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Editorial

A Vigilant Approach for the New Orthopedic Implant Implementation

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Joint implants used in arthroplasties are continuously redesigned aiming to achieve higher longevity with lower surgical morbidity. The clinically used implants are usually approved by the regulatory authorities, following standard preclinical and clinical studies. But even following this thorough evaluation, the actual clinical outcome in large populations is not clear and sometimes can cause to devastating failure of the implant that can't be predicted from the initial studies [1]. The risk for such failure of the arthroplasty can't be overemphasized.

In order to evaluate clinical outcome of orthopedic implants, two important and unique characteristics should be addressed - the relatively limited number of patients, below 100 patients in most studies, and the long term of follow up, i.e. usually several years. In orthopedic surgery for joint arthroplasty these requirements might challenge the effectiveness of traditional statistical tools for comparison of medical or surgical treatments, used in other clinical areas, with involvement of large cohorts of patients, with clear short-term outcome, that remains unchanged for long time periods.

To answer to this specific need to foresee long term outcome following endoprosthesis surgery, the surgical arthroplasties are evaluated and compared by using a specially adopted survival analysis to predict the long term follow up of prosthetic implants [2]. There are two main methods for survivorship analysis. In the classic "product limit method" according to Kaplan and Meier [3] the survival, i.e. success of the procedure, changes immediately following clinical failure and in relatively small groups of evaluated patients the confidence intervals used at the change points of the survivorship might be misleadingly overestimated or even show values above 100%. For a more reliable and realistic prediction of the hardware implantation procedures in small groups of patients a special adaptation of this method was developed [4]. This method is based on a "life-table" assuming that all the procedures were performed on the same (time zero), the patients reevaluated on the constant intervals. Thus, the cumulative success rate for each time interval and 95% confidence intervals of survival are determined. This method is applicable for a relatively small groups of patients and do not exceed 100% of survivorship.

In the follow up by the means of survival analysis, surgeons should be able to detect an unexpected early failure of newly used endoprosthesis implant, even in a relatively small patients' cohorts and subsequentially increase the chance for early recognition of insufficiently safe and/or effective endoprosthetic device.

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