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Diamagnetic Therapy Application as Add-on Treatment in Complex Limb Injuries: A Case Series Preliminary Report

Stefano Rocco[1], Sergio Razzano[2], Federica di Pardo[3], Siro Grassi[1], Antonello Rocco[1], Pietro Romeo[4*], Vincenzo Rania[5], and Cristina Vocca[5]

[1]*Medical Center Rocco - Meta di Sorrento (NA - Italy)*
[2]*Plastic Surgery Department - Caldarelli Hospital (Naples – Italy)*
[3]*RiAbilita Center- Melide (TI - Switzerland)*
[4]*Clinical Pharmacology and Pharmacovigilance, University of Catanzaro, Italy*
[5]*Operative Unit of Pharmacology and Pharmacovigilance, "Mater Domini" Hospital, 88100 Catanzaro, Italy*

***Corresponding author:** Pietro Romeo, Orthopedic Doctor; Clinical Pharmacology and Pharmacovigilance, University of Catanzaro, Viale Europa, 88100 Catanzaro (CZ).

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Abstract

Background: *In severe traumatic injuries of the lower limb, independent from the cause and therapeutic choice, the difficulties of surgical technique and the response to therapy are the most challenging aspects. Hence there is a need for choices and prudent procedures given that a failure is to be considered. Rehabilitation is the most important step after surgery and any valid support may have a particular relevance. Diamagnetism is a novel therapeutic tool that uses the peculiarity of the Pulsed Electromagnetic Fields (PEMF) in tissue healing, pain control, acute and chronic inflammation, and liquid displacement.*

These effects are thanks to the intensity and the characteristics of the magnetic field, as well as the way to activate the biological activity of the cells and, consequently, the healing processes. Methods: We report a series of 4 patients who suffered severe trauma to the lower limbs and underwent complex reconstructive surgery as well as advanced physiotherapy, including Diamagnetic Therapy. We assessed pain and physical capacities of the patients, before and after treatment.

Results and Conclusion: *The results and recovery time were satisfactory and, although our experience refers to a few cases, further experiences could better consolidate this more effective post-surgical treatment.*

Keywords: Complex Injuries, Reconstructive Surgery, Rehabilitation, Diamagnetic Therapy

Abbreviations

- **FADI**: Foot and Ankle Disability Index
- **HI:** High Intensity
- **NICE:** National Institute for Health and Care Excellence
- **NRS:** Numerical Rating Scale
- **PEMF:** Pulsed Electromagnetic Fields
- **ROM:** Range of motion

Introduction

Severe traumatic injuries of the lower limb can result in mangled extremities. The surgical treatment ranges between amputation and aesthetic-functional reconstruction. Below-knee amputation reduces the recovery time and allows a rapid return to socio-economic activities; reconstruction preserves the lower limb but creates a delay in the recovery process [1]. However, functional capacities, pain and rates of return to work are similar in time. There is no consensus regarding the best treatment choice, lower limb reconstruction is complex and highly challenging, and the techniques used vary depending on the severity and nature of the injury [2]. Skin grafts involve taking skin from another part of the patient's body and placing it on the damaged area in the case of superficial injuries [3].

Local flaps usually cover larger or deeper extents to bring the blood supply to the reconstructed area. For extensive substance losses, free flaps taken from a donor site far from the injury may be used [4]. The most common flap includes the latissimus dorsi alone or associated with the serratus anterior muscle flap, the ALT flap, and the vastus lateralis muscle flap. These methods aim to induce functional recovery and aesthetic appearance, ensuring the recovery of all daily activities [5, 6].

According to the most recent guidelines of the National Institute for Health and Care Excellence (NICE), rehabilitation after limb reconstruction should start as soon as possible and may include splinting, exercise, pain and swelling management, hand therapy, mobility and positioning, along with psychological support [7]. In the meantime, the integrating support derived from the biophysical stimulation of the areas receiving the graft by Pulsed-Electromagnetic Field (PEMF) is an effective tool able to activate the healing processes by modulating the local inflammation, as the origin of delayed healing, and stimulating regenerative process [8].

PEMF is a non-invasive and safe method used in Traumatology, Neurology and wound healing [9]. This paper aims to show the experience in four clinical cases of complex limb injuries treated with surgical reconstruction and rehabilitation, integrated with an original therapeutic tool based on the biological effects of PEMF, known as Diamagnetic Therapy.

Methods

This study relates to four clinical cases of complex lower limb injuries treated with reconstructive surgery and physiotherapy sessions, from September 2020 to September 2023. Reconstructive surgery was performed by a Surgeon expert in lower limb complex trauma, at the A. Cardarelli Hospital in Naples (Italy). A Physiotherapist with extensive experience in this field assessed and supervised the patients during the rehabilitative treatments and the application of Diamagnetic Therapy, at the Medical Center Rocco in Sorrento (Italy). All patients were also provided with psychological support.

Surgery

The surgical procedure was tailored according to the specific needs emerging from the characteristics and the severity of the injury. The damaged area is prepared for reconstruction with a flap through careful debridement. The procedure continues with the incision of the donor site according to a predetermined design, based on the Doppler of the perforators; then, the vascular pedicle is isolated. The flap is prepared in the recipient area through vessel anastomosis and tissue in-setting. In cases where the flap has not been harvested with a skin paddle, it is covered using partial-thickness skin grafts.

Physiotherapy Sessions

The Physiotherapy program consisted of standard kinesiotherapy exercises and a series of Diamagnetic Therapy sessions. All patients were treated 3 times a week, with a mean of 30 rehabilitative sessions (range 20-40). Kinesiotherapy exercises were always supervised by a physiotherapist and adapted to the clinical progress of each patient. The first sessions consisted of passive motion and isometric exercises. Then, a progressive program of active strengthening, exercises for the lower limb, including treatments with and without weight bearing, concentric and eccentric muscular activation, and electro-stimulation. Proprioceptive training was also performed using specific boards and platforms.

Educational training included wheelchairs and crutches, this last according to the static and dynamic load previously approved by the surgeon. For all patients, the main objectives of rehabilitation were to reach as soon as possible the standing position and gain full range of motion (ROM) of the whole damaged lower limb. Diamagnetic Therapy was applied using the CTU Mega 20® Diamagnetic Pump device (Periso SA – Pazzallo - Switzerland). The machine is provided with an electromagnetic coil producing a High-Intensity Low-Frequency Pulsed Electromagnetic Field, (2.2 Tesla - frequency< 50 Hz), with a repetition rate ranging from 2 to 7 Hz. Furthermore, a broad spectrum of electromagnetic frequencies, selective for each tissue, modulates the Magnetic Pulse according to the proper resonance frequencies of the tissues, ensuring diversified biological effects.

These are based on pain control mode for nociceptive or neuropathic pain, and selective stimulation of slow or fast nerve fibers. Furthermore, regenerative effects increase the flux of ions proper of transmembrane channels of the cells, the possibility of transdermal drug delivery [10, 11]. The protocols used for the treatments were adapted to each clinical situation. A summary of the modality used is reported in Table 1. The duration of each therapy ranged between 25-45 minutes, resulting from the different mechanisms of action reported.

Table 1: Diamagnetic therapy: different settings according to the desired stimulation type (upper row): selective movements of liquids respectively for the extracellular and endocellular environment, selective stimulation of the cell membrane, modulation of pain specifically for nociceptive fibres according to the intensity of pain and the NPRS scale (Numeric Pain Rating Scale: M= medium values of pain H= maximum values respectively corresponding to the intensities 0-3 and 6-9).

Mechanism of action	Movement of liquids Ext. = H, Int. = H or Ext. = H, Int. = 0	Biostimulation Cell membrane or Joint tissue or Fast nerve fibers	Pain control Nociceptive M or Nociceptive H
Minutes	15-25 (range)	5-10 (range)	5

Outcome

The primary outcome was pain measurement together with the ankle ROM before and after the therapeutic program, respectively measured through the Numerical Rating Scale (NRS) for pain, and the functional evaluation, before and at the end of the therapeutic program, with the Foot and Ankle Disability Index

(FADI) self-reported questionnaire. Baropodometry and the American Foot & Ankle Score were considered secondary outcomes. Baropodometry uses the Sensor Medica software, both in static and dynamic positions. Static measurements include the global analysis of the center of gravity and the specific load ratio for the right foot and the left one, for each hemi-side and each plantar loading area (calcaneus, midfoot and forefoot). Dynamic assessments consisted of gait analysis, focusing on the three phases of initial contact, midstance and push-off.

Results

Between September 2020 and September 2023, four patients with complex limb injuries were treated according to the standard protocol (see Methods). FADI questionnaire and the American Foot & Ankle Score showed the mean values pre- and post-rehabilitation assessment (Table 2).

Table 2: Foot & Ankle Disability Index (FADI) and American Foot & Ankle Score results (mean and ranges) reported pre- and post-rehabilitation in ROM and FADI values (n=4).

Evaluation	Pre-rehabilitation; mean (ranges)	Post-rehabilitation; mean (ranges)
FADI	9.62 (4.8-12.5)	97.1 (97.1-97.1)
American Foot & Ankle Score	16 (4-20)	93.25 (83-100)

Patient n° 1

A 17-year-old young male reported a car accident in the distal third of the leg with extensive loss of substance and a bimalleolar fracture on the left side, worsened by soft tissue infection from Pseudomonas Aeruginosa (November 2022). Reconstructive surgery consisted of a vastus lateralis muscle flap taken from the right thigh, preserving the lateral femoral cutaneous nerve and the motor branch of the femoral nerve, for the vastus lateralis muscle. The bimalleolar fracture was treated with an external fixator. Between January and April 2023, 30 sessions of Physiotherapy were carried out three times a week, as described in the "Method" section. At the start of the rehabilitation program, the patient's ROM and strength could not be evaluated because of the high level of pain (NRS 10/10), both for passive and active ROM.

He entered the Rehabilitation Lab with a wheelchair, without the possibility of loading on the injured limb. At the end of the program, the patient recovered 10 degrees of ROM in dorsal flexion, while the ROM in plantar flexion was fully gained. The NRS pain score reported 0 points in static mode and pain of 4 points in dynamic mode after a long walking time. The single load balance, and proprioceptive analysis of the wounded foot, showed the full load in monopodalic support for 5 seconds. In Figure 1 are reported pictures of pre- and post-rehabilitation.

Figure 1. a) Left wounded leg at the start of rehabilitation in post-surgery; b) Left leg at the end of the rehabilitation program.

The baropodometric exam (graphs in Appendix A) observed calcaneal varus on the bilateral stance, and an overloading of the whole lateral compartment, especially on the right foot, in the context of bilateral hollow foot. The maximum peak load was measured on the styloid compartment of the fifth radius on the right foot. The dynamic assessment reported a varus tendency and the bilateral forefoot internal rotation.

Patient n° 2

A 54-year-old male suffered a crushing injury in September 2021, with extensive damage to soft tissues in the ankle and the dorsal region of the left foot. Two-time surgery was necessary to obtain a valid myo-cutaneous flap from the gran dorsalis muscle harvested from the left dorsal region and a partial-thickness graft. Then, from November 2021 to February 2022, the patient underwent a series of 30 Physiotherapy sessions (see "Methods"), with a frequency of three times a week. As in the first case, at the starting point, the patient had a high pain score of 10 at the NRS score during passive or active movement. He could not maintain the bi-podalic standing position because of the impossibility of weight-bearing on the left foot.

Two years after the accident, the patient reached the complete recovery of the ROM in the tibio-tarsal joint and the foot. The patient reported the value of 0 at the NRS score in static mode; and 4 points in dynamic mode, after prolonged physical activity. The proprioceptive balance test of the damaged foot showed the maintenance of the static full load in monopodalic standing for 25 seconds. At the balance test over a tilting platform in monopodalic standing, the patient failed in the monopodalic phase, while in bipedal support he maintained balance for 60 seconds. In Figure 2 you can see the differences pre- and post-rehabilitation. More pictures can be found in Appendix B.

Figure 2: a) Left wounded leg post-surgery; b) Left leg at the end of the rehabilitation program

The strength at the dynamometer found no substantial differences between the two lower limbs. In the baropodometric exam (graphs in Appendix A), the static position showed a foot stance with a tendency to supination to the right side, with overload on the 5th metatarsal and the whole forefoot. Percentages of load and centre of gravity were generally shifted to the right. In dynamics, we registered bilateral metatarsal hyperload, slight supination of the left limb and good roll balance.

Patient n° 3

An 18 years female, was involved in a car accident with a complexity of injuries: severe left foot with extensive soft tissue tearing; loss of substance at the left foot in the dorsum, left heel, the left popliteal region and left anterolateral leg region; fracture of the anterior apophysis of the calcaneus, scaphoid, cuneiform bones and the base of the II, III, IV and V metatarsals bones. One week after the accident, the reconstructive surgery included fitting an anterolateral tight fascia-cutaneous flap, a vastus lateralis segment taken from the right thigh, and preserving the lateral femoral cutaneous nerve and motor branch. From December 2020 to April 2021, 40 rehabilitation sessions, with a frequency of three times a week. In Figure 3 you can see the differences between pre- and post- rehabilitation. More photos can be found in Appendix B.

Figure 3. a) status during a surgical procedure; b) after the rehabilitation program.

Three years after the traumatic accident, the patient reports a significant reduction of pain, from a level of 10/10 (NRS) at the start of the rehabilitation to 0 in static standing position and 5 after long waking distances. The ROM of the tibio-tarsal joint and foot were fully recovered. Balance and proprioception showed the maintenance of the full load in left monopodalic support for 30 seconds. At the balance test on an unstable board; in monopodalic support, the patient failed to maintain the balance, in contrast with the position in bipedal mode for 60 seconds. Static and dynamic positions were also investigated by baropodometry. Bilateral support in pronation, with the left hindfoot in valgus, was noticed in a static stance. In dynamics, no significant alterations were detected.

Patient n° 4

A 21-year-old man was involved in a motorbike accident at the end of August 2023. The clinical assessment after the trauma reports a right foot sprain with severe soft tissue involvement, complex and exposed calcaneal fracture, Lisfranc fracture with secondary osteomyelitis, and sub calcaneal ulcer (1.5 cm deep and 2 cm in diameter). The surgical procedure consisted of fitting an anterolateral tight fascia-cutaneous flap and a vastus lateralis segment taken from the right thigh, preserving the lateral femoral cutaneous nerve and motor branch for the vastus lateralis muscle. After surgery, the patient attended 30 sessions of Physiotherapy, from October 2023 to January 2024.

Six months after the accident, the patient showed a complete recovery of the tibiotarsus joint and foot ROM. Pain measurement showed 0 points at NRS in static standing position and 2 points at dynamic after long walking. Balance and proprioception observed maintenance of full load in monopodalic standing of the injured foot for 60 seconds. On the unstable board, the monopodalic stance balance test observed the maintenance of the position for 20" while the patient maintained the balance for more than 60 seconds in the bipedal stance. In Figure 2 you can see the differences between pre- and post- rehabilitation. More pictures can be found in Appendix B.

Figure 4. Clinical evolution from the start to the end of rehabilitation

At static baropodometric examination (graphs in Appendix A), we observed asymmetrical breech support, with a tendency to varus on the left foot, and varus on the right side in a slight equine stance with engagement of the external longitudinal arch. No evident pelvic dysmetria has been observed, although with the tendency in slight anterior rotation to the right side. The dynamic exam showed an asymmetrical stance during the roll, with the right foot in supination, and overload of the external compartment for midfoot and forefoot.

Discussion

In lower limbs, extensive complex traumatic loss of the muscle-cutaneous and bone tissue usually requires long-time surgery and prolonged treatments like drugs, rehabilitation, psychological support, and wound care. For their part, infections, and bone grafting failure may need the sacrifice of the limb which psychological consequences lead the patients to chronic pain, depression, social exclusion, isolation, poverty and drug addiction [12]. Appropriate surgical techniques, detailed guidelines, modern diagnostic tools, decision-making procedures, and risk analysis aim to attenuate these events [13, 14].

Accurate rehabilitation paths are decisive in improving the postoperative course and healing times. This is possible thanks to the early activation of the joints and the tendons, preventing joint contractures and the birth of scar tissue around the tendons and the fascia [15]. Not least, the biophysical stimulation of the tissues aims to accelerate the healing time, both directly or avoiding complications, thanks to the well-known bio-inductive effects increasingly attributed to these technologies, including changes in functional brain connectivity [16, 17]. PEMF are effective in bone healing and skin, in case of acute and chronic pain, and exert anti-inflammatory and related regenerative effects [18, 19]. A new, original way of administering the magnetic field to accelerate the healing times has been observed in an experimental setting of a Zebrafish model, and chronic ulcers [20, 21].

Furthermore, this technology named Diamagnetic Therapy, is also effective in challenging chronic pain, chronic oedema, lymphoedema and joint stiffness [22, 11]. Diamagnetic Therapy employs low-frequency-High Intensity (HI) Magnetic Fields (MF) contributing to the phenomenon of Diamagnetism. This depends on the atomic structure of the matter, given by no unpaired electrons, a "closed shell structure", and an anti-parallel spin alignment of the electrons, while the atomic magnetic moment is zero. When HI-MF hits the diamagnetic matter a repulsive effect occurs, contrary to the attractive phenomenon proper of ferromagnetism [23].

A great part of the biological matter is diamagnetic, and the water, ions, molecules and proteins involved in transmembrane fluxes, once exposed to HI-PEMF move faster producing a mechanical force that promotes the flow of biologically active molecules, both in the extracellular and intracellular environment [24]. This phenomenon regulates many functions of the cells: changes in membrane electric potential controlled by the Na+/K+ pump (de-polarization and hyper-polarization), changes in cell motility, intracellular metabolic processes, as well as the diffusion in the intracellular of active molecules [25]. Besides, selected changes in the Magnetic field gradient ensure the optimal amplitude of the electromagnetic signal [26]. Moreover, the Diamagnetic Technology (Diamagnetic Pump) acts on liquid drainage in the extracellular and intra-cytoplasmatic environment, and selectively interacts with the tissues, offering tailored treatments.

Our experience showed the effectiveness of advanced physiotherapy and the Diamagnetic Pump as an add-on in a series of challenging tissue injuries following traumatic accidents and undergoing complex microsurgery. The results were satisfying in terms of recovery time, and improvement in the quality of life. Diamagnetic Technology has proven to be valuable in the healing process, allowing the stimulation of damaged tissues, the improvement of local blood circulation and the promotion of cell regeneration. We don't observe side effects, no need for further surgery, infections, no amputation. Clinical courses were regular for all the patients and the healing progress was constant. None of the patients abandoned the treatments, and the pain control was effective. It is important to note that advanced physiotherapy with the diamagnetic pump has also shown positive results in patients with still open wounds, osteomyelitis and major ulcers, suggesting a potential extended use in different clinical settings.

This report has a limited number of cases without a control group. Static baropodometry, employed as an objective tool, provides valuable insights but it is not a definitive predictor of clinical outcomes reported by patients [27]. It can be considered an adjunctive tool and provides valuable information on the quality of life as observed in patients undergoing total knee arthroplasty [28]. By recognizing the limitations and complexities of baropodometry, clinicians can better tailor post-surgery rehabilitation providing an interesting insight into the function of the foot [29].

Conclusion

Although this report has a limited number of cases without a control group, the results suggest the importance and effectiveness of advanced physiotherapy in serious tissue injury in patients undergoing complex microsurgery. We can assume that without the combination of all therapies applied, it would have been difficult to achieve similar results, especially considering the complexity of the lesions. Specifically, diamagnetic therapy promotes rapid and effective healing, contributing to the maintenance of limbs and significantly the quality of life. Therefore, advanced physiotherapy is crucial in the treatment of patients with severe tissue injury. Further randomized controlled studies will be necessary to better define these results even in comparison to conventional treatments alone.

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Data Availability Statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

Conflicts of Interest

The authors declare no conflicts of interest.

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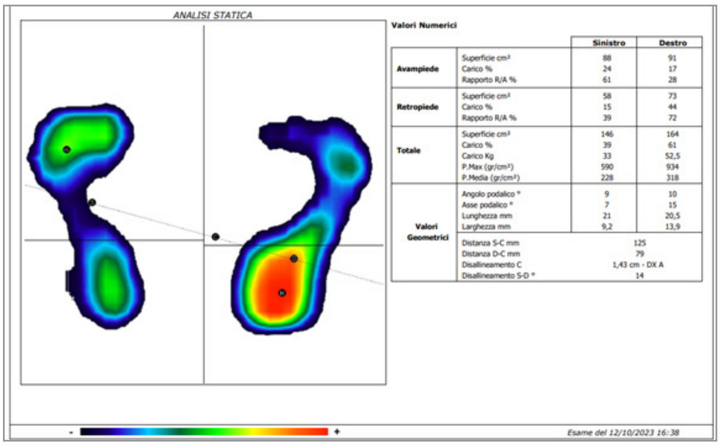
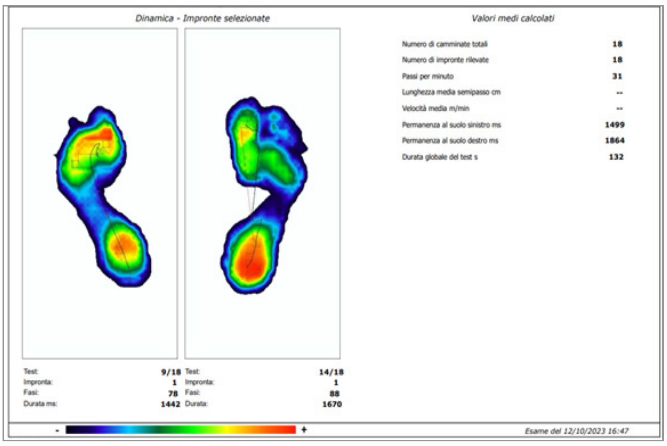
Appendix A

Baropodometries graphs for each patient, reported in both static and dynamic analysis.

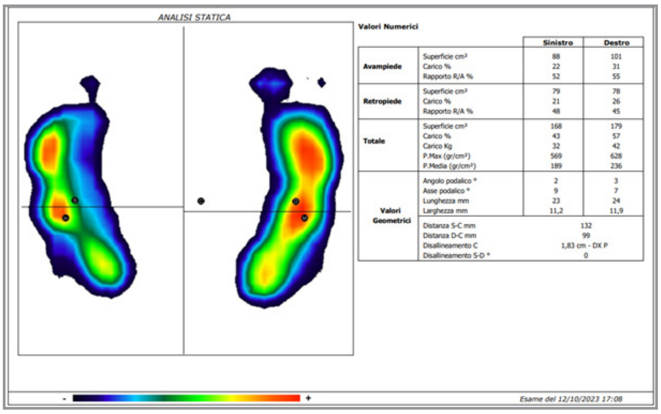
Patient1



Dynamic



Patient 2
Static:



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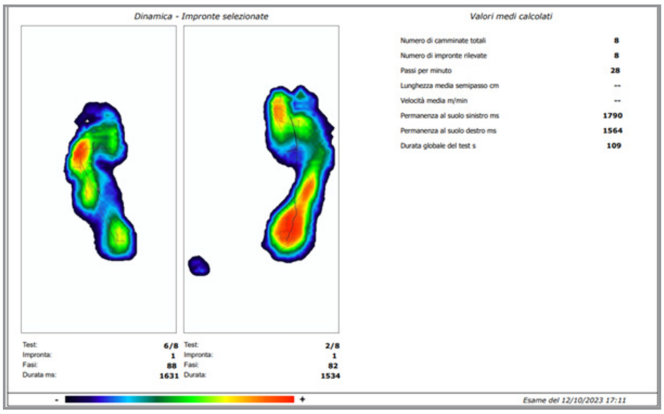
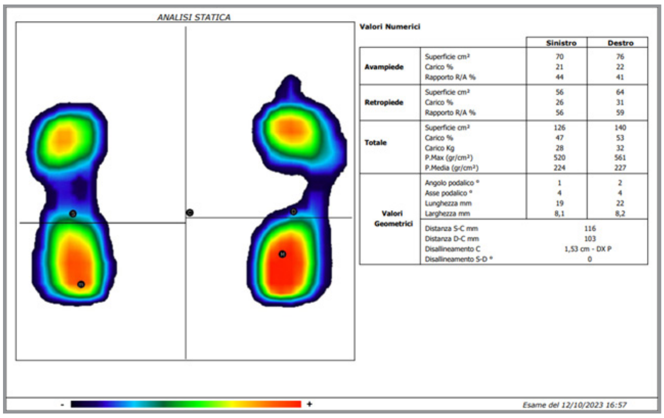


Patient 3
Static:



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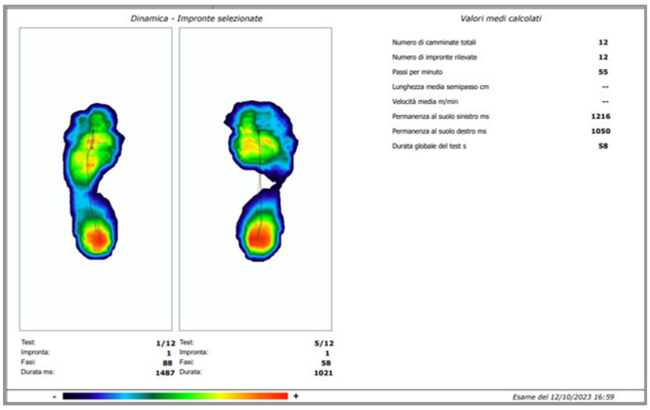
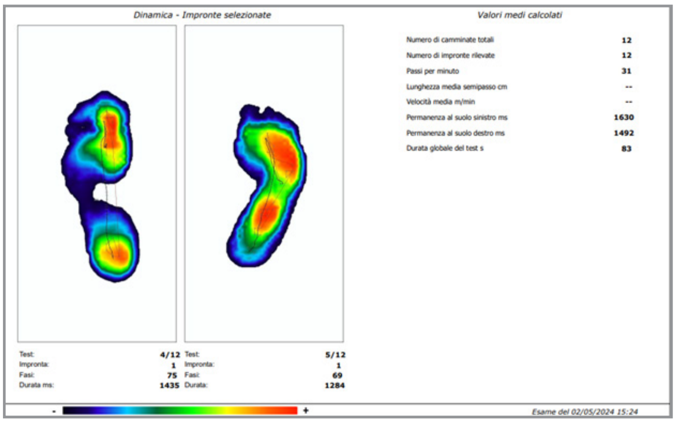


Patient 4
Static:



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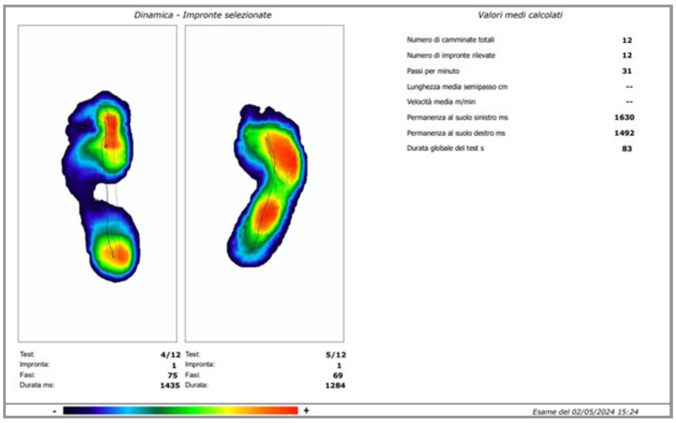
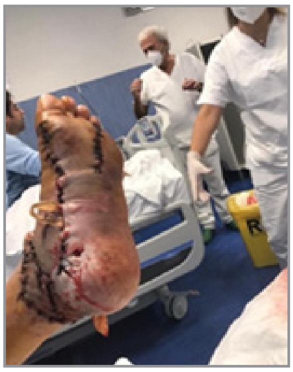


Appendix B

Patient 2

a.

b.



c.

d.

e.

f.

(a-b-c) Left wounded leg pre- and post-surgery. (c-d-e) Left leg at the end of the rehabilitation program

Patient 3

a.

b.

c.

d.

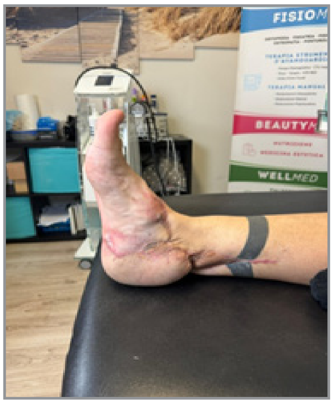
e.

(a-b-c) surgical procedure and healing process of the lesions (d-e)

Patient 4

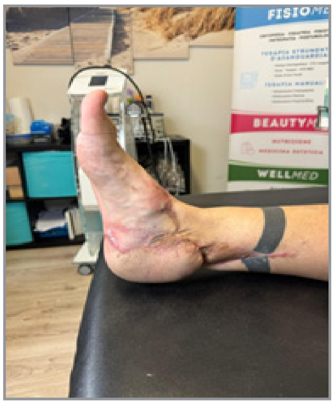
a.

b.



c.

d.



e.

f.

g.

h.

(a-b-c) Left wounded leg pre- and post-surgery. (c-d-e) Left leg at the end of the rehabilitation program