Institution: Nottingham Trent University (NTU)		
Unit of Assessment: C24 – Sport and Exercise Sciences, Leisure and Tourism		
Title of case study: Enhancing mobility in lower limb prosthesis users: economic and clinical impact from better access to advanced prosthetic devices.		
Period when the underpinning research was undertaken: 2016 – 31 December 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Names:	**Roles:**	**Periods employed by submitting HEI:**
Dr. Cleveland T. Barnett	Senior Lecturer	2010-present
Dr. Maria Bisele	Lecturer	2018-present
Mr. Liam Hughes	Academic Associate	2019-present
Period when the claimed impact occurred: 2018 – 31 December 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

The number of people worldwide with limb loss is increasing, with over 1.6 million in the US alone and 185,000 amputations every year. NTU research on advanced prosthetic hydraulic ankles and microprocessor-controlled knee devices demonstrated improved patient mobility and quality of life. NTU research impacts have increased sales of Blatchford Ltd's hydraulic ankle devices, including making it the preferred [text removed for publication] prescription option, and changed clinical practice improving patient's clinical outcomes. Blatchford Ltd have used NTU's research outcomes as research evidence for Medical Device Regulation compliance requirements, in white papers used for product promotion, sales and marketing, and tendering for clinical contracts, and in training at clinical sites in 52 countries.

2. Underpinning research

Incidence of limb loss worldwide is increasing. The 1.6 million people living with limb loss in the United States in 2008 was predicted to double by 2050. In the UK, the leading causes of amputation occurring in adults over 50 years are diabetes and/or peripheral vascular disease. Therefore, most new referrals to prosthetics centres (6,000 annually in the UK) involve older patients with health comorbidities. Although prosthetic device prescription is a key determinant of an individual's long-term health outlook and quality of life, they typically receive functionally basic prosthetic devices. Research is lacking relating to the efficacy of advanced prosthetic devices that have the potential to improve mobility and quality of life in prosthesis users. This prevents the widespread provision of more advanced devices, as awareness and prescription of these devices must be based upon their clinical efficacy. To address this issue, Barnett (from NTU's Exercise and Health Research Group, in our *Sport, Health and Performance Enhancement Research Centre*) has led work with Blatchford, a multi-award winning, world-leading prosthetic device manufacturer, since 2016. The research underpinning this case study has been supported with significant in-kind contributions from Blatchford (£80,495 to date) and has been conducted in collaboration with NHS Trusts and both academic and commercial colleagues.

Blatchford supported (staff time, prosthetic devices) an NTU-led cohort study which was the first in the world to quantitatively establish mobility improvements when using hydraulic ankle devices in transtibial prosthesis users with lower activity levels (**R1**). Participants walked further during clinical walking tests, with a more even distribution of limb loading and improved gait progression, when using a hydraulic ankle device compared to using a routinely prescribed rigid non-articulating device. This impact on patient mobility is highly significant given any improvement in mobility leading to increased quality of life is positive in a patient group with low mobility levels and associated health issues. These results confirmed findings from an earlier study, which showed that a prosthetic device's mechanical function consistently has a meaningful impact on gait (**R2**). This meant that clinicians could make effective decisions regarding prosthetic prescription based on a gait evaluation from a single session.

Further funded patient surveys and public consultation was conducted to shape the research programme and increase the magnitude of patient impact (**G1**). This led to a multi-centre randomised feasibility trial called STEPFORWARD, funded by the National Institute for Health

Research (**R3**, **G2**). Led by Hull University Teaching Hospitals NHS Trust, it involved four universities and three NHS Trusts; Barnett was a co-investigator, a member of the Nottingham site research team and Trial Management Group member. Advanced prosthetic devices such as hydraulic ankles and microprocessor-controlled knee devices are available within some healthcare systems internationally. Despite demonstrating the positive impact of hydraulic ankles on mobility (**R1**, **R2**) there was still a need to demonstrate their effectiveness and cost effectiveness vs. the standard basic devices routinely prescribed, in order for them to become part of standard care. For the trial, 55 participants were randomised across five sites. Whilst in the intervention (hydraulic ankle) group, quality of life scores increased, quality of life scores remained the same in the control group. Walking distances in the two-minute test increased by 7.8 m in the intervention group, compared with a *decrease* of 10.8m in the control group, and sedentary time decreased by 114 minutes in the intervention group compared with a smaller decrease of 34 minutes in the control group. A key outcome was that the study procedures proved feasible and acceptable to both participants and professionals delivering the study.

The success of the aforementioned projects related to hydraulic ankle provision in people with transtibial limb loss, convinced Blatchford to support further research in-kind at NTU (**G3**) focussing on transfemoral prosthesis users. An initial case study led by the University of Salzburg, in which NTU's Barnett was a co-investigator, was the first to demonstrate that during slope walking, intact limb hip joint loading was reduced when using a hydraulic ankle device in combination with a microprocessor-controlled knee, compared to a non-articulating ankle device (**R4**). This is significant as the hip and lower back are common sites of pain, discomfort and osteoarthritis for transfemoral prosthesis users. A full scale investigation, led by Barnett, into the effects of prosthetic knee and ankle component combination use on the function and performance in transfemoral prosthesis users, demonstrated that the combination of a hydraulic ankle and microprocessor-controlled knee, resulted in improved mobility during clinical mobility tests, when compared to less advanced combinations of prosthetic devices (**R5**). Beyond demonstrating improving patient mobility and well-being, NTU's research is highly relevant for countries with insurance-based healthcare systems such as the USA. There, clinical evidence informs the eligibility of claimants for more advanced prosthetic devices. Without these demonstrable benefits, these claims may be denied.

3. References to the research

Underpinning research quality evidenced by rigorously externally peer reviewed outputs:

R1. Barnett, C. T., Brown, O., Bisele, M., Brown, M. J., De Asha, A. R., and Strutzenberger, G. (2018). Unilateral trans-tibial amputees with lower activity levels walk more quickly when using a hydraulically articulating versus rigidly attached ankle-foot device. *Journal of Prosthetics and Orthotics*, **30(3)**, 158-164. http://doi.org/10.1097/JPO.0000000000000179

R2. De Asha, A. R., Barnett, C. T., Struckov, V. and Buckley, J. G. (2017). Which prosthetic foot to prescribe? Biomechanical differences found during a single session comparison of different foot types hold true one year later. *Journal of Prosthetics and Orthotics*, **29(1)**, 39-43. http://doi.org/10.1097/JPO.0000000000000119

R3. Mitchell, N.,Vanicek, N., Coleman, E., Watson, J., Bell, K., McDaid, C., Barnett, C. T. and Twiste, M. (2019). Self-aligning prosthetic device for older patients with vascular-related amputations: protocol for a randomised feasibility study (the STEPFORWARD study). *BMJ Open*, **9**, e032924. http://doi.org/10.1136/bmjopen-2019-032924

R4. Alexander, N., Strutzenberger, G., Kroell, J., Barnett, C. T., and Schwameder, H. (2018). Joint moments during downhill and uphill walking of a transfemoral amputee with a hydraulic articulating and a rigid prosthetic ankle - A case study. *Journal of Prosthetics and Orthotics*, **30(1)**, 46-54. http://doi.org/10.1097/JPO.0000000000000171

R5. Barnett, C. T., Sullivan, A. E., Hughes, L., Strutzenberger, G., Bisele, M. and A., R. De Asha. (2019). Does Prosthetic Componentry Affect Toe Clearance, Gait Stability and Inverted Pendulum Model Adherence In Unilateral Transfemoral Prosthesis Users? *Prosthetics and Orthotics International*, **43 (1)**, Supplement pp371. https://doi.org/10.1177/0309364619883197

The high quality of the underpinning research is further indicated by the following commercial and competitive peer reviewed public funding investment in the research and its dissemination:

G1. £500 grant received from the National Institute for Health Research to support patient and public involvement aimed at developing the *STEPFORWARD* trial and project.
G2. Title: "Patient acceptability of a novel prosthetic device: A randomised feasibility study in older patients with vascular-related amputations and multimorbidities", and associated *STEPFORWARD* trial; Funder: National Institute for Health Research; Programme: Research for Patient Benefit; Award ID: PB-PG-0816-20029; Total award value: £248,894.00; Dates: 01/04/2018 to 31/03/2020. Awardees Prof Natalie Vanicek, Dr Abayomi Salawu, Dr Catriona McDaid, Dr Cleveland Barnett, Dr Fergus Jepson, Dr Judith Watson, Dr Kerry Bell, Dr Martin Twiste, Dr Natasha Mitchell, Ms Susan Brisco.
G3. Recognising the value of evidenced-based research demonstrating the clinical efficacy of one of its medical devices, Blatchford Ltd has provided £80,495 in in-kind contributions (clinician time and componentry) during the impact period to support Barnett's research.

4. Details of the impact

Prior to studies led by and involving Barnett at NTU, there was limited evidence of the clinical efficacy and cost-effectiveness of advanced, self-aligning hydraulic ankle devices, compared with the basic standard devices routinely prescribed to transtibial prosthesis users with lower activity levels. The benefits of combining a hydraulic ankle device with a microprocessor-controlled knee device were also undocumented. Barnett's studies have increased provision of these advanced devices for the improvement of mobility in lower limb prosthesis users, leading to commercial benefits for prosthetics manufacturers and distributors, changes to clinicians' prescribing practices and increased patient satisfaction.

Economic impacts via improved commercial performance of a world-leading prosthetics manufacturer and across the wider industry.

Blatchford Ltd is a world-leading international prosthetic device designer, manufacturer and rehabilitation provider. Headquartered in the UK where its manufacturing operation is based, the company has nine office locations around the world including Russia, US and India. The self-aligning hydraulic ankle device used in Barnett's studies was the Avalon^{K2}, a commercially available ankle device manufactured by Blatchford, who also own the trademark and patent rights. The outcomes of the clinical studies at NTU (**G3**) have directly resulted in the commercial impacts benefiting Blatchford detailed below, including: ensuring its marketing strategy is based on peer-reviewed scientific evidence, increasing sales revenues and enabling the company to comply with stricter medical device regulations governing one of its largest markets (**S1**).

***Marketing strategy impacts*:** Blatchford's director of research and technology wrote: '*We take an evidence-based approach to product promotion and place science at the core of all our activities. Dr Barnett's work has helped us maintain that strategy in several important areas*' (**S1**). The research related to the hydraulic ankle devices (**R1**, **R2**) has been cited in six key documents produced by Blatchford to market its products, such as the Avalon^{K2} hydraulic ankle device and communicate the evidence underpinning their efficacy. For example, in November 2018 '*a white paper titled, "A Study of AvalonK2 ", of which Dr. Barnett's research constituted a key part, was downloaded 400 unique times in its first year. It has been extremely well received*' (**S1**). This paper outlined the benefits of hydraulic ankle devices for prosthesis users with lower activity levels, including Barnett's conclusions around increased walking speed (**S1**, **S2**). Research papers (**R1**, **R2**) were also cited in Blatchford's 2020 White Paper looking at the clinical benefits of hydraulic ankle devices more widely; one paper (**R1**) was cited in the company's product brochure for Avalon^{K2}; other papers (**R1**, **R2**, **R4)** were cited in Blatchford's 'clinical compendium' for hydraulic ankle-foot products (**S3**). Dr Barnett's research used in commercial documentation has helped "*provide a key part of the training and education of [the company's] staff both at the company's UK headquarters and distributors around the world*" (**S1**).

***Contract awards and increased sales revenues impacts*:** Barnett's research has led directly to an increase in Blatchford's sales revenues from its hydraulic ankle products, '*The research conducted by Dr. Barnett and its wide-reaching impact, has almost certainly led to an increase in*

the sales of our hydraulic ankle products' (**S1**). Specific examples are provided [text removed for publication].

***Regulatory compliance impacts*:** New EU Regulations for Medical Devices came into force in May 2017, imposing stricter requirements for the provision of clinical evidence to demonstrate user benefits. Implementation was planned for May 2020 but was delayed a year due to the onset of the COVID-19 pandemic. To meet the May deadline, Blatchford submitted Clinical Evaluation Reports for the Avalon^{K2} for which Barnett's research (**R1**, **R2**, **R4**) was a key source. Blatchford described Barnett's research contribution as '*of extremely high importance in the R&D department, as it is used as part of the clinical evidence in the Clinical Evaluation Reports*', a requirement for ensuring Medical Device Regulations compliance and thus enabling the company to continue accessing one of its important markets and maintain its global-leading position (**S1**).

Clinical impact via improvement to evidence-based professional development and changes to clinicians' prescription practices.

Impacts on professional development and training: Blatchford is a supplier of clinical services, such as rehabilitation and prosthetic provision, to national health services, the military and private sector providers and, as such, clinical education is a key component of its business model. For example, they provide 400,000 appointments annually at 23 NHS prosthetic clinics and five private clinics across the UK alone. Their Principal Prosthetist and Commercial Manager referred to papers (**R1**, **R2**, **R3**, **R5**) and commented, '*I have engaged with Dr. Barnett's research through such direct contact as well as journal publications and the conference presentations*' (**S4**), and followed with, '*I have used the research as a key part of the training and education I provide to our staff both at our UK headquarters and clinical sites in 52 countries around the world. For example, I have used the research and commercial documentation to train prosthetists in the fitting and adjustment of prostheses and to solve complex clinical cases. I have recently conducted four webinar series on these components (May 2020) that was attended by 309 people from 35 countries, including Argentina, Australia, Germany, India, Israel, Portugal, South Africa and Singapore*' (**S4**).

***Impacts on changes to clinicians' prescription practices*:** Barnett's research has informed clinicians' decision-making relating to prosthetic devices and changed their prescribing practices. One prosthetist (**S5**), who is responsible for fitting patients with new prosthetic legs and sees around 100 patients with lower limb amputation wrote that (specifically referring to) Barnett's research *'has resulted in me changing my clinical practices and I supply more hydraulic ankles to my patients*' and added that these changes '*have also benefitted my patients' clinical outcomes in terms of mobility and quality of life*.' The clinical lead for an NHS prosthetic clinic at Luton and Dunstable Hospital, with around 800 patients, said (specifically referring to) Barnett's research '*has resulted in me altering the centre prescription guidelines*' which has '*led to the prescription of more hydraulic ankles*', adding that '*these changes in my clinical practice have also benefitted my patients' clinical outcomes in terms of mobility and quality of life*' (**S6**). [text removed for publication]. Blatchford confirmed the global clinical impact of the research: '*Dr. Barnett's work is influencing prescription of devices throughout the world enabling access to more advanced technologies for lower activity amputees* (**S1**).'

Improved trial patient satisfaction, mobility and health outcomes.

This Avalon^{K2} device was also used in the NIHR project (**G2**) and associated *STEPFORWARD* trial, for which "*Blatchford and Sons have had no part in the study design, nor are they involved directly in the research, its subsequent analysis and ultimate dissemination*" (**S3**) in order to maintain the independence of the trial. Results from NTU's research contributions to the *STEPFORWARD* trial have demonstrated that more advanced prosthetic devices lead to better outcomes for patients (**S8**). Twenty-seven patients benefitted from using the self-aligning ankle device for the *STEPFORWARD* trial and all of them decided to keep the prosthesis at the end of it, indicating that they preferred it to a standard device and that it enhanced their ability to move around and their quality of life (**S8**). According to the final report submitted to the NIHR (**S8**): '*Some participants described how they felt more mobile in terms of using stairs, the ease of going on slopes, and walking on different surfaces. The transformation was sometimes immediate. Participants acknowledged that they still needed to be careful, but they felt overwhelmingly more*

confident when moving around.' This was corroborated by statements from the study participants themselves. On being provided with the new ankle device, one participant said *'You felt the difference as soon as they put the foot on and I stood up and walked. There was just no pressure in the knee, none in the hip and no pain at all…it was a lot better walking. It's more comfortable'* (**S9**). Another participant noted *'I'm not walking stiff. I'm walking like a normal person now'* with a further participant stating, *'I don't know what the price difference is but this (new ankle) is so much better and if you were learning to walk on one, this would be so much better to learn to walk on one'* (**S9**). The ankle device also became integral parts of people's lives, with a study participant exclaiming '*you can't have this (new ankle) leg back!*' (**S9**). One comment from a *STEPFOWARD* trial participant reflects the large personal impact the research has on the individual *'It's really changed my life doing the study and made it all better'* (**S9**).

5. Sources to corroborate the impact

* participant in the process of impact delivery

S1.* Testimonial letter: Director of Research and Technology, Blatchford Ltd, UK

S2. Web-link: "A Study of Avalon^{K2}", https://www.blatchford.co.uk/wp-content/uploads/2018/11/203266159-Avalon-K2-White-Paper-Iss1-AW-Web-Pages.pdf, White Paper, Nov 2018, Blatchford Products Ltd, UK. Section 'Increased Walking Speed'.

S3. Web-links: Documents published by Blatchford Products Ltd that cite NTU research:
https://www.blatchford.co.uk/wp-content/uploads/2020/02/435972449-Hydraulic-Ankle-White-Paper-Iss1-AW-Web-Pages.pdf Hydraulic Ankle White Paper;
https://www.blatchfordus.com/wp-content/uploads/2019/08/435968939-Hydraulic-Ankle-Clinical-Compendium-US-Iss2-AW-Int.pdf Hydraulic Ankle-Foot Clinical Compendium;
https://www.blatchford.co.uk/catalogue/feet/avalonk2/flyer/203266111%20Avalon%20Product%20Brochure%20Iss1%20AW%20Web%20Pages.pdf Avalon^{K2} brochure;
https://www.blatchford.co.uk/wp-content/uploads/2019/08/229451231-Orion3-End-User-Handout-Iss1-AW-Web-Pages.pdf Orion3 microprocessor knee end user guide;
https://www.blatchford.co.uk/wp-content/uploads/2020/02/335469244-Residual-Limb-White-Paper-Iss2-AW-Web-Pages.pdf Residual Limb Health White Paper.

S4. Testimonial letter: [text removed for publication]

S5. Testimonial letter: Clinic Manager/Clinical specialist, Proactive Prosthetics Ltd, UK

S6. Testimonial letter: Clinical Lead and Contract Manager, Luton and Dunstable Hospital, UK

S7. Testimonial e-mail: [text removed for publication].

S8.* Confidential report: Final report, *STEPFORWARD* trial and NIHR grant PB-PG-0816-20029

S9.* Confidential report: Summary report of qualitative feedback from patient users of the self-aligning ankle device, *STEPFORWARD* trial and NIHR grant PB-PG-0816-20029