MEDICOVI-REHA INSOLES

Study of the effect of the water-filled membrane sole MEDICOVI-REHA's continuous intensive sensorimotor activation and special mechanical movements of the soles of the feet in diabetics burdened with DPN (Diabetic Peripheral Neuropathy) and PDN (Painful Diabetic Neuropathy).

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Painful diabetic neuropathy (PDN) in feet and legs associated with (DPN) can be reduced or completely alleviated by the intensive sensorimotor activation and special mechanical movement of the soles of the feet, which is achieved through new technology in the water-filled membrane-sole MEDICOVI-REHA. The new technology will also be capable of mechanically helping a large group of these patients with the balance and seems to supply the soles of the feet with more energy (glucose etc.), which appears to counteract the development of neuropathy.

Abstract

A study shows that the new technology in the water-filled membrane-sole MEDICOVI-REHA, through a continuous intensive sensorimotor activation and special *mechanical* movements of the soles of the feet, can help diabetics burdened with DPN (Diabetic Peripheral Neuropathy) by improving the balance, and by being an alternative or a complementary effort to the medical treatment against PDN (Painful Diabetic Neuropathy). At the same time, it seems to supply the soles of the feet with more energy (glucose, etc.) which appears to counteract the development of neuropathy.

The study included 20 diabetics with DPN, of which 16 additional were burdened by PDN divided into 4 type I DM and 16 type II DM (mean age 55.8 years (range 49-76 years)) and with a mean diabetes duration of 14.7 years (1-40 years), with a mean neuropathy duration of 5.5 years (1-20 years).

The study shows:

That the membrane-soles largely **immediately** (**milliseconds**) improved the balance of the participants.

That most participants who were burdened with PND **quickly** (**days**) achieved a reduction and in some cases complete absence of problems with both cold feet and restlessness and pain in feet and legs at night.

That the membrane-soles during **long-term use** (**months**) seemed to build up more energy (glucose etc.) in the soles of the feet, as a markedly reduced growth of hard skin, increased flexibility and movement in the feet and toes, and increased sensitivity in the soles of the feet has been registered. The presumed supply of more energy (glucose, etc.) over time to the soles of the feet of diabetics seemed to have a reducing effect on the development of neuropathy and must thus be assumed to have a strong preventive effect against damage to the soles of the feet.

Problem

Diabetic polyneuropathy DPN (Diabetic Peripheral Neuropathy) has a lifetime prevalence of approx. 50% and is the most common diabetic late complication [1-5]. Due to the sensory loss, DPN is the leading cause of gait disturbance, which partly reduces mobility and partly increases the risk of falls, which especially causes problems for elderly diabetics. It is also estimated that neuropathy is to blame for up to 90% of all foot ulcers [23].

20 to 30% of patients with DPN suffer from neuropathic pain PDN [5-8] (Painful Diabetic Neuropathy). PDN causes pain and restlessness respectively, and cold feet at night, which often reduces nighttime sleep. Lack of night sleep has a number of negative effects on work, mood, self-esteem and social activities and will thus greatly reduce the individual's quality of life [6-9].

Current treatment

There are currently no obvious disease-modifying treatments available for diabetic neuropathy other than glycemic control and symptomatic treatment of PDN-related pain. There is no help against the loss of balance.

The pain treatment for PDN is unsatisfactory, as less than two thirds of the patients achieve sufficient pain relief [10], partly due to side effects (fatigue, lethargy, dizziness, etc.), which are often an obstacle to achieving the desired pain-relieving effect. [6,11]

Purpose

The purpose of this study is to examine to what extent the new technology in the water-filled membrane-sole MEDICOVI-REHA can help patients with DM in relation to discomfort caused by DPN (Diabetic Peripheral Neuropathy) and PDN (Painful Diabetic Neuropathy)

1. Introduction

1.1 The new technology opens up for dynamic orthopedics

The water-filled patented membrane-sole MEDICOVI-REHA is constructed by a water-filled undersole H20*, on top of which a pressure-distributing EVA upper sole is attached. The undersole is characterized by a special rigid and strong construction of the sides that enclose the water. This construction means that when the water is under pressure between the sides, a membrane is formed.

The new technology in the water-filled membrane-soles evokes 3 new dynamic orthopedic functions.

1 *Distribution of the body weight over a larger area of the sole of the foot.*

Due to the great strength and rigidity of the membrane, a large hydraulic pressure in the water in the membrane will momentarily build up under the load of the foot. The large hydraulic pressure presses a water film under most of the support surfaces of the sole of the foot, which due to the fluid dynamics immediately distributes the

load of the body over a larger area of the sole of the foot with a dynamic pressure relief of the soles of the feet as a result.

2 *Sensory impact on a large area of the sole of the foot*

At the slightest movement of the body, ultra-rapid pressure changes occur in the water. The pressure changes have a strong sensory effect on a large area of the sole of the foot, but are so rapid that they cannot be perceived by the consciousness.

This continuous sensory influence has a strong balance-improving effect. A property that is scientifically documented by Aalborg University. [12]

3 *Persistent mechanical massaging movement of the sole of the foot*

Loaded with the body weight, the sum of the ultra-rapid hydraulic pressure changes in the water forces the soles of the feet into a mechanically massaging motion of the feet. The mechanical movement is clearly noticeable during use.

1.2 Methods

Study design and subjects

Participants were recruited through the local diabetes associations.

Inclusion criteria: Diabetes mellitus DM, diagnosed DPN and recognized balance problem and / or PDN, with priority for diabetics with PDN. They have shoes where the soles can be removed so that there is room for the 4.5 mm membrane soles.

Exclusion criteria: Foot ulcers, and the use of adapted insoles and diseases other than DM, which could reduce the physical gait movement.

The study is composed of two groups. A small group of three diabetics who started using the membrane-soles in the spring of 2017, and a larger group of seventeen diabetics who started using the membrane soles in the spring of 2020.

The three participants who have used the membrane soles since 2017 have received new soles 3 times a year. The new participants were given 1 pair at the start, a pair after approx. 3 months and one after approx. 6 months

At the first and second handing out of the membrane-soles, the participant's balance was measured electronically standing on right and left foot resp.

1.3 Data collection

The data collection has taken place from April 2017 and is expected to be completed in 2020.

Before the first handing out of the membrane soles, the participants were informed about the functions of the membrane soles.

The participants' perception of their situation in relation to DPN and PDN, and the historical development relevant in this connection, was registered partly through interviews and partly through a basic form completed by the participants.

This information is at least 3 times during the study compared to the participants' current experiences with the use of the membrane soles.

The participants have occasionally stated how many hours a day they consider to have used the membrane soles.

1.4 Balances

1.4.1 The balance measurements

The measurement of the balance was made with Tekscan F-Scan Pressure Assessment System Version 5.2X. and the very thin measuring soles associated with the system, which can be placed in the participants' shoes.

Movement of center of pressure [13] was the basis for good and bad balance. The assessment is made visually on the basis of a print.

The balance was measured statically, where the participant stood at respectively right and left foot for 4 sec. at 70 Hz. The measurements were made with and without the membrane-soles in the shoes. The measurements were repeated three times in a row, wherein the two measurements that were visually most similar were used as the basis for the assessment of the balance.

The balance is measured at the time of the first two deliveries of the membrane- soles.

The first measurement was made immediately after the participants had the membrane soles in the shoes. I.e., the participants had by this time not walked/used with the membrane soles.

The balance problem for several of the participants was greater than we had initially expected in the organization of the study. A challenge that was solved by accepting that these participants, if necessary, supported with one finger on a table.

1.4.2. Results of the balance measurements

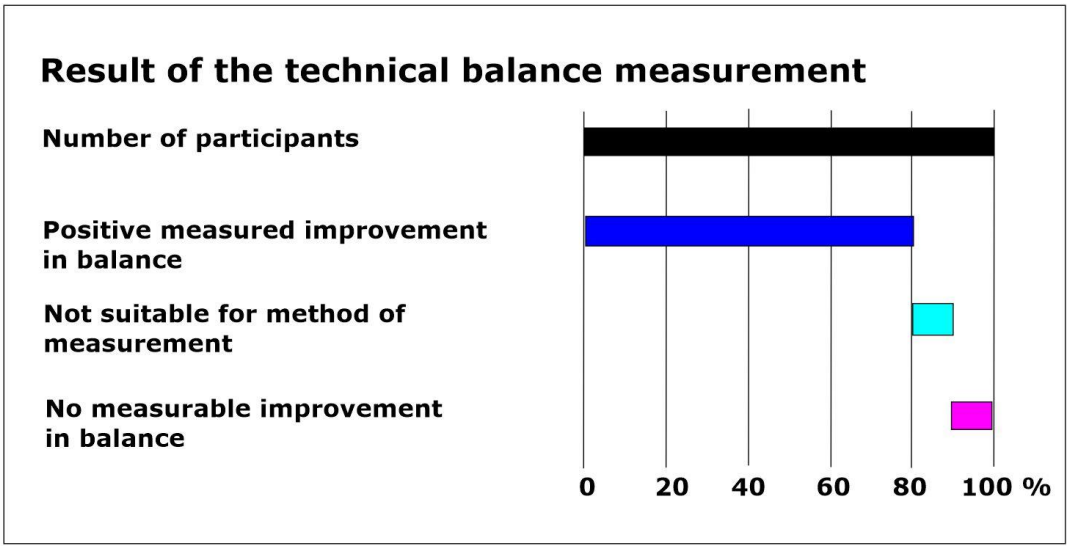
The results of the first balance measurements showed:

That 16 of the participants when measured experienced an improved balance using the membrane soles.

That no measurable improvement in the balance could be found in 2 of the participants.

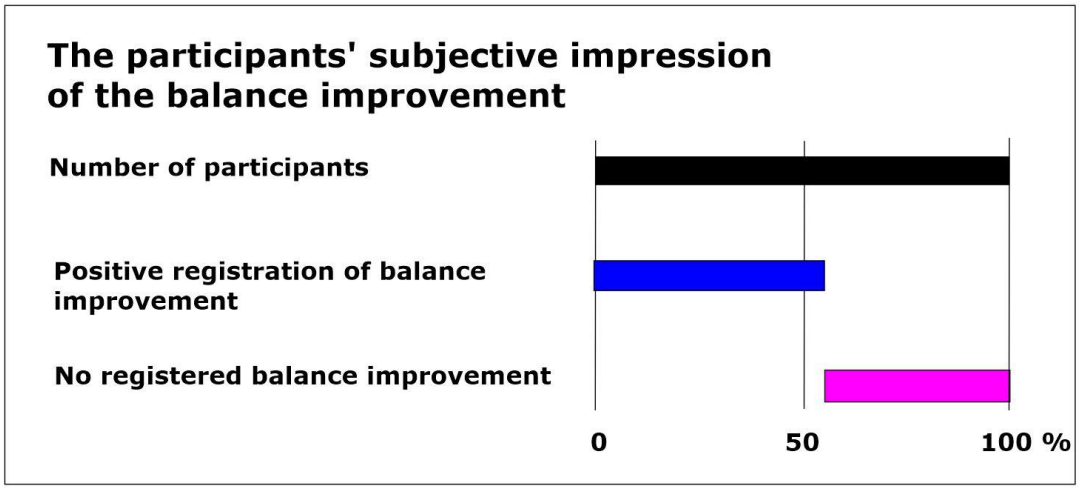
That 2 of the participants fell outside the suitability of the measurement method, as they both with and without the membrane soles could not stand without holding firmly onto a table.

The first balance measurement thus showed that 16 or 80% of the participants obtained an immediate, technically measurable, improved balance when using the membrane soles.



1.4.3 Participants’ perception of the improved balance

The technical measurements provide an objective expression of the balance, but it is not necessarily the same as the participants' subjective perception of the balance improvement.



11 of the 20 participants have reported to have registered an improved balance.

The degree of improved balance that participants perceive cannot be defined as it is highly subjective.

One of the 11 participants who registered an improved balance had initially such a poor balance that he could not stand on one leg during the technical measurements, so this participant is registered as not suitable for the measurement method in the table in 1.4.2.

Based on the 20 participants, the study thus shows that just over 50% of the participants have had a subjectively assessed improved balance.

1.4.3 Discussion of the balance-improving function

The membrane-improving property of the membrane-soles has previously been scientifically documented by Aalborg University for healthy students [12]. The study shows that the balance-improving function is a purely mechanical function based on the technical construction of the membrane soles.

I.e., the present study merely examines whether the balance-enhancing function can also help diabetics with DPN.

Based on the 20 participants, the study shows that just over 50% of the participants themselves are of the opinion that they have improved their balance. A balance improvement which has been strongly conducive to their quality of life.

It is to be expected that not all diabetics with balance problems will be able to benefit from the balance-improving function. There will be diabetics who are so burdened by DPN that the effect of the membrane soles is not sufficient to overcome the loss of the sensory responsiveness.

Conversations with the participants have shown that the balance problems cause bigger and bigger problems, which strongly impedes mobility and gives rise to nervousness in relation to falls.

One of many studies shows that the elderly with DPN often suffer falls. The study referenced here [13] shows that diabetics with DPN were 23 times more likely to fall and are 15 times more likely to report an injury, compared to matched non-neuropathic individuals.

There are increasingly more elderly people with diabetes, and therefore there will automatically also be more who, due to the development of DPN, will have a significant loss of balance.

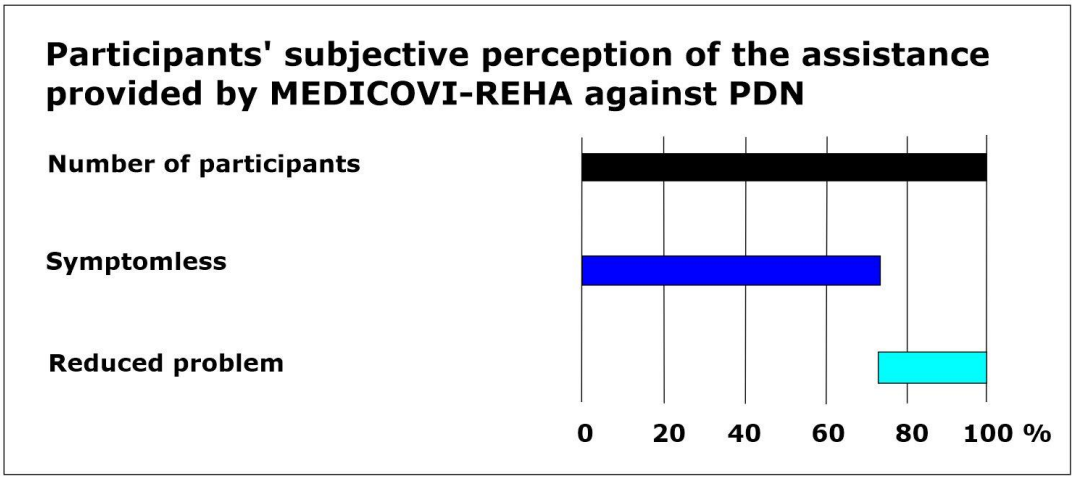
As there are currently no other options for helping diabetics with balance problems, the result of the study, which shows that just over 50% have registered an improved balance, must be perceived as strongly positive.

1.5 Painful diabetic neuropathy PDN

20 to 30% of patients with DPN suffer from neuropathic pain PDN (Painful Diabetic Neuropathy). PDN causes pain and restlessness respectively, and cold feet at night, which often reduces nighttime sleep. Lack of sleep has a number of negative effects on work, mood, self-esteem, and social activities and will thus greatly reduce the individual's quality of life [6-9].

1.5.1. Observations

15 of the participants in the study had problems with PDN distributed with 9 who had pain and restlessness in feet and legs, 4 who had cold feet and 2 who had both pain and restlessness, as well as cold feet at night.



The graph shows that just over 70% have become symptomless and almost 30% have had a reduced problem. Thus, of the 15 participants, everyone benefitted from the use of the membrane-soles in relation to PDN.

There is no distinction in the graph between pain and restlessness in the feet and legs, and cold feet. Both problems are included as the overall complication known as PDN (Painful diabetic neuropathy). It is important to note that the development shown has resulted from both the appropriate use of the membrane soles during the day and by appropriate replacement.

The effect of using the membrane soles has been shown to come relatively quickly, and for most within a few days.

No difference was recorded in the help the membrane-soles provide in relation to whether the participants were burdened with pain and restlessness in the feet and legs, or cold feet.

1.5.1.2 The connection between balance and PDN

PDN (Painful Diabetic Neuropathy) is a disorder that we, based on medical literature, have assumed would be directly proportional to the development of DPN in the soles of the feet.

Many studies have found that the loss of sensory perception in the soles of the feet is closely linked to the development of DPN and has a marked

detrimental effect on postural stability [14 - 15]. The studies thus show that for diabetics, there is a clear connection between the balance and the degree of neuropathy in the soles of the feet.

Based on the medical term PDN (Painful Diabetic Neuropathy), we expected that there would be a clear correlation between the balance measurements and the participant's perception of the affliction of PDN on the right and left foot, and leg, respectively.

With the exception of one participant, however, all the other participants stated that the problems with PDN came simultaneously or equally frequently in the right and left foot, and legs, regardless of whether we could technically measure a relatively large difference in the balance on the right and left foot.

Thus, 6 of the participants should have had significantly greater problems in the right or left sides, respectively, based on the balance measurements, if the affliction of DPN is considered to be the main cause of the problems.

Thus, this study has not been able to find a correlation between the development of DPN in the soles of the feet and the affliction of PDN.

1.5.1.3 Time the membrane-soles are used during the day

It is registered that the effect of the membrane soles depends on the time the soles are used during the day. For example, one has received significantly greater help after the participant started using the membrane soles in shoes both inside and outside the house.

The average daily use of the membrane soles for the participants has been 6.6 (interval 5-9) hours.

1.5.1.4. The wear of the membrane-soles

The many thousands of daily movements of the stiff and strong sides that enclose the water inside the soles cause wear on the sides. When the membrane soles wear in this way, the effect decreases.

The internal wear on the membrane-soles cannot be immediately seen on the membrane-soles. I.e., the membrane-soles look normal and you can feel the water in the soles. But the symptoms that the membrane soles had

relieved return, even though the participants have the normal daily hourly usage of the membrane-soles.

If the membrane soles are replaced, the problems are remedied immediately.

Since one cannot immediately see defects in the membrane soles during the mentioned wear, we assume that it is especially the sensorimotor effect that decreases during the wear.

Thus, there is a correlation between the load of the disease in relation to PDN in the feet and legs, and the daily effect that the membrane-soles must provide in order to achieve a satisfactory effect for users.

The effect of the membrane soles is mechanical and solely dependent on the service life and wear on the membrane soles and thus completely independent of the degree with which the diabetic is afflicted by PDN. Therefore, it will always be difficult to give an exact operating time for the membranes-soles, but by changing 3 times a year, most with our current experience will achieve a satisfactory effect.

1.5.2. Discussion about the help that the membrane soles provide against PDN

From the above, it appears that there is a connection between the affliction of the disease in relation to PDN in the feet and legs, and the daily effect that the membrane soles must provide, in order to achieve a satisfactory effect for the users.

This means that the special movement of the membrane soles and the strong sensory influence on the soles of the feet during the day must be building up an effect, or energy, in the soles of the feet, which reduces pain, restlessness and cold feet at night, or causes the complete absence of these problems during nighttime. There are really no other options, as the soles are of course not used at night.

At the same time, the analysis in 1.5.1.2 surprisingly shows that there is only a slight coincidence between the development of DPN in the soles of the feet and the affliction of PDN on the right and left foot measured from the balance.

Based on these indubitable findings, we have developed the following hypothesis for the function of membrane-soles in relation to PDN.

1.5.2.1 Hypothesis for the help of membrane soles against PDN

Genetically, we are developed to walk barefoot on two legs as hunter gatherers. The condition for this development has been that the soles of the feet have always been functional. Otherwise, survival would not be possible. Therefore, an ongoing energy supply to the soles of the feet to support the body has been crucial.

Exercising movements can activate insulin-independent mechanisms that increase glucose uptake into the cells, while building endurance in the cells [16]. Exercising movements increase the cells' insulin sensitivity so that the cells more easily absorb glucose [17].

We believe that the forced movement of the sole of the foot, that occurred when the sole of the human foot was pressed by the body weight to follow the uneven surface, activated the insulin-dependent mechanisms, and increased the cells’ insulin sensitivity. Through this, the soles of the feet of the natural human would continuously be supplied with the necessary energy for a long-term search for food, while great strength was built up in the soles of the feet.

This is supported by Vivi Lena Andersen's study [18] which shows that when the thin leather boot was replaced in the 16th century with the rim-sewn shoe that had such a thick sole that it could wear a heel, the problems with hard skin, corns, sunken forefoot, etc., arose.

The rigid shoe soles removed the original natural movement of the soles of the feet from the uneven surface. It reduced or stopped the insulin-independent mechanisms and reduced the insulin-sensitive effect of the energy uptake (glucose etc.). The ability of the soles of the feet to carry the weight of the body was thereby reduced, with the above-mentioned problems as a result. Today, this development is further burdened by the fact that we always walk on completely flat floors and roads.

When the insulin-dependent mechanisms, and the insulin-sensitive amplifying effect, are mechanically stopped by our use of shoes on flat surfaces, the energy supplied in the form of glucose becomes strongly dependent on the cells having a good reactivity with insulin.

Since our modern behavior has made the strength of the soles of the feet very dependent on a good reaction with insulin, the development of diabetes

in the short or long term will automatically cause the energy of the cells of the soles of the feet to decrease. Since the soles of the feet must carry the body weight, the decreasing energy of the soles of the feet will cause the body weight to press the soles of the feet increasingly more together. This compression of the soles of the feet reduces the lumen of the blood vessel, which limits or reduces blood circulation accordingly.

If the supply of energy is less than that which the soles of the feet need to carry the body weight, the soles of the feet in non-diabetics, e.g., those that have standing work, will also be squeezed together during the day.

Compression will squeeze certain blood vessels more, thereby making the lumen of the blood vessel smaller. This change in the lumen of the blood vessels will reduce the energy supply to the affected muscles and nerves. A development that first feels like discomfort, but which can later turn into pain.

For non-diabetics, the cells during rest by reaction with insulin will absorb glucose (energy) and thereby cancel the compression.

For the resting diabetic, the cells will, due to the cells' reduced reactivity with insulin, will find it harder and harder to achieving a completely cancel the compression.

In addition, the blood pressure in the foot during rest decreases, partly due to the decrease in the hydrodynamic pressure and partly due to the resting heart rate.

This means that if the lower blood pressure at night cannot adequately overcome the compression present, affected nerves will be undersupplied with energy. In our opinion, this may be a significant cause of PDN.

Neuropathic pain is due to lesion or dysfunction of the peripheral or central nervous system [19].

Damage to peripheral nerves results in hypersensitization that generates spontaneous impulses. When the nerve is able to repair itself, the sensitization is removed. In chronic disease such as diabetes with persistent nerve damage, a continued sensitization occurs with spontaneous symptoms [20].

Conversations with diabetics have shown that if pain occurs at night, these can be averted for some by continuing the sleep sitting in a chair. I.e., a position where the hydrodynamic pressure increases the blood pressure in the soles of the feet.

We believe that the hypersensitization of the nerves in the feet and legs at night, to a significant extent, occurs as a result of poor blood circulation in the soles of the feet, which leads to an undersupply of energy to the nerves. Conversely, we conclude that hypersensitization is reduced as the blood circulation increases, as the nerve is then able to repair itself to a certain extent or be able to function adequately again [20].

The new technology in the water-filled membrane-soles imposes the soles of the feet both with a strong massaging movement and an ultra-fast sensorimotor activation under the load of the body weight.

We are of the opinion that this special activation of the soles of the feet initiates the insulin-independent mechanisms [16] in the soles of the feet or makes the cells more sensitive to insulin [17], so that through the influence of the membrane-soles, the soles are added extra energy (glucose etc.). A process that is completely independent of the disease diabetes.

The extra energy and modulation that the membrane-soles add to the soles of the feet during the day counteract the compression.

This means that the compression will be less, when the diabetic has to sleep. The reduced blood pressure during rest thus has a greater opportunity to maintain a satisfactory energy supply to the nerves, reducing or completely avoiding hypersensitization.

This hypothesis is supported by the fact that the help from the membrane-soles lapses, both when the membrane soles wear or they are used for too few hours during the day. Thus, a quantity of energy, proportionally related to the affliction of the disease, must be supplied daily to the soles of the feet through the membrane-soles in order for the membrane-soles to provide the desired assistance.

1.5.3 Conclusion regarding the membrane-soles help against PDN

The study shows that painful diabetic neuropathy in the feet and legs (PDN), can be reduced or completely alleviated through a water-filled membrane-sole's intensive sensorimotor activation and special mechanical movement of the soles of the feet.

Considering that this help is without side effects, the membrane-soles should be an obvious alternative or chosen as a complementary effort to the medical treatment against PDN.

Although there are significant data on the molecular processes leading to cell damage in the nervous system due to hyperglycemia, the mechanisms specific for pain in diabetic neuropathy have not been identified [9].

The study shows that the reduced blood circulation in the soles of the feet, due to the daily compression of the soles of the feet, can be a significant cause of the activation of restlessness and pain in the feet and legs, and cold feet at night.

We assume that this is the first time that it has been technically possible mechanically, such as through the membrane soles' special activation of the soles, to supply the diabetic soles with extra energy. Therefore, it may also be the first time it has been possible to provide this very simple help to diabetics who are plagued with PDN. A help completely without side effects and which to a large extent will help diabetics both with balance and pain.

1.6 The long-term effect of using the membrane soles

1.6.1. Reduced growth of calluses (hard skin)

A very significant observation has been the strong decline in callus growth for those participants where the growth of hard skin has been a strain. Additionally, a reduction in crack formations in the heel has also been registered.

1.6.1.1 Discussion about reduced growth of hard skin

The formation of hard skin is usually considered a consequence of an external influence. For example, by the shoe's restriction of the foot causing the load from the body to rest on small areas of the foot’s surface or if there is a greater friction in small areas between the foot and the shoe.

The skin of the feet responds to this strain by producing extra thick skin at that site. This is to protect the underlying structures [21].

The cells of the soles of the feet thus have an ability to protect themselves by producing hard skin if the load exceeds a certain threshold value of the strength of the cell.

In 1.5.2.1, we explained that the energy of the soles of the feet for most diabetics will decrease in step with the development of the disease. As the energy of the cells decreases, the threshold value for the formation of hard skin decreases correspondingly. Therefore, the growth of hard skin will be initiated by less and less overloading from the body weight, and many diabetics will therefore experience a markedly increased growth of hard skin on the soles of their feet.

Hard skin occurs more often and builds up faster on diabetic feet [22].

1.6.1.2 Hypothesis for reduced growth of hard skin with the membrane-soles.

If the cells' uptake of energy (glucose etc.) is increased, it can be assumed that the threshold for initiating the production of the extra thick and keratinized skin is not exceeded to the same extent, thereby reducing the hard skin formation.

We are therefore of the opinion that the reduced growth of hard skin, which has been observed with prolonged use of the membrane-soles, occurs as a result of the large sensorimotor influence of the membrane soles and special movement of the sole of the feet, which are thought to increase the cells' uptake of energy (glucose, etc.).

The above-stated hypothesis can be understood in connection with the hypothesis in 1.5.2.1 regarding the help of the membrane soles against PDN. In accordance with our hypothesis, this is also based on the assumption that the sensorimotor influence of the membrane soles and special mechanical movement increase the uptake of extra energy (glucose etc.) in the cells.

1.6.2.1 Increased sensitivity

Several of the participants have noticed that they have gained greater sensitivity in the feet and soles of the feet.

After 6 months, a participant could begin to feel heat from the floor heating – a feeling that had been absent for many years.

The same participant registered in the same period an increasingly improved balance. A balance improvement that was proven by electronic balance measurements.

1.6.2.2. Discussion about neuropathy and increased sensitivity in the soles of the feet

It is generally believed that neuropathy in the soles of the feet is a consequence of endothelial dysfunction [23], where the disease adversely affects the endothelial cells in the walls of blood vessels.

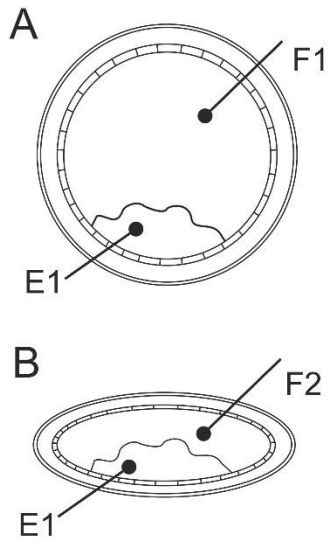
The blood flow affects the vessel wall with a frictional force [25], which over time develops a rough surface. It creates a process with both inflammation, formation of foam cells, and fat deposits, which over time creates narrowing of the vessels. This means that the energy supply to the nerve sheaths, that certain vessels supply, is reduced, or completely ceases.

The function of the nerve / conduction ability in the foot is thereby impaired or lost, with reduced sensation and sensation of pain as a result. This results in decreased balance and increased risk of foot ulcer formation.

In addition to the reduction in blood circulation in the blood vessel due to endothelial dysfunction, there is, as previously described, a compression of the blood vessel that occurs as a result of compression (1.5.1.3).

I.e., that the blood circulation in the blood vessels in the diabetic's soles can also be reduced by permanent blockages caused by endothelial dysfunction and by compression.

1.6.2.3. Discussion on endothelial dysfunction



The obstructions to the flow, which originate from endothelial dysfunction, are attached to the wall of the blood vessel and are a more or less solid structure. In a given cross-section of the blood vessel, the obstructions will constitute a certain limited area for the blood flow. An area that slowly increases over time. In the figure, this area is marked with E1.We have previously assumed that the compression causes the blood vessel to become increasingly more elliptical. This is shown schematically by the blood vessel going from figure A to figure B.

Since the obstacle area E1, caused by endothelial dysfunction, is thought to be reasonably consistent, the area will affect the blood flow in the blood vessel increasingly negatively

the more the body weight increases the compression of the soles of the feet, the lumen of the blood vessel shifting from F1 to F2.

Conversely, it is believed that the use of the membrane soles increases the uptake of energy (glucose, etc.) into the cells. With the extra energy, the cells can better counteract the compression with better blood circulation as a result.

Since the degradation of the endothelial cells in the blood vessels of the soles of the feet takes place over time, at a certain time there must be a wide range of flow obstacles in the various blood vessels, ranging from almost no obstruction to total blockage.

Therefore, the use of the membrane soles could increase blood flow in some of the blood vessels where blood flow was previously inhibited due to both endothelial dysfunction and compression. This development may partly explain the increased sensitivity in the soles of the feet, which has been registered in some of the participants in the study.

1.6.2.4. Discussion about the cause of the frequent occurrence of neuropathy in the soles of the feet in diabetics

As previously shown, diabetic polyneuropathy DPN (Diabetic Peripheral Neuropathy) has a lifetime prevalence of approx. 50% and is the most common diabetic late complication [1-5].

At the same time, it is estimated that neuropathy is responsible for up to 90% of all foot ulcers, as the normal pain response ceases with the development of neuropathy, whereby the diabetic does not respond soon enough to counteract the development of incipient foot ulcers [24].

But beyond this, the development of neuropathy in the soles of the feet, as shown here in the report, has many other negative elements.

However, there is no explanation in the medical literature as to why diabetics suffer the high frequency of developing neuropathy in the soles of the feet.

Based on the results of the study, we have therefore made the following hypothesis.

In 1.6.2.3 we have assumed that the compression will compress the diabetic's soles of the feet.

The compression of the blood vessel, at the same blood pressure, will with great certainty mean that the local flow rate can be significantly increased. High flow rate in the blood vessels with associated large frictional forces is believed to be the main cause of damage to the endothelial cells and thus to the development of endothelial dysfunction [24,25].

We are therefore convinced that it is the compression of the soles of the feet and the increased flow rate that the compression causes the increased frictional effect of the endothelial cells.

I.e., when insulin resistance reduces glucose in the cells of the soles of the feet, the energy in the cells will decrease. This will cause the weight of the body to press cells and blood vessels more together, which will reduce the blood flow in the blood vessels. At the same time, due to the relatively high blood pressure in the soles of the feet when we stand, it increases the speed of the blood flow. The increased velocity in the blood flow increases the frictional forces against the endothelial cells and may thus be the main reason for the frequent development of endothelial dysfunction in the blood vessels of the soles of the feet and therewith the development of neuropathy in the soles of the feet in diabetics.

We are therefore of the belief that the high frequency of the development of neuropathy in the soles of the feet in diabetics is due to endothelial dysfunction, which has the following causation.

1: The high blood pressure in the soles of the feet in a standing and walking position, due to the work pulse and the hydrodynamic pressure.

2: The compression of the soles of the feet.

3: The increased flow rate in the blood vessels, which is a consequence of the high blood pressure and the compression reduction of the lumen of the blood vessels.

1.6.2.5. Discussion about the possibility of preventing the development of neuropathy in the soles of the feet

The study has shown that the use of the membrane soles, to a given extent, can reduce the effect of pre-existing neuropathy.

Assuming that a significant reason for the development of neuropathy in the soles of the feet stems from the compression of the soles of the feet, as shown in 1.6.2.4., the development of neuropathy in the soles of the feet can be reduced by counteracting the compression – precisely what is achieved by using the membrane soles.

It is therefore recommended that the use of the membrane soles be started at as early a stage of the disease as possible, as this is the only option, in addition to the optimization of the regulation, to prevent neuropathy.

1.6.3 Increased movement and flexibility in the feet

Poor joint movement in the feet impedes gait movement and strains the soles of the feet less appropriately, which in particular increases the risk of injury to the ball of the foot [26]. Several of the participants have observed greater movement and agility in the feet using the membrane soles.

1.6.4 Conclusion about the long-term effect when using the membrane soles

Our modern behavior has removed the original natural movement of the soles of the feet on the uneven surface, which, based on our hypotheses, has stopped the natural uptake of fortifying glucose into the cells of the soles of the feet from the insulin-dependent mechanisms [16] and also reduced the insulin-sensitive effect [17]. Therefore, the energy of the soles of the feet has become strongly dependent on the cells having a good reaction with insulin.

The study shows that a major reason for the strong effect of the membrane-soles in relation to the diabetic foot and the problems derived from it lies in the provoked strong sensory influence and special mechanical movement of the soles of the feet. According to our hypotheses, this special activation of the soles of the feet will mean that extra energy (glucose, etc.) so that the soles of the feet have a better chance of resisting the load of body weight, which improves blood circulation in the soles of the feet.

The membrane soles thus seem to supply the soles of the feet with more energy (glucose, etc.), with which the soles of the feet can better withstand the load of the body. The greater load capacity of the soles of the feet seemed to increase blood circulation and counteract the harmful effect of

neuropathy, which, all other things being equal, must be a strong preventive measure for injuries to the soles of the feet.

1.7 Conclusion

The study shows:

That the membrane-soles will, to a large extent, be able to immediately improve the balance for diabetics who are burdened with DPN (Diabetic Peripheral Neuropathy).

That the membrane sole increases the blood circulation in the soles of the feet by reducing the compression.

That the membrane-soles can be an alternative or a complementary effort to the medical treatment against PDN (Painful Diabetic Neuropathy), especially since the membrane soles do not have unwanted side effects.

That the membrane soles during long-term use (months) seemed to build up energy (glucose etc.) in the soles of the feet, as a markedly reduced growth of hard skin has been registered, increases the flexibility and movement in the feet and toes, and increases the sensitivity in the soles of the feet.

That the build-up of more energy and thus greater load capacity in the soles of the feet of diabetics over time is believed to have a reducing effect on the development of existing neuropathy.

Likewise, it must be assumed that the membrane soles have both a strong preventive effect on the development of neuropathy and on the development of damage to the soles of the feet.

In light of the serious problems that the diabetic foot causes and the costs that the disease today bears on society, and the simple way in which the water-filled membrane sole MEDICOVI-REHA can help against:

- PDN (Painful Peripheral Neuropathy),
- Poor balance
- Poor blood circulation in the soles of the feet
- The development of neuropathy

An extra effort should be made both to have this new technology implemented in the healthcare sector and to verify the hypotheses put forward in the present study through larger studies.

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