COOL FEET

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1 ABSTRACT

This research concerns the combination of cooling techniques and materials used in a possible cooling shoe for patients with Epidermolysis bullosa simplex (EBS), a major type of the skin disorder Epidermolysis bullosa (EB). People suffering from EBS have fragile skin and blisters that form on their hands and feet. Walking causes blisters to form rapidly. The development of the blisters worsens in hot and humid weather. These symptoms can be alleviated by cooling the feet, keeping them dry and creating little friction. The Cool Feet project was brought to life, in order to research the design of a cooling shoe to help alleviate the symptoms. This research is divided into two parts: active and passive cooling. We will look at how the combination of these two parts can shape the design of the shoe and provide relief of the symptoms for patients with Epidermolysis bullosa simplex.

Additional Key Words and Phrases: Epidermolysis bullosa simplex, cooling shoes, active and passive cooling systems

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2 INTRODUCTION

Imagine going shopping on a summer day, going to your favorite stores with your friends, but not getting any further than your own street because of the blisters already forming on your feet[3]. People with Epidermolysis bullosa simplex suffer from this every day, especially in warm and humid weather conditions. One in 50.000 people suffer from this disease[21]. In this research we will focus on setting up recommendations to design cooling shoes for patients with Epidermolysis bullosa simplex.

Epidermolysis bullosa simplex (EBS) is the mild form of Epidermolysis bullosa (EB)[21]. EB is a genetic disorder caused by mutations in different genes. EBS mutations lay in K5 and K15 genes. In these genes lies the DNA to make keratin, type I and II of the intermediate filament protein. Those three tissues form the binding between two layers of the skin, the epidermis and underlying epithelial-related complexes[39]. The symptoms include rapid blister forming on hands and feet, or generally distributed, even mild internal blistering, although no scarring occurs, nail disformations and thickened calluses[21]. The friction and force on the skin at the feet and hands causes blisters to form, on a warm day patients cannot walk further than a 100 meter.

As of today there is no cure for the disease[11]. However, by keeping the conditions optimal, the aggravation of blisters can be prevented for patients with EBS. There are four factors the cause blistering to happen more rapidly: warm weather and therefore a high temperature in the shoe, a humid climate in the shoe, friction and force[10]. For this reason the demands of the shoe are:

- The temperature inside the shoe must be less than 15 degrees Celsius. At such an optimal temperature, it cools the feet down and alleviates the conditions of the blisters as they come up. Preferably adjustable, as it will differ during the day depending on what kind of temperature the patients will need[3][10].
- The humidity inside the shoe should be reduced to zero as much as possible, this requires the materials used to be moisture resistant such that it carries the moisture content away from the skin. As well as water resistance from outside sources[10].
- The friction inside the shoe should be as low as possible, hence the materials should have a low friction coefficient. As well as no seams on the inside of the shoe, as they tend to irritate the skin[10].
- Reducing the force on the skin is more difficult, one way to do so is to make the shoe lighter than they are now, by choosing light-weight materials and strong structures that take up less material[3][10].

The objective of this study is to answer the main research question: What combination of active and/or passive cooling could be used to accomplish a cooling shoe for people with Epidermolysis bullosa simplex? The expected outcome of this research will be one or multiple recommendations regarding materials for the shoe and cooling techniques to use, so designers can play and rely on our research when designing cooling shoes. The sub questions in this research are: “What material or structure would improve the humidity and ventilation of the shoes?”, “What material or structure would improve the flexibility of the shoes?” and “What material or structure would decrease the weight of the shoes?”.

First, an overview of existing literature will be provided. Followed by a description of the methods used in this research. Next, the results will be shown to evaluate them in the discussion. Afterwards, the limitations of this study will be discussed and suggestions for future works will be made. Lastly, the research will be concluded.

3 RELATED WORKS

3.1 Epidermolysis bullosa (EB)

3.1.1 General.

Pai and Marinkovich (2002)[23] state that epidermolysis bullosa is a family of skin diseases characterized by the formation of blisters on the skin. The main types of epidermolysis bullosa are epidermolysis bullosa simplex, hemidesmosomal epidermolysis bullosa, junctional epidermolysis bullosa, and dystrophic epidermolysis bullosa. In addition, Pai and Marinkovich indicate that currently, treatment for this skin disease consists of supportive care for skin and other organs

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as well as a combination of wound management, infection support for chronic wounds, surgical management as needed, nutritional support, and preventative screening for squamous cell carcinoma in recessive dystrophic epidermolysis bullosa.

3.1.2 *Simplex.*

When it comes to the simplex type of epidermolysis bullosa, the study by Pfendner and Bruckner (2016)[24] shows that, in addition to supportive care to protect the skin from blistering, use of dressings that will not further damage the skin and will promote healing whether open wounds also matter when it comes to treatment. In addition, there is also talk about agents/circumstances that must be avoided. For example, excessive heat can aggravate blistering and infection, and ill-fitting or roughly textured footwear and activities that traumatize the skin should be avoided.

The study by Pope et al. (2012)[25] provides insight into several recommendations regarding the treatment of epidermolysis bullosa (simplex). It becomes clear that patients with EB simplex (EBS) present predominantly with acral blisters exacerbated by heat and friction. A relevant recommendation is to select a dressing that is appropriate for the needs of the patient and the caregiver based on the subtype of EB. For example, the dressing choices would be individualized based on EB subtype, extent and wound location, dressing frequency, cost, and availability. In addition, wound healing requires an appropriate wound surface moisture balance. This can be achieved by using materials with occlusive, semi-occlusive, absorptive, hydrating, and hemostatic characteristics, depending on the wound characteristics and drainage.

3.2 Cooling

3.2.1 *Active.*

Today, cooling devices with Peltier elements are used for medical purposes, as can be seen in the study by Slanina et al. (2018)[42]. This study shows how Peltier devices are used as an active source of coldness and how this tissue cooling system is suitable for long-term temperature maintenance. The practical application of Peltier elements in feet cooling applications for patients with epidermolysis bullosa is described in the studies of Hou[14], Dadikozyan[9] and Brands[7], all Electrical Engineering students of the Eindhoven University of Technology. These studies show with the help of experiments and demonstrations how the use of Peltier elements can cause a significant decrease in temperature in shoes due to the Peltier effect. This cooling can serve as an alleviation for the symptoms of epidermolysis bullosa.

3.2.2 *Passive.*

Several applications are already known in the field of passive cooling. There are, for example, evaporative cooling garments that ensure that the human body can cool down. The concept of reducing the heat gained from the environment by evaporating the excess amount of water reserved in the cooling fabric, as can be seen in the study by Sarkar and Kothari (2014)[28]. Another application of passive cooling, according to the study by Taleb (2014)[13], takes place in buildings through the use of technology or design features that lower the temperature without the use of energy. Use is made of harnessing of natural ventilation and the minimizing of heat gain in line with applying good shading devices alongside the use of double glazing. The study by Rempel and Remington (2015)[26] also indicates that passive cooling strategies such as shading, natural ventilation and use of thermal stress are effective for cooling.

3.3 Ventilation

A technique that is often used to cool something down is ventilation. Ventilation can be active or passive and is regularly used in buildings. Whether they rely on window openings, ceiling fans or any other method, such techniques always seek to enhance convective cooling of the occupants by increasing the indoor air speeds (Blondeau, 1997)[6]. This convection of air can improve the condition of the air in the building since it circulates fresh air. In shoes, ventilation created by walking can cool the feet as described by Shimazaki et al.[41]: It can be seen that faster gaits result in higher ventilation rates. Air holes or a breathable fabric help this ventilation and make sure it can more easily take place.

3.4 Environment in shoes (effect on feet)

When excess heat is not able to leave the shoe for a certain amount of time there is more chance that the feet start forming blisters or get irritated. Besides that "these in-shoe conditions increase bacteria growth causing fungal infections and foot odour" according to Dessing et al.[22]. For people with Epidermolysis Bullosa this warm environment in shoes has an even bigger effect on the condition of their feet[10].

3.5 Materials in shoes

Shoes consist of a lot of different kinds of materials. Each material and structure has different purposes and characteristics. Leather, textiles, synthetic fabrics, rubber and foams are some of the materials that are generally used in the making of shoes[36][17]. The materials that they consist of differ according to the purpose that the shoe serves. Sport shoes use a lot of synthetic materials, because the structure and the color of the fabric can easily be customized to the desired properties[8]. While boots are for example often made of leather, because of its sturdiness and breathability[17].

4 METHODS

The research regarding materials, various features of the inlay sole/shoe to accommodate a neat design to, type of actuators and sensors needed to implement active cooling. Incorporating the combination of active and passive cooling methods could alleviate the chance to help prevent the severity of the blisters which would interfere with normal day-today activities.

This project has been worked on previously by the Electrical Engineering department, hence various perspectives and suggestions were provided from the teacher, who was coaching them, through which the next steps to be taken were provided. To gain more insights on how the problem arises and how it is assessed and dealt with, interviews with a healthcare professional from UMCG and a patient suffering from EBS were conducted. Taking this step helped us to plan a systematic focus on what the technical focus of the project should be about. A study plan containing the three phases which harboured technicalities were drafted to follow through with the decision making process. Further, these interviews helped us to formulate a questionnaire to ask the patients about the demands and how we would help them achieve these criterias. The questionnaire provided us an answer on what the majority of patients are in need of. Taking these answers as the basis for the analysis of materials and cooling systems, which were researched, as the best fit.

In order to analyze the research done on cooling and passive methods as well as the various materials to help support it, certain questions were written down in order to have a clear outlook on what needed to be achieved from this assessment. These questions were put in a tabular form to assess active, passive cooling and the various materials. These questions focused on the specifications of the material in order to help provide comfortable wearability for the user. The questions varied from the temperature that can be supported, the flexibility, durability, conductivity, moisture it can contain , water resistivity, expansion properties, tensile strength, chemical consistency, fracture toughness, weight and density. With segregating the information in these columns, it was easier to conclude which materials could support the cooling equipment within a temperature range of 5 to 15° C within the shoe.

Moreover, in order to achieve completion of this assessment, questions were formulated for the demands of the cooling systems as well. These questions were in accordance with the wearer's comfortability and safety. The main focus was to figure out what type of material would support the cooling efficiency and type such as thermal conductivity, moisture management, and tactile properties. Moreover, to provide ourselves with a basis if such a system can be fitted into a shoe. After a thorough analysis, the top 4 cooling systems were chosen for which materials for a shoe and sole were chosen respectively.

5 RESULTS

5.1 Demands and Needs

In total three interviews were held. Two were with an expert of the UMCG and one with a patient with EBS. These interviews were used to set up the questions and properties to select the cooling techniques and materials.

In the first interview with the UMCG expert, the same four demands already specified in the introduction were derived: Temperature inside the shoe should be around 5-15 degrees Celsius, a light-weight shoe, a non-humid condition inside the shoe and less or no friction. Apart from this, new properties also came into view such as that the shoe should be flexible, the skin is most vulnerable when both humid and warm and having the correct movement of the feet from heel to toe. The expert also mentioned a few materials and products to look at, including Skechers sneakers, orthopedic soles, plastazote, CoolMax fibre and undersocks for hikers[10]. The full interview including questions can be found in appendix A1 - UMCG interview 1.

The EBS patient shared their experiences. Through this interview, several other demands were found for the shoe such as the shoe should fit nicely (not too loose or too tight), in the summer they wear many different shoes so they have different pressure points daily, synthetic fabrics are not loved as they tend to be more sweaty, having cold feet is fine and carrying a backpack with a battery is also fine[3]. The full interview including questions can be found in appendix A2 - Patient 1 interview.

In the last interview with the UMCG expert no new demands were derived, but many other interesting sources were found, see appendix A3 for the full interview. All demands that are used in the analysis are seen in the two lists, List 1: The written out demands for cooling techniques and List 2: The written out properties for the materials.

List 1: The written out demands for cooling techniques.

- Is the material flexible as a sneaker?
- Can it stand big heats?
- Can it transport heat?
- Can it transport moisture one way and not the other way?
- Is the material water resistant?
- Is it durable, can it last more than two years?
- Are there compatible structures with their own properties and advantages?
- Is it a light-weight material?
- What is the chemical consistency of the material?
- What is the density of the material?
- What is the tensile strength of the material?
- What is the fracture toughness of the material?
- What is the specific heat of the material?
- What is the T-conductivity of the material?
- What is the T-expansion of the material?

List 2: The written out properties for the materials.

- How does the technique work? (short answer)
- What is the size of the system and would it fit into a shoe?
- What is the weight of the system (and it's battery)?
- What is the cooling capacity of the techniques, taken into account the body temperature?
- Is it safe to put the technique into a wearable?
- Is the temperature adjustable?
- What materials is the system made of?
- Is it integratable into a shoe?
- Is it flexible and foldable?
- Is it integratable in different size shoes?

5.2 Analysis

5.2.1 *Cooling Techniques.*

After formulating which demands the cooling techniques should meet (List 1: The written out demands for cooling techniques), two tables were drawn up. For both passive and active cooling techniques there is a separate table. In the tables it is analyzed whether it has the demands mentioned above. The tables here are shortened to checks and crosses, the full tables with explanations can be found in the appendix B1 - Full tables of materials and cooling techniques.

The techniques mentioned in the discussion are seen in Table 1: The summary of the best cooling techniques below.

Summary	**Heat sink**	**Convection cooling**	**Liquid cooled garments**	**TCF (temperature control footwear)**
How does it work?	Heat flow is guided away from the device (mostly for electronics)	Heat is transferred through the fluid from one side of the device to the other	Cooling liquid is circulated inside the tubes embedded in the garment by means of a battery operated pump. As the liquid becomes warmer by the body heat, it is carried away to a heat sink or cooler for re-cooling purposes.	The TCF of the present disclosure preferably has an open air system into the sole which comprises insole , midsole and out-sole to allow for good airflow and convection to occur at the heat sink. Thermoelectric cooler will preferably be attached to a heat sink using thermal-conductive adhesive that is commonly used with CPU's and heat sinks in high end computers.
Size of the system	Depends	Depends	As big as a garment since the tubes are embedded all over.	The parts are placed in the insole, mid-sole and out-sole respectively. Hence, the size would depend on the size of the heat sink, thermoelectric cooler, the plug along with the extra materials these components come with to passively cool. Additionally, insole material should be machinable and easy to implant in order for practitioners or manufacturers to be able to custom place the devices for each wearer.
Weight	Depends	Depends	Lesser weight and bulk	Could be heavy but depends
How cool is it?	Can work very effectively, when there is continuous air flow	Can be very cooling especially when the difference between outer and inner temperature is significant	Higher heat capacity of water in comparison to air so cooling efficiency improves. The cooling efficiency of liquid cooling garments depends on environmental conditions, tubing type and length, liquid inlet temperature, flow pattern(single loop or multi-loop) and flow rate	Consists of an active cooling system with thermoelectric inserts and cooling elements selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element. Hence the temperature is well regulated. The results of the study performed showed that active cooling of the feet is efficient
Is it safe?	Yes	Yes	There are inherent safety problems like water spillage leading to short circuits, steam burns and discomfort related to wet clothing	A closed loop passive control system will be used to control the amount of heat being removed from the plantar surface of the foot by TCF. This will act as a safety and energy conservation mechanism. Plug preferably comprises an upper surface comprising a low friction interface material manufactured with polytetrafluoroethylene (PTFE) film, such as ShearBan®, to protect the wearer's skin from damaging friction shear trauma.
Energy source			Battery operated pump. Rechargeable battery The amount of water available in the reservoir and the build up of inlet water temperature restricts the usage time of liquid cooling garments. A reservoir of one half litre is sufficient enough to provide a considerable amount of body cooling.	The power source comprises rechargeable batteries that may be recharged when in use and/or when not in use
Can it be controlled?	No	No	Yes	Yes
Material that it is made of	Aluminum, sometimes copper	Can be fluid or air	For better wearer comfort a three layer structure where the tubings are sandwiched between the inner and outer fabric layer is preferred. The inner layer needs to carry away the sweat in liquid or vapour form. For better performance, the inner layer must have good thermal conductivity, good moisture management and good tactile properties.	Material for insole and plug are an integral portion of this design because they are in direct contact with the wearer. Plug material preferably is thermoconductive while having a low durometer in order to accommodate the increased pressure under the high pressure areas Additionally, insole material should be machinable and easy to implant in order for practitioners or manufacturers to be able to custom place the devices for each wearer. The whole insole is preferably made of thermal insulation materials, and thermo- conductive gel pads are preferably placed at the high-pressure areas.
Integratable in shoes - Flexible and foldable - Integratable in different shoe sizes?	Yes, especially to cool the electronics	Yes	Yes it can be. If it is used in garments then it can be foldable and flexible.	Yes it can be integrated in shoes.The parts are custom placed for each wearer. The insole that is in direct contact with the foot needs to be machinable and easy to implant No info given about flexibility and foldability

Table 1. The summary of the best cooling techniques

5.2.2 *Materials.*

After formulating which properties the materials should meet (List 2: The written out properties for the materials), a table has been drawn up in which for each material, for both the shoe and the sole, it is analyzed whether it has the stated properties. The materials mentioned in the discussion are seen in Table 2: The summary of the best materials for the upper part of the shoe and Table 3: The summary of the best materials for the sole of the shoe below. The complete tables, with notes can be found in the appendix B1 - Full tables of materials and cooling techniques.

	Flexibility	**Temperature**	**Transport**	**Moisture**
GoreTex®	√	√	√	√
PrimaLoft	√	√	√	√
TENCEL	√	√	√	√
	Water resistance	**Durability**	**Structures**	**Weight**
GoreTex®	√	√	√	Light
PrimaLoft	√	√	√	Light
TENCEL	√	√	√	Light
	Chemical consistency	**Density**	**Tensile strength**	**Fracture toughness**
GoreTex®	√	not found	not found	not found
PrimaLoft	√	not found	not found	not found
TENCEL	√	not found	not found	not found
	Specific heat	**T-conductivity**	**T-expansion**	
GoreTex®	not found	not found	not found	not found
PrimaLoft	not found	not found	not found	not found
TENCEL	not found	not found	not found	not found

Table 2. The summary of the best materials for the upper part of the shoe

	Flexibility	**Temperature**	**Transport**	**Moisture**
Natural rubber	√	√	×	×
Vulcanized rubber	√	√	×	×
Thermoplastic rubber (TPR)	√	√	×	×
Polyurethane (tailorable, wide range)	√	√	×	×
Leather (insole)	√	×	×	√
CoolMax fibre/sock	√	√	×	√
Silicon	√	√	×	×
	Water resistance	**Durability**	**Structures**	**Weight**
Natural rubber	√	√	not found	High
Vulcanized rubber	√	√	not found	High
Thermoplastic rubber (TPR)	√	√	not found	High
Polyurethane (tailorable, wide range)	×	√	√	Light
Leather (insole)	not found	√	√	Mid
CoolMax fibre/sock	not found	√	√	Light
Silicon	√	×	√	Light
	Chemical consistency	**Density**	**Tensile strength**	**Fracture toughness**
Natural rubber	√	$950kg/m^3$	24 MPa	$0.14MPa * m^{1/2}$
Vulcanized rubber	√	not found	not found	not found
Thermoplastic rubber (TPR)	√	$0.91 - 1.3g/cm^3$	$0.5 - 2.4N/mm^2$	not found
Polyurethane (tailorable, wide range)	√	$0.05 - 1.7g/cm^3$	45 MPa	not found
Leather (insole)	√	not found	not found	not found
CoolMax fibre/sock	√	not found	not found	not found
Silicon	√	not found	not found	not found
	Specific heat	**T-conductivity**	**T-expansion**	
Natural rubber	$1900J/kg * C$	$0.14W/m/K$	$22010^-6/C$	
Vulcanized rubber	not found	not found	not found	
Thermoplastic rubber (TPR)	not found	not found	not found	
Polyurethane (tailorable, wide range)	$1700J/kg * C$	$0.42W/m/K$	$16010^-6/C$	
Leather (insole)	not found	not found	not found	
CoolMax fibre/sock	not found	not found	not found	
Silicon	not found	not found	not found	

Table 3. The summary of the best materials for the sole of the shoe

5.3 Validation

5.3.1 *Questionnaire.*

The questionnaire was sent to people with Epidermolysis Bullosa and a total of 55 people with different demographics answered the questions. The patients needed to answer questions in different categories: the prevention of the blisters and the demands and needs they feel the shoe should have. In some cases the answers were very similar and in other cases almost every patient answered something different.

Most patients agreed that their blisters are worse in warm and humid weather and blamed this on the fact that the skin gets more irritable in these conditions and that the friction and sweat makes it worse. Most of them combatted this problem by simply not walking a lot and cooling the feet with ice. Sneakers were the shoes that were mostly worn, but the brands were different for everybody. Most people refer to these shoes as light, airy and soft on the inside.

A cooling inlay sole was the most chosen option when being given the options: inlay sole, shoe or the sneaker kit idea [1]. Shoes with high flexibility, low moisture content and not too tight and not too loose were preferred. For the temperature the mass chose for 5 until 15 degrees inside the shoe and the option of being able to change the temperature.

Lastly natural materials were preferred like cotton for clothing and leather in shoes. While some people did like mesh synthetic fabrics for the shoes.

5.3.2 *Orthopedic shoemaker.*

After a conversation with the UMCG expert, see appendix A1 - UMCG interview 1, it emerged that a layer of 2 materials (in the case of 2 layers of socks) can provide optimal cooling conditions. To apply the same concept to a shoe, it is important to first validate this concept with an orthopedic shoemaker who is familiar with making shoes for patients with epidermolysis bullosa. That is why an interview took place with orthopedic shoemaker of OIM Orthopedie Haren. This interview showed that the orthopedic shoemaker mainly works with (artificial) leather (through craftsmanship) and is not familiar with the use of the materials from the analysis. Nevertheless, he indicated that in principle it is possible to combine materials and in this way create a layer of 2 different materials for the shoe, as the use of different materials for orthopedic shoes takes place more often in practice. The full transcript of the interview can be found in appendix C2 - Interview Orthopedic Shoemaker.

6 DISCUSSION

6.1 Initial combinations

After the analysis has taken place with regard to active and passive cooling options (see **??**) and materials for the shoe and sole (see **??**), a combination of the best cooling options and the best matching materials was put together (see Table 7). The best matching materials have been chosen primarily based on the thermal conductivity required by the cooling options to ensure optimal cooling conditions. The choice was equally based on which materials met the demands and needs of EBS patients and shoe properties.

To see which of these four options is most likely to succeed in cooling the foot as well as be wearable for the EBS patients, validation is needed. The questionnaire sent to EBS patients and the interview with the orthopedic shoemaker will both play a big part in this. Keep in mind that the best validation would be building prototypes and testing them with EBS patients. However, since ethical considerations did not allow this physical testing, the validation is mostly theoretical done.

	Material for the shoe	**Material for the sole**
Heatsink	TENCEL, Gore-Tex	Thermoplastic rubber, CoolMax fibre, mesh
Convection cooling	Primaloft	Polyurethane
Liquid cooling garments	Primaloft	Leather
Temperature adjustment cooling in shoes	Gore-tex	Silicon, polyurethane
Weighted ventilation	TENCEL, Gore-Tex	3D-printed, natural rubber, vulcanized rubber

Table 4. Combination of best cooling options and best matching

6.2 Questionnaire to EBS patients

The questionnaire validates the properties and demands set for both the materials and the cooling techniques. The 55 EBS patients want light, airy and soft shoes, similar to most sneakers. The participants stated they agree that a humid climate inside the shoe, warm weather and friction are the biggest problems. This is seen in regard to the material choice for a light-weight, non-synthetic, flexible and breathable material. Regarding their preference for inlay soles, it is something not integratable as all techniques have a bigger size. Furthermore, the participants shared the preference of being able to adjust the temperature in the shoes.

6.3 Orthopedic shoemaker (Herman Lok from OIM Orthopedie Haren)

Although Mr. Lok indicated that it is in principle possible to combine materials, he emphasized that it differs per material whether it can be combined with another material. This creates a layer of 2 materials for the shoe. Since this research concerns a theoretical model, it is important to do more research into the combination of materials for an orthopedic shoe and to carry out user tests in order to realize a practical application of this model.

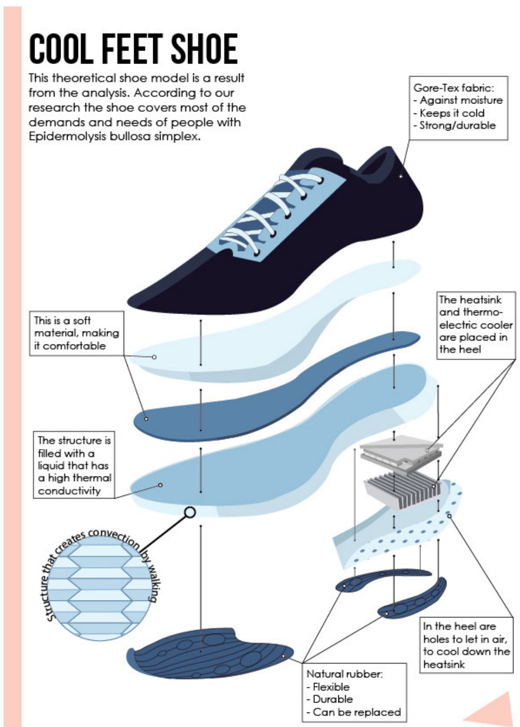

Fig. 1. Explanation of the shoe

6.4 Concluding combination

To conclude on what the best option would be as a recommendation for next projects, all factors mentioned above are taken into account. See Fig. 1. The best option would then include a combination of a heatsink, a thermoelectric cooler (abbreviated TEC, for the temperature control) and convection cooling. The thermoelectric cooler creates the Peltier effect, with the result that one side of the thermoelectric cooler is cool and the other side is hot. The structure of the sole, with holes on the side, allows for ventilation. The heatsinks side with a lot little pleads can be cooled down with this ventilation. The heatsink is placed on the hot side of the thermoelectric cooler, so the TEC can cool down. Mechanical convection, created by the movement of the person wearing the shoe, ensures that the coolness of the cool side of the thermoelectric cooler moves through the sole using a liquid. It is recommended to look into this combination and work it out in more detail than done here. In future work it should also be tested for it's capabilities, wearability and durability.

7 CONCLUSION

In this paper the combination of cooling techniques and materials used in a potential cooling shoe for patients with EBS was researched. Initially all current techniques and materials were considered. The qualitative methods that were implemented, among other things interviews with patients, clinical professionals and experts, provided the basis for formulating the quantitative methods of the analysis. The analysis was concluded with one theoretical model combining multiple techniques and materials.

The theoretical model considers multiple demands and needs of EBS patients: a low humidity inside the shoe, a temperature ranging from 5 to 10 degrees with the probability of adjusting the temperature by the wearer, flexible like a sneaker and light-weight. The concrete evidence was gathered through a well formulated questionnaire sent to EBS patients. The questionnaire gathered their current practises and their demands and needs.

This paper contributes to the research regarding cooling footwear (for people with EBS). In this paper we discuss numerous techniques and materials that can be used and formulate a theoretical model that would work the best. Next to that, this paper contributes to the knowledge about footwear for people with EBS in general.

8 LIMITATIONS

There were a few limitations that were encountered over the course of the project. One of these was that the group was obliged to have all the meetings online because of the Covid-19 pandemic. This also made it impossible to validate the materials in person with Herman Lok, orthopedic shoemaker from OIM Haren. Therefore this meeting was online and rested on the explanation skills of the expert and the group to still be able to validate the solutions.

Another struggle that was encountered was not being able to test the solutions on EB patients due to ethical reasons. Consequently the ways the ideas were validated was by the use of questionnaires and expert opinions.

Furthermore there seemed to be a limitation in the data that could be found on EB patients and solutions that would help, especially when it comes to cooling shoes. Some other data that was at first difficult to find, was data that talked about the specifics (humidity/temperature) these shoes should preferably have, to be ideal for EB patients. The same problem was encountered when researching newer materials, since there was not yet a significant amount of literature on these.

In the future the newest materials could be explored a bit more, providing there is more literature. For the future groups that will continue this project, it would be advised to integrate the research of this paper and the research of the Electrical Engineering reports into one design and to start testing the design as a whole.

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10 APPENDIX

A. Demands and Needs

A1 - UMCG interview 1.

This is an interview between the clinical professional from the UMCG in Groningen and the researchers. It was held in English. The complete minutes are written out below, the E stands for expert and the R stands for researchers.
The goal of this meeting: Discuss what the clinical professional (or other specialists) can do for us in the continuation of the project.

The expert first introduced herself. She does patient care and thus is most of her time in the hospital. She meets patients online if everything is okay, but when they have complications they have to visit. They are hoping for the vaccins(for Corona), they think it will be there around April or May, as the government is a little behind on schedule.

R: Thank you!
E: Of course we will help, love it when they do some cooling shoes or other things to help patients.

R: Our project and goal, as previous discussed over the email are: We are 4 students doing a research project on cooling shoes for people with EB. Our goal is to find materials and cooling techniques suited to do this. design cooling shoes to relieve discomfort/pain for people with EB Simplex. The main goal of the shoes is to prevent blisters.

R: We also heard about earlier contact between UMCG and Electrical Engineering students, the subject would have been Peltier elements and batteries. What role did UMCG play here?

E: Only with Patient 1 did she have some contact, talking about the project at university. She can't remember that she had contact with the technical people. They discussed some needs and demands for the shoe

R: We are using this technology, but have to design the full shoe (which means we have more aspects that we have to take into account, such as material)

E: EB is a disease that have a genetic alteration in the genes that make the adhesive pieces (wokkels, Dutch twisted paprika chips, which form helixes) Keratin fiber modules, makes their skin fragile. In warm weather and friction on skin it is even worse, blisters will form everywhere we're there is friction. EB Simplex mainly on the hands and feet Calluses have even more mechanical friction, take care of three things to reduce blister forming: temperature needs to be low, moist absorbing, no friction. The battery should at least hold for 6 hours, even 8 hours would be very nice.

R: What about rigid?
E: The change that something hits your feet or somebody steps on your feet very little, so that is not important, it is more important to have flexible and light shoes. Sketcher shoes are advised by the EB center in Great Britain. Great Britain has a big EB centrum. They advise sketcher shoes because the shoes are light-weight and support the natural gait and foot movement.

E: The skin is more fragile when wet and warm.

R: Do you make a sole?
E: We have Podologist (orthopedic shoemakers), who use plastozodes in their soles. Plastozodes form to the feet, but it has the thing that after two months it stops adepting. The other option is gel soles but they did not test it out yet.

E: She asked to her colleagues about moist taking materials, but that's not there yet. Cool Mags is a fabric that comes the closest to this as it brings material(moist) away for the skin. The downfall is that it has to go to a second layer of the socks. The two layers of socks takes away the friction of the skin, at least partly.

E: She will send us the tips form EB patients that are sportive. They did not yet know this in 2020 (so teams before us did not have this information yet).

E: Do you plan to make an entire shoe or inlay sole? R: Model of a shoe or sole is something we are still deciding on as the choice need to take multiple things into account.

E: The possibility of discussing experiences with EB Simplex patients about relieving the pain, preventing blisters and wearing shoes.

R: Show research questions:

(1) What materials and structures could be used to accomplish a shoe for Epidermolysis Bullosa Simplex patients that is flexible, ventilates and cools but is sturdy at the same time?
   (a) What material or structure would improve the ventilation of the shoes?
   (b) What material or structure would improve the sturdiness of the shoes?
   (c) What combination of active and passive cooling would improve cooling the feet?
   (d) What materials are good for people with Epidermolysis Bullosa Simplex?

E: I would revine it to EB Simplex patients. Rephrase the ventilation question. Sturdiness is not needed really, please make it light and flexible. The third sub question is really nice, the fourth as well. We also talked about that. The thing can be that focusing on an entire shoe is much more difficult. When you focus on a sole it is easier and as a woman you then have the possibility to change shoes. We mean a sole like and inlay sole, but getting in electronics and battery is harder.

E: Till when do you have?
R: We have till beginning of July

R: How is it threatened?
E: Blisters are always made open, drained as well and always covered up. They have flexible plaster that stretches in two ways, which prevents blisters forming on the open skin. Cooling as well till its warm, when they feel blisters coming up and they cool immediately. They change shoes every hour in the summer as multiple factors change between socks. They wear two layers of socks, one a mountain climbing undersoc and just a normal one to take the moisture. In the evening a cold tub of water is drawn to cool the burning sensation and stop the blisters from forming. Infections are common and need antibiotics

A2 - Patient 1 interview.
This is an interview between the patient 1 and the researchers. It was held in English. The complete minutes are written out below, the P1 stands for Patient 1 and the R stands for researchers.
The goal of this meeting: Discuss what the Patient 1 experiences daily and their demands and needs for the shoe.

Demographics/introduction
R: We have three parts. First the demographics, which are questions about you. Second, blister prevention and daily life will be questioned. Lastly, we will talk about the demands and needs for the shoe.

R: What is your name?
P1: Patient 1
R: How old are you?
P1: 26
R: When were you diagnosed?
P1: Her father has it to, and noticed it as a baby
R: How long have you been doing the cool feet project for?
P1: I think it started 1 year ago
R: Did you speak to other teams as well?
P1: Yes, I had a meeting with Daniel Tetteroo, Noortje Bax and Professor Cantatore

The blister prevention/daily life
R: Are the symptoms regular?
P1: The symptoms are way worse in the summer. In the winter I rarely have blisters, after about 10 to 15 minute walks they start to come up. In the spring temperature is rising and normally it starts at the beginning of March, after about 100 meters the blisters come up. The moisture in the air also really plays a role in this.
R: What would be the temperature you get blisters?
P1: Around 5/10 degrees it gets worse fast, meaning here the outside temperature not the temperature inside the shoe.
R: Wouldn't it be super cold inside the shoe if you constantly have such a cold temperature (around zero)?
P1: Having cold feet would not be a problem, it is better than the blisters.

R: Thick socks/shoes warm does it get worse?
P1: Synthetics materials are not the best. They build up moisture and heat.

R: Is it worse in a specific kind of weather?
When it is wet it is also worse. In Africa it would be worse, because of dry heat. In asia for example not.

R: What do you do to prevent blisters?
P1: Mostly not walking , bicycles and shoes that are very stretchy, no synthetic materials, flip flops in summer, which causes big blisters in between toes. Blisters cooling, gives pain relief. Best prevention is not walking.

R: What works the best?
P1: Mostly turning to other means of transport. Even in winter I will get blisters when walking for a long time.
R: What are comfortable shoes?
P1: No synthetic, warm shoes or heels.

R: How do you take care of your blisters?
P1: The patient does not use the material UMCG, does not treat them. Wait with treating them till they dry, on heel the patient does pops them and removes the liquid and bandages the wounds. Then it will heal.

R: How long does the prevention and care take in a day (average)?
P1: Not that much, it's that during the day you can't really do any care or prevention. Blister care is not really helpful for me.

R: When do you need to use a wheelchair?
P1: Sometimes, when it's a big event, a zoo or festival. She doesn't like to do it.
R: How often do you resort to using a wheelchair?
P1: 3 times a year, it depends on the holiday as well.

The needs and demands of shoe/sole
R: Would you like a shoe or a sole or a sock?
P1: A sole would do the best, in summer we have very different shoes, so there are different pressure points every day.
R: Do the blisters form all over your feet or more on bottom?
P1: More bottom indeed, if you have pressure points the blisters will eventually form there.
R: What kind of shoes do you normally wear?
P1: Mostly wear sneakers that are really stretchy, like Nikes, Vans, light shoes. Preferably with natural materials so leather (not synthetics), in summer flip flops. I have moccasins, very lightweight and soft. But the sole is really flat, so it can be painful while walking. I would like to have a shoe that is lightweight and soft, but the sole should not be thin.
R: Specific brands that are better than others?
P1: Nike, their running shoes and Vans can be okay as well, I have not yet found the perfect shoe.
R: Is this general for all patients?
P1: Definitely, everybody has different feet but most have natural materials that are light-weight and strachty. No brands in specific that work for everyone. Trying on shoes is very important, but it can be hard to find pressure points in one try. People are looking mostly for demping.
R: What temperature would be good for you?
P1: Perfect temperature is in the winter, so 0/5 degrees outside, the inside temperature should be tested or calculated as I don't know.
R: What about 10/15 inside?
P1: 15 is probably already too hot, being able to power it down would be ideal. When walking our feet tend to heat up… also when it is hotter outside as well, so I will mostly wear them during the summer.
R: Till how low should we go?
P1: 0 degrees is nice as outside temperature, 10 degrees it begins to be noticeable as outside temperature. Difference in if it is between sole/feet or just one temperature.
R: Moisture should be reduced to none right?
P1: No moisture is ideal. 2 socks is a nightmare for me as the warmth is killing. Cotton socks also get enough moisture away.
R: What kind of materials/ fabrics are comfortable to wear?
P1: Cotton, any material that is not synthetic. Sometimes you have those synthetic blouses which really sweat. Leather, linen, jeans
R: And silk?
P1: Silk is not yet experience

R: Our explain project: We are focusing on the material and structures and combining it with passive cooling. It is a research project.

R: What should be the weight of the shoe?
P1: I think the average sneaker would be great. Really heavy boots would be noticed.

R: Do you buy other soles in the shoes?
P1: No, not really, they make the shoes smaller, and not really any advantage.

R: How tight would you like your feet to fit into the shoes?
P1: Ideally, fit nicely to the shoe, there would be friction in loose shoes.
R: Can it be too tight?
P1: Only notice if shoes are hard otherwise no problem.
R: How flexible should the material be?
P1: Ideally, really flexible.
R: Do you mind carrying a backpack?
P1: No I wouldn't mind, if I am less uncomfortable all day maybe get a blister, it is certainly doable. Legs or ankle braces would be friction as well. Fanny packs would be more ideal blister wise.

R: When you go to the shoe store what do you do?
P1: Not really asking anything. I would look by myself, look at the shoes and see if they are flexible, by breaking the heel, if they are synthetic and then fit them. I try to see if they have many pressure points, because that is not doable for me.
Natural fabrics have favor of getting less sweaty, less warmth and I do notice the advantage.

R: For the introduction of our paper can we use an anecdote of your experiences in our introduction?
P1: Absolutely; In the summer it's in flip flops and still feel like I have second degree burns. It's this needle sensation of sensitive skin, it's painful and afterwards the blisters start to come up, they don't show not right away. After about a 100 meter I am in pain.

Ending:
R: Thank you!
R: Anything to add, information or feedback?
P1: Feel free to contact me any time.

A3 - UMCG interview 2.
This is an interview between the clinical professional from the UMCG in Groningen and the researchers. It was held in Dutch and was translated to english. The complete minutes are written out below, the E stands for expert and the R stands for researchers.
The goal of this meeting: Discuss what the EB center already has as solutions and to prepare the questionnaire.

R: Do you already have techniques or materials that cool?
E: No, we do not yet have any materials for the cooling. We do know that some interesting materials can be found on staycoolshop.nl. They sell special materials to cool.
R: Why does the silicone wrapping of last meeting work so well?
E: It is very specific in use, it sticks less to the wounds and thus you won't pull the epiderm with it. For underneath the foot they most times use foam bandages as it is more to cover open wounds, as well as absorbing moisture.
It is preventive, but you could use it as well for wounds. In the morning it is put on to the skin, so blisters are formed less and the pain is reduced.
R: Are there other materials used for this purpose?
E: In the OIM Haren an orthopedic shoemaker, Herman Lok, works to make shoes for the severe cases of EB. He doesn't completely understand EBS, but for materials he is the person to ask. I know they have Plastozodes, which form with the feet, but after months they need to be redone as the material stops to reform itself.
R: Is there an ideal material?
E: No there is no material ideal, but CoolMex fibers appear to be very nice. As it holds the moisture from the skin. We even received a "thank you!"-email over it.

R: About the questionnaire, how would you like to set that up?
E: You should send me a concept with the link to it. Then I can send it to the administrators of the 2 facebook groups, one hidden and one half hidden, half open. They can check if the questions are correct and can be asked to the "vulnerable" user group. If she hangs her name to it, it will be filled in a lot more. We can also throw it in the email group.
R: What language is the best?
E: Dutch is the head language, but some prefer english.
E: Also please write a short introduction for us to post it with, about who you are and the project and explain the next step.

R: Anything to add?
E: Check the guidelines for orthopedics in EBS, did I already mention this to you?
R: No, you did not, also not in the email.
E: I will send them after this meeting

B - Analysis

B1 - Full tables of materials and cooling techniques.
In the analysis we made four tables, two for cooling and two for materials. The cooling techniques were split into passive cooling techniques and active cooling techniques. The materials were split into sole sock and the upper, often fabric, part of the shoe. In this appendix the entire tables are shown, including all materials and techniques researched and the full descriptions in each cell. In the main report the full descriptions are minimized to keep them clear.

Cooling techniques table

[redacted]	Flexibility	Temperature	Transport	Moisture	Water resistance	Durability	Structures	Weight	Chemical consistency	Density	Tensile strength	Fracture toughness	Specific heat	T-conductivity	T-expansion
Sole															
Plastazote	✓, they adapt to the feets from, but stop after 2 months		✕, it is an insulator	✕, it has closed cells so this will not do great in water transport	✓, it will repel not completely resist	✕, it stops reforming after to months	✓, it is a structure itself	✓, light-weight	✓, Latex-free, non-toxic and hypoallergenic	✓, Wide range of densities, .045 g/cm3	560 kPa	1150 N/M	-70 - 105 C		elongation minimum 175
Natural rubber	✓, for rubber	✓, heat resistant	✕, no transport of temperature	✕, it will not transport water	✓, it is water resistant	✓, long lasting		✕, high weight	✓, from the rubber tree consists of polymers of the organic compound isoprene, with minor impurities of other organic compounds, plus water.	✕, high density, 950 kg/m3	✓, is high, 24 MPa	0.14 MPa*m1/2	high, 1900 J/kg*C	0.14 W/m/K	220 10^-6/C
Vulcanized rubber	✓, for rubber and more than natural rubber	✓, heat resistant	✕, no transport of temperature	✕, it will not transport water	✓, it is water resistant	✓, * 10 natural rubber		✕, high weight	✓, Vulcanization, chemical process by which the physical properties of natural or synthetic rubber are improved	✕, high density	✓, * 10 natural rubber		higher		lower
Thermoplatic rubber (TPR)	✓, for rubber	✓, heat resistant	✕, no transport of temperature	✕, it will not transport water	✓, it is water resistant	✓, long lasting		✕, high weight > lower than others	✓, a polymer blend or compound which, above its melt temperature, exhibits a thermoplastic character that enables it to be shaped into a fabricated article and which, within it's design temperature range, possesses elastomeric behaviour without cross-linking during fabrication	✕, high density > lower than the others, 0.91 - 1.3 g/cm3	0.5 - 2.4 N/mm2				
Resin rubber (outsole)			✓, has thermomechanical properties			✕, can be brittle	✓, it is a structure itself								
Polyurethane (tailorable, wide range)	✓, matresse till rubber flexibility	✓, can be heat resistant	✕, no transport of temperature	✕, it will not transport water	✕, it is not water resistand	✓, long lasting, elasticity memory	✓, it can have different structures, liqued to foam	✓, light-weight	✓, Polyurethane is produced in a polymerisation reaction between diols (or polyols: alcohols with two or more reactive hydroxyl –OH groups) and diisocyanates (or polyisocyanates: isocyanates with two or more reactive isocyanate –NCO groups). The result is a molecule bonded by urethane (COONH) linkages.	✓, 0.05 - 1.7 g/cm3	✓, can be low or high, 45 MPa	0.5 MPa*m1/2	1700 J/Kg*C	0.42 W/m/K	160 10^-6/C

Fig. 2. Part 1 of the entire Sole materials table

PVC (flexible)	✓, foam flexible	✓, can be heat resistant	✕, no transport of temperature	✕, it will not transport water	✓, it is water resistant	✓, long lasting but can be brittle	✓, has rigid and flexible form	✓, light-weight	✓, Whilst PVC is most frequently made from salt and oil, in some regions of the world PVC is made without using oil feedstock at all (substituting oil-derived hydrocarbon with bio-derived hydrocarbon feedstock)	✓, two densities, 1400 kg/m3	✓, can be low or high, 41 MPa	3.7 MPa*m1/2	1000 J/Kg*C	0.18 W/m/K	73 10^-6/C
Ethyl vinyl acetate (EVA)	✓, high elastic flexibility	✓, has low temperature performance	✕, no transport of temperature	✕, it will not transport water	✓, it will repel not completely resist	✓, long lasting		✓, light-weight	✓, ethylene vinyl acetate or EVA is a copolymer of ethylene and vinyl acetate with a structure	✓, 0.92 - 0.94 g/cm3, 950 kg/m3	✓, 7 - 40 MPa, 18 MPa	0.59 MPa*m1/2	2100 J/Kg*C	0. 35 W/m/K	170 10^-6/C
Leather (insole)	✓, high flexibility, not elastic though	✕, not heat resistance	✕, no transport of temperature	✓, it will transport moisture out		✓, mid lasting, but can be resoled	✓, not grainy, grainy and different sides of the leather	✓, mid-weight	✓, biological with an tanning process						
Cellulosic paper board (insole)	✕, not very flexibility, just soft	✕, not heat resistance	✕, no transport of temperature	✕, it will not transport water	✕, it takes up moisture and holds it	✓, mid lasting, takes up moist	✓, it is a structure itself	✓, light-weight	✓, Papers and paperboards comprise an overlapping network of cellulose fibers that self-bond to form a compact mat. They are printable and have physical properties which enable them to be made into various types of flexible, semirigid and rigid packaging. There are several different types of paper and paperboard.	942 Kg/m3	34 MPa	2.4 MPa*m1/2	1300 J/Kg*C	0.24 W/m/K	10 10^-6/C
Synthetic non woven insole board (insole)	✓, high flexibility		✕, no transport of temperature	✕, it will not transport water	✓, it is almost unaffected by moisture	✓, long lasting									

Fig. 3. Part 2 of the entire Sole materials table

Passive cooling	Heat sink (passive)	Passive cooling (natural ventilation)	Convection cooling
How does it work (short)	Heat flow is guided away from the device (mostly for electronics)	Making sure fresh, cool air can is supplied	Heat is transferred through the fluid from one side of the device to the other
Size of the system	Depends	Depends	Depends
Weight	Depends	Depends	Depends
How cool is it?	Can work very effectively, when there is continuous air flow	Can be very cooling when there is a lot is natural flow or wind	Can be very cooling especially when the difference between outer and inner temperature is significant
Is it safe?	Yes	Yes	Yes
Can it be controlled?	No	Yes, by opening/ closing the holes	No
Material that it is made of	Aluminium, sometimes copper	Differs	Can be fluid or air
Integratable in shoes -Flexible and foldable -Integratable in different shoe sizes?	Yes, especially to cool the electronics	Yes, mesh material can provide more natural ventilation	Yes
Additional sources	[5][12]	[13]	No, additional sources

Table 5. Part 1 of the passive cooling techniques

Passive cooling	PMC (Phase changed material)	Evaporative cooling garments	PCT's
How does it work (short)	The phase changing of the material makes the absorption of heat possible	The concept of evaporative cooling garment is to reduce the heat gained from the environment by evaporating the excess amount of water reserved in the cooling fabric	Bilayer structure fabric with high thermal comfort by increasing the dissipation of human thermal radiation and reducing solar energy absorption simultaneously
Size of the system	In buildings and in shoes	Depends	It is a fabric so can be customized (assumed).
Weight	Depends	Light and flexible	Lightweight
How cool is it?	Can be very cooling, since it absorbs the heat	It employs the large latent heat of water evaporation, which is around 2430 kJ/kg at 30°C more than seven times of the heat of ice fusion	Fabric showed a high heat dissipation power, which was 14.13, 17.93, and 17.93 W/m2. Does not affect the infrared wave radiation but affects visible light
Is it safe?	In buildings, yes	Drawbacks of using super absorbent, polymer particles can be listed as clamminess, uneven cooling, powdery deposits on skin or clothing, lumps and bulges and a little longer time of immersion	Yes
Can it be controlled?	No	No	No
Material that it is made of	Differs, sometimes saline	The three layer quilted structure consists of an absorbent core which is basically a nonwoven fibrous felt or batting, comprising a typical blend of three types of fibres, viz. cellulose, a cross-linked polyacrylate copolymer (super-absorbent fibre) and polyolefin bonding fiber. The preferred composition of these three types of fibre in the nonwoven structure is 40% polyacrylate, 30% cellulose and 30% polyolefin. The nonwoven structure has a typical basis weight of 120 g/m^2.	The fabric consisted of two layers, including a polyethylene film with nanopores (100–1000 nm in pore size) and a film made of nylon 6 nanofibers (ca. 100 nm in diameter) with beads (ca. 230 nm in diameter).
Integratable in shoes -Flexible and foldable -Integratable in different shoe sizes?	Maybe, is flexible	Yes, foldable and flexible but inconvenient since it needs to be dipped in water before use but not suitable for humid conditions as the effectiveness of evaporative cooling is inversely proportional to ambient relative humidity and cooling takes place on the outer surface of the garment, not inner surface which is nearer to skin.	Yes
Additional sources	[40][37]	No, additional sources	No, additional sources

Table 6. Part 2 of the passive cooling techniques

C - Validation

C1 - Answers from the questionnaire.
This is the questionnaire that was send to people with Epidermolysis bullosa. It was both in English and in Dutch. This is the link for the English version: https://forms.gle/DmLgAVZ4acdMB8fT9 and this is the link for the Dutch version: https://forms.gle/agR2z27MZ7yHEZK48. Above every answer the question is stated. The questionnaire has four sections:

(1) *A small introduction*

(2) *Prevention*

(3) *Demands and needs*

(4) *Thank you!*

As the user group was already very specific no demographics were asked.

A small introduction:
We are 4 students from the Technical Universiteit Eindhoven (TU/e). We are currently doing our bachelors in Industrial Design, which is about the design of products, systems and services. Currently in our second year of bachelors and working on Project 3 which is about "Cool Feet". Project Cool Feet is an ongoing project worked on by multiple student teams from different studies. Some electrical engineering students have already looked at cooling mechanisms, while other Industrial design students designed concepts. The project was initially brought to the TU/e by an EBS patient. For this project we work together with the Center for Blister Diseases of the University Medical Center Groningen (UMCG).

In this project, we will research how we can use materials and active cooling to help cool the feet of Epidermolysis bullosa (simplex) patients. At the end of this project, we will write a research paper advising the readers about materials, cooling as well as the design and concept of the shoe.

With this questionnaire we want to find out what helps with preventing the blisters and thus less pain. Next to that, we want to know what your personal demands and needs are for the shoe, as some might prefer it to be an inlay sole instead. Please give us your honest opinion.

Filling out this questionnaire will take 10-15 minutes to complete. Thank you in advance for your time!

This research is conducted for the course Project 3 Health, provided by the Technical Universiteit Eindhoven. I, the participant, have been given information and I understand what this research is about. I had enough time to decide whether to participate. I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this. I will send an email to a.m.c.leeman@student.tue.nl if I want to withdraw from the study.

	Air cooled garments	Liquid cooled garments	TFC (temperature control footwear)
How does it work (short)	Compressed air is supplied from an external air supply system and heat removal takes place both by convection as well as evaporation of sweat.	Cooling liquid is circulated inside the tubes embedded in the garment by means of a battery operated pump. As the liquid becomes warmer by the body heat, it is carried away to a heat sink or cooler for recooling purposes.	The TCF of the present disclosure preferably has an open air system into the sole which comprises insole , midsole and outsole to allow for good airflow and convection to occur at the heat sink. Thermoelectric cooler will preferably be attached to a heat sink using thermal-conductive adhesive that is commonly used with CPUs and heat sinks in high end computers.
Size of the system	Conventionally used in space suits but to accommodate in the shoes certain factors needed in space suits would not be necessary (For e.g., thickness of the suit to protect them from harsh conditions in space).	As big as a garment since the tubes are embedded all over.	The parts are placed in the insole, midsole and outsole respectively. Hence, the size would depend on the size of the heat sink, thermoelectric cooler, the plug along with the extra materials these components come with to passively cool. Additionally, insole material should be machinable and easy to implant in order for practitioners or manufacturers to be able to custom place the devices for each wearer.
Energy source -Battery kind -Battery life	In the space suits, cooling was marginal for work rates 348.9 W. Needs continuous power supply. Battery kind isn't measured.	Battery operated pump. Rechargeable battery. The water reservoir size and the build up of inlet water temperature restricts the usage time of liquid cooling garments. A reservoir of one half litre is sufficient enough to provide a considerable amount of body cooling.	The power source comprises rechargeable batteries that may be recharged when in use and/or when not in use.
Weight	Heavy and bulky	Lesser weight and bulk	Could be heavy but depends
How cooling is it?	Cooling efficiency is inferior due to low heat capacity of air.	Higher heat capacity of water in comparison to air so cooling efficiency improves. The cooling efficiency of liquid cooling garments depends on environmental conditions, tubing type and length, liquid inlet temperature, flow pattern(single loop or multi-loop) and flow rate.	Consists of an active cooling system with thermo electric inserts and cooling elements selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermo electric cooling element. Hence the temperature is well regulated. The results of the study performed showed that active cooling of the feet is efficient.
Is it safe?	Yes, it is a positive pressure system, a small leak or tear in the garment is less likely to contribute to contamination of the wearer.	There are inherent safety problems like water spillage leading to short circuits, steam burns and discomfort related to wet clothing.	A closed loop passive control system will be used to control the amount of heat being removed from the plantar surface of the foot by TCF. This will act as a safety and energy conservation mechanism. Plug preferably comprises an upper surface comprising a low friction interface material manufactured with polytetrafluoroethylene (PTFE) film, such as ShearBan®, to protect the wearer's skin from damaging friction & shear trauma. No info given about short circuits due to spillage.
Can it be controlled?	No	Yes	Yes
Material that it is made of	The outside layer of the garment is made of polyester to create a barrier between the surrounding air and the microclimate within the garment. The middle layer is composed of a moisture-wicking fabric, the main purpose of which is to increase the wearer's comfort by absorbing excess, non-evaporated sweat. (Sayed et al., 2019)[4]	For better wearer comfort a three layer structure where the tubings are sandwiched between the inner and outer fabric layer is preferred. The inner layer needs to carry away the sweat in liquid or vapour form. For better performance, the inner layer must have good thermal conductivity, good moisture management and good tactile properties.	Material for insole and plug are an integral portion of this design because they are in direct contact with the wearer. Plug material preferably is thermoconductive while having a low durometer in order to accommodate the increased pressure under the high pressure areas. Additionally, insole material should be machinable and easy to implant in order for practitioners or manufacturers to be able to custom place the devices for each wearer. The whole insole is preferably made of thermal insulation materials, and thermo conductive gel pads are preferably placed at the high-pressure areas.
Is the design patented?	N.A.	N.A.	Plug preferably comprises an upper surface comprising a low friction interface material manufactured with polytetrafluoroethylene (PTFE) film, such as ShearBan®.

	Air cooled garments	Liquid cooled garments	TFC (temperature control footwear)
Integratable in shoes -Flexible and foldable -Integratable in different shoe sizes?	Yes, it can be used with a smaller set of tubes and miniature jets to produce ambient or pre-cooled air. It will probably not be flexible/foldable enough.	Yes it can be. If it is used in garments then it can be foldable and flexible.	Yes it can be integrated in shoes.The parts are custom placed for each wearer. The insole that is in direct contact with the foot needs to be machinable and easy to implant. No info given about flexibility and foldability.

Table 7. The active cooling techniques

	Flexibility	Temperature	Transport	Moisture
Leather	√	×	√	×
Linen	×	√	√	√
Polyester	√	√	√	√
Rubber	√	√	×	×
Cotton	√	√	√	√
Synthetic leather (sub-form)	×	×	×	×
Gore-tex	√	√	√	√
Primaloft	√	√	√	√
Nylon	√	×	×	√
TENCEL (Lyocell)	√	√	√	√
	Water resistance	**Durability**	**Structures**	**Weight**
Leather	√	√	√	Mid-weight
Linen	×	√	√	Mid/lightweight
Polyester	√	√	√	Lightweight
Rubber	√	√	√	Lightweight
Cotton	×	√	√	Lightweight
Synthetic leather (sub-form)	√	√	√	Heavyweight
Gore-tex	√	√	√	Lightweight
Primaloft	√	√	√	Lightweight
Nylon	×	√	√	Lightweight
TENCEL (Lyocell)	√	√	√	Lightweight
	Chemical consistency	**Density**	**Tensile strength**	**Fracture toughness**
Leather	√	886 kg/m3	8 - 25 N / mm²	-
Linen	√	1,420 - 1,520 kg/m3	750 - 940 MPa	-
Polyester	√	1,290 - 1,400 kg/m3	48.3 - 72.4 MPa	4.5 - 5.5 MPa·m1/2
Rubber	√	920 - 930 kg/m3	22 - 32 MPa	0.15 - 0.25 MPa·m1/2
Cotton	×	1,520 - 1,560 kg/m3	350 - 800 MPa	-
Synthetic leather (sub-form)	√			
Gore-tex	√			
Primaloft	√			
Nylon	√			
TENCEL (Lyocell)	√			
	Specific heat	**T-conductivity**	**T-expansion**	**Sources**
Leather	0.36 cal/g/deg C	0.14 W/m·K	-	[16] [20]
Linen	1,220 - 1,420 J/kg·°C	0.25 - 0.3 W/m·°C	15 - 30 µstrain/°C	[34] [15]
Polyester	1,420 - 1,470 J/kg·K	0.138 - 0.151 W/m·K	115 - 119 µstrain/°C	[35] [18]
Rubber	1,800 - 2,500 J/kg·K	0.1 - 0.14 W/m·K	150 - 450 µstrain/°C	[19] [27]
Cotton	1,200 - 1,230 J/kg·°C	0.57 - 0.61 W/m·°C	15 - 30 µstrain/°C	[38] [32]
Synthetic leather (sub-form)				[33]
Gore-tex				[29]
Primaloft				[2]
Nylon				[31]
TENCEL (Lyocell)				[30]

,

Table 8. Material analysis for the shoe

I know that some people can access my data. These people are R. Latify, J.D. Braakhuis, A. Ravishankar and A.M.C. Leeman from the student team and their project coaches. I consent to gathering and usage of my data for scientific publication and additional research on my data. I understand my data is completely anonymous. I consent to my data being stored at the research location for another 6 months after this study.

☐ I consent

Prevention

In this section, we will ask about the things you do to prevent blisters, as that is our main focus. Knowing about the prevention will help us choose better materials for the shoe or sole that will be designed later.

When do the blisters come up?

☐ Warm weather
☐ Humid weather
☐ Shoes that are too big
☐ Shoes that are too small

	Flexibility	Temperature	Transport	Moisture
Plastazote	√, they adapt to the feets from, but stop after 2 months	√	√	√
PrimaLoft	√	√	√	√
TENCEL	√	√	√	√
	Water resistance	**Durability**	**Structures**	**Weight**
GoreTex®	√	√	√	Light
PrimaLoft	√	√	√	Light
TENCEL	√	√	√	Light
	Chemical consistency	**Density**	**Tensile strength**	**Fracture toughness**
GoreTex®	√	not found	not found	not found
PrimaLoft	√	not found	not found	not found
TENCEL	√	not found	not found	not found
	Specific heat	**T-conductivity**	**T-expansion**	
GoreTex®	not found	not found	not found	not found
PrimaLoft	not found	not found	not found	not found
TENCEL	not found	not found	not found	not found

Table 9. The summary of the best materials for the upper part of the shoe

□ Other…
Why?

What works best to prevent the blisters (in your case)?

How many hours in a day does it take to care for the blisters and prevent blisters (average)?

Do you resort to using a wheelchair (or an other medical device)?
□ Yes
□ No
□ Other medical device

How often do you use a wheelchair (or an other medical device)?

What kind of shoes do you normally wear? (sneaker, heels, etc.)

What brand of shoes do you normally wear?
Why?

Does one brand work better than the rest? And which one is that?
Why?

Demands and needs

In this section, we will ask about what the ideal shoe/sole/sock would be for you. This way we can give the teams after us advise about what kind of shoe/sole/sock they should design and what materials they could best use. This is the final questions section, after this is the demographics, which has three short questions about yourself.

Would you prefer an entirely customized shoe, an inlay sole that fits your existing shoes, a customizable shoe kit or something else?
- Shoe
- Inlay sole
- Sneaker kit (for example: https://www.sneakerkit.eu/)
- Other…

Should the shoe be flexible?
See Fig. 2.

- 1 not at all flexible
- 5 super flexible

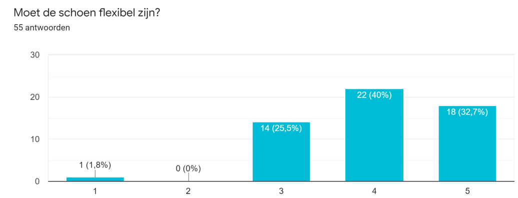

Fig. 4. Answers on how flexible the shoe should be

How least as possible should the moisture inside the shoe be?
See Fig. 3.

- 1 No
- 5 Yes

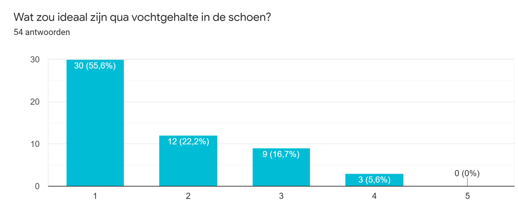

Fig. 5. Answers on the moisture content in the shoe

How tight fitting should the shoe be?
- 1 loose fitting
- 5 tight fitting

How much should the shoe weigh?
- Heavy mountain shoe
- Boots
- Sneakers
- Sport sneakers
- Sandals
- Flip flops

What temperature in the shoe would work for you? (Please select all that would work for you)
See fig. 4.

- 0-5 degrees
- 5-10 degrees
- 10-15 degrees
- 15-20 degrees
- 20+

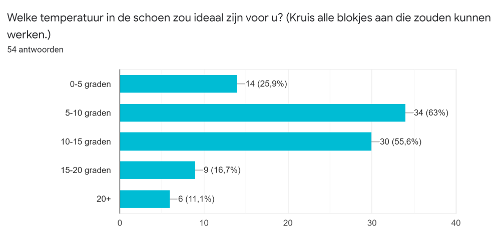

Fig. 6. Answers on the temperature range inside the shoe

Would you prefer to be able to adjust the temperature?
- Yes
- No

What materials are nice to wear (clothing included)?

Demographics

What is your gender?
- Female
- Male
- Other
- I prefer not to say

In what age range do you fall?
- 18-30
= 31-40
- 41-50
- 51-60
- 60+

How many years ago where you diagnosed?

Thank you!

We would like to thank you for filling in the questionnaire. If you have anything to add or have any feedback please write it down below. Otherwise you can hit the send button :)

C2 - Interview Orthopedic Shoemaker. This interview is done with an orthopedic shoemaker from OIM Haren, it was done in dutch (the transcript is translated to English). The interview was more of a discussion and general talk. Therefore the transcript of the interview is mostly the expert talking. The R are the researcher asking questions and the E is the expert (mister Lok) speaking.

R: Introducing our project
R: Do you have experience making shoes for epidermolysis bullosa (simplex)? Can you tell us a bit more about this?
E: Yes I do, but it will always be difficult because it varies per participant what you can do for them.

R: Tell what we have done so far and where we are now: final step of the analysis, in which we combine 4 active cooling options with materials that best meet the stated properties after research and interviews.

R: Show the 4 active cooling options and the corresponding materials: Heat sink: shoe → TENCEL / Gore-tex, sole → thermoplastic rubber, CoolMax fibre, mesh Convection cooling: shoe → Primaloft, sole → polyurethane Liquid cooling garments: shoe → Primaloft, sole → leather Temperature adjustment cooling in shoes: shoe → gore-tex, sole → silicon polyurethane Idea: shoe → gore-tex, TENCEL, sole → 3D printed, natural rubber or vulcanized rubber

E: The thing you see is that certain convection is happening through membranes. But the material is very often difficult to put in a shoe. That warmth and transpiration is not good and means that there is going to also be a lot of wound liquid and when this is absorbed by the material it gets dirty and hard and bacteria start to form. For example for an older woman we made a leather shoe with perforations in it so that it would be more breathable and a sole of silicon. However the pressure distribution materials are not really easy to clean. Even when the feet are in bandages they will still leak fluid and this fluid will get absorbed in the material.

Leather also gets hard after a certain time and when this happens it starts to sand the feet. However most top layers of the shoe are made of leather and with leather the feet get hot and are therefore not ideal for cooling.

With this disease you want to have material that distributes pressure and often over the whole foot. The structure usually is a top layer of the pressure distribution material, plastazote, but the structure is a bit open and the material needs to be changed almost monthly. But this is often used for people with diabetes. Thermoplastic rubber is often used in different manners. Polyurethaan also has a lot of different kinds and can be made by people themselves. But none of these materials have the characteristic of cooling itself. So you would want to have something like a convection shoe. That is what you are looking for, a certain airflow that is also breathable, but we do not have a solution for that. We also make high shoes with a leather inner layer and a tube and hard material that are in general not breathable.

We do not use materials like gore-tex or tencel for the shoes, the only thing we use is leather. The materials that you want to use have a different manner of how they need to be processed and used and we do not do that here. We did make a synthetic shoe for someone that needed a bicker shoe, which needed to combat liquid, because his other shoes would still get hard. This makes sure that the shoe does not get hard, however it is now not breathable anymore. Leather therefore always forms the basis for the shoes. The fact that these shoes get hard pretty fast makes that they will usually carry two pairs of shoes.

I do not have a lot of experience with making shoes for EB patients, but I do know from a woman that her feet are fully grown and she has successfully used orthopedic shoes. Also younger patients used orthopedic shoes, but that did not give good results. Sometimes the foot shape is adjusted so that it is difficult, vulnerable.

For an older woman the full shoe had a top layer of silicon, but more materials like EVA, cork and a top layer made of 5 mm silicone, printable and washable.When it comes to the outer layer of the shoe, we use leather and reinforcement materials in the heel and toe area in between the inside and outside.

About the weather conditions, they always wear them so rain and stuff is not really a thing.

You have to see that in convection shoes, the combination of shoe layers is well thought out, but that is often not possible in orthopedic shoe technology because of the way it is made and it is made per person per foot, there are differences in it. It seems desirable that they are breathable, but that is not possible for everyone due to the deviating feet. They do use a lot of different things but not with breathable shoes.

There are special socks for diabetic patients with thermoplastic materials.