Study to assess the safety and efficacity of a rehabilitation therapy with a s monoarticular exoskeleton for patients who have undergone knee arthroplasty

Promoter of the research study: Marsi -Bionics Company

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The most frequent cause of total knee replacement is to relieve the pain caused by wear and tear or advanced osteoarthritis, which incapacitates patients from carrying out their activities of daily living.

About 75,000 knee replacements are performed in Spain every year.

In the 100-bed HULZ, approximately 80 to 100 prostheses are performed each year.

The fundamental objectives of rehabilitation treatment after proximal tibial replacement (PTR) are: to prevent the complications of prolonged bed rest (thrombosis, pressure ulcers), to restore adequate functional mobility, to achieve at least 90° flexion with no extension deficit, to achieve independent walking with the possibility of going up and down stairs, to perform transfers without assistance and to enable the patient to independently perform activities of daily living (ADL).

The success of PTR depends not only on good surgical and anaesthetic technique, but also on a good rehabilitation programme adapted to the needs of each patient.

The use of robotic exoskeletons for knee rehabilitation after arthroplasty is a new avenue of rehabilitation treatment for this type of patient.

There are a growing number of studies in the literature on the effects of the use of exoskeletons in the clinical setting of gait support or rehabilitation of various pathologies.

Most studies have focused on the use of these devices for patients with neurological and neuromuscular pathologies such as stroke or spinal cord injury.

Fewer studies have evaluated the effectiveness of these devices for patients with climatological pathologies and their subsequent rehabilitation.

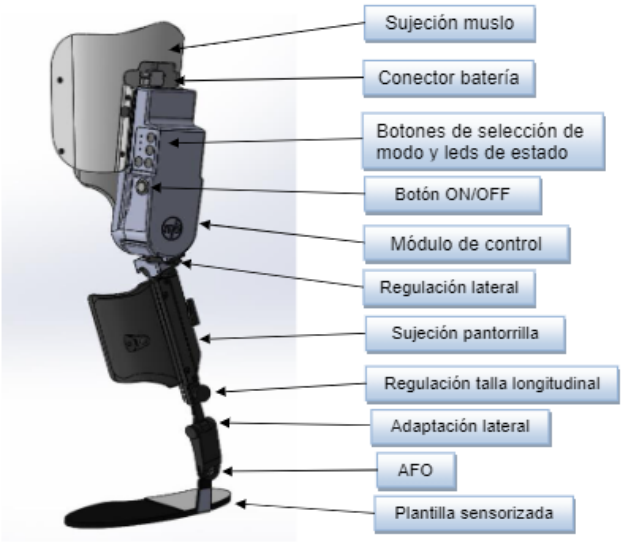
The main expected benefit is that the knee mobility of operated patients will improve faster when using the device to be evaluated. Previous tests have been carried out with the MAK exoskeleton in cases of patients with gait alterations due to ICTUS in which the safety and correct functioning of the exoskeleton has been proven.

The final objective would be to offer an alternative rehabilitation tool for knee prostheses that allows gaining functionality and achieving autonomy for daily life activities in the shortest possible time.

The study was approved by an Ethics Committee for research with medicinal products and by the Spanish Agency for Medicines and Health Products, in accordance with current legislation, Royal Decree 1090/2015 of 4 December and European Regulation 536/2014 of 16 April, which regulates clinical trials with medicinal products.

EXOSKELET: Acronym MAK (Marsi Active Knee), Device.

KNEE PROTESIS: Acronym PTR (Total Knee Prosthesis).



Esquema y componentes del dispositivo MAK

y Department of the Hospital and who were selected. They were informed about consent form.

- The patients to whom this rehabilitation device is applied obtain improvements in joint, muscle, perceived pain, swelling, function and complications resulting from the surgical operation.
- If the MAK device decreases the time needed to achieve the rehabilitation of the knee prosthesis.

This device has a motor at knee level that provides strength or slows down the movement. In addition, it has different programmes that adapt to your movement in real time.

During the sessions, you will always be supervised by a physiotherapist and a doctor who are trained in the use of this device.

The fundamental objectives of rehabilitation after PTR are: to prevent the complications of prolonged bed rest (thrombosis, pressure ulcers), to re-establish adequate functional mobility, to achieve at least 90° flexion without extension deficit, to achieve independent walking with the possibility of going up and down stairs, to perform transfers without assistance and to enable the patient to independently perform activities of daily living (ADLs).

The success of PTR depends not only on good surgical and anaesthetic technique, but also on a good rehabilitation programme tailored to the needs of the individual patient.

According to the reference by Dandy D Edwards, PTR is considered satisfactory if full extension is achieved, flexion is at least 100º, the lower extremity supports the patient's weight and if the joint is stable.

The treatment protocol of the study was 12 sessions of 45 minutes using the MAK device, 3 sessions during hospital admission and 9 outpatient sessions every other day in the Rehabilitation Service of the Hospital.

The rehabilitation treatment consisted of:

- Active mobilisations: the MAK performs a joint path marked by the rehabilitator depending on the aspect of the surgical wound, inflammation and pain.
- Assisted active mobilisations: within a defined joint pathway, the patient must mobilise his leg to complete his joint range.
- Strength training by means of exercise programmes with progressive resistance to strengthen the following muscle groups: quadriceps, hamstrings, calves and glutes. With a fixed angle of the MAK, the last degrees of extension are worked to strengthen the vastus internus.

The following parameters were measured in each session:

- The improvement of muscle strength
- The range of mobility of the knee, flexion and extension
- Pain perceived by the patient with the VAS scale
- Knee swelling with knee circometry
- Quadriceps muscle perimeter/volume
- Gait and balance scale
- Presence of postoperative complications

Adverse effects were recorded during the course of the study. The measurements were taken in order to observe the changes that occurred during the study period. In this way, we could evaluate the safety and efficacy of the Exoskeleton through the data collected.

The data collected from the evaluations would be assessed by medical personnel with expertise in post-operative rehabilitation of knee prostheses.

The following assessments were carried out:

- At hospital discharge.
- Every week until the end of the study, 4 assessments
- Final assessment: last day of the study

At the end of the sessions, one month after the surgical intervention, the patient would be assessed for discharge or, if the objectives had not been achieved, the patient would continue with conventional rehabilitation.

Study participants

The study was initially designed for 10 patients: five would participate in the experimental group using the MAK and the other five in the control group without using the device.

Due to difficulties in recruiting participants to complete the control group, mainly due to the COVID 19 pandemic, it was decided by the research team to terminate the clinical study without completing the control group. 6 patients completed the entire study.

To participate in the study they had to meet the inclusion or exclusion criteria:

Inclusion criteria:

- Patient who had undergone knee replacement surgery.
- Patient over 18 years of age or under 85 years of age.

Exclusion criteria:

- Weight over 100 kg
- Height greater than 190 cm or less than 150 cm
- Inability to understand simple commands.
- Skin or sensory impairment that prevents the application of restraints to the patient's skin.
- Appearance of postoperative complications that pose a risk for the time of rehabilitation.
- Presence of another pathology or alteration that constitutes a risk to movements with the knee

Statistical analysis

As this was a pilot group, no sample size calculations were performed.

For the statistical analysis the SPSS 21.0 package was used (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp).

Statistically significant results were taken as those with a p-value of less than 0.05.

Ethical and legal aspects

The study is under the protection of the law 14/2007 on biomedical research.

Risks of using the exoskeleton

There was a minimal risk of chafing of the patient's skin and muscle contractures after use of the device.

Based on the previous experience and years of service of the research staff in the field of rehabilitation, these risks were considered very unlikely.

Results of the study

Demonstrated that rehabilitation with the Exoskeleton in immediate postoperative knee replacement patients is safe, effective (healing, swelling and mobility), fast (12 sessions) and painless.

One month after surgery, an evaluation was performed consisting of measuring the participant's walking and balance ability (6MWT 6 Minutes Walking Test, FAC Functional Ambulation Categories and TUG Time Up and Go), the biomechanical and inflammatory properties of the operated knee (ROM Joint Range, BM Muscle Balance and perimeter) as well as the user's perception of the device (QUEST 2.0).

On walking and balance, patients were able to walk an average of 238.7 metres in 6 seconds one month after the intervention. On balance, participants obtained an average of 18.8 seconds to complete the test. On the FAC scale, a score of 4 out of 5 meant that patients are able to move on most terrains, needing assistance to go up and down stairs and ramps.

Biomechanical and inflammatory properties of the knees were measured by knee and quadriceps circumference, joint range with all patients achieving full extension 0 degrees and flexion between 95 and 120 degrees. The BM muscle balance, both in flexion and extension of the knee was 4 out of 5.

The user's perception of the device by means of the QUEST 2.0 scale, to the general question about the level of satisfaction was 4.6 out of 5, so the evaluation was positive.

Scientific evidence

So far, it suggests that rehabilitation in early postoperative PTR patients could be an improvement over conventional rehabilitation.

In a 2016 study using an exoskeleton to rehabilitate early postoperative PTR, a reduction in delayed extension of PTR was achieved and could be performed without increased pain (11).

In another similar study in 2017, an improvement in flexion and extension joint range was obtained, with less pain, but no improvement in muscle strength (12).

Three other studies conducted between 2017 and 2018 found improvements in extension lag, perceived pain during movements, gait and muscle strength in the quadriceps (13,14,15).

The benefits for the patient with the use of the MAK Exoskeleton are the early start of rehabilitation, which can be as early as the second day after surgery.

Fewer sessions, achieving medical discharge one month after the operation.

It is a painless treatment, as the range of mobility and speed of flexion and extension of the knee can be controlled with the exoskeleton. It requires less physical strain and more precision for the therapist who performs the treatment, being able to adjust the different programmes in real time. One hour of personalised attention by the therapist greatly reduces psychological stress and increases patient satisfaction.

The benefits for the scientific and medical communities of using the exoskeleton for rehabilitation are increased effectiveness and safety without adverse effects. Decreased rehabilitation time with medical discharge one month after the operation which helps to decrease the waiting list in Rehabilitation and Physical Medicine Services.

From August 2020 to January 2022 and during the Covid 19 pandemic, we have treated 56 patients who underwent knee prosthesis surgery with the MAK Exoskeleton in the hospital.

The results obtained at the end of the treatment have been very similar to the clinical trial, so we have designed a short-, medium- and long-term study to compare the results with control cases.

The demand is increasing due to the good results obtained with the MAK device. It is a safe, effective, quick and less painful treatment.

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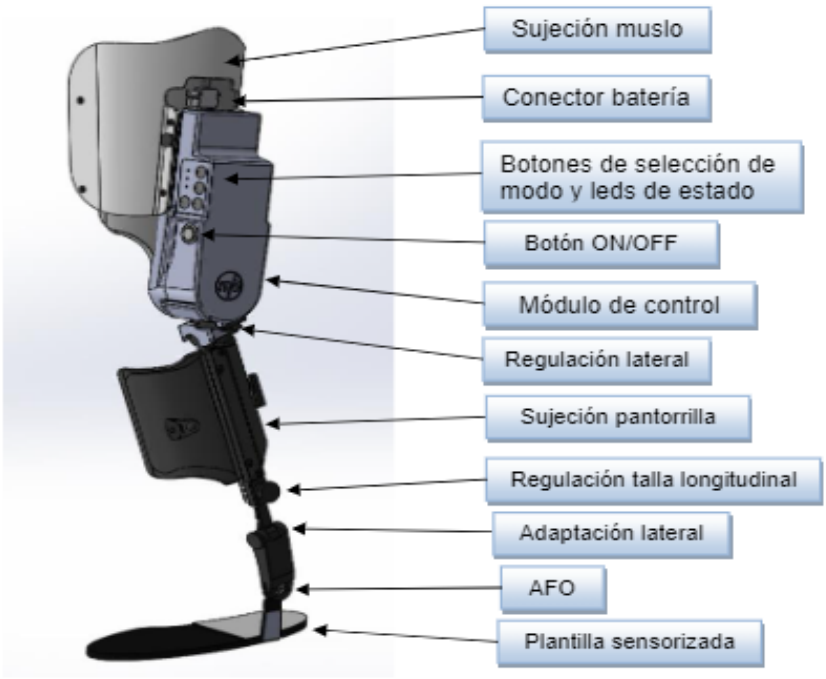

Esquema y componentes del dispositivo MAK