EFORT Updates 03/2021

Rolle, December 2021

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EFORT's Activities in 2021 – a Retrospect from the EFORT President

Presidential Editorial

Almost six months have passed since the 2021 Virtual General Assembly. Despite the difficulties, we are facing due to the ongoing COVID-19 pandemic and the reduced working hours of our Head Office, many activities are ongoing. Even though most meetings are online and virtual, we are optimistic for the year to come. The planning of the Congress in Lisbon 2022 is at full speed. The theme of the congress is **"Modern Patient Needs – Challenges and Solutions in O&T"**. We are indeed looking forward to a face-to-face meeting. Apart from this major event, I would like to take the opportunity to share some information on other ongoing activities.

Medical Device Regulation (MDR)

An important milestone on EU level is the Medical Device Regulation (MDR). Due to the pandemic there has been a delay of one year. But on 26 May 2021, the previous directive was replaced by a new regulation. The MDR will have effects on both surgeons, patients and industry. Patient safety is at center stage and backward and forward traceability by means of fully integrated Unique Device and Product Identifiers (UDI and UPI) are followed closely. The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices and in vitro diagnostic medical devices.
EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including better access to information for the public and healthcare professionals as well as enhanced coordination between the different Member States in the EU. EFORT continues to closely follow this development.

Meetings

EFORT Fora Programme

EFORT has participated in several FORA, some face to face and some in hybrid format. This fall, FORA have been organized together with several national societies, DKOU (Germany), BOA (UK), HAOST (Greece), SECOT (Spain), SOFCOT (France) and TOTBID (Turkey).

EFORT Session at the FEMECOT

EFORT has also organized a session at the FEMECOT (Mexican Orthopaedic and Trauma Federation) with virtual participation of several invited scientific presentations. I would like to thank all participants for their most valuable contributions on behalf of EFORT.

Meetings with National Societies

In November, the EFORT board has had virtual meetings with the national societies. This is an important activity enabling exchange of knowledge and perspectives in dialogue. Not unexpectedly, the effects of the COVID-19 pandemic on O&T have been vividly discussed. It is clear that there have been severe effects not only on elective surgery, but also on resident training. These effects will be carefully followed.

IPSSI

The Implant and Patient Safety Initiative (IPSI) has been upgraded to The Implant, Patient and Staff Safety Initiative (IPSSI). This has been a natural step in light of the pandemic as well as a need to focus on sustainable working life in Orthopaedics and Traumatology.

EFORT thus supports the European Medical Organisation on Violence Against Health professionals and as part of the IPSSI, is about the create another working group looking into this.

Cobalt toxicity

A working group on Cobalt toxicity has been initiated under the IPSSI umbrella. In order to raise awareness of this issue a webinar is planned on this topic on January 31, 2022. The title of the webinar is "Relevance of metal carcinogenicity for orthopeadics – controversies and concerns".

Whitebook

The Whitebook is in final administrative preparation and I would like to express my appreciation for the great work done by the three co-editors Per Kjaersgaard-Andersen and Jan Verhaar, EFORT Past Presidents as well as David Limb, the current EFORT Second Vice President.

CORE-MD

CORE-MD, the collaboration between the European Heart Association and EFORT, financed by Horizon 2020, is ongoing. To enable this EFORT has hired a new Policy & Public Health Officer from October.

EFORT Open Reviews (EOR)

As of January 2022, EOR (2021 Impact Factor is 4,618) will have a new publisher since our previous contract reached an end. Bioscientifica Ltd will be the new publisher. All content will remain freely available and fully searchable. EOR offers a unique opportunity to take advantage of a gold mine of knowledge. It clearly represents one of EFORTS prime products and I would like to thank the Editor in Chief Pierre Hoffmeyer, the entire editorial team and all authors for their valuable work and tireless efforts when materializing the EOR, our leading journal in O&T.

Education

EFORT Webinars

During the fall, three interesting EFORT webinars were given with replays available. The topics are: "The Periprosthetic Fractures of the Femur (Hip): Diagnosis and Treatment", "Total Hip Replacement and Lumbar Spine" and "3D Printed Reconstructions in Complex Pelvic Revisions and Oncology Surgery".

Bioskills courses

Updating of basic ethical principles in Bioskills courses is in progress in the Ethics committee. This is important in order to maintain trust and set up minimal requirement levels discussions and input from different parts of Europe.

Basic Science and Research Online course

The Education Committee is in the final phase of completing the 2nd Edition of the Basic Science and Research Online course. An application for CME accreditation is in progress.

On behalf of the EFORT Board

Prof. Dr. Li Felländer-Tsai
EFORT President 2021/2022

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23rd EFORT Congress in Lisbon, Portugal from 22 to 24 June 2022

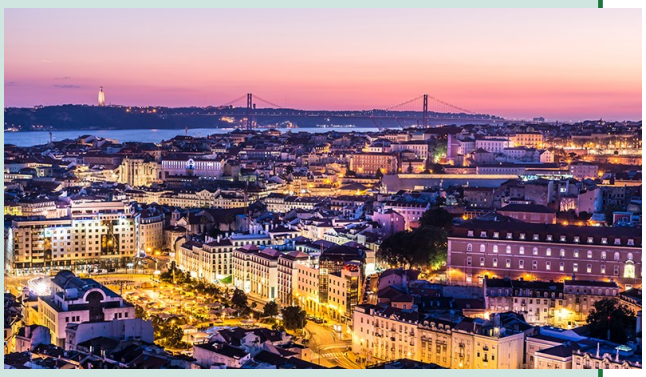
Key dates:

Notification for Abstract Acceptance Status
Monday 31 JANUARY 2022

Registration Presenting Authors Closes
Monday 28 FEBRUARY 2022 | 23:59 CET

Early Registration Deadline
Tuesday 15 MARCH 2022 | 23:59 CET

Advanced Scientific Programme Online
Tuesday 15 MARCH 2022



For more information, visit the official website https://congress.efort.org/

EFORT Implant, Patient and Staff Safety Initiative (IPSSI)

EFORT recommendations for off-label use, mix & match and mismatch in hip and knee arthroplasty

Keith Tucker, Klaus-Peter Günther, Per Kjaersgaard-Andersen, Jörg Lützner, Jan Philippe Kretzer, Rob G.H.H. Nelissen, Toni Lange, Luigi Zagra

During this era, when orthopaedic surgeons are being increasingly regulated and litigated against, most will agree that there are occasions when surgeons have to tread carefully between what they think is best for a patient and what is deemed 'correct' by regulators and lawyers. For the majority of the time most surgeons will practice evidence-based medicine, but patients are unique and there are times when standard techniques maybe not the best option for a patient. Most surgeons have the capacity to adapt their practice when they think it is necessary and go 'off-label'. EFORT consider these issues extremely important; they are all about patient safety, which is why they commissioned this appraisal in order to evaluate all aspects of these practices and to produce guidance for the benefit of patients, surgeons, manufacturers and regulators.

In this article we will attempt to clarify and suggest recommendations around the issues of off-label, including discussing the mixing and matching of implants from different

manufacturers in total joint arthroplasty ("mix & match") and commenting on 'mismatch'. The commentary and conclusions we have made are based on an extensive literature review and consensus meetings. We have reached out to the specialist groups that represent the surgeons who we hope will eventually be guided by our conclusions, and have taken careful note of their opinions.

→ For more information, please read the full article enclosed.

CORE-MD

The CORE-MD initiative, its potential impact on Orthopaedic practice.

Rob GHH Nelissen, Per Kjaersgaard-Andersen

Total hip and knee arthroplasties (THA and TKA) are considered highly effective treatments for symptomatic osteoarthritis to reduce pain and improve functionality for the patients, while lasting to function for decades. Outcome is basically determined by four factors: fixation of the implant within the bone, liner wear, implant infection and patient reported outcome scores (PRO). The first two outcome measures are seemingly easy to measure: loosening of the implant with revision as end-point being a surrogate for this migrating or loosened implant. Metrics for migrating implants like RSA (roentgen-stereographic analysis) can only be done prospective although CT measures for implant migration are being developed as is AI (machine learning) techniques. As is obvious, evidence is needed when introducing new implants to be used in patients.

Despite the discussion on the importance of evidence-based medicine and phased implant introduction for decades, still discussion exists which scientific methods to be used for new orthopaedic implants. The latter creates is not only confusing for stakeholders like orthopaedic surgeons and their patients, but also for Notified Bodies, regulators but also industry, since different, often not transparent, advice is given. For that matter, which metrics have to be used to evaluate new implants compared to which gold standard (e.g. the one with 10 year follow-up and a mean 95% survival or mean 5% revision) with which methodology (e.g. randomised controlled trials, non-inferiority trials, nested trials within national registries etc) still is in need of a framework to be used when new, innovative orthopaedic medical devices come to the market, with the aim to create more benefit than

risk for the patient. As for the multitude of orthopaedic articles on the value of PROs, although of importance in the patient-physician communication its place as one of the important tools and how to use it and which one to use in implant evaluation needs guidance for correct interpretation as well.

These two basic aspects, when interpreting the value of new implants for patients, seem obvious. However, how to implement them in a transparent and evidence-based way, so all stakeholders, including regulators, can easily use them, is the challenge the CORE-MD consortium has taken up this task in close collaboration between the European Society of Cardiology, Biomed Alliance and EFORT.

Application Expert Panel Members – Call from the EU Commission

How to apply?

All the relevant information can be found on the expert panel page with call. Interested candidates are invited to submit their application through the following website:

https://ec.europa.eu/health/md_expertpanels/application_en

Please note that the work of the expert panels shall comply with principles of high levels of expertise, independence, impartiality and objectivity, commitment, transparency and confidentiality.

News from the Biomedical Alliance Biomedical Alliance in Europe

Artificial Intelligence & healthcare: a match made in heaven?

AI & Healthcare: a match made in heaven? The use of Artificial Intelligence in healthcare is significantly increasing, with promising new developments that are transforming healthcare. AI has enormous potential to enhance patient care and facilitate health research, but there are also challenges and risks ahead

The BioMed Alliance organised an online discussion on the future of healthcare and the integration of AI in clinical practice and health research. At the occasion of the BioMed Alliance General Assembly, a series of interesting speakers shared their experience and knowledge on the use of AI and the regulatory framework that intends to facilitate the development and use of AI technologies, while mitigating risks. There were discussions on practical case studies, protecting public interest, the ownership of data, the role of clinicians in the deployment of AI in health and the involvement of patients. There was also time for questions and reflection on what the future will look like, and how we can ensure that clinicians, healthcare professionals and patients are part of the transition.

CORE-MD project: survey on education in regulatory affairs

BioMed Alliance recently conducted a survey that will allow us to get a better overview of education in regulatory affairs!

As part of our work on the CORE-MD project we ran a short questionnaire on education in regulatory affairs. This questionnaire assessed what sort of training or education exists to inform healthcare professionals about regulatory affairs, and particularly in relation to the EU Medical Devices Regulation. With this survey we aim to identify educational needs relevant to the assessment of high-risk medical devices.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246.

→ More information at https://www.biomedeurope.org/news/biomed-updates.html

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Season's Greetings

Season's Greetings and warm wishes for the coming year!

Prof. Dr. Li Felländer-Tsai, EFORT President 2021/2022

Prof. Dr. Rob Nelissen, EFORT Secretary General

Season's Greetings and a Happy New Year 2022 also from the entire Head Office Team. Thank you all for your valuable support during this challenging year!