18 subjects / 17 completed protocol

PROTEOR QUATTRO 2 MICROPROCESSOR KNEE

PROTEOR QUATTRO 2 MICROPROCESSOR KNEE (MPK) SIGNIFICANTLY IMPROVES SPECIFIC DAILY LIFE ACTIVITIES

MULTICENTER RCT

EVALUATION OF MPK DEVICES: A MULTICENTER, RANDOMIZED CROSS-OVER-TRIAL

OBJECTIVES

PRIMARY	EVALUATE SUBJECTS ABILITY TO ACHIEVE PERSONAL GOALS, INCLUDING LEVEL OF DIFFICULTY
SECONDARY	EVALUATE SATISFACTION AND QUALITY OF LIFE

METHOD

Protocol approved by national ethics committee (Protocol ID-RCB 2022-A01266-37). Each subject compared QUATTRO 2 to their typically worn MPK on:

PRIMARY

ACTIVITIES OF DAILY LIVING

Patient-Specific Functional Scale (PSFS)
Subjects identified two specific activities they were unable to do, or were difficult to achieve, with their typically worn MPK.

Subjects were asked to rate the level of difficulty of their defined activities from 0 (unable to achieve) to 10 (able to achieve) on their typically worn MPK and QUATTRO 2.

SECONDARY

SATISFACTION

Prosthesis Evaluation Questionnaire (PEQ)

QUALITY OF LIFE

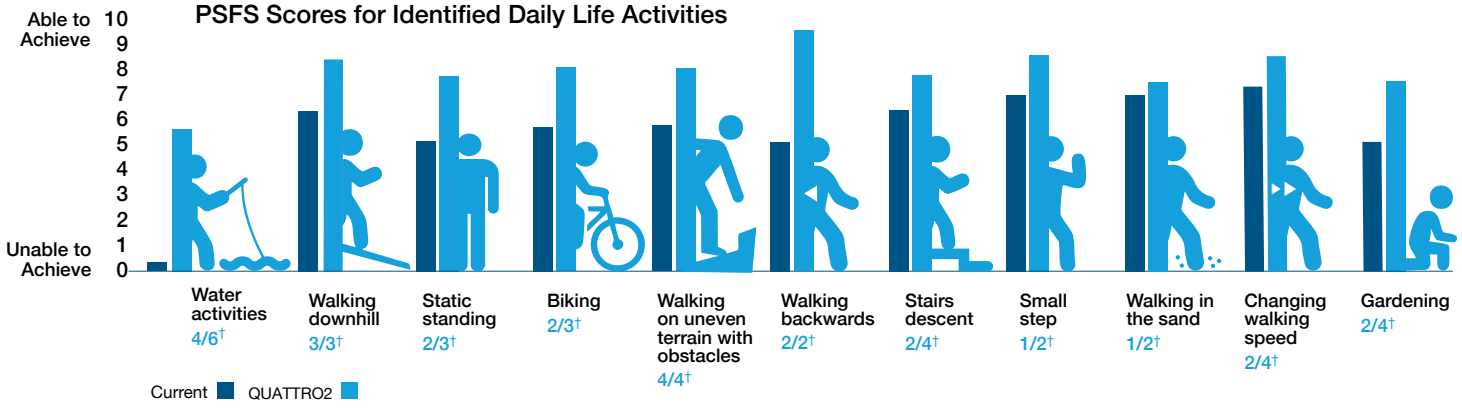
36-Item Short Form Survey (SF-36) to evaluate physical and mental health measures

KEY FINDINGS

Identified daily life activities improved with QUATTRO 2 compared to their typically worn MPK*

Subjects scored the **appearance of the QUATTRO 2** significantly higher than their typically worn MPK*

Subjects showed significantly **fewer physical limitations** with QUATTRO 2 than with their typically worn MPK*



*RCT, n=17, France, 2023-2024.

†Number of users that increased their score with QUATTRO 2 compared to typically worn MPK

10 subjects / 7 completed protocol

PROTEOR QUATTRO 2 MICROPROCESSOR KNEE

FUNCTIONAL TASKS EASIER TO PERFORM WITH PROTEOR QUATTRO 2 MICROPROCESSOR KNEE (MPK)

IRB APPROVED STUDY

SUMMARY OF THE IRB-APPROVED STUDY:

QUATTRO 2 Microprocessor Knee Allows Users to Complete Functional Tasks With Less Difficulty Than Typically Worn Microprocessor Knees (Montgomery JR, et al)

HYPOTHESIS

After 30 days of at-home use of the QUATTRO 2, subjects with a transfemoral amputation would be able to complete functional tasks with comparable or reduced difficulty with the QUATTRO 2 compared to using their typically worn prosthesis.

METHOD

Protocol approved by an independent IRB (Advarra IRB Protocol # Pro00048820):

At two timepoints, subjects were given 22 functional tasks to perform, assessing difficulty on a scale of 1 (greatest difficulty) to 9 (greatest ease)†

DAY 1
Subjects completed 22 functional tasks with their MPK

MPK SWITCH
Subjects were fit with QUATTRO 2 and wore it as their daily prosthesis for 30 days

DAY 30
Subjects completed functional tasks with QUATTRO 2

KEY FINDINGS

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EASIER FUNCTIONAL TASKS

Functional tasks rated as statistically significantly easier with QUATTRO 2

- **Walking backwards** p=0.038
- **Walking sideways** p=0.047
- **Walking over an obstacle of six inches in height** p=0.035
- **Kneeling on their prosthetic knee and standing** p=0.008
- **Swinging a golf club** p=0.038

*10 subjects with unilateral or bilateral transfemoral amputations participated in study; 7 subjects completed the full protocol without deviation and were included in analysis.
†Change in score (mean and standard deviation) was calculated from subjects' typical MPK to the second office visit with the QUATTRO 2 MPK after 30 days of at-home use. Socket and prosthetic foot remained the same. Paired, independent, two-tailed t-tests were performed on the functional task difficulty ratings. Significance was defined as a critical alpha of p<0.10.

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