THE IMPACT OF THE APPLICATION OF POLYCENTRIC KNEE MODULES ON BALANCE CONTROL AND THE LEVEL OF MOBILITY IN TRANS-FEMORAL AMPUTATION

VPLIV UPORABE POLICENTRIČNIH KOLENSKIH MODULOV NA NADZOR RAVNOTEŽJA IN POMIČNOST PACIENTOV PO NADKOLENSKI AMPUTACIJI

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Abstract

Introduction:
The aim of prosthetics supply after trans-femoral amputation is restitution of body structure with the new biomechanical unit – a prosthesis constructed according to the needed level of stability and mobility. Technical performance of the modular solutions is in the focus of recent studies, but they lack information on the practical application and the impact of modular solutions on body functions. This paper reports on the influence of a polycentric knee module compared to the single-axis prosthetic knee on maintaining postural balance, mobility and independence in people with unilateral trans-femoral amputation.

Methods:
In the Department of Rehabilitation and Orthopaedics Aids of the University Hospital Centre Zagreb, an analysis of patients' functions data was carried out in order to determine changes in balance and mobility when using polycentric knee module as opposed to prosthetic supply with a single-axis knee module. The data were collected by assessing the patients at our Department before and during secondary prosthetic supply in the period from 2012 to 2015. Mobility and balance were tested with the Amputee Mobility Predictor (AMP) test with Medicare functional classification level, Berg's Balance Scale (BBS), Timed Up and Go (TUG) and 10-meter walk test.

Ivleček

Uvod:
Namen oskrbe s protezo po nadkolenski amputaciji je zamenjava telesne strukture z biomehansko enoto – protezo, izdelano glede na zahtevano raven stabilnosti in pomičnosti. V zadnjem času se raziskave osredotočajo na tehnične značilnosti posameznih delov tovrstnih protez, ni pa podatkov o praktični uporabnosti in vplivu modularnih rešitev na telesne funkcije. V članku poročamo o vplivu policentričnega kolenskega modula v primerjavi z enoosnim protetičnim kolenom na vzdrževanje ravnotežja, pomičnost in neodvisnost pri pacientih po enostranski nadkolenski amputaciji.

Metode:
Na Oddelku za rehabilitacijo in ortopedske pripomočke Univerzitetne bolnišnice Zagreb smo analizirali podatke o telesnih funkcijah pacientov z namenom ugotoviti spremembe ravnotežja in pomičnosti pri uporabi policentričnega kolenskega modula namesto proteze z enoosnim kolenskim modulomPodatke smo zbrali z ocenjevanjem pacientov na našem Oddelku pred in po sekundarni oskrbi s protezo v obdobju od leta 2012 do 2015. Pomičnost in ravnotežje smo ocenili z Lestvico za napoved izida rehabilitacije po amputaciji spodnjega uda (Amputee Mobility Predictor, AMP) in pripadajočo ravnijo funkcioniranja po razvrstitvi Medicare, Bergovo lestvico za oceno ravnotežja, časovno merjenim testom vstani in pojdi in testom hitrosti hoje na 10 metrov.

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Results:
A statistically significant difference was found regarding the TUG and 10-meter walk test between the patients with single axis knee compared to polycentric knee; the latter were faster on average. The average level of mobility according to AMP scoring was statistically significantly higher with the application of polycentric knee. Correspondingly, 10 of the 15 patients moved from lower to higher K-level according to Medicare functional classification level. The BBS results were also statistically significantly in favour of the polycentric knee module.

Conclusion:
Polycentric knee module for people with trans-femoral amputation allows better control of balance and speed as well as greater mobility in comparison with single-axis knee. For patients with trans-femoral amputation it thus provides a higher level of independence in activities of daily living.

Key words:
lower limb amputation; body function; balance; prosthesis; independence

Rezultati:
Na časovno merjenem testu vstani in pojdi ter testu hitrosti hoje na 10 metrov se je pokazala statistično značilna razlika med skupinama, pri čemer so bili pacienti s policentričnim kolenskim modulom v povprečju hitrejši. Povprečna raven pomičnosti glede na AMP je bila statistično značilno višja pri pacientih s policentričnim kolenskim modulom; v razvrstitvi Medicare jih je na višjo raven napredovalo 10 od 15. Tudi dosežki na Bergovi lestvici ravnotežja so statistično značilno pričali v prid policentričnega kolenskega modula.

Zaključek:
Policentrični kolenski modul osebam po nadkolenski amputaciji omogoča boljši nadzor ravnotežja ter večjo hitrost gibanja in boljšo pomičnost v primerjavi z enoosno kolensko protezo. Pacientom po nadkolenski amputaciji tako omogoča večjo samostojnost pri dnevnih aktivnostih.

Ključne besede:
amputacija spodnjega uda; telesne funkcije; ravnotežje; proteze; samostojnost

INTRODUCTION

According to the ICF (1), the amputation of the lower extremities primarily changes the body structure and reduces body functions, resulting in the consequent limitation of activities and participation in everyday life. The aim of prosthetic supply in patients after trans-femoral amputation is restitution of body structure and functions with the new biomechanical unit – prosthesis, constructed according to the required level of stability and mobility.

Walking is the basic human need for mobility. To walk with a prosthesis after amputation is a major challenge, especially in trans-femoral amputation, which is accompanied by the loss of knee, ankle joint and associated muscles. Although prosthetic components may replace some of the functionality of the amputated limb, they cannot replicate the activity of the lost musculature (2), which makes the pattern of walking with the prosthesis in people with trans-femoral amputations very specific as opposed to the normal walking (2, 3).

Changes in the pattern of walking, instability in the stage of standing, and mental focus on the use of the prosthesis with increased energy consumption are the result of an unstable prosthetic knee. Falling in people with trans-femoral amputations can be associated with the physical and psychological factors. Reduced balance control, mental focus and the fear of falling reduce and limit mobility, social activity, participation and interaction with the environment (4, 5).

Technological development of prosthetic solutions opens a wider selection range of the knee modules, therefore offering better kinematics of walking in people with trans-femoral amputation. However, modern prosthetics is prohibitively expensive, because of complexity and cost of knee modules, which are the most important components of the above-knee prostheses. Selection of the knee module is a complex process that involves complex individual rehabilitation with prior assessment of all elements of body structure and physical performance and setting functional goals with the aim of the prosthesis becoming a new biomechanical unit. The main characteristics of patients that define the selection of lower limb prosthesis modules, in this case the knee module, are lifestyle, age, weight, physical force and residual limb length (6).

The rehabilitation team follows the patient through all phases of rehabilitation; all assessments, goal-setting, selection and application of prosthesis, prosthesis-aided mastering of functional activities with a special emphasis on bipedal walking and final reintegration into the world of functioning and participation. Mastering walking is the foundation of rehabilitation for people with amputations of the lower limbs and a prerequisite for full functional acceptance of the prosthesis (3). The success of rehabilitation and satisfactory mobility of persons with lower limb amputation correlates with prosthetic supplies that presupposes pre-prosthetic preparation (7).

Outstanding innovative advancements in technology have catalysed the modernisation of prosthetics, spurring a significant growth in the prosthetics market. Thanks to these developments, today's prosthetic devices cater to the specific needs of patients (8). Stability of the standing stage on prosthetic side depends on two factors: the mechanical stability of the prosthetic knee and it´s position, and voluntary contraction of the residual hip muscle (3). The mechanical stability is achieved by placing a rotation centre of a prosthetic knee posterior to the vector of ground reaction forces during standing, which prevents knocking of the knees when the body weight is transferred to the prosthesis (9). Voluntary stability of the prosthetic knee is achieved by hip extensor strength at the initial contact with the surface of the heel. However, stability during standing is not the only function of prosthetic knee. A uniform, controlled and smooth transition from standing into lateral movement is an important aspect of normal walking. Controlled movement of the knee during the swing phase can be obtained with other swinging control mechanisms, such as constant or variable friction and hydraulic control (10, 11). Single-axis-self-locking knee uses a constant friction during swinging phase, while self-locking mechanism is activated by weight transfer on the prosthesis, which prevents knocking of the knees during the standing stage, and only allows for flexion--extension pattern (open-closed knee). Polycentric knee module contains a variable centre of rotation and friction providing safety in all phases of walking. Thanks to its variable friction, large and unnecessary amplitudes in the knee movement are reduced, and minimal knee flexion is allowed while stepping on the heel, which greatly helps in more natural and safer walk with the prosthesis.

Technical performance of modular solutions is in the focus of recent clinical, empirically based studies, which at the same time lack information on the practical application and impact of modular solutions on body functions. Despite the wide variety of prosthetic knee designs available today, a lack of quantitative data concerning the specific performance parameters of different types of component designs remains (2).

This paper presents a practical application of the polycentric knee module, its impact on maintaining postural balance and level of mobility and independence, in relation to the single-axis knee module, in a secondary prosthetic supply of people with unilateral trans-femoral amputation. We wanted to determine whether there are changes present in balance and mobility when using polycentric knee module.

METHODS

In the period from 2012 to 2015 we invited a group of patients after transfemoral amputation who were having their first prosthesis or were candidates for secondary prosthetic supply at the Department of Rehabilitation and Orthopaedics Aids of the University Hospital Centre Zagreb. We assessed their functional status in order to determine whether there are changes in balance and mobility when using polycentric knee module as opposed to the prosthetic supply with single-axis knee module.

The analysis included only data from patients (*N* = 15, 11 males and 4 females, mean age 48 years, range 25-66 years) who received previously planned secondary prosthetic supply with polycentric knee module after the primary supply with single-axis knee module. Assessment included functional tests that were conducted by physiotherapists, later expanded with a detailed analysis of the rehabilitation team, before and during secondary prosthetic supply.

Each of the participants was medically stable before the assessment and was able to follow basic verbal instructions during testing without the risk of falling. During the assessment participants did not have any negative sensations, such as pain, weakness, fatigue or exhaustion, that would affect their test results. In the secondary prosthetic supply, the patients received polycentric knee module with the same form of knee bearing as in the primary supply, so that a period of adjustment to the new prosthesis knee bearing was avoided.

The Amputee Mobility Predictor (AMP) test was used to test balance and mobility together with the Berg Balance Scale (BBS). Timed Up and Go (TUG) and 10-meter walk test were also used before and during secondary prosthetic rehabilitation.

The AMP method was used for determining the functional capability of movements according to the Medicare functional

Table 1: *Medicare functional classification levels (11).*

Tabela 1. *Ravni funkcijske razvrstitve Medicare (11).*

K levels Raven	Description Opis
K - 0	The patient does not have the ability or potential to move or securely transfer with/ without mobility aids. The prosthesis does not affect the quality of life or mobility.
K - 1	The patient has the ability or the potential use of the prosthesis for transfer and even movement on flat surfaces. Typical for the in-house movement.
K - 2	The patient has the ability or potential to move and climb over low obstacles such as curbs, stairs or uneven surfaces. Typical of restricted movement in the community.
K -3	The patient is able to overcome most of the obstacles, in therapeutic or sports activity that requires the use of the prosthesis. Prosthesis provides a higher level of activity over the basic locomotion.
K - 4	The ability or potential to move that goes beyond the basic skills of walking, with a high level of stress, energy, or impact force on the foot. Typically for children, young adults and athletes.

classification level (11) from 0 to 4 (K-level) (13) (Table 1). This test contains 21 tasks, nearly all scored from 0 to 2, with a maximum of 47 points, and covers a large number of functional activities in which the balance is an essential and conditional component. Test is reliable and easy to perform, and does not require a lot of time and equipment (12, 14).

The BBS (14) is a 14-item scale that quantitatively assesses balance and risk for falls in older community-dwelling adults through direct observation of their performance and it measures both static and dynamic aspects of balance (16). Scores are recorded on a scale from 0 to 4 points; the maximal possible number of points is 56. Originally, the test was designed to assess the risk of falls in the elderly population, but research has shown the reliability of the test in the evaluation of balance in this particular population. During this study, the modified BBS was used, with 9 assignments and maximal possible total score of 36 points. Body functions were observed through performing the following tasks:

1. Movement from a seated to a standing position
2. Standing without support
3. Movement from a standing to a seated position
4. Standing without support, with legs being closed
5. Reaching ahead with stretched arms in a standing position
6. Raising objects of the floor from a standing position
7. 360-degree turn
8. Stepping ahead in a standing position
9. Standing on one foot

The TUG test is a simple, quick and widely used clinical performance-based measure of lower extremity function, mobility and fall risk (17). It measures the time required for participant to get from a chair, walk 3 meters, turn around, walk back to his chair and sit down (18). During this test the participant is using the same mobility aid as usual. The TUG test is a reliable instrument with adequate concurrent validity to measure the physical mobility of patients with an amputation of the lower extremity (18). Walking speed at 10 meters is measured in seconds and represents an evaluation test of walking speed. This test includes walking initiation, acceleration and deceleration (16).

RESULTS

Kolmogorov-Smirnov test did not indicate that any of the observed variables deviated statistically significantly from the normal distribution (all p-values > 0.1). Therefore, the variables were described as mean (M) and standard deviation (SD) and t-test was used for comparing means. Descriptive statistics for the studied variables are presented in Table 2 together with the results of statistical tests. There were statistically significant differences in favour of the polycentric knee module regarding the AMP scoring, TUG test time, 10-meter walking speed and BBS score. According to the Medicare functional classification level, 10 of the 15 patients moved from a lower to a higher K level when using polycentric knee module instead of the single-axis knee module (Table 3).

DISCUSSION

Our results show that when fitted with a polycentric knee module, our patients were able to get up and walk faster than when fitted with a single-axis knee module. It has been shown that patients who have been given a knee unit without oscillation control, such as single-axis unit, cannot change the cadence and speed of walk (20). The application of a polycentric unit enables such a change, depending on the current needs of the users (9). The ability to cross a certain distance in a certain time period represents an important aspect of daily activities, so our results speak strongly in favour of a polycentric knee module.

The level of mobility according to the AMP scoring was also statistically significantly higher on average when using a polycentric knee module. That corresponded to the transition of 10 out of the 15 patients (i.e., two thirds of the sample) from a lower to a higher K-level in the Medicare functional classification. Both results demonstrate the important impact of the polycentric knee unit on mastering activities that require rapid and variable walking speed.

Table 2. *Descriptive statistics of the studied variables and results of statistical tests.*

Tabela 2. *Opisne statistike za obravnavane spremenljivke.*

Assessment / Ocena	Min	Max	M	SD	*p**
AMP – single-axis module[1]	24	43	33.7	6.8	<0.01
AMP – polycentric knee module[2]	34	45	40.0	4.1	
TUG – single-axis module[1]	11.0	18.9	14.8	2.6	<0.01
TUG – polycentric knee module[2]	9.1	17.1	12.9	2.8	
10 m walk – single-axis module[1] (s)	10.0	18.7	14.0	2.9	<0.01
10 m walk – polycentric knee module[2] (s)	8.9	16.3	12.3	2.6	
BBS – single-axis module[1]	13	27	19.4	5.0	<0.01
BBS – polycentric knee module[2]	17	35	26.7	6.3	

Notes: N =15 for all variables; AMP - Amputee mobility predictor, TUG – Timed Up and Go test, BBS – Berg Balance Scale; * – from paired-samples t-test.

Opombe: N =15 za vse spremenljivke; AMP – Lestvica za napoved izida rehabilitacije po amputaciji spodnjega uda, TUG – časovno merjeni test vstani in pojdi, 10 m walk – test hitrosti hoje na 10 metrov, BBS – Bergova lestvica za oceno ravnotežja; 1 – enoosni kolenski modul, 2 – policentrični kolenski modul; * – za test t za odvisna vzorca.

Table 3. *Medicare functional classification level for all the patients with both prosthetic knee modules.*
Tabela 3. *Raven funkcioniranja po razvrstitvi Medicare za vse paciente z obema protezama.*

Patient / Pacient	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Single-axis knee module[1]	K3	K2	K2	K3	K3	K1	K1	K3	K4	K4	K3	K2	K2	K3	K1
Polycentric knee module[2]	K4	K3	K3	K3	K4	K2	K2	K3	K4	K4	K3	K3	K3	K4	K2

Opomba: 1 – enoosni kolenski modul, 2 – policentrični kolenski modul.

Unfortunately, there is not much quantitative data comparing the performance of different types of prosthetic components in the published literature (2).

Berg balance scale is a well-validated instrument for balance assessment in people with amputations of the lower limbs, but it cannot precisely define the difference between the groups at high and medium risk of falling (21). Our results of BBS assessment are in favour of the polycentric knee module. In general, the BSS is useful for evaluation of interventions aimed at improving balance of lower limb amputees (21), because the ability to maintain vertical balance while just standing reduces the risk of falls in people with trans-femoral amputation (22, 23). In addition, prosthetic knee stability is an important factor in determining which prosthetic knee component is most appropriate for the individual patient (2) and it constitutes important information for drafting the prosthetic rehabilitation plan.

The main limitation of our study is the small sample of participants. With a larger sample size, it might be desirable to categorise respondents according to age groups, thus taking into account the different needs and abilities of younger and older people. Generally speaking, it is an imperative to increase the number of studies on the effects of different forms of knee module on mobility, balance and other components of activities of daily living in order to set examples of good clinical practice in prosthetic supply. Despite the small sample size, our findings are therefore clinically important and can contribute to future research.

CONCLUSION

Polycentric knee module for people with trans-femoral amputation allows better control of balance, higher speed of walking and greater mobility. For patients with trans-femoral amputation it thus provides a higher level of independence in activities of daily living. The synergy of modern prosthetic technology, the rehabilitation team and the patient can result in the patient mastering complex activities that require physical condition and technical performance of modular solutions.

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