ISPO UK MS Socket Technology Workshop Report

The field of prosthetics has advanced exponentially in the last thirty years. With the integration of microprocessors, sensing and control into devices, we are now closer than ever to restoring biological function to amputees. However, the majority of this innovation has occurred in knees, ankles and feet, while the socket remains largely untouched. Bespoke to each individual patient, often hand-crafted, the socket constitutes the interface between the prosthetic limb and the wearer. While prosthetic components may seek to produce 'natural' forces and moments at the joints, the socket interface is an inherently 'unnatural' one, which determines how these 'natural' forces are transmitted up the chain to the user's body. A poorly-fitting socket will directly compromise the function of the prosthesis. It is often argued to be the most critical component of the prosthetic device and achieving a comfortable, well-fitting, functionally-efficient socket is often regarded by prosthetists as the "holy grail". You can have the most advanced limb in the world, but if the socket is uncomfortable, the patient won't wear it.

Following on from the highly successful ISPO UK members' society Osseointegration workshop in January 2018, the society organised a Socket Technology workshop on 25th April 2019. The day consisted of a series of talks, inviting practitioners and researchers in the field to share their experiences and opinions on the future of socket technology of prosthetic provision.

Workshop outcomes summary:

Patient

- Despite recent advances in prosthetic technology, discomfort and poor socket fit is still an issue for many patients.

Educators

- Challenges: different student backgrounds, different learning styles, large knowledge base to teach, reduced timeframe, adequate clinical experience.
- Continued revision of training helps to contextualise the application of underlying theory.

Clinicians

- Implementation of outcome measures to drive scientific evidence for best practices (shape capture, socket design, suspension, etc.)
- Establish standardised best practices to reduce variability of service across centres.

- Initial time and cost investment (training/equipment) may save time and cost later (socket remakes etc.)

Researchers

- Improve understanding of science of interface as a dynamic mechanical model.
- Investigate future technologies (materials, auto-adaptive sockets, etc.) with a focus on usability in everyday clinical practice.
- Consider the role of the user and their prosthesis in the development of future interface technologies.

ISPO UK MS SOCKET TECHNOLOGY WORKSHOP

"Embracing Technology to Improve Socket Comfort for Amputees: How can we improve current practice?"

Thursday 25th April 2019 9.30 am – 4.30 pm

Friends' House, 173-177 Euston Road, London, NW1 2BJ

(click on the link to view full details of the venue)

Agenda

09.30	Registration and coffee	
09.45	Introduction	Colonel Alan Mistlin DMRC CRG Chair
09.50	Consultants Perspective	Dr Imad Sedki
10.00	Undergraduate education, Salford	Dr John Head
10.20	Undergraduate education, Strathclyde	Laura Murray
10.40	Coupling -design to function	Dr Jing Tang
11.00	Predicting socket fit	Dr Joshua Steer
11.20	*"Scots Wa Hae Wi Sockets Bled"*	David Morrison
11.40	Service quality across centres, the challenges	Vicky Jarvis, Steeper
	12.00 – 12.45 Lunch	
12.45	"(whose) Best Practice!"	Richard Hirons
13.00	CAD CAM, the evidence and service benefits	Mike O'Byrne & Dominic Hannett, Opcare
13.25	Otto Bock	Alan Gordon, Otto Bock
13.50	'Hands on' transfemoral socket design	Alan McDougall, ProActive Prosthetics
14.15	"How to suck eggs"	Toby Carlsson, Pace Rehabilitation
14.40	Socket Master, development and preliminary results	Abdo Haidar, London Prosthetic Centre
15.00	Femoral control, socket evolution and future design	Joe McCarthy, Blatchford
15.20	Refreshments	
15.30	Interactive session and discussion	

Close 4.30 pm

Education and training

The common theme throughout the day seemed to be an emphasis on (a) training/education and (b) having the time for training. David Morrison of WestMARC in Glasgow, gave a very candid presentation on the prosthetic provision in Scotland where he expressed a need for greater evidence-based practice and standardised protocols between centres. The Scottish Specialist Prosthetics Service Funding may provide opportunities to purchase specialist, casting technology and licenses – not so readily available to those in other parts of the UK – but little time and availability of training for technical staff, as well as variations in funding between centres, mean that there is currently no guarantee of the best outcome for the patient. During audience discussion, Richard Hirons of Össur asked: "while a degree of clinician autonomy may help, is a 'free choice' around socket casting methods/techniques/designs a good thing?"

More fundamentally, presentations by Dr John Head and Laura Murray of the Universities of Salford and Strathclyde, described the methods used and challenges faced when initially training student prosthetists towards certification. Students come from a multitude of backgrounds; some practical, some academic, some technical, but very few with a prior knowledge of the field. The different learning styles present a challenge to teach everyone to the same level. Times have changed and whereby the training used to be four years of predominantly hands-on, practical experience, interspaced with academic 'blocks', there is now greater emphasis on the academic aspects of biomechanics and research. Students graduate from university with nearly 600 hours of 'clinical experience', although the responsibility afforded to them during their placements is largely dependent upon the centre at which they're placed. There was a suggestion that there might be a year of post-graduate, practical training before becoming fully licensed. The benefits of repeated training was reiterated by Alan McDougall (ProActive) and Alan Gordon (Otto Bock), who both moved within the industry, becoming product specialists and providing certification with specific devices. They described the experience as like "going back to school" and realising how the Biomechanics modules in their undergraduate training had directly related to the practice they had been implementing during their time with patients.

The added emphasis on research, however, has largely been a positive thing, with the Centre for Doctoral Training being set up as a collaboration between Salford, Strathclyde, Southampton and Imperial. While there is a current skew towards engineers, there is a need for clinicians to enter research to highlight real-world effects of advanced technology.

A "good" socket

A key issue that research might seek to address is how to effectively qualify and quantify what defines a "good" socket. Dr Imad Sedki of the Royal National Orthopaedic Hospital, Stanmore, outlined the gold standard: perfect load distribution, perfect comfort, perfect suspension, perfect aesthetics, inexpensive and lightweight. The trouble being many of these characteristics are subjective. Indeed, the highest priority of these – comfort – is difficult to measure consistently. There is even a question of whether this subjective measure should be the highest priority for all patients. Comorbidities such as peripheral neuropathy can affect a patient's ability to determine 'comfort' effectively.

Vicky Jarvis (Steeper group) asked the question of how to define quality in clinical services and posed the question to the audience: "how do we ensure consistency, reproducibility and measures of quality?" Patient-Reported Outcome Measures (PROMs) are a scientific way of trying to quantify subjective properties. The most commonly cited PROM is the Socket Comfort Score[1], whereby the patient is asked to rate their comfort out of ten. Its prevalence is largely due to its simplicity and speed to implement, but it provides little information and can vary largely between patients (it was suggested that the *change* in an outcome measure might be preferred to the absolute score). Other research has sought to provide greater detail, such as the work of Dr Bob Gailey at the University of Miami and the Comprehensive Lower-limb Amputee Socket Survey (CLASS), but the length of time required to implement this instrument hinders its clinical usage. Dr Sedki highlights a need for a socket-based PROM that trades-off between the detail of the data provided and the implementation time, which would make it a more viable and useful tool for clinicians. The need for better evidence-based practice was reiterated by Toby Carlsson (Pace Rehab) who described past methods as "black magic and alchemy!"

Once appropriate outcome measures are established and correctly implemented, they can be used to establish the evidence-based practice and monitor consistency of service. A 'big data' registry, such as AMPROM, currently under development by ISPO UK, could provide this evidence on the necessary scale.

A patient in the audience suggested that there was a need to help educate patients themselves on how to most effectively communicate how they feel to the prosthetists. Just because you become an amputee, does not mean you know all of the technical terminology and this would help the accuracy of any PROMs gathered.

Existing technologies

There is a lot of technology to assist with achieving better sockets that is already in use in centres around the UK. There are different casting techniques (surface matching, volume matching), casting methods (plaster cast, CAD CAM), casting jigs (Ice cast, Magicast) and

socket designs (HiFi[2], NU-Flex[3], Marlow Anatomical, Ischial containment, sub-ischial containment). On top of financial costs and a lack of training time, once again, the main problem is the lack of standardisation, meaning there is large variability between centres. This stems from the paucity of published scientific evidence to show that any single technology or method leads to improved patient outcomes compared to alternatives.

Early research into "hands-off" pressure casting techniques reported more consistency in the sockets produced, compared to manual casting[4] but other work found that pressure casting led to higher interface pressures[5]. In spite of both of these, there is little difference in terms of comfort[5]. A review article stated that "further quantitative biomechanical studies are needed" before a conclusion can be reached[6].

There is some evidence to suggest that HiFi sockets improve walking speed, gait parameters and symmetry[7–9], including some unpublished work from the University of Southampton to show that it reduces sagittal rotation of the femur relative to the socket by 20% and pistoning by 50%, compared to ischial containment. A criticism of these sockets, raised at the workshop, was the necessity to pay a license, which limited their use clinically.

As reported by Joe McCarthy (Blatchford) and Alan Gordon on the day, perhaps the socket technology with the most published scientific evidence is elevated vacuum suspension (EVS), many of which were highlighted by Gholizadeh et al. in their review article[10]. Research has reported EVS decreases pistoning[11–14], helps maintain residual limb volume[11,12,15–17], reduces interface pressure[18], aids wound healing[19–22], leads to healthier residual limb tissue[23] and reduces the risk of falls[24]. As with the NHS England Microprocessor Knee Commissioning Policy[25], with such an abundance of evidence of long-term health benefits with EVS, there is a strong argument that investment in this technology would prove to be a cost-effective solution for the health service.

Adjustable sockets are another relatively new innovation. Some concern was raised about taking control of the socket fit away from the certified prosthetist. Those with experience of adjustable sockets asserted that the changes are relatively minor and these are not a replacement for a good socket.

On a more fundamentally level, no matter how "good" the socket is, prosthetic alignment has a substantial influence on the patient's satisfaction. Alan Gordon reported on laser-based static alignment equipment that is available, while Alan McDougall recalled from his time travelling around different centres, the variability in the quality of alignment was eye-opening.

N.B. A very thorough review of all socket issues and technology was published recently by Paternò et al.[26].

"Hands-on" v CADCAM

The conventional method of capturing the residuum shape for socket design has always been "hands-on", taking a plaster cast. Many practitioners still prefer this approach as it provides something tangible, which allows the differentiation between hard and soft tissue types, and the inclusion of the pressure effects on the residual limb shape.

Advances in imaging and computing technology has led to a rise in the use of CADCAM to capture shape and rectify design, and even additive manufacture to produce the final socket within millimetre tolerances. In their presentation, Mike O'Byrne and Dominic Hannett (Opcare) asserted that it is more efficient, more reproducible (within *and* between prosthetists) and saves a substantial amount of time during rectification. In fact, the analysis they reported on the day suggested a 17.5% reduction in delivery time, as well as a 7.6% increase in 'right first time'. A recently published study showed that CAD modification of PTB sockets did largely produce consistent results between prosthetists, there was a low intra- and interclass correlation at some key landmarks, such as the fibula head[27].

However, as with many new technologies, the main barriers to acceptance are time for training, financial costs for equipment and pre-established bias of the individual to continue with a practice they trust. Richard Hirons reported on an investigation into the factors that affect the choice of different shape capture and casting methods. It was revealed that, rather than 'clinical' factors such as employer or number of years qualified, it was 'non-clinical' factors that had the greatest influence; "it's what we do here" or "my manager told me to do it this way".

NHS v Private Practice

Presentations from those working in private clinics, such as Alan McDougall and Toby Carlsson, brought to light the differences with the NHS and how this affects the service they can provide. As well as having extra equipment available, they have more time to engage the patient in the rehabilitation, talking them through things like the rectification process, to give the patient a better understanding. Some clinicians are able to let patients take a diagnostic socket home, for real-world use, not rushing to the definitive socket until both are happy. This makes socket adjustments and diagnoses quicker and easier, drastically reducing the number of remakes of the definitive sockets.

During an audience discussion, many bemoaned the way the NHS funding system is set up, highlighting flaws. Companies' intellectual property concerns – such as the design and shape of a socket – often impede optimal patient treatment. The current funding system was largely blamed for the variability in technology availability, inconsistent practices and the lack of training time between different centres across the UK.

The true difference between NHS and private practice was highlighted by a patient in the audience, who described seeing all the available technology as like "standing outside a sweet shop, looking in through the window, watching my brother inside".

Future technologies

A number of academic researchers presented their technology in development and explained how this might be used to improve future clinical practices.

The University of Southampton has built a strong prosthetics research group over recent years with two of their researchers reporting their findings. Dr Jinghua Tang talked about his published work using 3D motion capture systems to measure relative movement between the residual limb and the socket[28], the development of in-socket load sensors[29,30], and correlating the outcomes of the two techniques[31] to explain the effects of walking speed, suspension and socket fit on interface biomechanics. He emphasised how the socket interface must be considered essentially as an extra joint in the lower limb, with translation and rotation resulting from soft tissue movement. Dr Josh Steer, a researcher in residuum shape capture techniques[32,33], demonstrated a CAD socket rectification system that uses a simplified Finite Element Analysis technique to predict interface pressures, in real-time, resulting from different socket adjustments.

Innovation is not solely the domain of academics. Abdo Haidar (London Prosthetic Centre) reported on the development of a smart socket-fitting jig. The result of a large European Commission collaborative project between the centre, the University of Surrey, TWI and others, 'Socket Master' is designed to take quantitative measurements to reduce fitting time and the number of socket remakes[34]. This is achieved by capturing the shape of the residual limb under pressure, which could be varied and controlled separately between different points, closely simulating the residual limb's shape when the prosthetic socket is loaded.

Final thoughts

As a way of highlighting the main themes raised during the workshop, a word cloud was produced from the notes taken by the meeting minute-taker. While the conflict between the need for training and the lack of time is clear, it is also obvious that the patient and their comfort is a priority. In response to the lack of time for training, it was argued that training will, in the long-term, actually save time as the number of remade sockets will be reduced.

A multi-disciplinary understanding is imperative too. It is not just the prosthetist that benefits from training and continued education. Technicians, patients and even the surgeon performing the initial amputation all have an influence on whether a "good" socket is

achieved. This may currently be a luxury only afforded to those in private practice. Competitive tendering has resulted in unprecedented pressures on budgets and staffing, to the point that some centres in England are not able to prescribe MPKs in substantial numbers, despite the funding being available.

It was said at the workshop that "a dynamic mechanical problem requires a dynamic mechanical solution" and the way to achieve this would be through establishing best practice, which relies on research and evidence. Once established, this would improve standardisation of service provision. Colonel Alan Mistlin, consultant at Stanford Hall, stated that in other areas of medicine, going against best practice and consensus requires substantial justification and can have serious consequences if things go wrong.

While many criticisms were raised, the final word is given to a patient in the audience who said ***"…while it is good to always try to improve, I want you to know that amputees are mostly happy with the service you provide as prosthetists. You do good work."***

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