Institution: University of Hull

Unit of Assessment: C26: Sport and Exercise Sciences, Leisure and Tourism

Title of case study: Improving functional performance, prosthetic rehabilitation and falls prevention in transtibial amputees.

1. Summary of the impact

Lower-limb amputation (LLA) is associated with significant mobility, quality-of-life (QoL) and socioeconomic burdens. Research undertaken at the University of Hull relates to the early rehabilitation of amputees and their risk of falling. The research has influenced practice nationally and internationally by prompting clinicians to use these evidence-based recommendations for muscle strengthening and balance training and has informed policy at national levels. It inspired the *British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)*, to implement standardised recommendations in the *BACPAR Toolbox of Outcome Measures* in prosthetic rehabilitation. The findings of the Hull Early walking aid for rehabilitation of transtibial Amputees - Randomised controlled Trial (*HEART)* study, the first RCT comparing the biomechanics and clinical outcomes of early gait re-training with different Early Walking Aids (EWA), has made a significant impact on current healthcare practice and guidelines.

2. Underpinning research

The underpinning research was undertaken in Hull from 2005-2011. The work derived from the collaborative efforts between Dr. Vanicek with local NHS clinicians and healthcare providers examining the biomechanical factors that distinguish transtibial amputee fallers from non-fallers and the biomechanics and QoL factors of early gait retaining with EWA. The projects were led by Dr. Vanicek, in collaboration with other staff from the University of Hull, including Prof. Remco Polman (Reader, 2004-2008), Prof. Lars McNaughton (Professor, 2003-2008), and Dr. Cleveland Barnett (Ph.D student, 2007-2010). External collaborators included regional Clinical Amputee physiotherapists (Amanda Hancock, Barbara Brown) and vascular surgical Consultants (Prof. Ian Chetter and Dr. Patrick Coughlin) from Hull and East Yorkshire NHS Hospitals Trust. Dr. Siobhan Strike (Roehampton University) was an external academic collaborator.

A first study, an audit of clinical practice, investigated how physiotherapists monitored falls and whether the use of outcome measures in amputee rehabilitation was standardised in England. Shortcomings were identified in that physiotherapists did not monitor falls incidence regularly among their patients and that there was no consensus on the use of outcome measures. Subsequently, Vanicek et al. (2009a) compared the gait patterns of recent amputee fallers against non-fallers during level walking to make evidence-based recommendations for improving falls prevention programmes in LLA. This research suggested that falls prevention and prosthetic rehabilitation programmes should focus on targeting specific musculature of the prosthetic and intact limbs to improve stability and progression, particularly during weight transfer on to prosthetic single support. Vanicek et al. (2010) also identified biomechanical differences in amputee fallers and non-fallers during stair ascent, a more challenging task with greater falls risk than level walking. The findings suggested the non-fallers performed mechanically demanding tasks more cautiously. This group (2009b) were also the first to measure postural responses to dynamic perturbations objectively in amputee fallers compared to non-fallers utilising computerised dynamic posturography (Neurocom Equitest). The findings revealed the Sensory Organization Test and Motor Control Test protocols of the Equitest may be population-specific and are not suitable diagnostic tests for reliably identifying fallers from non-fallers in LLA.

Early walking aids (EWAs) are generic prosthetic devices that are routinely used as part of amputee rehabilitation for early mobilisation and gait re-education. In the UK, the two most popular EWAs include the pneumatic post-amputation mobility aid (PPAM) and the articulated amputee mobility aid (AMA). The latter, allows movement at the knee (in contrast to the rigid construct of PPAM) and thus mimics a more natural walking pattern during early rehabilitation. Previous studies had only evaluated these EWA individually. The group conceived and undertook the *HEART* study. This was the first RCT comparing amputees with different EWA during early rehabilitation (namely the PPAM compared to AMA). Mazari et al. (2010) were the first and only to demonstrate clearly that there were no differences between articulated and non-articulated EWAs for clinical and QoL outcomes in transtibial amputees. Barnett et al. (2009) reported independently the kinematic gait

patterns of amputees walking with the EWA. Despite different gait patterns with the EWAs during early mobilisation, the most significant gait adaptations occurred following receipt of a functional prosthesis. Thus, amputee physiotherapists were providing patients with the same level of long term care and clinical outcomes irrespective of which EWA was available to them and their patients.

3. References to the research

1. Vanicek N, Strike S, McNaughton L, Polman R. Gait patterns in transtibial amputee fallers vs. non-fallers: biomechanical differences during level walking. Gait and Posture 2009a; 29: 415-20. http://dx.doi.org/ 10.1016/j.gaitpost.2008.10.062. (Journal Impact Factor [JIF] 1.96)

2. Vanicek N, Strike S, McNaughton L, Polman R. Postural responses to dynamic perturbations in amputee fallers vs. non-fallers: a comparative study with able-bodied subjects. Archives of Physical Medicine & Rehabilitation 2009b; 90: 1018-1025. http://dx.doi.org/10.1016/j.apmr.2008.12.024. (JIF 2.358)

3. Vanicek N, Strike S, McNaughton L, Polman R. Lower limb kinematic and kinetic differences between transtibial amputee fallers and non-fallers. *Prosthetics and Orthotics International* 2010; 34: 399-410. http://dx.doi.org/10.3109/03093646.2010.480964. (JIF 0.62)

4. Barnett C, Vanicek N, Polman R, Hancock A, Brown B, Smith L, Chetter I. Kinematic gait adaptations in unilateral transtibial amputees during rehabilitation. Prosthetics and Orthotics International 2009; 33: 141-53. http://dx.doi.org/10.1080/03093640902751762. (JIF 0.62)

5. Mazari FAK, Mockford KA, Barnett C, Khan JA, Brown B, Smith L, Polman R, Hancock A, Vanicek N, Chetter IC. Hull early walking aid for rehabilitation of transtibial Amputees - Randomised controlled Trial (HEART). The Journal of Vascular Surgery 2010; 52: 1564-1571. http://dx.doi.org/10.1016/j.jvs.2010.07.006. (JIF 2.8)

6. **Successful grants (only amputee rehabilitation-specific grant awarded in the UK)**

2010 Co-Investigator (£3,000) Circulation Foundation, Owen Shaw Award Title: The e*ffects of gaming console use on balance performance and falls in amputees;* Investigators: Barnett C, Vanicek N, Polman R.

2009 Principal Investigator (£3,000) Circulation Foundation, Owen Shaw Award *Title: The use of outcome measures in outpatient amputee rehabilitation in the UK;* Investigators: Vanicek N, Polman R, Hancock A.

2008 Co-Investigator (£3,000) Circulation Foundation, Owen Shaw Award *Title: Gait and balance in new unilateral transtibial amputees;* Investigators: Barnett C, Vanicek N, Polman R.

2006 Principal Investigator (£3,000) Circulation Foundation, Owen Shaw Award *Title: Biomechanical performance in the sit-to-stand as a predictor for falling in transtibial amputees;* Investigators: Vanicek N, Strike S, Polman R.

2005 Co-Investigator (£8,000) Circulation Foundation, Owen Shaw Award and Hull & East Yorkshire NHS Trust *Title: Early walking aids for transtibial amputees - does an articulated knee have benefits;* Investigators: Hancock A, Brown B, Polman R, Vanicek N, Chetter IC.

4. Details of the impact The underlying aim of the research was to provide evidence-based recommendations to improve clinical standards and patient care whilst reducing falls in amputees and improving patient well-being. The knowledge gained through biomechanical analysis has been used nationally and internationally to inform and design appropriate and targeted exercise intervention strategies aimed at attenuating the loss of musculoskeletal function and reducing falls in lower limb amputees. The published works described above have had a significant clinical impact on amputee physiotherapy treatment and the revision of existing healthcare guidelines and policies related to lower limb amputees in the UK and more recently internationally in Australia (sources 1-10).

The 2008 audit findings revealed that 79% of lead physiotherapists within the main Disablement Services Centre across the UK used some form of outcome measure in amputee rehabilitation. However, there were no standardised procedures in place on frequency and the specific outcome measures (generic compared to population-specific) utilised. Moreover, only 7% of

physiotherapists audited monitored falls formally. These data were disseminated by invitation to the 2009 BACPAR annual conference (source no.1) having been published previously in their professional journal (source no.2). Recommendations made to standardise the use of clinical outcome measures resulted in the *BACPAR Toolbox of Outcome Measures* (2010), implemented by physiotherapists nationally (source no.3). Following on from the work done by Vanicek and colleagues (2008), more recent independent research has examined the current use of outcome measures by amputee physiotherapists, occupational therapists and prosthetists (Queen Margaret University, unpublished doctoral research, 2012). The investigator comments (source no.4) that this study revealed that all healthcare professionals surveyed were routinely using outcome measures in their clinical practice.

This higher survey value indicates that healthcare practitioners are now more aware of the relevance of outcome measures in monitoring patient progress and evaluating successful treatment. BACPAR acknowledge the contribution of Dr. Vanicek to the working group and are committed in updating the present *Toolbox of Outcome Measures* (2010) to reflect current and best practice (source no.5). Subsequent invited presentations by Dr. Vanicek to the Australian Physiotherapists in Amputee Rehabilitation (AustPAR), in September 2012 and June 2013, have further disseminated recommendations on the standardisation of outcome measures in clinical practice (source no.6). Head Physiotherapist at Port Kembla, NSW, Australia (source no.7), reports:

> *"Objective clinical outcome measures of walking velocity, Timed Up and Go, AMPPRO, two minute walk distance and the four square step test have become routine at our Rehabilitation Hospital. The feedback to the patients on their weight bearing progress, and speed has encouraged each new patient to progress a little more each day. I feel a great sense of accomplishment as each patient fulfils their goal of domestic or community ambulation with their prosthesis. Research in this area is vital to clinicians who in turn have a direct impact on each new amputee."*

Several published outputs (Vanicek et al. 2009a; Vanicek et al. 2009b; Vanicek et al. 2010; Barnett et al. 2009) make specific recommendations for targeted exercises strengthening specific lower limb musculature and joints during weight-transfer tasks for falls prevention. These research findings have significantly changed physiotherapy practice in the UK and internationally, by prompting clinicians to develop patient-specific falls prevention goals. Head of Physiotherapy in Port Kembla, NSW, Australia (source 7), states:

> *"Australian Physiotherapy in Amputee Rehabilitation (AustPAR) has progressed with Dr. Vanicek's research findings in regard to training balance control. The early use of mobility aids as temporary /interim prostheses has provided the modifiable prosthesis while the stump matures (Barnett et al, 2009)... The reported significance of hip and ankle strategies for balance control (Vanicek et al., 2009b) has changed my practice to devote more patient practice to hip extension exercise with the patient in late stance, and more eccentric lower limb exercises in preparation for recovery for a misstep (Vanicek et al., 2009a). My patients have found that strengthening and partial weight-bearing practice has prepared them for the whole gait practice and helped them to develop much more trust in the prosthesis".*

Additional impact of the underpinning research is reflected in the recently updated (2012) *Evidence Based Clinical Guidelines for the Managements of Adults with Lower Limb Prostheses*, by the Chartered Society of Physiotherapy, which makes specific reference to the work of the group within their guidelines on prosthetic rehabilitation programming (source no.9). Citing Barnett et al. (2009), together with other papers, new Guideline 4.4 (page 22) states;

- **The physiotherapist should prescribe a personalised exercise programme incorporating specific muscle strengthening and stretching exercises and maintaining/ improving joint mobility as part of the prosthetic rehabilitation programme**.

Several of the published outputs (Vanicek et al. 2009a; Vanicek et al. 2009; Vanicek et al. 2010; Barnett et al. 2009) have also informed guidelines on amputee rehabilitation programme design, including the appropriate selection of early walking aid according to the patient's abilities and the

centre's facilities as well as exercise prescription according to the patient's rehabilitation goals. Regional amputee specialists (Hull and East Yorkshire NHS Hospitals Trust (source no.8) state;

"The research has provided physiotherapists with specific evidence to guide practice to maximise the clinical impact of treatment programmes. This has informed National guidelines and provided new evidence to inform best practice".

The early impact of the published outputs from the group relating to the *Hull Early walking aid for rehabilitation of transtibial Amputees* (HEART) study have ongoing implications for sustainable and best clinical practice. Within the Table of papers referenced within Appendix 8 of the updated guidelines (2012), the following are stated:

- **Gait adaptations occurred once prostheses received. Different adaptations caused by PPAM-aid & AMA but walking performance and walking ability improved once prosthesis used.**
- **Study didn't show clear benefit of either EWA on gait patterns with prostheses but did mention documented benefits of accelerated healing and reduced time to casting from surgery using EWAs**.

The tabular summary also notes; **Transtibial amputees may benefit from additional exercises to increase muscle length & strength and joint mobility of lower limb** (source no.9). Consultant Vascular Surgeon and Clinical Director for Vascular Services at Hull & East Yorkshire NHS Hospital Trust (source no.10) comments:

> "*The economic implications of these research findings are clinically meaningful. EWAs are used extensively and routinely in all post-amputation rehabilitation programmes. It is now evident there is no significant clinical or quality of life advantage of using the more expensive AMA. Therefore, the AMA can be reserved for situations where the PPAM is unsuitable or unavailable without affecting a patient's treatment adversely. Healthcare providers can be confident they are delivering the same standard of care despite using a more economical alternative to the AMA*".

5. Sources to corroborate the impact

1. Invited Presentation by Dr. Vanicek. British Association of Chartered Physiotherapists in Amputee Rehabilitation. Annual Conference (2009), UK. Use of outcome measures in amputee rehabilitation in the UK.
2. Vanicek N, Strike S, McNaughton L, Polman R. The use of outcome measures in outpatient amputee rehabilitation in England. British Association of Chartered Physiotherapists in Amputee Rehabilitation (2008); 29: 13-19. Professional journal of BACPAR.
3. BACPAR Toolbox of Outcome Measures (Aitken K, Cole MJ, Cumming J, Donovan–Hall M (2010) BACPAR's Toolbox of Outcome Measures,Version1.
4. Unpublished doctoral research, 2012 Queen Margaret University, UK.
5. Clinical Specialist Physiotherapist, Chair of the British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR). The Royal Wolverhampton NHS Trust.
6. Invited Presentation by Dr. Natalie Vanicek. Australian Physiotherapists in Amputee Rehabilitation (AustPAR) in September 2012 and June 2013.
7. Physiotherapy Head, Port Kembla Hospital, PO Box 21, Warrawong, NSW 2502, Australia.
8. Clinical lead Physiotherapists: Amputee Rehabilitation and Clinical Manager Physiotherapy Inpatients. Department of Physiotherapy, Hull and East Yorkshire Hospitals NHS Trust.
9. Broomhead P, Clark K, Dawes D, Hale C, Lambert A, Quinlivan D, Randell T, Shepherd R, Withpetersen J. (2012) Evidence Based Clinical Guidelines for the Managements of Adults with Lower Limb Prostheses, 2nd Edition. Chartered Society of Physiotherapy: London.
10. Consultant Vascular Surgeon and Clinical Director of Vascular Services, Hull & East Yorkshire NHS Trust, UK.