Report from a Workshop on Test Standards for Direct Skeletal Fixation Failsafe Devices

20th August 2020

About the Workshop

A virtual workshop on Test Standards for Direct Skeletal Fixation Failsafe Devices was held on 20th August 2020 and hosted by the ARC Training Centre for Medical Implant Technologies (ARC CMIT).

The workshop program (Appendix 1) was convened by Professor Peter Lee, Director, ARC CMIT and Professor Sir Saeed Zahedi, Technical Director, Chas Blatchford & Sons, United Kingdom.

The aim of the workshop was to discuss the establishment of a test standard for Direct Skeletal Fixation (DSF) failsafe device that is a component of osseointegrated prostheses used by lower limb amputees. DSF requires a failsafe device to protect the bone and implant from mechanical overload. Several failsafe devices have been developed, however, each incorporated different design requirements (i.e. peak forces, bending moment and/or torsion). Consequently, the extent of protection against overload varies between devices. Device performance and comparison also becomes problematic since potential failures may relate to the differing protection limits rather than the actual failsafe mechanisms.

This workshop has arisen from recent discussions at the 2019 International Society for Prosthetics and Orthotics (ISPO) UK where it was recognised that there is ambiguity between the testing of the implant failsafe mechanism and the structural testing of prosthetics. Further discussion in this area is warranted.

Participants

Participants in the workshop comprised clinicians, engineers and technical specialist from the following organisations:

- Prof Peter Lee, Director, ARC Training Centre for Medical Implant Technologies (ARC CMIT), University of Melbourne;
- Prof Sir Saeed Zahedi OBE, FREng, FIMechE, Technical Director, Chas Blatchford & Sons, UK;
- Mr Mark Graf, Head of Prosthetic and Orthotics Service, Royal Melbourne Hospital, Australia;
- Adjunct Prof Laurent Frossard, Griffith University, Queensland University of Technology, University of the Sunshine Coast and Chief Scientist Officer, Your Research Project, Australia;
- A/Prof David Ackland, Deputy Director, University of Melbourne, Australia;
- Dr. Dale Robinson, Postdoctoral Fellow, ARC CMIT, University of Melbourne, Australia;
- A/Prof Jia-Yee Lee, Co-Manager & Enterprise Fellow (Medtech), ARC CMIT, University of Melbourne, Australia;
- Ms Meg Belmonte, Co-Manager, ARC CMIT, University of Melbourne, Australia;
- Dr William Lu, Researcher, Osseointegration Group of Australia & Osseointegration International P/L, Australia;
- Dr Henk Van De Meent, Head of the Medical Staff Rehabilitation Medicine, Radbound University, Netherlands;
- Ms Marta Bjornsdottir, Lead Engineer, Integrum , Sweden;
- Mr Klaus Zeier, Committee Manager, DIN Standards Committee Optics and Precision Mechanics, DIN, German Institute for Standardization, Germany;

- Mr Juan O'Choa, Design Engineer for Prosthetics, Chas Blatchford & Sons, UK;
- Dr Simone Oehler, Director of Verification, Ottobock & Convenor of TC168 group 3, Germany
- Dr Mike McGrath, Research Scientist, Chas Blatchford& Sons, UK;
- Mr Ruud Leijendekker, Physical Therapist and Researcher, Radboud University Medical Centre, Netherlands;
- Mr Mark Roberts, Development Engineer, Zimmer Biomet, USA;
- Mr David Moser, Director, Research and Technology, Chas Blatchford & Sons, UK;
- Mr Graham Harris, Principal Mechanical Design Engineer, Chas Blatchford & Sons, UK;
- Mr Frans Verhaegh, Director, Osseointegration International B.V., Netherlands;
- Mr Roy te Boome, Mechanical Engineer, Osseointegration International B.V., Netherlands.

Presentations

Keynote addresses were delivered by

- Mr Mark Graf, Head of Prosthetic and Orthotics Service, Royal Melbourne Hospital, Australia;
- Adjunct Prof Laurent Frossard, presented on current knowledge of applied loading to osseointegrated implants. A/Prof Frossard tabled an article that will soon be published and requested that this be circulated to participants.[1]
- Prof Peter Lee presented on the biomechanics of lower limb amputees for DSF
- Prof Sir Saeed Zahedi presented on industry perspective for structural testing and standards for DSF components.

Discussion and Key Points Raised by Participants

The use of osseointegration implants is growing around the world. Challenges associated with these implants remains.

The following safety issues associated with lower limb direct skeletal attachment of osseointegrated implants should be addressed to prevent replacement or removal of the implant:

- Stability;
- Infection;
- Breakage of fixation parts; and
- Periprosthetic fractures.

There is currently a lack of a clear set of standards to inform decision making for both patients and clinicians that will guide the selection of the right prothesis to meet the needs of the patient.

Benchmark data is limited to single-case, case-series or small cohort of patient data and their respective loading profile and at-risk scenarios such as falling. This dataset does not encompass a wider range of movements arising from more rigorous and robust daily activities.

A more comprehensive data on prosthetic loading profile in a range of movement would inform the development of appropriate standards. Better design of the failsafe device should minimise adverse events of osseointegrated implants.

The following questions were posed and discussed:

- Does the implant meet the needs of the patient and improve quality of life and health outcomes?
- Does the current implant design support the patient's daily activities and lifestyle? This is particularly pertinent with the younger cohort who tend to embrace more adventurous activities

[1] The e-print is available at https://eprints.qut.edu.au/203843/1/2020_Uni_MLB_Workshop_on_DSF_08_ePrint_02.pdf

than senior citizens. Consider loading and torques requirements for long distance cycling compared with golf.

- Are standards required for the failsafe mechanism? What are the safety concerns arising from the failure of the failsafe? Is it to prevent injury such as a bone fracture? Is it to prevent device breakage such as stem or abutment failure?
- What type of prosthetic loading profile data is currently being used by engineers to inform the design of the failsafe device? In a rehabilitation setting, it is clear that there are different risks associated with moving from static to dynamic prosthetic loading. There is currently insufficient loading profile data and related literature to inform design of the failsafe device that addresses safety concerns.
- What current standards are being used by manufacturers to inform design of the prosthetic osseointegrated implants? Most manufacturers default to using standards for the hip implant which are developed for patients who are over 65 years of age and the implant is used for 10-20 years.
- Should data be collected for rare adverse events? How should rare adverse events be defined when device failure occurs?
- Should the failsafe device be applied to different types of prosthesis?
- How should the test standard that will be developed to complement ISO103028?
- What are the challenges to be address by testing standards (e.g. subject specificity of bone strength and loading)?
- Should a working group be established under the Technical Committee of ISO/TC 168 Prosthetics and Orthotics?

Recommendation

A clear outcome from the workshop is the support to establish a preliminary working group to identify the scope of work that would form a proposal to establish a new working group (possibly classification 5 or 6) within ISO/TC 168 Prosthetics and Orthotics.

It is envisaged that this sub-working group's activities will be the seed to open up the requirement beyond fail safe mechanism. In addition, their deliberation and collaboration with multidisciplinary team will lead to better insights and definitions of needs for medical, surgical, orthopaedic, and therapist pathway for DSF prosthetic rehabilitation.

Contact

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Appendix 1

International Workshop

Online discussion on test standards for direct skeletal fixation failsafe devices

5 p.m. Australian Eastern Standard Time / 8 a.m. GMT +1 / 9 a.m. GMT +2
Thursday 20 August 2020

Registration: Free

Convenors

ARC Training Centre for Medical Implant Technologies (ARC CMIT)

International Society for Prosthetics and Orthotics (ISPO) UK Member Society

SPEAKERS

Professor Sir Saeed Zahedi OBE, FREng, FIMechE, Technical Director, Chas A Blatchford & Sons, United Kingdom

Professor Peter Lee, Director, ARC Centre for Medical Implant Technologies, University of Melbourne, Australia

Mark Graf, Head of Prosthetic and Orthotics Service , Royal Melbourne Hospital, Australia

ORGANISING COMMITTEE

Professor Sir Saeed Zahedi OBE, FREng, FIMechE. CTO, Blatchford, United Kingdom

Professor Peter Lee, Director, ARC CMIT, University of Melbourne

Dr. Dale Robinson, Postdoctoral Fellow, ARC CMIT, University of Melbourne

A/Professor Jia-Yee Lee, Enterprise Fellow (Medtech), ARC CMIT, University of Melbourne

Ms. Meg Belmonte, Manager, ARC CMIT, University of Melbourne

REGISTRATION

Please indicate your intention to attend by sending an email to Ms. Meg Belmonte, Manager, ARC CMIT: meg.belmonte@unimelb.edu.au

For workshop information, please contact Prof. Peter Lee: pvlee@unimelb.edu.au

ABOUT THE WORKSHOP

Lower limb amputees with Direct Skeletal Fixation (DSF) or osseointegrated prostheses require a failsafe device to protect the bone and implant from mechanical overload. A number of failsafe devices have been developed, however, each incorporated different design requirements (i.e., peak forces, bending moment and/or torsion). As a consequence, the extent of protection against overload varies between devices. Device performance and comparison also becomes problematic since potential failures may relate to the differing protection limits rather than the actual failsafe mechanisms.

The aim of this workshop is to discuss the establishment of a test standard for DSF failsafe device to ensure these safety devices provide sufficient protection against mechanical overload and to provide a baseline from which their performance may be directly compared.

PROGRAMME

5:00 p.m. AEST	**Welcome by Prof. Peter Lee & Prof. Sir Saeed Zahedi**
5:05 p.m. AEST	**Launch of the workshop**
5:10 p.m. AEST	**Mark Graf, Head of Prosthetic and Orthotics Service , Royal Melbourne Hospital**
5:15 a.m. AEST	**Keynote Lectures (Chair: Prof. Peter Lee)**
	Adjunct Prof. Laurent Frossard Current knowledge of applied loading to osseointegrated implants
	Prof. Peter Lee, Director, ARC CMIT Research on the biomechanics of lower limb amputees with DSF
	Prof. Sir Saeed Zahed, CTO, Blatchford Industry perspective for structural testing and standards for DSF components
6:15 p.m. AEST	**Discussions (Chair: Prof. Sir Saeed Zahedi)** • Advantages/disadvantages of standardized test device for manufacturers • How test standard should look – applicability of other standards (ISO10328) • Challenges to address by testing standard (e.g. subject-specificity of bone strength and loading) • Steps forward – future research
6:45 p.m. AEST	**Discussions**
7:20 p.m. AEST	**Closing statements (Prof. Peter Lee)**
7:30 p.m. AEST	**Close of workshop**

SPEAKERS

Professor Peter Lee BEng PhD

Professor Peter Lee is the Director of the Australian Research Council (ARC) Training Centre for Medical Implant Technologies and the Chief Investigator in the ARC Training Centre for Personalised Therapeutic Technologies. As Director of the ARC Training Centre for Medical Implant Technologies, he leads the largest industry-university-hospital partnership in Australia focusing on orthopaedic and maxillofacial implants to train a new generation of interdisciplinary engineers in biomechanics, materials and manufacturing for the orthopaedic and maxillofacial implant industry. Professor Lee specialises in biomechanics for lower limb prostheses and orthoses, developing the Pressure Cast (PCAST) system to produce low–cost artificial limbs using a portable and easy-to-use prosthetic socket fitting system that requires less technical skill and labour. He is currently the Associate Editor for Medicine in Novel Technology and Devices (Elsevier), Frontiers in Pharmacology, Translational Pharmacology (Frontiers), and Deputy Editor for Journal of Orthopaedic Surgery and Research (Springer Nature).

Professor Sir Saeed Zahedi OBE, FREng, FIMechE, RDI, PhD

Professor Sir Saeed Zahedi is the Technical Director of Chas A Blatchford & Sons, a UK company that designs and manufactures artificial limbs and assistive devices for physically disabled people. He is Immediate Past Chair of ISPO UK Member Society and remains actively involved in the ISPO UK Committee and the wider activities of ISPO International. Professor Sir Zahedi is the Coordinator of MovAiD, a cross-disciplinary project under the EU Horizon 2020 Program comprising a consortium of companies that looks at the future of integrated products and services to enable manufacturing of Movement Assistive Devices (MADs). Sir Professor Zahedi is a multi-award winning author and presenter of over 125 papers, books and scientific publications, 35 patents and plays a leading role in a number of industry and professional regulatory bodies, particularly those pertaining to patient safety. He is a passionate advocate for people without limbs and a leader in engineering for nearly four decades.

Mark Graf BP&O, BEd

Mark Graf is Head of Prosthetics & Orthotics at the Royal Melbourne Hospital and teaches in the La Trobe University Clinical School programme. His area of special interest is in lower limb amputee.

Adjunct Professor Laurent Frossard

Professor Laurent Frossard is Director of his consulting company YourResearchProject Pty Ltd and an Adjunct Professor in several universities in Australia and overseas. Prof Frossard is a bionic limbs scientist who is passionate about developing ground-breaking prosthetic solutions to improve life of individuals suffering from limb loss. Over the last 15 years, Prof Frossard's work has been mainly focused on individuals with limb loss fitted with socket-suspended as well as cutting-edge bone-anchored and neuro-prostheses attached directly to the skeleton using osseointegrated implant. He is considered as one of the few independent experts in bionic limbs internationally acknowledged as an au-

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