ISPO Osseointegration Seminar Report

On January 18th, the ISPO UK members' society organised the latest of its one day workshops, this time focusing on direct skeletal fixation (DSF), or osseointegration (OI), of external prostheses. The day consisted of experts and trailblazers in the field reporting their progress and research findings, as well as testimonials from patients who had been through the procedure.

The overarching theme of the day was multidisciplinary collaboration, which was apparent from the broad range of disciplines in the list of attending delegates. In order to fully represent this diversity, the ISPO UK MS has invited feedback from a member from four job roles: a prosthetist, a physio, a consultant and an engineer. With this approach we hope to accurately convey the viewpoints of the different members of the prosthetic medicine team, with respect to the state of the art of osseointegration, as well as the usefulness of such organised events.

ISPO UK MS OSSEOINTEGRATION WORKSHOP

Challenges and Perceptions: – Direct Skeletal Fixation Following Amputation

Thursday 18th January 2018 9.30 am – 4.00 pm

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

0900 – 0925 hrs	**Registration and coffee**
0925 – 0930 hrs	**Introduction**
0930 – 0950 hrs	**Evidence review** - *Dr Sellaiah Sooriakumaran, Queen Mary's Hospital, Roehampton*
0950 – 1005 hrs	**Patient experience** – *Gemma Trotter*
	Overview of direct fixation techniques: *Patient assessment, selection, aftercare, failsafe design, future developments*
1005 – 1040 hrs	**Endo Exo** – *Dr Marcus Orgel, Hannover Medical School, Hannover, Germany*
1040 – 1115 hrs	**Branemark System** – *Dr Max Ortiz, Chalmers University of Technology, Gothenburg. Dr Yan Li, Karolinska Inst, Stockholm*
1115 – 11.50 hrs	**ITAP** – *Fiona Fitzgerald, ITAP team*
1150 – 1225 hrs	**OGAP-OLP** – *Associate Professor Al Muderis*
1225- 1315 hrs	***Lunch***
1315 – 1330 hrs	**Patient experience** – *Caroline Rutley-Frayne*
1330 – 1345 hrs	**Biomechanics and ISO Standards** –*Sir Saeed Zahedi, Chas A Blatchford & Sons Ltd*
1345 – 1400 hrs	**CRG/NHS and Direct Skeletal Fixation** – *Col Alan Mistlin DMRC Headley Court, Carolyn Young, NHSE*
1400 – 1420 hrs	**UK Military Update**- - *Lt Col Rhodri Phillip, Mr Jon Kendrew*
1420 – 1500 hrs	**Reports from UK clinics:** **DMRC Headley Court** – *Ms Kate Sherman* **PACE Rehabilitation** – *Mr Toby Carlsson* **RNOH Stanmore** – *Ms Morven McAlinden* **Dorset Orthopaedic Ltd** – *Mr Matthew Hughes*
1500 – 1515 hrs	***Refreshments***
1515 – 1555 hrs	**Panel discussion:** *"How do we ensure the UK has robust and ethical governance for all amputees considering, or who have undergone, a direct skeletal fixation procedure?"*
1555 - 1600 hrs	Summary & Close

The Potential Patient

Christopher Harwood
Douglas Bader Centre, Roehampton.

Firstly, it is only because of ISPO's UK presence and its international influence that the top practitioners from around the world and commissioners were drawn together for this one-day workshop to speak on this foremost of subjects: Osseointegration in the field of prosthetics.
Secondly, this was rewarded with a capacity audience attending, and then standing room only, such was the keenness of clinical allied health professionals involved. Surgeons, rehabilitation medicine consultants, therapists, prosthetists, together with the NHS commissioners and allied business sector providers to listen to the speakers and gain further knowledge and understanding of the variety of pioneering surgeries available for the limb patient and be involved in the panel discussion.

The presentations
It began with an evidence review that set out the stage for the patient assessment, selection, rehabilitation and aftercare, failsafe design of the implant and components and future developments. Currently, three lower limb and one upper limb osseointegration surgical techniques are in practice and listed in no particular order; Brånemark in Sweden, Endo Exo in Germany, OGAP-OLP in Australia and ITAP for upper limbs in the UK. Several patients gave their experiences of different systems, one measured over the decades of use. Brånemark was first trialled in the UK for lower limb users at Queen Mary's Hospital, Roehampton, London, where the bedrock of experience was gained by the consultant team and clinicians with a small cohort of selected patients. Another patient spoke of the more recent experience of OGAP-OLP in Sydney and positive outcomes. Workshop topics included the biomechanics and ISO standards, reports from the four current UK clinics, clarifications from Clinical Reference Group of NHS England on DSF and an update on UK Military veterans' involvement and experience. The day concluded with an animated panel and audience discussion on ethical governance for all amputees considering the procedure and those who have undergone DSF.

Personal perspective
From my point of view, as a unilateral above knee amputee going on 64 years, (registering as an ISPO student) I do appreciate the development of the engineering, material options and the technological advances that have assisted me to gain the most in my life since I was operated on as an infant. Also, the dedication of those specialists who provide this NHS service. I have remained as a suction socket user and respect the patients who have undergone the process of preparation and extensive rehabilitation that osseointegration has meant for them. Generally, the rewards and liberation for the patient are always apparent. The long-term health benefit savings to the NHS may still being produced but their ongoing support is vital and being taken forward by selected limbless military veterans as new pioneers under another surgical system OGAP-OLP being carried out in Australia. Its lead surgeon and associate Professor Al Muderis was a speaker at this workshop.
From my starting up a voluntary patient user group in 2004, and recently as its Chairman, I have followed the introduction of osseointegration at Roehampton under the Brånemark

system and kept the pioneering patients wellbeing on our user group's agenda so that they are not forgotten. To remember also that it is less than 20% of the lower limb amputee population who would wear an above knee prosthesis. It is an estimate that it is a small percentage of users who are unable to tolerate wearing a socket and their needs and the concern of their clinicians must never be ignored or refused.
Osseointegration acceptance is a step forward in prosthetics yet its older cousin of tooth implants in dentistry is now an everyday treatment. Also, successful pioneering development and practice in the veterinary field is now renowned under Professor Noel Fitzpatrick. How fortuitous for the ISPO and its audience that he addressed us and what a sharp perspective on the subject and the technical aspects he spoke of. The opportunity of collaboration in advances and practice from the different disciplines both demanding the same rigor and passion for best results at the operating theatre and to the physiotherapy clinic for a successful recovery and a return to a useful and pain free life.
Every person who becomes a new amputee quickly realises that it is socket comfort of the residual limb, its support and alignment to the rest of the prosthesis that is crucial to leading an independent life and being able to live normally again. To have an internal bone fixation that protrudes out of the skin, to connect with the failsafe unit and prosthesis, does make a socket redundant but opens freedoms unimaginable before for the right patient, where a conventional socket approach is not the answer. We heard directly from patient experiences who spoke from the platform of how their amputated limb feels almost restored with the prosthetic knee and foot functioning as one with the body, such a transformation from battling with socket fitting problems (especially if you happen to have both upper and lower limb loss). Their inspiring successes in life balance and work achievements were directly attributable to their osseointegration fitting. By the same token, challenges and disappointments encountered and setbacks were also shared on that journey. It is always a tricky call to make when a trial of a new surgical procedure happens and a suitable patient is aware of the risks and consequences of failure. It is an ever-present responsibility of the clinicians and patient to explore carefully the physical demands being put through the limb and a close recording of any incidents that may befall the patient. In addition to assure the patient that the service provision is life long and will include advances in interventions to those individuals who were the first guinea pigs and that they are not left as a marooned case where complications have arisen.

Health economics
The pressure of funding these advancements is not all on the NHS. The audience heard from other qualified health providers in the UK and their track record on the pathway of osseointegration supported by remarkable case studies, as an example, of an elderly female and a younger male. Osseointegration is not a silver bullet but it deserves wider consideration for those fees private patients undertake or injury claims agree and long-term recalls that they enter.
The day produced open discourse on methods and data presented was helpful to all. I noted with some regret that the ITAP presentation was short as no data was able to be shared at this stage, for reasons of commercial confidentiality and intellectual property protection. The audience was quite dumbfounded at this announcement from the platform. The spectre of commercial gain and future profit appeared to stand in the way of shared progress and mutual advances among peers. The ethos of openness that the ISPO UK wishes to foster

among its members suffers when business introduces industrial competitiveness over and above patient relief and availability of care.

Concluding remarks
The day was worthwhile I was impressed with the level of technicality and care over governance and standards. The forum discussions will continue. Even in the refreshment breaks there was a real buzz and energy between members and peers. Lastly, most pleased to see the participation of the NHS England commissioners' team; judging by their questions and their presentation, there was no doubting their engagement and commitment. This was also demonstrated with speakers from the military affirming that osseointegration has a place in limb fitting for their injured personnel and veterans. Let us see what happens for civilians. Thank you ISPO UK.

The Prosthetist

Alison Stenson
Prosthetist and Clinical & Contract Manager, Sheffield Mobility & Specialist Rehabilitation Centre

This was a very insightful and interesting workshop with lots of quality presenters from around the world. The presenters included surgeons, engineers, prosthetists and scientists.

The presentations
The surgeons discussed their outcomes and techniques, primarily focusing on the move from two stage surgery to single stage surgery. The complications and risks have reduced as the surgical techniques have developed, including refining the implant design. The majority of procedures remain for trans-femoral amputees however an increasing number of trans-tibial amputees are being considered – the risks and complications of this level are higher and this may be reflective of the experience of the surgeons, although this is likely to change as time and numbers increase.
The Australian rehabilitation programme has been largely adopted throughout the world with three phases of rehabilitation: initial loading, initial prosthesis, definitive prosthesis. The whole process takes approximately three months. Although running is not advised within the first 12 months, other lower-impact sports (e.g. cycling, swimming) are allowed.
Max Ortiz discussed his experiences of the Brånemark system – Totally integrated bionic arm using Targeted Muscle Reinnervation – integrating a DSF and electrodes for upper limb amputees. This process provides a totally self-contained system providing the user with full function regardless of position of the arm. The system produces much stronger signals and has to date shown improved patient control of the functional device. This has led to developing the technology to give the user sensory feedback.

NHS coverage
Responsibility for funding and coverage in the UK causes some issues. For patients who come into the NHS, the health service will only cover the cost of the prosthesis if they would have been eligible for that prosthesis anyway. However this is only to the same

commissioning level as all other NHS patients. Therefore, if the patient came in with a Genium, for example, then they will not be covered. They would only be supported to the current level of funding of MPK under the current MPK policy (Veterans will continue to be funded via VPP).

The Failsafe

This is the biggest issue for all prosthetists and the "elephant in the room" of all funding debates. As this is not a part issued within normal NHS commissioning, it is *not* covered by NHS funding. The surgeons don't consider this part of the surgical intervention as it is not part of the DSF. Although all the patients will arrive in our clinics with the original failsafe in situ. The ongoing costs and associated costs with this item are not clear. The Failsafe is also the part the prosthetists will have most issues with if the patient has problems. They are expensive, they are not made to ISO standards, they change design frequently (13 iterations of the Australian one) and they do tend to fail. We have been told that they are now available from the Netherlands, however communication on the parts, options and prices has not been circulated to prosthetists in the UK.

Prosthetic training

This has been identified as another issue for prosthetists. There is none as part of our standard practice at the moment, meaning that prosthetists are battling with finding out about the parts once the patient arrives at the clinic. This was highlighted as an issue to ISPO and area for training – work-in-progress for ISPO. From a prosthetic fitting point of view, alignment can be troublesome. This can be largely dependent on residual limb length – i.e. the longer the residuum, the more complicated it can be if you can't fit offset adapters distal to the failsafe, especially in unilateral amputees. Alignment may be compromised or challenging. Shorter residuums give the prosthetist the ability to stagger offset adapters to achieve the required stability for the prosthesis.

Emergency care

If the DSF breaks or becomes infected etc. the NHS would carry out emergency treatment which could include removal. However, as implantation is not an NHS procedure, they would not replace it or re-do it.

The patient

Osseointegration does, on the face of it, seem to be a good choice for *some* patients – initial results are positive. The patients who have undergone the technique report improved proprioception, "osseoperception", prosthetic control and comfort. Toby Carlsson mentioned the "unfitables" and the "unbeatables" as the patients who go for this type of procedure, therefore it is suitable for some. Patients must be aware of the long term unknown and be prepared for this. It may be an excellent option for the next 15-20 years but, as this is still emerging, the results for the long term are still subjective and cannot be definitively known. It seems after 15 years many are removed and re-amputation has occurred/been required due to bone resorption (up to 50% of femur length), so if patients know the risks and are prepared for that possibility then it is still a valid option. The first patient in Sweden has had it removed after 23 years. A patient representative speaking on the day had DSF by the Brånemark system in 2003. It had to be removed twice in 2013 and

since has had her residuum shortened by 8cm due to e-coli in the bone. In spite of this, she is currently waiting to have it done again (now four years without a leg).

Concluding thoughts
It seems the surgeons are pioneering the surgical technique (mostly moving from a two stage process to single stage) but the long term functional benefits are still unknown. It is very likely that more patients will filter into the NHS centres over the next few years and so services need to be informed, trained and prepared to treat these patients appropriately.

The Physio

Maggie Walker
Senior Physiotherapist, Queen Mary's Hospital, Roehampton

ISPO UK hosted a comprehensive workshop in London on the 18th January 2018, exploring the 'Challenges and Perceptions of Direct Skeletal Fixation following Amputation'.
The day was attended by nearly 100 delegates who were keen to share experiences, improve their knowledge and understanding of direct skeletal fixation techniques, be updated with patient outcomes and discuss the future of where this exciting but challenging development in the specialty of amputee surgery and rehabilitation is heading.

Personal experience
As a physiotherapist based at Queen Mary's Hospital, Roehampton, I have been fortunate to be involved in Osseointegration since 1997, when the first UK amputee underwent osseointegration using the Brånemark method from Sweden. This was part of a Department of Health funded trial. My physiotherapy experience within osseointegration solely lies in being part of the multidisciplinary team management of amputees who have undergone the Brånemark system.

The presentations
Over the past two decades, different teams worldwide have developed their own bone implant systems and rehabilitation programmes. This workshop gave an immense opportunity for renowned leaders in the field of direct skeletal fixation to present their systems, share their encouraging results and be honest about complications, as well as discuss the future. The fully packed programme included presentations from teams from Sweden (The Brånemark Method), Germany (Endo-Exo Method), Australia (OGAAP-OLP) and the UK (ITAP). A detailed evidence review was also presented as well as time given for two patients to share their experiences of having direct skeletal fixation and the impact it has had on their quality of life – highlighting the positive impact but also the challenges of trying to overcome some complications.

UK coverage
Direct skeletal fixation for amputees is currently not available as a 'routine procedure' on the NHS. However, over the past few years, amputees have gone privately to the different countries to have the surgical procedure and then return to the UK for ongoing

rehabilitation via Private Prosthetic Clinics. The Military have also undertaken a direct skeletal fixation programme for a number of bilateral transfemoral amputees. Presentations and updates on patients' outcomes to date and clinicians' experiences were also shared. As well as an educational overview of prosthetic fitting, alignment, biomechanics and ISO standards, a presentation was given by NHS England informing delegates of where direct skeletal fixation lies within the NHS. That is, it is not routinely commissioned and commissioning will need to occur through evaluation. A policy would need to be developed and the pathway would definitely not be simple. There are many grey areas about where responsibilities lie, for example who takes responsibility in the event of complications if the implant breaks or the prosthesis breaks? If the development of a policy was started in the near future, it would likely take at least two years before it may be agreed and implemented. This is not dissimilar to the hard work put in to develop and approve the recent NHS England MPK Policy.

The question of the panel discussion was 'How do we ensure the UK has a robust and ethical governance for all amputees considering, or who have undergone a direct skeletal fixation procedure?' This discussion was led by Professor Noel Fitzpatrick, otherwise known as the 'Supervet'. He shared his extensive knowledge on treating animals with direct skeletal fixation and challenged the speakers and delegates to collaborate more with him and to share experiences to develop practice for our patients.

Unanswered questions

This incredibly informative day which was so well supported, highlighted the interest of health care professionals in this topic and proved that direct skeletal fixation is here to stay. But it has left so many unanswered questions. These need to be addressed before the procedure is to be commissioned routinely in the NHS. In my physiotherapy experience of treating direct skeletal fixation patients, I know that when it works well, it transforms a patient's life. To see the mobility, function and quality of life restored for a person is humbling. However, we are aware of potential complications such as infection, implants having to be removed, mechanical issues with the failsafe designs etc., and these can have a negative effect on a patient's life if not managed appropriately.

Some of the unanswered questions that Sir Saeed Zahedi outlined at the end of the day and that require further research and development are:

1. Looking into the different surgical techniques – some are a single stage procedure, some are a two stage procedure, some implants are a screw-fix technique, some are a press-fit technique. What about the penetration site – a skin to metal interface or a skin to bone interface?
2. The rehabilitation pathway – some protocols are very speedy and patients are fully mobilising within three months. Some can take up to eighteen months.
3. The failsafe design needs urgent attention as it appears to be the cause of a number of mechanical incidents. Each system is using a different design – should there be one design that is reliable, safe, not putting the patients at risk and can be used on all the different systems?
4. The management of addressing complications e.g. revision surgery, antibiotics?

5. There is a definite need for teams to work together, collaborate, share experiences, improve data collection, have an international register, look at long term costs and health economics as well as having a supportive network for the education and training of clinicians. The small numbers of patients often require a disproportionate amount of time spent with them and clinicians need time and support.

Concluding thoughts
The numbers of direct skeletal fixation amputees in the UK are growing, although remain small in comparison to other areas of health. Long term results are still not known. There is a duty of care as health care professionals to look after and manage the patients who have had direct skeletal fixation from 20 years ago on the NHS as part of the original Department of Health funded project, as well as more recent amputees who have undergone the procedure as part of the Military or Privately. ISPO UK should be congratulated for organising this comprehensive day. As a profession, we look forward to further study days like this.

The Consultant

Dr Imad Sedki
Consultant in Rehabilitation Medicine, The Royal National Orthopaedic Hospital, Stanmore

ISPO UK organised a well-attended full day workshop in central London with presentations from main international stakeholders on the subject of Direct Skeletal Fixation Following Amputation (DSF). The program included a general introduction and evidence review, patients experience talks, different surgical techniques and implants, NHS England views and funding issues, UK military update and reports from various UK clinics. The day was concluded in a panel discussion including questions and comments. The main points of discussion during the day were as follows.

Medical and Surgical Aspects
DSF is a relatively new technique that is becoming increasingly popular in view of improved functional outcomes when performed on a carefully selected group of amputees. Implant design and surgical techniques have been evolving rapidly with an expanding body of knowledge regarding the short and long-term complications and their management. Discussions focused on the following main points:

- Implant fixation employs two main techniques based on either Screw Fit or Press Fit type implants. The newer Press Fit implants utilise novel coating for rapid integration in addition to the special shape and design of the implant
- Different types of infections and red flags regarding deep infection and implant loosening
- Longitudinal Studies are needed to reduce significant complications such as infection and osteomyelitis. There is also a need to agree a standard approach for the management of infections, use of antibiotics and decision for revision

- Advantages and disadvantages of different surgical procedures with a focus on Skin to Bone adhesion techniques vs Skin to Implant adhesion.

Rehabilitation Pathways

There is a general trend towards shorter post-operative rehabilitation pathway and one-stage procedures. The main points of discussion were as follows:

- Post surgical recommended rehabilitation protocols and the variations between different teams
- Physiotherapy progress from initial wound healing, to loading and period of integration
- Walking training and long-term fitness programme including recommended activities and limitations in different systems
- Follow up maintenance after 3-9 months of rehabilitation

Engineering

DSF is evolving in different pathways and a unified approach that follows internationally agreed standards is urgently needed.

- There are currently different evolving designs of the Fail Safe Mechanism, which are incompatible between different implant designs. There is an urgent need to agree an optimal Fail Safe Mechanism design based on Structural ISO Standards
- FDA approval of the full prosthesis (both internal and external). Currently the implant is considered to be an endoprosthesis but the Abutment and Fail Safe mechanism are considered to be parts of the exoprosthesis, attracting different funding streams as prosthetic components
- There is a need for a uniform model and approach to Implant Design based on the accumulated knowledge base internationally
- Open Access to intellectual property and know-how, including data so far
- Optimisation of implant design based on open access data
- TMR control interface and biological nerve connection provide a promising development to optimise prosthesis control in combination with DSF.

Health Economics – Cost justification

DSF comes at a relatively high initial cost, however it is expected to result in long-term health care savings, reduced reliance on social care systems and improved user participation. The main points for consideration are:

- Long-term costs of low back pain, osteoarthritis, increased risk of falls and soft tissue complications in amputees provide valid justification to consider DSF as a cost effective option in selected cases, mainly when functional outcomes with a well manufactured prosthetic socket are suboptimal
- There is a need to establish an international register for DSF with open access to promote statistical analysis, commissioning planning and scientific research. ISPO is considered to be best placed to support such a project

- Quality Added Life Years are variable between different countries and cost effectiveness should be considered in light of local health economics vs. medical and functional outcomes of DSF

Concluding thoughts
DSF is currently not funded routinely by NHS England, and is governed by specific guidelines and limitation by government funded healthcare and insurance companies in other countries. Although NHS England will cover the cost of the exo-prosthesis components (excluding the abutment and fail-safe mechanism) and deal with the acute medical complications of DSF (i.e residual limb related issues), it does not cover revision surgery or implant related issues for patients who paid for DSF treatment privately.

The Engineer

Dr Mike McGrath
Bioengineer & ISPO UK member

I decided to attend the ISPO osseointegration workshop because this is an area of prosthetics that I had not had a great deal of exposure to. I had seen presentations about it at past conferences and read journal articles about the outcomes, but I was keen to hear the details from those at the heart of the pioneering research. From what I gathered on the day, the engineering aspects of DSF seem to generally boil down to two aspects; the abutment attachment method and the failsafe device.

Engineering in surgery
The method of abutment attachment was largely discussed from the perspective of surgical technique. Some were championing a 'press fit' technique over 'screw fit'. While it didn't seem as though a consensus was reached on whether one method was ultimately more beneficial to patient outcomes, it was clear that both had been applied with a good deal of success. It was highlighted that, in terms of surgical research, the point at which the abutment leaves the skin is the area where improvements will be required. While internally, the interface between abutment and bone is less of an issue, the interface between abutment and the skin is very prone to infections, as the skin struggles to heal around the foreign object. One proposed technique was healing the skin to the distal tip bone. Whether or not this method has a significant effect on reducing infection and explant rates in the long term remains to be seen.

The failsafe
The failsafe device is probably the most immediate engineering challenge. Considering a trans-femoral amputee, the abutment obviously has to be strong, in order to sustain the loading that the biological femur is naturally subjected to. However, the danger is that excessive loading may cause the abutment to fracture the bone around it. This can have serious consequences including infection, explantation and possibly re-amputation at a higher level. A failsafe device would be designed to trip a particular mechanism at a defined loading threshold – below the level at which the bone may fracture.

Defining these load thresholds is difficult. There has been a fair amount of work exploring the loading for femoral DSF using finite element computer simulations[1], as well as practical human measurements during activities of daily living[2] and simulated falling[3]. The findings highlight that all degrees-of-freedom of loading – three dimensional forces and three planes of rotation – could potentially cause a failure and, as a consequence, any failsafe device must be sensitive to all six. This is a real engineering challenge in itself.
The other question is how the mechanism of the failsafe would work. While a complete detachment would save the prospect of internal bone fracture, it would almost certainly result in a fall, which could have other, equally dangerous consequences to the health of the patient. Perhaps some sort of semi-detaching solution, like a clutch mechanism, might be the answer, but it would still need to allow some degree of load bearing to permit stumble recovery and mitigate the risk of falling.
Finally, as with all medical devices, the failsafe would be subject to ISO test standards for structural integrity and fatigue. As far as I am aware, standards for such a device don't yet exist, so there is a necessity for discussion and collaboration between leading experts in the field to properly inform the development of these standards.

Health economics
As with any advancing technology, the economic impact will always be a factor. Broadly speaking, is the increased financial burden justifiable against the size of the effect on quality of life? One method of providing this justification is to calculate the incremental cost effectiveness ratio (ICER). Without going into too much mathematical detail, this value can be calculated from the results of certain patient-reported outcome measures (PROMs), including EQ-5D-5L (EuroQoL – recommended by NICE) and SF-36 (RAND corporation).
There is no fixed threshold for the NHS for which an ICER is acceptable or rejected but the guidelines on the NICE website[4] state:

"NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective … As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors considered above."

There has been one study that investigated this value for DSF, published in P&O International[4]. The Authors cite ICERs of up to AU$53,500 (~£30,000) so they are reaching the upper limits of what may be deemed acceptable in the UK. However, this was based on only 16 subjects over a six year period.
The real solution, as mentioned on the day, is collaboration to produce 'big data'. An ISPO UK initiative is underway, working with the University of Southampton, to develop an online repository of anonymised outcome measure data. AMPROM (Amputee Reported Outcome Measures) would be made available for prosthetists, patients and researchers alike, allowing 'data mining' to enable large scale analyses of a prosthetic technology such as DSF. By eliminating the problem of access to DSF patients, this seems to be the most feasible way to produce the necessary scale of results to justify this technology.

Concluding remarks

It is clear that the success of DSF so far has been (and any future success will be) a result of interdisciplinary collaboration. Each patient needs the surgeon, prosthetist, physiotherapist, rehab team, prosthetic design engineer, and many others working together and all focussed on the same goal. On a wider scale, for DSF to be a real prospect for patients, research groups and industry need to work together, sharing data to advance the technology and justify the economic impact.

References

[1]Helgason et al. *Med Eng Phys*. 2009; 31(5):595–600.
[2]Lee et al. *Clin Biomech*. 2007; 22(6):665–73.
[3]Frossard et al. *Prosthet Orthot Int*. 2010; 34(1):85–97.
[4] https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness
[5]Frossard et al. *Prosthet Orthot Int*. 2017 [Published online ahead of print].