Embroidering for cycling

Studying the impact of vulvar cancer on cycling mobility and developing embroidered resistive pressure sensors to investigate saddle pressure while cycling

F.P. van Beurden

TU Delft

Embroidering for cycling

Studying the impact of vulvar cancer on cycling mobility and developing embroidered resistive pressure sensors to investigate saddle pressure while cycling

by

F.P. van Beurden

to obtain the degree of Master of Science in Biomedical Engineering
at the Delft University of Technology,
to be defended publicly on Monday 13 February, 2023 at 09:30.

Student number:	4470575	
Project duration:	October 18, 2021 – February 13, 2023	
Thesis committee:	Dr. N. J. van de Berg,	TU Delft & Erasmus MC, supervisor
	Dr. H. C. van Doorn,	Erasmus MC
	Prof. Dr. J. Dankelman,	TU Delft
	Prof. Dr. K. M. B. Jansen,	TU Delft

An electronic version of this thesis will be available after this date at
`http://repository.tudelft.nl/`.

Preface & contents

Preface

In front of you is the final product of my graduation project at the Delft University of Technology. When the subject of this thesis was brought to my attention, it seemed like the perfect fit for me. As a strong advocate for commuting by bicycle, I wanted to help the people who aren't able to do so. After a short email conversation with my supervisor Nick van de Berg, we had our first of many online meetings. I'm very happy with the final outcome and the progress I made during this graduation project. However, I could never have accomplished this on my own.

First of all, I would like to thank Nick. He pointed me in the right direction, improved the study by challenging me to be critical and was very helpful with extensive feedback. I would also like want to thank Lena van Doorn, for guiding me through the medical maze of the Erasmus MC and motivating me, Kaspar Jansen, for providing me with enough enthusiasm and the embroidery materials, and Jenny Dankelman, for guiding me through final moments. I would like to thank Wanda Wendel-Vos and Marjolein Duijvestijn from the RIVM for their help in interpreting and obtaining accurate reference values for the SQUASH.

Furthermore, I want to thank my sister Elise and the rest of the staff at Stadslab Rotterdam. The embroidery machine was broken at the TU Delft, but Stadslab acquired theirs right on time for me to use it for my project. I was always welcomed with lots of interest, helping hands and a really creative environment. I also want to thank Jacques Brenkman and Jos van Driel from the 3ME meetshop, for providing me with their expertise on electrical readout systems and assembling most of the circuit boards.

Of course, I also want to thank my family and friends, who supported me extensively throughout the course of the project. Discussing the thesis with me, being my test subjects, but most of all giving me the time to clear my mind and relax. Finally, I like to thank my girlfriend Lucy, who I have known as long as this thesis, for being there with me the whole time. Thank you all!

F.P. van Beurden
Delft, January 30, 2023

Contents

This thesis consists of two chapters. The first chapter addresses a problem which was noticed by doctors from the Erasmus MC. This chapter starts on the next page and is named: *Impact of vulvar carcinoma on mobility and cycling ability.* To compare several commercial solutions to the problem, a test setup was developed. This development is described from page 11 in the second chapter, named *Evaluating the usability of embroidered sensors to measure saddle load distributions during cycling.* The thesis is accompanied with an appendix, which starts at page 22.

Impact of vulvar carcinoma on mobility and cycling ability

Franciscus van Beurden, 4470575
MSc Biomedical Engineering

***Abstract*—*Introduction:* Bicycling can become a painful experience for women with vulvar cancer. As cycling benefits a person's health and self-reliance, it is important to study and minimise the impact of vulvar cancer on cycling. This study investigated the mobility, activity and cycling ability after surgical treatment of vulvar carcinoma with the use of three questionnaires.**
***Method:* The study population consisted of 134 women who were diagnosed with vulvar carcinoma at Erasmus MC between 2018 and 2021. The questionnaires EQ-5D-5L and SQUASH were conducted with the aim to assess quality of life (QoL) and physical activity respectively. The third questionnaire, GO-Bicycling, was developed specifically to assess the bicycle mobility of the current study population.**
***Results:* Altogether, 84 patients (63%) responded to the recruitment, with a mean age of 68 ± 12 (mean ± S.D.) years. The found overall QoL was 0.832 ± 0.224, and the observed patient reported health index was 75.6 ± 20.0. Of the study population, 34.2% adhered to the Dutch physical activity guidelines and 48.1% cycled weekly. Concerning their bicycling ability, 34.9% of the respondents indicated they were impeded in their cycling by their vulva. The desire to make more or longer bicycling journeys was shared by 57.1% of the patients.**
***Conclusion:* the study shows that cycling ability is being reduced by vulvar carcinoma and its treatment. The respondents engage less in physical activity and report more mobility problems than female reference groups of the same mean age. Additional ways to reduce the complaints need investigation, while already available aids offer potential to get woman with vulvar cancer back in the saddle.**

***Index Terms*—Bicycling ability, cycling, vulvar carcinoma, physical activity, mobility, EQ-5D-5L, SQUASH**

I. INTRODUCTION

Bicycling is a quick, affordable, flexible and sustainable means of urban transportation, while being fairly easy to learn [1]. In the Netherlands, kids learn how to traverse traffic at a young age, promoting independence and freedom [2]. Supported by the high-quality infrastructure, makes cycling an integral part of life in the Netherlands, where it accounted for a quarter of all journeys in 2021 [3]. An additional benefit is the potential to battling climate change, as a global shift towards a Dutch use of bicycles could reduce the carbon emission of the global passenger car fleet by 20% [4].

Apart from the ecological, social and economic benefits, bicycling is also associated with substantial health benefits. A systematic review by Oja et al. concludes that all 16 included studies show a positive relationship between cycling and health [5]. Cycling improves cardiorespiratory fitness, lowers risk of obesity and offers a low-impact form of exercise for people with rheumatoid arthritis [6]. Cities around the world are improving their cycling infrastructure, as safe cycling paths encourage people to cycle more [7].

Even though the health benefits outweigh the health risks [8], the downsides should not be ignored. Apart from traumatic injuries, most injuries originate from overuse which can result in pains in the knee, neck/shoulder, hands, buttock and perineum. The saddle usage is distinctive for cycling, as the support it gives differs quite a lot from other seats, e.g. chairs or couches. The traditional saddle design puts pressure on the perineum, a body part not evolved for supporting body weight, but this is not a problem for most people. The pressure is not desired when the skin of the perineum is thin and irritated, which is the case in woman with vulvar cancer or lichen sclerosus. For them, cycling may become a painful experience. Data on the prevalence of the impairment are not available. There are aids available which are sold to improve cycling comfort, however it is unknown if such solutions are effective for this target group.

Brief clinical background

Vulvar carcinoma is a malignant tumour of the skin of the labia. Although it is often diagnosed in post-menopausal women, the malignancy is emerging among younger women, possibly due to infection with the human papillomavirus (HPV) [9]. The incidence of vulvar malignancies is between 2 and 7 per 100.000 and year, which makes it an uncommon but serious health issue [10]. The location of the tumour, in combination with the possibility to remain asymptomatic, has a negative impact on the duration till it is diagnosed. If there are symptoms, they are usually non-specific and include itching, burning, pain and bleeding [11]. The disease, or severe consequences, can be prevented by encouraging vaccination against HPV and self-examination in women with lichen sclerosus [12]. Lichen sclerosus is a skin disease most common in the genital areas, from which vulvar cancer has a higher risk to develop [13]. It causes itching, pain, dysuria and restricts the skin in its flexibility. Similar to a vulvar carcinoma, it makes the skin very sensitive to chafing, which occurs frequently during physical activity.

Aim and structure

This study investigates mobility, activity and cycling ability after surgical treatment of vulvar carcinoma. Mobility and activity are assessed by conducting the validated EQ-5D-5L and SQUASH questionnaires and the cycling ability is evaluated by using a non-validated Gynaecological Oncological – Bicycling (GO-Bicycling) questionnaire. After the introduction, the research methodology will be described in section II, consisting of the study population, the METC procedure, the questionnaires used and the data analysis. The results will be presented in following section. Hereafter, the results are discussed, and the study is finished with the conclusion. In Appendix A, you will find the questionnaire bundle. Appendix B contains the research protocol along with the patient information letter.

II. Method

A. Study population

The study population consists of women diagnosed with vulvar carcinoma at Erasmus MC between 2018 and 2021. Whether patients cycled at all did not influence inclusion, all surviving patients were included. Patients were excluded if they : emigrated (n=2), were unable to read and write Dutch (n=1) or suffered from dementia (n=1). Patients were approached between March and May 2022. This recruitment took place by sending patients an email, which contained a link to the digital questionnaires in the data management platform from the Erasmus MC (Castor EDC, Amsterdam, the Netherlands). After two and a half weeks a reminder was sent. Finally, a letter containing a printed version of the questionnaires was sent by conventional mail to patients that did not yet respond or who had indicated that they did not wish to receive e-mail. This seemed necessary as our study population has a relatively high mean age, which correlates with lessened digital usage [14]. In the end, 134 patients were approached for this study. All participants included in the study received a patient information letter, providing background information on the goals of this study, the expected time to complete the questionnaires and how the participants' privacy was protected. The patients were also informed that their participation was voluntary and without costs. All participants gave consent before filling in the questionnaires.

B. METC

As this study falls under medical scientific research, it must be reviewed by the Medical Ethics Review Committee, METC for short. Since the Netherlands has strict rules on research involving test subjects, the METC has assessed whether the study falls under the Medical Research Act (WMO). The METC's aim is to protect the rights, safety and welfare of participants. Therefore, they assess whether the research is useful, well-designed, subjects are given correct information, the risks of the research are not too big and whether the research does not ask too much of the subjects. To test this, a research protocol had to be submitted, which can be found in Appendix B. As this study was a questionnaire, it was not assumed that it would be subject to the WMO. This was also confirmed when the study was approved by the Medical Ethics Review Committee of the Erasmus MC (protocol: MEC-2022-0077, date of approval: 17-02-2022).

C. Questionnaires

The aim was to measure the patients' experiences of quality of life (QoL) and physical mobility. To achieve a good comparison, reference values are needed, so a validated questionnaire is desirable. Since there is not one questionnaire that addressed all of these topics, it was decided to use a combination of three questionnaires. The first two are the validated questionnaires EQ-5D-5L and SQUASH, which assess quality of life and physical activity. The third questionnaire is a non-validated questionnaire, specifically designed to assess the bicycle mobility of the current target group. The questionnaire bundle (in Dutch) can be found in Appendix A.

EQ-5D-5L

The EQ-5D-5L is an instrument to measure and describe health. The questionnaire consists of two parts, the descriptive part (EQ-5D) and the visual analogue scale (EQ VAS). The EQ-5D lets patients indicate their health state in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. For each dimension, the patient can choose from five levels of health: no problems, slight problems, moderate problems, severe problems and extreme problems. Each answer results in a number from 1 (no problems) to 5 (extreme problems), which can be combined into a 5-digit number representing the patient's state of health. For example, if a respondent indicates severe self-care problems and no problems in the other dimensions, the resulting number would be 14111. This method results in 3125 different health states, which can be assigned a QoL index (I_{QoL}). A constrained Tobit model is used to analyse these different health states. The model with Dutch tariffs was developed in the Dutch validation study by Versteegh et al. [15]. The equation to obtain the QoL index is shown in Eq. 1:

$$I_{\text{QoL}} = 1 - c_0 - \beta_i^{MO} - \beta_i^{SC} - \beta_i^{UA} - \beta_i^{PD} - \beta_i^{AD} \quad (1)$$

The QoL index has a maximum value of 1 at health state 11111. When the health state deviates from 11111, the constant c_0 = 0.047 is subtracted. $\beta_i^{MO}, \beta_i^{SC}, \beta_i^{UA}, \beta_i^{PD}$ and β_i^{AD} are penalties depending on the health state in different dimensions. With the EQ VAS, the respondent is asked to indicate their overall health index, using a 100-point visual analogue scale (VAS). Here, 0 is the worst imaginable health, and 100 the best imaginable health.

Reference values for the QoL index for Dutch woman (all ages) was 0.86 ± 0.17 [15], mobility problems (any) for Dutch women in the age group 65-69 were reported by 16% and the health index was 83.2 ± 11.8 [16]. Permission to use the EQ-5D-5L was requested from the EuroQol Research Foundation (Registration ID: 46792).

SQUASH

The Short QUestionnaire to ASsess Health enhancing physical activity, SQUASH for short, is a questionnaire aimed at evaluating the duration and intensity of activities done by participants [17]. Respondents are asked to complete the questionnaire with an average week in the past few months in mind. The domains of the activities are: commuting, work or school, household and leisure, in which the respondent reports its activity, with the duration and intensity. The questionnaire ends with the following question: *On average how many days a week, all things considered, do you spend at least half an hour cycling, doing odd jobs, gardening or playing sports?*

The results of this questionnaire are used to check whether respondents meet the Dutch physical activity guidelines, drawn up by the Dutch National Institute for Public Health and the Environment [18]. The guidelines consist of two parts, both of which must be met to comply. For the first part, respondents must do at least 150 minutes of moderately intensive exercise per week, spread over at least seven activities. Activities are considered of at least moderate intensity if the metabolic equivalent of task (MET) score was at least 3.0. The second part requires either two activities a week which are muscle and bone strengthening, or one activity a week which is muscle and bone strengthening and one activity a week which is muscle strengthening activities. The reference value for Dutch women in the age group 65-69 who met the physical activity guidelines is 46.5% [3].

GO-Bicycling

The problem-specific questionnaire was designed in collaboration with doctors from the Gynaecological Oncological department to evaluate relations between vulvar carcinoma and its treatment on bicycle use. The questionnaire starts with general questions about medical history, ability to cycle and type of bicycle used. After, the types and intensities of complaints during and after bicycling are registered. The standard complaints were: pain in the sit bones, pain in the skin of the vulva, itching and chafing, which respondents could score with a Likert scale, using the levels: no, slight, moderate, and severe. Other complaints can be added by the respondent if necessary. The questionnaire continues by asking whether respondents feel impeded by the vulva in cycling and whether they have wishes to cycle more in the future. It further asks about modifications in cycling to increase comfort, before ending by asking if the respondents would be interested in the results of this study or participating in a follow-up study.

D. Data analysis

Different software programs were used for the statistical analysis of the results. Excel Version 2210 (Microsoft, Redmond, WA, USA) was used to generate basic descriptive statistics and figures. MATLAB R2021A (Mathworks, Natick, MA, USA) was used to calculate statistical tests and correlation coefficients and to produce corresponding figures. For the processing of the results of the SQUASH questionnaire, SPSS 28.0.1.1 (IBM, Armonk, NY, USA) was used. The provided syntax [19] was for a newer version of the SQUASH questionnaire that included questions for children attending gym or swimming classes at school, so the syntax was slightly altered to fit our dataset and exclude these variables. The authors of the syntax were consulted and they noticed no abnormalities in the results. Since not all of the data was normally distributed, a one-sample Wilcoxon signed-rank test was chosen with a significance level of α = 0.05. Due to the method of the conducting questionnaires, participants could have only completed these partially. The number of respondents per question is indicated in graphs and text with 'n'.

III. Results

Of the 134 approached patients, 84 returned their questionnaires (response rate: 63%). Of these, 60 completed all questions of the three questionnaires, while the remaining 24 completed an average of 62% of the questions. The respondents had an average age of 68 ± 12 (mean ± S.D.) years, with the youngest being 40 and the oldest being 92 years old. The non-respondents had an average age 68 ± 17 years. It is worth noting that the four youngest included patients did not respond to the questionnaire. Most patients have undergone at least one vulvectomy (75/81), while fewer patients had received radiotherapy (18/81). These characteristics are summarized in Table I.

TABLE I
PARTICIPANT CHARACTERISTICS

Characteristic	Count
Total	84
Age (range: 40-92)	
< 65	29 (34.5%)
≥ 65	55 (65.5%)
Gynaecological Oncology history (n = 81) [a]	
Vulvectomy	75 (92.6%)
Radiotherapy on vulva and/or groin	18 (22.2%)

[a] The numbers do not add up to 100%, as the respondents could have underwent both procedures.

A. Patient-reported outcomes

Table II shows a summary of patient-reported outcomes from the validated questionnaires including the reference values.

EQ-5D-5L

The difference between the found overall QoL index (0.83 ± 0.22) and the reference value (0.86 ± 0.17) was insignificant (p = 0.44). The patient-reported health index (76 ± 20) was observed to be lower than the reference value (p = 0.0025). Of the 84 patients, 26 (31%) reported experiencing any (slight to extreme) problems, which is more than the reference value (16%). The age distribution, health state level distribution and comparison of the overall QoL and VAS scores with the Dutch reference values are shown in Fig. 1.

By applying linear least squares fits to the data and calculating the Pearson correlation coefficients a correlation could be found between the QoL index and the health index (ρ = 0.573). This correlation was not shown between the health index and age (ρ = -0.033) or between the QoL index and age (ρ = 0.006). These results are displayed in figure 2.

SQUASH

The results from the SQUASH questionnaire show that the physical activity guidelines were met by 34.2% (27/79) of the respondents, as can be seen in Table II. The first criterion,

TABLE II
OUTCOMES OF EQ-5D-5L & SQUASH

Metric	Reference conditions	Reference value	Patient-reported outcome
EQ-5D-5L			
QoL index	Dutch woman, all ages [15]	0.858 ± 0.168	0.832 ± 0.224
Mobility problems (any)	Dutch woman, 65-69 years [16]	16.0%	31.0%
Health index (VAS)	Dutch woman, 65-69 years [16]	83.2 ± 11.8	75.6 ± 20.0
SQUASH			
Physical activity guideline, total	Dutch women, 65-69 years [3]	46.5%	34.2%
Physical activity criterion 1: min\week	Dutch women, 65-69 years [3]	52.4%	36.7%
Physical activity criterion 2: muscle\bone strengthening	Dutch women, 65-69 years [3]	84.5%	82.3%
Weekly bicycle use	Dutch women, 65-69 years [3]	64.4%	48.1%
Weekly sport participation	Dutch women, 65-69 years [3]	40.9%	30.4%
Walking total min\week	Dutch women, 65-69 years [3]	367 ± 387	240 ± 303
Bicycling total min\week	Dutch women, 65-69 years [3]	194 ± 257	96 ± 169
Sport participation min\week	Dutch women, 65-69 years [3]	123 ± 261	48 ± 129

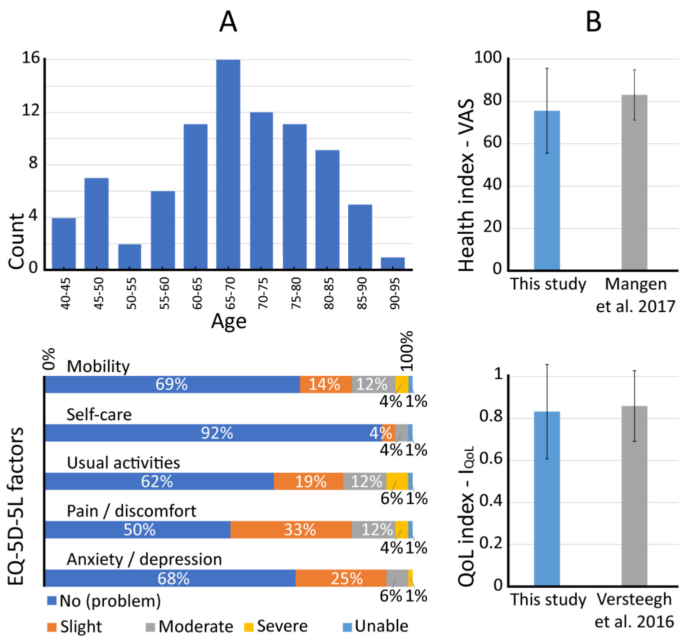


Fig. 1. Age distribution and health state level distribution are presented as a column and a stacked bar graph (A). Overall QoL and health indices are shown next to the Dutch reference values (B). For all four graphs, n = 84.

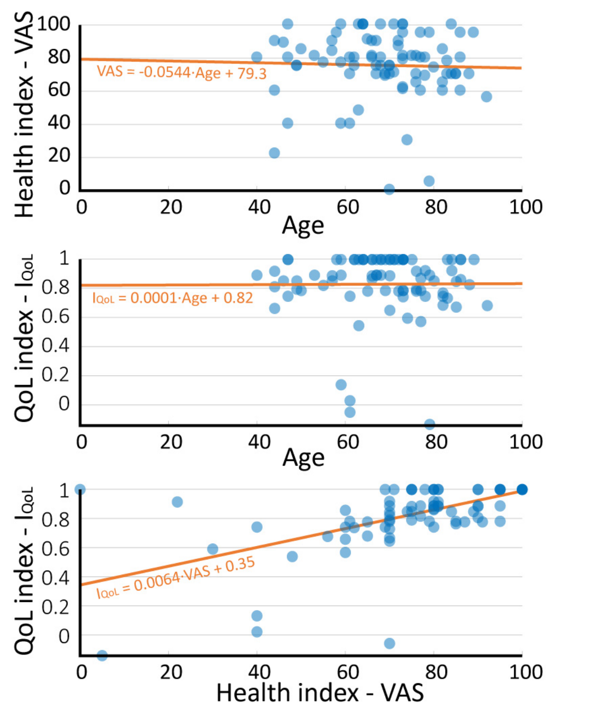


Fig. 2. Scatter plots with a linear fit line show the relations between age, QoL index and health index. N = 84 for these three graphs.

150 minutes/week of moderate intensive activities, was met by 36.7% (29/79). The second criterion, bone and muscle strengthening activities, was met by 82.3% (65/79). Weekly bicycle use was reported by 48.1% of the patients, while 30.4% participated in a sport at least once a week. Respondents spent 75 ± 192 minutes per week gardening and 28 ± 97 minutes per week on odd jobs. Time spent by patients for walking (240 ± 303 min/week, $p<0.0001$), bicycling (96 ± 169 min/week, $p<0.0001$), and participating in sport activities (48 ± 129 min/week, $p<0.0001$) is also lower than the reference group. The average amount of days where the respondent spent at least half an hour cycling, doing odd jobs, gardening or playing sports was 3.9 ± 2.7 days/week.

GO-Bicycling

Moderate to severe problems with cycling were experienced by 18.1% (13/72) of vulvar carcinoma patients, while 22.2% (16/72) reported they were unable to bicycle. When asked if the vulva impedes their ability to cycle, 34.9% (22/63) of the respondents indicated this is the case. This is visualized in Fig. 3. Most respondents owned either a city bike (25/56) or an electrical bike (23/56), while a few (3/56) owned both. Patients with no or slight bicycling problems stated they could bicycle a distance of 19 ± 17 km, and a duration of 73 ± 53 min. On the other hand, patients with moderate or severe bicycling problems stated they were able to bicycle a distance of 9 ± 16 km and a duration of 37 ± 68 min. When comparing the patients with no or slight bicycling problems to those with moderate or severe bicycling problems, the found differences in distances ($p = 0.007$) and durations biked ($p = 0.003$) were significant. The desire to make more or longer bicycling journeys was shared by 57.1% (36/63) of respondents and 31.7% (20/63) had tried at least one aid or adjustment to improve comfort. The most common adjustment was the purchase of a new saddle (14/20). Of the group who indicated not having tried aids, 57.1% (24/42) said they were unaware of the existence of such aids.

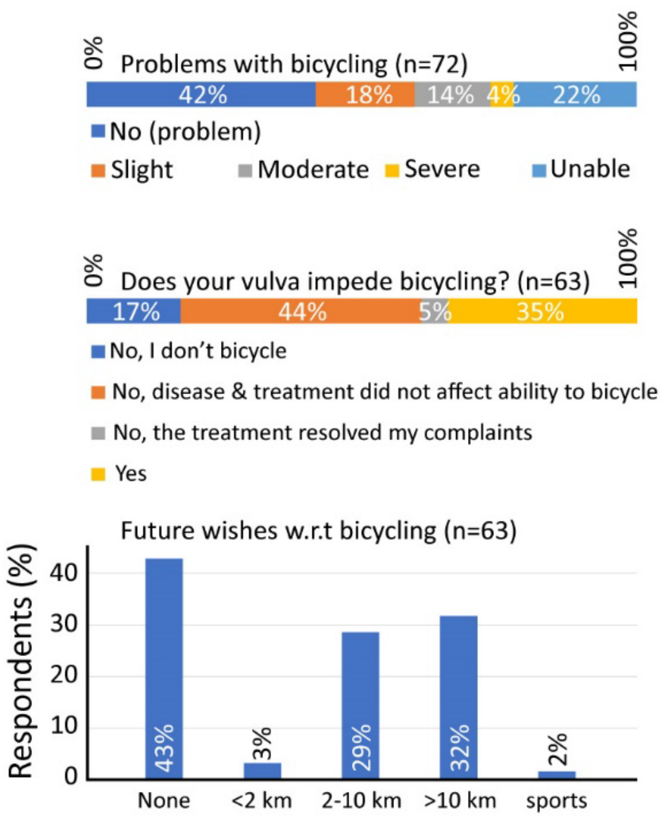


Fig. 3. Results of the GO-Bicycling questionnaire, showing the prevalence of problems with bicycling, their relation to problems of the vulva (top), and the desire to bicycle more (bottom).

The prevalence of types of pain and discomfort experienced by vulvar carcinoma patients are presented in Fig. 4. Frequently-reported complaints during bicycling included moderate to severe pain in the skin of the vulva (24.5%, 14/57), pain in the sit bones (23.2%, 13/56), and chafing (25.5%, 14/55), whereas itching was reported less often (8.9%, 5/56). The complaints are slightly more distinct during cycling, where the biggest difference is in pain in the sitbones, with 46% (31/56) of the respondents reporting any complaint during and 33% (43/64) reporting any complaint after cycling.

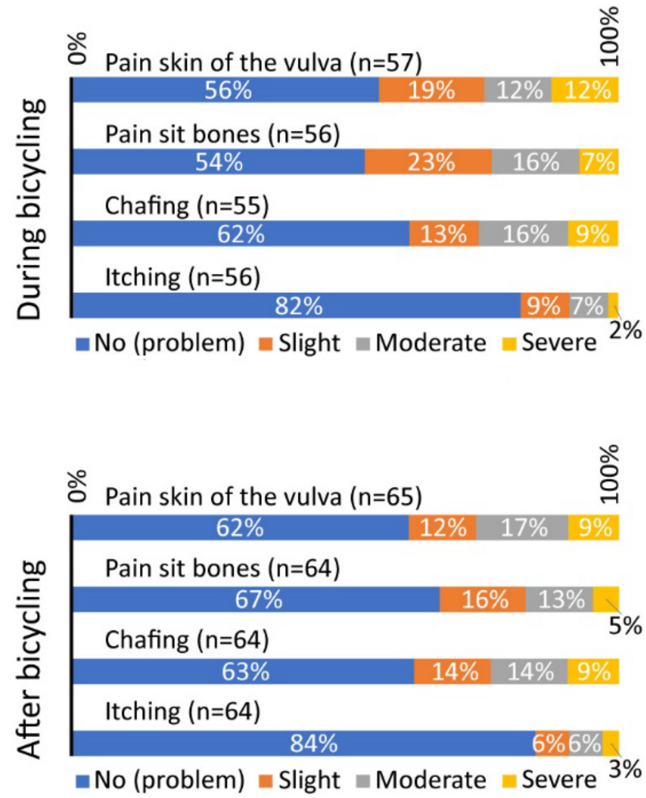


Fig. 4. These two stacked bar graphs present the distribution of experienced complaints during and after cycling.

IV. Discussion

The goal of this study was to assess the impact of vulvar carcinoma on mobility, physical activity and bicycling, by studying women treated for vulvar carcinoma. This was done using three questionnaires: EQ-5D-5L, SQUASH and a problem-specific GO-Bicycling questionnaire.

Comparing the outcomes of the EQ-5D-5L with reference values, it was found that although a higher proportion of participants had mobility problems (31.0% vs 16.0%), this did not significantly decrease the overall QoL index (0.832 vs 0.858). However, there is a reduction in the health index (75.6 vs 83.2).

The SQUASH results confirm the decrease in mobility and provide more detailed insights into the way mobility is affected. The Dutch physical activity guidelines were met by 34.2%, which is substantialy lower than the reference value of 46.5%. Participants spent fewer minutes per week walking (240 vs 367 min), significantly less time bicycling (96 vs 194) and participating in sports (48 vs 123) compared to females of the same age group.

The GO-bicycling questionnaire showed that 34.9% of the respondents felt that they were impaired in their cycling ability by their vulva. Pain in the skin of the vulva or the sitbones, together with chafing, were the most often reported problems while cycling.

The results from the SQUASH show less activity in all areas. While these findings suggest that the study population may be considerably hindered in their mobility, it is also possible that the method used in this study may have resulted in an bias of reported activity levels. As most participants completed the questionnaires remotely in the online survey environment, this may have caused participants to not understand or misunderstand the question. For example, the physical version of the SQUASH is only one page long, while online multiple actions are required to traverse the questionnaire. Nevertheless, the results are in agreement with the other questionnaires, where the questions about mobility problems were more straightforward.

Though 69% of the respondents experience no problems in their mobility, only 42% experiences no problems with cycling. This suggests that the reduced cycling ability does not directly translate into decreased mobility, i.e. the missed cycling can be compensated by walking, cars or public transport. Nonetheless, more than half of the respondents indicated that they would like to cycle more. Whereas the effectiveness of cycling aids in improving comfort may be patient-specific, it might be worth to recommend patients general aids. These aids may include use of (chamois) cream, optimized bicycle fit and posture, special bib shorts [20], or saddles with cutouts [21]. As 24 of the respondents reported being unaware of such aids, these low effort solutions offer potential.

One limitation of this study is the lack of validation and reference values for the problem-specific questionnaire. Literature on, and thereby also reference values of, problems with functional bicycling is scarce, as most cycling literature focuses on sports. The questions were formulated in a similar way to the EQ-5D-5L and SQUASH questionnaires, e.g., "I have slight problems with bicycling" as one of the answer levels, and "think about an average week in the past months". Another limitation of this study is the study population, as it is quite small. It would be interesting to conduct a similar study, but then with either a larger study population, a control group of woman without vulvar carcinoma or by specifying vulvar carcinoma patient subgroups.

Our results may be affected by a non-response bias, but the directional tendency is unknown. Non-responders may be less interested in the topic because they do not experience problems or do not bicycle at all. Six participants stopped the questionnaire after having reported being unable to cycle at the beginning of the GO-bicycling, which is unfortunate as it would be interesting to know the reason for their inability. However, the response rate is fairly high (63%) and the impact of such a bias would be small. Unfortunately, a group of 11 respondents inadvertently received a version of the questionnaire in which levels of pain and discomfort were inquired 'before' and 'after' bicycling, instead of 'during' and 'after'. This was the only difference between questionnaires. It was decided to include and show all data, with the exception of these 11 responses on this one question. This explains why the number of respondents in Fig. 4 is higher after bicycling, compared to during bicycling. The COVID-19 pandemic may have also affected the mobility and physical activity, but our understanding of lasting effects is currently limited.

In conclusion, our study has shown that vulvar carcinoma patients experience a high prevalence of problems with cycling, with 40.3% reporting moderate or severe difficulties. These difficulties are also associated with reduced levels of physical activity, with patients spending half as much time cycling and participating in sports compared to Dutch reference values. Despite this, our study did not find a significant decrease in overall quality of life among vulvar carcinoma patients, although they did report a higher number of mobility problems. Pain and discomfort in the vulva, sit-bones, and chafing were commonly reported both during and after cycling. These results suggest the need to investigate ways to improve comfort and support vulvar carcinoma patients in increasing their physical activity, mobility, and self-reliance.

References

[1] J. Pucher and R. Buehler, "Making cycling irresistible: lessons from the netherlands, denmark and germany," *Transport reviews*, vol. 28, no. 4, pp. 495–528, 2008.

[2] A. F. Orsini and C. O'Brien, "Fun, fast and fit: Influences and motivators for teenagers who cycle to school," *Children Youth and Environments*, vol. 16, no. 1, pp. 121–132, 2006.

[3] [Dataset] CBS RIVM, "National health survey/lifestyle monitor." 2021. [Online]. Available: https://statline.rivm.nl/#/RIVM/nl/dataset/50080NED/table?dl=6D346

[4] W. Chen, T. A. Carstensen, R. Wang, S. Derrible, D. R. Rueda, M. J. Nieuwenhuijsen, and G. Liu, "Historical patterns and sustainability implications of worldwide bicycle ownership and use," *Communications Earth & Environment*, vol. 3, no. 1, pp. 1–9, 2022.

[5] P. Oja, S. Titze, A. Bauman, B. De Geus, P. Krenn, B. Reger-Nash, and T. Kohlberger, "Health benefits of cycling: a systematic review," *Scandinavian journal of medicine & science in sports*, vol. 21, no. 4, pp. 496–509, 2011.

[6] W. R. Patberg and J. J. Rasker, "Weather effects in rheumatoid arthritis: from controversy to consensus. a review." *The Journal of Rheumatology*, vol. 31, no. 7, pp. 1327–1334, 2004.

[7] J. Hong, D. P. McArthur, and J. L. Stewart, "Can providing safe cycling infrastructure encourage people to cycle more when it rains? the use of crowdsourced cycling data (strava)," *Transportation research part A: policy and practice*, vol. 133, pp. 109–121, 2020.

[8] J. J. de Hartog, H. Boogaard, H. Nijland, and G. Hoek, "Gezondheidsvoordelen van fietsen vele malen groter dan de gezondheidsrisico's," *Tijdschrift Vervoerswetenschap*, vol. 49, no. 1, pp. 24–45, 2013.

[9] Y.-J. Kang, M. Smith, E. Barlow, K. Coffey, N. Hacker, and K. Canfell, "Vulvar cancer in high-income countries: Increasing burden of disease," *International journal of cancer*, vol. 141, no. 11, pp. 2174–2186, 2017.

[10] A. A. Chokoeva, G. Tchernev, E. Castelli, E. Orlando, S. B. Verma, M. Grebe, and U. Wollina, "Vulvar cancer: a review for dermatologists," *Wiener Medizinische Wochenschrift*, vol. 165, no. 7, pp. 164–177, 2015.

[11] A. Tan, A. K. Bieber, J. A. Stein, and M. K. Pomeranz, "Diagnosis and management of vulvar cancer: A review," *Journal of the American Academy of Dermatology*, vol. 81, no. 6, pp. 1387–1396, 2019.

[12] L. J. Rogers and M. A. Cuello, "Cancer of the vulva," *International Journal of Gynecology & Obstetrics*, vol. 143, pp. 4–13, 2018.

[13] M. C. Bleeker, P. J. Visser, L. I. Overbeek, M. van Beurden, and J. Berkhof, "Lichen sclerosus: Incidence and risk of vulvar squamous cell carcinomalichen sclerosus: Incidence and vulvar cancer risk," *Cancer Epidemiology, Biomarkers & Prevention*, vol. 25, no. 8, pp. 1224–1230, 2016.

[14] B. Niehaves and R. Plattfaut, "Internet adoption by the elderly: employing is technology acceptance theories for understanding the age-related digital divide," *European Journal of Information Systems*, vol. 23, no. 6, pp. 708–726, 2014.

[15] M. M. Versteegh, K. M. Vermeulen, S. M. Evers, G. A. De Wit, R. Prenger, and E. A. Stolk, "Dutch tariff for the five-level version of eq-5d," *Value in health*, vol. 19, no. 4, pp. 343–352, 2016.

[16] M.-J. J. Mangen, M. Bolkenbaas, S. M. Huijts, C. H. van Werkhoven, M. J. Bonten, and G. A. de Wit, "Quality of life in community-dwelling dutch elderly measured by eq-5d-3l," *Health and quality of life outcomes*, vol. 15, no. 1, pp. 1–6, 2017.

[17] G. W. Wendel-Vos, A. J. Schuit, W. H. Saris, and D. Kromhout, "Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity," *Journal of clinical epidemiology*, vol. 56, no. 12, pp. 1163–1169, 2003.

[18] R. M. Weggemans, F. J. Backx, L. Borghouts, M. Chinapaw, M. T. Hopman, A. Koster, S. Kremers, L. J. van Loon, A. May, A. Mosterd *et al.*, "The 2017 dutch physical activity guidelines," *International Journal of Behavioral Nutrition and Physical Activity*, vol. 15, no. 1, pp. 1–12, 2018.

[19] W. Wendel-Vos, S. van den Berg, M. Duijvestijn, and E. de Hollander, "Beweegrichtlijnen en wekelijks sporter: van vragenlijst tot cijfer," 2020.

[20] A. S. T. Larsen, K. L. Norheim, R. Z. Marandi, E. A. Hansen, and P. Madeleine, "A field study investigating sensory manifestations in recreational female cyclists using a novel female-specific cycling pad," *Ergonomics*, vol. 64, no. 5, pp. 571–581, 2021.

[21] A. S. Larsen, F. G. Larsen, F. F. Sørensen, M. Hedegaard, N. Støttrup, E. A. Hansen, and P. Madeleine, "The effect of saddle nose width and cutout on saddle pressure distribution and perceived discomfort in women during ergometer cycling," *Applied Ergonomics*, vol. 70, pp. 175–181, 2018.

Evaluating the usability of embroidered sensors to measure saddle load distributions during cycling

Franciscus van Beurden, 4470575
MSc Biomedical Engineering

Abstract*—*Introduction: **Seated comfort during cycling is a subjective measure that can be objectively estimated by pressure measurements. Several measurement options are available to compare the variety of bicycle saddle designs, such as the emerging smart textiles. In this study, embroidered resistive pressure sensors are developed and their performance is evaluated. A test setup is created in which the sensors are incorporated into a pressure-sensing saddle cover to compare saddles while cycling.**
Method: **The textile sensors are developed by stitching conductive yarns and resistive polymers to a base fabric. A pressure mat consisting of 32 embroidered sensors is designed and attached to a bicycle saddle cover. The data from the pressure mat was analysed using data acquisition systems and then calibrated by means of fits. The sensors were evaluated in three phases: as single sensors, as part of a pressure mat, and during a cycling test. The single sensors were tested on the repeatability, range, drift and uniformity by observing the change of resistance when the sensors was subjected to several load conditions. In the third phase, six female participants tested three different saddles on which the produced saddle cover was placed. After the test, a short questionnaire was conducted on comfort.**
Results: Phase 1: **A non linear negative relation is observed between the sensors resistance and the applied load, with a usable pressure range of up to 66 kPa.** ***Phase 2:*** **The pressure mat was calibrated using separate exponential fits for each of the 32 sensors.** ***Phase 3:*** **The test setup produced clear heatmaps which show the pressure distribution during cycling. The traditional saddle design results in substantialy more pressure around the perineum than two other tested designs. Subjectively, no clear consensus was shown as in which saddle design was favoured.**
Conclusion: **The use of embroidered pressure sensors to measure pressure distribution offers potential for use in low-cost prototyping. The test setup presented in this study proved to be effective for analyzing the load distribution on a saddle. As the design of the sensors can be fully customised, further research is required to optimise the performance and durability of the sensors.**

***Index Terms*—Embroidered force sensitive resistors, Pressure sensors, Embroidery, Cycling, Saddle pressure**

I. Introduction

In the previous chapter we have shown that women with a history of vulvar carcinoma can experience cycling as uncomfortable or painful, resulting in reductions in patient mobility and bicycle use. Research shows that cycling comfort can be improved by adapting the saddle design [1, 2]. The standard bicycle saddle design has remained the same since the introduction of the bicycle. This design lets most of the cyclist's weight rest on the saddle via the sit bones, but a portion is also supported by the perineum. Support through the perineum can be experienced as painful, for example because of medical conditions like lichen sclerosus or vulvar cancer. To improve cycling comfort, special saddles have been developed and marketed, aiming to reduce perineal pressure. However, the effectiveness of these saddles in improving comfort has not yet been studied for this patient group.

Interface pressure between a seat and person, and the corresponding load distribution are recognized as the main objective measures for determining seated comfort [3, 4]. These measurements are used for seats in different environments, ranging from automotive [3], offices [4, 5] to horses [6]. Another environment in which pressure measurements are frequently used for determining seated comfort is for cyclists [7, 8, 9]. Various pressure mats are available for this, but most of these and the related research are aimed at high-intensive saddle use, i.e. for sports. The regular city bike saddle is used differently by the cyclist. For example, a city bike is designed to facilitate a pleasant ride rather than a quick one, and the cyclist also adopts a different posture, illustrated in Fig. 1. This causes the pressure distribution and the amount of pressure on the saddle to be different as well [10].

Fig. 1. Postures adopted while using a city bike [11] (left) and a road bike [12] (right).

A good pressure sensor minimally distorts the type of contact between opposing surfaces. As saddles are (to an extent) soft and deformable, a good saddle pressure sensor needs to allow these deformations. Fabrics and yarns are deformable and have been used and developed by humans for years, resulting in many different textiles. Nowadays, conductive yarns are also available, although they are not yet widely utilized. These yarns can be made by weaving metal threads into textiles or by coating yarn with metal. Possible applications range from an embroidered speaker [13], a knitted strain sensor [14], to an embroidered pressure sensor [15]. The latter technique offers potential for prototyping, due to the low production cost and easily accessible production process.

Brief technical background

Resistive textile pressure sensors are based on the principle of Force Sensitive Resistors (FSR). These force sensors consist of two electrodes with a resistive material in between, whose electrical resistance changes when a pressure or force is applied. This change in resistance follows from the change in contact area between the electrode and the resistive material, which is called the interface effect [16]. In case of the textile sensors, the electrodes consist of conductive yarn, while the resistive material is a resistive polymer sheet. As pressure is applied, the contact between the yarn and sheet increases, as can be seen in the right portion of Fig. 2. The volume resistance of the yarn and the sheet resistance of the resistive material remain nearly constant. As the resistances are in series, the total resistance of the sensor R is a sum of the resistances of both electrodes R_e, the resistive material R_v and the contact between the electrodes and the resistive material R_s, illustrated in Fig. 2.

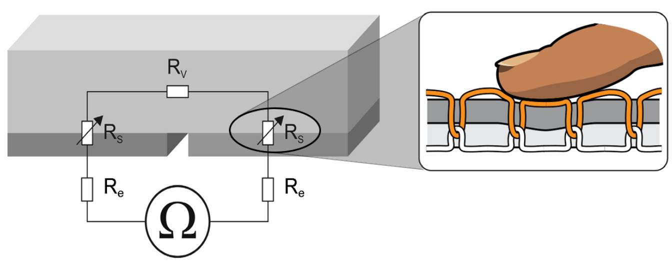


Fig. 2. Visualisation of the series of resistances (left) in Weiss et al. [16] and the interface effect (right) in Aigner et al. [15].

To produce an embroidered pressure sensor, two conductive threads need to be stitched to a resistive fabric, which is attached to a base fabric using non-conductive yarn. The layer order in which these are stitched can be changed to produce different arrangements: two electrodes on top of the resistive fabric, both electrodes in between the base and resistive fabric or one electrode on either side of the resistive fabric [15]. A stabilizer is also utilized to prevent the embroidery yarns from deforming the base textile, which can result in an increased amount of stitching errors [17].

Aim and structure

In this thesis chapter, a pressure mat was developed with 32 separate embroidered pressure sensors. This pressure mat is incorporated into a saddle cover allowing measurement of pressure distribution on a bicycle saddle. The aim of this study is to evaluate the performance of these sensors and assess how useful the test setup is in determining a difference in pressure distribution on bicycle saddles. The structure of this paper is as follows. After this introduction, the method section describes the pressure mat design and production, electrical readout system, sensor evaluation and test setup. After, the results of the evaluation and saddle test are presented. The results from this study are then discussed and directions for further research are suggested. In the end, a brief conclusion is drawn. Accompanying this chapter are appendices C, D and E. Appendix C shows pictures of the manufacturing of the saddle cover, appendix D contains the questionnaire used during the saddle test, and appendix E presents the calibrated fits of the pressure mat.

II. Method

A. Pressure mat design

To ensure that the measurements between saddles are comparable with each other, it was decided to make one saddle cover which would fit all saddles in the saddle test. The selected saddles are a traditional saddle from Selle Royal, the ISM Metro saddle and the SQlab 621 M-D Line Active City saddle, which can be seen in Fig 3.

Fig. 3. From left to right, a traditional saddle from Selle Royal, the ISM Metro saddle and the SQlab 621 M-D Line Active City saddle.

Saddles were covered with a layout of 32 sensors (2 data acquisition – DAQ – systems with 16 connectors each) to be able to detect the pressure distribution, which can be seen on the left side of Fig. 4. A textile layer with stitched conductive threads is added under the sensors, to transfer the signal from the sensors to the DAQs. This was preferred over copper wire cables, since the thin threads interfere less with the perceived comfort. The threads continued until the backside of the saddle cover, where the signal is transferred to electric cables. The sensors and thread are covered by two layers of cotton for durability and a stretch saddle cover is placed on top. A visualization of the layers can be seen on the right side of Fig. 4.

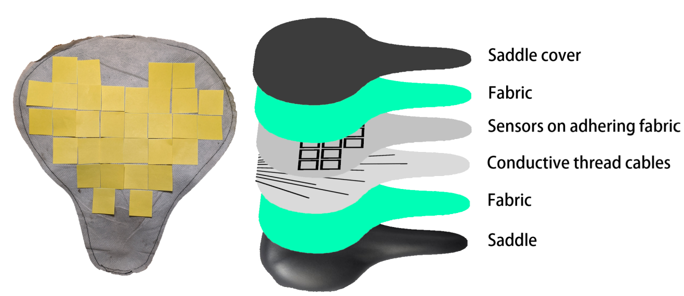


Fig. 4. The layout used to position 32 sensor upon the saddle cover (left) and the five layers that make up the saddle cover (right).

Each of the 32 sensors has the same pattern design, which can be seen in Fig. 5. The distances are t (total width) = 17 mm, e (distance between electrodes) = 2.6 mm and s (stitch length) = 3 mm. This pattern is called the InterDigitated Electrode (IDE) configuration [18], with connection pads on the bottom part of the sensor. The comb-like design is widely utilized for sensing applications due to the ease of the fabrication process and the high sensitivity [18]. This and four other designs, all described in the paper by Aigner et al. [15], were produced for evaluating the principle of embroidered pressure sensors. The experiments showed a good pressure range and resolution from the IDE configuration, while also yielding the least amount of manufacturing errors. These experiments were not extensive however, so more research into the design patterns would be interesting. Mixed layering was chosen, which is where both electrodes are on opposite sides of the resistive fabric. The IDE design used differs from the general IDE design in that the electrodes enter the active area of the sensor at opposite corners. The reason for this change was observations during early testing, as it was found that the sensors with the general IDE design were more sensitive close to the connection pads. The resistance of the yarn is quite high, so the upper part of the electrodes was not fully utilised, as the current takes the path of the least resistance. This is improved in the design used.

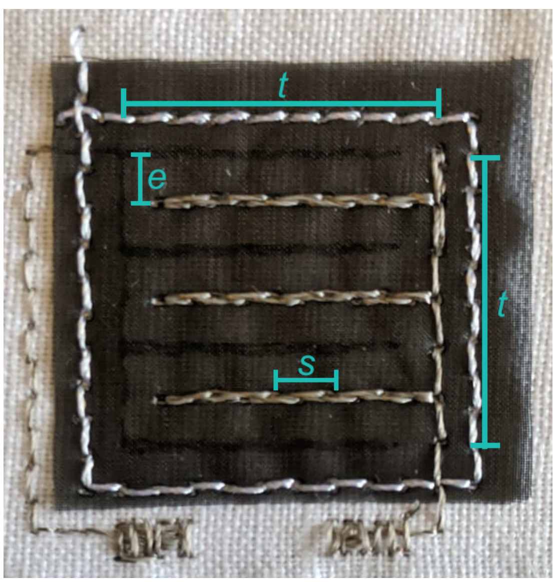


Fig. 5. Final design of embroidered resistive sensor, with total width t = 17 mm, electrode distance e = 2.6 mm and stitch length s = 3 mm. The conductive yarn starts at the bottom at the connection pads. In the sensor, the electrode stitched on the resistive fabric is clearly visible (gray), the electrode beneath is less visible (black).

B. Pressure mat production

To generate the embroidery files for the sensors, Processing 4.0b8 (The Processing Foundation) was used in combination with the PEmbroider library (The Frank-Ratchye Studio for Creative Inquiry). This produced .pes files which could be imported into PE-design 11 (Brother, Bad Vilbel, Germany), which then were exported to the embroidery machine, a Brother Entrepreneur Pro X.

Different materials were selected to use for the production of the sensors. For the conductive yarn, Silver-tech 120 (AMANN, Bönnigheim, Germany) was used, while Carbotex 03-82 CF (SEFAR, Thal, Swiss) was selected for the resistive fabric. Silver-tech 120 is a polyaminde/polyester hybrid thread coated with silver . It has a resistance of 530 Ω/m and is embroided using a needle size of 75-90 Nm [19]. Carbotex 03-82 CF is a monofilament fabric made of polyamide 6.6. It has a sheet resistance in the region of 1k Ω [20]. A close up picture of the yarn and fabric can be seen as the cover of this thesis. The base textile was a standard white cotton, while the stabilizer was Madeira Cotton Stable, 50 g/m2. The production of the sensors went as follows.

The base textile was placed in an embroidery hoop with the stabilizer. Then, the hoop was inserted into the embroidery machine, after which the embroidery process was started. This consisted of the first electrode being stitched to the base textile, then fastening the resistive fabric to the base textile with regular non-conductive yarn and then finishing the sensor by adding the second electrode. The textile was then detached from the hoop, after which any residual textile was removed by scissors. The sensors were also marked with a code consisting of a letter and a number, e.g. C5. This way, 50 sensors were produced, from which 32 were used in the pressure mat. The selection process is described in the evaluation section.

To fix the sensors in the previously mentioned layout, they were placed on a layer of adhering fabric. The layer with stitched conductive threads was put under the sensors and connected to them by handsewing thread through the layers. To connect the thread to copper wire cables, the threads were stitched around stripped ends of electrical cables. The two layers of green cotton fabric were sewed to the sensors and thread layers using a sewing machine, which completed the pressure mat. Using the same machine, the pressure mat was then sewn onto a stretch saddle cover. The finalized saddle cover with the electrical readout system can be seen in Fig. 6. Additional pictures of the manufacturing process can be found in appendix C.

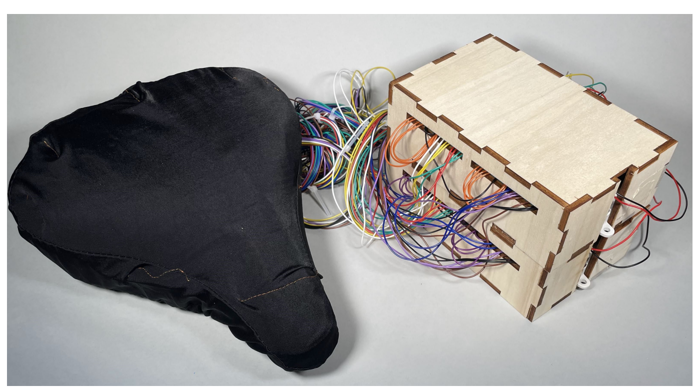


Fig. 6. Saddle cover and electrical readout system

C. Electrical readout system and data analysis

To read out multiple sensors simultaneously, two NI 6211 DAQs from National Instruments (National Instruments, Austin, TX, USA) were used. The DAQs read voltages, so the resistance change needs to be converted to a voltage difference. For this, each sensor had their own INA125 instrumentation amplifier (Burr-Brown, Tucson, AZ, USA). This amplifier uses a Wheatstone bridge, where the sensor acts as one of the resistors. In Fig. 7, the electrical circuit of the amplifier can be seen. Here, R2 = R3 = 1k Ω, Rg = 56k Ω and R4 = the sensor. Using a potentiometer as R1, the resistance was decreased from 2k Ω until the output was stable. This resulting resistance was usually close to the zero load resistance of the sensor, which differed per sensor. The output of the amplifier was then connected to the DAQ. The DAQs were connected to a laptop, which used Labview 2018 18.0 (National Instruments, Austin, TX, USA) to acquire the values of each sensor with a sampling frequency of 40 Hz. The data was then analysed and fitted using MATLAB R2021A (Mathworks, Natick, MA, USA).

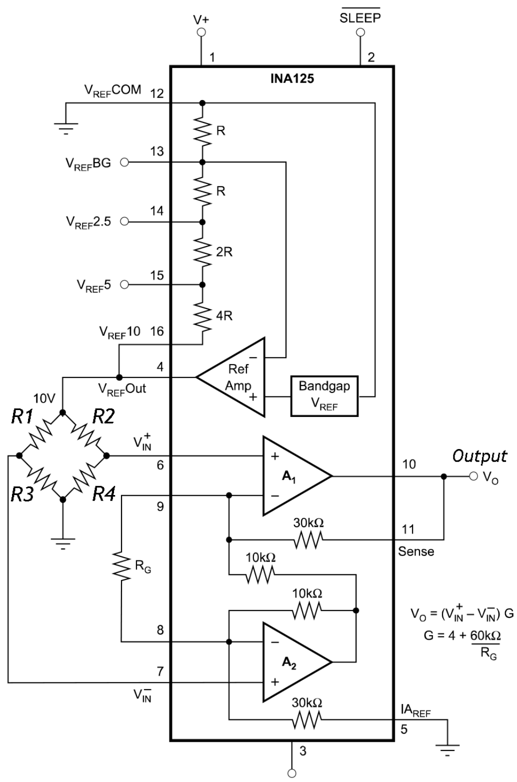


Fig. 7. Circuit diagram of the instrumentation amplifier INA125 [21], with the embroidered sensor as resistance R4. The output on the right of the diagram connects to the DAQ system.

D. Evaluation

The sensors were calibrated and the behavior was tested by applying loads on the sensor and observing the change in output of the sensor. The sensors were tested in three phases: firstly as single sensors, secondly as part of the pressure mat and thirdly during the saddle test. In the first phase, the resistances were measured using a Voltcraft VC860 multimeter. In the second and third phase, the output was measured using the DAQ systems. The first phase was used to gain a better understanding of the behavior of the embroidered sensors and to select 32 sensors for the pressure mat. The second phase was used to determine the load-voltage relationship and calibrate the sensors. Weights were used to apply loads on the sensor in the first and second phase. As the weights had different diameters, a PMMA-plate (21x21 mm, 2 g) was placed in between the sensor and the weight to equally distribute pressure over the full contact area. Sensor D4 with the PMMA-plate on top can be seen on the left in Fig. 8.

Phase 1: preliminary testing and sensor selection:
For the first phase, five different tests were conducted to evaluate sensor performance:

Test A: repeatability. This test was conducted to evaluate the spread between measurements with the same load. A load of 1100 g was applied to the plate on the sensor ten times in succession. The 100 g weight was added as weights of 1 kg were too big to fully rest on the sensors. This was done twice, for three sensors.

Test B: range. To test the maximum applied load which could still be distinguished from a lesser load, sensors were tested with loads up to 11.1 kg. Weights of 1 kg, 3 kg, 5 kg, 7 kg, 9 kg and 11 kg were added on top of the plate and a 100 g weight. The second picture from the left in Fig. 8 shows the setup when applying a total load of 11.1 kg to the sensor. This was done twice, for three sensors. The threshold to distinguish different load conditions was determined to be the average standard deviation of the tests found in Test A.

Test C: selection. This test was conducted to select 32 out of the 50 sensors for the saddle cover. The resistance was measured with five load conditions: no load, 2 g (PMMA-plate), 102 g, 202 g and 502 g. This was done for all 50 sensors and measurements were repeated three times per sensor. The quality of the sensor was determined by looking at the following characteristics: the standard deviation between measurements of the same weight and the distance between average values when the sensor was loaded with 102, 202 and 502 grams. The quality of a sensor was considered good when the standard deviation was low and the distance between the averages was high.

Test D: drift. To investigate the drift in the sensor response, a period of 60 seconds was chosen between two measurements. A load of 502 g was applied to the sensor for this period. The resistance was measured five seconds after application and 60 seconds later. This was done six times, for six sensors.

Test E: uniformity. In order to test whether the sensor

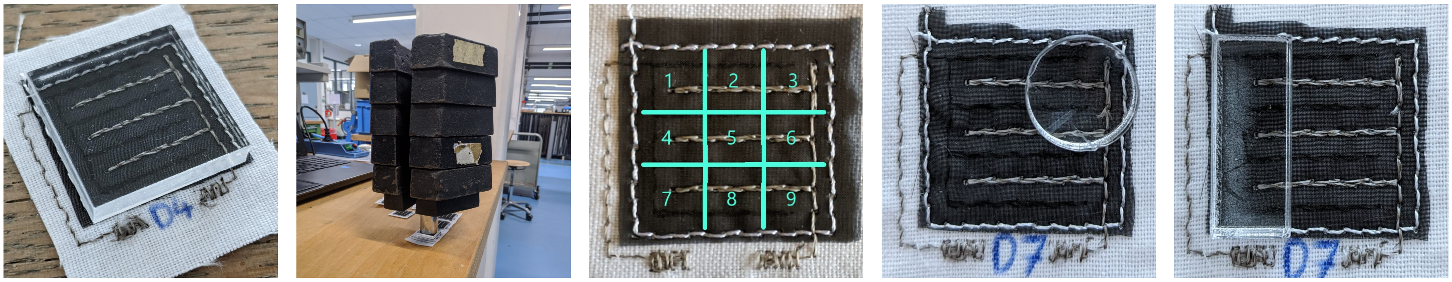


Fig. 8. Pictures of the first evaluation phase, with from left to right: the square PMMA-plate on top of a sensor (I), a sensor with an applied load of 11.1 kg (II), the grid which separates the sensor into the areas tested for uniformity (III), the circular (IV) and the rectangular (V) PMMA-plate.

reacts similarly in different parts of the sensor's active area, a small circular and a rectangular PMMA plate were used (as shown in the two pictures on the far right of Fig. 8). The active area was divided in nine different parts, visualized in the middle of Fig. 8. The circle was placed on all nine parts. The rectangle was placed horizontally to the right from numbers 1, 4 and 7, and vertically downwards from 1, 2 and 3. The applied weights were 50 g, 100 g and 200 g. This test was carried out for one sensor.

Phase 2: pressure mat calibration:
The data used for calibration of the pressure mat was obtained in a similar manner to the Test C. However, instead of sequentially adding the weights per sensor, all sensors were tested sequentially per weight. The used weights were 100 g, 200 g, 500 g, 1000 g, 1500 g, 2000 g and 3000 g and were all applied 5 times to the 32 selected sensors. The PMMA-plate has an area of 441 mm^2, so the weights correspond to pressures of 2.22 kPa, 4.45 kPa, 11.1 kPa, 22.2 kPa, 33.4 kPa, 44.5 kPa and 66.7 kPa. During a upright cycling test with a female participant pool, Freunek et al. [10] found a maximum pressure of 29 ± 10 kPa, which is in accordance with our chosen pressure range. The data was imported into MATLAB and used to create a fit for each of the sensors. This was done using the 'fit' function. The used fittype was 'exp1', which fits the data on a single-term exponential, shown in Eq. 1.

$$load(kg) = a * e^{b*V} \tag{1}$$

Here, a and b are obtained from the fit and V is the voltage value acquired from the DAQ. The resulting value is the equivalent of the load applied to the sensor, if it would be applied to the PMMA-plate on a sensor. For visualization purposes, the calibrated data is then translated onto a heatmap using MATLAB. The colorscale turbo is used, which is a rainbow-like scale from 0 (dark blue), to 1 (dark red). Here, 0 equals to the value obtained when there is no pressure, while 1 is chosen to equal to the maximum calibrated pressure of 66.7 kPa. To compensate for occasional short circuits, a threshold of 100 kPa was chosen. Values above this threshold were converted to NaN. It was observed that two of the sensors were damaged during the production process. As these two sensors did not contribute to the results and were only causing a distraction, it was decided to represent them on the heatmap with a gray square.

Phase 3: saddle test:
To compare the comfort experience between the three saddles, a test was conducted which included both a pressure measurement and a questionnaire. The test setup consisted of a stationary bike (as shown in Fig. 9) on which the saddle could be exchanged. The produced saddle cover was put on top of the saddle, with the readout electronics located on a table nearby. Six female participants (age range: 20 – 24) were invited to the TU Delft, to test each of the saddles by cycling on them for five minutes. Each possible saddle order was used one time. The tests are categorised by combining the participant number and a letter for the saddle, e.g. Test 3B. Here, A stands for the traditional saddle, B for the ISM saddle and C for the SQlab saddle. After the data was collected, the following post-processing was conducted to compare the saddles. For each sensor, the periods were averaged over the 10 seconds sample. Next, the averages from the tests was combined by taking the median separately for each saddle. This was chosen over mean, as it was noticed that outliers had an excessive impact on the mean.

Fig. 9. Test setup used during the saddle test.

As the experienced comfort is also dependent on the bike fit [22, 23], it is important to standardize bike adjustments. Following the rule of thumb from the Dutch Cyclists' Union

[24], the saddle height was determined to be set to 1,09 times the crotch height. The crotch height was measured by the participant herself, using a tape measure. For reference, the participants' weight were also measured. Finally, a picture was taken from the side view during cycling to enable the assessment of posture. After testing the saddles, the participants completed a questionnaire to assess their experiences with each saddle. The questionnaire asked what saddle design the participant uses in their daily life, whether the test setup was adjusted properly and what complaints were experienced during the test. The questionnaire concluded with the question: *Which saddle did you find the most and which the least comfortable?* The questionnaire (in Dutch) can be found in appendix D.

III. Results

Phase 1: preliminary testing and sensor selection:

Test A: repeatability. A load of 1102 grams was placed and then taken off 10 times in succession on three sensors, twice, to result in 6 series. The results from these series are shown in Fig. 10 as continuous lines, while the standard deviations calculated from the series are shown in Table I. Where both series from A3 (blue) show a discrepancy between values, the series from E1 and A9 show relatively less difference between values. By averaging the standard deviations, an indication of 3 Ω was determined as the distinguishing point.

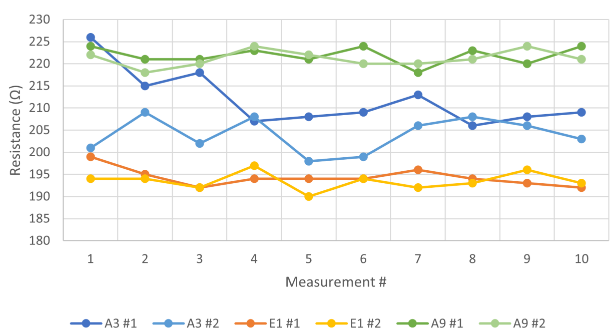


Fig. 10. Results from Test A - repeatability. Each line represent a series of 10 measurements where a load of 1102 g was applied.

TABLE I
RESULTS TEST A: REPEATABILITY.
LOAD OF 1102 G WAS APPLIED 10 TIMES FOR EACH SERIES.

Series	A3 #1	A3 #2	E1 #1	E1 #2	A9 #1	A9 #2
Average (Ω)	212	204	194	194	222	221
SD (-)	6.3	3.9	2.1	2.0	2.0	1.9

Test B: range. Results from the range determination of sensors A3, E1 and A9 are shown in Fig. 11. A non linear negative relation is observed; i.e. the ratio between measured resistances decreases as the weight increases. For example, the measured difference between applying a load of 1.1 kg and 3.1 kg for A3 #2 is 18 Ω, however between 3.1 kg and 5.1 kg this is 2 Ω. Since that is below the indication found in Test A, loads between 3.1 and 5.1 kg or higher are difficult to distinguish. All values from this test are shown in Table II.

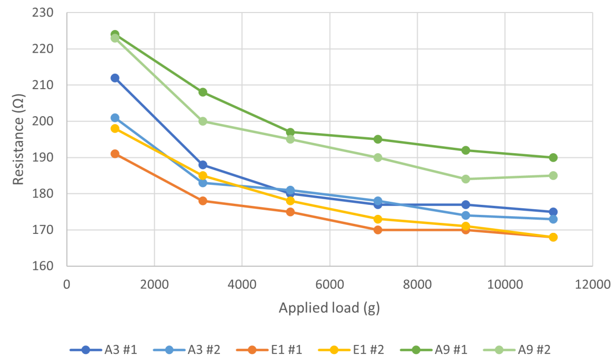


Fig. 11. Results from Test B - range. Sensors were tested with loads up to 11102 grams.

TABLE II
RESULTS TEST B: RANGE.
SENSORS WERE TESTED WITH LOADS UP TO 11102 GRAMS.

Load (g)	A3 #1	A3 #2	E1 #1	E1 #2	A9 #1	A9 #2
1102	212	201	191	198	224	223
3102	188	183	178	185	208	200
5102	180	181	175	178	197	195
7102	177	178	170	173	195	190
9102	177	174	170	171	192	184
11102	175	173	168	168	190	185

Test C: selection. On each of the 50 sensors, 15 measurements were carried out, amounting to 750 measurements in total. Average resistance values and standard deviations for each loading condition can be seen in Table III. Figure 12 shows exemplar results from sensors E1 and F4. The resistance when there is no load or just the PMMA-plate is significantly higher than with weights. In this minimal load condition the standard deviation in resistance values also increased. When weights are applied, the resistance drop sharply as the values from individual measurements converge. As the load increases, the change of resistance between load conditions decreases, similar to the results from Test B.

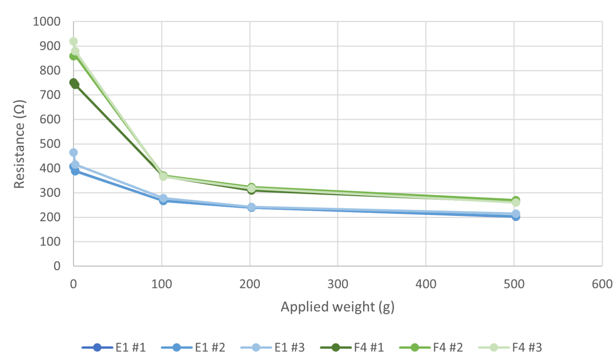


Fig. 12. Results from Test C - selection. All sensors were tested with loads from 0 to 502 g. Note that the values on this y-axis is considerably different from the other tests.

Test D: drift. The difference of resistance five seconds after load application and 60 seconds afterwards was tested for six sensors. Figure 13 shows the results for the three sensors

TABLE III
RESULTS TEST C: SELECTION.
RESISTANCE VALUES ARE AVERAGED OVER ALL 50 SENSORS.

Load (g)	Resistance mean (Ω) ± SD (-)
0	671 ± 264
2	624 ± 256
102	326 ± 44
202	281 ± 29
502	239 ± 17

A3, E1 and A9. The blue bars represent the resistances from the first measurement, while the orange bars represent the resistances 60 seconds later. For the most part, the resistances decreased after 60 seconds. The mean change was -2.0 ± 3.4 Ω, with a maximum and minimum of +6 Ω to -10 Ω. The average change for all sensors can be seen in Table IV.

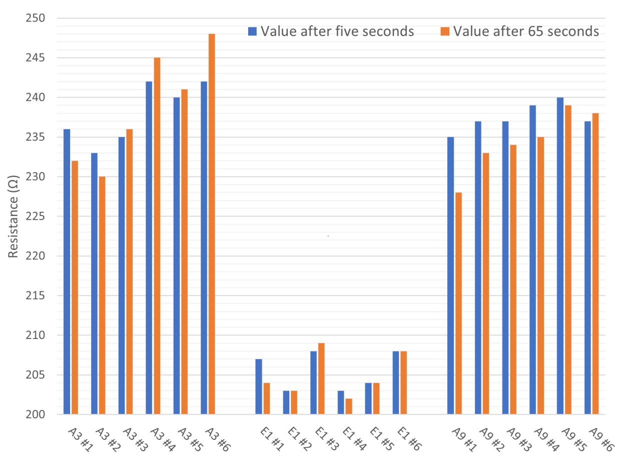


Fig. 13. Results from Test D - drift. Each sensor was tested 6 times and resistance values were obtained after 5 (blue) and 65 (orange) seconds of applying a load of 502 grams

TABLE IV
RESULTS TEST D: DRIFT.
CHANGE IN RESISTANCE AFTER 60 SECONDS, AVERAGED OVER 6 MEASUREMENTS OF A 502 G LOAD

Series	A3	E1	A9	D9	F4	D4
Average change (Ω)	-0.67	0.50	3.0	3.7	5.5	0.17
SD (-)	3.7	1.4	2.8	2.3	2.9	3.1

Test E: uniformity. The results from this test are displayed in Table V. The different cells represent the grid shown in Fig. 8 and the values in these cells represent the corresponding resistance. Furthermore, each cell has a color scale ranging from red (lowest resistance) to white (highest resistance). The lowest resistances are generally observed in the middle of the sensor.

Phase 2: pressure mat calibration:
Fig. 14 shows the graphs containing the data points and the corresponding fit for four sensors. Similar graphs for all sensors can be found in appendix E. A fit was created for each of the 32 sensors used in the pressure mat except one, which was damaged during the production process.

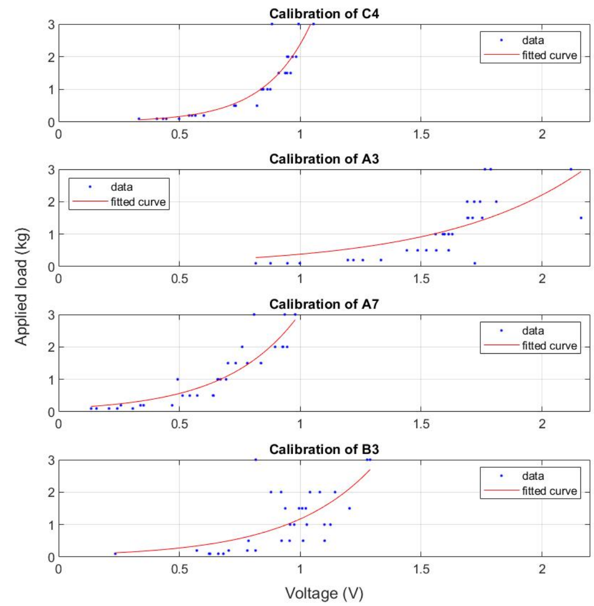


Fig. 14. Data and fitcurve for sensors C4, A3, A7 and B3.

Phase 3: saddle test:
The saddle test was completed by all six participants for all three saddles, resulting in 18 tests. The tests lasted five minutes, but a sample of 10 seconds was selected from each test for further analysis. Using MATLAB, the data was fitted and the cycling periods were identified. The periods from the sample were plotted over each other, of which the result for test 6B can be seen in Fig. 15. The period was clearly visible for most of the sensors. Fig. 16 shows the resulting heatmap for each saddle. The heatmaps indicate that the traditional saddle design results in substantially higher pressure on the perineum compared to the other two saddle designs, from which the corresponding heatmaps only show a minimal pressure on the perineum.

Questionnaire. After cycling for fifteen minutes, the respondents filled in their questionnaire. Each participant respondent that they used a traditional saddle in their day-to-day life. The pressure and complaints were experienced differently per person, but in general the results correspond with the saddle design. Pain in the vulva was experienced most often using the traditional saddle, while pain in the sit bones occured during the use of the ISM and SQlab saddle. Itching was reported little and chafing occured the least while using the ISM saddle. The ISM saddle was considered the most comfortable by three of the six participants, followed by the traditional saddle and then the SQlab saddle, with two and one votes respectively. Table VI shows the distribution of participants' saddle preference.

TABLE V

RESULTS TEST E: UNIFORMITY.

EACH VALUE REPRESENTS A SINGLE MEASUREMENT. THE ACTIVE SENSOR AREA WAS DIVIDED INTO 9 SQUARE SECTIONS (SEE FIG. 8), WHICH WERE COVERED INDIVIDUALLY BY THE CIRCLE OR PER THREE BY THE RECTANGLE. THE INTENSITY OF THE COLOR REPRESENTS THE RESISTANCE CHANGE, WITH THE DARKEST RED INDICATING THE LOWEST RESISTANCE.

Sensor C7		*50 gram*			*100 gram*			*200 gram*	
Circle	465	410	415	458	395	395	377	374	370
	418	434	429	415	360	395	363	333	362
	458	458	458	445	375	428	383	367	403
Rectangle vertical	469	349	410	427	330	380	399	316	351
Rectangle horizontal		389			419			363	
		389			366			343	
		425			389			348	

TABLE VI

SADDLE PREFERENCE

NUMBERS INDICATE AMOUNT OF PARTICIPANTS.

Saddle design	Traditional	ISM	SQlab
Most comfortable	2	3	1
Least comfortable	3	1	2

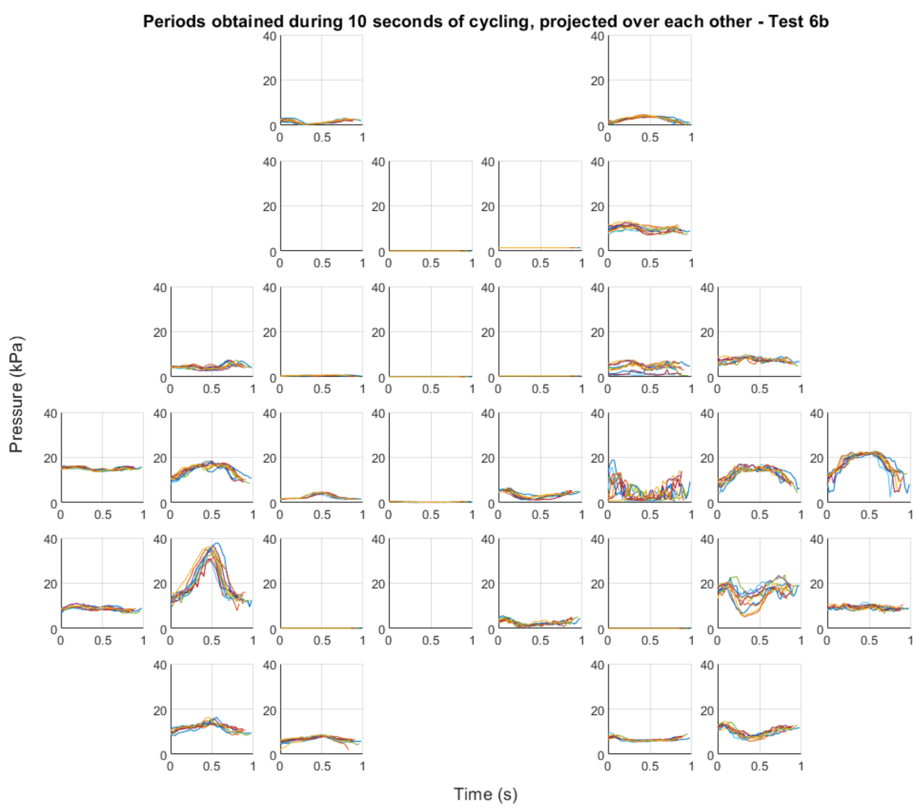


Fig. 15. Graphs for each of the 32 sensors during one test with the ISM saddle. The periods of a 10 second were identified and plotted on top of each other.

Fig. 16. The three saddles with their corresponding heatmaps projected on top, of which the values were averaged over the six participants.

IV. Discussion

In this thesis, a test setup was designed to compare the interface pressure on different cycling saddles during cycling. This was done using a stationary bike and three different saddles, on which a self-developed pressure-sensing saddle cover was placed. The setup resulted in heatmaps that clearly show the distribution of the interface pressure, which can be used to identify the location of potential trouble spots. Pressure distribution was measured using 32 embroidered resistive pressure sensors that were fabricated and evaluated for use in the setup. The resistance of the sensors decreases when pressure is applied, for which a non-linear negative relationship is observed. The sensors performance was found to be adequate for the use in a saddle pressure mat.

The heatmaps shown in Fig. 16 show the highest pressure around the vulva area for the traditional saddle, which is consistent with the results from the questionnaire. A low pressure around the perineum was found for the ISM and SQ-lab saddle, which corresponds with the saddle design. The three heatmaps do not show such a difference in the area where the sit bones are supported. Individual cyclic periods can be identified and analysed for the separate sensors, as shown in Fig. 15.

The pressure sensors used in this study showed a satisfactory repeatability for two out of the three sensors tested. Additionally, the sensors were found to have a usable pressure range of up to 66 kPa, which corresponds to the pressures experienced in upright cycling [10]. Sensor drift was found to be acceptable for four of the six tested sensors. Furthermore, as shown in test C, the non-linear behaviour results in a decreasing standard deviation of the sensor readings as the applied pressure increases. The results from the uniformity test seem to be in line with the theory presented in the *Brief technical background*. The resistance drops the most if the contact area of both electrodes is increased, but is more affected by the electrode sewn on top than by the electrode in between the resistive and base fabric. This difference is most obvious when looking at the results from the 'rectangle vertical' load case. How this translates to the integration of the sensors in the pressure mat is unknown. The qualitative performance of the sensors in the pressure mat is decent, as the sensors are able to capture the cyclic periods clearly, which can be seen in Fig. 15. Overall, these characteristics of the pressure sensors demonstrate their effectiveness in measuring pressure distribution in this study.

The behaviour of the pressure sensors is in line with the results found by Aigner et al. [15], although they found superior performance in terms of repeatability from sensor-to-sensor. Test C compared all 50 sensors produced and showed a relatively high standard deviation. This can be partly attributed to mistakes made during the delicate manufacturing process. In addition, the embroidery settings can be further optimised, such as the balance between the upper and lower thread tension, or the stitch length. It is important to optimise the embroidery process before starting production of the sensors, as this will increase the repeatability from part-to-part. Not much research has been done on different sensor designs, or how small design variations affect the sensor performance. It will be interesting to conduct further research into the different designs and the relationship with non-embroidered pressure sensors.

While the results of this study provide valuable insights, there are several factors that have affected the findings and should be acknowledged. The first being the two malfunctioning sensors in the pressure mat, which were replaced by a permanent grey square on the heatmap. The location of these two sensors is unfortunate, as they would be where the sit bones are seated. As a consequence, no good conclusion can be drawn on how the pressure distribution at the sit bones differs between saddles. During the saddle test it was also found that a few other sensors did not work as expected which increased gradually over the different tests. Replaceable sensors could be an improvement for a new version of this pressure mat, but this would need to be designed carefully to avoid introducing other flaws. Another improvement would be a DAQ system which presented the pressure distribution live during the tests. The presented DAQ system performed well but other systems may be more suitable for this use case.

Another limitation is the use of a single saddle cover. As can be seen in Fig. 3 and Fig. 16, not all three tested saddles are the same size. While the saddle cover was well-fitted for the traditional and the ISM saddle, the SQ lab saddle is considerably larger. Because of this, there were no sensors in the rear part of the saddle. Other pressure-sensing saddle covers, such as GeBiomized's [25], do not have this issue. They are specifically designed for road bike saddles, which have a more consistent geometry than city bike saddles. To tackle the wide variety of city bike saddles, it would be useful to increase the amount of sensors, design multiple saddle covers or separate the pressure mat from the saddle cover. Furthermore, the layout of the presented saddle cover can be improved. The layers are thin and therefore interfere minimally with the comfort experience, but are not very durable. The connections of the thread layer with the sensor layer and the copper wire cables were prone to defects. To combat the problems that arose from the different connections, it is advised to embroid the entire system in the least possible steps. Linking sensor patterns, as shown in the paper by Aigner et al. [15], could be very useful for this. It might increase the complexity of the system, but would eliminate the need for a thread cable layer.

The embroidered resistive pressure sensors were found to be feasible for the use in a pressure-sensing saddle cover, however there is significant room for future research as the literature on these sensors is scarce. Most of the tests during phase 1 were performed on only one or a few of the sensors, with a limited number of load conditions which differed from one test to another. The opportunity for improvement in the methodology of this phase is partly due to the vast possibility of tests that can be carried out. Investigating the drift and repeatability of the sensors for other load conditions can give a better indication of distinguishability of sensor readings. Conducting more tests will provide a better understanding of the non linear behaviour and performance of the sensors.

As the sensors fall under smart textiles, it would also be beneficial to test the sensors after incorporation in clothing, as it is currently unknown how the sensors react to washing, drying, and daily use. One feature that these sensors possess that other pressure sensors do not is the breathability property of textile. This could be valuable for studying, for example, foot pressure or bedsores. However, optimisation of the sensors is needed to get the performance closer to that of non-embroidered sensors.

The rationale of this study was to develop a test setup which can be used to compare solutions for the decreased cycling ability of females with vulvar cancer. An improved version of the pressure measuring saddle cover with fully functional sensors will be able to provide information of the total pressure distribution, also in the sit bones area. This will be a good objective tool, providing guidance in the saddle selection and adjustment process. This will hopefully increase sitting comfort while cycling and allow patients to use their bikes again.

V. Conclusion

In conclusion, the use of embroidered resistive pressure sensors to measure pressure distribution offers potential for use in low-cost prototyping. This study presented an effective test setup for analyzing the load distribution on a saddle. The developed pressure-sensing saddle cover was utilized to compare the pressure distribution on three different saddles. The saddle cover consisted of 32 pressure sensors of which the performance of the sensors was found to be adequate. As the sensors are fully customisable, further research into this relatively new field of research is required to optimise the performance and durability of the sensors.

References

[1] Y.-L. Chen and Y.-N. Liu, "Optimal protruding node length of bicycle seats determined using cycling postures and subjective ratings," *Applied Ergonomics*, vol. 45, no. 4, pp. 1181–1186, 2014.

[2] A. S. Larsen, F. G. Larsen, F. F. Sørensen, M. Hedegaard, N. Støttrup, E. A. Hansen, and P. Madeleine, "The effect of saddle nose width and cutout on saddle pressure distribution and perceived discomfort in women during ergometer cycling," *Applied Ergonomics*, vol. 70, pp. 175–181, 2018.

[3] S. J. Park, S. N. Min, M. Subramaniyam, D.-H. Lee, H. Lee, and D. G. Kim, "Analysis of body pressure ratio for evaluation of automotive seating comfort," SAE Technical Paper, Tech. Rep., 2014.

[4] A. Naddeo, R. Califano, and P. Vink, "The effect of posture, pressure and load distribution on (dis) comfort perceived by students seated on school chairs," *International Journal on Interactive Design and Manufacturing (IJIDeM)*, vol. 12, no. 4, pp. 1179–1188, 2018.

[5] R. Zemp, W. R. Taylor, and S. Lorenzetti, "Are pressure measurements effective in the assessment of office chair comfort/discomfort? a review," *Applied Ergonomics*, vol. 48, pp. 273–282, 2015.

[6] B. Belock, L. Kaiser, M. Lavagnino, and H. Clayton, "Comparison of pressure distribution under a conventional saddle and a treeless saddle at sitting trot," *The Veterinary Journal*, vol. 193, no. 1, pp. 87–91, 2012.

[7] E. Bressel, T. Reeve, D. Parker, and J. Cronin, "Influence of bicycle seat pressure on compression of the perineum: a mri analysis," *Journal of biomechanics*, vol. 40, no. 1, pp. 198–202, 2007.

[8] J. J. Potter, J. L. Sauer, C. L. Weisshaar, D. G. Thelen, and H.-L. Ploeg, "Gender differences in bicycle saddle pressure distribution during seated cycling," *Medicine & Science in Sports & Exercise*, vol. 40, no. 6, pp. 1126–1134, 2008.

[9] J. I. Priego Quesada, P. Pérez-Soriano, A. G. Lucas-Cuevas, R. Salvador Palmer, and R. M. Cibrián Ortiz de Anda, "Effect of bike-fit in the perception of comfort, fatigue and pain," *Journal of sports sciences*, vol. 35, no. 14, pp. 1459–1465, 2017.

[10] J. Freunek, S. Litzenberger, and F. Michel, "Saddle-pressure distribution and perceived comfort during inclined and upright cycling."

[11] Pngset, "Cyclist silhouette at getdrawings," 2022. [Online]. Available: https://pngset.com/download-free-png-lpmgx

[12] TopPNG, "road cyclist silhouette," 2022. [Online]. Available: https://toppng.com/road-cyclist-silhouette-PNG-free-PNG-Images_68927

[13] T. Preindl, C. Honnet, A. Pointner, R. Aigner, J. A. Paradiso, and M. Haller, "Sonoflex: embroidered speakers without permanent magnets," in *Proceedings of the 33rd Annual ACM Symposium on User Interface Software and Technology*, 2020, pp. 675–685.

[14] B. Bozali, S. Ghodrat, L. Plaude, J. J. van Dam, and K. M. Jansen, "Development of low hysteresis, linear weft-knitted strain sensors for smart textile applications," *Sensors*, vol. 22, no. 19, p. 7688, 2022.

[15] R. Aigner, A. Pointner, T. Preindl, P. Parzer, and M. Haller, "Embroidered resistive pressure sensors: A novel approach for textile interfaces," in *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems*, 2020, pp. 1–13.

[16] K. Weiß and H. Worn, "The working principle of resistive tactile sensor cells," in *IEEE International Conference Mechatronics and Automation, 2005*, vol. 1. IEEE, 2005, pp. 471–476.

[17] D. Agu, R. J. Eike, A. Cliett, D. Michaelson, R. Cloud, and Y. Li, "Investigation of e-textile dipole antenna performance based on embroidery parameters," *Textile Research Journal*, vol. 92, no. 15-16, pp. 2771–2783, 2022.

[18] N. Mazlan, M. Ramli, M. M. A. B. Abdullah, D. C. Halin, S. M. Isa, L. Talip, N. Danial, and S. Z. Murad, "Interdigitated electrodes as impedance and capacitance biosensors: A review," in *AIP Conference proceedings*, vol. 1885, no. 1. AIP Publishing LLC, 2017, p. 020276.

[19] "Silver-tech 120." [Online]. Available: https://www.amann.com/products/product/silver-tech/

[20] R. Schwödiauer, "Sheet resistance of carbotex and eeonyx," 2017.

[21] "Ina 125 datasheet," 1997. [Online]. Available: https://www.ti.com/lit/ds/symlink/ina125.pdf

[22] F. Baino, "Evaluation of the relationship between the body positioning and the postural comfort of non-professional cyclists: a new approach." *The Journal of sports medicine and physical fitness*, vol. 51, no. 1, pp. 59–65, 2011.

[23] H. H. Christiaans and A. Bremner, "Comfort on bicycles and the validity of a commercial bicycle fitting system," *Applied ergonomics*, vol. 29, no. 3, pp. 201–211, 1998.

[24] "Alles over frame- en zadelhoogte." [Online]. Available: https://www.fietsersbond.nl/de-fiets/onderdelen/fiets-op-maat/

[25] "Saddle pressure mapping." [Online]. Available: https://gebiomized.de/en/products/measurement/gp-bike/

Appendix A
Questionnaire bundle (Dutch)

Vragenlijstbundel: Mobiliteit van vulva-carcinoom patiënten.

De vragenlijst bestaat uit drie gedeeltes. Het eerste gedeelte is de EQ-5D-5L vragenlijst , waarmee we uw algemene gezondheid zullen inschatten. In het tweede gedeelte, de SQUASH vragenlijst, stellen we vragen over uw algemene mobiliteit. In het derde deel van de vragenlijst willen we met u nagaan in hoeverre de huidproblemen en de behandeling effect hebben gehad op het gebruik maken van de fiets.

Zet bij iedere groep in de lijst hieronder een kruisje in het hokje dat het best past bij uw gezondheid VANDAAG.

MOBILITEIT

Ik heb geen problemen met lopen ☐
Ik heb een beetje problemen met lopen ☐
Ik heb matige problemen met lopen ☐
Ik heb ernstige problemen met lopen ☐
Ik ben niet in staat om te lopen ☐

ZELFZORG

Ik heb geen problemen met mijzelf wassen of aankleden ☐
Ik heb een beetje problemen met mijzelf wassen of aankleden ☐
Ik heb matige problemen met mijzelf wassen of aankleden ☐
Ik heb ernstige problemen met mijzelf wassen of aankleden ☐
Ik ben niet in staat mijzelf te wassen of aan te kleden ☐

DAGELIJKSE ACTIVITEITEN *(bijv. werk, studie, huishouden, gezins- en vrijetijdsactiviteiten)*

Ik heb geen problemen met mijn dagelijkse activiteiten ☐
Ik heb een beetje problemen met mijn dagelijkse activiteiten ☐
Ik heb matige problemen met mijn dagelijkse activiteiten ☐
Ik heb ernstige problemen met mijn dagelijkse activiteiten ☐
Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren ☐

PIJN/ONGEMAK

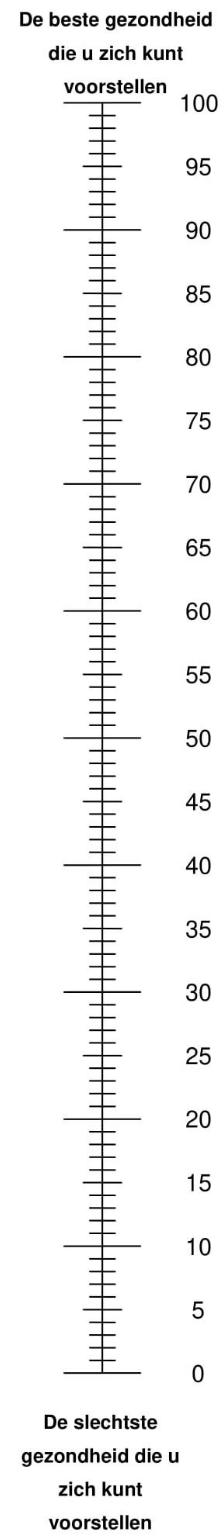
Ik heb geen pijn of ongemak ☐
Ik heb een beetje pijn of ongemak ☐
Ik heb matige pijn of ongemak ☐
Ik heb ernstige pijn of ongemak ☐
Ik heb extreme pijn of ongemak ☐

ANGST/SOMBERHEID

Ik ben niet angstig of somber ☐
Ik ben een beetje angstig of somber ☐
Ik ben matig angstig of somber ☐
Ik ben erg angstig of somber ☐
Ik ben extreem angstig of somber ☐

- We willen weten hoe goed of slecht uw gezondheid VANDAAG is.
- De meetschaal loopt van 0 tot 100.
- 100 staat voor de beste gezondheid die u zich kunt voorstellen.
  0 staat voor de slechtste gezondheid die u zich kunt voorstellen.
- Markeer een X op de meetschaal om aan te geven hoe uw gezondheid VANDAAG is.
- Noteer het getal waarbij u de X heeft geplaatst in het onderstaand vakje.

UW GEZONDHEID VANDAAG = ☐



Neem nu in uw gedachten een normale week in de afgelopen maanden. Wilt u aangeven **hoeveel dagen per week** u de onderstaande activiteiten verrichte, hoeveel minuten u daar dan **gemiddeld** op zo'n dag mee bezig was en hoe inspannend deze activiteit was?

WOON-WERK/SCHOOL VERKEER (heen en terug)	**aantal dagen per *week***	**gemiddelde tijd per *dag***		**inspanning (omcirkelen a.u.b)**
Lopen van/naar werk of school	☐ dagen	☐ uur	☐☐ minuten	langzaam/gemiddeld/snel
Fietsen van/naar werk of school	☐ dagen	☐ uur	☐☐ minuten	langzaam/gemiddeld/snel
Niet van toepassing	☐			

LICHAMELIJKE ACTIVITEIT OP WERK EN SCHOOL		**gemiddelde tijd per *week***	
Licht en matig inspannend werk (zittend/staand werk, met af en toe lopen, zoals bureauwerk of lopen werk met lichte lasten)		☐☐ uur	☐☐ minuten
Zwaar inspannend werk (lopend werk, waarbij regelmatig zware dingen moeten worden opgetild)		☐☐ uur	☐☐ minuten
Niet van toepassing	☐		

HUISHOUDELIJKE ACTIVITEITEN	**aantal dagen per *week***	**gemiddelde tijd per *dag***	
Licht en matig inspannend huishoudelijk werk (staand werk, zoals koken, afwassen, strijken, kind eten geven/in bad doen en lopen werk, zoals stofzuigen, boodschappen doen)	☐ dagen	☐ uur	☐☐ minuten
Zwaar inspannend huishoudelijk werk (vloer schrobben, tapijt uitkloppen, met zware boodschappen lopen)	☐ dagen	☐ uur	☐☐ minuten
Niet van toepassing ☐			

VRIJE TIJD	**aantal dagen per *week***	**gemiddelde tijd per *dag***		**inspanning (omcirkelen a.u.b)**
Wandelen	☐ dagen	☐ uur	☐☐ minuten	langzaam/gemiddeld/snel
Fietsen	☐ dagen	☐ uur	☐☐ minuten	langzaam/gemiddeld/snel
Tuinieren	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar
Klussen/doe-het-zelven	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar

Sporten (Hier maximaal 4 opschrijven)
bijv.: tennis, handbal, gymnastiek, fitness, schaatsen, zwemmen

1.	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar
2.	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar
3.	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar
4.	☐ dagen	☐ uur	☐☐ minuten	licht/gemiddeld/zwaar

TOTAAL
Op gemiddeld hoeveel dagen per week bent u, alles bijelkaar opgeteld, tenminste een half uur bezig met fietsen, klussen, tuinieren of sporten? ☐ dagen per week

In dit derde deel van de vragenlijst willen we met u nagaan in hoeverre de huidproblemen en de behandeling effect hebben gehad op het gebruik maken van de fiets. Neem nu weer in uw gedachten een normale week in de afgelopen maanden.

ALGEMEEN

Hoe oud bent u op dit moment? …………………… jaar

Bent u geopereerd aan de vulva?

Ja ☐

Nee ☐

Bent u bestraald op de vulva?

Ja ☐

Nee ☐

Fietsen

Ik heb geen problemen met fietsen ☐

Ik heb een beetje problemen met fietsen ☐

Ik heb matige problemen met fietsen ☐

Ik heb ernstige problemen met fietsen ☐

Ik ben niet in staat om te fietsen ☐

Kunt u aangeven hoelang u kunt fietsen? …………………… minuten

Kunt u aangeven hoe ver u kunt fietsen? …………………… kilometer

Kunt u aangeven op wat voor een fiets u fietst? *(meerdere antwoorden mogelijk)*

Stadsfiets ☐

Elektrische fiets ☐

Trekking fiets / mountain bike ☐

Racefiets ☐

Anders: ………………………………………………………………

KLACHTEN

Wij weten dat veel vrouwen verschillende klachten ervaren tijdens of na het fietsen. Kunt u *op de volgende bladzijde* aangeven hoe u de volgende klachten tijdens en na het fietsen ervaart?

Tijdens het fietsen:

Pijn in de zitbotjes

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Pijn in de huid van de schede/vulva

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Jeuk

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Schurend of brandend gevoel

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Andere klachten, namelijk:

……………………………………………………………………………………….

Na het fietsen:

Pijn in de zitbotjes

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Pijn in de huid van de schede/vulva

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Jeuk

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Schurend of brandend gevoel

Geen ☐ Een beetje ☐ Matig ☐ Ernstig ☐

Andere klachten, namelijk:

……………………………………………………………………………………….

Wordt u door de vulva belemmerd in het fietsen?

Nee, ik fietste voor de behandeling ook niet ☐

Nee, ik kan nog net zo goed fietsen als voor deze ziekte en behandeling ☐

Nee, door de behandeling is de belemmering verminderd of verholpen ☐

Ja ☐

Ik zou deze activiteiten in de toekomst vaker willen doen *(meerdere antwoorden mogelijk)*

Fietsen tot 2 km ☐

Korte fietstochten, 2 – 10 km ☐

Lange fietstochten, > 10 km ☐

Sporten op de fiets ☐

Geen ☐

AANPASSINGEN

Ook zijn wij benieuwd of u bekend bent met - en gebruik maakt van - hulpmiddelen voor het fietsen, zoals een speciaal zadel, andere afstelling of andere fiets.

Heeft u aanpassingen gedaan om weer beter te kunnen fietsen?

Ja ☐

Nee ☐

Indien ja, namelijk: *(meerdere antwoorden mogelijk)*

Een nieuwe fiets aangeschaft ☐
Andere afstelling van de fiets (bijv. zadelhoogte aangepast) ☐
Een nieuwe zadel aangeschaft ☐
Speciale fietskleding aangeschaft ☐
Anders, namelijk:

…………………………………………………………………………………………

Indien nee, bent u bekend met het bestaan van hulpmiddelen voor het fietsen?

Ik wist niet van deze hulpmiddelen af ☐
Ik wist dat deze hulpmiddelen bestonden, maar niet hoe ik hier aan moest komen ☐
Ik wist dat deze hulpmiddelen bestonden, maar dit is me de moeite niet waard ☐
Anders, namelijk:

…………………………………………………………………………………………

Er zijn speciale fietszadels op de markt om de druk op de vulva te verminderen.

Hoeveel zou u bereid zijn hieraan uit te geven als zo'n zadel voor u werkt?

0 - 50€ ☐
50€ - 100€ ☐
100€ - 150€ ☐
150€ - 200€ ☐
200+€ ☐

In verder onderzoek willen wij kijken hoe we het zitgemak van mensen kunnen verbeteren in de hoop dat fietsen (beter) mogelijk wordt, bijvoorbeeld door gebruik te maken van een aangepast zadel.

Bent u geïnteresseerd om hier (kosteloos) aan mee te doen?

Ja ☐
Nee ☐

Wilt u een bericht over de resultaten van het huidige onderzoek ontvangen?

Ja ☐
Nee ☐

Indien u bij een van de vorige twee vragen ja heeft ingevuld, kunt u hieronder dan aangeven hoe u benaderd wilt worden. *(mail/telefoon/brief etc.)*

…………………………………………………

Indien u nog vragen of opmerkingen heeft, kunt u die hier opschrijven.

Mobiliteit van vulva-carcinoom patiënten

Protocol ID	**OZBS82.22031**
Short title	**Mobiliteit van vulva-carcinoom patiënten**
Version	**1.0**
Date	**1 February 2022**
Coordinating investigator	*F. van Beurden* *f.vanbeurden@erasmusmc.nl*
Principal investigator	*Dr. Ir. N.J.P. van de Berg* *n.vandeberg@erasmusmc.nl*
Subinvestigator	*Dr. H.C. van Doorn* *h.vandoorn@erasmusmc.nl*
Sponsor	***Gynaecological Oncology, Erasmus MC*** ***BioMechanical Engineering, TU Delft***
Subsidising party	***Not applicable***
Independent expert	***Not applicable***
Laboratory sites	***Not applicable***
Pharmacy	***Not applicable***

PROTOCOL SIGNATURE SHEET

Name	**Signature**	**Date**
Coordinating investigator **Frank van Beurden**		**01-02-2022**
Principal investigator **Nick van de Berg**		**01-02-2022**
Head of department **Heleen van Beekhuizen**		**01-02-2022**

Inhoudsopgave

Mobiliteit van vulva-carcinoom patiënten 1
Summary 3
Rationale 3
Objective 3
Study design 4
Study population 4
Intervention 4
Main study parameters/endpoints 4
Nature and extent of the burden and risks associated with participation, benefit and group relatedness 5
Literatuur 5
Bijlage A: Brief patiënt 6

Summary

Rationale

De fiets is een onmisbaar onderdeel van het Nederlandse leven en wordt over de gehele wereld meer en meer als vervoersmiddel gebruikt. In Nederland zijn de 15 miljard kilometer die jaarlijks gefietst worden goed voor een kwart van al onze verplaatsingen (1). Ook in de literatuur komt de fiets goed naar voren, met voordelen in ecologisch, sociaal, economisch en gezondheidsgebied (2, 3). Buiten de voordelen zijn er ook nadelen aan het fietsen, zoals de zadelpijn die voortkomt uit het contact tussen de fietser en het zadel. Ongetraind een relatief lange fietstocht maken, de verkeerde afstelling van de fiets of een verkeerd zadel kan leiden tot pijn en gevoelloosheid van het zitvlak. Dit is een welbekend probleem, met een scala aan oplossingen en bedrijven die dit probleem trachten te verhelpen.

Bij vrouwen met vulvakanker is de huid van de vulva vaak dun en geïrriteerd, wat voor pijn zorgt in contact met een zadel. Voor hen kan deze activiteit zo pijnlijk worden, dat ze er soms voor kiezen om algeheel met fietsen te stoppen. Dit kan een grote impact hebben op de mobiliteit en de kwaliteit van leven, zeker in Nederland. Vulvakanker is een zeldzame vorm van kanker en het vertegenwoordigt 5 a 6% van de gynaecologische maligniteiten voor vrouwen (4). Risicofactoren voor het krijgen van vulvakanker zijn een infectie met het humaan papillomavirus en lichen sclerosus (5). Bij lichen sclerosus is de huid rondom de vulva ook dun en gevoelig, waardoor fietsen voor vrouwen met lichen sclerosus ook pijnlijk kan worden.

Dat fietsen pijnlijk is, komt door het contact van de vulva met het fietszadel. Er zijn speciale fietszadels op de markt die fietsen weer toegankelijk moet maken voor deze groep door dit contact te beperken, maar er is nog geen wetenschappelijke onderbouwing hiervoor.
Ook ontbreekt informatie over de impact die de vrouwen ervaren op hun mobiliteit door deze aandoening. In dit onderzoek willen we achterhalen hoe groot die impact is.

Objective

Het doel van deze studie is om informatie te verkrijgen over de ervaren kwaliteit van leven en veranderingen in mobiliteit bij vrouwen met vulvakanker. De aanname is dat hun mobiliteit, zeker als het gaat om hun fietsmobiliteit, is afgenomen door de aandoening en dat dit ook de kwaliteit van leven vermindert. Deze aanname zal via dit onderzoek onderzocht worden.

Study design

Het onderzoek maakt gebruik van een digitale vragenlijstbundel, welke zal worden uitgezet in het programma Castor. Deze vragenlijstbundel, genaamd vragenlijstbundel Mobiliteit van vulva-carcinoom patiënten, bestaat uit drie delen. Het eerste deel is de gevalideerde vragenlijst EQ-5D-5L, het tweede deel is de gevalideerde vragenlijst SQUASH (Short QUestionnaire to ASses Health enhancing physical activity) en het derde deel is een eigen vragenlijst, bestaande uit 10 vragen. De vragen van EQ-5D-5L en de eigen vragenlijst zijn voornamelijk meerkeuzevragen, bij SQUASH wordt gevraagd naar tijdsindicaties. De patiënten krijgen in een open veld de mogelijkheid om opmerkingen te maken. Wij schatten dat het invullen van de vragen 15 minuten in beslag zal nemen.

Study population

De studiepopulatie bestaat uit vrouwen die gediagnostiseerd zijn met een vulvacarcinoom in de laatste 5 jaar. Vrouwen die geen Nederlands spreken/lezen of waarvan geen emailadres beschikbaar is, worden geëxcludeerd. Vrouwen welke weinig tot niet fietsen worden ook geïncludeerd, niet relevante vragen worden voor hen uit de vragenlijst gehouden.

Intervention

Niet van toepassing.

Main study parameters/endpoints

De EQ-5D-5L vragenlijst wordt gebruikt om de kwaliteit van leven te beoordelen.

Primair eindpunt: Hebben de patiënten een lagere kwaliteit van leven dan gemiddeld? Van deze vragenlijst zijn normaalwaardes beschikbaar voor mensen in Nederland. Hiermee zullen de antwoorden vergeleken worden.

De SQUASH vragenlijst beschrijft de algemene mobiliteit.

Primair eindpunt: Voldoen de patiënten aan de bewegingsnorm? Deze bewegingsnorm is opgesteld door het Nederlandse Ministerie van Volksgezondheid. Deze vragenlijst wordt door het RIVM 4-jaarlijks afgenomen bij zo'n 400.000 Nederlanders, waarvan de data op te vragen zijn. Deze data zullen gebruikt worden om de antwoorden van de patiënten mee te vergelijken.

De eigen vragenlijst zal gebruikt worden om specifiek de fietsmobiliteit te beschrijven.

Primair eindpunt: Welke klachten ervaren patiënten door hun ziekte en voelen zij zich hierdoor belemmerd in het fietsen?

Data collectie

Alle gegevens worden onder een unieke patiënten-studie code worden verwerkt en opgeslagen. De onderzoeker houdt een apart en versleuteld studylog bij waarin de studiecode en de tot patiënt herleidbare gegevens staan. Rapportage zal gepseudonimiseerd worden gedaan.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

Deelname aan dit onderzoek heeft geen gevolgen voor de patiënt of haar behandeling. Er zijn geen risico's verbonden aan deelname aan het onderzoek. Er wordt eenmalig een vragenlijstbundel opgestuurd naar de patiënt. Het invullen hiervan zal ongeveer 15 minuten duren. Er worden geen ingrijpende, belastende of intieme vragen gesteld. De patiënt kan aangeven of ze in de toekomst eventueel benaderd zou willen worden voor verder onderzoek en of zij op de hoogte gebracht wil worden van de uitkomsten van de studie.

Literatuur

1) Centraal Bureau voor de Statistiek. (2021, 30 juni). *Mobiliteit; per persoon, persoonskenmerken, vervoerwijzen en regio's* [Dataset]. Geraadpleegd van https://opendata.cbs.nl/statline/#/CBS/nl/dataset/84709NED/table?dl=611E4
2) de Hartog, J. J., Boogaard, H., Nijland, H., & Hoek, G. (2013). Gezondheidsvoordelen van fietsen vele malen groter dan de gezondheidsrisico's. *Tijdschrift Vervoerswetenschap, 49*(1), 24-45
3) Pucher, J., & Buehler, R. (2008). Making cycling irresistible: lessons from the Netherlands, Denmark and Germany. *Transport reviews*, *28*(4), 495-528.
4) Siegel, R. L., Miller, K. D., & Jemal, A. (2019). Cancer statistics, 2019. *CA: a cancer journal for clinicians*, *69*(1), 7-34.
5) Rogers, L. J., & Cuello, M. A. (2018). Cancer of the vulva. *International Journal of Gynecology & Obstetrics*, *143*, 4-13.

Bijlage A: Brief patiënt

Informatiebrief

Officiële titel: Mobiliteit van vulva-carcinoom patiënten

Beste mevrouw,

In het verleden bent u gediagnostiseerd met een vulva-carcinoom (schaamlipkanker). Dit kan effect hebben op uw mobiliteit (de mate waarin u zich gemakkelijk kan verplaatsen), onder andere bij het fietsen. Op dit moment proberen we een beeld te krijgen van hoe groot dit probleem is door na te gaan hoe vrouwen dit ervaren. Wij willen daarom aan alle vrouwen die in de afgelopen vijf jaar gediagnostiseerd zijn met een vulva-carcinoom een aantal vragen voorleggen. Dit is de reden dat u deze brief krijgt. Wij hopen dat u de tijd wil nemen om de vragen te beantwoorden. Het invullen van de vragenlijst zal ongeveer 15 minuten duren.

Als u de vragenlijst volledig invult en verzendt, geeft u toestemming aan ons om uw antwoorden voor dit onderzoek te gebruiken. Om uw privacy te beschermen, zullen we uw gegevens coderen. Zodra de gegevens zijn verwerkt, zullen deze niet meer herleidbaar zijn. Deelname is vrijwillig: wel of niet deelnemen heeft geen gevolgen voor uw behandeling. Als u de resultaten van het onderzoek per email wenst of benieuwd bent naar verdere vorderingen, kunt u dat in de vragenlijst aangeven.

Wij willen u bij voorbaat hartelijk danken voor het invullen van deze vragen,

Met vriendelijke groet,
Het onderzoeksteam

Frank van Beurden, student Biomedical Engineering
Nick van de Berg, post-doc onderzoeker Gynaecologische Oncologie
Dr. Lena van Doorn, Gynaecologisch Oncoloog

Indien u nog vragen heeft over het onderzoek, kunt u contact opnemen via het volgende mailadres: f.vanbeurden@erasmusmc.nl, of via telefoonnummer +31 – 6 – 57 65 18 12.

Appendix C
Pictures of the saddle cover manufacturing process

Fig. 1. A batch of 24 sensors right after the embroidery process.

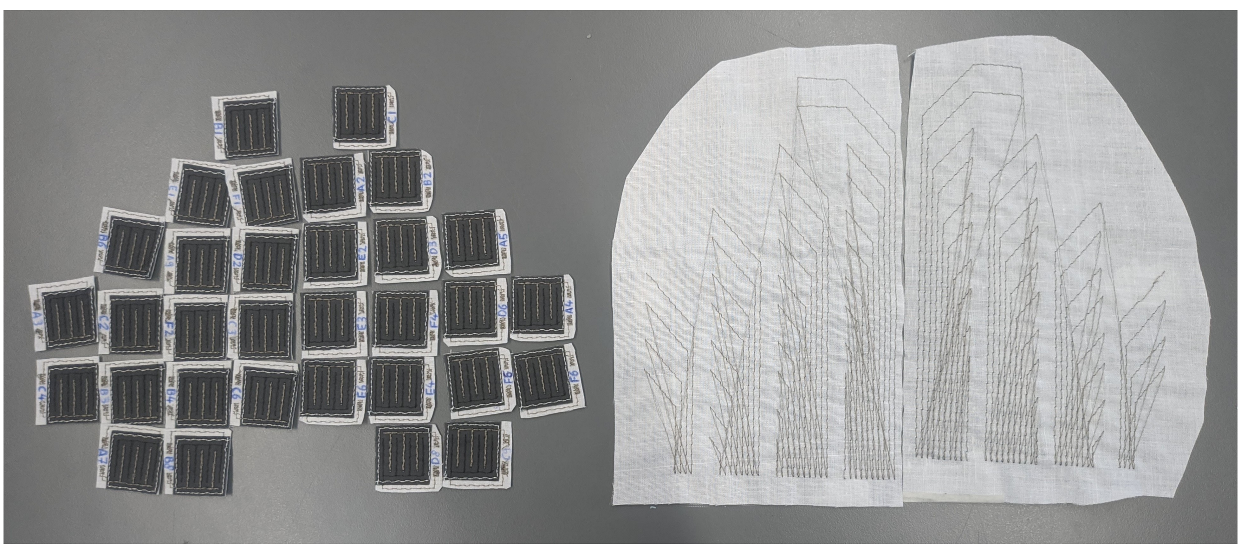


Fig. 2. The 32 selected sensors and the conductive thread layer.

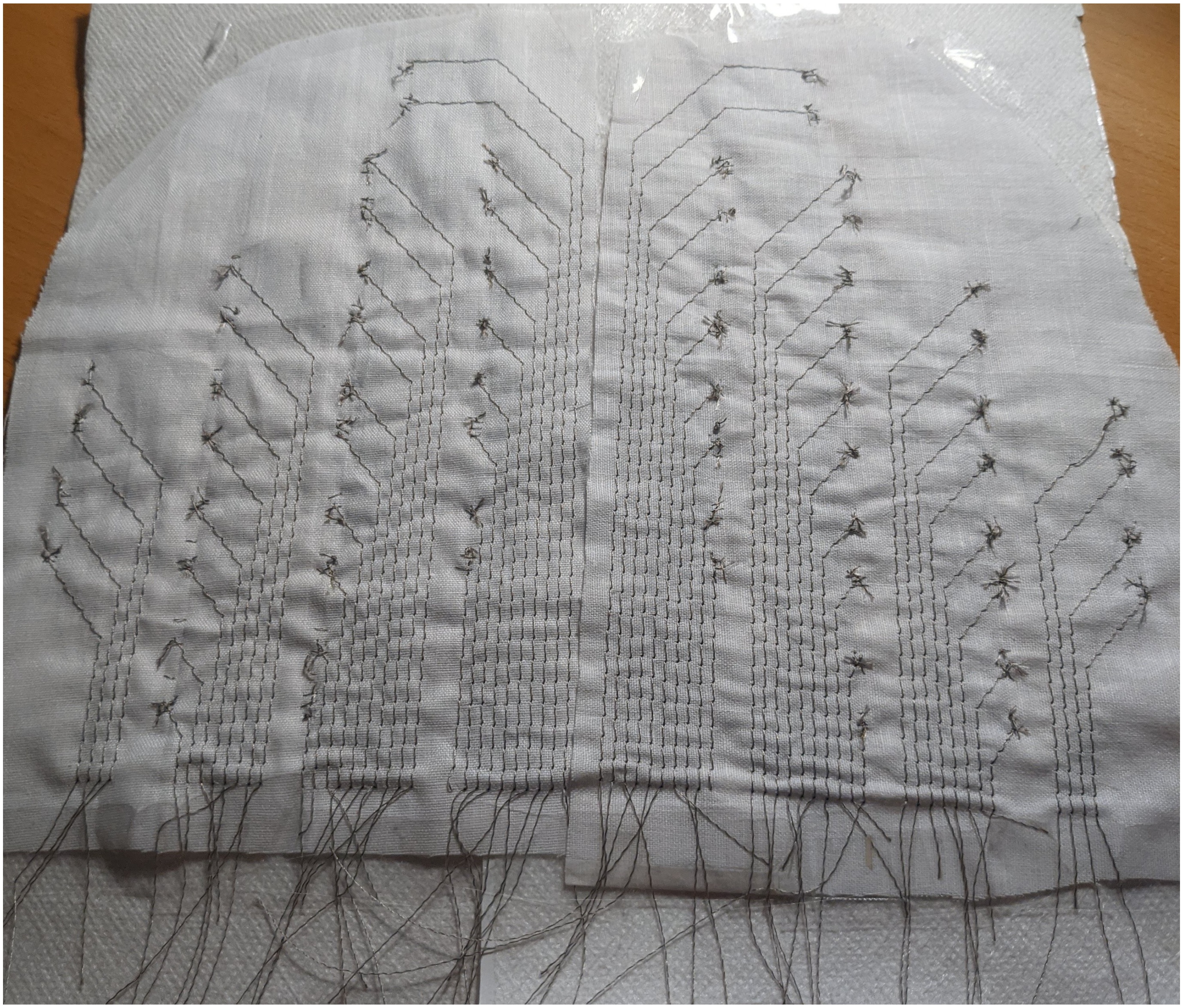


Fig. 3. The layer with conductive thread cable after manual connection to the sensor layer (not shown).

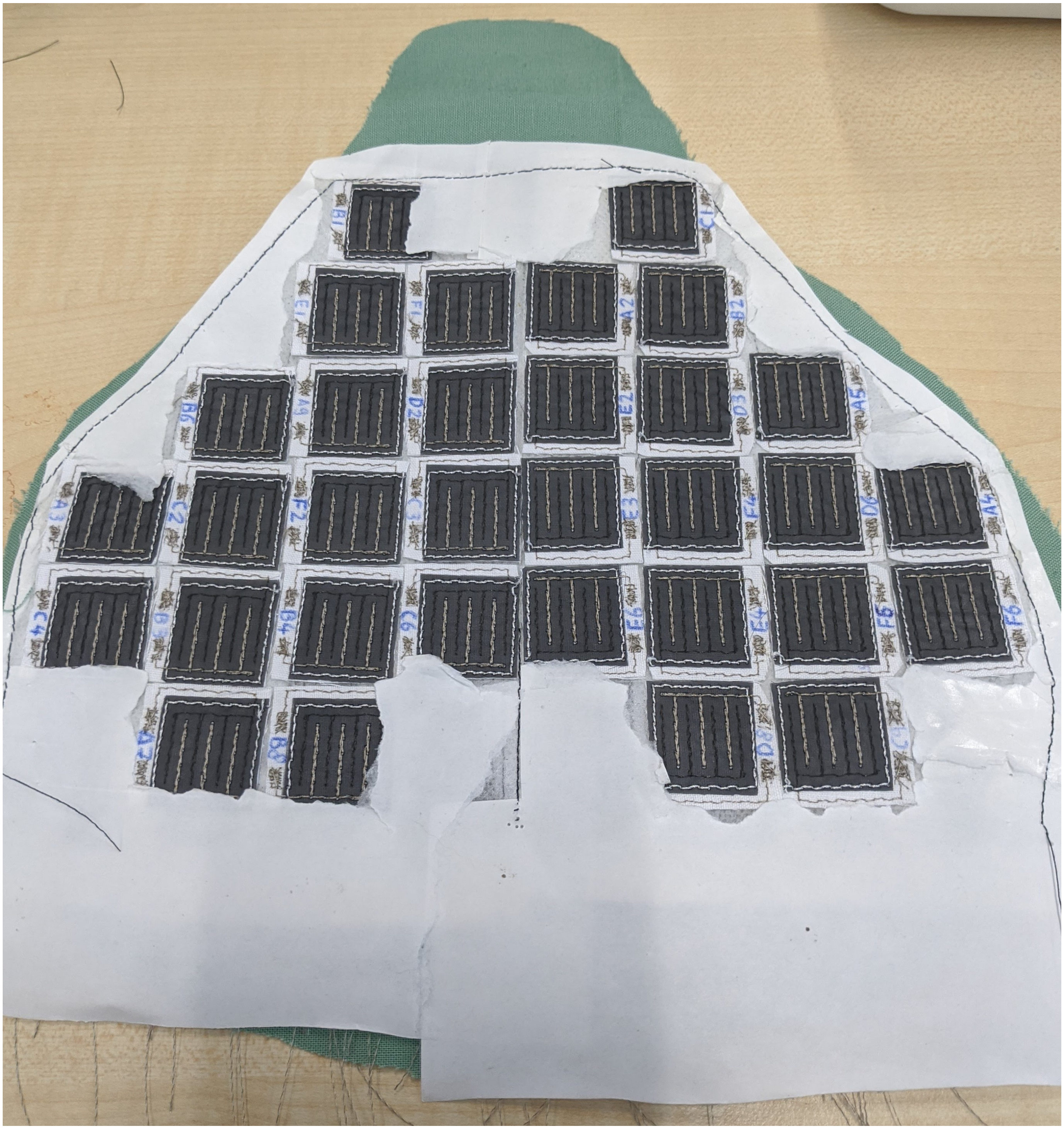


Fig. 4. The sensor and thread layer (not shown) attached to one layer of green fabric.

Fig. 5. Transition from conductive threads to usual electrical cables

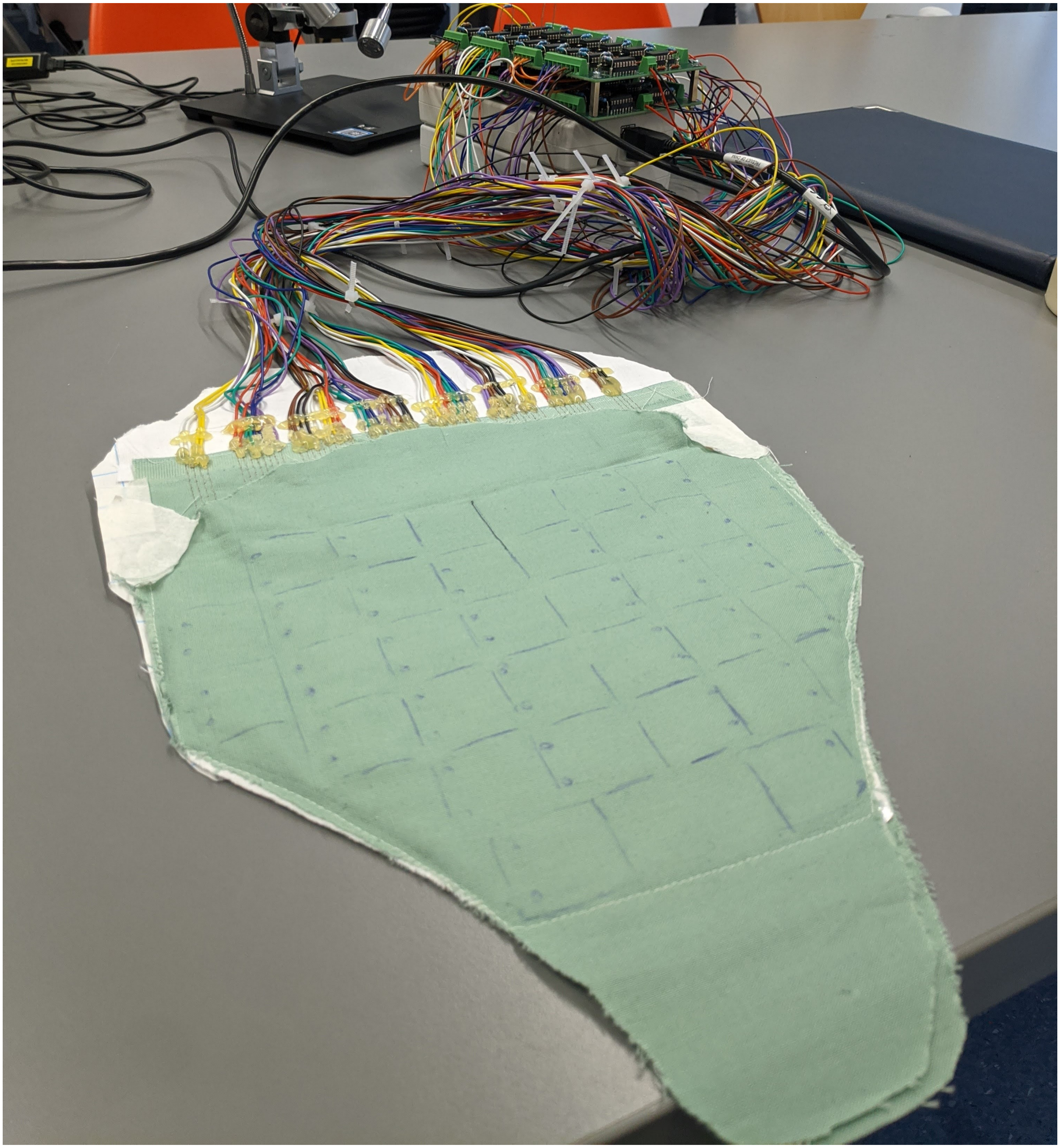


Fig. 6. Pressure mat

Fig. 7. The saddle cover attached to the pressure mat

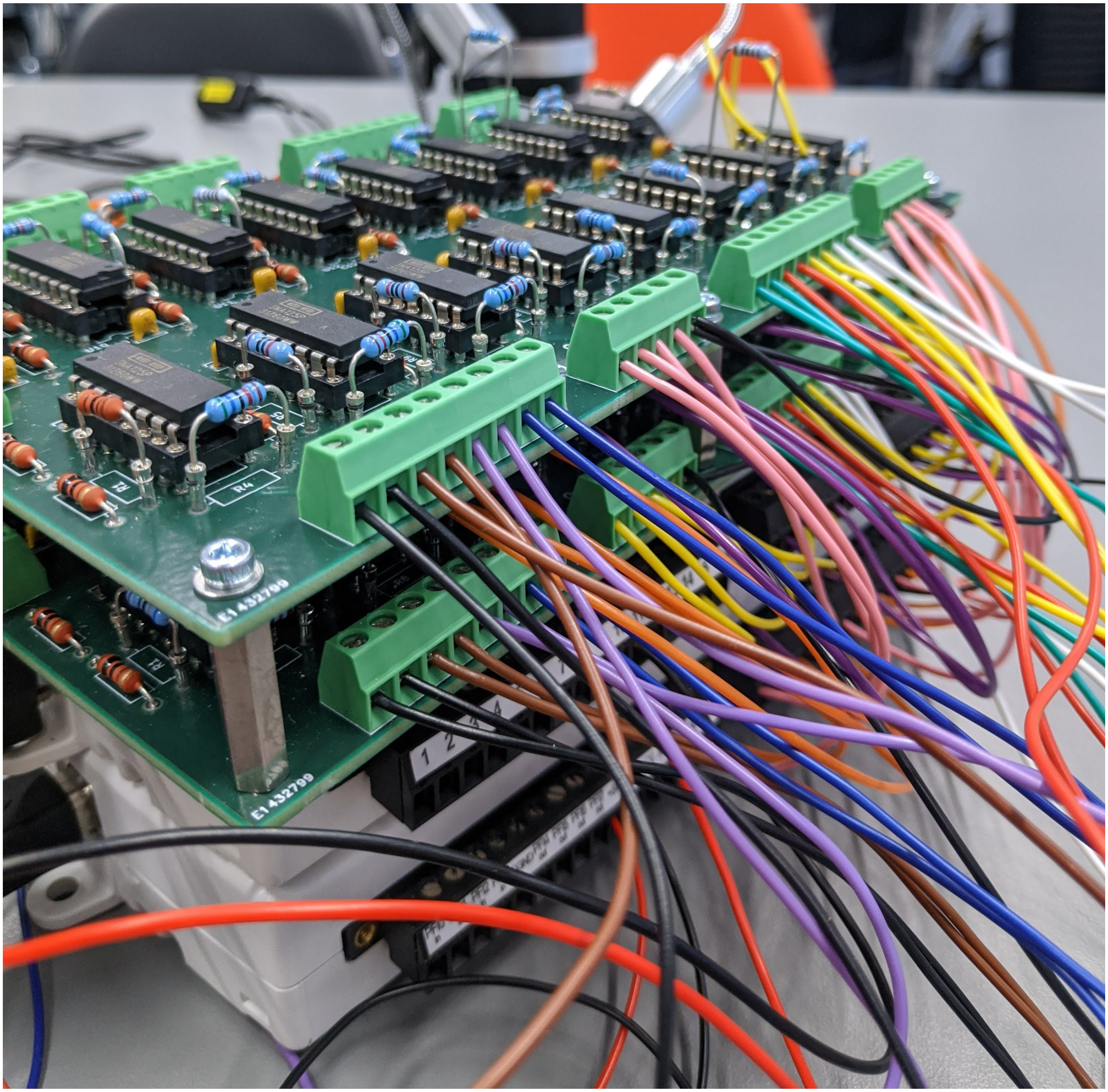
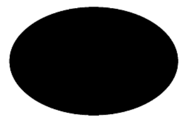
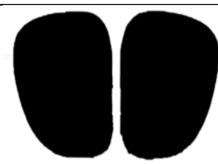


Fig. 8. Two circuit boards with amplifiers on top of the two DAQs.

APPENDIX D
SADDLE TEST QUESTIONNAIRE (DUTCH)

Afsluitende vragenlijst Zadeltest

1. Welke vorm zadel sluit het beste aan bij het zadel dat je thuis gebruikt?

1	2	3	4	5
				

☐ 1) traditioneel zadel
☐ 2) rokzadel
☐ 3) zadel bestaande uit twee delen
☐ 4) zadel met een uitsparing
☐ 5) sportief zadel
☐ 6) anders, namelijk: ………………………….

2. Waren de fiets en de zadels goed afgesteld?
   - Zadel A: ………………………………….
   - Zadel B: ………………………………….
   - Zadel C: ………………………………….

3. Hoeveel druk ervaarde je van het zadel tijdens het fietsen?
   - Zadel A: (geen, een beetje, matig, ernstig)
   - Zadel B: (geen, een beetje, matig, ernstig)
   - Zadel C: (geen, een beetje, matig, ernstig)

4. Kun je aangeven hoe je de volgende klachten ervaarde per zadel?
   - Pijn in de zitbotjes
     - Zadel A: (geen, een beetje, matig, ernstig)
     - Zadel B: (geen, een beetje, matig, ernstig)
     - Zadel C: (geen, een beetje, matig, ernstig)
   - Pijn in de huid van de schede/vulva
     - Zadel A: (geen, een beetje, matig, ernstig)
     - Zadel B: (geen, een beetje, matig, ernstig)
     - Zadel C: (geen, een beetje, matig, ernstig)
   - Jeuk
     - Zadel A: (geen, een beetje, matig, ernstig)
     - Zadel B: (geen, een beetje, matig, ernstig)
     - Zadel C: (geen, een beetje, matig, ernstig)
   - Schurend gevoel
     - Zadel A: (geen, een beetje, matig, ernstig)
     - Zadel B: (geen, een beetje, matig, ernstig)
     - Zadel C: (geen, een beetje, matig, ernstig)
   - Andere klachten, namelijk: ………………………….

5. Welk zadel vond je het meest en welke het minst comfortabel?

Appendix E
Calibration of pressure mat

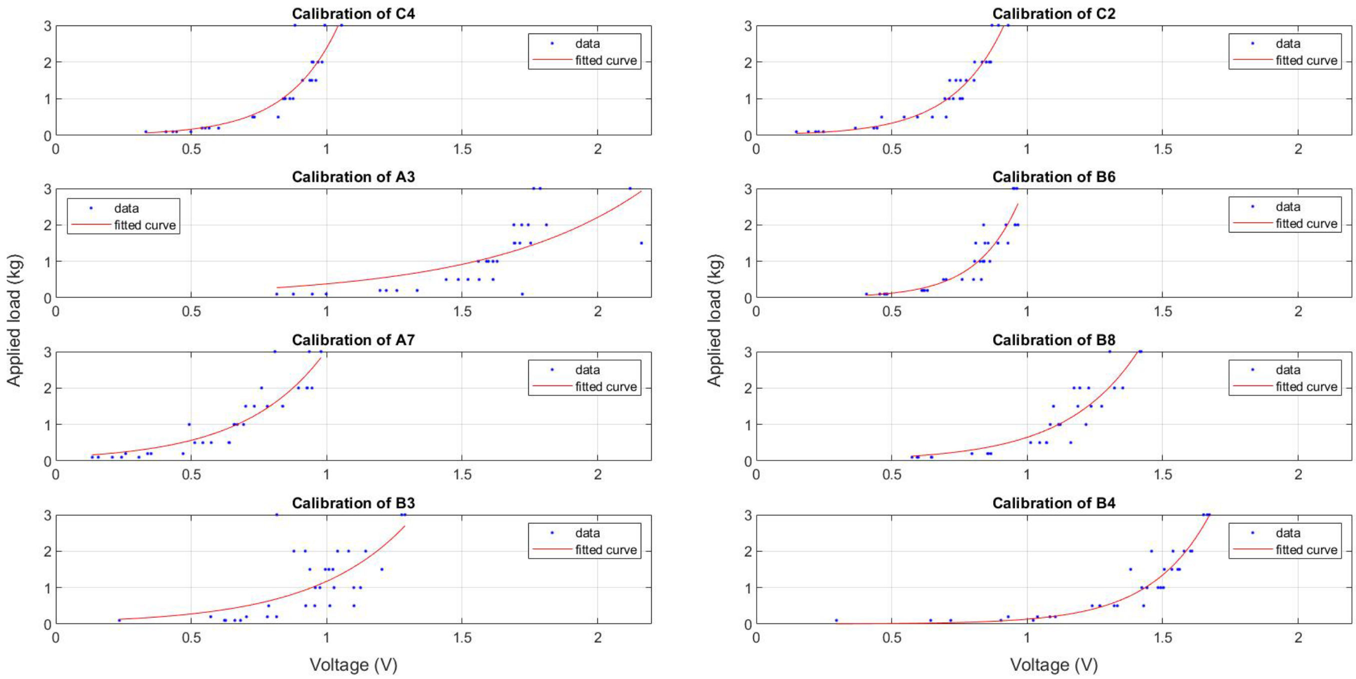


Fig. 9. Data and fitcurve for eighth sensors

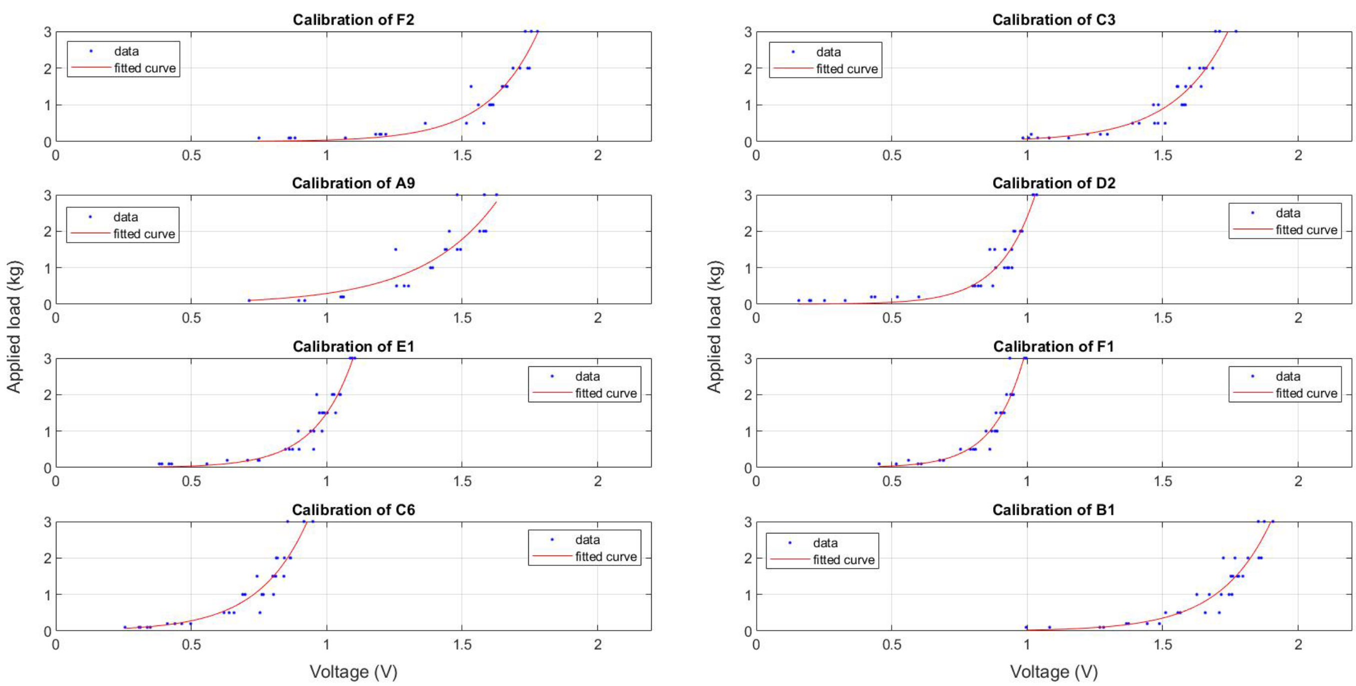


Fig. 10. Data and fitcurve for eighth sensors

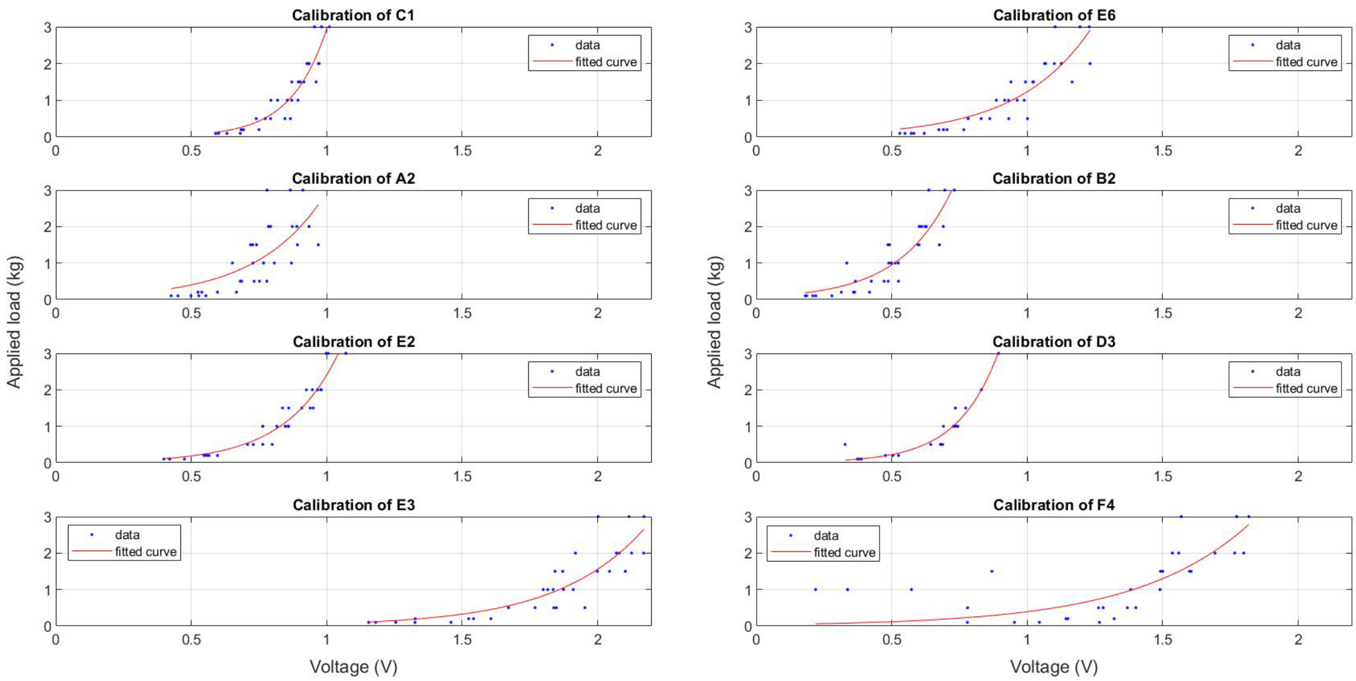


Fig. 11. Data and fitcurve for eighth sensors

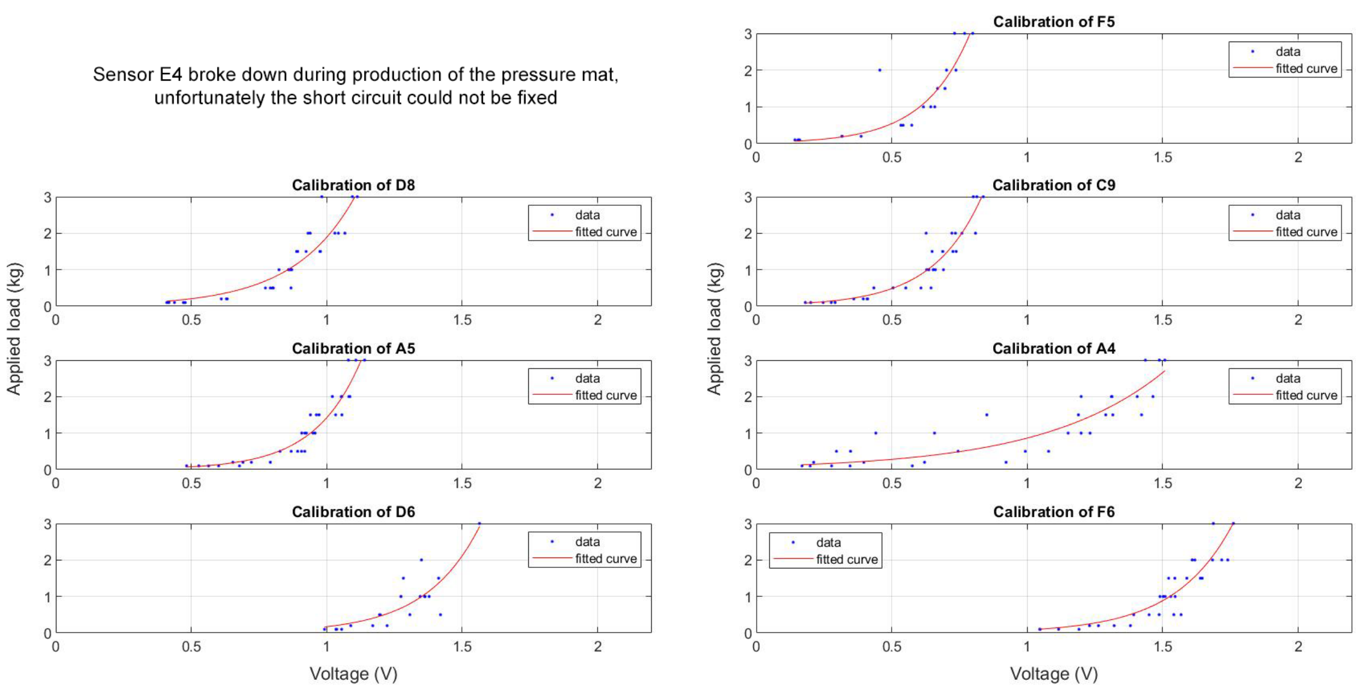


Fig. 12. Data and fitcurve for eighth sensors