Influence of design to implement a thermographic device for preventing diabetic foot ulceration

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The term Design Thinking highlighted the importance of design as a creative tool in promoting effective innovation; its importance has been increasing in academia as in business. Thus, today design is a more recent area of investigation whose main requirements define the limits and perspectives according to theory. In practice, it is necessary to establish the differentiation of values and innovations that make the object of study desirable. This article aims to show that the Universidad Autónoma de Querétaro’s (UAQ) design-led thermal camera research and development, encourages collaboration between researchers, engineers and designers to implement this technology in a medical device whose goal is to prevent the formation of ulcers in patients with diabetic foot. The concepts applied to reach the goal are "Radical change of meaning" and "Interpreters" of the Design-Driven Innovation and the adoption of the method called “Asignification” developed in Germany by The Dark Horse design studio.

keywords: design; diabetic foot; innovation; thermography

Introduction
Design is inherent in any human development. Everything that surrounds us is a result of the creation and inventiveness of people and business force. The design process has led to research with the purpose of documenting how to apply creativity in the daily creation of competitive products or services. Among these aspects is the user-centred design of Don
Norman in 1993, then moving to Norman’s emotional design in the 2004, and Design Driven Innovation proposed by Roberto Verganti in 2003.

All the research proposals on the cognitive processes of design and social behaviour are classified within Design Thinking, a term popularized by its application in business development by the company IDEO founded by David M. Kelley in 1991. These design theorists converge towards the journey from form to function through three main variables: morphology, technology, and usability. However, Verganti and Norman agree on the link between message-emotions to engage users with meaning in everything they prefer to consume (Zampollo, 2015), linking experiences and intangible characteristics that broaden the way of innovation (Malaver, Pérez, & Rodríguez, 2016).

In linguistics, meaning is defined as the way of expressing or representing a concept (Royal Spanish Academy, 2016), then “Asignification” is the act of breaking with the representations of established concepts; Verganti claims that design discourse is the result of the interpretation of different cultural languages. "Interpreters" or agents of change share information that leads to the resignification of the meanings perceived by costumers. It is therefore possible to conceptualize objects or services that people desire as shown by Rampino (2011) in the “The innovation pyramid” (p. 13) in Figure 1 below.

![The Innovation Pyramid](image)

**Figure 1 The Innovation Pyramid. Source: Adaptation from Rampino. L. (2011).**

Design then is not just about generating ideas, it is a thought structure to answer two simple questions What? And How? So where is there space to innovate or design? It becomes the intangible activities of the designer who will give the answer through new How’s? and What’s? through experiences and meanings (Dorst, 2015).

This feature of design is promoted as an alternative to solve complex problems in fields such as in sports to win more medals by mixing design thinking with training (Coyle, 2016); in the field of economics and administration, it is needed to break the paradigms of indices of innovation capability based on technological levels (Malaver et al., 2016); as a reform in the implementation and development of civil protection programs in urban areas affected by hurricanes (Ovink, 2015); and in the development of agriculture (Yagita and Shirasaka, 2015). In the field of research, design is an effective tool for technology adoption and promotion of new products, services, processes and systems (Matarranz,
2012). This latest example is the objective of this research and demonstrates how Design influences the adoption and development of a device for preventing diabetic foot ulceration.

**Diabetic foot**
The design of a medical device to prevent the formation of ulcers in patients with diabetic foot was selected since the prevalence of type 2 diabetes mellitus (DM2) has 6.4 million cases in Mexico; one out of three deaths is due to this disease (World Health Organization, 2016). The absence of symptoms in the early phase is the main disadvantage in the timely detection of diabetic foot, which causes serious health complications such as amputation of the lower extremities (Ojeda et al., 2012). Twenty percent of patients diagnosed with T2DM will develop ulcers due to risk factors such as poor quality of diet, obesity, depression, and stress that accelerates the development of the disease (Pérez, Villalpando, Shamah, & Méndez, 2014).

Diabetic foot has among its main health implications, the formation of ulcers, which when not detected as an infection in tissues which severely affects the bones, nerves and blood supply. If this ulceration is not detected at an early stage and the lesion is neglected, then limb amputations are the only option. In order to contribute to the solution of this problem, numerous investigations have been carried out to develop more advanced methods of diagnosis and control.

**Technology review for prevention and treatment of diabetic foot**
As a proposal for the study of the medical protocol for diagnosis of diabetic foot, we attempt to present a classification of the most important studies related to the following variables such as temperature, blood pressure, loss of sensitivity, as well as biomechanical points of support for the foot. For the analysis of these variables we use methods that are divided into invasive and non-invasive.

**Invasive diagnostic methods**
It applies to procedures and devices that involve chemicals called contrasts that are injected or tools to physically penetrate the patient's body (Cofepris, 2016). These methods are applied in cases of arterial calcification or to verify etiological factors that in most cases end in surgery due to the lack of timely diagnosis.

Among the invasive methods related to the pressure variable, we can mention arteriography, angiography (CT or MRI) and biopsy (Castro et al., 2009; Contreras, Ibañez, Roldán & Torres, 2014).

Invasive diagnostic methods were the only technologies in the market between from 1970 to 1980 (Banerjee, Beckmann, Busch, Buzzi, & Thomas, 2012; Comín, Nerín, Villarroya, Pérez & Marco, 1999), and have hardly changed to the present time.

**Non-invasive diagnostic methods**
Applies to procedures and devices where no tools are involved to break the skin or physically penetrate the patient's body (Cofepris, 2016). These methods are used in the early stages of diabetic foot, grade 0 and 1 according to Wagner scale.

**Blood pressure variable**
The most well-known non-invasive methods related to the blood pressure variable are: photoplethysmography, the ankle-brachial index (ABI), ergometry and Eco-Doppler. The aim of the Eco-Doppler is to develop an arterial map to decide whether amputation will be performed on the upper or lower leg section (Castro et al., 2009; Contreras et al., 2014; López, Dotor, Silveira, Giannetti, & Herrera, 2009).

**Loss of sensitivity variable**

Regarding these types of methods, those related to the loss of sensitivity variable are the 128 Hz tuning fork. The most current alternative to this type of tool is the Biotesiometer®, a device that emits electrical charges that are necessary to evaluate the sensitivity in the foot using algorithms; The Semmes-Weinstein monofilaments of 10 g are within this group, so are (Armstrong, Lavery, Vela, Quebedeaux, & Fleischli, 1998; Castro et al., 2009; Contreras et al., 2014).

**Biomechanical foot points**

The methods associated with biomechanical foot points are the following: simple podography, Tempstat® pedigree - the most viable technological proposal to date - and baropodometry, in two very common brands: F-scan® and Pedar-X® (Castro et al., 2009; Júbiz, Márquez, Márquez & Brugés, 2012).

**Temperature variable**

Finally, the variable of interest in this research is the temperature among the devices related to thermograms is the Podimetrics ™ device a network of sensors shown in Figure 2, used to analyze the variations of temperature and pressure in the sole of the foot. This is an application of telemedicine that was the thesis subject of Eng. Robert Som in 2013. Among his advisors was Dr. Amstrong, a research pioneer in the correlation of temperature variations and diabetic foot conditions. Currently, this device is in the commercialization phase through a spin off from the University of Texas. Infrared thermometers such as the GlucoQuick® brand are also included in this classification (Hernandez, Peregrina, Rangel, Ramirez, & Renero, 2015; Peregrina et al., 2014; Vilcahuaman, 2013).
Figure 2 Radical and Incremental innovation examples. Description of products.

<table>
<thead>
<tr>
<th>Product</th>
<th>Neuropad™</th>
<th>Podimetrics™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Picture</strong></td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patent</th>
<th>US 2013/0261494 A1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author / Year</strong></td>
<td>Nanosystem Pharmaceutical, 2012</td>
</tr>
<tr>
<td><strong>Fortress</strong></td>
<td>Patch test for the early detection of Diabetic Foot</td>
</tr>
<tr>
<td><strong>Price</strong></td>
<td>800 MX</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>Prediagnosis</td>
</tr>
<tr>
<td><strong>Wagner Scale</strong></td>
<td>0 y 1</td>
</tr>
<tr>
<td><strong>Measures</strong></td>
<td>0.04x2x2cm</td>
</tr>
<tr>
<td><strong>Other specifications</strong></td>
<td>Foot Sweat Test</td>
</tr>
<tr>
<td><strong>Medical availability</strong></td>
<td>Medical Staff / Patient</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td>90%</td>
</tr>
<tr>
<td><strong>User interaction</strong></td>
<td>Noninvasive</td>
</tr>
<tr>
<td><strong>Market competition</strong></td>
<td>—</td>
</tr>
<tr>
<td><strong>Subject of study</strong></td>
<td>Diabetic Foot Prevention</td>
</tr>
</tbody>
</table>

**Role of design in disruptive technological development**

The innovation of all these medical devices is incremental, which has been analysed in countless engineering documents in biomedical, computational or electronic areas. However, if design is allowed to direct technological development and research, representative products are conceptualized that break with the usual methods for diabetic foot prevention, as it is the example of Neuropath™ compared to the aforementioned Podimetrics™ device illustrated in Figure 2.

*A patch of clear polyethylene adhesive, which protects against outside environmental humidity. This patch includes another patch inside impregnated with 11.56 mg of cobalt dichloride. Each molecule must react with at least 5 molecules of water to change its initial blue colour and turn pink. The change in colour of the dressing allows us to observe the disorder of the sudomotor function allowing us to diagnose peripheral autonomic neuropathy early.* (Sánchez, de Planell, Moliné & Alvarez, 2016, p. 99)

**UAQ’s Thermography proposal**

This technology has the advantage of being a non-invasive method as well as not requiring a specialized technician to operate in Health Clinics and Medical Offices. This was tested in the thesis entitled "Therapeutic evaluation of the diabetic foot and its association with diabetic retinopathy" (Vásquez, 2013) of the Faculty of Engineering. Its scope was delimited to obtain an interface for software, and develop a blockage to avoid thermic noise, a prototype is shown in Figure 3. The analysis of the scientific literature was the
basis for establishing four important factors in the operation of the equipment (Kaabouch et al., 2010; Nagase et al., 2011; Sun et al., 2006):

- Temperature controlled at 24°C ± 1°C in the space for taking infrared pictures.
- Foot areas –angiosomes related- to be segmented by the algorithm for image processing.
- The patient’s position was established as supine position.
- Time of stabilization of the patient, with respect to the temperature are 15 minutes and 10 minutes for recovery of physical stimuli.

The configuration of this system has been summarized in the study of other tissues of the body as it is the case of investigation of temperature-breast cancer or temperature-emotions. The continuous improvement of the technology has miniaturized the software and optimized the algorithm, for instance in Figure 4, technological research established requirements such as patient hygiene. Patients are suggested to bathe with neutral soap, without lotion, creams or powders so as not to affect the photography. Another aspect to be mentioned in previous research is the interaction with a Board of doctors as advisors in the consulting protocol for patients and equipment used to assess the diagnosis, the technical knowledge of the disciplines involved has been considered again.
The development of the prototype has been carried out in order to provide a doctor's tool for obtaining and analysing data, as well as to show the evolution and efficiency of the last device compared with the previous one, in which the design takes part only in the formal and functional aspect of the prototype. A commercial objective has not been visualized until they are registered in the Mexican Institute of Industrial Property (IMPI), this is to protect the knowledge developed so far. Once the design is released, it will be verified if the product is viable, considering technical specifications studied and the market requirements.

Pushing new ideas forward Design. Pulling together Design elements
Under the scheme proposed to solve contemporary problems by Kees Dorts in his book Frame Innovation: Create new thinking by design. Design is characterized by being open with no boundaries, complex because it is immersed in many relationships and elements, dynamic since they are changing with the passage of time and are networked across organizations. Therefore, the design method is nonlinear, it is iterative, and each stage is constantly nurtured with new activities generating knowledge of interest to the designer. They can no longer be solved with trusted routines. In twenty years the design disciplines have been developed considerably so their techniques have matured to offer an alternative to problem solving strategies and replace the trend of designers to "do aesthetically appealing things," although some in the guild are not interested in leaving it (Dorst, 2015).

Latin America abandons innovation trend
In 2010, the Community Innovation Survey (CIS) carried out by the European index Innovation reveals the limitation of verifying innovation in countries such as Latin America, excluding them from the high technology industry; the medium and low technology sectors are not considered, although these are the main sources for these countries. The perspective of the Oslo Manual (OECD, 2005) relegates design to formal aspects, tangibility, appearance or participation in product functionality, use and performance. Like CIS, there are conceptualizations and measurements of innovation in different countries, which do not adequately describe the design-innovation relationship that is the central factor in the humanization of technologies. However, the Design fulfils as a process to generate innovation in this geographical area (Arundel, Bordoy, & Kanerva, 2008; Salter and Tether, 2006). The ability to identify, assimilate and apply existing knowledge of innovation by Latin firms in their context has not been recognized, which demands to adapt with the intervention of design and engineering (Malaver et al., 2016). Since activities of design are absorbed by other activities such as R+D, in the technological field; in the academic field have emerged proposals such as using and interacting, doing and user-driven innovation as alternatives at technology push.

Radical change of meaning
This concept indicates the point where the design processes are unified, to generate infinite proposals after answering the questions, How to get to the solution that breaks with the established norms? How to generate new meanings? Projecting the object of study in a framework that links future trends to the present, and links emotions that generate new experiences. Every time we live unknown experiences, our perception
expands, generating new concepts. So to generate a radical or disruptive innovation it is necessary to release the User Centred Design, not to be incorrect, but in another phase of the design process; here at this point, the goal of Design Driven Innovation is interwoven with what is a research process to generate unknown experiences, obtaining the radical meanings that we seek to express, we apply the User-Centred Design to improve concepts and finally with the tools of industrial design we materialize these new meanings; These levels of research in the area of design are illustrated in Figure 5 below (Verganti, 2009).

![Figure 5: Design Driven Innovation as Research. Source: Verganti. R. (2009).](image)

**Interpreters**
The actors who interpreted the phenomena that we are interested in, through their different products their designs are called interpreters by Roberto Verganti. Because design is a product of culture, designers do not work alone all phenomena are always immersed in collective research.

Scientist generate primary knowledge then technicians pick up research to be applied as products, but interpreters influence people’s point of view and behaviour as consumers, they asignificate objects and make them desirable. To choose the interpreters it is necessary to create a link based on the interest of the research phenomenon and the disruptive project instead of money our expertise of meaning may be offered, as well as technology know-how, testing tools such as books, papers, concept products and presentations. Interpreters are so important at design discourse because they know other different ways to persuade people to give new meanings to products (Sigolotto, 2010).

**The three stages of products development**
Design plays an active role in Malaver and Vargas’s three main stages to develop products:

1. Emergence of the idea and conceptualization
2. Materialization
3. Marketing and communication.

It is well known that value of the product is defined in the conceptualization stage, which is the major contribution of design when using the language to generate a new message before technology (Verganti, 2008).
The first challenge of this project is to actively participate during the first stage of identifying and translating the needs of consumers in the health sector into a medical tool which may be capable of coping with needs with technological advances generated by UAQ’s thermography. The second stage of the product development, called materialization, is the most recognized by the innovation sector due to its plan, models and prototypes. Finally, the third one is focused on marketing, apart from packaging or advertising. The design requires proposals for new interaction models, new consumer experiences with the product or brand (Creusen and Schoormans, 2005). Uber or Airbnb, Inc. are examples of a new way of commercialization. In this stage, the second challenge of this project is to validate the acceptance of the product.

The proposal for validating how design influences a technology implement is to develop a device trial through establishing what the value of the product is and the new consumer experience of the proposed idea. The conceptualization tools might be a presentation prototype, a user manual, maintenance instructions, input from suppliers, a brochure and promotional video.

Methodology to be applied

The methodology consists of two main points; the first is the interaction with technology which is the most important, since it requires different design approaches that allow the development of the proposed device. So the thermographic technology used in this project has two main technological elements: hardware consisting of an infrared (IR) camera and a software that is the image recognition algorithm, both require different approaches for their analysis. As to the second point, this refers to various users involved. The interaction with the device can be considered of two types: direct and indirect; that is, the equipment or device will be operated by medical personnel, who are considered the direct user, while the patient will be the indirect user, since it will be the one who provides the feet section required to generate the termogramas (Money et al., 2011). The first challenge of this research will be to determine and select the "Interpreters" (Verganti, 2008), without contaminating the information or avoiding small and unprofitable elections. Once these points and intentions have been clarified, the work of this disruptive research delimited (Hernández, Fernández & Baptista, 2014), with the application of this mixed methodology for the two technological elements and for the different levels of users, essential sources for the delimitation of both qualitative and quantitative variables, which will be correlated to characterize the project in order to explain, describe and evaluate the phenomenon of study, from the design field.

Asgification Method

Then, based on the designing process, five stages are presented in Figure 6 that constitute the main method to be used - proposed by the German study The Dark Horse, one of "Interpreters", who agreed to participate in the revision of the design process – method that specifies in each stage of the elements and actors mentioned above influence or are influenced during the investigation (Kumar, 2012).
INPUT

The information gathered from the research process (theoretical framework of the state of the art, etc.) will also be directed by the design, as well as the analysis of existing products, along with the interpretation of technology and the cultural context in which the research is carried out, this is the impetus for the vision of trends, and even contemplates the breakdown of paradigms in the development of auxiliary tools in medical diagnosis, all of which will allow to define the "Interpreters" to define insights for development of the prototype of the proposed medical device.

360 RESEARCH

This stage is an analytic challenge, because it will be the moment to be interpreter of all the languages involved in the hard data. It is useless to mix the technological and research information because, although the design will be the link to interpret the messages emitted by the different participants in the context of health (Verganti, 2009), it is necessary to reflect on this subject to try to solve the following question. How to reinterpret the information obtained? The pretension to answer such a question will be in a planned selection of "Interpreters", to form a trans-disciplinary team, chosen by their experience to observe through all the socio-cultural, technological and design perspectives and to identify the variables that will characterize the conceptualization of the design proposal, as to manufacture of a prototype. For the aforementioned selection, photographic studies and some videos showing control consultancies will be carried out to organize the information in representative charts for which the informed consent of the participants is integrated into the project. The interviews are semi-structured to all those involved in the cycle: the sample will be obtained with medical staff, with the aim of working mainly with general practitioners, Algologist, Chiropractors, Podiatrists, and Internists.

Doctors will be invited without discriminating as to their length of practice, whether beginners or experienced, since both youth and maturity can meet the qualities required by the project. To get the necessary insights it is required to work with physicians - specialists will be visited in OUTPUT -stage 5- to conclude the study. The patients involved during the validation of the equipment are over 6 years Type 2 diabetes -incidence age specified by medical specialist above-. It would be desirable to integrate some biomedical engineers, technicians and / or sellers of medical devices, with the aim of providing
feedback to the needs of clients in the diagnosis as well as in the control of Type 2 Diabetes Mellitus.

SYNTHESIS

The variables needed to maintain and impact the reliability of the study will determine the design of the device, which in turn, through its insights, requirements and specifications, will generate innovation to promote a technological transfer in the market. The cultural, technological and morphological aspects should be unified, towards the use of this new product as an aid to medical diagnosis. To represent the aforementioned aspects related to diabetic foot monitoring, descriptive models, analytical models and info-graphics will be applied (Milton and Rodgers, 2013). It is also sought to confirm that with the use of thermography in the control consultation, it is possible to avoid the formation of ulcers, up to 30 days before they manifest themselves.

CONCEPTUALIZATION AND TANGIBLE EVIDENCE

This stage is fundamental, because it is a mixture between conceptualization and rapid prototyping, since it will mark the moment of involving the user - especially the expert user - in the validation of each rapid prototype, in order to achieve an effective design; the user feedback this validation with its qualification on effectiveness, ease of use, cleaning, etc., acceptance of materials, and thus collaboration in the practice of co-innovation in the proposal. Therefore, the users will be, doctors, patients, vendors and even medical equipment repairing technicians. From this stage will arise the development of the process of the Industrial Design profession that requires detailing processes, materials, assemblies and finishes for the final proposal and the production of an alpha prototype or presentation prototype.

OUTPUT

The achievement of this last stage of research will be a planning of the prototype of preproduction and a test of some visual elements of a model of technology transfer product package, which will culminate in a university project, by validation via a trial with Instituto Mexicano del Seguro Social (IMSS) to offer continuity to previous projects carried out by Campus San Juan del Río of the UAQ. Similar to Research 360, stage 2, five doctors will be invited with the characteristics mentioned in that stage. Each doctor who agrees to test the equipment requires directing patients considered fit to perform the thermographic follow-up for a month. It is aimed at a sample of people who present diabetic foot determined. Two groups will be formed: Experimental Group and Control Group A. The difference between these two tests will be that the first one will use the thermographic equipment to be designed, while the second will use the traditional equipment available at the clinic in Santa Bárbara. The designer must carry a feedback for a future redesign as the main actor of a continuous model of innovation executed in a real context with objective results, which will allow constant evaluation of user satisfaction, use and requirements of a team that evolves to meet market demand. In case the contact with IMSS is not achieved, the second option may be clinic Santa Bárbara.
Application of design, method and concepts

Interpreters’ selection
The first is Dark Horse, a design company established in Berlin, supported this research and allow the use of their method to implement and develop the thermographic device. As well they will share expertise applying the design tools to establish insights and the conceptualization process; this research will share the results of customer’s behavior and the final proposal of the device.

Introduce Thermography to medical consultation
A general practitioner and Nutritionist in chronic diseases, is the first user accepted who knows and uses the UAQ’s thermographic device. She is a volunteer at Enfermeria de Salud Integral (ENSAIN by its acronym in Spanish) in Campus San Juan del Rio. She worked with five patients invited by the head nurse of ENSAIN, all the actors signed a Consent of Participation, all personal information of patients is confidential that’s why it will refer to them only as patient 1, 2, 3, 4 and 5. At Consent It’s established too three different seasons to analyze context and behavior from all participants.

First Insights

Based on the test that was carried out at ENSAIN, the information obtained is the following which is the activities carry out by the patients to get medical advice and who are the actors enumerate in Table 1. It is also important to the emotions linked in all the process, all these variables are the manner to highlight where innovation opportunities are and why the radical change of meaning could improve ulceration prevention.

Table 1 Actors from Patient Journey

<table>
<thead>
<tr>
<th>Person</th>
<th>Role</th>
<th>Responsibilities</th>
</tr>
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<tbody>
<tr>
<td>Doctor</td>
<td>Professional that controls the degenerative</td>
<td>To guide the patient in the care required for his illness.</td>
</tr>
<tr>
<td></td>
<td>disease of the patient with diagnosis and</td>
<td>Prescribe medicines.</td>
</tr>
<tr>
<td></td>
<td>mediation.</td>
<td>Inform the patient about required treatments and studies.</td>
</tr>
<tr>
<td>Nurse</td>
<td>Professional that provides care and direct</td>
<td>Measure patient’s vital signs.</td>
</tr>
<tr>
<td></td>
<td>care to patients in the clinic.</td>
<td>Informs patients of the order in which they will be assisted.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supports the Doctor during consultation if required.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remind patients appointment dates</td>
</tr>
<tr>
<td>Family and</td>
<td>They support patients and take care of them</td>
<td>They carry, accompany or collect them for consultation.</td>
</tr>
<tr>
<td>friends</td>
<td>at home.</td>
<td>Support the taking of medicines.</td>
</tr>
<tr>
<td>Other Patients</td>
<td>Because they are empathetic in the process,</td>
<td>Offer support.</td>
</tr>
<tr>
<td></td>
<td>influence patient experience.</td>
<td>Take advantage of the meeting to encourage their peers.</td>
</tr>
</tbody>
</table>

The activities are divided into 6 main steps to describe interaction between actors, devices and emotions involved or other significant variables such as time. This information was obtained from three different meetings to do an analysis of the patient journey, then it is
The two devices available were introduced to the physician. The first operates with a Flir A310™ camera, it is more complex to assemble and design for plantar pictures only, the physician did not use it by herself. In Figure 8 shows from P1 to P5 example pictures of visible image of five different patient’s foot then from A1 to A5 are plantar thermographs. The first requirement born in this season when Doctor told an advice that perform lateral and dorsal foot’s pictures demonstrate in picture R5. The second operates with a Flir Lepton™ camera, is the size of a tablet and plug into the power outlet. The doctor was invited to use it by herself during her consulting session and she accepted in Figure 8 gives an example from L1 to L4 about her work.
Figure 8 The visible diabetic foot and patient’s Thermographs

From this first approach with a physician and five patients, it was verified that steps 1, 2 and 3 of the methodology are met. We will continue to work with more doctors to corroborate that the requirements obtained are the definitive ones to begin the conceptualization and development of the product. The requirements are listed below:

- 360 freedom mobility allow to perform lateral and dorsal pictures of foot. Damage above ankle indicates patient needs a Doppler study.
- Time required for thermograph pictures is 3 minutes equal of points by pressure evaluation.
- Intuitive interface like zoom action, one click to take the thermograph and easy access to keyboard.
- Improved reaction rate of the interface.
- Allow to keep track of poorly controlled patients.
- Live thermographic vision to explore patient and see the extension of damage at real time.
- Doctor decides when to take pictures or create/open patient files.

**Design challenges and start influence**

It is important to connect the use of the thermographic device live vision with the Doctor’s experience and knowledge for diagnosing a diabetic foot pattern, both are important factors that influence technology adoption and provide effective feedback to the medical research. This insight is based on the Doctor patient 1’s photograph experience, because the thermographs are all in bright and dark blue-green shades as a result as bad blood pressure control due to a high dose of medication, she suggested lowering the dose and
measuring the daily pressure for 5 days, ruling out a clinical picture of low blood flow that causes diabetic foot.

The application of new meaning through design is required to maintain the human-machine link (influence emotions) to innovate devices and to improve the technology as it enriches the definition of the diabetic foot pattern to adopt thermography in the diabetic patient consultation routine, as a consequence the regular use of the device will give feedback for future system requirements and telemedicine with the objective of automating the diagnostic.

When analyzing the interaction among medical, patient, and device other important new meaning found was 360 freedom mobility to take pictures as Doctor advice and here is the first conceptualization challenge, the idea for thermic noise-active-blockage and how it works with cooling base too.

**Conclusion and future work**

The technological problem is proposed together with a research and design plan for the implementation of a thermographic device for the prevention of plantar ulcers in diabetic patients and it was possible to highlight the importance of design as an influence to aligned designers, engineers and doctors activities to develop the product.

Emphasize 1, 2 and 3 stages of the proposed “Asignification” method, emotions increase the understanding for implementation, knowledge and experience in medical device development (MDD) process to create one for preventing diabetic foot ulceration and dismiss stress at patient journey. Breaking with the traditional steps of the medical sector that avoid the possibility of conceptualize in contact with final users, high volume production, based on pilot distribution and production programs.

This developing methodology delimited “interpreters” actions in theory and in practice strengthens the interaction between teamwork and human-research, then, it is possible to achieve "radical change of meaning" in the adoption of technology through influencing user behavior/routine and selection preferences. First three steps show an iterative process between INPUT, 360 research and Synthesis method stages because the cycle has been repeated 3 times to reach the requirements as 360 freedom mobility, Live thermographic vision on as long as the doctor wishes or the idea of thermic noise-active-barrier and how to interact with pictures required of different foot positions.

The present work may be the basis for future research and work on how Dark Horse interaction will help to avoid redundancy of existing products and to define the diabetic foot pattern to look for thermography with an Algiologist work to be performed from April to May and support general practitioners in detecting pre-diabetic foot ulceration symptoms as a result, they send their patients with the appropriate specialist to be attended with the purpose of preventing the formation of ulcers, as more information in 360 research stage will be collected and processed in Synthesis stage, Ideation process at Conceptualization stage will be strong and will facilitate the evolution of rapid prototyping, verifying or replacing current data validation. Data will tell volume production needed in medical market for our thermograph device then select distribution network, process and material.
References


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