

Study of the water-filled membrane-insole T40's effect on diabetics with Diabetic Peripheral Neuropathy (DPN) in the soles of the feet

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Summary

The participating diabetics, who all suffer from diabetic peripheral neuropathy (DPN) in the soles of the feet, experienced an immediate improvement of their balance when using the special water-filled membranes-insoles T40. The balance was further improved by prolonged use of the membranes. Additionally, the diabetics achieved more feeling and more movement in the soles of the feet.

The combination of the physical movement of the membranes, and strong sensory effects on the soles of the feet, seemed to counteract or reduce the harmful effects of the neuropathy over time.

Painful Diabetic Neuropathy (PDN), such as pain and unrest in the feet and legs at night, as well as cold feet, has ceased completely.

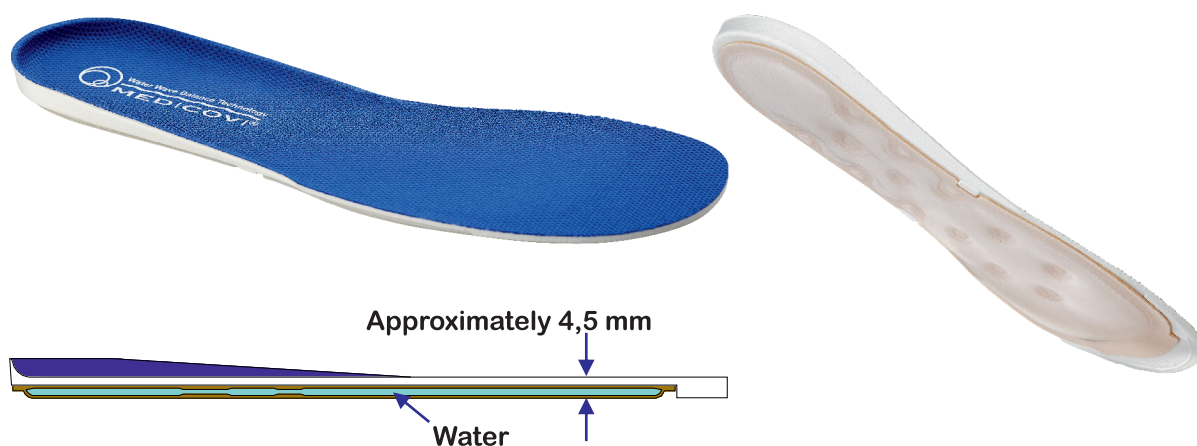
Moreover, the growth of hard skin was markedly reduced, which strongly indicates that the movement and the additional sensory influence forms greater strength in the soles of the diabetics.

Abstract

A scientific study from Aalborg University (1) documents that the special water-filled membrane H20* provides such a powerful sensory influence on the sole of the foot that healthy young students immediately achieve a better balance.

The patented water-filled membrane H20* is an integral part of the water-filled membrane-insole T40.

It is therefore desirable to investigate whether the balance improving effect, in both the short and long term, can also help diabetics with DPN in the soles of the feet.



The water-filled membrane-insole T40

Methods

There exist multiple methods of measuring and classifying the systems for determining the extent and severity of neuropathy in the diabetic sole.

It is also possible to electronically measure the balance and establish the relationship between the balance and the development of DPN in the soles of the feet. (2,3,4) We have chosen this method as it gives a better comparable result compared to the assessment of the T40's improving effect.

The balance measurements are made with the Tekscan F-Scan Pressure Assessment System Version 5.2X. 70 Hz are used for the balance measurements. The recorded measurements are printed for visual assessment, where the fluctuation of the center of pressure (5) is used as an indication for good and poor balance. I.e. the less fluctuation of the center of pressure and the more uniform the center of pressure progresses in movement, the better the balance.

The measurements are made on the right and left feet, respectively, for 3 seconds with and without the membranes T40. Similar measurements were made during walking for 4-6 seconds depending on the diabetic's walking speed. This measuring program is reasonably analogous to the study at Aalborg University (1).

Study participants:

In the local diabetes association, we found three diabetics. The only criterion was DPN in the soles of the feet and problems with the balance. The participants' data can be described as follows:

Participant 1

49-year-old woman diagnosed with diabetes I 23 years ago. She had been diagnosed with neuropathy for 12 years. She had balance problems and no heat/cold reaction. She suffered from unrest and pain in her legs, which reduced her sleep. She had painful Morton's Metatarsalgia in one forefoot.

Participant 2

47-year-old male diagnosed with diabetes I 27 years ago and with neuropathy 25 years ago. He had problems with the growth of hard skin and cracked skin in the heel and has had 5-6 foot ulcers. He had balance and walking problems (small drop foot) and no heat/cold reaction.

Participant 3

77-year-old male diagnosed with diabetes II 2 years ago. He had problems with the balance and almost no feeling in the feet and a lack of movement of the toes. He had major problems with the growth of hard skin. He had such cold feet that it caused problems with his sleep. He also had myositis in his legs. (The myositis periodically limited certain balance measurements.)

The Results

We have chosen to show the most interesting measurements, as well as included the most important experiences / observations that the participants have registered with the use of the membranes-sole T40.

Participant 1

On Fig. 1, 3 balance measurements of participant 1 standing on the right foot without T40 are shown. (I.e. with socks in ordinary shoes without insoles.)

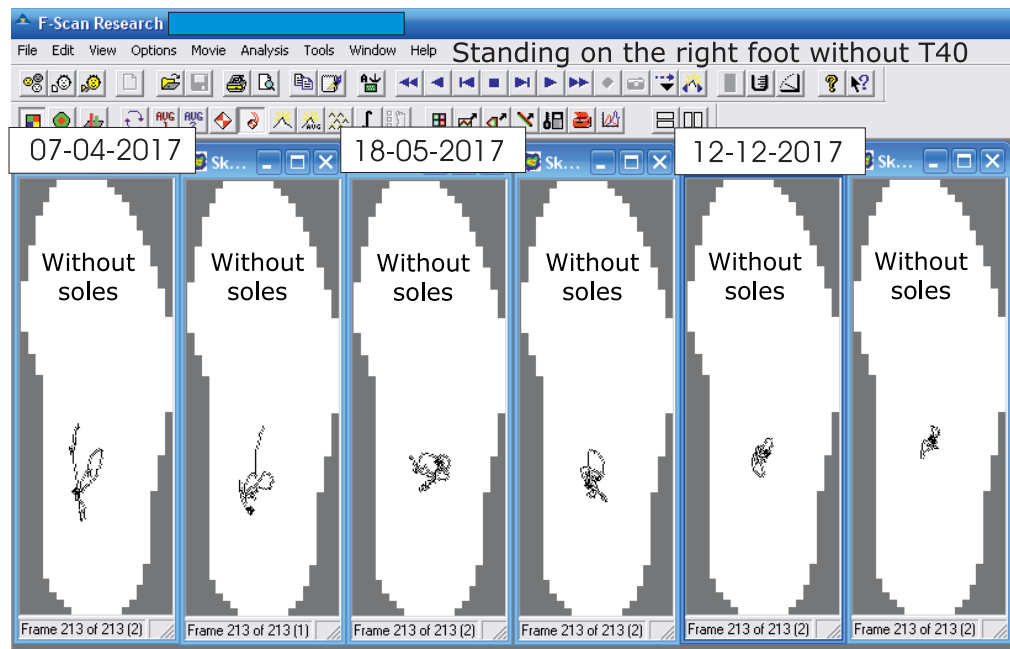


Fig. 1

It is clear, **and very positive**, that the balance has improved over time. The participant perceives that the balance without the T40 has improved. She also clearly states that the help that the T40 provides with the balance has become significantly better.

Ca. 7 months after participant 1 started using the T40, some of the heat/cold reaction returned, as the participant began to be able to feel the floor heating. A feeling she had missed in the last 10 years.

Participant 1 suffered greatly from PDN in the form of severe pain and unrest in the feet and legs. Problems that caused insomnia.

The pain and the unrest in the feet and legs quickly diminished, with the sleep improving as a result. After the 1 months, the pain and the unrest in the feet and legs were completely gone and there were similarly no issues with sleeping.

However, the pain and unrest returns if participant 1 does not change the insoles every 4 months. The many thousands of movements that the membranes in the T40 impose on the soles of the feet wear on the membranes. When the membranes wear, a slight evaporation of the water occurs through the sides of the membrane. This reduces the effect of the membranes, i.e. the sum of both the sensory influence and the membranes' physical movement of the soles of the feet.

There is thus a correlation between the effect of the membranes and the pain in the feet and legs that comes from PDN

Morton's Metatarsalgia

The pain caused by Morton's Metatarsalgia disappeared within the first 14 days using the T40. Under load, a large hydraulic pressure is developed in the water in the membranes, which, due to the large strength and relatively rigid construction of the membranes, develops a new form of dynamic pressure distribution. The combination of this new dynamic pressure distribution and the membrane's provoked movement of the soles of the feet is generally very pain reducing, making the reduction of pain expected.

Participant 2

The balance

Fig. 2 and 3 show balance measurements of participant 2 standing on the right and left feet, respectively, with and without T40.

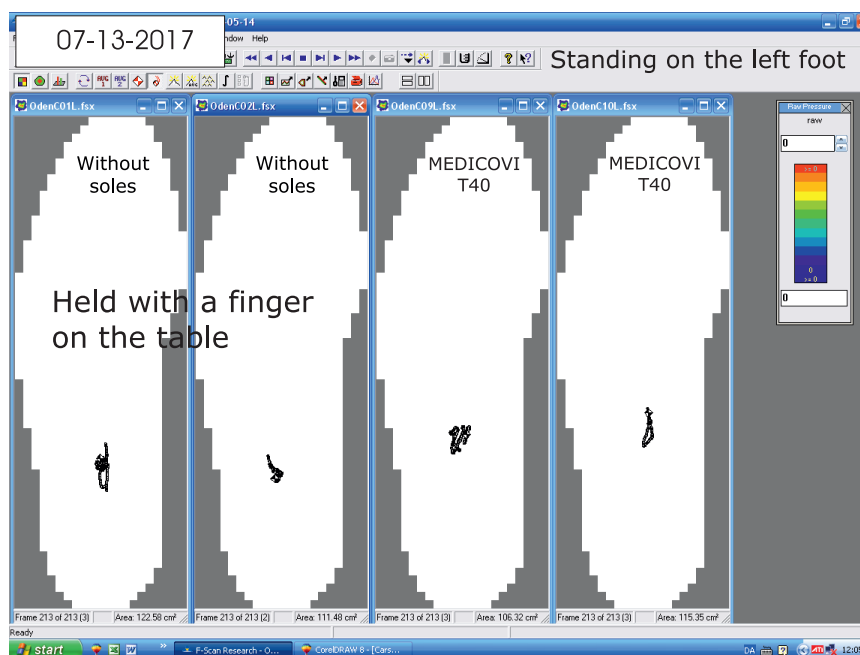


Fig. 2

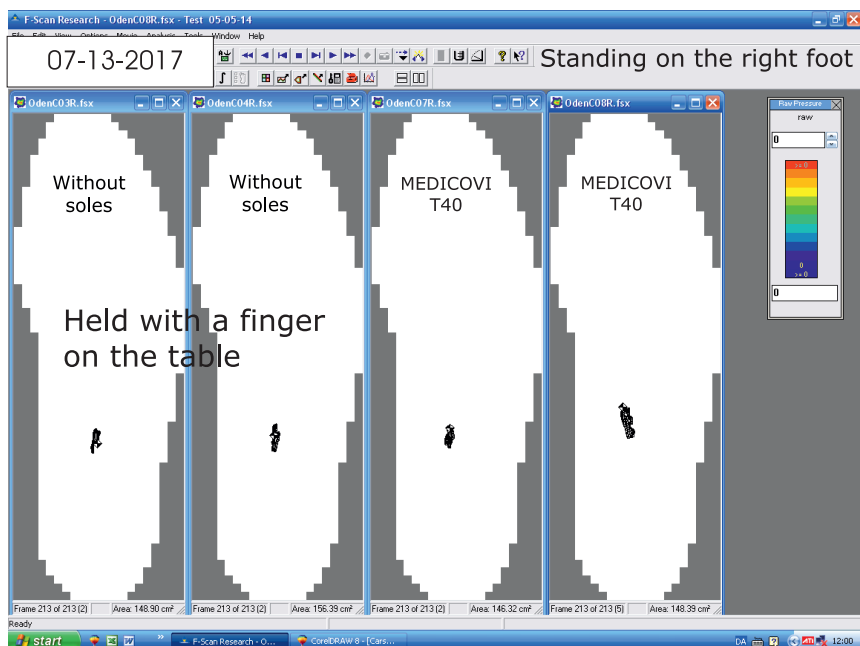


Fig. 3

Without T40, participant 2 could not stand without having to hold onto the table. With T40, participant 2 could immediately stand on one leg with both the right and left feet.

Fig. 4 shows the balance measurement of 3-4 steps with and without the T40.

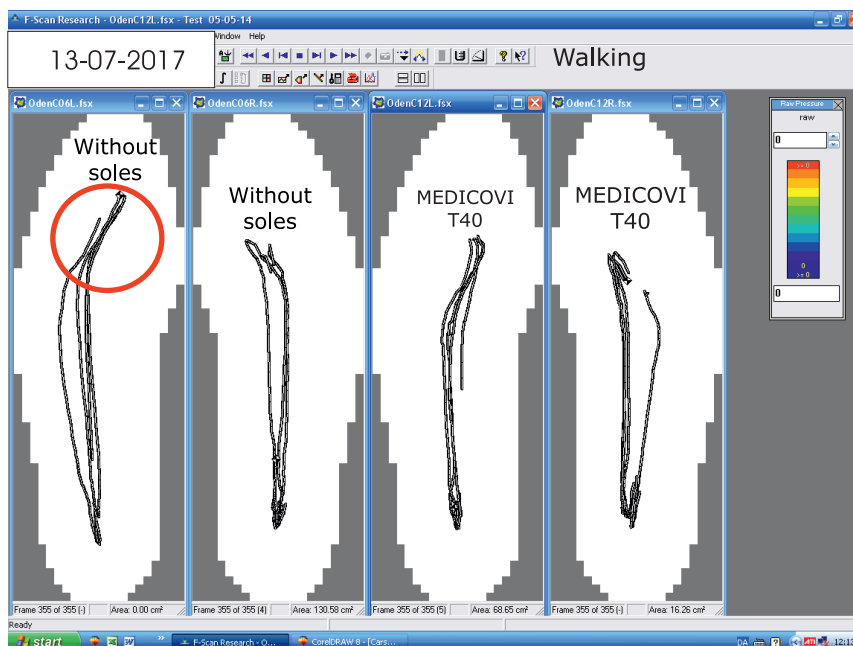


Fig. 4

Without the T40 there is a tendency to drop foot on the left foot. With the T40, this tendency is almost gone. This is not surprising, as the membranes' immediate balance-improving effect normally strongly reduces the tendency to drop foot.

Fig. 5 shows the balance measurements of participant 2 standing on the left foot without T40 recorded on 13-07-2017 and 19-12-2017 respectively. At the first measurement, participant 2 only maintained his balance by relying on a table. 5 months later the balance could be maintained without support.

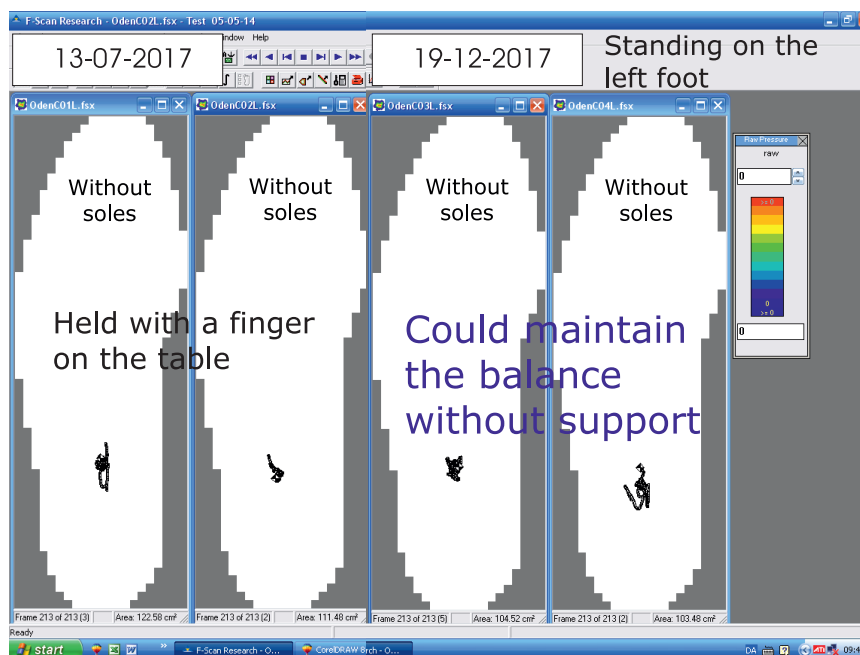


Fig. 5

Participant 2 also feels that his balance has improved significantly, especially when using the T40, which he constantly does.

Tough/hard skin

The growth of hard skin during this time period is so greatly reduced that participant 2 can now easily tend to his feet himself. The cracks in the skin with small ulcerations in the heel have also disappeared.

Participant 3

The balance

Fig. 6 and 7 show balance measurements with and without T40 for participant 3 standing on the right and left feet respectively.

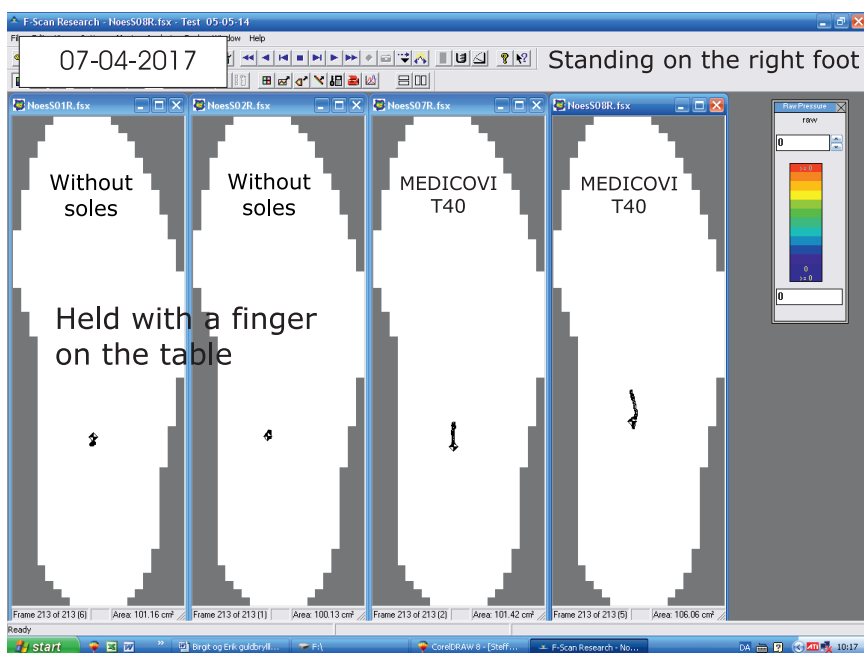


Fig. 6

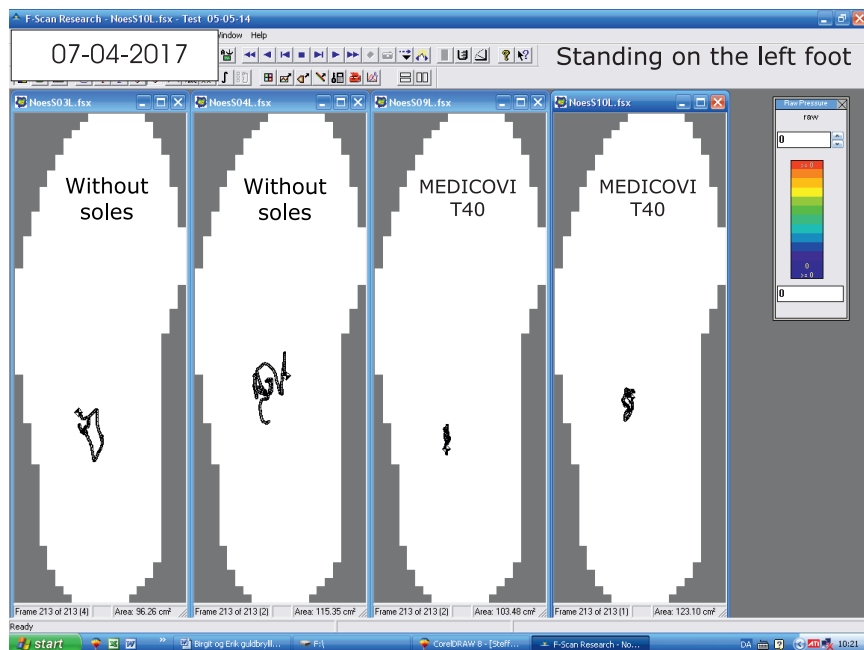


Fig. 7

It is evident that participant 3 immediately gained a better balance on both feet with T40.

Fig. 8 shows 2 balance measurements of 3-4 steps without T40, from 07-04-2017 and approx. 8 months later on 20-12-2017. Here, it is evident that with prolonged use of the membranes, the balance is improved.

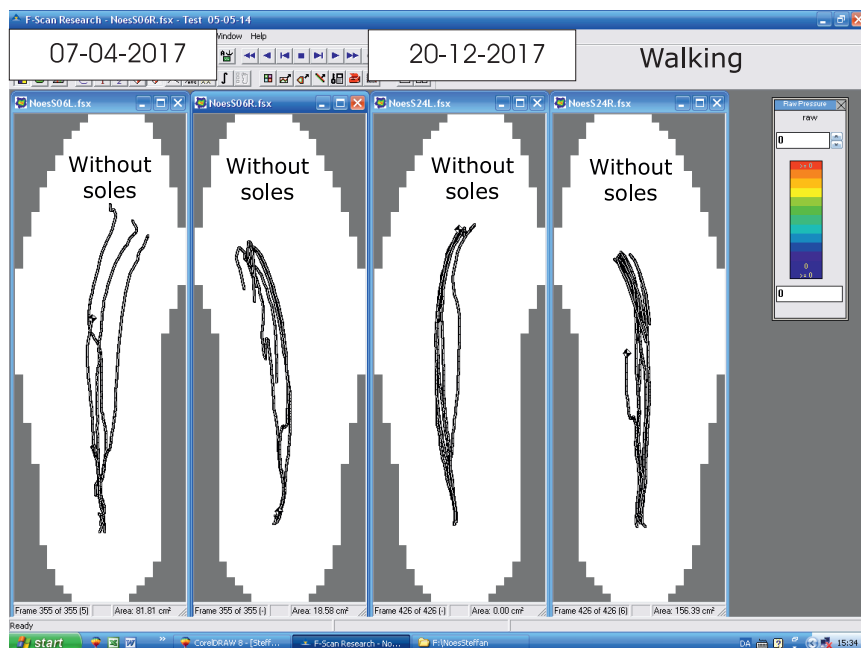


Fig. 8

Participant 3 feels that he has gained a better balance, especially when he wears the T40.

PDN expressed by very cold feet at night

After a few days with the T40, the feet began to warm up again and now participant 3 has nicely warm feet and sleeps well at night.

Mobility of the toes

Initially, participant 3 could not move his toes. After 3 days wearing T40, the mobility of the toes returns, a movement that has only improved over the time period.

Tough/hard skin

Participant 3 has had major problems with hard skin. The chiropodist could basically peel off the hard skin. The problem has now become much smaller and the chiropodist has stated that his feet have become much better.

Summary on the basis of the three diabetics' use of T40 they first 6-8 month

The balance-improving construction of the membranes

The patented membrane is made up of very strong inflexible and slightly rigid films, i.e. the membrane is almost without elasticity. Therefore, a great hydraulic pressure will form in the water when the membrane is put under load by the foot. Due to the stiffness of the membrane, the hydraulic pressure will force a water film in under most of the supporting surface of the sole. At the slightest movement of the body, ultra-fast water movements occur in the membrane, which spread over a very large area of the surface of the foot.

We therefore assume that these ultra-fast water movements affect the sensory nerves over a very large area of the surface of the foot with a faster and more powerful signal of the body's movement, and that it is this sensory effect that immediately improves balance.

The immediate mechanical improvement of the balance occurs thus alone as a result of the membranes' patented construction.

Most diabetics suffering with DPN in the soles of the feet can expect an immediate improvement of the balance with T40

Neuropathy in the soles of the feet of diabetics is usually not distributed evenly. In most cases, there will be a variation of sensitivity on the different areas of the surface of the foot, ranging from no response to a near-normal reaction.

The membranes' immediate balance improvement of is achieved by partly enhancing the sensory influence of the nerves whose sensitivity is only partially reduced, and partly by affecting the sensory nerves in a much larger area of the surface of the foot.

As shown, the water-filled membrane in the T40 has provided all three participants an immediate improved balance, as expected.

It can be confidently stated that the vast majority of diabetics suffering from DPN in the soles of the feet will achieve an immediately improved balance with T40, even if the DPN is greatly advanced.

The balance-enhancing effect is naturally important, as it provides the diabetic with a better mobility and reduce the risk of falls.

Discussion

In addition to the immediately improved balance, the first 6-8 months of using the T40 membrane soles showed:

- That the balance has improved over time
- That the problems with PDN have disappeared
- That the growth of hard skin has greatly decreased.

These are three very important factors related to the problems with the diabetic foot

Balance has improved over time

It is commonly medically described that DPN in the soles of the feet occurs as a consequence of endothelial dysfunction. Development of endothelial dysfunction is considered to be irreversible, which is why over time documenting positive development of the balance raises the question of whether other conditions could be contributing to the development of DPN in the soles of the diabetics.

The new technology in the water-filled membrane soles of the T40 may have activated processes that have not previously been observed, because it has not been technologically possible to influence the soles of the feet in a similar way.

To seek a comprehensive explanation for both the improved balance recorded over time, the assistance achieved with the problems of PDN and the reduced growth of hard skin, we have had to look into our genetic evolution.

The genetic evolution of the sole of our feet and our modern behavior

Genetically, we are developed to walk barefoot on two legs as hunters and gatherers. The condition for this development has been that the soles of the feet have always been perfectly functional. Otherwise, survival would not be possible. Therefore, a continuous supply of energy to the soles of the feet to carry the body has been essential.

Exercising movements can activate insulin-independent mechanisms that increase glucose uptake into the cells, while at the same time increasing the strength and endurance of the cells (6).

We believe that the forced movement of the sole of the foot, which occurred when the first humans' soles, loaded by the body weight, were pressed to follow the uneven ground, enabled the insulin-independent mechanisms. Through this, the soles of the natural man would both continuously supply the necessary energy for a long search for food, while at the same time building great strength in the soles of the feet.

Vivi Lena Andersen's study (7) shows that when in the 16th century the thin leather boot was replaced with the stitched shoe that had such a thick sole that it could carry a heel, the problems with hard skin, corns, sunken forefoot, etc. arose.



The thin leather boot



The durable rim-sewn shoes, that had such a thick sole that it could carry a heel

The rigid shoe soles removed the original natural movement of the soles of the feet from the uneven ground. It reduced or stopped the insulin-independent mechanisms for uptake of glucose. The ability of the soles to carry the weight of the body was thereby reduced, with the aforementioned problems to follow. Today, this development is further burdened by the fact that we always walk on completely flat floors and roads.

When the insulin-independent mechanisms are mechanically stopped by the use of our shoes on flat surfaces, the carrying capacity of the soles of the feet becomes strongly dependent on the cells having a good insulin responsiveness.

Passivation of the soles of our feet, which our modern behavior entails in relation to our genetic development, is perhaps the major reason why the disease diabetes causes the major and very serious problems with the diabetic foot.

Hypothesis

For most, the disease diabetes will reduce the cells' reactivity with insulin over a shorter or longer period.

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 the disease will automatically cause the strength of the cells of the soles of the feet to decrease. As the soles of the feet must carry the body weight, the decreasing strength of the soles of the feet will cause the body weight to press the soles more and more together.

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 of healthy persons, e.g. people who have standing work, will also be squeezed together during the day. Compression will squeeze specific blood vessels more together, which will reduce energy supply to the affected nerves. A development that initially feels like discomfort but can later turn into pain.

For healthy individuals, the cells at rest, by reaction with insulin, will absorb glucose (energy) and thereby accumulate the necessary strength to abolish compression, thus restoring the protective structure of the soles of the feet and blood circulation to the nerves.

Compression neuropathy

For the resting diabetic, the cells, due to the cells' reduced responsiveness to insulin, will experience a harder and harder time obtaining the necessary strength to completely abolish compression.

This development may cause a more or less permanent compression of the soles of the foot, given that the flow in the capillaries becomes difficult or may stop altogether. It cannot be ruled out that it will cause the energy supply to certain nerves to be reduced or completely halted, causing the nerve function to cease. According to this hypothesis, neuropathy in the soles of the feet may also occur as a result of compression. We have chosen to call it compression neuropathy.

Thus, in compression neuropathy, the nerve is intact, but the protective cells around the capillaries, that supply the nerve with energy, do not have enough strength to protect the blood flow due to the impaired responsiveness to insulin.

The new technology in the water-filled membrane-insoles T40 forces the soles of the feet under load by the body weight into a special massaging movement and an ultra-fast sensory-motoric activation.

It is possible that this particular activation of the soles of the feet initiates the natural insulin-independent mechanisms (6), so that additional strength-enhancing energy is added indirectly to the soles. A process that will be completely independent of the disease diabetes.

If the T40 membrane soles add the extra energy, it is conceivable that the protective cells build up so much strength that they can restore their protection of the blood vessels to such an extent that the blood flow to the nerves can function again.

This interpretation could explain the recorded improved balance over time.

The problems with PDN - pain and discomfort in feet and legs, as well as cold feet at night

Assuming the above-mentioned compression hypothesis is valid, the flow in the blood vessels of the soles of the feet would, to some extent, be hampered by the compression.

In the upright position, it could be assumed that the normal pulse and the hydrostatic pressure would increase the blood pressure in the soles of the feet – so much that, despite the compression, it would have allowed for a supply of energy to the nerves, so that the nerves did not respond with hyper-sensitization.

If the diabetics are resting, blood pressure will drop in the soles of the feet, both as a result of the change in hydrostatic pressure and of the resting heart rate. It is conceivable that during rest, reduced blood pressure becomes so low that the blood flow is unable to break the suppression caused by the compression. Hereby, it is conceivable that certain nerves are undersupplied with energy, which is possibly the cause of hyper-sensitization.

This assumption is supported by conversations with diabetics who have stated that when pain occurs at night, they can often be averted by continuing to sleep while sitting in a chair. I.e. a position where the hydrodynamic pressure increases the blood pressure in the soles of the feet.

We presuppose that the membrane-insoles T40 initiate the insulin-independent mechanisms (6) through their special effect on the soles of the feet every day. The extra energy supplied will in this manner counteract the compression of the soles of the feet, which will thereby be less than they would otherwise have been when the diabetic is asleep. The reduced blood pressure during resting thus has a greater possibility of overcoming the suppression caused by the compression, so that a satisfactory supply of energy to the nerves can be maintained. Thus, Maser RE (8) shows that when the nerve is able to repair itself, the sensitization is removed .

This could explain the reasons why the neuropathic pain and discomfort in the feet and legs at night ceases with the use of T40. Just as it could explain why the problems return when the effect drops in T40 due to wear.

Assuming the above, the blood flow in the soles of the feet during rest will be increased by the use of T40, which may explain why one of the participants of this study feels that their freezing cold feet at night have now become warm.

Reducing the growth of hard skin

The cells of the soles of the foot form hard skin when the pressure load exceeds a given threshold in relation to the strength or bearing capacity of the cells. The hard skin forms a protective plate that distributes strain over many cells, thereby relieving and protecting the individual cell.

As a result of the cells' reduced responsiveness to insulin, the strength of diabetic soles drops, which we think is why many diabetics experience a strong increase in hard skin growth.

Two of the participating diabetics were severely afflicted by the growth of hard skin, a problem which is now greatly reduced.

Assuming that the membrane-insoles T40 supply extra energy to the cells of the soles of the feet through the natural insulin-independent mechanisms 6), it will increase the threshold value of the cells, thus greatly reducing the growth mechanism for the formation of hard skin, resulting in decreased hard skin growth.

Building greater strength in the soles of diabetics

When long-term use of the membranes shows a markedly reduced growth of hard skin, it indicates that the cells have gained greater strength during the time period.

The decreased strength and carrying capacity are a major risk factor for the development of foot ulcers.

Therefore, the possibility of T40 building greater strength and bearing capacity in the soles of the feet's cells through the activation of the natural insulin-independent mechanisms may be of great importance for the protection of the diabetic soles.

According to our hypothesis, the increased strength will counteract the compression and thereby increase blood circulation in the soles of the feet. The increased circulation could also be thought to be of great importance for the speed of the healing of diabetic foot ulcers.

Litterateur

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