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Platinum Priority – Editorial and Reply from Authors

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Patient's Reported Outcome and Reconstructive Urethral Surgery: A “First Toe in the Water”

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Urethral strictures are a frequent source of lower urinary tract symptoms (LUTS) in men, but a systematic analysis on patients' quality of life (QoL) is rarely reported in the literature. The clinical history and follow-up thus far have been used to gain a summary view of the symptoms experienced by patients before the surgery and the impact of urethroplasty after urethral reconstruction. Urologists are familiar with several tools of measuring QoL in patients suffering from urinary incontinence (UI) or LUTS. They include voiding diaries and questionnaires and may represent the most important clinical review of the impact of symptoms and the benefit of treatment from a patient perspective [1].

Tannenbaum and Corcos performed a systematic review of the literature on outcome measures for the assessment of UI and LUTS in adults [2]. They classified the available instruments by type (ie, subjective measures, objective measures, clinical observations, QoL, and combined instruments) and by the assessment of their psychometric properties (reliability, validity, and responsiveness) [2]. Although the authors found several clinical tools (ie, voiding diaries, the Incontinence Impact Questionnaire, the King's Health Questionnaire, the Incontinence Quality of Life Questionnaire, the Urogenital Distress Inventory, and the International Consultation on Incontinence Questionnaire), none of them provides a method for the standardised collection of LUTS or other subjective phenomena for patients with urethral strictures [2].

In this issue of *European Urology*, Jackson and colleagues tried to bridge the existing gap in the field of reconstructive urethral surgery [3]. Because a systematic literature review failed to identify a condition-specific patient's reported

outcome measure (PROM) sufficiently robust for use in urethral stricture surgery, the authors investigated the question sets from existing validated instruments (eg, the International Prostate Symptom Score) that could be used in patients who underwent urethral stricture surgery [3]. They were able to show that the resultant tool was valid and reliable according to established psychometric criteria [3]. Jackson and colleagues should be praised for their work: Their “first toe in the water” sounds scientifically robust in its construction and rigorous in analysis. Their paper, however, prompts several considerations.

The PROM questionnaire was used by Jackson et al to record the presence and severity of LUTS as well as the impact of symptoms on patient's QoL before and after urethroplasty [3]. They adequately developed such an instrument as a multistep structured process that incorporates a psychometric analysis culminating in a conclusion supported by the measure's validity, reliability, and responsiveness. Given the current number of disease- and surgery-specific issues in patients who underwent urethroplasty for urethral strictures the PROM of Jackson et al failed to cover most outcomes of interest (eg, morbidity of oral mucosa graft harvesting, history of previous urethral surgery, changes in aesthetic appearance of male genitalia, sexual dysfunction, and ejaculatory dysfunction).

Barbagli et al, using a specific nonvalidated questionnaire, recently investigated oral morbidity and patient satisfaction in a homogeneous group of patients who underwent oral graft harvesting from a single cheek using the same standardised technique [4]. The questionnaire included 6 questions designed to investigate *early* complications (first 10 postoperative days) and 13 questions

designed to investigate *late* complications (3 mo after surgery) and patient satisfaction [4]. The authors reported that harvesting an oral graft from a cheek with wound closure is a safe procedure with a high patient satisfaction rate [4]. This information is extremely worthwhile for counselling patients when you decide to perform an oral mucosa graft urethroplasty and should provide information that overcomes the focus on the urethra and gains data on each patient as an integrated person.

The paper by Jackson et al [3] did not take into consideration the historical disease- and surgery-specific burden. Analysis and correlation of clinical outcome and QoL assessment in patients treated for anterior urethral stricture disease might reveal surprising findings that could not be covered by a LUTS-oriented questionnaire. Barbagli et al recently investigated QoL and satisfaction of 173 patients who underwent temporary or definitive perineal urethrostomy for complex anterior urethral stricture diseases [5]. Although one-stage techniques showed a higher objective success rate (83.5%) compared with the series of patients who underwent perineal urethrostomy (70%), >173 patients (only 3%) reported they were unsatisfied [5,6]. A PROM should allow us to understand why a large group of patients preferred to use a lower success rate technique (perineal urethrostomy) instead of a higher success rate technique (one-stage repair). That is the challenge PROMs have to address. Patients generally have undergone an innumerable number of prior failed operations, they are “tired,” and they do not accept the possibility of another complete failed urethroplasty [5].

The one-stage repair provides restoration of micturition through a normal standing position and avoids patient discomfort caused by perineal urinary diversion that patients often do not accept for religious, hygienic, cultural, or psychological reasons [5]. However, patients with severe urethral stricture or with a perineostomy are already accustomed to seated voiding because of LUTS. We have to ensure that the voice of the patient is heard at the time of decision for surgery. The development of a robust PROM will become fundamental for us, and we should respect patients' expectations according to their perspective. To perform a simpler surgery is not a sign of inadequacy on the part of the surgeon but a sign of great humility and humanity essential to anyone involved in restoring the integrity of the human body. The patient perspective is worth pursuing.

Finally, although Jackson and coworkers explained their decision not to include sexual and ejaculatory evaluations, we strongly believe it is a real limitation in the general understanding of PROM. In a review of our series of 153 who underwent a bulbar end-to-end procedure at a median follow-up of 68 mo, 139 (90.8%) were successful (high objective success rate), 14 patients experienced ejaculatory dysfunction, 1 had a cold glans during erection, 7 had a glans that was neither full nor swollen during erection, and 11 had decreased glans sensitivity [7]. All these patients were satisfied with the improvement of their LUTS but not their sexual function. Jackson's PROM would have lost that.

Our personal experience with the nonvalidated questionnaires we have used since 2007 has driven changes in our daily surgical practice. Today, we avoid completely transecting the bulbar urethra in nontraumatic strictures, we always perform the closure of the oral harvesting site, and we always give patients with an anterior complex urethra stricture the option of perineal urethrostomy.

The US Food and Drug Administration and the European Medicines Agency have pointed out the importance of patient-reported outcomes, which are any outcomes evaluated directly by the patient and are based on patients' perception of the disease and its treatment [8,9]. The paper by Jackson et al [3] is a first step at the beginning of a long journey, and it forces us to create and use questionnaires that can measure all the important aspects of a patient's health status after urethral surgery. They should be developed to cover single-dimension and multidimensional measures of symptoms, health-related QoL, health status, adherence to treatment, and satisfaction with urethral reconstruction. We believe that in the future it will be mandatory to develop specific questionnaires for urethral pathology on the basis of a clearly defined conceptual framework that acknowledges the importance of patients' perspectives or expectations.

The paper by Jackson et al [3] is only on the threshold of our knowledge about the usefulness of urethral reconstruction. Unfortunately, it covers only part of the spectrum of the processes following urethral surgery. We need to realise that one of the most important and rate-limiting process of care is adequate recognition of patients' problems before and after the reconstruction of the urethra, an organ involved in urinary and sexual function. It is true that possibly no system of quality assessment adequately addresses and recognises patients' expectations, but in this era of patient-centred approaches to reconstructive treatments, problem recognition should be incorporated into systems such as the quality and outcomes framework dealing with multidomains. It is not easy to do, although it will be highly useful for everyone with urethral stricture disease who seeks care.

Conflicts of interest: The authors have nothing to disclose.

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Platinum Priority

Reply from Authors re: Guido Barbagli, Massimo Lazzeri. Patient's Reported Outcome and Reconstructive Urethral Surgery: A "First Toe in the Water". *Eur Urol* 2011;60: 69–71

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We were interested to read this editorial by Barbagli and Lazzeri [1], but the authors do not seem to have read our paper [2]. Even their subtitle, "A First Toe in the Water," suggests this. The "first toe in the water" was the use of nonvalidated questionnaires to assess patient outcome, with which the authors themselves have considerable experience, described at length in this editorial. The whole point of our paper is to describe the validation of an outcome questionnaire for men undergoing urethral stricture surgery, representing a considerable advance over the nonvalidated questionnaires the authors cite and that, quite simply, are not valid by definition. In comparison to previous work, we feel that we have achieved at least a foot in the water, if not a leg!

We have described the process of developing a patient-reported outcome measure (PROM) for patients undergoing urethral stricture surgery, as the title of our paper states, and we fundamentally disagree with Barbagli and Lazzeri that it "fails to address most of the outcomes of interest to these patients." It allows men to rate their voiding symptoms and overall quality of life (QoL); these are the reasons why patients come to see us and are the only solid indications for treatment. Men embark on urethral stricture surgery for a variety of reasons, but usually they wish to improve their voiding symptoms and their life as a whole. Sexual and erectile dysfunction and oral mucosa graft harvesting-related problems are significant unwanted side

effects of urethroplasty but are unrelated to the expected benefits of treatment. Should these side effects cause sufficient morbidity to outweigh the benefit conferred by a return to normal voiding, one might expect to see an overall negative shift in health-related QoL (HRQoL). This was not apparent in our study—quite the reverse. Equally, we wanted to make sure that our PROM remained broadly applicable to patients undergoing any form of treatment for urethral strictures to make it a useful tool in comparative trials. Morbidity related to graft harvesting is specific to augmented urethroplasty and would be irrelevant to patients undergoing, for example, anastomotic urethroplasty. The only common factor is overall HRQoL.

We are happy to agree with Barbagli and Lazzeri that our PROM does not account for adverse effects, nor should it. We also agree that the PROM does not account for positive or negative changes in sexual function or cosmesis; it became clear during validation that these changes were not of great concern to men considering the effects of surgery for voiding dysfunction due to a urethral stricture. We also agree that the PROM does not assess patient preference, but this is not what a PROM is designed to do.

In short, our PROM assesses the outcome of patients for whom the primary problem is lower urinary tract symptoms and specifically voiding difficulty due to stricture disease. For those who present primarily with other problems, for example, poor cosmetic results and penile curvature from previous surgery for hypospadias, we would need a different instrument and, indeed, it is out plan to create a suite of PROMs for genitourethral surgery. The urethral stricture PROM marks the first part of that process. In this way, we can all use the same outcome measures, whether they be patient reported or clinician centred, and consequently, we will be able to stop all of the wasted effort on nonvalidated questionnaires, of which Barbagli and Lazzeri cite several of their own as examples.

Conflicts of interest: The authors have nothing to disclose.

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