Meshworks – Ortho Solutions

F&A User Group Summary Report

27th January 2023

Executive Summary

Meshworks and Ortho Solutions host an annual User Group meeting, which gives surgeons the opportunity to share their experiences with Meshworks, give feedback on the current implant design, help establish clinical standards and steer the direction of research for Patient-Specific Implants of this kind. The purpose of this report is to summarise the key points raised and discussed for each of the aforementioned areas, and to provide first-time Meshworks users with recommendations for implant design and surgical technique, as well as an insight into the ongoing developments and collaborations between Meshworks and their clinician network.

The relative advantages of various implant geometries and additional articulating or fixation features were reviewed and discussed at length. To ensure evidence-based practice, the group decided upon a new PMCF approach involving a clear definition of the desired dataset, an industry-sponsored clinical investigation, and writing a range of white papers. Attendees also shared their tips for deciding upon a design, surgical technique and recovery advice for a patient based on their specific indication. Finally, several actions were agreed upon to establish a 'Professional Education Network', with the aim of providing new clinicians with training and support on their first cases.

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1 Introduction

The first Ortho Solutions and Meshworks User Group meeting took place on 27th January 2023, with the purpose of attendees sharing their experiences with Meshworks' implants and comparable custom devices. Through case study presentations and chaired discussions, the group shared feedback and ideas on implant design, creating clinical standards and data collection for evidence-based practice. The attendees consisted of nine Foot and Ankle Consultants, one trauma/ limb reconstruction consultant, three Meshworks Design Engineers and the Ortho Solutions National Marketing Manager.

The day was divided into two sessions:

The first was a series of sixteen case study discussions where seven surgeons presented their approach to the decisions made in the design, surgery, and follow-up stages of the Meshworks (or equivalent) implant. Indications included trauma to the distal tibia, talar fractures and dislocations, AVN, limb salvage, chronic infection, failed TARs, severe deformities and stiffening of the foot, rheumatoid conditions and non-union of talar fracture fixation. Patients ranged from 30-85 years old, with varying soft tissue health, BMIs, and lifestyles. The implants prescribed for these pathologies consisted of Meshworks and Meshworks-Equivalent partial and non-articulating fusion cages (CTBI), and fully articulating custom talus spacers (CTS). This sparked conversations on surgical techniques, relative advantages of different designs, and the gaps in Meshworks' current design offerings.

The second session worked towards establishing clinical standards and continuing the conversation about data collection and research to ensure governance, MDR compliance and to enable future research and innovation. The following sections detail the conversations which arose from all sessions, grouped by discussion topic.

1.1 Patient Cohort Background

At the time of the meeting, Meshworks and Ortho Solutions have worked with 21 surgeons from across England and Wales to deliver bespoke Ti6Al4V implants for the foot, ankle, and distal tibia. Of the 35 cases that have entered Meshworks' pipeline, 26 devices have been successfully implanted into patients, and a further 9 are at the design or production stage. Table 1 below summarises the implants prescribed to all patients that have entered the Meshworks pipeline.

Table 1: Summary of indications and prescriptions for all Meshworks cases as of 27th Jan 2023

Indication	# Cases	# CTS (Fully articulating)	# CTS (Partial articulation)	# CTBI (Partial articulation)	# CTBI (non-articulating)
Talar AVN	19	5	2	1	11
Failed TAR[1]	12	0	0	4	8
Charcot Foot	2	0	0	0	2
Trauma to Distal Tibia	1	0	0	0	1
Leg lengthening Correction	1	0	0	0	1

[1] Meshworks implants have been prescribed for revision surgeries following Cadence, Mobility, Infinity and STAR Total Ankle Replacements.

2 Design Feedback

2.1 Design Process

Surgeons who presented case studies involving Meshworks Implants expressed their enthusiasm for the collaborative nature of the design process –during and post design meeting – and the flexibility in design geometry depending on the patient case. Meshworks proved to be more open and receptive to innovation and introducing design variations that would optimise patient outcomes, rather than being limited by manufacturing constraints.

2.2 Implant Geometries

Case presentations sparked discussions about the relative advantages of the different implant geometries that Meshworks currently offer for their CTBIs (fusion cages). Regarding cage geometries, spherical or hemi-spherical cages enables multi-planar complex deformity correction, whereas anatomically matched surfaces at bone interfaces reduces procedure complexity, is deformity fitting and keeps more of the patient's bone stock (Figure 1). In terms of features, the addition of solid Ti6Al4V 'fins' or 'keels' to add rotational stability were discussed, as well as the limitations of fusion cages with an articulating TNJ feature: the group concluded that it is best practice to preserve the native talar head wherever possible, fixing it to a non-articulating CTBI via a screw running through the implant.

It was established that a trade-off exists between implant geometry complexity, and simplicity of surgical procedure. The decision of what additional features to include in a case are dependent on several patient-specific factors, including the nature of their deformity, metabolic bone health, the planned surgical approach and the shape of the patient' s anatomy.

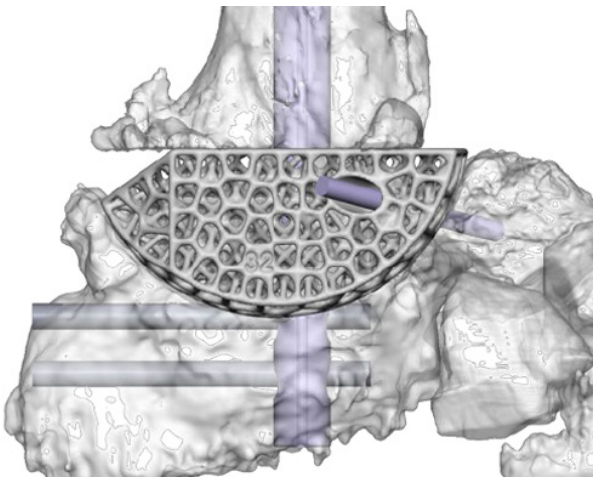

Figure 1: A 'hemi-spherical' CTBI geometry

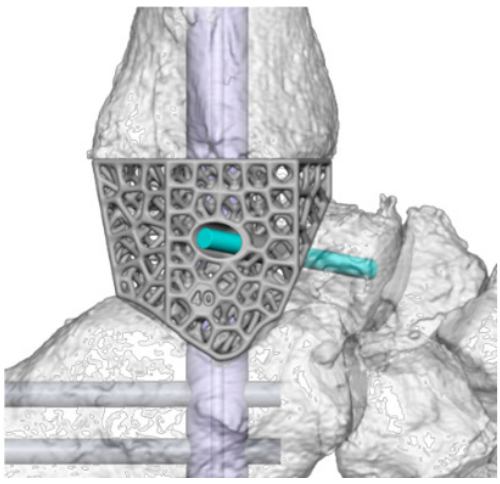

Figure 1: A CTBI with an anatomically matched inferior surface.

Attendees also discussed a potential functional value limit to adding complex geometries to the cage, which is currently undefined due to small case numbers and the unique nature of PSIs. Therefore, careful patient selection, MDT meetings, establishing clinical standards, collaborations with other Meshworks surgeon users, and Post Market Clinical Follow-up is key to the success of fusion cages with additional complex features.

Meshworks engineers also introduced the vision for future product developments and the user group contributed with their opinions and expertise on the designs and technicalities of bringing these to market.

3 Data Collection & Evidence-based Practice

The collection of PMCF and PMS data, along with other independent research activities, play an integral role in ensuring implant efficacy, safety, and continued improvements to the design. However, several hurdles exist to obtaining such data due to the inherent complexity of data handling within and across UK NHS trusts, which often results in poor clinician compliance. Therefore, a focus of the meeting was to define the critical outcome parameters that Meshworks should be measuring and reach a consensus on a data collection system that would maximise surgeon buy-in. In doing so, the time burden on clinicians will be reduced and the generated dataset will be more complete, and of higher quality.

3.1 Definition of PMCF dataset

The user group reached a clear consensus about what data Meshworks should collect to provide a valuable and complete dataset. This included the agreeing upon the which PROMs to use, and the collection timepoints. In terms of imaging, it was concluded that X-rays and CTs at pre-op and 1 year should be requested as standard unless there is suspicion of an early failure. Alongside the radiographs taken 1-year post-op, surgeons shall be asked to fill in a questionnaire which assesses the success of the procedure with respect to wound healing, infection, implant loosening/subsidence, osseointegration, and quality of adjacent cartilage of articulating surfaces. Failure analysis, together with any complaints or reports of adverse events will be delivered on an ad-hoc basis and used to carry out Kaplan Meier survivorship analysis.

Meshworks sought the users' opinions on the Intra-operative feedback form that they are currently provided with, and plans were made to add more detail to diagnose failures or adverse effects. (Since cases can vary significantly in chosen surgical technique, patient health/pathology and other unforeseen circumstances).

Discussions also took place about the current lack of patient imaging standards for fusion cages and in ankle arthrodesis procedures. Currently, notable discrepancies exist between UK trusts in the imaging method and timepoints used in routine practice, as well as their access to imaging techniques and how the images are interpreted by clinicians.

3.1.1 Data Collection Method

The User Group unanimously agreed that a Meshworks-sponsored Clinical Investigation should act as the primary data collection method, since clinician compliance is high for participating trusts which would ensure a sufficient dataset to satisfy regulators. To increase buy-in before the Clinical Investigation is launched, Meshworks shall state what data they seek to collect on the case enquiry form (surgeon prescription) which the prescriber will need to read and sign against to proceed with the design process. If this is the first time that a Meshworks implant has been supplied to their hospital, Meshworks shall supply a data sharing agreement.

3.2 Publications & White Papers

Publications play a key role in increasing the credibility of Meshworks' implants in the clinical sphere, and white papers are a useful tool for education, generating clinical standards and marketing. Meshworks proposed an infrastructure for the white papers and publications that Meshworks and their users could collaborate on in the coming years. Individual attendees expressed interest in various aspects of the infrastructure and contributed with other opportunities to collaborate in their areas of research.

4 Generating Clinical Standards

4.1 Surgical Tips

4.1.1 Patient Classification & Treatment decisions

What implant geometry & features is best for my patient?

A trade-off exists between implant geometry complexity and surgery complexity. In theory, complex cage geometries such as lips, steps, or keels provide some additional stability, but not enough research has taken place to demonstrate sufficiently improved patient outcomes to outweigh the added procedure complexity. One user provided the following rules of thumb to decide what implant geometry to use based on the patient's pathology (Table 3):

Table 3: A guide on what fusion cage to choose based on the patient's talar defect.

Talar defect		
Type 1A	**Type 2B**	**Type 2C**
Spherical fusion cage	Keystone cage with fusion to talar head	Keystone cage, talar head replacement with TNJ fusion

What recovery instructions should we give to our patients?

For the Foot and Ankle Arthrodesis procedures, the general advice given is elevation and rest with limited activity for the first two weeks to allow for wound healing, followed by non-weight bearing activities for 6 weeks, and then commencing a partial and graduated return to full weightbearing in a boot over 6-12 weeks. In contrast, the trauma surgeon's standard practice is to encourage unrestricted weight bearing immediately after the procedure.

When should I preserve the Sub Talar Joint?

One discussion on a trauma case triggered a question about the benefits of retaining the STJ rather than performing a TTC fusion. No clear consensus was reached, but surgeons usually opt for sacrificing the STJ due to the unpredictable bone stock at the joint and added stability. decide what implant geometry to use based on the patient's pathology (Table 3):

4.1.2 Surgical technique

For a TAR revision procedure:

The user group unanimously recommended to perform a two-stage procedure. In the first stage, remove hardware, collect biopsy samples and implant a cement spacer. The patient should then be called back for a CT scan when the clinical picture suggests resolution of any indicators of infection and the patient is ready for second stage implantation. This will eliminate the risk of infection, the CT scan quality will be less affected by metal artefacts, and there is a better idea of the patient's bone stock. The implant will then be designed using the patient's anatomy post first stage.

Cement spacers:

Cement spacer dislocation is a problem encountered in two-stage procedures. External fixation gives the ankle additional stability and aids soft tissue recovery, which reduces the risk of dislocation occurring. Additionally, positioning a k-wire through the spacer makes for easier removal during the second stage.

If a patient has poor soft tissue health or suspected chronic infection:

It is advised to enter through previous wounds, or there is a higher risk of the wounds breaking down when closing up the new incision. If there are still signs of infection after a course of antibiotics end, consider performing another first stage procedure. SPECT scans may provide useful diagnostic information if chronic infection is suspected.

How to pack the CTBIs with graft:

Currently, the most common method of packing the fusion cages with graft is by 'thumbing in' mortalised fibula, i.e. holding the implant in both hands and using their thumbs to press graft into the Voronoi structure. A combination of autograft and antibiotic cerement is often used to fill the cage. Variations of this standard grafting technique included using bone aspirate or RIA which is semi-liquid. By grafting the entire implant, bone on-growth and overgrowth is initiated as well as in-growth, which increases the chance of successful fusion.

4.2 Professional Education Network

Ensuring governance and appropriate training for new surgeons becomes increasingly important as case numbers increase, and use expands to more trusts in the UK. To reduce the risk of consultants selecting an unsuitable patient or deciding upon surgical techniques that could increase the likelihood of undesirable outcomes, Meshworks will add a check to ensure that a local MDT group meeting is conducted before design meeting and if not, offer to initiate contact with an experienced Meshworks User in their field. In a similar vein, a Meshworks "expert group" will be established, where members are available to guide a less experienced consultant in the design meeting.

5 Actions and Next Steps

After the User Group Meeting, the findings were written up in detail in a report, which was added to Meshworks' Device Technical File. From these findings, the Meshworks design team drew up a list of actions, made up of internal and collaborative actions with members of the User Group, and a plan for executing them.