



ASSESSMENT OF FUNCTIONING IN PERSONS WITH UNILATERAL LOWER LIMB AMPUTATION USING SUBSETS OF INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH (ICF)

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Abstract

Background- The International Classification of functioning, disability and health (ICF) is a comprehensive and universally accepted framework to describe and classify functioning, disability and health in persons.

Objectives- To determine the functioning in persons with unilateral lower limb amputation through the selected subsets of ICF in two levels of amputation, i.e. transtibial and transfemoral amputation, with comparison of the functioning according to their levels of amputation.

Method- Questions framed according to the guidelines of the codes of the different categories of ICF from the domains of 'Body Functions', 'Activities and Participation' and 'Environmental Factors' were asked to each patient in the study. Based on the qualifiers, the Proforma and Persons' data sheet were filled, which included tables of ICF & Demographic and Clinical Characteristics.

Results- Fifty persons (35 males and 15 females) with a median age of 43.5 years and a level of amputation as transtibial (70%) and transfemoral (30%) were included in the study. On comparing between two groups of amputation, the difference in the result of the functioning of skin structure (s810), maintaining the body position (d415) and Individual attitudes of immediate family members (e410) were found to be statistically significant.

Conclusions- Lower extremity amputees who completed comprehensive rehabilitation still experience several impairments, limitations and restrictions, emphasizing the need for a tailor-made multidisciplinary rehabilitation program.

Keywords- Disabled Persons, Amputation, Surgical, Musculoskeletal System, Lower Extremity

Introduction

Lower limb amputation is a chronic health condition and a common cause of long-term disability. It has a major impact on almost every aspect of a person's life and is a truly life-altering event, affecting the physical, functional, and psychological dimensions of a person's world.¹ The decision to amputate a limb is not made lightly; amputation is performed as a lifesaving measure for those affected by severe trauma, infection, or peripheral arterial disease.^{2,3} The International Organisation for Standardization (ISO) terminology for the description of acquired lower limb amputations is the following: Hemipelvectomy, Hip disarticulation, Transfemoral, Knee disarticulation, Transtibial, Ankle disarticulation, Partial foot, Digit(s).⁴ The current functional classification systems and outcome measures for persons with amputation are often tailored to local needs, and there is a lack of consensus regarding uniform or the most appropriate outcome measures.⁵ For example, the K classification system mandated in the USA and in some Australian states classifies only the functional mobility with the use of a prosthesis for a person with an amputation. Although the K classification is a relatively simple functional scale, there are no clear guidelines for the exact process of how to categorize an individual into the five levels of function in the classification. Outcomes in prosthetic rehabilitation are influenced by various factors, including psychological and cognitive aspects, medical co-morbidities, pre-morbid level of function and compliance. Therefore, research on outcomes is difficult, and at times, conclusions from studies are conflicting and confusing.^{6,7} Since the endorsement of the International Classification of Functioning, Disability and Health (ICF) by the World Health Assembly in May 2001, a comprehensive and universally accepted framework to describe and classify functioning, disability and health in individuals with amputation has been available.⁸ The ICF classifies functioning into the components of body structures and functions, activities and participation, environment and personal factors [Figure 1]. Personal factors are currently not categorized in the ICF.⁹ ICF contains a total of 1495 meaningful and discrete or mutually exclusive categories, and taken together, cover the whole spectrum of human functioning. In response to the challenge of implementing the ICF in clinical practice, a series of joint projects were initiated by the ICF Research Branch of the World Health Organization (WHO) Collaboration Centre at Ludwig-Maximilians University in Munich and the Classification, Assessment and Surveys team at WHO in 2001.¹⁰ The collection of these categories should be comprehensive enough to include all the relevant aspects of a health condition and function but at the same time be practical and feasible.¹¹ There is a dearth of adequate literature and evidence of the use of ICF in lower limb amputees in India in spite of an extremely valuable tool for the functional evaluation of such persons. This study has been structured and designed to determine the functioning in persons with unilateral lower limb amputation through the selected subsets of International Classification of Functioning, Disability and Health [ICF] in two levels of amputation, i.e. transtibial and transfemoral amputation, with comparison of the functioning in the persons with amputation according to their levels of amputation.

MATERIALS AND METHODS

This cross-sectional analytical study was completed over a span of one and a half years in adherence to the guidelines of the Helsinki Declaration. The Institutional Ethics Committee approved the study protocol and the patient informed sheet and informed consent were taken prior to the study from each study participant.

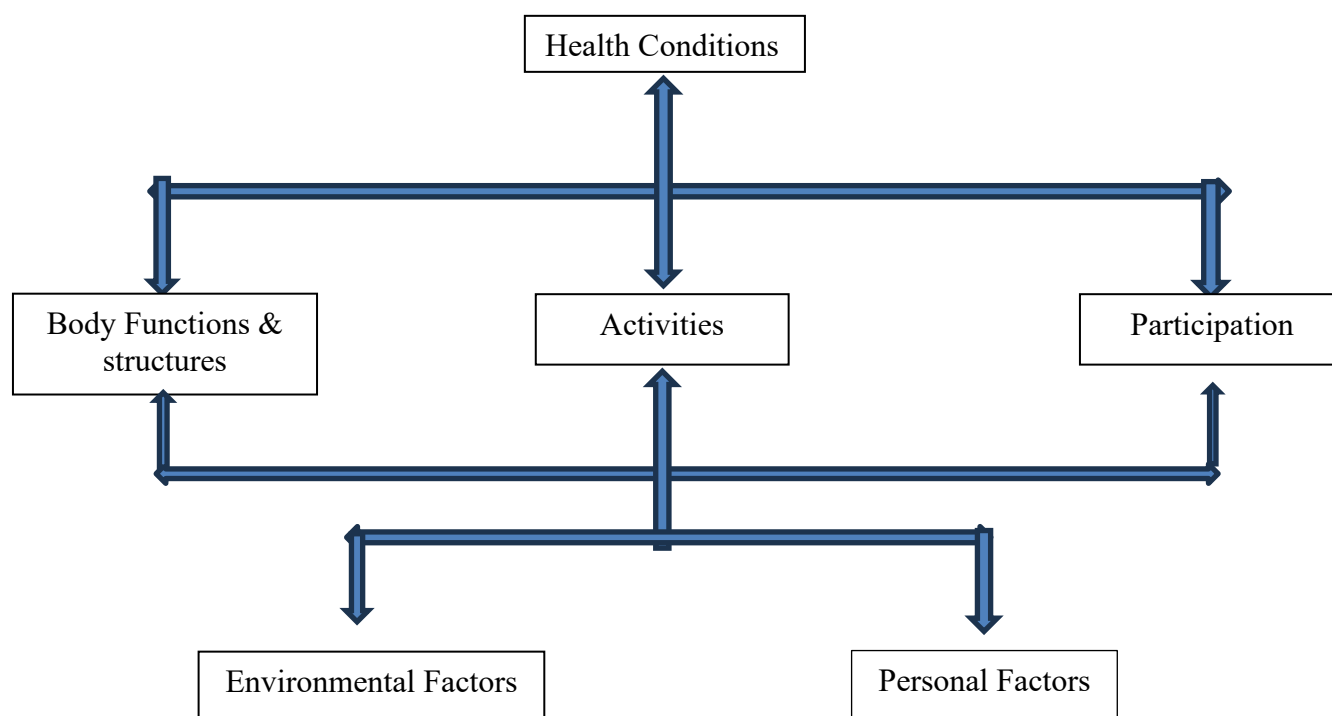


Figure 1- ICF Model (International Classification of Functioning, Disability & Health)

Sample size & Rationale: 50 cases.

Sample size had been calculated with the help of Epi Info (TM) 3.5.3. EPI INFO, which is a trademark of the Centres for Disease Control and Prevention (CDC). As per the study by Ghosh Das *et al.*, the most common cause of amputation was trauma (70.3%).¹² Thus, for this study, $p = 0.703$. The number of subjects required for this study was $50.46 \sim 50$ with a power 82%. The formula used for sample size calculation is as follows: $n = \frac{4pq}{L^2}$, where n = required sample size, $p = 0.703$ as per the study by Ghosh, Das *et al.*

$q = 1 - p$, L = Loss % (Loss of information)

Calculation:

Here $p = 0.703$, $q = 1 - p = 0.10$, $\text{Loss}\% = 18\%$

$4pq = 4 \times 0.703 \times 0.297 = 0.8352$

$L^2 = (0.703 \times 0.18)^2 = 0.0166$

So, $n = 0.8352 / 0.0166 = 50.46 \sim 50$

Inclusion criteria:

- (1) Person's age group between 21yrs to 60yrs.
- (2) Unilateral transtibial and transfemoral amputation
- (3) Age of amputation more than one year.

Exclusion criteria:

- (1) Persons with severe cognitive impairment.
- (2) Persons other than transtibial and transfemoral amputation
- (3) Any other systemic illness that interferes with daily activities.
- (4) Unwillingness to participate in the study.

Sampling: Non-Random Sampling Technique

Study technique:

The patient data sheet contains the different subsets of ICF categories. Persons were asked about each body function, body structure and activities and participation. Each code has a definition along with

inclusion criteria and exclusion criteria. The questions were asked of the persons keeping with this definition. The qualifiers for each category were accordingly marked as per the patient's statement to denote the extent of the problem in his/her current health condition. A disability of 0-4% was rated as "disability none". A disability of 5-24% was rated as "mild disability". A disability of 25-49% was rated as "disability moderate", .50-95% as "disability severe/serious", and 96-100% as "disability complete". Now the categorisation is as such- "A" denotes disability. "B" denotes to disability mild and moderate. "C" denotes disability severe and complete. Persons were to be asked to rate each environmental factor as a barrier or a facilitator in their present health condition. The responses were noted as - No Barrier: [A], Facilitator: [B], Barrier: [C], Not-applicable: [D]. The selected Body function subsets were b152: emotional functions, b180: Experience of self and time function, b28015: sensation of pain, b770: gait pattern functions. The selected Body structure subset was s810: skin structure. The selected Activities and participation subsets were d130: copying, d415: maintaining a body position, d450: walking, d470: use of transportation, d530: Toileting, d920: Recreation and leisure. The selected Environmental factors subsets were e1151: Assistive products and technology for personal use in daily living, e1201: Assistive products and technology for personal Indoor and outdoor Mobility and transportation, e210: Physical geography, e310: Immediate family, e325: Acquaintances, peers, colleagues, neighbors and Community members, e410: Individual attitudes of immediate family members, e425: Individual attitudes of acquaintances, peers, colleagues, neighbors and community members. Statistical Analysis was performed with the help of Epi Info (TM) 7.2.2.2. EPI INFO is a trademark of the Centers for Disease Control and Prevention (CDC). Descriptive statistical analyses were performed to calculate the means with corresponding standard deviations (S.D.). The test of proportion was used to find the Standard Normal Deviate (Z) to compare the difference in proportions, and the Chi-square test was performed to find the associations. In the cases where one of the cell frequencies was less than 5 corrected Chi-square was used to find the association between variables. A t-test was used to compare the means. Row% was used to compare the percentage between two groups, and Column (Col)% was used to compare the percentage within a group. $p < 0.05$ was taken to be statistically significant.

RESULTS

Fifty persons with a median age of 43.5 years, with males (70%) and mostly married (78%) and professionally active (62%) with educational qualification of 'middle school certificate' of Kuppuswamy education score¹³ (62%). Trauma (82%) was the most common cause of amputation, with transtibial amputation (70%) being the most common level. The age of amputation was mostly 1-5 years (50%), with time since using the prosthesis being less than one year (46%). The persons of the two groups (Transtibial and Transfemoral) were matched for their age, sex, marital status, occupation, level of education, aetiology, level of amputation, the age of amputation and the time since using the current prosthesis. The proportion of persons with no disability in the functioning of skin structure (s810) was significantly higher in the Transtibial level of amputation (88.6%) as compared to Transfemoral level of amputation (60.0%) ($Z=4.62$; $p < 0.0001$), and this was also statistically significant between the two groups ($p=0.02$) [Figure 2]. The proportion of persons with no disability in functioning of maintaining body position (d415) was significantly higher in the Transtibial level of amputation (40.0%) as compared to the Transfemoral level of amputation (0.0%) ($Z=7.07$; $p < 0.001$). And it was statistically significant between the two groups ($p=0.002$) [Figure 3].

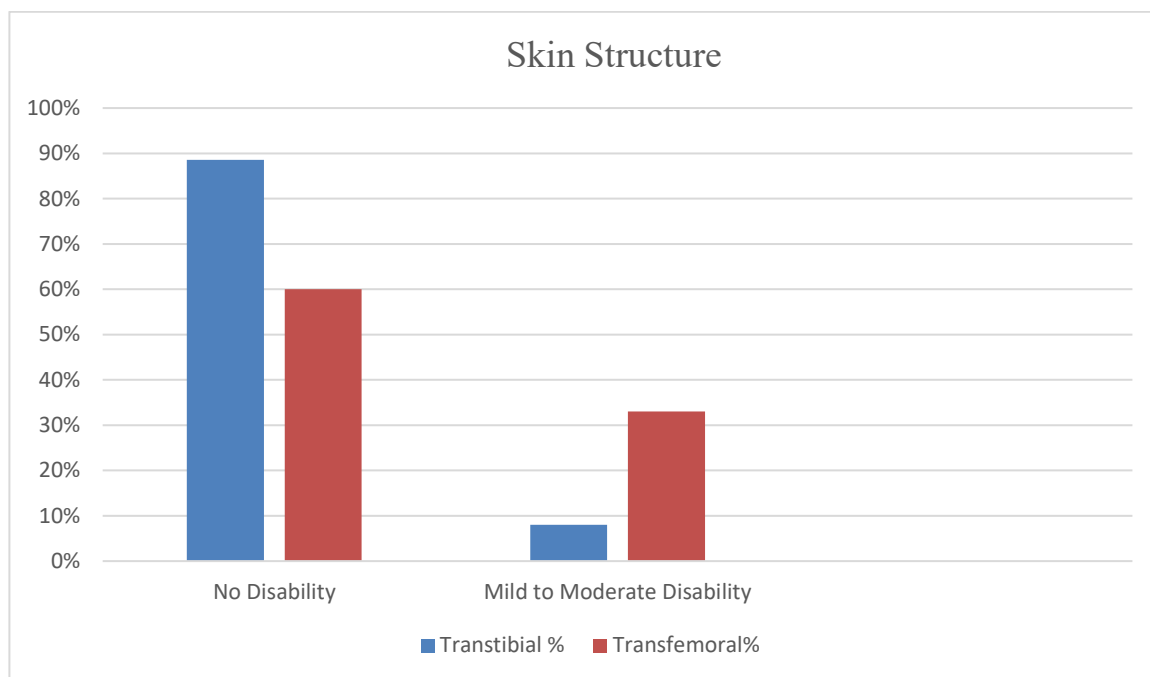


Figure 2- Skin Structure- Proportion of patients with no disability was significantly higher in Transtibial level of amputation (88.6%) as compared to Transfemoral level of amputation (60.0%) ($Z=4.62$; $p<0.0001$).

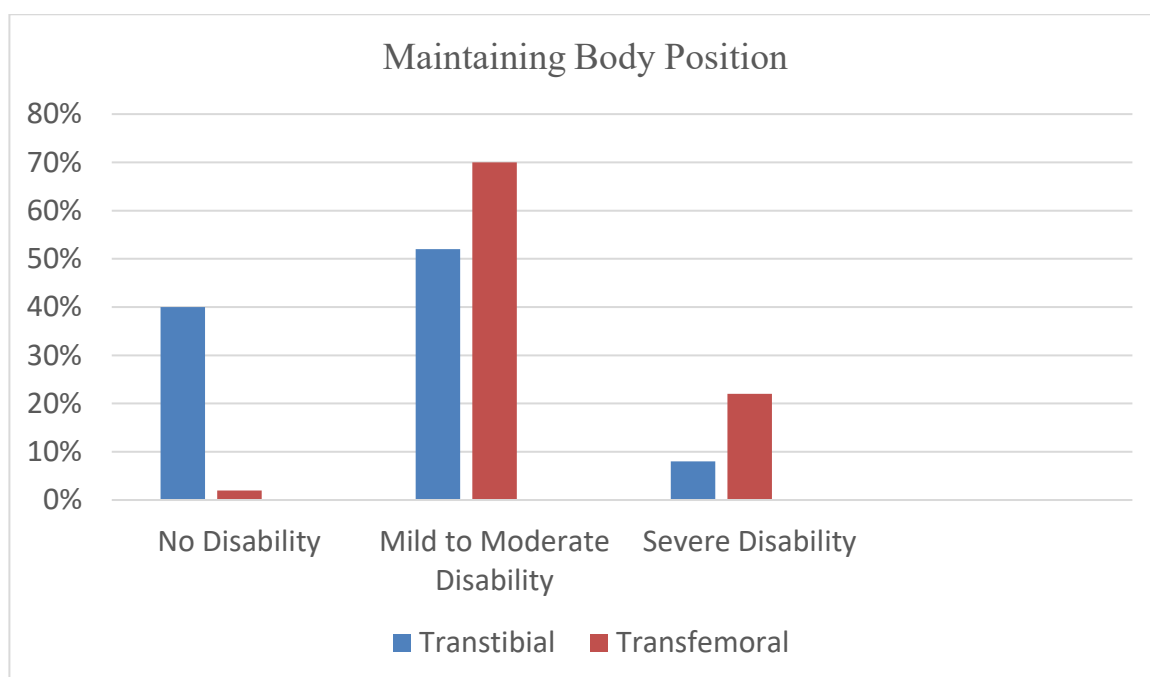


Figure 3- Maintaining Body position- Proportion of patients with no disability was significantly higher in Transtibial level of amputation (40.0%) as compared to Transfemoral level of amputation (0.0%) ($Z=7.07$; $p<0.001$).

There was no barrier impact on individual attitudes of immediate family members (e410) in the persons with Transfemoral amputation (60.0%) as compared to Transtibial level of amputation (28.6%) ($p=4.46$; $p<0.0001$) [Figure 4], and this was statistically significant between the two groups ($p=0.03$).

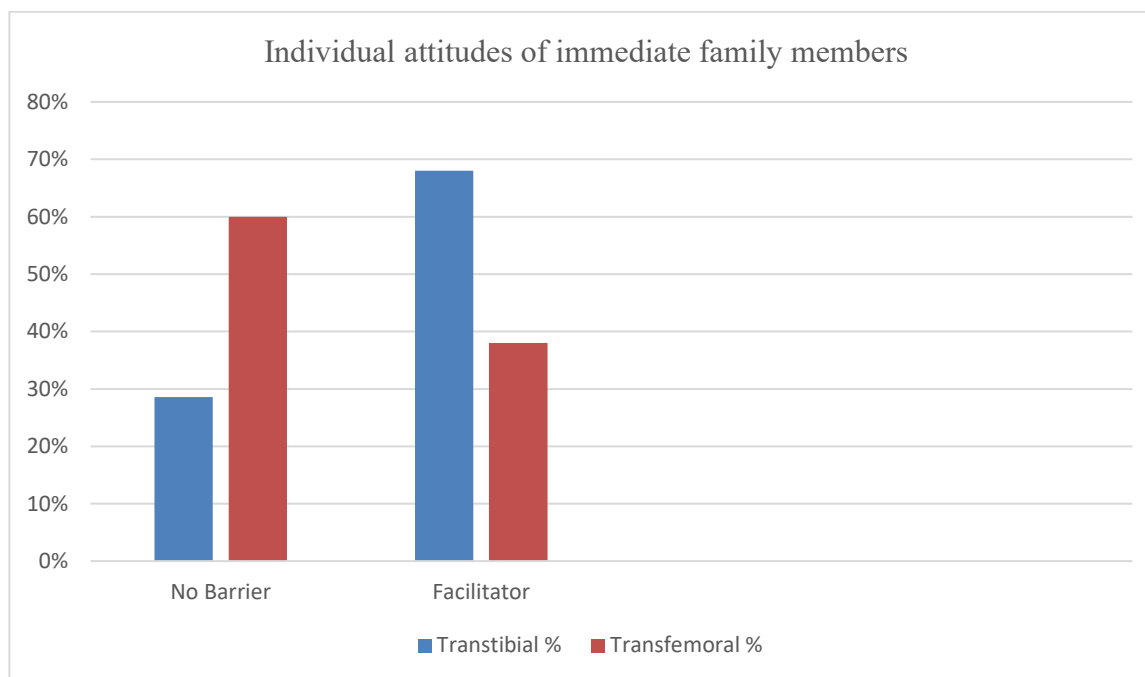


Figure 4- Individual attitudes of immediate family members- Proportion of patients with no barrier was significantly higher in Transfemoral level of amputation (60.0%) as compared to Transtibial level of amputation (28.6%) ($p=4.46$; $p<0.0001$).

DISCUSSION

Trauma (82%) was the most common aetiology for lower limb amputation in the present study. Sansam *et al.* published a review of literature regarding the walking ability in lower limb amputation and found that the majority of the amputees were from traumatic events.¹⁴ The most common level of amputation in this study was of transtibial level of amputation. In the present cross-sectional study time since using the current prosthesis was mostly less than one year. There was no significant association between the time since using the prosthesis and the level of amputation.

In the present study, the proportion of persons having disability associated with the skin structure was significantly higher in the transfemoral level of amputation than in the transtibial amputation. Nancy L *et al.* published the article about the dermatological conditions associated with the use of prosthesis in lower limb amputation¹⁵ and found that different skin problems in the persons with transtibial amputation were four times more than the persons with transfemoral amputation and predicted two contributing factors for this result. The first one being that there was a higher chance of the presence of more bony prominences in the persons with transtibial, Syme's and partial foot amputation than with a transfemoral residual limb. Secondly, transtibial, Syme's, and partial foot amputees tend to be more active than transfemoral amputees and often spend more time wearing and walking in their prostheses. But in the present study, surprisingly, there were higher incidences of skin problems in transfemoral amputations. This might be due to the poor skin care and poor donning and doffing practices by the study population. Secondly, India is a tropical country, and there is a higher level of humidity in most areas, and the institute belongs to that area; there is a higher chance of increased sweating at the residual limb, which might lead to various skin problems.

The functioning of maintaining the body position was a significant disability in persons with transfemoral amputation. W. C. Miller *et al.* studied the balance confidence among persons with lower limb amputation¹⁶ and didn't find any significant difference in maintaining the body position among different levels of amputation. The main factor affecting this functioning might be the higher level of amputation in transfemoral amputees and the size of the residual limb.

The immediate family, as an environmental factor, was not significantly associated with the two groups of amputation, but the attitude of immediate family members was significantly associated with the two groups of amputation. There was a higher proportion of neutral effects from the side of

immediate family members on the persons with transfemoral amputation. A study published by N. Mugo described that amputation is a burden on the lives of family members, and the rehabilitation should also aim for the person as well as the family members.¹⁷ H. Burger described the attitude of family members towards the amputee as a barrier to their functioning.¹⁸ Hence, the rehabilitation program should integrate the counselling of the family members and should provide the knowledge regarding the functioning of the amputees and the barriers in daily activities. The education of the family members should include the identification of the problems and helping the amputee to overcome the obstacles.

CONCLUSION

The present study highlighted not just the medical aspects of the patient's condition but also how the patient was functioning in the environment and dealing with the different functional, social as well as external barriers in his day-to-day life. From the person's perspective, such a detailed interview regarding his experience was reassuring and helped in building an intimate doctor-patient relationship. From the physician's aspect, this ICF-based data helped in planning a constructive individualised rehabilitation programme.

An ICF-based tool or software would be ideal for the implementation of preventive and curative measures at the personal, societal as well and national level. Persons following lower limb amputation who completed comprehensive rehabilitation still experience several impairments, limitations and restrictions. Rehabilitation team members should address these facts and try to alleviate their impact on the functioning of persons following lower limb amputation.

LIMITATION OF STUDY

1. There is a lack of published studies on the application of ICF on amputation in an Indian Setting. Thus, the references were drawn from international studies as well as epidemiological studies in relation to amputation from India.
2. The majority of studies on the application of ICF on amputation are multicentre studies, often involving more than one country and sometimes multidisciplinary. This study being a single-centre study, a smaller sample size could be taken.
3. Further follow-up is required to study the implementation of different treatment strategies and the changes in the qualifiers of the categories.

Author role statement:

Sushil Kumar Nayak¹ (conceptualisation, methodology, supervision, writing- original draft, software, validation, formal analysis)

Nirmalya Mohapatra² (data curation, visualisation, writing- review & editing, project administration)

Rabisankar Sahu³ (resources, software, validation, resources investigation, formal analysis)

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REFERENCES

- 1 Coffey L, Gallagher P, Horgan O, Desmond D, MacLachlan M. Psychosocial adjustment to diabetes-related lower limb amputation. *Diabet Med.* 2009 Oct;26(10):1063-7. doi: 10.1111/j.1464-5491.2009.02802. x. PMID: 19900240.
- 2 Stansbury LG, Lalliss SJ, Branstetter JG, Bagg MR, Holcomb JB. Amputations in U.S. military personnel in the current conflicts in Afghanistan and Iraq. *J Orthop Trauma.* 2008 Jan;22(1):43-6. doi: 10.1097/BOT.0b013e31815b35aa. PMID: 18176164.
- 3 Ryer EJ, Trocciola SM, DeRubertis B, Lam R, Hyncek RL, Karwowski J, Bush HL, Mureebe L, McKinsey JF, Morrissey NJ, Kent KC, Faries PL. Analysis of outcomes following failed

- endovascular treatment of chronic limb ischemia. *Ann Vasc Surg.* 2006 Jul;20(4):440-6. doi: 10.1007/s10016-006-9101-4. Epub 2006 Jul 25. PMID: 16865606.
- 4 Schuch, C. Michael and Charles H. Pritham. International Standards Organization Terminology: Application to Prosthetics and Orthotics. *Jpo Journal of Prosthetics and Orthotics.* 1994; 6: 29-33.
- 5 Condie, E., Scott, H. and Treweek, S. (2006) Lower Limb Prosthetic Outcome Measures: A Review of the Literature 1995 to 2005. *Journal of Prosthetics and Orthotics*, 18, 13-45.
- 6 Deathe AB, Wolfe DL, Devlin M, Hebert JS, Miller WC, Pallaveshi L. Selection of outcome measures in lower extremity amputation rehabilitation: ICF activities. *Disabil Rehabil.* 2009;31(18):1455-73. doi: 10.1080/09638280802639491. PMID: 19479574.
- 7 Gailey, Robert. (2006). Predictive Outcome Measures Versus Functional Outcome Measures in the Lower Limb Amputee. *JPO: Journal of Prosthetics and Orthotics.* 18. P51-P60. 10.1097/00008526-200601001-00006.
- 8 World Health Organization. The International Classification of Functioning, Disability and Health (ICF). Geneva: WHO, 2001.
- 9 World Health Organization. ICF Checklist. Version 2.1a, Clinician Form for International Classification of Functioning, Disability and Health, 2003. Retrieved May 24, 2008 from <http://www3.who.int/icf/checklist/icf-checklist.pdf>
- 10 Stucki G, Grimby G. Applying the ICF in medicine. *J Rehabil Med.* 2004 Jul;(44 Suppl):5-6. doi: 10.1080/16501960410022300. PMID: 15370740.
- 11 Cieza A, Brockow T, Ewert T, Amman E, Kollerits B, Chatterji S, Ustün TB, Stucki G. Linking health-status measurements to the international classification of functioning, disability and health. *J Rehabil Med.* 2002 Sep;34(5):205-10. doi: 10.1080/165019702760279189. PMID: 12392234.
- 12 Pooja, Ghosh & Sangeeta, Lahiri. (2013). Prevalence and aetiology of amputation in Kolkata, India: A retrospective analysis. *Hong Kong Physiotherapy Journal.* 31. 36–40. 10.1016/j.hkpj.2012.12.002.
- 13 Sharma, Rahul. (2012). Kuppuswamy's Socioeconomic Status Scale – Revision for 2011 and Formula for Real-Time Updating. *Indian journal of pediatrics.* 79. 961-2. 10.1007/s12098-011-0679-3.
- 14 Sansam K, Neumann V, O'Connor R, Bhakta B. Predicting walking ability following lower limb amputation: a systematic review of the literature. *J Rehabil Med.* 2009 Jul;41(8):593-603. doi: 10.2340/16501977-0393. PMID: 19565152.
- 15 Dudek NL, Marks MB, Marshall SC, Chardon JP. Dermatologic conditions associated with use of a lower-extremity prosthesis. *Arch Phys Med Rehabil.* 2005 Apr;86(4):659-63. doi: 10.1016/j.apmr.2004.09.003. PMID: 15827914.
- 16 Miller WC, Speechley M, Deathe AB. Balance confidence among people with lower-limb amputations. *Phys Ther.* 2002 Sep;82(9):856-65. PMID: 12201800.
- 17 Nellie Njambi Mugo. The effects of amputation on body image and well-being - a systematic literature review. Theseus. 2010.
- 18 Burger H, Marincek C. The life style of young persons after lower limb amputation caused by injury. *Prosthet Orthot Int.* 1997 Apr;21(1):35-9. doi: 10.3109/03093649709164528. PMID: 9141124.