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To be or not to be, cured,some considerations

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We thank Dr Maggiore and colleagues for their comments regarding our paper, “Incontinence Outcomes in Women Undergoing Primary and Repeat Midurethral Sling Procedures” (1). Patient-reported outcomes in pelvic floor disorders are increasingly being obtained in clinical trials and of note are actually mandated by some research funding bodies. (2) Actual patient-reported outcomes (PROs) in general measure important patient perceptions at several levels, including symptoms, function or impact, general health perceptions and health-related quality of life and ideally should be complemented by objective measures. (3) As you noted because of the nature of this study design, it would have been unfeasible to expect to perform an objective evaluation including a cough stress test as this would have put significant burden on the patient, many of whom live a long distance from this institution. Because there is so little understanding of the differences between these 2 patient groups, we did not wish to use a composite subjective definition of “cure”, but rather a definition that reflected the patient’s sense of her leakage, with regard to what the sling was designed to do, that is, treat stress urinary incontinence. The other information specifically regarding symptom specific impact, impression of improvement and satisfaction were used to supplement our understanding of what changes there are in these various levels of PRO between women undergoing a primary mid-urethral sling compared to those women having a repeat mid-urethral sling. Furthermore, because the follow-up for our patients varied from 12 to 60 months, the global impression of improvement may have been somewhat problematic because it is typically reported at least initially at a shorter outcome time-point (12 months) in order to reduce the inherent recall bias of condition before surgery. Certainly in a trial or study comparing outcomes say of 2 interventions, where the baseline patient population is homogenous, it would make more sense to consider the use of a patient perception of improvement as a primary outcome measure *a priori*. Our approach allowed the reader, in a sense come to their own conclusion regarding the primary and secondary outcomes and the overall comparative effect of the mid-urethral sling treatment outcomes in these two different patient populations.

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