

ClinicalTrials.gov ID: NCT05392907

Unique Protocol ID: 747-2020-OSS-AUSLBO-20124

Cover page

Title	Forensic-medical aspects of lower limb prosthetics: An observational study
NCT number	NCT05392907
Date	April 29 th 2025

Study protocol

Rationale

The loss of a lower limb is an extremely disabling event that limits not only the ability of interaction with the outside world (Activities of Daily Living, ADLs), but impacts also on the representation of oneself. Many efforts have been implemented in the last two decades for the technological development of prostheses that can take the place of the lower limb. Furthermore, lower limb amputation also represents a relevant clinical condition from a medical-welfare point of view, and according to epidemiological studies it is destined to grow enormously in the coming decades, due to the aging of the general population and the increase of the number of subjects with chronic vascular and/or metabolic diseases. Likewise, over the years, thanks to the technological progress in the field of limb prostheses, a change in the condition of the prosthetic amputee have been observed. Nonetheless, past studies have shown the permanence of numerous problems: the majority of the population with lower limb amputation experience impaired mobility and a decreased physical abilities, pain syndromes (including phantom limb pain) and refer discomfort and dissatisfaction in wearing the prosthetic limb. Therefore, a precise definition of the impact of lower limb amputation on the activities of the daily life, mobility, work and social participation, and quality of life is fundamental to support the healthcare activities and services aiming at improving the quality of life of subjects with amputation. Such features of interest can be well investigated by the administration of questionnaires. The "Prosthetic Mobility Questionnaire" (PMQ), available in the Italian version, investigates self-perceived mobility through 12 items motor skills in the daily context. This questionnaire have demonstrated good psychometric properties in measuring mobility in subjects with lower limb amputation using a prosthesis. The "Trinity Amputation and Prosthetic Experience Scales" (TAPES), is a multidimensional self-administration tool, designed with the purpose of understanding the experience and adaptation of subjects using a prosthesis. It is divided into several sections that investigate psychosocial adaptation, restriction of motor and social-work activities, level

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of satisfaction with the prosthesis, the presence of pain and other medical problems. In the medico-legal field, the assessment and evaluation of psycho-physical suffering following a traumatic event is a very topical and discussed topic, however there is still a lack of assessment tools and lack of clarity on the use of the existing ones, in providing a quantification of psycho-physical problems arising as a result of a damaging event.

Objective

To evaluate mobility and self-perception of individuals with a lower limb amputation.

Endpoints

1. Prosthetic mobility questionnaire (PMQ)
2. Trinity Amputation and Prosthesis Experience Scales (TAPES)

Study design

Observational, cross-sectional, single arm.

Inclusion criteria

- Subjects aged between 18 and 65 years
- Unilateral trans-femoral or trans-tibial amputation
- Experienced prosthesis users (at least two years)
- Subjects that provided written informed consent to study participation and data publication

Exclusion criteria

- Severe comorbidities
- Psychological impairment
- Pregnancy
- Patient not collaborative

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Drop-out criteria

- Voluntary withdrawal

Procedures

The subject will be convoked by a clinical operator who will explain the finalities and modalities of the study. After the signature of the informed consent, the PMQ and TAPES questionnaire will be provided. Their completion will be done in a single session.

Study duration: 12 months

Statistical plan

Descriptive statistics will be used to report aggregated values for the scores of TAPES and PMQ questionnaires.

Specifically:

- TAPES: each patient's score is obtained by summing the value of each item. Then, an aggregated data is reported as mean value and minimum/maximum values of each patient's score (unit of measure: units on a scale).
- PMQ: each patient's score is obtained by summing the value of each item. Then, an aggregated data is reported as median value and interquartile range (unit of measure: units on a scale).

Demographic data have been collected only for management purposes, as per the internal guidelines of the rehabilitation centre.

Results

Aggregated data

QUESTIONNAIRE	MEDIAN	IQR

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TAPES Psychosocial adjustment	57	52 – 63.25
TAPES Activity restriction	8	4.75 - 11
TAPES Prosthetic satisfaction	40	37 – 44.25
PMQ2.0	31.5	25 - 35