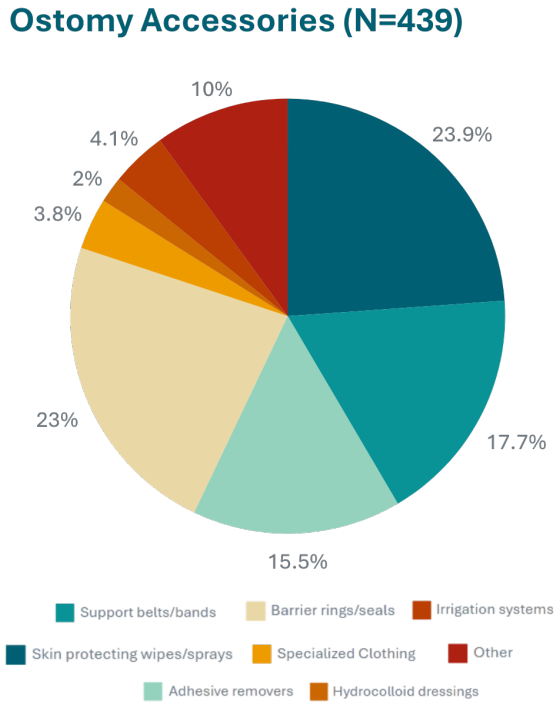


Figure 3.4.4a Accessories used among the respondents

This discrepancy between prescription philosophy and frequent accessories use may reflect a gap between professional guidance and the actual experience of ostomates. The frequent use of accessories suggests that standard pouching systems alone do not adequately meet their individual needs. Especially in the areas regarding leakage prevention, skin protection, and comfort. It can also indicate a trial-and-error approach in daily care, where ostomates adapt beyond medical advice to gain a sense of control and reliability in their routines. This highlights the importance of understanding user-driven adaptations and preferences in the design and prescription of ostomy care products.

OVERALL SATISFACTION WITH MATERIALS

The majority of respondents reported being satisfied with their current ostomy materials. This satisfaction was often associated with comfort, ease of use, and a reliable sense of security in daily life. Respondents described their materials as "*comfortable to wear and change*" and emphasized that "*comfort and usability are okay, and the material is reimbursed.*" Such evaluations were typically linked to reduced worries about leakage, skin irritation, or product failures, which contributed to a feeling of peace of mind and routine stability. For many, the availability of well-fitting and reimbursed materials alleviated practical and emotional burdens, allowing them to maintain daily activities without constant concern.

MATERIAL PROBLEMS

Despite overall satisfaction, many respondents reported persistent material issues. Leakage remains a persistent challenge among ostomates who are experiencing problems with their pouching system, "*I've had a lot of leakage issues. My current material has reduced the problem, but it still happens.*" Most of them use additional accessories, such as paste rings to prevent leakages, "*Using a paste ring prevents leakage, but without it, I experience leaks.*" The effectiveness of adhesives, especially in more moist contexts, does significantly impact leakages as well. This causes ongoing stress for many ostomates.

Filter malfunctions were another major concern, even if respondents mentioned that they were happy with their material, the filters did not live up to the standards of the other components. Ostomates mention that noise or odour is challenging, but the filters do not work well against this. Some even mentioned that they prefer the filters to be removed from the designs. Problems

encountered because of the filters are, clogging, ballooning, and pancaking among others. The following quote highlights these problems, "*It's frustrating that the filter creates a vacuum effect, preventing stool from moving down and causing ballooning.*" If this happened the pouch became more visible, more changes of material were needed, and sleep could be disrupted, "*Great material, but the filter doesn't last through the night. My sleep gets interrupted when my pouch fills with air, and my intestine protests.*"

Skin irritation and poor fit were also noted. Ill-fitting adhesives led to discomfort, itching, or pain and often required manual modification: "*Skin irritation from the adhesive, each time I have to cut and adjust a lot before the pouch fits properly.*"

Additionally, noisy pouch materials were cited as a source of discomfort in social or intimate contexts. Ostomates mentioned that the material used within the pouches made loud crinkling sounds. This was apparent even for ostomates, who were satisfied with their material.
These recurring issues highlight that even when ostomates report general satisfaction, technical limitations in current systems continue to affect the daily lives of ostomates.

FUNCTIONAL CHARACTERISTICS OF MATERIALS

To enhance reliability and comfort, many ostomates reported the routine use of the aforementioned additional accessories. While these additions increase functionality, they also reflect underlying inadequacies in the base products.

Accessory use was often linked to challenges in wear time, skin compatibility, or fit. One respondent mentioned, "*I always have to carry materials with me; I suffer from pancaking and ballooning.*" Adhesive failure under warm or moist conditions was frequently reported, especially during physical activity or hot weather.

Concerns were also raised about rigid or poorly compatible parts. Mainly pouch size and rigidity of the device interfered with discretion. This was particularly visible in summer clothing: "*The edge of the bag sticks out a lot, especially in summer clothes, it looks really ugly.*"

Additionally, aesthetic and functional mismatches contributed to dissatisfaction with functionality. These consisted of visible or transparent pouches or incompatibility between baseplate and bag These responses highlight that while current materials can be made functional through adaptation, they are not inherently robust for all users or contexts. The widespread reliance on accessories indicates a gap between available product performance and individual user needs.

SUPPORT AND ACCESS

While often framed as a separate challenge, support and access are important aspects to how ostomates experience their materials. The usability and effectiveness of products cannot be separated from whether individuals can consistently obtain, afford, and receive guidance on them. Material satisfaction, adaptation, and trust in care is shaped by these factors. This means that the theme Ostomy Material Experience covers not only technical performance, but also the systems that enable or constrain the use of these materials.
Across countries the availability and affordability of ostomy material differ. Especially when looking at the insurance, in the Netherlands users get full reimbursement for the pouching systems. In the USA a lot is financed out of pocket, "*Even with insurance, my personal contribution for ostomy supplies this year exceeded $500.*"This leads to disparities in care. This difference became most apparent between the Dutch and English responses. Ostomates from the UK and Belgium also mentioned financial reimbursement.

Also many users reported some restrictions on the amount and type of ostomy materials they could use according to their insurance. This was especially apparent in accessories like adhesive remover sprays, protective powders, and cleaning wipes. These were not covered by insurance, yet many ostomates reported using them and as being a necessity. Some even had to switch to cheaper materials, which led to problems, "*I always had good ostomy materials, but my insurer*

deemed them too expensive, so they stopped covering them. The cheaper alternative causes problems, including leaks."

Another aspect covered was that ostomates did not know what materials were available for them. They did not get any updates on new or innovative products, and others mentioned that the WOC nurse was not easily available for help.

CONTRADICTIONS

There were many contradictions between experiencing problems with material or being really happy with the material at hand. If the material did fit the individual well, they did often not experience mayor challenges like leakages or skin irritation.

Another contradiction was the different views on material innovation. A part was excited about innovations, while others mentioned that the q*uality decreased with new innovations. One individual mentioned a big decrease in quality,* "*After 33 years of using the same materials, the comfort level has declined. Pouches are noisier and attaching them to the baseplate has become more difficult.*"

Moreover, a contradiction was found was between how insurance covers this material in different countries. Besides this, some mentioned that healthcare professionals gave adequate information and help if this was needed. While others did not know how they could get this help or reported that it was not adequate. This was also the same for having information on different materials available.

3.4.5 Improvement of Ostomy Materials

This theme captures user ideas for enhancing ostomy products, aesthetic options, and addressing usability and fit barriers. While many respondents expressed general satisfaction with their current systems, numerous detailed suggestions emerged for improvements which will be discussed as part of the following subthemes.

FUNCTIONAL AND STRUCTURAL ENHANCEMENTS

Respondents emphasized a strong need for improved adhesive performance, particularly under conditions involving sweat, water, or physical activity. An idea mentioned regarding this can be seen in the following quote: "*The adhesive doesn't stick well when it comes into contact with water. A combination of a baseplate and a ring might work well.*" Poor adhesion was frequently mentioned as a cause of leaks and discomfort. There was also clear interest in waterproof materials, sealing reinforcements, and effective pancaking prevention. For the adhesion mechanism ostomates wanted more skin-friendly materials as well, or even materials which could aid in skin healing, as mentioned: "Maybe make the adhesive skin-friendly, for example by incorporating substances that protect and heal the skin."

Many ostomates highlighted that the use of a pouch system only is often not enough for leakage reduction. This is often solved by using ostomy accessories like sealing or barrier example. "*I create an extra sealing ring to increase the height of the existing barrier to prevent leakage.*" These enhancements to the existing material emphasize once more the gap between existing products and the complete fulfilment of needs.

Next to this, many ostomates use filter improvements, as current filter solutions are not effective. Some put a sticker on the filter to prevent pancaking, others add a peppermint to the bag for Odor control. A mentioned improvement, was the addition of a valve: "*Include a valve to let air out, I struggle a lot with air buildup."*

AESTHETIC AND PERSONALIZATION PREFERENCES

How a medical device worn outside of the body looks is a crucial aspect for users. Struggling with style or colour options was a frequently covered issue. This could cover aesthetic reasons, like

wanting different coloured pouches. Or for example making the pouches less transparent so output is not clearly seen through the material, "*I specifically want the pouch to be discreet and not transparent, so that others can't see anything.*" These two aspects are mere examples of aesthetic and personalization preferences, as the wishes or needs varied widely among responses. Some wanted bigger bags, some wanted bags in all colours of the rainbow, while others wanted non visibility.

USABILITY AND FIT IMPROVEMENTS

Many users reported that the stoma material was not available in their preferred size, thus they would cut within the materials to make it more fitting, "*With square baseplates, the edges curl up due to my abdomen's curvature, so I cut the adhesive into a round shape for a better fit.*" The flexibility of materials is another domain often mentioned, ostomates have different views but flexible materials are preferred, "*The baseplate could be more flexible?*" Others also discussed that they could swim freely with a pouch system, yet changing the system just after swimming was difficult. This led to walking around with a wet pouch causing discomfort.

CONTRADICTIONS

Every individual has their own needs, meaning the expected improvements to ostomy material are highly individualized. A key point of divergence covered material firmness and flexibility. Some ostomates expressed a clear preference for softer, more pliable materials that enhance comfort and reduce sensory intrusiveness. While others emphasized the need for more rigid materials to maintain structural integrity in specific contexts, "*The water pouches should be made of firmer material.*" A second contradiction area was the use of filters. Several participants requested improved filters to manage ballooning and odour more effectively, emphasizing their functional value. Yet others wanted a complete removal of filters, "*Maybe make pouches without filters. They sometimes cause leaks.*"

Another contradiction could be seen in the difference between aesthetic expression versus discretion. Some respondents called for more colour and design variety to better align with personal identity and confidence in public settings: "*More colour choices for pouches right now, it's just beige and black."* Others valued discretion much more.

These contradictions illustrate that even within a shared set of challenges, ostomates hold differing priorities. This underscores the necessity of modular and customizable solutions that can be tailored to individual anatomical, functional, and psychosocial needs, rather than relying on one-size-fits-all designs.

3.4.6 Perceptions of Pouch-Free Periods

The questionnaire also covered the perceptions of ostomates regarding temporary pouch-free periods. Thus, it is important to look at willingness of ostomates to learn more about such periods. There was a varied response, 47.7% expressed interest, while 26.6% was uncertain, and 25.7% indicated no interest (Figure 3.4.6a). Between participant characteristics, only age has a relationship with interest in pouch-free periods ($\chi^2 = 59.101$, $p < 0.001$), after the sensitivity analysis the results were still significant ($\chi^2 = 27.092$, $p = 0.007$). This indicated that the participants in the 65+ age group were most likely to show no interest in pouch-free periods (72.7% selected no). This may be explained by a higher level of routine stability or long-term adaptation of older participants. This can lead to a reduced desire for change, as also highlighted in the following quote: "*I am so used to my stoma that I don't let my life be controlled or limited by the pouch.*"

Another interesting aspect was how such period could be a solution or supplement to the experiences of ostomates. The highest proportion of respondents (25.3%) selected a moderate effect on quality of life (QoL) of such period, represented by a 3 on a five-point scale. Within this context quality of life refers to the definition of WHO (WHOQOL, 2012), QoL is defined as ''*an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.*" The finding

that only 11.6% of ostomates anticipated an extreme impact of pouch-free periods on their quality of life suggests that such moments are not seen as a singular solution. Still, pouch-free periods may offer meaningful benefits in specific context for ostomates. Targeted interventions that support user dignity, autonomy, and well-being are considered valuable in healthcare design, particularly when they enhance everyday life (Croot et al., 2019). Building on this qualitative information, the following subthemes will explore the reasonings behind the aforementioned aspects and the contextual use situations of pouch-free periods.

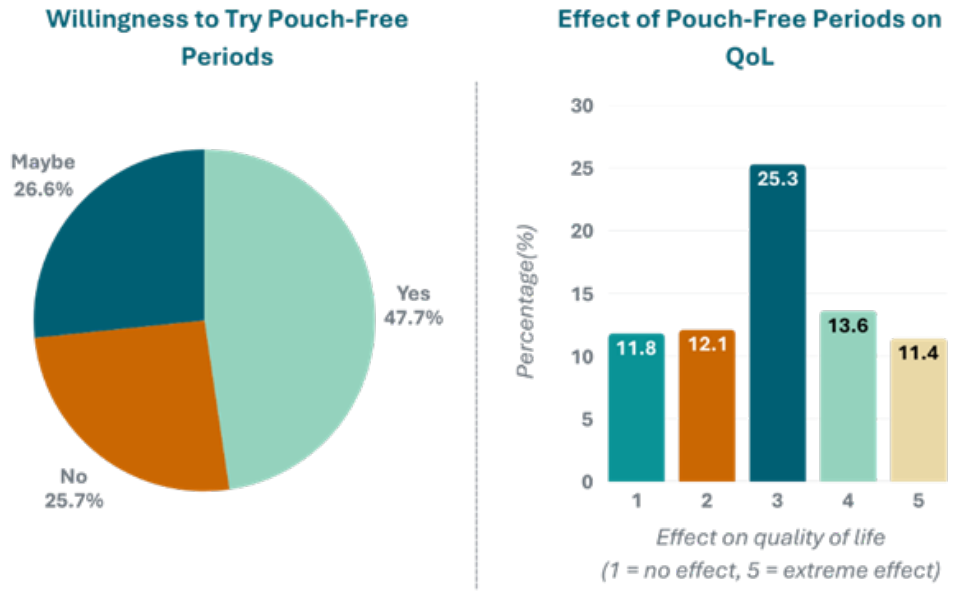


Figure 3.4.6a Distribution of interest in pouch-free periods and perceived effect on QoL

INTEREST AND MOTIVATION

Enduring challenges were significantly associated with interest in pouch-free periods ($p < 0.001$). If respondents experienced challenges, they were more likely to express interest. Psychological challenges had the highest proportion of interest (66.4%), followed by social (63.0%) and physical (55.7%). Thus, psychological burden appeared to be the strongest motivator based on closed-ended response proportions. Building on this, for many ostomates it was about the potential to gain more comfort, freedom, or confidence in specific situations. As one respondent noted, "*It would be nice to test if it works, swimming without a pouch. But my happiness doesn't depend on it.*" This type of situational curiosity was the most frequently expressed attitude among the interested participants.

Key motivations included the potential for greater physical freedom, such as working in the garden or walking without interruption: "*It would be wonderful to work in the garden for a few hours without constantly running to the toilet.*" For others, their interest was tied to sports and active lifestyles: "*I'm a passionate athlete, swimming, cycling, running marathons. If that could be done without a pouch, it would be more comfortable.*"

Psychological motivators were also expressed frequently in the closed-ended responses. Some respondents highlighted how pouch-free periods could enhance self-image and intimacy, expressing a desire to feel more attractive and less self-conscious: "*I would feel more attractive without the pouch; there's always something 'in between.'*" Others associated the idea with emotional relief, particularly the reduction of stress related to leakage or the visibility of the stoma in social contexts, "*Then it isn't visible. And that gives me confidence.*"

These responses suggest that pouch-free periods are not about completely bypassing pouch based care. It emerged as a context specific alternative, providing relief to moments in which physical or emotional burdens are heightened. An important aspect to this was introducing

pouch-free periods without rejecting the routines that ostomates had come to accept and adapt to.

CONCERNS AND PERCEIVED RISKS

Despite the interest, many respondents voiced serious concerns about the feasibility and safety of pouch-free periods, these can be seen in Figure 3.4.6b. The aspect most concerned about were risk of leakage (77.2%), followed by doubts about product effectiveness (61.2%) and difficulties in managing the device (35.3%). These percentages are percent of cases, as the question allowed for multiple answer choices. A commonly expressed worry was: "*I'm afraid it won't work or that it will leak.*"

Figure 3.4.6b Distribution most common concerns regarding temporary pouch-free periods

A key concern was the technical feasibility of pouch-free use, especially among ileostomates. Respondents questioned how such a solution could function reliably with unpredictable and continuous output: "*A temporary solution without a pouch seems nearly impossible. I'm curious what it would be, but for me, the question is: how reliable would it be?*"

Another common concern was adaptation to current routines. Some respondents are accustomed to their pouch system and they were hesitant to change what already worked: "*After 18 years with a pouch, it's hard to even imagine what exactly is meant by a temporary alternative.*"

Concerns also related to control and predictability. For some, the pouch provided necessary reassurance, especially when output timing was uncertain: "*I don't defecate at fixed times, so you can never be without [a pouch].*" Another respondent reflected, "*It would be great if it were possible, but in the end, it's still a technical solution to something, while the real challenge lies in the social or human side. Do you have enough confidence to go out without a pouch?*"

PREFERRED CONTEXTS AND DURATION

In which context, such a product would be used is analysed by asking the ostomates which activities were preferred for pouch-free periods. More answers could be chosen, leading to reported percent of cases. shows that swimming was the most preferred activity (56.4%), followed by intimacy and sports. Swimming is separate from sports in the options, as swimming could also be a recreational activity. The most preferred activities can be seen in Figure 3.4.6c.

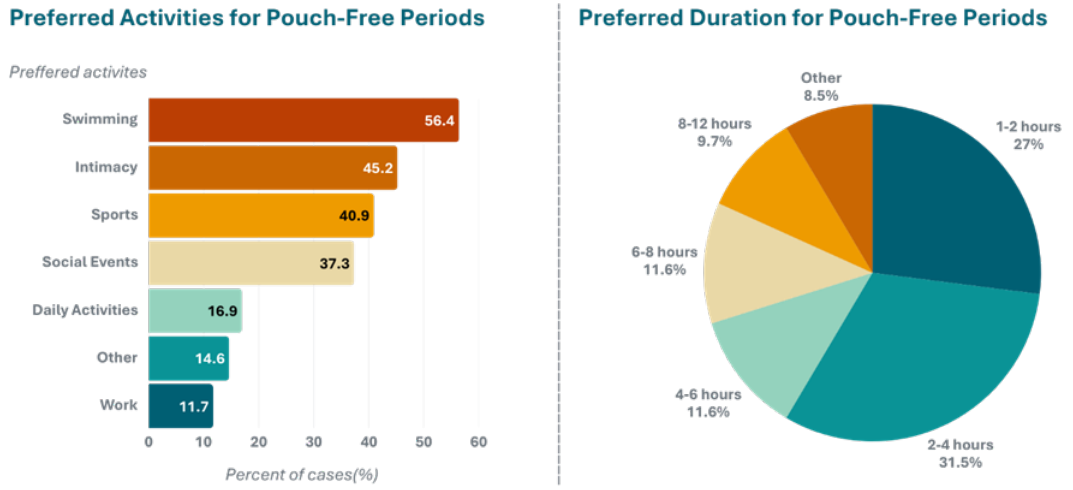


Figure 3.4.6c Preferred activities and duration for pouch-free periods

These findings are enriched with the open-ended responses, as ostomates also mentioned broader scenarios such as vacations and social outings, where managing pouch-related logistics is perceived as burdensome. As one participant noted, "*Especially at the beach and on holidays, it's annoying to always be searching for a toilet.*"

Many ostomates mentioned the need for greater physical freedom. Activities such as gardening, walking, or outdoor work were often mentioned as moments where a pouch-free period could reduce interruption and increase comfort: "*It would be wonderful to work in the garden for a few hours without constantly running to the toilet.*" Another respondent explained, "*A pouch on your belly is a limitation in my daily life.*" Sports and exercise were also common motivations, particularly among those with active lifestyles. Others also emphasised concerns about pouch security during movement and the fear of leakage while exercising.

Intimate moments formed another context where pouch-free use was considered valuable, both for practical reasons and for improved emotional connection. Respondents described the pouch as disruptive or distracting during sex, with one remarking, "*During intimacy, it [the pouch] often gets in the way or becomes a distraction.*"

Because pouch-free use is contextual it was necessary to gain insights in the preferred duration for a pouch-free period. The most selected timeframe was 2 to 4 hours, followed by 1 to 2 hours. This again suggests a preference for short-term, context-specific use, rather than continuous wear. Figure 3.4.6c presents the distribution of preferred duration responses.

CONTRADICTIONS

The data set also revealed contradictions between response in how pouch-free periods are perceived. These highlight that acceptance of such a period is shaped by not only practical needs, but also psychological adaptation, trust in the system, and the perceived benefit.

Contradictions are found between the promise of freedom and the comfort of certainty. For some ostomates a moment without a pouch provided relief and autonomy: "*It would be wonderful to live without the fear of leakage or an overfilled pouch.*" While others felt more secure with their routines and feared losing stability: "*It's going well now, so maybe I'd feel insecure without a pouch, afraid it might leak or press in an uncomfortable way.*"

Another contradiction became apparent in how the respondents view their pouch, it could be a limitation or just an aspect of their daily routine. One noted that "*The bag makes things uncomfortable, so if there's another way, I'd prefer it.*" Others were content with the current situation: "*I've become so familiar with my pouch that it no longer restricts my life.*"

There was also a relationship between curiosity and scepticism, as some were interested but this depended on the perceived benefit of the device. Yet, a big group also noted that they are curious but did not believe it would be possible: "*I don't think it's possible, so I'm curious about the creative solution you're promising.*" These diverging views show that pouch-free periods are not universally seen as positive or negative. Their value depends on personal routines, experiences, and levels of trust.

3.5 Key Insights

The following key insights inform the co-design process:

- Physical challenges are still at the foreground and are closely linked to emotional and social burdens. Common physical challenges reported were leakage, skin irritation, and mobility restrictions persist and are closely linked to emotional and social burdens.
- There is a overall satisfaction with the current pouch based systems. However, these systems can not fulfil all users needs regarding autonomy, discretion, and anatomical differences.
- More than half of the respondents rely on accessories and DIY adaptations next to the pouch systems, this reveals a gap between standard products and real-world user needs.
- Material satisfaction is shaped not only by product functionality, but also by access to materials, and informational support.
- Psychological adjustment and self-image are strongly influenced by leakage anxiety, pouch visibility, and social exposure.
- Fear of leakage, social stigma, and intimacy-related discomfort have a significant affect on social an relational participations.
- Preferred contexts for pouch-free use are diverse but typically involve short-term, high-burden activities where pouch wear is experienced as restrictive. These contexts cover physical activity, intimacy, and social outings among others.
- Contradicting perceptions about the stoma range from empowering to burdensome. This highlight the need for modular, adaptable solutions tailored to individual needs.
- Temporary pouch-free periods attract strong situational interest. This is particularly the case among ostomates with higher physical, psychological, and social challenges.
- Statistical associations suggest that age, stoma type, and challenge type influence both the experience of burden and openness to pouch-free alternatives.

Chapter 4: From Insights to Concepts Through Co-Design

This chapter presents the results of the co-design study, which was conducted to explore, validate, and refine user needs and concept directions for a temporary pouch-free ostomy solution. It includes the applied methodology, the structure of each session, and thematic analyses of participant contributions. Activities such as context mapping, reversed brainstorming, Crazy 8s sketching, and concept evaluation are discussed in relation to the insights they generated. The findings directly inform the final synthesis of user needs and design requirements. The following research sub questions will be partially answered within this chapter, What challenges do ostomates face in current pouch-based care, and how are these reflected in product solutions, What are the key needs and wishes of ostomates regarding ostomy care, and How do ostomates perceive and experience the idea of a temporary pouch-free period?

4.1 Methodology

Co-design is a participatory design methodology that actively involves stakeholders in the development of products of services. This method helps to ensure that need, preferences, and lived experiences of users directly inform the innovation process (Sanders & Stappers, 2014). In healthcare co-design has proven to be a powerful and recognized tool for patient-centred innovation. It improves usability and acceptance of medical devices (Greenhalgh et al., 2016; Peters et al., 2024). Thus, providing solutions that align with the needs and wishes of ostomates means integrating them in the design process. In medical device development clinical and technical feasibility is often prioritized above user experience. Co-design tries to mitigate this issues by ensuring a collaborating between all stakeholders. Furthermore, online co-design can expand access by enabling participation from individuals who might otherwise be excluded due to location, mobility, or personal circumstances. While online co-design requires additional preparation and moderation, it offers new ways of building rapport, accessing home contexts, and supporting autonomy. Specifically when participants are given control over how and when they engage. (Fails et al., 2022).

The co-design approach is also informed by the recognition that innovation must respond to more than technical requirements alone. Kessler (2016) argues that the experience of wearing an ostomy pouch is not shaped only by physical fit and function but also by identity-based narratives. These narratives influence how users integrate these technologies into their life. Co-design enables the surfacing of these embodied perspectives early in the development process. Besides this, it supports the creation of interventions that are not only technically sound but also socially and emotionally meaningful. This approach leads to greater design acceptance and improves overall patient well-being (Masterson et al., 2024).

4.1.1 Participant selection

Initial interest in the session was assessed through the survey. Respondents could voluntarily leave their e-mail addresses for a follow up. For those who expressed interest an information brochure detailing the co-design process(Appendix C1), along with a short survey to confirm participations and most wanted participation dates was created. It became evident that due to travel constraints some respondents did not have the possibility to travel to the physical location. This changed the studies approach to include both physical and online co-design sessions, to ensure inclusivity and accommodate motivated participants unable to travel. All invited participants were asked to sign an informed consent document, in which workshops purpose, activities, and assured confidentiality was explained. This form can be found in Appendix C2. No more than eight participants were invited to both sessions, to ensure that every participant could voice their needs and wishes without falling into the background. Figure 4.1.1a portrays the participants of the co-design sessions.

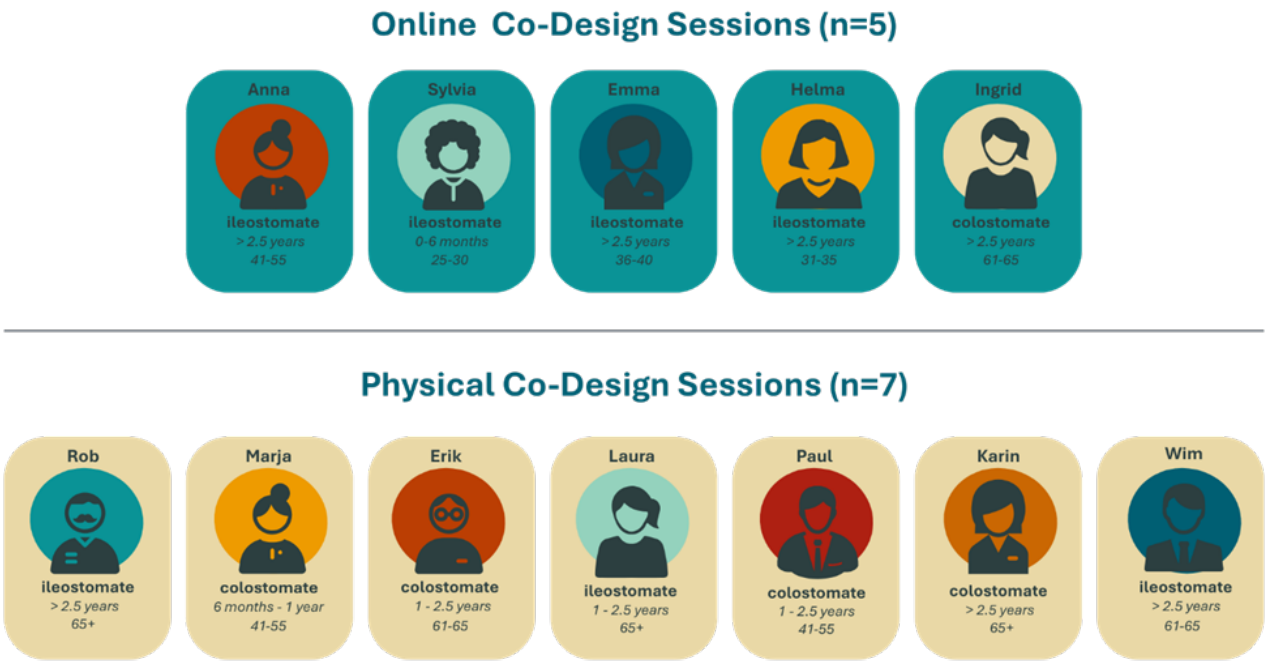


Figure 4.1.1a Overview of co-design participants. Participants are shown by pseudonym, stoma type, stoma duration, and age group. The physical group (n = 7) attended both Session 1 and Session 2 in full, with five participants also present at Session 3. The online group (n = 5) participated in Session 1, but only four attended Session 2. No online Session 3 was conducted.

4.1.2 Session Format and Logistics

PRE-SESSION METHODS AND CONTEXTUAL GROUNDING

Before co-designing it is important to gain early insights into the lived experiences of ostomates. For this a fly-on-the-wall (Farrell & Fessenden, 2024) observation was conducted at the Radboudumc with a Wound, Ostomy, and Continence (WOC) nurse. This unobtrusive ethnographic method involves the researcher silently observing real-world interactions in situ to capture natural behaviors and contextual nuances without interfering. The WOC nurse is shadowed during routine patient consultations, of these interactions notes on verbal and non-verbal interactions is taken. Preliminary observations, such as discomfort during change, frustration over leakage, and emotional burden informed the context mapping phase. These insights informed the context mapping exercise that followed.

Context mapping is employed to introduce participants to the co-design process, and elicit their initial experiences, emotions and priorities. Context mapping is a generative research technique used to access rich tacit knowledge in the early stages of design. Tacit knowledge refers to experiential and unspoken understanding people have. This is difficult to articulate but can be accessed through expressive and generative methods. These include making, drawing, and mapping among others. (Visser et al., 2005). In this thesis, the context mapping was a homework assignment and delivered through an interactive PowerPoint presentation. It was designed to take 30 minutes, and facilitator support was available through online meetings. The full context mapping exercise can be found in Appendix C3.

Twelve ostomates completed the context mapping exercise independently. This could be completed either digitally or by printing the materials for tactile engagement, depending on the personal preferences and technological ability. All exercises were conducted in Dutch, as this reflects the participants' preferred language.

Before directly going into the exercises some explanation and information was given about how to use the template, what context mapping is, and what was expected from the participants. They had one month to finish the exercise, making sure no time pressure was imposed. The first activity was chronologically mapping a typical day in the life, within the map participants showed the influence of their stoma on the activities as well. Emotional responses to the activities were assigned using a visual icon set, followed by a card-based reflection on values and limitations related to pouch-free periods. The final task involved making a collage of an ideal day. The exercise templates used by the participants can be seen in Figure 4.1.2a. Participants were encouraged to use symbols, illustrations, and shapes from the embedded generative toolkit or supplement with their own material. This approach enabled access to both temporal and symbolic dimensions of experience showing the knowledge often overlooked in conventional formats.

Figure 4.1.2a Context mapping exercises

CO-DESIGN LOGISTICS AND MATERIALS

A total of five co-design sessions were conducted: three physical sessions and two online. Each involved a consistent set of participants, to ensure continuity, trust, and iterative insight-building. The physical sessions (n=7) were held at the headquarters of the Stomavereniging in Utrecht and lasted approximately two hours. The online sessions, conducted via Microsoft Teams and the collaborative platform Mural were limited to 1.5 hours to reduce fatigue. To facilitate hands-on engagement remotely, the online participants received a custom physical co-design toolkit by mail. An online Session 3 was not organized. Instead, remote participants received a concise summary of Session 2 results via Microsoft Forms, in which they could provide feedback on the user needs and concepts, next to this they could also vote for their preferred concept and discuss concept improvements. Their responses were reviewed in parallel with in-person feedback of Session 3.

Furthermore, all sessions followed a structure with clearly defined objectives and participatory exercises adapted from established co-design methodologies (Sanders & Stappers, 2014). Activities were tailored to the needs of this study and iteratively refined based on participant feedback collected via brief post-session evaluation forms. The structure of each session will be discussed in 4.3: Co-Design Process and Outcomes. Both the online and physical session consisted from the same exercises, the online version was shortened to fit in the allocated 1.5 hours. At the end of each session a short evaluation form is distributed, with the same questions, to see what could be improved for the following co-design session. Lastly, a summary of the results from each session was e-mailed to the participants to refresh their memory and to ask for

input on whether the results were in line with their experiences, perceptions, and intended contributions.

MATERIALS

During both the physical and online sessions, a variety of materials were provided to the participants, as shown in Figure 4.1.2b. These included templates, sticky notes, low-fidelity prototyping materials, pen, paper and elements from a generative toolkit.

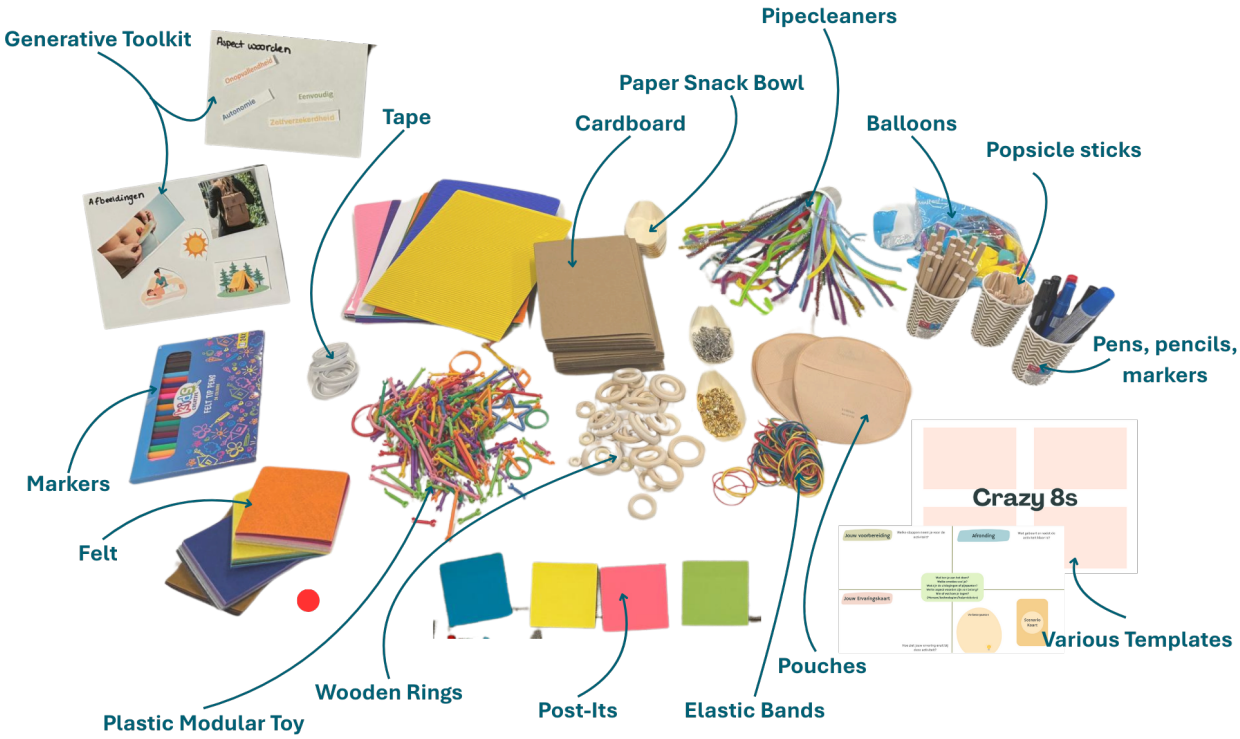


Figure 4.1.2b Materials used in the co-design sessions

As shown in Figure 4.1.2b, the materials provided to participants also included a custom-designed generative toolkit. The generative toolkit played an important role in discovering latent needs, which are unarticulated needs not yet expressed or recognized. It was designed to support both the context mapping and experience mapping exercise conducted during Co-Design Session 1. Applying one consistent toolkit across both exercises familiarized the participants with the tool. During Co-Design Session 1, this helped reducing barriers to expression and participation

The toolkit is in Dutch to be in line with the session language. It consists of a mix of elements to help participants express themselves. Starting with words that described emotional and physical states (e.g., “tired,” “safe,” “firm”) and key design considerations like “absorbent” and “invisible”. This was chosen to help participant articulate both their experiences and product expectations. Next, emoticons were used to show moods, whereas abstract shapes were used to reflect sensations. Lastly, simple images of situations like swimming or dressing were included to trigger memories and experiences.

This combination supported diverse ways of expressing needs and experiences, especially non-verbal insights related to ostomy care. The elements were designed to be arranged on templates

such as the collage or experience map. Especially, to construct personal narratives and lived experiences. The full toolkit is available in Appendix C4.

4.1.3 Analytical Approach

Similar to the questionnaire phase, a thematic analysis was used to analysis qualitative data from the co-design process. Co-design lacks a standardized analysis framework, but thematical analysis offers flexibility in identifying patterns across diverse data types (Braun & Clarke, 2006). The initial coding and thematic structure are derived from the questionnaire and served as the foundation for interpreting the context mapping and co-design results. This structure was iteratively adapted throughout the sessions to incorporate emerging themes. With this approach consistency is ensured throughout methods, while allowing space for new and emerging user insights.

4.2 Contextual Groundwork

Before co-designing it is of importance to familiarize with the context of use. This involves considering the daily realities, challenges and coping strategies employed by ostomates. Establishing this groundwork ensures that the following co-design process is informed and grounded in lived experience.

4.2.1 Fly-on-the-Wall Observations

The fly-on-the-wall method is used by the researched to familiarize with the context of ostomy care. Meaning which products are used, what advice is given, and what challenges are discussed by the ostomates. Three consultations were observed during a routine care day at Radboudumc with a specialized WOC nurse: (1) a recently operated ostomate learning self-care, (2) a long-term user with persistent nocturnal leakage, and (3) a patient with a prolapsed stoma. The first patient showed anxiety during pouching and asked about adhesive removers, which the nurse discouraged by mentioning that a correct pouch system did not need removers. After the patient insisted, she gave a few wipes to bring home. The second patient expressed emotional fatigue from ongoing leakage, prompting a renewed product recommendation for a night pouch. The third faced sealing difficulties due to stoma prolapse. The nurse demonstrated how one could wet a gauze and gently try to push the intestine inside. Besides this, she shared informal techniques to manage moisture, which was sprinkling powdered sugar on the stoma. These encounters highlighted recurring issues, like early-care insecurity, emotional distress, and anatomical challenges. This observation helped the researcher to get an insight into daily practices of ostomates. Which directly informed together with the information from the questionnaire, the design of the context mapping exercise. Prompts and visuals were tailored to explore daily uncertainties, emotions, and physical discomfort.

4.2.2 Context Mapping

Analysis began by revisiting the thematic network developed from the questionnaire (Figure 3.3.1a), assessing whether existing themes and subthemes remained valid. New subthemes were inductively added where recurring patterns or emotional expressions fell outside the original framework. The raw data from the context mapping exercise can be found in Appendix C8.

THEMATIC FINDINGS

The results from the context mapping affirmed some aspects of the thematic network developed from the questionnaire. This affirmation is expanded with a new theme. In this section, emerging patterns are discussed in terms of their thematic relevance and the depth they add to existing categories. Figure 4.2.2a portrays these aspects in the thematic network. The grey themes are not touched upon by the context mapping. The new theme and the corresponding subthemes are colour-coded green.

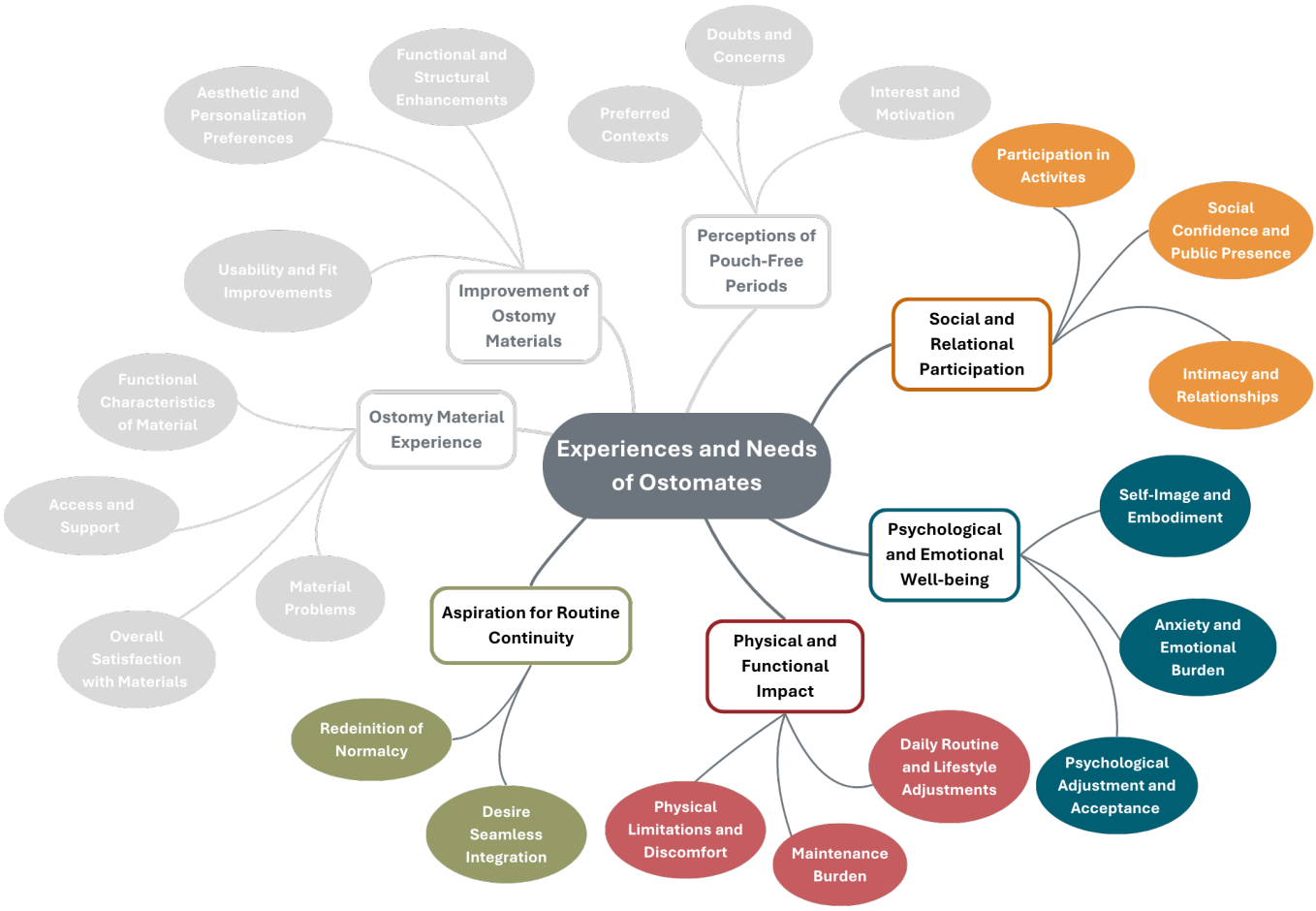


Figure 4.2.2a Affirmation and Expansion of the thematic network

THEME 1: PHYSICAL AND FUNCTIONAL IMPACT

This theme remained clear across all exercises. The timeline exercise reported frequent disruptions such as waking up to empty the pouch at night, or needing extra time and effort for morning routines. Next to this activities such as showering, dressing, and preparing for the day required additional caution and planning. This was seen similarly in physical activities like walking, cycling, and higher intensity sports. These activities necessitated functional adjustments to avoid leakage or discomfort according to the ostomates. Thus, rather than creating a new subtheme, these insights reinforce and expand the theme Physical and Functional Impact with nocturnal interruption, high-effort care tasks, and precautionary adjustments during movement.

THEME 2: PSYCHOLOGICAL AND EMOTIONAL WELL-BEING

Because the context mapping focused on emotional mappings and reflective exercises, valuable information enriched the second theme. A key recurring trend was anticipatory anxiety, especially in the context of leakage or detachment in public, during intimacy, or while sleeping. Emotional stress is not only reactive but often pre-emptive as well. This enriched the existing Psychological and Emotional Well-Being theme. The emotion cards related activities such as daily routines, social outings, or sport activities, with stress, fatigue and anxiety. While value cards emphasized the desire for no more worries, and bodily and activity freedom. The collages also portrayed nature, rest, and wellness as a desired emotional state. This suggests that the pursuit of tranquillity and reduced worry is central to psychological adaptation.

THEME 3: SOCIAL AND RELATIONAL PARTICIPATION

Ostomy related limitations were often linked to social engagement. Thematic insights included the desire for spontaneity, freedom of movement, and discrete participation in social, sporting, and recreational activities. There was also an apparent need to carry supplies, access toilets quickly, or manage odours. These concerns could also be seen in intimacy and relationships. Bodily safety and confidence were influenced by fears of leakage or physical harm, leading to barriers for social participation.

The ideal day colleges reinforced the value of social connection. With family meals, nature walks, and shared leisure as central to life satisfaction. However, such moments were often depicted as conditional on reliable bodily functioning and reduced ostomy-related interference.

NEW THEME: ASPIRATION FOR ROUTINE CONTINUITY

Different from the questionnaire, a new theme emerged from the context mapping. This was the Aspiration for Routine Continuity. The participants did not put extraordinary activities in their ideal day college, many envisioned simple daily routines. Like cooking, working, relaxing, being able to move your body, or even commuting uninterrupted by ostomy concerns. This represents a distinct form of adaptation. This theme highlights a Redefinition of Normalcy. Participants Desire Seamless Integration of the ostomy into their life with minimal disruption, not through denial but through pragmatic acceptance and routine stability.

While this theme shares similarities with Theme 1: Physical and Functional Impact, it differs due to its distinct conceptual orientation. Theme 1 focuses on disruptions such as leakage, time-intensive care, and mobility limitations that interfere with daily life. In contrast, the Aspiration for Routine Continuity represents a forward looking perspective rooted in participants' values. Rather than reporting challenges, participants made their desire for ordinary, undisturbed routines in which ostomy care is seamlessly integrated clear. Within this theme not the problems are highlighted, but what is aspired to.

TAKE AWAYS FOR THE CO-DESIGN SESSION

Findings from the context mapping exercise directly informed the structure and facilitation of the first co-design session. The exercises that elicited the most engagement, such as the timeline and value cards, were used to shape the content and flow of the Gallery Walk activity. This activity aimed to validate and deepen prior questionnaire insights. Next to this, ideal-day and timeline insights inspired the activities provided for the scenario-based experience mapping of pouch-free periods. Visual tools from the context mapping kit were reused to support symbolic thinking and create continuity across sessions. These were part of the generative toolkit, and participants did not need to familiarise themselves with the toolkit again. Moreover, usability challenges encountered during the context mapping, covering ambiguous instructions and digital access issues, led to improved session design. The first co-design session included clearer prompts, simplified materials, and more hands-on facilitation.

4.3 Co-Design Process and Outcomes

Each session is organized into four parts, covering the objective, activities, key results, and extracted needs or ideas. This section covers the key result, extracted needs or ideas, and the thematic analysis of the co-design sessions.

4.3.1 Session 1: Identifying Needs and Priorities

OBJECTIVE

To collaboratively validate key insights from the questionnaire and context mapping. To explore user-defined needs for both general ostomy care and short-term pouch-free use and introduce participants to pouch-free solutions currently in development. The session aims to create a shared understanding of the design context and target group. While also establishing a clear problem statement to guide the design process.

ACTIVITIES

The exercises employed during the first co-design session are summarized in Table 4.3.1a. This includes their objectives and descriptions.

Table 4.3.1a Overview of Co-Design Session 1 Exercises and Goals. Supporting materials and templates used can be found in Appendix C5.

Exercise Name	Goal	Description
Metaphor Exercise	Elicit emotions about pouch-free living and stimulate discussion	Participants sketched metaphors to express their initial feelings and associations regarding pouch-free living
Gallery Walk	Validate and expand insights from the questionnaire	Participants annotated result posters with sticky notes indicating recognition, surprise, or missing elements
Product Poster Rotation	Explore design strengths and weaknesses of existing pouch-free solutions	Participants rotated between posters of OriVaPort, Hydrustoma, and TIES, reviewing visuals and short descriptions
Experience Mapping	Identify preferred activities and needs across pouch-free use phases	Participants mapped an activity experience across four phases: before, during, after, and improvements, supported by the generative toolkit

KEY RESULTS

All results are derived from the notes and raw data from Session 1, this raw data is presented in Appendix C9. Across all exercises, participants expressed recurring needs for discretion, bodily confidence during movement or rest, minimal preparation, and a sense of normalcy in daily and social life. The Metaphor Exercise captured a range of emotional responses to pouch-free periods. Curiosity, relief, and freedom, but also anxiety and uncertainty (e.g., “zomer, zwemmen” vs. “overlopende emmer”).

During the Gallery Walk, participants validated the prevalence of physical discomfort, emotional strain, and social limitations previously identified in the questionnaire. Interest in pouch-free periods was especially high among younger participants and those with chronic skin issues. However, concerns were raised about the short duration of proposed use and unclear benefits, highlighting the need for realistic framing.

In the Product Poster Rotation, participants evaluated three pouch-free systems in development. Elements such as gas venting and breathable designs were appreciated. Feedback revealed concerns about unclear functionality, leakage risks, discretion, and compatibility across stoma types. Trust, reliability, and safety were emphasized as critical design criteria. One participant liked the surgical TIES concept, yet others mentioned that they do not perceive such limitations of the stoma to try something like that. Besides this, a clear worry was about geting blockages or the stoma not functioning correctly after use. They did not believe that the OriVa Port could be leakage free. Besides this, there was no added value of the Hydrustoma according to particpants. Only the manual gas venting was appreciated. The design of the OriVa Port was appreciated. But they also made clear that they would need to empty numerous times. They would not use it.This activity offered early insights into user perceptions and critical concerns regarding the practical application of pouch-free systems.

The Experience Mapping further revealed burdensome aspects. Sleep was disrupted by nightly routines and discomfort, which prompted suggestions for nighttime-specific solutions. Swimming led to strong positive emotions but remained linked to worries about visibility and control. The third group covered social events that highlighted preparation burdens and a persistent need for discretion and flexibility.

Overall, the findings reflect cautious optimism. Participants welcomed innovation but remained wary of safety, usability, and confidence in real-world use. These insights directly inform the development of refined personas, problem statements, and design directions in the following stages.

EXTRACTED OUTCOMES

The session yielded a preliminary persona (Figure 4.3.1b) and a draft problem statement, synthesized from both questionnaire findings and co-design outputs. These preliminary outcomes will be refined during Session 2 and further developed in Chapter 5, to guide subsequent design development. In addition, a first set of user needs related to general ostomy care and temporary pouch-free periods was identified based on participant input during the exercises. These needs inform the prioritization and concept development activities in the following sessions. The preliminary problem statement, translated into English, is formulated as follows:
How can a product solution be developed that enables individuals with an intestinal stoma to temporarily control their output without compromising on reliability, safety, or ease of use, thereby making pouch-free periods possible?

Figure 4.3.1b Preliminary Persona in Dutch

4.3.2 Session 2: Ideation and Concept Development

OBJECTIVE

Facilitate design activities aimed at developing user-informed concepts for temporary continence without an ostomy pouch. Within the session the extracted outcomes of Session 1 will be validated and adapted. Participants will be guided through structured ideation techniques, including Crazy 8s, reversed brainstorming, and low-fidelity prototyping. This is done to elicit creative solutions and identify promising directions for further refinement.

ACTIVITIES

The exercises employed during the second co-design session are summarized in Table 4.3.2a. This includes their objectives and descriptions.

Table 4.3.2a Overview of Co-Design Session 2 Exercises and Goals. Supporting materials and templates used can be found in Appendix C6.

Exercise Name	Goal	Description
Persona and Problem Statement Refinement	Validate and adapt initial persona and problem statement from session 1 output	Participants reviewed a predefined persona and problem statement, adding reflections on ambiguities and assumptions using post-its
Reversed Brainstorming	Identify potential failure scenarios to reverse-engineer user needs	Participants brainstormed failure scenarios for temporary continence control products, using the prompt: “How can we make the product as unreliable as possible?”
Crazy 8s	Rapidly sketch diverse early concepts for short-term pouch-free solutions	Participants sketched eight different ideas within eight minutes, each representing a concept for temporary pouch-free continence
Low-Fidelity Prototyping	Build and document early physical representations of selected concepts	Participants formed teams to prototype one selected Crazy 8s idea using basic materials, documenting function, context of use, and key features

KEY RESULTS

The refinement exercise revealed continued ambiguity around concepts such as "control" and "safety''. They needed more clarity about what control and safety meant. These findings underscore the need for clearer articulation of user priorities. For the persona, the participants mentioned that it was smarter to split it up into two personas: ileostomate and colostomate. Besides this, they mentioned that the age might not be fitting to the participant group.
The reversed brainstorming activity covered the prompt “How can we make the product as unreliable as possible?”. Participants came with critical failure scenarios, like leakage, discomfort, allergic reactions, hernia, unclear materials instructions, and material failures among others. These inversions were subsequently translated into fundamental user needs which will be reflected in Chapter 5: Synthesis of Findings.

The Crazy 8s sketching exercise produced a wide range of conceptual directions, from mechanical plugs, valves, and diaphragms to pharmaceutical and neuro-regulatory solutions. Common themes included self-regulation, intuitive use, minimal invasiveness, and discreet

application. Participants often proposed hybrid systems combining internal containment with external safety mechanisms. Also, some lifestyle-based management strategies were mentioned like taking medication.

In the final low-fidelity prototyping round, teams translated selected concepts into tangible models using simple materials. This resulted in low-fi prototypes such as: De Klep, Stoma Spiraal, Kurk 2.0, and Belly Balloon. These showed different priorities, for instance compatibility with existing materials, having a concealed fail safe, or the need for a discontinued plug product. Across these outcomes, trust in function, stoma health, and not more effort than current systems emerged as non-negotiable design principles.

EXTRACTED OUTCOMES

The second co-design session provided refined user needs and updated personas based on validation activities. These extracted outcomes will be further detailed in Chapter 5: Synthesis of Findings to guide the design development process. In addition, the preliminary problem statement was adapted based on participant input regarding safety considerations, duration of pouch-free use, and flexible application. The adapted problem statement helps to guide the co-design sessions, and lets the participants know what the co-design results will yield. This is the improved problem statement: *How can a product solution be developed that enables individuals with an intestinal stoma to achieve temporary control of their output for periods of up to four hours, thereby facilitating short-term pouch-free use?*

Building on this foundation, the ideation activities produced a wide array of participant generated solutions that addressed both practical and emotional user needs. The Crazy 8s exercise provided recurring aspects such as the need for discretion, secure closure, intuitive usability, and options for both internal and external control mechanisms. The Low-Fi prototype ideas generated by participants were not considered final designs, but instead functioned as input and inspiration for the researched led design synthesis, which will become clear in Chapter 5 and 6. The lo-fi prototypes made by the participants can be seen in Figure 4.3.2a and the full set of raw data of this session is included in Appendix C10.

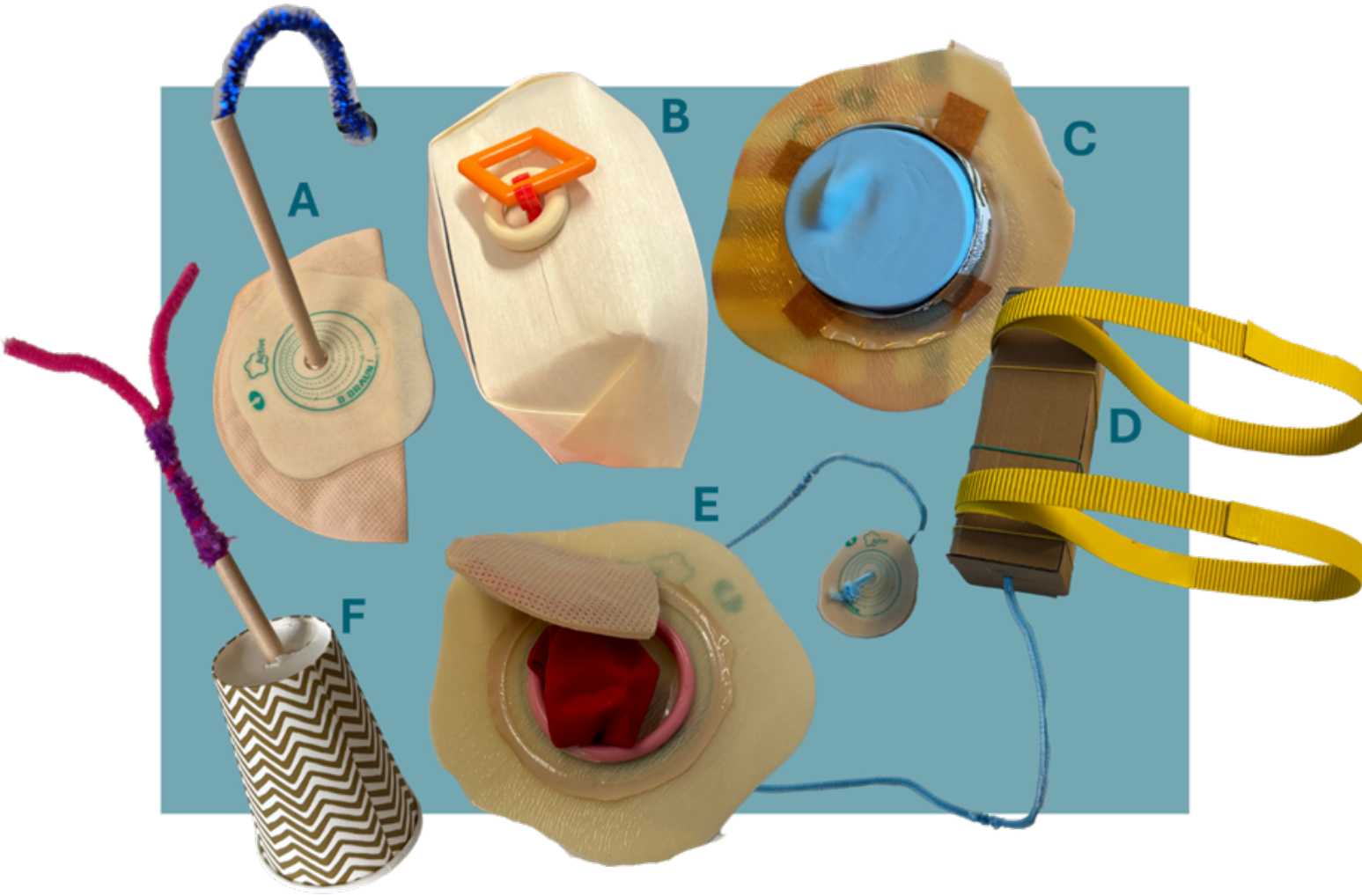


Figure 4.3.2a Low-fi prototypes made by participants in co-design session 2. A: Kurk 2.0, a flexible, custom-fit plug designed to temporarily block output for short periods, with sensor indicating removal time. B: STOP (plug), a simple, self-inserted plug for temporary output control (up to four hours), emphasizing ease of use and affordability C: De Klep, a soft click-in two-piece system allowing short pouch-free periods, particularly for activities like showering or bathing. D: Poepzuiger, a suction-based system combining a pump and reservoir to collect output temporarily E: Belly Balloon, a cap with a fail-safe balloon that collects output if needed, designed for comfort and discretion. F: Stoma Spiraal, a reusable spiral insert that temporarily blocks output, focusing on easy insertion and cleaning.

KEY DESIGN OUTCOMES

The ideation activities in Session 2, especially the Crazy 8s sketches and low-fidelity prototypes served as direct inspiration for two concept directions: Morning Glory and FlexiSeal. The concept overview can be seen in Figure 4.3.2b. These concepts represent recurring design themes and user priorities, which are derived from the co-design process rather than coming from an external ideation process. This approach is used to make sure the participants could see the effect of their input in the design process.

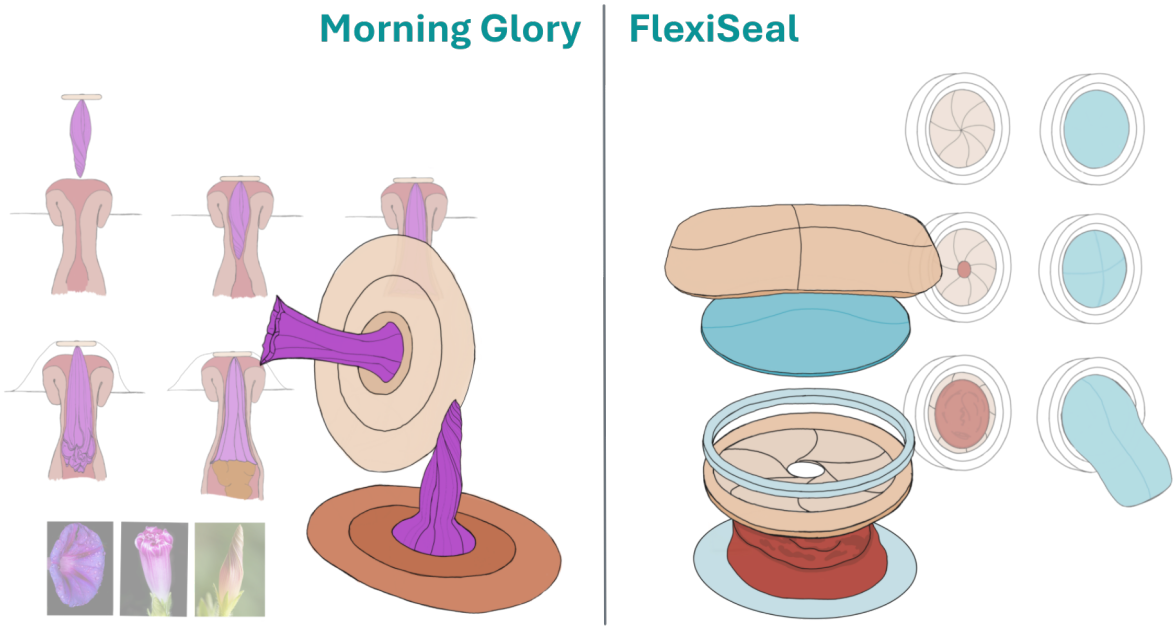


Figure 4.3.2b Concept Overview

Morning Glory was informed by the popularity of plug-like concepts across participant sketches and prototypes. These reflected a desire for discretion, low-profile wear, and internal placement. However, concerns regarding safe containment and pressure regulation did became apparent as well. Many of the initial sketches lacked a clear solution for handling sudden output or preventing discomfort. In response, the Morning Glory concept was developed as a soft, absorbent reservoir with a floral-inspired closure mechanism. These were inspired by the aesthetics and closing principle of the morning glory flower. Within this design concepts aspects such as comfort, emotional acceptance, and minimal visual presence are prioritized. Such aspects were emphasized by the participants during the ideation and early evaluations.

On the other hand, FlexiSeal responded to user needs covering control, autonomy, and reassurance. Prototypes such as De Klep, Belly Balloon, and Kurk 2.0 highlighted a strong interest in user-managed timing of output release. Besides this, these concepts also covered fail-safe features for unexpected waste output. The FlexiSeal concept therefore centres around a manually operated valve system that allows output to be released on demand. The valve system is an iris valve, as this allows for controlled and specific opening capacities. It also includes a balloon-like containment insert that expands when the cap of the device is opened. When the insert is not contained by the cap anymore, waste can flow into it and it can be discreetly discarded. Besides this, is supports use in public or active contexts where timing, confidence, and ease of use are crucial.

Together, these two contrasting directions reflect important aspects identified during the co-design sessions:

- Morning Glory emphasizes passivity, absorption, and discretion.
- FlexiSeal emphasizes active control, safety feedback, and usability in dynamic settings.

The concepts will be presented and evaluated in the following session together with the ostomates. They will not be presented as final solutions, but as starting points for discussion and evaluation. The development of the concepts show how including participant input , even in low-fidelity form, can be translated into valuable concept directions.

4.3.3 Session 3: Refinement and Evaluation

OBJECTIVE

To prioritise and discuss user needs related to general ostomy care and temporary pouch-free periods. These needs are based input from the literature review, questionnaire study, and preceding co-design sessions. In addition, the session aimed to critically evaluate two preliminary design concepts in relation to these prioritised needs. Besides this, the session aimed to support evidence-based selection of a preferred direction and to elicit targeted user input for iterative refinement.

ACTIVITIES

The exercises employed during the third co-design session are summarized in Table 4.3.3a. This includes their objectives and descriptions.

Table 4.3.3a Overview of Co-Design Session 3 Exercises and Goals. Supporting materials and templates used can be found in Appendix C7.

Exercise Name	Goal	Description
Prioritization of User Needs	Identify, validate, and prioritize key user needs for ostomy care and temporary pouch-free periods	Participants categorized user needs using a traffic-light voting system, distinguishing high-priority, desirable, and non-priority needs
Choosing Concept Direction	Evaluate two preliminary design concepts based on prioritized user needs	Participants reviewed two concepts through visual and descriptive overviews, providing feedback via sticky notes, discussion, and voting
Concept Evaluation and Redesign	Critically assess and refine the preferred concept based on key dimensions	Participants evaluated the chosen concept in terms of material, function, user-friendliness, and aesthetics, then proposed redesign ideas to improve the concept
Naming Exercise	Strengthen participant ownership and reflect on the co-creation outcome	Participants individually proposed names for the refined concept, followed by a group voting process to select the final name

KEY RESULTS

During the needs prioritization exercise it became apparent that pouch-free solutions must reliably prevent leakage, offer discretion, and support autonomy. Participants also valued having secure closure mechanisms, intuitive handling, and minimal preparation. Because it was mentioned that the system should integrates seamlessly into daily activities such as swimming, intimacy, and sports. Looking at the user needs specifically for temporary pouch-free periods, they emphasized the need for predictable short-term continence, physical comfort, and effective gas and odour management.

These prioritized needs directly informed the evaluation of the two concepts, Morning Glory and FlexiSeal. FlexiSeal emerged as the preferred concept direction, receiving a total of four votes (4 in-person, 0 online), compared to three votes for Morning Glory (1 in-person, 2 online). Aspects within the FlexiSeal which were liked among participants are the integrated filtration, discreetness, and user controlled emptying. Yet, concerns were raised regarding potential internal pressure buildup, limited output capacity (10–30 mL), and challenges related to emptying in public settings. Some participants also compared the expected sensation to a stoma blockage, expressing hesitancy about comfort and safety.

Feedback on the Morning Glory centred around its passive absorption functionality and aesthetic appeal. This concept's soft materials use, discreteness, and symbolic framing were valued. However, participants were uncertain about the saturation indicators, leakproof sealing, and potential risks to the intestine. Compared to the Flexiseal the aforementioned aspects bet the concept less suitable for short term continence control. Lastly, participants expressed that the name FlexiSeal was fitting for the concept and decided to keep it as is.
Overall, the session indicated a preference for a solution which balances discretion, autonomy, reliable containment, and controlled management of output. These results provide a foundation for refining the FlexiSeal in Chapter 6. The raw data on which the results are based can be found in Appendix C11.

EXTRACTED OUTCOMES

This session helped validate and prioritize the user needs, and led to the selection of the FlexiSeal as preferred concept direction. Improvements should be made to enhance comfort, increase output capacity, and simplifying hygiene. Participants also urged to make sure that a better fit is considered for varying stoma shapes. Concerns about pressure buildup and device use in public spaces were raised repeatedly as well. A key outcome of the session was the recognition diversity in user preferences and expectations regarding pouch-free solutions. The close voting results between the concepts and varied feedback highlighted that a one-size-fits-all solution is unlikely to address individual user needs. While refining the concept modular or combined design strategies should be considered. These should offer adaptability in features such as absorption, venting, and closure. But also the possibility for users to choose between different structural solutions, such as an internal or external mechanism depending on their individual needs and activity contexts.

4.3.4 Thematic Analysis Co-Design

The thematic framework from the questionnaire, and the additional identified theme through the context mapping exercise is used as a deductive lens to start analysing the co-design data. Deductive thematic analysis means applying pre-existing themes to new qualitative material to export its validity and identify additional patterns. This approach provided continuity between research phases and enabled rapid interpretation of rich, multi-modal data collected through the co-design sessions.

The co-design sessions validated four previously defined themes: physical and functional impact, psychological and emotional well-being, social integration and participation, and aspiration for routine continuity. These categories were not only reaffirmed, but expanded through the identification of new subthemes. Within the theme of psychological and emotional well-being, participants described the importance of technological reassurance through predictive feedback.

This reflecting the emotional comfort gained from alert systems, either active of passive, that warn for potential device failure. Within the theme of routine continuity the subtheme seamless sensory integration became apparent. This subtheme describes designs that are not only functional, but also minimally perceptible during wear. These additions reflect a growing emphasis on affective and sensorimotor dimensions of design acceptance.

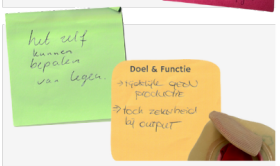
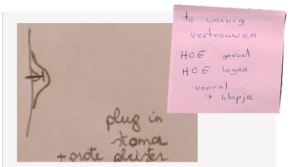
In addition to refining the existing framework, the co-design process also revealed entirely new thematic patterns that were not captured in earlier phases. These new themes are introduced in the following section.

EMERGING CO-DESIGN THEMES

Thematic analysis of the three co-design sessions led to five new themes. These themes were derived from structured session outputs, including written reflections, sketches, prioritisation forms, and discussions. Data were synthesised into patterns of experience and meaning that extend the questionnaire-based network. The analysis focused on what participants expressed, made, and selected. This provided a qualitative interpretation of how they experience, evaluate, and imagine pouch-free use.

Each theme captures distinct yet interrelated concerns: discretion during movement, control over timing, bodily confidence, trust in context, and safety. Table 4.3.4a summarises these themes along with its subthemes, illustrative examples, and selected visual references. The visual materials are in Dutch and serve as evidence of the thematic reasoning process.

Table 4.3.a Newly emerging themes from the co-design session

Theme	Definition	Subthemes	Supporting Results	Visual Reference
Discreet Mobility	Experiences of managing discretion and physical comfort during movement and social interaction	• Visibility during activity • Sensory disruption (odor, bulk)	Participants' concerns about discretion and comfort during activities, based on reflections on swimming (Session 1), movement-friendly design ideas (Session 2), and prioritisation of discretion needs (Session 3)	
Temporal Control	Experiences of diminished control due to anticipatory stress and care-related timing demands	• Anticipatory planning • Interruptive care	Experiences of disrupted routines and anticipatory stress were reflected in the experience maps and gallery walk reflections (Session 1), planning-focused design ideas (Session 2), and prioritisation of autonomy-related needs (Session 3)	
Bodily Confidence	A sense of bodily trust and ease emerging from intuitive, integrated interaction with the device	• Embodied fit • Natural use perception	Efforts to restore a natural sense of bodily control were reflected in discussions about self-regulation (Session 1), internal and body-integrated design concepts (Session 2), and prioritisation of intuitive and non-intrusive use (Session 3)	
Contextual Trust	Trust in use is shaped by situational familiarity, personal control, and past experience with similar devices	• Scenario-dependent confidence • Trust transfer from familiar devices	Differences in trust were illustrated by comments on when participants would feel confident using a device (Session 1), ideation on known devices (Session 2), and prioritisation of use scenarios that felt manageable and predictable (Session 3)	
Situated Safety	Experiences of physical and functional safety shaped by use context, bodily condition, and device interaction	• Risk during use • Time and capacity boundaries • Safe fit and removal	Across all co-design sessions, safety emerged as a consistently central concern, with participants repeatedly emphasising the importance of being certain that the device would not pose risks to their physical health or fail during use	

Although safety is typically considered an implicit technical requirement participants repeatedly mentioned it as a lived and pressing concern. Across all sessions, safety was framed not only in terms of leakage or product failure, but also in relation to skin damage, hernia risk, and discomfort during use. Continues mention revealed that safety, for ostomates, is not an abstract compliance issue. It is a situated experience shaping emotional confidence, perceived reliability, and the willingness to adopt alternative designs. These findings support the inclusion of Situated Safety as a distinct theme rather than an assumed baseline. Together, the themes also reveal the added value of co-design in surfacing tacit and embodied forms of knowledge that are difficult to access through surveys alone.

4.4 Key Insights

- Leakage prevention, discretion, and control are non-negotiable priorities for pouch-free use. Many ostomates emphasised the need for reliable sealing, secure closure mechanisms, and autonomy over output management.
- Safety is experienced as a multidimensional and situated concern. This covers leakage, internal pressure, skin damage, hernia risk, and emotional reassurance. Thus, it is not just a technical constraint, but tied to perceived bodily integrity and emotional confidence.
- Participants prioritised seamless integration into daily life, especially for activities such as sleeping, swimming, intimacy, and social events. This highlights the importance of minimal preparation and low disruption.
- Sensory and symbolic discretion was an emerging concept. Products should be not only visibly discreet but also not felt, noticed, or associated with stoma-related anxiety during use.
- Users desire diverging modes of control, as some favour active, manual release systems , while others prefer passive, absorbent designs , illustrating divergent coping styles and preferences.
- Short-term pouch-free use is primarily valued in specific, high-burden scenarios. Scenarios often covered included bathing, intimacy, swimming, and social outings supporting the need for flexible, situational solutions rather than full-time replacement.
- Perceived product safety and trust significantly affect adoption of innovations. Concerns about pressure build-up, stoma blockage, and unclear instructions discouraged acceptance of otherwise interesting concepts.
- The co-design process surfaced unspoken fears and embodied experiences, such as anticipatory anxiety, blockage sensations, and preference for tactile reassurance. Such insights were not covered the questionnaire phase.
- •Discrepancies in comfort, priorities, and use context highlight the need for modularity, with options for internal and external placement, active and passive use, and different forms of closure and venting.
- Participants associate product failure not only with inconvenience but with emotional strain and social withdrawal as well. This reinforces the emotional stakes of even short-term pouch-free usage.
- Trust-building features like transparency of function, visual confirmation, and familiar routines enhanced acceptability of novel concepts, especially among initially sceptical participants.

Chapter 5: Synthesis of Findings: User Needs and Design Requirements

This chapter synthesizes insights from the literature review, questionnaire study, and co-design sessions to create an understanding of the user needs and requirements derived from the results. With the use of methodological triangulation core insights and patterns are validated. This chapter presents these results in the form of user needs, persona's, experience maps, and design requirements for temporary pouch-free design. The following research questions will be covered in this chapter: What are the key needs and wishes of ostomates regarding ostomy care? And what design and user requirements must be considered to support the potential implementation of temporary pouch-free periods in ostomy care?

5.1 Triangulation of Results

Triangulation of results aligns with the best practices in mixed-methods research, as the convergence of evidence mitigates the potential biases of in single-method approaches (Fetters et al., 2013; O'Cathain et al., 2016). The triangulation is employed to enhance the credibility and depth of this study, by integrating the findings from the literature review, questionnaire study, and co-design sessions. These sources are cross-examined to validate key results and uncover complimentary or contradictory perspectives.

First, the literature provided a foundation of academic knowledge on ostomy care challenges, materials and technical developments, and early pouch-free innovations. Recurring challenges such as leakage, skin complications, psychological burden, and the limitations of current devices were highlighted. The questionnaire did build on these results, by validating the themes with the experiences and individual variations among a broader group of ostomates. Meanwhile, the co-design sessions offered a deeper foundation of user needs. Not only were challenges articulated, but also latent knowledge was uncovered which cannot be easily revealed through literature and surveys alone.

The cross-validation revealed a strong consistence across the sources. The core challenges, leakage anxiety, skin health concerns, emotional burden, and the limitations to social participation were identified through all methods. Another important supporting factor influencing confidence and social engagement was the discreetness of the device. This included minimizing visibility, sound, and odour related to the stoma and ostomy device.

Moreover, empirical data from the questionnaire and co-design sessions provided important user insights about the emerging pouch-free devices discussed in the literature review. These user insights covered acceptance thresholds, desired features, and emotional conditions for successful adoption of temporary pouch-free periods.

Complementary findings became apparent throughout the methods as well. One instance emphasized within the literature were material limitations, these were not only validated through the questionnaire but also expanded through user reported DIY adaptations, such as improvised sealing techniques and custom venting solutions. Building on this the co-design sessions reframed material concerns around user priorities such as discretion, autonomy, and trust in device performance. Material failure is not viewed as only a technical problem, as participants discussed its emotional impact. Failures were directly linked to anxiety, loss of confidence, and reduced willingness to engage socially.

Strong consistencies were observed across sources, yet several important contradictions became apparent as well. The questionnaire indicated a broad interest in temporary pouch-free periods, but the co-design sessions revealed that the enthusiasm and willingness to try was conditional. There are clear reservations related to safety, hygiene, pressure regulations, and emotional reassurance. This highlights that initial interest cannot be straightforwardly translated into real-world acceptance. Another aspects were the differences observed in tone, while survey responses emphasized frustrations and systemic limitations in the current care, the co-design participants adopted a more optimistic and solution oriented mindset. These divergences underscore the value of methodological triangulation: not only to validate themes, but also to surface contextual dependencies and nuanced user expectations that might otherwise remain hidden. Building on this integrated understanding, the following section presents the extracted user needs and adapted personas that informed the design development.

5.2 User Needs

This section synthesizes the user needs identified throughout this thesis, and are presented in a KANO model influenced by the prioritization of user needs (co-design Session 3).The resulting needs reflect the lived experiences, expressed challenges, and future aspirations of ostomates, both in general ostomy care and in the context of temporary pouch-free use. In addition, the needs were further contextualized through the development of refined personas and experience maps, These illustrate variations in user motivations, daily routines, and the heterogeneity of experiences across the ostomy population. The full user needs list can be found in Appendix D1, each traceable to its source and rationale.

5.2.1 User Needs

To support design translation, the 27 validated user needs were grouped into five categories, and are presented in Table 5.2.1a.

Table 5.2.1a User Needs Categories

User Needs Categories	Covered Needs
Physical and Functional Needs	Reflects foundational product expectations such as leakage prevention (UN1), secure skin adhesion (UN2), gas control (UN8), and hygienic cleaning (UN13)
Psychological and Emotional Needs	Covers autonomy (UN10), aesthetics (UN14), reassurance (UN15), and the reduction of emotional burden (UN24)
Social and Contextual Needs	Emphasizes discretion (UN6, UN7), active lifestyle compatibility (UN19–UN22), and spontaneous participation
Technical and Usability Needs	Include temperature resilience (UN16), sustainability (UN17), and intuitive management (UN9, UN12)
Safety and Risk Needs	Covers injury prevention (UN3), skin protection (UN4), and overall reliability (UN27)

Following this categorization of the needs, a Kano Model is employed to distinguish between baseline expectations, performance-related features, and emotionally engaging attributes. The Kano model is a framework that categorizes features based on their impact on user satisfaction. It distinguishes between must-haves (basic expectations), performance needs (where satisfaction increases with better performance), and attractive needs (unexpected features that enhance satisfaction) (Violante et al., 2020). In this study, the model was adapted to classify user needs rather than product features. This was done to help identify essential requirements and opportunities for emotional value. The prioritization done by participants in the third co-design session informed the Kano categorization. This categorization was than completed by subsequent analysis and triangulation. Two needs related to general ostomy care (UN25 and UN26) were excluded, as they reflect systemic rather than product-specific concerns. This final classification can be seen in Figure 5.2.1a.

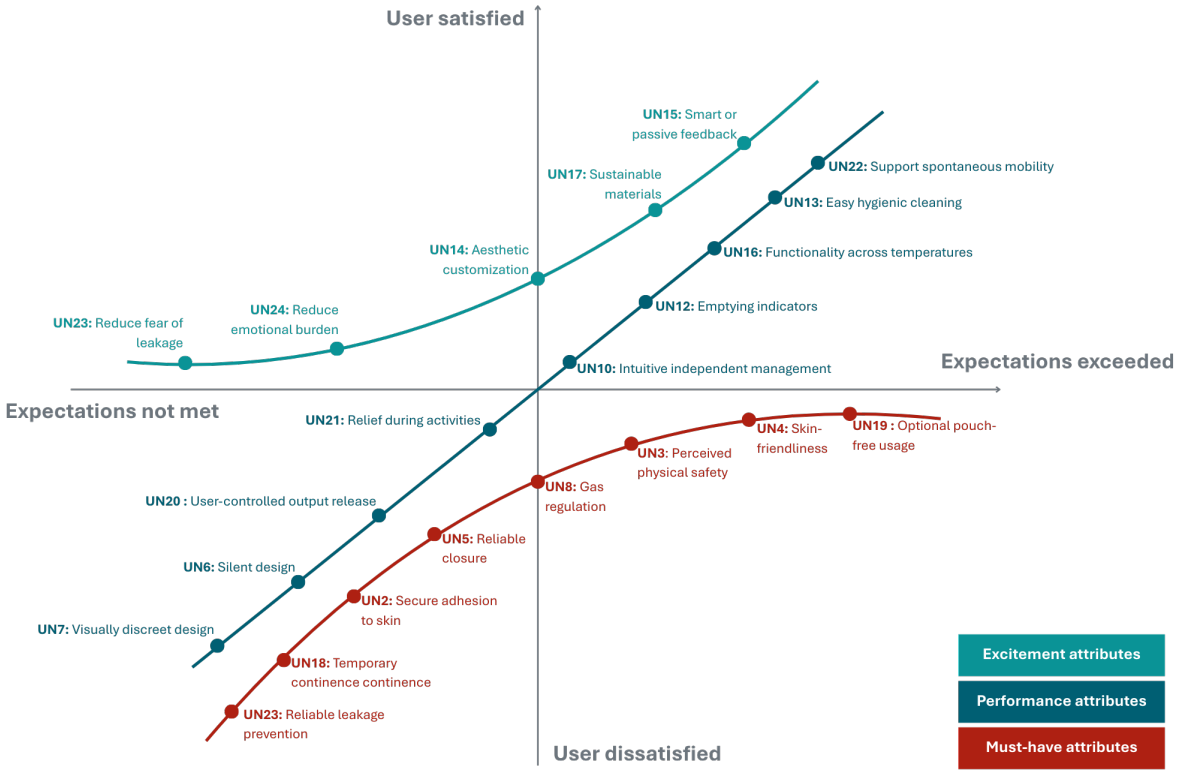


Figure 5.2.1a Kano model of user needs

The Kano model revealed that leakage prevention, secure adhesion, and physical safety are essential baseline needs. Such needs must be addressed before higher-level needs can have a meaningful impact on user acceptance. In contrast, needs like intuitive autonomy, aesthetic personalization, and feedback mechanisms offer opportunities for differentiation and emotional value. Prioritizing must-haves early ensures functionality and trust in the design. While the performance and excitement attributes can enhance individual experience. To contextualize these needs, refined personas and experience maps were developed. These tools illustrate the diversity of user journeys and guide the design development introduced in the next chapter.

5.2.2 Personas and Experience Maps

To complement the structured synthesis of user needs, two refined personas were developed. These personas are based on the co-design results, and reflect two distinct individuals with different lived experiences. This highlights the diversity within the ostomy community, which was a recurrent theme throughout. Every ostomate's journey is unique, however the following two personas present the patterns most observed. One patterns was that of ostomates, who are well-adjusted seeking situational freedom and discretion. On the other hand, some ostomates were managing daily burden, anxiety, and unpredictability. The decision to differentiate by stoma type was essential, given the clear clinical and experiential differences in output, care routines, and emotional impact. This was again highlighted by the feedback of co-design participants. The following personas in Figure 5.2.2a and 5.2.2b serve as narrative tools to translate abstract needs into concrete and context based design directions. The age chosen for the personas reflected the age groups of the co-design participants. The participants from the online sessions had a younger age average than the participants from the physical sessions. These differences are reflected in the personas as well.

SAM VAN DIJK (AGE 60, COLOSTOMATE)

Sam is well-adjusted and experiences minimal daily disruption. Her interest in pouch-free use is situational. She prioritizes comfort, aesthetics, and ease of use, seeking solutions that enhance quality of life without compromising safety.

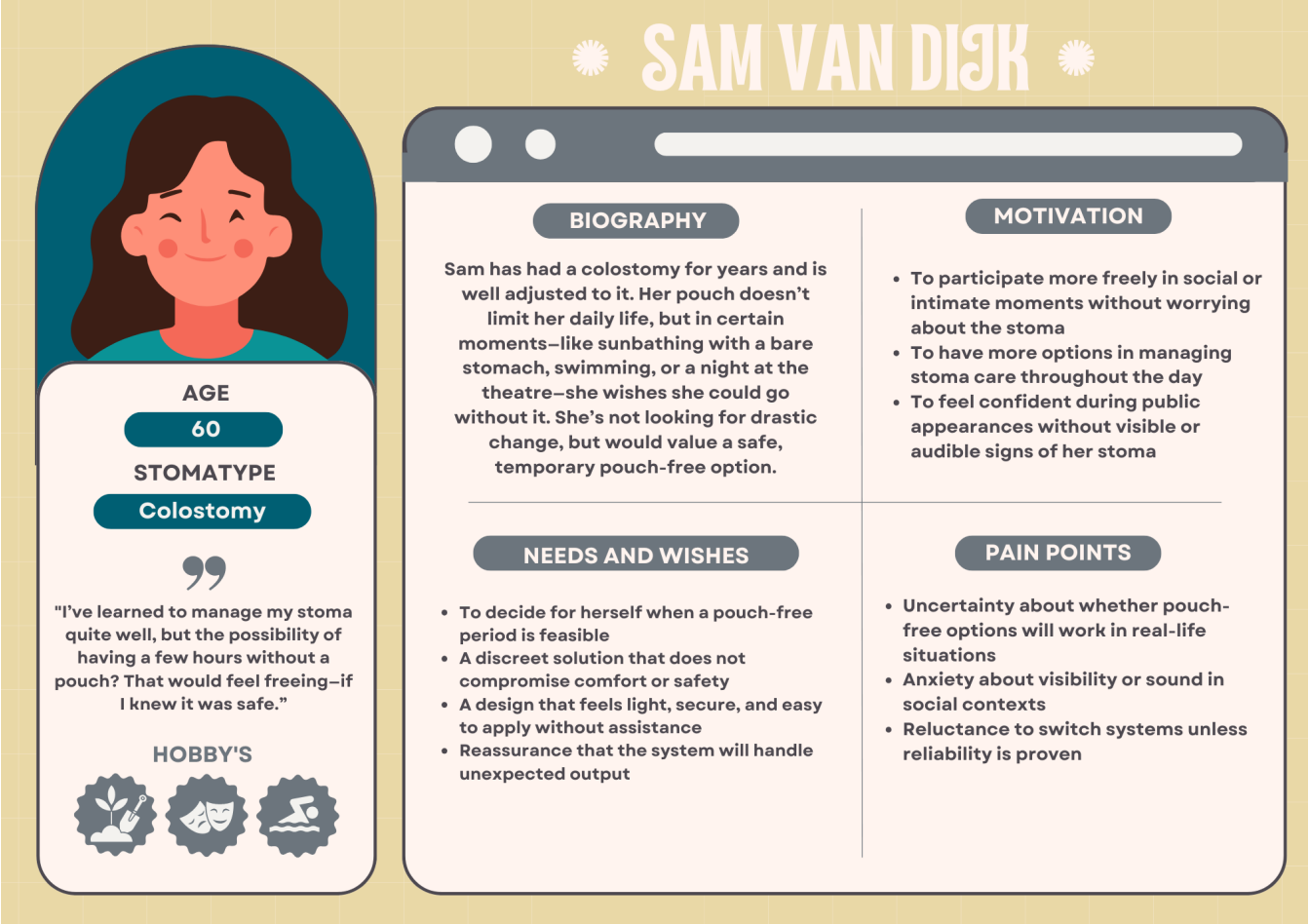


Figure 5.2.2a Persona Sam

EMRE YILMAZ (AGE 40, ILEOSTOMATE)

Emre has a high-output stoma and faces significant daily challenges, including frequent emptying and anxiety about leakage. He is open to pouch-free use if it reduces hassle and risk. His experience is shaped by material discomfort, physical strain, and a need for reliability during active or unplanned activities.

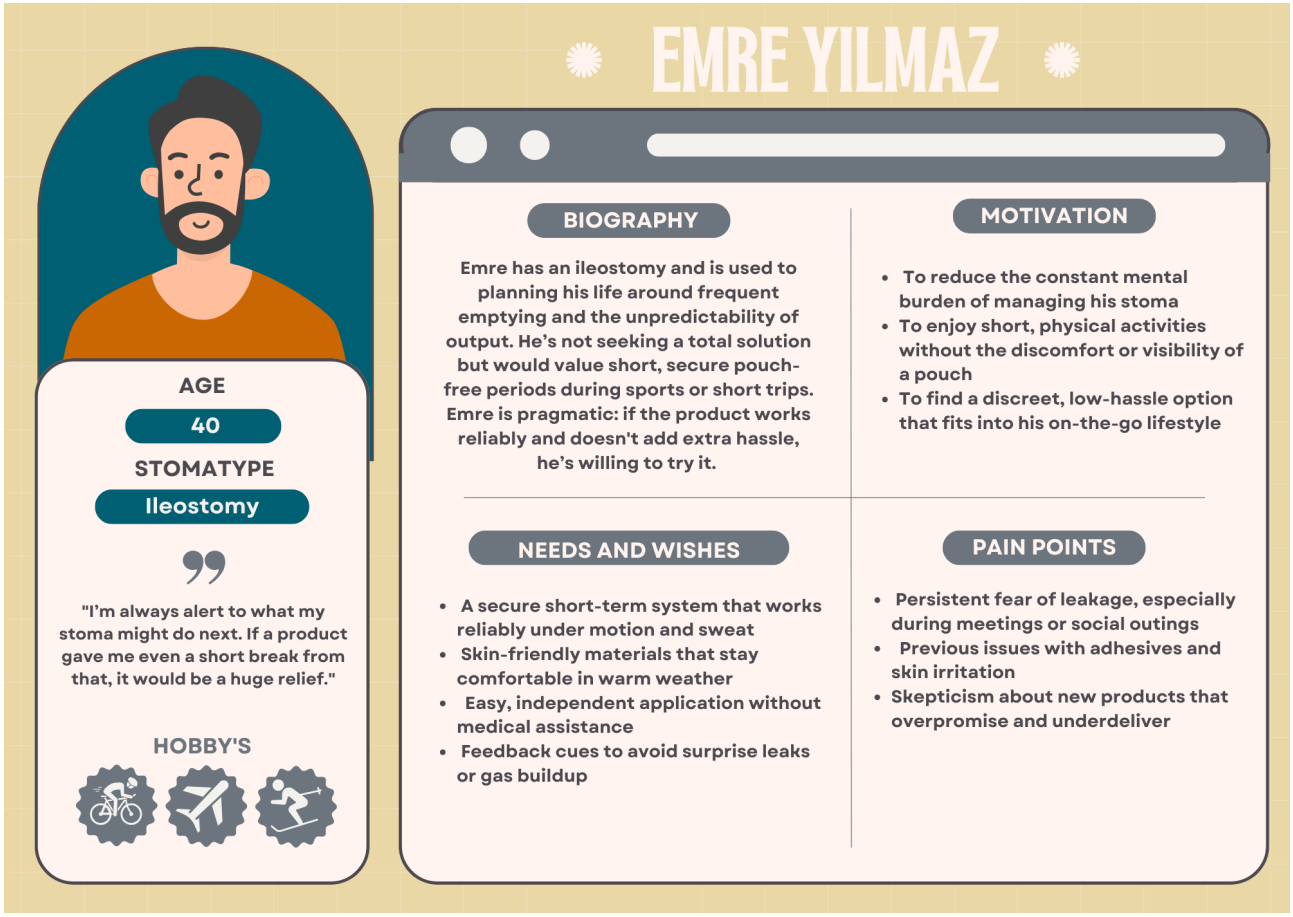


Figure 5.2.2b Persona Emre

Following the persona development, experience mapping was used to explore how ostomy care shapes everyday experiences and emotional responses. These maps are often used in UX journey maps that charts sequential product interaction. In this thesis the maps present activity based scenarios in which stoma management plays a role. Each map outlines six categories: care routines, activity preparation, social activities, recreational activities, physical activities, and intimate moments. While Sam's experience map shows a relatively stable and positive trajectory, with focused challenges in intimacy and visibility, Emre's map illustrates a more hyper aware daily life with multiple high-stress moments and ongoing psychological and physical stain. Visual icons were used to indicate the emotional weight of each domain. It is important to note that these experiences or emotions are not universal and are shaped by individual context. Quotes from the questionnaire and derived design opportunities are also included to link each activity domain to actionable insights. Figure 5.2.2c and 5.2.2d present these experience maps.

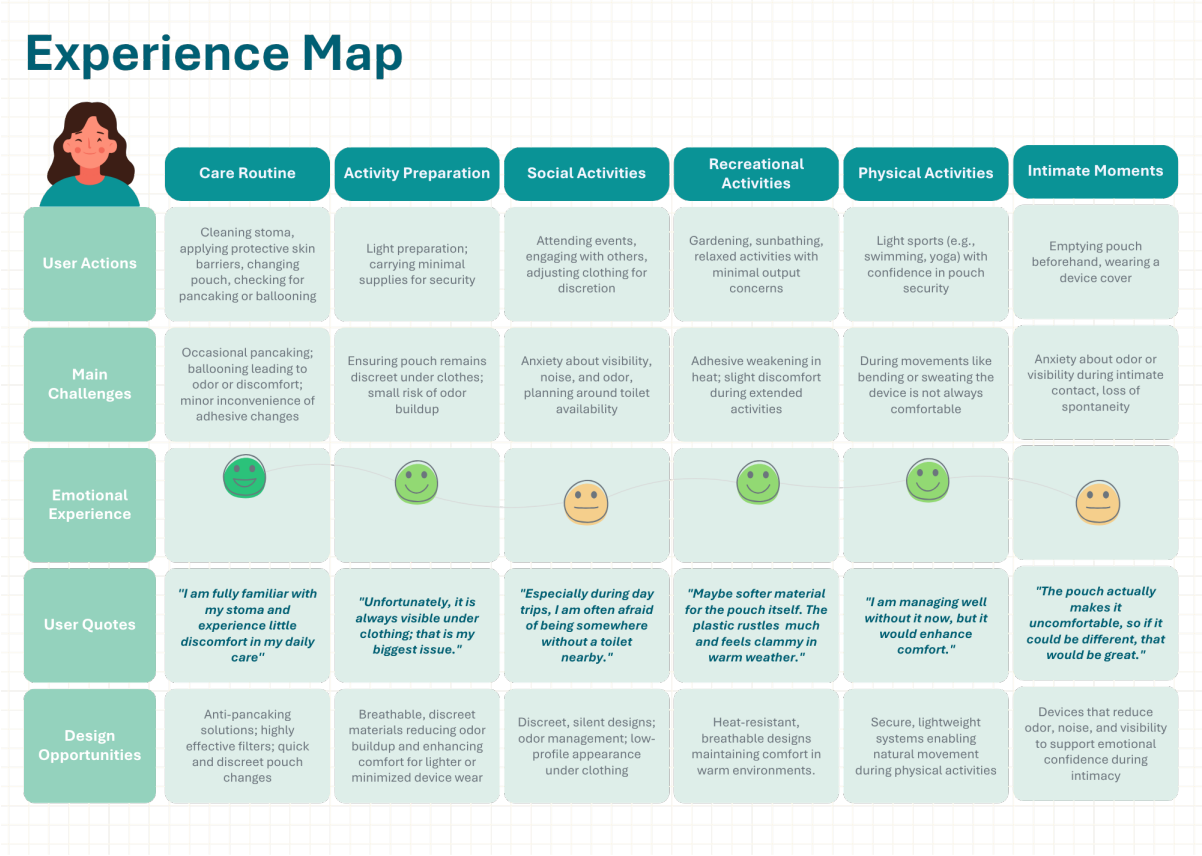


Figure 5.2.2c Experience map Sam, neutral/positive experience

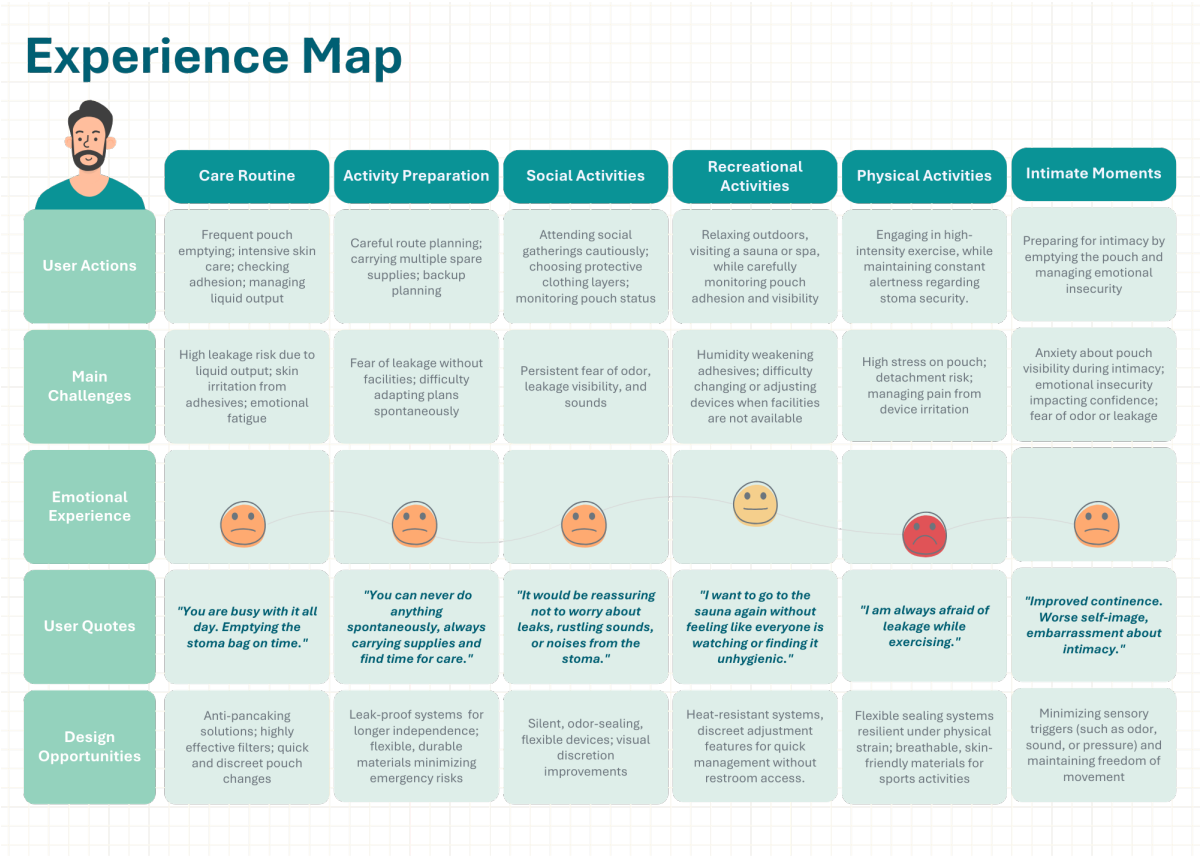


Figure 5.2.2d Experience map Emre, neutral/negative experience

The personas and experience maps again demonstrate the wide variability in ostomy-related needs. This underscores the importance of adaptive, modular product strategies over one-size-fits-all solutions. These tools like the personas and experience maps were critical for translating triangulated user needs into concrete and emotionally responsive design directions. They not only guided ideation and concept development but also informed the formulation of specific, context-aware requirements that can be seen in the next section.

5.3 Design Requirements

The following section covers the complete requirements framework for the design of a temporary pouch-free ostomy device. These requirements are uncovered through the mixed-method approach. They are categorized into functional, technical, and user requirements, and paired with testable specifications. These specifications are defined by validated thresholds or performance criteria. The thresholds are grounded in the findings of literature review (Chapter 2), specifically: medical and physiological safety limits (Section 2.5.1), regulatory and ISO standards (Section 2.5.2), technical feasibility and integration (Section 2.5.3), and material performance (Section 2.5.4). This structure ensures that the design is both evidence-based and aligned with user priorities.

5.3.1 Functional Requirements

Functional requirements describe what the device must do to support temporary continence, autonomy, and fallback to standard care. These requirements are listed in Table 5.3.1, and reference to the specifications presented in Table 5.3.5.

Table 5.3.1 Functional Requirements

Requirement	Description	Specification
FR1-CONTROL	The device shall provide control over stoma output for at least 2 hours	SPEC1-CONTAINMENT, SPEC5-POSITION, SPEC14-SEALPRESSURE, SPEC15-SEALSURGE
FR2-EMPTYING	The device shall allow manual emptying without needing to remove the device	SPEC2-EMPTYING
FR3-INDEPENDENT	The device shall be applicable and removable without assistance	SPEC3-APPLICATION, SPEC4-GRIP
FR4-POSITION	The device shall function when the user is seated or reclined	SPEC5-POSITION, SPEC13-SEALFLEXION
FR5-FILL	The device should indicate when it is nearing full capacity	SPEC6-FILLLEVEL
FR6-PLACEMENT	The user should be able to confirm correct device placement visually or tactually	SPEC7-FEEDBACK
FR7-PROFILE	The device shall maintain a low external profile during wear	SPEC8-HEIGHT
FR8-VISUAL	The device shall be visually discreet under tight clothing	SPEC8-HEIGHT, SPEC51-AESTHETICS, SPEC51-AESTHETICS
FR9-SOUND	The device shall operate without emitting noticeable noise during typical movements	SPEC9-NOISE
FR10-EXTRA	The device shall function without extra adhesives, straps, or external clip	SPEC10-ADHESION
FR11-MODULAR	Key components of the device should be individually replaceable	SPEC11-REPLACE, SPEC65-MODULARITY
FR12-DETECTION	The device should detect internal pressure changes	SPEC12-PRESSURE, SPEC61-ILPPAIN
FR13-FALLBACK	The device shall allow the user to revert to a standard pouching system without assistance in case of failure or discomfort	SPEC56-FALLBACK

5.3.2 Technical Requirements

Technical requirements define how the device must perform under physical, mechanical, and environmental conditions. These requirements are listed in Table 5.3.2, and reference to the specifications presented in Table 5.3.5a and Table 5.3.5b .

Table 5.3.2a Technical Requirements

Requirement	Description	Specification
TR1-SEALING	The device shall maintain a leak-proof and stable seal during user movements and posture changes	SPEC1-CONTAINMENT, SPEC5-POSITION, SPEC10-ADHESION, SPEC13-SEALFLEXION, SPEC14-SEALPRESSURE, SPEC15-SEALSURGE, SPEC22-MOTION, SPEC24-FITDYNAMIC, SPEC46-MECHANICAL
TR2-WATERTIGHT	The device shall remain watertight during immersion in water	SPEC16-WATERTIGHT
TR3-THERMAL	The device shall maintain full functionality and structural integrity under high-temperature conditions	SPEC17-THERMAL, SPEC66-TEMPERATURE
TR4-FLOWCONTROL	The device should contain stoma output without causing blockage or excessive backup	SPEC28-HIGHOUTPUT, SPEC61-ILPPAIN
TR5-CLEANABILITY	The device shall be cleanable without special tools or complex disassembly	PEC18-CLEANING, SPEC34-STABILITY, SPEC55-ASSEMBLY
TR6-GASVENTING	The device shall passively or actively release gas without fluid escape, excessive noise, or odor	SPEC19-GASVENTING, SPEC53-FILTERPORE
TR7-ODORFILTER	The device shall include a passive odor filter that does not require user activation	SPEC20-ODOR, SPEC19-GASVENTING, SPEC53-FILTERPORE
TR8-SEALPRESSURE	The device shall maintain sealing integrity under internal pressure	SPEC14-SEALPRESSURE, SPEC46-MECHANICAL
TR9-STRUCTPRESSURE	The device shall maintain structural integrity under internal pressure	SPEC15-SEALSURGE, SPEC31-STRUCTURE
TR10-POWERFREE	The device shall operate without requiring electricity, wireless connection, or app integration	SPEC21-POWER
TR11-MOTIONRESIST	The device shall maintain seal functionality during intensive physical activity	SPEC22-MOTION, SPEC24-FITDYNAMIC
TR12-STOMAFIT	The sealing interface should accommodate a range of stoma sizes	SPEC23-FITSTOMA, SPEC60-STOMAPROTRUSION
TR13-DYNAMICFIT	The sealing interface shall adapt to changes in stoma shape during activities	SPEC24-FITDYNAMIC, SPEC57-SKINSTRAIN, SPEC30-TOPOLOGY
TR14-REUSE	The device shall maintain functionality and sealing performance after repeated use	SPEC25-USECYCLES, SPEC32-DURABILITY, SPEC34-STABILITY, SPEC11-REPLACE
TR15-MOISTURE	The skin-contacting layer shall allow moisture transfer to prevent skin maceration	SPEC26-MOISTURE
TR16-PRESSUREAVOID	The device shall avoid exerting direct pressure on the stoma and minimize surrounding pressure	SPEC27-PERISTOMALPRESSURE, SPEC59-ISCHEMICLIMIT
TR17-HIGHOUTPUT	The device should manage high-output stoma flow without leakage or pressure buildup	SPEC28-HIGHOUTPUT, SPEC61-ILPPAIN

Table 5.3.2b Technical Requirements Continued

Requirement	Description	Specification
TR18-REREGULATE	The device shall regulate internal pressure to prevent rupture or failure	SPEC12-PRESSURE, SPEC14-SEALPRESSURE, SPEC61-ILPPAIN, SPEC59-ISCHEMICLIMIT
TR19-LOWASSEMBLY	The device shall be designed to avoid complex assembly steps during preparation, application, or maintenance	SPEC55-ASSEMBLY
TR20-NOTRAUMA	Skin-contacting components shall not cause mechanical or chemical trauma such as redness, pressure marks, or skin irritation during use	PEC35-DERMATOLOGY, SPEC36-SKINREMOVAL
TR21-WEAR	The device shall remain safe for continuous short-term wear without increasing infection or trauma risk	SPEC37-CONTINIOUS
TR22-ANTIMICROBIAL	Reusable surfaces should achieve antimicrobial cleaning performance	SPEC47-ANTIMICROBIAL, SPEC33-BIOFILM
TR23-HYDRATION	Stoma-facing surfaces should preserve mucosal hydration during use	SPEC23-FITDYNAMIC, SPEC26-MOISTURE
TR24-PAINREMOVAL	The device shall be removable without causing pain or skin irritation	SPEC36-SKINREMOVAL, SPEC38-PAINREMOVAL
TR25-STOMATYPE	The device should be compatible with both colostomies and ileostomies	SPEC64-STOMATYPE, SPEC1-CONTAINMENT

5.3.3 Material Requirements

Material requirements specify the necessary properties of materials used in skin- or output-contacting parts. These requirements are listed in Table 5.3.3, and reference to the specifications presented in Table 5.3.5.

Table 5.3.3 Material Requirements

Requirement	Description	Specification
MR1-BIOSAFETY	Skin- and mucosa-contacting materials shall comply with biological safety standards	SPEC29-BIOCOMPAT, SPEC35-DERMATOLOGY, SPEC36-SKINREMOVAL, SPEC37-CONTINIOUS, SPEC38-PAINREMOVAL, SPEC39-BIOEVAL
MR2-FLEXTOPOLOGY	The skin-contact layer should be soft, flexible, and adapt to varying abdominal topographies	SPEC30-TOPOLOGY, SPEC57-SKINSTRAIN, SPEC58-ELASTICMODULUS, SPEC62-HARDNESS1
MR3-STRUCTURERESIST	The structure shall resist collapse under minor impacts and abdominal pressure	SPEC31-STRUCTURE, SPEC63-HARDNESS2
MR4-DURABILITY	All components should tolerate repeated bending and twisting without damage	SPEC32-DURABILITY
MR5-ACOUSTICSILENCE	Materials shall dampen sound during movement to support discreet use	SPEC9-NOISE
MR6-ODORRESIST	Materials exposed to output should resist odor absorption	SPEC20-ODOR, SPEC33-BIOFILM, SPEC34-STABILITY
MR7-BIOFILMRESIST	Materials exposed to output shall resist biofilm formation	SPEC33-BIOFILM, SPEC47-ANTIMICROBIAL
MR8-CHEMRESIST	Exposed surfaces should be non-porous and chemically resistant to allow easy cleaning	SPEC18-CLEANING, SPEC34-STABILITY
MR9-POSTUSEODOR	The materials shall not retain or emit unpleasant odors after use and cleaning	SPEC33-BIOFILM, SPEC34-STABILITY

5.3.4 User Requirements

User requirements reflect the needs, preferences, and values expressed by ostomates during the survey and co-design activities. These requirements are listed in Table 5.3.4, and reference to the specifications presented in Table 5.3.4.

Table 5.3.4 User Requirements

Requirement	Description	Specification
UR1-INDEPENDENTUSE	The device shall support independent use	SPEC3-APPLICATION, SPEC21-POWER, SPEC45-USABILITY, SPEC50-ONBOARDING
UR2-ACCESSIBILITY	The device should support independent use by users with limited hand strength or vision	SPEC4-GRIP, SPEC67-TACTILECUES, SPEC45-USABILITY, SPEC50-ONBOARDING
UR3-MODESWITCH	The device shall allow switching between pouch and pouch-free modes without tools or assistance	SPEC48-TRANSITION, SPEC56-FALLBACK
UR4-ADAPTSHAPE	The device shall conform to irregular abdominal shapes	SPEC30-TOPOLOGY, SPEC57-SKINSTRAIN, SPEC58-ELASTICMODULUS, SPEC62-HARDNESS1
UR5-TOOLFREE	The device shall be applicable and removable without tools	SPEC3-APPLICATION, SPEC4-GRIP, SPEC55-ASSEMBLY
UR6-NOTRAUMA	The device shall not cause pain or trauma upon application or removal	SPEC36-SKINREMOVAL, SPEC38-PAINREMOVAL, SPEC59-ISCHEMICLIMIT
UR7-AESTHETICS	The device shall have an aesthetically pleasing, non-medical appearance	SPEC51-AESTHETICS
UR8-BREATHABLE	The device shall support breathability during continuous wear	SPEC26-MOISTURE
UR9-AUTONOMY	The device should support user autonomy by enabling temporary pouch-free use	SPEC48-TRANSITION, SPEC49-CONTEXTUSE, SPEC67-TACTILECUES, SPEC45-USABILITY, SPEC50-ONBOARDING
UR10-MODULARITY	The device should support modular or customizable elements	SPEC65-MODULARITY
UR11-CONTEXT	The device shall support reliable use across a range of physical, social, and rest activities	SPEC22-MOTION, SPEC49-CONTEXTUSE
UR12-ONBOARDING	The device shall include onboarding materials that enable independent use	SPEC50-ONBOARDING
UR13-VISUALDISCREET	The device shall offer color options that are discreet and visually neutral	SPEC51-AESTHETICS, SPEC8-HEIGHT
UR14-INTUITIVE	The device shall be intuitive to use for most users after short instruction	SPEC45-USABILITY, SPEC50-ONBOARDING
UR15-TACTILECUES	The device shall include tactile or shape-based cues to support users to reassure the user of proper sealing and function	SPEC7-FEEDBACK, SPEC67-TACTILECUES

5.3.5 SPECIFICATIONS

This section outlines the measurable specifications. Each specification translates one or more functional, technical, material or user requirement into a testable performance criterion. This structured translation supports traceability from user needs to verifiable product performance. These specifications are listed in Table 5.3.5a-d, and reference to the requirements presented in Table 5.3.1-5.3.4. Some aspects and values were not covered in Chapter 2, these consist of grip strength, abdominal flexion, and noise in dB. For the noise level of the design ≤ 10 dB is chosen as ostomates should be confident that others will not notice the device or stoma. This number is chosen as it represents normal breathing sounds (Cochary, 2021). Furthermore, for the grip strength numerous values are mentioned, yet Salaffi et al. (2021) mentioned that the mean grip strength of patients with limited hand dexterity is about 17 kg. Thus, the device should be usable by ostomates with a grip force ≤ 17 kg. Lastly, abdominal flexion is discussed, this aspect is of importance in the context of exercise. Abdominal flexion is highly person specific and depends on the type of exercise at hand, one study mentions that the flexion during running is at his highest 36.4 (5.2) degrees among study participants (Warrener et al., 2021). Thus for the specification a numerical value is chosen which is at least > 42 degrees.

Table 5.3.5a Specifications 1-18

Specification	Description
SPEC1-CONTAINMENT	The device shall contain Bristol Stool Scale types 3–7 output for at least 2 hours without leakage, verified through a simulated wear test (ISO 8670-2)
SPEC2-EMPTYING	The user shall be able to manually empty the device in ≤30 seconds, validated by a timed usability study following ISO 62366-1 human factors engineering protocols.
SPEC3-APPLICATION	The device shall be applied and removed in ≤1 minute, validated through timed testing in accordance with ISO 62366-1.
SPEC4-GRIP	The device shall be operable by users with a grip strength ≤ 17 kg, without requiring tools or assistance, measured via grip dynamometer as part of ISO 62366-1 usability testing
SPEC5-POSITION	The device shall retain full containment while the user is seated, standing, or reclined, without seal failure, evaluated using posture-based wear simulation under ISO 8670-2
SPEC6-FILLLEVEL	A visual, tactile, or mechanical signal should activate when the internal fill level reaches ≥80% of maximum capacity, verified via threshold activation and user response testing
SPEC7-FEEDBACK	The device shall provide confirmation of correct placement through a visual or tactile signal, evaluated under ISO 62366-1 usability test conditions
SPEC8-HEIGHT	The total device height shall not exceed 10 mm during wear, including under conditions of sitting or bending, measured with calipers in a simulated-use scenario
SPEC9-NOISE	The device shall emit ≤10 dB(A) during normal movement, measured at 0.5 m distance, assessed according to ISO 3744 acoustic testing standards
SPEC10-ADHESION	The device shall maintain functional sealing and retention without adhesives, straps, or clips, verified through physical integrity testing during active wear
SPEC11-REPLACE	User-replaceable parts shall maintain leak-tight performance after ≥20 replacement cycles, tested via repeated use simulation and leakage verification
SPEC12-PRESSURE	The device may detect internal pressure changes within a sensitivity range of ±5 mmHg, validated using manometric calibration in a controlled pressure chamber
SPEC13-SEALFLEXION	The seal shall prevent leakage during > 52° of abdominal flexion, verified through dynamic simulation under ISO 8670-2
SPEC14-SEALPRESSURE	The seal shall maintain full integrity under continuous internal pressure up to 20 mmHg without leakage or deformation, representing typical abdominal, verified via ISO 8670-2 pressurization testing
SPEC15-SEALSURGE	The seal shall withstand transient internal pressure surges up to 180 mmHg for ≤5 seconds without structural failure or blowout, validated using burst and impulse pressure tests under ISO 8670-2
SPEC16-WATERTIGHT	The device shall remain fully watertight after 2 hours of submersion at 1.5 meters depth, without fluid ingress, deformation, or performance loss., complicance shall be verified using immersion testing based on ISO 8670-2
SPEC17-THERMAL	The device shall retain structural and sealing integrity after 30 minutes of exposure to 120°C, evaluation include heat chamber endurance and seal integrity checks
SPEC18-CLEANING	Reusable parts of the device shall be cleanable in ≤1 minute using 70% alcohol or neutral soap, without tools, assessed for compliance with ISO 17664

Table 5.3.5b Specifications 19-35

Specification	Description
SPEC19-GASVENTING	The device shall allow ≥200 mL of gas to vent per hour at ≤10 mmHg pressure without fluid leakage, perceptible odor, or noise exceeding, tested under ISO 17299-3 (odor), ISO 3744 (sound), and visual barrier protocols
SPEC20-ODOR	The integrated passive filter shall reduce ≥90% of sulfur-based and organic odorants, validated using ISO 17299-3 or equivalent gas chromatography
SPEC21-POWER	All device functions shall operate without reliance on batteries, electronics, or software, verified by design inspection and documentation review
SPEC22-MOTION	Seal detachment or leakage shall occur in ≤2% of dynamic use cases, including walking, bending, and simulated physical activity, evaluated using dynamic wear testing
SPEC23-FITSTOMA	The device should securely fit stomas ranging from 10 mm to 55 mm in diameter without user modification, confirmed via physical fit tests on standard anatomical models
SPEC24-FITDYNAMIC	The seal shall remain leak-proof under conditions of abdominal wall movement and stoma deformation, validated using strain-based testing with flexible anatomical models
SPEC25-USECYCLES	Reusable components shall maintain full functionality and sealing after ≥100 cleaning and usage cycles, tested via mechanical fatigue cycling and post-test leakage analysis
SPEC26-MOISTURE	The MVTR of the skin-contacting layer shall be ≥ 200 $g/m^2/24h$, tested in accordance with ISO 2528 (gravimetric method)
SPEC27-PERISTOMALPRESSURE	Interface pressure exerted by the device on peristomal skin shall remain <20 mmHg under all conditions. Evaluated using Tekscan pressure sensor mapping
SPEC28-HIGHOUTPUT	The device should safely manage continuous liquid effluent up to 50 mL/hour for a minimum of 2 hours without leakage or overflow, validated using continuous flow bench testing with BSFS 6–7 stool simulants
SPEC29-BIOCOMPAT	All materials in direct or indirect contact with skin or stoma tissue shall comply with ISO 10993-1, ISO 10993-5, and ISO 10993-10, demonstrating non-cytotoxicity, no skin irritation, and no sensitization, validation via in vitro cytotoxicity, irritation, and sensitization assays
SPEC30-TOPOLOGY	The device shall conform effectively to peristomal skin height variations of up to ±15 mm, ensuring seal integrity and user comfort, validated through usability testing with participants exhibiting varied stoma topographies, following ISO 62366-1 procedures
SPEC31-STRUCTURE	The device shall resist collapse and deformation under static pressure between 20–30 mmHg and withstand minor mechanical impact. Verified via pressure plate testing and drop impact simulation
SPEC32-DURABILITY	All flexible and jointed materials shall endure ≥500 bending and twisting cycles without cracking, delamination, or leakage, evaluated through repetitive mechanical load cycling
SPEC33-BIOFILM	After repeated exposure and cleaning, device surfaces shall retain no perceptible odor and demonstrate resistance to biofilm formation, verified using ISO 22196 or ASTM E2180 after contact with fecal simulants
SPEC34-STABILITY	Materials shall remain non-porous and chemically stable after ≥100 cleaning cycles with soap or alcohol-based agents, validated using ISO 17664-compatible chemical resistance testing
SPEC35-DERMATOLOGY	≥95% of users shall experience no signs of erythema, edema, itching, or sensitization following 2-hour device wear, confirmed via ISO 10993-10 patch testing

Table 5.3.5c Specifications 36-53

Specification	Description
SPEC36-SKINREMOVAL	Device removal shall cause no visible trauma or skin stripping in ≥95% of users after 2-hour wear, via ICDRG scale and test procedures from ISO 10993-10
SPEC37-CONTINIOUS	No visible peristomal skin damage shall be observed after 14 consecutive days of daily 2-hour wear, assessed through a longitudinal clinical usability test via ICDRG scale and test procedures from ISO 10993-10
SPEC38-PAINREMOVAL	At least 95% of users shall report a pain score ≤2 on a 10-point visual analogue scale (VAS) upon removal of the device. Data collected via validated usability questionnaire and pain assessment
SPEC39-BIOEVAL	All device materials shall comply with ISO 10993-1, ISO 10993-5, and ISO 10993-10, demonstrating biocompatibility, non-cytotoxicity, and absence of irritation or sensitization
SPEC40-MDR	The device shall fulfill the requirements for Class I or IIa classification under EU MDR 2017/745, including safety, performance, and labelling standards
SPEC41-CER	The device shall meet the evidence criteria under MDR Annex XIV for clinical safety and performance evaluation. Outcome documented in a Clinical Evaluation Report (CER)
SPEC42-STERILITY	Sterile device components shall meet sterility assurance levels validated under ISO 11137 (radiation) or ISO 11135 (ethylene oxide)
SPEC43-RISK	Device risks shall be systematically identified, evaluated, and mitigated in accordance with ISO 14971:2019
SPEC44-QMS	The device shall be developed under a certified ISO 13485 quality management system
SPEC45-USABILITY	Usability shall be validated under ISO 62366-1 with representative users, showing safe and effective operation
SPEC46-MECHANICAL	Seal strength, fatigue resistance, and retention shall be validated according to ISO 8670-2
SPEC47-ANTIMICROBIAL	Reusable surfaces shall achieve ≥99% microbial load reduction after standard cleaning and maintain $<10^3$ CFU/cm^2 bacterial presence after 2 hours, verified via surface swab testing in accordance with ISO 22196
SPEC48-TRANSITION	Users shall be able to independently switch between pouch and pouch-free modes without tools or assistance, in ≤30 seconds, verified through usability testing with ≥90% task success in simulated real-world scenarios (per ISO 62366-1)
SPEC49-CONTEXTUSE	The device shall function without leakage, discomfort, or odor across various activities, including swimming, sleeping, travel, and light exercise. Scenario-based performance tests must achieve ≥95% success rate across all activity types
SPEC50-ONBOARDING	The device shall include clear, accessible onboarding materials (visual and written). After reviewing, ≥90% of users must be able to use the device independently without further guidance, validated through usability studies with first-time users
SPEC51-AESTHETICS	The device shall have a low-visibility profile under clothing and a neutral appearance rated as “discreet” or “acceptable” by ≥80% of users in a visual preference survey, tested using standardized product photography and visual analog scales
SPEC52-INSERTGEOMETRY	Device insertion depth shall not exceed 60 mm and shall feature an atraumatic rounded or conical tip, validated through anatomical model testing and user-reported VAS scores ≤3/10 during insertion
SPEC53-FILTERPORE	The integrated filter membrane shall have a pore size of 0.2 to 0.5 µm, allowing gas venting while preventing liquid and microbial penetration, confirmed via ISO 17299-3 testing and SEM imaging

Table 5.3.5d Specifications 54-67

Specification	Description
SPEC54-BIODEGRADABLE	Disposable components intended as biodegradable shall achieve ≥70% degradation after 45 days in composting conditions, per ISO 14855-2, validated through standardized degradation simulation
SPEC55-ASSEMBLY	The device shall contain ≤10 parts in total, with ≤5 assembly steps, all executable without tools, assembly and disassembly usability shall be validated via ISO 62366-1 user tests and cleaning process assessments
SPEC56-FALLBACK	The device shall allow reversion to a standard 2-piece ostomy pouching system without additional tools, components, or clinical assistance, validated in emergency-use simulations and fallback protocol usability tests
SPEC57-SKINSTRAIN	The skin-facing material shall accommodate up to 30 mm of displacement and 29% strain under peristomal motion without loss of seal or causing discomfort, validated through dynamic strain modeling and simulated wear tests
SPEC58-ELASTICMODULUS	The elastic modulus of the skin-contacting material shall fall within skin-matching ranges: 4.6–20 MPa (tensile), 0.42–1.12 MPa (torsional), and 0.13–0.26 MPa (suction), tested using uniaxial tensile, torsional, and suction-based tests
SPEC59-ISCHEMICLIMIT	Interface pressure on peristomal skin shall not exceed 30 mmHg, the threshold above which capillary perfusion may be compromised, validated through pressure sensor mapping during wear simulations and verified under ISO 10993-10
SPEC60-STOMAPROTRUSION	The device should securely accommodate stoma protrusions ranging from <5 mm to >30 mm without leakage or mechanical instability, validated using standard anatomical stoma models with variable protrusion heights
SPEC61-ILPPAIN	The device shall not induce intraluminal pressures exceeding 45 mmHg, as higher values may trigger pain due to occlusion or flow resistance. Pressure buildup shall be measured during simulated use with manometric testing, and user discomfort shall remain below VAS ≤3/10 under peak flow conditions
SPEC62-HARDNESS1	The skin-contacting interface shall have a Shore A hardness, ensuring both skin conformity and structural stability, verified using durometer testing in accordance with ISO 7619-1
SPEC63-HARDNESS2	The rigid housing or outer shell shall have a Shore D hardness providing sufficient mechanical support and impact resistance, verified using durometer testing in accordance with ISO 7619-1
SPEC64-STOMATYPE	The device should be compatible with both colostomies and ileostomies, effectively managing outputs corresponding to BSFS 3–7, validated using fecal simulants and user testing per ISO 8670-2
SPEC65-MODULARITY	The device should support optional modular components hat enable users to customize functionality without compromising seal, hygiene, or usability, all modular adjustments must be executable independently by users without tools and validated through usability testing under ISO 62366-1
SPEC66-TEMPERATURE	The device shall maintain structural and functional integrity when stored or used within a temperature range of –10°C to +120°C. Validated through thermal stress testing (ISO 22391 or equivalent) and visual/mechanical inspection post-exposure
SPEC67-TACTILECUES	The device shall include tactile, shape-based, or positional cues (e.g., alignment ridges, tabs, or snaps) to enable use by individuals with reduced vision or sensory feedback, verified through accessibility-focused usability testing under ISO 62366-1

5.4 Key Insights

Through methodological triangulation, core themes such as leakage anxiety, skin health, emotional burden, and social limitations were validated and expanded on in this chapter. While survey data revealed broad interest in pouch-free use, co-design highlighted critical conditions for adoption which underscores that interest does not mean acceptance. Next to this, user needs were grouped and prioritized using the Kano model. Providing design focus that balances safety, autonomy, and emotional value. Further on, to contextualize insights, two personas and experience maps were created to represent the diversity of ostomate experiences. These tools humanize the design process and emphasize the importance of adaptive, context-sensitive solutions. The chapter concludes by translating these insights into a structured requirement framework with measurable specifications, which will guide the design phase.

Key insights informing the next chapter:

- Core needs such as leakage prevention, secure adhesion, and confidence in performance were confirmed across all methods.
- While interest in pouch-free use was high, actual willingness depends on safety, comfort, and psychological reassurance.
- Personas and experience maps showed the contrast between situational and burden-driven motivations for pouch-free use.
- Requirements must reflect both universal safety thresholds and highly personal lifestyle variations.
- Triangulated insights directly shaped functional, technical, material, and user requirements with validated performance specifications.

Chapter 6: FlexiSeal: A Conceptual Design Response

This chapter outlines the translation of prioritized user needs into a concept development. It presents the selected concept, explains key design decisions, and details how requirements were addressed in the development of a temporary pouch-free ostomy solution. This chapter also shows the design guidelines. Lastly, the concept is evaluated. This chapter focuses on the main design challenge: Develop a conceptual product solution that aligns with the key needs and expectations of ostomates, enabling temporary ostomy-pouch-free periods.

6.1 Concept Justification

The following concept was developed in response to unmet user needs identified through literature, survey, and co-design data. These needs reflected a consistent desire for short-term pouch-free autonomy. This was specific to contexts where wearing an ostomy pouch imposes physical, psychological, or social burdens. While not all users experienced these challenges equally, many reported situations where the pouch limited them. These limitations were apparent in comfort, discretion, or not being to participate socially. The concept aims to address this by enabling user-controlled, context-specific pouch-free periods that feel safe, hygienic, and empowering. Most importantly without trying to replace the pouch systems completely.

As confirmed in Co-Design Session 3, participants expressed divergent preferences for the presented concept directions. The participants emphasized a desire for context-based choice, adapting the product to situations such as exercise, recreation, intimacy, or social events. In these situations needs for discretion, comfort, or desired safety vary. Participants also required different products for their individual needs. This resulted in a modular design approach built around a reusable base unit with a mechanical iris valve that provides manual flow control. This component, was positively received in the co-design sessions.

With the design ostomates can select between two interchangeable inserts based on situational and individual needs:

(1) a plug-like absorbent insert for discreet use
(2) a balloon-like insert that passively collects minor leakage but only expands fully upon cap release
This conceptual direction, named FlexiSeal, embodies the key insights about autonomy, discretion, modularity, and emotional reassurance emphasized throughout the co-design process. The improved FlexiSeal, presented in Figure 6.1a, reflects an integrated response to mixed preferences.

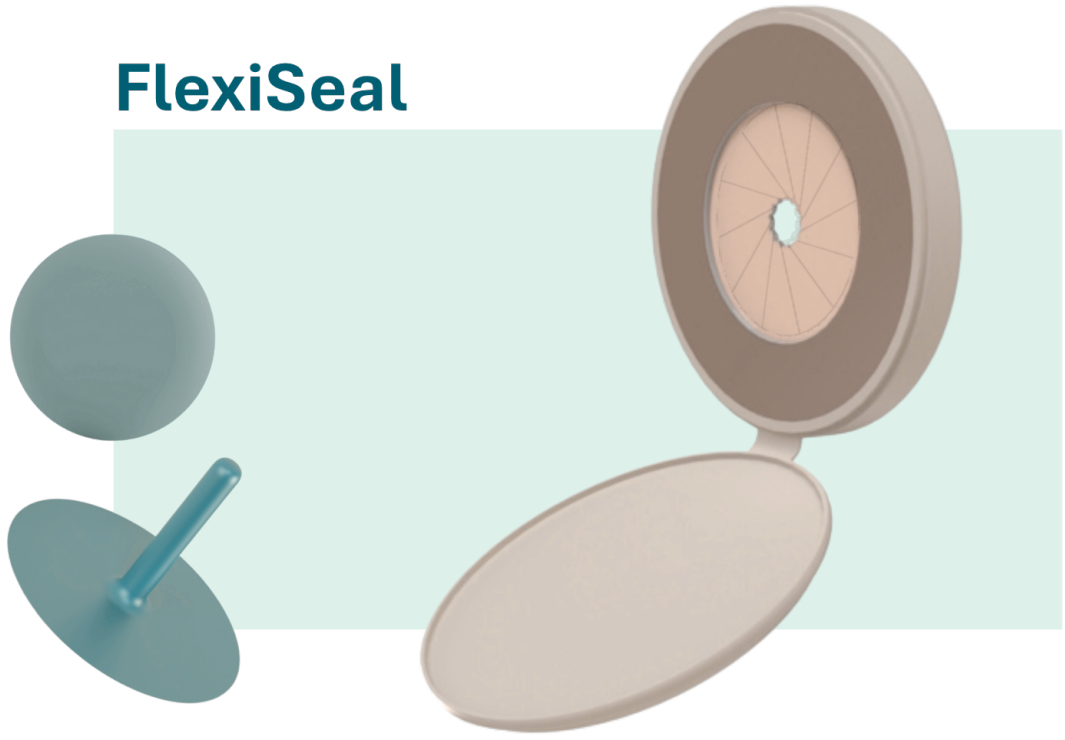


Figure 6.1a Improved FlexiSeal concept

The modular insert approach evolved to support both discretion and security. These changes are based on session feedback that there is not a one-size fits all solution. Furthermore, the system's compatibility with existing two-piece baseplates directly responded to concerns about adoption barriers and user trust. Co-design participants also emphasized the need for a fallback mechanism. This leads to the inclusion of an emergency reversion option to standard pouches.

Figure 6.1b presents the user interaction, which will be built upon in section 6.3.3. At this moment the device size is decided by individual anatomical variations, as mentioned in the previous chapter a one size fits all approach will not work in the context of ostomy care. Depending on stoma size, protrusion, and anatomical topography this device will be designed to fit the person. Furthermore, with the information gathered throughout a set of design guidelines are made, presented in the next section.

Figure 6.1b User Interaction FlexiSeal

6.2 Design Guidelines

This section translates the triangulated user insights, formal requirements, and co-design evaluations into a set of best-practice design guidelines. These guidelines may support future pouch-free development. These guidelines represent recommendations for how the device should function, feel, and fit into ostomates' lives. Acting as a bridge between technical feasibility and user experience. Table 6.2a covers the design guidelines and categories.

Table 6.2a Design Guidelines

Categories	Design Guideline
Usability and Comfort	**DG1:** Prioritize intuitive, tool-free handling to reduce stress during application and removal, even for users with limited dexterity
	DG2: Favor soft, skin-compatible materials that reduce discomfort during insertion and removal
	DG3: Provide clear, accessible cues to help users confidently verify placement before activation
	DG4: Design for comfort across both active and resting body states, avoiding stiffness or bulk that might restrict movement
Discretion and Aesthetic Integration	**DG5:** Emphasize visual and acoustic discretion to support wearability in public and social contexts
	DG6: Offer aesthetic customization (e.g., color, form) to help the product blend with skin tones or clothing
	DG7: Use emotionally sensitive design features, such as soft textures or symbolic naming, that enhance user dignity and acceptance
	DG8: Design surfaces to resist odors and microbial buildup, promoting confidence in long-term use
Functional Reliability and Feedback	**DG9:** Enable predictable, short-term containment of output to support active lifestyles without anxiety
	DG10: Include feedback mechanisms to help users anticipate when emptying or removal is needed
	DG11: Support safe, user-controlled emptying that feels manageable in public or private settings
	DG12: Integrate pressure regulation and venting strategies to avoid discomfort and reassure users of system safety
Modularity and Adaptability	**DG13:** Accommodate diverse stoma anatomies and abdominal profiles to ensure inclusive usability
	DG14: Facilitate modularity to enable personalized configuration or future adaptation of components
	DG15: Allow users to easily transition between pouch-free and traditional systems depending on activity or context
Hygiene and Environmental Responsibility	**DG16:** Ensure the product can be used and cleaned hygienically, even outside ideal settings
	DG17: Consider sustainable, biocompatible materials to align with users' environmental values

Together, these guidelines act as a decision making framework to guide concept refinement. These guidelines ensure that technical solutions remain accountable to the emotional, social, and practical realities of pouch-free ostomy use. Each reflects not just what the device must do, but how it should be experienced in the daily lives.

6.3 Improved Concept

This chapter presents the improved concept developed through the iterative co-design process: FlexiSeal. The concept integrates insights from user needs, technical constraints, and co-design feedback. The concept is intended as a two-piece system compatible with existing ostomy baseplates.

6.3.1 System Overview

FlexiSeal is a low-profile and manually controllable concept. It is designed for short-term use (up to four hours), allowing users to manage their stoma output in a safe, hygienic, and discrete manner. The device is modular and works in combination with a standard two-piece baseplate. This allows users to retain their preferred adhesive system. This approach reduces adoption barriers and builds on clinically established materials familiar to users.
A key innovation of the concept lies in its user selecting insert system, enabling individuals to choose between different internal configurations based on their specific needs and activity context. Two core insert types have been developed to accommodate a range of user scenarios and preferences. Figure 6.3.1 shows the FlexiSeal overview.

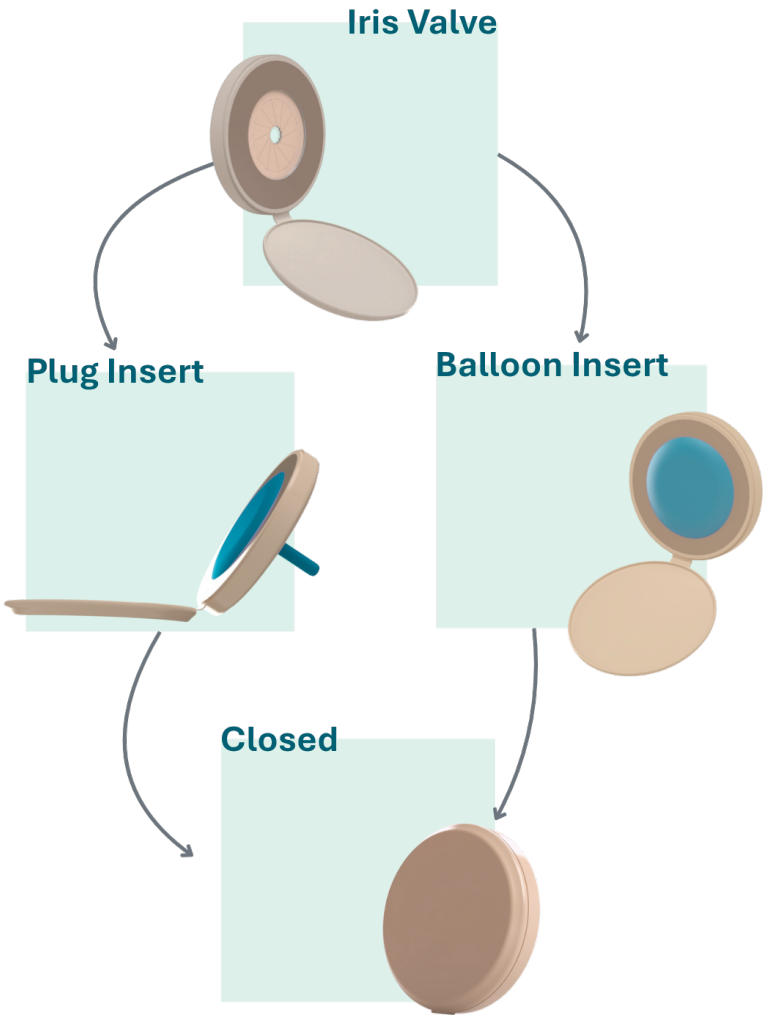


Figure 6.3.1 Overview of FlexiSeal configurations

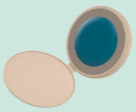
6.3.2 Functional Components

The design consists of different components to make pouch-free periods feasible. Table 6.3.2 portrays these components. This section highlights these, starting with the semi-rigid outer shell which provides structural integrity and alignment

The housing is a living hinge based lid and valve, with a lip and groove closing mechanism. In contrast to the pouch-free designs discussed during Session 1, the FlexiSeal adds the extra and desired component of control without worrying about intestinal pressure buildup or if there is a toilet nearby. FlexiSeal supports two interchangeable insert types, both inserts can be secured via an adhesive backing inside the reusable housing. The modular approach is influenced by Co-Design Session 3 and may provide better usability, personalization, and long-term satisfaction. A manually operated iris valve controls stoma flow. When closed, it blocks output and enables short-term continence. When rotated open, it directs output into the selected insert. The visual markings on the turning mechanism reinforces user autonomy and enables intuitive operation without the need for tools.

Furthermore, it is important for future iterations to integrate a passive venting mechanism into the housing to release gas and prevent internal pressure buildup. The vent can include an activated carbon filter layered with a microporous membrane to neutralize odours and minimize sound. Besides these components the material selection is of importance as well.

Table 6.3.2 Components of the FlexiSeal

Component	Purpose	Mechanism	Material	Justification
Snap-Fit Backplate 	Fixed base that connects to existing adhesive baseplate, anchoring point for the rotating body.	Snap-fit geometry mates with standard flanges, no rotation ensures stability on body	TPU Shore 90A	Ensures safe use with trusted materials and allows quick return to standard pouch as a failsafe (based on co-design sessions)
Rotating Outer Casing 	Holds the iris valve and adhesive interface for inserts, also protects stoma from potential impact	Rotates independently on the fixed backplate via a detent-based snap ring, aligns valve and insert	TPU Shore 90A	Provides low-profile, flexible movement and control without compromising structure (discreetness and safety from questionnaire and co-design sessions)
Iris Valve 	Manual valve to regulate waste flow from the stoma, enables user-controlled continence and pressure management	Turning the ring opens overlapping blades in steps, with colored lines indicating the opening level	TPU Shore 90A	Provides safe, intuitive mechanical control, addressing participant concerns about reliability and lack of control in other pouch-free concepts
Insert A: Plug 	Internal plug for low-output moments, absorbs minimal output	Adheres to the outer ring of the iris valve via an adhesive backing; the plug is inserted through a semi-closed valve and held securely in place	PU foam + TPU shell	Users valued discreet options and choice; plug suggestions and dislodgement concerns supported keeping the iris valve for added security
Insert B: Balloon dome 	Disposable, stretchable insert that expands under pressure, serving as a discreet failsafe and offering pouch-like function without the appearance	Expands like a balloon under internal pressure only when the cap is open and the valve is rotated, adheres to the valve ring with adhesive	Consists of an inner SAP pad or PU foam, a middle stretchable TPU film, and an outer hydrophobic TPU shell	Provides hygienic, pouch-like function without visual stigma. Multi-layer design balances stretch, absorption, and clean handling. Supports mobility and night use
Cap with Living Hinge and Snap Fit 	Protective cover for valve, insert, and stoma, and enables safe and discreet closure	Attached via a continuous TPU living hinge and secured with a lip-and-groove snap fit on the casing	TPU Shore 90A	Users requested a simple, low-bulk cover. Living hinge prevents extra parts and supports intuitive, hygienic use

MATERIALS AND BIOCOMPATIBILITY

To ensure a balance between strength, flexibility, and safety most core components of the are currently intended to be made from medical-grade Thermoplastic Polyurethane (TPU). This material supports flexible snap-fits, a reliable iris valve, and a durable living hinge. TPU with a Shore 90A hardness can also conform to the body, and is cleanable with soap and water. Moreover, the disposable inserts are made from conforming and absorbent materials such as PU foam, stretchable TPU film, and hydrogel-based cores. These combinations allow the inserts to handle output effectively while also making sure the outer layer stays hygienic for disposal.

Even though, the abovementioned materials are fitting to the design the material choices are still exploratory. Exact refinements will be made through prototyping and testing. Because other options are also viable at this conceptual point, for example PA12 or PEEK could provide more rigidity in structural parts. On the other hand, silicone-infused resins might improve comfort where the device contacts skin. While, SAP-coated nonwovens and hydrogel composites are being explored for better absorption. And for moving parts like the valve, materials such as POM or polypropylene may offer better performance.

All options will be evaluated against ISO 10993 standards for biocompatibility. The final selection will depend on how materials behave in real conditions, especially under pressure, moisture, movement, and repeated handling.

The design is customizable via 3D scanning to make sure of the correct anatomical fit. The reusable components are suitable for injection molding or 3D printing. This is chosen so adjustments can be made based on stoma locations and abdominal topography. The disposable inserts can be manufactured using thermoforming, lamination, and heat-sealing techniques already common in the medical absorbent products industry.

6.3.3 Interaction and Use

The intended interaction with FlexiSeal is simple and user-directed. It is designed to support temporary pouch-free periods across various activities. The use storyboard is shown in Figure 6.3.3. The user attaches the device to their standard baseplate, selects the appropriate insert type, and adjusts the iris valve to control flow. After use, the insert can be replaced or discarded, and the reusable housing rinsed with water or mild soap. Below the intended use is presented in line with MDR.

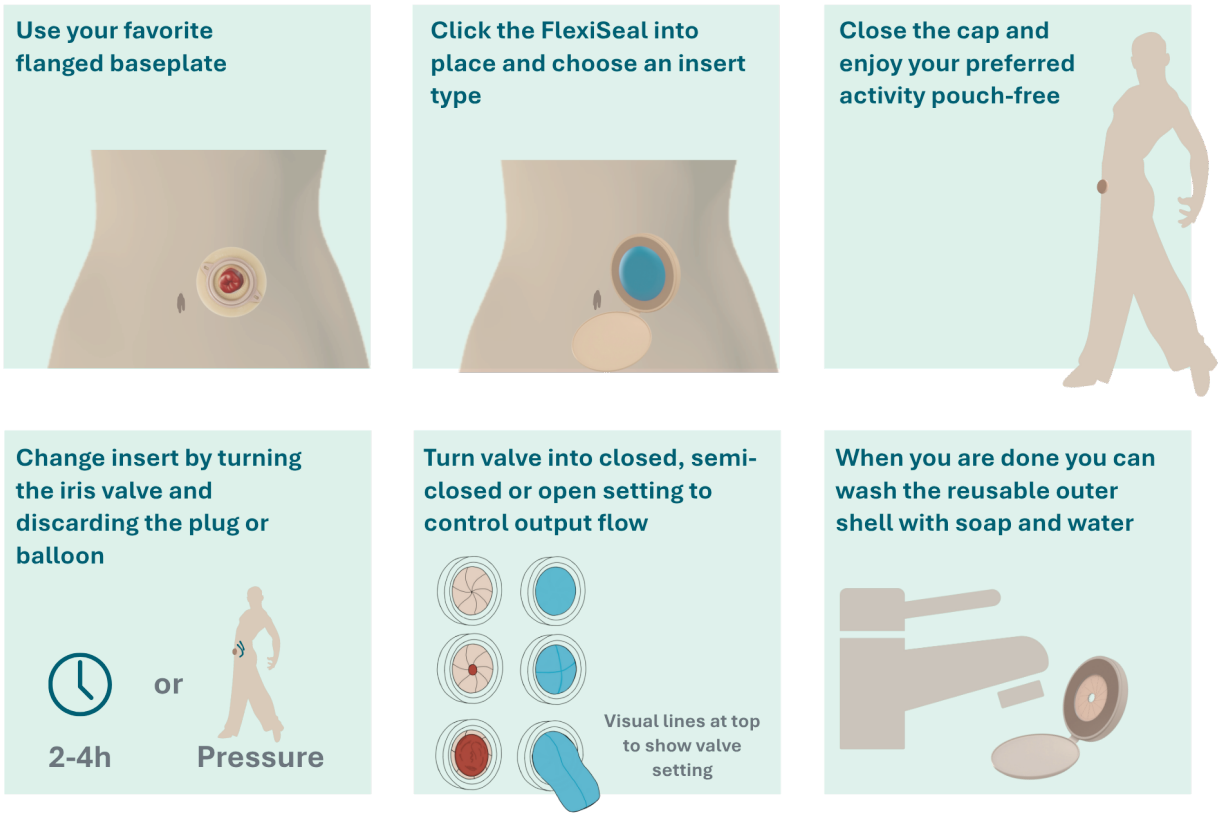


Figure 6.3.3 Storyboard

INTENDED USE

FlexiSeal is a modular, non-active, reusable medical device designed for the short-term management of intestinal stoma output in adults with a colostomy or ileostomy. It supports user-controlled, pouch-free periods of up to four hours during specific activities such as exercise, bathing, intimacy, or travel. The system includes a manually operated iris valve and interchangeable single-use inserts that either can occlude the stoma (plug) or collect output in a soft, expandable reservoir (balloon). FlexiSeal is compatible with standard two-piece adhesive baseplates and is intended to be self-managed by users in non-clinical settings. It is not designed to replace the pouching systems and is not suitable for urostomy patients, children, or individuals who are unable to safely operate the device due to cognitive or physical limitations.

6.3.4 Evaluation of Concept

COMPARISON TO EXISTING SOLUTIONS

FlexiSeal addresses some of the limitations of both conventional pouches and early pouch-free innovations. This is done by addressing pressure buildup, user discretion, and anatomical fit. Unlike bulkier or surgically implanted systems, it offers a lightweight, removable, and body-responsive alternative that better accommodates dynamic use context

HUMAN-CENTRED CONSIDERATIONS

The concept is especially suited to users seeking temporary control without fully replacing their existing system. It supports user autonomy through manual operation and offers flexibility for varied preferences and routines. However, further development is needed to address high-output ileostomies, limited hand function, and irregular stoma geometries. The modular architecture provides a foundation for future personalisation, but broader applicability must be tested in further development.

EVALUATION AGAINST REQUIREMENTS

Not all requirements are fully satisfied at this stage of the conceptual design. The evaluation that follows assesses the extent to which the concept aligns with the requirements highlighted in Chapter 5. The level of fulfilment is categorised as fully met, partially met, or not yet met. These categories explain These classifications help identify both the strengths of the current design and the areas requiring further development or validation.

Starting with the functional requirements. The concept meets most functional goals, mainly those related to independent control, discreet use, and modularity. Certain expected features such as a fill indicator and pressure sensor are not yet integrated. These gaps reflect the conceptual stage of development and highlight areas for prototyping and usability testing. Table 6.3.4a portrays these fulfilment levels of the functional requirements.

Table 6.3.4a Fulfilment levels of the functional requirements

Requirement	Fulfilment Level	Justification
FR1-CONTROL	⚠	Expected containment with inserts for up to 4 hours, but not yet clinically verified
FR2-EMPTYING	✓	Iris valve and inserts enable manual emptying of output
FR3-INDEPENDENT	✓	Designed for independent attachment and removal
FR4-POSITION	⚠	Concept assumes posture versatility, but not validated in trials
FR5-FILL	✗	No visual or tactile fill indicator included yet
FR6-PLACEMENT	✓	Tactile cues included at baseplate and valve interface
FR7-PROFILE	✓	Low-profile geometry based on FlexiSeal insert design
FR8-VISUAL	⚠	Streamlined silhouette, flush-fitting valve reduces visibility. However, not validated against different stoma geometries
FR9-SOUND	⚠	Not making use of rustling material, but venting and stoma sound damping is not covered yet. No validation
FR10-EXTRA	✓	Relies on standard baseplate, no added support mechanisms
FR11-MODULAR	✓	Modular insert-housing design supports part replacement
FR12-DETECTION	✗	No integrated sensor for pressure detection
FR13-FALLBACK	✓	Baseplate compatibility ensures easy switching incase of emergencies

Following this, the technical requirements are looked at. For the technical requirements it has proven more difficult to evaluate them against the conceptual design. As in theory most requirements should work but none are tested in real-life conditions. Table 6.3.4b portrays the fulfilments of the requirements. Additionally, features such as odour filtering and antimicrobial surfaces are not yet implemented in the conceptual design, because the focus was on output control at this stage. The current design provides a strong structural foundation but requires technical validation through targeted engineering tests.

Table 6.3.4b Fulfilment levels of the technical requirements

Requirement	Fulfilment Level	Justification
TR1-SEALING	⚠	Concept aims for secure sealing, but not yet validated in motion scenarios
TR2-WATERTIGHT	⚠	Assumed watertight design, but not immersion-tested
TR3-THERMAL	⚠	Material choices which could withstand such temperatures are chosen, behaviour under heat is not yet tested
TR4-FLOWCONTROL	✓	Interchangeable inserts allow flow modulation
TR5-CLEANABILITY	✓	Modular design and odour/biofilm resistant materials can cleaned, real world usage needs to be verified
TR6-GASVENTING	⚠	Gas venting only through iris valve at the moment, not known if it works without leaking output
TR7-ODORFILTER	✗	Odour filter not yet included in current conceptual design
TR8-SEALPRESSURE	⚠	Passive venting and valve relieve pressure, not tested in real life conditions
TR9-STRUCTPRESSURE	⚠	Material strength assumed, not validated
TR10-POWERFREE	✓	Fully mechanical system
TR11-MOTIONRESIST	⚠	Sealing during activities is assumed with snap - fit closure, and existing baseplate use, not tested
TR12-STOMAFIT	✓	Designed with flexible interfacing options, the baseplates already available
TR13-DYNAMICFIT	⚠	Designed for stoma adaptations, but this can be improved with more material research
TR14-REUSE	⚠	Reusable materials chosen, but durability not confirmed
TR15-MOISTURE	✓	Breathable materials assumed and chosen
TR16-PRESSUREAVOID	✓	Housing not in direct contact with stoma, should not lead to surrounding pressure. Not tested in daily and activity use
TR17-HIGHOUTPUT	⚠	Insert options provide volume control, not tested under high flow
TR18-REREGULATE	⚠	Valve acts as pressure relief, but threshold not quantified
TR19-LOWASSEMBLY	✓	Modular design with only inserts to be clicked on device by users
TR20-NOTRAUMA	⚠	Biocompatible materials assumed
TR21-WEAR	⚠	Short-term wear is assumed safe, not clinically verified
TR22-ANTIMICROBIAL	⚠	Antimicrobial properties not integrated, but assumed with material choice
TR23-HYDRATION	⚠	No drying agents used, hydration retention unverified
TR24-PAINREMOVAL	⚠	Removal planned to minimize skin trauma, can be improved with silicone baseplate addtion
TR25-STOMATYPE	✓	Insert and seal adaptable to both types of intestinal ostomies

The third category of requirements covered the medical aspects. Table 6.3.4c covers these fulfilment levels. Medical safety has been considered in terms of material flexibility and chemical resistance. However, essential criteria such as biocompatibility, odour control, and biofilm resistance are not yet completely fulfilled. This is expected at the conceptual stage and again underscores the importance of clinical testing for requirements evaluation.

Table 6.3.4c Fulfilment levels of the medical requirements

Requirement	Fulfilment Level	Justification
MR1-BIOSAFETY	⚠	Material biocompatibility presumed but unverified
MR2-FLEXTOPOLOGY	✓	Material flexibility and softness integrated in concept
MR3-STRUCTURERESIST	⚠	Structural resilience intended, not yet tested
MR4-DURABILITY	⚠	Durability under repeated stress not yet assessed
MR5-ACOUSTICSILENCE	⚠	Soft inserts assumed quiet, not verified acoustically
MR6-ODORRESIST	⚠	No specific odour-resistant material integrated, materials chosen can resist odour
MR7-BIOFILMRESIST	✗	No biofilm-prevention strategy currently in place
MR8-CHEMRESIST	✓	Material selection considered chemical resistance
MR9-POSTUSEODOR	✗	Post-use odour not yet addressed through material selection

Lastly, the user requirements are discussed. Within this category more requirements are fulfilled, especially when comparing this to the technical and medical requirements. This may be rooted in the human-centred foundation of this thesis, as participant involvement was a key contributing factor to the development of the FlexiSeal. The concept aligns closely with core user values but will benefit from broader usability evaluation and refinement as well. Table 6.3.4d shows the fulfilment of the user requirements.

Table 6.3.4d Fulfilment levels of the user requirements

Requirement	Fulfilment Level	Justification
UR1-INDEPENDENTUSE	✓	Designed for solo application and control
UR2-ACCESSIBILITY	⚠	General ease of use considered, not optimized for limited dexterity or vision
UR3-MODESWITCH	✓	Modular design enables seamless switching
UR4-ADAPTSHAPE	⚠	Concept accommodates variability, but untested across topological morphologies
UR5-TOOLFREE	✓	No tools required for either insert or housing
UR6-NOTRAUMA	⚠	Designed for comfort, but no user validation yet
UR7-AESTHETICS	✓	Form and color designed for discreteness
UR8-BREATHABLE	✓	Breathable materials included for comfort
UR9-AUTONOMY	✓	Supports controlled short-term wear with manual release
UR10-MODULARITY	✓	Interchangeable inserts enable personalization
UR11-CONTEXT	⚠	Tested conceptually, but not validated across diverse activities
UR12-ONBOARDING	✗	No onboarding content developed yet
UR13-VISUALDISCREET	✓	Neutral color palette applied for the outer parts to reduce visibility
UR14-INTUITIVE	⚠	Initial feedback is positive, but no formal usability test
UR15-TACTILECUES	✓	Tactile cues integrated into valve and connection zones

6.4 Key Insights

- FlexiSeal addresses key user needs by providing short-term, pouch-free control through a modular and context based adaptable design
- The concept includes two interchangeable insert types (a plug for discreet use and a balloon for passive containment) supporting flexibility, choice, and personalisation.
- The inclusion of a manual iris valve, with the additions of tactile/visual indicators enhances autonomy, safety, and intuitive handling.
- Internal pressure buildup is mitigated with the help of the iris valve. However, internal pressure regulation is not actively regulated and future research is needed.
- By using compatibility with existing baseplates a fail-safe mechanism is employed if a quick change of device is needed.
- Compatibility with existing baseplates reduces adoption barriers, while future integration of reusable silicone baseplates could enhance sustainability and comfort.
- Although the concept shows strong potential, it remains unvalidated; future research must confirm its performance in real-world conditions. With a focus on sealing, wear-time safety, and user comfort during movement.

Chapter 7: Discussion and Conclusion

This chapter covers the limitations, strengths, implications of this thesis, and interpretation of key results within this research. Next to this, the conclusion will answer the covered research questions throughout this thesis.

7.1 Discussion

This thesis explored the feasibility and design of temporary pouch-free periods for intestinal ostomates. Within this study insights from literature, a questionnaire, and three co-design sessions are combined. The results are thematically coherent, but require critical interpretation to assess their broader implications, validity, and methodological boundaries. This discussion reflects on the key findings, situates them within design and healthcare contexts, and outlines methodological strengths, limitations, and directions for future research.

7.1.1 Interpreting Key Findings

The recurring challenges across methods consist of leakage, discomfort, discretion, and emotion burden. These challenges, among others, highlight the limitations of current pouch based care and the psychosocial burden in ostomy care. However, these issues are not only functional but deeply embodied, shaping the autonomy and confidence of ostomates. Furthermore these findings also support the discovered aspect that medical design must account for emotional as well as technical safety.

However, contradictions also played an important role in the analysis. Some participants described their ostomy as a means to regain independence, while others reported it as a limiting factor in activity based daily life. Also whereas quantitative findings showed moderate satisfaction with current materials, qualitative insights highlighted significant functional and emotional challenges. This complexity reinforces the need for human-centred innovation that accommodates diverse lived experiences rather than relying on generalised assumptions.

Moreover, the interpretation of key findings covered the user needs and emotional realities, pouch-free interest and conditions, and design preferences. Within this study core user needs are identified covering functional, technical, emotional, and contextual areas. These findings show that pouch-free design is not just about engineering. It is about supporting confidence, safety, and dignity in real-life situations. Safety or perceived safety is not abstract, it was embodied in ostomates' fears, habits, and trust in the device. Moreover, nearly half of survey respondents expressed interest in temporary pouch-free periods. However, this interest was conditional. Concerns about leakage, pressure, hygiene, and usability shaped their willingness to try alternatives. These was validated in the co-design, were excitement was shown for innovation, but the adoption related intuitive operation, fail-safes, and suitability for specific moments. This translated into design preferences, were control of output and perceived safety were desired. However, concerns remained about pressure, comfort, and usability. These preferences are translated into a conceptual design for pouch-free periods, which offers an adaptable systems for autonomy and security.

7.1.2 Methodological Strengths and Limitations

Methodological triangulation was a key strength, it enhanced both the breadth and depth of the insights gather throughout this thesis. The questionnaire provided a foundation for understanding general trends and correlations, while qualitative responses enabled contextual interpretation. Co-design sessions expanded on these by generating creative responses and exposing latent needs not easily accessed via standard tools.

However, several limitations should be acknowledged. The questionnaire recruitment was based on convenience sampling, likely overrepresenting digitally literate or highly engaged individuals. Convenience sampling can limit the generalizability of results. Future research could mitigate this by employing targeted recruitment through clinical networks or in person sampling of underrepresented groups.

Following the questionnaire the co-design sessions were rich in qualitative data, yet limited in both duration and participant demographic diversity. Another important aspect is that the study focused exclusively on the perspectives of ostomates. Thus other key stakeholders such as WOC nurses, caretakes, or surgeons were not involved. This did help to focus on the lived experiences of ostomates, and provided deep and experience driven insights. However, future work would benefit from the inclusion of additional stakeholders. Another limitations was the facilitation of the co-design sessions, there was no additional facilitator support in the last two sessions. This might have influenced dynamic facilitation or the ability to follow complex group interactions in greater depth. . Similarly, the thematic analysis was conducted by a single researcher. While data triangulation added robustness, it is important to involve additional coders or conduct member checks. This would reduce interpretive bias and enhance analytic trustworthiness.

Within the online sessions technical difficulties provided a big problem, especially in the first session. Participants could not attend the online collaboration tool, and the lack of extra facilitators led to one researcher helping everyone. For the following sessions the participants were asked to try the platform beforehand, this significantly lessened the technical difficulties. Other options to so solve this could cover aspects such having a technical facilitator during the sessions. Moreover participant fatigue, and the absence of additional facilitators in later sessions likely limited data richness. Some tools, such as the context mapping, were also found cognitively demanding. Future sessions should ensure clearer instructions, built-in support, and better pacing. Simplifying generative tools and allowing time for reflection may improve accessibility and engagement.

7.1.3 Contribution to Design Research and Practice

This thesis contributes to growing research landscape on human-centred medical device design. It demonstrates that participatory methods can reveal needs that remain hidden in traditional clinical or engineering frameworks. While current ostomy care revolves around the golden standard of pouching systems, this research shows that pouch-free innovations are both desired and feasible. Especially, if they are carefully tailored to bodily, emotional, and situational realities. This study advocates for adaptable solutions that allow users to change between configurations based on their daily routines and risk tolerance. This perspective aligns with recent healthcare design paradigms calling for emotionally responsive and situationally aware technologies.

The findings challenge standard engineering assumptions by showing that user needs are dynamic, context dependent, and emotionally complex. FlexiSeal, as a conceptual design, embodies this discussed shift it, such design is not intended to replace all pouch systems but to offer adaptable support and relief for short-term scenarios. Its modularity, discretion, and intuitive control reflect a direction in which design is led not only by function, but by lived experience.

This work reinforces a broader move within healthcare innovation towards systems that acknowledge psychological safety and emotional well-being as integral to effectiveness. It argues that truly human-centred design must accommodate vulnerability, uncertainty, and the desire for autonomy.

7.1.4 Future Directions and Practical Implications

To advance beyond the conceptual level further research must reiterate and refine user needs, requirements, and the design. Following this, clinical testing under realistic conditions is essential to assess sealing performance, hygiene risks, and material resilience. Structured risk analysis and regulatory alignment will be necessary before such product can be market ready.
For aspects like usability testing, it is important to prioritise diverse users, as the lived experiences of ostomates are widely varied. In parallel, onboarding support which can be instructional and emotional must be developed to foster confident use. Another area for future research covers the design of perceived safety, ostomates often mentioned that they wanted the product to be safe in

use. This is more than an engineering constraint, ostomates wanted to see and feel how this design was safe. Further research should also focus on designing for perceived safety.
The implications of this thesis were not only covered by the design development, this research suggests that a broader shift is needed in how medical safety is conceptualised and designed for. Rather than focusing solely on technical thresholds, future innovations should integrate perceived and embodied safety as critical design parameters. Additionally, the success of co-design in uncovering nuanced, emotionally driven needs reinforces its value in complex healthcare innovation contexts.

7.2 Conclusion

This thesis investigated the feasibility, desirability, and design potential of temporary pouch-free periods for individuals with an intestinal stoma. A mixed-methods approach is employed, which combined a literature review, a questionnaire (N=770), and co-design sessions(N=12). Through this method the study uncovered challenges in current pouch based ostomy care and explored alternative solutions grounded in lived experience.

The findings highlight that many ostomates seek greater autonomy, discretion, and comfort in their care routines. Existing pouch-based systems, while functionally reliable for many, often fall short in addressing emotional, social, and situational complexities. The proposed idea of temporary pouch-free use was met with cautious interest, dependent on perceived safety, hygiene, intuitive use, and reliable containment. Many expressed frustration with limitations related to leakage, body image, and social participation. These unmet needs often stem from the emotional and situational burdens of continuous pouch use, which are for some insufficiently addressed by existing products.

The concept of temporary pouch-free periods was met with cautious but persistent interest. Ostomates showed willingness to consider such pouch-free alternatives, specifically in context based activities such as intimacy, sports, recreational activities, and social activities. However, the interest proved to be conditional as should ensure secure containment, hygienic use, intuitive operation, and a strong sense of safety. This highlighted that safety is not merely a technical parameter, but also an embodied and perceptual one that must be actively designed for.

Technical and medical factors such as stoma output consistency, pressure buildup, skin compatibility, and abdominal movement emerged as key design constraints. These factors shaped the design space and informed the design requirements and specification. Literature and clinical data provided a basis for understanding physiological thresholds, while the materials offered promising directions for improving fit, flexibility, and moisture control.

Co-design activities further revealed strong preferences for solutions that support routine adaptability, fail-safe mechanisms, and emotional reassurance. These preferences informed the development of two concept directions, which offer contrasting approaches to discreet, short-term containment. The FlexiSeal is chosen and adapted with the results from the co-design sessions, to make present a pouch-free concept grounded in user needs, requirements, and design guidelines.

The study contributed a validated set of user needs, design requirements, and conceptual design strategies to support future pouch-free innovation. While real-world testing and broader stakeholder inclusion remain necessary. While the solution remains at a conceptual stage, the work demonstrates that pouch-free alternatives are both desired and technically possible. For this desirability the close alignment with the lived experience of ostomates is necessary. Future research should pursue clinical validation, broader stakeholder engagement, and long-term usability testing. Ultimately, this thesis lays the foundation for a shift in ostomy care: from standardised containment to adaptable, user-informed solutions that better integrate into the routines, bodies, and lives of those they are meant to serve. This thesis establishes a solid foundation for reimagining ostomy care beyond the pouch. Toward solutions that empower ostomates, accommodate diversity.

Chapter 8: Recommendations

This chapter covers the recommendations for advancing pouch-free innovation and improving broader ostomy care. Recommendations are made across three levels: product refinement, clinical integration, and care innovation.

Chapter 8: Recommendations

Several aspects to advance pouch-free ostomy solutions are covered in this thesis. This advancement can be made through future research, design development, and clinical implementation.

Research efforts should expand stakeholder involvement beyond users. These should include stoma care nurses, surgeons, product engineers, care takers, and insurers. Their perspectives are essential for ensuring the success of a medical device. Particularly in the domains of clinical relevance, technical feasibility, and policy alignment. Besides this, the inclusion criteria for the design use should also be broadened to reflect a more diverse populations, to improve design inclusivity and generalizability.

Structured clinical studies are needed to evaluate the conceptual design like FlexiSeal under real-world conditions. These should assess safety, hygiene, comfort, and usability. But above all the real world feasibility of the working principle. As the concepts remain exploratory, no formal risk analysis was conducted. Thus future development must follow MDR (2017/745) regulations, including ISO 14971 (risk management), ISO 10993 (biocompatibility), and IEC 62366 (usability engineering), to support eventual CE certification.

Design directions should prioritize modularity and adaptability, allowing users to switch between pouch-based and pouch-free modes depending on context and individual needs. Reliable containment, intuitive pressure regulation, and user feedback mechanisms are critical to support autonomy and safety implied by the pouch-free concept. Customization is another relevant area, this can be realised through parametric 3D design to address anatomical variations among the ostomate population. Further on, material choices must balance discretion, hygiene, and comfort, responding to ostomates' preference for soft, low-profile, and odour-reducing solutions. For the material aspect the use of sustainable and recycle materials are preferred over single-use products. If single-use is necessary for future design, one should consider biodegradable materials.

Clinical implementation requires dedicated training, ideally led by stoma care professionals with the additional support of peer network. Where possible, smart feedback systems (e.g., sensors for leakage or pressure) may enhance safety, but the addition should be validated with ostomates. Another value lies with onboarding protocols of new innovative materials. If such protocols are clear, this can ehelp with psychological preparedness among ostomates. Finally, engagement with insurers and policymakers is essential to secure reimbursement and support adoption of a novel pouch-free device. Because these aspects connect to material experience, all should be considered for clinical implementation of such design.

For the support of long term adoption, innovation should extend beyond new devices, and also reach into the care systems. Future efforts within medical device design should promote co-design as a standard development practice, enabling ongoing dialogue between users, clinicians, and designers. It is essential to recognise ostomates as the experts of their own experiences. Listen, guide, and aid in their discovery of lived experience to create a valuable product solution together. True innovation recognises that products alone cannot solve complex challenges, as they must be paired with responsive services, inclusive communication, and sustained collaboration.

AI Statement

During the preparation of this work the author used Grammarly in order to refine text, and used Chat GPT to translate English documents in to Dutch (preferred co-design language). After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the work.

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