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EXAMINATION OF THE EFFECTIVENESS OF LOWER LIMB EXOSKELETONS IN THE REHABILITATION PROCESS OF PATIENTS WITH SPINAL CORD INJURIES

PhD thesis

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List of Abbreviations

ADL - Activities of Daily Living

ASIA Scale - American Spinal Injury Association Impairment Scale

BAI - Beck Anxiety Inventory

Barthel Index - Barthel Index for activities of daily living

BBS – Berg Balance Scale

BDI-SF - Beck Depression Inventory Short Form

BIA – Body Impedance Analysis

BMD - Bone Mineral Density

BMI – Body Mass Index

DALY - Disability-Adjusted Life Year

DEXA – Dual Energy Absorption

EMA – European Medicine Association

ETT-TUKEB - Egészségügyi Tudományos Tanács Tudományos és Kutatásetikai Bizottsága - Scientific and Research Ethics Committee of the Medical Research Council

FDA – Food and Drug Agency

LEE - Lower Extremity Exoskeleton

LVA – Lateral Vertebral Assessment

MBUT – Modified Body Uneasiness Test

NEAK - Nemzeti Egészségbiztosítási Alapkezelő - National Health Insurance Fund Manager

NNGYK - Nemzeti Népegészségügyi és Gyógyszerészeti Központ - National Center for Public Health and Pharmaceuticals

NTSCI – Non-traumatic Spinal Cord Injury

OGYÉI - Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet - National Institute of Pharmacy and Nutrition

PTE – Pécsi Tudományegyetem - University of Pécs

QoL – Quality of Life

SCI – Spinal Cord Injury

SCIM - Spinal Cord Independence Measure

SDI – Socio-demographic Index

SE-RK – Semmelweis Egyetem Rehabilitációs Klinika (korábban OMINT - OORI (Országos Mozgásszervi Intézet - Országos Orvosi Rehabilitációs Intézet)) - Semmelweis University Department of Rehabilitation (formerly National Institute of Medical Rehabilitation)

SF-12 – 12-item Short From Survey

SF-36 – 36-Item Short Form Survey

TCT – Trunk Control Test

TSCI - Traumatic Spinal Cord Injury

WHOQOL – World Health Organisation Quality of Life

YLD – Years Lived with Disease

1. Introduction

1.1. The History of Exoskeletons

By definition, an exoskeleton is an external frame that supports or protects the body of a living organism - such as an insect - from the outside, in contrast to the human (internal) skeleton (endoskeleton) and many animal skeletons, which are covered by skin. It can also be defined as an artificial external frame, a load-bearing structure capable of locomotion that encompasses the human body. They combine human intelligence with the strength of a robot. It can have medical applications when the aim is to replace or operate injured limbs. In military functions, research is primarily focused on increasing the load-bearing capacity of the human body. Exoskeletons are increasingly used in the economy as well, being employed in more and more places to facilitate strenuous physical work. When categorizing by applications, we can distinguish between lower limb and upper limb exoskeletons used for gait rehabilitation, human motion assistance, and extension of physical abilities and human strength.

The first known description of a device reminiscent of an exoskeleton is the "running aid" by Russian inventor Nicholas Yagn, which was patented in 1890. There is no written evidence that this device was ever built (Figure 1) [1].

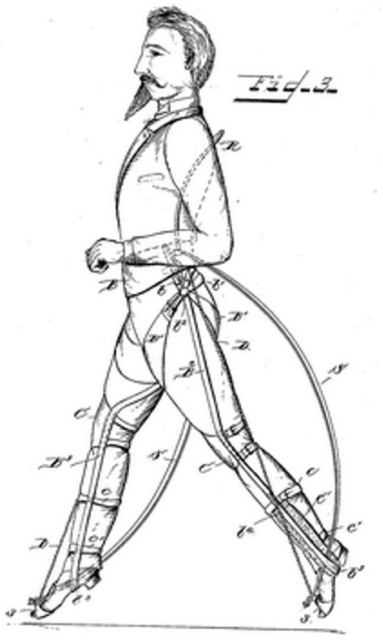


Figure 1: N. Yagn: “running-aid” [2]

Later, from the second half of the 20th century, there was increasing interest in exoskeleton technology. Researchers from the United States, Japan, Germany, and other countries developed new designs and devices. The development was accelerated by advancements in related fields such as mechanical and electric motors, automation, biology, physiology, and materials science. In 1948, Russian biomechanist Nicholai A. Bernstein designed a device powered by electric motors for soldiers injured in World War II, but it was never commercialized. One of the first partially functioning exoskeletons, called Hardiman, was built by General Electric, the project began in 1965. It was enormous due to the space requirements of hydraulic structures. The Hardiman aimed to increase human strength and endurance for lifting heavy loads and performing tasks in hazardous environments (Figure 2) [3].

Figure 2: General Electric's exoskeleton, the „Hardiman" [4]

A year later, in Belgrade at the Mihajlo Pupin Institute, Prof. Miomir Vukobratovic developed an anthropomorphic exoskeleton to assist the movement of paraplegics. His work laid the foundation for the development of modern humanoid robots. The exoskeleton was successfully applied in more than 100 clinical trials, however,

limitations in motor technology and energy storage of the time prevented further development of the device [5].

These early prototypes were not practical and limited widespread application. By the end of the 20th century, exoskeleton technology expanded into the area of medical rehabilitation and mobility assistance for individuals with disabilities. Research initiatives focused on developing powered exoskeletons to help those with spinal cord injuries, stroke, and neuromuscular disorders to stand, walk, and perform daily activities.

From the 2000s, developments accelerated. The Berkeley University project, BLEEX (Berkeley Lower Extremity Skeleton) exoskeleton, was supported by DARPA (Defense Advanced Research Projects Agency) [6]. In 2010, also at Berkeley University, the eLEGS system was created for rehabilitation purposes. This system uses a human-machine interface to transform natural movement into external frame movement, controlled by an algorithm. Sensors on the frame detect external stimuli and body position to complement the algorithmic control [7].

Paths opened for commercially available exoskeletons, such as ReWalk, which received regulatory approval for clinical use in 2014 and is now used in rehabilitation centers worldwide. ReWalk was the first robotic exoskeleton to receive FDA clearance for personal use in North America (Figure 3) [8].

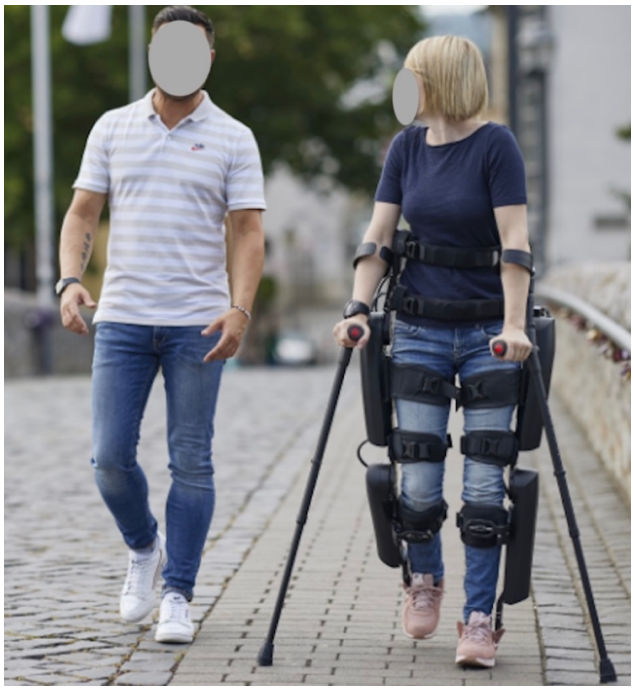


Figure 3: ReWalk 6.0 exoskeleton in use [9]

In recent years, rapid development has been observed in exoskeleton technology, driven by miniaturization, advanced actuation systems, and progress in artificial intelligence and human-machine interfaces. Lightweight, wearable exoskeletons with modular designs and intuitive control interfaces offer new opportunities to enhance mobility for people with disabilities, increase physical capabilities, and improve quality of life. Additionally, exoskeletons can be applied in industries such as manufacturing, construction, and logistics, where they augment human capabilities and reduce the risk of musculoskeletal injuries. Despite significant advancements, challenges remain in optimizing exoskeleton design, performance, and accessibility. Further research is needed to address issues such as user comfort, adaptability to diverse environments, and integration with existing healthcare systems. Moreover, cost-effectiveness and technology accessibility pose barriers to widespread adoption in clinical and community settings. As the technology continues to evolve, exoskeletons promise to revolutionize healthcare, industry, and human performance, enabling individuals to achieve new levels of independence and capability [10].

1.1.1. Types of Exoskeletons

Passive Exoskeletons

Passive exoskeletons, also known as mechanical or orthotic exoskeletons, provide structural support and mechanical assistance without using external power sources. They are typically used in industrial settings to help workers maintain proper posture, reduce musculoskeletal strain, and minimize the risk of ergonomic injuries. These exoskeletons are generally lightweight and do not require external power, making them suitable for applications where simplicity and low cost are priorities [11].

Hybrid Exoskeletons

Hybrid exoskeletons combine passive elements with minimal actuation systems or control units. They may use small motors or controllable dampers to adjust the support provided by passive components. These exoskeletons offer a balance between the simplicity of passive systems and the adaptability of active systems [12].

Active Exoskeletons

Active exoskeletons use electrically, hydraulically, or pneumatically powered actuators to deliver assistive forces directly to the user's joints. These exoskeletons can be further classified based on their control strategies:

a. Position-controlled exoskeletons: Focus on controlling joint angles and following predetermined trajectories.
b. Torque-controlled exoskeletons: Provide specific assistive torques at the joints.
c. Impedance-controlled exoskeletons: Adjust their stiffness and damping properties to match the user's movements [13].

Application-Specific Exoskeletons

Exoskeletons can also be categorized based on their intended use:

a. Rehabilitation exoskeletons: Designed to facilitate movement and rehabilitation for individuals with neurological or musculoskeletal conditions.
b. Assistive exoskeletons: Intended to support mobility challenges for those with permanent disabilities or the elderly.
c. Performance-enhancing exoskeletons: Developed to enhance the physical capabilities of able-bodied individuals, often for military or industrial applications.

Joint-Specific Exoskeletons

Some exoskeletons focus on supporting specific lower limb joints:

a. Hip exoskeletons
b. Knee exoskeletons
c. Ankle exoskeletons
d. Multi-joint exoskeletons (supporting combinations of hip, knee, and ankle)

Soft Exoskeletons

This is a newer category of exoskeletons that use soft, flexible materials and actuation systems to provide assistance. They are generally lighter and more comfortable than rigid exoskeletons but offer less support for high-load applications [14].

Each type of exoskeleton has its own advantages and disadvantages, with the choice depending on factors such as intended application, user needs, energy requirements, and

cost. As technology advances, the boundaries between categories may blur, resulting in more versatile and adaptable exoskeleton designs.

1.1.2. Application Areas of Exoskeletons

Exoskeletons offer a wide range of applications across various fields, including healthcare, industry, defense, and assistive technologies.

Rehabilitation

In healthcare, exoskeletons play an increasingly important role in rehabilitation, particularly for individuals with mobility impairments due to spinal cord injuries, stroke, or neuromuscular disorders. They facilitate gait training, promote neuroplasticity, and improve functional outcomes by enabling individuals to stand, walk, and perform daily activities. Research has shown that exoskeleton-assisted gait training can improve mobility, muscle strength, and quality of life for individuals with neurological disabilities.

Assistive Exoskeletons

These are designed to support mobility challenges for those with permanent disabilities or the elderly [14].

Industrial Ergonomics

Exoskeletons are used in industrial environments to reduce physical strain, prevent injuries, and increase productivity of workers performing repetitive or physically demanding tasks. Passive exoskeletons provide mechanical support and a certain degree of relief to the musculoskeletal system, reducing fatigue and the risk of ergonomic injuries. These performance-enhancing exoskeletons were developed to enhance the physical capabilities of able-bodied individuals, often for military or industrial applications. They are particularly beneficial in sectors such as manufacturing, construction, and logistics, where workers are exposed to high physical demands and repetitive movements (Figure 4).

Figure 4: industrial exoskeleton [15]

Military and Defense Applications

In the military, exoskeletons are used to enhance soldier performance, increase endurance, and improve survival capabilities in challenging environments. Powered exoskeletons provide increased strength, agility, and load-bearing capacity for soldiers, enabling them to carry heavy loads over long distances and navigate uneven terrain more effectively. Additionally, exoskeletons equipped with sensors and communication systems can improve situational awareness and provide real-time feedback to users and commanders [16].

1.1.3. Benefits and Challenges of Exoskeletons

Exoskeletons offer numerous benefits across various fields, while also presenting challenges that need to be addressed for widespread application and effectiveness.

The following can be listed among the benefits:

Enhanced Physical Capabilities

Exoskeletons can increase human strength, endurance, and mobility, enabling individuals to perform tasks that would otherwise be physically strenuous or impossible.

Rehabilitation Assistance

In healthcare, exoskeletons facilitate gait training and rehabilitation for individuals with mobility impairments, contributing to improved functional outcomes and quality of life.

Injury Prevention

In industrial settings, exoskeletons reduce the risk of musculoskeletal injuries by offloading the body and promoting proper ergonomic positioning during repetitive tasks.

Increased Productivity

By reducing fatigue and physical strain, exoskeletons increase worker productivity and efficiency, resulting in improved performance.

Several challenges and issues to be resolved arise:

Cost and Accessibility

Exoskeletons can be expensive, limiting their access to individuals and organizations with fewer resources. Cost-effective design and favorable health insurance environments are among the potential solutions to this challenge.

Complexity and Usability

Effective operation of exoskeletons often requires specialized training and expertise, posing a challenge in terms of usability. Simplifying control interfaces and improving user experience are critical for widespread adoption.

Control and Adaptation

User feedback on control interfaces and interaction modes is essential for optimizing user experience and performance. Intuitive control schemes, feedback mechanisms, and customization options enhance user control and satisfaction with the device. Studies have

demonstrated the importance of user-centered design principles and iterative testing in refining control algorithms and interfaces to meet user needs and preferences [17].

Comfort and Fit

Comfort and proper fit are essential for user experience and long-term compliance. Exoskeletons must be ergonomically designed and adjustable to accommodate different body types and preferences [18].

Studies have shown that discomfort and pressure points can negatively impact user experience and adherence, highlighting the importance of ergonomic considerations in exoskeleton design. Key factors influencing comfort include:

- Weight distribution
- Adjustability for different body sizes
- Breathability of materials
- Pressure distribution at contact points [19]

Technological Limitations

The development of exoskeleton technology is constrained by limitations in power sources, energy efficiency, and durability. Overcoming these limitations requires advancements in materials science, robotics, and human-machine interfaces. Specific challenges include:

- Battery life and power-to-weight ratio
- Miniaturization of components
- Durability of materials under repeated use
- Efficient actuation systems

Addressing these challenges requires interdisciplinary collaboration, innovation, and stakeholder engagement to maximize the potential benefits of exoskeleton technology while mitigating risks and ensuring responsible use.

1.1.4. Regulatory and Ethical Considerations of Exoskeleton Technology

The development and application of exoskeleton technology raise important regulatory and ethical considerations that must be taken into account to ensure safety, effectiveness, and responsible use.

Regulatory Frameworks

Exoskeletons are subject to regulatory oversight to ensure their safety, efficacy, and compliance with standards. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) treat exoskeletons as medical devices. They regulate device classification, pre-market testing, labeling requirements, and post-market surveillance [20].

Safety and Risk Management

Ensuring the safety of exoskeleton users is paramount, necessitating rigorous risk assessment, hazard analysis, and mitigation strategies. Safety standards, such as ISO 13482 for assistive robots and ISO 60601 for medical electrical equipment, provide guidance for the design, testing, and validation of exoskeletons. Manufacturers and developers are responsible for identifying and addressing potential risks, including mechanical failures, software errors, ergonomic issues, and adverse events, to minimize the likelihood of harm to users [21].

Ethical Considerations

Ethical considerations related to exoskeletons include issues of autonomy, privacy, informed consent, equity, and social impact. Users must have autonomy to make informed decisions about exoskeleton use, including understanding the risks, benefits, and alternatives. Additionally, privacy concerns arise from the collection and use of user data by exoskeletons, necessitating transparent data management practices and safeguards against unauthorized access or misuse. Ensuring equitable access to exoskeleton technology is crucial for addressing healthcare disparities and promoting social justice. Addressing regulatory and ethical considerations requires collaboration among stakeholders, including regulatory authorities, industry, healthcare providers, researchers,

and advocacy groups. By integrating regulatory compliance, safety standards, and ethical principles into the design, development, and spread of exoskeletons, stakeholders can promote responsible innovation and maximize the potential benefits of this transformative technology.

1.1.5. Recent Developments in Exoskeleton Technology

Recent advancements in exoskeleton technology have pushed the field forward, enabling new capabilities and expanding the potential applications of these devices.

Soft Exoskeletons

Soft exoskeletons represent a recent innovation in the field, using flexible materials and textile-based actuators to provide assistance and support. Unlike traditional rigid exoskeletons, soft exoskeletons offer increased comfort, adaptability, and natural movement, making them suitable for a wider range of applications, including healthcare, industrial, and assistive technologies. These devices leverage advancements in materials science, biomechanics, and wearable technology to provide lightweight and user-friendly solutions for individuals with mobility impairments and workers in physically demanding environments (Figure 5) [22].

Figure 5: ReWalk ReStore soft exoskeleton [23]

Autonomous Control Systems, AI, and Neuroprosthetic Integration

Coser et al. present in their review work the commonly used algorithms for controlling robotic systems, such as control, gait pattern classification, motion-interaction sensing, and motion planning for robotic systems. Machine learning algorithms, artificial intelligence, and sensor fusion techniques enable exoskeletons to predict user intentions, optimize assistance levels, and adapt in real-time to changes in terrain or task requirements. Autonomous exoskeletons offer enhanced performance, safety, and usability, paving the way for more intuitive and natural interactions between humans and machines. It's important to highlight that the exoskeletons currently employed in clinical practice do not incorporate artificial intelligence algorithms, despite the scientific literature reviewed in this study demonstrating the potential of these methods to enhance robot-assisted gait. This suggests a gap between cutting-edge research and practical clinical applications in the field of robotic rehabilitation [24].

The integration of exoskeletons with neuroprosthetic devices and brain-computer interfaces is a cutting-edge area of research with transformative potential. Through direct interface with the nervous system, these integrated systems allow individuals with paralysis or limb loss to control exoskeletons using neural signals. Advancements in neural decoding algorithms, neural interface technologies, and neurorehabilitation protocols have facilitated progress in this field, leading to promising results in preclinical studies and early clinical trials [25].

Interdisciplinary approaches are fostering collaboration in areas such as robotics, neuroscience, and biomechanics. These recent developments underscore the evolving nature of exoskeleton technology.

1.1.6. The Future of Exoskeleton Technology

The future of exoskeleton technology holds promising advancements. Emerging trends and research directions are shaping the evolution of exoskeletons towards more capable, adaptable, and user-friendly systems.

Enhanced Intelligence and Adaptability

Future exoskeletons are expected to become more intelligent and adaptable to individual users' needs. This will involve:

- Advanced sensing technologies and gait analysis to better understand and respond to user movements and intentions
- More sophisticated learning algorithms for real-time reactions, providing personalized support for each user's unique gait patterns and rehabilitation needs
- Incorporation of artificial intelligence and machine learning to enhance the capabilities of these devices [26]

Improved Human-Robot Collaboration

The main focus will be on enhancing the interaction between the user and the exoskeleton, including:

- Development of more intuitive control systems and interfaces
- Advanced brain-computer interfaces or sophisticated biosensors for more accurate interpretation of user intentions
- Seamless integration with the user's natural movements

Increased Efficiency and Energy Management

Researchers are working on improving the energy efficiency and power consumption of exoskeletons:

- Development of more efficient energy management systems
- Use of lightweight materials to reduce overall device weight
- Advanced battery technology or alternative energy sources to extend operating times of powered exoskeletons [27]

Modular and Customizable Designs

Future exoskeletons may incorporate more modular structures, allowing for:

- Easier customization and adaptation to different user needs
- Creation of versatile devices that can be quickly adjusted or reconfigured for various purposes or users [28]

Enhanced Safety and Comfort

Improving the safety and comfort of exoskeletons will be a crucial trend, including:

- Development of better mechanisms for fall prevention
- Improved ergonomics and more user-friendly interfaces
- Focus on making exoskeletons easier to don and doff, and more comfortable for extended use [27]

Integration of Advanced Materials

The use of advanced materials, such as smart materials or lightweight composites, could revolutionize exoskeleton design, enabling:

- Creation of more flexible, durable, and lightweight devices
- Better mimicry of natural human movement [29]

Advanced Rehabilitation Monitoring and Evaluation

Future exoskeletons are likely to include more sophisticated systems for tracking and evaluating rehabilitation progress, such as:

- Integrated sensors and data analysis tools for detailed feedback on user progress
- Assistance for healthcare professionals in optimizing rehabilitation strategies [28]

In conclusion, the future of lower limb exoskeleton technology focuses on creating smarter, more efficient, and user-friendly devices that seamlessly integrate with the human body. These advancements aim to extend the application of exoskeletons beyond their current rehabilitation use, potentially transforming mobility assistance and human performance enhancement across various fields.

1.2. Spinal Cord Injury

The spinal cord is part of the central nervous system and serves as the main connection between the brain and the periphery it controls. It contains a large number of nerve cells (gray matter) that participate in motor, sensory, or autonomic functions. A significant portion of the spinal cord consists of nerve fibers (white matter), which can be ascending (sensory pathways) that transmit impulses from the periphery to the center, or descending

(motor pathways) that relay central commands to target organs. Nerves branching from the cervical region innervate the neck, upper limbs, and respiratory muscles; those from the thoracic region innervate the trunk; and those from the lumbar-sacral region innervate the lower limbs, bladder, rectum, and genitals.

The consequences of spinal cord injury depend on two factors: the extent of the injury and its spinal level. If the injury is complete, total paralysis and sensory loss are expected, which will not improve. If partial or affecting only certain cells or fibers, there is a chance for improvement. In such cases, the remaining nerve fibers and cells can take over some functions to a certain extent, and damaged but not dead structures can regain their original state and function. Rehabilitation can build on this process to a great extent. The level of the injury in the spinal cord is extremely important for the outcome due to the aforementioned anatomical relationships.

Paralysis resulting from spinal cord injury can sometimes be accompanied by painful muscle tension of a spastic nature. Sensory loss can alter the entire body schema, causing the patient to feel alienated from the insensitive body parts. Autonomic deficits can affect breathing, thermoregulation, sweating, elimination functions, bowel movements, and sexual activity.

1.2.1. Epidemiology of Spinal Cord Injury

Spinal cord injury (SCI) is a severe condition that results in significant physical, emotional, and socioeconomic burdens. Understanding the epidemiology of SCI is crucial for developing effective prevention strategies, improving treatment approaches, and appropriately allocating healthcare resources.

The epidemiology of SCI encompasses the study of its incidence, prevalence, and associated risk factors, supporting healthcare planning, injury prevention strategies, and the development of effective rehabilitation programs. SCI can result from traumatic or non-traumatic causes, leading to partial or complete loss of motor, sensory, and autonomic function below the level of injury.

Global Incidence and Prevalence

While 15% of the population is affected by disability, less than 0.1% of the population has a spinal cord injury. Global spinal cord injury cases saw a significant rise between 1990 and 2019. The estimated number of cases in 2019 reached 9 million, representing a 52.7% increase from 1990 figures. Despite this substantial growth in absolute numbers, the age-standardized incidence rate remained relatively constant for both males and females over this period. In 2019, this rate stood at 11.5 cases per 100,000 population. This data suggests that while the overall burden of spinal cord injuries has increased, possibly due to population growth and aging, the risk for an individual of a given age has not changed significantly since 1990. A study from April 2024 suggests that more than 15 million people are living with spinal cord injuries [30].

Global Burden of Disease Study

The 2019 Global Burden of Disease Study provides comprehensive global estimates for SCI burden:

- Incidence: Approximately 0.9 million new SCI cases worldwide in 2019
- Prevalence: About 20.6 million prevalent SCI cases globally
- Years Lived with Disability (YLD): SCI accounted for 6.2 million YLDs

The study highlighted the relationship between SCI burden and the Socio-demographic Index (SDI). Regions with lower SDI generally have higher rates of SCI and associated disability, underscoring the importance of socioeconomic factors in SCI risk and outcomes [31].

Age and Gender Distribution

SCI disproportionately affects different age groups and genders:

- Gender: Most studies consistently show higher SCI incidence in males compared to females
- Age: The age distribution of SCI varies by etiology:
    - Traumatic SCI (TSCI) more commonly affects younger adults, with peak incidence often in the 20-29 age group
    - Non-traumatic SCI (NTSCI) is more common in older adults, with increasing frequency among those over 50

- Participants over 50 were more likely to suffer incomplete SCI and central cord syndrome

Temporal Trends and Seasonal Patterns

Ding et al.'s study revealed important trends in age-standardized rates: age-standardized prevalence rate slightly increased, age-standardized incidence rate decreased, and age-standardized YLD rate decreased [31]. These trends suggest that while the overall burden of SCI is increasing due to population growth and aging, the risk of new injuries may be slightly decreasing when adjusted for age.

Ugiliweneza et al.'s study identified temporal patterns in SCI occurrence:

1. Day of the week: More SCIs occur on weekends, likely due to increased recreational activities and alcohol consumption
2. Seasonal variation: SCI incidence often increases in warmer months, particularly for motorcycle and diving-related injuries
3. Time of day:
    - Falls peaked during the 6:00-12:00 period
    - Sports and recreational accidents, as well as drug abuse histories, were associated with injuries peaking during the 18:00-24:00 period [32]

These temporal patterns provide valuable insights for targeting prevention efforts and allocating emergency resources.

1.2.2. Etiology and Demographic Factors of Spinal Cord Injury

In low and middle-income countries, factors such as road traffic accidents, falls from heights, and interpersonal violence significantly contribute to the burden of SCI. In high-income countries, sports-related injuries, medical/surgical complications, and lifestyle factors may also play a role [33].

Traumatic vs. Non-Traumatic Spinal Cord Injury

Spinal cord injuries are generally categorized as either traumatic (TSCI) or non-

traumatic (NTSCI). The distribution between these two categories varies by region and over time.

Traumatic Spinal Cord Injury

TSCI remains a significant cause of disability worldwide, with its distribution varying by region (Figure 6). Common causes of TSCI include:

1. Traffic accidents: Often the leading cause, especially in younger age groups.
2. Falls: Increasingly common, particularly among older adults.
3. Violence: Including gunshot wounds, which are more prevalent in certain regions.
4. Sports and recreational activities

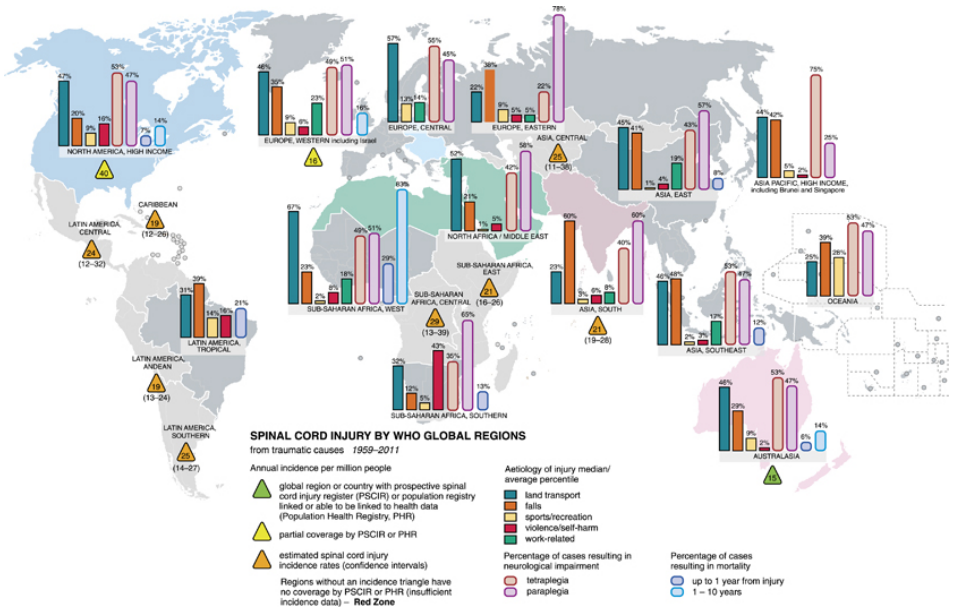


Figure 6: Incidence and causes of TSCI by region [34]

Middle East and North Africa:

The annual incidence of TSCI: 23.24 per million population. Demographic data shows: 77% male, most commonly affecting the 20-29 age group [33].

Europe:

European TSCI demographic data provides significant insight into the characteristics and trends associated with this condition. Regarding age and gender distribution, Amidei et al.'s study reported that TSCI incidence is higher in males than females, with

a male-to-female ratio of about 3:1. The average age at injury has increased, indicating that more older adults are experiencing TSCI.

In Europe, leading causes of TSCI include falls, especially among older adults, and road traffic accidents, which are more common among younger individuals. Cervical injuries are the most frequent, followed by thoracic and lumbar injuries. Incomplete injuries occur more often than complete injuries [35].

North America:

North American traumatic spinal cord injury demographic data reveals important trends and characteristics. Based on two key references, here are the essential findings: In a study on spinal cord injury registry by the North American Clinical Trials Network, Vedantam et al. found: Regarding age trends, the age of TSCI patients significantly increased over time. Concerning injury mechanism, falls became the primary cause of injuries, especially among older adults (over 50), who were more likely to suffer incomplete SCI. There was a statistically significant increase in cardiac complications and a decrease in pulmonary complications during the study period [36].

Hungary:

In Hungary, the case number falls between the prevalence values of the United States and Western Europe. It primarily affects males, and there is a bimodal distribution regarding age groups: one peak is between 15-29 years, while the other prominent age group is found in those over 50 years old [37].

Non-Traumatic Spinal Cord Injury (NTSCI):

The epidemiology of NTSCI also reveals important trends and characteristics in various populations (Figure 7).

The most common causes of NTSCI include:

1. Degenerative spine diseases
2. Neoplasms (tumors)
3. Vascular disorders
4. Infections
5. Autoimmune diseases

These non-traumatic causes generally result in paraplegia rather than tetraplegia. Regarding the level of injury, patients with NTSCI predominantly present with paraplegia, which usually arises from the aforementioned non-traumatic causes [38].

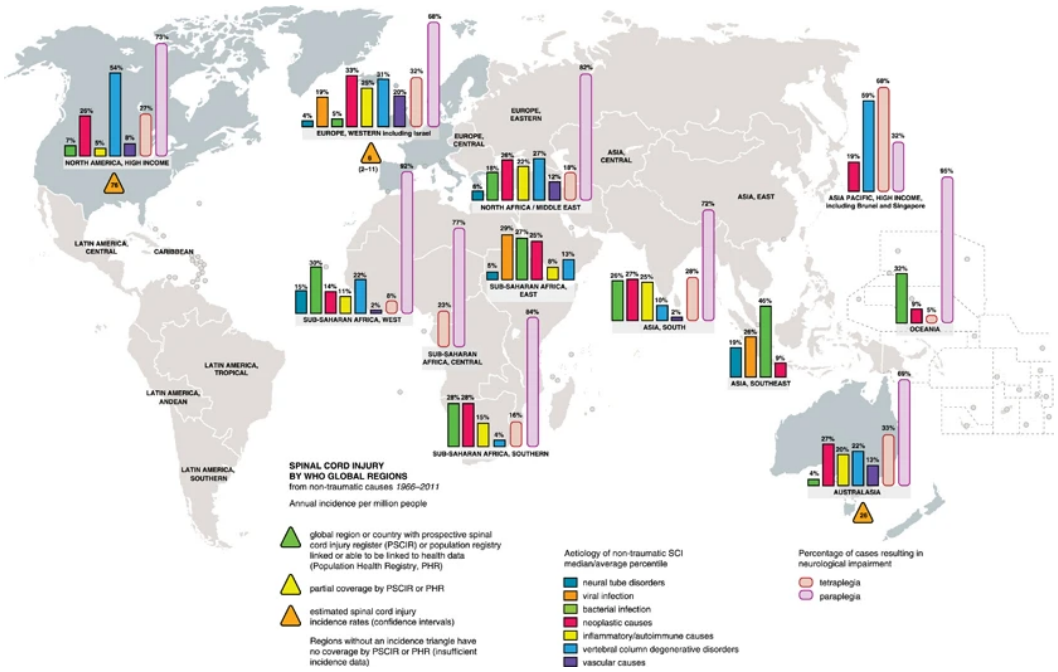


Figure 7: Incidence and Causes of NTSCI by Region [39]

NTSCI more frequently causes incomplete injuries, is often associated with more comorbidities, and patients in this group are generally older than TSCI patients. In Alberta, Canada, NTSCI patients were approximately 10 years older than TSCI patients, with an average age of 54.5 years. The 1-year mortality rate for NTSCI was about 2.4 times higher than for TSCI [40].

Incidence and Prevalence

New et al.'s study aimed to create global maps of NTSCI epidemiology, highlighting the need for a living data repository to better understand the worldwide distribution and trends of NTSCI [41].

Choi et al., analyzing data from South Korea, found that the incidence of NTSCI has been growing faster than that of TSCI in recent years. By 2020, NTSCI surpassed TSCI in incidence, especially among older individuals, with the gender gap being less pronounced in NTSCI [38].

These epidemiological findings highlight the growing importance of NTSCI as a public health issue, particularly among aging populations. A Hungarian-language publication has been released on the potential applications of exoskeletons for the older NTSCI population [42]. The increasing incidence of NTSCI relative to TSCI in some regions points to the need for targeted interventions, prevention strategies, and health planning to address the unique challenges posed by non-traumatic spinal cord injuries.

Regional Variations

The global incidence of SCI varies significantly across different regions and countries. A systematic review examining studies published between 1950 and 2012 found that:

- The global incidence of SCI ranged from 8.0 to 246.0 cases per million population annually.
- The global prevalence ranged from 236.0 to 1,298.0 per million population [43].

These wide ranges highlight the significant regional differences in SCI epidemiology, which can be attributed to variations in healthcare systems, reporting methods, and risk factors across different countries.

1.2.3. Complications and Comorbidities Associated with Spinal Cord Injury

Several secondary complications are associated with SCI that can significantly impact quality of life and long-term outcomes:

1. Chronic pain: Affects a large proportion of SCI patients, including neuropathic, musculoskeletal, and visceral pain types [44].
2. Cardiovascular complications: SCI patients are at increased risk of cardiovascular disease due to reduced physical activity and autonomic dysfunction.
3. Respiratory complications: Especially common in higher-level injuries, leading to increased morbidity and mortality.
4. Urogenital complications: Most common are urinary tract infections, bladder dysfunction and consequent kidney problems, as well as sexual function disorders.
5. Pressure ulcers (decubitus): A common and potentially serious complication due to sensory impairment, especially in patients with reduced mobility.

6. Spasticity: Affects a large proportion of SCI patients, impacting function and quality of life.
7. Osteoporosis and fractures: Due to inactivity of paralyzed body parts, weight loss, and hormonal changes.
8. Psychiatric disorders: Including depression and anxiety, which can significantly affect rehabilitation and long-term outcomes.

Severity and neurological level of injury significantly influence prognosis and functional outcomes in SCI.

Mortality:

SCI carries an increased risk of mortality, especially in the acute phase and with more severe injuries. A 70-year British study on causes of death after traumatic SCI found:

- Life expectancy improved over time but remains below that of the general population.
- Leading causes of death have shifted from kidney failure and other SCI-specific complications to cardiovascular diseases and cancers, more closely reflecting the general population [45].

Treatment and Management Trends:

SCI treatment has evolved significantly over time, showing trends towards earlier interventions and more comprehensive rehabilitation:

1. Surgical timing: Trending towards earlier surgical intervention when indicated.
2. Rehabilitation: Comprehensive, multidisciplinary rehabilitation remains the cornerstone of SCI management. Setting realistic goals in rehabilitation is crucial for improving outcomes.
3. Neuroprotective strategies: Research continues in pharmacological and other interventions to limit secondary injury and promote neurological recovery.
4. Assistive technologies: Advancements in assistive devices and technologies are improving functional outcomes and quality of life for SCI patients [46].

1.2.4. Quality of Life and Long-Term Outcomes of Individuals with Spinal Cord Injury

The quality of life for individuals with spinal cord injury is influenced by a complex interaction of physical, psychological, and social factors. The level and severity of injury significantly impact quality of life and long-term outcomes. Individuals with complete injuries at higher spinal cord levels often experience more severe motor and sensory function impairments and greater limitations in daily activities compared to those with partial or lower-level injuries. Research has identified several key areas that significantly influence quality of life in this population:

Secondary Health Conditions:

Secondary health conditions are prevalent among individuals with long-term SCI and can significantly impact quality of life. Adriaansen et al. found that the most common conditions include musculoskeletal pain (63.5%), edema (38.7%), neuropathic pain (34.1%), and urinary tract infections (33.3%) [47].

Pain Management:

Pain is a significant factor affecting quality of life in individuals with SCI. Koukoulithras et al., analyzing 57 previous studies, examined various interventions for pain relief in SCI patients. The study found that gabapentin and pregabalin effectively treat chronic neuropathic pain, with pregabalin also beneficial in reducing anxiety and sleep disorders [48].

Psychosocial Factors:

Psychosocial factors, such as social support, coping strategies, and mental health, play a significant role in determining quality of life and long-term outcomes. Social support networks, including family, friends, and peer support groups, can provide emotional support, practical assistance, and opportunities for social engagement, which are essential for maintaining well-being and quality of life. Additionally, addressing psychological issues such as depression, anxiety, and adjustment disorders is crucial for promoting mental health and overall quality of life among individuals with SCI [49].

Health Behavior and Social Support:

Multidisciplinary rehabilitation programs addressing physical, psychological, and social needs can help individuals maximize their independence, function, and participation in daily activities. However, disparities exist in access to healthcare and rehabilitation services, particularly in low- and middle-income countries, leading to differences in outcomes among individuals with SCI [50].

Community Integration and Participation:

Community integration and participation are key indicators of quality of life and long-term outcomes for individuals with SCI. Accessible environments, transportation, housing, and employment opportunities are essential for promoting independence, social inclusion, and engagement in meaningful activities within the community. However, barriers to community integration, such as architectural obstacles, discrimination, and lack of accessibility, continue to pose challenges for individuals affected by SCI [51].

Successful reintegration is facilitated by family support, financial stability, religious practices, and participation in leisure activities [52]. Comprehensive rehabilitation programs addressing both physical and psychological aspects of recovery are crucial [53]. Occupational therapy and independent living programs can expand knowledge of community resources and prepare patients for return.

Transportation and mobility issues pose significant challenges for SCI patients. Employment and economic barriers also hinder successful reintegration.

Addressing these challenges requires a multifaceted approach involving all stakeholders, including implementing disability policies, addressing training gaps, promoting research programs, and equipping rehabilitation centers with specialized spinal units.

1.2.5. The Global Burden of Spinal Cord Injuries

The global burden of spinal cord injury encompasses various aspects, including incidence, prevalence, mortality, disability-adjusted life years (DALYs), and economic

costs. DALYs measure the total burden of disease, combining years of life lost due to premature mortality and years lived with disability. SCI significantly contributes to the global disease burden, causing a substantial number of DALYs lost annually. The physical, psychological, and socioeconomic consequences of SCI contribute to the considerable burden on individuals and society. According to the Global Burden of Disease Study 2019:

- In 2019, there were approximately 20.6 million people worldwide living with SCI.
- The global incidence of SCI was about 0.9 million new cases in 2019.
- SCI accounted for an estimated 6.2 million years lived with disability (YLDs) globally.

While the age-standardized rates of SCI incidence, prevalence, and YLDs showed only small changes, the absolute numbers increased significantly between 1990 and 2019:

- Global prevalence of SCI increased by 81.5%
- Global incidence of SCI increased by 52.7%
- Global YLDs due to SCI increased by 65.4%

These trends highlight the growing global burden of SCI, despite relatively stable age-standardized rates, emphasizing the need for improved prevention and management strategies worldwide (Figure 8) [54, 55].

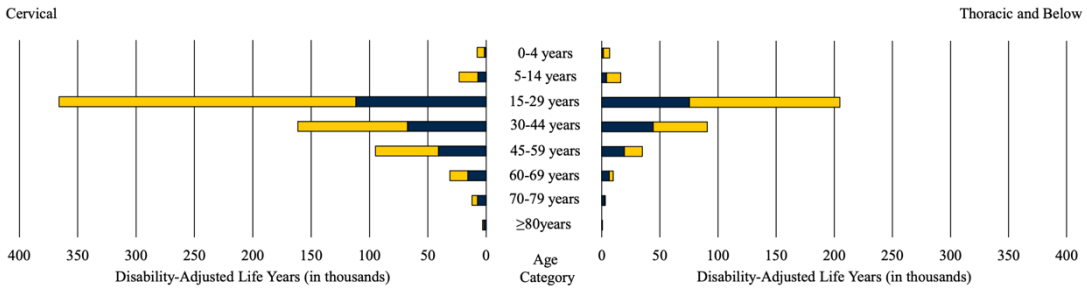


Figure 8: DALY Values for TSCI Cases: Blue bars: Years of life lost, Yellow bars: Years lost due to disability [55]

Economic Costs:

Spinal cord injury imposes significant economic costs on healthcare systems, individuals, and society as a whole. Direct medical costs include expenses related to acute care, rehabilitation, assistive devices, and long-term health needs. Indirect costs, such as lost productivity, unemployment, and caregiver burdens, further increase the economic

impact of SCI. The financial implications of SCI underscore the importance of prevention, early intervention, and comprehensive rehabilitation services.

A study examining the relationship between secondary health conditions, healthcare costs, and quality of life found that individuals who reported unmet healthcare needs had more secondary health conditions and higher healthcare costs, highlighting the economic burden of SCI and its impact on quality of life [56].

Health Inequalities:

Disparities in access to healthcare services and resources contribute to differences in SCI outcomes between high-income and low- and middle-income countries. In many resource-limited settings, individuals with SCI face challenges in accessing timely medical care, rehabilitation services, and assistive technologies, leading to poorer outcomes and reduced quality of life.

Addressing the global burden of SCI requires a multifaceted approach that includes prevention strategies, improvements in acute and long-term care, increased access to rehabilitation services, and efforts to reduce health disparities.

1.2.6. Prevention of Spinal Cord Injury, Preventive Strategies

Given the significant personal and societal impacts of SCI, prevention remains crucial. Key strategies include:

1. Road traffic safety initiatives: Including improved traffic laws, vehicle safety standards, and public education campaigns.
2. Fall prevention programs: Particularly important for older adults, including home safety assessments and balance training.
3. Sports safety measures: Proper equipment, rule changes in high-risk sports, and education on safe practices.
4. Violence prevention: Including firearm measures and community-based violence reduction programs.
5. Workplace safety: Implementation and enforcement of occupational safety standards, especially in high-risk industries.

6. Public education: Raising awareness about SCI risks and prevention strategies across all age groups.

Future Directions and Research Needs:

Despite significant progress in understanding SCI epidemiology, several areas require further research:

1. Improved global data: More comprehensive and standardized data collection across regions for better understanding of global SCI patterns.
2. NTSCI epidemiology: Further studies on incidence, prevalence, and risk factors of non-traumatic SCI, which is becoming increasingly important.
3. Long-term outcomes: Longitudinal studies to better understand the long-term trajectory of SCI patients, including aging with SCI.
4. Health disparities: Research on the impact of socioeconomic factors on SCI risk, treatment, and outcomes.
5. Prevention effectiveness: Evaluation of various prevention strategies to identify the most effective approaches for different populations.
6. Emerging treatments: Ongoing research into new therapeutic approaches, including stem cell therapies, neuroprosthetics, and neuromodulation.

The epidemiology of spinal cord injury is complex and dynamic, with significant variations across regions, age groups, and time. While the overall burden of SCI remains substantial, there are encouraging trends in some areas, including slight decreases in age-standardized incidence rates and improvements in treatment and outcomes. Key findings include:

1. Global prevalence of SCI is increasing, largely due to population growth and aging, despite slight decreases in age-standardized incidence rates.
2. Many regions are experiencing a shift towards older age at injury and an increasing proportion of incomplete injuries.
3. Falls are becoming an increasingly important cause of SCI, especially in older adults, while traffic accidents remain significant causes in younger age groups.
4. Non-traumatic SCI is increasingly recognized as a significant contributor to the overall SCI burden and is growing in incidence in some regions.

5. Modern care management trends include earlier surgical intervention and a focus on comprehensive, goal-oriented rehabilitation.
6. Prevention strategies remain crucial, with targeted approaches needed to address changing demographics and causes of SCI.

Understanding these epidemiological trends is essential for health planning, resource allocation, and developing effective prevention and treatment strategies. As the global population continues to age and healthcare systems evolve, ongoing research and surveillance will be crucial in addressing the changing landscape of spinal cord injuries.

1.3. Research Conducted with Exoskeletons, Research Directions

In recent years, an increasing number of publications have appeared examining the effects of exoskeleton gait training on patients with spinal cord injuries. Most studies follow changes in individual physiological functions, with few researches investigating the simultaneous changes in multiple physiological parameters and quality of life indicators. Below, I present international research findings related to the physiological parameters we also examined.

Regarding **bone density**, Karelis and colleagues studied the effects of exoskeleton gait training on body composition and bone thickness in individuals with spinal cord injuries. Participants completed a personalized 6-week program, three times a week, for up to 60 minutes. After the intervention, a significant increase was observed in the lean body mass of the lower limbs, as well as a segmental decrease in lower limb fat mass. A 14.5% increase in tibial bone thickness was observed. They concluded that exoskeleton gait training is associated with improvements in body composition and potentially bone health [57]. Xiang and colleagues examined the physiological effects of exoskeleton gait training in 40 participants but found no change in bone density between pre- and post-study conditions and the control group [58].

Examining the impact on **body composition**, numerous studies suggest that exercise programs using exoskeletons effectively prevent continuous muscle loss in patients with

SCI and reduce body fat to maintain health [59]. Rigoli and colleagues conducted a comprehensive study examining the effects of exoskeleton gait training on energy expenditure and body composition in SCI patients. Summarizing the results of ten studies, they found that robotic exoskeleton training did not significantly change energy expenditure compared to other therapies. They observed significant changes in body composition data, especially in fat mass reduction, but also pointed out the poor quality of the studies examined and the methodological and therapeutic differences [60]. Asselin and colleagues investigated the effects of exoskeleton-assisted gait training on soft tissues and body composition in individuals with spinal cord injury. They studied eight patients who used the robotic device 40 times. The participants experienced a significant reduction in body fat. Six out of the eight participants lost visceral fat tissue, while the group's lean mass did not change significantly. In conclusion, they reported that regular and sustained use of powered exoskeletons in patients with SCI may reduce fat mass, which could indicate an improvement in overall health status [61].
These studies indicate that lower limb exoskeleton gait training is associated with improved body composition, including increased lean mass, decreased fat mass, and potential improvement in bone health of individuals with SCI. These changes could have a significant impact on the overall health and quality of life of SCI patients.

Chun and colleagues monitored **gastrointestinal changes** in their study. They examined the changes in gastrointestinal functions during exoskeleton gait training in ten SCI patients over a 12-14 week period. Their results showed that at least 50% of participants reported improvements in bowel function and overall gastrointestinal function. 80% of the subjects reported improved stool consistency, while one out of ten indicated deterioration in bowel function after the training sessions [62]. Hu and colleagues demonstrated in their research that exoskeleton gait training can improve bowel function in patients with spinal cord injury. According to the results, five participants from the experimental group and three from the control group reported improvement in at least one bowel-related indicator, including increased frequency of bowel movements, decreased daily time spent on bowel management, and reduced need for external assistance. Their study suggested that exoskeleton gait training may moderately improve bowel function

in SCI patients and is associated with changes in gut flora abundance, particularly an increase in beneficial bacteria [63].
Gorman and colleagues' research found that the effects may vary depending on factors such as gender, completeness of injury, and time since injury. They showed that individuals with complete injuries may experience greater improvement in stool consistency [64].
Additional studies are required to gain a deeper understanding of the mechanisms driving these changes and to validate the long-term impact of exoskeleton use on gastrointestinal function in patients with spinal cord injuries.

Williams and colleagues documented **urogenital changes** in a study involving six SCI patients using Ekso and Lokomat exoskeletons. They found that pelvic floor muscle activity was higher in the Ekso group; however, there were no clear changes in lower urinary tract functions in either group. This experimental work demonstrated the feasibility of an exoskeleton gait training program targeting lower urinary tract functions. Training with the Ekso device activated pelvic floor muscles, but it remains unclear how musculoskeletal training affects lower urinary tract function [65].
In summary, while exoskeleton training shows promise for improving urogenital functions in SCI patients - particularly in activating pelvic floor muscles and increasing satisfaction with bladder management - the direct impact on lower urinary tract function remains unclear. Larger, controlled studies are needed to establish definitive benefits and understand the underlying mechanisms.

Ilse J.W. van Nes and colleagues conducted **quality of life (QoL) assessments** in a study involving 21 participants. They examined QoL changes after an eight-week, 24-session robotic exoskeleton training program within a homogeneous group of SCI patients. Following the training period, participants experienced a notable enhancement in their quality of life (QoL). The Short Form-36 with Walk Wheel (SF-36ww) assessment revealed improvements across several subdomains, including reduced pain, better social engagement, enhanced mental well-being, and a more positive overall health perception. Patients reported greater satisfaction with their bladder management; however, their contentment with bowel function remained constant. The researchers concluded that even

for patients with relatively high baseline QoL, short-term exoskeleton training improved their QoL, reduced pain, and increased satisfaction with bladder management. However, they emphasized that these findings require further controlled studies in SCI populations [66].

Baunsgaard and colleagues used the **SCIM (Spinal Cord Independence Measure) questionnaire** to evaluate changes in pain, spasticity, range of motion, daily activities, bowel and lower urinary tract function, and QoL after robotic exoskeleton gait training. Fifty-two participants underwent three training sessions per week for eight weeks using the Ekso GT exoskeleton (Ekso Bionics). Results showed:

- SCIM III scores increased from 73 to 74 among participants over eight weeks.
- Recently injured participants increased their SCIM III scores from 62 to 70 but showed no significant changes in life satisfaction.
- Range of motion, bowel function, and lower urinary tract function did not change over time.
- Training did not induce new pain; spasticity decreased after a single session.

The researchers concluded that SCIM III scores and QoL longitudinally improved in participant subgroups [67].

While studies indicate improvements in functional independence and QoL for SCI patients using exoskeletons, no specific information is available on changes in the Barthel Index for this population. Future research using the Barthel Index as an outcome measure could provide more direct evidence of changes in daily activities among SCI patients using exoskeletons. Further research is needed to confirm these findings across larger samples and diverse injury levels to better understand the long-term effects of exoskeleton training on urogenital functions, QoL, and functional independence in SCI patients.

Xiang and colleagues also monitored changes in **trunk control and balance**. Their study summary mentions the use of a trunk control test during exoskeleton gait training for SCI patients, though their publication has not yet undergone peer review. Their objectives included examining changes in respiratory function, motor function, walking, and activities of daily living during exoskeleton training for SCI patients, compared to traditional exercise programs. The experimental and control groups participated in 16

training sessions of 50-60 minutes, four times a week for four weeks. Participants in the experimental group received exoskeleton gait training, which assisted with standing, walking, and stair climbing. Their results indicate that forced expiratory vital capacity improved in the experimental group, but they found no differences in the trunk control test, muscle tone, or bone density [68].

More targeted research is needed to determine how exoskeleton training directly affects Trunk Control Test performance in SCI patients.

Raab and colleagues conducted a case study to investigate how exoskeleton training can influence the quality of life of patients with spinal cord injuries. They documented the progress of the first six months of ReWalk training, using the SF-36 questionnaire as the primary outcome measure for quality of life. Secondary outcome measures included the ASIA scale (American Spinal Injury Association Impairment Scale), Berg Balance Scale, and Dynamic Gait Index. By the end of the study period, improvements were observed in quality of life, mobility, fall risk, motor skills, and control of bladder and bowel functions. They demonstrated the positive impact of robot-assisted gait training on various aspects of quality of life. Future studies should aim to validate this effect on a larger number of patients and at different injury levels [69].

Maggio and colleagues tracked **changes in mood**, among other factors. Patients with spinal cord injuries often complain about changes in body representation, which can lead to potentially negative physical and psychological consequences. Their study aimed to evaluate the effect of Ekso-GT exoskeleton gait training on body representation and quality of life. The research involved 42 SCI inpatients, randomized into control and experimental groups. The modified Body Uneasiness Test (MBUT) was considered the primary outcome measure, while the Short-Form-12 Health Status Questionnaire (SF-12) and Beck Depression Inventory (BDI-SF) were used as secondary measures to assess the training's impact on quality of life and psychological state. Nonparametric statistical analysis showed significant differences between the two groups, with patients in the experimental group achieving significant improvements in almost all test scores compared to the control group. Their data suggested that Ekso-GT training could be beneficial in achieving positive changes in body representation for patients with SCI [70].

Holanda and colleagues conducted a systematic review of 2941 articles with the aim of comparing robotic gait devices and systematizing the scientific evidence for these devices as a tool for rehabilitation of individuals with SCI. The studies showed promising results in reducing pain perception and spasticity, changes in proprioceptive capacity, reflex behavior, and electrical activity at the muscular and cortical levels. They documented increases in gait speed, step length, and distance covered, as well as improvements in bowel, cardiovascular, respiratory, metabolic, and psychological functions [71].

Summary of Research Findings

The research suggests that lower limb exoskeleton gait training in SCI patients is associated with improvements in body composition and potentially bone metabolism. Changes in urogenital functions are promising, particularly regarding patient satisfaction with bladder management and activation of pelvic floor muscles. Numerous studies show improvements in functional independence and quality of life, but there is no specific information on changes in the Barthel Index for SCI patients using exoskeletons. Future research using the Barthel Index as an outcome measure could provide more direct evidence of changes in daily activities for SCI patients using exoskeletons.
Larger, controlled studies are needed to determine definitive and clinically significant benefits and to understand the underlying mechanisms. These changes could have a significant impact on the overall health status and quality of life of SCI patients.

2. Objectives

The University of Pécs (PTE) won a European Union grant in 2018 (GINOP-2.3.3-15-2016-00032, titled "Neurorehabilitation and Human-Machine Interface Research Center"), which enabled the acquisition of two ReWalk 6.0 lower extremity exoskeletons (LEE) and the establishment of a research project in collaboration with Semmelweis University's Department of Rehabilitation (SE-RK, formerly OMINT-OORI).

In January 2020, the National Institute of Pharmacy and Nutrition (OGYÉI) approved and registered the non-interventional study titled "Multicenter clinical study on the role of ReWalk lower extremity human exoskeleton in rehabilitation" under case number OGYÉI/1271/2020 [Appendix 1].

In December 2019, official training by the ReWalk company took place at SE-RK. Nine physical therapists and five doctors participated and received certification to operate and use the ReWalk 6.0 lower extremity exoskeleton.

The study, originally scheduled to begin in spring 2020, selected six patients from the SE-RK spinal cord injury patient database, with a 3-person experimental group and a 3-person control group. The control group consists of individuals from the same patient population who also meet the inclusion criteria but receive only standard rehabilitation. However, due to the first wave of the COVID-19 pandemic affecting Hungary, the study had to be postponed in spring 2020. Due to continuously changing medical protocols related to the pandemic, the study could not continue in autumn 2020, and the outpatient visits of the 6 enrolled participants could not be fully realized.

During this period, we had the opportunity to use the device with two hospitalized spinal cord injury patients [72].

The approved research began in September 2021 with two previously enrolled male partners. Due to participants' health issues and repeated pandemic measures, the study had to be halted in January 2022. Finally, the research restarted in May 2023 with two participants.

The University of Pécs had already used the device for gait training with an SCI patient before the study began, but ultimately no patients from this institution were included in the study. Therefore, our work exclusively presents case studies of two individuals with SCI at SE-RK, with whom we were able to start the study in spring 2023.

The primary aim of the research was to evaluate the effects of high-intensity gait therapy using a lower extremity exoskeleton on certain functional and physiological parameters in spinal cord injury patients.

Our hypothesis is that high-intensity gait training can prevent or reduce the inactive lifestyle resulting from spinal cord injury and the development of associated complications. The training may have a significant impact on mental state and quality of life, and with the use of the exoskeleton, those suffering from spinal cord paraplegia may develop a more independent and active lifestyle. Our research focuses on the effects of robot therapy with lower extremity exoskeletons on bone density, body composition, gastrointestinal tract, urogenital tract, mental state, and quality of life.

The resulting data may allow for the examination of financing possibilities for the domestic spread and adaptation of the device and technology in practical, rehabilitation, and research areas.

3. Methods

To achieve the research objectives, the research teams from the University of Pécs (PTE) and Semmelweis University's Department of Rehabilitation (SE-RK) developed a protocol for a prospective, controlled study, taking into account the criteria set by the ReWalk exoskeleton manufacturer. According to the original protocol, the research was conducted over a six-month period, comparing the results with patients who received traditional rehabilitation.

3.1. Test Methods

During the study, we recorded and monitored the following functional and physiological parameters (Table 1).

Table 1.

Parameter to be examined	**Examination tool, method**
Bone density	DEXA examination
Effects on body composition	Impedance analysis
Gastrointestinal and urogenital changes	Abdominal ultrasound, urodynamic examination, defecation parameters
General well-being, quality of life	Questionnaires

Bone Density

The parameters included DEXA scanning for bone density determination, which was also a criterion in the inclusion period. DEXA measurements were performed by Prof. Dr. Csaba Horváth and colleagues at the Department of Internal Medicine and Oncology, Faculty of General Medicine, Semmelweis University. DEXA stands for "dual-energy X-ray absorptiometry", a medical imaging test that uses low-level X-rays to measure bone density. According to medical science, this is the fastest and most useful examination method for diagnosing osteoporosis, and its great advantage is that it is painless [73]. During the DEXA examination, in addition to the bone density index, lateral vertebral

assessment (LVA morphometry) was also performed. LVA is a low-dose lateral X-ray of the spine using a DEXA scanner, which can detect previous moderate and severe vertebral fractures. Trend calculations and graphs were created from the measured data.

Body Composition

Changes in body composition were monitored using bioimpedance measurements with a mobile impedance analyzer suitable for use in a lying position. The measurements were performed by dietitians at SE-RK. To improve the accuracy of the bioelectrical impedance analysis (BIA) scale, the institute's dietitians advised participants to arrive fasting on the day of measurement. Measurements were taken in a lying position starting at 8 AM.

BIA is a technique for determining body composition. It is painless and measures the speed at which a low-level electrical current passes through the body. Different body tissues allow electrical currents to move at different speeds. Adipose tissue has a higher resistance (impedance) than muscle tissue or water in the body. Therefore, higher resistance indicates a higher body fat percentage. Most BIA scales estimate total fat, muscle, water, and bone mass and percentage based on this ratio. Other data such as height, gender, and body weight are also used to calculate the results, which are necessary to determine body fat percentage.

According to numerous studies, exercise programs using exoskeletons effectively prevent continuous muscle loss in patients with SCI and reduce body fat to maintain health.

Gastrointestinal and Urogenital Functions

To analyze gastrointestinal and urogenital functions, we performed urodynamic examinations and questionnaire surveys. For stool type, the Bristol Stool Form Scale was used, where the person filling out the form must choose from seven different stool types (Figure 9).

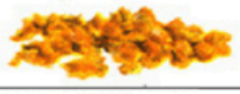
Types	Pictures	Description
Type 1		Separate hard lump, like nuts
Type 2		Sausage-shaped But Lumpy
Type 3		Like sausage but with cracks on its surface
Type 4		Like sausage & Snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passes easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, No solid pieces

Figure 9: Bristol stool form scale [74]

The urodynamic examination was conducted at SE-RK, where participants were required to have a negative urine bacteriological sample beforehand, confirming the absence of infection.

Urodynamic testing is a diagnostic procedure that evaluates the function of the lower urinary tract, including the bladder, sphincters, and urethra, in relation to urine storage and voiding. These tests focus on the bladder's ability to store and empty urine, as well as monitoring bladder contractions [75].

Data on general well-being and quality of life were recorded using the following questionnaires:

WHOQOL-BREF – World Health Organisation Quality of Life

The WHOQOL-BREF is a 26-item version of the WHOQOL-100 questionnaire, assessing the quality of life, health, and well-being of both ill and healthy individuals, as well as healthcare professionals. Each item is scored from 1 to 5 on a response scale, then converted to a 0-100 scale. A score of 0 indicates the worst possible health state, while 100 indicates the best possible health state in that area. The patients' physical, psychological, social, and environmental health states are evaluated separately [76].

36-Item Short Form Survey (SF-36)

The SF-36 is a widely used self-report health measure originally developed as a tool for assessing quality of life in the Medical Outcomes Study. It consists of 36 questions covering eight health domains [77, 78]. Scores for each domain range from 0 to 100, with higher scores indicating better health. The overall score provides a general measure of quality of life (QoL), from low to high. The total score can be divided into a physical component summary and a mental component summary. Research suggests that interpreting SF-36 scores can be challenging, and this should be done in relation to the overall score or profile [79]. According to Lins and colleagues, the SF-36 cannot be used as a single indicator of general health-related QoL, as it measures two dimensions: physical and mental [80].

Trunk Control Test (TCT)

The Trunk Control Test is primarily used to evaluate trunk movement in patients with neurological conditions. The test is performed on a bed and consists of four tasks: rolling to the weaker side, rolling to the stronger side, maintaining balance in a sitting position on the edge of the bed with neither foot touching the ground for at least 30 seconds, and sitting up from a lying position. The TCT score is determined by adding the scores from the four tasks (between 0 and 100) [81].

Spinal Cord Independence Measure (SCIM)

The SCIM aims to assess the functionality of spinal cord injury patients in three specific areas: self-care, respiration and sphincter management, and mobility. Scores range from 0 to 100, where 0 indicates total dependence and 100 indicates complete independence [82]. The SCIM questionnaire has not been officially validated in Hungarian. The adaptation to Hungarian was done through an unofficial translation, and the translated questions were read aloud to the participants [Appendix 2]. The scores range from 0 to 100, where 0 indicates total dependence and 100 indicates complete independence. The SCIM can also help clinicians determine treatment goals and objectives for patients with SCI [82].

Barthel Index for Activities of Daily Living

The Barthel Index is a scale applicable to activities of daily living (ADL) that measures a person's ability to perform everyday activities [83]. The guidelines for interpreting Barthel scores are as follows:

- Scores from 0 to 20 indicate "total" dependence
- Scores from 21 to 60 indicate "severe" dependence
- Scores from 61 to 90 indicate "moderate" dependence
- Scores from 91 to 99 indicate "slight" dependence

A score of 100 indicates complete independence. Lower scores reflect increasing dependence on support needed to carry out activities of daily living. Scores between 100 and 60 indicate mild dependence or need for assistance, between 55 and 40 indicate moderate dependence, between 35 and 20 indicate severe dependence, and scores below 20 indicate that the subject requires total care [84].

Berg Balance Scale (BBS)

The Berg Balance Scale (BBS) measures a patient's ability to safely balance during a series of predetermined tasks. It consists of a 14-item list, with each item scored on a five-point ordinal scale from 0 to 4, where 0 represents the lowest level of function and 4 the highest level of function [85]. According to the assessment:

- Scores from 0 to 20 indicate that the individual will likely require wheelchair assistance for safe mobility
- Scores from 21 to 40 indicate that the person will need some form of walking aid

Beck Depression Inventory Short Form (BDI-SF)

The Beck Depression Inventory Short Form (BDI-SF) is a 13-item self-report scale that measures characteristic attitudes and symptoms of depression. The BDI-SF scoring system is calculated as follows:

- Below 4: normal mood state
- 5-7: mild depression
- 8-15: moderate depression
- Above 16: severe depression [86]

Beck Anxiety Inventory (BAI)

The BAI was used to measure the severity of anxiety. This is a 21-item, multiple-choice self-report questionnaire that focuses on the individual's feelings over the previous week, primarily on somatic symptoms. The total score is calculated by summing the 21 items, with evaluation as follows:

The maximum score is 63.

- 0-21 points = low anxiety
- 22-35 points = moderate anxiety
- 36 points and above = strong, severe anxiety, potentially indicating a concerning level of anxiety [87]

3.2. The Device

For the user's safety, comfort, and functionality, the ReWalk 6.0 Personal Exoskeleton can be customized (Figure 10).

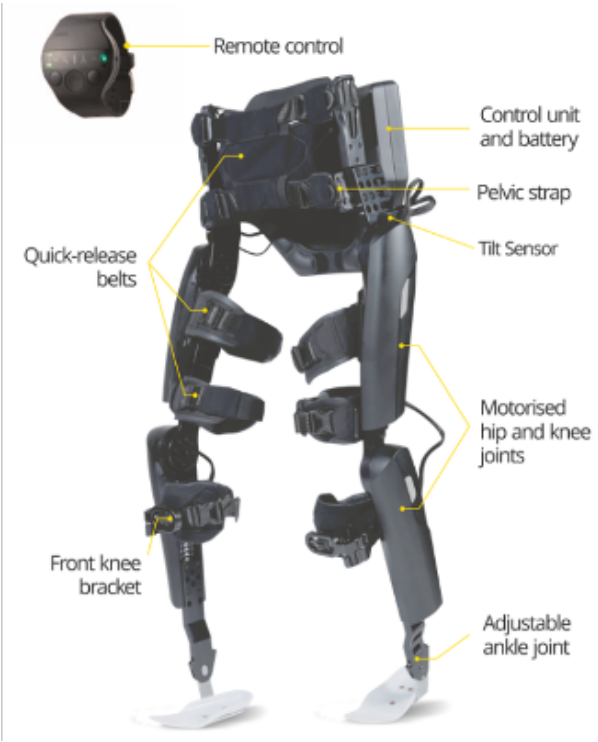


Figure 10: ReWalk 6.0 exoskeleton [88]

The device can be connected to a computer, and individual settings can be adjusted using the manufacturer's control software. The software settings can be stored separately for

each user, modified if needed, and recalled. The movement speed, assistance force, and step length can be adjusted for different functions (standing up, walking) (Figures 11, 12). Additionally, various feedback signals (sound, vibration) can be configured here.

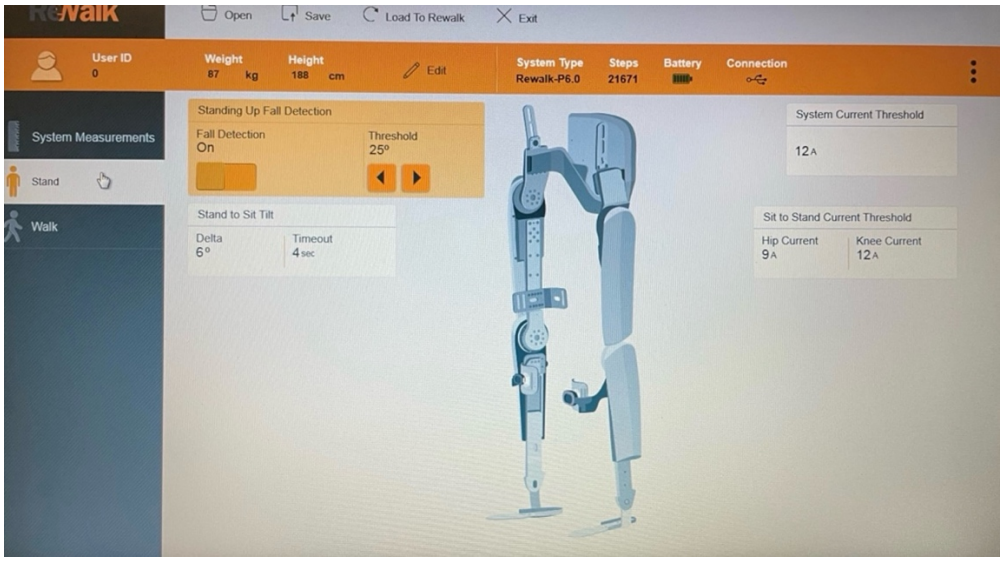


Figure 11.: software configuration options for the standing function [89]

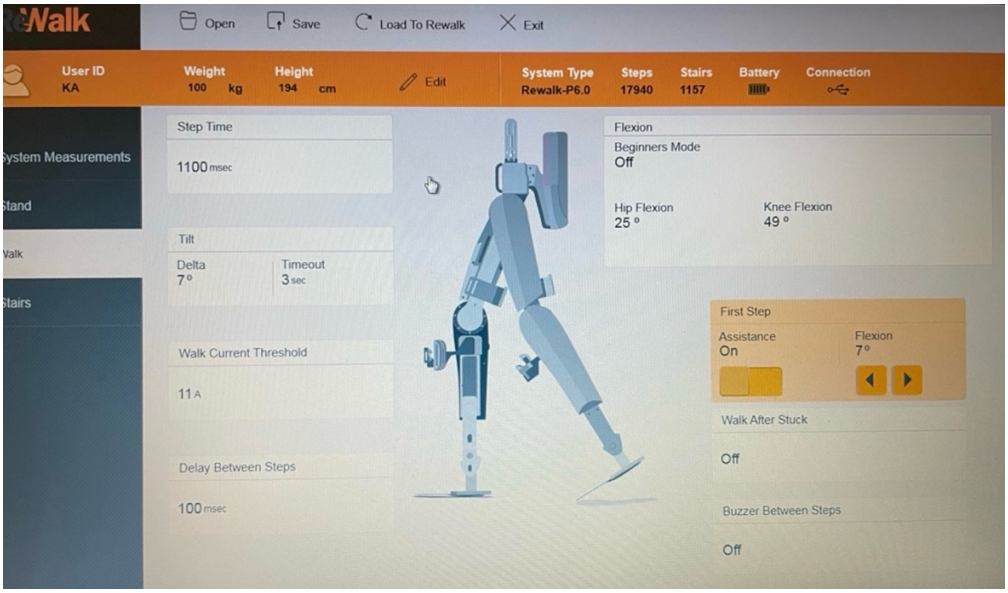


Figure 12.: software configuration options for the walking function [89]

The hardware settings and adjustments of the device - the exoskeleton itself - were made for each user before use (Figure 13), according to the parameters measured during the initial sessions (Figure 14).

Figure 13.: pelvic belt adjustment [89]

Figure 14.: participant assessment [89]

The battery-powered system includes a wearable external frame that is self-supporting, so it does not burden the user with its weight during use. The length of the frame supporting the thigh and lower leg is adjustable (Figure 15), as is the sagittal plane tilt of the foot. The size of the foot parts and the relative spatial position of the 4 different sized pelvic rings can also be customized for each individual (Figure 16).

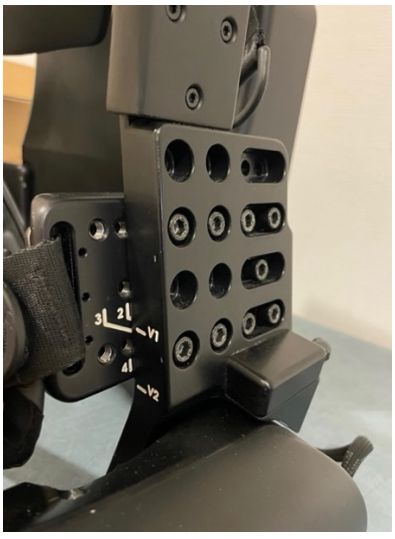


Figure 15.: adjustable lower leg [89] Figure 16.: connection of pelvic and thigh [89]

The electromotors allow movement of the knee and hip joints, with their strength and range of motion customizable for each individual. The frame is secured to the leg using

adjustable straps below the knee, at the distal and proximal parts of the thigh, and around the torso. The foot plates are fixed by wearing shoes, with the device's foot part inserted into the shoe like an insole. Proper adjustment and use of crutches at an optimal height is also necessary for intended use. Users control the exoskeleton's movement regulation through buttons on a wrist-mounted controller (Figure 17) or buttons attached to the hip section. They can make subtle modifications by shifting their center of gravity, even while walking. The device's body repeatedly moves and generates a series of steps that simulate natural and functional walking. Customizable ankle joints and software settings allow clinicians to modify each patient's gait pattern for efficiency and comfort.

Figure 17.: The controller [89]

Users who meet the parameters specified in the inclusion criteria are enabled to stand up, sit down, and walk in a manner similar to natural movement patterns.

3.3. Therapy and Gait Training

During training sessions, each patient was accompanied by at least two therapists who had completed the manufacturer's certification. Initially, one therapist stood in front of the patient, operating the controlling watch (controller). The other therapist stood behind the patient, holding both sides of the exoskeleton's battery, assisting in the execution of

maneuvers. The therapeutic program was divided into four phases. The first three phases originally consisted of five intensive training sessions per week, each lasting 60-90 minutes. The final phase involved lower-intensity training to maintain safe and functional walking. The four therapeutic phases:

1. The first phase involved personalized preparatory physiotherapy, focusing on strengthening the upper limbs and trunk muscles, ensuring functional sitting balance and trunk control. An additional task was to gain proper knowledge of the device, learn its control, and use the controlling watch (controller).
2. During the second phase, participants learned to independently don the device, including transferring from the wheelchair to the exoskeleton set in a sitting position. This phase also included standing up with the device using crutches. Participants practiced proper standing stability with the device, optimal weight-bearing on crutches, and mastering and confidently controlling weight shifts. The patient needed to feel secure in a standing position, able to shift their body weight in all directions, with crutch support being essential elements of walking with the device. Sitting down with the exoskeleton was also part of this phase.
3. In the third phase, participants learned to walk independently and turn in different directions. This phase required the most time and practice for participants.
4. The fourth phase involved lower-intensity maintenance gait therapy.

Blood pressure measurements were taken three times during each session: at the beginning, middle, and end of gait training. Current achievements, milestones, step counts, and other events such as adverse incidents were recorded.

Gait training sessions were planned for a 6-month period according to the protocol. Psychologists were available during the study and follow-up period to monitor any psychological issues. Due to practical limitations (transportation during the pandemic), we found it difficult to maintain the original schedule, so we adjusted to two to three sessions per week.

3.4. Inclusion Criterias

The inclusion criteria for the study were established and applied according to the ReWalk Robotics (now Lifeward) guidelines:

- Spinal cord injury with paraplegia or paraparesis below the thoracic IV vertebra
- At least 4 months since the injury
- Functional use and adequate muscle strength of the hand, shoulder, and upper limb for mandatory crutch use
- Hip T-score ≤ -3.5 on DEXA test
- Intact skeletal system, with no fresh, unconsolidated fractures affecting assistive device use or walking, apart from stable or stabilized spinal injury
- Ability to stand confidently with a device similar to EasyStand, to rule out orthostatic hypotension - dizziness when standing up
- Good general health
- Height between 160-190 cm
- Femur length (from hip axis to knee axis) 43.5-56 cm, lower leg length (from knee axis to foot bottom) 36-48.5 cm
- Maximum body weight of 100 kg
- Appropriate, physiological lower limb joint range of motion, without contractures

Based on the Semmelweis University Department of Rehabilitation's spinal cord injury patient database, 27 patients were initially identified as suitable for the earliest planned study start date. Of these, six agreed to participate in the study, with a 3-person experimental group and a 3-person control group.

3.5. Study Participants

Due to the pandemic, the start of the study was delayed, and we were forced to postpone it several times. During the COVID pandemic, SE-RK could not accept outpatients. During this time, the clinic staff successfully mobilized two hospitalized patients who used the device on three occasions. We were also able to use the device with another SCI patient who was originally included in the study; however, medical adverse events

eventually led to the discontinuation of the training. Below, I present the two male spinal cord injury participants with whom we were able to start the research in spring 2023.

Participant 1

K.Á. is a male patient born in 2000. In 2017, as a result of falling from a height, he suffered a fracture of the 4th and 5th thoracic vertebrae and a complete spinal cord injury. His rehabilitation took place at SE-RK. In the fall of 2019, he was selected for the exoskeleton study, which he was able to start two years later. At that time, he was able to take a maximum of 288 steps during a training session over 30 successful sessions. In March 2022, he contracted a COVID infection, which was followed by prolonged post-COVID symptoms. He underwent a pulmonology check-up, and full recovery took several months. In addition, the patient developed a severe toenail infection, which prevented further exoskeleton gait training. A year later, in May 2023, we were able to restart the study period with him (Figure 18).

Figure 18.: K.Á. exoskeleton gait training [89]

Participant 2

A.Á. is a male patient born in 2006. In June 2022, he suffered polytrauma due to a fall from a height. He was diagnosed with bilateral pneumothorax, lung and liver contusions, rib fractures, an unstable fracture of the 10th thoracic vertebral body, and fractures of the transverse processes of the 11th thoracic to 2nd lumbar vertebrae. He underwent spinal stabilization surgery at Kaposi Mór Hospital, where decompression, laminectomy, and screw fixation were performed on the T8-T12 thoracic segment. From July 2022, the patient underwent complex rehabilitation at SE-RK, where he learned independent wheelchair mobility and intermittent bladder catheterization. After an adaptation leave, he continued rehabilitation in September 2022. Regarding sensation, there is anesthesia below the 12th thoracic vertebra on the right side and below the 11th thoracic vertebra on the left side. In terms of motor function, there is full function in the upper limbs, with no voluntary movement in the lower limbs. Regarding autonomic function, the patient performs self-catheterization five times daily. There is moderate spasticity in the lower limbs. Reflexes are physiological in the upper limbs, while in the lower limbs, there are increased patellar and foot reflexes, with bilateral positive Babinski reflex. No contractures are observed, sitting posture is maintained, and the patient is self-sufficient. In May 2023, the patient participated in the exoskeleton study (Figure 19).

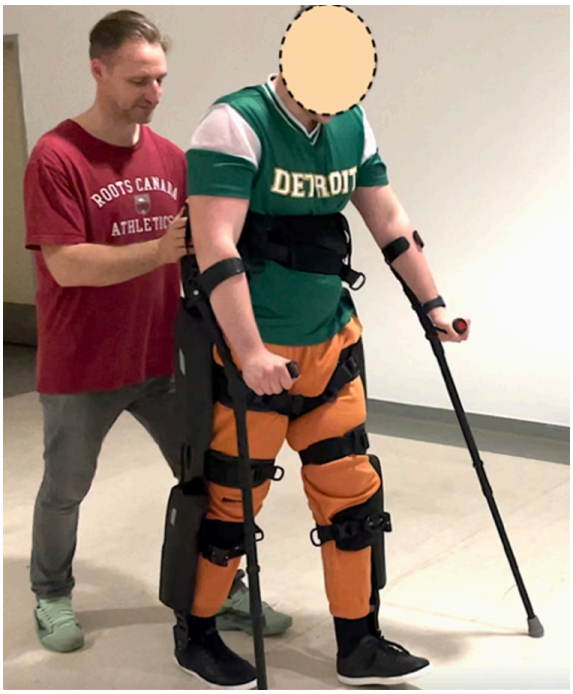


Figure 19.: A.Á. exoskeleton gait training [89]

3.6. Data Analysis Methods

Data collection began with examinations according to the inclusion criteria, measuring participants' physiological parameters, and administering questionnaires, which were repeated at the conclusion of the study. Bone density was determined using DEXA scans, while changes in body composition were monitored through bioimpedance measurements. To analyze gastrointestinal and urogenital functions, we conducted urodynamic examinations and questionnaire surveys. Data on general well-being and quality of life were recorded using questionnaires and tests. During gait training, blood pressure measurements were taken three times at each session. We documented current achievements, milestones, step counts, and other events (e.g., adverse events). Changes in the resulting data were presented in absolute values and percentages.

4. Results

4.1. Bone Density

According to K.Á.'s BMD (Bone Mineral Density) measurements, a decrease was observed in all areas except the first lumbar vertebra. Specifically a 3.7% decrease in the L1-L3 lumbar vertebrae, a 4.6% decrease in the L2-L4 lumbar vertebrae and a 1.6% decrease in the left femoral neck. In the forearm, a slight increase in BMD was observed a 1% increase in the right radius and a 1.1% increase in the left radius area. The lateral vertebral assessment (LVA morphometry) showed no significant change in the average height of the measured vertebrae, with the greatest improvement measured in the 12th thoracic vertebra (Tables 2 and 3). The BMD measurement results are also shown in the trend data (Table 4). Trend curves illustrate the BMD changes measured in the lumbar vertebrae and left radius (Figures 20, 21) [Appendix 3].

Table 2: K.Á. osteodensitometry values

Osteodensitometry	**K.Á.**					
Region	**BMD [g/cm^2]**		**T-score**		**Z-score**	
	28.03.2023.	**04.08.2023.**	**28.03.2023.**	**04.08.2023.**	**28.03.2023.**	**04.08.2023.**
L1	1,273	1,304	0,9	1,2	0,5	0,5
L2	1,634	1,507	3,3	2,2	2,9	1,5
L3	1,635	1,554	3,3	2,6	2,9	1,9
L4	1,418	1,400	1,5	1,3	1,1	0,6
L1-L2	1,459	1,412	2,2	1,8	1,8	1,0
L1-L3	1,525	1,466	2,6	2,1	2,2	1,4
L1-L4	1,495	1,448	2,3	1,9	1,9	1,2
L2-L3	1,634	1,532	3,3	2,4	2,9	1,7
L2-L4	1,558	1,487	2,7	2,1	2,3	1,3
Left humerus neck	1,079	1,062	0,1	-0,1	-0,4	-0,8
Left humerus	0,954	0,966	-1,0	-1,0	-1,5	-1,6
Right femur neck	1,100	1,081	0,2	0,1	-0,3	-0,6
Right femur	0,980	0,936	-0,8	-1,2	-1,3	-1,9
Left radius	1,035	1,046	0,5	0,6	0,5	0,6
Right radius	1,060	1,065	0,7	0,8	0,7	0,8

Table 3: K.Á. LVA morphometry

LVA Morphometry	K.Á.							
Region	Average height (%)		P/A ratio (%)		M/P ratio (%)		A/P ratio (%)	
	28.03.2023.	04.08.2023.	28.03.2023.	04.08.2023.	28.03.2023.	04.08.2023.	28.03.2023.	04.08.2023.
T8	108	103	106	98	89	97	94	102
T9	101	105	102	104	92	90	98	96
T10	107	106	96	99	97	96	104	101
T11	106	108	113	102	92	92	89	98
T12	103	110	115	98	91	97	87	102
L1	104	105	114	105	93	96	88	95
L2	103	105	100	104	101	95	100	96
L3	99	96	92	92	105	99	108	108
L4	98	99	88	97	103	94	113	103

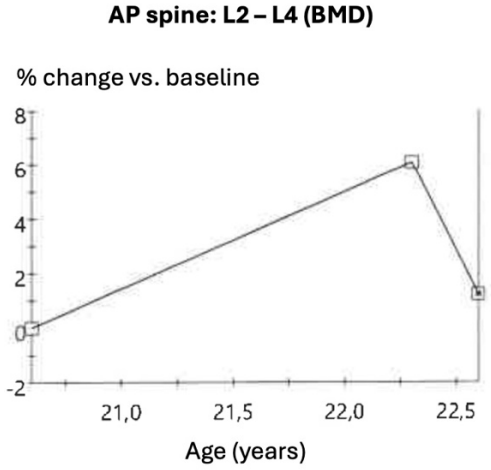


Figure 20: K.Á. DEXA test, BMD trend curve of lumbar vertebrae L2-L4 [90]

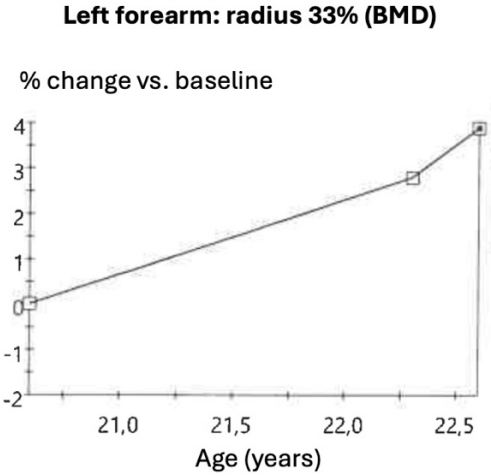


Figure 21: K.Á. DEXA test, left radius BMD trend curve [90]

Table 4: K.Á. tendency values

	Date and age at time of measurement		
	04.08.2023.; 22,6 years	**28.03.2023.; 22,3 years**	**22.07.2021.; 20,6 years**
	Tendency: L2-L4		
BMD [g/cm²]	1,487	1,558	1,469
Change vs. baseline (%)	1,2	6,1	baseline
Change vs. baseline (%/year)	0,6	3,6	baseline
	Tendency: left femur neck		
BMD [g/cm²]	1,062	1,079	1,078
Change vs. baseline (%)	-1,5	0,1	baseline
Change vs. baseline (%/year)	-0,7	0,1	baseline
	Tendency: right femur neck		
BMD [g/cm²]	1,081	1,100	1,195
Change vs. baseline (%)	-9,5	-7,9	baseline
Change vs. baseline (%/year)	-4,7	-4,7	baseline
	Tendency: left radius		
BMD [g/cm²]	1,046	1,035	1,007
Change vs. baseline (%)	3,9	2,8	baseline
Change vs. baseline (%/year)	1,9	1,7	baseline
	Tendency: right radius		
BMD [g/cm²]	1,065	1,060	
Change vs. baseline (%)	0,5	baseline	
Change vs. baseline (%/year)	1,3	baseline	

A.Á.'s BMD datasets showed an increase in the lumbar region, except for the second vertebra, with a 1.8% BMD increase in the L2-L4 lumbar vertebrae. We observed a decrease in the femoral neck and femur areas, with a 0.9% decrease in the left femoral neck. In the forearm, we noted a 4.7% increase in the left radius area. There was no significant difference in the LVA morphometric data (Tables 5, 6). The BMD changes measured in the lumbar vertebrae and left radius are illustrated by the trend data and curves for the given area (Figures 22, 23, Table 7) [Appendix 4].

Table 5: A.Á. osteodensitometry values

Osteodensitometry	**A.Á.**					
Region	**BMD [g/cm²]**		**T-score**		**Z-score**	
	08.03.2023.	**04.08.2023.**	**08.03.2023.**	**04.08.2023.**	**08.03.2023.**	**04.08.2023.**
L1	0,963	1,049	-	-	-1,2	-0,8
L2	1,232	1,191	-	-	0,1	-0,4
L3	1,057	1,097	-	-	-1,1	-1,0
L4	0,907	0,960	-	-	-2,2	-2,0
L2-L3	1,139	1,141	-	-	-0,6	-0,7
L2-L4	1,049	1,068	-	-	-1,2	-1,2
Left humerus neck	1,096	1,086	-	-	0,0	-0,2

Left humerus	0,872	0,846	-	-	-1,7	-2,0
Right femur neck	1,165	0,944	-	-	0,5	-1,3
Right femur	0,834	0,773	-	-	-2,0	-2,5
Left radius	0,974	1,020	-	-	-	-
Right radius	-	0,946	-	-	-	-

Table 6: A.Á. LVA morphometry

	A.Á.							
Region	**Average height (%)**		**P/A ratio (%)**		**M/P ratio (%)**		**A/P ratio (%)**	
	08.03.2023.	**04.08.2023.**	**08.03.2023.**	**04.08.2023.**	**08.03.2023.**	**04.08.2023.**	**08.03.2023.**	**04.08.2023.**
L1	98	100	111	110	91	94	90	91
L2	83 *	81	146	132	77	85	69	76
L3	100	101	95	89	89	96	106	113
L4	100	99	112	103	112	88	89	97
***moderately wedge shape**								

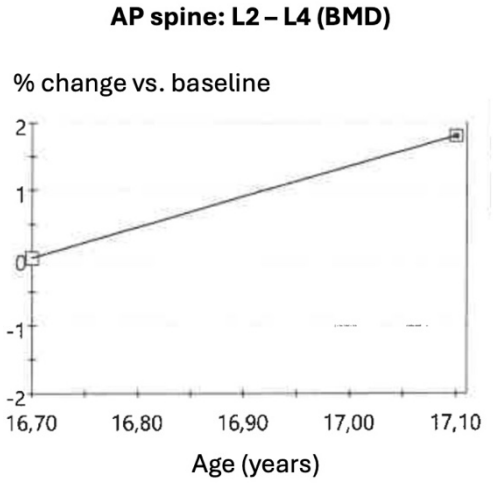


Figure 22: A.Á. DEXA test, BMD trend curve of lumbar vertebrae L2-L4 [90]

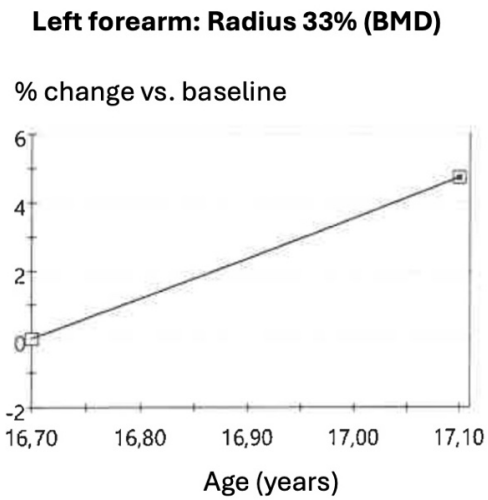


Figure 23: A.Á. DEXA test, left radius BMD trend curve [90]

Table 7: A.Á. tendency values

	Date and age at time of measurement	
	08.03.2023.; 16,7 years	**04.08.2023.; 17,1 years**
	Tendency: L2-L4	
BMD [g/cm²]	1,049	1,068
Change vs. baseline (%)	baseline	1,8
Change vs. baseline (%/year)	baseline	4,5
	Tendency: left femur neck	
BMD [g/cm²]	1,096	1,086
Change vs. baseline (%)	baseline	-0,9
Change vs. baseline (%/year)	baseline	-2,3
	Tendency: right femur neck	
BMD [g/cm²]	1,165	0,944
Change vs. baseline (%)	baseline	-19,0
Change vs. baseline (%/year)	baseline	-46,8
	Tendency: left radius	
BMD [g/cm²]	0,974	1,020
Change vs. baseline (%)	baseline	4,7
Change vs. baseline (%/year)	baseline	11,6
	Tendency: right radius (radius 33%)	
Germany Reference Table: no data available for the right forearm (radius 33%) area.		

4.2. Body Composition

K.Á.'s data showed decreases in body weight (2.1 kg), fat-free mass index (0.47%), and visceral adipose tissue (1.2 kg). An increase in absolute fat mass (1.14 kg) was observed, while skeletal muscle mass decreased by 1.21 kg (Table 8). According to A.Á.'s body composition measurements, we observed an increase in body weight of 1.6 kg, a decrease in fat-free mass index (0.41%), and a decrease in visceral adipose tissue of 0.32 kg. The absolute fat mass value decreased by 0.14 kg, while the skeletal muscle mass value increased by 0.45 kg (Table 9).

Table 8: K.Á. body composition values

K.Á.			
	30.08.2021.	03.08.2023.	Δ
Body Mass Index (BMI)	27,1	27,1	0
Absolute fat mass value	27,12	28,26	-1,14
Fat-free mass value	74,88	71,64	3,24
Skeletal muscle mass (SMM) value	35,99	34,78	1,21
SMM (torso) value	15,9	15,58	0,32
SMM (right leg) value	7,49	7,2	0,29
SMM (left leg) value	7,53	7,03	0,5
SMM (left arm) value	2,55	2,45	0,1
SMM (right arm) value	2,52	2,51	0,01
Total Body Water value	55,46	52,94	2,52
Extracellular water value	24,88	22,9	1,98

Weight value	102	99,9	2,1
Height value	1,94	1,92	0,02
Total energy expenditure value	3119,22	3074,95	44,27
Resting energy expenditure value	2228,01	2196,39	31,62
Fat Free Mass Index (FFMI) value	19,9	19,43	0,47
Fat Mass Index (FMI) value	7,2	7,67	-0,47
PhaseAngle value	4,83	5,64	-0,81
visceral adipose tissue value	2,91	1,71	1,2
Extracellular water to total body water ratio	44,85	43,25	1,6

Table 9: A.Á. body composition values

A.Á.			
	18.05.2023.	03.08.2023.	Δ
Body Mass Index (BMI)	30,47	29,96	0,51
Absolute fat mass value	39,33	39,19	0,14
Fat-free mass value	63,82	65,56	-1,74
Skeletal muscle mass (SMM) value	30,59	31,04	-0,45
SMM (torso) value	13,21	13,33	-0,12
SMM (right leg) value	7	7,14	-0,14
SMM (left leg) value	6,32	6,39	-0,07
SMM (left arm) value	2,04	2,16	-0,12
SMM (right arm) value	2,02	2,02	0
Total Body Water value	47,4	48,7	-1,3
Extracellular water value	20,77	21,4	-0,63
Weight value	103,15	104,75	-1,6
Height value	1,84	1,87	-0,03
Total energy expenditure value	3143,46	3177,19	-33,73
Resting energy expenditure value	2245,33	2269,42	-24,09
Fat Free Mass Index (FFMI) value	18,85	18,75	0,1
Fat Mass Index (FMI) value	11,62	11,21	0,41
PhaseAngle value	5,46	5,34	0,12
visceral adipose tissue value	3,23	2,91	0,32
Extracellular water to total body water ratio	43,82	43,94	-0,12

4.3. Gastrointestinal and Urogenital Changes

During the urodynamic examination, no significant change was observed in bladder compliance (Figures 24, 25).

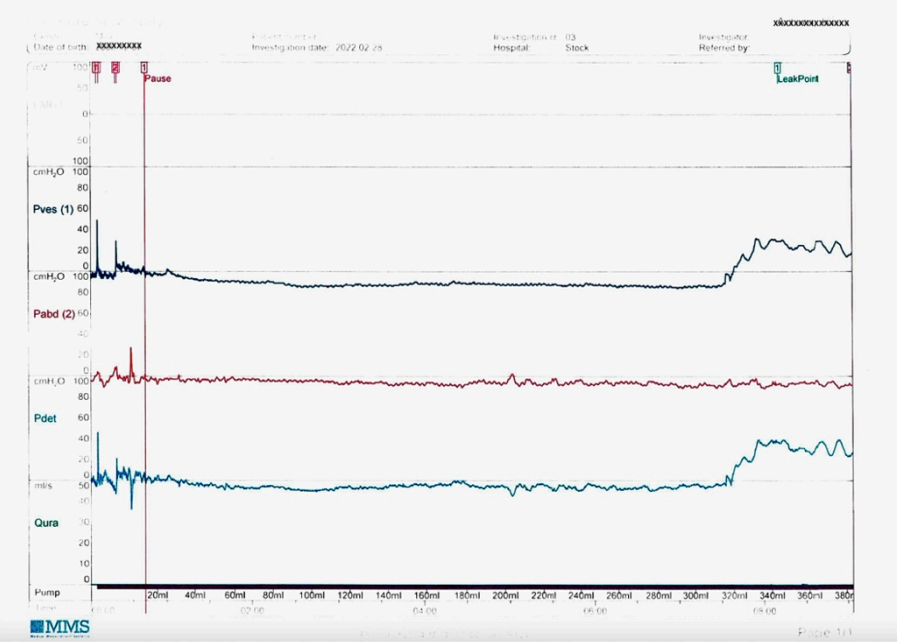


Figure 24: K.Á.'s first urodynamic examination values [91]

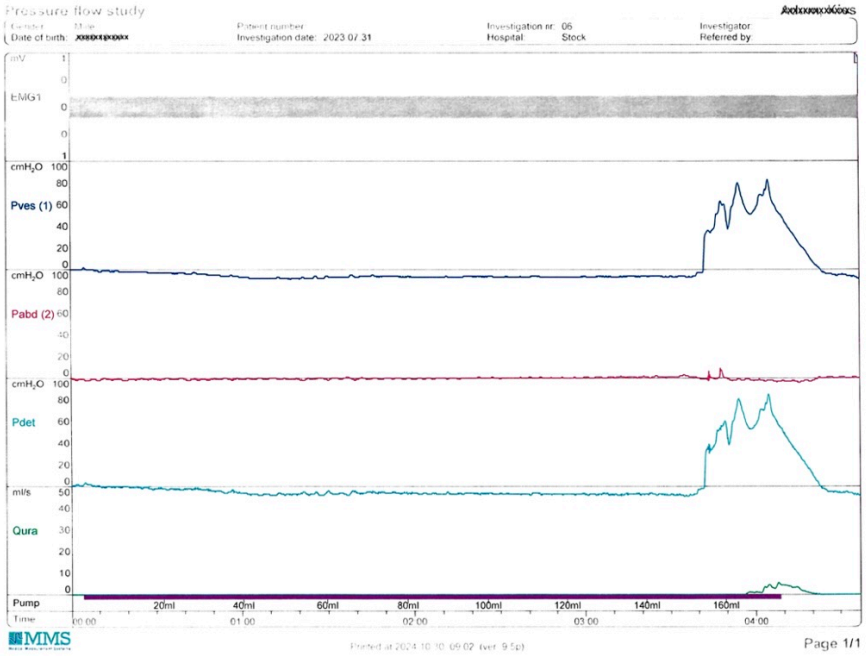


Figure 25: K.Á.'s control urodynamic examination values [91]

The Bristol Stool Form Scale did not show clinically significant changes in stool type (Table 10).

Table 10: Bristol Stool Scale values

Bristol Stool Scale			
K.Á.		**A.Á.**	
27.09.2021.	03.08.2023.	08.05.2023.	31.07.2023.
Type 3	Type 3	Type 1, 3	Type 3

4.4. Questionnaires Regarding the General Condition and Cooperation of Patients

For both patients, we used questionnaires that focused on well-being, functionality, mobility, and gastrointestinal functions. The recording dates for the questionnaires were marked as follows:

- K.Á.: T1.1: 27th of September, 2021; T1.2: 3rd of August, 2023
- A.Á.: T2.1: 8th of May, 2023; T2.2: 31st of July, 2023

4.4.1. Trunk Control Test

Both participants showed identical performance at the beginning and end of the three-month period, with 74 points (Table 11).

Table 11: Trunk Control Test

Trunk Control Test	**K.Á.**			**A.Á.**		
	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Rolling from a supine position to the weak side	12	12	0	12	12	0
Rolling from a supine position to the strong side	12	12	0	12	12	0
Sitting balance	25	25	0	25	25	0
Sitting up from a lying-down position	25	25	0	25	25	0
Total score	**74**	**74**	**0**	**74**	**74**	0

4.4.2. Spinal Cord Independence Measure

Both participants completed the SCIM tests with identical scores, and the examination results and measured changes were also the same (Table 12).

Table 12: SCIM values

SCIM	**K.Á.**			**A.Á.**		
	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Self-care (0-20)	18	18	0	18	18	0
Respiration and sphincter management (0-40)	31	31	0	31	31	0
Mobility (0-40)	19	19	0	19	19	0
Total SCIM score	**68**	**68**	**0**	**68**	**68**	0

4.4.3. Barthel Index

K.Á.'s scores remained unchanged, performing equally at the beginning and end of the study. A.Á.'s values showed minor changes in toilet use and bathing, improved bladder function, and the total score improved by 1 point.
Both cases indicate "slight dependence or need for assistance" (Table 13).

Table 13: Barthel Index values

Barthel Index (0-100)	**K.Á.**			**A.Á.**		
	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Feeding	10	10	0	10	10	0
Transfers (bed to chair and back)	15	15	0	15	15	0
Grooming	5	5	0	5	5	0
Toilet use	10	10	0	10	8	-2
Bathing	5	5	0	4	5	1
Mobility (on level surfaces)	5	5	0	0	0	0
Stairs	0	0	0	0	0	0
Dressing	10	10	0	10	10	0
Bowels	10	10	0	8	8	0
Bladder	5	5	0	3	5	2
Total score	**75**	**75**	**0**	**65**	**66**	**1**
	Moderate dependency	**Moderate dependency**		**Moderate dependency**	**Moderate dependency**	
Change in absolute value	**0**			**1**		
Change in percentage	**0%**			**1.54%**		

4.4.4. Berg-Balance Scale

In the Berg Balance Scale assessment, both participants showed slight improvement. K.Á. improved by 1 point (22 → 23) and A.Á. improved by 2 points (20 → 22) compared to their initial scores (Table 14).

Table 14: Berg Balance Scale values

Berg Balance Scores	**K.Á.**			**A.Á.**		
Lowest level of function=0; highest level of function=4	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Sit to stand	0	0	0	0	0	0
Standing unsupported	0	0	0	0	0	0
Sitting unsupported	3	3	0	2	3	1
Stand to sit	0	0	0	0	0	0
Transferring from one chair to another	4	4	0	4	4	0
Standing with eyes closed	0	0	0	0	0	0
Standing with feet together	0	0	0	0	0	0
Reaching forward with outstretched arms	3	4	1	3	3	0
Picking up an object from the floor	4	4	0	3	4	1
Turning to look behind	4	4	0	4	4	0
Turning 360 degrees	4	4	0	4	4	0
Stepping onto and off a step	0	0	0	0	0	0
Placing one foot in front of the other (tandem stance)	0	0	0	0	0	0
Standing on one foot	0	0	0	0	0	0
Total score	**22**	**23**	**1**	**20**	**22**	**2**
Change in percentage	**+ 4.55%**			**+ 10%**		

4.4.5. SF-36, the 36-item Short Form Survey

According to the SF-36 values, K.Á. showed no change in responses to bodily pain, while values decreased in other areas of the survey. For A.Á., most responses remained unchanged, however, values decreased in terms of role limitations due to emotional problems, mental health, and vitality (Table 15).

Table 15: SF-36 scores K.Á. and A.Á.

SF-36	**K.Á.**			**A.Á.**		
0-100 scores = 0-100%	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Physical functioning	35	10	-25	55	55	0
Bodily pain	100	100	0	90	90	0
Role limitations due to physical health	75	50	-25	25	25	0
Role limitations due to emotional problems	100	0	-100	100	66,7	-33,5
Mental health	92	72	-20	64	60	-4
Social functioning	75	37,5	-37,5	75	75	0
Vitality	80	50	-30	55	50	-5
General health perceptions	85	75	-10	90	90	0

4.4.6. WHOQOL-BREF Questionnaire

According to the WHOQOL-BREF assessment during the study, K.Á. showed a 4-point improvement, while A.Á. experienced a 10-point decrease in the total score (Table 16).

Table 16: Participants WHOQOL-BREF scores

WHOQOL-BREF	**K.Á.**			**A.Á.**		
1 = never; 2 = rare; 3 = sometimes; 4 = often; 5 = always	**T1.1.**	**T1.2.**	Δ	**T2.1.**	**T2.2.**	Δ
Overall quality of life	4	4	0	4	5	1
General health	3	4	1	4	3	-1
Pain and discomfort	1	1	0	1	3	2
Dependence on medical substances and medical aids	1	1	0	1	2	1
Positive feelings	4	4	0	3	1	-2
Spirituality, religion and personal beliefs	5	4	-1	3	2	-1
Thinking, learning, memory and concentration	4	4	0	4	3	-1
Freedom, physical safety and security	5	5	0	4	4	0
Home environment	5	4	-1	4	4	0
Energy and fatigue	4	4	0	5	4	-1
Bodily image and appearnace	5	4	-1	3	3	0
Financial resources	4	5	1	4	4	0
Opportunities for acquiring new information and skills	4	5	1	3	2	-1
Participation in and opportunities for recreation/leisure activities	2	3	1	4	4	0
Mobility	2	1	-1	5	4	-1
Sleep and rest	3	4	1	4	3	-1
Activities of daily living	4	4	0	3	3	0
Work capacity	4	4	0	4	2	-2
Self-esteem	4	4	0	3	2	-1
Personal relationships	4	4	0	3	2	-1
Sexual activity	4	4	0	2	2	0
Social support	4	5	1	2	2	0
Physical environment	5	4	-1	5	5	0

Health and social care: accessibility and quality	2	4	2	3	2	-1
Transport	3	4	1	4	3	-1
Negative feelings	1	1	0	3	4	1
Total score	**91**	**95**	**4**	**88**	**78**	**-10**
Change in percentage	**+ 4.4%**			**- 11.36%**		

4.4.7. Beck Depression Inventory

For K.Á., the BDI-SF scores remained within the normal range before and after LEE gait training, increasing by 3 points (0 → 3).

Meanwhile, A.Á.'s assessment showed an initial score of 9, which increased to 12 by the end of the 3-month trial period. According to the BDI-SF scoring system, A.Á.'s score rose from the normal range to mild mood disturbances (9 → 12) (Table 17).

Table 17: BDI-SF values

	BECK Depression Inventory	**K.Á.**			**A.Á.**		
		T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
1	0 – I do not feel sad 1 – I feel sad much of the time 2 – I am sad all the time – I am so sad or unhappy that I can't stand it	0	0	0	0	0	0
2	0 – I am not discouraged about my future 1 – I feel more discouraged about my futura than I used to 2 – I do not expect things to wok out for me – I feel my future is hopeless and will only get worse	0	0	0	1	1	0
3	0 – I do not feel like a failure 1 – I have failed more than I should have 2 – As I look back, I see a lot of failures 3 – I feel I am a total failure as a person	0	0	0	1	1	0
4	– I get as much pleasure as I ever did from the things I enjoy 1 – I don't enjoy things as much as I used to 2 – I get very little pleasure from the things I used to enjoy 3 – I can't get any pleasure from the things I used to enjoy	0	1	-1	0	1	1
5	0 – I don't feel particularly guilty 1 – I feel guilty over many things I have done or should have done 2 – I feel quite guilty most of the time 3 – I feel guilty all of the time	0	0	0	1	1	0
6	0 – I don't feel I am being punished 1 – I feel I may be punished 2 – I expect to be punished 3 – I feel I am being punished	0	0	0	0	0	0
7	- I don't have any thoughts of killing myself – I have thoughts of killing myself, but I would not carry them out 2 – I would like to kill myself 3 – I would kill myself if I had the chance	0	0	0	1	1	0
8	0 – I have not lost interest in other people 1 – I am less interested in other people 2 – I have lost most of my interest in other people 3 – I have lost all of my interest in other people	0	1	-1	0	2	2
	0 – I make my decisions about as well as I ever could						

9	1 – I put off making decisions more than I used to 2 – I have greater difficulty in making decisions more than I used to 3 – I can't make decisions at all anymore	0	0	0	0	0	0
10	0 – I don't feel that I look any worse than I used to 1 – I am worried that I am looking old or unattractive – I feel there are permanent changes in my appearance that make me look unattractive 3 – I believe that I look ugly	0	0	0	2	2	2
11	0 – I can work about as well as before – It takes an extra effort to get started at doing something – I have to push myself very hard to do anything 3 – I can't do any work at all	0	1	-1	1	1	0
12	0 – I don't get more tired than usual 1 – I get tired more easily than I used to 2 – I get tired from doing almost anything 3 – I am too tired tod o anything	0	0	0	1	1	0
13	0 – My appetite is no worse than usual 1 – My appetite is not as good as it used to be 2 – My appetite is much worse now 3 – I have no appetite at all anymore	0	0	0	1	1	0
	Total score	**0**	**3**	**3**	**9**	**12**	**3**
	Change in percentage				**+ 33.33%**		

4.4.8. Beck Anxiety Inventory

During the trial period, both patients' scores changed, but remained within the low anxiety (0-21) range (Table 18).

Table 18: Beck Anxiety Inventory values

BECK Anxiety Inventory	**K.Á.**			**A.Á.**		
0 = not at all; 1 = mildly but it didn't bother me much; 2 = moderately – it wasn't pleasant at times; 3 = severily – it bothered me a lot	T1.1.	T1.2.	Δ	T2.1.	T2.2.	Δ
Numbness or tingling	0	0	0	1	1	0
Feeling hot	0	0	0	2	1	-1
Wobbliness in legs	0	0	0	0	0	0
Unable to relax	0	1	1	1	1	0
Fear of worst happening	0	0	0	0	0	0
Dizzy or lightheaded	0	0	0	0	1	1
Heart pounding/racing	0	0	0	1	1	0
Unsteady	0	0	0	2	1	-1
Terrified or afraid	0	0	0	0	0	0
Nervous	0	1	1	1	1	0
Feeling of choking	0	0	0	0	0	0
Hands trembling	0	0	0	2	1	-1
Shaky/unsteady	0	0	0	0	1	1
Fear of losing control	0	0	0	0	0	0

Difficulty breathing	0	0	0	0	0	0
Fear of dying	0	0	0	0	0	0
Scared	0	0	0	0	0	0
Indigestion or discomfort in abdomen	0	0	0	0	0	0
Faint/lightheaded	0	0	0	1	1	0
Face flushed	0	0	0	2	0	-2
Hot/cold sweats	0	0	0	2	1	-1
Total score	**0**	**2**	**2**	**15**	**11**	**-4**
Change in percentage				**- 26.67%**		

4.5. Results of Gait Training

The participants' pulse and blood pressure were measured before, during, and after each session. We also recorded the number of steps taken using the device and documented any adverse events.

For K.Á., we used the exoskeleton 17 times, twice a week, with each training session lasting approximately 60 minutes. The maximum number of steps per session, 640 steps, was achieved during the 12th training. The average number of steps per session was 301. The peak pulse was measured at 127 during the 16th session. The 10-meter walk test time was 32.44 seconds. Due to spasticity in the left foot, we often used a bandage to secure the shoe.

A.Á. was able to use the device 14 times, twice a week, also for approximately 60 minutes each time. The maximum recorded pulse rate was 112 during the 6th and 12th sessions, and high blood pressure was measured during the 6th (162/95) and 14th (143/93) training sessions. At these times, A.Á. experienced dizziness, and we stopped the gait training. The maximum number of steps was 1727 during the 12th session, with an average of 480 steps per session during the study period. The 10-meter walk test time was 26.39 seconds.

5. Discussion

The clinical assessments were successfully conducted thanks to the partners, demonstrating that the model works. The study focused on the effects of lower extremity exoskeleton robot therapy on certain functional and physiological parameters in patients with spinal cord injury. We observed changes in most measured parameters, although the magnitude of change was minimal in many cases. Our hypothesis that high-intensity gait training can prevent or reduce complications associated with spinal cord injury was largely confirmed.

Body composition data measured during the study period indicated a decrease in weight, fat-free mass index, and visceral adipose tissue for K.Á. Absolute fat mass increased, while skeletal muscle mass decreased. We assume that the prolonged COVID-19 infection between measurements and the subsequent post-COVID syndrome contributed to a more sedentary lifestyle. The study explicitly shows that illnesses occurring during training negatively impact the parameters of SCI patients.

A.Á.'s skeletal muscle mass and weight increased, while absolute fat mass values decreased, presumably indicating the benefits of LEE gait training. Similar results were reported by Rigoli et al., who observed significant changes in body composition data, particularly in fat mass reduction [60].

For both participants, changes in bone density were minimal due to the short study period. Data measured on the upper limbs and forearms showed a minimal increase in bone density, suggesting effects from leaning on crutches during gait training. Changes in bone metabolism were documented by Karelis and colleagues. They examined the effects of a 6-week exoskeleton-assisted gait training on body composition and bone thickness in individuals with spinal cord injury. Their conclusion suggests that gait training is associated with positive changes in body composition and potentially bone health [57].

We did not observe clinically significant changes in gastrointestinal parameters. According to Chun et al.'s research results, at least 50% of participants reported general improvement in gastrointestinal functions, 80% reported improvement in stool consistency, while one out of ten participants indicated deterioration in bowel functions [62]. Williams and colleagues suggest that exoskeleton training may be promising for

improving urogenital functions in SCI patients, particularly in terms of pelvic floor muscle activation and patient satisfaction with bladder management [65].

We did not find significant differences in patients' TCT, SCIM, Barthel Index, and BBS scores. Validation of the SCIM may be warranted, as this test was applied for the first time among SCI patients in our country. These data could also reflect previous successful rehabilitation outcomes, as appropriate mobility was achieved during inpatient rehabilitation. Park and colleagues also used the TCT and BBS questionnaires in their study and observed improvement, although the extent of improvement was not clinically significant [92].

For both participants, the majority of SF-36 scores decreased or remained unchanged with minimal changes. On the WHOQOL-BREF questionnaire, K.Á. reported minimal improvement, while A.Á. reported a slight decrease.

Similar quality of life measurements were conducted by Ilse J.W. van Nes and colleagues. In their study, QoL significantly improved after the training period, with improvements observed in the Short Form-36 with Walk Wheel (SF-36ww) categories of mental health, social functioning, pain, and general health perception. They concluded that a short-term exoskeleton training improved the quality of life, pain, and satisfaction with bladder management for SCI patients. However, they emphasized that these findings require further studies in SCI populations [66].

The BDI-SF scores for K.Á. increased minimally, with no change in the mood range according to the scale. For A.Á., the range changed from normal to mild mood disturbances. These results dynamically showed that processing the trauma caused by spinal cord injury takes a long time in the young SCI population. The realization of hope for new, significant therapeutic possibilities may also be a reason for the deterioration in mood. This underscores the importance of psychological support and background during the study.

In the BAI tests, both participants reported minimal changes, but the ranges did not change, with both remaining in the low anxiety range.

A.Á.'s data showed improvement in physical parameters but a decrease in mental health indicators, which may be related to the documented suicidal thoughts at the time of SCI.

Maggio and colleagues tracked changes in mood. They used the Beck Depression Inventory as a secondary measure. The experimental group participants achieved

significant improvement in almost all test scores, in contrast to the decrease in mood questionnaire results we measured [70].

The patients showed significant improvement in the LEE gait training sessions, and their motivation remained high throughout the period. Observing the participants' progress and their acquisition of basic exoskeleton skills was an extremely motivating experience.

Limitations

During recruitment, potential participants' limited access to transportation services posed a challenge, making it difficult for them to reach the study site. In the initial phase of the study, during intensive gait training (5 sessions per week, 60-90 minutes per session), it was challenging for participants' parents or caregivers to take significant time off work.

The first scheduled study start date coincided with the first wave of the COVID-19 pandemic and associated restrictions, including the closure and isolation of healthcare institutions. Later, the pandemic affected both participants and therapists, further slowing the study's progress. Due to these reasons, we were ultimately able to begin work with only two study partners. The participants' health issues and lack of continuity also presented challenges, as well as the resulting relatively short data collection period.

Strengths of the Study

This was the first and unique study in Hungary among SCI patients that examined the effects of lower extremity exoskeleton gait training using a large number of instrumental and questionnaire-based tests. There are few such comprehensive studies internationally, which can serve as a model for planning and implementing future studies and everyday practice gait training.

The data may allow for the study of possibilities for domestic adoption and applicability of the technology and device in practical, rehabilitation, and research areas.

The study closing documentation, scientific, medical-professional, and ethical evaluation were accepted by the Medical Technology Department of the National Public Health and Pharmaceutical Center (NNGYK) and the Scientific and Research Ethics Committee of the Health Science Council (ETT TUKEB). At its meeting on April 30, 2024, ETT TUKEB also accepted the research plan report from a professional-ethical perspective, indicating that the research results can be further published and utilized [Appendix 5].

6. Summary

The essence of our research was to examine the effects of gait training using the ReWalk 6.0 lower extremity exoskeleton, focusing on changes in physiological and quality of life functions among SCI patients. Data collection was conducted through instrumental and questionnaire-based assessments.

For both participants, regarding bone density, we observed a decrease in the femoral neck area and an increase in the forearms.

In body composition data, one participant showed a decrease in weight and skeletal muscle mass, with an increase in absolute fat mass. The other participant experienced an increase in weight and skeletal muscle mass, while absolute fat mass decreased.

There were no clinically significant changes in gastrointestinal parameters.

We found no substantial changes in patients' TCT, SCIM, Barthel Index, and BBS scores.

The participants' SF-36 values mostly decreased.

On the WHOQOL-BREF questionnaire, we observed improvement in one participant and a decrease in the other.

BDI-SF questionnaire values increased, while BAI tests showed no change in anxiety range.

Regarding gait training, step counts increased during the study.

Our experiences highlight the need for a more detailed understanding of patients' and caregivers' knowledge and attitudes towards exoskeletons. It's important to determine the minimum number of weekly treatments needed to achieve clinically significant effects in primary and secondary outcomes. Furthermore, it's advisable to examine whether exoskeleton gait training for SCI patients would be more effective in inpatient or outpatient care within the current legal and infrastructural environment.

The study included multiple outcome measures to track patient parameters such as physiological indicators, mobility, functionality, health status, and quality of life. It's important to consider which outcomes should be recorded at what intervals, keeping in mind the measurement properties of the tools, the human and technical resources required for extensive research, and patients' tolerance for examination.

The case studies proved that the model works, and clinical assessments were successfully conducted.

The study also contributed to expanding therapists' professional knowledge and practical experience with robotic therapy devices and exoskeleton use, providing a solid foundation for work with additional exoskeletons received under the EFOP 5.3.6 project at SE-RK.

The project's indirect success is demonstrated by the modification of national healthcare social security financing regulations. New publicly funded therapeutic methods supported by the National Health Insurance Fund (NEAK) were accepted through legislation, including outpatient LEE gait training. In August 2024, it was announced that NEAK supports the inclusion of 9 additional centers, 7 of which perform exoskeleton therapy [Appendix 6].

It can be said that Hungary is joining those countries that use robotic technology in their therapeutic practice [93].

Our future plans include further exploration of the adaptability of LEE gait training in the rehabilitation process of spinal cord injury patients, with the aim of involving more patients and developing more effective evaluation methods.

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9. List of My Publications

List of my own publications related to the dissertation

1. Shenker, B; Tóth, L; Maróti, P; Fehér, M; Cserháti, P. Alsó végtagi exoszkeleton alkalmazása gerincvelősérültek rehabilitációja során. REHABILITÁCIÓ: A MAGYAR REHABILITÁCIÓS TÁRSASÁG FOLYÓIRATA 33: 2-3 pp. 105-105., 1 p. (2023). Absztrakt / Kivonat (Folyóiratcikk)

2. Shenker, Benjamin; Fehér, Melinda; Erdősi, Petra; Papp, Leila; Vadai, Kitti; Hrivnák, Gergely; Tóth, Luca; Maróti, Péter; Horváth, Csaba; Cserháti, Péter. Examining the Efficacy of Lower Extremity Exoskeletons in the Rehabilitation Process of Spinal Cord Injury Patients: Case Studies. ACTA POLYTECHNICA HUNGARICA 20: 8 pp. 111-131., 21 p. (2023)

3. Shenker, Benjámin; Tóth, Luca; Maróti, Péter; Fehér, Melinda; Cserháti, Péter. Gerincvelősérültek alsó végtagi exoszkeletonnal végzett rehabilitációja a COVID-járvány alatt. REHABILITÁCIÓ: A MAGYAR REHABILITÁCIÓS TÁRSASÁG FOLYÓIRATA 32: 3 pp. 79-79., 1 p. (2022). Absztrakt / Kivonat (Folyóiratcikk)

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9. Tóth, L; Bors, V; Pallag, A; Pinczker, V; Dóczi, T; Cserháti, P; Shenker, B; Büki, A; Nyitrai, M; Maróti, P. Traumás gerincvelősérültek rehabilitációja alsó végtagi humán exoskeletonnal. ORVOSI HETILAP 161: 29 pp. 1200-1207., 8 p. (2020). Összefoglaló cikk (Folyóiratcikk)

List of my own publications independent of the dissertation

1. Shenker-Horváth, K; Shenker, B. A táplálkozás és folyadékfogyasztás hatása a fascia rendszerre (2017). Magyar Gyógytornász-Fizioterapeuták Társaságának XI. Kongresszusa, Győr, 2017. október 11-14., E-poszter

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11. Appendices

Appendix 1

OGYÉI
Országos Gyógyszerészeti
és Élelmezés-egészségügyi Intézet
Orvostechnikai Főosztály

1051 Budapest, Zrínyi u. 3.
Levélcím: 1372 Postafiók 450.
Tel.: (1) 8869-329, Fax: (1) 8869-489
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Ügyiratszám: OGYÉI/1271-2/2020
Tárgy: Engedélyező határozat
ügyintéző:

HATÁROZAT

Prof. Dr. Büki András klinikaigazgató (PTE Klinikai Központ Idegsebészeti Klinika, 7623 Pécs, Rét u.2.), mint kérelmező által benyújtott a *„ReWalk alsó végtagi humán exoskeleton rehabilitációban betöltött szerepének multicentrikus klinikai vizsgálata"* című beavatkozással nem járó vizsgálatot az Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (a továbbiakban: OGYÉI)

engedélyezi és
OGYÉI/1271/2020 ügyszámon
nyilvántartásba veszi.

vizsgálat címe:	*REWALK ALSÓ VÉGTAGI HUMÁN EXOSKELETON REHABILITÁCIÓBAN BETÖLTÖTT SZEREPÉNEK MULTICENTRIKUS KLINIKAI VIZSGÁLATA*
vizsgálati alanyok száma:	20/20 fő
vizsgálati alany neme:	F/N
vizsgálati alany életkor-határai:	18 ≤év
vizsgálat képviselőjének neve:	Prof. Dr. Büki András klinikaigazgató
vizsgálat képviselőjének címe:	7623 Pécs, Rét.u.1.
vizsgálat vezető:	Prof. Dr. Büki András klinikaigazgató
vizsgálat helyei, címei:	1.*Pécsi Tudományegyetem, Idegsebészeti Klinika* 7623 Pécs, Rét.u.1. 2.*Országos Orvosi Rehabilitációs Intézet* 1121 Budapest, Szanatórium. u.19.
vizsgálat beadásának ideje:	2019.11.07.
vizsgálat várható befejezése:	2021.12.31.

A vizsgálat az engedélyezés során beadott vizsgálati terv előírásai szerint végezhető.

engedélyezőt a vizsgálat befejezéséről és ezzel egyidejűleg az engedélyező részére megküldi a vizsgálati dokumentáció másolatát."

A jogorvoslatról szóló tájékoztatás az Ákr. 116. § (4) bekezdésének d) pontján, valamint a közigazgatási per indítására vonatkozó lehetőség az Ákr. 114 § (1) bekezdésén alapul.

Az OGYÉI jelen döntését az Ákr. 80. § (1) bekezdés és az Ákr. 81. § értelmében, a Korm. rendelet 17. § (1) bekezdés c) pontja alapján, az Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézetről szóló 28/2015. (II. 25.) Korm. rendelet (a továbbiakban: 28/2015. Korm. rendelet) 3.§ o) pontjában foglaltak alapján, országos illetékességgel eljárva hozta meg.

E határozat az Ákr. 82. § (1) bekezdés alapján a közléssel jogerős.

Az igazgatási szolgáltatási díjon felül, eljárási cselekmény kapcsán eljárási költség nem merült fel, ezért annak megállapításáról és viseléséről nem rendelkeztem.

Budapest, 2020.01.09.

Dr. Szerdi Kornél
/főosztályvezető /

A határozatot kapják:

1.) Ügyfél – kérelmező,
2.) ETT TUKEB,
3.) NEAK
4.) Irattár, helyben.

Appendix 2

ÖNELLÁTÁS

1. Evés és ivás

0. Mesterséges táplálásra vagy gyomorszondára van szükségem
0. Teljes segítségre van szükségem az evéshez/iváshoz
1. Részleges segítségre van szükségem az evéshez/iváshoz vagy az adaptív eszközök fel-/levételhez
2. Önállóan eszem/iszok, de adaptív eszközökre vagy segítségre van szükségem az étel vágásához, italt önteni vagy edényeket kinyitni
3. Önállóan eszem/iszok segítség és adaptív eszközök nélkül

2. (a) A felsőtest és a fej megmosása

A felsőtest és a fej mosása magában foglalja a szappanozást és a szárítást, valamint a vízcsap használatát.

0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem
2. Független vagyok, de adaptív eszközökre vagy speciális felszerelésre van szükségem (pl. rúd, szék)
3. Független vagyok, és nincs szükségem adaptív eszközökre vagy speciális felszerelésekre

(b) Az alsó test lemosása

Az alsó test mosása magában foglalja a szappanozást és a szárítást, valamint a vízcsap használatát.

0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem
2. Független vagyok, de adaptív eszközökre vagy speciális felszerelésre van szükségem (pl. rúd, szék)
3. Független vagyok, és nincs szükségem adaptív eszközökre vagy speciális felszerelésekre

3. (a) A felsőtest öltöztetése

A felsőtest öltöztetése magában foglalja a ruhák, például pólók fel- és levételét, blúzok, ingek, melltartók, kendők vagy ortézisek (pl. karkötő, nyakmerevítő, fűző)
A könnyen felöltözhető ruhák gombok, cipzárak vagy fűzők nélküliek.
Nehezen öltözködő ruhák azok, amelyek gombos, cipzáros vagy fűzősek.

0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem, még könnyen felöltözhető ruhákkal is
2. Könnyen felöltözhető ruhákhoz nem segítségre van szükségem, hanem adaptív eszközökre, speciális felszerelésre
3. Független vagyok, könnyen felöltözhető ruhákkal. Segítségre van szükségem vagy eszközökre, vagy egy adott beállítás szükséges nehezen öltözhető ruhákkal
4. Teljesen független vagyok

(b) Az alsó test öltöztetése

Az alsó test öltöztetése magában foglalja a ruhák, például a rövidnadrág fel- és levételét,
nadrágok, cipők, zoknik, övek vagy ortézisek (pl. lábléc)
A könnyen felöltözhető ruhák gombok, cipzárak vagy fűzők nélküliek.
Nehezen öltözködő ruhák azok, amelyek gombos, cipzáros vagy fűzősek.

0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem, még könnyen felöltözhető ruhákkal is
2. Könnyen felöltözhető ruhákhoz nem segítségre van szükségem, hanem adaptív eszközökre, speciális felszerelésre
3. Független vagyok, könnyen felöltözhető ruhákkal. Segítségre van szükségem vagy eszközökre, vagy egy adott beállítás szükséges nehezen öltözhető ruhákkal
4. Teljesen független vagyok

4. Ápolás

Kérjük, gondoljon olyan tevékenységekre, mint a kéz- és arcmosás, fogmosás, fésülés, borotválkozás vagy sminkelés

0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem
2. Független vagyok az adaptív eszközökkel
3. Független vagyok adaptív eszközök nélkül

LÉGZÉS ÉS ZÁRÓIZMOK

5. Légzés

Kérjük, csak egy négyzetet jelöljön be, attól függően, hogy szüksége van-e a légzőcső (légcső).

Légcsőre van szükségem…

0. valamint állandó vagy időről időre támogatott lélegeztetés,
2. valamint extra oxigén és sok segítség a köhögésben vagy a légzőcső menedzsmentjében
4. valamint csekély segítség a köhögésben vagy a légzőcső kezelésében

Nincs szükségem légzőcsőre…

6. de extra oxigénre vagy sok segítségre van szükségem köhögéskor vagy maszkra (pl. Pozitív végkilégzési nyomás (PEEP)) vagy időről időre támogatott lélegeztetés (pl. kétszintű pozitív légúti nyomás (BIPAP))
8. és csak kevés segítség vagy stimuláció köhögés esetén
10. és önállóan tud lélegezni és köhögni mindenféle segítség és adaptív eszköz nélkül

6. Hólyagkezelés

Kérjük, gondoljon arra, hogyan üríti ki a hólyagot. [A 6. pont pontozása: lásd A függelék]

a) Belső katéter használata

0. Igen → Kérem, lépjen a 7a. kérdésre
1. Nem → Kérjük, válaszoljon a 6b és 6c kérdésekre is

(b) Időszakos katéterezés
0. Teljes segítségre van szükségem
1. Magam csinálom segítséggel (önkatéterezés)
2. Én magam csinálom segítség nélkül (önkatéterezés)
3. nem használom

(c) Külső vízelvezető eszközök (pl. óvszerkatéter, pelenkák, egészségügyi eszközök)
0. Teljes segítségre van szükségem a használatukhoz
1. Részleges segítségre van szükségem a használatukhoz
2. Segítség nélkül használom őket
3. Kontinens vagyok vizelettel és nem használok külső vízelvezető eszközöket

7. Bélkezelés [7. pont pontozása: lásd a B. mellékletet]
(a) Szüksége van-e segítségre a bélrendszer kezelésében (pl. kúpok)?
0. Igen
1. Nem

(b) A bélmozgásom…
0. szabálytalan vagy ritkán (3 napon belül ritkábban)
1. rendszeres (legalább 3 naponta egyszer)

(c) Széklet inkontinencia („baleset") történik…
0. havonta kétszer vagy többször
1. havonta egyszer
2. egyáltalán nem

8. WC használata
Kérjük, gondoljon a WC használatára, a nemi szervek és a kezek tisztítására, ruházat fel- és levétele, valamint egészségügyi betét vagy pelenka használata.
0. Teljes segítségre van szükségem
1. Részleges segítségre van szükségem, és nem tudok megtisztítani magam
2. Részleges segítségre van szükségem, de meg tudom tisztítani magam
4. Nincs szükségem segítségre, de adaptív eszközökre (pl. rudak) vagy speciális beállításra van szükségem (pl. kerekesszékkel megközelíthető WC)
5. Nincs szükségem segítségre, adaptív eszközökre vagy speciális beállításra

MOBILITÁS

9. A következő négy tevékenység közül hányat tud elvégezni segítség nélkül, ill. elektromos segédeszközök
- a felsőtest elfordítása az ágyban
- az alsótest elfordítása az ágyban
- felül az ágyban
- fekvőtámasz gyakorlása kerekesszékben (adaptív eszközökkel vagy anélkül)
0. nincs, segítségre van szükségem ezekhez a tevékenységekhez
2. egy
4. kettő vagy három
6. mindegyik

10. Átszállás az ágyból a kerekesszékbe

0. Teljes segítségre van szükségem
1. Részleges segítségre, felügyeletre vagy adaptív eszközökre van szükségem (pl. csúszó deszka)
2. Nincs szükségem segítségre vagy adaptív eszközökre
2. nem használok kerekesszéket

11. Átszállás a kerekesszékből a WC-be/kádba

A transzfer magában foglalja a kerekesszékből vagy az ágyból a WC-re való átszállást is

0. Teljes segítségre van szükségem
1. Részleges segítségre, felügyeletre vagy adaptív eszközökre (pl. kapaszkodókra) van szükségem
2. Nincs szükségem segítségre vagy adaptív eszközökre
2. nem használok kerekesszéket

12. Mozgás bent

Kérjük, csak egy négyzetet jelöljön be, attól függően, hogy általában a kerekesszékkel vagy gyalogosan mozogni beltéren.

kerekesszéket használok. Hogy mozogjak, én…

0. teljes segítségre van szüksége
1. elektromos kerekesszékre vagy részleges segítségre van szüksége a kézi kerekesszék kezeléséhez
2. független vagyok kézi kerekesszékben

Bent sétálok, és…

3. felügyeletre van szüksége járás közben (járást segítő eszközzel vagy anélkül)
4. sétáljon járókerettel vagy mankóval, egyszerre mindkét lábával lendüljön előre
5. mankóval vagy két bottal járni, egyik lábát a másik elé téve
6. séta egy bottal
7. járás csak lábortézissel (pl. lábsínnel)
8. járás járást segítő eszközök nélkül

13. Közepes távolságok megtétele (10-100 méter)

Kérjük, csak egy négyzetet jelöljön be, attól függően, hogy általában a kerekesszékkel vagy gyalogosan, mérsékelt távolságok (10-100 méter) megtételéhez.

kerekesszéket használok. Hogy mozogjak, én…

0. teljes segítségre van szüksége
1. elektromos kerekesszékre vagy részleges segítségre van szüksége a kézi kerekesszék kezeléséhez
2. független vagyok kézi kerekesszékben

Mérsékelt távolságokat gyalogolok, és…

3. felügyeletre van szüksége járás közben (járást segítő eszközzel vagy anélkül)
4. sétáljon járókerettel vagy mankóval, egyszerre mindkét lábával előre lendülve

5. mankóval vagy két bottal járni, egyik lábát a másik elé téve
6. séta egy bottal
7. gyaloglás csak lábortézissel (pl. lábsínnel)
8. járás járást segítő eszközök nélkül

14. 100 méternél hosszabb mozgás a szabadban

Kérjük, csak egy négyzetet jelöljön be, attól függően, hogy általában a kerekesszékkel vagy gyalogosan mozogni a szabadban 100 méternél hosszabb ideig.

kerekesszéket használok. Hogy mozogjak, én…

0. teljes segítségre van szüksége
1. elektromos kerekesszékre vagy részleges segítségre van szüksége a kézi kerekesszék kezeléséhez
2. független vagyok kézi kerekesszékben

Több mint 100 métert sétálok, és…

3. felügyeletre van szüksége járás közben (járást segítő eszközzel vagy anélkül)
4. sétáljon járókerettel vagy mankóval, egyszerre mindkét lábával előre lendülve
5. mankóval vagy két bottal járni, egyik lábát a másik elé téve
6. séta egy bottal
7. gyaloglás csak lábortézissel (pl. lábsínnel)
8. járás járást segítő eszközök nélkül

15. Lépcsőn fel és le

Kérjük, csak egy négyzetet jelöljön be, attól függően, hogy fel tud-e lépni vagy sem és le a lépcsőn.

0. Nem tudok fel-le menni a lépcsőn

Fel-le tudok menni legalább 3 lépést…

1. de csak segítséggel vagy felügyelettel
2. de csak eszközökkel (pl. korlát, mankó vagy bot)
3. segítség, felügyelet vagy eszközök nélkül

16. Átszállás a kerekesszékből az autóba

Magában foglalja a kerekesszék autóba helyezését és kivételét is.

0. Teljes segítségre van szükségem
1. Részleges segítségre, felügyeletre vagy adaptív eszközökre van szükségem
2. Nincs szükségem segítségre vagy adaptív eszközökre
2. nem használok kerekesszéket

17. Átszállás a padlóról a kerekesszékbe

0. Segítségre van szükségem
1. Nincs szükségem segítségre
1. Nem használok kerekesszéket

PONTOZÁS (a klinikusnak teljesítenie kell)
Kérjük, használja a következő táblázatokat a 6. és 7. tételhez.

Item 6

SCIM-SR Item			Score in SCIM-SR
6A	**6B**	**6C**	
0	Not relevant if 6A=0	Not relevant if 6A=0	0
1	0	0	6
1	0	1	6
1	0	2	6
1	0	3	6
1	1	0	6
1	1	1	6
1	1	2	6
1	1	3	6
1	2	0	6
1	2	1	6
1	2	2	9
1	2	3	11
1	3	0	6
1	3	1	6
1	3	2	13
1	3	3	15

Item 7

SCIM-SR Item			Score in SCIM-SR
7A	**7B**	**7C**	
Not relevant if 7B=0	0	Not relevant if 7B=0	0
0	1	1	5
0	1	2	5
1	1	1	8
1	1	2	10
0	1	0	5
1	1	0	5

Öngondoskodás alskála, 1-4 (0-20) .....

Légzés és záróizmok kezelés alskála, 5-8 (0-40) .....

Mobilitási alskála, 9-17 (0-40) .....

ÖSSZES SCIM PONT (0-100) .....

SCIM befejezésének dátuma:

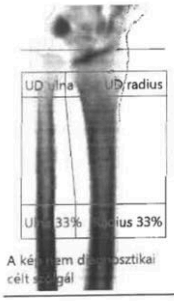
Appendix 3

Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,

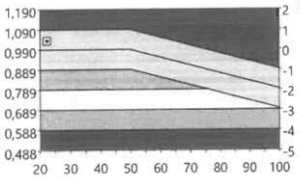
Telefon: (__) __-___

Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVATH CS
Születési idő:	20[redacted]	**Kor:**	22,3 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	90,0 kg	**Mérve:**	2023. 03. 28. 10:16:08 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:39:02 (18)

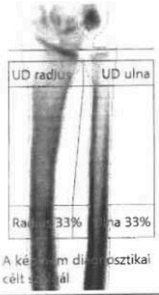


A kép[illegible]sztikai cél[illegible]gál

Bal alkar: Radius 33% (BMD)

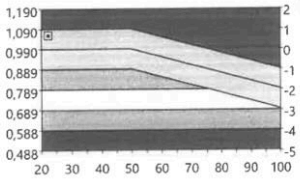


Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	1,035	0,5	0,5



A kép[illegible]sztikai cél[illegible]gál

Jobb alkar: Radius 33% (BMD)



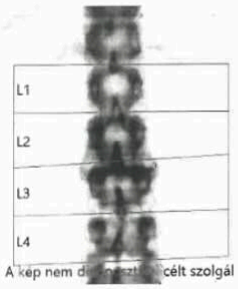
Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	1,060	0,7	0,7

Major Osteoporotic Fracture:	-
Hip Fracture:	-
Population:	(nincs)
Rizikó tényezők:	Nincs

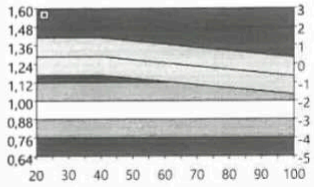
Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,
Telefon: (___) ___-____

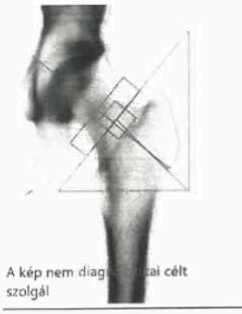
Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVATH CS
Születési idő:	[redacted]	**Kor:**	22,3 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	90,0 kg	**Mérve:**	2023. 03. 28. 10:16:08 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:39:02 (18)



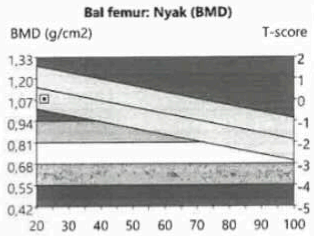
A kép nem d[redacted]cél szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
L1	1,273	0,9	0,5
L2	1,634	3,3	2,9
L3	1,635	3,3	2,9
L4	1,418	1,5	1,1
L1-L2	1,459	2,2	1,8
L1-L3	1,525	2,6	2,2
L1-L4	1,495	2,3	1,9
L2-L3	1,634	3,3	2,9
L2-L4	1,558	2,7	2,3

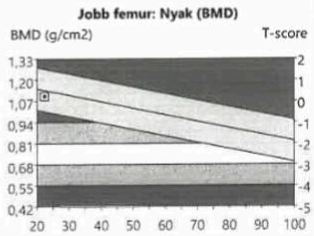


A kép nem diag[redacted]kai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak bal	1,079	0,1	-0,4
Teljes bal	0,954	-1,0	-1,5

A kép nem diag[redacted]kai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak jobb	1,100	0,2	-0,3
Teljes jobb	0,980	-0,8	-1,3

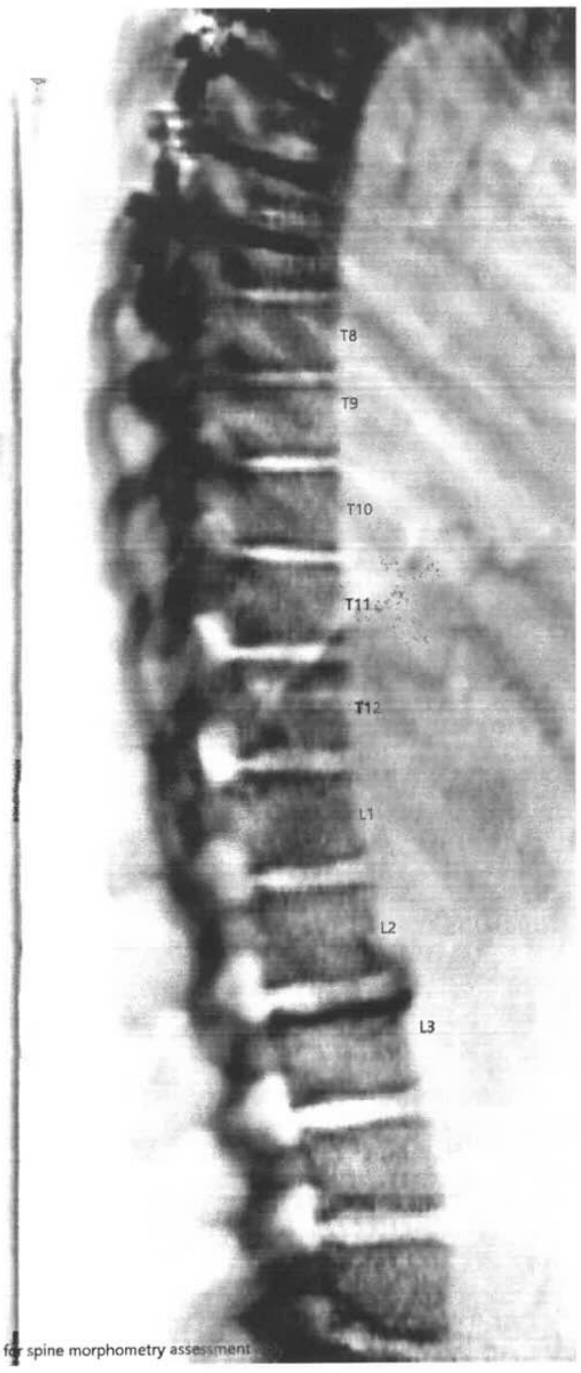


Image for spine morphometry assessment

Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor
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Telefon: (__) __-___

Páciens:	K[redacted]
Születési idõ:	2[redacted]
Kor:	22,3 évek
Magasság / Testsúly:	194,0 cm 90,0 kg
Nem / Populáció:	Férfi Fehér
TAJ:	[redacted]
Vizsgáló orvos:	DR HORVATH CS
Mérve:	2023. 03. 28. 10:30:59 (18)
Analizált:	2023. 08. 29. 9:43:41 (18)

LVA Morphometria

Régió	Átlagos magasság (%)	P/A Arány (%)	M/P arány (%)	A/P arány (%)
T8	108	106	89	94
T9	101	102	92	98
T10	107	96	97	104
T11	106	113	92	89
T12	103	115	91	87
L1	104	114	93	88
L2	103	100	101	100
L3	99	92	105	108
L4	98	88	103	113

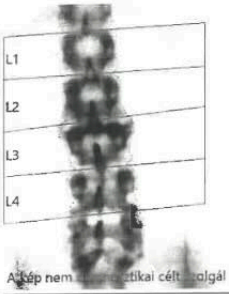
Megjegyzés:

A referencia a(z) L2,L3,ésL4-on alapul.; A magasság precizitása (±1SD) 1 mm, az arány precizitása 0,05
Date created: 2023. 08. 29. 9:43:47 18; Fájlnév: d128sraxuq.dfm; LVA; 76,3,00:22,24:54,0 0,00:19,60 1,20x1,05 26,4:%Zsír=5,2%; 0,00:0,00 0,00:0,00; Szkennelési mód: Standard; 83,0 µGy

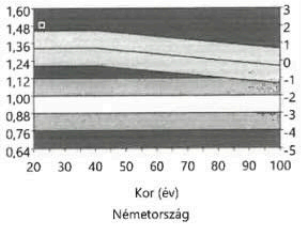
Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,
Telefon: (___) ___-____

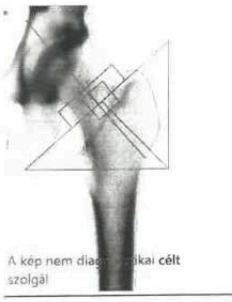
Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVATH CS
Születési idő:	[redacted]	**Kor:**	22,6 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	100,0 kg	**Mérve:**	2023. 08. 04. 8:08:31 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:47:42 (18)



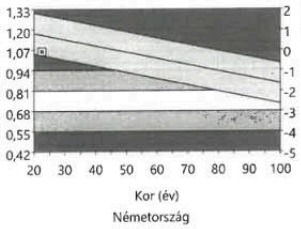
A kép nem diagnosztikai célt szolgál



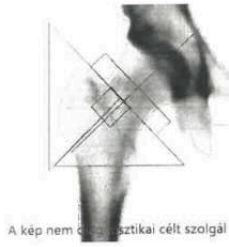
Régió	BMD (g/cm2)	YA T-score	AM Z-score
L1	1,304	1,2	0,5
L2	1,507	2,2	1,5
L3	1,554	2,6	1,9
L4	1,400	1,3	0,6
L1-L2	1,412	1,8	1,0
L1-L3	1,466	2,1	1,4
L1-L4	1,448	1,9	1,2
L2-L3	1,532	2,4	1,7
L2-L4	1,487	2,1	1,3



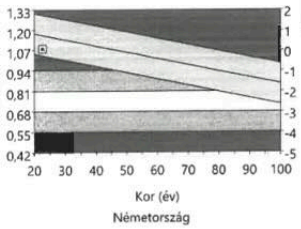
A kép nem diagnosztikai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak bal	1,062	-0,1	-0,8
Teljes bal	0,966	-1,0	-1,6



A kép nem diagnosztikai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak jobb	1,081	0,1	-0,6
Teljes jobb	0,936	-1,2	-1,9

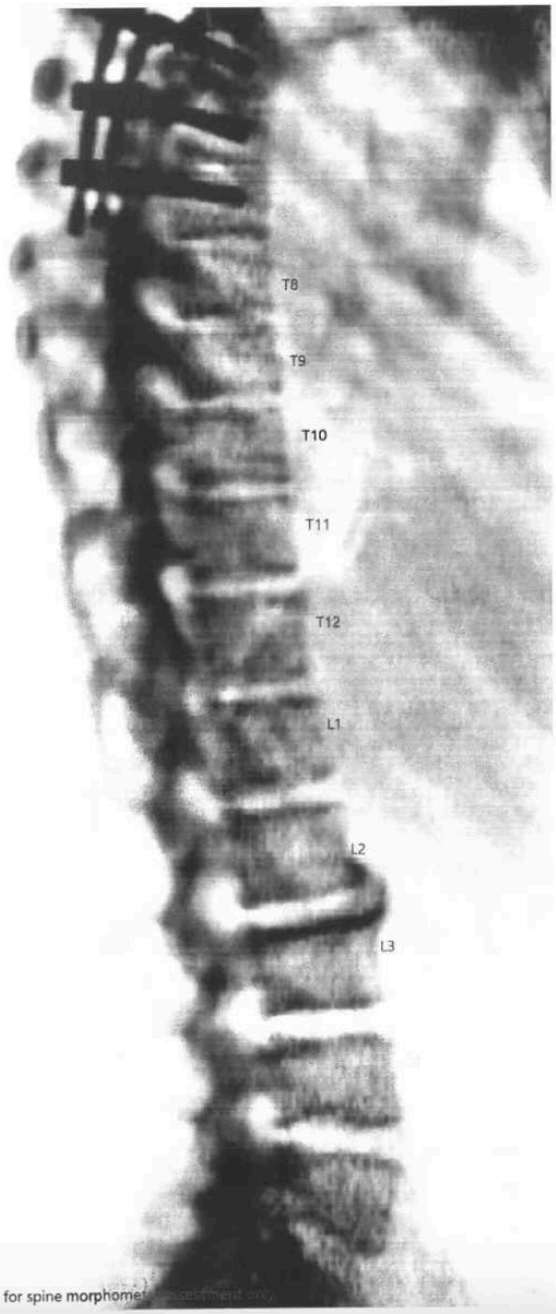


Image for spine morphometric assessment only

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Telefon: (__) ___-___

Páciens:	XXXXXXXX
Születési idő:	XXXXXXXXX
Kor:	22,6 évek
Magasság / Testsúly:	194,0 cm 100,0 kg
Nem / Populáció:	Férfi Fehér
TAJ:	XXXXXXXXX
Vizsgáló orvos:	DR HORVATH CS
Mérve:	2023. 08. 04. 8:22:09 (18)
Analizált:	2023. 08. 29. 9:53:21 (18)

LVA Morphometria

Régió	Átlagos magasság (%)	P/A Arány (%)	M/P arány (%)	A/P arány (%)
T8	103	98	97	102
T9	105	104	90	96
T10	106	99	96	101
T11	108	102	92	98
T12	110	98	97	102
L1	105	105	96	95
L2	105	104	95	96
L3	96	92	99	108
L4	99	97	94	103

Megjegyzés:

A referencia a(z) L2,L3,ésL4-on alapul.; A magasság precizitása (±1SD) 1 mm, az arány precizitása 0,05
Date created: 2023. 08. 29. 9:53:27 18; Fájlnév: z1suyraxuq.dfm; LVA; 76,3,00:22,24:54,0 0,00:21,68 1,20x1,05 27,9:%Zsir=5,6%; 0,00:0,00 0,00:0,00; Szkennelési mód: Standard; 83,0 µGy

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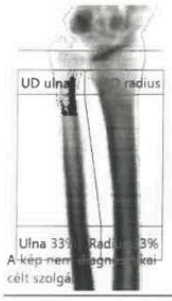
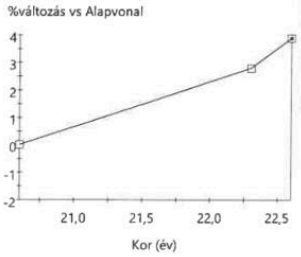
Telefon: (__) __-___

Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVATH CS
Születési idő:	[redacted]	**Kor:**	22,6 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	100,0 kg	**Mérve:**	2023. 08. 04. 8:08:31 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:47:42 (18)

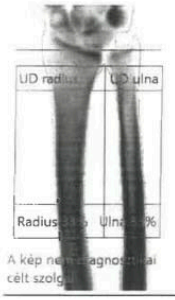


Bal alkar: Radius 33% (BMD)

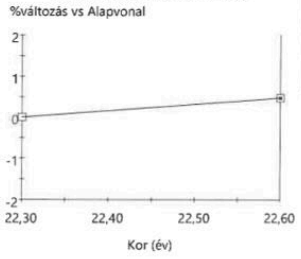


Tendencia: Radius 33%

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	22,6	1,046	3,9	1,9
2023. 03. 28.	22,3	1,035	2,8	1,7
2021. 07. 22.	20,6	1,007	alapvonal	alapvonal



Jobb alkar: Radius 33% (BMD)



Tendencia: Radius 33%

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	22,6	1,065	0,5	1,3
2023. 03. 28.	22,3	1,060	alapvonal	alapvonal

Major Osteoporotic Fracture:	-
Hip Fracture:	-
Population:	(nincs)
Rizikó tényezők:	Nincs

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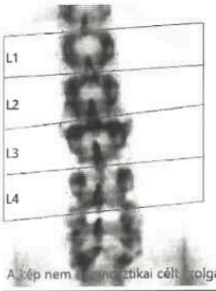
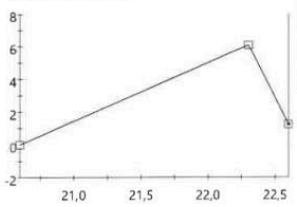
Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,
Telefon: (__) __-___

Páciens:	[redacted]			**Vizsgáló orvos:** DR HORVATH CS	
Születési idő:	[redacted]	**Kor:**	22,6 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	100,0 kg	**Mérve:**	2023. 08. 04. 8:08:31 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:47:42 (18)



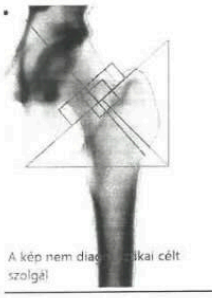
A kép nem diagnosztikai célt szolgál

AP gerinc: L2-L4 (BMD)



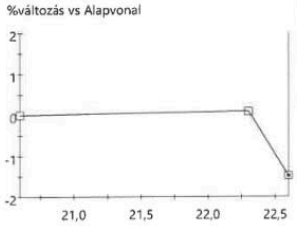
Tendencia: L2-L4

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	22,6	1,487	1,2	0,6
2023. 03. 28.	22,3	1,558	6,1 *	3,6 *
2021. 07. 22.	20,6	1,469	alapvonal	alapvonal



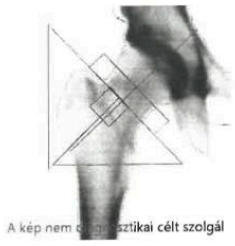
A kép nem diagnosztikai célt szolgál

Bal femur: Nyak (BMD)



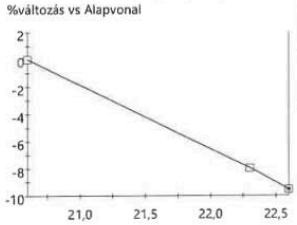
Tendencia: Nyak bal

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	22,6	1,062	-1,5	-0,7
2023. 03. 28.	22,3	1,079	0,1	0,1
2021. 07. 22.	20,6	1,078	alapvonal	alapvonal



A kép nem diagnosztikai célt szolgál

Jobb femur: Nyak (BMD)



Tendencia: Nyak jobb

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	22,6	1,081	-9,5 *	-4,7 *
2023. 03. 28.	22,3	1,100	-7,9 *	-4,7 *
2021. 07. 22.	20,6	1,195	alapvonal	alapvonal

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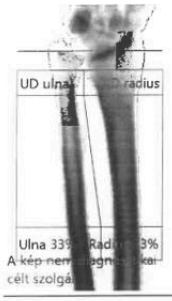
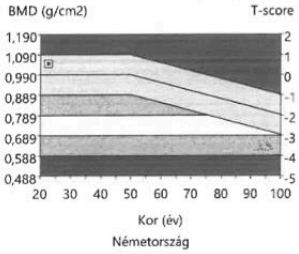
Telefon: (__) __-___

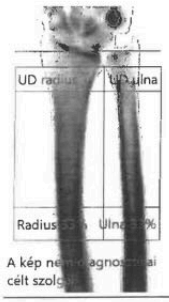
Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVATH CS
Születési idõ:	[redacted]	**Kor:**	22,6 évek	**TAJ:**	[redacted]
Magasság:	194,0 cm	**Testsúly:**	100,0 kg	**Mérve:**	2023. 08. 04. 8:08:31 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:47:42 (18)



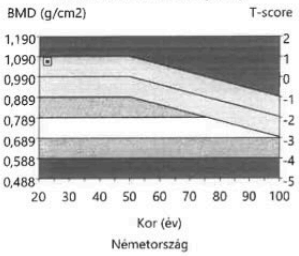
A kép nem diagnosztikai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	1,046	0,6	0,6



A kép nem diagnosztikai célt szolgál



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	1,065	0,8	0,8

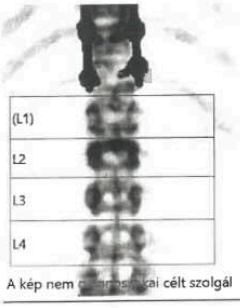
Major Osteoporotic Fracture:	-
Hip Fracture:	-
Population:	(nincs)
Rizikó tényezők:	Nincs

Appendix 4

Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

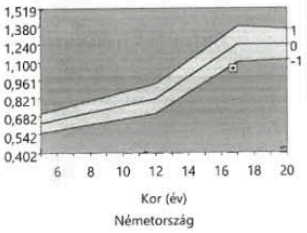
Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,
Telefon: (__) __-____

Páciens:	XXXXXXXXXX			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	XXXXXXXXXX	**Kor:**	16 évek 8 hónapok	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	88,0 kg	**Mérve:**	2023. 03. 08. 10:10:50 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:42 (18)

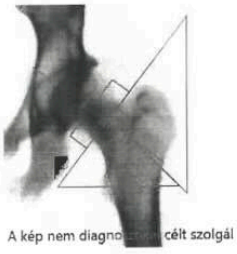


A kép nem diagnosztikai célt szolgál

AP gerinc: L2-L4 (BMD)

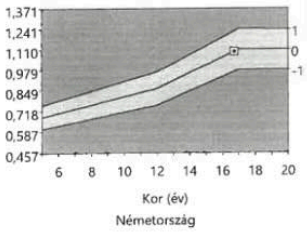


Régió	BMD (g/cm2)	YA T-score	AM Z-score
L1	0,963	-	-1,2
L2	1,232	-	0,1
L3	1,057	-	-1,1
L4	0,907	-	-2,2
L2-L3	1,139	-	-0,6
L2-L4	1,049	-	-1,2

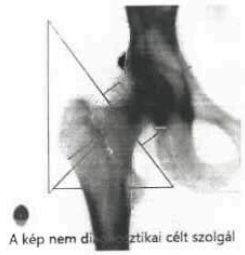


A kép nem diagnosztikai célt szolgál

Bal femur: Nyak (BMD)

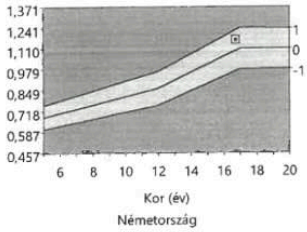


Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak bal	1,096	-	0,0
Teljes bal	0,872	-	-1,7



A kép nem diagnosztikai célt szolgál

Jobb femur: Nyak (BMD)



Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak jobb	1,165	-	0,5
Teljes jobb	0,834	-	-2,0

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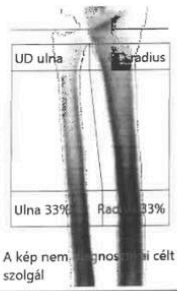
Telefon: (__) ___-____

Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	[redacted]	**Kor:**	16 évek 8 hónapok	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	88,0 kg	**Mérve:**	2023. 03. 08. 10:10:50 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:42 (18)



A kép nem [illegible]nosztikai célt szolgál

Németország Reference Chart: No reference data for Bal alkar [Radius 33%] region. Németország Referencia Populació nem támogatja a páciens Kor Bal alkar Denzitometria -t.

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	0,974	-	-

Statisztikailag a megismételt vizsgálatok 68%-a 1SD-n belül van (± 0,010 g/cm2 for AP gerinc L2-L4 BMD); (± 0,014 g/cm2 for Bal femur Nyak BMD); (± 0.020 g/cm2 for Bal alkar Radius 33% BMD); Németország AP gerinc; Male Referencia Populáció (v113); Németország Femur; Male Referencia Populáció (v113); Németország (kor 20-40) Alkar; Male Referencia Populació (v113); AP gerinc Matched for Age, Sex, Ethnicity; Bal femur Matched for Age, Sex, Ethnicity; Lunar calibration in use.; WHO meghatározás: Osteopenia fehér nők:Normális értékT-score nagyobb vagy egyenlő -1,0 SD; Osteopenia = T-score -1,0 és -2,5 SD között; Osteoporosis = T-score egyenlő vagy alacsonyabb -2,5 SD; (WHO meghatározás csak a megfelelő adatbázis kiválasztásakor alkalmazható - fiatal fehér nő)
Date created: 2023. 08. 29. 9:34:56 18; Fájlnév: pp27rraxuq.dfx; AP gerinc; 76,3,00:50,03:12,0 0,00:10,20 0,60x1,05 22,5:%Zsír=29,7%; 0,00:0,00 0,00:0,00; Szkennelési mód: Standard; 37,0 µGy; Bal femur; 76,3,00:50,03:12,0 0,00:11,64 0,60x1,05 19,4:%Zsír=29,8%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 53; Szkennelési mód: Standard; 37,0 µGy; Jobb femur; 76,3,00:50,03:12,0 0,00:12,00 0,60x1,05 19,9:%Zsír=26,3%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 54; Szkennelési mód: Standard; 37,0 µGy; Bal alkar; 76,0,15:50,03:12,0 0,00:6,20 0,60x1,05 5,5:%Zsír=18,1%; 0,00:0,00 0,00:0,00; Alkar hossza: 30,3 cm; Szkennelési mód: Standard;Nem ültetett; 2,0 µGy

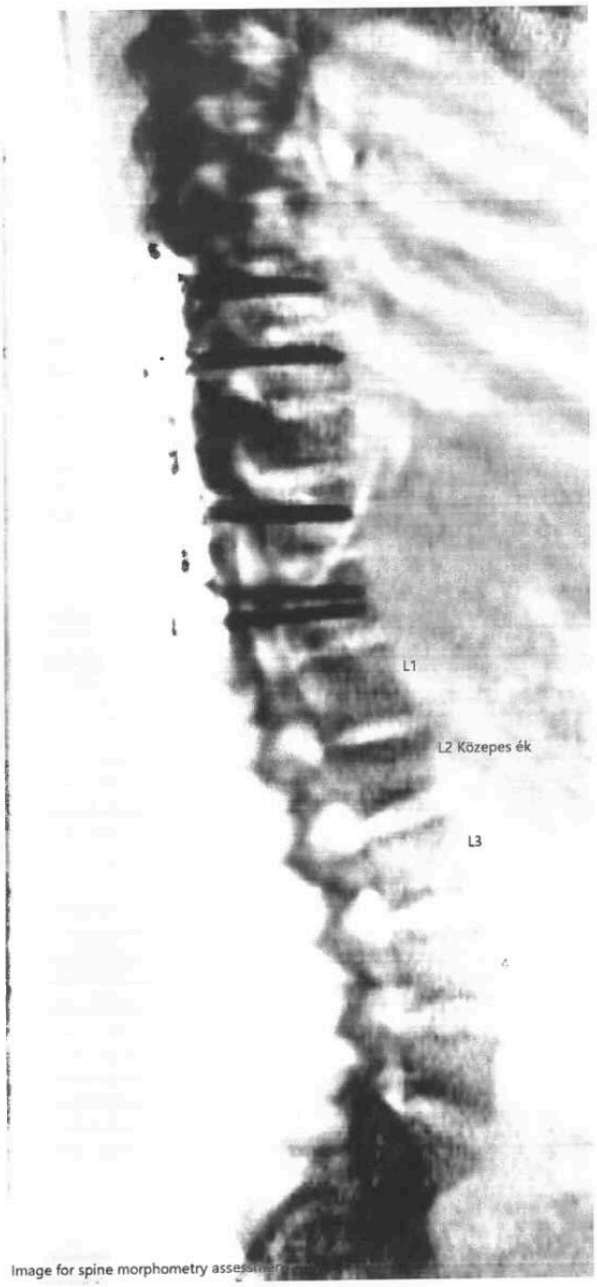


Image for spine morphometry assessment

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Telefon: (__) ___-____

Páciens:	XXXXXXXXX
Születési idő:	XXXXXXXXX
Kor:	16 évek 8 hónapok
Magasság / Testsúly:	187,0 cm 88,0 kg
Nem / Populáció:	Férfi Fehér
TAJ:	(nem meghatározott)
Vizsgáló orvos:	DR HORVÁTH CS
Mérve:	2023. 03. 08. 10:24:07 (18)
Analizált:	2023. 08. 29. 9:30:31 (18)

LVA Morphometria

Régió	Átlagos magasság (%)	P/A Arány (%)	M/P arány (%)	A/P arány (%)
L1	98	111	91	90
L2	83	146	77	69
L3	100	95	89	106
L4	100	112	81	89

Közepes ék

Megjegyzés:

A referencia a(z) L3ésL4-on alapul.; A magasság precizitása (±1SD) 1 mm, az arány precizitása 0,05
Date created: 2023. 08. 29. 9:30:41 18; Fájlnév: j837rraxuq.dfm: LVA; 76,3,00:22,24:54,0 0,00:19,36 1,20x1,05 29,1:%Zsír=7,0%; 0,00:0,00 0,00:0,00; Szkennelési mód: Standard; 83,0 µGy

Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

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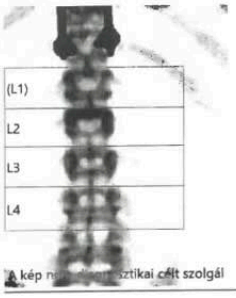
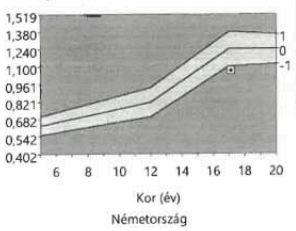
Telefon: (__) __-____

Páciens:	XXXXXXXXXX			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	XXXXXXXXXX	**Kor:**	17 évek 1 hónap	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	104,0 kg	**Mérve:**	2023. 08. 04. 8:39:09 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:33 (18)



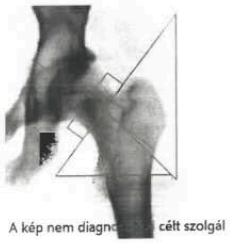
A kép n... diagnosztikai célt szolgál

AP gerinc: L2-L4 (BMD)



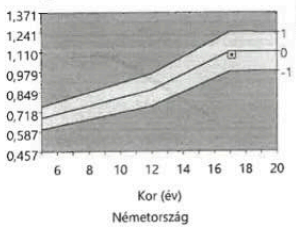
Németország

Régió	BMD (g/cm2)	YA T-score	AM Z-score
L1	1,049	-	-0,8
L2	1,191	-	-0,4
L3	1,097	-	-1,0
L4	0,960	-	-2,0
L2-L3	1,141	-	-0,7
L2-L4	1,068	-	-1,2



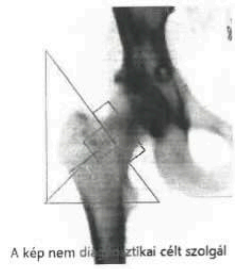
A kép nem diagnosztikai célt szolgál

Bal femur: Nyak (BMD)



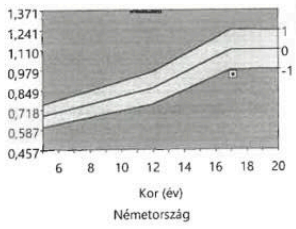
Németország

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak bal	1,086	-	-0,2
Teljes bal	0,846	-	-2,0



A kép nem diagnosztikai célt szolgál

Jobb femur: Nyak (BMD)



Németország

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Nyak jobb	0,944	-	-1,3
Teljes jobb	0,773	-	-2,5

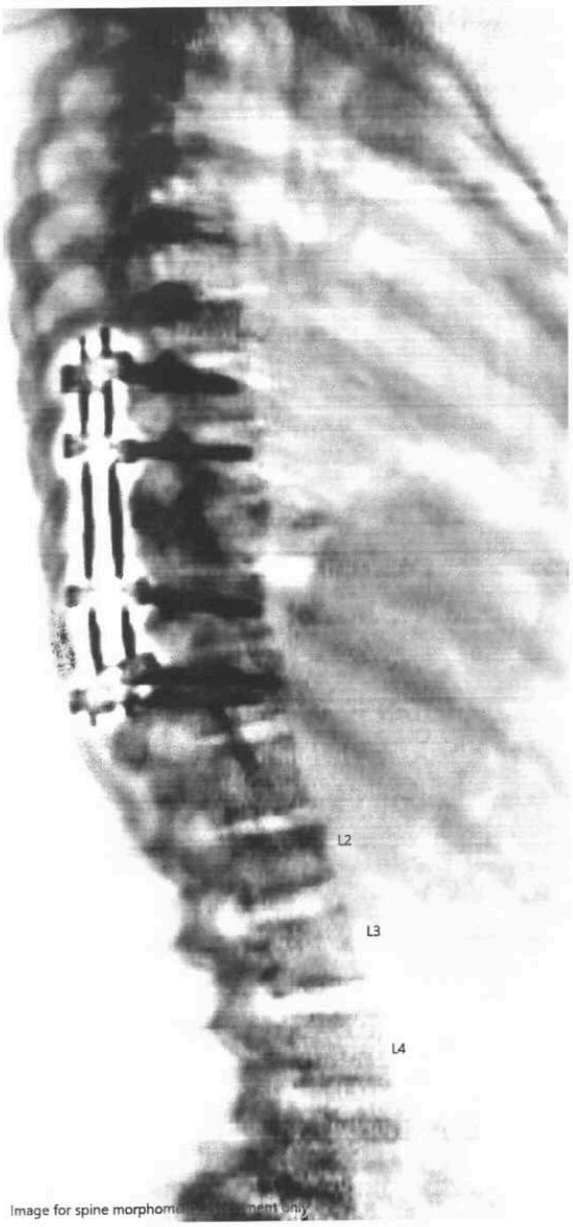


Image for spine morphom[illegible]ment only

Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

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Telefon: (___) ___-____

Páciens:	XXXX XXXX
Születési idõ:	XXXX.XX.XX
Kor:	17 évek 1 hónap
Magasság / Testsúly:	187,0 cm 104,0 kg
Nem / Populáció:	Férfi Fehér
TAJ:	(nem meghatározott)
Vizsgáló orvos:	DR HORVÁTH CS
Mérve:	2023. 08. 04. 8:55:31 (18)
Analizált:	2023. 08. 29. 9:32:22 (18)

LVA Morphometria

Régió	Átlagos magasság (%)	P/A Arány (%)	M/P arány (%)	A/P arány (%)
L1	100	110	94	91
L2	81	132	85	76
L3	101	89	96	113
L4	99	103	88	97

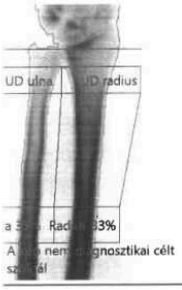
Megjegyzés:

A referencia a(z) L3ésL4-on alapul.; A magasság precizitása (±1SD) 1 mm, az arány precizitása 0,05
Date created: 2023. 08. 29. 9:32:28 18; Fájlnév: entuyraxuq.dfm; LVA: 76,3,00:22,24:54,0 0,00:16,16 1,20x1,05 28,3:%Zsír=11,6%; 0,00:0,00 0,00:0,00; Szkennelési mód: Standard; 83,0 µGy

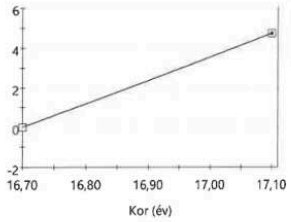
Semmelweis Egyetem I.sz. Bel. Klinika ODM Labor

Budapest , Korányi Sándor u. 2/a., Tel: +36 (1) 210-0278/51519,
Telefon: (__) ___-____

Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	[redacted]	**Kor:**	17 évek 1 hónap	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	104,0 kg	**Mérve:**	2023. 08. 04. 8:39:09 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:33 (18)

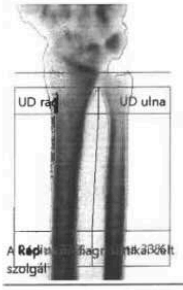


Bal alkar: Radius 33% (BMD)



Tendencia: Radius 33%

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	17,1	1,020	4,7	11,6
2023. 03. 08.	16,7	0,974	alapvonal	alapvonal



Németország Reference Chart: No reference data for Jobb alkar [Radius 33%] region. Németország Referencia Populació nem támogatja a páciens Kor Jobb alkar Denzitometria -t.

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	0,946	-	-

(*) Indicates significant change based on 95% confidence interval. (LSC= 0,028 g/cm² for AP gerinc L2-L4 BMD); (LSC= 0,039 g/cm² for Bal femur Nyak BMD); (LSC= 0,055 g/cm² for Bal alkar Radius 33% BMD); Statisztikailag a megismételt vizsgálatok 68%-a 1SD-n belül van (± 0,010 g/cm2 for AP gerinc L2-L4 BMD); (± 0,014 g/cm2 for Bal femur Nyak BMD); (± 0,020 g/cm2 for Bal alkar Radius 33% BMD); Németország (kor 20-40) Alkar; Male Referencia Populació (v113); Lunar calibration in use.; WHO meghatározás: Osteopenia fehér nők:Normális érték:T-score nagyobb vagy egyenlő -1,0 SD; Osteopenia = T-score -1,0 és -2,5 SD között; Osteoporosis = T-score egyenlő vagy alacsonyabb -2,5 SD; (WHO meghatározás csak a megfelelő adatbázis kiválasztásakor alkalmazható - fiatal fehér nő)
Date created: 2023. 08. 29. 9:55:58 18; Fájlnév: 2ysuyraxuq.dfx; AP gerinc; 76,3,00:22,24:27,0 0,00:9,66 0,60x1,05 23,6:%Zsír=35,5%; 0,00:0,00 0,00:0,00; Szkennelési mód: Vastag; 83,0 µGy; Bal femur; 76,3,00:50,03:12,0 0,00:11,40 0,60x1,05 20,0:%Zsír=33,0%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 53; Szkennelési mód: Standard; 37,0 µGy; Jobb femur; 76,3,00:50,03:12,0 0,00:13,32 0,60x1,05 20,1:%Zsír=30,0%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 54; Szkennelési mód: Standard; 37,0 µGy; Bal alkar; 76,0,15:50,03:12,0 0,00:6,20 0,60x1,05 5,5:%Zsír=23,0%; 0,00:0,00 0,00:0,00; Alkar hossza: 30,3 cm; Szkennelési mód: Standard;Nem ültetett; 2,0 µGy; Jobb alkar; 76,0,15:50,03:12,0 0,00:6,20 0,60x1,05 5,4:%Zsír=25,7%; 0,00:0,00 0,00:0,00; Alkar hossza: 30,3 cm; Szkennelési mód: Standard;Nem ültetett; 2,0 µGy

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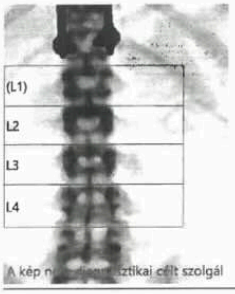
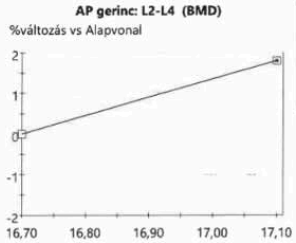
Telefon: (___) ___-____

Páciens:	[redacted]			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	[redacted]	**Kor:**	17 évek 1 hónap	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	104,0 kg	**Mérve:**	2023. 08. 04. 8:39:09 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:33 (18)

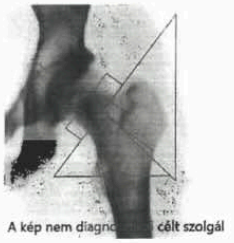


A kép n[redacted]ztikai célt szolgál

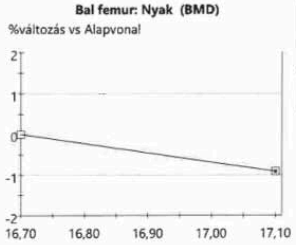


Tendencia: L2-L4

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	17,1	1,068	1,8	4,5
2023. 03. 08.	16,7	1,049	alapvonal	alapvonal

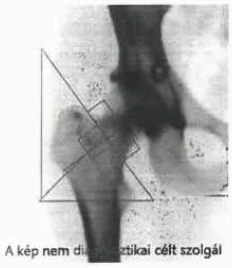


A kép nem diagnó[redacted] célt szolgál

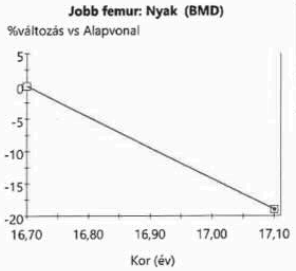


Tendencia: Nyak bal

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	17,1	1,086	-0,9	-2,3
2023. 03. 08.	16,7	1,096	alapvonal	alapvonal



A kép nem di[redacted]ztikai célt szolgál



Tendencia: Nyak jobb

Mérés dátuma	Mérés kora	BMD (g/cm2)	Change vs alapvonal (%)	Change vs alapvonal (%/év)
2023. 08. 04.	17,1	0,944	-19,0 *	-46,8 *
2023. 03. 08.	16,7	1,165	alapvonal	alapvonal

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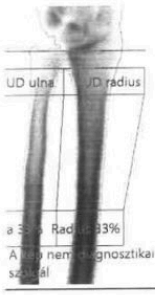
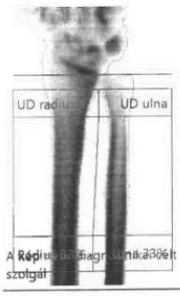
Páciens:	XXXXXXXXXX			**Vizsgáló orvos:**	DR HORVÁTH CS
Születési idő:	XXXXXXXXXX	**Kor:**	17 évek 1 hónap	**TAJ:**	(nem meghatározott)
Magasság:	187,0 cm	**Testsúly:**	104,0 kg	**Mérve:**	2023. 08. 04. 8:39:09 (18)
Nem:	Férfi	**Populáció:**	Fehér	**Analizált:**	2023. 08. 29. 9:29:33 (18)



Németország Reference Chart: No reference data for Bal alkar [Radius 33%] region. Németország Referencia Populació nem támogatja a páciens Kor Bal alkar Denzitometria -t.

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	1,020	-	-



Németország Reference Chart: No reference data for Jobb alkar [Radius 33%] region. Németország Referencia Populació nem támogatja a páciens Kor Jobb alkar Denzitometria -t.

Régió	BMD (g/cm2)	YA T-score	AM Z-score
Radius 33%	0,946	-	-

Statisztikailag a megismételt vizsgálatok 68%-a 1SD-n belül van (± 0,010 g/cm2 for AP gerinc L2-L4 BMD); (± 0,014 g/cm2 for Bal femur Nyak BMD); (± 0,020 g/cm2 for Bal alkar Radius 33% BMD); Németország AP gerinc; Male Referencia Populáció (v113); Németország Femur; Male Referencia Populáció (v113); Németország (kor 20-40) Alkar; Male Referencia Populació (v113); AP gerinc Matched for Age, Sex, Ethnicity; Bal femur Matched for Age, Sex, Ethnicity; Lunar calibration in use.; WHO meghatározás: Osteopenia fehér nők:Normális érték:T-score nagyobb vagy egyenlő -1,0 SD; Osteopenia = T-score -1,0 és -2,5 SD között; Osteoporosis = T-score egyenlő vagy alacsonyabb -2,5 SD; (WHO meghatározás csak a megfelelő adatbázis kiválasztásakor alkalmazható - fiatal fehér nő)
Date created: 2023. 08. 29. 9:31:07 18: Fájlnév: 2ysuyraxuq.dfx; AP gerinc; 76,3,00:22,24:27,0 0,00:9,66 0,60x1,05 23,6:%Zsír=35,5%; 0,00:0,00 0,00:0,00; Szkennelési mód: Vastag; 83,0 µGy; Bal femur; 76,3,00:50,03:12,0 0,00:11,40 0,60x1,05 20,0:%Zsír=33,0%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 53; Szkennelési mód: Standard; 37,0 µGy; Jobb femur; 76,3.00:50,03:12,0 0,00:13,32 0,60x1,05 20,1:%Zsír=30,0%; 0,00:0,00 0,00:0,00; Nyak szög (fok)= 54; Szkennelési mód: Standard; 37,0 µGy; Bal alkar; 76,0,15:50,03:12,0 0,00:6,20 0,60x1,05 5,5:%Zsír=23,0%; 0,00:0,00 0,00:0,00; Alkar hossza: 30,3 cm; Szkennelési mód: Standard;Nem ültetett; 2,0 µGy; Jobb alkar; 76,0,15:50,03:12,0 0,00:6,20 0,60x1,05 5,4:%Zsír=25,7%; 0,00:0,00 0,00:0,00; Alkar hossza: 30,3 cm; Szkennelési mód: Standard;Nem ültetett; 2,0 µGy

Appendix 5

Aláíró: Dr. Szabó Enikő
(2024.05.15.)

NEMZETI NÉPEGÉSZSÉGÜGYI ÉS GYÓGYSZERÉSZETI KÖZPONT

Egészségügyi Engedélyezési és Innovációs Technológiai Igazgatóság

Orvostechnikai Főosztály

Iktatószám: NNGYK/GYSZ/14366-4/2024.
Tárgy: Végzés befejezésről
Válasz esetén kérjük, hogy a fenti ügyiratszámra hivatkozzon!

Országos Mozgásszervi Intézet
Országos Orvosi Rehabilitációs Intézet

Budapest
Szanatórium u.19.
1121

Adószám: 15846042-2-41

V É G Z É S

A Nemzeti Népegészségügyi és Gyógyszerészeti Központ (a továbbiakban: NNGYK) Orvostechnikai Főosztálya az **Egészségügyi Tudományos Tanács Tudományos és Kutatásetikai Bizottsága** (székhelye: 1054 Budapest, Alkotmány u. 25. (a továbbiakban ETT TUKEB) **tudományos, orvos-szakmai, etikai értékelését**

e l f o g a d t a

a „ReWalk alsó végtagi humán exoskeleton rehabilitációban betöltött szerepének multicentrikus klinikai vizsgálata" című beavatkozással nem járó vizsgálat (a továbbiakban: Vizsgálat) záródokumentációja tekintetében.

A végzés ellen önálló jogorvoslatnak helye nincs. Az ügyfelet megillető jogorvoslati jog az eljárásban meghozott határozat, ennek hiányában az eljárást megszüntető végzés ellen igénybe vehető jogorvoslat keretében gyakorolható.

INDOKOLÁS

Prof. Dr. Büki András klinikaigazgató (PTE Klinikai Központ Idegsebészeti Klinika, 7623 Pécs, Rét u.2.) 2019.november 7.-én kérelmet nyújtott be, hogy a *„ReWalk alsó végtagi humán exoskeleton rehabilitációban betöltött szerepének multicentrikus klinikai vizsgálata"* című, beavatkozással nem járó vizsgálatot megkezdhesse.

Székhely: 1097 Budapest, Albert Flórián út 2-6.,
Telephely: 1135 Budapest, Szabolcs utca 33., Tel.: +36 1 886 9300,
e-mail: amd@nngyk.gov.hu
Hivatali kapu KRID azonosító: 346558928 (OGYEIEUGY)

Az OGYÉI a hiánypótlások teljesítés után, annak értékelése, és az ETT TUKEB fenti szakhatósági állásfoglalásának alapján a Korm. rendelet 17. § (1) bekezdés (c) pontja értelmében a beavatkozással nem járó vizsgálat megkezdését az OGYÉI **engedélyezte és OGYÉI/ 1271/2020** ügyszámon vette nyilvántartásba.

A kérelmező időközben külföldre távozott és **Dr. Cserháti Péter** intézeti igazgató (Semmelweis Egyetem Rehabilitációs Klinika) **2024. március 10-én** megküldte a gondosan szerkesztett és a részletekbe menő elemzést tartalmazó vizsgálat záródokumentációját.

Az ETT TUKEB **2024. április 30-i** ülésén szakmai-etikai szempontból a kutatási terv beszámolóját **elfogadta.**

A kutatás eredményei a továbbiakban publikálhatók, felhasználhatók.

A fellebbezés lehetőségét az **Ákr. 112. § (1)-(2)** bekezdése zárja ki. A végzés az **Ákr. 82. § (1)** bekezdése értelmében a közléssel végleges.

Az NNGYK a jelen döntést a fent hivatkozott jogszabályhelyek, továbbá a **235/2009. (X. 20.) Korm. rendelet** 17. § (1) bekezdés c) pontja alapján eljárva hozta meg. Az NNGYK hatósági kijelölését a Nemzeti Népegészségügyi és Gyógyszerészeti Központról szóló **333/2023. (VII.20.) Korm. rendelet 8. § 13.** pontjában foglalt kijelölés adja meg.

Budapest, elektronikus időbélyegző szerint

Dr. Müller Cecília
országos tisztifőorvos
nevében és megbízásából

Dr. Szabó Enikő
helyettes országos tisztifőorvos

Kapják elektronikusan:
1.**Országos Mozgásszervi Intézet (**Semmelweis Egyetem Rehabilitációs Klinika)**: adószám: 15846042-2-41**
2.ETT TUKEB - KRID: 157408960 (ETTTUKEB)
3.PTE KK KRID KÓD:641936355
4.Irattár, helyben.

Appendix 6

Nemzeti Egészségbiztosítási Alapkezelő

NEAK közlemény
a 2024. augusztus 12. napján befogadott többletkapacitásokról

Az egészségügyi ellátórendszer fejlesztéséről szóló 2006. évi CXXXII. törvény végrehajtásáról rendelkező 337/2008. (XII. 30.) Korm. rendelet (a továbbiakban: Korm. rendelet) *15/A. §* alapján a Többletkapacitási-befogadási Bizottság elnöke felterjesztette a 2024 áprilisában tartott ülésén megtárgyalt befogadási kérelmek elbírálására vonatkozó javaslatát az egészségügyért felelős miniszter részére, aki a javaslatról az államháztartásért felelős miniszter előzetes hozzájárulásával dönt.

A Korm. rendelet *15/A. § (3) bekezdése* alapján az alábbi táblázatban teszem közzé a Korm. rendelet szerint befogadott többletkapacitásokat.

A mellékelt táblázatban szereplő befogadott többletkapacitásokra – az egyéb jogszabályi feltételek fennállása esetén – **a finanszírozási szerződés legkorábban 2024. szeptember 1. napjával köthető meg,** határozatlan időtartamra, **amennyiben a szolgáltató ekkor már a szerződéskötéshez szükséges valamennyi érvényességi kellékkel rendelkezik.** A finanszírozási szerződéskötési jogosultság hatályát veszti, ha a szolgáltató a befogadási időpontot követően egy éven belül nem kezdeményezi a szerződés megkötését.

Budapest, 2024. augusztus 12.

Kiss Zsolt
főigazgató