Advantages of flexible wrist units in arm prostheses.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21163

Source
Nationaal Trial Register

Health condition

Amputees, upper limb, prosthesis.

Sponsors and support

Primary sponsor: University Medical Center Groningen, Center for Rehabilitation
Source(s) of monetary or material Support: Steunstichting OIM Brabant

Intervention

Outcome measures

Primary outcome

This study assesses the value and added value of a wrist that can be put in a flexion position and a wrist that can not only be put in a flexion position but can also move freely in a neutral position compared to a rigid wrist unit.

Secondary outcome

1. Expectations about functionality of the new prosthetic wrist, compared to own prosthesis;

2. Joint angles (compensatory movements) during execution of several ADL (activities of daily living) tasks;

3. Pressure inside the socket of the prosthesis;

4. Functionality during usage of the prosthesis;

5. Satisfaction of the patient and information about benefits/disadvantages.

Study description

Background summary

Background:

For the usage of the hand of an arm prosthesis, accurate positioning of the hand is of high importance. Conventional prostheses are usually equipped with a wrist unit that can only rotate. This implies that the position of the hand in space is mainly determined by the more proximally located joints, i.e. the shoulder and elbow, and even the trunk. Several studies reported that restriction of flexion/extension and/or restriction of pronation/supination in the wrist both reveal compensatory motions from more proximally located segments (Adams, Grosland, Murphy, & McCullough, 2003; MacPhee, 2007; Carey, Jason Highsmith, Maitland, & Dubey, 2008; Bertels, Schmalz, & Ludwigs, 2009).

Besides this, it is clear that many ADL require a certain degree of flexion or extension in the wrist, or a certain degree of rotation. For example, it is described that eating requires 30 degrees flexion/extension and 30 degrees radial/ulnar deviation (Heckathorne, 2004).

Recently, two prosthetic wrists that have more motion capabilities than just rotation were put on the market: the Flex wrist of Otto Bock ® can be fixed in different flexion/extension modes (-40, -20, 0, 20, 40), while the Multiflex-wrist of Motion Control ®) can not only be secured in the flexion/extension direction (-30, 0, 30), but also, in the neutral position (0) the wrist can move freely in the flexion/extension direction and in the radial/ulnar direction. Only very limited research has been performed to establish the value and possible added value of such flexible wrist units (Bertels, Fiedler, & Schmalz, 2008; Petersen, 2008; Kyberd, 2012). Importantly, systematic research aiming to determine advantages in patients has not been performed.

It is expected that wrists with more degrees of freedom contribute to a higher experienced functionality and satisfaction with the prosthesis. Also, movement patterns are expected to be more natural and to reveal less compensatory movements.

Aim:

The aim of this study is to explore the value and added value of a wrist that can be put in a flexion position (Flex-wrist, Otto Bock ®) and a wrist that can not only be put in a flexion position but can also move freely in a neutral position (Multiflex wrist, Motion Control ®) compared to a rigid wrist unit (Otto Bock ® and Motion Control ®, respectively), using a range of tests covering all factors of the domains Functional Impairments and Activities & Participation as described in the International Classification of Functioning and Health.

Study design:

The study will be a cross-over study, in which each patient uses two different wrist components of two different manufacturers for their prostheses. The period of study for each patient is three months. Each patient uses two different wrists. There is a pre-measurement, three interim measurements (at the changing of the wrist and/or hand) and a post-measurement. In addition, one month after completion of the wearing of the test hands a follow-up measurement takes place.

Measurements start with a general questionnaire and with a short evaluation of expectations. VAS (Visual Analogue Scale) scores are determined to assess expectations about functionality of the new prosthetic wrist, compared to own prosthesis. During the execution of ADL (Activities of Daily Living) tasks, movements of the trunk, shoulder and elbow are measured. The pressure inside the socket of the prosthesis will be measured with pressure sensors. To assess functionality, the Box and Block test and Southhampton Hand Assessment Procedure (SHAP) are used. Satisfaction of the patient is measured by questionnaires, namely TAPES (Trinity Amputation and Prosthesis Experience Scale) and OPUS (Orthotics and Prosthetics Users' Survey), and VAS scores. A semi-structured telephonic interview is conducted at the end of the research to ask the user about experienced advantages and disadvantages of the wrists.

Population:

The population consists of eight patients with an arm amputation (from University Medical Center Groningen or Revant Rehabilitation Center Breda), either due to ULRD or ULA. In this research project, only patients with a below elbow amputation will be included. The results

could potentially also apply to patients with a more proximal amputation level. To be able to estimate compensatory movements while performing the movement tasks, reference values will be gathered from eight healthy subjects of same age and gender.

Study objective

The aim of this study is to explore the value and added value of a wrist that can be put in a flexion position (Flex-wrist, Otto Bock ®) and a wrist that can not only be put in a flexion position but can also move freely in a neutral position (Multiflex wrist, Motion Control ®) compared to a rigid wrist unit (Otto Bock ® and Motion Control ®, respectively), using a range of tests covering all factors of the domains Functional Impairments and Activities & Participation as described in the International Classification of Functioning and Health.

Study design

All parameters listed in 'secondary outcomes' are assesses at baseline, at 2, 4, 6, and 8 weeks (after using a wrist unit during a two-week period). One month after completing the test period of eight weeks, a telephonic interview takes place to ask patients for experienced advantages/disadvantages of the prosthetic wrists.

Intervention

Eight patients use two different prosthetic wrists, either put in fixed or flexible position. Total duration of the test period is 8 weeks.

Eight healthy participants are used to gather reference values of movement trajectories of several activities of daily living.

Contacts

Public
Center for Rehabilitation, UMCG
CB41
P.O. Box 30.001
Marieke Deijs
Groningen 9700 RB
The Netherlands
+31 (0)50 3613259
Scientific
Center for Rehabilitation, UMCG
CB41
P.O. Box 30.001
Marieke Deijs
Groningen 9700 RB

The Netherlands
+31 (0)50 3613259

Eligibility criteria

Inclusion criteria

1. Having at least one year experience with using a myo-electrical lower arm prosthesis with a passive wrist unit. Patients using an active, static wrist unit can join the project when not enough participants can be found who use a passive wrist unit;

2. Wearing the prosthesis for at least four hours a day;

3. The prosthetic hand has got one degree of freedom (opening and closing the hand);

4. Able to undergo tests and to fill out questionnaires.

Exclusion criteria

1. Co morbidities that could influence the results of the study (for example, neurological disorders or rheumatic diseases that can influence arm function);

2. Having experience with a Flex-wrist or Multi-flex wrist.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2013
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion
Date: 06-05-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38501
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3818
NTR-old	NTR3984
CCMO	NL44256.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38501

Study results

Summary results
N/A