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Testing a novel, affordable body-powered prosthetic arm for children

Submission date
18/12/2019

Recruitment status
No longer recruiting

Registration date
20/12/2019

Overall study status
Completed

Last Edited
12/03/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Most upper limb (UL) prosthetics are generally not affordable for a vast majority of patients in low and middle-income countries. Also, the current prosthetics are often not appropriate for application in these more challenging environments. Despite significant advances in prosthetic technology, the most popular and affordable UL prosthetics for adults and children remain body-powered (BP). A BP prosthesis uses a Bowden cable (like the standard bicycle brake cables) to connect movements of the upper extremity (UE) to movements of the terminal device (hook-shaped or anthropomorphic). This technology is more than 100 years old, and it still dominates much of the market. However, the use of cables severely limits/restricts the movement possibilities of the user. An exciting prospect is the ability to provide new customised, BP prosthetics that allow the patient to position the hand anywhere in space freely. This is particularly promising for children who have a lost or missing limb, as their prosthetic operating space should not be limited as they grow and develop. This study is looking to see how acceptable and appropriate a new body-powered prosthetic arm with a novel control is to the study volunteers.

Who can participate?
Boys and girls with acquired upper limb loss or congenital upper limb absence aged between three and 17 years and in good health

What does the study involve?
Participants are measured, complete a survey, and undergo tests including breathing, grip strength, hand and prosthetic function, and quality of life.

What are the possible benefits and risks of participating?
The researchers cannot promise that the study will benefit the study volunteer directly; however, by participating in this study, they will be contributing to our knowledge of how to further develop affordable body-powered prosthetic arms. The information gathered during the usability study, questionnaire-based survey and prosthetic outcome measures will hopefully inform affordable prosthetic designs and potentially benefit those living in low- and middle-income countries. The study participants and their parent(s) and legal guardian(s) will be reimbursed for their travel and food costs for the day of the study-related visit. The selected

study procedures in a laboratory setting are safe for human participants, and there are no known potential risks. The participants might feel mild discomfort during the use of a Velcro strap to attach the prosthetic arm to the participant's residual limb in Stage II.

Where is the study run from?
Mobility India – Rehabilitation Research & Training Centre and St John's Medical College Hospital in Bangalore (India)

When is the study starting and how long is it expected to run for?
February 2019 to December 2024

Who is funding the study?
1. Engineering and Physical Sciences Research Council (EPSRC)
2. Global Challenges Research Fund (GCRF)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
3D-printed breathing-powered prosthetic arm for children

Study objectives
The Natural Interactions Lab (https://www.oxfordnil.com/) at Oxford University is working on developing a radical new body-powered (BP) prosthetic arm. This ambitious research project wants to push the boundaries, and provide a step-change in affordable, BP prosthetic designs for children and young adults, through the development of a personalised prosthetic that uses a novel type of control. The 3D-printed breathing-powered prosthesis provides a patient-specific prosthesis option that can be used without limiting any of the body movements of the user.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/05/2020, St John’s Medical College Hospital Institutional Ethics Committee (St John's Medical College & Hospital, Sarjapur Road, Bangalore - 560 034, India; +91 (0)80 49466346 / 48; sjmcierb@gmail.com, sjmc.ierb@stjohns.in), ref: 265/2019
2. Approved 03/02/2020, Oxford Tropical Research Ethics Committee (OxTREC, University of Oxford Research Services, University Offices, Wellington Square, Oxford OX1 2JD, UK; +44 (0) 1865 (2)82106; oxtrec@admin.ox.ac.uk), ref: 61-19

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Upper limb (arm) difference (congenital/acquired)

Interventions
Sampling method: Non-probability sample (convenience sampling, although purposeful sampling is preferable if prevalence and subjects with necessary characteristics [e.g. device wearers versus non-wearers, congenital versus acquired limb deficiency, paediatric prosthetic users within different age-groups, etc] in the target patient database permits)

Expected duration of participant participation: About 4 hours per visit

Number of visits: Two visits (a visit each for Stage I and Stage II), and an additional study visit, if required

The entire user-centred trial of the 3D-printed breathing-powered prosthetic arm is divided into two stages, i.e., Stage I and II as detailed below:
Stage I:
– Qualitatively assess how children with upper limb loss or absence find breathable control as a prosthetic control option via a bench test.
– Characterise the group of prosthesis users with a questionnaire-based survey for gaining insights on demographics, satisfaction levels, patterns of wear, challenges faced, priorities, etc.
Stage II:
– Assess/clinically validate how the breathing-powered prosthesis (with a compatible and personalised socket made by the clinical team) enables children with limb loss or absence in functional task execution via select outcome measures.

All suitable prosthesis users treated at St John’s Medical Hospital and Mobility India (and their affiliate organisations) as the Patient Identification Centres will be screened by our Bangalore-based clinical partners (who are part of the patient's existing clinical care team will be accessing the patient's records). Parent(s)/legal guardians of the identified prosthesis users would be firstly provided with the Patient Introductory Letter and Patient Information Sheet. Note: The Patient Information Sheet, Informed consent forms, and Informed assent forms will be translated and made available in six local languages (i.e. English, Hindi, Kannada, Malayalam, Tamil, and Telugu).

Steps carried out by the GCP-trained investigator:
1. Audio-visual consent taking and getting signatures on Informed consent and Informed assent forms
2. Measurement of anthropometric dimensions and prosthesis sizing data
3. Questionnaire-based survey. In addition to these, participant demographics, anthropometric data, handedness, peak expiratory flow rate, grip strength, and prosthesis sizing data will be collected both in Stage I and Stage II.
4. Qualitative feedback after functional task execution (Usability testing) from the child and their parent(s) or legal guardian for Stage I
5. Performing select outcome measures both in Stage I and Stage II
6. Reimbursement to the volunteer (via their parent(s) or legal guardian(s)) for their participation time as well as travel and food costs both in Stage I and Stage II

Follow-up: Not applicable

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
Timepoints for all of the outcome measures: baseline only

Stage I (n = 15):
1. Qualitative usability testing of breathing control provided by the study participants and their parent(s) or legal guardian via a Likert scale and open-ended questions; patient-reported and researcher observed
2. Published outcome measures such as:
2.1. Baby version of the Southampton Hand Assessment Procedure (babySHAP), a clinically validated hand function test
2.2. University of New Brunswick (UNB) Test of prosthetic function for measuring prosthetic function (observer-rated measure with a dual rating scale used to evaluate performance and spontaneity of use)

Stage II (n = 30):
1. Published outcome measures such as:
1.1. Baby version of the Southampton Hand Assessment Procedure (babySHAP), a clinically validated hand function test
1.2. Prosthetic Upper Extremity Functional Index (PUFI) for measuring upper limb-focused functional abilities (observer-rated measure with a dual rating scale used to evaluate performance and spontaneity of use)
1.3. Paediatrics Outcome Data Collection Instrument (PODCI) (or Paediatric QOL Inventory (PedsQL)) test - well-validated musculoskeletal health questionnaires for measuring participation and Quality of Life

Secondary outcome measures
Timepoints for all of the outcome measures: baseline only

Stage I (n = 50):
Description of demographics and needs analysis using a questionnaire-based survey by the study participants and their parent(s) or legal guardian via questionnaires such as Quebec User Evaluation of Satisfaction with assistive Technology 2.0 (QUEST 2.0) and (Nagaraja et al. 2016)

Overall study start date
01/02/2019

Completion date
04/12/2024

Eligibility

Key inclusion criteria
1. Aged 3-17 years
2. Wearer or non-wearer of prosthetic device
3. Bilateral level of amputation (only Stage I)
4. Non-disabled children (only Stage I)
5. Parent or legal guardian is willing and able to give permission and informed assent for his or her ward’s participation in the study
6. Free of neurological and musculoskeletal pathology (apart from upper limb (UL) loss or absence for prosthesis users, and as reported by the participants or their clinician) that would impair upper limb motor control during a goal-oriented task execution in a seated position

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
50

Total final enrolment
15

Key exclusion criteria
1. Any medical conditions, assessed by their treating healthcare professionals, that would contraindicate the use of prosthetic arm prototypes, such as difficulties in breathing, skin abrasions, and musculoskeletal injuries
2. Inability to give the information required or to perform the test tasks

3. Wounds or ulcers in the residuum
4. Transcarpal level of amputation (for Stage II)

Date of first enrolment
01/02/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
India

Study participating centre
St. John's Medical College Hospital
St. John’s National Academy of Health Sciences
Sarjapur Road
Bangalore
India
560034

Study participating centre
Mobility India - Rehabilitation Research & Training Centre
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Sponsor type
University/education

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Funder(s)

Funder type
Government

Funder Name
Global Challenges Research Fund (GCRF)

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study will be published in journals, international conferences, etc. The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases, and any other publications arising from the study. Authors will acknowledge that the study was

funded by the Engineering and Physical Sciences Research Council (EPSRC) Impact Acceleration Account (Award EP/R511742/1) and the Global Challenges Research Fund (Award KCD00141). Authorship will be determined in accordance with the ICMJE guidelines, and other contributors will be acknowledged. After the conclusion of the study, the Investigator can direct the interested study participants to the relevant research publication as and when it is published.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical and confidential reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		29/07/2022	12/03/2024	Yes	No
Results article		05/12/2022	12/03/2024	Yes	No