

# Reaching Consensus for Comprehensive Outcome Measurement After Urethral Stricture Surgery: Development of Study Protocol for Stricture-Fecta Criteria

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**Abstract:** Urethral stricture disease is a very heterogeneous condition where different urethral segments can be involved as a result of diverse etiologies which come with variable prognosis. The surgical management of urethral strictures, and in particular urethroplasties can result in very diverse outcomes on many levels and, currently, there is absolutely no consensus about what should and what should not be considered a “success” after urethral surgery. In the wake of well-established quality criteria in urologic oncology, such as tri- or pentapecta outcomes, and given the lack of agreement on meaningful outcomes after urethral surgery, we aim to introduce our study protocol as the first step of a multistep research endeavor to reach consensus on comprehensive urethroplasty outcomes within a novel conceptual framework: the “stricture-fecta criteria”. The development of stricture-fecta will be based on a Delphi consensus involving some of worldwide most influencing reconstructive urologists.

**Keywords:** urethral stricture, urethral stenosis, urethrotomy, urethroplasty, pentapecta

## Introduction

In 2005, Bianco et al defined biochemical recurrence-free survival with continence and potency preservation as a triad of ideal outcomes after radical prostatectomy in prostate cancer patients, which has evolved as a popular and important quality metric coined the “trifecta” outcome.<sup>1</sup> This simple and innovative concept allows for an immediate assessment of both oncological and functional outcomes after surgery and facilitates the interpretation of a “successful” procedure. Over time, this trifecta was extended to “pentapecta”,<sup>2</sup> and the same principle was adopted for other oncological procedures, such as partial nephrectomy.<sup>3</sup>

Urethral stricture disease is a very heterogeneous condition where different urethral segments can be involved as a result of diverse etiologies which come with variable prognosis. This complex nature of the disease asks for a wide range of therapeutic strategies, which nowadays mainly involve endoluminal procedures and open reconstructive surgery.<sup>4</sup> The failure of first-line

endoscopic treatment such as direct vision internal urethrotomy most likely requires further open urethroplasty, which is a delicate surgical procedure and often associated with poor satisfactory outcomes. Many surgical techniques have been proposed and developed based on stricture location and type. Broadly speaking, open urethroplasty can be subdivided into excision and primary anastomosis and augmentation techniques using substitution grafts or flaps.<sup>4</sup> Endoluminal treatments are mostly reserved for primary, isolated, short strictures at the bulbar segment of the urethra or for patients unable or unwilling to undergo a more invasive reconstruction. Open reconstructive surgery, on the other hand, is more versatile and better fit to combat the more challenging disease. Herein, a multitude of surgical techniques can be administered according to the various patient and stricture characteristics, the patient's wishes and preferences, the knowhow and experience of the surgeon and the tools available in the particular treatment setting. That being said, it is an unsurprising fact that urethroplasties can result in very diverse outcomes on many levels and, currently, there is absolutely no consensus about what should and what should not be considered a "success" after urethral surgery.<sup>5,6</sup>

In that regard, some authors underline the importance of functional outcomes, such as uroflowmetry improvement, and others give more weight to the absence of stricture recurrence, which is by itself an extremely subjective, heterogeneous, and variable term. Notably, the Trauma and Urologic Reconstructive Network of Surgeons (TURNs) has recently shown that "recurrence-free survival" is hugely dependent on the definition used and "success rates" show significant differences depending on how treatment success is defined.<sup>7</sup> Moreover, patient-reported outcome measurements (PROMs), such as patients' treatment satisfaction and validated, procedure-specific questionnaires,<sup>8</sup> have gained in importance and are recommended as outcome metrics by contemporary guidelines.<sup>7,9</sup> In the wake of well-established quality criteria in urologic oncology, such as tri- or penta-fecta outcomes, and given the lack of agreement on meaningful outcomes after urethral surgery, we aim to introduce our study protocol as the first step of a multistep research endeavor to reach consensus on comprehensive urethroplasty outcomes within a novel conceptual framework: the "stricture-fecta criteria".

## Study Protocol

As a starting point, a literature review will be performed and the methodology of similar publications using the Delphi technique, such as CACTUS, a consensus-based guideline for surgical training, will be mirrored.<sup>10</sup> All members of the Trauma and Reconstructive Urology Working Party of the European Association of Urology (EAU) Young Academic Urologists (YAU) will propose and collect a battery of potential outcome measures, which may be considered for the final stricture-fecta outcomes for patients undergoing urethroplasty for an urethral stricture. In the first Delphi round, an online questionnaire will be generated through Google Forms and distributed accordingly, providing participants the opportunity to approve, modify, or dismiss each of the suggested stricture-fecta items. The participants will be given the opportunity to comment and give written feedback on how to refine each item and propose alternatives. A pilot study will be conducted prior to round one to ensure that participants understood the questions. A panel of at least 100 selected worldwide reconstructive urological surgeons with great expertise in urethroplasty will be invited by the authors to participate in the development of the "stricture-fecta". The selection criteria include "being a renowned expert with international experience" and "participation in courses and masterclasses as teachers or tutors". Invitations to participate will be distributed among internationally active societies and boards such as TURNs, the EAU Section of Genitourinary Reconstructive Surgeons (ESGURS), the EAU ad hoc guideline panel on urethral strictures, and the Society of Genitourinary Reconstructive Surgeons (GURS). Basically, all invited experts will be asked to vote on the base of the following question: "When you perform a urethroplasty for urethral stricture, what are the major objectives that you aim to achieve?". Following the feedback given by the participants, the stricture-fecta will be reviewed, adjusted, and prepared for a second Delphi round, when it will be distributed again to all participants who completed round one. Participants will be asked to rate the importance of reporting each potential stricture-fecta item according to a 9-point Likert scale (range from 1, "not important", to 9, "extremely important") as per the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group. If an item receives a scoring of at least 7 by  $\geq 70\%$  of the respondents and not more than 15% rate the item with 3 or less, the outcome measure will be forwarded to the next round.<sup>8</sup> Failing the former scoring criteria will result in excluding the potential stricture-fecta item from further selection. The proposed items are the following:

1. Uroflowmetry: Q max  $\geq$ 15 mL/sec.
2. At least 10 mL/s improvement of Qmax from baseline.
3. Post-void residual  $\geq$ 150 mL.
4. Urethra can be passed without disrupting the integrity of mucosal lining by flexible cystoscopy.
5. No anatomical recurrence on urethrography.
6. Freedom from stricture retreatment (including dilation, urethrotomy, urinary derivation including all types of catheters, redo urethroplasty, endoluminal treatment, suprapubic diversion).
7. Patients' satisfaction (subjective – not rated).
8. Treatment satisfaction evaluated by validated PROM tools (USS PROM or ICIQ-Satisfaction).
9. Significant improvement in validated voiding scores (eg, USS PROM six-item LUTS score or I-PSS).
10. No impact on incontinence or sexual function (as measured by validated tools, eg, IIEF, MSHQ, ICIQ-UI).
11. Lack of postoperative complications (wound infection-dehiscence, urinary fistulae, etc).

The participants will be given the chance to propose editing or advice as well as additional items. After each round, further three items, which scored less, will be excluded. The number of Delphi rounds needed will not be predefined. The process will go ahead without following Delphi rounds until the agreement for the top five items is by a majority of votes. The study was not submitted to any IRB approval since it does not rise any ethical concerns nor sensitive data.

## Conclusions

Urethral surgery remains one of the most delicate niches of reconstructive urology, and yet, it is still unclear what the primary outcomes should be for the surgeon operating a patient with a urethral stricture. Defining the stricture-fecta as a worldwide, consensus-based comprehensive outcome battery after urethroplasty is our ambitious goal in order to unite reconstructive urologists all over the world, to improve comparability of outcomes and to eventually move forward to high-quality trials and multi-institutional studies that speak the same language and can lead to high-quality data and guidelines on how to treat our patients best.

## Disclosure

The authors report no conflicts of interest in this work.

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