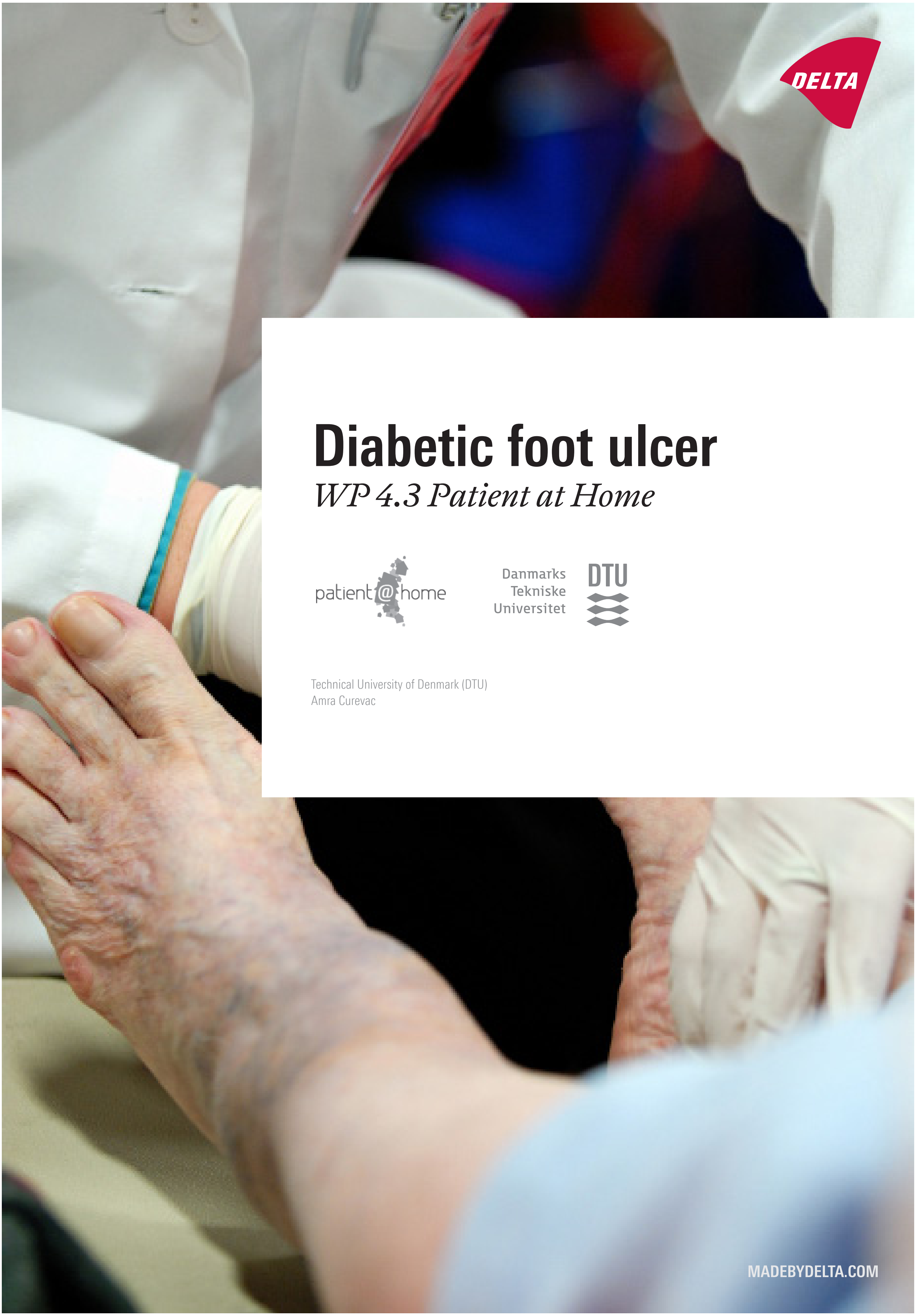


Diabetic foot ulcer

WP 4.3 Patient at Home

Danmarks Tekniske Universitet

Technical University of Denmark (DTU)
Amra Curevac

MADEBYDELTA.COM

1. Introduction

In Denmark 306.638 patients are diagnosed with diabetes and the number has doubled in the last 10 years. Diabetes cost the Danish government 11.5 million Euro daily. [16]

Patient@home is Denmark's largest organization working with welfare-technological research and innovation initiative with focus on new technologies and services for rehabilitation and monitoring of the Danish public health sector. The increasing population average life expectancy while more patients are diagnosed with chronic diseases will challenge the Danish public sector. There is a great demand on communication between patient and health professionals, and a need to include patients to take responsibility and monitor their own disease. Patient@home has an ongoing project, in collaboration with DELTA called "Diabetic Foot Ulcers". The projects focus on the diabetic foot and explore new technologies and tools to help the patient and health professionals to grade and characterize diabetic foot ulcers. [45]

Background and current partners
Around 3,000 Danes become affected by Diabetic Foot Ulcers every year. Treating the disease is deemed to incur costs in the order of 900 million DKK annually. Diabetic Foot Ulcers are very complex conditions where damages to neighbouring nerves or vasculars as well as infections may have a significant adverse effect on the development of the disease. This means that the risk of complications and even death is increased. Consequently, there is a great need for technologies that can describe Diabetic Foot Ulcers in a better and broader context.

Partners currently involved in this project include: DELTA: Danish Electronics, Lights and Acoustics, Odense University Hospital: Department of Endocrinology, Pallas Infomatik, Sensor Medical, South Danish University: Mads Clausen Institute, and Cure4u.

Project Aim
This assignment investigates and identifies the critical issues which arise with each subproject by study scientific literature and current products on the market of relevant use corresponding to DELTAs product development ideas.

The six subprojects under PATH are:
- Patient empowerment
- Family empowerment
- Validation of knowledge among nurses
- Ulcer Camera Monitoring
- Multisensor Intelligent Bandage
- On-foot enclosure

Background
The human body is dependent on glucose supply as an energy source. Glucose enters the body through our food supply and ends up in the blood stream.

Insulin is a peptide hormone that stimulates the uptake and storage of glucose in the body's cells. Insulin causes the cells in the liver, skeletal muscles and adipose body cells to remove glucose from the blood and convert it to glycogen. Glycogen is then stored primary in the liver but also in the skeletal muscles. In this way the blood glucose level is kept at a suitable range while the cells obtain energy.

If the blood glucose level is not maintained within a certain range and diabetes is poorly controlled, sequelae can develop e.g. nephropathy, retinopathy, atherosclerosis, the diabetic foot and even ultimatively death. In the absence of insulin glycogen is not produced which means glucose is not removed from the blood and hyperglycemia occurs. This condition is referred to as Diabetes Mellitus.

Diabetes Mellitus is a common endocrinological disorder, where the regulation of insulin and glucose is disturbed. Two forms of diabetes exist; type I (insulin-dependent) and type II (non-insulin-dependent). Type I is characterized by a destruction of the insulin producing cells in the Islets of Langerhans in the pancreas, resulting in diminished or total absence of insulin production. Type II is characterized by a resistance or reduced insulin sensitivity and insucient insulin production and is partially associated to western lifestyle. Diabetics with type I need insulin injections on a daily basis, whereas diabetics with type II in most cases can manage their disease by changing life style or receive certain oral antihyperglycemic agents including insulin. The change in life style would include healthy diets, weight loss and regular physical activity.[41]

Diabetic Foot Ulcers
One common sequelae of diabetes, as mentioned, is the Diabetic Foot Ulcer (DFU). The main concern is poor healing of the ulcer causing further complications. Two to three percent of people with diabetes will develop a foot ulcer each year and 85% of all amputation of lower limbs is preceded by a foot ulcer [29] It is estimated that the prevalence of DFU amount to 22.000 Danish people and 3000 new cases occurs each year. In Denmark 4000 patients are living with amputated limbs as a consequence of DFU. Most of the patients mentioned are elderly and therefore have decreased mobility and an increased need for help doing everyday tasks. [53]

The diabetic foot can be defined as infection, ulceration and/or destruction of deep tissues linked to neurological abnormalities and peripheral vascular disease in the lower limb (Figure 1.1) [20]

DFU is a result of combined risk factors occurring together in diabetic patients. The risk factors include peripheral arterial disease, peripheral neuropathy, vascular disease, limited joint mobility, repeated trauma from abnormal load distribution of the foot and foot deformities. In the majority of patients peripheral neuropathy plays a central role and is present in almost 60% of diabetic patients with foot ulcers. One in three people who are above age 50 and have diabetes will develop peripheral artery disease. [29]

Peripheral Artery Disease
Atherosclerosis is a cardiovascular disease which affects not only the vessels that feed the heart but also those that serve the rest of the body. Blood clots and atherosclerotic plaque can reduce blood flow to the limbs and result in the condition called Peripheral Artery Disease (PAD). Symptoms include pain, weakness, numbness and cramping in the limbs and also slow wound healing. There are many noninvasive assessments for PAD, the important ones will be listed below in section 2.3.2.

Peripheral Neuropathy
The nervous system of the body is divided into the central nervous system and peripheral nervous system. The central nervous system includes the brain and the spinal cord, while the peripheral nervous system is a network of nerves transmitting signals from the brain to the rest of the body. The peripheral nerves can be divided into sensory, motor and autonomic nerves. Sensory nerves transmit sensations of touch, temperature, position, and pain from the body's periphery to the brain. Motor nerves transmit information from the brain for the contraction of various muscles. Autonomic nerves transmit the brain's commands to organs such as the heart, lungs, and liver.

High blood glucose level can lead to peripheral neuropathy due to chemical changes in the body. Peripheral neuropathy, meaning nerve dysfunction to one 3 or more of the peripheral nerves, results in loss of sensation in pain, temperature, touch etc. Peripheral neuropathy may be divided into sensory neuropathy, motor neuropathy and autonomic neuropathy.

Sensory neuropathy is associated with loss of pain and pressure awareness, and loss of temperature sensation. Due to the lack of sensation the patient's foot is vulnerable to temperature changes, minor injuries and pressure. A minor friction or poorly fitting shoes may result in a foot ulcer, which the patient may not notice.

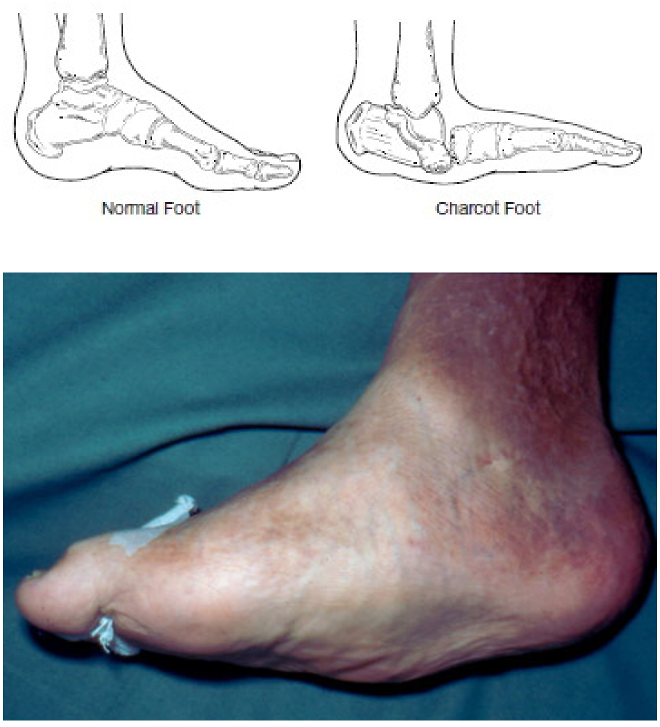
Motoric neuropathy affects the patient's foot and leg muscles, and the foot biomechanics. This can lead to foot deformities, limited joint mobility and atrophy. Foot deformities can turn into a drop foot, lead to thickening of the skin and callus formation and develop in to foot ulcer.

Autonomic neuropathy refers to damage of the autonomic nerves. The damage can disrupt the signals from brain to sweat glands and blood vessels. This can lead to a decrease in production of sweat and other components of the body's natural moisturizing factor. The consequence is a disruption in the skins epidermal barrier leading to dry skin with cracking and ssuring. [53] [15] [44]

Charcot Foot
Patient's with DFU are also at risk for develop Charcot Foot. Charcot neuropathic osteoarthropathy, also referred to as Charcot foot is a condition affecting joints, soft tissue and bones. Jordan et al. 1936 was the rst to describe the association between Charcot foot and diabetes.[58] The cause of the condition is not certain, but it is characterized by a slow degeneration of the joint and bones in the foot resulting in loss of the normal foot architecture (Figure 1.2). Patients with peripheral neuropathy are also at risk developing Charcot foot because of the decreased sensation.
Charcot foot can appear after a trauma such as a sprain, falling, fracturing or dropping something on the foot. It can also appear after a minor repetitive trauma e.g. long walk. If the patient continues to walk on the injured foot, the shape will eventually change from a normal shape into a convex shape. The patient will have problems

Figure 1.1: Diabetic Foot Ulcer [50]

Figure 1.2: Normal Foot (left) and Charcot Foot (middle and right) [7]



walking and an increased foot temperature, redness on the foot, swelling in the area and pain or soreness. [7]

Diagnosis is based on medical history, symptoms and imaging methods. Imaging methods include X-ray which provide information about bone structure 4 and alignment, however the foot may be normal in the initial phase. Magnetic resonance imaging (MRI) is the method of choice for diagnostic purposes of Charcot foot because it can differentiate Charcot foot from similar foot injuries or diseases e.g osteomyelitis (bacterial bone infection). A common used classifcation system of severity of the Charcot Foot is the three stage system described in Table 1.1

Treatment of the patient is based on the stage of Charcot Foot, presence or absence of foot ulcers and infection. Immobilization and mechanical protection by casts to prevent further deformities and collapse is recommended. [7][59]

Diagnosis And Treatment Of DFU

The main goal of treatment of DFU is to obtain healing of ulcer. Glycemic control is essential to the patient but many problems can be avoided by proper foot care and well-fitting footwear.

Wagner classification is used to classify the foot ulcer. The foot ulcer can be divided in stages 0-5.

Wagners stage 0	No ulcer, may have thickening of the skin or deformity.
Wagners stage 1	Superficial ulcer
Wagners stage 1A	Superficial ulcer with infection
Wagners stage 2	Deep ulcer, penetrating to ligaments and muscle, no infection
Wagners stage 3	Deep ulcer with infection
Wagners stage 4	Localized gangrene
Wagners stage 5	Extensive gangrene involving whole foot [15] [52]

Some studies use the University of Texas Wound classification, which include complications occurring with ischemia and how the ulcer is spread. There are no evidence that one classification system is more accurate than the other.

Diagnostic tests for factors leading to DFU are use of Monofilament and calculation of the Ankle brachial blood pressure index. Medical management of the foot ulcer includes offloading/pressure relief, debridement, treatment of infections and surgical management.

Monofilament

One of the diagnose methods for neuropathy is by using a mono lament. The mono lament is used to investigate touch perception by pressing the mono lament on different places. The investigations clarifes if the patient are aware when the pressure is applied to the feet and when it stops.[53] Ankle-Brachial Blood Pressure Index (ABI) ABI is one of the noninvasive vascular screening tests used to identify PAD. ABI is defined as equation (1.1):

<u>ABI = systolic blood pressure (SBP) at ankle SBP at arm (1.1)</u>

The measurement can be performed using a handheld Doppler and sphygmomanometer. A Doppler is an ultrasound test, which uses sound waves to measure the blood ow through blood vessels by applying a transducer to the skin. Sphygmamometer is a blood pressure meter. The severity of PAD is defined using the Ankle Brachial Index (see Table 1.2). ABI's measurement is limited due to calci cation of larger arteries e.g. mediasclerosis and to overcome this limitation studies propose calculating the systolic blood pressure at the toe (TBP) and calculating the toe brachial index (TBI) done by Photoplethysmography. [21]

Table 1.2: Ankle Brachial Index [15]

ABI reading	Interpretations
0.9-1.2	Normal
0.5-0.9	Moderate PAD
<0.5	Severe PAD

Off Loading/Pressure Relief

Pressure relief of the foot is an essential component of DFU treatment. Continuous walking on insensitive foot prevents DFU from healing. How to reduce the pressure depends on the location and the severity of an ulcer. Studies indicate that the pressure relief system has to achieve a threshold of a peak pressure <200KPa to maintain healing. Pressure relief by correct foot wear has proven to have an e ectiveness on prevention of DFU. Gyan et al 2012 and Apelqvist et al. 2012 [15] [20] propose some of the following pressure relief techniques:

- Non weight bearing items: crutches, bed, wheelchair
- Adequately fitting shoes for indoor and outdoor use, half shoes or wedge shoes
- Shoe cutouts
- Total contact casting

If footwear can not prevent the DFU to heal or reoccur the patients activity level should be decreased.

Debridement

Debridement comprises a method to remove non-vital tissue to improve or facilitate wound healing. Proper debridement is necessary to reduce the risk of infection. The DFU will not heal if non viable tissue and debris is present. There are many methods of debridement: surgical, enzymatic, biological and autolytical. After debridement a dressing should be applied to prevent ulcer from contamination and absorption of excessive fluids etc.

Infections

Infection in the ulcer is caused by colonization of bacteria or other microorganisms resulting in a delay in ulcer healing. Infection occurs when the body's immune system can not protect it self against bacterial growth. The infection can also affect the surrounding tissue causing cellutis (bacterial skin infection) or an acute or chronic osteomyelitis. Once an ulcer is complicated by infection it can in worse case lead to amputation of the lower limb. Infection in the ulcer can spread and cause infection in the rest of the body. The non-healing ulcer results in signi cant pain and discomfort. The ulcer requires a moist environment in order to heal. Sterilized equipment should be used and the dressing of the wound needs to be changed daily or at regular intervals. The health professionals can also provide the patient with many forms of antibiotics (topical, oral, intravenous) to treat the infection. [57] [20]

Surgical Management
Treatment for DFU vary depending on the severity of the wound. In general, the treatment methods are those mentioned above: offloading, removal of debris, keep the wound clean, and promote healing. The goal is to avoid amputation. If the condition results in a severe loss of tissue or a life-threatening infection, an amputation may be the only option. Amputation does not always mean loss of the entire leg or foot. There are many levels of surgical interventions including partial foot amputation, partial toe amputation etc. The health care professionals will make a thorough assessment and determine what is best for the patients recovery.
After surgery patient often experience improved general health due to treatment of the infection.

Patient empowerment
The focus of DELTA regarding their patient empowerment project is to enable the patients to care for their DFU on their own. One of the goals is to develop a device that helps the patient to be in control of their own disease by a home monitor system. This chapter will give a short overview of why the patient should be empowered, medical devices that can be used to patient empowerment, which problems may occur and possible solutions.

Prevention
Studies show that patients with DFU underestimate the severity of the disease. They experience their symptoms as being trivial and as a consequence the diagnosis and treatment is delayed. In 1989 the World Health Organization and International Diabetes Federation met with representatives from government health departments in Europe to create a set of goals for the medical care of patients with diabetes mellitus. This resulted in St. Vincent Declaration. One of the goals was to reduce amputations caused by diabetes with 50%. To reach this goal international guidelines emphasize the need to reduce the incidence for DFU by preventive efforts, including patient education about DFU and self-examination.[56] Prevention efforts are effective, the amputation rate has decreased, but there is insucient evidence that this is only due to patient education. Improvement in technology and treatment can also have a ected the positive result. Today information about diabetes and its consequences can be easily accessed by using the internet. Using the internet also means communication with doctors and other health care sta /experts is easy. However, information from health professionals and the internet come useless if patients does not know how to act upon it. Studies show that many patients forget the important message of untreated foot ulcers and react when the ulcer is occurring. The patient needs to be more aware and involved in their health situation by empowerment. Empowerment is a practice where patients achieve greater control of decisions and practices a ecting their health. Empowerment in this case help patients identify, control and manage their DFU.

How can the patient be empowered?
The first step for patient empowerment is educating the patients about DFU and consequences that may occur e.g informing the patient about the 12s's of foot care (see Table 1.3). Communication between health care professionals and the DFU patient is a significant factor for the education and the treatment of DFU. It is recommended that patient education is developed based on the patients´ needs and abilities. [53] The second step is patient self-monitoring. The patient can regulate diabetes by using self-monitoring medical devices and note observation in a questionnaire provided by health care professionals. The current market provides several medical devices for self-monitoring of diabetes. As an example the patient can check the feet for DFU by using a self-exam foot mirror (see Figure 1.3). The foot mirror enables the patient to see the not visible areas of the feet without bending. [6]

The patient can keep track of the blood glucose level with a home blood glucose meter which can help the doctor understand and determine if the glucose is too high/low (see Figure 1.4).

Furthermore, telemedicine is another way of self-monitoring which is described in the next section.

Telemedicine
Studies suggest the use of telemedicine for patient empowerment

Table 1.3: The 12 S's of foot care[29]

Consideration	Action
Sugar	*Check your blood sugar regularly*
Smoking	*Stop smoking*
Sores*	*Check for sores on the feet every day*
Scale or callus	*Check for scale (caused by dry skin or fungus) and callus (caused by too much pressure)*
See the bottom of feet	*Bottom of the needs to be visual and checked Socks Wear socks with no seems are optimal Light colored socks are optimal so if drainage occurs it can be seen*
Shoes	*Proper fitting shoes with plenty of room is required*
Steps	*Keep shoes on feet at all times to avoid damage*
Shower and wash	*Foot hygiene needs to be maintained every day*
Soak	*Soaking is not recommended*
Safe nail care care	*Nails needs to be cut straight across* Skin *Chemical treatments should be avoided. Moisturizing feet is recommended*

*blisters, cuts, open skin.

Figure 1.3: An example of a self exam foot mirror is the Telescoping Self Exam Foot Mirror 20012.[6]

Figure 1.4: The Abbott Diabetes Care Freestyle Lite is a blood glucose meter that helps people with diabetes to manage their condition.[37]

and to enable the experts monitor the increasing number of patients. Telemedicine is use of medical information exchanged from one site to another via electronic communications. Telemedicine tools use telecommunication technology including email, smartphones, wireless tools, audio and video conferencing. Clemensen et. Al 2005 [38] investigated the use of telemedicine to enable a visiting nurse at the patients home, to coordinate the treatment of DFU with experts in the hospital. The study tested The Universal Mobile Telecommunication System which consisted of a videophone and an Internet based patient record. The conclusion in the study was that the clinicians and patients found the equipment easy to use, the nurse could start the treatment immediately with the doctors advice and the patient saved time not going to the hospital.

Furthermore Clemensen et Al 2008 [39] showed that it is possible for experts at the hospital to conduct clinical examinations of DFU and make a clinical decision using video consulting.

Dafoulas et al. 2012 [22] propose the use of an open mobile telemedicine platform called SANA for diabetic foot monitoring. SANA is a Mobile Health (mHealth) project developed by Massachusetts Institute of Technology (MIT).

SANA connects healthcare workers to medical professionals. It is an Android based system which can be customized and be used to transmit medical les such as notes, audio and video through a cell phone to a central server for archiving and adding the les into an electronic medical record. SANA consists of a web connected server and phones. The advantage of SANA is that it can be customized to the user and is a step-by-step procedure. The proposed telemonitoring platform could be an alternative telecare service, but the platform has not been validated through a clinical trial.

Telemedicine in Denmark

Several pilot studies for telemedicine implementation have been tested in Denmark and shows promising results. As a part of the Danish Government new digitalization reform strategy The Municipalities' Association (Kommunernes Landsforening (KL)) made a proposal in April 2013 for the Telehealth Strategy. One of the goals in 2015 was to have 80% of the communication between health care professionals and the citizens digitalized by the end of that year. [55] [48]

The new strategy initiated Denmark's largest ongoing telemedicine project expanding from year 2012-2014. In the project four patients groups are participating: COPD (Lung disease) patients, diabetes and wound assessment patients, in ammatory gastro disease patients, and pregnant women. All of the patients have IT equipment in their home to measure and register relevant data. All information is stored in a common database providing the health care professionals full access to the data uploaded and enables them to keep track if anything needs to be changed e.g. medication.

The telemedicine diabetes and wound assessment project started in September 2012. The purpose is to test the efficiency and effectiveness of the wound assessment done by the visiting nurses using telemedicine. The procedure when the nurse is visiting the patient at home is as follows:

A visiting nurse takes a picture of the wound with a cellphone and upload the picture to a web based patient journal.

The nurse documents all observations of the wound on a tablet or cellphone.

A doctor or a specialized nurse at the hospital can open the journal and conduct a clinical examination. The advantage with the diabetes and wound assessment project, seen from the Governments perspective is that the visiting nurse will become an expert in wound assessment through time due to the communication with experts. Additionally it is estimated that patient hospital visitation will decrease resulting in saving the Danish Health Care System 34 million Euros a year. It was not possible to gather information which telemedicine devices and application is used in the ongoing project.

Examples of products

Representative FDA class II telemedicine products on the market are AirStrip One Patient Monitoring and American Well's Online Care Mobile:

AirStrip One Patient Monitoring

AirStrip One Patient Monitoring has created an app to provide health professionals access their patient's data despite their location. Health professionals can use the app on their smartphone or tablet and log on to patient records hence patients can be closely monitored without health professionals being present at the same location. [5]

American Well's Online Care Mobile

American Well has launched a mobile app enabling the patient to have immediate, live conversations with health professionals at any given time of the day by connecting online. The app can be downloaded and is available for Android and iOS devices. [3]

Advantages and disadvantages of telemedicine

The advantage of using telemedicine for patient empowerment is easy implementation. All of the technologies can be developed to match smartphones and tablets, hence the technologies will become an extension of patients own IT use. Using smartphones and tablets means that the patient does not have to buy extra equipment if they already own a smartphone or a tablet and therefore it is cost-effective seen from the patients' perspective. Another nancial bene t with telemedicine is reduction of home health utilization. The patient could be monitored every day which can reduce visits by the nurse to a few times a week and thereby increase each visit time.

The disadvantages of using smartphones or tablets are the ethical dilemmas e.g. patient autonomy. The patient is fully in charge of decision making relating to the disease, this means that the health professional vs patient relationship will be decreased and changed. Another problem which might occur is that the patient can manipulate with the measurements.

The requirement for many of the telemedicine health technologies is access to the internet or smartphone. Smartphones and other technologies have a possibility of error occurring by not connecting online. Devices can have a technological error; an example is that the health professional does not receive the image of the ulcer from the patient. A human error may occur, which may happen if the patient has not received enough guidance on how to use the technology.

The security and privacy questions need to be considered as well regarding who will have access to the patient data. A breach of confidentiality can occur because the information is stored as data.

Telemedicine can be one way to empower the patient with DFU even though all of the studies investigated require a nurse to be present. A solution using telemedicine is that the patient could be provided with a similar simple system, as mentioned above, using the smartphone camera to record the condition of the ulcer and to illustrate how severe it is. The rating of the ulcer could be included in an app for the smartphone or tablet. The nurse can use the information to prepare and estimate treatment time.

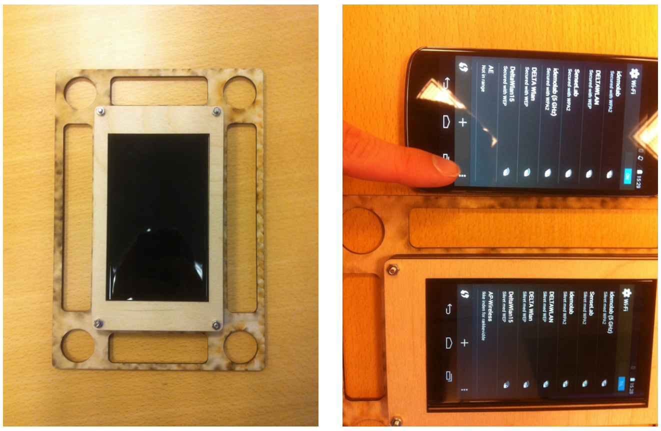
DELTA has developed a prototype containing of two smartphones to enable the patient to take images of their own feet.
The system contains of two phones connected to each other via a video exchange to simulate an automated camera feed (see Figure 1.5). When the patient needs to examine the feet one phone is used as a remote view nder. The other phone, which is placed in a wooden casting, can be placed or hanged in a position to see the ulcer from the perspective of the rst phone. The images can be taken and sent to the 12 health professionals. The device is meant for patients with reoccurring ulcers or patient without bandages covering their ulcers.

Further Investigation

Further investigation needs to be done to improve DELTA's remote view finder system. Critical questions to be answered and few considerations with this system are e.g: Are the images valid due to image quality and resolution? The wounds are often shiny and lights play a signifcant role for the image taken, can the device still be used? Who should teach the patient to use the device? Patients are elderly and may not be able to pick the wooden casting up or correct it once it is placed under their feet? Which position should the patient place the feet for the health care professionals can use the image?

This chapter will give an overview of why family members have difficulties in involvement of the patient disease, examples of existing medical devices on the market which correspond to DELTA's ideas to involve the family members of DFU patients.

Figure 1.5: DELTA's prototype containing of two smartphones. One phone is placed in a wooden casting (left) and the other smartphone is used as a remote view finder (right). Partners: Thomas Brigsted Jensen, Pallas Informatik, Knud Yderstraede, MD, Ph.D at Odense University Hospital in the Department of Medical Endocrinology.



2. Family Empowerment

The families of DFU patients do often not know how to contribute and help the DFU patient. DELTA's goal with the family empowerment project is to involve family members in the treatment and management of the patient conditions by providing them with home monitoring devices.

Family involvement
Diabetes and DFU does not only affect the patient but also their families and their daily routines. Family members often take an active role in helping the patient executing complex self management tasks. The family has to adapt (eating habits, monitoring the patient) to the patient's conditions and the patient's routine. However studies show that patients self-management can be a ected (positively or negatively) by family encouragement, behavior and involvement. [24] [36] Improved self management of a chronic disease has been linked together with the amount of emotional and practical support the patient receives from their closest family and friends. National Institute of Diabetes and Digestive and Kidney Diseases, USA writes in a statement that in order to stay healthy family support is critical for people living with diabetes. [40]

Looking at diabetes from a safety point of view it is important that family and people closest are educated and informed about diabetes. If the patient is taking medication or insulin there is a risk for hyper/hypoglycemia. If an ulcer is developing rapidly there is a risk for a serious infection. The closest people need to know how to recognize the conditions and how to react and help.

Rosland et al 2013 [36] study showed that family members and friends are willing to assist the patients with chronic illnesses with medication use and communication with providers, but they feel constrained by privacy concerns 14 and a lack of patient health information. The study proposed a solution which contained of developing an innovative program designed to facilitate disease management support. The program should include education of the disease and identifying changes of the disease.

Zulman et al 2013 [26] suggested to provide family members and friends with e ective health information technology which could help indicate patients symptoms and status. The health information system should also share the information with health care professionals. The goal is to provide the patients and family members with a form of security and help nurses share information internally and between patient and nurse.

Medical devices
Representative telemedicine tools similar to DELTAs ideas includes devices from Bosch and Philips. The devices will be described briefly: Bosch-Healthcare has developed two telehealth devices called Health Buddy and T400 Telehealth system where the patient can enter their vital signs from home. The patient information is transmitted and color-coded (red/yellow/green) to help health professionals see deviations from evidence-based care parameters. If the color code is yellow or red the health professionals are suggested to call or visit the patient.

The difference between the two devices are:
Bosch's Health Buddy System supports self-management for patients requiring long-term care coordination through comprehensive health management programs where Bosch's T400 Telehealth System supports multiple daily transmissions of vital sign and symptom data to care providers for patients who require careful monitoring of compliance with care post-hospitalization. [11]

Philips Healthcare have developed in-home monitoring device called Telestation. Patients can use wireless measurement devices to take their vital signs and implement them in the Telestation. The information will be transmitted to Philips secure server and health professionals can access and view the information by using an application called Clinical Review.

Bosch and Philips telehealth devices can connect to a variety of medical peripheral devices which makes the device easy to customize to each patient. Compatible devices include blood glucose meters, blood pressure monitors, pulse oximeters, peak flow meters and weight scales. (see Figure 2.1)

One idea and product DELTA is working on for family empowerment is providing the patient with a technological display system which can inform the family and relatives of the patient's mood. In detail DELTA's idea is to provide the family with a system which notify the family of how the patient is doing, how severe the ulcer is and how the patient's activity level is. Most of the DFU patients are elderly and feel embarrassed to complain of pain and call their children even though they are hurting. The purpose of the DELTA's system is to inform the families of how the patient is feeling indirectly.

The prototype system developed by DELTA contains of an artefact which is a physical object in the home called the Moodmeter, and an app for a smartphone made for the family/relatives which correspond to the Moodmeter. The application is simple providing information about the score of patient's mood, score activity level, sorescore and nally a total score.

Figure 2.1: Health Buddy System from Bosch Healthcare (left) and Telestation from Philips Healthcare (right)[12] [46]

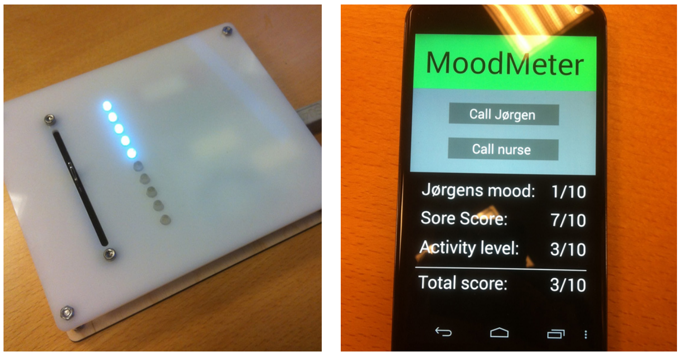
When the patient is in a good or a bad mood, the patient can enter their mood by rating it on the Moodmeter (see Figure 2.2). The activity level score will correspond to a tness tracker e.g. a bracelet and the sorescore will be rated of the visiting nurse. All of the scores will be added to the total score which determines if the family needs to take contact to the patient. If a sudden drop in the total score occurs the family will be informed by a noti cation from the app. The family can determine when to call the patient.

Further Investigation
The development of the Moodmeter is in an early phase and lots of question needs to be answered before the product can go further in its development stages. Some questions and considerations to be answered are:

How should the patient scale the pain score?
Which validated system should be used which is understandable for older patients?
How many times a day should the patient use the Moodmeter?

The patient will expect a call from the family if s/he by rating the mood with a low score knowing they are informed. What happens if the patient does not receive the call?

Figure 2.2: DELTA's prototype of the Moodmeter (left) and the app for smartphone (right).



Partners:
Morten Georg Jensen, IdemoLab, DELTA.
Henrik Gundsø, C4U Technologies ApS.
Knud Yderstraede, MD, Ph.D at Odense University Hospital in the Department of Medical Endocrinology.
Michael Schulssen and Michael Niebling Llobet, Sensor Medical.

3. Validation of knowledge among nurses

Visiting nurses collaborate in treatment of DFU. This chapter differs from the other chapters in this report because DELTAs aim of this project is to answer the question of how the visiting nurses share information and how valid is the information between them.

This chapter will provide information of how the nurses share information and what problems occurs gathering knowledge from one nurse to another.

Nurses play an important role due to their involvement in preventing and detecting diabetes and its further complications. They have an effective role in prevention of DFU by educational interventions and an effective role to provide health services. [33]

It is common that skills and expertise by the nurses are passed on to one another. Student nurses learn the practical part of their study by working alongside with experienced and committed nurses who are able to demonstrate care routines.

The endings in Estabrooks et al. 2005 [27] study shows that nurses practical knowledge can be categorized into four broad groupings:

Social interactions
Experimental knowledge
Documentary sources
Priori knowledge

Social interactions describe the communication processes between nurses, nurse to doctor and nurse to patient. This includes sharing information and knowledge. The study shows that nurses rely more on social interactions among peers, meaning the information gained from another nurse or doctor, than e.g. academic journals. The reason given is the easy access to immediate practical knowledge, the unique support they are receiving and colleagues' experience. 18

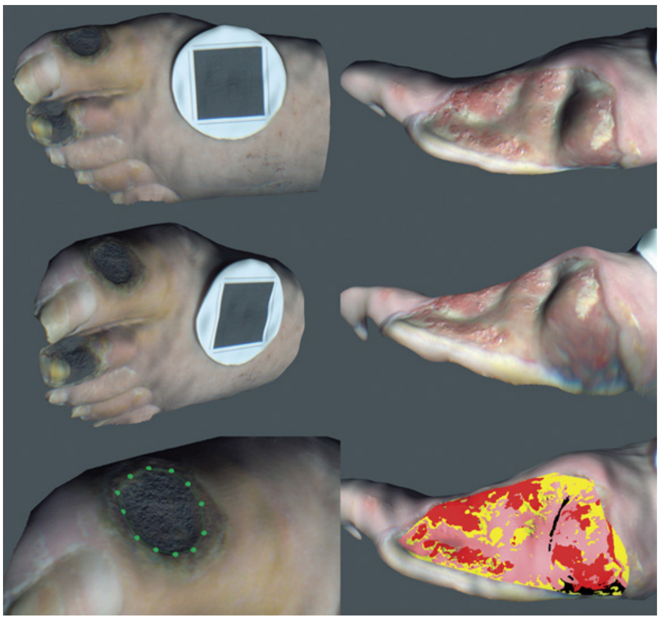
Experimental knowledge is gained through observation. It is based on what has worked or not worked previously, and further based on the nurse's intuition. Documentary sources are patient charts, procedure manuals, books and journals. Patient charts describing patient history is valuable source of knowledge, and the treatment is based on this. Books and journals were not used frequently by the nurses and the reasons given were time limitations and that the information was not presented in an understandable form to nurses.

Priori knowledge is gained from nursing school, common sense, personal beliefs etc. The study shows that foundational knowledge gained at nursing school is not sucient in practice, but knowledge gained from peers and at work was more useful.

The problem occurring with nurses gathering knowledge from one another is if one nurse is not adapting to new technologies and is reluctant to change. As a consequence new methods will not be implemented and the patient will not receive the recommended care. Estabrooks et al. 2005 [27] study illustrates examples where nurses sometimes rejects evidence based patient care protocols if they believe it is not in accordance with their own knowledge. This becomes an issue if the health professionals are adopting innovative interventions that are based on best practice and research based evidence. Majid et al. 2011 [10] study illustrates that evidence based practice (EBP) provides better patient care but is have limitations with implementation due to lack of time, resources and knowledge.

In many hospitals, including Denmark's largest hospital Rigshospitalet, educational programs are available containing knowledge sharing from experienced nurses to the less experienced nurses. These programs are made to improve quali cations and provide security for the less experienced nurse by practical knowledge. It is difficult to answer how e ective the programs are because of limitations of nding information in this report, but money are invested in the programs which may increase the potential of knowledge sharing.[30]

Foot ulcer image taken by Eykona imaging system.



4. Ulcer Camera Monitoring

DELTA's goal is to develop a handheld in-home 3D imaging system which can be used by visiting nurses to provide information about DFU. In this chapter ongoing research projects and launched products related to 3D imaging systems for DFU will be described.

Imaging techniques for examination of DFU
The common method for examination of the DFU is visual examination. The description of the observed ndings is recorded in the clinical notes by use of medical expressions. Many words can be used to describe the appearance of the ulcer, but if one health professional has lack of knowledge about specific medical expression important information can be omitted.

Today conventional digital two dimensional (2D) cameras are used for illustrating the foot ulcer and to provide visualization to the recordings in the patient journal. Using conventional digital photo cameras for diagnosis of the DFU have many disadvantages. Factors as lightning conditions in the room, wound distancing, focus and the patient's ability to position the feet in a standardized way can affect the picture quality. Limb curvature may not appear on the image taken and the ulcer can appear different on the image which may affect further patient proceedings. Another disadvantage to consider is that in some cases, because of the patients condition, it requires another person to take the picture of the DFU, which is a problem if the patient live alone, obese and bedridden. Finally, most of the 2D cameras used are not speci cally designed for wound imaging [34][49]

Many studies have investigated the development and usability of image system for DFU diagnosis. Bus et. Al (2010) [34] developed a foot imaging device that provides high quality digital images of the plantar surfaces of the feet under standardized conditions with respect to foot positioning, camera orientation and lightning conditions. The foot imaging device used contained of a camera module featuring a charge 20 coupled device image sensor, light sources, mirror, glass plate, foot support, a lid, a computer and a plastic housing. Accordingly the device is self-operational and the image taken by the device is sent automatically to a central database server using the internet. Images of the patients feet were taken three times with a two week and four week interval.

The images were first compared to live assessments, and then compared to the pictures taken during the weeks. This was done to provide indications if the image system device can be used for DFU diagnosis.

The study data indicated that clinical signs of diabetic foot can be diagnosed from high quality photographs. However Bus et al study contradicts Prompers et al. (2007). The images taken in Bus et al.(2010) was of the plantar surfaces of the foot, but according to Prompers et al. (2007) [35] study 52% of the diabetic foot ulcers appears non-plantar but instead on the dorsum of the foot. This is a limitation if the patient has a non-plantar ulcer. Bus et al.(2010) study also indicated that the device should be used of trained health professionals to get the optimal results, which limits the patients and patient family participation.

An image device providing a full overview of the foot and ulcers are needed. Researchers are developing 3D imaging technologies for assessment and full visualization of the feet and occurring DFU. Some examples of existing 3D image technologies are Eykona and Silhouette.

Eykona
Bowling et al. (2011) developed a handheld 3D imaging system used for assessment of DFU. The handheld 3D imaging system is called Eykona Wound measurement system. [17] The Eykona Wound Measurement System provides a full color 3D model of the wound using the hand-held camera, advanced computer vision software and a disposable optical marker.

Eykona software can allow health professionals to zoom in on images and measure the foot ulcers length, depth, volume and surface by marking the wound with a computer mouse as seen Figure 4.1. The figure illustrates a foot ulcer image taken by the Eykona. The white disc with black square pattern acts as a calibration marker attached to the healthy skin close to the wound. The left pictures are views of a necrotic toe wound, and the right picture illustrates views of a amputation site. Color segmentation displays are shown on the lowest row. Figure 4.1: Foot ulcer image taken by Eykona imaging system. [18]

The goal with the Eykona camera is to provide health professionals with the understanding how the wound is healing, allow them to plan the treatment accordingly and be more ecient. The images can be evaluated without the need for patients to visit hospitals. Eykona is not harmful and without ionizing radiation compared to other 3D imaging process techniques such as CT scan. [1]

The author was unable to find regulatory information regarding Eykona on their webpage.

Silhouette
Silhouette by Aranz Medical Limited is a electronic wound documentation and reporting system. The Silhouette system is made up of three main parts and can be integrated to electronic medical systems: a point of care imaging device, smart software and a wound information database. Silhouette contains of: The SilhouetteStar wound camera which takes high quality images of wounds. The SilhouetteConnect driver software which calculates 3D measurements of the wounds area, depth and volume by using laser technology.

The SilhouetteCentral database to collect all information from the SilhouetteStar camera and SilhouetteConnect. Silhouette has the following regulatory approvals:

FDA 510(k) approval
CE Mark
Health Canada – Therapeutic Products Directorate
TGA approval (Australia)
WAND registration (New Zealand)

Hyperspectral Imaging
Studies Studies are exploring the potential of Hyperspectral Imaging (HSI) for diagnosis and managment of chronic wounds as DFU. Yudovsky et al (2010)[31] study showed that HSI can be used to assess the risk of DFU development and predict healing of the ulcer by using in vivo measurements.

HSI is a combination of digital imaging and spectroscopy. Spectroscopy is the study of wavelength composition of electromagnetic radiation. Hyperspectral means that the electromagnetic spectrum is divided in many bands. The human eye can only see the visible band of the light spectrum (red, green, and blue) and this is also what a normal digital camera captures. Many more bands of nonvisible light exist to the left and right of the visible spectrum (ultraviolet, x-ray). HSI divides regions of the nonvisible spectra into many bands and creates visible images from them. Images are built one slice or \ frame" at a time building a complete image. For any given slice and pixel, detailed spectra are captured creating a 3D datacube where each slice represents a di erent wavelength. By combining selected wavelengths an image can be constructed showing tissue properties of interest. HSI contains of a sensor which receives the re ected light bouncing o the tissue and converts it to electrical signals.

The amount of oxygen in the tissue is one of the key factors in wound healing. The absorption of oxygen can be measured by HSI. The tissue oxygenation observed from HSI is found to predict wound healing in DFU and indicate risk of delayed healing.

However HSI has many limitations. Yudovsky et al. study (2010) and previous HSI studies showed HSI potential to be used routinely in the clinic. The limitations are that measurement with HSI was done by using expensive measurement tools not suitable for mass production. Another limitation is that there are no standards for use of HSI due to biological variability and inconsistent data. [31][2]

Advantages and disadvantages of 3D imaging systems
The advantage of using 3D measurement and imaging systems on DFU is the accuracy of the measurement compared to other wound measurement systems. The patient can bene t from this technology in an illustrative manner and 23 due to visualization may accept changes e.g. new treatment plan. [49] The imaging systems does not require any preparation or special requirements from the patient. By providing the visiting nurse with a handheld system s/he can easily take images without moving the patient around.

The disadvantage is the cost of 3D image system compared to a digital 2D camera. Savage et al (2013) mentions the preparation time as a disadvantage. The nurses felt the preparation time for taking a 3D image is longer and thus prefer the 2D image which they believe is sucient. Bowel et al (2010) reported limitations in 3D imaging systems ability to show important wound characteristics such as exudation and moistness, which the health professional can see by normal visual examinations. All of the devices have to take in account the large variation in foot anatomy of diabetic patients.

Future Investigation
HSI is a promising technique for detection of DFU because it is a noncontact and a noninvasive method. The disadvantage of HSI is the cost. The use of HSI in clinical matter to assess DFU and other chronic wounds is going to require access to low cost HSI cameras. Other disadvantages are mentioned in section 6.1.3.

Other potential imaging techniques for further investigation for assessment of ulcer healing are Multiphoton Microscopy and Optical Coherence Tomography. DELTA is working to develop a 3D image system to allow visiting nurses take images of patients feet with an early stage of DFU. The goal is to take an image from various angles and turn into a 3D image by using an existing smartphone app.

One app DELTA is testing is the free 123D Catch app which can turn ordinary photos into 3D models. [8] The app is a cheap solution and can give a temporary overview of the ulcer. However the risk of error and mistakes with the image is high due to the amount of images that have to be taken to generate the 3D model of the wound and it requires that the patient does not move their feet. The patient location determines if the visiting nurse can create the image and which angle the visiting nurse will capture. A lot of user studies needs to be done to provide the best solution.

Partners:
Thomas Brigsted Jensen, Pallas Informatik.
Knud Yderstraede, MD, Ph.D at Odense University Hospital in the Department of Medical Endocrinology.

5. Multisensor Intelligent Bandage

The Multisensor Intelligent Bandage project by the partner team and DELTA focuses on using microelectromechanical sensors to monitor different parameters and factors in the ulcer.

The goal is to develop a sensor which is integrated into an embedded system to provide wireless transfer to a monitoring device e.g a bandage. This chapter will provide information why such a system is needed, what a sensor is and how different sensors can be applied to ulcer care.

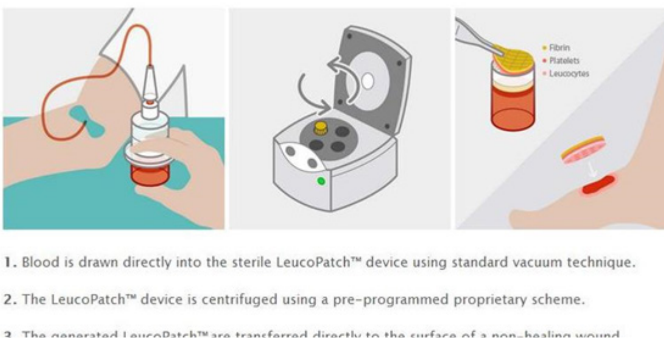
Partners:
Fei Yu, Syddansk University, Assistant Professor, Ph.D at The Mads Clausen Institute.
Knud Yderstraede, MD, Ph.D at Odense University Hospital in the Department of Medical Endocrinology.
Charlotte Schmidt, Eglu.
Michael Schulssen and Michael Niebling Llobet, Sensor Medical.

Bandage
One common complication for preventing the ulcer from healing is infection. Infection is strongly related to amputation especially in combination with PAD. [20] The challenge is to detect the infection before it reaches a stage called advanced infection; redness, heat, swelling, smell, pain and tissue breakdown. To protect the ulcer from getting infected the health professionals use bandages to cover up the ulcer after treatment. The bandage is uncovered for test and monitoring purposes.

One method to test the ulcer for infection is the swab test. The swab taken from the ulcer is analyzed in a microbiology laboratory for bacteria. The swab method and uncovering the bandage have many disadvantages and can cause further complications. One example is by removing the bandage it can damage the upper layer of the ulcer, expose the ulcer and disrupt the healing process. The swab method for testing is invasive disrupting the ulcer and do not provide information what is happening deeper in the ulcer. Furthermore the swab method can take hours to days to analyze. [28]

There is a need for simple, rapid methods to monitor the ulcers and detect the infections in an early stage by not disrupting the healing process of the ulcer.

Figure 5.1: Leuco Patch [47]



Researchers have looked in to sensors as a diagnostic tool in wound healing. 25

An electronic sensor is a device that senses a condition and typically transforms the sensed parameter into a current or voltage. There are many sensors available on the market, but the sensor measurement of interest for DFU should take following parameters into consideration[32]:
Temperature
Color Moisture
Conductivity
Mechanical impendence
Movement
pH value
Bacterial Products.

In the next section different types of sensors and exsisting products will be described shortly.

Sensors

Temperature sensors:
Mainly there are di erent temperature sensors; contact sensors and noncontact sensors. Contact sensors are required to be in physical contact with the skin to measure the temperature while noncontact sensors measure the thermal radiation. A temperature sensor of relevance for DFU is one comparing temperature in the ulcer with the non-ulcerated area or one simply detecting the temperature without disrupting the ulcer. Calor (heat) is a symptom of infection in wounds and can be used as an indicator of an ulcer. Temperature of skin and wounds can be measured by using hand held infrared thermometers. Armstrong et al 2007 [13] showed that infrared skin thermometers are able to show early signs of ulceration when measuring the difference of temperature of the feet.

There are several infrared thermometers on the market, the most common one is the Spot Infrared Thermometer which measures the temperature at a spot on a surface.[32]

Pressure Sensors:
The typical pressure sensor measures pressure of gases and liquids. A pressure sensor of relevance for DFU is one measuring pressure from the bandage, foot wear or environment. Many di erent pressure sensors are on the market and examples of pressure sensors applied in insoles for shoes will be described in chapter 7.

Moisture and pH sensors**:**
Ulcer Ulcer healing, like many biochemical processes in the body, is in uenced by pH value. The pH of an ulcer can a ect many di erent phases of the healing 26 process such as oxygen levels, cell

proliferation and bacterial growth. The pH scale is the negative logarithm of the concentration of H+ ions in a solution: pH=-log[H+].

Schneider et al. (2007) [25] review of chronic wounds suggests that the pH value oscillates between pH 7-8. However the wounds are complex and many factors play a signi cant role resulting in change of pH value such as bacterial colonization.[23]

Moisture levels from ulcers can determine how well an ulcer heals. Further- more a moisture sensor can provide information on the need for change of the bandage based upon moisture readings taken from inside the dressing.

Ongoing studies have a goal to develop a smart bandage measuring pH and moisture.

Ongoing research and existing projects

FRONTS:
A team at University of California Berkeley Electrical Engineering Department are working on a project called FRONTS (Flexible Resorbable Organic Nano- material Therapeutic Systems), whose aim is to develop a smart bandage to monitor wound healing by reading electrical elds. When a ulcer on the body occur the epidermal (skin) cells replicate and move to the wounded area creating ionic concentration to shift which generates the electrical fields. FRONTS goal is to detect and measure the elds and thereby track the healing process. [51]

WoundSense:
The company Ohmedics has developed WoundSense which is a sterile moisture sensor that can be placed on the wound at dressing change. A small hand held meter can be attached to the sensor and provide information if the dressing needs to be changed. A moisture scale divided in five categories provides information of the moisture level: Wet, Wet to Moist, Moist, Moist to Dry and Dry.

Ohmedics is also working on to develop a system which allows the meter and sensor to communicate with a mobile app for patient home monitoring. The idea is to make an app for visiting nurses that can check if the patient needs a dressing change. If the dressing does not need a change, the visiting nurse can avoid unnecessary visits to patients.

WoundSense is approved by EU as a Class IIa Medical Device and have received the CE mark. [42]

A future product Ohmedics is working on is disposable pH Sensors. They have developed a disposable printed pH sensor which is currently being tested.

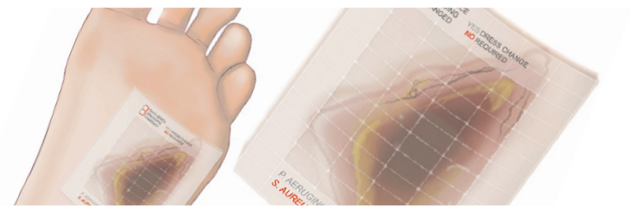
Sutures:
Dae-Hyeong et al. (2012) [19] have developed sutures coated with sensors to monitor wounds and speed up healing. The sutures are made of silicon membranes, gold electrodes and wires which are nanometers thick. Two different temperature sensors are embedded in polymer or silk strips on the sutures forming a winding pattern. One is a platinum nanomembrane resistor which changes its resistance with temperature. The other is a silicon diode that shifts its current output with temperature. The winding pattern of the sutures is important due to the exibility if they are to be threaded on a needle and sewn through a wound. The suture can detect infection in a wound, and in the future might be able to actively promote healing in the wound by placing them in a bandage. The sutures have been tested in vivo only.

Leuco Patch:
Lundquist et al (2012) [14] have developed a autologous leukocyte and plateletrich brin patch for potential healing of diabetic ulcers called Leuco Patch. The Leuco Patch device is using patients own blood to create the patch see Figure 5.1 After processing the Leuco Patch is transferred directly to the clean and debrided wound. The patch release large amount of growth factors and immune cells into the wound where growth factors stimulates the wounds own broblasts cells to start dividing and immune cells remove bacteria and remaining debris by phagocytosis. When the broblasts cell divides they generate additional collagen and growth factors and this creates a well perfused granulation tissue. The granulation tissue cause the epithelial cover to regenerate from the wound edges. LeucoPatch is currently in a ongoing clinical trial stage.

Advantages and disadvantages of Multisensor Intelligent Bandage
This project is still in very early development phase of the multisensor intelligent bandage. There is a lot of potential for multisensor intelligent bandages. Today there is technology available for measuring moisture, proteins, gases, temperature etc. and these have the potential to make the transition into ulcer sensors bandages. One of the advantages of the ulcer sensors is that it could be a potential solution to diversity of the experience of the health professionals who are not specialized in ulcer management. The sensors could provide objectivity by identifying key parameters. Another advantage is that it will improve DFU patient's outcome by providing information to health care professionals how the wound is doing and which state the wound is in. The problem with the sensors intended to use on ulcers is the different proteins, bacteria, concentration levels and other biological components that are present which makes it dicult to create a multisensor bandage taking all bacterial components in consideration.

Dargaville et al. (2012) created a hypothetical model what they think a future wound dressing would look like which corresponds to the proposed tideas. The dressing use image technologies and indicators for infection, pH and informs the time of last dressing change, see Figure 5.2.

Figure 5.2: An illustration of the future wound dressing incorporating color map of the wound, pH measurement, infection feedback and indicator displaying if the dressing needs changing [23]



6. On-Foot Enclosure

DELTA's aim of this project is to develop an on-foot enclosure to monitor DFU on a continuous basis.

The on-foot enclosure should collect data of pressure, edema and temperature of the ulcer to the health care professionals by providing the patient with a sensor system containing e.g a sock, insole. This chapter will shortly mention the current methods of pressure measurement by health professionals and provide examples of existing onfoot measurement systems.

Partners:
Fei Yu, Syddansk University, Assistant Professor, Master in engineering of innovation & business at The Mads Clausen Institute.
Knud Yderstraede, MD, Ph.D at Odense University Hospital in the Department of Medical Endocrinology.
Michael Schulssen and Michael Niebling Llobet, Sensor Medical.
DELTA.

Pressure measurement by sensors
Decreased sensation in the feet and too much pressure at one part of the patients feet can result in ulceration, infection and amputation. The Braden Scale for predicting pressure sore risk is among the most widely and recommended used tools for predicting a pressure ulcer. The Braden scale assess the patient risk by examination of six areas: sensory perception, skin moisture, activity, mobility, nutrition and friction/shear (see Appendix A). However Kottner et al. (2010) study does not recommend using the Braden scale due to high measurement errors.[54]

A simple tool with a great accuracy is needed for prediction of pressure ulcers. Representative products with potential for prediction of DFU will be described in the following section.

Smart Sock:
The German Company Alpha-Fit GmbH has developed a prototype of a 3D pressure measurement for the foot called the "Smart Sock". The product con- tains of a sock made of textile and sensory laments. The sensory laments are placed on the textile which enables the sock to measure surface pressure. According to Alpha-Fit GmbH the smart Sock can be used to prevent DFU of the upper foot by measuring pressure areas. No references on research studies were found on their homepage.[4]

Surrosense Rx:
The Canadian Company Orpyx Medical Technologies have developed an insole that collects data of pressure applied to the plantar part of the feet called The SurroSense RX system. The SurroSense Rx system contains of an insole and of a shoe pod.

The insole contains of sensors that are able to transmit data from the pod to a smartwatch or a smartphone app. The shoe pod is placed in front of the shoe by a clip and is connected to the insole by a wire. The pod collects data sent to the smartphone and watch, see Figure 6.1. The user can see a pressure map displayed on the smartphone/watch which identifies the critical pressure areas on the foot enabling the user to change behavior, walking pattern or situation.

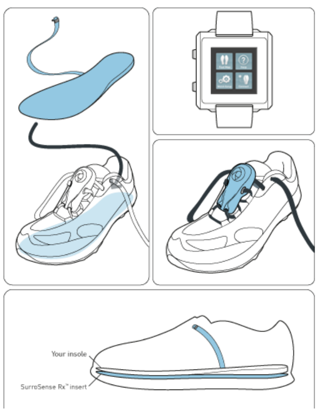
Research on the SurroSense Rx was done by Ferber et al. (2013) [9], but the full article is delayed and will be available on September 1 2014. [43] SurroSense Rx is launched on the market and is approved as a Class I medical device from Food and Drug administration (FDA), USA. The SurroSense Rx has also received the CE Mark meaning the product can be sold in the European Union.

Orpyx Medical Technologies are also in the process of developing SurroGait Rx which is a pressure-sensing insert. The goal is to be able to inform the user when the feet is exposed to damage and may also provide substitute sensation for sensory loss in the feet.

Open Go
The German company Moticon has developed a insole, which is a part of their OpenGo Science package, to measure plantar pressure applied to the feet. The OpenGo package consists of the wireless insole; the analysis software called Beaker, an ANT and enabled USB ash drive for the data transfer. The OpenGo insole can be used in any shoe and contains of 13 pressure sensors, a 3D acceleration sensor and a temperature sensor. As soon as the user starts moving the insole is activated automatically and analyzes the foot pressure distribution.

DELTA has developed a prototype of a system containing of an insole with pressure sensors and a sock with a sensor measuring band. The system can be connected to software on the computer by wireless functions. The insole pressure sensors can measure how the pressure is distributed on the feet and if there is a di erence from day to day pressure. With these data it can be seen if the patient has more or less pressure at one part of the feet or if the walking pattern has changed indicating a possible DFU. The measuring band can measure change in size in the ankle used to measure occurring edema. The goal is to implement a temperature sensor measuring di erence in patient feet, or using materials for cooling down the feet.

Figure 6.1: Components of SurroSense Rx by Orypx Medical Technologies [43]



7. Conclusion

DELTA's aim of this project is to develop an on-foot enclosure to monitor DFU on a continuous basis.

DELTA's PATH project ideas can be realized with inspiration of the current available technologies on the market. All of the projects are useful for prevention and treatment of diabetic foot ulcers even though they are in an early development stage and further investigations needs to be done. The project with the most potential for diabetic foot ulcer prevention is the On-foot Enclosure project based on the existing technology which can be implemented to DELTA's ideas.

Bibliography

1A, Zhou. 'A Survey of Optical Imaging Techniques for Assessing Wound Healing'. International Journal of Intelligent Control and Systems Vol. No. 3, September 2012, 79-85, 2012, 36–42.
A.T, Shish. 'Charcot Foot'. American College of Foot and Ankle Surgeons, 2006, 36–42.

B, Ferber R. Webber T. Everett. 'Validation of Plantar Pressure Measurements for a Novel In-Shoe Plantar Sensory Replacement Unit'. Journal of Diabetes Science and Technology Volume 7, Issue 5, September 2013, 2013, 36–42.

B, Majid S. Foo S. Luyt. 'Adopting Evidence-Based Practice in Clinical Decision Making: Nurses' Perceptions, Knowledge, and Barriers'. J Med Libr Assoc. 2011 July; 99(3): 229–236, 2011, 36–42.

C, Armstrong DG Holtz-Neiderer K. Wendel. 'Skin Temperature Monitoring Reduces the Risk for Diabetic Foot Ulceration in High-Risk Patients'. The American Journal of Medicine Volume 120, Issue 12, Pages 1042-1046, December 2007, 2007, 36–42.

C, Lundquist R. Holmstrøm K. Clausen. 'Characteristics of an Autologous Leukocyte and Platelet-Rich Fibrin Patch Intended for the Treatment of Recalcitrant Wounds'. Wound Rep Reg (2013) 21 66–76 © 2012 by the Wound Healing Society, 2013, 36–42.

Chand G., Kumar S., Mishra K.A. 'Diabetic Foot'. Clinical Queries: Nephrology 0102(2012) 144-150, 2012, 2012, 36–42.

H, Dae-Hyeong K. Shuodoo W. Keum. 'Thin, Flexible Sensors and Actuators as "Instrumented" Surgical Sutures for Targeted Wound Monitoring and Therapy'. Small 2012, 8, No. 21, 3263-3268, 2012, 36–42.

J, Apelqvist. 'Diagnostics and Treatment of the Diabetic Foot'. Endocrine 41:384-397 2012, 2013, 384–397. doi:10.1007/s12020-012-9619-x.

J, Bowering K. Embil. 'Foot Care'. Canadian Journal Of Diabetes, 37(2013) S145-S149, 2010, 36–42.

J, Bowling F. King L. Paterson. 'Remote Assessment of Diabetic Foot Ulcers Using a Novel Wound Imaging System'. Wound Repair and Regeneration (2011) 19:25-30, 2005, 36–42.

J, Dafoulas G. Koustias S. Behar. 'Development of a mHealth Open Source Platform for Diabetic Foot Ulcers Tele-Consultations'. Telecommunications Engineering Volume 83, 2012, P 158-164, 2005, 36–42.

J, Dargaville T. Farrugia B. Broadbent. 'Sensors and Imaging for Wound healing: A review'. Biosensors andBioelectronics41(2013)30–42, 2012, 36–42.

J, Rosland A. Heisler M. Piette. 'The Impact of Family Behaviors and Communication Patterns on Chronic Illness Outcomes: A Systematic Review'. J Behav Med (2012) 35:221-239, 2012, 36–42.

J, Schneider L. Korber A. Grabbe S. Dissemond. 'Influence of pH on Wound-Healing: A New Perspective for Wound-Therapy?' Arch Dermatol Res (2007(298:413-420, 2007, 36–42.

John, Zulman M. Donna Piette. 'Facilitating Out-of-Home Caregiving Through Health Information Technology: Survey of Informal Caregivers' Current Practices, Interests, and Perceived Barriers'. J Med Internet Res 2013 July; 15(7): E 123, 2013, 36–42.

K, Estabrooks C. Rutakumwa W. O'Leary. 'Sources of Practice Knowledge Among Nurses'. Qual Health Res 2005 15: 460, 2005, 36–42.

K, Harding. 'Diagnostics and Wounds: A Consensus Document'. World Union of Wound Healing Societies (WUWHS), 2007, 36–42.

K, Woo Y. 'Understanding Diabetic Foot'. Lipincott Williams and Wilkins Nursing 2013, 2013, 36–42.

L, Yudovsky D. Nouvong A. Pilon. 'Hyperspectral Imaging in Diabetic Foot Wound Care'. J Diabetes Sci Technol 2010;4(5):1099-1113, 2010, 36–42.

LJ, Mølgaard. 'Electronic Sensor Technologies For Wounds'. Madebydelta.com 2012, 2012, 36–42.

M, Aalaa M. Tabatabaei Malazy O. Sanjari. 'Nurses' Role in Diabetic Foot Prevention and Care; a Review'. Journal of Diabetes and Metabolic Disorders 2012, 11:24, 2012, 36–42.

M, Bus S. A. Hazenberg C. Klein. 'Assessment of Foot Disease in the Home Environment of Diabetic Patients Using a New Photographic Foot Imgaing Device'. Journal of Medical Engineering & Technology, Vol 34, No.1 January 2010, 43-50, 2010, 36–42.

M, Prompers I. Hiujberts. 'High Prevalence of Ischemia, Infection and Serious Comorbidity in Patients with Diabetic Foot Disease in Europe'. Springer Verlag 2006, 2005, 36–42.

M, Rosland A. Heisler M. Janevic. 'Current and Potential Support for Chronic Disease Management in the United States: The Perspective of Family and Friends of Chronically Ill Adults'. Families, Systems and Health 2013, Vol 31 No.2, 119-131, American Physiological Association, 2013, 36–42.

N, Clemensen J. Larsen S. Ejskjaer. 'Telemedical Treatment at Home of Diabetic Foot Ulcers'. J Telemed Telecare 2005 11:14, 2005, 36–42.

N, Clemensen J. Larsen S. Kirkevold M. Ejskjaer. 'Treatment of Diabetic Foot Ulcers in the Home: Video Consultations as an Alternative to Outpatient Hospital Care'. International Journal of Telemedicine and Applications 2008, 2005, 36–42.

O, Bjålie G. J. Haug E. Sand. 'Menneskets Anatomi Og Fysiologi IBN 87-12-03264-6'. Gads Forlag, 2013, 36–42.

Regioner, Regeringen / KL /Danske. 'Telemedicin - En Nøgle Til Fremtidens Ydelser'. Digitaleringsstyrelsen August 2012, 2010, 36–42.

S, Savage J. Jeffery. 'Use of 3D Photography in Complex Wound Assessment'. Journal of Wound Care Vol 22, No 3, March 2013, 2005, 36–42.

Sundhedsstyrelsen. 'National Klinisk Retningslinie for Udredning Og Behandling Af Diabetiske Fodsår'. Sundhedsstyrelsen 2013, 2013, 36–42.

T, Kottner J. Dassen. 'Pressure Ulcer Risk Assessment in Critical Care: Interrater Reliability and Validity Studies of the Braden and Waterlow Scales and Subjective Ratings in Two Intensive Care Units'. International Journal of Nursing Studies 47 (2010) 671–677, 2010, 36–42.

V, Leese G. P. Reid F. Green. 'Stratification of Foot Ulcer Risk in Patients with Diabetes: A Population-Based Study'. Journal Compilation a 2006 Blackwell Publishing Ltd Int J Clin Pract, May 2006, 60, 5, 541–545, 2006, 36–42.

WHO, and IDF. 'The Saint Vincent Declaration'. Sain Vincent (Italy), 10-12 October 1989, 2010, 36–42.

WR, Jordan. 'Neuritic Manifestations in Diabetes Mellitus'. Arch Intern Med 1936 57: 307 66, 1936, 36–42.

Z, Ramanujam CL Facros. 'An Overview of Conservative Treatment Options for Diabetic Charcot Foot Neuroarthropathy'. Diabetic Foot and Ankle 2011, 2: 6418, 2011, 36–42.

DELTA
Venlighedsvej 4
2970 Hørsholm
Denmark
Tel. +45 72 19 40 00
delta@delta.dk
madebydelta.com