

Interview and Balance Assessment of 8 Patients with Multiple Sclerosis

Using MEDICOVI Sensory-Active Insole T40

A Study Based on the F- Scan[®] In-Shoe Plantar Pressure Analysis

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Abstract

This study aims to evaluate the effect of the sensory-active, water-filled MEDICOVI insole T40 in patients with multiple sclerosis (MS), with a particular focus on balance, mobility, pain, and quality of life. The insoles are designed to stimulate the soles of the feet through continuous sensorimotor activation and specific pressure distribution movements, which are hypothesised to positively influence balance, reduce pain, and improve blood circulation in the feet of individuals with MS.

The sensory activation effect of the insoles has previously been documented in the scientific study MEDICOVI H20: Variability of Centre of Pressure in Healthy People during Standing and Walking, conducted at Aalborg University. The results demonstrated that MEDICOVI's water-filled insoles significantly improve postural control in healthy individuals, particularly in situations requiring increased balance capacity. These findings provide a theoretical foundation for the targeted use of this technology in individuals with balance impairments, such as MS patients.

The present study included eight participants diagnosed with MS (seven women, one man) with a mean age of 45 years (range: 35–60 years). The mean disease duration was 11 years (range: 1–26 years). All data collection, including qualitative interviews and quantitative balance assessments, was conducted in the participants' private homes.

Following an initial interview, participants were provided with MEDICOVI insoles T40. Follow-up interviews and electronic balance assessments were conducted after 1–4 weeks and again after 5–12 weeks.

Results:

- All participants demonstrated measurable improvements in balance
- Five participants reported increased physical activity levels
- Two participants who initially relied on foot drop orthoses were able to discontinue their use after six weeks with the insoles
- Several participants reported increased warmth in the feet and reduced back pain
- One participant diagnosed with neurosarcoidosis experienced significant pain relief

These findings indicate that the applied technology may have a positive effect on balance, mobility, pain perception, and blood circulation in individuals with MS, potentially contributing to an overall improvement in quality of life. Further controlled studies with larger sample sizes are recommended to validate these results.

Purpose

Multiple sclerosis (MS) is a chronic, progressive neurological disorder that frequently leads to impaired mobility and reduced balance. While the disease remains incurable, both clinical experience and preliminary research suggest that the patented, sensory-active, water-filled MEDICOVI insoles system may contribute to improved balance, mobility, and general comfort in individuals with MS.

The sensory activation effect of these insoles system has previously been documented in the scientific study MEDICOVI H20: Variability of Centre of Pressure in Healthy People during Standing and Walking, conducted at Aalborg University with support from the Danish Agency for Science, Technology and Innovation. This study demonstrated that MEDICOVI's water-filled insoles significantly enhance postural control in healthy individuals, particularly under balance-challenging conditions. These results support the theoretical assumption that the technology may also be clinically relevant for individuals with balance impairments, including MS patients.

The primary objective of the present study is to investigate to what extent the sensory-active insoles MEDICOVI T40 can improve balance in individuals with MS, thereby potentially enhancing mobility and quality of life.

Methodology

To objectively evaluate the potential balance-enhancing effect of MEDICOVI's sensory-active insoles, electronic balance assessments were conducted using the F-Scan® In-Shoe Plantar Pressure Analysis System (Tekscan, USA). This system enables continuous recording and analysis of plantar pressure distribution during standing and walking activities, providing an indirect measure of postural stability and balance.

In parallel, participants' subjective experiences and perceptions regarding the use of the insoles were collected through semi-structured interviews.

It is important to note that electronic measurements solely document changes in quantitative balance parameters and do not necessarily reflect whether the participant subjectively perceives an improvement in balance. Conversely, there may be instances where the participant reports a subjective improvement that is not immediately detectable through quantitative measurement data.

The study included eight participants diagnosed with multiple sclerosis (seven women, one man). The mean age of the participants was 45 years (range: 35–60 years), and disease duration varied from 1 to 26 years, with an average of approximately 11 years.

All interviews and measurements were conducted in the participants' own homes to ensure a comfortable and realistic testing environment. Following the initial interview and baseline measurement, participants were provided with MEDICOVI insoles T40. Follow-up interviews and balance assessments were conducted after 1–4 weeks of use, and the same procedure was repeated after an additional 5–12 weeks.

MEDICOVI T40

The T40 consists of a patented water-filled membrane, which is coated on the upper side (facing the sole of the foot) with a soft, comfort-enhancing foam layer that cushions the foot and pumps air beneath it.

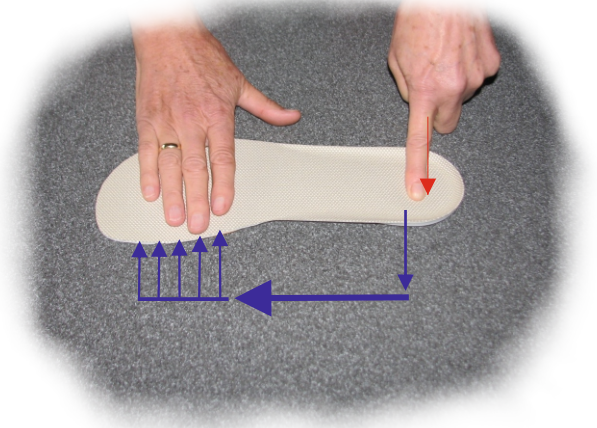
The T40 is anatomically shaped and approximately 4 mm thick, making it best suited for footwear with removable insoles that can be replaced by the T40.



Balance-Enhancing Mechanism of the Insoles

The unique balance-enhancing effect of the MEDICOVI insoles is achieved through a combination of their solid structural design and the integrated water chambers within the insoles. Water's ability to flow and redistribute instantaneously creates continuously varying pressure patterns beneath the plantar surfaces of the foot—particularly in the forefoot and heel regions. These pressure variations generate rapid, intense sensory signals directed to the body's nerves and muscles.

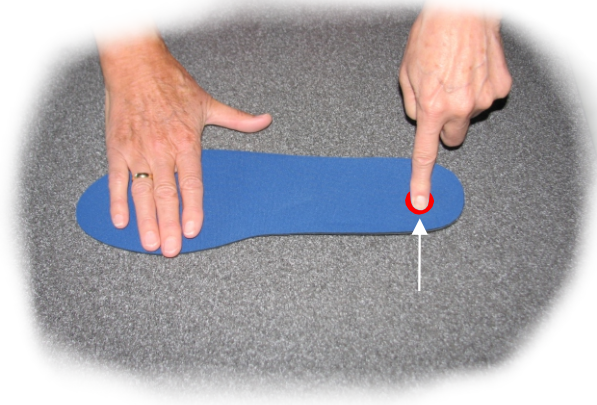
To illustrate this principle, a simple test can be performed: By placing the fingertips of the right hand on the forefoot area of a MEDICOVI insole and simultaneously applying gentle pressure to the heel area with the left hand, the pressure can be felt across all the fingertips of the right hand. This is because even minimal pressure applied to the heel is transmitted through the water within the insole, activating a wide area under the foot.



Translating this to the human body, when a person is standing or walking, even minor movements—such as subtle weight shifts in the heel—rapidly generate pressure changes that propagate throughout the insole. These changes are detected by the nerves and muscles of the body as sensory signals, enabling the body to react and adjust balance more efficiently.

By contrast, if the same test is performed on a conventional, rigid insole, pressure applied to the heel cannot be felt in the forefoot. There is no transmission of pressure and thus no enhanced sensory feedback.

In summary, MEDICOVI insoles function as a balance-enhancing system by converting even small body movements into distinct sensory signals through the hydraulic pressure of the integrated water chambers. This process improves the body's ability to detect and correct imbalances quickly and effectively.



Relief of the Foot, Knee, Hip, and Back

Traditionally, relief of the foot, knee, hip, and back is achieved by using insoles individually adapted to the shape of the foot. MEDICOVI's sensory-active, water-filled insoles introduce a new dimension to this approach. They combine targeted pressure relief with continuous micro-movements beneath the foot, contributing to the reduction or elimination of pain in the feet, knees, hips, and lower back. This form of dynamic relief is unique to the construction and function of MEDICOVI insoles.

Theoretical Background of the Relief Principle

The underlying theory of the MEDICOVI insoles' effect is based on the understanding that pain and discomfort in the body's load-bearing structures often result from static, prolonged, and uneven pressure. When tissues in the foot are subjected to constant, unvarying pressure, blood circulation and cellular energy supply are restricted. This weakens the structural resilience of the tissues and may lead to pain due to compression of nerves.

In modern daily life, we almost exclusively wear shoes that lock the foot into a fixed position. This leads to repetitive strain and uneven loading of the foot's soft tissues. Many people experience temporary relief of pain or discomfort simply by changing shoes, as this alters the distribution of pressure to different areas of the foot.

Dynamic Pressure Relief with MEDICOVI

In MEDICOVI insoles, the integrated water chambers generate hydraulic pressure that instantly adapts to even the smallest body movements. As a result, continuously changing pressure patterns are formed beneath the sole of the foot—comparable to changing shoes hundreds of times throughout the day. This constant variation in loading prevents the tissues from being exposed to prolonged, repetitive pressure, thereby reducing the risk of pain and discomfort.

This dynamic relief effect extends throughout the kinetic chain, potentially contributing to the reduction of strain on the knees, hips, and lower back.

Additionally, the hydraulic properties of water ensure natural pressure equalisation, as fluids cannot be compressed. This means that pressure is evenly distributed across the entire plantar surface, providing further relief to specific, high-pressure areas of the foot.

The Interrelationship Between Balance and Pain Relief

It is important to emphasise that the balance-enhancing and pain-relieving effects of MEDICOVI insoles are inherently interconnected. Improved balance, reduced pain, and increased comfort constitute an integrated overall effect resulting from the use of the insoles. For this reason, the present study documents both changes in participants' balance and their general well-being, as these factors are naturally linked.

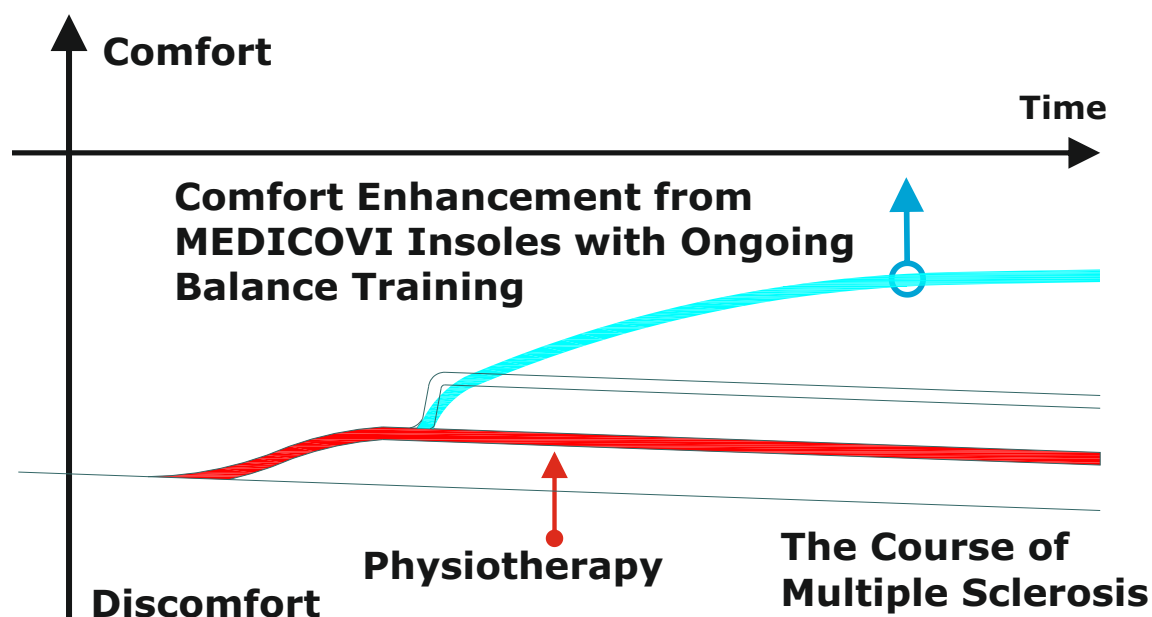
Blood Circulation

The use of sensory, water-filled MEDICOVI insoles naturally increases movement in the feet and legs. This heightened activity stimulates blood circulation, which often results in a noticeable warming sensation in the feet. Particularly during the initial period of use, this sensation of warmth may feel intense; however, it will gradually be perceived as normal.

In individuals who have offloaded or avoided placing weight on a foot or leg for an extended period, the warming sensation may be especially pronounced during the first few days. This is due to the reactivation of blood flow in previously underused or unloaded areas.

Comfort and Balance Training

Multiple sclerosis (MS) often affects the body by inducing a general sense of discomfort and reduced physical well-being, understood in the broadest sense. Physiotherapy has been shown to be effective in alleviating this discomfort, provided that training is performed regularly. Based on this relationship, the accompanying diagram has been created. It is important to emphasise that the illustrated improvements in comfort resulting from both physiotherapy and the use of MEDICOVI insoles are schematic representations and do not reflect precise measurements, as such values cannot be objectively quantified.



The diagram illustrates that physiotherapy typically requires an initial adjustment period before noticeable improvements in comfort occur. Once achieved, this increased comfort can be maintained through consistent training. If physiotherapy is discontinued, the beneficial effects will gradually diminish.

In contrast, the use of MEDICOVI insoles often results in an immediate improvement in comfort, due to the combined balance-enhancing and pressure-relieving effects of the insoles. However, similar to physiotherapy, most individuals will quickly experience a recurrence of discomfort if the insoles are not used.

Activity-Dependent Balance-Enhancing Effect

The documented balance-improving effect of MEDICOVI insoles is attributable to their patented design, which amplifies the body's sensory response to even minimal movements or weight shifts. When the body sways slightly, pressure changes are rapidly transmitted through the insole's water chambers, activating nerves and muscles and thereby supporting postural control.

This effect is activity-dependent: the more time spent standing or walking while wearing the insoles, the greater the balance-enhancing training effect. The increased activity helps strengthen the musculature, which is a key factor in maintaining balance over time.

A significant advantage of MEDICOVI insoles is that they can be used by individuals regardless of physical or cognitive ability. While conventional physiotherapy requires a certain level of mobility and mental engagement, the insoles can be used without prior training, making them accessible to a broader range of patients.

Balance Assessment

Equipment for Balance Assessment

To assess balance, the F-Scan® In-Shoe Plantar Pressure Analysis System (Tekscan, USA) was used. This system employs ultra-thin electronic measurement insoles, placed directly between the foot and the shoe's inner sole without causing discomfort for the user.

The measurement insoles are structured as a grid of small fields, each containing a pressure sensor (load cell). Each sensor records the portion of body weight applied to its specific area. Using advanced software, a point is calculated for each foot representing the body's centre of pressure (COP) projected onto the plantar surface. Balance assessments were conducted with a measurement frequency between 40 and 80 Hz, ensuring detailed capture of movement patterns.



The results are displayed on a screen, showing the plantar pressure distribution of the foot. The software continuously marks the centre of pressure (COP) points and connects them with lines, illustrating the movement pattern of the body's COP corresponding to postural sway during the measurement period.

The length and width of this trajectory—the area within which the centre of pressure moves—serve as indicators of balance stability. A larger movement area suggests reduced balance control, whereas a smaller area indicates better postural stability. It is important to note that these measurements are relative and primarily suitable for comparing balance within the same individual over time. The results are not directly comparable between different individuals and may not necessarily reflect the participant's subjective perception of balance.

Initial Balance Assessment – Methodology

All measurements were conducted in the participants' private homes to ensure a realistic and comfortable testing environment.

During the first phase of the study, two different measurement setups were used, depending on the physical conditions within the home and the functional abilities of each participant

Balance Measurement – Method and Setup

First Measurement Setup

The initial three balance assessments were carried out using an indoor golf putting mat, measuring 200 cm in length and 30 cm in width. This choice was based on previous experience with balance assessments conducted on golf courses.

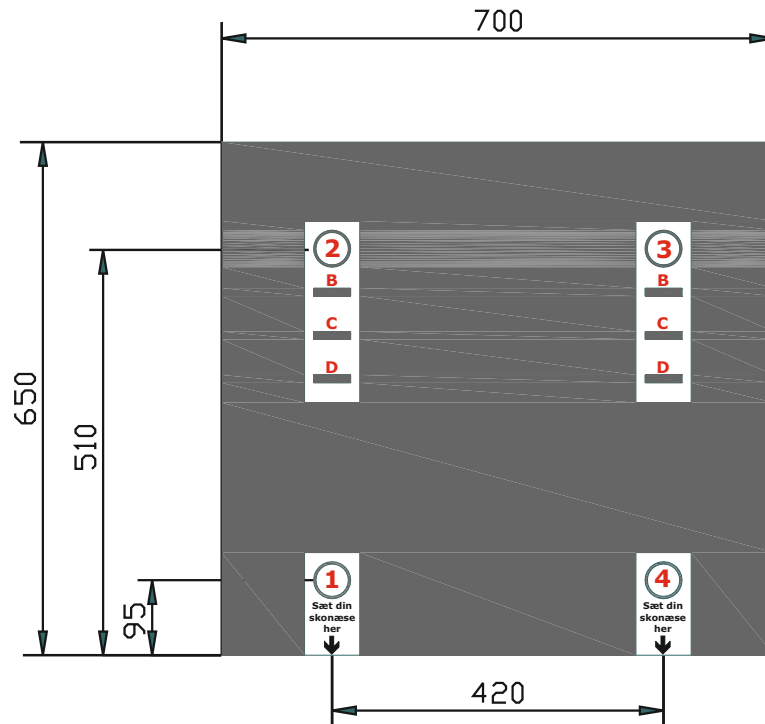
The assessment consisted of two parts:

First, the participant stood still, leaning slightly forward, focusing on striking a golf ball with a putter. Each measurement lasted 4 seconds, and the test was repeated three times, both with and without MEDICOVI insoles placed in the shoes.

Subsequently, the participant was instructed to walk around the golf mat. This exercise was repeated twice, again both with and without the insoles.

However, it soon became evident that this measurement setup posed challenges. Space limitations in the participants' homes were often restrictive, and several participants struggled to perform the golf ball task effectively. As a result, the methodology was revised.

Second Measurement Setup



This method also consisted of two parts:

Part 1:

The participant stood with their feet positioned next to two arrows marked on the floor (labelled "1" and "4"). Using a pointer stick approximately 70 cm in length, the participant was instructed to calmly point alternately at positions 1-2-3-4-1-2, and so on, for 10 seconds. The length of the pointer required the participant to lean slightly forward. At the same time, the participant was asked to stand as close to the measurement plate as possible.

Additional positions marked with the letters B, C, and D were prepared in advance in case any participants were unable to reach points "2" and "3". However, all participants were able to reach the planned positions. This test was performed three times, both with and without the MEDICOVI insoles in the shoes.

Part 2:

The participant stood in the same position as before but was instructed to simply alternate pointing between "2" and "3" without making unnecessary movements. This test was conducted once while pointing to "2" and once while pointing to "3"—both with and without the MEDICOVI insoles.

Second Round of Balance Assessments

During the second visit, the following methods were

Second Measurement Setup:

The second measurement setup was repeated. An additional test was introduced, in which participants were asked to stand with their feet together instead of slightly apart. However, this part of the test was quickly discontinued, as several participants were unable to maintain stability in this position.

Third Measurement Setup:

A 2-meter measuring stick was placed on the floor. Participants were instructed to walk back and forth along the measuring stick at a normal pace. This test was performed twice, both with and without the MEDICOVI insoles placed in the shoes.

Practical Organization of the Study

To ensure convenience for the participants and to obtain a realistic picture of their everyday life, all interviews and balance assessments were conducted in the participants' own homes.

The study involved a minimum of three visits per participant:

- **First Visit:** The participant was informed about the function of the insoles and received one or two pairs of MEDICOVI insoles T40. During the same visit, any specific problems or challenges were discussed.
- **Second Visit** (1–4 weeks later): The first balance assessment was conducted, followed by a structured interview.
- **Third Visit** (5–12 weeks later):
The balance assessment was repeated, along with another follow-up interview.

To facilitate recruitment, initial contact was made with an acquaintance who had a family member diagnosed with multiple sclerosis. This quickly led to contact with the local chapter of the Danish Multiple Sclerosis Society (Scleroseforeningen) and other networks in the area. Through this approach, eight individuals with MS were successfully recruited, all of whom expressed a desire to participate in the study. Most of the participants were already acquainted through local activities and physiotherapy sessions.

Participants

The eight participants were selected without any prior personal acquaintance. The group consisted of individuals with multiple sclerosis from the local area who voluntarily agreed to participate in the study.

The eight participants had a mean age of approximately 45 years, with an age range of 35 to 60 years. The average duration of MS diagnosis was approximately 11 years, ranging from 1 to 26 years.

Five participants exhibited clear asymmetry in lower limb loading, meaning they actively avoided placing weight on their "weaker leg."

One participant used foot drop braces on both legs, while another used a brace on one leg.

Three participants used a rollator for daily mobility.

Two participants were employed in flexible part-time jobs, while the remaining participants were retired.

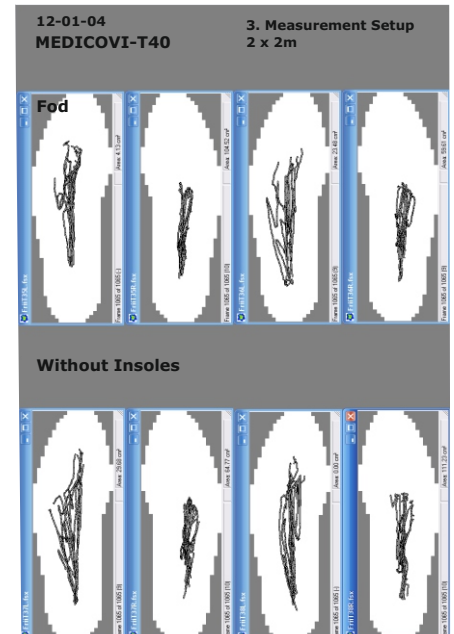
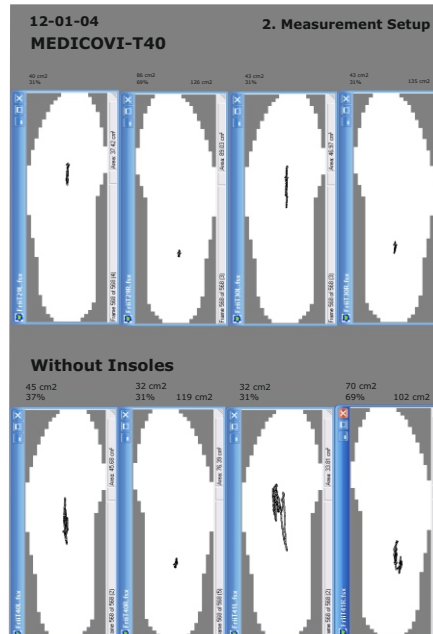
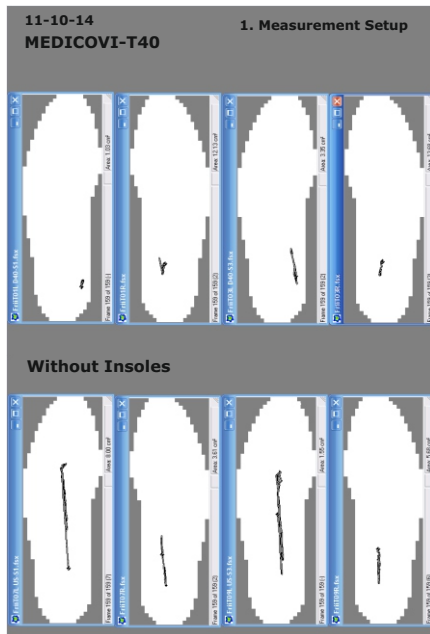
A common characteristic among all participants was their high level of engagement in self-directed physical activity. They regularly attended physiotherapy sessions, participated in group training, and performed exercises at home.

The group represented considerable diversity in terms of both balance impairments and pain levels, which reflects the broad variability typically observed among individuals with multiple sclerosis. As such, the results of this study are considered highly transferable to other MS patients facing similar challenges.

Results of the Balance Assessments

The following pages present selected measurement results. For each participant, one result from the initial balance assessment and two results from the second assessment are shown. In addition, the most important observations for each participant are briefly summarized.

Participant 1

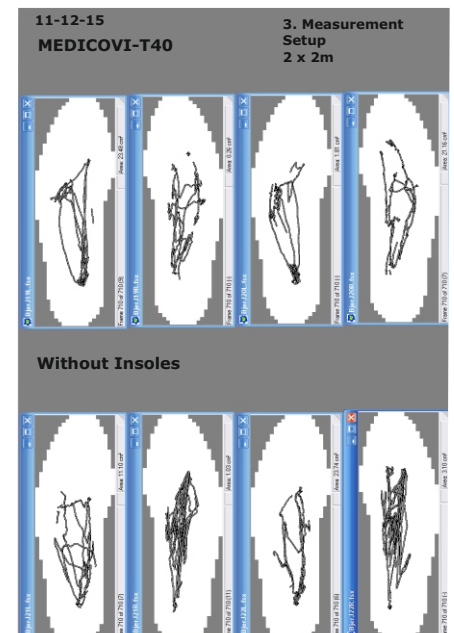
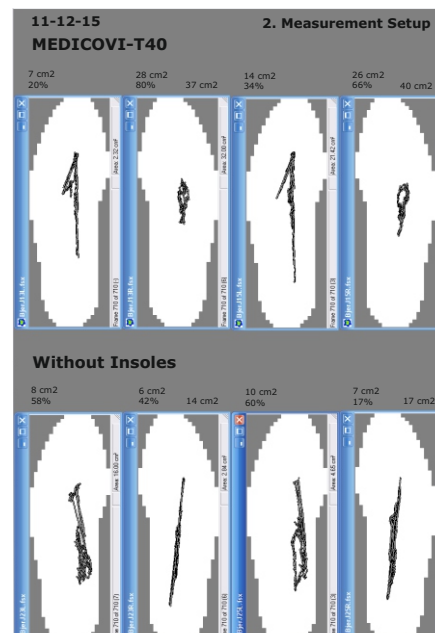
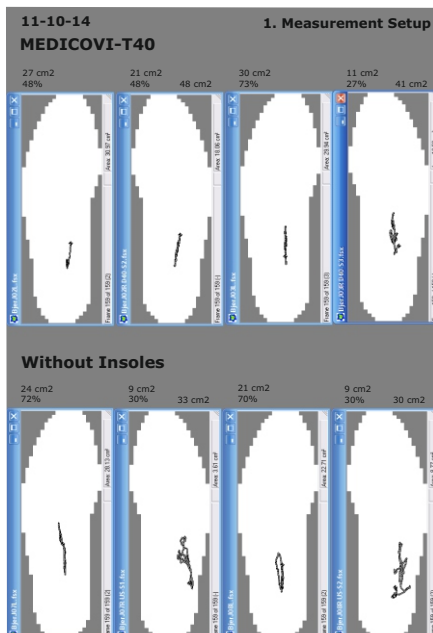


First Measurement

Second Measurement

- Previously used a foot drop brace on the left leg but no longer requires it.
- Has regained warmth in the feet.
- Measurements show improved balance in stationary tests, although the walking test remains a challenge.
- The participant reports experiencing better balance and has increased physical activity levels.

Participant 2

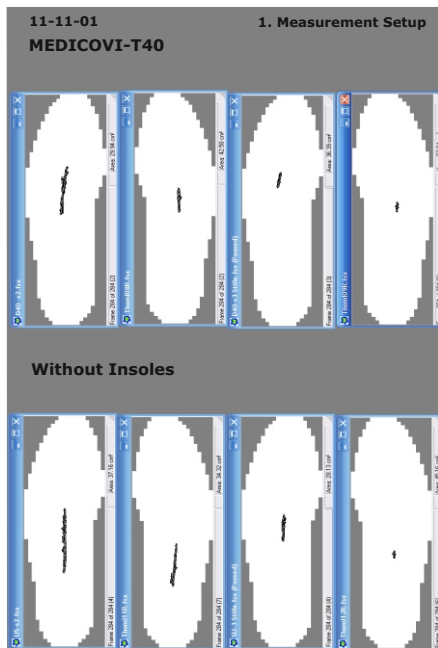


First Measurement

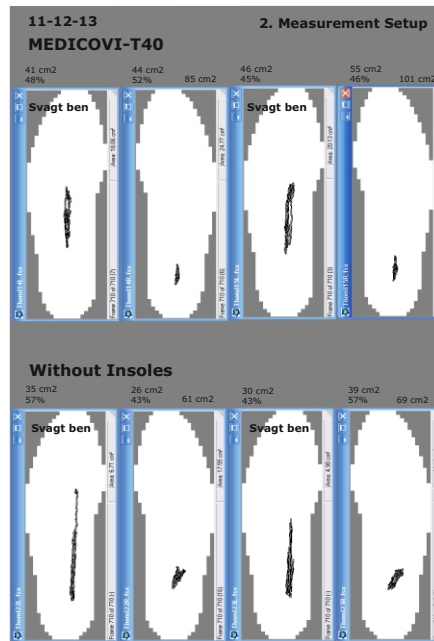
Second Measurement

- Measurements indicate improved balance in stationary tests, while improvements in the walking test are less pronounced.
- The participant perceives the balance effect but also experiences a form of overstimulation and requires a longer adjustment period.

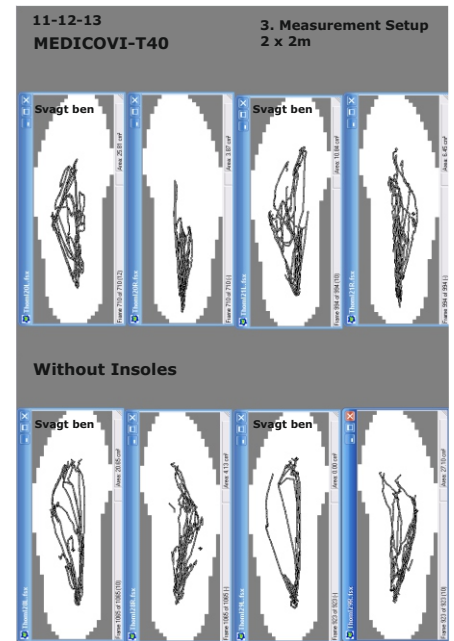
Participant 3



First Measurement

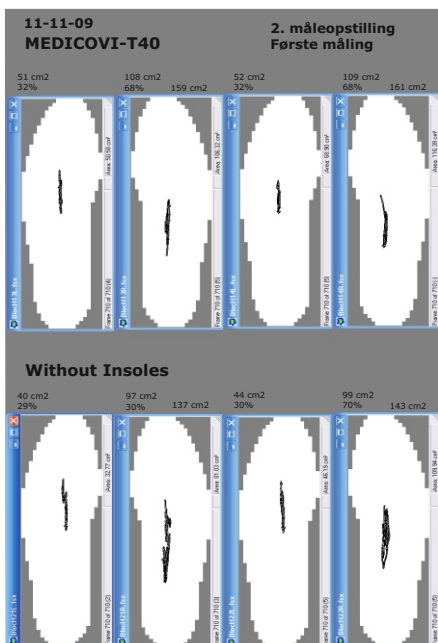


Second Measurement

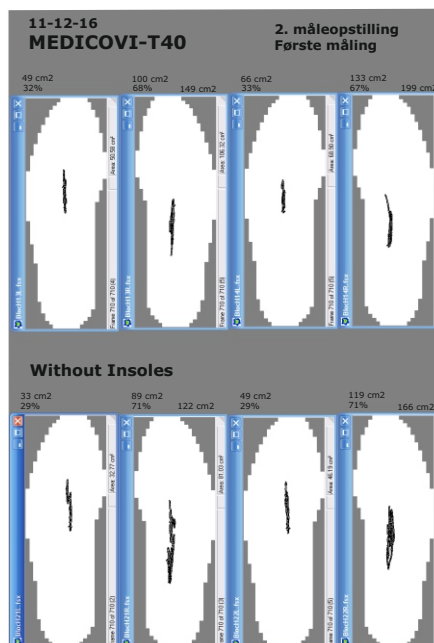


- Suffers from pronounced nerve damage (neuropathy).
- Measurements demonstrate improved balance in stationary tests and increased control during the walking test.
- The participant does not subjectively perceive improved balance but appreciates the warming effect provided by the insoles.

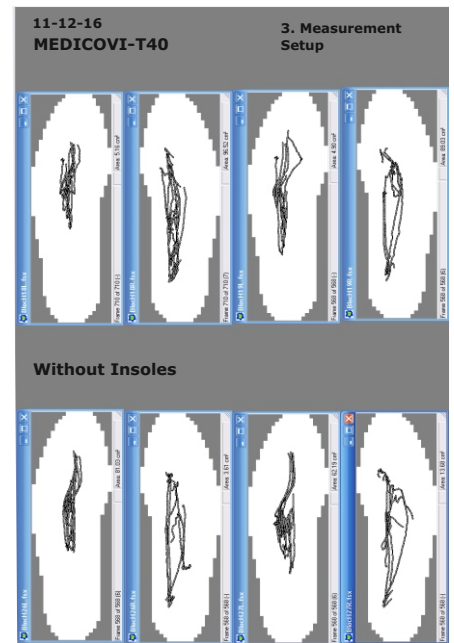
Participant 4



First Measurement

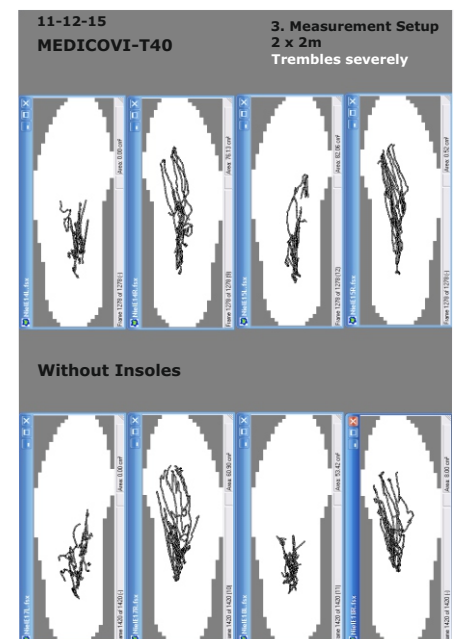
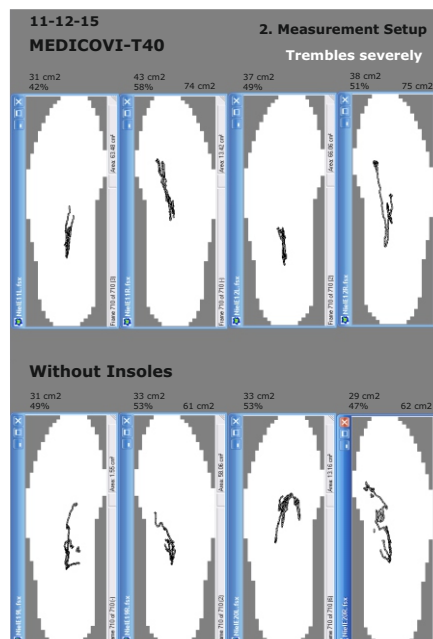
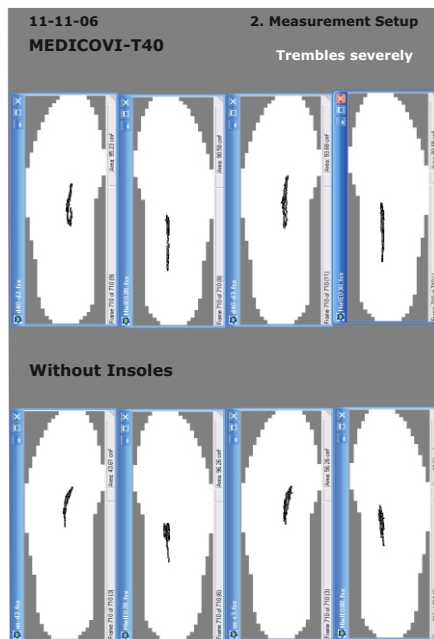


Second Measurement



- Measurements indicate improved balance in stationary tests and slight improvement in walking control, particularly on the right foot.
- The participant does not subjectively notice improved balance but enjoys using the insoles.

Participant 5

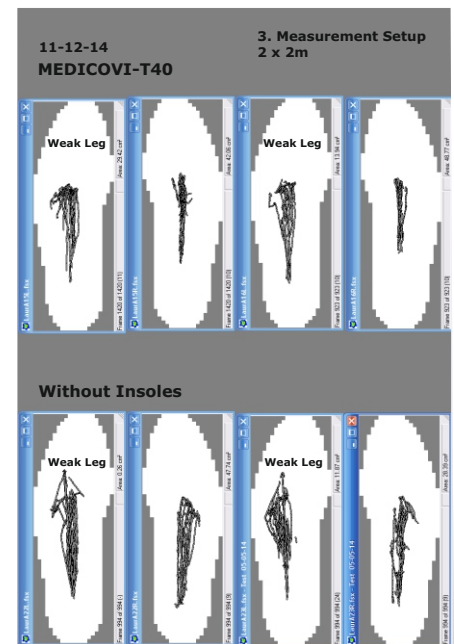
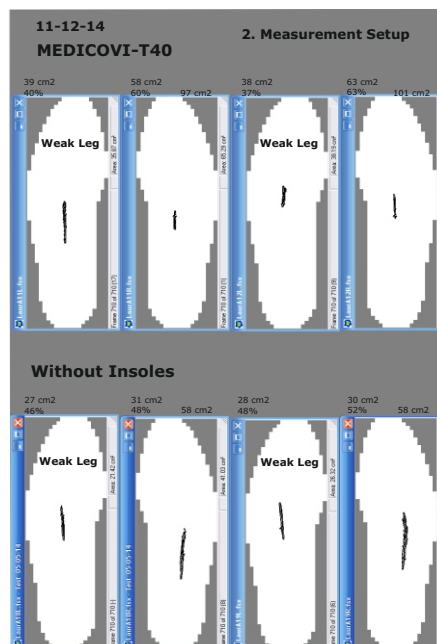
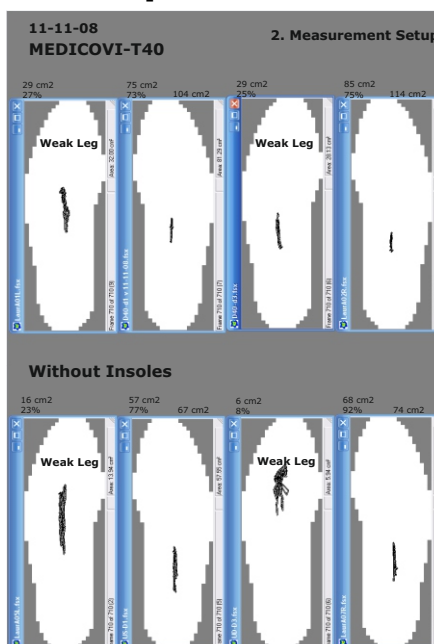


First Measurement

Second Measurement

- Previously used foot drop braces on both legs but now walks without them.
- Has regained warmth in the feet.
- Experiences considerable tremors.
- The second round of measurements shows significantly improved balance and better walking control, especially on the right foot.
- The participant reports noticeably improved balance, increased leg strength, and a higher activity level.

Participant 6

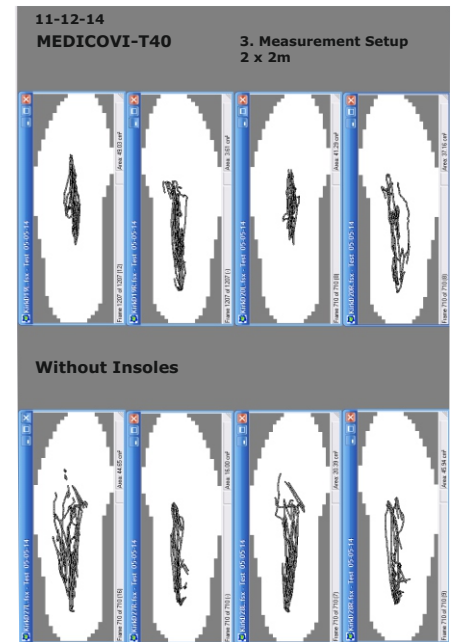
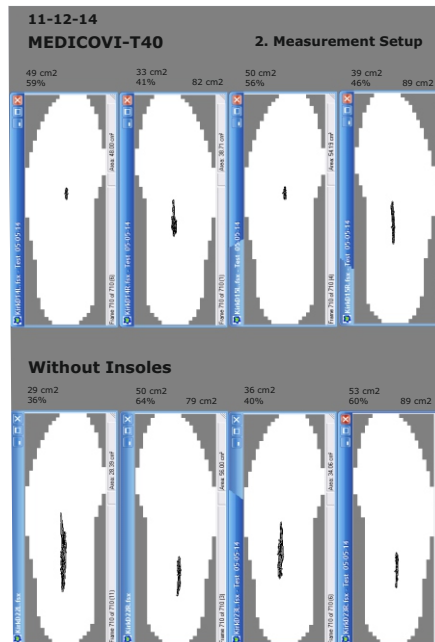
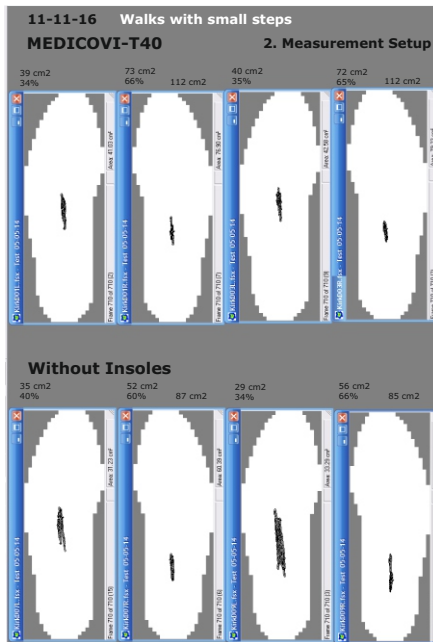


First Measurement

Second Measurement

- Walks with very small steps.
- Measurements demonstrate significantly improved balance and better walking control, especially on the right foot.
- The participant subjectively reports improved balance and has increased their activity level.

Deltager 7

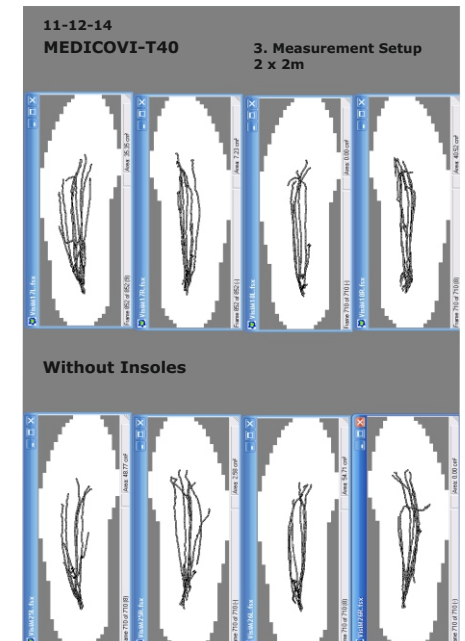
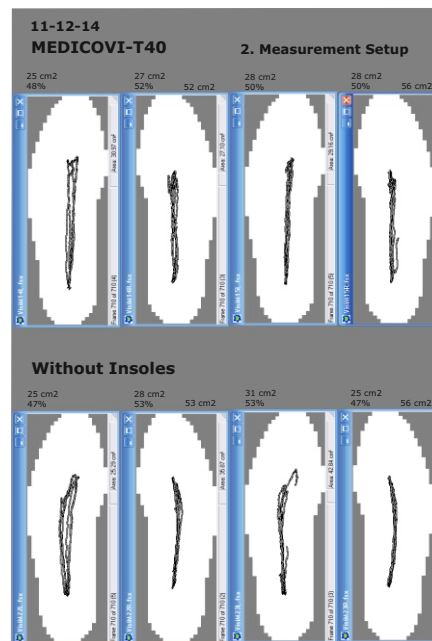
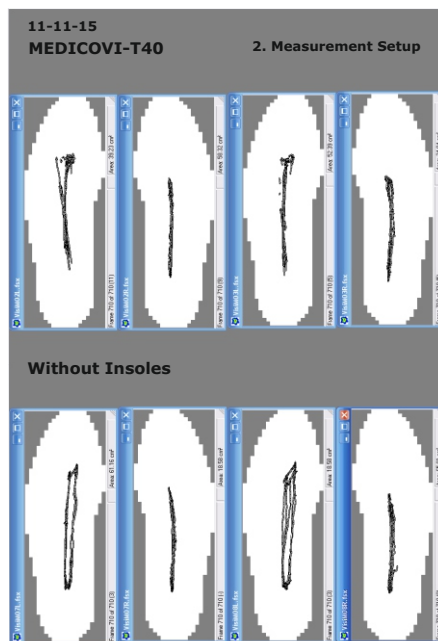


First Measurement

Second Measurement

- Experienced severe balance impairment and intense lower back pain.
- Measurements show substantial improvements in balance and better walking control, particularly on the left foot.
- The participant now reports clearly improved balance, reduced back pain, and increased activity levels.

Deltager 8



First Measurement

Second Measurement

- Does not have balance problems but suffers from severe pain due to the connective tissue disease neurosarcoidosis.
- Before the study: severe pain, tingling in the feet, and pain in both thighs.
- Measurements show improved balance in stationary tests.
- After using the MEDICOVI T40, the tingling in the soles of the feet has disappeared, thigh pain has significantly decreased, and the participant is now able to wear the same shoes all day without the need for frequent shoe changes.

Foot Drop Braces – Experiences and Considerations

In the study, two participants used foot drop braces—some on one foot, one on both. We encouraged participants to attempt walking without the braces, as prolonged use may weaken the muscles in the feet and legs. Over time, this can negatively affect both balance and gait function.

In this study, two individuals used foot drop braces:

- One used a brace on the left foot
- One used braces on both feet

Both participants now walk without the braces. We had the opportunity to discuss their experiences with foot drop braces and the associated challenges.

Participants' Experiences with Foot

- Braces are cumbersome to put on and take off
- They are generally uncomfortable to wear
- Gait patterns become unnatural
- Sensory feedback from the ground is reduced, increasing the risk of tripping, e.g., over door thresholds
- Shoes wear out more quickly
- Braces may cause cold feet and impaired blood circulation
- Overall activity levels tend to decrease, as the braces make walking more

On the other hand, foot drop braces provide essential support by keeping the foot elevated, reducing the risk of stumbling. This illustrates the common dilemma faced by individuals with multiple sclerosis: while braces improve step security in the short term, they may compromise muscle strength and balance in the long term.

Why Does Foot Drop Occur?

In individuals with foot drop, the foot "hangs," meaning the toes make contact with the ground before the heel during walking. This significantly increases the risk of stumbling. The condition is typically caused by a combination of the following factors:

- Reduced sensory feedback from the foot to the brain regarding foot position (impaired sensation and proprioception)
- Muscle weakness in the foot and lower leg—especially when fatigued, it becomes difficult to maintain proper foot positioning during gait.
- Foot drop braces assist by keeping the forefoot elevated, thereby reducing the risk of stumbling. However, they may also contribute to physical inactivity and further muscle weakening.

MEDICOVI Insoles as a Supplement or Alternative to Foot Drop Braces

The sensory-active MEDICOVI insoles significantly enhance the perception of foot positioning and movement. The amplified sensory stimulation of the foot increases awareness of both the ground surface and the gait process itself. It is likely this effect that has enabled several participants to walk without the use of foot drop braces.

As one participant described after switching to MEDICOVI insoles: "I can feel the movement under my feet and sense door thresholds and uneven surfaces much better, so I no longer trip over small obstacles like I did with foot drop braces. At the same time, my feet have become pleasantly warm—the braces always gave me cold feet. For the first time in three years, I dared to walk outdoors without foot drop braces. Now, I exercise more without the braces and have gained more strength in both my feet and legs."

Single-Leg Balance

At the beginning of the study, single-leg balance was not a primary focus. However, it quickly became apparent that five participants clearly had a "weaker" leg, which they subconsciously avoided loading.

The measurement results show that participants place the majority of their body weight on the "stronger" leg, while the "weaker" leg tends to move uncontrollably, similar to an attempt to stand on one leg—a task that, as any ballet dancer can confirm, requires extensive training and high levels of body control. For these participants, this uneven weight distribution occurs subconsciously, naturally leading to impaired balance.

Moreover, the constant subconscious offloading of the weaker leg results in progressive muscle weakening over time. This creates a negative cycle, in which both balance and mobility gradually deteriorate.

We asked participants whether their physiotherapy sessions specifically targeted the weaker leg. The general impression was that little focused attention is given to strengthening this leg. It is therefore recommended that physiotherapy programmes consider developing targeted interventions to address the issue of imbalanced lower limb loading.

Conclusion

The electronic measurements demonstrate that all participants achieved measurable improvements in balance when using the MEDICOVI insoles T40. However, the interviews revealed that not all participants perceived the same level of subjective improvement, which is likely attributable to variations in disease severity and individual symptom profiles.

Overall, the insoles produced the anticipated balance-enhancing effect, though both the intensity and subjective experience of this effect varied between individuals. The most notable outcomes of the study include:

- Five participants reported increased levels of physical activity
- The two participants who previously used foot drop braces are now able to walk without them—indicating that MEDICOVI T40 insoles can serve as an effective supplement or alternative to foot drop braces
- The participant with the connective tissue disease neurosarcoidosis experienced significant pain relief
- One participant reported a marked reduction in lower back pain
- Most participants experienced increased warmth in the feet

These findings clearly indicate that MEDICOVI T40 insoles not only improve balance but also provide additional relief and quality-of-life benefits, which, for some participants, were considered equally or even more important than the balance-enhancing effect itself.