

## Correspondence

### Strategy for RSA migration thresholds

*Sir,*—We have read with great interest the paper by Molt et al. 2016 comparing the 5 year migration of the tibial component measured with RSA for the Triathlon and Duracon TKP in 60 patients. The authors also look at the predictive value of 3 different migration thresholds in 42 patients with complete data:

MTPM of < 0.5mm at 1 year (Pijls et al. 2012)

MTPM < 0.2mm between 1 and 2 year (Ryd et al. 1995)

MTPM < 0.3mm between 2 and 5 years (Ryd et al. 1995)

It is good practice to continue evaluating and updating migration thresholds. When doing so it is important to use each threshold the way it is intended to be used. It appears that Molt et al. have misinterpreted the Pijls migration threshold (Pijls et al. 2012). This threshold is defined as the mean migration (MTPM) at 1 year with a 95% confidence interval for a group of patients, whereas Molt et al. used it to classify individual migration as stable or at risk and then calculate a percentage at risk for the implant in a specific patient. The Pijls migration thresholds were developed as guidelines to be used in a phased introduction of new TKP to protect patients from potential disasters. Consequently these thresholds are relatively strict to minimize the probability of patients being exposed to potential disasters. After reviewing and analysing 50 RSA studies with 847 TKPs and 56 survival studies with 20,599 TKPs for the last 30 years of RSA it has never occurred that a TKP with a mean migration of less than 0.5mm MTPM at 1 year had a higher revision rate of 5% at 10 year for aseptic loosening. A threshold of 0.5mm MTPM at 1 year was thus considered to be safe i.e. acceptable. On the other end of the spectrum it has never happened that a TKP with mean migration of more than 1.6mm MTPM at 1 year had a lower revision rate of 5% at 10 years for aseptic loosening. A threshold of 1.6mm MTPM at 1 year was thus considered to be unsafe i.e. unacceptable. A TKP with a mean migration between 0.5 and 1.6 was classified as “at risk”, since revision rates for aseptic loosening higher than 5% were observed in this group at 10 years follow-up although the majority of TKP had revision rates lower than 5%. This “at risk” group thus requires further follow-up with RSA to establish whether or not the migration stabilizes (ie. Ryd 1 to 2 year threshold) (Pijls et al. 2012). Therefore the evaluation of the migration of a new TKP (or any implant-bone fixation method, like bone cement) with RSA as part of a phased introduction could benefit from

a strategy that composes multiple, sequential thresholds rather than a single threshold as also previously indicated by Pijls et al. Furthermore, due to its accuracy, with RSA far less patients are exposed to a potential less well fixed implant, since it will be earlier withdrawn from the market (Nelissen et al. 2011)

The comparison of Molt et al. of the 3 thresholds seems trivial since the 3 thresholds do not measure the same migration: MTPM at 1 year, MTPM between 1 and 2 years, MTPM 2 to 5 years. Moreover, there is a chronological order of the thresholds (1, 2 and 5 years) and therefore they can be used as a strategy of phased introduction (i.e. decision when market introduction is warranted), but not as a strategy preferring one threshold over the other. For example at 1 year follow-up the Pijls threshold identifies TKP with acceptable, “at risk” and unacceptable migration. However, at 1 year we still need to wait a year before the first Ryd threshold can be used. From a Bayesian perspective it is logical to subject the “at risk” group of implants (or better yet, all groups) of the Pijls threshold to the Ryd 2 year and maybe even the Ryd 5 year thresholds. This strategy ensures both the maximal use of the available (highly accurate) RSA information, as well as the use of multiple decision moments to ensure patient safety.

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*Sir,*—We are pleased that our paper on thresholds for RSA migration has evoked a discussion on how present knowledge can evolve into a strategy.

First, we did not in any way want to detract from or be derogatory towards the paper by Pijls et al. Quite the contrary, indeed. Their paper is a seminal one based on a huge quantity of data – and a lot of work.

What we, in fact, showed was a cohort of patients where the “mean” migration according to Pijls indicating “at-risk” behavior proved to be erroneous when subjected to a more stringent analysis based on individual results. “Means” correspond to lumping-together of individual data by statistical

methods and informative precision is lost. Hence, materials being “at risk” by Pijls, i.e. being neither “good” nor “bad”, should be subjected to more rigorous analysis in order to delineate whether the “at risk” suspicion stands. In our cohort this was not the case.

So we see a strategy where an initial analysis already after 1 year according to Pijls et al. could be made and, where “at risk” behavior should result in prolonged analysis by the Ryd et al. method. This is what Pijls and Nelissen now proposes and we would fully subscribe to this suggestion.

In the final analysis, again, it is a question of exposing as few patients as possible to a new technology before it has been proven safe.

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