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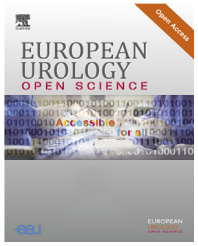

European Association of Urology

Reconstructive Urology

Proximal Urethrostomy Versus Urethroplasty for Complex Urethral Strictures

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Abstract

Background: The optimal treatment for complex urethral stricture (CUS) is yet to be determined. Comparisons of methods based on validated questionnaires or objective outcome measures are lacking.
Objective: To compare proximal urethrostomy and urethroplasty for CUS using objective measures and validated questionnaires, and to evaluate trends in subgroups of patients who underwent proximal urethrostomy as the intended definitive treatment versus first-stage urethroplasty.
Design, setting, and participants: We identified all patients who underwent proximal urethrostomy at our center from 2004 to 2021. The control group comprised patients who underwent urethroplasty for CUS (strictures >6 cm, recurrent posturethroplasty strictures, or CUS due to lichen sclerosus or past hypospadias surgery).
Outcome measurements and statistical analysis: The primary outcome was a recurrent stricture at a minimal follow-up of 1 yr. The secondary outcomes included validated questionnaires, uroflowmetry, and residual urine volume. Survival was compared by a Kaplan-Meier analysis.
Results and limitations: The study included 57 proximal urethrostomy and 75 urethroplasty patients. Results for these two groups were as follows: the cumulative incidence of stricture recurrence over a median follow-up of 46 mo was 22.6% for proximal urethrostomy versus 36.2% for urethroplasty (p = 0.106); no statistically significant differences were observed between groups in terms of postoperative quality of urination or life, satisfaction with outcome, and erectile function. Both groups had a significant improvement in urinary flow after surgery (19.65 vs 20.29 ml/s), with no difference between the groups (p = 0.796); the proximal urethrostomy group had a significant improvement in postvoid residual after surgery, but there was no difference between the groups in the last follow-up visit (79.16 vs 52.03 ml; p = 0.245). A subgroup analysis of the proximal urethrostomy

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group showed no significant differences in cumulative primary or secondary outcomes. Limitations included the retrospective design and the relatively small study population.
Conclusions: Comparisons of the two groups revealed no significant differences in stricture recurrence, results of validated questionnaires, or objective measures of urination.
Patient summary: Proximal urethrostomy is equivalent to urethral reconstruction, and it should be offered as a viable solution for complex urethral stricture.

1. Introduction

Long strictures of the anterior urethra or strictures following failure of endoscopic treatment are usually treated by urethroplasty. While urethroplasty using excision and primary anastomosis techniques has a success rate of over 90% for short and bulbar strictures [1], the success rate is lower for complex strictures of the anterior urethra (hereinafter CUS), including long strictures or strictures due to previous urethroplasties or hypospadias surgeries, or due to lichen sclerosus. Depending on the etiology and length of the stricture, previous interventions, and the surgical technique used, the estimated stricture recurrence rate after urethroplasty ranges between 10% and 50% [2–5]. An alternate technique to achieve voiding without obstruction is proximal urethrostomy, which can be used as either a permanent solution or a temporary initial stage of a staged urethroplasty in patients with CUS. Although patients may be reluctant to undergo proximal urethrostomy due to psychological reasons such as urinating while sitting, scattered urinary stream, or changes in ejaculation, the former is a less complex surgery than urethroplasty.

The common perception is that the respective treatment intents of the two procedures are intrinsically different. While proximal urethrostomy abandons the chance of treating the obstructed urethra and thus may be considered palliative, the intent of urethroplasty is to regain normal function of the urethra. This having been said, the two techniques share a common goal to alleviate urethral obstruction, allowing unimpeded urination. Since these two strategies may be offered to patients with CUSs, we found it interesting to compare the outcomes of the two surgeries, both objective and patient-centered subjective measures, in order to be able to offer our patients better preoperative counseling.

The best surgical approach to CUS is currently a subject of controversy, one of the reasons being that there are very few studies comparing proximal urethrostomy and urethroplasty for patients with CUS. In particular, there is a paucity of comparative studies that include both subjective measures, such as validated questionnaires, and objective measures, such as urinary flow and postvoid residual volume (PVR). To validate our working hypothesis for this study that proximal urethrostomy is not inferior to urethroplasty in patients with CUS, we examined the stricture recurrence rate after proximal urethrostomy versus urethroplasty for CUS. We compared the two groups of patients using the subjective measures of validated self-reporting questionnaires and the objective measures of urinary flow and PVR.

2. Patients and methods

2.1. Study population and design

This is a retrospective cohort study based on the experience of a single surgeon belonging to our unit. The study group included all 57 patients who underwent proximal urethrostomy, for CUS, from 2004 to 2021. For the purpose of this study, we considered patients who underwent perineal urethrostomy to the proximal bulbar urethra or penoscrotal urethrostomy to the distal bulbar urethra as patients undergoing proximal urethrostomy. The majority of patients underwent perineal urethrostomy. These patients were divided into two subgroups: those for whom the surgery was the definitive planned treatment and those for whom the surgery was part of a staged urethroplasty strategy but who ultimately chose to forgo the complementary reconstructive surgery. The control group comprised 75 patients who underwent urethroplasty for CUS during the same period. The patients in this group underwent urethroplasty using mucosal grafts, skin flaps, combined techniques, or staged urethroplasty for CUS, defined as strictures longer than 6 cm, recurrent posturethroplasty strictures, or strictures due to lichen sclerosus and/or past hypospadias surgeries.

2.2. Outcomes and measures

The primary outcome was stricture recurrence, diagnosed by cystoscopy, urethrography, or the need for an additional procedure to treat the recurrent stricture symptoms. Urethral irregularity that allowed the free passage of a 16 Fr flexible cystoscope was not considered a stricture. For the primary outcome analysis, we included only patients with a minimum follow-up of 1 yr. In addition, for the other analyses, we retrieved data for patients who had died or were lost to follow-up after their last clinic follow-up visit.

The secondary outcomes included objective measures (peak urinary flow rate and PVR) and subjective measures (clinical variables evaluated according to validated questionnaires Supplementary material]) [6–8] concerning satisfaction with the outcome and urination (Urethral Stricture Surgery—Patient-Reported Outcome Measure; [USS-

PROM]), quality of life (EQ-5D and EQ-VAS), and erectile function (International Index of Erectile Function [IIEF-5]). There were a few limitations regarding the use of the questionnaires in our study. For USS-PROM, question number 8 was omitted because most patients in the proximal urethrostomy group do not urinate standing and thus could not report their urinary stream in relation to the picture for that question. In addition, USS-PROM was used by us only from 2019, when the Hebrew translation of this questionnaire was first validated [9]. Finally, the use of the questionnaires was limited to patients who could comprehend, read, and answer on their own; thus, illiterate patients or those with cognitive impairment could not provide these data. We measured the improvement in the objective variables after the surgeries in relation to the baseline measures for each group. We also compared the two groups according to the last recorded follow-up visit. In addition, we made every effort to make telephone contact with patients for whom up-to-date data were missing regarding the need for an additional procedure due to recurrent stricture or for whom we did not have completed questionnaires, in order to fill out the questionnaires using a telephone call transcript (Supplementary material). We invited these patients to complete uroflowmetry and PVR at our center, when possible. We also compared patient characteristics including age, stricture length and location, etiology, and past procedures. The length of the stricture was determined by a voiding cystourethrogram or the operative report. The Institutional Helsinki Committee at Shaare Zedek Medical Center (approval number 0170-21-SZMC) approved the study. The patients consented orally to answering the questionnaires.

2.3. Statistical analysis

To compare quantitative variables between the two independent groups, a *t* test or the nonparametric Mann-Whitney *U* test were used. Changes within groups for quantitative variables were examined using the nonparametric Wilcoxon paired signed-rank test. The chi-square or Fisher's exact test was used to examine the relationship between two categorical variables. The Kaplan-Meier survival analysis model with a log-rank test was applied to compare survival between groups. Nonparametric tests were used to evaluate variables the distribution of which was nonnormal in small subgroups. All statistical tests were two tailed, and a p value of $\leq$5% was considered statistically significant.

3. Results

3.1. Patients and outcomes

The study cohort comprised 132 patients: 57 underwent proximal urethrostomy and 75 underwent urethroplasty. The average age at the time of the procedure in the proximal urethrostomy group was 49 yr compared with 43.13 yr in the urethroplasty group (p = 0.044). The average stricture length in the proximal urethrostomy group was 7.53 cm, compared with 7.93 cm in the urethroplasty group (p = 0.363). Patients undergoing proximal urethrostomy had significantly more pan anterior (48.2%) and penile (37.5%) strictures than the urethroplasty patients, who had more bulbar (49.3%) or penobulbar (14.7%) strictures. The proximal urethrostomy group had significantly more strictures due to hypospadias (44.6%) and lichen sclerosus (17.9%), while patients undergoing urethroplasty had more idiopathic strictures (24.7%). There were no significant differences in past procedures, except for past proximal urethrostomy, which was more common among the proximal urethrostomy group (7%; Table 1).

The cumulative incidence of stricture recurrence, at a median follow-up of 46 mo, was 22.6% for the proximal urethrostomy group, compared with 36.2% for the urethroplasty group (p = 0.106). The mean time to stricture recurrence, if this occurred, was similar between the two groups (p = 0.514; Fig. 1). Ten patients with a minimum follow-up of less than 1 yr were not included in this analysis. Among the patients without stricture recurrence, the results of all questionnaires at the time of the last follow-up visit after surgery (or follow-up telephone interview) were similar (no significant differences between the groups), as were the results of the objective measures of the peak urinary flow and PVR, where available. In both groups, there was a significant improvement in urinary flow after the surgeries without any difference between the proximal urethrostomy and urethroplasty groups (19.65 vs 20.29 ml/s; p = 0.796). There was a statistically significant improvement in PVR only in the proximal urethrostomy group after surgery, but there was no significant difference between the proximal urethrostomy and

Table 1 – Stricture and patient characteristics of the urethroplasty (U) and proximal urethrostomy (PU) groups

	U	PU	*p* value
No. of patients	75	57	N
Age (yr), mean (SD)	43.13 (18.2)	49 (15.72)	0.044
Stricture length (cm), mean (SD)	7.93 (4.87)	7.53 (5.72)	0.363
Stricture location, no. (%)			
Pan anterior	21 (28)	27 (48.2)	0.018
Penile	6 (8)	21 (37.5)	0.000
Bulbar	37 (49.3)	6 (10.7)	0.000
Penobulbar	11 (14.7)	2 (3.6)	0.036
Etiology, no. (%)			
Hypospadias	17 (23.3)	25 (44.6)	0.010
Idiopathic	18 (24.7)	6 (10.7)	0.044
Traumatic catheterization	23 (31.5)	13 (23.2)	0.298
LS	3 (4.1)	10 (17.9)	0.010
Inflammatory	8 (11)	1 (1.8)	0.077
Trauma	4 (5.5)	1 (1.8)	0.385
Past procedures, no. (%)			
Hypospadias repair	16 (24.6)	23 (40.4)	0.063
Dilatation	52 (80)	39 (68.4)	0.143
VIU	26 (40)	16 (28.1)	0.166
U	23 (35.3)	21 (36.8)	0.867
PU	0 (0)	4 (7)	0.045
CIC	2 (3.1)	4 (7)	0.416
Prostatectomy	5 (7.7)	3 (5.3)	0.722
Technique of procedure, no. (%)			
PU by intention	N	(52.6)30	
First-staged U	N	(47.4) 27	
Graft	48 (64)	N	
Flap	6 (8)	N	
Combined technique	16 (21.3)	N	
Staged U	5 (6.7)	N	

CIC = clean intermittent catheterization; LS = lichen sclerosus; N = data not available; SD = standard deviation; VIU = visual internal urethrotomy.

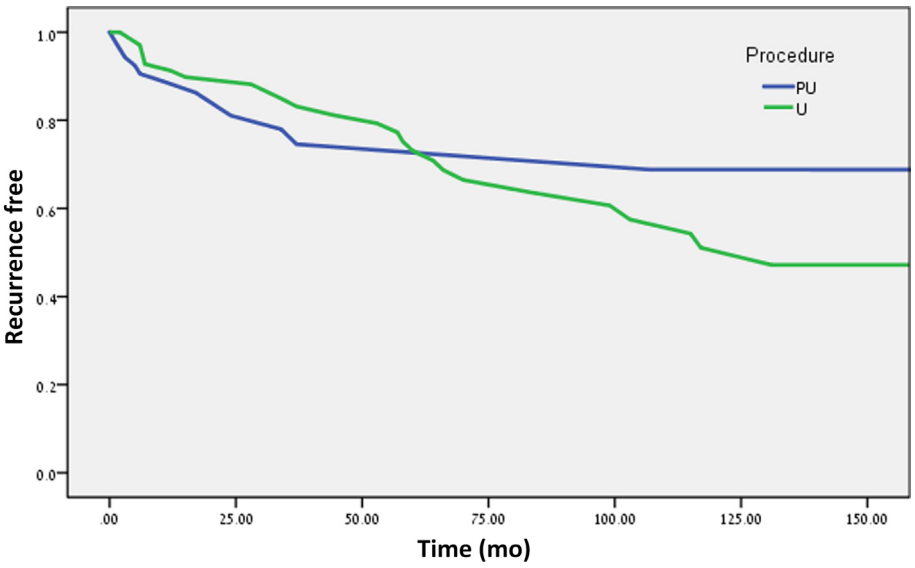


Fig. 1 – Recurrence rate of urethral stricture in patients undergoing urethroplasty (U) versus proximal urethrostomy (PU).

urethroplasty groups for PVR values at the last recorded follow-up visit (Fig. 2A and 2B).

The duration of follow-up was similar for the two groups, both for the time of filling out the questionnaires ($p = 0.257$) and for the time of uroflowmetry and PVR ($p = 0.077$). Of the proximal urethrostomy and urethroplasty patients, 63.4% and 79.4%, respectively, reported that the residual urinary symptoms interfered little or not at all with their daily routine, and 88.6% and 94.9%, respectively, reported being satisfied or very satisfied with the outcome of the surgery (Table 2).

3.2. *Subgroup analysis*

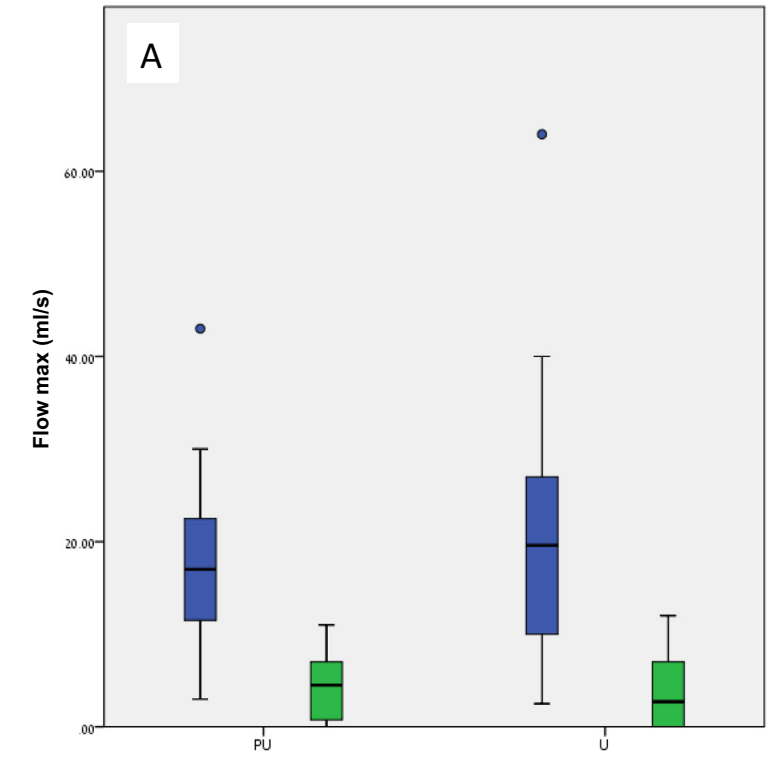
A subanalysis was performed to identify trends in the proximal urethrostomy group by comparing patients who underwent proximal urethrostomy by intention with patients who underwent first-stage urethroplasty and then chose to forgo the complementary reconstructive surgery with closure of the urethrostomy. The measures used for comparison in these subgroups were similar to those used for the proximal urethrostomy versus urethroplasty comparison, except for the exclusion of past surgeries and improvement in urinary flow and PVR.

For the 57 patients in the proximal urethrostomy group, the surgery was the definitive treatment in 30 and a first-stage urethroplasty in 27; the average ages of the patients were 56.03 and 41.19 yr, respectively ($p = 0.000$), and the mean stricture lengths were 9.15 and 5.9 cm, respectively ($p = 0.037$). Patients undergoing proximal urethrostomy by intention had significantly more pan-anterior (60%) or bulbar (20%) strictures caused by traumatic catheter insertion (33.3%), while patients undergoing first-stage urethroplasty had more penile strictures (65.4%) caused by previous hypospadias surgeries (69.2%; Supplementary Table 1). The cumulative incidence of urethral stricture recurrence during the follow-up period was 27.6% in the proximal urethrostomy by intention group, compared with 16.7% in the first-stage urethroplasty group ($p = 0.344$). The average time to recurrence was similar between the two subgroups ($p = 0.198$; Supplementary Fig. 1).

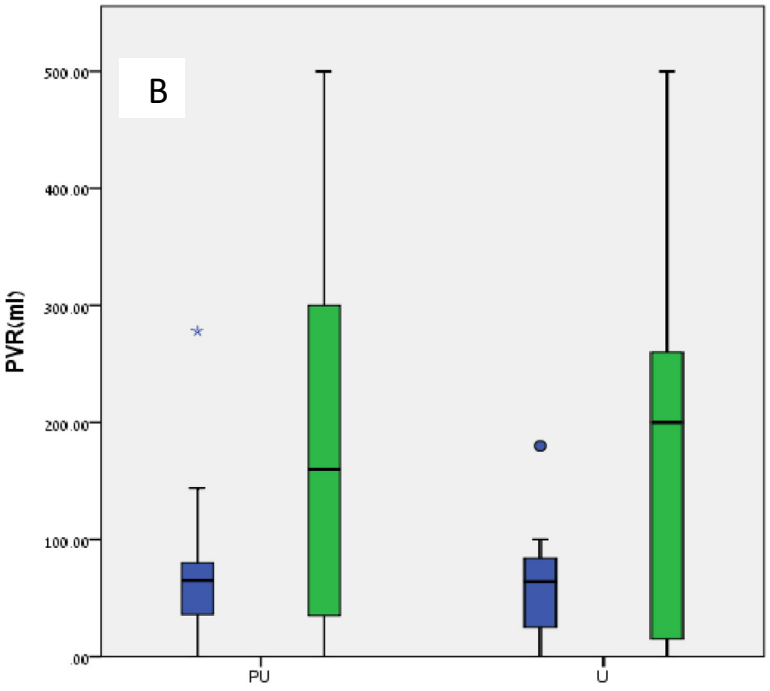
According to the EQ5-VAS questionnaire regarding general health status, patients undergoing proximal urethrostomy as first-stage urethroplasty perceived themselves as healthier than those undergoing proximal urethrostomy by intention. Nevertheless, there were no statistically significant differences between the two subgroups in the other questionnaires or objective measures of peak urinary flow and PVR. In response to the USS-PROM questionnaire, 64.3% of the proximal urethrostomy by intention patients and 62.5% of the first-stage urethroplasty patients reported that the residual urinary symptoms interfered little or not at all with their daily routine; similarly, 83.3% and 94.1%, respectively, reported being satisfied or very satisfied with the outcomes of the surgery (Supplementary Table 2).

4. Discussion

In addressing the question of the optimal surgery for CUS, there was no statistically significant difference in stricture recurrence rate comparing proximal urethrostomy and urethroplasty. Findings for the objective measures (peak urinary flow and PVR) and the subjective measures (validated questionnaires concerning satisfaction, urination, quality of life, and erectile function) were similar for the proximal urethrostomy and urethroplasty groups. Of note, this study addressed only the aspect of erectile function and not other aspects of male sexual function, such as ejaculatory function and sexual satisfaction. In our experience, erectile function is most often brought up by patients in discussion prior to surgery. Other studies reporting on perineal urethrostomy, mentioned later in this discussion, reported mostly on erectile function as well. Both groups showed a statistically significant improvement in the peak urinary flow at the last recorded follow-up visit after the surgery



	ΔFlow mean (ml/s)	IQR	*p* value
U	16.30	5–22	0.000
PU	13.88	7.55–16.53	0.000



	ΔPVR mean (ml)	IQR	*p value*
U	123.91	−20 to 240	0.074
PU	123	−to 19 251	0.020

Fig. 2 – (A) Peak urinary flow and (B) postvoid residual urine before and after urethroplasty (U) and proximal urethrostomy (PU). IQR = interquartile range; PVR = postvoid residual.

versus the flow before the intervention. Furthermore, for patients undergoing proximal urethrostomy, there was a statistically significant improvement in PVR compared with baseline values obtained before the surgery.

The subanalysis of the proximal urethrostomy group revealed that patients who underwent the surgery as part of a multistage program were younger, had shorter penile strictures, and perceived themselves as healthier than patients who underwent proximal urethrostomy by intention. These patients intended to undergo a complex procedure that usually includes a mucosal or skin graft, and thus, as expected, their preoperative health was better than that of the patients destined for proximal urethrostomy by intention—considered a "palliative" intervention—to relieve urinary symptoms. Nevertheless, the subanalysis showed no difference in the stricture recurrence rate during the

Table 2 – Comparison of subjective [a] and objective [b] measures between the urethroplasty (U) and proximal urethrostomy (PU) groups

	U	PU	*p* value	95% CI of mean of difference
PROM Q 1–6, mean (%)	6.06 (34)	5.28 (29)	0.526	−3.235 to 1.669
PROM Q 7—interference of urinary symptoms with life: a little or not at all, no. (%)	27 (79.4)	19 (63.4)	0.141	N
PROM Q 9overall satisfaction with the outcome of the operation: satisfied or very satisfied, no. (%)	37 (94.9)	31 (88.6)	0.413	N
EQ-5D—any problem with quality of life, no. (%)	11 (33.3)	14 (46.6)	0.28	N
EQ-VAS, mean (no.)	83.88 (33)	78.45 (29)	0.319	−16.247 to 5.386
IIEF-5, mean (no.)	20.75 (28)	19.35 (26)	0.424	−4.899 to 2.092
Flow max (ml/s), mean (no.)	20.29 (39)	19.65 (35)	0.796	−5.533 to 4.256
PVR (ml), mean (no.)	52.03 (35)	79.16 (31)	0.245	−19.030 to 73.295
Mean months of follow-up for objective measures	68.77	49.11	0.071	N
Mean months of follow-up for subjective measures	84.67	74.94	0.257	N

CI = confidence interval; IIEF-5 = International Index of Erectile Function; N = data not available; PROM = patient-reported outcome measures; PVR = postvoid residual; Q = question; VAS = visual analog scale.

[a] Urinary symptoms (PROM Q 1–6), interference with life (PROM Q 7), satisfaction with the outcome of the surgery (PROM Q 9), quality of life (EQ-5D and EQ-VAS), and sexual function (IIEF-5).

[b] Peak urinary flow and PVR.

follow-up period, with both groups having similar quality of life, urination, erectile function, and urinary flow measures. These results may indicate that the high success rate of proximal urethrostomy in both groups (proximal urethrostomy by intention and as staged urethroplasty) cannot be attributed solely to the lower age and morbidity of those undergoing proximal urethrostomy as staged urethroplasty.

The literature comparing the outcomes of proximal urethrostomy versus urethroplasty for the treatment of CUS is sparse. Nonetheless, in an observational-descriptive study of a cohort of 173 patients with CUS, who underwent proximal urethrostomy as part of a staged urethroplasty, the authors reported a success rate of 70%. Of those patients, 97% were satisfied or very satisfied with the results of the surgery, and 73.4% refused the second-stage surgery to close the urethrostomy [10]. Another study that reviewed 403 patients with CUS, who underwent different reconstructive surgeries, found a ten-fold increase over a decade in the use of proximal urethrostomy compared with the other surgeries. Furthermore, the success rate of the proximal urethrostomy was 94.8% over a median follow-up of 50.7 mo—higher than that for urethroplasty using a mucosal graft or skin graft [11]. In a recently published study, the success rate of proximal urethrostomy for CUS was 92.9% at a median follow-up of 34 mo. The majority (84.6%) of the patients were satisfied or very satisfied with the surgery outcome. This study reported an improvement in subjective symptoms (questionnaires) and objective measures of urination [12]. The higher recurrence rate in our study versus the aforementioned study (22.6% vs 7.1%) is probably related to the longer median follow-up of our patients. Additionally, the aforementioned study did not compare proximal urethrostomy with urethroplasty but reported only on patients undergoing proximal urethrostomy.

Two additional studies are of interest. Murphy et al [13] compared the improvement in subjective measures in patients with CUS who underwent proximal urethrostomy versus urethroplasty, defining CUS as any stricture longer than 6 cm. Similar to our study, there was no difference in the stricture recurrence rate at a 2-yr follow-up, and both their groups demonstrated an improvement in quality of urination, without any harmful effect on erectile function [13]. Verla et al [14], who reported on patients undergoing staged urethroplasty for CUS, found that almost half of the patients ultimately chose to forgo the complementary reconstructive surgery, preferring to remain with the proximal urethrostomy. Most of them were satisfied with sitting while urinating and expressed concerns regarding the possibility of stricture recurrence due to another operation. The researchers concluded that in patients with CUS, proximal urethrostomy should be proposed as a reasonable alternative for CUS from the start [14].

The best approach to assess the outcome of urethral stricture surgeries is still undecided [15]. It may include the evidence of stricture on cystoscopy or imaging studies (anatomical outcomes), urinary flow and PVR (functional outcomes), or validated questionnaires relying on the patients' subjective symptoms and satisfaction. For example, PVR is a controversial measure for follow-up after urethral stricture surgery, as the daily variation in a patient's residual urine may exceed 600 ml [16]. Age, bladder dysfunction, and other causes of bladder outlet obstruction, such as prostatic obstruction, may also affect PVR. The current trend to assess the outcome of surgery focuses on patient satisfaction as the prime measure of success, since an important aim of treating urethral strictures is to maintain good quality of life [17]. For this reason, we included in our study both objective and subjective measures in order to validate our hypothesis.

Our study has several important strengths: we expanded the definition of CUS to include patients after failed reconstructive surgeries and those with strictures due to lichen sclerosus or past hypospadias surgeries. We assessed both subjective and objective outcomes to enhance the significance of the results, and to complete the data, we made telephone contact with patients who had not attended the follow-up clinic. Furthermore, we used the USS-PROM questionnaire, a specific tool for urethral stricture disease, and not the International Prostate Symptom Score questionnaire, which is widely used but has not been validated

specifically for urethral stricture [18]. In addition, the study was based on a relatively large number of patients who had undergone surgery over 15 yr with extensive postoperative follow-up despite the rarity of CUS. Finally, we also included a subanalysis to examine trends in the proximal urethrostomy group.

The study has a number of limitations, the first of which was its retrospective design. However, with such low numbers of patients, a prospective randomized study is not easily achievable, if at all. Although we selected a control group according to the appropriate parameters in order to create similar groups as possible, we were unable to filter out the differences completely, as can be seen by the differences in age, stricture location, and etiology. It seems that the cases in the urethroplasty group were less severe according to these characteristics. Patients in the proximal urethrostomy group had more penile or pan anterior strictures due to hypospadias or lichen sclerosus, known risk factors for urethroplasty failure.

In this case, we would expect this would result in a higher failure rate and impinge our hypothesis. However, since the results between the groups are similar, it only strengthens the hypothesis despite the worse "starting conditions" of the proximal urethrostomy group. These findings emphasize the potential superiority of proximal urethrostomy and that it should not solely be regarded as a palliative solution.

The proximal urethrostomy group also had a higher mortality rate during the follow-up period—four patients (7%) versus two patients (2.6%) in the urethroplasty group (none of the deaths was perioperative). Second, patients who tend to continue follow-up are usually those who develop complications or those with worse outcomes. However, this bias would probably affect both groups of patients, thereby mitigating its significance. Furthermore, we tried to offset this effect by obtaining missing data by telephone interviews for those patients who had not attended the clinic for follow-up visits. The retrospective nature of this study, the long time required to collect a sufficient number of patients with the less common CUS over which surgical techniques evolved, and the intrinsic heterogeneity of the surgical techniques needed to solve CUS, all contributed to the surgical procedures used in the control group being much more diverse than those in the proximal urethrostomy group. This may lead to some bias in favor of proximal urethrostomy. A subanalysis of the control group by technique would not be possible, as this would fragment the group into small groups to allow for a meaningful analysis. This may be offset partially by the fact that the long time needed to collect sufficient patients also allowed for long-term follow-up with more mature data.

Although the wording of the questionnaires is neutral, a bias is possible as a result of the way in which the patients understand the questions or of a desire to make a certain impression on the interviewer. Finally, a noninferiority study examining the differences between groups such as this is based on previous knowledge from research. Given the lack of data in the literature and the small population of the study, the findings may not have sufficient power to substantiate the hypothesis that proximal urethrostomy is not inferior to urethroplasty in patients with CUS, although the data presented appear to support this notion.

5. Conclusions

The common surgeries for CUS are urethroplasty and proximal urethrostomy, although studies regarding the best treatment are inconclusive. Our study shows that proximal urethrostomy is at least equivalent to urethroplasty in terms of success rate, objective measures of urinary flow and PVR, and subjective measures that include validated questionnaires. We conclude that proximal urethrostomy should be offered and discussed with patients with CUS together with urethral reconstruction, balancing their advantages and disadvantages, as a viable solution as part of an informed and shared decision-making process.

Author contributions: Nir J. Rahav had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Shenfeld, Rahav.
Acquisition of data: Shenfeld, Rahav, Udah, Cohen.
Analysis and interpretation of data: Shenfeld, Rahav.
Drafting of the manuscript: Rahav, Shenfeld.
Critical revision of the manuscript for important intellectual content: Shenfeld.
Statistical analysis: Bdolah-Abram.
Obtaining funding: None.
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Supervision: Chertin.
Other: None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2024.02.008.

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