scientific justification and clinical approach

1. INTRODUCTION

According to the Oxford dictionary, physiotherapy is described as *"the treatment of disease, injury, or deformity by physical methods such as massage, heat treatment, and exercise rather than by drugs or surgery."*

Physiotherapists apply these physical methods using their own hands, exercise and, in many cases, the support of external systems that favour the achievement of the objectives set for the improvement of the patient. For decades, the development of electrotherapy devices, mechanisms that support mobilization, or tools that favour diagnosis and research, have had a growth proportional to the knowledge of the effectiveness of physiotherapy itself.

Robotics is exploding in the biomedical change, and its integration for the improvement of treatments is a fact. ADAMO ROBOT provides the physiotherapist with assistance in diagnosis and treatment that is an excellent support for improving musculoskeletal pathologies. These contributions have great potential from a **DIAGNOSTIC AND THERAPEUTIC** point of view:

1.1 DIAGNOSIS

- The diagnostic phase focuses both on providing information to facilitate a primary diagnosis as well as on providing a support tool for monitoring the pathology. For this purpose, the device has a thermographic camera:

- Thermography is a hot topic in recent years since it provides cheap and harmless immediate objective information. Likewise, thermographic images can help functional cognitive therapies to better understand the injury mechanisms.
- Asymmetric temperature differences between sides (between 0.3 and 0.6ºC), have been proposed as a pathology indicator. These indicators can help physiotherapists to emit a better diagnosis and to adapt the treatment based on thermal evolution. It is interesting to remember that the robot can heat or cool an area of treatment (1).
- Thermographic diagnosis (2–4), in turn, has two different approaches:
    - Static: where the patient must comply with study conditions that do not influence the temperature of the area to be studied. This type of study will provide valuable information on thermal dysmetria or evolution in an inflammation, for example, or in a radiculopathy where the temperature will be lowered (5) but may be limited to be able to give an interpretation of certain musculoskeletal pathologies that have variables other than thermal. In this sense, ADAMO Robot's proposal is the growth towards Deep learning and the treatment of Big Data, to provide information to the therapist based on the experience of the data.
    - Dynamic: thermography is used to check how much and how fast a muscle vascularized, and therefore warms up, after a demand for physical activity. This will allow the therapist to know before an injury, or in the evolution of the same, to propose the most appropriate treatment based on this information (5,6).

1.2 THERAPEUTIC

Physiological effects derived from the robot's treatment have already been scientifically assessed:

1.2.1 Pressure and massage:

Pressure and massage have been studied for multiple musculoskeletal pathologies, cancer, fibromyalgia, etc. (7–9). These treatments could be defined as "the mechanical manipulation of body tissues with pressure and rhythmic movements with the aim of promoting health and well-being (10).

For the treatment of these disorders, the use of manual therapy and different types of pressure are the first option for conservative treatment (7), with the aim of improving the processes of contraction, relaxation and collagen production. Among these techniques, ischaemic pressure, pressure release and pressure with manual movements are commonly used. It has been estimated that in general, pressure and massage can sometimes account for up to 45% of the total physiotherapy treatment time (11).

Scientific evidence has studied in different areas the effects produced by tissue pressure in different conditions and pathologies on the organism, recognising that these effects are not focused on just one area of a person's biology, but that there are theoretical models that explain their effects in the biomechanical, psychological, neurological and physiological fields (12,13) (image 1): mechanical effects; chemical effects; central effects; motor and sensory effects.

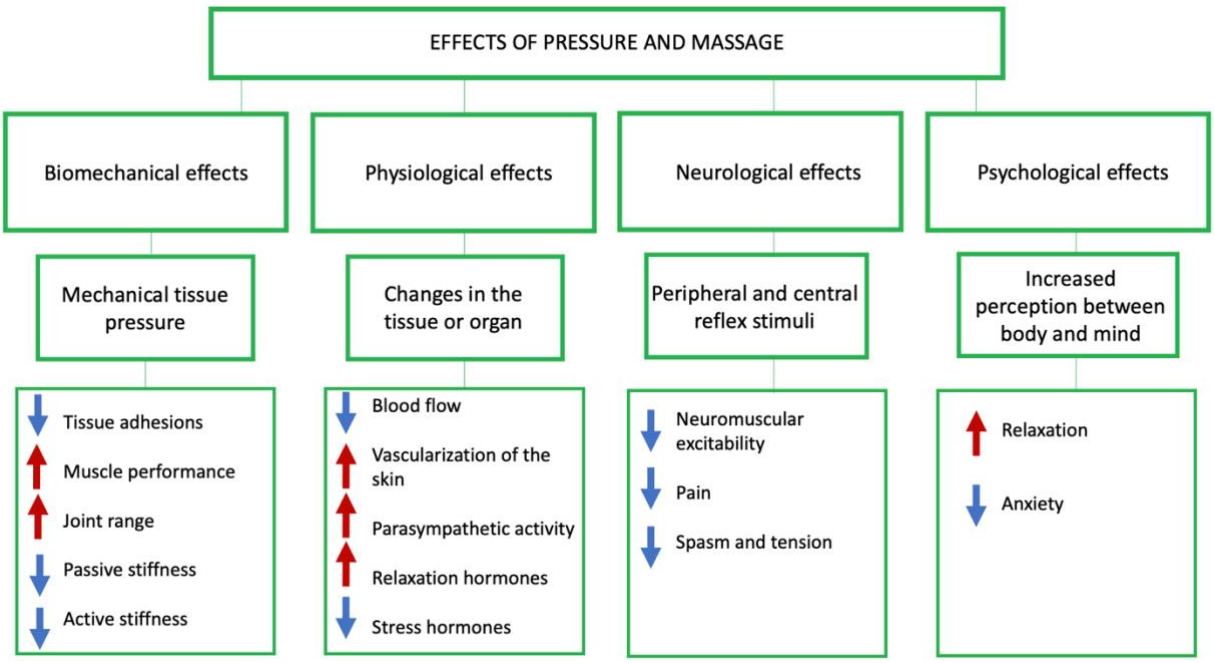


Image 1. Weerapong P, Hume PA, Kolt GS. The Mechanisms of Massage and Effects on Performance, Muscle Recovery and Injury Prevention: Sports Medicine. 2005;35(3):235-56

These techniques have been studied and proven effective in the treatment of myofascial pain syndrome (14). Fascia tissue is a connective tissue found throughout the body, covering from the most superficial areas (superficial fascia) to the deep connections of joints and muscles. Fascia has nerve endings and Pacini and Ruffini corpuscles, so it plays an important role in proprioception and motor coordination due to its relationship with the neuromuscular spindles, i.e. it helps control movement and has its own innervation which makes it relevant in the sensitivity and proprioception of movement as well as in the pathologies derived from it (15). In addition to its relationship with the nervous system, it also has a direct relationship with the vascular and lymphatic system, thus participating in the thermoregulation of tissues.

Myofascial pain syndrome is known to occur in many musculoskeletal pathologies. Fascial tension can generate hyperactivity in the neuromuscular spindles and therefore a chronic activation of the muscle fibres, with an increase in acetylcholine, which is usually found in myofascial pain and trigger points (15). This syndrome is most prevalent in back problems (neck and lower back) due to amplified risk factors in today's societies, such as sustained postures or repetitive movements for which the tissue system is not prepared (16). This type of pathology causes local and referred pain, stiffness, reduced joint range, muscle weakness, difficulty in movement (17).

Likewise, due to the different speeds between fibers that conduct pain (C and A fibers) and fibers that conduct pressure (Aß), the activation of spinal interneurons can block the transmission of nociceptive stimuli to higher nerve centers (18).

The control gate theory is based on the same principle; pain can be blocked by pressing the surface and by controlling the neurological mechanism (19). In addition, the pressure generated by compressed air at skin level can block the release of allogeneic substances (substance P, bradykinin, histamine) (20) and prevent the activation of different ion channels in the nociceptive fibres that cause pain (21).

1.2.2 Thermal Therapy:

The use of temperature to generate physiological response stimuli is used from the beginning of conservative treatment. Specifically in physiotherapy, temperature is a basic physical tool that sometimes becomes the only treatment and in most cases a fundamental coadjuvant treatment. Temperature has a direct influence on the acceleration or decrease in cellular metabolism, on the speed of nerve conduction, on the regulation of the circulatory system, among others, which are fundamental for homeostasis in the human body.

Heat application.

The use of heat as a treatment, both in acute and chronic pathologies, has been the subject of research (22), and its effects have been demonstrated to increase the temperature of the skin (23), at the intra-articular level, in the muscle (24), and to create vasodilation, which finally provides a proliferation in the tissues with an increase in local metabolism and a greater consumption of oxygen thanks to faster catalysed biochemical reactions (22). This metabolic change also modifies the elasticity of the connective tissue (25) and thus influences a movement

with less joint tension and increased joint range (26). It is also useful to use heat to improve strength, pain and even quality of life (image 2).

Cold application

The use of cold with the intention of lowering the local temperature has a great application for the control of pain and numerous pathologies of the human body. Cold generates a decrease in blood flow by activating a vasoconstrictor reflex produced by the sympathetic nervous system (27). This vasoconstriction reduces edema and slows down the production of inflammatory mediators such as leukocytes (28). Likewise, the decrease in blood flow also decreases oxygen supply to the tissues and thus decreases local metabolism (29). Cold also slows down the speed of nerve conduction, making the signals sent by the nociceptors weaker and thus producing less interpretation of pain by the central nervous system (30). Thanks to these physiological influences of cold, it can be said that its use is very useful in the treatment of pain, reduction of edema and inflammation (traumas, sprains, post-surgery, etc.), muscle spasms and regulator of the nervous system (image 2).

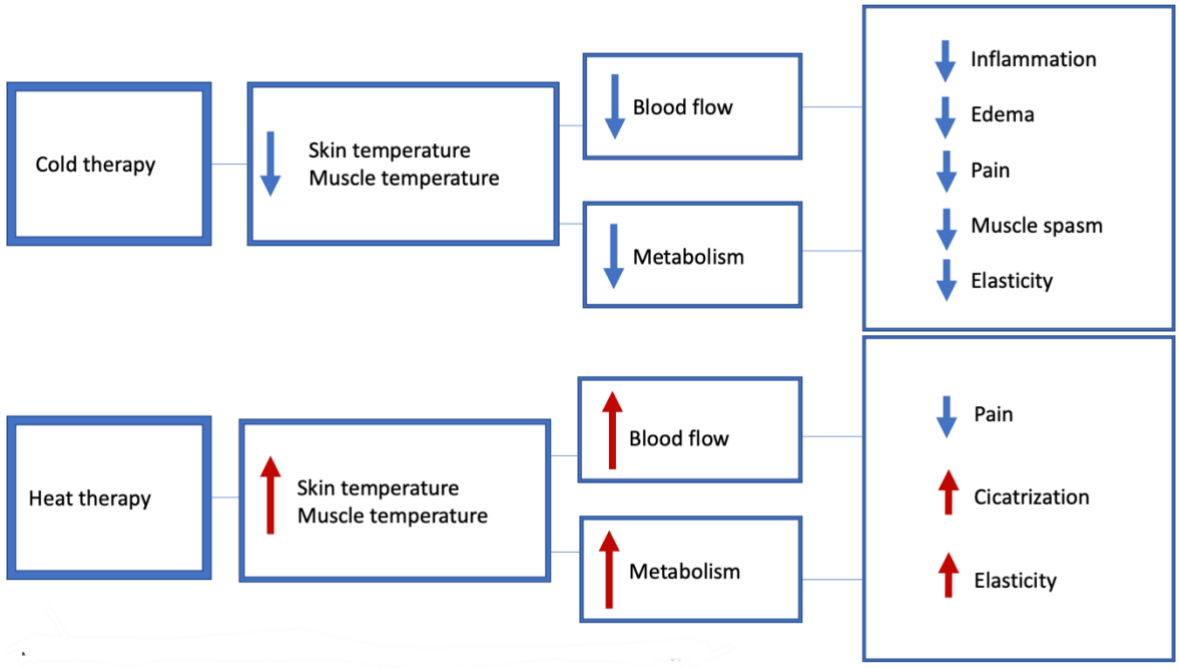


Image 2. Malanga GA, Yan N, Stark J. Mechanisms and efficacy of heat and cold therapies for musculoskeletal injury. Postgraduate Medicine. 2 de enero de 2015;127(1):57-65

ADAMO Robot allows the physiotherapist to apply sustained pressure or massage sweeps, without contact, together with thermal therapy, becoming a support tool that will enhance patients´ recovery.

The growth areas brought by ADAMO Robot are immense. Patient recognition and personalization of patient care, or support for diagnosis and treatment through big data

processing, can streamline clinical processes, fostering better and faster recoveries through earlier and more accurate diagnoses, and therefore logistical cost savings in healthcare systems.

It should be noted that ADAMO Robot is potentially a tool to help the physiotherapist and, therefore, the patient. The humanization of the use of these tools is basic to achieve evidence-based physiotherapy, which is supported by 3 fundamental legs, which must be balanced, and none of them can disappear in the humane treatment of a patient (31):

- Scientific evidence: research and the scientific method is crucial to validate hypotheses and objectify clinical acts.
- Clinical experience: the therapist's lived events, processing of experiences, empathy, tone of voice, psychology, etc., are influential factors in the recovery and accompaniment of the patient. Scientific evidence supports this, in fact, one would be meaningless without the other.
- Patient preferences: Patients' opinions, history, and biopsychosocial factors may determine their preferences and should be considered to generate a more accurate understanding of the problem and make a more precise solution proposal.

1.3 COMPRESSED AIR

Compressed air allows pressure treatment of human tissue, which, in a regulated manner, generates physiological reactions derived from the same pressure. Due to Newton's law of cooling, the difference in body temperature with respect to the temperature of the compressed air (whether hot or cold) will generate a rate of change proportional to this difference, i.e. the application of cold compressed air to an inflamed area, which will be warmer due to its increased blood circulation, will result in a decrease in temperature in the inflamed area. Conversely, if the compressed air is warmer than a stiff, hypovascularised and therefore colder area, the area will be warmed. In addition to this physical effect, there are also effects on the central nervous system due to the pressure exerted by the air itself.

Compressed air has already been investigated with positive results in terms of its physiological effects on body temperature in the lower limbs (32), producing improvements in healing in pathologies such as diabetic foot (33) and in the most prevalent musculoskeletal pain such as lumbago (34).

On the other hand, it should be noted that the air produces pressure on the tissue without stimulating certain neurotransmitters, which produces a sensation of zero pain in the patient. A clinical study (pending publication; 2023) has been carried out over 700 sessions, in which the patient's perception of the use and sensation of thermoregulated compressed air has been excellent due to the comfort of the treatment, even in pathologies that started from a more acute situation on palpation.

1.4 LOGISTIC: Robotics Systems

Collaborative robots are having a great penetration in the industrial world with the intention of streamlining and improving people's work environment (35). This success is being applied in the healthcare world and has even seen applications that are themselves a technological innovation

for the benefit of the patient. Successful robots have already been established in microsurgery and in assisting people with disabilities (36). According to Rogers' theory of innovation (37) the adoption of new technologies such as robotics requires the fulfilment of 5 fundamental factors:

- Generates a perceived advantage in the idea it replaces.
- Compatible with existing values.
- Must not be complex to understand.
- Can be tested and moulded to the user's needs.
- It must be observable and visible to others.

These factors explain in the current context how robotics and even Artificial Intelligence being adopted in the world of healthcare require the active participation of healthcare professionals and patients (36). Surveys of professionals and patients show that robotics is perceived as an opportunity to improve the rehabilitation workflow (38).

For these reasons, robotics is spreading by leaps and bounds in the world of health and specifically in the world of physiotherapy with (36), with the intention of offering clinical improvements and logistical optimisations in Health Systems.

2. PATHOLOGIES TREATED BY ADAMO ROBOT TECHNOLOGY AND CLINICAL CASES

In this scientific clinical context, the use of pressure and temperature gives ADAMO Robot versatility to treat almost any musculoskeletal pathology where there are no general contraindications, like those for the application of massage therapy or thermotherapy, such as fever, rheumatic diseases in acute phase, open wounds, infectious diseases, and some others. Furthermore, contraindications are reduced with this device because the physiological stimulus is not bioelectric and can be received by patients with prostheses, pregnancy, pacemakers, etc. Thus, we understand that compressed air pressure treatment is a safe and effective therapy, although it is important to emphasize the importance of the diagnosis and decision making by a health professional in order to apply the treatment.

By modifying the application parameters: speed, time, temperature, type of movement, number of cycles, ADAMO Robot can be used to treat, among other pathologies:

The following is a list of the most common pathologies treated in physiotherapy centres.

PATHOLOGY	ADAMO TREATMENT TIME	TEMPERATURE SETTING	TYPE OF MOVEMENT	NUMBER OF SESSIONS PER WEEK	ESTIMATED NUMBER OF SESSIONS	NUMBER OF WEEKS
Muscle spasm	15-20´	high	pendular linear point by point	3	6	2
Joint stiffness	10´	high	pendular	5	15	3
Myofascial problems: trigger points, myofascial pain syndrome	10´	high	pendular point by point discontinuous point by point	3	9	3
Ankle sprain	5-1´	medium, low	pendular linear	3	9	3
Cervical sprain/Whiplash	10-15´	medium, low	pendular point by point	3	18	6
Carpal tunnel syndrome	10´	medium, low	pendular linear	5	20	4
Plantar fasciitis	15´	high	pendular point by point	5	15	3
Bursitis	10´	Low, médium, high	Point by point	5	15	3
Cervical pain, back pain, low back pain	15-20´	Medium, high	pendular point by point discontinuous point by point	3	12	4
Tension headaches	15´	high	pendular point by point	3	9	3
Arthritis (in non-acute phase)	10´	Medium, high	pendular point by point discontinuous point by point	3	12	4
Arthrosis	10-15´	high	pendular point by point discontinuous point by point	5	20	4
Tendinopathies	10-15´	Medium, high	pendular point by point discontinuous point by point	5	15	3
Chondropathies	15-20´	high	pendular point by point	5	15	3

Post-surgical treatments: prostheses, ligament reconstructions, herniated discs, etc.	5-10´	Low, medium	Pendular Linear point by point discontinuous point by point	3	18	6
Fibromyalgia	10-15´	medium	pendular point by point	3	24	8
Neurological problems: paralysis, paresis, recovery from strokes	10´	high	pendular	3	24	8
Scars	5´	high	pendular point by point	5	10	2
Aesthetic treatments	15-20´	Low, high	Pendular Linear point by point discontinuous point by point	3	12	4

The following notes should be taken into account:

- The data reflected in this table, regarding the programming parameters of the robot are dependent on the final clinical decision of the healthcare professional, and are exclusively proposed according to the experience obtained. It is known that these parameters must be varied according to the evolution and state of the pathology, taking into account more acute or inflammatory phases vs. more chronic and/or degenerative phases.
- Recovery estimates are highly variable and depend on the rest of the actions in a physiotherapy session, such as mobilisations or therapeutic exercise.
- ADAMO ROBOT can support the physiotherapist in part of his manual tasks related to massage therapy and certain tissue manipulations to which thermotherapy is added. It does not replace the complete functions necessary for the rehabilitation of a person.
- This table does not reflect the benefit obtained by the diagnostic support through thermography provided by the device, which is of great value to health insurers in helping to objectify discharges.

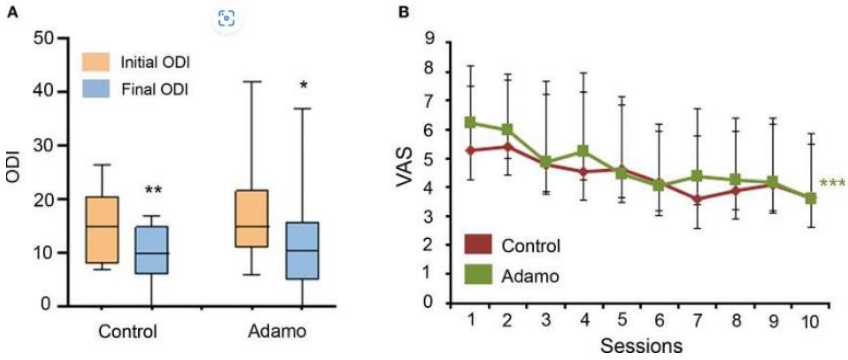
3. RESEARCH PUBLISHED

Using a Robot to Treat Non-specific Low Back Pain: Results From a Two-Arm, Single Blinded, Randomized Controlled Trial

Front Neurorobot. 2021; 15: 715632. Published online 2021 Sep14. Doi: 10.3389/fnbot.2021.715632 PMCID: PMC8478348 PMID: 34594197

Authors: Honorio Marín-Méndez, Patricia Marín-Novoa, Silvia Jiménez-Marín, Itziar Isidoro Garijo, Mercedes Ramos-Martínez, Miriam Bobadilla, Eduardo Mirpuri, Alfredo Martínez.

Non-specific low back pain (NSLBP) affects many people and represents a high cost for health care. Manual pressure release of myofascial trigger points is used to treat NSLBP and is very effective but difficult to standardize since it is provided by different therapists, which also suffer musculoskeletal complications from this highly repetitive activity. A robot designed for this purpose may help in reducing these problems. Here, we present data from a two-arm, single-blinded, randomized controlled clinical trial evaluating the efficiency of a therapeutic massage robot (ADAMO) in reducing NSLBP (clinicaltrials.gov, registration number: NCT04882748). Forty-four patients were randomly distributed into the two arms of the study (robot vs. control). A physician filled the Oswestry disability index (ODI) before starting the treatment and at the end of it, in a blind fashion. In addition, patients filled a visual analogue scale (VAS) after each of the 10 treatment sessions. The ODI and the VAS were analyzed as the primary and secondary outcome measures. Both treatments (robot and control) resulted in a significantly lower ODI ($p < 0.05$). On the other hand, robot-treated patients significantly reduced their VAS levels ($p = 0.0001$) whereas control treatment did not reach statistical significance. Patients of both sexes obtained similar benefits from either treatment.



Overweight patients (body mass index ≥ 25kg/m2) in the robot arm benefited more from the treatment ($p = 0.008$) than patients with normal weight. In conclusion, the ADAMO robot is, at least, as efficient as regular treatment in reducing low back pain, and may be more beneficial for specific patients, such as those with excessive weight.

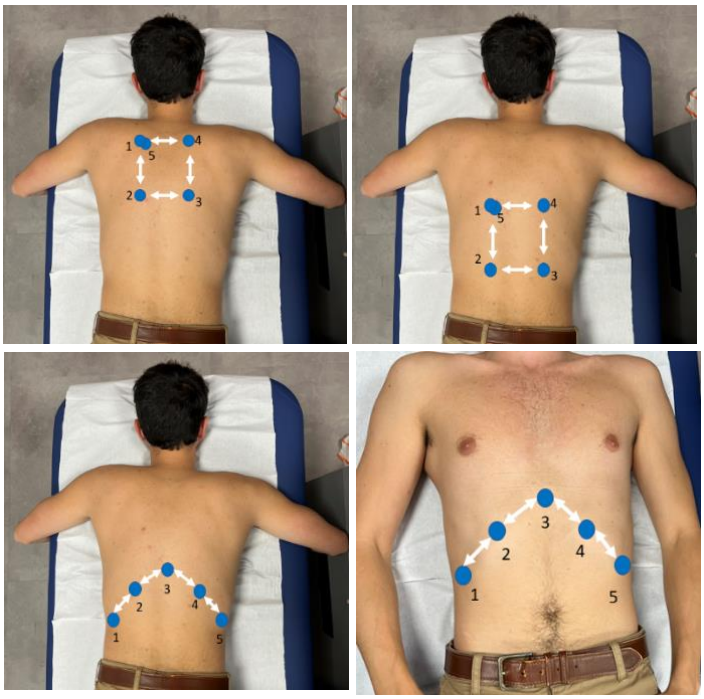
4. COMPLETED PUBLICATIONS PENDING PUBLICATION

Rehabilitation treatment for post-covid patients through machine assisted thoracic massage

Authors: ADAMO Robot, Fundación Rioja Salud (FRS) – Innovation Centre of the San Pedro Hospital (HSP), Centro Hospitalar e Universitário de Coimbra, Agnes-Karll Laatzen Hospital, Laatzen and Clinics for Rehabilitation Dr Miroslav Zotovic, hospital in SERBIA.

The BREATHE project, conducted under the European initiative DIH HERO (Digital Innovation Hubs in Healthcare Robotics), represents a groundbreaking scientific endeavor focused on revolutionizing respiratory therapy through the integration of robotics technology. This article presents an overview of the BREATHE project, highlighting its objectives, methodologies, and key findings.

The primary goal of the BREATHE project was to develop and evaluate the efficacy of an innovative robotic system, named ADAMO Robot, in improving respiratory function and overall well-being in patients with persistent COVID. Through a multidisciplinary approach, the project brought together experts in robotics, physiotherapy, and respiratory medicine to design a comprehensive treatment protocol.



The BREATHE project employed a rigorous research methodology, including a combination of clinical trials, patient monitoring, and data analysis. The project team conducted extensive assessments and measurements to evaluate the impact of ADAMO Robot on various respiratory parameters, such as lung capacity, oxygenation levels, and breath control. Furthermore, patient feedback and subjective assessments were collected to gauge the overall acceptance and satisfaction with the robotic therapy.

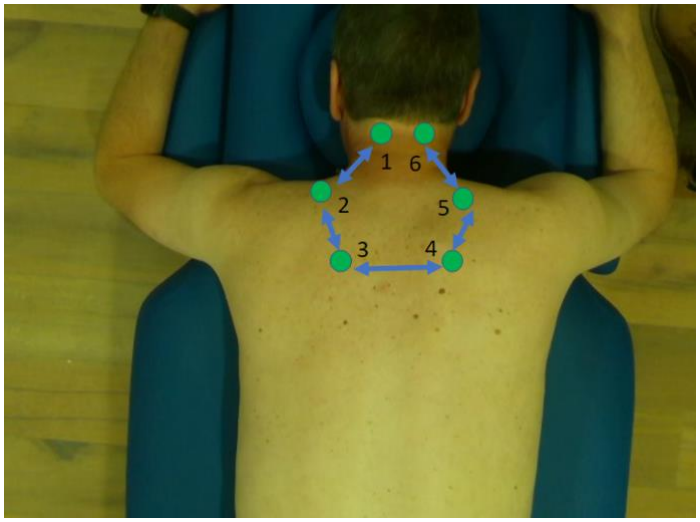
The preliminary data supports the main hypothesis of the study that suggests that the combined therapy is as beneficial as the usual therapy: Adamo Robot + Exercises vs Exercises. It also confirms the good performance of the ADAMO robot in overweight patients compared to the control group. It is expected that the overall analysis of the data and the increase in sample size will allow for significant differences to be found between the groups.

In conclusion, the BREATHE project, supported by the DIH HERO initiative, has demonstrated the immense potential of robotics in transforming respiratory therapy. The collaboration between experts in robotics and healthcare has paved the way for novel treatment approaches, bringing us closer to a future where robotics technology plays a vital role in improving the lives of individuals with chronic respiratory conditions.

5. RESEARCH WITH APPROVED ETHICS COMMITTEE SCIENTIFIC BROCHURE AND CLINICAL APPROACH

Phase II unicentric study to validate a CE-marked robotic device for non-specific cervicalgia rehabilitation

Objective: The objective of this study is to validate the efficacy and safety of a CE-marked robotic device, ADAMO Robot for the rehabilitation of non-specific cervicalgia.



Methods: This is a unicentric, randomized, double-blind, controlled clinical trial. The study will include 60 patients with non-specific cervicalgia who will be randomly assigned to either the experimental group (robotic device) or the control group (conventional physiotherapy). The primary endpoint will be pain reduction measured by visual analogue scale (VAS) at 4 weeks after treatment. Secondary endpoints will include improvement in neck mobility, quality of life, and patient satisfaction. Adverse events and device-related complications will also be monitored.

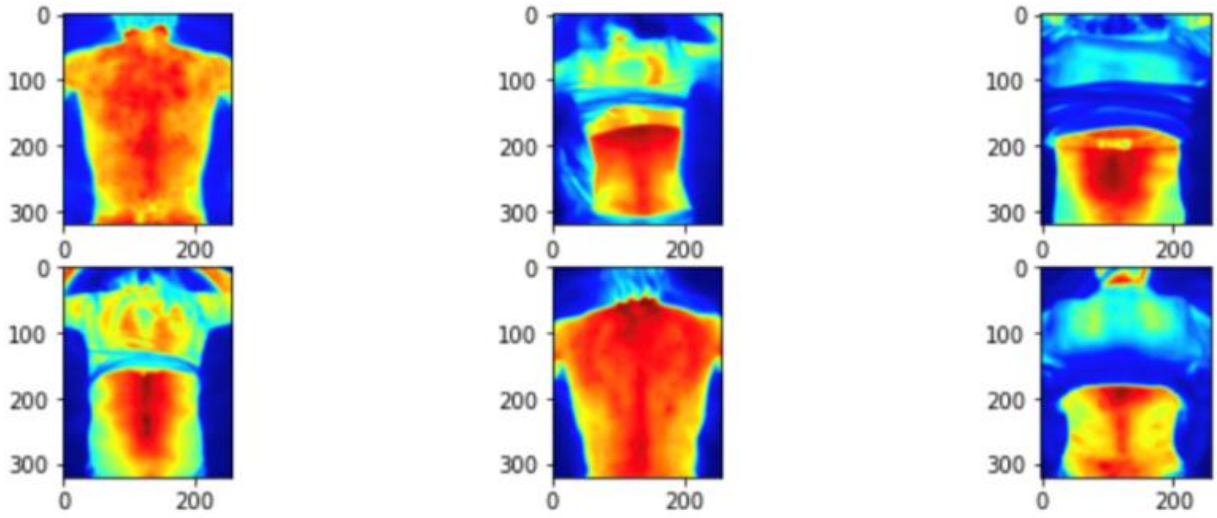
Results: The study is currently ongoing, and results are not yet available. However, preliminary data suggest that the robotic device is safe and well-tolerated by patients.

Conclusion: Non-specific cervicalgia is a common condition that can cause significant pain and disability. Current treatment options are limited and often ineffective. This study aims to validate ADAMO Robot for non-specific cervicalgia rehabilitation. If successful, this device could provide an innovative and effective treatment option for patients suffering from this condition. The results of this study have the potential to significantly impact the field of physical therapy and improve patient outcomes.

Design of Deep Learning Models for Image Diagnosis and Treatment through Thermal Imaging Analysis for the Adamo Robot Product

Authors: Álvaro José García Tejedor, Alberto Nogales Moyano, Samir Nabulsi, Carlos Jiménez, Manuel Rodríguez.

This project presents a comprehensive study on the design of deep learning models for image diagnosis and treatment through thermal imaging analysis for the Adamo Robot product.



The main objective of this project is to integrate deep learning models into the ADAMO Robot ecosystem to improve its diagnostic and treatment capabilities. To achieve this goal, two use cases will be addressed. The first one involves making a prognosis of whether a patient suffers from cervicalgia based on patient data and a thermal image. In the second case, anomalies in the cervical-dorsal and dorsal-lumbar areas will be detected solely through thermal imaging to recommend a treatment associated with that area that can be performed by the ADAMO robot.

It is essential to compile information about previous work in this field to obtain useful insights into how many data are required to train models, what technical characteristics images should have, which models are most efficient in processing data, and their approximate accuracy. This information will help in developing effective deep learning models for image diagnosis and treatment through thermal imaging analysis.

The study was conducted by Álvaro José García Tejedor, Alberto Nogales Moyano, Samir Nabulsi, Carlos Jiménez, and Manuel Rodríguez. The authors used various tools and technologies such as Python programming language, TensorFlow library for machine learning algorithms implementation, OpenCV library for image processing tasks, among others.

In conclusion, the study provides valuable insights into designing deep learning models for image diagnosis and treatment through thermal imaging analysis for the Adamo Robot product. The results obtained from this study will help in improving the diagnostic and treatment capabilities of the ADAMO Robot ecosystem, which can have a significant impact on the healthcare industry.

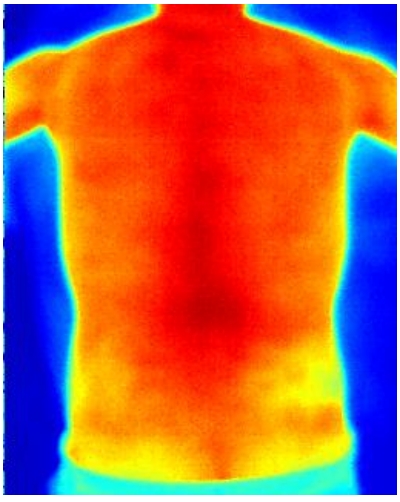
Effects of treatment with Robot Adamo on "tender points" to improve pain and sleep quality in women with fibromyalgia in the Community of Madrid.

Authors: Manuel J Rodríguez Aragón and Davinia Vicente Campos.

Fibromyalgia is a chronic disorder characterized by widespread musculoskeletal pain, fatigue, and sleep disturbances. The aim of this study was to evaluate the effects of treatment with Robot Adamo on "tender points" to improve pain and sleep quality in women with fibromyalgia in the Community of Madrid. The study was conducted using an online format for data collection, both before and after treatment. The primary objective was to assess the effects of Robot Adamo on musculoskeletal pain and sleep quality, while secondary objectives included evaluating its effects on local musculoskeletal temperature at "tender points". The study found that treatment with Robot Adamo had beneficial effects on temperature, quality of life, pain, and sleep quality in women with fibromyalgia. Specifically, there was a significant reduction in musculoskeletal pain and improvement in sleep quality after treatment. Additionally, local musculoskeletal temperature at "tender points" increased significantly after treatment. These findings suggest that Robot Adamo may be a promising tool for managing symptoms associated with fibromyalgia. In conclusion, this study provides evidence for the effectiveness of Robot Adamo as a non-invasive treatment option for improving pain and sleep quality in women with fibromyalgia. Further research is needed to confirm these findings and explore the potential mechanisms underlying the observed effects.

Effect of continuous pressure with thermoregulated compressed air of therapeutic robot on patients with trigger point 1 of the upper trapezius muscle.

Introduction: Myofascial pain syndrome is a frequent pathology linked to the appearance of trigger points, without a clear explanation for their appearance. Trigger points have been considered as one of the main causes of myofascial pain syndrome, constituting a great challenge for public health systems.



Objective: To evaluate the effects of continuous thermoregulated pressure from ADAMO Robot on myofascial pain and range of motion in patients with trigger point 1 of the upper trapezius muscle.

Methods: The study is a randomized clinical trial of analytical experimental longitudinal and prospective non-blinded type.

Results: The study aims to offer treatment with ADAMO Robot on trigger point 1 of the upper trapezius muscle, in case the results are statistically significant in favour of the intervened group. The recruitment will be done through an informative poster that will be disseminated through social networks and will be placed visibly in the physiotherapy department. The poster will

contain a QR code and a link to a questionnaire where inclusion and exclusion criteria for the study will be collected. Subsequently, eligible subjects will be contacted for the study.

Conclusion: The use of ADAMO Robot technology can help alleviate myofascial pain and improve quality of life for patients with trigger point 1 of the upper trapezius muscle.

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Individualized Treatment
24/7 Availability
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Shorter Treatments 10-15 Min
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Contactless Treatment
Secure Cloud Storage
Thermography, Diagnostic, Follow up
Increase Numbers of Treatments