INTRODUCTION

Since its launch more than 10 years ago, Össur’s RHEO KNEE has had a marked impact on the microprocessor-controlled knee (MPK) market and the lives of thousands of people living with limb loss worldwide. The RHEO KNEE design has continued to evolve through a constant process of listening, observing and testing. On its journey to produce the optimal MPK, Össur learns from and works closely with users and CPOs, tailoring functionality to support distinct needs.

Following the introduction of the third-generation RHEO KNEE in 2014, the level of market acceptance globally has been exceptionally high. The knee’s core technology has been further developed and it is this technology, combined with the knee’s unique default swing principle, which offers important benefits to a wide range of users, from high K2 to low K4.

Different by design

The RHEO KNEE design is different, unique even in the MPK market, in that its operating principle is not based on hydraulic technology. Instead, it is operated by what could be called an “electronic brake”, whereby resistance is continuously adapted to the user’s needs and situation.

The scientific term for the electronic brake principle is “magnetorheology”, after which RHEO KNEE is named. This highly responsive and proven technology, pioneered by the aerospace, defense and automotive industries, utilises electromagnetic force to rapidly alter the viscosity of magnetic fluid in the knee. This allows an almost instantaneous shift from the high resistance required for stability in stance phase, to the low resistance needed for a dynamic, free swing phase. The result is a virtual “zero lag” experience that simulates the natural function of a physiological knee joint.

A variety of sensors continuously measure knee angle, speed, pressure, direction and changes in walking patterns. This information is relayed to the microprocessor, which translates it into a continuous stream of instructions, instantly increasing or decreasing resistance as required.

THE NEW RHEO KNEE® 3 AND RHEO KNEE® XC

In May 2016, Össur launched the new RHEO KNEE. Available in two models – RHEO KNEE 3 (Dynamic Solutions) and RHEO KNEE XC (Impact Solutions) – the design continues to build on the magnetorheologic operating principle, with the added advantage that the knee is now weatherproof. Additional functionality in the RHEO KNEE XC version introduces running, cycling and step-over-step stair ascent capabilities.

In 2015, a clinical test was conducted comparing the functionality of the new RHEO KNEE to other microprocessor-controlled knees. When scrutinising the clinical test results, the added value in this enhanced design becomes apparent.

CLINICAL TESTING

Clinical evidence reveals that the new RHEO KNEE (RHEO KNEE 3 and RHEO KNEE XC) supports increased user mobility and improvements in a number of activity parameters.

Testing incorporated a number of outcome measures widely recognised in the field, such as 6-Minute Walking Tests and L-Tests, where users of the new RHEO KNEE walked longer distances and faster than on other microprocessor-controlled knees (MPKs). Borg Scale scores indicated that after performing a physical exercise, test subjects were less exerted than on other MPKs. Furthermore, PEQ questionnaires indicated that the new RHEO KNEE increased users’ perceived quality of life. The aforementioned findings are all statistically significant except the Borg Scale.

Users have said that the new RHEO KNEE is more stable in stance and more dynamic in swing than previously. They have also indicated that the new design feels lighter and more supportive than other MPKs, both at heel-strike and at toe-off. Users of the RHEO KNEE XC version felt able to ascend and descend stairs with confidence and ease, as well as maintain their physical condition by being more active.
The testing was conducted by means of a non-blinded, two-group design, with both groups comparing the new RHEO KNEE (using the RHEO KNEE XC version) to their current knee. All test subjects used their existing sockets throughout the testing, without modifications. One group consisted of nine people who had previously used an earlier version of a magnetorheologic microprocessor-controlled knee (MPK), and the second group comprised four previous users of an MPK incorporating hydraulic technology with stair-ascent recognition.

All 13 users completed a three-week evaluation in a multi-center trial, performing the following tests in the order indicated:
- Borg Scale CR 10 pre
- 6MWT
- Borg Scale CR 10 post
- L-Test
- Stair and cycle evaluation
- PEQ MS 12/5 - functional ability and prosthesis satisfaction

All 13 test subjects were satisfied with the new RHEO KNEE and preferred it over their previous prosthesis. The test subjects all showed improvements in mobility, perceived safety and functioning. Results for the 6MWT, L-Test and PEQ showed statistical significance in the improved parameters:
- The average walking distance in the 6MWT increased significantly, from 428.23 m to 506.00 m.
- The L-Test times were reduced significantly in all test subjects, with mean times decreasing from 21.46 secs to 19.46 secs after three weeks.
- The PEQ MS 12/5 data averaged across all users increased significantly, from 3.07 to 3.59 (on a scale of 0-4).
- The Borg Scale CR 10 outcome, measured before and after the 6MWT performance, decreased from 3.04 to 1.93 (no statistical significance).

The clinical test was designed to evaluate the mobility and satisfaction of unilateral transfemoral amputees using the new RHEO KNEE during daily activities.

The RHEO KNEE XC version used in the test features an enhanced extension assist, step-over-step stair-ascent capability, automatic cycling recognition and a weatherproof design. These features are not present in earlier magnetorheologic MPKs. The hydraulic MPK previously used by one of the groups of test subjects included stair ascent mode in a weatherproof design, but no automatic cycling recognition.

In general, the test confirms the hypothesis that the new RHEO KNEE supports higher activity levels, with users enjoying increased mobility and indicating higher levels of satisfaction in the perceived functioning of their prosthesis.

6MWT:
The typical six-minute walking test (6MWT) performance of transfemoral K4 level amputees is 419.76 m, and an increase of more than 45 m is deemed to be a true and scientifically proven improvement. The test subjects improved their average performance by 78 m, which is almost on par with active service personnel in the US, who perform on average at 542 m ± 676.

PEQ:
The PEQ MS 12/5 is a validated system of self-assessment by users of prosthetic functioning and satisfaction. The test subjects reported a statistically significant improvement in satisfaction and functioning compared to their previous microprocessor-controlled knees (an average of 3.59 versus 3.07 on a scale of 0-4).

STAIR ASSESSMENT INDEX:
The new RHEO KNEE XC version allows for step-over-step stair ascent with smooth and easy transitioning into and out of stairs. The Stair Assessment Index is a validated method of assessing stair mobility. Test subjects demonstrated a statistically significant improvement in stair mobility, as measured by the Stair Assessment Index (8.75 versus 5.69 on a 0-13 analog scale).

L-TEST:
The L-Test serves as an indicator for functional mobility and consists of a 20 meter timed test performed on a flat, hard surface. It includes two transfers and four turns. In the L-Test validation study, the best performance by a transfemoral amputee (due to trauma) was measured at 17.1 secs, which is 3 secs slower than the baseline measure for the best performer in this clinical test. Test subjects showed a significant improvement 2 secs on average after transitioning to the new RHEO KNEE, which also helps to support their comments concerning the light, easy control of swing phase.
The clinical test results indicate that the advanced technology in the new RHEO KNEE allows active users to step up to another performance level. The enhanced design significantly improves the mobility, agility and satisfaction in prosthetic function for active unilateral transfemoral users. And test-subject satisfaction levels with perceived safety and performance indicate that use of the new RHEO KNEE can enable a more active lifestyle.

MORE MOBILITY | LESS FATIGUE | HIGHER QUALITY OF LIFE

When using the new RHEO KNEE:
- Users increased their mobility in comparison to their usual MPK.
- Users reported less fatigue than with their previous prosthesis, and at the same time they walked longer distances.
- Users walked faster and further.
- Users graded their prosthetic device and quality of life higher than with their previous MPK.

REFERENCES