Institution: Staffordshire University		
Unit of Assessment: UoA-12 Engineering		
Title of case study: Reducing the burden of Diabetic Foot disease by utilising biomechanical knowledge for evidence-based foot assessment and insole prescription		
Period when the underpinning research was undertaken: 1 Aug 2013 – 31 Mar 2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name:	**Roles:**	**Period employed by submitting HEI:**
Roozbeh Naemi	Professor in Biomechanics	2009-present
Panagiotis Chatzistergos	Associate Professor	2012-present
Aoife Healy	Associate Professor	2009-present
Nachiappan Chockalingam	Professor of Clinical Biomechanics	1998-present
Period when the claimed impact occurred: 1 Jan 2014- 31 Dec 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Research at the Centre for Biomechanics and Rehabilitation Technologies (CBRT) has focused on preventing and treating diabetic foot ulcers. The research has produced impact with new biomechanical assessment protocols for at-risk patients and with new technologies for prescribing biomechanically informed insoles. Impacts include:

New clinical practice: Contributed expertise to establish foot-specific labs at AR Hospitals (India) and Koç University Hospital (Turkey). Implemented new patient assessment protocols and achieved improved patient outcomes at AR Hospitals, Koç University Hospital, Hospital Militar Geriatrico (Peru), and Abbas Medical Centre (Tanzania).

New prescription technologies: Improved, individualised, insole manufacturing at Technofootbed (Spain), Cadscan (UK), and Podiatry Foot Clinic (Malta). Achieved cost savings and improved financial positions for these organisations.

2. Underpinning research

Diabetic foot ulcers are the world's most common cause of lower-limb amputations. They lead to around one million amputations annually worldwide. Between 19% and 34% of people with diabetes develop foot ulcers, and these ulcers increase the risk of death after 5 years to 70%. This risk is 2.5 times the risk of death for a non-ulcerous patient with diabetes. CBRT research focused on new ways to address these problems. The tissue and biomechanical characteristics that make feet vulnerable to ulceration are not well understood. In addition, conventional insoles to protect the diabetic foot from mechanical trauma and ulcers are often prescribed without the clinician considering the individual differences in the way the weight is distributed on the sole of the foot. Seeking to improve treatment outcomes for patients, CBRT has worked with partners to secure almost GBP3,000,000 collaborative funding from the EU, Innovate-UK and the NHS to conduct the research.

Research into Diabetic Foot Assessment

CBRT researchers developed a new, unique approach to using ultrasound elastography to investigate the mechanical properties of the sole of the foot, including its stiffness and thickness. They established that softer heel pads are associated with foot ulceration in diabetic patients [**3.1**]. Further research at CBRT demonstrated that assessing the mechanical properties of an individual's sole of the foot can improve accuracy in predicting diabetic foot ulceration [**3.2**].
In places where healthcare resources are limited, such as many countries in Africa, where the prevalence of diabetic foot ulcers is high, assessing soft tissue mechanical properties is challenging due to difficulties in getting access to ultrasound elastography machines. To address this challenge, CBRT researchers conducted novel research and established a set of easily measurable parameters, which combine neurological and foot-specific biomechanical characteristics, to assess the risk of foot ulcers in diabetic patients. They found that clinically viable measurements related to the foot's neuromechanical aspects, including excessive forefoot load and impaired sensation to touch, can be used to assess the risk of foot ulceration in patients with diabetes [**3.3**].

Research into Diabetic Foot Insole Prescription

Insoles are used to reduce ulcer risk by easing pressure underneath the foot during walking. The systematic review conducted at CBRT revealed a need for an individual-specific approach to footwear prescription for preventing diabetic foot ulcers [**3.4**]. CBRT research pioneered a systematic approach to insole prescription using a computational method [**3.5**] and validated it using experimental analyses [**3.6**]. The approach uses the patient's weight to identify the insole stiffness that can best redistribute pressure underneath the foot. This knowledge has led to the development of the Customised Support Structure, which CBRT filed as a patent in December 2017 (Deformable Support Structure, PCT/ 5170/4243PGB). In collaboration with Cadscan Ltd, CBRT then developed an ultra-customisable insole for NHS use. This collaboration won GBP1,100,000 worth of funding (the University's share c. GBP160,000) from NHS England. Initial clinical studies have established the technology's efficacy in reducing diabetic foot ulceration risk.

3. References to the research

6 journal articles in peer reviewed journals.

3.1 Naemi, R., Chatzistergos, P., Sundar, L., Chockalingam, N., Ramachandran, A., 2016. Differences in the mechanical characteristics of plantar soft tissue between ulcerated and non-ulcerated foot. J. Diabetes Complications 30, 1293–1299. eprints.staffs.ac.uk/2424
3.2 Naemi, R., Chatzistergos, P., Suresh, S., Sundar, L., Chockalingam, N., Ramachandran, A., 2017. Can plantar soft tissue mechanics enhance prognosis of diabetic foot ulcer? Diabetes Res. Clin. Pract. 126, 182–191. eprints.staffs.ac.uk/3080
3.3 Naemi, R., Chockalingam, N., Lutale, J.K., Abbas, Z.G., 2019. Can a combination of lifestyle and clinical characteristics explain the presence of foot ulcer in patients with diabetes? J. Diabetes Complications 33, 437–444. eprints.staffs.ac.uk/5439
3.4 Healy, A., Naemi, R., Chockalingam, N., 2013. The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: A systematic review. J. Diabetes Complications 27, 391–400. eprints.staffs.ac.uk/1355
3.5 Chatzistergos, P.E., Naemi, R., Chockalingam, N., 2015. A method for subject-specific modelling and optimisation of the cushioning properties of insole materials used in diabetic footwear. Med. Eng. Phys. eprints.staffs.ac.uk/2400
3.6 Chatzistergos, P.E., Naemi, R., Healy, A., Gerth, P., Chockalingam, N., 2017. Subject Specific Optimisation of the Stiffness of Footwear Material for Maximum Plantar Pressure Reduction. Ann. Biomed. Eng. 45, 1929–1940. eprints.staffs.ac.uk/3066

Collaborative funding of GBP2,957,853 from 9 peer reviewed grants. Awards include EUR809,238 for DiabSmart (2011-2015) and EUR504,000 for STANDUP (2018-2021) from the European Commission; GBP961,859 for Automatic Creation (2016) and GBP99,785 for Low-Cost Insoles (2015) from SBRI; GBP164,130 for Low-cost in-shoe pressure measurement (2018-2019) and GBP150,191 for 3D perfusion mapping (2018-2019) from Innovate UK; GBP166,082 for ViscoTurf (2017-18) from Biomedical Catalyst; GPB149,222 for ViscoTurf Prevent (2020) from NIHR and GBP93,756 from Newton Institutional Links.

4. Details of the impact

The research has generated impact in two key areas:

- CBRT research into *Diabetic Foot Assessment* has directly benefitted a major hospital and its five satellite centres across India, the main Tanzanian diabetic foot clinic, and two major hospitals in Turkey and Peru. They adopted the biomechanically informed assessment protocols developed at CBRT, which led to an improved diagnosis of the foot at risk of diabetic ulcers. The hospitals' better understanding of diabetic foot ulceration risk factors has benefitted patients and improved clinical outcomes.
- CBRT research into *Diabetic Foot Insole Prescription* has benefitted a major Spanish manufacturer of diabetic footwear. This research has led to increased profits at one UK SME. The research has also led to an increase in the number of products, turnover, and profit for a company in Spain. It has lowered costs and improved patient outcomes in a Maltese foot clinic.

4. 1. Improving Diabetic Foot Assessment in Clinics

4. 1. 1. AR Hospitals (India)

Establishing a foot lab: As part of the 2011-2015 DiabSmart project, CBRT researchers were instrumental in establishing a foot lab at AR Hospitals in 2014. The Team established the lab's testing protocol and coordinated selecting appropriate biomechanical tools for purchase. The lab made comprehensive foot assessment possible for all patients [**5.1**].

New training: AR Hospitals has five satellite centres in India. There was a general lack of knowledge and experience of biomechanical risk factors for ulceration across these centres. AR Hospitals used CBRT research to provide these centres with new, targeted training. CBRT research that established biomechanical risk factors for ulceration [**3.1, 3.2, 3.3**] formed the basis of this training programme. The CEO of AR Hospitals describes the knowledge transfer process: *'The collaborative research which revealed the role of biomechanical risk factors in diabetic foot ulceration was used as the basis for the systematic training of 5 of our staff … The knowledge transfer which happened during the project and ongoing collaboration was then transferred to other staff (circa 80 practitioners) … This has influenced and provided awareness of the importance of biomechanics within the diabetic foot care provision across all AR Hospital satellite centres which have been treating circa 400 patients each day'* [**5.1**].

Changes to clinical practice: This training has enabled these centres to utilise biomechanical assessment in their day-to-day clinical practice. An AR Hospitals doctor confirms this improvement in clinical practice: '*research led by CBRT and conducted at our hospital bridged the gap between academic evidence and clinical practice. This has resulted in the assessment of the soft tissue at the sole of the foot to be incorporated in the assessment of the foot for our diabetic foot patients in the clinic*'. The changes in practice led to the establishment of a new role (headcount 1; FTE1) in AR Hospitals. The doctor reports: '*One of the key accomplishments of our collaboration was setting up a biomechanics lab in our hospital in 2014. A new foot technician position has been created, with the responsibility for assessing the biomechanical risk factors related to the diabetic foot for patients at each visit*' [**5.2**].

Improved outcomes: The development of a multidisciplinary team for the treatment of diabetic foot disease has improved the quality of practice and patient satisfaction [**5.2**]. The foot lab and training contributed to a more evidence-based approach to diabetic foot disease diagnosis. They generated measurable improvement in patient outcomes at AR Hospitals, '*Collectively, the engagement with CBRT has influenced a population size of 1,000,000 patients in the geographical area of Chennai of Tamil Nadu and the adjacent states of South India…this could be evidenced through a significant decrease in the number of ulcerations in patients under our care*' [**5.2**].

4. 1. 2. Hospital Militar Geriatrico (Peru)

New assessment protocols: The Hospital is a major centre for old-age care in Peru. The Day Hospital Unit team used the CBRT research to enhance their awareness of tissue mechanics in diagnosis of diabetes complications. The work extended the Day Hospital Unit team's understanding of the effect of diabetes on tissue glycation and, especially, diabetic foot assessment. Prior to their participation in our study, the Day Hospital Unit '*were not aware of the effect of diabetes on the soft tissue at the sole of the foot*' [**5.3**].

Improved patient outcomes: CBRT's ultrasound elastography methods allowed the Day Hospital Unit to provide more evidence-based assessment and to decrease over- and under-treatment of patients. The Hospital reports '*this has led to a stratified approach to assessment and care of diabetic foot in our hospital which have significantly improved our capacity for diagnosing and treatment of patients with diabetic foot disease*'. The collaboration with CBRT has led to significant improvement in health outcomes for diabetic patients, '…*all our diabetic patients (50 per week) now receive appropriate and related treatment of their feet according to their blood sugar level. This has shown to be effective in decreasing the over and under treatment of patients, and has led to significant saving in the resource at our hospital. We have seen 10% reduction in annual ulceration rate*' [**5.3**].

4. 1. 3. Abbas Medical Centre (Tanzania)

New assessment protocols: Abbas Medical Centre operates one of the main diabetic foot clinics in sub-Saharan Africa, a hub that provides training to healthcare workers in developing

countries in Africa and elsewhere. CBRT collaborative work with the Centre [**3.3**] has directly changed their diabetic foot assessment clinical practice. Where the clinic would previously assess many foot-related parameters, CBRT research led them to focus on specific parameters that are stronger indicators of the risk of diabetic foot ulceration. The Director of Abbas Medical Centre states '*this has resulted in saving an estimated 15 min of appointment time for each patient and … on average has changed from 60 min to 45 min*'. The Director estimates a 20% reduction in ulceration rates '*and significant decrease in the socioeconomic burden of the disease*' [**5.4**].

Financial sustainability from Improved patient outcomes: The changes have led to a priority appointment system for those at the highest risk of diabetic foot ulceration, which has resulted in '*optimised efficacy and savings in [Abbas Medical Centre] resources*', leading to both improved care and financial sustainability. As the Director reports, the research '*has been instrumental in achieving a new standard of care for our patients with diabetes. It has contributed to the present sustainability of our medical centre*' [**5.4**].

4. 1. 4. Koç University Hospital (Turkey)

New clinical protocols: In 2018 Naemi designed an audit of diabetic foot patient care at Koç University Hospital. The audit established a need to assess biomechanical factors in diagnosing and treating patients with diabetic foot complications. The Hospital implemented Naemi's recommendations in 2019. A Hospital practitioner, who sits on the Diabetic Foot and Wound Care Council in Istanbul, explains that Naemi's work was '*translated into our practice with the endocrine team members (7 physicians and 2 diabetes nurse) … being able to use clinically viable methods such as biomechanical assessment to assess the risk of ulceration. This team assesses over 20,000 patients per year. The changes have led to incorporating biomechanics into foot assessment routine at the diabetic foot clinic*'. The practitioner testifies that '*The collaboration with CBRT was pivotal to enhance my team's research capacity and build our competencies in the area of biomechanics*' [**5.5**].

New biomechanical assessment training: CBRT led research-based capacity-building activities to help implement the new protocols. The activities were focused on the role of biomechanics in reducing risk of mechanical trauma to the foot. They were delivered to 20 practitioners, nurses, and doctors who work in diabetic foot care [**5.5**].

A new foot biomechanics lab: In 2019, CBRT contributed consultancy and expert advice to set up a dedicated foot biomechanics lab at Koç University Hospital. The lab is equipped with gait analysis and pressure measurement systems for essential biomechanical and diabetic foot evaluation. The lab has significantly improved the capacity for diagnosing and treating patients with diabetic foot disease. '*Despite this being a basic setting, essential biomechanical and diabetic foot evaluation equipment are now used in this lab in our hospital. This has significantly improved our capacity for diagnosing and treatment of patients with diabetic foot disease*' [**5.5**].

Improved patient outcomes: The new protocols, training, and lab have enabled the Hospital's diabetes team to include range of motion, neuropathy, and foot posture checks into their regular daily clinical assessment. Hospital staff describe '*significant'* improvements in patient outcomes. The practitioner reports that the '*diabetes team now consider measures like range of motion, and neuropathy as well as assessment of foot posture into their regular daily clinical assessment, which has led to significant improvements in patient outcome*', and that '*Although the improvements were only implemented two years ago, we have already seen more … high-risk feet without developing ulcers in early stages which is important for diabetic foot ulcer prevention*' [**5.5**].

4. 2. Improving Diabetic Foot Insole Prescription

A further step after assessment of patients at risk is prescription of appropriate insoles to alleviate diabetic foot problems. Our work has provided this process with new resources:

4. 2. 1. Technofootbed (Spain)

Improved insole materials: In 2015 CBRT research into insole materials selection and weight offloading [**3.4**,**3.5**] led to the diabetic footwear manufacturer, Technofootbed, adopting a superior insole material (PU). PU is more durable and shows better cushioning properties than conventional diabetic sandal materials. Sandals with PU insoles last more than a year,

compared to conventional diabetic sandals' six-month lifespan. Technofootbed now manufactures PU insoles in a systematic, evidence-based way to ensure their suitability for individual diabetic patients. The CEO states that CBRT research '*has impacted and changed our practice by facilitating evidence-based manufacturing insoles*' **[5.6]**.

Company growth: CBRT research has supported Technofootbed's successful expansion of their product range. Since 2015, their collaborative developments with CBRT have created an increase of 50% in the number of their new footbed/insole products. These products have seen turn-over increase by EUR300,000. Since the completion of their knowledge transfer work with CBRT, Technofootbed has established a strong diabetic footwear market presence in the UK and in Europe, with a 10% rise in gross profit [**5.6**].

4. 2. 2. Cadscan (UK)

New 3D-print system for custom insoles: CBRT research into optimised 3D-printed insoles [**3.6**] led to a new IP patent application. These insoles assist the treatment of diabetic foot conditions by providing greater comfort and reduced walking pressure for diabetic patients. Since 2018, CBRT has worked with Cadscan, a UK SME, to introduce these insoles into NHS use. With Cadscan, CBRT has developed a manufacturing system to facilitate the automatic creation of these low-cost insoles that help prevent diabetic foot ulcers. For the first time, the system has allowed 3D manufacturing of fully compliant/soft insoles. Cadscan's CEO reports the collaboration with CBRT '*has acted as a catalyst leading to a change of direction for the business toward footwear products*' [**5.7**]. Cadscan now markets 3D-printed orthotics with the registered trademark 'Imprints' [**5.8**]. In 2019 the work enabled Cadscan to win an approximate GBP80,000 contract to supply 1,800 custom insoles to the NHS for use in a trial with diabetic patients in Cheshire and Merseyside [**5.7**].

Uptake in the NHS: Cadscan's CEO reports: '*The 3D printed insoles have been well received by the NHS as a result of their efficacy in reducing pressure underneath the foot during walking. There is currently a trial in progress to assess the effect of these 3D printed insoles in preventing diabetic foot ulceration in a real life setting. This trial involving community foot prevention services located in two CCG areas in Cheshire and Merseyside has shown positive early results*' and identifies that the work '*can lead to a reduction in the cost of insoles/orthotics by around 10 times per pair*' [**5.7**].

4. 2. 3. Podiatry Foot Clinic (Malta)

Improved outcomes: CBRT has collaborated with the Podiatry Foot Clinic to implement our 3D insole printing technology. The Clinic owner, who is also the Chair of the European Network for Podiatry Educators, reports '*we have started using 3D printed insoles within our clinical practice*' to treat people with diabetic foot conditions, leading to '*significant improvements in patient outcomes*' [**5.9**].

Cost savings for patients and service providers: The Clinic owner reports the technology can mitigate cost concerns. '*Within some of our clinical work*', he writes, '*we have adopted 3D printed insoles that are more economically viable due to being low cost. The cost of these 3D printed insoles is very low at approximately EUR 50 for two pairs. This is much less expensive compared to the more complex orthotics costing circa EUR 200 each.'* He acknowledges the impact as on-going, with a *'significant cost saving for our health services and the patients'* [**5.9**].

5. Sources to corroborate the impact

5.1 Testimonial: Founder and Chair of Dr A Ramachandran's Diabetes Hospitals, India
5.2 Testimonial: Consultant Physician and Head of Diabetic Foot Clinic in AR Hospital, India
5.3 Testimonial: Consultant Geriatrist in Day Hospital Unit, Hospital Militar Geriatrico, Peru
5.4 Testimonial: Founding Director of Abbas Medical Centre, Tanzania
5.5 Testimonial: Professor and Clinical Practitioner, Koç University Hospital, Istanbul, Turkey
5.6 Testimonial from CEO, Technofootbed, Spain
5.7 Testimonial from CEO, Cadscan Ltd, UK
5.8 Press release featuring Cadscan Ltd, UK
5.9 Testimonial: Director of Podiatry Foot Clinic and Associate Professor at University of Malta