User Evaluation Trial of Lower Limb Prosthetic Devices

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Surgeon General Report

Surgeon General Health Research Program
SGR-2013-013
March 2014
User Evaluation Trial of Lower Limb Prosthetic Devices

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March 2014

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Abstract

Objective: To assess whether the Ottobock X3 microprocessor knee and the BiOM microprocessor ankle offer benefits beyond that of CAF members’ current prostheses.

Design: Intervention crossover user-evaluation trial with repeated measures. Independent variable: prosthetic device.

Participants: X3 Group: Males (n = 3, mean age: 38 ± 9.5 yrs SD) with unilateral, above-knee amputations. BiOM Group: Males (n = 2, mean age: 29.5 ± 4.2 yrs SD) with unilateral, below-knee amputations.

Main Outcome Measure: Performance scores on the Six Common Military Task Fitness Evaluation (CMTFE). Secondary outcome measures: Comprehensive High-Level Activity Mobility Predictor (CHAMP) Test, Timed Stair Ascent/Descent, and various preference surveys (Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R), Satisfaction with Prosthesis (SAT-PRO), and the Activities-specific Balance Confidence (ABC) Scale).

Results: CMTFE (measured tasks): X3 Group improved on four of the five (measured) tasks; BiOM Group (n = 1) improved on two of the five (measured) tasks. Both groups improved on all elements and final score of the CHAMP test and stair climb. Preference test scores improved for both groups.

Conclusions: Both groups demonstrated an overall increase in functional performance and personal preference. Caution should be used in drawing conclusions from these results due to the small sample size and the presence of confounding variables.

Recommendations: It is recommended that a follow-up study of longer-duration be conducted to evaluate the technical performance of the trial prostheses relevant to operational (extreme) environments. Such studies should incorporate sufficient prostheses familiarization training.

Keywords: ABC (Activities-specific Balance Confidence) Scale, Amputee, BiOM, Canadian Armed Forces, CAREN (Computer Assisted Rehabilitation Environment), CHAMP (Comprehensive High-Level Activity Mobility Predictor) Test, CMTFE (Common Military Task Fitness Evaluation), Ottobock, Prosthesis, Prosthetic, SAT-PRO (Satisfaction with Prosthesis), TAPES-R (Trinity Amputation and Prosthesis Experience Scales – Revised)
Résumé

**Objectif** : Déterminer si la prothèse de genou Ottobock X3 contrôlée par microprocesseur et la prothèse de cheville BiOM contrôlée par microprocesseur peuvent offrir des avantages médicaux supérieurs à ceux offerts par les prothèses actuellement utilisées par les membres des FAC.

**Conception** : Étude croisée d’évaluation par les utilisateurs avec mesures répétées. Variable indépendante : appareil prothétique.

**Participants** : Groupe X3 : hommes (n = 3 ; âge moyen : 38 ans; ET ± 9,5 ans) avec amputation unilatérale au-dessus du genou. Groupe BiOM : hommes (n = 2 ; âge moyen : 29,5 ans; ET : ± 4,2 ans) avec amputation unilatérale sous le genou.


**Résultats** : ECPTMC (tâches mesurées) : chez le groupe X3, une amélioration a été constatée dans quatre des cinq tâches (mesurées); chez le groupe BiOM (n = 1), une amélioration a été constatée dans deux des cinq tâches (mesurées). Dans les deux groupes, une amélioration a été constatée dans tous les éléments ainsi que dans le score final à l’évaluation CHAMP et au test de montée d’escalier. Les scores au test sur les préférences ont augmenté chez les deux groupes.

**Conclusions** : Chez les deux groupes, on a constaté une augmentation générale du rendement fonctionnel et de la préférence personnelle. Il faut être prudent au moment de tirer des conclusions à partir de ces résultats, compte tenu de la petite taille de l’échantillon et de la présence de facteurs de confusion.

**Recommandations** : Il est recommandé d’effectuer une étude de suivi sur une plus longue période, dans des environnements opérationnels (extrêmes) pertinents, afin d’évaluer le rendement technique des prothèses mises à l’essai. Cette étude devrait prévoir une période de formation d’une durée suffisante pour permettre aux utilisateurs de se familiariser avec les prothèses.

*Mots clés : Échelle ABC (Activities-specific Balance Confidence), amputé, BiOM, Forces armées canadiennes, Système informatisé d’environnement de réadaptation (CAREN), évaluation CHAMP (Comprehensive High-Level Activity Mobility Predictor), évaluation de la capacité physique à accomplir les tâches militaires communes (CMTFE), Ottobock, prothèse, prothétique, questionnaire SAT-PRO (Satisfaction with Prosthesis), échelle TAPES-R (Trinity Amputation and Prosthesis Experience Scales – Revised)*
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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>Activities-specific Balance Confidence</td>
</tr>
<tr>
<td>AED</td>
<td>Automated External Defibrillator</td>
</tr>
<tr>
<td>CAF</td>
<td>Canadian Armed Forces</td>
</tr>
<tr>
<td>CAREN</td>
<td>Computer Assisted Rehabilitation Environment</td>
</tr>
<tr>
<td>CBI</td>
<td>Compensation Benefit Instructions</td>
</tr>
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<td>CF H Svcs Gp HQ</td>
<td>Canadian Forces Health Services Group Headquarters</td>
</tr>
<tr>
<td>CFEME</td>
<td>Canadian Forces Environmental Medicine Establishment</td>
</tr>
<tr>
<td>CFHS</td>
<td>Canadian Forces Health Services</td>
</tr>
<tr>
<td>CFMWS</td>
<td>Canadian Forces Morale and Welfare Services</td>
</tr>
<tr>
<td>CFPSA</td>
<td>Canadian Forces Personnel Support Agency</td>
</tr>
<tr>
<td>CFTPO</td>
<td>Canadian Forces Taskings, Plans, and Operations</td>
</tr>
<tr>
<td>CHAMP</td>
<td>Comprehensive High-Level Activity Mobility Predictor</td>
</tr>
<tr>
<td>CMTFE</td>
<td>Common Military Task Fitness Evaluation</td>
</tr>
<tr>
<td>D Med Pol</td>
<td>Director of Medical Policy</td>
</tr>
<tr>
<td>DAIP</td>
<td>Directorate of Access to Information and Privacy</td>
</tr>
<tr>
<td>DFIT</td>
<td>Directorate of Fitness</td>
</tr>
<tr>
<td>DRDC</td>
<td>Defence Research and Development Canada</td>
</tr>
<tr>
<td>ESS</td>
<td>Edgren Side Step</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>IAT</td>
<td>Illinois Agility Test</td>
</tr>
<tr>
<td>LCI-5</td>
<td>Locomotor Capabilities Index</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>MPA</td>
<td>Microprocessor-Controlled Ankle</td>
</tr>
<tr>
<td>MPFS</td>
<td>Minimum Physical Fitness Standards</td>
</tr>
<tr>
<td>MPK</td>
<td>Microprocessor-Controlled Knee</td>
</tr>
<tr>
<td>PAR-Q</td>
<td>Physical Activity Readiness Questionnaire</td>
</tr>
<tr>
<td>SAT-PRO</td>
<td>Satisfaction with Prosthesis</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SLS</td>
<td>Single Leg Stance</td>
</tr>
<tr>
<td>TAPES-R</td>
<td>Trinity Amputation and Prosthesis Experience Scales Revised</td>
</tr>
<tr>
<td>TT</td>
<td>T-Test</td>
</tr>
</tbody>
</table>
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Introduction

As a result of Canada’s participation in the war in Afghanistan, many Canadian Armed Forces (CAF) members have been severely injured [1]. There are currently 36 CAF members with lower limb amputations, not all necessarily the result of combat-related injuries [2]. It has been recognized that these wounded soldiers often have motivation for activity levels far beyond that of typical civilian amputees [3]. This has necessitated the development of the CAF Physical Rehabilitation Program which strives to meet the more demanding needs of these highly motivated individuals [1]. The emergence of new prosthetic technologies has allowed these motivated individuals to return to or pursue more physically demanding activities and/or vocations. As per the recommendations in the After Action Report on the Ossur Power Knee and Symbiotic Leg Trial prepared by Lt(N) Turcotte, trials such as the current one should be performed regularly to expose CAF members to new technologies and to ensure the most suitable options available are made available to CAF amputees [4].

There is evidence showing that Microprocessor-Controlled Knees (MPK), such as the Ottobock X3, can produce a more natural gait [5], load distribution [5], and improved balance [6]. Similarly, powered Microprocessor-Controlled Ankles (MPA), such as the BiOM, have been shown to produce net positive work which reduces the loading of the unaffected leg [7], more closely emulates natural gait [7], reduces the metabolic cost of ambulation [8], and may increase shock absorption [9]. These factors are thought to be critical in reducing secondary musculoskeletal conditions associated with lower limb amputation and long-term prosthesis use. These conditions may include: degenerative changes at the knee and hip joint of the intact limb due to altered biomechanics; osteopenia and subsequent osteoporosis due to insufficient loading through the long bones of the lower limb; and low back pain linked to poor prosthetic fit and alignment, postural changes, leg-length discrepancy, amputation level, and general deconditioning [10].

The Canadian Forces Health Services Group has received multiple requests from currently serving CAF amputees who wished to trial new-to-Canadian market prosthetic devices. Some requests have been initially denied due to lack of military-specific supporting evidence of benefit.

The Canadian Forces Environmental Medicine Establishment (CFEME) was approached to conduct this user evaluation trial to evaluate whether two products (BiOM and Ottobock X3) do provide increased benefits to CAF members. Specifically, the purpose of this trial was to assess whether the BiOM and the X3 prostheses improve participants’ ability to meet the CAF ‘Universality of Service’ fitness requirements and to determine whether these prostheses would offer other benefits beyond what is offered by their current prostheses.

It was anticipated that the results from this trial would indicate that these trial prostheses may increase the number of members able to return to full duty, enhance the member’s quality of life, and expand their options for alternative vocations. Positive results would aid in justifying the inclusion of theses prostheses in the member’s benefits entitlements. It was intended that this research will help inform Canadian Forces Health Services personnel and policy makers regarding the benefits of emerging prosthetic technology.
BiOM Prosthesis Descriptions

(See Figure 1)

The BiOM Ankle System is produced by BiOM (recent name change), Inc. The BiOM consists of three main elements, which include: a motorized ability to plantarflex and dorsiflex the foot through the gait cycle, a microprocessor which controls the motor, and a battery which powers the motor. This prosthesis is reportedly the only one available that provides net positive work during walking [11].

The BiOM has a mass of 2.2 kg, is most beneficial for short residual limbs, and is compatible with many pre-existing transtibial or transfemoral prostheses. When fitted to pre-existing prostheses, the BiOM prosthesis must then be “dynamically-aligned” by a trained prosthetist. BiOM claims three distinct advantages over other prostheses: powered propulsion, stiffness modulation, and personal bionic tuning. Personal bionic tuning refers to the ability to modulate, using Bluetooth technology, ankle responses during gait to allow amputees to walk at various speeds within normal parameters as for non-amputees [11].

Ottobock X3 Prosthesis Descriptions

(See Figure 2)

The X3, made by Ottobock, is an enhanced version of their Genium and X2 products. The Genium is an MPK prosthesis. It is designed for amputees with unilateral or bilateral knee disarticulation or transfemoral amputations. It is also suitable for people with unilateral hip disarticulation amputations and those with hemipelvectomy amputation with good walking ability. It is claimed to be compatible with various models of prosthetic feet. Ottobock claims the Genium, with its integrated Bluetooth-controlled microprocessor, allows users to climb stairs, step over obstacles, walk forwards and backwards, sit more naturally, and stand more easily [12].
The X3 enhancements to the Genium, as reported by Ottobock, include: a higher grade of waterproofing, enabling the prosthesis to be submerged in one meter of water for up to thirty minutes; enhanced corrosion resistance; a dedicated running mode, which allows the prosthetic to respond better during running; and sound reduction (warning beeps can be silenced for stealth) [12],[13].

Figure 2: Genium Prosthetic Knee.

**Methods**

**Selection of Participants**

Five participants were selected by the CAF Physical Rehabilitation Program from a pool of currently-serving CAF members with unilateral lower limb amputation. All participants were deemed healthy and medically fit to participate. The BiOM Group had an average prosthesis usage of 3.1 ± 1.2 years Standard Deviation (SD). The X3 Group had an average prosthesis usage of 10.7 ± 12.1 years SD. Two of the three X3 Group participants are currently fitted with the Genium X2 and the third participant uses the Ossur Total Knee. The two BiOM Group participants are currently fitted with the Ottobock Harmony P2 and Ossur Vari-Flex XC, respectively.

**Study Design**

This study was an intervention crossover user-evaluation trial with repeated measures. The independent variable was the prosthetic device (BiOM or X3).
Experimental Protocol

(See Diagram 1)

Members were selected to participate in one of two intervention groups (BiOM or X3) based on their preference, amputation level, and number of products available.

Diagram 1: Experimental Protocol.
At intake, participants went through the informed consent process, completed background questionnaires, including the Physical Activity Readiness Questionnaire (PAR-Q), and underwent heart rate and blood pressure assessments.

Participants were provided a demonstration and had the opportunity to practice each performance task prior to testing. Participants then completed the three performance tests (detailed below), first using their current prostheses to establish a baseline, and then, after a period of familiarization training (described below) using the trial prostheses, re-attempted the performance tests. The fitting and alignment of the trial prostheses were conducted by each participant’s own prosthetist. Each participant used one socket throughout the trial. Preference tests (detailed below), were administered to each participant upon completion of the pre- and post-intervention performance tests.

Trial prosthesis familiarization included both formal and informal training. Formal familiarization training, conducted by a CAF Physiotherapy Officer, was tailored to the needs of each participant and employed various standard physiotherapy training techniques, but primarily utilized The Ottawa Hospital Rehabilitation Centre’s Computer Assisted Rehabilitation Environment (CAREN) system (Motek Medical BV, Amsterdam, The Netherlands) (see Figure 3). Informal familiarization training allowed participants to use the trial prostheses on their own for a full day and two nights (see Figure 4).

Figure 3: CAREN System at the Ottawa Hospital Rehabilitation Centre.
Performance Tests

Three different performance tests were administered: the CMTFE, the Comprehensive High-Level Activity Mobility Predictor (CHAMP) Test, and a Timed Stair Ascent/Descent Test. Each test is described in more detail below.

The CMTFE is the fundamental tool for assessing Universality of Service fitness requirement for CAF members. The CMTFE will replace the “Five Common Military Tasks” as the Minimum Physical Fitness Standard for Universality of Service and will be officially implemented on April 1, 2014. Until this trial, there had not been any CAF lower limb amputees officially challenge the CMTFE. Two of the five participants, both in the X3 Group, reported having previously trialed the CMTFE in 2009 and March 2013, respectively.
The CMTFE is comprised of six separate tasks: Escape to Cover, Vehicle Extrication, Stretcher Carry, Picking and Digging, Picket and Wire Carry, and Sandbag Fortification (see Figure 5 to Figure 11). To successfully complete the CMTFE, candidates must meet the following minimum standards: Escape to Cover (< 68 sec), Vehicle Extrication (safe completion with 86 kg), Stretcher Carry (safe completion with 86 kg), Picking and Digging (< 1080 sec per component; combined time of < 2160 sec), Picket and Wire Carry (< 1050 sec), and Sandbag Fortification (< 900 sec). See reference for further details regarding the CMTFE [14].

Figure 5: CMTFE, Escape to Cover.
Figure 6: CMTFE, Vehicle Extrication.
Figure 7: CMTFE, Stretcher Carry.
Figure 8: CMTFE, Picking.
Figure 9: CMTFE, Digging.
Figure 10: CMTFE, Picket and Wire Carry.
The CHAMP Test is comprised of four individual tests including the Single Leg Stance (SLS), Edgren Side Step (ESS) Test, T-Test (TT), and Illinois Agility Test (IAT) (see Figure 12 to Figure 15). See reference for a full description [15].
Figure 12: CHAMP Test, Single Leg Stance.
Figure 13: CHAMP Test, Edgren Side Step.
Figure 14: CHAMP Test, T-Test.
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The Timed Stair Ascent and Descent Test was conducted on a standard staircase (17 regulation steps) and involved having participants ascend and descend the entire staircase twice, as fast as safely possible.

Preference Tests

Surveys, which assessed the participant’s perception of their mobility, balance, energy expenditure, comfort, ease of use, and overall prostheses satisfaction, were administered following the baseline and subsequent retesting. Two questionnaires, the Houghton Score Questionnaire and the Locomotor Capabilities Index (LCI-5), were administered only at entry to the trial to establish prostheses usage and self-perceived functional abilities. Three questionnaires, the Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R), Satisfaction with Prosthesis (SAT-PRO), and the Activities-specific Balance Confidence (ABC) Scale were administered pre- and post-intervention.

The Houghton Scale is a disease-specific self-report measure of functional mobility for lower extremity prosthetic users. Clients are asked to rate their performance in the first three questions on a four-point ordinal scale. The first three questions include: the amount of time the prosthesis is used, the manner in which it is used, and whether a mobility device is used when ambulating outside. The fourth question relates to one’s perception of stability when walking over three terrains with a “yes” or “no” response option for each. The responses are added to provide a cumulative score ranging from zero (poor performance) to 12.
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(medium performance). Higher scores are associated with greater performance, comfort, and ambulation.
Devlin et al. 2004 reported the Houghton Scale to be responsive to change in prosthetic use [16].

The Trinity Amputation and Prosthesis Experience Scale – Revised (TAPES-R) is a multidimensional self-report questionnaire designed to capture psychometric data associated with adjusting to and wearing a prosthesis [17],[18]. The questionnaire is divided into six individual subscales (General Adjustment, Social Adjustment, Adjustment to Limitations, Activity Restriction, Aesthetic Characteristics, and Functional Characteristics) and an 11-point discrete scale of overall satisfaction with the prosthesis, each of which can be scored and interpreted independently. It can therefore be used to objectively measure quality of life issues. Further research was recommended by Gallagher and MacLachlan, to learn how sensitive the scale and its items are to change in clinical status [19]. Pre-intervention, participants were asked to complete the entire TAPES-R. Because a number of the subscales are dependent on the participant having used their prosthesis for an extended period, which was not the case for the trial prosthesis, only those subscales deemed applicable (Aesthetic Characteristics, and Functional Characteristics) and the 11-point discrete scale of overall satisfaction were administered to participants post-intervention.

The SAT-PRO is a fifteen-question survey of a participant’s overall satisfaction with their prosthesis. The SAT-PRO has demonstrated reliability and validity in senior populations [20]. It was administered pre- and post- intervention; however, four questions were deleted on the post-intervention version (Modified SAT-PRO) as they were not relevant (unanswerable) to participants trialling a new prosthesis.

The ABC self-report scale assesses participant’s perceived level of balance confidence carrying out various routine activities. Participants are asked to rate 16 activities related to their confidence in performing the task without losing their balance. Participants are instructed to choose one of the percentage points on an 11-point 0% to 100% scale where 0% represents no confidence and 100% represents complete confidence. In Miller’s study, balance confidence of unilateral transtibial and transfemoral amputees measured by the ABC Scale proved to be reliable with a strong support for validity [21].

Data Analysis

The data analysis was primarily descriptive. Within-subject and within-group pre- and post-intervention descriptive analysis was conducted.

Results

Performance Test Results

The primary outcome measure of this trial was performance on the CMTFE. As shown in Table 1, the X3 Group average improved in all categories except Escape to Cover. Two of the three X3 Group participants passed both the pre- and post-intervention CMTFE. Although X3 Group participant 005 did not pass either CMTFE, the only task which was not improved post-intervention was the escape-to-cover (See Table 2).
Table 1: X3 Group, Average CMTFE Percentage Improvement/Decline.

<table>
<thead>
<tr>
<th>Task</th>
<th>Pre-</th>
<th>Post-</th>
<th>Improvement (%)</th>
<th>Decline (%)</th>
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<tbody>
<tr>
<td>Escape to Cover (sec)</td>
<td>72</td>
<td>75</td>
<td>–</td>
<td>3.7%</td>
</tr>
<tr>
<td>Vehicle Extrication*</td>
<td>Pass**</td>
<td>Pass**</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Stretcher Carry*</td>
<td>Pass</td>
<td>Pass</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Picking (sec)</td>
<td>347</td>
<td>317</td>
<td>8.6%</td>
<td>–</td>
</tr>
<tr>
<td>Digging (sec)</td>
<td>605</td>
<td>554</td>
<td>8.4%</td>
<td>–</td>
</tr>
<tr>
<td>Picket and Wire Carry (sec)</td>
<td>1139</td>
<td>1074</td>
<td>5.7%</td>
<td>–</td>
</tr>
<tr>
<td>Sandbag Fortification (sec)</td>
<td>306</td>
<td>271</td>
<td>11.3%</td>
<td>–</td>
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</tbody>
</table>

*Note that Vehicle Extrication and Stretcher Carry are ‘pass or fail’ tests.
** Only two of the three X3 Group participants passed.

Table 2: Individual X3 Group Participants, CMTFE Improvement/Decline.

<table>
<thead>
<tr>
<th>Task</th>
<th>Participant 003</th>
<th>Participant 004</th>
<th>Participant 005</th>
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<tbody>
<tr>
<td></td>
<td>Pre-</td>
<td>Post-</td>
<td>Change (%)</td>
</tr>
<tr>
<td>Escape to Cover (sec)</td>
<td>56</td>
<td>61</td>
<td><strong>-8.9</strong></td>
</tr>
<tr>
<td>Vehicle Extrication (kg)</td>
<td>116**</td>
<td>116</td>
<td><strong>0.0</strong></td>
</tr>
<tr>
<td>Stretcher Carry (kg)</td>
<td>86</td>
<td>86</td>
<td><strong>0.0</strong></td>
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<tr>
<td>Picking (sec)</td>
<td>369</td>
<td>295</td>
<td><strong>20.1</strong></td>
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<tr>
<td>Digging (sec)</td>
<td>734</td>
<td>700</td>
<td><strong>4.6</strong></td>
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<td>Picket and Wire Carry (sec)</td>
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<td>941</td>
<td><strong>-8.4</strong></td>
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<td>Sandbag Fortification (sec)</td>
<td>274</td>
<td>269</td>
<td><strong>1.8</strong></td>
</tr>
</tbody>
</table>

*Positive percentages indicate improvement; negative percentages indicate decline.
** For research purposes, participants were allowed to increase the weight of the simulated patient beyond the minimum standard; however, for safety reasons during post-intervention, candidates were limited to attempt the greater of either the minimum standard or the maximum weight achieved during their baseline test.

Only one of the two BiOM participants completed both the pre- and post- intervention CMTFE Test. Participant 001 passed the pre-intervention CMTFE but withdrew from the post-intervention testing.
The single BiOM participant who completed both the pre- and post-intervention for the CMTFE showed improvements in the Escape to Cover and Digging (although the combined time for Picking and Digging was slower) and declined in the Picking, Picket and Wire Carry, and Sandbag Fortification (see Table 3).

### Table 3: BiOM Group (n = 1), CMTFE Improvement/Decline.

<table>
<thead>
<tr>
<th></th>
<th>Pre-</th>
<th>Post-</th>
<th>Improvement (%)</th>
<th>Decline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escape to Cover (sec)</td>
<td>46</td>
<td>44</td>
<td>4.3%</td>
<td>–</td>
</tr>
<tr>
<td>Vehicle Extrication*</td>
<td>Pass</td>
<td>Pass</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Stretcher Carry*</td>
<td>Pass</td>
<td>Pass</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Picking (sec)</td>
<td>384</td>
<td>471</td>
<td>–</td>
<td>22.7%</td>
</tr>
<tr>
<td>Digging (sec)</td>
<td>561</td>
<td>501</td>
<td>8.4%</td>
<td>–</td>
</tr>
<tr>
<td>Picket and Wire Carry (sec)</td>
<td>742</td>
<td>752</td>
<td>–</td>
<td>1.3%</td>
</tr>
<tr>
<td>Sandbag Fortification (sec)</td>
<td>247</td>
<td>272</td>
<td>–</td>
<td>10.1%</td>
</tr>
</tbody>
</table>

*Note that Vehicle Extrication and Stretcher Carry are ‘pass or fail’ tests.

Both the X3 and BiOM Groups showed improvement in all elements of the CHAMP test. The X3 Group’s total CHAMP Score improved 13.9% while the BiOM Group’s improved by 12.1% (see Tables 4 and 5).

### Table 4: X3 Group, Average CHAMP Test Improvement/Decline.

<table>
<thead>
<tr>
<th></th>
<th>SLS (s)</th>
<th>ESS (m)</th>
<th>TT (s)</th>
<th>IAT (s)</th>
<th>Total Score (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>22.3</td>
<td>12</td>
<td>32.9</td>
<td>43.8</td>
<td>41.7</td>
</tr>
<tr>
<td>Post-</td>
<td>22.4</td>
<td>13.7</td>
<td>26.8</td>
<td>37.0</td>
<td>47.5</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>0.1</td>
<td>13.9</td>
<td>18.7</td>
<td>15.5</td>
<td>13.9</td>
</tr>
</tbody>
</table>

### Table 5: BiOM Group, Average CHAMP Test Improvement/Decline.

<table>
<thead>
<tr>
<th></th>
<th>SLS (s)</th>
<th>ESS (m)</th>
<th>TT (s)</th>
<th>IAT (s)</th>
<th>Total Score (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>34.2</td>
<td>22</td>
<td>14.92</td>
<td>23.7</td>
<td>71.9</td>
</tr>
<tr>
<td>Post-</td>
<td>48.0</td>
<td>23.5</td>
<td>14.85</td>
<td>21.6</td>
<td>80.6</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>40.2</td>
<td>6.8</td>
<td>0.4</td>
<td>8.7</td>
<td>12.1</td>
</tr>
</tbody>
</table>
The X3 Group improved on their average stair ascent and descent times by 27.4% and 2.8%, respectively (see Table 6).

**Table 6: X3 Group, Average Stair Ascent and Descent Times.**

<table>
<thead>
<tr>
<th></th>
<th>Ascent (s)</th>
<th>Descent (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>15.1</td>
<td>10.1</td>
</tr>
<tr>
<td>Post-</td>
<td>11.0</td>
<td>9.9</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>27.4</td>
<td>2.8</td>
</tr>
</tbody>
</table>

The BiOM Group improved their average stair ascending time by 23.8%, but lengthened their average descending time by 5.0%. Further breakdown of the data shows that participant 001 improved his post-intervention descending time; however, participant 002 increased his descending time by a greater margin, leading to a slower group average descending time (see Table 7).

**Table 7: BiOM Group, Average Stair Ascent and Descent Times.**

<table>
<thead>
<tr>
<th></th>
<th>Ascent (s)</th>
<th>Descent (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>8.4</td>
<td>7.6</td>
</tr>
<tr>
<td>Post-</td>
<td>6.4</td>
<td>7.9</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>23.8</td>
<td>–</td>
</tr>
<tr>
<td>Decline (%)</td>
<td>–</td>
<td>5.0</td>
</tr>
</tbody>
</table>

**Preference Test Results**

Both the X3 and BiOM Groups indicated increased satisfaction in their Overall Prosthesis Satisfaction scores. The X3 Group scores improved by 12.0% and the BiOM Group improved by 11.1% (see Tables 8 and 9).

**Table 8: X3 Group, Average Overall Prosthesis Satisfaction (Discrete Scale, 0 – 10).**

<table>
<thead>
<tr>
<th></th>
<th>Average Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>8.3</td>
</tr>
<tr>
<td>Post-</td>
<td>9.3</td>
</tr>
<tr>
<td>Improvement</td>
<td>12.0%</td>
</tr>
</tbody>
</table>
Table 9: BiOM Group, Average Overall Prosthesis Satisfaction (Discrete Scale, 0 – 10).

<table>
<thead>
<tr>
<th></th>
<th>Average Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>9</td>
</tr>
<tr>
<td>Post-</td>
<td>10</td>
</tr>
<tr>
<td>Improvement</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

For the X3 Group, the TAPES-R average Aesthetic Satisfaction and Functional Satisfaction scores showed an improvement of 4.3% and 4.7%, respectively (see Table 10).

Table 10: X3 Group, TAPES-R Pre- and Post- Intervention Average Aesthetic Satisfaction Scores.

<table>
<thead>
<tr>
<th></th>
<th>Aesthetic Satisfaction (Out of 9)</th>
<th>Functional Satisfaction (Out of 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>7.7</td>
<td>14</td>
</tr>
<tr>
<td>Post-</td>
<td>8</td>
<td>14.7</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>4.3</td>
<td>4.8</td>
</tr>
</tbody>
</table>

For the BiOM Group, there was no change recorded from pre- to post- intervention average Aesthetic Satisfaction scores. The BiOM Group ratings for Functional Satisfaction improved by 3.7% (see Table 11).

Table 11: BiOM Group, TAPES-R Pre- and Post- Intervention Average Aesthetic Satisfaction Scores.

<table>
<thead>
<tr>
<th></th>
<th>Aesthetic Satisfaction (Out of 9)</th>
<th>Functional Satisfaction (Out of 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>7.5</td>
<td>13.5</td>
</tr>
<tr>
<td>Post-</td>
<td>7.5</td>
<td>14.0</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>0.0</td>
<td>3.7</td>
</tr>
</tbody>
</table>

The X3 Group pre- and post- intervention average scores on the Modified SAT-PRO Survey were 93.9% and 95.5%, respectively; an improvement of 1.7%. The BiOM Group pre- and post- intervention scores were both 98.9% (see Tables 12 and 13).
Table 12: X3 Group, Modified SAT-PRO Survey Pre- and Post- Intervention Scores.

<table>
<thead>
<tr>
<th></th>
<th>Modified SAT-PRO Survey (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>93.9</td>
</tr>
<tr>
<td>Post-</td>
<td>95.5</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Table 13: BiOM Group, Modified SAT-PRO Survey Pre- and Post- Intervention Scores.

<table>
<thead>
<tr>
<th></th>
<th>Modified SAT-PRO Survey (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>98.9</td>
</tr>
<tr>
<td>Post-</td>
<td>98.9</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

The ABC Scale average scores for X3 Group improved by 4.8%. The average scores for the BiOM Group improved by 1.1% (see Tables 14 and 15).

Table 14: X3 Group, ABC Scale Pre- and Post- Intervention Average Scores.

<table>
<thead>
<tr>
<th></th>
<th>ABC Scale (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>91.3</td>
</tr>
<tr>
<td>Post-</td>
<td>95.6</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Table 15: BiOM Group, ABC Scale Pre- and Post- Intervention Average Scores.

<table>
<thead>
<tr>
<th></th>
<th>ABC Scale (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-</td>
<td>98.3</td>
</tr>
<tr>
<td>Post-</td>
<td>99.4</td>
</tr>
<tr>
<td>Improvement (%)</td>
<td>1.1</td>
</tr>
</tbody>
</table>
At intake, the average score on the Houghton Scale was 11.4 out of 12. Four of the five participants scored 12 with one scoring nine out of 12. The average score on the Locomotor Capabilities Index-Five (LCI-5) was 55.8 out of a possible 56.

In addition to the standardized questionnaires, participants were also provided the opportunity to respond to open-ended questions regarding the perceived strengths and weaknesses of the trial prostheses. In the following paragraphs, their comments have been amalgamated and summarized.

**Perceived Strengths of the BiOM as Identified by the BiOM Group**
- Enables easier stair climbing and steep hill climbing/running (increased stability and reduced effort);
- Creates less stress on the unaffected leg because it no longer has to compensate as much for the residual limb;
- More energy at the end of the day because you have reserved the energy you formerly would have spent over-using the unaffected leg;
- Increased endurance during walking;
- Increased range of motion at the ankle joint enables increased mobility and increases balance;
- Able to get down on knees without pain; a much more natural kneeling position;
- Enables a more natural gait which reduces discomfort;
- Plantar flexion at the ankle makes sitting much more comfortable;
- Easy to change battery, with no requirement to plug in the foot;
- Batteries take only 45 minutes to charge and last more than 5 hours with high-level activity;
- Increased confidence during everyday activities; and
- “Makes me feel, for the most part, that I have my leg back”.

**Perceived Weaknesses of the BiOM**
- Battery is a bit bulky and has a shorter life than desired; and
- Not waterproof.

**Perceived Strengths of the X3 as Identified by the X3 Group**
- Water capable – shower, swimming, beach environment, water skiing, boating;
- Being able take a shower (especially while away from home, such as at work or a fitness facility) without having to hop to and from the shower would be extremely beneficial – for safety and psychosocial reasons;
User Evaluation Trial of Lower Limb Prosthetic Devices

• Feels more secure ascending/descending stairs and during everyday activities;
• Allows a more natural gait – not circumducting the hip, but swinging the leg in the sagittal plane;
• May enable walking through snow (where there is an anterior-to-posterior force pushing against the prosthesis); and
• Battery power is less of a concern.

Perceived Weaknesses of X3

• Bulky and heavy;
• Waterproofing seems tested, but not really mastered. (The permissible depth is very shallow and following submersion the crevices of the device must be dried with a towel);
• Learning the stair climbing technique is challenging;
• Battery cannot be recharged below 0°C and is less effective in extreme temperatures;
• A [loose] remote control is not practical. The prosthesis itself should either have a compartment for storage of the remote or the remote should be replaced by a smartphone “App” (mobile application software);
• This prosthesis is not designed for speed and therefore requires the user to change to a running foot when needed; however, there is no capacity to quickly switch to another foot type, which means users would have carry two legs [on military exercises, operations, etc.]; and
• Unconfirmed whether water can be used to cool the prosthesis when/if it overheats.

The following is a summation of physically demanding activities participants noted they would like to be able to do, but currently are unable due to the limitations of their prosthesis: endurance activities, run on uneven ground, conduct military operations in snow, rappel, static line military parachute, and swim. In a related question, participants identified the following as barriers to activities (directly due to their need to use a prosthesis): loss of knee flexion (BiOM Group), exposure to water (X3 Group), slow ascending stairs and going up and down ladders (X3 Group), and feeling unstable on uneven ground (X3 Group).

Discussion

The primary objective of this study was to determine whether the trial prostheses (X3 or BiOM) would provide increased benefits to CAF members as compared to their currently used prostheses.

Advances in prostheses technology continue to hold promise for improving quality of life and offer amputees expanding potential for partaking in more and more physically demanding activities and/or making these demanding activities more comfortable for the user. As the initial surveys (Houghton Scale and LCI-5) indicate, and the performance test results confirm, these participants are very high-performance functioning amputees.
Performance Tests

In the present study, an overall improvement in the performance tests can be seen for both the X3 and BiOM Groups. The notable exceptions, in which performance decreased, were the BiOM Group’s stair descent and CMTFE results, specifically the Picking, Picket and Wire Carry, and Sandbag Fortification. Of note, the decreased performance in these instances is attributable only to BiOM Participant 002. BiOM Participant 001 improved on the stair descent and withdrew from the post-intervention CMTFE. Participant 002 was ill with a minor cold throughout the study and it is unknown what effects this may have had on his performance with only 48 hours between test re-test.

Whereas the CMTFE was designed to assess the physical ability of (able-bodied) military members to perform specific military tasks, the CHAMP test was designed to assess the physical capabilities/mobility of high-functioning lower limb amputees [22]. In this context, the results demonstrating greater improvement on the CHAMP versus the CMTFE are understandable as the latter test is less-dependent on prosthetic-related factors (i.e. even with a superior prosthesis, tasks such as picking, digging, and carrying, which are largely dependent on upper body strength, hand-eye-coordination, overall cardiovascular conditioning, and technique, may not be improved to the same extent that a task such as the CHAMP Edgren Side Step).

The decline in performance on the post-intervention Escape to Cover task may relate to the comments from the participants that this prosthesis is bulky and heavy and not a “speed” prosthesis. However, this theory disagrees with the results demonstrated in the CHAMP Tests (TT, ESS, and IAT) which are similarly dependent on agility and running speed.

The dramatic improvement in the Single Leg Stance performance of the BiOM Group is attributed to the BiOM’s “bionically tuned” ankle joint which permits dorsiflexion and plantarflexion and therefore the ability to have the foot flat in response to and independent of terrain or knee/hip joint angle. As reflected in the ‘strength’s feedback’ section above, the benefits of increased balance and a responsive ankle joint influence most areas of improved ability and comfort – walking (including on various terrain types), sitting, and kneeling.

Stair climbing was greatly improved in both groups. It is likely that the BiOM users benefitted by the active plantar flexion propulsion and their increased balance confidence. The X3 Group improved as well, despite the fact that most, if not all, of the climb attempts were made using the ‘old’ (hip-abduction climbing technique) and not the computer-processor enhanced technique allowed by the X3. This was to be expected given the limited duration of familiarization training.

The relatively small changes in stair descent times are likely due to the fact that the majority, if not all of the participants, descend stairs using a technique that is already very fast and largely independent of the type of prosthesis used. The participants simply used the prosthesis as a pivot to swing their other leg to the next step; the need for an articulating joint being less crucial due to the fact that the next step is naturally lower than the previous step.

There are other factors to consider when reaching conclusions about the results of this study. Did fatigue play a part in decreasing post-intervention trials? The protocol attempted to give adequate rest between pre- and post-intervention testing; however, the tests are quite strenuous and one rest day, which included physical therapy training, may not have been sufficient. On the other hand, it is possible that a training effect may have enhanced post-intervention performance. It has been shown previously that CMTFE results require three to
four repeated trials prior to stabilizing [23]. Because the X3 is simply the next generation X2, it is possible that the two X3 participants that were currently using the X2 had an easier transition to the X3 and may have contributed to minimizing the changes between pre- and post-intervention.

It is also important to note the possibility of an underlying secondary participant motivation to produce improved results as the participants were cognizant that their results could have an effect on policy makers’ decision regarding the acquisition of the trial prostheses. There was also potential for pre-intervention motivation as successful completion of CMTFE was recognized and updated in participants’ medical and administrative files. So, after passing the initial CMTFE, it is possible that participant motivation waned, although observationally, this did not appear to be the case. Whether sufficient time for familiarization training was provided is also a concern. Certainly it was observed that the X3 users did not utilize the specific gait technique allowed by the MPK that is intended to enhance stair climbing. Aldridge study allowed participants three weeks to become familiar with the BiOM and still concluded that the duration of training time may have been insufficient [24].

The extent to which these factors affected the results is indeterminable. It is the assumption of the authors that these factors, to some extent, balanced each other and were not considerable enough to alter the conclusions drawn.

**Preference Tests**

All of the preference tests, excepting the BiOM Group’s Modified SAT-PRO Survey, which was unchanged following the intervention, showed that participants preferred the trial prostheses to their current prostheses. These surveys are not limited to overall preference but cover a range of issues including comfort, functionality, mobility, balance, energy expenditure, aesthetics, and confidence. The margins between pre- and post-intervention preference tests were not great and the scores were quite favourable for both, but there was a clear trend towards increased preference for the trial prostheses.

Participant feedback to the open-ended questions provided good insight into the prostheses factors valued by the users and those they wish to see improved. To summarize the key points, the BiOM was found to increase mobility and reduce discomfort and could be improved by decreasing the size/weight and extending the life of the battery. The BiOM users would also like to see the prosthesis waterproofed.

The X3 users were impressed by their increased mobility and balance and the X3’s battery life. The waterproofing was a valued attribute, but they indicated the depth limitations were too constraining and that having to dry the crevices of the prostheses after each use was not practical, especially in an operational environment. The X3 was found to be bulky and heavy, and not optimized for running, which in an operational environment, might obligate a soldier to carry a second “running” leg. Many of the other comments related to the need for further research/field testing to determine the environmental and military vocational limitations of the X3.

These comments should not detract from the fact that, overall, both trial prostheses were still preferred to the participants’ current prostheses. These amputees, being so highly functional and motivated, with such ambitious personal goals, have set equally high demands of the prosthetic companies. For the below-knee amputees, the idealized prosthesis would add to the BiOM water-proofing, the ability for long-distance running, and a light-weight, long-lasting battery. For the above-knee amputees, the demands would include an X3 that is a lighter weight, with a fully-integrated computer processor-controlled knee and ankle joint,
improved water-proofing for higher water depth, with the capability of fast running (without the need to switch the below-knee segment).

**Conclusions**

The overall conclusion regarding both prostheses is that they do demonstrate the potential to improve the quality of life of members and enable them to take part in more physically demanding activities. The nature of this trial however, being relatively short in duration and without a sufficient sample-size to determine statistical significance, limits the extent to which conclusions can be drawn. On the other hand, in a population such as this, it is unlikely that an adequate sample-size of CAF amputees would ever be achieved, and delaying a recommendation while awaiting higher quality research would be a disservice to CAF amputees.

Two key considerations integral to any prosthetic procurement decision making process would likely include a cost-benefits analysis and a comparison of other comparable commercially available prostheses. The scope of this trial did not call for such an evaluation; however, it should be noted that there is a significant increase in cost from mechanical prostheses to microprocessor-controlled prostheses and that there are numerous other comparable prostheses available on the market which could be considered.

In addition to achieving the stated purpose, this trial also delivered many important secondary benefits. This trial provided many of the key partners involved in the care and management of CAF amputees, an opportunity to liaise. CAF Rehabilitation Personnel were able to conduct a presentation for the attending civilian prosthetists treating our CAF members. It allowed The War Amps representatives an opportunity to meet with CAF amputees and it allowed amputees to come together to discuss their issues. The prosthetists received training and were able to speak in-person with the technical experts from the prosthetic companies. And finally, this trial demonstrated the use of the CAREN System in the rehabilitation and training of the amputee population.

**Recommendations for Future Trials**

The trialled prostheses do appear to increase the individual’s potential physical performance for affected CAF members. Further research is recommended, especially if these prostheses are to be used in an operational environment. It would be prudent to validate the technical specifications regarding such things as: maintenance requirements, usability in austere environments, battery specifications, lifespan, costs, compatibility with CAF dress and equipment, fire and safety hazards, noise considerations, weight restrictions, and training requirements for users. A follow-up study to evaluate such aspects would consume considerable time and resources, all the while delaying the members’ acquisition of the prostheses.

A more timely and expedient method for further evaluation might be to purchase the product for selected individuals, provide sufficient prosthetic familiarization training commensurate with member’s needs (perhaps 4 – 6 weeks), to use the device during regular military training (i.e. non-operational) duties and field exercises with a requirement that functional data is collected and monitored over an extended period of six months. Proper and sufficient training, under the guidance of the patient’s medical team, appears to be paramount to achieving the best outcome for the patient and should precede any such field trials.
The authors would like to thank The War Amps for the generous support of this project, and specifically Karen Valley for coordinating arrangements for all of the prosthetists to attend. Thank you to David Nielen, Courtney Bridgewater, and Sean Gehring of The Ottawa Hospital Rehabilitation Centre; to the PSP Staff and the Canadian Forces Morale and Welfare Services who administered the CMTFE; to Gary Sjonnesen from Ottobock and Jeff Newell from OrtoPed (Canadian BiOM distributor) for providing the prostheses and technical expertise; to Dr. Don McCreary, HREC (Human Research Ethics Committee) DRDC Toronto Research Centre; to Pte Stan Dubanevich; to all of the prosthetists who participated; and, most importantly, thank you to the subjects who participated in this strenuous trial and provided their valuable input.

Funding Acknowledgement

Surgeon General Health Research Program, Department of National Defence and The War Amps of Canada.
References


# User Evaluation Trial of Lower Limb Prosthetic Devices

**Authors:** Honey, J.M.; Godsell, P.A.; Peralta-Huertas, J.F.; Besemann, M.H.; Spivock, M.D.

**DATE OF PUBLICATION:** March 2014

**NO. OF PAGES:** 44

**DESCRIPTIVE NOTES:** Technical Report

**PROJECT OR GRANT NO.:** Not applicable to Surgeon General

**CONTRACT NO.:** Not applicable to Surgeon General

**ORIGINATOR'S DOCUMENT NO.:** SGR-2013-013

**OTHER DOCUMENT NO(S).:** Not applicable to Surgeon General

**DOCUMENT AVAILABILITY:** Approved for Public Release; Distribution Unlimited

**DOCUMENT ANNOUNCEMENT:** Unlimited Announcement
Objective: To assess whether the Ottobock X3 microprocessor knee and the BiOM microprocessor ankle offer benefits beyond that of CAF members’ current prostheses.

Design: Intervention crossover user-evaluation trial with repeated measures. Independent variable: prosthetic device.

Participants: X3 Group: Males (n = 3, mean age: 38 ± 9.5 yrs SD) with unilateral, above-knee amputations. BiOM Group: Males (n = 2, mean age: 29.5 ± 4.2 yrs SD) with unilateral, below-knee amputations.

Main Outcome Measure: Performance scores on the Six Common Military Task Fitness Evaluation (CMTFE). Secondary outcome measures: Comprehensive High-Level Activity Mobility Predictor (CHAMP) Test, Timed Stair Ascent/Descent, and various preference surveys (Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R), Satisfaction with Prosthesis (SAT-PRO), and the Activities-specific Balance Confidence (ABC) Scale.

Results: CMTFE (measured tasks): X3 Group improved on four of the five (measured) tasks; BiOM Group (n = 1) improved on two of the five (measured) tasks. Both groups improved on all elements and final score of the CHAMP test and stair climb. Preference test scores improved for both groups.

Conclusions: Both groups demonstrated an overall increase in functional performance and personal preference. Caution should be used in drawing conclusions from these results due to the small sample size and the presence of confounding variables.

Recommendations: It is recommended that a follow-up study of longer-duration be conducted to evaluate the technical performance of the trial prostheses relevant to operational (extreme) environments. Such studies should incorporate sufficient prostheses familiarization training.

Objectif : Déterminer si la prothèse de genou Ottobock X3 contrôlée par microprocesseur et la prothèse de cheville BiOM contrôlée par microprocesseur peuvent offrir des avantages médicaux supérieurs à ceux offerts par les prothèses actuellement utilisées par les membres des FAC.


Participants : Groupe X3 : hommes (n = 3 ; âge moyen : 38 ans ; ET ± 9,5 ans) avec amputation unilatérale au-dessus du genou. Groupe BiOM : hommes (n = 2 ; âge moyen : 29,5 ans ; ET : ± 4,2 ans) avec amputation unilatérale sous le genou.

Principaux indicateurs de résultats : Résultats aux six évaluations de la capacité physique à accomplir les tâches militaires communes (ECPTMC). Indicateurs secondaires de résultats : évaluation CHAMP (Comprehensive High-Level Activity Mobility Predictor), montée/descente
d’escalier chronométrées et diverses enquêtes sur les préférences (échelle TAPES-R [Trinity Amputation and Prosthesis Experience Scales – Revised], questionnaire SAT-PRO [Satisfaction with Prosthesis] et échelle ABC [Activities-specific Balance Confidence]).

Résultats : ECPTMC (tâches mesurées) : chez le groupe X3, une amélioration a été constatée dans quatre des cinq tâches (mesurées); chez le groupe BiOM (n = 1), une amélioration a été constatée dans deux des cinq tâches (mesurées). Dans les deux groupes, une amélioration a été constatée dans tous les éléments ainsi que dans le score final à l’évaluation CHAMP et au test de montée d’escalier. Les scores au test sur les préférences ont augmenté chez les deux groupes.

Conclusions : Chez les deux groupes, on a constaté une augmentation générale du rendement fonctionnel et de la préférence personnelle. Il faut être prudent au moment de tirer des conclusions à partir de ces résultats, compte tenu de la petite taille de l’échantillon et de la présence de facteurs de confusion.

Recommandations : Il est recommandé d’effectuer une étude de suivi sur une plus longue période, dans des environnements opérationnels (extrêmes) pertinents, afin d’évaluer le rendement technique des prothèses mises à l’essai. Cette étude devrait prévoir une période de formation d’une durée suffisante pour permettre aux utilisateurs de se familiariser avec les prothèses.

13. KEYWORDS, DESCRIPTORS or IDENTIFIERS (Technically meaningful terms or short phrases that characterize a document and could be helpful in cataloguing the document. Use semi-colons as delimiters.)

ABC (Activities-specific Balance Confidence) Scale, Amputee, BiOM, Canadian Armed Forces, CAREN (Computer Assisted Rehabilitation Environment), CHAMP (Comprehensive High-Level Activity Mobility Predictor), Test, CMTFE (Common Military Task Fitness Evaluation), Ottobock, Prosthesis, Prosthetic, SAT-PRO (Satisfaction with Prosthesis), TAPES-R (Trinity Amputation and Prosthesis Experience Scales – Revised)