PROBLEMS, CAUSES AND DIRECTIONS FOR IMPROVEMENT OF OSTOMY MATERIAL

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Problems, Causes and Directions for Improvement of Ostomy Material

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About this research
This research is carried out as part of a graduation assignment for the master Industrial Design Engineering at the University of Twente. It took place during September till December 2020. A total of 199 people with a stoma participated in a digital questionnaire. In the following interviews, 16 ileo- and colostomates were interviewed, as well as 7 specialised wound and stoma nurses. Follow-up research is carried out in 2021.

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The Gastrointestinal tract, including the digestive organs, lies completely within the body and is connected to the outside world through natural orifices: at the entrance by the mouth and at the exit by the anus. There are reasons why the natural exit needs to be replaced by an artificial opening, also known as an ostomy or stoma. Intestinal stoma’s are most the common type and are needed to evacuate stool from the body without using the rectum. Currently, there are 38,000 ostomates with an intestinal stoma in the Netherlands (Stoma vereniging, 2019). This number increases yearly by 7000 users on average (Stoma vereniging, 2019).

In order to support the collection of bodily waste, a pouch or ostomy bag can be used. This may either be a one-piece or a two-piece system. A one-piece system is a combination of a collection bag with an integrated adhesive baseplate (van der Leden, 2007). A two-piece system differs from a one-piece in that the collection pouch and adhesive baseplate are two separate pieces. The advantage of this is that the baseplate can be attached to the abdomen for a longer time and does not have to be removed and re-attached every time the bag is changed. Regardless of the system type, many ileo- and colostomates experience physical and psychological problems in their daily life which leads to a decrease in the Quality of Life.

One way to reduce these problems or limit the consequences may be found in innovation of the materials. The practical implementation of using an ostomy bag as well significant problems and the root causes are mapped. This is done by means of a questionnaire and follow-up interviews. The outcomes form the basis for directions to prevent physical problems experienced by the ostomates. The first phase is a statistical approach, whereas the second phase is a qualitative approach which shows the perspectives of both the ostomates and wound, ostomy and continence (WOC) nurses.

In the end, both approaches and perspectives are combined to form a well-rounded conclusion.
For the questionnaire, all willing participants aged above 18 years with an ileo- or colostomy who were able to read and understand Dutch were included. The questionnaire is finalised with the website Qualtrics with a University of Twente account. It consisted of 63 closed and 20 open questions. It focused on gaining more insights around three major themes: usage, problems & causes and solutions. When drawing up the format, the questions and formulation were assessed by five different individuals prior to the study and clearance was given by the Ethical Committee of the University of Twente of the Natural Sciences and Engineering Sciences domain. The participants were invited via a link that was distributed via various online channels like social media, patient associations and panel groups. The questionnaire was open for three weeks. The collected data of the questionnaire was analysed by one researcher via reviewing the frequency of specific answers given in case of closed-ended questions. The open-ended data is condensed by categorisation.

A total of 199 responses on the questionnaire were valid.
The questions asked for this category were focused towards the physical and psychological problems experienced by the participants. Respondents were asked what problems were experienced, what the frequency was and how severe the problems were.

77.8% (n=155) of the responses in the questionnaire indicated they have had a physical problem. In these results, it can be seen that the participants with ileostomies experience 1.15 times more problems in comparison with the colostomy users and that a one-piece system gives 1.28 times more problems than a two-piece system.

The most prevailing problems are leakages (n=135), followed by skin problems (n=120) and pancaking (n=67). The severity, on a scale of 1 (no hinder) to 5 (extreme hinder), is 2.36, 2.90 and 3.33 respectively. Other problems are depicted in Figure 1.

80.0% (n=161) experienced a combination of physical problems. The majority of respondents experiences a combination of 2 problems. Skin problems and leakages are a combination seen often (n=97).

Next to this, 38.7% (n=77) of the users indicated to have had mental problems, whereas 33.7% (n=67) of the users indicated that these issues can be linked to having an ostomy or experiencing problems with the current materials.
Causes

By providing pre-defined options, participants could tell what they believed was the root cause for their problems. Additionally, it was possible to state other reasons and to add additional information via open-ended questions.

For skin problems, the participants indicated that the most common origins for these problems, as can be seen in Figure 2, are frequent removal of the base plate (n=19), a wet environment as a result of transpiration underneath the base plate (n=30), the composition of the substances in the material which can cause an allergic reaction (n=52), and (aggressive) excrement that touches the skin (n=86). This output has a pH-value between 5.5 and 7.5 (Osuka et al., 2012). This is higher than the peristomal skin which is physiological neutral at a pH-value between 4.5 and 5.5 (Boyles & Hunt, 2016). The output touching the skin is a result of leakages or pancaking.

Figure 2. Causes for skin problems

Pancaking can be explained as ‘stool sits on and around the ostomy and fails to drop down into the appliance’ (Oakmed Healthcare, 2020). This issue is mostly due to the fact that the consistency of the output is either too thick or too thin (n=48). Other reasons mentioned are the ostomy bag drawing a vacuum (n=25) and the base plate not adhering well to the skin during the whole period of use (n=15) as shown in Figure 3.

Figure 3. Causes for pancaking

Leakages are mainly caused by pancaking (n=73). Next to this, the base plate does not always fit properly around the ostomy (n=50). Thereby, the fact that the base plate does not adhere well to the skin due to various reasons (n=48) is another cause for having leaks.

Figure 4. Causes for leakages
Current solutions

For this part, the questions focused on how the problems experienced were currently solved and what products and methods were used during the care routine.

Participants stated no optimal solution has been found for them to reduce the physical problems they experience. There are solutions available, but, according to them, these solutions focus on temporary measures which do not lead to a sustainable solution. This varies from bringing extra material, renewing the system preventively or using supplementary aids.

The most used additional tools for (peristomal) skin problems are barrier wipes, sprays and powders (n=42), special creams (n=26) and fillers (n=14). For leakages these are fillers (n=16), flange extenders (n=10) or convex plates (n=4).

Usually up to 2 products and methods are combined, because one product is often not capable of solving the issue(s) to the fullest.

Directions for improvement

Questions regarding prevention and limitation of problems were asked. In particular it was asked how the current usage of the material was seen and which role material could play in preventing or limitation of problems.

The ostomates graded the current usage of the material with an 8.0 on a scale of 1 to 10.

Thereby, the participants also see potential in optimising the ostomy material to prevent and reduce the physical issues experienced as can be seen in the boxplots in Figure 6.

In this figure the value of the lowest whisker starts at 1, indicating being not able to play any role in solving, whereas the most upper whisker, and thus the value 5, means being able to solve the problem as a whole.

The highest potential benefit of better material is foreseen for the skin problems (X= 3.17, s = 1.51, range = 1 - 5), due to the highest median (3). Thereby the average and median are relatively close, indicating that participants agreed on this matter. For the leakages (X= 3.17, s = 1.62, range = 1 - 5) and pancaking (X= 3.67, s = 1.69, range = 1 - 5) a lesser potential is seen when comparing the medians. However, the big dispersion and discrepancy between the median and average show that a dichotomy takes place for these subjects. This is in line with the corresponding standard deviations. A part of the respondents did not see potential for improvement for these matters, while the other half sees greater potential. This is especially the case for leaks due to the upper quartile reaching the value of 5.

Figure 5. Average grade current usage material

Figure 6. Boxplots skin problems, leakages and pancaking
Respondents for the follow-up group interviews were selected from the respondents of the questionnaire and based on in- and exclusion criteria. The most important criteria were the ability to speak and understand Dutch, experiencing one of the three major problems (skin problems, leaks or pancaking), having a frequent (more than once per month) experience of these problems and having no other diagnosed skin trauma’s or diseases. After defining specific dates, email contact took place to plan the interviews. The ostomates were divided in heterogeneous groups of three to four people. Each group contained at least one ileostomy bag user and one colostomy bag user, both men and women. The time the participants had their ostomies was diverse.

The interviews were composed of a semi-structured format with open-ended questions that were divided into three main categories: current usage, problems and solutions. The format was assessed by five unbiased individuals prior to the study. The interviews took place via the online programme Skype and were recorded by phone. Conditions about the fact that all matters discussed are private, the data is anonymised in the end and that interviews are only an instrument to collect data and determine understanding in the problems and experiences were discussed beforehand. All data collected during the interview with the ostomates was coded with a code consisting of type of ostomy, date of the interview, pseudonym number and the time the participants had their ostomies. All data was categorised according to three main themes and after categorisation, the technique of induction was used to analyse the interviews.

In total, 16 ostomates participated in the interview sessions.

**Ostomates interview**

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<td><strong>Average age</strong></td>
<td>52.1 years</td>
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<td><strong>Average years ostomy</strong></td>
<td>6.5 years</td>
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<td><strong>s = 12.1; range 26 - 70</strong></td>
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The interviews with the ostomates confirm the findings of the questionnaire. Thereby, they explained why the current material is graded with an 8.0, even though they experience problems. Users explained to (partly) accept and sometimes consider it normal to have these problems, since they do not expect the material to function for 100%. Next to this, they tell that having an ostomy, with the additional problems, is better than living with more severe diseases, since it increased their quality of life.

The interviewees also stated that the material itself is fine. According to them, the problems experienced are due to the interaction between the material and the usage by the user. This interplay creates problems.

Additionally, using additional materials can offer a (partial) solution improving the functioning. The vast amount of supplementary aids is appreciated. However finding the right materials or tools is described as a long quest in which ostomates are unable to see the wood for the trees.

“This is due to multiple reasons:

- Many accessories are available;
- An overview of all materials is hardly found;
- It’s a process of trial and error;
- What works is highly person dependant;
- Users often lead this search themselves.

This shows a discrepancy between what the care professionals offer based on their expertise and the demand for help and current practice among users.

When speaking about solutions, it shows that the use of additional tools are focused on absorbing liquids, reducing the possibility of liquid spreading, filling up cavities and folds to make the base plate fit better around the ostomy, increased skin healing and protection of the skin.

The users participating in the interview believe that leakages have a significant impact on the quality of life and experience of having an ostomy. It is also a starting point for other problems, they tell. Therefore, it is stressed to focus on this issue when searching for improvements. Suggestions for improvement are:

- Knowing the exact moment a leakage starts;
- Focus on making the plate more flexible to make it fit better around the ostomy and be able to adapt to bodily changes;
- Neutralise the pH of the output;
- Introduce a screening to see what kind of base plate and material fits best to someone’s skin.

Thereby, the interviews showed that most users are very interested in new innovations and changes and would like to be more involved in this.
Dutch WOC nurses working as specialised caretakers in hospitals and in the home care sector were included for another set of interviews. As with the interviews with the ostomates, the interviews with the care professionals follow a similar procedure. However, a few aspects differ:

First of all, the participants are divided into heterogeneous groups of one to two people. The main reason for this groupsize is the number of nurses willing and having the time to participate in the research. This results in a total of seven interviews. Secondly, no prior questionnaire was distributed among the professionals. Another difference is that the interviews with the WOC nurses are held via Skype or by phone, because of the limitations of the (hospital)computers.

In total, 7 WOC nurses participated in the interview sessions.
The general view the care professionals had on the usage of ostomy materials is that the experience varied greatly between users and that it depended on multiple aspects. Especially the number and severity of problems experienced reduces the acceptance and usability. The WOC nurses recognise the problems mentioned by the users. The negative synergy between these issues was stipulated by the professionals.

The WOC nurses indicated that solving these problems is currently done by determining the root cause: They see that it often has to do with negligent usage by the users and unnecessary use of additional accessories. Problems can be prevented by correctly applying and using the current materials. The professionals prefer solving problems by optimising the usage instead of adding extra materials. This while the user often have the question to use other or extra tools since they think they can solve problems with supplementary aids.

All in all, the professionals think that the basic material is sufficient and should only be extended with supplementary aids in rare cases.

"Less is more" according to the professionals.

In order to reduce the physical problems, the professionals agree that more focus has to be placed on optimal usage of the current materials, instead of finding and adding additional tools. They believed, just like the users in the questionnaire, that the basic materials itself can be a solution when applied and used right. Therefore, focus on sufficient usage and giving the right guidance is important to take into account as well.
Many users experienced physical problems: leakages and skin problems are the most frequently mentioned issues. Thereby, the problems also strongly influence and affect each other, creating a (negative) synergetic vicious circle.

The problems had multiple causes, but most of them can be traced back to the interplay between the material and the user. On the one hand there is sometimes improper usage of the material. On the other hand, the material is not always able to adhere well and adapt to the body.

Users indicated to see most potential in finding a solution to reduce and prevent leakages. Thereby, when fewer leakages are experienced, this can decrease mental problems as well.

In order to reduce the leakages and other physical problems, the following points to take into account are suggested:

- It is believed that basic material itself can be a solution when applied and used right by the users. Therefore focus should be on usage by the user or a lesser need for precise application;
- The development of an improved solution should focus on solving problems instead of limiting them;
- A general solution that works for every user will be hard to find.

What can be concluded is that the problem is an interplay between usage by the user and the material. The next steps should focus on preventing leaks.


