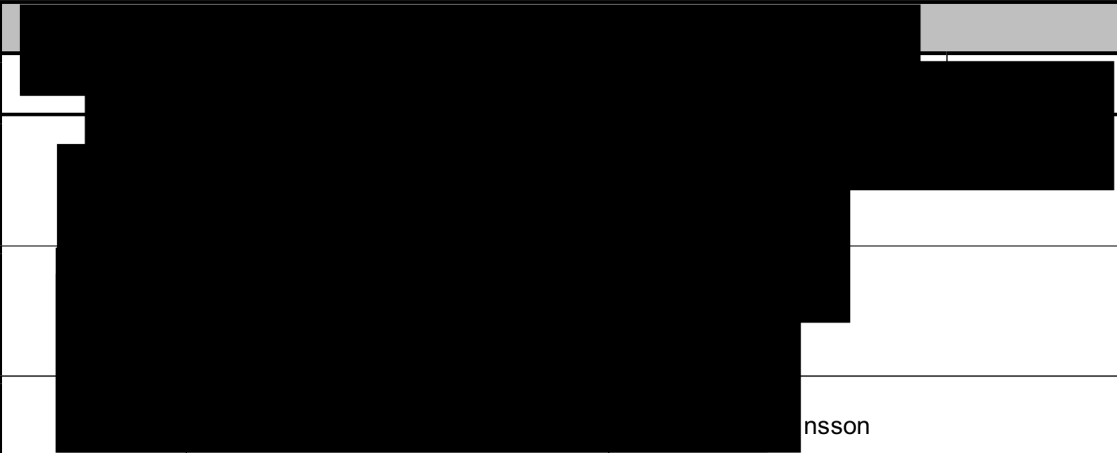


Connect Balance TF - Clinical Investigation Protocol

An investigation of function and usability of a new adaptable socket system

Off-The-Shelf Sockets

CONFIDENTIAL DOCUMENT

		
		nsson
		08.10.2020
Refer to electronic approval of document for complete approval information.		
		
	Product Manager:	Guðlaug Sigurðardóttir

This document contains information that is confidential and proprietary to Össur. Neither this document nor the information therein may be reproduced, used or distributed to or for the benefit of any third party without the prior consent of Össur.

This document is uncontrolled when printed unless indicated otherwise.

[Redacted]

[Redacted]

implementation

Sponsor:	Date of Signature:
[Redacted]	

[Redacted]

[Redacted]

[Redacted]

[Redacted]

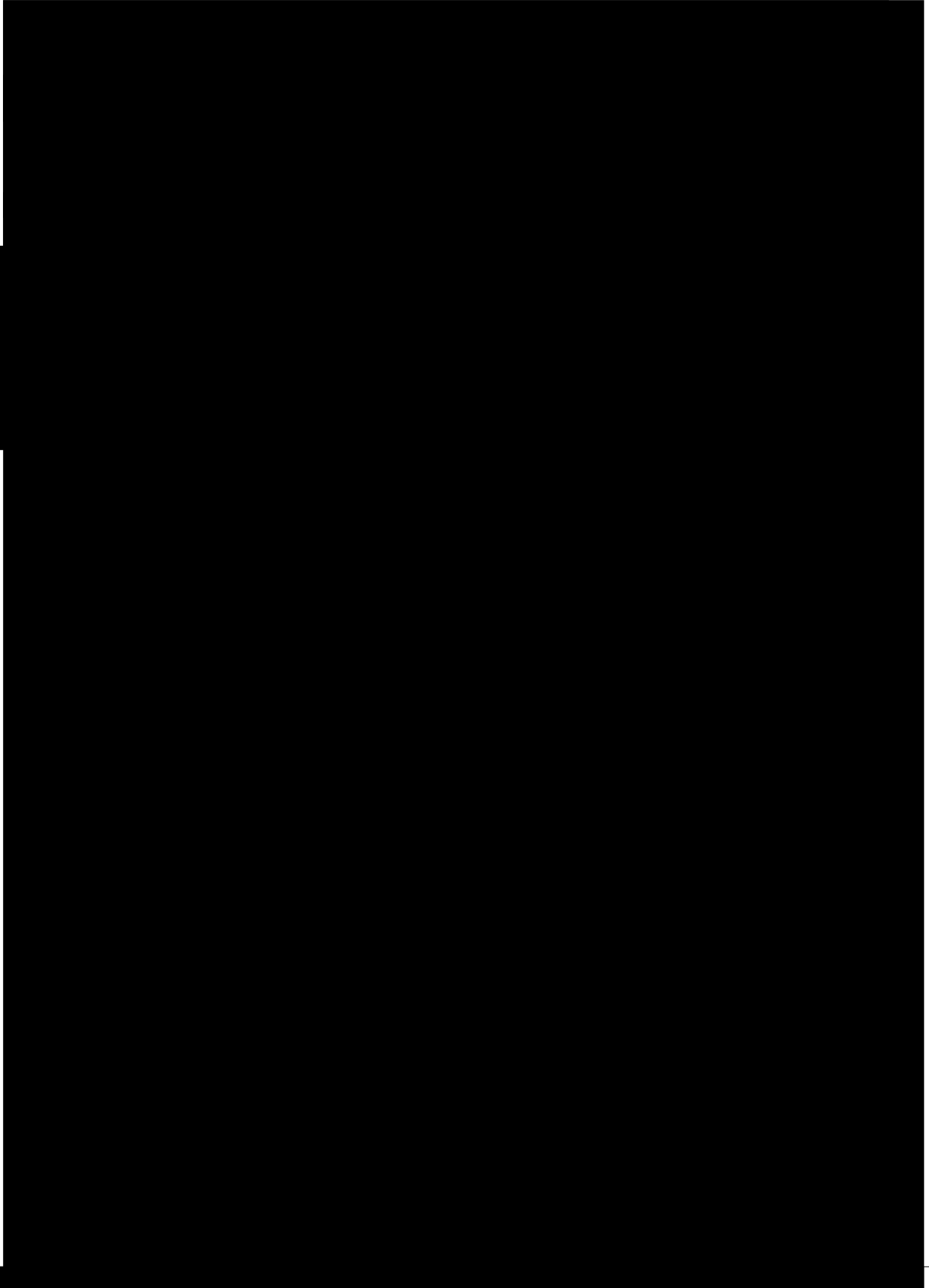


Table of Contents

1	How to Refer to This Document	6
2	Summary.....	6
3	Changes from Previous Revision	9
3.1	Changes for Revision 1.00.....	9
3.2	Changes for Revision 2.00.....	9
4	Abbreviations	10
5	Investigational Device.....	12
6	Justification for the Design of the Clinical Investigation	16
7	Objectives and Hypotheses.....	17
8	Design of the Clinical Investigation	21
8.1	General	21
8.2	Investigational Device(s) and Comparator(s).....	22
8.3	Subjects	22
8.4	Procedures.....	25
	i) Recruitment	25
	ii) Test procedure.....	25
	iii) Measurements and data collection.....	26
8.5	Compensation.....	27
	iv) Subject.....	27
8.6	Responsibilities	27
8.7	Study monitoring and Oversight.....	28
9	Investigational Device Accountability	28
10	Statistical Considerations	28
10.1	Sample size calculation	28
10.2	Additional statistical matters.....	29
11	Amendments and Deviations from the Protocol (CIP).....	29
11.1	Amendments.....	29
11.2	Deviations	29
12	Statement of Compliance	30
13	Ethical Considerations	30
13.1	Anticipated clinical benefits.....	30
13.2	Device related risk	30
13.3	Risk of Study (To Patient)	31
13.4	Risk Mitigation.....	32
13.5	Risk-to-Benefit Rationale	32
13.6	REC Review and Communications	32
13.7	Vulnerable populations	32
13.8	Informed Consent	32
13.9	Participant confidentiality – Data management.....	32
14	Evaluation of Adverse Events and Device Deficiencies.....	33
14.1	Definitions of adverse events, effects and deficiencies.....	33
14.2	Reporting procedures	33

14.3	Suspension or premature termination of the clinical investigation.....	34
15	Publication Policy	34
16	References.....	35
17	Annex	35
17.1	Two-minute walk test - 2MWT	35
17.2	Timed up-and-go (TUG).....	35
17.3	Comprehensive Lower-limb Amputee Socket Survey (CLASS).....	35
17.4	Socket Comfort Score (SCS).....	36
17.5	Suspension Questionnaire.....	36
17.6	Prosthesis Evaluation Questionnaire (PEQ)	36
17.7	Usability questionnaire on CONNECT TF.....	37

Tables

Table 1	Summary of procedures and visits	8
Table 2	Identification and Description of the Investigational Device.....	12
Table 3	Technical and functional features.....	16
Table 4	Evaluations and Instruments	17
Table 5	Clinical Performance and Clinical Safety Claims for Evaluation	18
Table 6	Endpoints, test methods and hypotheses.....	19
Table 7	Inclusion/Exclusion criteria	23
Table 8	Visit schedule and procedures	26
Table 9	Hazards arising from device use (risk of study to patient).....	31

1

2 Summary

This clinical investigation will be of a single group non-randomized open label prospective repeated measures (ABBA) design.

The primary objective of this clinical investigation is to evaluate how the CONNECT TF compares to traditional handmade sockets, specifically that it provides reliable suspension and improved usability and comfort for the amputee, and that it enables single clinical visit for fitting.

The title of the investigation is:

An investigation of function and usability of a new adaptable socket system

Device(s) being tested:	For simplification the device under evaluation in this Clinical Investigation will be referred to as "investigational device" throughout this document. <u>Investigational device:</u> CONNECT TF socket (CTFS), pre-market device used within the intended purpose. The subjects will be asked to use the investigational device as their primary prosthesis for up to six weeks. Individual exposure will differ between subjects. Subjects are expected to use it for their daily living activities as they would with any other prosthesis. <u>Comparator device:</u> The current conventional prosthetic socket (CCPS) for the TF amputee subject, will be used. It has the same intended use as the investigational device. Furthermore, it is indicated for the same condition and population group. It is a widely accepted device type, providing clinical benefits to the user, and the most common type of such a device on the market. Subject will be fitted with the same foot-pylon-knee prosthetic system as used with their CCPS, with the CONNECT TF socket.	
Instruments and equipment:	<u>Instruments:</u> PIS, subject profile, device usage, CLASS, PEQ-RLH, PEQ-Noise, suspension questionnaire, volume fluctuations evaluation, donning and doffing questionnaire, amputee usability evaluation, fitting log, study log, preference and evaluation, 2MWT, TuG. <u>Equipment for each subject:</u> pen/pencil, printed out CRFs, investigational device (assembled but unadjusted CONNECT TF), Össur adaptors, Össur locking liner. Foot-pylon-knee prosthetic device combination. <u>Equipment required at facility:</u> Adjustable torque wrench; 3-10Nm range, stop watch (smart phone), chair with armrests, 2x cones/markers, long measurement tape, video camera (smart phone).	
Subjects recruited:	Inclusion criteria:	Exclusion criteria:
At least 15 test subjects (amputees) shall finish the	Lower limb amputees Uni- or bilateral TF amputees	Other amputees

protocol, up to 25 may be recruited	40 < body weight < 125Kg	40> body weight > 125Kg
	Activity level: K1- low K3;	
	Liner size: 28-45; <i>Max 1 user in sizes 28 and 45, respectively</i>	
	Residual limb parameters; perineum to distal end: 205 to 280 mm	Amputees with broken skin on the residual limb
	Older than 18 years	Younger than 18 years
	Prosthetic users for more than 3 months	Prosthetic users for less than 3 months
	Components of CCPS functionally compatible to Össur components (foot-pylon-knee combination)	Using no liner
	Users understanding the function of the device	Using microprocessor controlled prosthetic knees not manufactured by Össur
	Willing and able to participate in the study and follow the protocol	Users not understanding the function of the device
Procedures:	There are four scheduled study events. <u>At the initial visit</u>, the first study event, for each subject a qualified researcher will obtain an informed consent. Prior to fitting the patient subject to CONNECT TF he/she will be asked to provide feedback and perform tasks on/using their current conventional prosthetic socket. The patient subjects will be fitted with the CONNECT TF within the standard methods of prosthetic fitting, alignment, introduction, training and walking on various terrain. The PI/CPO will conduct the fitting and aligning of the CONNECT TF. A Co-Investigator will time the fitting procedure; from unpacking the device until it is correctly adjusted and properly fit to the subject. Data on initial feedback on the device will be collected from the subjects using the instruments specified above. Afterwards an appointment at 2 weeks is made and the subjects leave the clinic on the device. If the fitting of CONNECT TF fails, i.e. the PI/CPO does not manage to fit the device properly or the subject cannot use the device as intended during training at the clinic, a new appointment is made, if the subject is willing to continue participation. <u>The second event will be according to the appointment scheduled 2 weeks earlier.</u> During this visit the same set of information will be gathered from/on the subjects as at the initial visit using the conventional socket (Measurement II). A 6WFU visit is scheduled and the subject leaves on the CONNECT TF socket. <u>The third event will be according to the appointment scheduled at the previous visit.</u> During this visit set of information will be gathered from/on the subjects as at the initial visit using the conventional socket (Measurement II). A final 6WFU visit is scheduled and the subjects are fitted back to and leave on their current conventional socket.	

The fourth event will be according to the appointment scheduled at the previous visit. During this visit set of information will be gathered from/on the subjects as at the initial visit using the conventional socket (Measurement II). End of study.

Table 1 Summary of procedures and visits

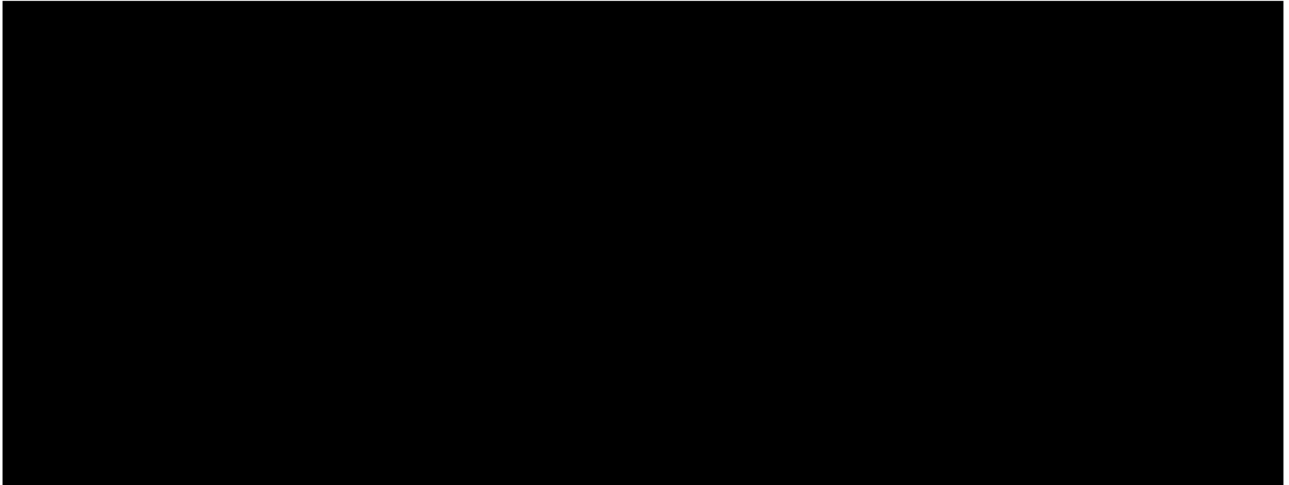
Procedure/Activity	Recruitment phase:	Initial visit: current device	Initial visit: investigator device	2week Follow-up visit: investigational device	6week Follow-up visit: investigator device	Final visit: current device
Potential subjects identified, fitting inclusion/exclusion criteria	√					
PI calls potential subjects and screens by telephone; appointment made	√					
Informed consent obtained		√				
Subject profile collected		√				
Measurements Ia		√				
Fitting and training on investigational device			√			
Measurements Ib			√			
Measurements II		√		√	√	√
Subject fitted back on previous device					√	
Compensation payment			√	√	√	√
End of study						√

3 Changes from Previous Revision

3.1 Changes for Revision 1.00

Initial release.

3.2 Changes for Revision 2.00



3.3 Changes for Revision 3.00



4 Abbreviations

2MWT	2-Minute Walk-Test
2WFO	2-Week Follow-up
6WFO	6-Week Follow-up
ADE	Adverse Device Effect
AE	Adverse Event
AR	Adverse Reaction
BL	Baseline
CA	Competent Authority
CCPS	Current Conventional Prosthetic Socket
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
CI	Co-Investigator
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
CLASS	Comprehensive Lower-limb Amputee Socket Survey
CP	Certified Prosthetist
CPO	Certified Prosthetist and Orthotist
CRF	Case Report Form
CTFS	CONNECT TF Socket
EDS	Electronic Data capture Service
FU	Follow-Up
GCP	Good Clinical Practice
CIB	(Clinical) Investigator's Brochure
ICF	Informed Consent Form
IDMF	Investigational Device Management Form
IFU	Instructions For Use
LPI	Local Principal Investigator
PEQ	Prosthesis Evaluation Questionnaire
PI	Principle Investigator
PIS	Participant Information Sheet
RBRP	Research Body Responsible Person
REC	Research Ethics Committee
SAE	Serious Adverse Event
SADE	Serious Adverse Device Event
SFCS	Socket Fit Comfort Score
SOP	Standard Operating Procedure
SOTA	State-Of-The-Art
SRA	Sponsor Research Assistant

TF	Trans-femoral
TuG	Timed Up-and-Go
USADE	Unanticipated Serious Adverse Device Effect
VAS	Visual-Analog scale

5 Investigational Device

The investigational device is a pre-market device and will be labeled according to regulations concerning investigational devices. The investigational device is classified as a Class I device and does not require FDA clearance for testing.

See **Table 2** for details on the investigational device.

Table 2 Identification and Description of the Investigational Device

Summary description of the investigational device and its intended purpose:	The device is a prosthetic socket intended to be adjusted by the CPO directly on an amputee's residual limb. It is Class I, a low-risk product, that utilizes new technology for a well- established concept. Exo-prosthetic devices are by their nature non-invasive. The investigational device is a non-sterile, non-invasive, reusable (i.e. non-disposable), single user device, which is used as part of prosthetic system. The device is intended as a part of a system that replaces function or aesthetics of a missing limb. More specifically, it is intended to transfer weight bearing forces from the surface of the residual limb to a prosthesis. Additionally, the device is intended to act as part of the interface for attaching other prosthetic components of the prosthetic leg to the amputee.
Manufacturer of the investigational device:	Össur hf. Grjóthals 5 110 Reykjavik Iceland
Name or number of the model/type, including software version and accessories, if any, to permit full identification:	CONNECT TF Version 1.0
Traceability during and after the investigation:	Investigation Device Management Form (IDMF) will be used to track the use of each device within the clinical investigation using the device serial number generated by the manufacturing quality system.
Intended purpose of the investigational device in the proposed clinical investigation:	Intended purpose of the investigational device in the proposed clinical investigation is within the intended purpose as described above. See following chapters on the intended purpose of the investigational device in the proposed clinical investigation for details.
The populations and indications for which the investigational device is intended:	The device is indicated for lower limb amputees (bi- or unilateral) with the potential to use a prosthesis. See inclusion/exclusion criteria for further information.

I device is intended:	
Description of the investigationa I device:	



--	--



Summary of the necessary training and experience needed to use the investigational device:	Training requirements for subjects and procedures relating to fitting and use of a device will for all general purposes be equivalent to the training and procedures required for using a CE-marked device of a similar type. The device should be supplied and fitted by a certified CPO/CO/CP.
Specific medical or surgical procedures involved in the use of the investigational device:	N/A

Table 3 Technical and functional features

#	Feature	Description (if not obvious)	Covered by this investigation:
1	Click-lock		Yes
2	Self-adjusting shells		Yes
3	Openable system		Yes
4	Tensioning handle and mechanism		Yes
5	Circumference		Yes
6	Strut angle		Yes
7	Telescopic height adjustment		Yes
8	Indicators for objective adjustments		Yes
9	Label		Yes
10	Pre-assembled device		Yes
11	Washable (waterproof/weatherproof)	Waterproof/weatherproof as defined by Össur	No
12	Brim		Yes
13	Whole device	The device as a system	Yes
14	Pull to release knob		Yes

6 Justification for the Design of the Clinical Investigation

Socket fit and proper choice of suspension system are associated with user's mobility, comfort, and satisfaction. The prosthetic socket shall mainly stabilize the residual limb in the sagittal and coronal planes; provide body weight support; control the prosthetic knee voluntarily; ensure proper function of muscles; and offer harmony of appearance, function, and comfort, both dynamically and statically. The importance of total contact socket fit is great, all areas within the socket shall make contact with the residuum, since lack of contact may result in edema, socket migration, and compromised control of the prosthesis. [1]

When subscribing a socket, a clinical determination on the type of socket design is made based on the individual's level of voluntary control and the stability required. Prosthetists need to decide whether a suspension system is suitable or not for various residual limb conditions such as residual limb length, shape, muscle strength, soft tissue, bony prominence, pain, aspiration of amputee, level of activity and upper limb strength. There are two general classifications of socket construction, the hard socket and the flexible inner socket with a rigid frame. A hard socket is a single-walled, static socket that is designed to be in direct contact with either the user's skin or an interface such as a roll-on gel liner or prosthetic sock. The flexible inner socket is capable of elastic movements and consists of rigid outer frame for stability. The design can also be used in direct contact with user's skin or a liner and/or prosthetic socks. [1]

A medical necessity-benefit analysis was conducted as part of the clinical evaluation plan [2], with input from risk management activities, based on the hazard analysis worktable [3]. The output of those analysis is reflected upon in Tables 6 and 7 below, identifying the needs that the investigational device is potentially addressing. Relationship between individual needs and specific device features is identified in the clinical evaluation plan [2].

By the outcome of the analysis and previous experience with clinical investigations in prosthetics it was concluded to conduct a repeated measures ABBA analysis, comparing patients' current socket at baseline and

6-week follow-up (6WFU) vs. the CONNECT TF at 2-week follow-up and 6WFU¹. See Table 4 Evaluations and Instruments on the evaluation that will be conducted. See appendix for instruments.

The aim of the investigation is to collect data on the practical and clinical value of an off-the-shelf prefabricated prosthetic socket compared to traditional handmade socket.

Table 4 Evaluations and Instruments

Format	Evaluation, Instrument
Performance testing	2MWT, TuG
Self-reports	CLASS Socket Fit Comfort Score PEQ Residual Limb Health PEQ G1 – K&L Sounds "How many socks do you use per day?" "Rate ease of use of the device" "Amputee's satisfaction with doffing process" "Amputee's satisfaction with donning process" "Rate ease of tensioning CONNECT TF" "Rate ease of cleaning the device"
Logbook	Use of the device, , Weight transfer, Socket adjustment, Number of clinical sessions to fit per subject = 1 CPO can successfully log socket setting CPO can successfully fit a new Connect TF according to a previously logged setting

Repeated measures analysis has the advantage of increased power vis-à-vis group allocations and reduction in error variance associated with individual difference, as each subject acts as its own control. This is important for studying amputees as the group is a small proportion of the total population, and with specific inclusion/exclusion criteria the total eligible population becomes very small, making it difficult to find and recruit subjects to attain an acceptable level of power. This limited population pool often results in slightly heterogeneous sample, as the amputees available are few and far between, in every sense. Furthermore, no single amputation procedure and therefore amputated stump is exactly the same, making the experience of each amputee a bit unique. The within-subject design significantly reduces the individual differences when comparing the two conditions.

The drawback of the design is the potential of "carryover effects", i.e. experience from one condition can affect outcome or performance in the other condition, creating a confounding extraneous variable that varies with the independent variable. Such effects are: practice, positive carryover effect to the latter condition; and fatigue, negative carryover effect to the latter condition.

The clinical investigation is designed to evaluate whether the investigational device is suitable for the purposes and the population for which it is intended. It is designed in such a way as to ensure that the results obtained have clinical relevance and scientific validity and address the clinical investigation objectives.

7 Objectives and Hypotheses

The primary objective of this study is to evaluate the efficacy of the investigational device compared to state-of-the-art prosthetic technology, i.e. conventional handmade sockets, regarding comfort, mobility – in the context of quick one-visit fitting - and usability for low active TF amputees.

Secondary objectives of the study are to further validate that the safety and other performance parameters of the investigational device are comparable (no worse) to the state-of-the-art sockets. Additionally, to evaluate the usability of pull to release knob and release handle specifically.

¹ Note, the 6WFU visit may be up to 12 weeks post initial visit, depending on availability.

Table 5 Clinical Performance and Clinical Safety Claims for Evaluation

Claim	Relates to
The Connect TF is safe to use as intended	Safety
The Connect TF provides improved comfort compared to conventional sockets	Safety
The Connect TF is an easy to use socket	Performance
It is easy to put on	Performance
It is easy to take off	Performance
It is easy to tension	Performance
CONNECT TF allows for socket fitting and delivery in one session	Performance
Clear size selection	Performance
Fast and effective initial setup	Performance
Socket fit can be adjusted with user on socket	Performance
The Connect TF allows objective fitting and adjustments to the socket	Performance
The Connect TF provides the CPO with the ability to replicate socket fit	Performance
The CONNECT TF facilitates improved clinical notes/records	Performance
The Connect TF is easy to clean	Performance
The Connect TF improves user mobility	Performance

For all hypothesis:

O_a is the Outcome of specific test method

Where $O \in \{$

$\mu =$ is the average of respective endpoint

T = is the average time measured of endpoint
 R = is the absolute rate measured of endpoint
};

And where $a \in \{$
 b = baseline on CCPS,
1 = 2 week visit on CTFS,
2 = 6 week visit on CTFS,
3 = 12 week visit on CCPS
};

and $|M_{NI}|$ is the margin of non – inferiority;

Table 6 Endpoints, test methods and hypotheses

	Alternative Hypothesis	Test Method	Endpoint	Acceptance Criteria
A i)	The CONNECT TF provides improved sitting comfort compared to current socket.	Self-report: CLASS	Difference in CLASS sitting comfort item (1 item)	$H_0: \mu_3 \geq \mu_2$ $H_1: \mu_3 < \mu_2$ $p < 0.025$
A ii)	The CONNECT TF provides improved overall socket satisfaction compared to current socket.		Difference in CLASS overall score (15 items)	$H_0: \mu_3 \geq \mu_2$ $H_1: \mu_3 < \mu_2$ $p < 0.025$
B i)	Amputee can successfully achieve suspension with CONNECT TF	Self-report: Donning and Doffing questionnaire – “Donning satisfaction” item (10 point Likert scale)	Difference in “Donning satisfaction” item (average of 1 item)	$H_0: \mu_3 \geq \mu_2$ $H_1: \mu_3 < \mu_2$ $p < 0.05$ And acceptance of either A_i or A_{ii}
B ii)	The CONNECT TF provides improved donning experience compared to current socket.			
C i)	Amputee CONNECT TF doffs when intended.	Self-report: Donning and Doffing questionnaire – “Doffing satisfaction” item (10 point Likert scale)	Difference in “Doffing satisfaction” item (average of 1 item)	$H_0: \mu_3 \geq \mu_2$ $H_1: \mu_3 < \mu_2$ $p < 0.025$ And acceptance of B
C ii)	The CONNECT TF provides improved doffing experience compared to current socket.			
D	The CONNECT TF system is easy to use for amputee.	Self-report: Amputee usability evaluation – “ease of use” and “ease of tensioning” items (10 point Likert scale)	Absolute score (average of 2 items)	$H_0: \mu_2 < 6$ $H_1: \mu_2 \geq 6$ $p < 0.025$ and acceptance of C or L

E	Subjects report no worse RLH using the CONNECT TF when compared to current prosthesis.	Self-report: <i>PEQ – Residual Limb Health</i> (0-10)	<i>Difference in PEQ – Residual Limb Health subscale score</i> (average of 6 items)	$H_0: \mu_3 \geq \mu_2 + M_{NI} $ $H_1: \mu_3 < \mu_2 + M_{NI} $ $ M_{NI} = 0,5 \text{ mm}$ $p < 0.05$ and acceptance of D
F	CONNECT TF is suitable for intended use	Objective observation: <i>Study log</i>	<i>Absolute rate (R) of subjects failing to complete the CTFS 6WFU due to socket issues</i>	$H_0: R_2 > 15\%$ $H_1: R_2 \leq 15\%$ $p < 0.05$ and acceptance of E
G	CONNECT TF provides no worse mobility when compared to current prosthesis.	Objective outcome test: <i>2MWT</i>	<i>Difference in average distance to complete</i>	$H_0: \mu_3 \geq \mu_2 + M_{NI} $ $H_1: \mu_3 < \mu_2 + M_{NI} $ $ M_{NI} = 30 \text{ m}$ $p < 0.05$ and acceptance of F
H	CONNECT TF provides acceptable accommodation to residual limb volume increases.	Self-report: <i>Volume Fluctuation evaluation – “discomfort when tensioning” item</i> (10 point Likert scale)	<i>Absolute score</i> (1 item)	$H_0: \mu_2 < 6$ $H_1: \mu_2 \geq 6$ $p < 0.05$ and acceptance of G
I	CONNECT TF accommodates no worse to residual limb volume decreases compared to current socket.	Self-report: <i>Volume Fluctuation evaluation – sock item</i> (natural number: 0-n)	<i>Difference in sock/day use</i> (average of 1 item)	$H_0: \mu_3 \leq \mu_2 + M_{NI} $ $H_1: \mu_3 > \mu_2 + M_{NI} $ $ M_{NI} = 0,5 \text{ sock}$ $p < 0.05$ and acceptance of H
J	Users rate the noise from using the CONNECT TF as no worse compared to using current prosthesis.	Self-report: <i>PEQ – Sounds</i> (10 point Likert scale)	<i>Difference in PEQ – Sounds subscale score</i> (average of 2 items)	$H_0: \mu_3 \geq \mu_2 + M_{NI} $ $H_1: \mu_3 < \mu_2 + M_{NI} $ $ M_{NI} = 7,5 \text{ mm}$ $p < 0.05$ and acceptance of I
K	CONNECT TF provides no worse balance during ambulation compared to current socket.	Objective outcome test: <i>TuG</i>	<i>Difference in average time to complete</i>	$H_0: \mu_3 \leq \mu_2 - M_{NI} $ $H_1: \mu_3 > \mu_2 - M_{NI} $ $ M_{NI} = 4,5 \text{ sec}$ $p < 0.05$ and acceptance of J

L	The CONNECT TF can be fitted in a single session.	Objective observation: <i>Fitting log</i>	<i>Absolute time (T) to fit: excluding alignment and assembly of rest of prosthesis</i>	$H_0: T_1 \geq 15 \text{ minutes}$ $H_1: T_1 < 15 \text{ minutes}$ $p < 0.05$ and acceptance of B
M	The CONNECT TF can be fitted while amputee loads the prosthesis.	Objective observation: <i>Fitting log</i>	<i>Absolute rate (R) of feature successfully used in subject fittings</i>	$H_0: R_1 < 90\%$ $H_1: R_1 \geq 90\%$ $p < 0.05$ and acceptance of L
N	The pull to release knob is acceptable to the user profile of the CONNECT TF	Self report: Usability questionnaire <i>"Please rate the difficulty of pulling and holding the knob in the outermost position when doffing the socket" (10 point Likert scale)</i>	<i>Average score</i>	$H_0: \mu_2 < 5$ $H_1: \mu_2 \geq 5$ $p < 0.025$ And acceptance of M

8 Design of the Clinical Investigation

8.1 General

The investigation will be of a non-randomized single group open label prospective repeated measures (ABBA) design. Amputees are a small proportion of the general population. The population group specified in the inclusion/exclusion criteria is a further subsample of amputees. For practical reasons, i.e. to achieve statistical

The primary endpoint is stated in line 1 in Table 6, and the secondary endpoints are in the following rows, in that respective order of significance. See previous chapter on objectives and hypothesis and Table 6 for rationale, and methods for evaluating variables.

All data will be collected and analyzed at the end of study when all subjects have completed all procedures. Drop-outs and withdrawals may be replaced if needed to achieve the target sample size.

See chapter **10.2 Sample size calculation**.

Equipment required for each subject:

- Pen/pencil
- Printed out CRFs (see chapter 8.4; instruments, questionnaires, logs, etc.)
- Investigational device: unadjusted CONNECT TF system
 - Össur adaptors
 - Össur locking liner
- Foot-pylon-knee combination to form a complete prosthetic system with the CONNECT TF

Equipment required at facility for all subjects:

- Adjustable torque wrench; 3-10Nm range
- Stop watch (smart phone)
- Chair with armrests
- 2x cones/markers
- Long measurement tape
- Video camera (smart phone)

The equipment used does not require specific monitoring, maintenance or calibration procedures.

8.2 Investigational Device(s) and Comparator(s)

The subjects will be asked to use the investigational device as their primary prosthesis for up to 6 weeks. Exposure will differ between subjects based on their habits and preferences: Subjects are expected to use it for their daily living activities as they would with any other prosthesis, for up to 18 hours a day depending on each subject's discretion. The comparator device will be used for a minimum of 6 weeks within the timeframe of the investigation. Subjects will evaluate and provide feedback on their exposure of the comparator prior to them being fitted to the investigational device and after using CONNECT TF socket for a minimum of 6 weeks.

Subjects should use only their assigned socket during each 6-week interval.

The comparator device is the current conventional prosthetic socket (CCPS), generally handmade, for transfemoral amputees. It has the same intended use as the investigational device. Furthermore, it is indicated for the same condition and population group. It is a widely accepted state-of-the-art device, providing clinical benefits to the user.

The subjects will be fitted with the CTFS along with the remaining part of their prescribed prosthetic system (foot-pylon -knee) to ensure consistency. The necessary Össur adaptors will be provided when adaptation to prescribed system is needed. When necessary, subjects will be provided with an Össur locking liner compatible with CTFS.

Up to 20 subjects are to be enrolled and therefore up to 20 investigational devices will be used, as the devices are intended to be used by a single patient; one for each subject.

8.3 Subjects

All patient subjects will be dispositioned as follows:

- Screen Failure: Subject did not pass screening (inclusion/exclusion) procedures, not called in for clinical visit;
- Candidate for enrollment: Passed screening procedures, accepts to come in for clinical visit;
- Enrolled: Subject signs informed consent;
- Fitted: Subject leaves the clinic on the investigational device;

- Discontinued: Candidate for enrollment or Enrolled subject whose participation ended because they withdrew consent, were withdrawn by the Investigator, were lost to follow up, or died.

See Table 7 Inclusion/Exclusion criteria for inclusion/exclusion criteria for patient subjects.

Table 7 Inclusion/Exclusion criteria

Inclusion: Only patients with the following characteristics are eligible for study entry:	Exclusion: Patients with the following characteristics are not eligible for study entry:
Lower limb amputees - Uni- or bilateral TF amputees	Other amputees
40 < body weight < 125Kg	40> body weight > 125Kg
	
	
	Amputees with broken skin on the residual limb
Older than 18 years	Younger than 18 years
Prosthetic users for more than 3 months	Prosthetic users for less than 3 months
Components of CCPS functionally compatible to Össur components (foot-pylon-knee combination)	Using no liner
Users understanding the function of the device	Using a microprocessor controlled prosthetic knee not manufactured by Össur
Willing and able to participate in the study and follow the protocol	Users not understanding the function of the device

A subject can withdraw from participation at any time, at his/her discretion, and this will not have any consequences for the participant's treatment.

In such cases a report stating reasons for discontinuation of the participant shall be prepared by the PI. No further investigational procedures concerning the subject will be conducted, except for a statement explaining the reason for withdrawal (if subject is willing), including but not limited to: interacting or interviewing the subject in order to obtain data on him/her; obtaining additional private information on the subject by either observing the subject or collecting or receiving such information from any source.

The PI can withdraw the participant from the trial at any time. The reasons shall be documented. There are no pre-specified criteria for discontinuation of participants from the trial.

The discontinuation of participants in the trial may result in replacement with new participants. If withdrawal is for permission to follow the

[REDACTED]

202

The total time period required to implement the clinical investigation is expected to be minimum of 17 weeks. Each individual subject is expected to participate in the clinical investigation for a minimum of 12 weeks. The estimated time needed to include this number (enrolment period) is 5 weeks.

8.4 Procedures

relating to the duration of the study, number of clinical visits required, and the investigational device will be answered.

Potential risk of participating in the investigation will be explained to the subject at this point to the candidate for enrolment.

The study team will communicate to the study monitor the number of users they have identified that meet the inclusion criteria and are willing to participate.

ii) Test procedure

There are four scheduled study events: baseline (BL) visit, 2-week follow-up (2WFU) visit, 6-week follow-up (6WFU) visit on Connect TF socket (CTFS) and twelve week follow-up (12WFU) on current conventional prosthetic socket (CCPS); see Table 5. Note, the 6WFU visits may be up to 12 weeks post initial visit, depending on availability.

At the baseline visit, a researcher qualified to obtain informed consent will seat the subject and proceed as described in chapter 13.8 *Informed consent*.

Prior to fitting the patient subject to CONNECT TF he/she will be asked to provide feedback and perform tasks on/using their CCPS. The subjects will then be fitted with the CTFS within the standard methods of prosthetic fitting, alignment, introduction, training and walking on various terrain.

The PI (CPO) will conduct the fitting and aligning of the CONNECT TF socket.

A study team member will time the fitting procedure; from unpacking the device until it is correctly adjusted and properly fit to the subject.

Data on initial feedback on the device will be collected from the subjects using the instruments specified above. Afterwards an appointment at 2 weeks is made and the subjects leave the clinic on the device.

If the fitting of CONNECT TF fails, i.e. the CPO does not manage to fit the device properly or the subject cannot use the device as intended during training at the clinic, a new appointment is made, if the subject is willing to continue participation.

The second event will be according to the appointment scheduled two weeks earlier. During this visit the subject comes in on the CTFS and the same set of information will be gathered from/on the subjects as at the initial visit using the current conventional prosthetic socket. Afterwards an appointment at 6 weeks from baseline is made and the subjects leaves the clinic on the CTFS.

The third event will be according to the appointment scheduled four weeks earlier. During this visit subject comes in on the CTFS and the same set of information will be gathered from/on the subjects as at the initial visit using the CCPS and at the second visit using the CTFS. Afterwards an appointment at 12 weeks from baseline is made, or 6 weeks from being fitted back to the CCPS.

All subjects will return the investigational device and fitted back on their previous prosthesis: the subjects return the CTFS and leave the clinic on their original device, the CCPS.

If any subject will have problems fitting back to their CCPS due to volume changes they will be provided with a new socket and liner fitted to the remaining parts of their previous prosthetic leg. A new visit will be scheduled, and the subject will be allowed to use the CTFS until successfully fitted back; time to 6WFU for CCPS will be initiated when they have been successfully fitted back.

The fourth and final study event will be according to the appointment scheduled six weeks earlier. During this visit the same set of information will be gathered from/on the subjects as at the initial visit using the current conventional prosthetic socket. All subjects will be compensated for their participation in the study as described in chapter 8.5.

See Table 7 Inclusion/Exclusion criteria and instruments in Annex and attachments for details.

See Table 8 Visit schedule and procedures below on the instruments used at each visit.

iii) Measurements and data collection

Table 8 Visit schedule and procedures

Activity	Instrument/ Outcome Measure	Recruitm. phase	BL visit: CCPS	BL visit: Post CTFS Fit	2WFUv isit: CTFS	6WFU visit: CTFS	12WFU visit: CCPS
Potential subjects identified, fitting incl./excl. criteria		√					
		√					
			√				
CRF: Background	PIS		√				
	Subject profile		√				
	Current prosthesis		√				
CRF: Measurements	Device usage		√		√	√	√
	CLASS		√	√	√	√	√
	SFCS		√	√	√	√	√
	PEQ-RLH		√		√	√	√
	PEQ-Noise		√		√	√	√
	Suspension questionnaire (in- house instrument)		√		√	√	√
	Volume Fluctuations evaluation (in- house instrument)		√		√	√	√
	Donning & Doffing questionnaire		√	√	√	√	√
	Amputee usability evaluation of CTFS (in-house instrument)			√	√	√	
	TuG-test		√		√	√	√
	2MWT		√		√	√	√

	Fitting log				√	√	√
	Study log				√	√	√
	Preference & evaluation				√	√	√
Subject fitted with investigational device			√		√		
			√				
Subject fitted back on previous device					(√ if subject wants to end study)	√	
Compensation payment				√	√	√	√
End of study					(√)		√

Instruments and activities will be administrated for each visit/event as described in the table above, from top to bottom as applicable.

For each subject there are four scheduled visits to the study site and CRFs administrated five times during the course of the study as detailed above.

8.6 Responsibilities

Sponsor

- Investigate possible vigilance cases/SAEs

- Identify sites
- REC communication
- Collect Data
- Investigate possible vigilance cases/SAEs
- Screen subjects
- Explain trial to participants
- Responsible for obtaining informed consent from test subjects
- Conduct trial procedures

- Analyze data
-
- Write report

Monitors

- REC communication
- Monitor investigation
- Collect Data
- Analyze results
- Write report

8.7 Study monitoring and Oversight

A study Monitor will monitor the study to ensure all procedures are followed correctly and according to the study protocol. He will gather and review all study data and inform the PI of missing data or nonconformities to the study protocol.

The study monitors and PI will maintain communication on a minimum biweekly basis, via telephone and email. The PI will provide the study monitors with information of all scheduled study visits.

9 Investigational Device Accountability

The device will be provided as needed for the study population. Devices will not be packaged but will be labeled according to regulatory requirements. Subjects will not be blinded.

The study team will keep records documenting the receipt, use and return of the investigational device, including:

- Date of receipt
- ID of each investigational device
- Date of use
- Subject ID
- Date of device return
- Date of return of unused, expired or malfunctioning investigational devices, as applicable

10 Statistical Considerations

The dataset will be assessed with inferential statistics based on the acceptance criteria for the data, as applicable, as described in Table 6 **Endpoints, test methods and hypotheses**.

Outcomes at each timepoint will be visually inspected for normality using histograms and qq-plots. If the data are deemed to be normal the hypothesis will be tested using a two-tailed, paired, student's t-test for 2WFU evaluation and mixed models for the 6WFU evaluation. Non-normal data will be tested using the Wilcoxon signed-rank test.

Subgroup analysis will be based on analysis of the primary hypothesis. Additionally, subgroup analysis will be conducted to identify patient profiles that may/will not benefit from the investigational device, e.g. activity level and type of prosthesis.

10.1 Sample size calculation

Power analysis for the estimated required sample size was conducted using GPower. See protocol below:

t tests – Means: Difference between two dependent means (matched pairs)

Analysis: A priori: Compute required sample size

Input:	Tail(s)	=	One
	Effect size dz	=	0.6977363
	α err prob	=	0.05
	Power (1- β err prob)	=	0.8
Output:	Noncentrality parameter δ	=	2.7023211

Critical t	= 1.7613101
Df	= 14
Total sample size	= 15
Actual power	= 0.8221007

It is therefore expected that at least 15 subjects are required to complete the protocol with a power of 0,8 and significance at 0,05 for evaluating the primary hypothesis. Effect size was estimated based on previous feasibility investigation (alpha test).

Given the drop-out rate an estimated total of 25 subjects may be recruited.

For pass/fail criteria, see Table 6 **Endpoints, test methods and hypotheses**.

10.2 Additional statistical matters

There is no provision for interim analysis and no criteria for early termination of the clinical investigation on statistical grounds.

Any deviations from the statistical plan provided in this protocol will have to be approved by the sponsor and the reasons for the deviation reported in the clinical investigational report. Drop outs and withdrawn participants will be included in the data analysis for the procedures that they completed. They will be grouped together and compared to the group that finished the protocol. Any statistical differences of the two groups will be reported. If the participants have not provided any data, they will not be included in the data analysis. No particular information will be excluded from the statistical analysis and tests, as described above.

11 Amendments and Deviations from the Protocol (CIP)

11.1 Amendments

Any amendments to this protocol must be first approved by the sponsor and PI and then be evaluated by the REC and, where appropriate regulatory authorities, before being implemented.

For non-substantial changes (e.g. minor logistical or administrative changes, change of monitor(s), telephone numbers, renewal of insurance) not affecting the rights, safety and well-being of human subjects or not related to the clinical investigation objectives or endpoints, a simple notification to the REC and, where appropriate, regulatory authorities can be sufficient.

11.2 Deviations

Investigators are not allowed to deviate from this protocol without a formal approval from the REC, if the deviation affects subject's rights, safety and wellbeing, or the scientific integrity of the clinical investigation. Any such deviation from the protocol is to be documented in detail and the report sent to the REC.

Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior approval of the sponsor and the REC. Such deviations shall be documented and reported to the sponsor and the REC as soon as possible.

Investigators can request for an approval from the sponsor for a deviation if the deviation does not affect subject's rights, safety and wellbeing, or the scientific integrity of the clinical investigation.

In case of a deviation from this protocol taking place without prior approval from the sponsor, and REC as applicable, it shall be reported to the sponsor within 24 hours of PI knowledge of the deviation. The PI responsible for the deviation is to send a report to the sponsor no later than five days after the deviation was reported. The report shall include:

- Reason for deviation
- When deviation took place
- Circumstances of the event
- Identification of all subjects affected by the deviation, if any
 - Details how each subject is affected, e.g. rights, safety or wellbeing

- Details how this deviation might affect the scientific integrity of the clinical investigation

The sponsor and the REC will evaluate any deviations that take place without prior approval on a case-by-case basis. If the deviation affects subject's rights, safety and wellbeing, and the scientific integrity of the clinical investigation the PI shall be disqualified from further participation in the clinical investigation.

12 Statement of Compliance

The clinical investigation is sponsored by Össur Iceland ehf.

It shall be conducted:

- in accordance with the ethical principles that have their origin in the Declaration of Helsinki
- in compliance with the ISO 14155 International Standard
- in compliance with any regional or national legislations, as applicable

The clinical investigation shall not commence until the required approval from the IRB/REB/REC, and regulatory authority as applicable, has been obtained.

Any additional requirements imposed by the IRB/REB/REC or regulatory authority shall be followed, as applicable.

Subjects are provided with the same health insurance cover as for other legally marketed Össur devices.

13 Ethical Considerations

13.1 Anticipated clinical benefits

A patient using the investigational device may or may not benefit clinically from using the device vis-a-vis using another prosthetic socket commercially available. Anticipated benefits include, but may not be limited to:

- Improved comfort of wearing a prosthetic socket compared to traditional sockets
- Improved usability; donning, doffing and overall use – compared to traditional socket
- New socket delivery and fitting in a single visit; within 15 minutes.

Compared to not using a prosthetic socket, as a part of prosthetic system the patient will benefit significantly in terms of mobility and ability to live independently.

Additional benefit for the user during the testing is that he/she helps in developing a new prosthetic socket.

13.2 Device related risk

Each device designed and manufactured by Össur is subjected to thorough risk assessment, analysis and control, with failure mode effect analysis and hazard analysis, according to QM1673 Risk Management process, based on ISO 14971 (Risk Management for Medical Devices).

The FMEA and hazard analysis are tools for identifying harms, the sequence of events, their probability, and the potential failures that can cause these harms. Anticipated adverse device effects and residual risks associated with the investigational device, are identified in the Hazard Analysis Documentation [3] and evaluated in the Risk Management Report [4].

The device will have been placed on the market by Össur, considered safe to use for the intended purpose, before the initiation of the study.

Foreseeable adverse events and anticipated adverse device effects, together with their likely incidence are expected to be in line with the data provided above. Mitigation beyond standard clinical practice and the information provided in the IFU for the device is not required. This also applies to potential treatment of harms stemming from these events or effects; standard clinical practice and IFU statements will be followed.

13.4 Risk Mitigation

For each device designed by Össur risk mitigation is part of the design process according to ISO 14971. Furthermore, each participant fitted with the device for the first time will be trained by a fully qualified professional until the user can demonstrate sufficient understanding of the product operation and demonstrate minimum ability level in its operation. This process is the same as the usual training process deployed for normal fitting of a prosthetic socket system.

As part of the training process, the participant will be informed on the risks inherent in using a prosthetic socket, and explicitly a socket of this type with additional features, in an uncontrolled environment. Moreover, the participant will be provided with the product literature (e.g. Information for User), as well as being informed and trained on how to use the product.

13.5 Risk-to-Benefit Rationale

The development of a prosthetic medical device is controlled by a multi-level verification and validation processes before being authorized for field testing and subsequent release. The Validation & Verification process execution coupled to the risk management and control strategy deployed for CONNECT TF ensure that the residual risk associated with use of the device in typical daily living conditions does not exceed risks level associated with the operation of any such device under similar conditions.

The residual risks of the investigation and the investigational device are minimal and are significantly outweighed by the benefits of participating in the investigation.

13.6 REC Review and Communications

The study protocol (CIP), informed consent form, and other study documentation forms require REC review and approval. Communication to and from the REC shall be directed from or to the primary Össur contact, a Study Monitor. Continuous communication will be maintained between Össur and the REC, as required. Moreover, communication will be maintained between the PI and the REC, as required.

13.7 Vulnerable populations

No vulnerable populations will be enrolled.

13.8 Informed Consent

The Research Body Responsible Person/Principal Investigator or any researcher qualified, will obtain from the subject, written signed informed consent form to his/her inclusion in the study, after explaining the rationale for and the details of the study, the risks and benefits of alternative treatments, and the extent of the subject's involvement. The subject will receive a copy of the informed consent.

The subjects will be informed that their participation is voluntary and that they can withdraw from participation at any time, at his/her discretion and this will not have any consequences for the participant's treatment.

In case the information on the ICF changes, and subjects need to be provided with new information, the PI will contact each subject by phone and explain the new information as required.

password secured file. This list will be destroyed at the end of the study. Only investigators involved in the trial will have access to this information.

Frames in video recordings will only contain the lower extremities of subjects and any ambulatory assistance provided with their hands. Frames containing the face or other identifiable features of subjects will be deleted immediately, if accidentally captured. Identifiable items like tattoos or birthmarks will be blurred or obscured if captured on frames.

The data of subjects that withdrawn from participation will be deleted unless a specific agreement with these subjects to evaluate their data can be obtained.

The screening form will be in paper format and will be stored by the PI in a locked container. All documents will be collected by Study Monitor and/or PI.

A representative of the sponsor, sponsor research assistant, will be present at the study location. A declaration of confidentiality to be signed by the representative, ensures necessary data protection.

in the study can have access to the results, on demand, when the CIR is internally published.

Study results, data, and documentation will be stored for a minimum of 10 years.

14 Evaluation of Adverse Events and Device Deficiencies

For a list of foreseeable adverse events and anticipated adverse device effects, together with their likely incidence, mitigation or treatment see chapter 13.2 above.

14.1 Definitions of adverse events, effects and deficiencies

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.

An adverse device effect (ADE) is any adverse event related to the use of an investigational medical device, including events resulting from insufficient or inadequate instructions for use, operation, malfunction, etc.

A serious/severe adverse event (SAE) is an AE that:

- Is life-threatening or fatal
- requires or prolongs hospitalization
- results in permanent impairment of a body function
- or results in permanent damage to a body structure.

A serious/severe adverse device effect (SADE) is an adverse device effect that has resulted in any of the consequences characteristic of a SAE.

An anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk management for the device.

An unanticipated serious adverse device effect (USADE) is a SADE that is related to device usage not identified in the risk management for the device.

A device deficiency (DD) is the inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling.

A use error (UE) is an act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user.

See ISO 14155:2011 for details.

14.2 Reporting procedures

All device related adverse events will be investigated. Adverse events that are serious, unanticipated and (possibly) device related shall be reported to the sponsor by telephone as soon as possible. The complete

adverse event investigation form shall be scanned and emailed to the sponsor within 24 hrs. Within ten days the Sponsor will report to the REC. Any serious device related adverse event will lead to the immediate termination of the trial. In this case all participants will be contacted immediately and advised to stop using the investigational device. An appointment will be made for them to return the trial device.

Participants will be provided the contact information of the investigator and told to call them in the event of an adverse event. Furthermore, an investigator will contact them weekly to check up on any problems.

The investigator shall supply a copy of the complete adverse event investigation form, together with a cover letter y) device related.

Any device deficiencies that did not lead to an adverse event but could have led to a medical occurrence

- if either suitable action had not been taken,
- if intervention had not been made, or
- if circumstances had been less fortunate,

shall be reported according to the same procedure as if an ADE had taken place, specified above.

14.3 Suspension or premature termination of the clinical investigation

The sponsor/principal investigator, the REC, and the regulatory authorities can decide about investigation continuation. The clinical investigation can be suspended or prematurely terminated if the serious adverse device effects are considered disproportionately large compared to the possible benefits of the intervention. If the investigation is terminated or suspended all participants will be informed and appropriate follow-up will be assured. If sponsor/principal investigator terminates or suspends the investigation the relevant REC and regulatory authorities will be provided with a detailed written explanation of the termination or suspension.

The sponsor/principal investigator can upon completion of the analysis of the reason(s) for a suspension decide

16References

17Annex

17.1 Two-minute walk test - 2MWT

The two-minute walk test (2MWT) is widely used among lower-limb amputees. Reported mean values collected from a cohort of 290 lower limb amputees following the initial fitting of the prosthesis; within 48 hours of the patient's discharge from an inpatient rehabilitation admission; and at the patient's three-month outpatient follow-up as well as values for a cohort of "prosthetically and medically stable". Good inter-rater and intra-rater reliability has been reported for the 2MWT.

2MWT for Lower-Limb Amputees Undergoing Inpatient Rehabilitation

Assessment	Mean $\pm$ SD m
Baseline*	27.9 $\pm$ 18.1
Discharge*	41.1 $\pm$ 28.5
3 Month f/u*	69.6 $\pm$ 40.9
Legacy Outpatient†	99.2 $\pm$ 15.1

17.2 Timed up-and-go (TUG)

The most frequently used position transfer test is the timed up-and-go (TUG). In this outcome measure, the patient rises from a seated position, walks three meters at a self-selected speed, turns around, and returns to the chair where he reseats himself. As with the earlier measures, it is simply a timed event with the clinician timing from the moment the patient leaves the chair until he is reseated.

17.3 Comprehensive Lower-limb Amputee Socket Survey (CLASS)

CLASS is a self-report measure of prosthetic socket satisfaction for lower limb amputees, designed to provide an effective means of communication for the patient to describe with clarity, the quality of their socket fit during common activities. CLASS evaluates static and dynamic features of socket stability, suspension, comfort and appearance and has been reported to be a reliable, quick and easy report measure¹.

17.4 Socket Comfort Score (SCS)

The Socket Comfort Score (SCS) was developed in an attempt to quantify the rather subjective experience of socket discomfort and pain. It is based on the numerical rating scale (NRS) commonly used in pain clinics. However, because the scale assesses comfort rather than pain, the numerical values are reversed with higher SCS values assigned to a more comfortable socket fit.

The SCS is administered by asking the patient the following question: "If 0 represents the most uncomfortable socket fit you can imagine and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment? Despite its simplicity, the SCS has shown correlations between patient reports, clinical findings of the physician (redness, pressure marks, sores etc.), and the prosthetic fit as judged by the prosthetist. The measure has also demonstrated sensitivity to change as socket adjustments and socket replacements aimed at improving comfort resulted in higher SCS values. Ultimately, the SCS is intended to provide a level of standardization to a phenomenon that has historically been treated in purely descriptive forms².

17.5 Suspension Questionnaire

The scale was developed for an investigation of the Iceross Seal-In® High Profile liner to assess socket/liner suspension throughout the day for lower limb amputees and consists of nine questions. The Suspension questionnaire presented below will be used to evaluate the suspension of the systems investigated in this trial. A total score is calculated from the 6 questions that make up the scale. The questions are not of equal importance and the weight per question is presented below. Each question is answered on a scale from 0 – 10 where 0 = Completely Disagree and 10 = Completely Agree. The Suspension sum score is calculated by multiplying the selected answer with the appropriate weight percentage. The maximum possible total score is therefore 10.

- 1 20% I feel stable in the socket throughout the day
- 2 20% I have a good suspension between the liner, seal and socket in the morning
- 3 20% I have a good suspension between the liner, seal and socket in the afternoon
- 4 20% I have a good suspension between the liner, seal and socket in the evening
- 5 10% I feel no up and down movement in the socket when walking
- 6 10% I feel no rotation in the socket when walking (during swing phase)

Three additional questions on Suspension will be included, but will not be part of the total sum score, since they are not deemed paramount when assessing the suspension.

- 7 I am satisfied with the suspension after sitting relaxed in a chair for 3 minutes
- 8 I am satisfied with the suspension when ascending and descending stairs
- 9 I am satisfied with the suspension during higher activities such as long walks, running or during sports

17.6 Prosthesis Evaluation Questionnaire (PEQ)

The Prosthesis Evaluation Questionnaire (PEQ) measures prosthetic-related quality of life. It consists of 82 items grouped into nine subscales. In addition, there are individual questions not contained in the subscales regarding satisfaction, pain, transfers, prosthetic care, self-efficacy, and importance. The PEQ scales are not dependent on each other, so it is reasonable to use only those scales of interest. For each scale used, all of the individual questions that make up that scale must be included. The questions refer to the 4 weeks immediately preceding the administration of the instrument and are scored using a visual analogue scale (100-mm line). There is no total score. A guide gives coding instructions for all questions and groups the questions under different subscales. Each subscale score is computed by excluding any unanswered questions and averaging the answers within each subscale. The PEQ is a self-report instrument. The time taken to complete is not reported. It is also available in French. The PEQ has been published and is reported to be valid. Additional testing has shown the PEQ to have good reliability (internal consistency and test-retest) and good to excellent construct validity³.

17.7 Usability questionnaire on CONNECT TF

1. How easy/difficult is it to understand the Connect TF Operating instructions? (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

2. Rate the ease/difficulty of cleaning your prosthesis: (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

3. How easy/difficult is it to tension Connect TF? (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

4. How easy/difficult is to remove the prosthesis? (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

5.

Comments:

Additional questions on design of pull to release knob and handle:

6. Please rate the difficulty/ease of turning the knob in order to fully engaging the pin in the locking mechanism (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

7. Please rate the difficulty/ease of pulling and holding the knob in the outermost position when doffing the socket (1 = Extremely Difficult 10 = Extremely Easy)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9	10

8. Have you experienced accidental loosening/untensioning of the handle of the CONNECT TF socket?

☐	☐
Yes	No

a. **If Yes**, how often? Please describe the circumstances?

9. Please share any additional feedback you may have on the use and feel of the knob and handle of the CONNECT TF socket.

External references:

1. Gailey, R. et al. The development and internal consistency of the comprehensive lower limb amputee socket survey in active lower limb amputees. *Prosthet. Orthot. Int.* 309364618791620 (2018). doi:10.1177/0309364618791620
2. Hanspal, R. S., Fisher, K. & Nieveen, R. Prosthetic socket fit comfort score. *Disabil. Rehabil.* 25, 1278–1280 (2003).
3. Legro, M. W. et al. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. *Arch. Phys. Med. Rehabil.* 79, 931–938 (1998).