

Guest editorial

Radiostereometric analysis of early implant migration – a valuable tool to ensure proper introduction of new implants

Worldwide, millions of total hip and knee replacements are inserted every year and new designs are introduced continuously, sometimes with catastrophic results. In 1995, Henrik Malchau (Malchau 1995) presented an algorithm for optimal introduction of new implants. The algorithm was based on 15 years of clinical research including the Swedish Hip Arthroplasty project and the development of radiostereometric analysis (RSA) to evaluate implant fixation.

Bengt Mjöberg, one of the pioneers of RSA, used implant migration as detected by RSA to define loosening (Mjöberg 1986, 1991). He compared contrast and radionuclide arthrography, bone scintimetry, and RSA and concluded that RSA was the most sensitive method for detection of loosening. He also noted that implant migration over time was more sensitive for detection of loosening than prevocational investigations with RSA. He suggested that mechanical loosening should be defined as early migration after the operation.

10 years later, sufficiently large patient materials were available to study the clinical relevance of early implant migration measured with RSA (Kärrholm et al. 1994, Ryd et al. 1995). These 2 studies evaluated the predictive value of early migration for the risk of subsequent revision of a cemented matte stem and different designs of tibial components. The hypothesis that early migration could be used as a surrogate variable for clinically relevant loosening was confirmed. These findings were supported by observations of a high degree of early migration for certain implant designs, which after longer follow-up showed high clinical failure rates (Mogensen et al. 1982, Snorrason and Kärrholm 1990, Thanner et al. 1995).

Further development of the RSA technique enabled measurement of stem/cement interface motion, which was necessary to understand the behavior of polished stems and the failure patterns of stems with a rough surface. Polished stems showed continuous subsidence inside the cement mantle and, early after implantation, a magnitude of migration well above what was acceptable for a cemented stem with matte or rough surface. Even though polished stems may subside substantially more than matte or rough ones, there is also an upper limit for polished stems being well above the average value for the specific stem studied (Nieuwenhuijse et al. 2012).

Pioneer studies of early designs of uncemented prostheses with smooth surfaces that were not designed for biological fix-

ation showed high degrees of early migration, but at that time the clinical implications of this finding were not always understood (Wykman et al. 1988). Uncemented implants should preferably not migrate at all, but many designs still do. Wolf et al. (2010) reported a mean subsidence of 1.7 mm after 5 years for the clinically well-documented CLS stem. Most of this subsidence probably occurred within 1 year, which appears to be the maximum time limit for migration of cementless stems to not result in fibrous fixation or loosening.

Thus, the upper limit and time frame for acceptable early migration vary depending on several factors such as type of implant and type of fixation, and also other circumstances such as whether bone graft has been used. For some types of implant with several interfaces such as cemented stems and modular implant designs, motion may occur at different interfaces, which makes interpretation of migration data complicated.

With these concerns in mind, it is gratifying that the 2 papers by Piljs et al. (2012a,b) in this issue of *Acta Orthopaedica* show that acceptable migration during the first postoperative year of the tibial component in total knee replacement and during the first 2 postoperative years of acetabular cups stays within 0.2–0.5 mm depending on the implant type studied and the migration parameter used (MTPM, proximal migration). These studies also established an unacceptable upper limit of 1.6 mm migration at 1 year for tibial components and 1 mm at 2 years for cups. This magnitude of unacceptable cup migration confirms earlier observations of the Lubinus SP1 stem, where the upper limit of acceptable subsidence was 1 mm (Kärrholm et al. 1994).

It should be emphasized that these limits are based on revision rates within 5 or 10 years. With longer follow-up and inclusion of younger and more active patients, these limits should probably be adjusted downwards. Some implants such as cemented polished stems and many designs of uncemented stems might tolerate subsidence of about 1 mm, and occasionally more during the first year. In these cases, migration between 1 and 2 years and even up to 3 years might have a predictive value. Some cemented stems with a comparatively rough surface such as the Spectron EF Primary stem may occasionally destabilize in the cement mantle after the first 2 years, and there may be also other designs that require longer follow-

up before a reliable prediction of long-term performance can be made. Better knowledge is needed for interpretation of the clinical significance of early migration of different implant designs. According to our current understanding, there is no doubt that migration below or just above the detection level of RSA is a good prognostic sign concerning risk for clinical loosening, even if many types of implant can tolerate higher levels of early migration.

Loosening and wear are 2 important reasons for failure, which can be predicted with RSA, but failure of total joint replacements may have many other causes. Modern surface replacements may fail because of fracture, synovitis, pseudotumors, and high metal ion levels. The ASR design, now withdrawn from the market because of a high frequency of fractures and build-up of wear debris, showed good early fixation—illustrating that methods other than RSA are necessary to detect failure mechanisms (Penny et al. 2012). Some patients are dissatisfied for unknown reasons. However, the absence of implant-related complications is a prerequisite for good long-term outcome.

Despite the fact that the algorithm for introduction of new implant designs was established more than 15 years ago, new and unproven prostheses still find their way onto the market too quickly. Some of them have been used extensively without having passed all the steps in the stair of optimal introduction, and have resulted in large-scale failures. Today, most of the commonly used implants, which are suitable for most of our patients, have an outstanding track record that new implants must compete with. These new designs often have inferior—or at best equal—performance to contemporary standards. The growing evidence that measurement of early implant migration is one of the ways of avoiding large-scale failures reminds us that all new implants should be studied in this way, as part of a stepwise introduction. Fast spread of undocumented new implants should be part of orthopedic history.

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