

Institution: University of Central Lancashire		
Unit of Assessment: 24 - Sport and Exercise Sciences, Leisure and Tourism		
Title of case study: Improvements in non-surgical treatments in orthopaedic conditions of the lower limb		
Period when the underpinning research was undertaken: 2004-present		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Prof Jim Richards	Professor	2004-current
Dr Ambreen Chohan	Research Fellow	2009-current
Dr Jonathan Sinclair	Reader	2011-current
Period when the claimed impact occurred: 2014-present		
Is this case study continued from a case study submitted in 2014? N		
1. Summary of the impact (indicative maximum 100 words)		
<p>Our work has developed an algorithm which identifies clinical subgroups in patients with patellofemoral pain and shown that targeted interventions using these subgroups improves patient outcomes. Our work on non-surgical treatments for knee pain has helped over 50,000 patients per year across Southeast Asia and changed prescription guidelines in New Zealand. In addition, our work has provided evidence to support the use of Orthotic Walkers which have been shown to provide a more effective treatment for the management of ankle injuries. Our work was used as evidence which changed the Korean insurance reimbursement system's status of Walkers in 2017, helping approximately 20,000 patients per year in South Korea.</p>		
2. Underpinning research (indicative maximum 500 words)		
<p>Our work on patellofemoral pain was the first to determine the biomechanical effects on the three-dimensional movement and control of the knee when using taping and proprioceptive bracing [1] and demonstrated that improvements in knee control are possible. In addition, our work was the first to identify differences in knee stability in patients with patellofemoral pain when compared with healthy individuals. This helped to establish that patients with patellofemoral pain whom demonstrate deficits in knee stability may be treated using such interventions. Our work provided a "proof of principle", which explored the improvements in control and mapped these improvements to pain and function and showed their effectiveness during rehabilitation [2]. This work contributed to the consensus statements of the International Patellofemoral Pain Research Retreats (2010-2018) and led to the subsequent hosting of this event at University of Central Lancashire and Manchester University in 2016.</p> <p>The Targeted Interventions for Patellofemoral Pain Studies (TIPPs) group, funded by Arthritis Research UK (ARUK), was established in 2009 and included colleagues from 11 Universities across four countries. This group, led by staff from University of Central Lancashire, explored the existence of clinical sub-groups in people with patellofemoral pain and successfully identified three sub-groups: a weak and tight muscle group, a weak and over-pronated group, and a previously unidentified strong group (figure 1). This work resulted in an algorithm being developed at the University of Central Lancashire using hierarchical clustering techniques, which allowed the allocation of patients to their respective subgroups [3]. The TIPPs algorithm was used to confirm the presence of similar sub-groups in the wider population and showed clinically important benefits when using targeted interventions for each subgroup compared to a multimodal treatment consisting of a combination of all components of the treatments within all three targeted interventions [2].</p>		

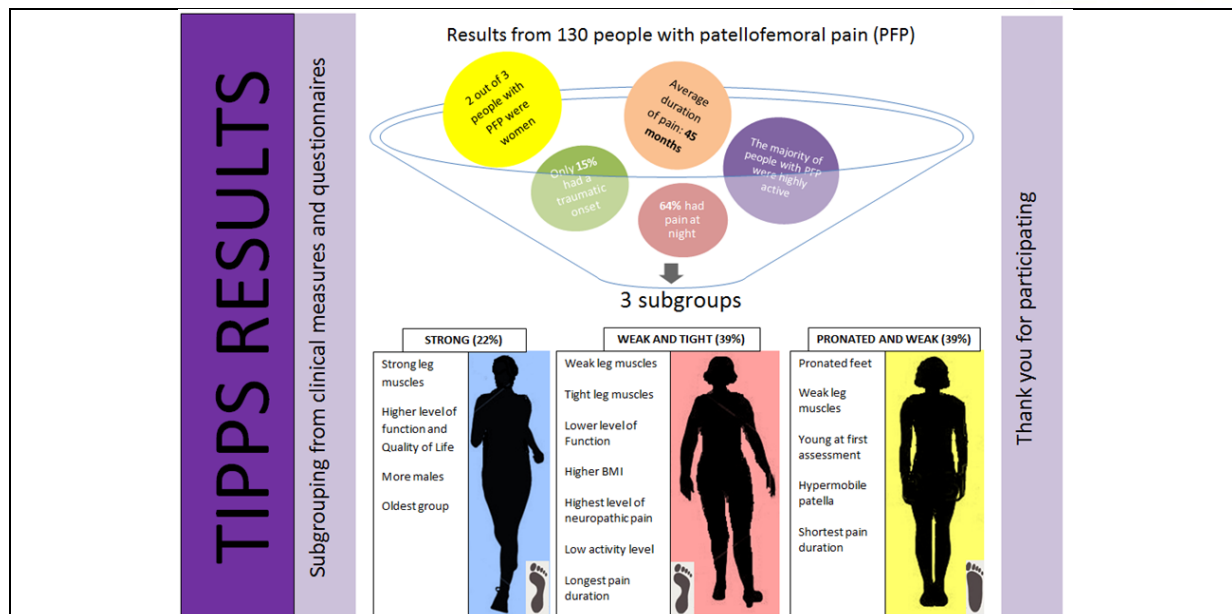


Figure 1 - Three clinical sub-groups of people with patellofemoral pain

A collaboration between Manchester Metropolitan University, University of Central Lancashire and Edge Hill University secured further funding from ARUK (2016) and Versus Arthritis (2019) to develop a mobile app (Appatella). Appatella was released on Google Play in 2018 [A], incorporating the algorithm, allowing dissemination to clinicians and implementation into clinical practice. This enabled clinicians to sub-group these patients within the clinical setting for the first time, which is being used by key opinion leaders to guide patients through targeted rehabilitation programmes in Southeast Asia [B].

Much of our work aims to provide clinicians with evidence about treatments to assist patient recovery after injury. This has included the efficacy of knee bracing in Patellofemoral Pain, Anterior Cruciate Ligament injuries and knee Osteoarthritis [1, 2, 4, 5]. However, another example of our work is the testing and development of Orthotic Walkers [6] (Figure 2), which are used in the management of ankle fractures and Achilles tendon ruptures and have been shown to provide a faster and more effective recovery than immobilisation casting techniques. Our work was the first paper to report the biomechanical effects on the movement and loads on the knee and hip joints when wearing these devices. This work considered the design of the footplate and angle of inclination of the shank in different Orthotic Walkers and determined that different designs showed different loads and gait patterns. This is an important factor, as the correct load is required to optimise the healing process, and we were subsequently asked to input in the design and testing of the next generation of Orthotic Walkers for DJO inc.



Figure 2 Orthotic Walker

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

1. Selfe J, Thewlis D, Hill S, Whitaker J, Sutton C, Richards J, (2011) A Clinical Study of the Biomechanics of Step Descent Using Different Treatment Modalities for Patellofemoral Pain. Gait & Posture. 34; 92-96.
2. Yosmaoglu, HB, Selfe J, Sonmezer E, Sahin IE, Duygu SC, Ozkoslu MA, Richards J, Janssen J (2020). Targeted Treatment Protocol in Patellofemoral Pain: Does Treatment

- Designed According to Subgroups Improve Clinical Outcomes in Patients Unresponsive to Multimodal Treatment? Sports Health. 12(2):170-180 DOI:10.1177/1941738119883272
3. Selfe J, Dey P, Callaghan M, Witvrouw E, Richards J, Sutton C, Stokes M, Martin D, Dixon J, Hogarth R, Baltzopoulos V, Ritchie E, Arden N, Turner D, Janssen. J. (2016) Are there three main subgroups within the patellofemoral pain population? A detailed characterisation study of 127 patients to help develop targeted Intervention (TIPPs). British Journal of Sports Medicine. DOI:10.1136/bjsports-2015-094792
4. Hanzlíková I, Richards J, Hébert-Losier K, Smékal D (2019). The effect of proprioceptive knee bracing on knee stability after anterior cruciate ligament reconstruction. Gait & posture 67, 242-247
5. Jones RK, Nester CJ, Richards JD, Kim WY, Johnson DS, Jari S, Laxton P, Tyson SF (2013). A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis, Gait & Posture. 37; 3:368-372. DOI: 10.1016/j.gaitpost.2012.08.002
6. Richards J, Payne K, Myatt D, Chohan A (2016). Do orthotic walkers affect knee and hip function during gait? Prosthetics and Orthotics International 40;137-141

all articles cited are from peer reviewed journals
All outputs can be supplied by the HEI on request

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

The annual prevalence of patellofemoral pain (PFP) in the general population is estimated to be around 23%. No standardised treatment for PFP exists, therefore physiotherapy treatment varies widely and comprises of a mixed package, or multimodal approach, which is delivered on a trial-and-error basis and leads to poor outcomes, with 90% of people reporting pain for at least four years following diagnosis. Our work demonstrates a paradigm shift by identifying specific patient sub-groups using six low cost, quick and simple clinical assessments requiring minimal equipment. This allows clinicians to identify subgroups and therefore provide targeted interventions for specific presentations, with the goal of improving patient outcomes in those unresponsive to treatment.

In order to implement the subgrouping, the app “Appatella” was developed [A]. This offers a direct link with our subgrouping algorithm without the need for complex calculations and incorporates instructions on how to perform the clinical assessments without the need for additional training. Appatella is a GDPR compliant, digital clinical tool available in both Android and Apple iOS formats, which consists of three main components. Firstly, a clinician interface, which allows subgrouping to guide treatment decision-making through the algorithm. Secondly, a clinician/patient interface which delivers clinical interventions, including outcome measures and reminders. Finally, a web-based database tool for clinicians and researchers that allows the creation and storage of clinical interventions with outcome measures. This uses a variety of media which can be deployed and implemented through the mobile app. The feedback received to date shows that clinicians recognise the subgroups and strongly support the need to develop a quick and simple system to allocate patients to these subgroups [B, C]. Since 2018 the beta version of Appatella has been downloaded by over 1,000 clinicians across 30 countries and is due to be released fully in late 2020. This will facilitate the assessment and subgrouping as well as the delivery of targeted treatments for this problematic condition.

In 2015 we presented the concept of a “ladder of intervention” for musculoskeletal knee problems at the World Confederation for Physical Therapy. This led to the development of the concept of assessing four key factors: Pain, Alignment, Strength and Stability (PASS). Our work has shown there are a number of interventions that can have a positive effect on all these factors. These include functional and proprioceptive knee bracing which we have demonstrated can help patients with Patellofemoral Pain, Anterior Cruciate Ligament injuries and knee Osteoarthritis [1,2,4,5]. The PASS concept has gained considerable clinical and commercial interest and has been incorporated into the marketing strategy for DJO inc., one of the largest providers of medical devices and services in the world [D]. We have had a

significant impact on practitioners through over 200 invited talks to clinical groups, sports clubs, companies and academic groups in over 30 different countries across six continents since 2013, and a series of YouTube videos which have been viewed over 15,000 times [E]. This has had a positive effect on the prescription of knee bracing; for example, a seminar tour by Professor Richards in New Zealand in 2018 resulted in a 23% increase in knee brace sales, indicating a change in clinical practice with an increase in the prescription of knee bracing, this was directly attributed to the presentation of our research findings and was described as **“a direct and measurable positive impact on our business”** by the New Zealand sales manager for DJO Global [F]. This has subsequently produced a **“noticeable shift of treatment in the rehabilitation space towards the use of functional bracing to aid in the improvement of movement patterns, reduce pain and immobility secondary to fear avoidance”** which has led to changes in New Zealand’s Accident Compensation Corporation (ACC) policy, which now funds the prescription of lower limb bracing through physiotherapy and podiatry [F]. This is a significant development that emphasises the acceptance of bracing as an important part of the rehabilitation process and a way to get people back to work in less time than without bracing. Furthermore, seminars by Richards across the Asia Pacific region between 2014-2020, which considered the prescription of bracing for knee instability, has influenced the management of over 50,000 patients across Southeast Asia and has been directly attributed to our work [B, C, D, G]. Additionally, in South Africa in 2019, Richards ran a similar seminar series. In a survey of approximately 300 delegates, 88% indicated they would be likely or very likely to change their clinical practice as a result of what they had learned.

Up until 2017, South Korea has used Plaster of Paris casting for treating ankle fractures. In 2017, our work on Orthotic Walkers was submitted as evidence along with nine other papers to the National Health Insurance system in South Korea to promote the use of Orthotic Walkers over traditional treatment methods [D, I]. As a result, these devices were approved for use in clinical practice which included financial reimbursement. Estimates based on sales indicate that around 20,000 patients per year, who would have been treated using Plaster of Paris casting, are now been treated using Orthotic Walkers, which have been shown to provide a faster and more effective recovery [I]. In addition, our work features strongly in the marketing materials from DJO Inc., which has been used as marketing evidence on the efficacy of these devices [I]. DJO Inc. sell millions of these devices each year globally. These marketing materials are distributed to clinicians and consumers worldwide to help them make informed treatment choices.

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

- [A] Launch of Appatella <https://digitallabs.mmu.ac.uk/what-we-do/products/appatella/>, 2018.
- [B] Letter from Pedorthic Technology Limited, Hong Kong
- [C] Letter form Head of the Arthroscopy and Sports Injury Unit, Hospital Kuala Lumpur, Malaysia
- [D] Impact of the Ladder of Intervention, PASS concept and work on Orthotic Walkers from DJO Asia Pacific.
- [E] Educational videos viewed over 15,000 time on YouTube
<https://www.youtube.com/watch?v=vVYrHsnfMAg>
<https://www.youtube.com/watch?v=mcfnXHGmYKQ>
- [F] Evidence of change in practice and policy in New Zealand, 2019
- [G] Letter from the CEO of the Tonic Asia Group healthcare centers, Kuala Lumpur, Malaysia
- [H] Letter Changing clinical practice in South Africa
- [I] Evidence of inclusion of our work on Orthotic Walkers as marketing evidence and its impact on South Korea reimbursement