POSSIBILITIES AND PROSPECTS FOR PROVIDING PATIENTS WITH NEW GENERATION ORTHOPAEDIC DEVICES

Birutė Sinkutė[1*], Minvydas Gražulevičius[1], Vaida Keršienė[1], Zigmas Bolzanas[1]
[1]St. Ignatius of Loyola College, Vilniaus str. 29, LT-44286, Kaunas, Lithuania
[*]Corresponding author: birute.sinkute@ilk.lt

ABSTRACT

Orthopaedic braces are widely used orthopaedic devices designed to stabilise joints, reduce pain, and facilitate rehabilitation after injuries, surgeries, or chronic diseases. The demand for these products is growing due to an increase in musculoskeletal disorders, an ageing population, sports injuries, and trends in preventive care.
Due to increasing demand for non-invasive treatments, the orthopaedic braces market in Europe is growing at 5-7 per cent per year. People over 65 years of age are more likely to suffer from osteoarthritis, osteoporosis, and spinal problems, which increases the need for back, foot, knee, and hip braces.
The increasing popularity of amateur sports (e.g., running, football) leads to more ligament injuries and post-operative rehabilitation that require the application of splints.
Technological progress enables the production of lightweight, "smart" splints with various sensors via 3D printing. The development of e-commerce (over-the-counter) makes splints easily accessible.
The need for orthopaedic splints is stable and growing, especially for preventive and rehabilitative purposes.
Research arm: to review the prospects and possibilities of providing patients with new-generation orthopaedic technical devices.
Research tasks:

1. To reveal the need for orthopaedic technical devices.
2. To discuss patient testing with Digitsole equipment.
3. To explain new technologies for the production of orthopaedic braces.

Research methods: experiment, analysis of scientific literature.

Keywords: *braces, 3D printing, Digitsole equipment, orthopaedic technical devices, foot.*

1. INTRODUCTION

Digitsole Pro is a wearable technological solution for objective gait assessment based on sensor-equipped insoles rather than stationary laboratory instrumentation. The system is designed to enable biomechanical evaluation of walking and running in environments that reflect everyday movement, thereby reducing dependence on fixed gait laboratories and complex motion capture installations. This approach aligns with current trends in gait research, which emphasise ecological validity and repeated functional assessment (Prisco et al., 2025).
A distinctive feature of Digitsole Pro is that it is provided as a fully transportable assessment kit, housed in a dedicated carrying case that allows the entire system to be easily moved and deployed in different locations. This portable case contains all hardware components required for gait analysis and enables clinicians to perform assessments in outpatient clinics, rehabilitation facilities, community settings, or patients' homes. The compact, organised structure of the kit eliminates the need for permanent installation and supports flexible use across multiple clinical environments [1].

The Digitsole Pro kit includes a complete range of smart insoles for multiple shoe sizes, enabling assessments across different individuals without custom manufacturing. The insoles are thin and designed to fit inside standard footwear, preserving natural gait mechanics. Each insole can be paired with detachable electronic sensor units, which are responsible for data acquisition and wireless transmission. The kit also includes charging equipment and protective compartments that facilitate repeated use, storage, and efficient preparation between measurement sessions [1].
Embedded in the insoles are miniaturised inertial measurement units comprising multi-axis accelerometers and gyroscopes. These sensors record dynamic characteristics of foot motion, including changes in acceleration and angular velocity throughout successive gait cycles. The modular construction allows sensor units to be easily removed for charging and reattached for subsequent measurements, supporting high clinical throughput and routine use [1].
During data collection, raw inertial signals generated by foot movement are continuously recorded and transmitted to the analytical platform. These signals are not evaluated directly but are processed through proprietary algorithmic pipelines that incorporate artificial intelligence–based methods. The processing converts sensor-level data into clinically interpretable gait parameters, including spatiotemporal measures such as walking speed, cadence, step timing, and phase distribution, as well as kinematic indicators of foot orientation and movement behaviour [2].
The system provides simultaneous access to multiple categories of gait metrics. Spatiotemporal parameters provide a general characterisation of locomotor performance and rhythm, while kinematic indicators enable a more detailed analysis of foot motion during the stance and swing phases. The combination of these outputs enhances sensitivity to gait asymmetries and movement irregularities, which may be associated with musculoskeletal dysfunction, neurological impairment, or altered motor control [3].
The accompanying software environment supports structured visualisation and reporting of results, allowing clinicians to compare measurements across sessions and monitor changes over time. This functionality is particularly relevant for evaluating rehabilitation, tracking functional recovery, or informing decisions related to orthotic intervention. Because measurements can be performed in natural walking environments, the resulting data may provide a more representative picture of functional mobility than assessments restricted to controlled laboratory settings [4].
Overall, Digitsole Pro integrates a portable hardware kit, wearable inertial sensing technology, and algorithm-driven data interpretation into a single assessment system. Its design supports repeated, non-invasive gait evaluation across diverse environments and contributes to the growing application of digital tools in personalised rehabilitation and functional movement analysis (Digitsole, 2023; Prisco et al., 2025).
Patient testing was performed using Digitsole pro portable equipment for biomechanical analysis of movement.
Digitsole is designed to improve patient outcomes through AI-based motion analytics.
The technology in the insole records walking steps, running strides, and the orientation of a foot in space.
Aiding in recovery from neurological, orthopaedic, and age- or sport-related conditions.
The Digitsole Pro kit allows analysis of patients' walking or running in place. It can be carried everywhere, it weighs less than 3 kg.
It includes 6 pairs of insoles with 2 connected chips & a charger.

Results of the walk provide general values for the recording, independent of laterality. Symmetry close to 100% indicates good congruence between left and right steps.
On the other hand, less symmetry may indicate different behaviours of the lower limbs and therefore either an abnormality in one foot or both feet affected in different ways. Speed is a good indicator of walking quality and range.
Walking too fast or too slow may be the first sign of a locomotion problem. Pace is strongly correlated with speed and will therefore also be a qualitative indicator of walking.

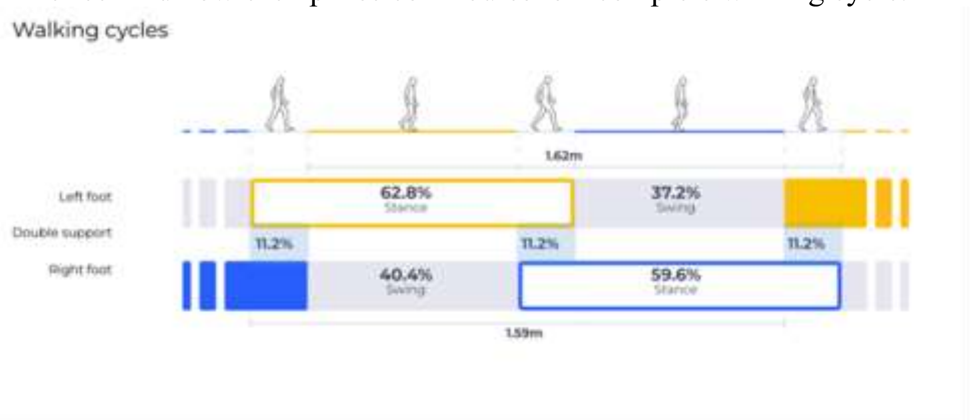
2. TWO PATIENTS NAMED A AND B TESTED THE DIGITSOLE EQUIPMENT.

A Patient: All parameters fall within normal ranges except for symmetry. A symmetry value of 88% indicates a slight imbalance between the left and right limbs, suggesting uneven loading or a possible early sign of gait dysfunction.

Patient B
The gait analysis shows very good symmetry (96%), meaning both legs work almost equally during walking. Cadence (106 steps/min) is within the normal range, indicating a steady and efficient rhythm. Walking speed (4.5 km/h) also falls within typical adult values. Overall, the results reflect a stable and functional gait pattern.

This figure shows the percentage durations of the different running phases: stance, swing and double support phase, and the length of the cycle. As in the rest of this document, the left foot is represented in orange and the right foot in blue; stance times are in a darker colour, while swing phases are in a lighter colour. Double support is located between the two feet, in grey. Finally, the cycle lengths are at the top for the left side (orange) and at the bottom for the right side (blue)

Patient A: The figure shows that during walking, the stance phase accounts for the largest portion of each step (about 60% of the cycle), while the swing phase occupies the remaining ~40%. There are also short periods of double support (about 11%), during which both feet are briefly on the ground. The left and right steps are slightly different in length (1.62 m for the left, 1.59 m for the right), indicating small natural asymmetries in gait. Overall, the measurements highlight how weight is transferred between the feet and how each phase contributes to a complete walking cycle.



Patient B

The walking cycle shows balanced stance and swing phases between both feet. The left foot spends 63.4% in stance and 36.6% in swing, while the right foot shows very similar values (64.1% stance, 35.9% swing). The periods of double support (13.7%) are equal on both sides, indicating stable and symmetrical gait mechanics. Overall, the results indicate a consistent, well-coordinated walking pattern.

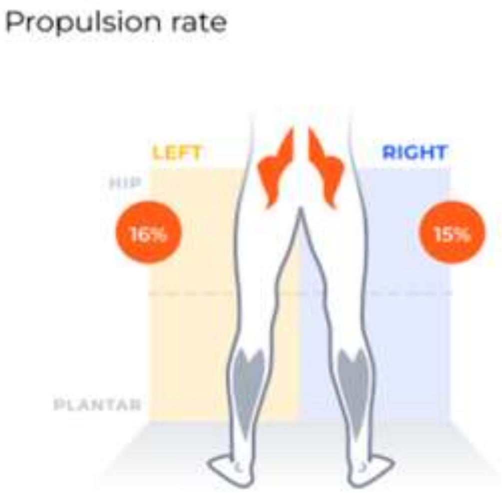
This diagram represents the displacement of the centre of support (black line) at the foot during the support phase. We can assess pronation and supination of the foot by measuring the displacement of the centre of support at key moments in the stride sequence (heel and toe landing, heel and toe lift-off).
This information is supplemented by the duration of each phase (between key moments), expressed in milliseconds (as above) when the cursor is in the "Absolute" position and in percentages of the support time when it is in "Relative".

Patient A: The centre-of-pressure progression shows clear differences between the two feet. Propulsion is significantly shorter on the left (53 ms) and much longer on the right (226 ms), indicating an asymmetrical push-off phase. In contrast, the flatfoot phase is longer on the left (518 ms) and shorter on the right (316 ms), suggesting a delayed transition through mid-stance on the left. Loading response times (L 102 ms, R 96 ms) are nearly symmetrical and within normal variation. Overall, the data indicate a temporal imbalance between the two feet, mainly during flatfoot and propulsion phases, which may reflect functional asymmetry and should be considered when planning treatment.

Patient B
The gait line shows very similar movement patterns between the left and right foot. The timing of each phase—loading, flatfoot, and propulsion—differs only slightly, indicating good overall symmetry. A slightly longer flatfoot phase on the left side may reflect mild stability or control adjustments, but no major imbalance is seen. Overall, the results suggest a stable and well-coordinated gait.

The propulsion ratio is the ratio of the propulsion speed (foot speed at lift-off of the toes) to the average stride speed (average foot speed during swing phase). Using this ratio, we can determine whether the speed of foot movement is generated more by the plantar flexors or the hip flexors. We can then highlight the muscle group and the deviation from perfect balance. In this example, the hip flexor muscles are mainly used, so the feet accelerate during the swing phase in a quasi-symmetrical way, with a 6 percentage-point difference between the left and right feet.

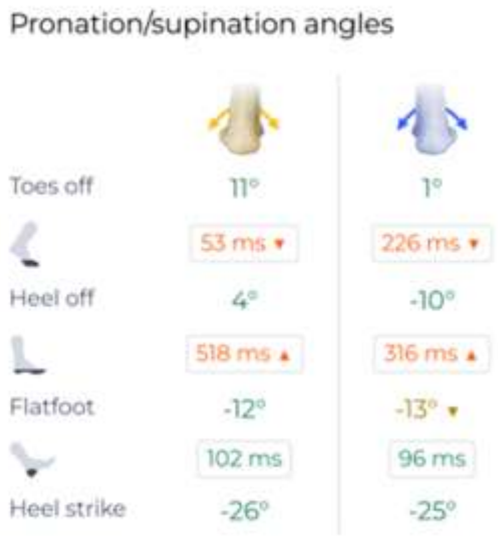
Patient A: The propulsion ratio indicates that both feet rely more on the hip flexors than the plantar flexors to generate forward movement. The left foot shows 16% additional hip contribution, and the right 15%, which is almost symmetrical. Overall, this suggests balanced but hip-dominant propulsion, with the swing-phase acceleration primarily driven by the hips rather than the ankle muscles.



Patient B
The propulsion rate shows a slightly higher push-off effort on the left side (8%) than on the right (4%). This means the left leg contributes more power during the final phase of the step. The difference is small and suggests only a mild asymmetry in push-off strength, with overall propulsion remaining balanced and functional.

During the stance phase, we measure pronation/supination angles at the four key moments of the step sequence: heel landing, toe landing, heel lift-off, and toe lift-off. This angle corresponds to the lateral inclination of the foot in relation to the ground. We propose a corridor of normality (green) based on the literature and adapted to Digitsole Pro, in consultation with health professionals, representing the sequence of a healthy subject, to compare the mean value (black line) and the variability (grey lines) of your patient. This example shows a normal foot placement on the right and a quasi-normal placement on the left, with a slight pronation tendency. Then, viewing the movement from flat-foot to heel-off, the feet are slightly pronated compared to the normal values. During the propulsion phase, there is very slight supination on the left, leading to normal values at toe-off. On the right, there is a very slight pronation, which better corresponds to a normal roll-off leading to a normal toe-off, although in the pronated part of this norm. On the Digital Gait Line, on each side of the graph, we find the duration of each phase of the sequence: loading, flat foot, and propulsion. As this representation is dynamic, the spaces corresponding to these durations, along with the juxtaposition of the curves of the angles during the sequence, allow one to appreciate their symmetry.

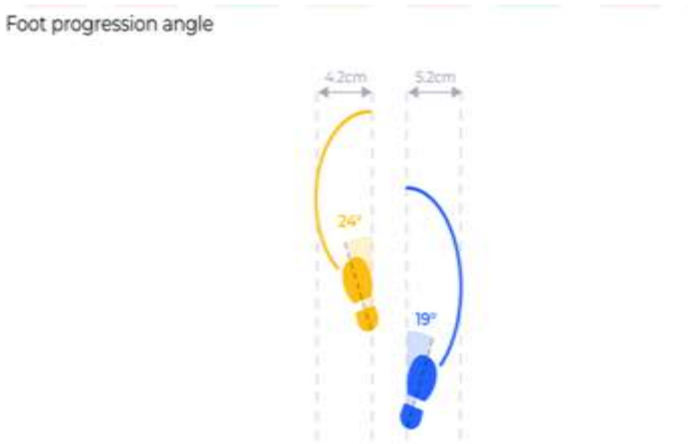
Patient A: Foot placement is largely within normal limits, with minor asymmetries. The left foot shows a slight pronation tendency, especially from flat-foot to heel-off, while the right foot follows a more normal pattern with minimal pronation during roll-off. Overall, the gait is mostly normal, with a slight left pronation and minor temporal asymmetries between the feet, especially during propulsion.



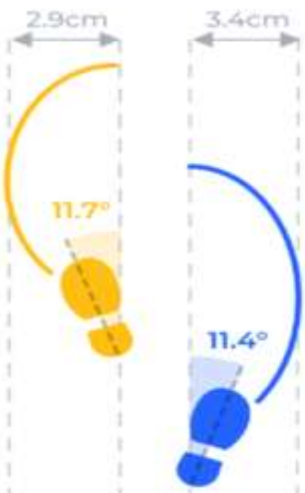
Patient B
The angles of the left and right foot are very similar in all phases. This indicates symmetrical, stable foot movement without significant deviations.
The right foot pushes off slightly more efficiently, as it transitions into mild supination during the propulsion phase.

The Step Progression Angle (SPA) is expressed in degrees and corresponds to the foot's orientation relative to the patient's gait trajectory. To be precise, it is a question of opening or closing the feet. A healthy person is supposed to walk with a slight outward opening of the feet. Step Progression Angle and Circumduction are represented on this graph. This is the maximum lateral distance the foot travels during the swing phase, relative to the line joining two consecutive landings of the same foot. For a healthy subject, this value is close to zero. It will then tend to be high for subjects with a neurological/spastic type of limp.
Patient A: The patient demonstrates a slight gait asymmetry and reduced foot symmetry, likely related to hip/leg alignment issues. Observation and analysis suggest that the patient may be walking with the legs slightly turned or misaligned, which may contribute to uneven loading and differences in propulsion. Regular targeted

exercises for hip mobility and leg alignment are recommended to improve gait symmetry and reduce asymmetry over time.

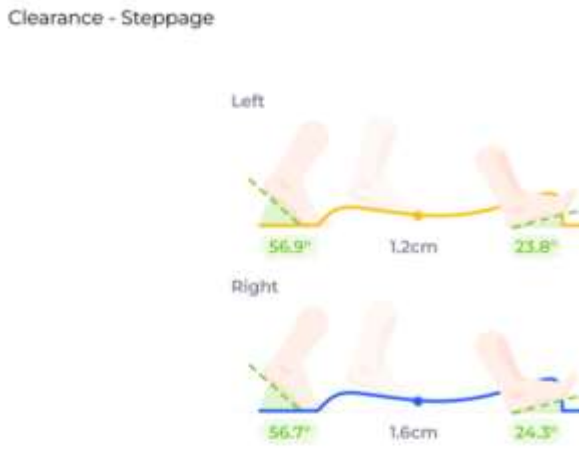


Patient B: The left foot displays an outward angle of 11.7°, while the right foot shows a very similar outward angle of 11.4. The step width is also indicated: 2.9 cm on the left and 3.4 cm on the right. Overall, the results suggest symmetrical and consistent gait mechanics, with both feet pointing outward to a similar degree.

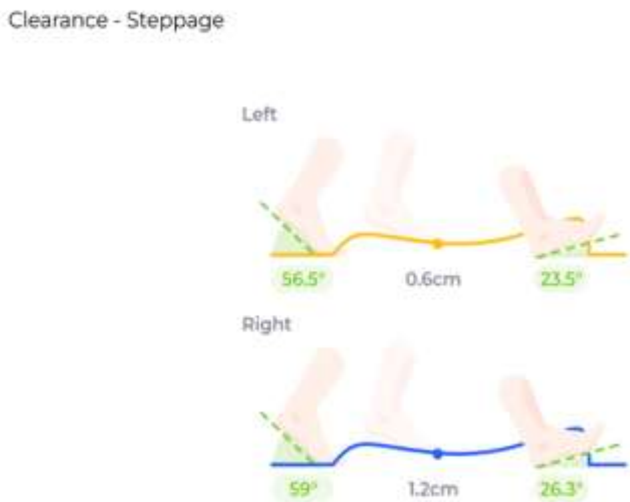


In this graphic representation, we see the Clearance, the minimum distance between the toes and the ground during the swing phase of the step. The question here is having information on the free passage of the step; indeed, with a height that is too low, the foot could encounter an obstacle during the swing phase, at the very least causing a loss of balance and, in the worst case, a fall. On the left, the propulsion angle is shown. It is the plantar flexion angle between the ground and the foot in the sagittal plane at toe off. This angle is related to the capability to generate good propulsion, so it should be different from 0. Finally, on the right, you can find the Step page, also known as the angle of attack. This is the angle between the foot and the ground in the sagittal plane at heel strike. A healthy person does not place the foot flat or walk with the toes.
Patient A: The toe clearance during the swing phase is adequate, with the left foot at 1.2 cm and the right at 1.6 cm, indicating a low risk of tripping. The propulsion angles are similar for both feet (L 56.9°, R 56.7°), showing effective push-off capability. The

steppage (angle of attack) at heel strike is also balanced (L 23.8°, R 24.3°), indicating proper foot placement without flat-foot landing. Overall, swing phase and foot-ground angles are largely normal and symmetrical, suggesting safe and functional gait in terms of clearance and propulsion.



Patient B:
The left foot lifts 0.6 cm off the ground with ankle angles of 56.5° during push-off and 23.5° during landing. The right foot shows slightly higher clearance at 1.2 cm, with similar ankle angles (59° at push-off and 26.3° at landing).
Overall, both sides demonstrate low clearance but fairly symmetrical movement, with the right foot lifting slightly higher during swing.



These results can be widely used in orthopaedic technology to improve diagnostics, treatment, prevention, and patient care with orthopaedic equipment.
The data can be integrated into orthopaedic research to develop new technologies, such as 3D-printed orthopaedic braces made from synthetic and biodegradable polymers.
Additive manufacturing (3D printing) is increasingly used to produce orthopaedic braces, enabling the creation of personalised, precisely tailored products for each patient's anatomy.

This allows for improved comfort, reduced weight, and faster production than traditional methods such as casting, sheet moulding, or lamination.

The main additive manufacturing techniques for the production of orthopaedic technical devices are: binder jetting, direct energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination, and vat photopolymerisation.
The main materials used in 3D printing orthopaedic devices: PEEK (polyether Ether Ketone), PE (polyethene), PC (polycarbonate), PET (polyethene terephthalate), PP (polypropylene), TPE (thermoplastic elastomer), TPU (thermoplastic polyurethane), ASA (acrylonitrile-styrene-acrylate), PA (polyamide), PLA (polylactic acid), ABS (acrylonitrile-butadiene-styrene).
The printed splints feature high precision, smooth surfaces, and light weight, making them convenient for patients to use daily after various injuries and illnesses.
They can be individually adjusted to the body's anatomy, which helps ensure better rehabilitation and comfort.

3. CONCLUSIONS

1. The use of orthopaedic braces is justified and appropriate. Braces are needed to stabilise the affected area, reduce pain, improve function, and prevent the progression of the condition and its potential complications, especially as people age.
2. Digitsole smart equipment is a significant and promising solution in the field of orthopaedic technology, as it combines biomechanical data collection, advanced analysis and personalised treatment capabilities. Integrated pressure, motion, and temperature sensors enable accurate assessment of foot loads, gait characteristics, and functional disorders in real-world conditions, which is especially important when designing and adjusting orthopaedic braces.
3. 3D technologies allow for precise adaptation of braces to the individual anatomy of each patient, ensuring greater comfort, functionality and more effective treatment results. In addition, 3D technologies shorten production time, reduce the likelihood of errors, and enable the creation of lightweight, aesthetically pleasing orthopaedic technical devices.

REFERENCES

1. Digitsole. (2026). Digitsole Pro clinical kit: Portable gait analysis system including insoles, sensors, and charger (official product page). Retrieved January 2026, from https://www.digitsole.com/clinical studies/newly published gait analysis study demonstrates excellent repeatability of Digitsole smart insole AI-based solutions.

2. Prisco, G., Pirozzi, M. A., Santone, A., Esposito, F., Cesarelli, M. C., Amato, F., & Donisi, L. (2025). Validity of wearable inertial sensors for gait analysis: A systematic review. Diagnostics, 15(1), 36. https://doi.org/10.3390/diagnostics15010036
3. Lin, S., Evans, K., Hartley, D., Morrison, S., McDonald, S., Veidt, M., & Wang, G. (2025). A review of gait analysis using gyroscopes and inertial measurement units. Sensors, 25(11), 3481. https://doi.org/10.3390/s25113481
4. Perez-Lasierra, J. L., Azpíroz-Puente, M., Alfaro-Santafé, J. V., et al. (2024). Sarco-penia screening based on gait assessment with inertial measurement units: A systematic review. BMC Geriatrics, 24, 863. https://doi.org/10.1186/s12877-024-05475-3