

<b>Institution:</b> University of Plymouth		
<b>Unit of Assessment:</b> UoA3		
<b>Title of case study:</b> Improving the management of pelvic girdle dysfunction with an innovative orthosis.		
<b>Period when the underpinning research was undertaken:</b> 2008-Present		
<b>Details of staff conducting the underpinning research from the submitting unit:</b>		
<b>Name(s):</b>	<b>Role(s) (e.g. job title):</b>	<b>Period(s) employed by submitting HEI:</b>
Jennifer Freeman Jonathan Marsden	Professor of Physiotherapy Professor of Rehabilitation	1998-Present 2007-Present
<b>Period when the claimed impact occurred:</b> 2014-2020		
<b>Is this case study continued from a case study submitted in 2014?</b> N		
<p><b>1. Summary of the impact</b> (indicative maximum 100 words)</p> <p>Pelvic girdle dysfunction is associated with pain, instability and limitation of mobility and functioning in the pelvic joints. It is a common condition, being seen in 5% of all sporting injuries and 350,000 pregnant women in the UK. Pelvic girdle dysfunction is a difficult to manage, neuro-musculoskeletal problem that can lead to significant associated societal and economic costs.</p> <p>Collaborating with DM Orthotics Ltd (UK), we have developed, evaluated and brought to market an innovative pelvic orthotic product in the form of customised pre-tensioned lycra support shorts. This targeted support allows optimal pain-free movement, which has led to enhanced performance of medal winning Paralympians. The product has also improved pain control at a meaningful level, for pregnant women by on average 17%. Aligned with this, the company has expanded its product range and diversified into new areas, with increased turnover and increased market penetration into European and American markets, providing it with a competitive advantage.</p>		
<p><b>2. Underpinning research</b> (indicative maximum 500 words)</p> <p>Over the past 15 years, Professors Jon Marsden and Jenny Freeman have led a multi-disciplinary research team in the School of Health Professions at the University of Plymouth, developing and evaluating an innovative pelvic orthosis to improve the management of pelvic girdle dysfunction. This pelvic orthosis, designed in the form of panelled lycra shorts, applies consistent targeted compression through strategically positioned, customised reinforced lycra panels that provide the necessary stability around the pelvic girdle to allow efficient and pain free movement. Compared to traditional rigid belts, this dynamic pelvic orthosis further provides improved aesthetics and comfort, thereby enhancing wear time and the associated benefits gained.</p> <p>As part of a government-funded Knowledge Transfer Partnership (KTP) with DM Orthotics Ltd, we undertook early mechanistic work to establish the effect of the direction of applied force on pelvic pain in elite athletes (3.1). This informed the development of a novel dynamic orthosis for pelvic girdle dysfunction in sports professionals, a condition that is particularly resistant to management leading to a dramatic impact on performance, an average 85 days' time lost to play per club per season and, in premiership football alone, an estimated £8.8 million financial loss of income to individuals and clubs. Having developed this novel dynamic pelvic orthosis, we then evaluated it in professional rugby players and athletes, demonstrating its effectiveness (3.2 &amp; 3.3) using single case study and randomised controlled study designs.</p>		

Our research subsequently expanded into the area of pelvic girdle dysfunction for pregnant women. Further laboratory-based work investigating the mechanical properties of the fabric components informed modifications of this product for use in pregnant women at various stages of gestation. Subsequently, a European Union funded randomised controlled clinical trial evaluated this novel intervention, demonstrating its effectiveness in significantly reducing pain, by a meaningful level, in pregnant women compared to established usual practice with the traditional rigid pelvic belts (3.4). Chronic pelvic pain following pregnancy can also impact significantly on the ability for both the father and mother to attend work, to be productive at work, and the mother's ability to care for their growing child; as well as their own quality of life. We have subsequently demonstrated through our research that the use of this dynamic pelvic orthosis in the post-natal period impacts positively on pain, function and quality of life (3.5). Further, this research, combined with an additional multi-centre audit (3.6), has provided evidence of the effectiveness of orthoses for scoliosis in children with cerebral palsy. This has resulted in a more targeted treatment of this difficult to manage commonly occurring condition.

### 3. References to the research (indicative maximum of six references)

- 3.1 Sawle L, Freeman JA, Marsden J, Matthews M. Exploring the effect of pelvic belt configurations upon athletic lumbopelvic pain. *Orthotics and Prosthetics International*. 2012; 37(21); 124 - 131.
- 3.2 Sawle L, Freeman J, Marsden J. A Pilot RCT Investigating the Effects of Targeted Compression on Athletes with Pelvic / Groin Pain. *Journal of Sports Rehabilitation*. 2017:1-34.
- 3.3 Sawle L, Freeman J, Marsden J. The use of a dynamic elastomeric fabric orthosis (DEFO) in supporting the management of athletic pelvic and groin injury. *Journal of Sport Rehabilitation* 2016; 25: 101-110.
- 3.4 Cameron L, Watkins K, Marsden J, Freeman J. Management of Antenatal Pelvic Girdle Pain (MAPS): A double blinded, randomised trial evaluating the effectiveness of two pelvic orthoses. *International Journal of Women's Health Care* 2018; 3 (2); 1-9
- 3.5 Cameron L, Watkins K, Marsden J, Freeman J. Management of post-partum pelvic girdle pain: A Replicated Case Series of Single Case Studies Evaluating the Effectiveness of a Customised Dynamic elastomeric Fabric Orthoses (DEFO). *Physiotherapy* 2017; 103: E50-E15.
- 3.6 Matthews M, Blandford S, Marsden J, Freeman J. The use of dynamic elastomeric fabric orthosis suits as an orthotic intervention in the management of children with neuropathic onset scoliosis: A review of routine clinical data collection. *Scoliosis and Spinal Disorders*. 2016, 11:14

### Indicative Grants:

A total of £469,659 grant income has been generated relating to the design and evaluation of these orthotics: (1) Freeman et al. European Social Fund, Combined Universities of Cornwall (ESF-CUC) PhD Studentship. "Pelvic girdle pain during pregnancy: evaluating the effectiveness of a novel intervention, the dynamic elastomeric fabric orthoses", 2011 – 2014. European Social Fund Research Programme, £22,615 (2) Marsden et al. "The use of orthotic lycra garments to reduce lumbo pelvic pain and accelerate functional recovery in sportspeople", 2008 - 2010. Knowledge Transfer Partnership, Department of Health. £81,621. (3) Freeman et al. Evaluating the Management of chronic Pelvic girdle Pain following pregnancy (EMaPP): A randomised controlled feasibility trial. NIHR, Research for Patient Benefit £250,432.00. 2021 – 2023. Awarded: December 2020 (4) Cameron et al. "Managing Chronic Post-Partum Pelvic Girdle Pain: Evaluating Effectiveness of Combined Physiotherapy and a Dynamic Elastomeric Orthoses", 2015-2016. Physiotherapy Research Foundation. £19,230. (5) Marsden et al "To develop innovative customised Dynamic Elastomeric Fabric Orthoses (DEFO) to optimise foot and ankle function for use in sports and for people with long-term neurological conditions". 2014 – 2016. Knowledge Transfer Partnership (KTP). £155,970 (6) Freeman et al "A multi-centre audit of clinical management of neuropathic scoliosis in children" Short Knowledge Transfer Partnership Jan–August 2013. £37,839 (7) McKee et al "The effectiveness of a dynamic

elastomeric fabric orthoses compared to standard orthoses in the management of plantar fasciitis: A feasibility study". Plymouth Hospital. NHS Charitable Funds. 2014-2015 £4,795.

#### **4. Details of the impact** (indicative maximum 750 words)

Our research benefits diverse stakeholder groups, including individual sports people and women ante-and post-partum with pelvic girdle dysfunction. It enhances clinical service delivery by Healthcare professionals, performance capability of sporting associations and the productivity, competitiveness and resilience of the partner SME.

Traditionally, orthotics have been made of rigid materials that do not accommodate movement. In recent years, the research team's work has been at the forefront of the development and use of elastomeric (lycra®) fabrics, which has revolutionised the approach to these orthotics for pelvic pain management. As underlined by Martin Mathews, Chairman of DMOrthotics Ltd: *"The design of our dynamic orthoses have been directly informed by the laboratory based work undertaken at University of Plymouth, and our product line expansion has been enhanced by the demonstration of clinical effectiveness in this client group"* [5.1].

#### **Impact on health, well-being and performance**

Pelvic girdle dysfunction accounts for an estimated 5% of all sporting injuries. With elite athletes, pelvic girdle pain can be particularly devastating, dramatically affecting performance.

##### *Sporting performance:*

Our research has been highly influential in providing a state-of-the art product to provide stable, pain-free movement and correct alignment, enabling improvements in motor performance and function. Evidence for improvements in athletes' performance with this innovative orthotic is highlighted by "team DMO" (i.e. DMOrthotics). These athletes hail from a range of disciplines including Track and Field, Para-cycling, Para-archery, Para-canoe and Boccia. The line-up consists of World Champions and Paralympians including Kadeena Cox, Sophia Warner, Anne Dickins, Jeanette Chippington, David Smith, Jess Stretton, Patrick Wilson, Claire Taggart and Evie Edwards. These sports related orthoses have been adopted by Sport England for multiple gold medal winning Paralympians and Olympians where the smallest changes can sometimes mean the difference between being a medal winner or not. For some, the orthotics was so effective that they broke their personal best the first time they trialled this in training [5.2].

Paralympian and double gold world champion sprinter Sophia Warner commented in 2014: *"I was blown away by how effective they were when I first put them on. The strength from the reinforcement panelling was so powerful. I was astounded – it felt like this was the first thing that would really work"*. Sophia's coach Jonas Taiwah was also impressed, highlighting that *"Sophia's main problem was that she was using muscles for stability instead of power down her left side which made her inefficient. The shorts (the lycra pelvic support shorts) changed this. This vastly increased the stability in her left leg, which in turn increased her stride length, improving her power output."* [5.3]. When Sophia first started using the orthotic, her times improved by 5.3%, which was enough to win the London Disability Athletics Challenge [5.4].

##### *Pregnancy-related pelvic pain and dysfunction*

Pelvic girdle dysfunction occurs in 70% of pregnant women (350,000 women in the UK at any point in time). Of these, 15% of women suffer severe antenatal pain, which results on average, in 7 weeks off work, an increased incidence of depression and a significant reduction in quality of life. Further, 10% of all women continue to suffer severe and chronic pain following delivery, which does not respond to a wide range of other treatments. Some endure this pain for over a decade. Such pain significantly affects everyday activities such as moving in bed, walking, carrying items, driving, and caring for their child. Women with severe pelvic girdle pain have increased health risks/costs as they have a higher request for induction of labour and elective caesarean section and safety issues related to care of the baby/toddler/child.

Our randomised controlled trial shows that in pregnant women, our innovative pelvic orthotic reduces pain (as assessed by a numerical pain rating scales) by an average of 17%. The

reduction in pain is even greater post-partum with an average reduction in pain of 54% (range 18-90%) and average improvement in daily function (as measured by the Pelvic Girdle Questionnaire) of 46% (range 23-62%). This is reflected by the personal experience of women. One woman, for instance, commented that *"I was really struggling with my day-to-day function as my (1 year old) son was wanting to be picked up and carried all of the time, and I was really struggling with the constant changes in position...(The lycra support shorts) really made a massive difference... it gave me the support in the areas that I needed it to, to remind me of the posture I should be in.... it helped tremendously with my sleep ... I wore it virtually every day, all day, for a good year or so"* [5.5]. Her subjective experience is supported by objective clinical outcome measures, which demonstrated a reduction in pain of 56% and an improvement in daily function of 47%. This typifies the experience of women who have begun wearing these orthotics both during pregnancy and in the early (<6 months) and late (>6 years) post-partum period (6).

### **Impact on commerce and the local economy**

Our research has been pivotal to DMO establishing a new division to their company, DMO Sports. The expanded DMO Sport range of bespoke products, such as the patented DMO REPS™, particularly targets high-performance athletes including Paralympians and Olympians. Chairman of the DMO Ltd (UK) Board Martin Matthews commented: *"The results are phenomenal and we're extremely proud to play a part in helping such an exceptional group of athletes reach their full potential."* [5.1]

Martin Matthews further stated that *"Refinement of the basic methods of applying corrective and compressive forces, derived from our collaborative research, directly led to the company modifying pre-existing items such as our scoliosis suits, and expanding our product range, the audience we target and our mode of delivery"* [5.1]. For example, at the end of 2019 the Company instigated production of stock items for both the sports and pregnancy products, enabling these to be sold at a reduced cost and in greater volume. This allowed the Company to continue to trade during the Covid-19 pandemic, when assessments for bespoke products were not possible. The design principles taken from our research also translated into stock items for other conditions such as hypermobility syndromes. Further, in May 2020 the pelvic orthoses were developed into customised pregnancy leggings with a fashion slant aiming at the high-end market. Overall, these research-driven developments have helped to make the company more resilient whilst other companies no longer have a market presence in this area of dynamic orthoses.

In addition, these developments have provided the company with a competitive advantage, affording the opportunity to gain increased market penetration and sales, including those overseas (Singapore, USA, Germany) necessitating the employment of a UK and Export Sales manager [5.1]. Since 2008 whilst UoP have been working with the company, DMOOrthotics have increased its workforce from 15 to 55, its number of units produced per week from 40 to 250, with an accompanying threefold increase in factory footprint. Further, Martin Matthews Chairman of DMOOrthotics Ltd stated: *"I can honestly say that the research directly impacted on this growth.... since working with you we have had 8 papers and multiple conference presentations ... without this I would have been fried alive if we hadn't had data to present ... the work we have done with you has contributed to about 15% of all literature in the field"* [5.1] Such data and evidence of effectiveness is now mandatory for all Class 1 medical devices (EU Regulation on Medical Devices 2017/745). Our research provided the required evidence and our research training has upskilled the Company's workforce to systematically document and submit this evidence in August 2020 [5.7].

### **Impact on clinical practice and service delivery**

Clinical Pathways are multidisciplinary evidence-based management tools for a specific group of patients with a predictable clinical course; they directly influence care provision. They are a key tool used to manage the quality and outcomes of healthcare through reducing variability in clinical practice. Our research has raised awareness of the significance of pelvic pain in pregnancy in collaborating clinical academics (e.g. Dr Lee Cameron, Clinical Lead Specialist

Physiotherapist in Orthopaedics CYMRU NHS Wales). As a direct result, in 2019 Newport NHS Trust developed and implemented a Clinical Pathway to improve the management of pelvic girdle dysfunction in women during and after pregnancy. Dr Cameron stated: *“I developed the Clinical Pathway, which exists in the Trust, for managing women with pregnancy related PGP... As a direct result, women on this pathway could begin to access the orthotic (lycra support shorts) without barriers [5.8]”*.

As well as contributing to the development of Clinical Pathways, our researchers and research outputs have influenced educational programmes within the clinical NHS setting, thereby enhancing the expertise and practice of clinicians delivering patient care. This is highlighted by the following quote referring to training of physiotherapists in Wales and South West England: *“The Womens’ Health Team and I (Dr Cameron) were responsible for training related to ante and post-partum PGP, and education about the orthotics (lycra support shorts) was a key element of this. This has had considerable influence as we are one of the biggest Trusts in Wales. This knowledge, in turn has extended to other Trusts through the Advanced Practitioners training... There has been excellent feedback from the training sessions, with comments such as “I never used to treat women with this pain, but the training has provided the fantastic tools to be able to manage these women more effectively” [5.8].*

In addition, to extend the implementation of our research findings outside the NHS, our research team has undertaken field-based educational sessions with sports physiotherapists and sports scientists at a variety of sporting clubs and organisations including Plymouth Argyle Football Club, Bristol Rugby Football Club, Football Association at St Georges Park Football Club, Wales Women’s Football Team and Sport England. This resulted in orders of these orthoses by these clubs [5.9].

## **5. Sources to corroborate the impact** (indicative maximum of 10 references)

- 5.1 Interview with Martin Matthews, Chair of the Board DMOrthotics
- 5.2 DMOrthotics Meet the Paralympians using DMO Products on their way to international glory. DMOrthotics Web-page 13.11.2016. <https://www.dmorthotics.com/news/team-dmo-meet-paralympians-using-dmo-products-their-way-international-glory/>
- 5.3 DMO increase sport performance for Paralympian. DMOrthotics Web-page 28.3.2014. <https://www.dmorthotics.com/news-events/dmo-sport-increase-performance-for-paralympian>
- 5.4 Power of 10 British Athletics, Sophia Warner, Paralympian Track and Field Athlete, <https://www.thepowerof10.info/athletes/athleteslookup.aspx?surname=warner&firstname=sophia&club=>
- 5.5 Interview from Single case study 2 participant with post-partum pelvic girdle pain
- 5.6 Dr Lee Cameron Thesis (2020) Evaluation of an Orthotic Intervention for the management of pregnancy related pelvic girdle pain PhD thesis available at PEARL repository University of Plymouth
- 5.7 Email from Dan Severn, Chief Executive Officer/ Marketing Officer of DMOrthotics
- 5.8 Interview with Dr Lee Cameron, Clinical Lead Specialist Physiotherapist in Orthopaedics, CYMRU NHS Wales
- 5.9 Email from Dr Leanne Sawle, Innovation Fellow, Clinical Innovation Hub, Cardiff School of Medicine