CORE-MD

Coordinating Research and Evidence for Medical Devices

The CORE-MD initiative and its potential impact on orthopaedic practice

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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 prospectively although CT measures for implant migration are being developed as are 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 about which scientific methods to be used for new orthopaedic implants. This is confusing not only for stakeholders like orthopaedic surgeons and their patients, but also for Notified Bodies and regulators, and for industry, since different, often not transparent, advices are 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), and 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.