Advantages of a flexible wrist unit compared to a static wrist unit in people using an arm prosthesis.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38501

Source
ToetsingOnline

Brief title
Advantages of flexible wrist units in arm prostheses.

Condition

- Other condition
- Musculoskeletal and connective tissue disorders congenital

Synonym
upper limb amputation

Health condition

amputatie zowel verworven als congenitaal

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Steunstichting OIM Brabant

Intervention

Keyword: Flexible wrist, Patients, Prosthesis, Upper limb

Outcome measures

Primary outcome

This study assesses the value and added value of a wrist unit that can be put in a flexion position and a wrist unit 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

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

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

- Pressure inside the socket of the prosthesis.

- Functionality during usage of the prosthesis.

- Satisfaction of the user and information about benefits/disadvantages.

Study description

Background summary

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, either passively or actively. 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). For other activities, like driving in a car, riding a bike, lifting objects, closing a zipper or buttons, or handling tools, maximally 80 degrees of flexion/extension and 60 degrees of radial/ulnar deviation is needed (Heckathorne, 2004).

Recently, two prosthetic wrist units 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 prostethic users has not been performed.

It is expected that wrist units 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.

Study objective

The aim of this study is to explore the value and added value of a wrist unit that can be put in a flexion position (Flex-wrist, Otto Bock ®) and a wrist unit 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 participant uses two different wrist components of two different manufacturers for their prostheses. The period of study for each participant is three months. Each participant uses two different prosthetic wrists of different manufacturers, in two different states (passive and flex). After using a prosthetic wrist in a certain state, a measurement takes place (M1 - M4). One month after completion of the wearing of the test hands, a follow-up measurement takes place. Before starting the test period, one measurement (M0) is conducted using the participants* own prosthesis, to enable the participant to get used to the measurement procedures, and to be able to check for individual differences between the participants at baseline. The pre-measurement and interim measurements will each take maximally 2.5 hours, including all questionnaires, equipping participants with measurement instruments, appropriate number of breaks, etc. Actual measurement time will be shorter.

Each participant will follow a test period of two blocks of four weeks (see Table 1). Within a block a Flex wrist (Otto Bock ®) or a Multiflex-wrist (Motion Control ®) is used for two weeks. Furthermore, the same hands but with a rigid wrist unit are used for another two weeks in that same block. Within a block four participants start with a flexion/extension wrist unit and four participants start with a rigid wrist unit. Furthermore, four participants start with the Otto Bock ® hands and four participants start with the Motion Control ® hands. The exchange between the replacements will take place on one day. The wrist units are equipped with a Quick-Disconnect system, which enables to change very easy between the prosthetic hands. Before getting a new wrist component, each participant is asked to fill out a very short questionnaire assessing expectations with regard to functionality of the new device, because registration of the expectations of the user is expected to be important to be able to refer to, when drawing conclusions with regard to satisfaction.

Measurements start with a general questionnaire and with a short evaluation of expectations. The other measurements take place within the domains Functional Impairments and Activities & Participation of the ICF (International Classification of Functioning and Health). VAS (Visual Analogue Scale) scores are determined to assess expectations about 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. By measuring joint angles, compensatory movements from the elbow and shoulder joints that are necessary in these tasks can be quantified. 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.

Intervention

N.A.

Study burden and risks

Prosthetic hands that are comparable with the own prosthetic hand of the participant are used. Participants might only suffer from light muscle soreness the next day due to the execution of the tests. Also, the pressure sensor that is placed in the socket of the prosthesis can possibly cause light irritation of the skin. The risks associated with participation in this study can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
-Having at least one year experience with using a myo-electrical lower arm prosthesis with a passive wrist unit. People using an active, static wrist unit can join the project when not enough participants can be found who use a passive wrist unit.
-Wearing the prosthesis for at least four hours a day.
-The prosthetic hand has got one degree of freedom (opening and closing the hand).
-Able to undergo tests and to fill out questionnaires.
Participants only participate after providing written informed consent. ;Healthy participants:
- Matching one participant (prosthetic user) for hand dominance (prosthetic user*s dominant hand is concerned as the non-amputated hand), age, gender, length and weight.

Exclusion criteria

Prosthetic users:
-Co morbidities that could influence the results of the study (for example, neurological disorders or rheumatic diseases that can influence arm function).
-Having experience with a Flex-wrist or Multi-flex wrist. ;Healthy subjects:
- Having any complaints of the musculoskeletal system.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2013
Enrollment:	16

Type:	Actual

Medical products/devices used

Generic name:	Motion Control ProPlus Hand;left and right;7 □;with Multiflex wrist; Otto Bock Transcarpal Hand;left
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21163
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44256.042.13
Other	NTR (TC = 3984)
OMON	NL-OMON21163