



Learning from actual practice: registry studies promote quality treatment

Data collections surrounding joint implants and orthopaedic interventions often do a better job than clinical studies in revealing the strengths and weaknesses of artificial joints. The data situation for endoprosthetic registries could still stand improvement, however. EFORT wants to change that with its initiative "NORE" according to EFORT experts.

Geneva, 1 June 2016 – What kinds of prosthetic joints are frequently used in a specific country? How durable are they and how often do they cause complications? How extensive is the blood loss when an artificial knee joint is implanted? All of the above are items of data that can be collected in regional or national registries. "Studies based on registry data are incredibly valuable. Unlike clinical studies, which are conducted under very specific conditions, registry data reflects medical practice with all its irregularities and can even render visible the strengths and weaknesses of implants, hospitals or even individual surgeons," Prof Rob Nelissen (Leiden University Medical Center, The Netherlands) said at the 17th Congress of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) in Geneva. About 6,000 experts from around the globe are attending this major scientific event to discuss the latest findings in their field.

Registry studies as a form of quality control

Prof Nelissen has been occupying himself with registry data for decades. He himself was initially surprised that the evaluations of registry data point out so clearly the direction, in which things must go: "Good registry data have the potential for assuring much greater safety for patients. It should be mandatory for certain key data surrounding orthopaedic interventions to be collected and worked with. The orthopaedic industry is already being compared to the fashion industry for its tendency to always introduce new designs. New prosthetic models often crowd out already established implants with excellent life spans without having to undergo extensive clinical tests. Registry studies could put a stop to this practice, but also facilitate innovation in a more controlled way." An example: Just as five ostensibly premium hip and knee joint replacement prostheses were about to be introduced on the European market, international registry data and studies were evaluated from countries where the implants were already in use. The concentrated experience of about 13,000 patients with more than 15,000 implants showed that the new products had proved problematic in a number of respects. As they were by no means superior to the tried-and-tested standard used implants, the expert opinion strictly advised against using them.

Greater safety for patients, lower costs

Prof Nelissen emphasized yet another advantage: "Assuring a data-based approach for greater quality in endoprosthetics ultimately also means creating a more effective and less expensive way of providing health care." In one of his studies, the life span of knee prosthetics was put to the test. The data coming from national joint registries in Australia, New Zealand and Sweden suggested that a certain testing procedure (Roentgen Stereo-photogrammetric Analysis, RSA) could detect within two years in small series of 60 patients, whether the implant is well integrated in the bone. The 2-year-mark is predictive for failure of the implant in more than 80 per cent of cases at ten years follow-up, thus preventing massive introduction of "bad" implants for patients. As a result, 22 to 35 percent of patients are spared the need to have their "bad" prosthesis replaced due to early loosening. Assuming that the revision for failure of an artificial knee joint costs USD 37,000 in the United States,

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17th EFORT Congress 2016 – Media contact: Dr Birgit Kofler, B&K Kommunikationsberatung; E-mail: kofler@bkkommunikation.com; Mobile: [+43 676 6368930](tel:+436766368930); Tel. Vienna: [+43 1 3194378 13](tel:+431319437813); Tel. Berlin: [+49 172 7949286](tel:+491727949286)

using RSA-testing of prostheses, could save more than USD 400 million a year, depending on the number of implants performed in a country.

NORE Initiative to improve the data situation

EFORT launched NORE (Network of Orthopaedic Registries of Europe) in 2015, so that joint replacement prostheses and surgical interventions involving joints could be checked more effectively in the future. “The advantages of the registries are now obvious, yet the data situation could stand improvement in some cases”, said EFORT Secretary General Prof Per Kjærsgaard-Andersen (South Danish University, Denmark). “NORE has set the goal of promoting the development of registries surrounding joint replacement prosthetics and of harmonising and standardising the collections of data and the reports.” In pioneering countries such as Australia, The Netherlands, Norway and Sweden, the complete data on joint implants began to be recorded in registries back in the late 1990s. Other countries have not collected any information down to the present day – or only in certain clinics or for certain implants, which makes the results less meaningful. Available data is often difficult to compare with other registries, even nomenclature is a problem. The EFORT Secretary General made this demand: “Registries should become mandatory in all countries. To be specific, they must provide full coverage and be done in a way that allows meaningful comparison.”

Data pool also for non-experts

NORE is not pushing for a joint data pool, but at symposiums it does urge people to engage in the necessary discussions surrounding data recording and harmonization and is active in sharing knowledge. Prof Kjærsgaard-Andersen reported as follows: “NORE is currently assisting Egypt and Turkey with the task of introducing national registries.” In the future, national registry data should be similarly easy to compare worldwide as is already the case in the Nordic countries. Prof Kjærsgaard-Andersen: “Registry data is not only an important basis for highly complex studies but can also be prepared for the general population. In Sweden, for example, any person interested in the subject can conduct research on certain data to obtain information about the life span of implants or to compare complication rates in certain hospitals.”