ABSTRACT

Introduction

Ankle-foot and knee components are important determinants of mobility for individuals with transfemoral amputation. Individually, advanced ankle-foot and knee components have been shown to benefit mobility in this group of people. However, it is not clear what affect a variety of combinations of ankle-foot and knee components have on mobility test performance.

Methods

Nine adults with unilateral transfemoral amputation completed the Two-minute walk test (2MWT), the Timed up-and-go test (TUG), the L-test and a custom locomotion course (Loco) in four randomised prosthetic conditions. These conditions were each a combination of an ankle-foot component (rigid, non-articulating; RIG or a hydraulically articulating; HYD) and a knee component (non-microprocessor-controlled; NMPK or a microprocessor-controlled; MPK). The test-retest reliability and concurrent validity of the custom locomotion course was also established.

Results

The best performance in all mobility tests was associated with the MPK+HYD combination, followed by the MPK+RIG, NMPK+HYD and NMPK+RIG combinations. This effect was statistically significant for the Two-minute walk test (p=0.01, η_p^2 = 0.36) and on threshold for the L-test (p=0.05, η_p^2 = 0.36) but not statistically significant for the locomotion course (p=0.07, η_p^2 = 0.38) or the Timed up-and-go test (p=0.12, η_p^2 = 0.22). Locomotion course performance had good to excellent test-retest reliability and strong concurrent validity.

Conclusion

Using a combination of a hydraulically articulating ankle-foot and a microprocessor-controlled knee resulted in the highest performance in mobility tests. This was observed in contrast to combinations of prosthetic components that included a rigid ankle-foot component and/or a non-microprocessor-controlled knee component.

KEYWORDS: Microprocessor knee; hydraulic ankle; transfemoral; mobility.

INTRODUCTION

The individual components that make up prosthetic limbs vary widely. Components can be quite basic with limited functionality, through to more sophisticated and complex components that use advanced materials and electronics. More advanced componentry is often perceived to be of greater benefit to the individual user in terms of mobility and wider health status. In order to understand and evaluate the effects of a new component on the user, investigators try to experimentally control as many factors as possible between component manipulations. This approach isolates the effects brought about by changing or altering a single component. There are situations however, where multiple functional components are required to interact to form an effective prosthetic limb. Examples of such components used to construct a whole prosthetic limb, include the ankle-foot component for transtibial prosthesis users and additionally, the knee component for transfemoral prosthesis users.

In terms of ankle-foot components, previous research has demonstrated many adaptations that occur when individuals with lower limb amputation use more functionally advanced, passive prosthetic ankle-foot components. These include improved push off mechanics and step length symmetry [1–4] associated with using energy storing and returning feet. Increased walking speed [5,6], reduced residuum distal end loading [7], improved toe clearance during swing [8] and decreased metabolic cost of walking [9] have been observed when using hydraulically articulating ankle-foot components. Individuals with lower limb amputation display a preference for these components, when compared to less functionally advanced components [2,10,11]. Therefore, these adaptations are interpreted as being beneficial to individuals with lower limb amputation.

With regards to prosthetic knee componentry, several adaptations are associated with using more functionally advanced microprocessor-controlled knee components (MPK), when compared to non-microprocessor-controlled knee components (NMPK). These include increased physical activity [12], walking speed [13,14] and walking gait kinetic symmetry [15]. The use of MPK components has also been predicted to reduce fall risk [16]. More advanced prosthetic components have been reported to lead to broader social and economic benefits. These include improved quality of life for the user of an MPK and reduced direct and indirect healthcare costs associated with MPK provision [16]. As a result, healthcare policymakers have commissioned such advanced prosthetic components e.g. MPK components, routinely in national healthcare systems [17].

The literature is extensive regarding the benefits of an individual component for individuals with lower limb amputation. However, little is known regarding how combinations of components interact to affect mobility. Identifying the optimal combination of both ankle-foot and knee components for improving mobility in individuals with unilateral transfemoral amputation (IUTF), for example, is critical. At present, it is not clear whether this optimal solution would be exclusively comprised of more advanced componentry or not. Understanding how different combinations of ankle-foot and knee components affect mobility will allow for a more objective selection of prosthetic limb prescription, regardless of how extensive the componentry range available to an individual patient and/or clinician is.

Therefore, the purpose of this study was to assess whether varying the combination of ankle-foot and knee components used by unilateral transfemoral prosthesis users, influenced outcomes from tests of mobility. The combinations assessed, comprised of a basic, non-articulating or an advanced, hydraulically articulating ankle-foot component, combined with either a microprocessor-controlled or a non-microprocessor-controlled knee component. Given the benefits associated with advanced component user, we hypothesised that a combination of more advanced components (e.g. hydraulic ankle-foot component and MPK), would result in improved performance in mobility test outcomes.

METHODS

Participants

A group of IUTFs (n=9, ♂ 9) and a group of otherwise healthy control participants (CON, n=10, ♀2, ♂8) were recruited for the current study (Table 1). Inclusion criteria for the IUTF group were; aged 18 or over, able to negotiate obstacles such as ramps and stairs i.e. commensurate with a K3 mobility level[18], able to walk continuously for at least two minutes at a time, had good (corrected, if necessary) vision and had no unresolved cardiovascular complaints. Individuals in the IUTF group were excluded if they; experienced undue musculoskeletal pain causing them to stop and be unable to continue when walking at a self-selected speed, were unable to complete tasks due to disease/illness (e.g. rheumatoid arthritis), had a current neuromuscular or musculoskeletal injury, or fell regularly (>1 a month) as determined using the PROFANE fall definition [19]. They were also excluded if their residuum had significant blisters, wounds and/or rashes which prevented the prosthesis, sock and liner being worn comfortably, or they had any other substantial changes to the physical condition of the residuum that required medical attention. The CON group were recruited using the same inclusion/exclusion criteria, excluding criteria specifically related to amputation status. The study was approved by a national healthcare research ethics committee [XXXXXXXXX] and all participants provided written informed consent prior to participation in the study.

Table 1 here

Table 1. Participant characteristics of individuals with unilateral transfemoral amputation (IUTF) and otherwise healthy controls (CON).

Study Design

Individuals in the IUTF group completed the mobility tests described below in four prosthetic conditions. The four conditions were made up of a combination of one of two ankle-foot component options and one of two knee component options. The ankle-foot component options were a rigidly attached, non-articulating ankle-foot component (RIG; Esprit, Blatchford Ltd, Basingstoke, UK) and a hydraulically articulating component (HYD; Echelon, Blatchford Ltd, Basingstoke, UK). The knee component options were a non-microprocessor knee component that each participant had either used previously and/or was currently using (NMPK, see Table 1) and a microprocessor-controlled knee component (MPK; Orion3, Blatchford Ltd, Basingstoke, UK). The conditions were abbreviated as; MPK+HYD, MPK+RIG, NMPK+HYD, NMPK+RIG. No other prosthetic components were altered, and all participants had current or prior experience of using all knee and ankle-foot components. The ordering of the four different combinations was randomised via a random number generator. The alteration of prosthetic componentry was conducted by an experienced, licensed prosthetist.

Study Protocol

Participants completed the following mobility tests in the same order, on the same day for each prosthetic condition: Two-minute walk test (2MWT), the Timed up-and-go test (TUG), the L-test and a custom locomotion course (Loco), which included stair and ramp ascent and descent, obstacle negotiation and turning (Figure 1). Participants completed a practice trial and then recorded trials of the 2MWT, until consecutive trials were within 10% of each other. Participants completed three trials of the TUG, L-Test and Loco, with rest periods as required. The reliability and validity of the 2MWT [20,21], TUG [22] and L-Test [23] have been demonstrated previously in individuals with lower limb loss. The test-retest reliability and concurrent validity of the custom locomotion course is reported in the current study.

Figure 1 here

Figure 1. A plan view (A) including walking lengths and representative sketch (B) of the custom locomotion course used in the current study.

Data and Statistical Analysis

The final trial from all mobility tests was used to compare the test outcomes obtained when under four different combinations of prosthetic componentry. Initially, the normality of data distribution was assessed using a Shapiro-Wilk test. A one-way repeated measures analysis of variance was conducted and where the assumption of sphericity was violated, a Greenhouse-Geisser correction factor was applied. Multiple post-hoc comparisons were adjusted for using a Sidak correction with effect sizes (partial eta squared) calculated for each statistical comparison. The alpha level of statistical significance was set at p=0.05.

The test–retest reliability for the Loco outcomes were established for all prosthetic combinations in the IUTF group and for the CON group by calculating intraclass correlation coefficients (ICCs) using a two-way mixed-effects model for absolute levels of agreement. The ICCs were calculated between the first and second and, the second and third trials of the Loco test. The test–retest reliability for the Loco outcomes between trials was then categorised as either poor (<0.5), moderate (0.5 – 0.75), good (0.75 – 0.9) or excellent (>0.9) [24]. The concurrent validity between the Loco and the 2MWT, TUG and L-test was assessed using Pearson's Product-Moment Correlation (*r*). Correlation coefficients were defined as small (0.1< | r | <0.3), moderate (0.3< | r |<0.5) or strong (| r | >0.5) [25]. All statistical analyses were conducted in IBM SPSS software (v.26 IBM, Portsmouth, UK).

RESULTS

Outcomes from mobility tests

Across all mobility tests, an order of performance according to the combination of prosthetic components used was observed. Participants' best performance was observed when using the MPK+HYD combination, followed by the MPK+RIG, NMPK+HYD and finally the NMPK+RIG combination (Figure 2, Table 2). This effect was statistically significant for two-minute walk distance ($F(3,24) = 4.50$, p=0.01, $\eta_p^2 = 0.36$) and on threshold of significance for the L-test ($F(1.28,10.21) = 4.51$, p=0.05, $\eta_p^2 = 0.36$) (Table 2), post hoc tests did not reveal which combinations resulted in these significant effects. The effect was not statistically significant for the locomotion course ($F(1.14,7.97) = 4.37$, p=0.07, $\eta_p^2 = 0.38$) and for the Timed up-and-go test ($F(3,24) = 2.19$, p=0.12, $\eta_p^2 = 0.22$) (Table 2).

Figure 2 here

Figure 2. Group mean ± 95% confidence interval and individual participant mobility test outcomes for each combination of prosthetic componentry. Control data is for visual representation only and was not used in within group statistical analyses.

Test-retest reliability and concurrent validity of the locomotion course outcomes

The test-retest reliability of the Loco, between trials one and two and between trials two and three, was excellent (>0.9) for all prosthetic combinations in the IUTF group and for the control group (Table 3). In addition, evaluation of the 95% confidence interval range suggested that test-retest reliability might be better between trials two and three, with lower ICC bounds ranging between good (0.76, MPK+RIG) to excellent (0.96, NMPK+RIG) (Table 3). Generally, strong (r>0.5) concurrent validity was observed for all prosthetic combinations in the IUTF group and for the control group when contrasting the Loco with the 2MWT, the L-Test and the TUG (Table 3). Exceptions were the relationships between the Loco and the TUG in the CON group (*r* = 0.04, p=0.91) and the Loco and 2MWT using the MPK+HYD combination (*r* = -0.53, p=0.18) and the NMPK+HYD combination (*r* = -0.63, p=0.10) in the IUTF group.

Table 2 here

Table 2. Full reporting of group means, lower (LL) and upper (UL) bounds of 95% confidence intervals and full statistical analyses with *F* statistic, p value and effect size (partial eta squared, η_p^2) for each outcome measures' main effects.

Table 3 here

Table 3. Test–retest reliability and concurrent validity for the locomotion course outcomes for the UTF group (all prosthetic combinations) and the CON group. Test-retest reliability is assessed using intraclass correlation coefficients (ICCs), including the lower and upper bound of the 95% confidence interval, between trials one and two, and two and three from the locomotion course. Concurrent validity between the locomotion course and the 2MWT, TUG and L-test is assessed using Pearson's Product-Moment Correlation (*r*).

DISCUSSION

The current study assessed whether varying the combination of ankle-foot and knee components used by unilateral transfemoral prosthesis users, influenced outcomes from tests of mobility. Results show that the combination of prosthetic components used in mobility tests, has a significant bearing on the test outcomes.

In all four mobility tests undertaken in the current study, the order of performance, from best to worst, was MPK+HYD, MPK+RIG, NMPK+HYD and finally NMPK+RIG. This prosthetic combination effect was statistically significant for the 2MWT (p = 0.01) and on the threshold of statistical significance for the L-test (p = 0.05). Given that the order of performance between prosthetic conditions was consistent across all mobility tests, it seems reasonable to posit that, despite the lack of statistical significance in some instances, the results reflect a general benefit to mobility of using a combination of more advanced prosthetic components. A clear implication of this is that where there is the option, a more advanced combination of prosthetic components should be selected/prescribed, if increased mobility is the objective. During locomotion, intact biological limbs have been conceptually modelled a single 'limb' system [26–28]. In addition, it has been shown that the ankle, knee and hip joints function in a complimentary and compensatory fashion during locomotion in people without limb loss [29–31]. Therefore, it may seem unsurprising that the use of a combination of more advanced prosthetic components with greater mechanical functionality would lead to improvements in mobility. However, establishing the effects of an MPK and hydraulically articulating ankle-foot component is relevant as these combinations are realistic and commonly prescribed options in national healthcare systems. It must be noted that advanced prosthetic components are also often prescribed for reasons not necessarily directly related to mobility e.g. safety and quality of life. The current data do not speak to these issues, nor the underlying biomechanical basis for the changes in mobility observed. Future research should seek to clarify the underlying mechanisms for these changes in mobility, to understand where and how these components benefit mobility in IUTFs. The clinical relevance of the differences observed must also be considered. For example, the minimal clinically important difference (MCID) for the L-test (4.5 seconds) [32], exceeds the range of scores from the current study, suggesting reduced clinical importance of the observed differences. However, this MCID threshold was determined in a different sample with very different characteristics, potentially limiting this interpretation.

The observation that performance is improved in IUTFs when completing mobility tests when using one advanced component alongside a more basic component, also builds on previous reports of these components' efficacy in terms of mobility [14,16]. Outcomes from all four of the tests completed in the current study suggested that when individuals used an MPK, in combination with a rigid ankle-foot component, their performance was better than when using a NMPK in combination with a hydraulically articulating ankle-foot component (Figure 2). This highlights a key point related to prosthetic knee provision. For the IUTFs in the current study, prosthetic knee functionality was seemingly more influential than prosthetic ankle-foot function. This supports the current focus on commissioning and/or reimbursement of MPKs in healthcare systems [16,17], as knee component functionality seems to be an appropriate initial focus for improving mobility in IUTFs. This data also supports previous findings that MPKs enhance the ability of IUTFs to perform activities of daily living [12–15]. Interestingly, the provision of an advanced ankle-foot component with both an MPK and NMPK had positive influences on mobility, which has implications for prosthetic prescription and patient selection. As described above, where an MPK is prescribed, the addition of an advanced ankle-foot component may afford an additional benefit to mobility. Furthermore, where MPK components are not available, feasible or desirable, for cost or practicality reasons, the mechanical function of an advanced ankle-foot component, such as the hydraulic ankle-foot components assessed in the current study, could also provide additional mobility benefits [33]. This may be of particular use to IUTFs in low resource settings or with multiple options for prosthetic limbs. Of course, the data from the current study must be viewed in the context of the ability of the participants recruited. Even with a rigid ankle-foot and NMPK combination, all participants were able to safely and effectively complete several challenging mobility tests, suggesting even the more basic components allow for effective locomotion.

The custom locomotion test designed as part of the current study was found to have good to excellent test-retest reliability and strong concurrent validity. The dimensions of the walking course may restrict its use to larger research centres. Also, its set-up may not reflect realistic environmental situations people may find themselves for example, climbing stairs using handrails. However, the locomotion course may provide information regarding mobility in general, whilst also enabling researchers to segment relevant tasks for further investigation e.g. stair negotiation. The addition of instrumentation e.g. force-sensing capabilities in the staircase, would further increase researchers' ability to interrogate the underlying biomechanics in studies such as those presented here.

There were a few important limitations in the current study. The first, and likely most common issue with such experimental designs, is that it was not possible to blind participants to the prosthetic component manipulations. This was due to the differing requirements of each component during the fitting and set-up procedures. Thus, it is highly possible that our results were affected by individuals' preconceptions and/or preferences towards certain component combinations. Another key limitation was the acute nature of the prosthetic manipulations. Although the test data suggested a good level of familiarisation with each combination of prosthetic components, results may have been accentuated had participants been afforded a longer accommodation period. This was not possible in the current study, as in some cases, longer term change to participants' prosthetic prescription would have negatively affected adherence, given lack of flexibility and deviation from the prosthetic prescription provided by their national healthcare provider. A final key limitation of the current study were the sample characteristics (all male participants secondary to trauma) and size, leading to limited generalisability and potential under powering of the study. We aimed to recruit individuals from local limb centres who possessed both MPK and NMPK components to reduce accommodation effects of these manipulations. Alongside health concerns of human testing owing to the COVID-19 pandemic from February 2020, participant recruitment was curtailed. Notwithstanding, we feel that the consistency of our results across prosthetic component combinations and mobility tests, support our conclusions.

CONCLUSION

The use of more functionally advanced prosthetic knee and ankle-foot componentry, particularly when used in combination, have a positive effect on mobility in individuals with unilateral transfemoral amputation. This information may inform decisions around prosthetic prescription and policymaking, where varied options for prosthetic components are available.

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Figure 2. Group mean ± 95% confidence interval and individual participant mobility test outcomes for each combination of prosthetic componentry. Control data is for visual representation only and was not used in within group statistical analyses.