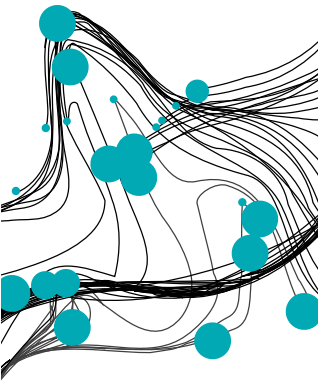

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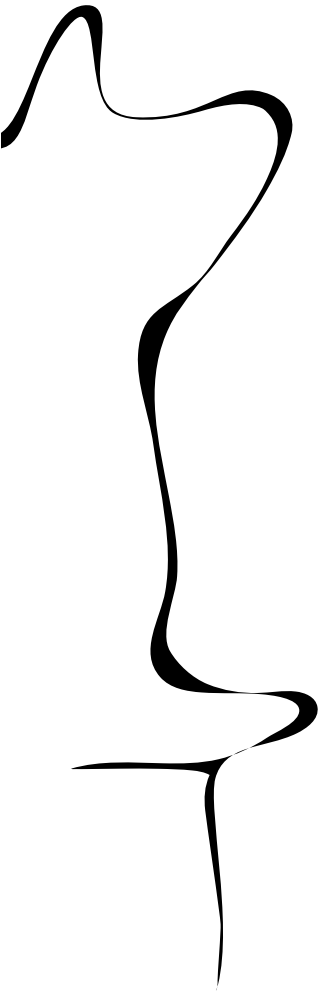

DESIGNING AN AT-HOME WOUND MONITORING DEVICE TO ADDRESS THE NEEDS OF PATIENTS WITH DIABETIC FEET AND THEIR HEALTHCARE PROVIDERS

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Abstract

This thesis investigates the development of an at-home wound monitoring device to address the challenges associated with diabetic feet patients. The primary objective is to translate the needs of patients, caregivers, and wound care specialists into design requirements for the device. This is carried out by conducting a literature review and state-of-the-art analysis by examining existing wound monitoring solutions and interviewing the relevant stakeholder groups, collecting their feedback. The study uncovers a compilation of software and hardware requirements, and proposes an initial concept of the device, outlining how these requirements can be incorporated into a functional design. The scope of the study is limited to diabetic feet patients, a subgroup of chronic wound patients. The results showcase a proposed solution that enables caregivers from homecare organisations to monitor patients' wounds at their residences quickly, easily and reliably. This solution embodies an at-home wound monitoring device that consists of a sensor module, a mechanical arm, and a foot stabilizer. The solution has been worked out into a functional prototype. The data collected with this solution holds the potential to predict future wound development. This research contributes to the field of chronic wound care by providing new insights into opportunities for at-home wound monitoring of diabetic feet.

Keywords:

Chronic wounds, diabetic feet, at-home monitoring device, context-of-use analysis, preference analysis, user-centred design, medical equipment design.

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1. Introduction

Background

Chronic wounds, also referred to as complex wounds, are wounds that do not progress through a normal, orderly, and timely sequence of repair [1]. It is estimated that there are approximately 500,000 patients with complex wounds in the Netherlands every year [2]. These wounds can have various underlying causes. Common variants include arterial and/or venous leg ulcers, pressure ulcers and diabetic foot ulcers [2]. The underlying causes are defined in the naming: arterial disease, prolonged pressure and diabetes. Currently, the monitoring and care of complex wounds comes with various challenges, affecting millions of patients and healthcare providers worldwide. Challenges include dealing with increased healthcare costs [3-5] and transport costs [3], and keeping up with regular visits to the hospital [see Appendix A-6]. Hospital visits are especially challenging for patients who struggle with transportation and require assistance from a caregiver. These challenges arise from the need for frequent periodic visits to the hospital, and from the fact that these visits often take a lot of time, due to the amount of care and wound monitoring that is required.

This research focuses on diabetic foot ulcers as a use case. These are wounds at the feet, caused by diabetes mellitus. This is a chronic, metabolic disease characterized by elevated levels of blood glucose. This reduces the ability of the skin to heal itself, which can result in problematic wounds. In 2019 it was estimated that there were more than 1.1 million patients with diabetes mellitus in the Netherlands [6].

The Diabetic Foot guideline describes that in 2015, there were at least 20,000 patients with a diabetic foot ulcer in the Netherlands [7]. This was with an estimated prevalence of 2 to 3% of the total diabetes population. Approximately 15% of these patients had to undergo an amputation of (a part of) the leg [7].

Research has also shown that timely identification of risk factors can prevent serious foot problems, including amputation [7]. The direct costs of treating a foot ulcer in the Netherlands in 2005 were approximately €16,000 [7]. One study showed that, when patients are timely referred to a wound expertise centre, it could reduce costs up to 2500 euro per patient per year [8].

Implications of an at-home wound monitoring device

Implementing an at-home wound monitoring device in homecare would provide an opportunity for proactive care; by monitoring and comparing wound images over time, the healing process can be tracked, interpreted, and potentially even predicted. Next to imaging, the device could possibly detect upcoming infections by measuring the temperature gradient across the foot and measuring bacteria presence with UV light. When the wound deteriorates, the system can alarm the healthcare provider on time, such that amputations can be prevented.

The need for research

Presently, wound care and wound monitoring is done at the patients' home, and at hospitals. An at-home wound monitoring device is necessary to reduce the amount of hospital visits required, improve the monitoring frequency and quality of at-home measurements. This would reduce the amount of time required per hospital visit, the workload for the healthcare professionals at the hospitals, healthcare costs and travel costs. Monitoring the wound more frequently increases the chance for timely identification of wound deterioration, and amputation prevention. There is a need for research on the possibilities for patients and caregivers to monitor the wound easily and reliably at home on a regular basis, such that the measurements can be sent to the hospital wirelessly.

Design thinking and context-of-use

This study makes use of design thinking as a method to find a practical solution for an at-home wound monitoring device. Design thinking can be defined as "A non-linear, iterative process that teams use to understand users, challenge assumptions, redefine problems and create innovative solutions to prototype and test" [9]. In the field of healthcare, design thinking has many practical implications that can be adapted to different circumstances [10]. It can be used to balance contextual factors like users, stakeholders, and resources with clinical evidence [10]. An important facet of design thinking is understanding the context of the problem before a developing a solution. This can be achieved through a context-of-use-analysis. This can be defined as "the dissection of the use of a product, system, or service into the various components of users, tasks, equipment (hardware, software, and materials), and physical and social environment in which the product, system, or service is used" [11]. When developing a medical device, doing an analysis on the intended context of use early on is useful to provide a (medical device) manufacturer enough information to make informed design decisions [12]. In one study, in order to improve a medical device, the context of use analysis consisted of exploratory interviews with patients and clinicians, observations of clinicians in the work context, and semi-structured interviews with clinicians [12]. Similar methods are used in this research: It consists of 7 interviews with clinicians and patients, and an observation day with a homecare organisation.

Stakeholders

An at-home wound monitoring device has many stakeholder groups. According to our work and analysis, the needs of four stakeholder groups are important for the physical design of the device: The diabetic foot patients, their qualified caregivers from home care organisations, the wound care professionals from the hospitals and the product developers [13]. These needs are identified in the context-of-use-analysis.

Research Questions

From the context-of-use analysis, we want to answer the following research question:

> "What physical design features should be incorporated into an at-home wound monitoring device to meet the needs of patients with diabetic feet and their healthcare providers?"

This question will be further examined by addressing the following sub-research questions:

> "What are the needs of patients with diabetic feet and their healthcare providers?"
>
> "What data about the patient and their wound is useful for the monitoring and healing prediction of diabetic feet?"
>
> "What monitoring methods can be implemented into the device to acquire patient- and wound data?"
>
> "How should the physical design of the device be developed to implement the necessary monitoring methods?

Report Structure

This thesis is divided into 4 chapters. Chapter 1 describes the current situation, addresses the need for research, and introduces the research questions. Chapter 2 starts out with a comparative context of use analysis to find the needs of the stakeholders (patients, qualified caregivers and healthcare professionals) regarding an at-home wound monitoring device. These user needs are then translated into functional requirements for the product. It also gives an overview of the state-of-the-art on existing

wound monitoring devices. This is followed up by chapter 3, Methods & Design. In this chapter, a decision is made on which mechanics should be implemented in the design, based on the functional requirements. Throughout this process, physical prototypes are realized through 3D printing. The end goal of the design phase is to have a concept for a basic functional prototype that meets the user needs. Chapter 4 concludes the report by summing up the main findings, answering the research questions and addressing future work. The appendices contain summaries of the interviews that have been conducted with patients, caregivers and wound care professionals, and an overview on what information is gathered during a patient's homecare treatment.

2. Background Research

Firstly, this chapter starts out with a comparative context of use analysis to find the needs of the relevant stakeholder groups for the wound monitoring device, and the resulting design requirements for the device. Secondly, this chapter gives an overview of the state of the art in the realm of wound monitoring devices.

2.1 Comparative context-of-use analysis

This context-of-use analysis compares the findings from research conducted at hospitals in the Twente area. These hospitals are the ZGT hospital in Almelo, the MST hospital in Enschede, and Deventer hospital (DZ). In addition, further field research has been done with an observation day at the national homecare organisation QualityZorg. In total, this analysis includes 7 interviews with key interviewees (see Table 1). Summaries of the interviews are showcased in Appendix A. These interviewees fall within the main stakeholder groups whose needs are specifically relevant for the design of the device, according to our work and analysis [13].

Name	Stakeholder group	Function	Institution
Eddy Koopman	wound care professionals from the hospitals	Wound care specialist	DZ / WEC
Miriam Blokhuis-Arkes	wound care professionals from the hospitals	Nurse practitioner, specialized in complex wounds and vascular surgery	MST / WEC
Mirjam Geling	qualified caregivers from home care organisations	Qualified wound nurse	QualityZorg
Josine Cornet	qualified caregivers from home care organisations	Qualified wound nurse	QualityZorg
Annemiek Stienstra	qualified caregivers from home care organisations	Nurse practitioner with 20 years' experience with diabetic foot	QualityZorg
Patient 1	diabetic foot patients	Diabetic foot patient	QualityZorg (patient)
Patient 2	diabetic foot patients	Diabetic foot patient	QualityZorg (patient)

Table 1. Key interviewees.

2.1.1 Interview Testimonials

Interview Eddy Koopman

Eddy Koopman is a seasoned wound care specialist at the wound expertise centre at Deventer hospital. He pointed out that he expects that merely 10 to 20% of patients would be able to use a monitoring device independently. This is because of their poor physical condition, and old age. He pointed out that the average age of patients with chronic wounds is easily 70 or higher. The average age of patients with specifically diabetic feet is 71 [see Appendix A-1]. This age range also comes with a lack of experience with modern technology. He pointed out that with this patient category, it is a good idea to let caregivers from home care organizations handle the device when they visit the patient and care for their wounds. According to him, the device would need to be as simple as possible, and it would be useful to have it operated using a mobile phone.

Interview Miriam Blokhuis-Arkes

Miriam Blokhuis-Arkes is a nurse practitioner at the Wound Expertise Centre (WEC) at Medisch Spectrum Twente (MST). She is specialized in diagnosis and treatment of complex wounds and the negative factors which influence wound healing and in vascular surgery. She has shaped the diabetic foot clinic, which became the WEC. She mentions 90 to 95% of diabetic feet patients receive homecare. Their bandages are changed 2 to 3 times per week, and only a small number of patients can do this

themselves. She also mentioned that keeping the foot still is often not a problem. Sometimes there are spasms / vibrations, but this is quite rare. Regarding the device, Mirjam states that it is desirable. She recommends that it should be transportable, easy to disinfect and not too bulky. Ideally it should be self-thinking and have an alarm function [see Appendix A-2].

Interview Mirjam Geling

Mirjam Geling, qualified wound nurse from QualityZorg has confirmed similar judgements regarding who should be using the device. To make measurements of the wound, bandage removal is essential. According to her, most patients are not able to remove or replace their bandages on their own. Only some younger patients or informal caregivers could be able to learn it. In addition, she explained that patients with diabetic feet receive home-based wound care by a qualified wound nurse, ranging from daily to 2 or 3 times per week. Currently they have a policy to take a photo weekly, which is enough to see the healing trend. During these visits, the wound nurse gathers patient- and wound data (including pictures) in an electronic patient's file (EPD) called PatDoc. This is accomplished through an iPad application and requires an account with nurse privileges. Her impression of the device is positive. She approves the use of UV-light to detect bacteria presence, as it eliminates the need for obtaining a wound culture. She also approves to do temperature measurements all over the foot. She thinks the use of a mechanical arm is ideal, since manually taking photos can be difficult. She recommends that the device should make quality photos, be user friendly and has no sharp corners. The footrest should be ergonomic, lightweight, easy to set up, easy to carry and small [see Appendix A-3].

Interview Josine Cornet

Josine Cornet is a qualified wound nurse at QualityZorg, a nationwide homecare organization specializing in complex wound care. She works in the Rotterdam region. Besides homecare she works at multiple hospitals. She works at the Maasstad hospital, where she helps many patients with burn wounds. She also collaborates with the Erasmus hospital, where she helps patients with dermatological diseases. She mentions during the interview that most caregivers from QualityZorg drive to the patients with a small car, and some use an electric bike [see Appendix A-4]. In addition, some patients live in flats without a working elevator. This is important to consider regarding the transportability of the device. Josine mentions that wounds can occur on the side or bottom of the foot or can be as large as the entire top of the foot, in case of an amputation wound. However, she mentions that diabetic foot patients have virtually no wounds on the ankles. This is useful information for developing a foot stabilizer. Regarding the device she thinks it is useful if it can identify problems at an early stage to prevent amputations. She most notably recommends that the device should be very easy to use for the patients, such that they should only have to place their foot. It should be about the size of a paving stone, being 40 x 30 x 15 cm. It should also be integrated into an existing healthcare software system for documentation. She suggests using a screen or box for darkening the wound for taking a picture. More recommendations from Josine can be found in Appendix A-4.

Interview Annemiek Stienstra

Annemiek Stienstra is a nurse practitioner at QualityZorg. She has 20 years of experience on diabetic foot. She has done a poster presentation on the data QualityZorg has gathered about diabetic feet patients, at the International Diabetic Foot Congress. This event takes place in The Hague, once every 4 years. She mentioned that during an at-home visit, foot positioning can differ quite a lot, since they must improvise. Obese patients usually cannot get the foot to knee height, so their foot should rest lower [see Appendix A-5]. She also mentioned that the detection of bacterial flora is not that useful, as it does not change the treatment. This conflicts with the opinion of Mirjam Geling. However, she does state that bacterial detection is of added value compared to what is already measured with PatDoc. Annemiek does state that it should measure signs of infection (redness, swelling and warmth) as these change the treatment that is required. Temperature measurement should be accurate in the range of +- 0.2 degrees Celsius. She most notably recommends that the device should be below 15 kg (according to ARBO regulations), and that it can be used standalone, without the need for a stool of some sort. She also

suggests using a one-time use plastic cover for darkening the wound when taking a picture. She agrees that the device should be somewhat self-thinking and can send messages about the wound healing progress. More recommendations from Annemiek can be found in Appendix A-5.

Interview Patient 1

Patient 1 is a male of 59 years old and has diabetes. He currently has an amputation wound on his left foot. The front of this foot has been amputated about 1 year ago. He has no feeling in the wound. He wears a cast with support blocks and receives home care 3 times a week. He visits the hospital once every 2 weeks, but he struggles to do this regularly. This is because he needs help with driving a car and walking inside from the parking lot. He indicates that comparing the wound before and after a period of 3 days, is significantly less insightful than when comparing the wound over a period of 2 to 3 weeks. This gives an indication for monitoring duration. The patients first impression of the device is positive. However, he doubts whether the device can accurately predict progress with just surface measurements, as internal factors are also important. He states that he is willing to use the device and would feel safe to do so when the device would move independently. During the interview, caregiver Josine Cornet stated that it would be useful if a light turns on and a sound goes off when the device starts to move independently.

Interview Patient 2

Patient 2 is a male of 54 years old and has diabetes. He currently has an open wound on the bottom of his right foot, between the sole and the toes (see Figure 14, Appendix A-7). This wound has formed and become infected around early 2020. The index and middle toe have been amputated in 2018. The patient can feel sensations and pain everywhere on the foot, except for in the wound. The wound is treated twice per week, with a duration of about 30 minutes. He also has very bad vision and cannot wear glasses because he receives injections that keep changing his vision. Because of this and the wound location, it is difficult for him to view the wound. During a homecare visit, he lies on his back on the couch, with his leg on the armrest of the couch (see Figure 15, Appendix A-7). His first impression of the device is okay. He is curious if the device can help him in his situation. He likes to be informed by the caregiver of the progress of the wound. He is willing to use the device if a caregiver would offer it and would feel safe to do so.

2.1.2 Stakeholder Needs

According to our work and analysis, there are four main stakeholders groups whose needs are specifically relevant for the design of the device [13]. These stakeholders include patients, healthcare professionals (at the hospitals) and caregivers (at the patient's home), and the product development team.

The needs of the first three stakeholders are found by conducting semi-structured interviews, as showcased in the interview testimonial section and Appendix A. The needs of the fourth stakeholder group are found through discussions with various professionals from the Robotics and Mechatronics group at the University of Twente. The needs are divided into 3 categories: hardware, software, and user experience. This is done because this study focuses particularly on the physical design, and further studies will continue with the software. The resulting stakeholder needs are depicted in Table 2.

	Patients	Healthcare Professionals (at the hospitals)	Caregivers (qualified homecare nurses)	Product development team
Hardware	Safe	High quality images	Easy to disinfect	Sustainable
	Robust / not vulnerable	Measures temperature gradient across the foot	Easy to set up	Commercially viable
	Can monitor all areas of the foot	Measures bacteria and fungi presence	Transportable	
	Stabilizes foot	Measures type of bacteria and fungi	Robust / not vulnerable	Low maintenance
	Comfortable / Ergonomic / Soft	Consistent exposure	Consistent exposure	Accurate positioning
	Usable at patients' home	Minimised external light	Simple / Minimalistic	Consistent positioning
	Sturdy and heavy		Compact / Small	
			Light	
			Standalone (no need for a stool)	
User Experience	Easy to use / user-friendly / low use resistance		Easy to use / user-friendly / low use resistance	
	Brief usage time		Brief usage time	
			Has a user manual	
			Gives adequate positioning guidance during use (if operated manually)	
Software	Provides accurate feedback on wound status	Sends updates on healing process remotely	Provides accurate feedback on wound status	Complies with international guidelines for medical devices and data privacy
	Motivates use by indicating progress	Self-thinking: Analyses wound data and presents conclusions	Allows for additional data input	
	Data privacy	Trustworthy conclusions		
		Alerts when needed, based on conclusions		
		Allows for a method to get an insight of the overall location of the wound		
		Compatible and integrated with healthcare data systems		
		Streamlined wireless information exchange with hospitals		
		Calculates surface area		
		Calculates tissue type distribution		
		If possible, can interpret or measure humidity. Without touch.		

Table 2. Stakeholder needs for the device.

2.1.3 Design Requirements

The needs of the stakeholders can be translated into design requirements for the device. These requirements are defined to be clear and quantifiable. This means that there is no room for misunderstanding and design errors, and the design can be validated. The translation of needs into design requirements is depicted in Table 3.

Need	Design requirement
High quality images	Camera quality of at least 12.3 MP [13]
High quality images	Autofocus
Sends updates on wound healing remotely	Wi-Fi (connectivity for secure data transfer to hospital)
Simple	Has enough internal data storage to independently store measurements from the sensors
Ease of use	Bluetooth
Ease of use	Wireless [13]
Ease of use	Power storage for a full day of use, max 12 patient visits [Appendix A-4]
Ease of use	Can be controlled by a mobile phone
Ease of use	Height Adjustable
User-friendly	Device accommodates most feet sizes (between EU size 30 and 48) [14]
Easy to transport	Device should fit within the dimensions of a small suitcase of 40x30x15 cm [Appendix A-4]
Easy to transport	Includes features to improve transportability (e.g. handles, folding, wheels)
Light	Weight in between 1 and 15 kg, according to ARBO regulations [Appendix A-5]
Safe	Must not touch or damage the wound / skin
Safe	Does not have sharp corners
Safe	Foot stabilizer contact points are easy to disinfect: Smooth surfaces, non-porous, simple shapes, cleaning chemical resistant, devoid of gaps and crevices
Stabilizes foot	Includes foot stabilizer that can stabilize feet in multiple orientations
Stabilizes foot	U-shaped foot stabilizer
Comfort	Foot stabilizer is ergonomic and soft
Can monitor all areas of the foot	4 degrees of freedom servo arm with wide range of motion
Can monitor all areas of the foot	Camera can position itself perpendicular to every surface of the foot
Accurate positioning	Range finder sensor with a minimum sensing distance of 8 cm and an accuracy of +- 5mm
Accurate & consistent positioning	Automatic positioning
Can measure temperature	Infrared camera with an accuracy of about +- 0.2 degree Celsius ideally. Otherwise, 1 degree Celsius [Appendix A-3]
Can measure bacteria presence in wound	High-efficiency UV LEDs with a wavelength of 405 nm [15-16]
Consistent exposure	Dimmable White LEDs with diffuser plate
Minimised external light	Includes a feature to darken the wound (e.g. DarkDrape, sheet, screen, box)

Table 3. Design requirements.

2.2 State of the art: Wound monitoring devices

The current landscape of wound healthcare already makes use of various devices for monitoring wounds at the feet area. This section showcases 6 devices from this landscape by outlining their functions and comparing them.

One notable device from this realm is the **MolecuLight**. It has 2 versions: The MolecuLight i:X and the MolecuLight DX [17]. These devices are depicted in Figure 1a and 1b. These are fully developed handheld fluorescence imaging devices designed for wound care. They are used to detect and localize elevated bacterial loads in chronic wounds. The devices work by emitting a specific wavelength of ultraviolet light (405nm) that causes bacteria to fluoresce. In combination with the use of an optical filter, the bacteria are made visible under the device's camera. When making fluorescence images, it is required for the room to be darkened. The devices can also make normal pictures and digitally measure wound dimensions.

Figure 1a. MolecuLight i:X in use [18].

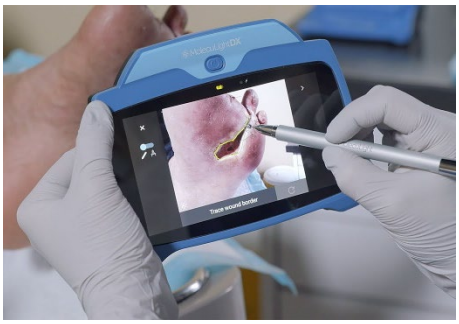

Figure 1b. MolecuLight DX in use [19].

The **PRODIGI** (**P**ortable **R**eal-time **O**ptical **D**etection **I**dentification and **G**uide for **I**ntervention) is also a handheld fluorescence imaging device that enables real-time, high-resolution visualization of key pathogenic bacteria in wounds [20]. It is a prototype device, used for clinical investigational testing. An image of the PRODIGI device in-use can be seen in Figure 2.

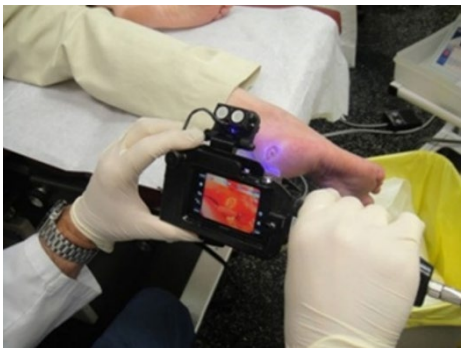

Figure 2. The PRODIGI in use [20].

The **FlirOne Pro** is a commercial thermal imaging camera attachment for smartphones. In one study, this device was used together with a Samsung Galaxy Tab S4 to create a 3D model of a foot with both thermal and colour data [3]. The goal of the study was to such a model using low-cost commercial devices to facilitate wide deployment in hospitals and remote care centers. The 3D model was made with the use of "Structure from Motion" (SfM) photogrammetry. The images are taken handheld, in a recommended arc-shape motion, such that a 3D model could be fabricated. The thermal data is then projected onto this model. These resulting data can be useful for both raising patient awareness and clinical evaluation. However, more research is required to define the relationship between the different metrics and the evolution of the wound. An image of the FlirOne Pro device being used for this study, can be seen in Figure 3.

Figure 3. The FlirOne Pro being used for thermal photogrammetry [3].

The company **DEMCON** has manufactured a **photographic foot imaging device** that makes high quality photographs of the plantar surface of the foot [4]. The goal of this device is to assess the signs of diabetic foot disease. The device is used by placing the feet in heel cups and resting them against an adjustable foot support bar. By pressing a button, the device takes 3 pictures of the bottom of the feet, with different lighting conditions. The device can be seen in Figure 4. The device has some disadvantages: The support bar blocks vision on a part of the foot, and it touches the skin. It also can not take pictures of other parts of the foot, aside from the plantar surface.

Figure 4. The photographic foot imaging device manufactured by DEMCON [4].

One case study conducted by Chanjuan Liu at the University of Twente, together with the company **DEMCON**, developed an **experimental setup** for diabetic foot imaging [21]. This setup is shown in Figure 5. The device had three functions: Thermal imaging, hyperspectral imaging and photometric imaging. The ultimate objective of the study was to develop an intelligent telemedicine monitoring system that could be deployed at the patients' home environment for frequent examination of the patients' feet, to detect pre-signs of ulceration in a timely manner.

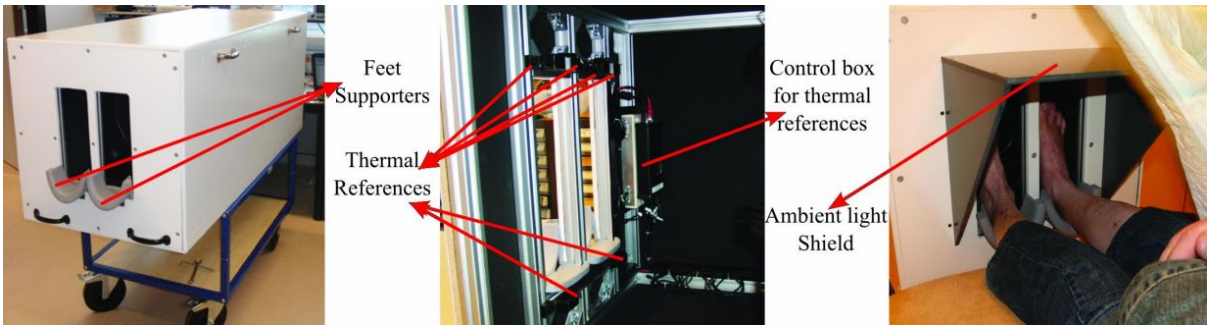

Figure 5. The experimental setup for diabetic foot imaging [21].

During at-home visits, wound nurses at national homecare organisation QualityZorg make use of an electronic patient file (EPD) called **PatDoc** [see Appendix A-3]. This EPD stores substantial patient- and wound-data. It can be used with a website, or an application that can be downloaded on any modern smartphone or tablet. It can also be used to take and store pictures of the wound. Data is manually entered in PatDoc by the qualified wound nurse, with the help of their required expertise. To enter new data, it is required to log in with a nurse account. A patient can log in with his personal account, to view his monitoring history. PatDoc is specific to QualityZorg, and most hospitals and general practitioners that work together with QualityZorg can access it. Figure 6 shows PatDoc being used during an at-home visit. An overview of the data that is being stored in PatDoc, can be found in Appendix A-7.

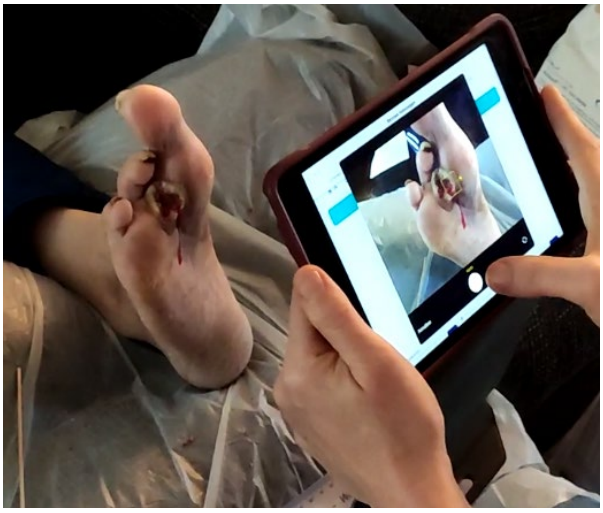

Figure 6. PatDoc being used to take a picture of a diabetic foot wound. (René van Koolwijk ©)

The competitive edge

As shown above, there are quite a few wound monitoring devices on the market. We can compare these existing solutions with a competitive matrix (see Table 4). This matrix outlines the desired features by end users, and to what extent each solution has them. To ensure that our new concept has a competitive advantage compared to the existing solutions, it should embody most, if not all features. As shown in the table, there is not a wound monitoring device currently on the market that combines temperature measurements, bacterial measurements, and automatic, non-handheld camera positioning. When these methods are combined into one device, the measurements will provide a more comprehensive understanding of the wound history and status. This understanding can aid in the prediction of the future healing progress of the wound. It's not certain if a program can use the measurements to predict wound healing independently, without a qualified wound care professional. But if this is possible, that would be ideal.

	MolecuLight i:X / DX	PRODIGI	FlirOne Pro + smartphone	DEMCON photographic foot imaging device	DEMCON experimental setup	PatDoc	New concept at-home wound monitoring device
Bacterial measurement	✓	✓	✗	✗	✗	✗	✓
Temperature measurement	✗	✗	✓	✗	✓	✗	✓
Photographic Images	✓	✓	✓	✓	✗	✓	✓
Video	✓	✓	✗	✗	✗	✓	✓
Portable	✓	✓	✓	✗	✗	✓	✓
Low-cost	✗	✗	✓	✗	✗	✓	✓
Automatic positioning	✗	✗	✗	✗	✗	✗	✓
For all foot areas	✓	✓	✓	✗	✗	✓	✓
Does not touch the wound	✓	✓	✓	✗	✓	✓	✓

Table 4. Competitive matrix: wound monitoring devices and their functions.

3. Methods & Design

The methods and design phase consists of conceptualization and prototyping of the wound monitoring device. Concepts are generated with the help of design sketches, and a prototype is built with the help of rapid prototyping techniques like 3D printing and laser cutting. Parts of the prototype (i.e. the foot stabilizers) are evaluated by way of user testing with wound care professionals and patients. This chapter starts out by showcasing the final concept, and the prototype build of this concept. Following this, the main components from the concept are individually described.

3.1 Final concept and prototype build

A render of the concept that has been chosen for further development and prototyping is shown in Figure 7. The main components numbered in the figure are as follows:

1. Sensor module
2. Servo arm
3. Foot stabilizer
4. Baseplate

This concept stabilizes the foot of the patient and takes measurements of the wound by automatically positioning the sensor module in front of the wound. The sensor module is positioned by adjusting the servo arm and rotating this arm around the baseplate. The concept can easily be folded up, such that it can be transported easily with the handle. A render of model in a folded-up position is shown in Figure 8. Further considering the transportability of the device, it's dimensions and weight are also important. In the folded-up position, it has a size of approximately 49 x 41x 15 cm. Unfortunately, this is slightly larger than the design requirement of 40 x 30 x 15 cm. However, it is not possible to make the device any smaller since it should accommodate all foot sizes. When the device is in use, the maximum distance the servo arm will horizontally stick out, is 33 cm approximately. When taking a top-down picture, the servo arm has a maximum height of approximately 70 cm. These dimensions should be considered when setting up the device.

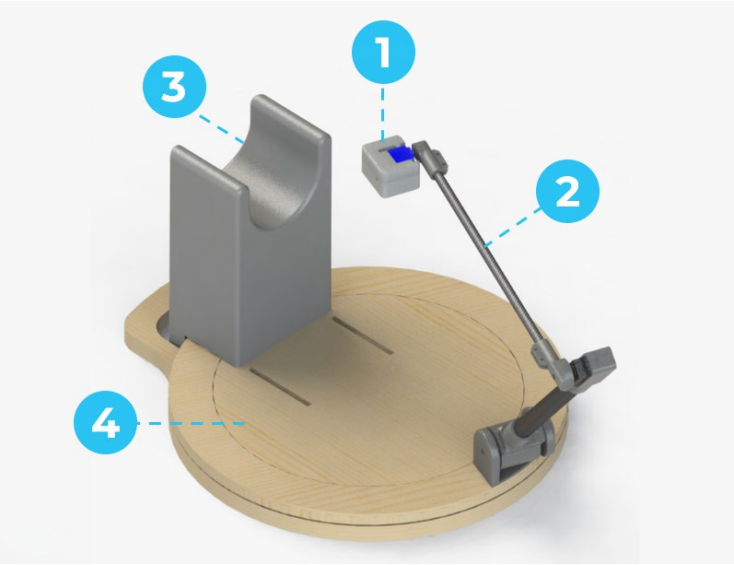

Figure 7. Render of the chosen concept, in functional position. (René van Koolwijk ©)

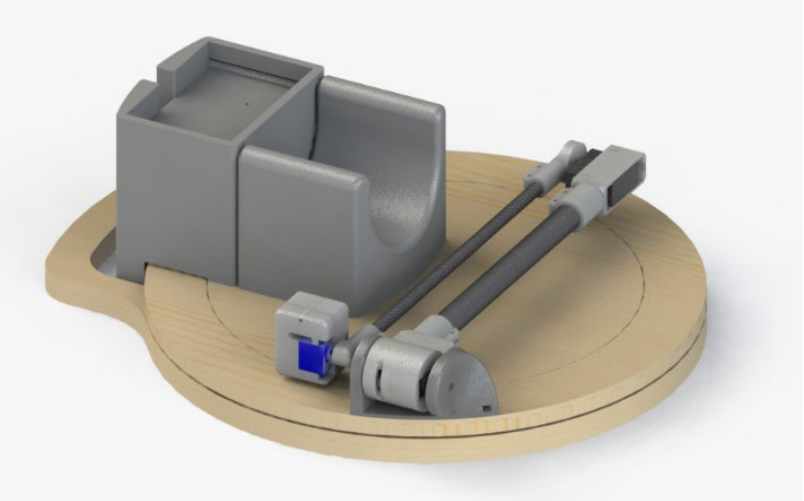

Figure 8. Render of the concept in folded-up position. (René van Koolwijk ©)

The concept has been realised in a prototype, which can be seen in Figure 9. The weight of this prototype is approximately 3.5 kg. The base is made of laser-cut plywood, and the housing parts are 3D-printed with PLA filament.

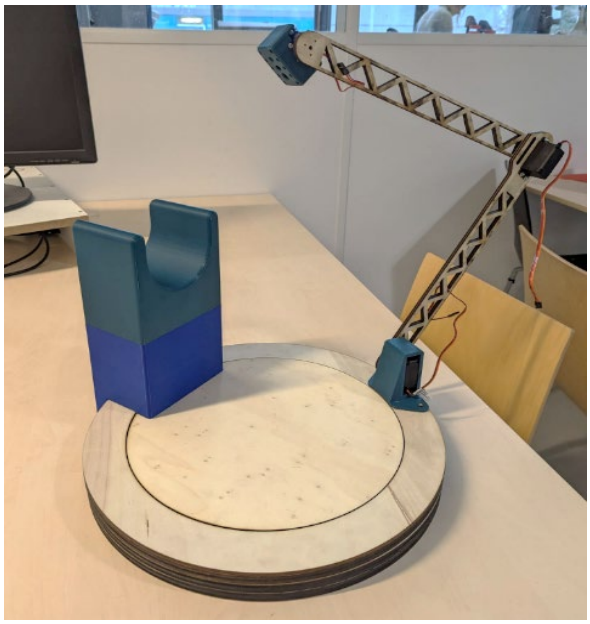

Figure 9. The constructed prototype. (René van Koolwijk ©)

The prototype contains various electronics. The electronics that were used for the entire prototype, including the ones for the sensor module specifically, are shown in Table 5.

	Electronics	Function	Specifications
Sensor Module	Camera	Making high quality images of the wound, and visual guidance for positioning.	ArduCam 64MP HQ camera, 9152 x 6944 sensor resolution, autofocus
	Thermal camera	Measuring the temperature gradient across the foot.	PIM365 MLX90640 Thermal Camera, 32 x 24 pixels, 1°C accuracy
	Range finder sensor	Measuring position relative to the wound.	TOF050F distance sensor module, VL6180X sensor, 2 to 50 cm range
	White LED	Illuminating the wound.	5pcs. Clear white LED diode
	UV LED	Illuminating bacteria and fungi in the wound.	5pcs. 405 nm UV LED diode
Servo Arm	Top servo	Adjusting pitch angle of the servo module.	Reely 8G analog servo S0008. 8g, 11Ncm, 6V, plastic
	Middle servo	Moving the upper half of the servo arm.	Micro-servo S-0060 MG analoog. 52g, 52Ncm, 7.4V, metal
	Bottom servo	Moving the lower half of the servo arm.	Servo S150MH 15kg 25Z. 56g, 150Ncm, 6.6V, metal
Foot Stabilizer	Stepper motor	Revolving the entire servo arm around the foot.	NEMA 17, 24VDC, current rating 1A, Single shaft, 0.56 Nm, 2 phase, bipolar (6 wires), 380 grams
	Arduino UNO	Controls the movement of the servos and controls the stepper motor driver	ATmega328P microcontroller, 16 MHz clock speed, 14 digital I/O pins, 6 analog input pins, 32 KB flash memory, 2 KB SRAM.
	Stepper motor driver	Controls the stepper motor movement	DRV8825, 8.2-45V, 1.5A (2.5A peak), 1/32 micro stepping, Overcurrent protection, 3.3V/5V logic, Thermal shutdown.
	Arduino CNC Shield	Mounts the stepper motor driver onto the Arduino	VNGARD967058, GRBL compatible, headers for stepper motors, 6 end stops, 12 to 36V DC.
	Raspberry Pi 4B	Handles imaging software, serial communication to the Arduino, control inputs, data storage.	Quad-core Cortex-A72 (ARMv8-A) 64-bit processor, 4 GB RAM, Wi-Fi, Bluetooth, 4 USB 3.0 ports, HDMI, microSD slot
	Limit Switch	Used for calibrating the position of the servo arm.	3-pin configuration, Normally Open (NO) contact type
Baseplate	n/a	n/a	n/a

Table 5. Electrical components used in the prototype, their functions and their specifications.

3.2 The sensor module

The sensor module is the component that does all of the measurements of the wound. It is located at the end of the servo arm. When the module operates, it starts with measuring its distance to the wound, which is used for the positioning relative to the wound. Secondly, it illuminates the wound with white light, and takes a picture. Thirdly, the wound is illuminated with UV-light, and another picture is taken. Lastly, a thermal picture is taken. A render of the sensor module that has been developed is shown in Figure 10. The numbered components in the image are as follows:

1. High quality camera
2. White and UV LEDs
3. Distance sensor
4. Thermal camera

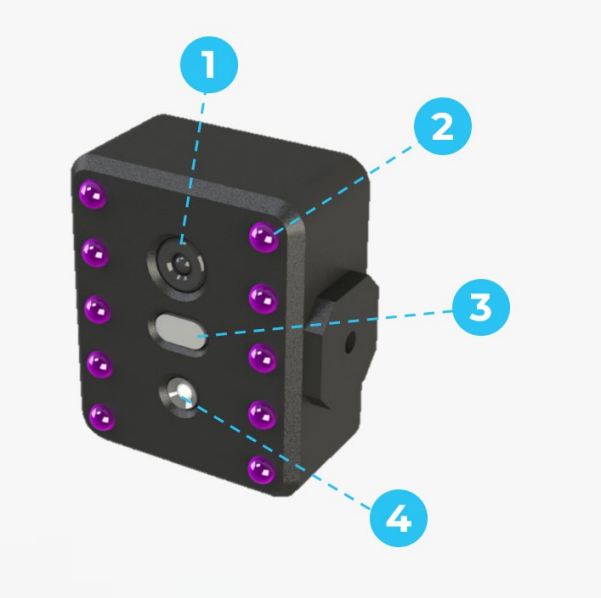

Figure 10. The sensor module. (René van Koolwijk ©)

3.3 The servo arm

During conceptualization, there were three design requirements that together ensured the need of a mechanical arm:

1. It should be able to position the sensors perpendicular to every surface of the foot.
2. It should be able to reproduce measurements from the same distance and angle to the wound, each time.
3. The positioning of the camera module should be done automatically by the device, instead of manually by the caregiver.

Keeping in mind that it should be a low-cost solution, and the fact that it should be feasible regarding the development of a prototype within the timeframe of the project, the concept of a servo arm has been chosen to move the camera mechanically.

A render of the servo arm that has been developed is shown in Figure 11. The numbered components in the image are as follows:

1. Top servo (small)
2. Middle servo (medium)
3. Bottom servo (small)
4. Top segment (carbon fibre)
5. Bottom segment (carbon fibre)

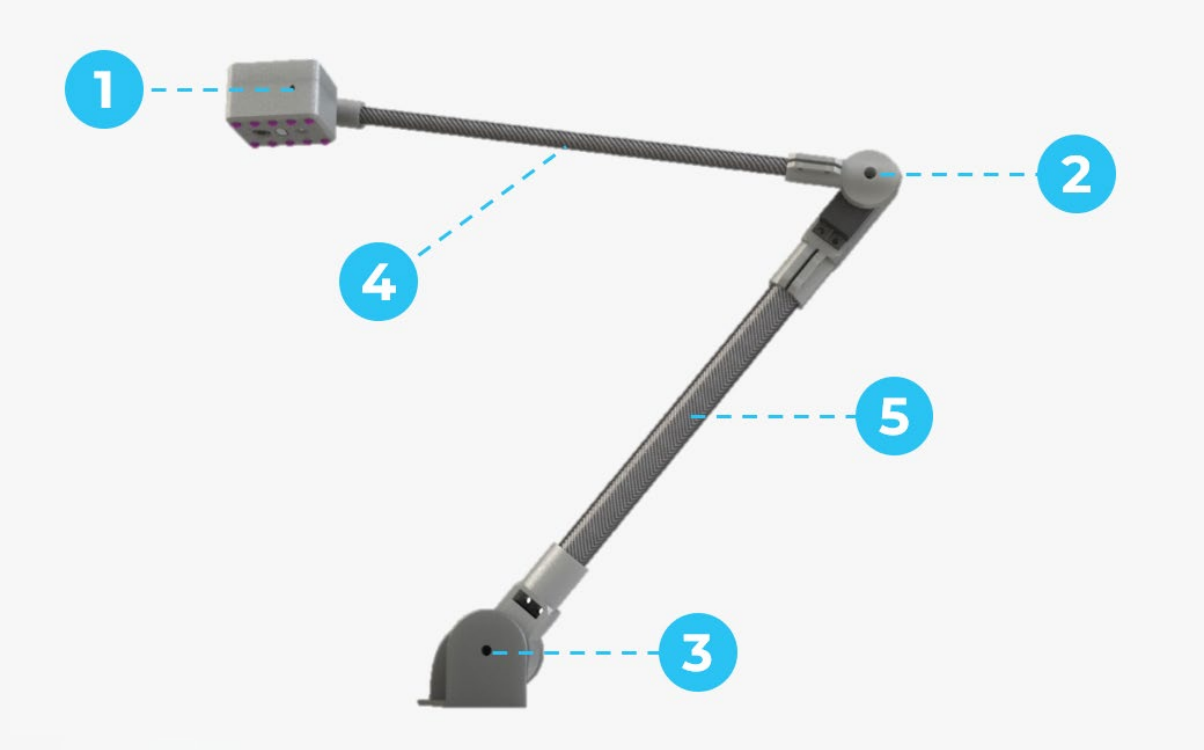

Figure 11. The servo arm. (René van Koolwijk ©)

3.4 The foot stabilizer

For the development of the foot stabilizer, it was important to determine whether clamping the patient's ankle was necessary to enhance foot stability. In addition, it was important to identify which stabilizing method the patients preferred. To answer these questions, three versions of foot stabilizers were developed, depicted in Figure 12 a, b and c. The first one did not use a clamping mechanism, the second one used a screw mechanism that was manually adjustable, and the third one used a compliant mechanism which clamps the ankle automatically whenever it's used. These stabilizers were tested with 2 diabetic foot patients, during an observation day with QualityZorg. The tests were carried out in the home environments of the patients. Images of the testing procedure can be seen in Figure 13 a and b.

Figure 12a. U-shaped version. (René van Koolwijk ©)

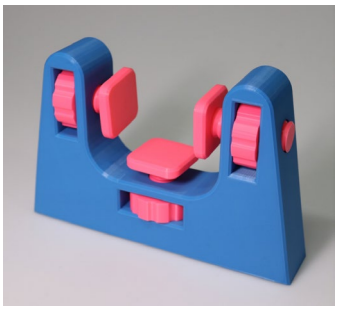

Figure 12b. Manually adjustable version. (René van Koolwijk ©)

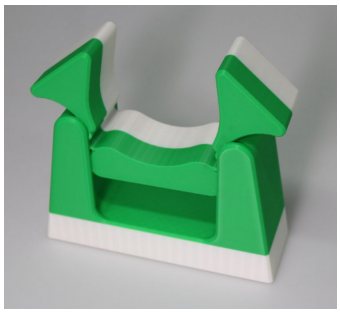

Figure 12c. Compliant mechanism version. (René van Koolwijk ©)

Figure 13a. Patient 1 testing the compliant mechanism version. (René van Koolwijk ©)

Figure 13b. Patient 1 testing the U-shaped version. (René van Koolwijk ©)

The patients were asked to rate the stabilizers on a scale from 1 to 10, based on 4 criteria: Stability of the foot, comfort, ease of use and appearance. Unfortunately, the patient 1 was not willing to use this rating system. He did explain while testing the manually adjustable version, that this version seemed the best, since it was easy to use, and that it could clamp the ankle well. He stated that sometimes his muscles shake uncontrollably, which would make a clamping mechanism useful. However, afterwards he concluded that the stabilizers do not differ significantly enough in functionality to choose one version that's optimal; they all work about equally well.

Patient 2 did use the rating system and gave all foot stabilizers very similar scores. The U-shaped version scored slightly better than the others; on average 0.25 points higher. A summary of the scores he gave is listed in Table 6 in Appendix A-7. In addition, he stated that he thinks it's not necessary to clamp the ankle to stabilize the foot.

The foot stabilizers have also been showcased to Josine Cornet during an interview. She prefers the U-shaped version, as it looks the most comfortable [see Appendix A-4]. She thinks the manually adjustable version looks too complicated.

Through these results, a clamping mechanism was deemed not to be required, and the U-shaped version of the foot stabilizer has been chosen for further development. The resulting prototype houses the main electrical components, like the Arduino and the Raspberry Pi (see Table 5). With this version there are 2 orientations in which the patient can position their foot, as shown in Figure 14a and 14b. One of these orientations is chosen based on the wound location on the foot.

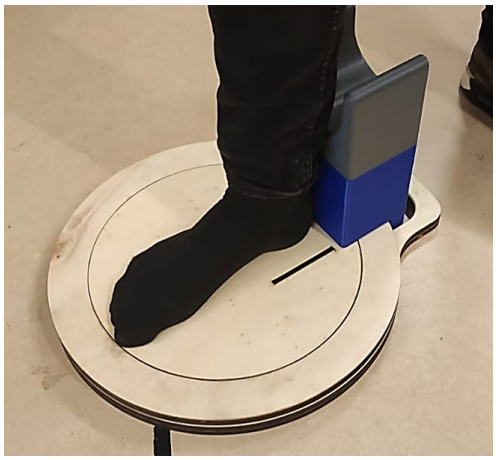

Figure 14a. Foot position 1. (EU size 47) (René van Koolwijk ©)

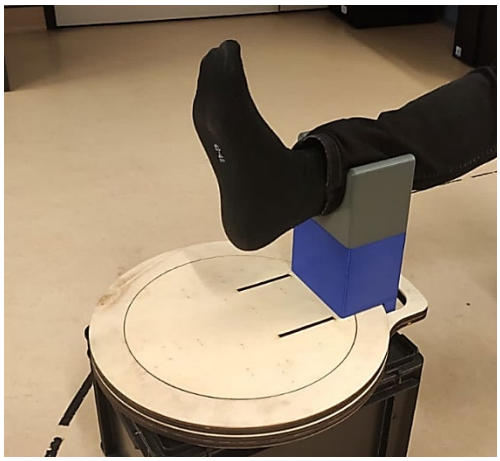

Figure 14b. Foot position 2. (EU size 47) (René van Koolwijk ©)

4. Conclusion

This study has explored the process of designing an at-home wound monitoring device for individuals with diabetic foot conditions. Through a context-of-use-analysis containing 7 semi-structured interviews with healthcare professionals, qualified caregivers, and diabetic foot patients, we confirmed the need for such a device. During this analysis, we have made a compilation of stakeholder needs and design requirements for the device. These findings were used to develop a concept and a working prototype of the device. The result embodies a lightweight, portable device that stabilizes the patients' foot and performs measurements of their wound automatically. The device contains a foot stabilizer, baseplate, servo arm and a sensor module. The requirement we uncovered that was the most impactful for the design of the device, was the necessity for the device to be operated by the caregiver, rather than by the patient. Other findings that highly impacted the physical design of the device include the need for automatic positioning, foot stabilization, and various wound measurement techniques. The need for safety and ease of use has also been shown to be imperative to guarantee user interest, trust, and sustained use of the device.

Overall, this study contributes to the field of chronic wound care by providing new insights into opportunities for at-home wound monitoring of diabetic feet. Insights from this study can be applied to new endeavours on developing wound monitoring devices for anatomical regions beyond the feet.

Limitations

As we conclude this research, it is essential to acknowledge the limitations encountered during the study. One significant limitation is that the concept developed in this study focuses on monitoring wounds exclusively at the feet. Therefore, it's incapable of monitoring wounds elsewhere on the body. Given that leg wounds are a common chronic wound type, future studies could address this limitation by developing a device specifically designed for monitoring wounds on the legs, while applying the monitoring techniques proposed in this research.

Another notable limitation is on regulatory issues. Developing a device that has medical implications involves adhering to various regulations and obtaining approvals. Therefore, before introducing the device to the market, this limitation should be addressed.

Future work

This study has made significant progress in the development of a concept and a prototype for a wound monitoring device. However, further prototype development is required to test the repeatability and accuracy of the measurement components. Once this phase is completed, the next step would be to redesign the device for volume production, preparing it for market entry.

While this study has shown a compilation of both hardware and software requirements, the primary focus has been on refining the physical design exclusively. Further research should also encompass software development, making use of the outlined software requirements.

Appendix A: Interview summaries

Appendix A-1: Eddy Koopman

Time and date of the interview: 9 November 2023, 10:00 - 11:00

Location: Online

Present during the interview: Eddy Koopman, Imme Ebben, Filip van der Kroft, René van Koolwijk

Section 1: Biography

Eddy Koopman is a seasoned wound consultant at the Deventer Hospital, responsible for bandages and anti-decubitus aids. He is also case manager / wound care specialist at the Wound Expertise Centre (WEC) at this hospital, which specializes in complex wound care. With about 30 years of experience in wound care, Eddy is a key opinion leader.

Section 2: Hospitals and QualityZorg

On average, patients come to the WEC between once every 2 weeks and once every 4 weeks.

Polyclinically, the WEC has 400 new referrals per year, of which 100 are diabetic feet, 80 with ulcers.

90% of these patients receive home care, with a duration of 30 minutes per home visit.

Clinically, the WEC has 1000 new consultations per year of which 80 are with diabetic feet, 60 with ulcers.

Eddy mentions that hospitals in the Twente area make use of an information system called HiX, developed by ChipSoft. These hospitals include ZGT Almelo, ZGT Hengelo, MST Enschede and Deventer Hospital. This system contains an observation sheet called HiXWond, which contains all data about wounds.

He mentions QualityZorg, a nationally operating home care organization exclusively focused on wound care. It is staffed with nurse practitioners, and it stands out for its reliable, long-term patient data, which is collected in an electronic patient's file called PatDoc. This EPD stores data about surface area and tissue types but does not predict wound healing.

According to Eddy, this data may have a value statistically, but not for the treatment of an individual patient.

Section 3: Clinical insights on diabetic feet

Important wound variables according to Eddy:

- Surface area / size
- Depth
- Tissue type distribution
- Degree of dead tissue
- Change over time
- Humidity
- Temperature, especially between feet
- Degree of oedema

- Blood supply & drainage problems
- Pulsations
- Degree of undermining
    - *This is when the wound runs under the skin, further than you can see with the naked eye. Eddy notes that the device will most likely not be able to measure this.*

Important patient variables according to Eddy:

- Who referred the patient
- Where the patient came from
- The reason for referral
- Prehistory
- Medication
- Anamnesis
- Physical examination
- What kind of compression and pressure relief is used

The diabetic foot is not the most common chronic wound. It is arguably the most publicized group. Ulcus cruris (leg wounds) are very common.

The size of the wounds varies greatly. During Eddy's consultation hour on one morning, the wound sizes (in cm2) were: 2, 70, 12, 5, 4, 3, 54, 3.

Eddy emphasizes the importance of incorporating internal patient parameters to predict a starting infection.

According to Eddy, the most important data often forgotten in communication is the degree of infection symptoms. This includes temperature (fever), redness, swelling and pain. The WEC also uses blood sampling with a C-reactive protein (CRP) test.

Section 4: Recommendations and take-home messages for the development of the device

According to Eddy, the device needs to fulfil the following requirements:

- Nurse-proof
- Vandalism-proof
- Idiot-proof
- Very simple
- Robust
- Not vulnerable
- Very easy to use
- Easy to disinfect
- Data privacy

Eddy points out that it would be useful to control the device via a mobile phone. This needs to be done by a caregiver, as the diabetic foot patients have an average age of 71 years.

Eddy pointed out that the device should make clear what the general location of the wound is, as pictures are sometimes taken very close to the wound.

Pictures should be made perpendicular to the wound.

Eddy thinks that pictures should be made once every 2 weeks. Daily monitoring is far too much, as wound change is too slow.

According to Eddy, the patient should be able to easily read the information that the device collects whenever desired. Wound progress is a significant motivation booster to keep up the therapy.

Eddy thinks that implementing UV light for detecting bacteria will have added value.

Eddy mentions that the device should have an alarm function. For this, the device is should draw conclusions on its own. The final assessment needs to be done by a qualified caregiver. The device should not make treatment decisions.

Eddy mentioned the report “Organisatie van de Wondzorg” by vascular surgeon Robbert Meerwaldt at MST, which contains data about woundcare in the Netherlands.

Eddy mentioned an ongoing, unpublished study which shows that the sooner a patient is treated at the WEC, the shorter the treatment is needed.

Appendix A-2: Miriam Blokhuis-Arkes

Time and date of the interview: 30 November 2023, 12:00 - 13:00

Location: Online

Present during the interview: Miriam Blokhuis-Arkes, Imme Ebben, Filip van der Kroft, René van Koolwijk

Section 1: Biography

Miriam Blokhuis-Arkes is a nurse practitioner at the Wound Expertise Centre (WEC) at Medisch Spectrum Twente (MST). She is specialized in diagnosis and treatment of complex wounds and the negative factors which influence wound healing and in vascular surgery. She has shaped the diabetic foot clinic, which became the WEC.

Section 2: Hospitals and QualityZorg

The aim for patients is to visit the hospital once every 5 to 6 weeks.

Initial consultation at the WEC takes one hour. Treatment is around 45 minutes.

There are 650 new patients on an annual basis at the WEC.

The majority has diabetic feet, often with arterial disease. 90 to 95% of diabetic feet patients receive home care. Only a small group can replace their bandages themselves. There is an aim to change bandages 2 to 3 times a week.

Wounds under the foot (plantar ulcers) are put in a cast. These are replaced 2 to 1 times a week.

Home care caregivers come to the patient's home 2 to 3 times a week for the treatment of the wound. After further healing, this scales down to 1 time per week.

Section 3: Clinical insights on diabetic feet

Important wound variables according to Miriam:

- Surface area
- Depth
- Bone contact
- Inflammation
- How well the bandages are applied
- Pressure points / stains on casts
- Pain
- Presence of oedema

Important patient variables according to Miriam:

- Nutrition

Wounds on diabetic feet are often 0.5 to 1 cm

Depth varies, also because of undermining. In general, they are smaller wounds, but often several wounds.

Diabetic foot patients are not always compliant when it comes to certain treatments like having to wear medical footwear.

There is little insight into the disease in lower social environments. Some patients do not realize the seriousness of their wounds, which can result in neglect and deterioration of the wound.

Arterial disease affects the temperature of the skin. Miriam states that, when using temperature to predict a starting infection, arterial disease could result in an incorrect prediction of starting infection. Arterial disease often differs per foot.

Keeping the foot still is often not a problem. It sometimes happens that there are spasms or vibrations, but that is a small minority.

Wound healing should be established within 2 to 3 weeks.

Section 4: Recommendations and take-home messages for the development of the device

According to Miriam, the device needs to fulfil the following requirements:

- Not too bulky
- Transportable
- Easy to disinfect

The wound-monitoring device is considered desirable, according to Miriam. Currently, wound nurses take photos and consult with the WEC via e-mail, and sometimes by phone. The WEC wants wound nurses to reach out, not all nurses.

According to Miriam, it would be nice if the device is self-thinking, such that it can interpret whether there is an infection. An alarm function within the wound monitor device is wanted, so there is no need to contact manually anymore. She emphasized that there is a need for an instrument in home care that can indicate whether the wound is doing well or not.

Miriam doubts whether the foot stabilizer and servo arm are always necessary.

Pictures of interdigital ulcers (wounds between the toes) may be difficult to make with the device.

Miriam states that existing handheld wound monitor systems sometimes make use of a photography method which shows the previous picture at reduced opacity in the viewfinder, which can be used to take a second picture with the same framing and angle.

Wound care advice should only be given by healthcare providers, not by the wound monitor device.

Appendix A-3: Mirjam Geling

Time and date of the interview: 30 November 2023, 16:00 - 17:00

Location: Online

Present during the interview: Mirjam Geling, Imme Ebben, Filip van der Kroft, René van Koolwijk

Section 1: Biography

Mirjam Geling is a qualified wound nurse at QualityZorg, a nationwide homecare organization specializing in complex wound care.

Section 2: Hospitals and QualityZorg

About half to three-quarters of patients at QualityZorg suffer from diabetic foot, by estimation. A small number of patients can replace bandages themselves, but this is usually done by the wound nurse.

Patients with a severe wound (moist) will receive a visit from a qualified caregiver every day. Otherwise 2 to 3 times a week. The policy is to take a photo weekly. With exceptionally slow healing, this is less frequent.

The time of treatment at home is between 25 min and an hour.

Sometimes hospitals and homecare organisations disagree on the frequency of care a specific patient needs.

QualityZorg stores patient information in and electronic patients file (EPD) called PatDoc on a weekly basis, including photos of the wound, dimensions, colour of exudate, step-by-step. Some hospitals can access PatDoc. Mirjam mentions PatDoc is quite sophisticated, so she is unsure if other systems can be integrated easily. But if it's possible, it is desirable. PatDoc is specific to QualityZorg, and most hospitals that work together with QualityZorg can access it. With PatDoc it takes 5 to 10 minutes to take a picture. Mirjam has also worked with the ONS system, which is another electronic client file.

Caregivers at QualityZorg don't use a temperature measurement, they only feel it with the hands.

The only thing they have with them to take the photos is an iPad.

The age of the patients at QualityZorg varies between 25 and 75 years.

Section 3: Clinical insights on diabetic feet

Important wound variables according to Mirjam:

- How the bandage is wrapped
- State of the wound & edges
- Moisture level
- Redness
- Presence of yellow / green slough
- Depth
- Length
- Width
- Scabs
- Callus formation
- Type of wound
- Healing speed

- Exudate colour and amount

Important patient variables according to Mirjam:

- Remedies that had a positive impact on the healing speed
- Underlying conditions (e.g., auto-immune disease or vascular disease)

The wounds on the feet differ in size, but it is approximately up to 5 cm.

Patient's homes can be quite unhygienic.

Some patients are not willing to change their lifestyle (e.g., quit smoking) to improve their wounds.

It is common for a diabetic foot patient to have multiple wounds.

If an infection is detected sooner, the patient can take fewer antibiotics.

Section 4: Recommendations and take-home messages for the development of the device

According to Mirjam, the device needs to fulfil the following requirements:

- Quality photos
- User-friendly
- Foot stabilizer
    - Ergonomic
    - Light
    - Easy to set up
    - Easy to carry
    - Small
- No sharp corners
- Adjustable in height

Mirjam's first impression of the system is positive. She likes that a UV photo is taken, since caregivers sometimes suspect that bacteria are present, without knowing for sure. Normally, to confirm this, a wound culture must be taken and sent to the hospital for examination. In the home situation this is difficult because caregivers usually do not carry the tools for this procedure with them. A doctor, specialist or general practitioner must give permission first, and then the tools must be sent to the client.

Mirjam is positive about measuring temperature difference. She emphasized that it is useful to measure temperature all over the foot, and in different places of the wound.

According to Mirjam, it is not necessary to measure the temperature of the healthy foot, because there is already enough temperature difference on the foot with the wound itself.

Mirjam thinks the concept with the foot stabilizer and servo arm is ideal, since manually taking photos can be quite difficult, especially when taking photos under the heel. Therefore, the device would be a relief.

Currently, the process of positioning a leg and taking a photo is mainly improvisation, resulting in bad pictures. In her opinion, an ergonomic foot stabilizer can improve this.

According to Mirjam, the device should not give advice for wound care because there are too many different treatments. Advice should be given by professionals.

Mirjam thinks that not all homes have a room that can be darkened for a picture.

An accuracy of about 1 degree Celsius is desirable for the temperature sensor, in her opinion.

Mirjam thinks it's helpful for the device to make interpretations of the data and show summarized insights. However, experts should be able to get insights on the raw data as well, when necessary.

Mirjam thinks that taking a photo prior to cleaning the wound is not of much use. However, measuring humidity prior to cleaning could be possible and possibly useful.

Mirjam has written a thesis on ergonomic working in wound care in home care. She mentions it's quite difficult to invent something ergonomic that works well.

Appendix A-4: Josine Cornet

Time and date of the interview: 6 December 2023, 15:45 – 16:45

Location: Online

Present during the interview: Josine Cornet, Imme Ebben, Filip van der Kroft, René van Koolwijk

Section 1: Biography

Josine Cornet is a qualified wound nurse at QualityZorg, a nationwide homecare organization specializing in complex wound care. She works in the Rotterdam region. Besides homecare she works at multiple hospitals. She works at the Maasstad hospital, where she helps many patients with burn wounds. She also collaborates with the Erasmus hospital, where she helps patients with dermatological diseases.

Section 2: Hospitals and QualityZorg

Josine sees 8 to 12 patients a day, with 1 to 2 of them having diabetic wounds. Patients wounds also consist of burns and ulcer cruris (leg wounds) due to vascular problems.

Patients receive daily home care when the wound is inflamed, has a lot of exudate, or has a risk of deterioration. Patients with a stable wound receive home care 2 times a week.

A wound photo is taken once a week, according to their policy.

Home treatment takes between 15 and 45 minutes, according to Josine.

QualityZorg still makes a written report during each visit, next to a PatDoc update. There's a feature in PatDoc for patients to log in and view information, but it's not really used much yet.

Caregivers at QualityZorg all have the same toolbox, containing disposable curettes and scalpels, gauzes, alcohol for disinfection, scissors, gloves, a disposable tape measure and plastic sheets for making a clean working area.

Most caregivers drive to the patients with a small car, some use an electric bike. Some patients live in flats without a working elevator.

Section 3: Clinical insights on diabetic feet

Important wound variables according to Josine:

- Presence of necrotic & vital tissue
- Depth
- Moisture
- Maceration (skin softening)
- Pus
- Pain
- Bone contact / osteomyelitis (bone inflammation)
- Redness
- Warmth
- Callus formation

Important patient variables according to Josine:

- Diabetes control
- How the patient feels (e.g. fever symptoms)

- Insulin
- Sugar regulation

Some patients have an amputation wound. These occur when the skin becomes inflamed, after an amputation. Appendix F summarizes an interview we did with a patient with this condition.

There can be multiple wounds per foot. Some wounds can occur under calluses on the side or bottom of the foot, caused by pressure points.

Wound size can be as large as the entire top of the foot, in the case of an amputation wound.

Calluses and macerations are removed during a home visit by a qualified wound nurse prior to taking a photo.

In diabetic foot patients, there are virtually no wounds on the ankles. Therefore, the foot stabilizer can always be used. Sometimes, patients have wounds at the top of the foot. In all cases, these patients can still place their foot normally, flat on the ground to take a picture.

When patients have deep inflammation, they often feel pain when palping (touching & feeling the skin), even with neuropathy. Neuropathy is a condition where the nerves are damaged, such that the patient does not feel pain in that particular area.

Section 4: Recommendations and take-home messages for the development of the device

According to Josine, the device needs to fulfil the following requirements:

- Slightly heavy to improve sturdiness
- Not too heavy to improve transportability
- Sturdy foot stabilizer
- Soft foot stabilizer
- Limited resistance for patients (they should only have to place their foot)
- Secure data traffic
- Trustworthy
- Streamlined information exchange with hospital
- Practical
- About the size of a paving stone: Maximum 40x30x15 cm.
- Weight of 1kg

Josine often finds it difficult to take a picture, due to poor lighting, shadows due to skin folds, or the positioning of the patient.

Josine mentions that all patients are comfortable with having their picture taken.

According to Josine, the person who operates the device must have appropriate knowledge about diabetic feet wounds. However, she is unsure whether the device has any added value when the staff are very knowledgeable.

Josine thinks the device is useful if it can identify problems at an early stage, to prevent amputations or complications.

From the three showcased prototypes of the foot stabilizer, Josine prefers the U-shaped foot stabilizer, as it looks the most comfortable. The threaded foot stabilizer looks too complicated.

Josine confirms that it is not necessary to support the knee, or to stabilize other parts of the foot.

Josine mentions that the patient should be able to access information about the healing progress at the stage of prevention.

Josine thinks it is possible to make the rooms at the patient's homes dark enough for taking pictures, but it will be a burden. She therefore suggests using a screen or box instead.

Josine thinks that wound temperature measurements are interesting as supplementary information, but not decisive information.

According to Josine, experts should be able to access the raw data to draw their own conclusions. Aside from that, the device can draw conclusions to give quick insights to experts.

Josine suggests putting the device in a suitcase with wheels, to improve transportability.

Josine finds it advantageous to integrate the device into an existing healthcare system.

According to her, it's desirable to minimize the frequency of logging in, to reduce resistance.

Appendix A-5: Annemiek Stienstra

Time and date of the interview: 18 December 2023, 15:30 – 16:30

Location: Online

Present during the interview: Annemiek Stienstra, Imme Ebben, Filip van der Kroft, René van Koolwijk

Section 1: Biography

Annemiek Stienstra is a nurse practitioner at QualityZorg, a nationwide homecare organization specialized in complex wound care, with 20 years' experience on diabetic foot. She has done a poster presentation on PatDoc data from QualityZorg about diabetic feet, at the International Diabetic Foot Congress. This event takes place in The Hague, once every 4 years.

Section 2: Hospitals and QualityZorg

In a period of 6 years, 11380 patients were treated by QualityZorg. 11% Of those patients had a diabetic foot wound. That's 1281 people with 2618 diabetic foot wounds. Often times, patients have multiple wounds.

Usually, a patient receives care at home 2 to 3 times a week. Sometimes on a daily basis. This policy is determined by the hospital for each patient. Home care does not always agree with this policy.

The duration of a foot treatment at home varies between 20 and 45 minutes. The visit takes even longer when they use at-home vacuum therapy. This involves applying negative pressure to a wound, to improve blood flow and promote healing.

Annemiek mentions that the positioning of the leg during treatment at home differs per healthcare provider. Annemiek often sits on a chair without armrests and puts the patients' foot on the chair, between her legs. Obese patients cannot get the foot to knee height, so their foot cannot rest on a stool.

Annemiek mentions that the movement of the foot differs per patient, sometimes the muscles remain very tense, and sometimes relaxed.

QualityZorg cannot measure blood sugar levels. They have to ask the patient about this.

Some wound and patient information is collected in PatDoc. They also make a report on paper where other information is noted.

Annemiek thinks it would be useful to integrate the device in an existing system such as PatDoc, because then it will be used more.

Patients and general practitioners (GPs) can also use PatDoc, however they are usually not interested. Patients often only want to know if the wound is getting smaller. GP's usually think it takes too much time.

Annemiek believes that a photo should be taken once a week or once every 2 weeks, to be able to follow the healing of the wound properly. The policy is once a week, but this is not always necessary in case of slow healing. Annemiek indicates that it is not very insightful for the healthcare provider to take a new photo if the wound has changed 1 millimetre in 1 week. However, a small change of 1 millimetre could be useful for the predictive power of a program, in predicting wound healing.

Annemiek does indicate that a wound can suddenly change within a week. Therefore, measurements should be taken more frequently than once a week. However, she thinks this is not feasible because of the workload in healthcare.

Annemiek has tested the MolecuLight. She wasn't very enthusiastic about the device itself, because the flora that lit up don't necessarily have much effect on the wound and the treatment that is needed. The healing of the wound can still progress in the presence of the flora, so the device is not very useful. Only in case of redness, swelling and warmth (i.e. the signs of infection), does the treatment change and medication is needed.

At QualityZorg, they have already tested 2 wound measurement systems, measuring the surface area and a 3D measurement, but they were not very successful. Measurements need to be stored in PatDoc, otherwise they will never be used.

Annemiek mentioned there is an ongoing study in Leiden University Medical Center, where Professor Ewout Steyerberg from biomedical data science is making a predictive model of healing based on the PatDoc data. The purpose of this tool is to predict how long it will take for a wound to close. Annemiek thinks that wound size and infection presence are the most important PatDoc data for this study.

Annemiek also mentioned an ongoing research project called Homeland, which investigates the functional requirements of a temperature measurement at home, to prevent diabetic foot problems, mainly for patients who have already had wounds. They focus on the temperature increase at pressure points before inflammation occurs and a wound develops. This study is carried out by researchers Sicco Bus and Jaap van Netten at the Amsterdam University Medical Center. Voetcentrum Wender (podiatry) is also involved.

Section 3: Clinical insights on diabetic feet

Oftentimes patients are not aware of the severity of their situation, especially when they have neuropathy.

Important wound variables according to Annemiek:

- Pressure on the wound
- Hygiene
- Infection
- Tissue type
- Whether tissue needs to be removed
- Presence of calluses
- Degree of oedema

Annemiek mentions calluses are an expression of pressure, and pressure is negative for the wound. However, she thinks it's difficult for a device to measure because there's no clear outline. The caregiver may notice the presence of calluses when palping, because it is stiffer and harder tissue.

Important patient variables according to Annemiek:

- General blood sugar levels
- Medication
- Polyneuropathy
- Limited joint mobility
- Arterial disease
- All factors of diabetes

These variables are all largely processed in PatDoc.

Section 4: Recommendations and take-home messages for the development of the device

According to Annemiek, the device needs to fulfil the following requirements:

- Weight follows ARBO regulations: under 15kg
- Easy to use
- Easy to install
- Not too big
- +- 0.2 degrees Celsius accuracy
- Easy to disinfect
- Complies with international guidelines for medical devices and privacy legislation.
- Standalone (no need for a stool)
- Not too heavy
- Minimalistic

Annemiek's first impression of the device is positive. She states that, compared to what is already measured with PatDoc, the measurements on temperature and bacteria presence are of added value.

Annemiek believes that a support under the ankle is enough support to keep the foot stable.

Annemiek thinks its better if the caregiver tells the patient about the wounds progress, instead of the device, because the context is often more complicated than the measurements. Because of this complexity, it could be useful if the measurement data could be combined with information from the patient about neuropathy and arterial disease.

Annemiek believes the device should draw conclusions based on measurements, and that the caregiver receives a message about the progress of the wound.

Annemiek thinks it's not convenient to have to darken the patient's room for making a picture. She suggests using a similar solution like the one-time use DarkDrape for the MolecuLight.

Annemiek doubts the usefulness of detecting bacteria in a general sense, as they already know they're present. It would be useful if the device can detect which specific bacteria or fungi are present. Perhaps the combination of temperature, bacteria, fungi and wound size is useful for a program to predict the healing progress.

According to Annemiek, in the Homeland study it is mentioned that it is required that the temperature can be measured with an accuracy of +- 0.2 degrees Celsius. She believes this corresponds to the European standard for thermometers in healthcare.

Annemiek mentions that the ease of use for the caregiver is highly important.

Appendix A-6: Patient 1 Observation Day QualityZorg

Time and date of the interview: 22 December 2023, 14:00 – 15:00

Location: At patient's home in Den Haag

Present during the interview: Josine Cornet, Patient 1, Imme Ebben, René van Koolwijk

Section 1: Patient Information

The patient is a male of 59 years old and has diabetes. He currently has an amputation wound on his left foot. The front of this foot has been amputated about 1 year ago. He has no feeling in the wound. He wears a cast with support blocks and receives home care 3 times a week.

His diabetic foot problems started with 2 small, deep wounds under the big toe, which had been neglected for years. During this time, he received care once per week, at the hospital or by homecare.

Section 2: Hospitals and QualityZorg

A homecare visit takes about 30 to 45 minutes.

The patient is able to sit comfortably on the couch for long periods of time with his foot stretched out in front of him, resting on the edge of the couch (see Figure 15). The caregiver indicates that most patients sit on a couch or on a chair during treatment, and that the leg is placed on a table or chair that sits at about the same height.

The patient visits the hospital once every 2 weeks. He struggles to do this regularly, as he cannot do this alone, because someone needs to drive a car and he has trouble walking inside from the parking lot.

He can access the photos of QualityZorg, but he likes to view this together with a caregiver, rather than independently. He likes to stay up to date on the wounds progress, and he keeps track of the size and depth of the wound himself.

The patient needs to rest and should not put any strain on the wound, according to the advice given by the healthcare providers. He is motivated to follow that advice.

The patient indicates that comparing the wound before and after a period of 3 days, is significantly less insightful than when using a period of 2 to 3 weeks.

Figure 15. Treatment of patient 1 during an at-home visit. (René van Koolwijk ©)

Section 3: Recommendations and take-home messages for the development of the device

The patients' first impression of the device is positive. However, he doubts whether the device can accurately predict progress with only surface measurements. He emphasizes that internal factors are also very important.

The patient also indicates that it is important to take into account how the leg should lie in the support.

The patient would be willing to use the device, and he would feel safe to do so, even when the device would move independently.

Josine Cornet indicates that it would be useful if a light turns on and a sound goes off when the device starts to move independently.

Section 4: Testing foot stabilizers

The patient finds the 3D printed foot stabilizers too light and too unstable. He is convinced, however, that stability is improved when the circular base is connected.

During testing, the patient states that the foot stabilizer with the manually adjustable screws seems the best because it is easy to use, and that he can clamp the ankle well. He also indicates that sometimes his muscles start shaking uncontrollably, which makes a clamping mechanism useful.

However, after testing each foot stabilizer, the patient thinks that they don't differ significantly enough in functionality to choose one version that's optimal. In his opinion, they all work about equally well.

The patient did not want to score each foot stabilizer based on the 4 criteria we had indicated.

Appendix A-7: Patient 2 Observation Day QualityZorg

Time and date of the interview: 22 December 2023, 16:00 – 17:00

Location: At patient's home in Leiden

Present during the interview: Josine Cornet, Patient 2, Imme Ebben, René van Koolwijk

Section 1: Patient Information

The patient is a male of 54 years old and has diabetes. He currently has an open wound on the bottom of his right foot, between the sole and the toes. This wound has formed and become infected around early 2020. The index and middle toe have been amputated in 2018. The patient can feel sensations and pain everywhere on the foot, except for in the wound. The wound is treated twice per week, with a duration of about 30 minutes. The patient also has fast-growing calluses. Pieces of it were also sent to the lab to see if it was malignant, but that turned out not to be the case. A picture of the foot with the wound can be seen in Figure 16.

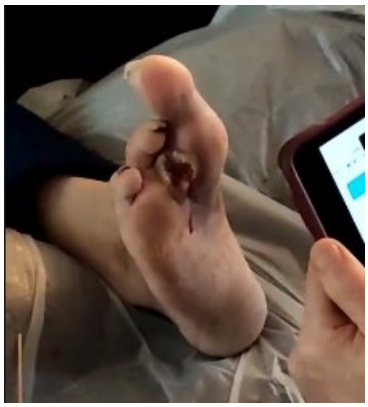

Figure 16. The wound on the right foot of patient 2.
(René van Koolwijk ©)

The patient has very bad vision. One eye has only 5% vision, and the other only 50%. Because of this, and the location of the wound, it is very difficult for the patient to view the wound himself.

The patient cannot wear glasses because he receives injections for his eyes, which keep changing his vision. In the morning of the observation day, the patient also had injections.

Section 2: Hospitals and QualityZorg

During a homecare visit, the patient lies on his back on the couch, with his leg on the armrest (see Figure 17).

The patient doesn't go to the hospital anymore because they can't do much for him. If the wound becomes inflamed, or an amputation is needed, he will visit the hospital. Currently, QualityZorg is the only institution that provides care to the patient.

Healthcare workers advise the patient to avoid putting stress and strain on the wound. He is motivated to follow this advice.

Josine states that a nerve reaction (e.g. a pain stimulus) can occur during treatment, which can cause the foot to move.

Additional information that happened to come up during the interview: ZGT Almelo WEC uses honey as an anti-inflammatory agent. They also have their own apiary for fresh raw honey. QualityZorg sometimes also uses honey.

Figure 17. Treatment of patient 2 during an at-home visit. (René van Koolwijk ©)

Section 3: Recommendations and take-home messages for the development of the device

The patients' first impression of the device is okay, he is curious if it can help him in his situation. After all this time, he is open to new solutions.

The patient likes to be informed of the progress of the wound by the healthcare provider. Seeing the information himself is not very important to him.

The patient is willing to use the device if a caregiver would offer it. He would feel safe using the device.

The patient indicates that, if the device provides insight into what the wound looks like and what has changed, he will be even more motivated to care for the wound.

The patient thinks that it is not necessary to clamp the ankle to stabilize the foot.

Section 4: Testing foot stabilizers

The patient has been asked to rate the 3 foot stabilizers based on 4 criteria. He had to rate these criteria from 1 to 10 for each foot stabilizer. The results can be seen in Table 6.

	U-shape	Manually adjustable	Compliant mechanism
Stability of the foot	9	9	9
Comfort	9	9	8
Ease of use	9	8	9
Appearance	9	9	9
Average	**9**	**8.75**	**8.75**

Table 6. Foot stabilizer ratings by patient 2.

The foot stabilizers score very similarly. The U-shape version scores on average 0.25 points higher than the manually adjustable version and the compliant mechanism version.

Appendix B: Electronic Patients Files

Appendix B-1: PatDoc

LICHAMELIJK ONDERZOEK

Pijnscore [0-10]

Periwond

- ☐ Callus
- ☐ Candita
- ☐ Cellulitis
- ☐ Contactdermatitis
- ☐ Crustae
- ☐ Eczemateus
- ☐ Erythematosquameus
- ☐ Geen bijzonderheden
- ☐ Maceratie
- ☐ Mycose
- ☐ Ondermijning

Botcontact ja / nee

Wondfoto [upload]

Afmetingen lengte [cm] breedte [cm] diepte [cm]

Fase van wondheling

- ☐ Debridement – droge necrose
- ☐ Debridement – fibrineus beslag
- ☐ Debridement – pus
- ☐ Debridement – vast beslag
- ☐ Debridement – vervloeiende necrose
- ☐ Epithelialisatie – re-epithelialisatie
- ☐ Epithelialisatie – stagnerende epithelialisatie
- ☐ Granulatie – hypergranulatie
- ☐ Granulatie – vital granulatieweefsel

Infectie

- ☐ Biofilm
- ☐ Functieverlies
- ☐ Geen
- ☐ Kleur exsudaat
- ☐ Pijn
- ☐ Roodheid
- ☐ Verdacht van infectie
- ☐ Warmte
- ☐ Zwelling

Oedeem

- ☐ Dependency oedeem
- ☐ Geen
- ☐ Lipoedeem
- ☐ Lymfoedeem
- ☐ Post-traumatisch
- ☐ Stase-oedeem

Exsudaat

- ☐ Droog
- ☐ Nat
- ☐ Vochtig
- ☐ Zeer nat

Neuropathie [ja / nee]

Limited joint mobility [ja / nee]

SAMENVATTING (voorbeeld patient 2)

[wond 3 jaar geleden ontstaan, is even dicht geweest. Mei 2020 wezen zwemmen met zwemschoentjes, hierdoor waarschijnlijk verweekt en open gegaan. Meerdere malen toc, dit leverde resultaat op maar geen volledige genezing.
03-02: weinig wondexsudaat, avitaal weefsel in de wond, geen tekenen van een infectie aanwezig. Geen botcontact waargenomen.
17-02: weinig wondexsudaat, geen klinische tekenen van een infectie. Weinig wondexsudaat. Callus verwijderd.
08-04: gister bij alrijne geweest, is schoongemaakt.
02-05: debridement. Geur aanwezig. Dhr voelt zich niet ziek. Geen pus bij palpatie
26-05: veel callus verwijderd, geen klinische tekenen van infectie, ionosorb volledig verzadigd, geur aanwezig.
02-06: Geen klinische tekenen van infectie
06-01: wond en callus status que, verbonden met urgotull ag.
4-11 dhr heeft 10 dagen in het ziekenhuis gelegen ivm bacterien. Voet was woensdag in het ziekenhuis verzorgd. T: rood, dhr heeft kuur per infuus, M: vochtig tot droog, E: Callus minimaal voor dhr.
23-06: vochtig weefsel, woekerend beeld, veel callus. 2 dagen geleden verwijderd. Dhr ervaart geen pijn.
9/9: callus moet altijd weer verwijderd worden, oud bloed om heen, moeilijk om weg te poetsen. Patient heeft geen pijn.
4-7 hyperketose, geen tekenen van infectie
25-7 veel callus verwijderd tot bloeden, lang afgedrukt kaltestat ingezet met dubbele super absorber.
15-09: veel callus verwijderd, forse wild groei van avitaal weefsel. Geen klinische tekenen van infectie. De wondranden zien er gemacereerd uit.
26-9: fors gedebrideerd tot bloedens.
17-10: status quo, flink gedebrideerd.
14-11: omgevingshuid flink gemascereerd, onbekend wat de oorzaak van al het vocht is. Wellicht een infectie? Hoewel de klinische tekenen dit niet laten zien. In verband met het bloeden kaltostat ingezet.]

Medische indicatie: ***[****Diabetisch ulcus]*

Behandelingsdoel

- ☐ *Curatief*
- ☐ *Palliatief*

BEHANDELING

Behandeling

- ☐ Debridement autolytisch
- ☐ Debridement biologisch
- ☐ Debridement chemisch
- ☐ Debridement chirurgisch
- ☐ Debridement enzymatisch
- ☐ Debridement mechanisch
- ☐ Epthelialisatie wondbedekker
- ☐ Gipsen
- ☐ Granulatie NPWT
- ☐ Granulatie wondbedekker
- ☐ Offloading
- ☐ TCC

Overig *[urgo ag]*

Materiaalkeuze *[kaltostat bij bloedingen. GEEN ZILVERNITRAAT gebruiken!]*

Compressietherapie

- ☐ Geen
- ☐ LINKS ACT
- ☐ LINKS lange rek zwachtel
- ☐ LINKS manuele lymfedrainage
- ☐ LINKS mechanische compressie
- ☐ LINKS TEK
- ☐ LINKS verbandkous
- ☐ RECHTS ACT
- ☐ RECHTS lange rek zwachtel
- ☐ RECHTS manuele lymfedrainage
- ☐ RECHTS mechanische compressie
- ☐ RECHTS TEK
- ☐ RECHTS verbandkous

Compressietherapie materiaalkeuze *[voer in]*

Appendix B-2: HiXWond

Voorgeschiedenis

Intoxicaties

De patiënt heeft nooit gerookt.
De patiënt drinkt alcohol, minder dan 2 eenheden per dag.
De patiënt gebruikt geen drugs.

Lichamelijk onderzoek

Debridement uitgevoerd van: (*wond >5cm/wond <5cm/callus verwijderd)

Aanvullend onderzoek

Conclusie

(..)
Wondgenezing belemmerende factoren: (*ischemie/veneuze insufficiëntie/infectie/intoxicaties/voeding/pijn/oedeem/immobiliteit/druk van buitenaf/sensibiliteitsstoornis/cognitie of compliance/trofische stoornis/medicatie/glucoseregulatie/onderliggende dermatologische aandoening).
Arterieel: (*normale rustperfusie/in principe voldoende rustperfusie voor genezing/verminderde rustperfusie).
Wondfase: (debridementsfase/granulatiefase/epithelialisatiefase/genezen).

Diagnose

Beleid

Ten aanzien van wondgenezing belemmerende factoren:
Ischemie: (*nvt/conservatief/indien binnen 4-6 weken onvoldoende genezingstendens verdere vaatanalyse overwegen/recent revascularisatie gehad/recent revascularisatie gehad maar nog niet optimaal/op wachtlijst voor)
Infectie: (*nvt/wondkweek afgenomen/antibiotica voorgeschreven)
Intoxicaties: (*nvt/verwijzing rookstoppoli)
Voeding: (*nvt/dietiste icc)
Pijn: (*nvt/pijnmedicatie voorgeschreven)
Oedeem: (*nvt/start compressie middels/op wachtlijst voor)
Druk van buitenaf: (*nvt/drukontlasting middels vilt/ drukontlasting middels verbandschoen/ drukontlasting middels darcoschoen/drukontlasting middels rebacare/Total Contact Cast/wisselligging)
Medicatie: (*nvt/ja)
Glucoseregulatie (*nvt/glucoseregulatie via huisarts/glucoseregulatie via internist)
Wondbehandeling (..)
Thuiszorg ingeschakeld: (*nvt/Zorgschakel/Carint Reggeland)

Overige acties

Figure 18a. HiX content.

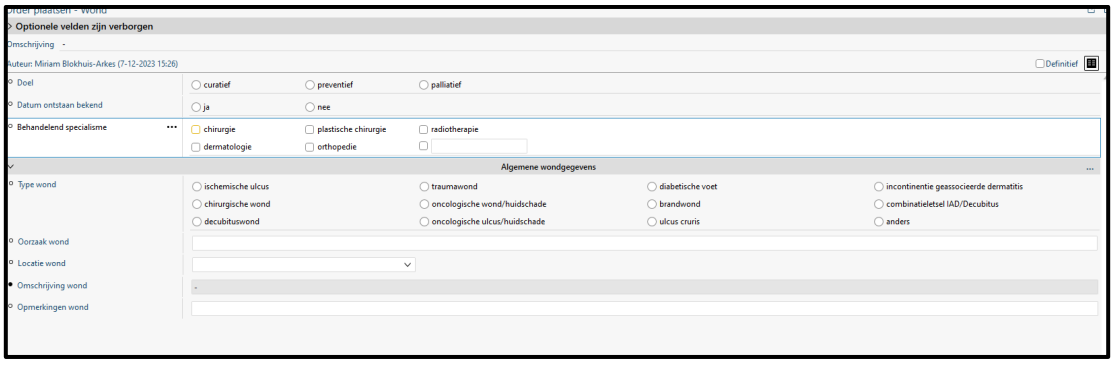

Figure 18b. HiX content.

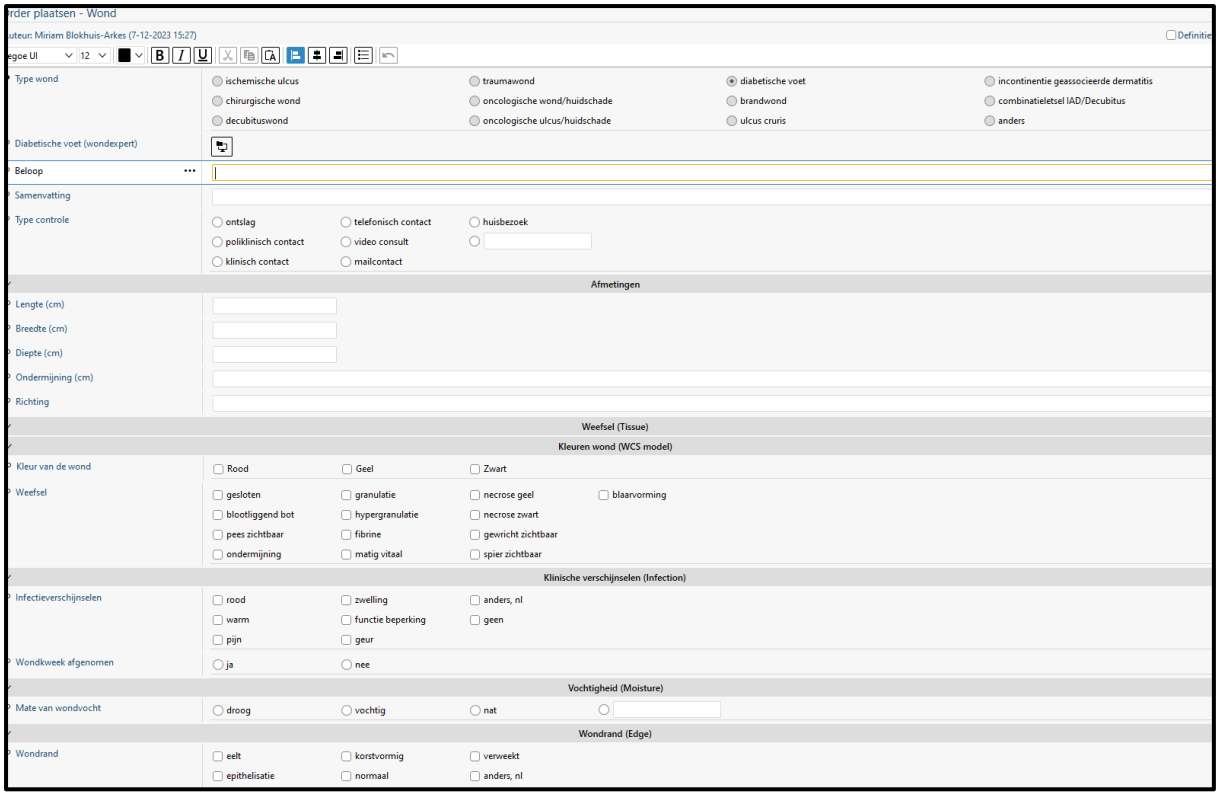

Figure 18c. HiX content.

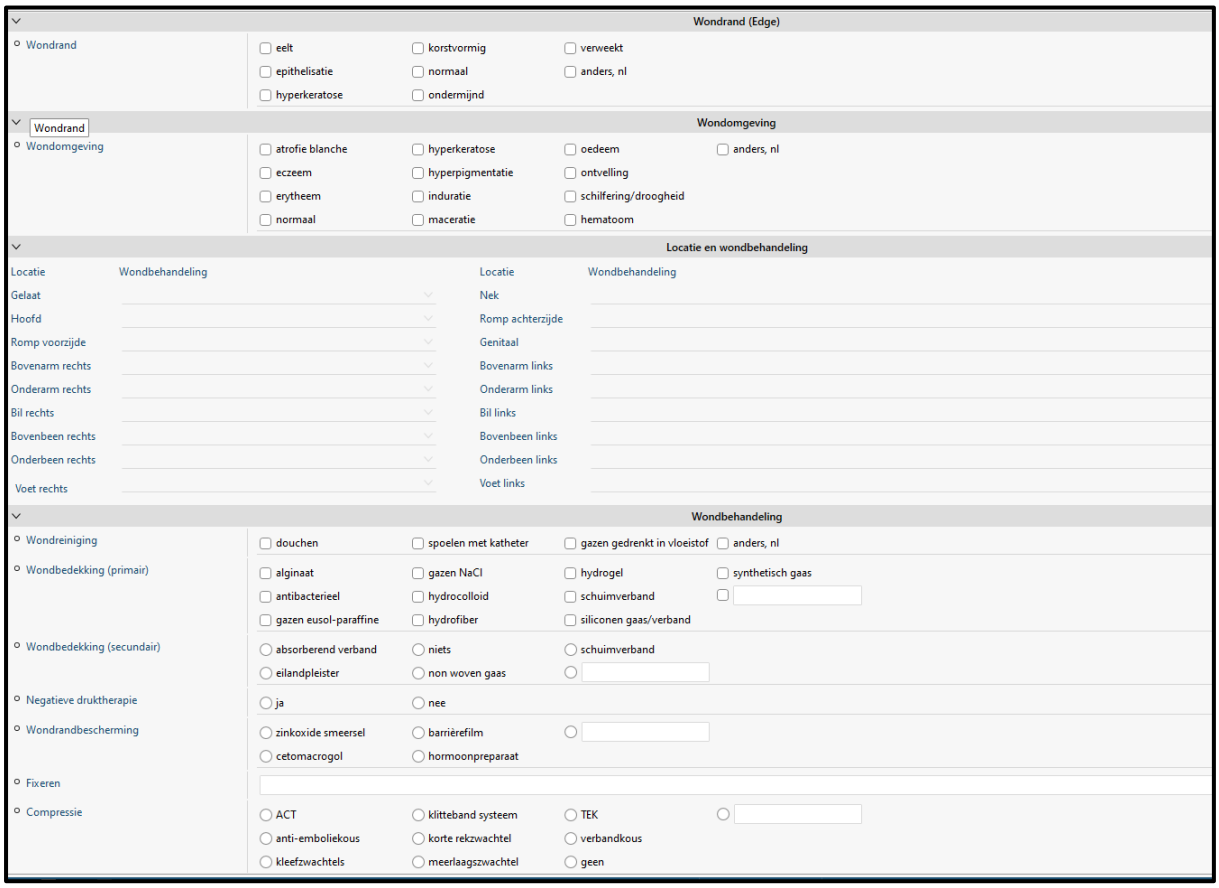

Figure 18d. HiX content.

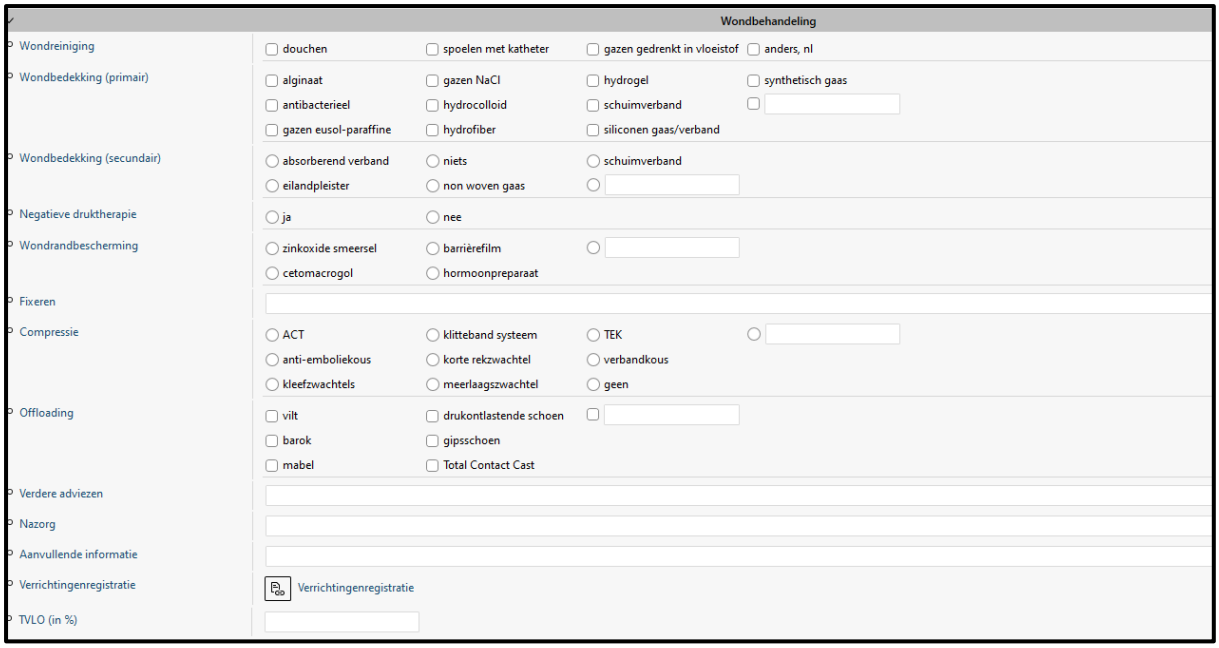

Figure 18e. HiX content.

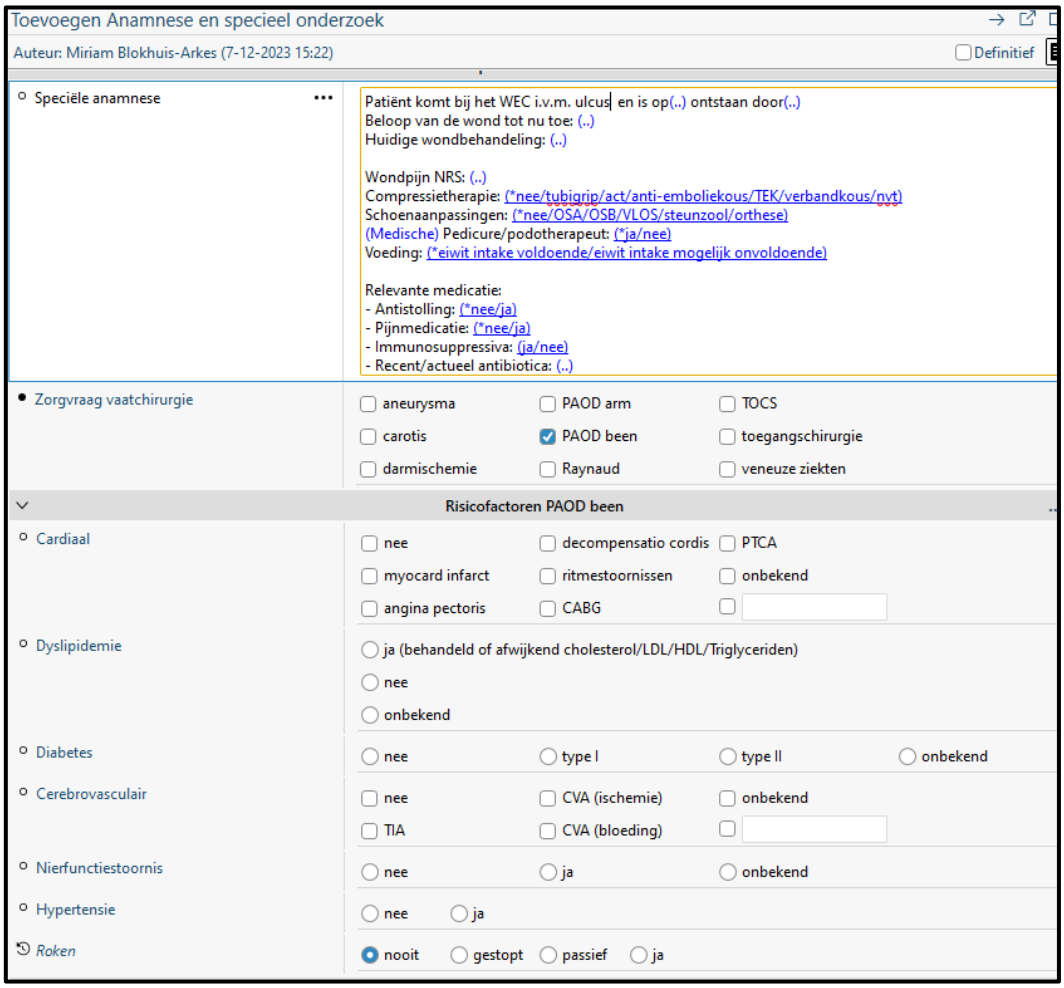

Figure 18f. HiX content.

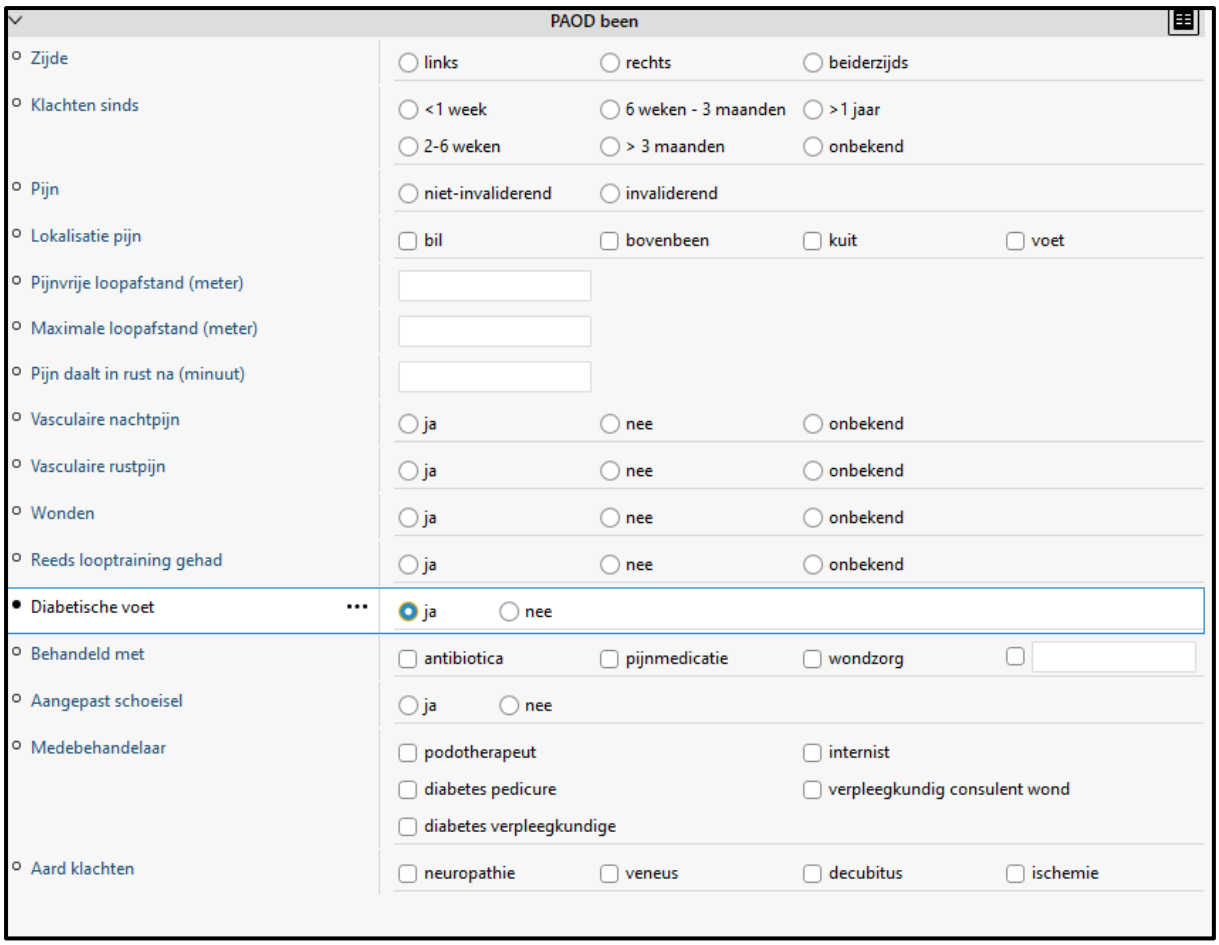

Figure 18g. HiX content.

References

[1] Bowers, S., & Franco, E. Chronic Wounds: Evaluation and Management. *Am Fam Physician, 101*(3), 159-166. (2020)

[2] Capgemini Consulting. (2014). Innovatie van complexe wondzorg: Nederlandse Zorgautoriteit.

[3] Gutierrez, E., Castaneda, B., Treuillet, S., & Hernandez, I. Multimodal and multiview wound monitoring with mobile devices. *Photonics, 8*(10). (2021)

[4] Hazenberg, C. E. V. B. (2013). Diabetic foot in the era of Telemedicine. Utrecht: Utrecht University.

[5] Mennes, O. A. (2021). Laser speckle contrast imaging for assessing microcirculation in diabetic foot disease. University of Twente, Techmed Centre: Biomedical Photonic Imaging.

[6] Nielen, M., Poos, R., Korevaar, J., Nivel, & RIVM. (2020). Diabetes mellitus in Nederland. Prevalentie en incidentie: heden, verleden en toekomst.

[7] Ekelmans, N. Diabetische voetzorg is multidisciplinair teamwerk. *Nederlands Tijdschrift voor Diabetologie, 19*(2). (2021)

[8] Rondas, A. A. L. M., Schols, J. M. G., Halfens, R. J. G., Hull, H. R., Stobberingh, E. E., & Evers, S. M. A. A. Cost analysis of one of the first outpatient wound clinics in the Netherlands. *MAG Online Library Journal of Wound Care, 24*(9), 426-436. (2015)

[9] Interaction Design Foundation. (2016). What is Design Thinking (DT)? Retrieved February 12, 2024, from https://www.interaction-design.org/literature/topics/design-thinking

[10] Oliveira, M., Zancul, E., & Fleury, A. L. Design thinking as an approach for innovation in healthcare: Systematic review and research avenues. *BMJ Innovations, 7*(0). (2020)

[11] Kolb, M., & Custom Interactions. (2023). What exactly is a “context of use analysis”? Retrieved February 13, 2024, from https://custom-interactions.com/en/knowledge/what-exactly-is-a-context-of-use-analysis/

[12] Marcilly, R., Da Costa, S. B., Boog, C., Beuscart-Zéphir, M.-C., de Jonckheere, J., & Pelayo, S. Impact of the context of use analysis for the extension of an existing medical device: an analgesia monitor case study. *Studies in health technology and informatics, 194*, 139-144. (2013)

[13] Ebben, I. (2023). Developing an instrument prototype for a wound care computer system: University of Twente.

[14] Jurca, A., Zabkar, J., & Dzeroski, S. Analysis of 1.2 million foot scans from North America, Europe and Asia. *Scientific Reports, 9*. (2019)

[15] MolecuLight Inc. (2018). MolecuLight i:X Technical Specifications (pp. 2).

[16] MolecuLight Inc. (2017). MolecuLight i:X User Manual.

[17] MolecuLight Inc. MolecuLight: Introducing Point-of-Care Imaging for Wound Care. Retrieved December 16, 2023, from https://moleculight.com/

[18] MolecuLight Inc. (2021). STANDARD IMAGING of wounds with the MolecuLight i:X®device. Retrieved February 1, 2024, from https://www.youtube.com/watch?v=tB6GzDfs2Ts

[19] MolecuLight Inc. Moleculight DX training videos. Retrieved February 1, 2024, from https://moleculight.com/moleculightdx-training-videos/

[20] Dacosta, R. S., Kulbatski, I., Lindvere-Teene, L., et al. Point-of-Care Autofluorescence Imaging for Real-Time Sampling and Treatment Guidance of Bioburden in Chronic Wounds: First-in-Human Results. *PloS one, 10*(3). (2015)

[21] Liu, C., van der Heijden, F., Klein, M. E., van Baal, J. G., Bus, S. A., & van Netten, J. J. (2013). *Infrared Dermal Thermography on Diabetic Feet Soles to Predict Ulcerations: a Case Study.* Paper presented at the SPIE: Advanced Biomedical and Clinical Diagnostic Systems XI.