Long-Term Efficacy of Distal Penile Circular Fasciocutaneous Flaps for Single Stage Reconstruction of Complex Anterior Urethral Stricture Disease

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Purpose: We determined the overall efficacy and predictors of success of the distal penile circular fasciocutaneous flap in the management of complex anterior urethral stricture disease not due to lichen sclerosus.

Materials and Methods: We performed a retrospective review of all patients undergoing reconstruction of complex anterior urethral strictures without lichen sclerosus repaired from 1985 to 2006. Primary and overall stricture-free survival curves were estimated using the Kaplan-Meier method. Cox proportional hazards regression analysis was used to identify univariate and multivariate predictors of flap success.

Results: A total of 124 patients met the inclusion and exclusion criteria. Median patient age was 48 years (range 16 to 83). Median followup was 7.3 years (range 1 month to 19.5 years). Median stricture length was 8.2 cm (range 0.5 to 24). At 1, 3, 5 and 10 years the overall estimated stricture-free survival rates were 95%, 89%, 84% and 79%, respectively. On multivariate analysis smoking (HR 4.0, 95% CI 1.2–12.9, p = 0.02), history of hypospadias repair (HR 4.4, 95% CI 1.3–14.6, p = 0.01) and stricture length 7 to 10 cm (HR 7.0, 95% CI 1.4–34.7, p = 0.02) were predictive of failure.

Conclusions: Fasciocutaneous flap urethroplasty has good and durable success rates in the treatment of complex anterior urethral strictures. Predictors of failure included smoking, history of hypospadias repair and longer stricture length.

Key Words: urethra, penis, urethral stricture, surgical flaps, tissue transplantation

Complex anterior urethral strictures can be a significant challenge due to urothelial scarring and fibrosis of the surrounding corpus spongiosum. Short bulbar strictures may be cured with a single DVIU, and for those in whom that treatment fails the gold standard is anastomotic urethroplasty.[1] Similarly excellent results have been realized with repair of longer bulbar strictures using buccal mucosa grafts.[2] The management of strictures that extend beyond the bulbar urethra or those isolated to the pendulous urethra, is less well-defined. These strictures were initially managed with 2-stage repairs.[3] However, as the field of urethral reconstruction developed there was a move toward 1-stage repair using free grafts made of skin, pedicle based flaps or combined approaches.[4,5] Additionally, given the success of buccal mucosa in the bulbar urethra, its application to the penile urethra has also been tested more recently.[6]

The distal penile circular FCF technique of urethroplasty was first reported in 1993.[7] This method was a modification of that described by Quartey in which a circumferential island of distal penile skin or foreskin is mobilized on a vascular pedicle and used for urethral repair.[8] Benefits to the use of distal penile skin include its nonhirsute nature, proximity to the urethra, length (13 to 15 cm), flexibility and versatility. Earlier reports have proven the skin to be a reliable urethral substitute, particularly when the dorsal urethral plate can be preserved.[9] Even in previously circumcised men good cosmetic results can be attained with this technique. Lichen sclerosus may involve the distal penile skin and is a relative contraindication to repair using a FCF.

Initial success rates with the FCF to repair complex anterior strictures have been high. However, followup in most series has been short. Few other series have had sufficient patients to investigate factors which influence FCF outcome. In light of the recent interest in the use of buccal mucosa grafts in anterior urethral strictures of any length and complexity, it is relevant to reassess the long-term success of the FCF in the management of anterior urethral strictures not due to LS as well as to determine predictors of failure.

MATERIALS AND METHODS

Patient Population

Following approval from the institutional review board the University of California, San Francisco urethroplasty database was reviewed. The database contains records of more than 1,000 patients treated surgically for urethral stricture disease by a single surgeon (JWM). A dedicated coordinator abstracts more than 75 variables per patient, and patient status as well as vital status is updated regularly based on

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clinic visits, telephone visits and the social security death index.

The records of all patients who underwent fasciocutaneous flap urethroplasty between 1985 and 2006 were selected, and 159 patients were identified. Patients treated using a combined approach with primary excision and end-to-end anastomosis or buccal mucosal grafts were included. A total of 35 strictures due to LS as well as 1 tubularized flap were excluded from analysis. The remaining 124 patients represent the study cohort.

Followup

Clinical history and uroflowmetry were performed at 3-month intervals for the first year and then yearly thereafter. Patients living far away or those who had moved out of the region, visited the referring urologist and information was gathered by correspondence. A voiding study was performed at catheter removal, and retrograde urethrography was performed at 3 months, 1 year and depending on recurrent symptoms or change in peak urinary flow or pattern on noninvasive testing. Primary success was defined as subjective and objective improvement in urinary flow, absence of radiographic evidence of stricture, and no further need for urethral instrumentation. Overall success included those patients requiring a single urethral dilation or DVIU to achieve these criteria.

Statistical Analysis

Primary and overall stricture-free survival curves were estimated using the Kaplan-Meier method. Patients were censored at last clinical evaluation (ie lost to followup date) or death. The log rank test was used to identify potential predictive variables with continuous variables split by median value. In addition to these results we used other previously known or suspected predictors of urethroplasty outcome to form our 12 study variables. Since no specific risk categories exist for age, stricture length or flap width, these variables were converted to categorical variables by quartiles. For BMI the World Health Organization definitions of normal (18 to 25), overweight (25 to 30) and obese (greater than 30) were used.

Cox proportional hazards regression analysis was used to identify univariate and multivariate predictors of flap success. Backwards step-wise modeling with the likelihood ratio statistic was used for variable entry and removal, which were set at 0.05 and 0.1, respectively. All potential risk factors (except BMI, which had more than 25% missing variables) were included in the multivariate model to increase accuracy and decrease bias. The alpha value was set at 0.05 for all analyses and 95% confidence intervals were calculated. Analysis was performed using commercially available statistical software (SPSS®).

TABLE 1. *Early, intermediate and late complications after fasciocutaneous flap urethroplasty*

	No.
Early complications:	
Hematoma	7
Seroma	1
Transient neuropathy	4
Compartment syndrome	1
Death within 30 days	1
Intermediate complications:	
Urinary extravasation	13
Mild distal penile skin necrosis	3
Late complications:	
Distal penile skin necrosis (2 yrs out)	1
Urethral diverticulum	1
Mild decrease in sensation	3
Significant decrease in sensation	2

TABLE 2. *Clinical features of patients who underwent fasciocutaneous flap urethroplasty between 1985 and 2006*

Median age at surgery (range)	48	(16–83)
Median BMI (range)	28.7	(20.5–53.7)
No./total No. history smoking (%)	22/93	(24)
No./total No. history DM (%)	7/98	(7)
No./total No. history vasculopathy (%)	16/98	(16)
No. stricture etiology (%):		
Unknown	53	(43)
Trauma	20	(16)
Hypospadias	19	(15)
Catheter/instrumentation	29	(23)
Other	3	(2)
No. prior treatment of stricture disease (%):		
None	28	(23)
Dilation	15	(12)
DVIU	31	(25)
Hypospadias repair	19	(15)
Urethroplasty	31	(25)
No. stricture location (%):		
Fossa navicularis	16	(13)
Penile urethra	30	(24)
Bulbar urethra to penile urethra	78	(63)
Median stricture cm (range)	8.2	(0.25–24)
No. repair type (%):		
FCF only	92	(74)
FCF + patch graft	13	(11)
FCF + end-to-end	19	(15)
Median an flap width (range)	2.0	(1.0–2.6)

RESULTS

Between 1985 and 2006 we identified 124 patients who met the inclusion criteria. Median patient age was 48 years (range 16 to 83). Median followup was 7.3 years (range 1 month to 19.5 years). There were 26 patients lost to followup at a median of 10 months (range 1 month to 9.5 years). There were 32 stricture recurrences, all of which were at the proximal or distal anastomosis of the FCF. No recurrent strictures were due to missed LS. A total of 16 patients died during followup at a median of 7.5 years after surgery (range 1 month to 10.9 years). With the exception of 1 patient who died suddenly within 30 days of surgery of unknown causes, no other death was presumed to be potentially related to patient stricture disease. Overall few major complications occurred and they are listed in table 1.

Table 2 shows the demographic and clinical information for these patients. Diabetes mellitus was either insulin or noninsulin dependent (no HgbA1c available). Patients with a vasculopathy were defined by a history of cerebral, coronary, or peripheral vascular events or revascularization. Stricture etiology varied and the plurality of strictures was idiopathic. Of strictures 63% started in the bulbar urethra although none was isolated to it. These patients were treated with BMG during the study period. Of the patients 77% had undergone prior urethral manipulation at another institution. Median stricture length was 8.2 cm (range 0.5 to 24). Repair of these strictures required a median flap width of 2.0 cm (range 1.0 to 2.6). The method of repair was FCF alone in 74% of patients.

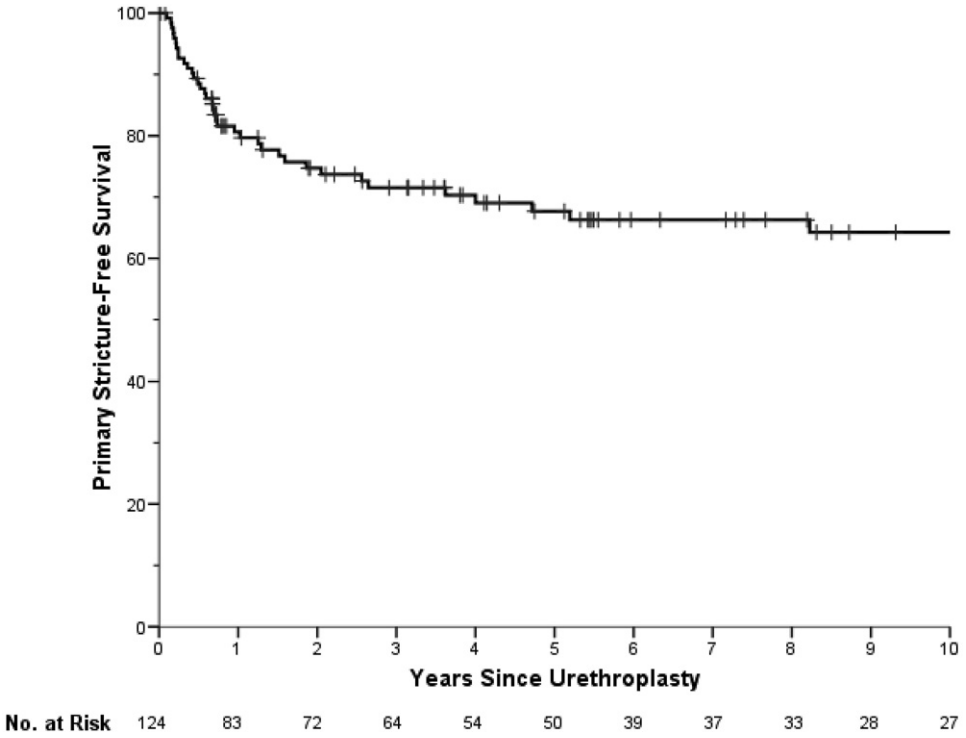

FIG. 1. Kaplan-Meier estimate of primary stricture-free survival

Figures 1 and 2 demonstrate the K-M estimated primary and overall stricture-free survival curves as well as the number at risk for each point. Primary estimated stricture-free survival at 1, 3, 5 and 10 years was 80%, 72%, 67% and 61%, respectively. With the judicious use of a single dilation or DVIU the overall estimated stricture-free survival at 1, 3, 5 and 10 years was 95%, 89%, 84% and 79%, respectively.

Univariate and multivariate Cox regression analysis of significant predictors of primary stricture-free survival can be found in table 3. Prior urethroplasty (HR 2.0, 95% CI

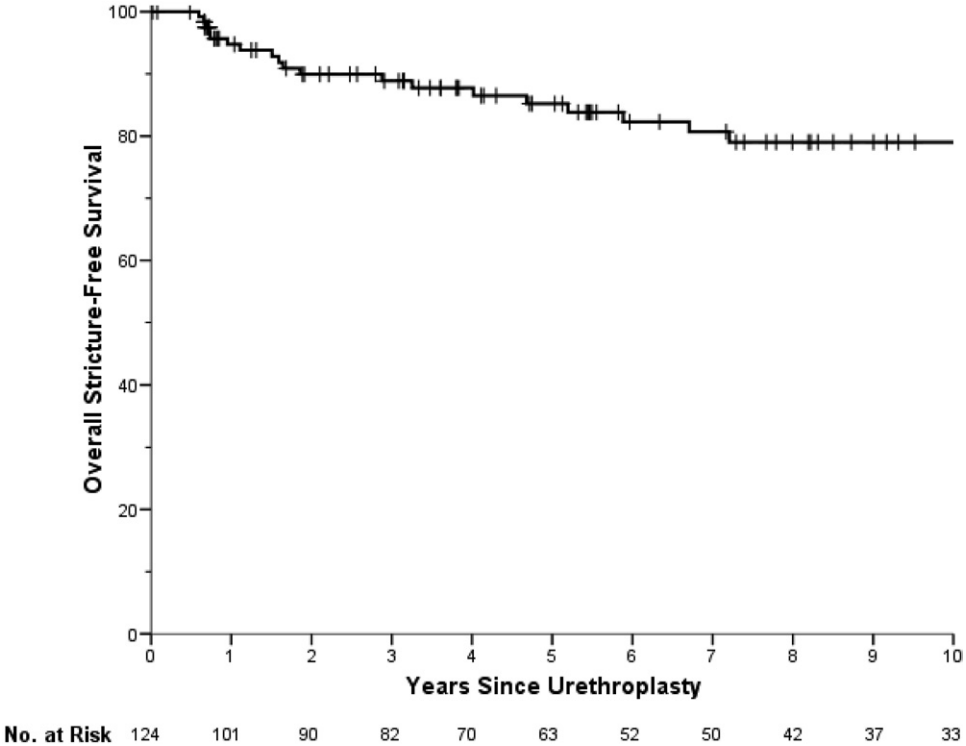

FIG. 2. Kaplan-Meier estimate of overall stricture-free survival

TABLE 3. *Univariate and multivariate analysis of potential prognostic factors for primary stricture-free survival*

	Univariate		Multivariate	
	HR (95% CI)	p Value	HR (95% CI)	p Value
Age (quartile):		0.11		0.49
Younger than 35	1.0 (referent)	—	1.0 (referent)	—
35–48	1.4 (0.6–3.5)	0.45	0.7 (0.1–3.6)	0.28
48–59	0.5 (0.1–1.6)	0.24	0.2 (0.1–1.4)	0.19
Older than 59	1.8 (0.8–4.4)	0.17	0.6 (0.2–2.6)	0.73
BMI:		0.47		
Normal	1.0 (referent)	—		
Overweight	1.9 (0.4–8.4)	0.40		
Obese	1.2 (0.3–5.5)	0.83		
Smoking	1.6 (0.8–3.2)	0.18	5.1 (1.7–15.1)	<0.01
DM	0.6 (0.2–2.0)	0.41	0.2 (0.1–1.4)	0.12
Vasculopathy	1.2 (0.6–2.7)	0.60	0.8 (0.2–2.8)	0.80
Trauma	1.1 (0.5–2.2)	0.80	0.7 (0.2–2.6)	0.75
Hypospadias	0.9 (0.3–2.2)	0.76	3.2 (1.0–10.7)	0.06
Prior urethroplasty	2.0 (1.0–3.8)	0.04	3.2 (1.1–9.1)	0.03
Stricture location:		0.30		0.26
Fossa	1.0 (referent)	—	1.0 (referent)	—
Penile	1.1 (0.5–2.8)	0.76	1.5 (0.7–16.7)	0.23
Bulbar-penile	1.8 (0.8–2.8)	0.16	2.5 (0.5–17.5)	0.78
Stricture length (cm):		0.14		<0.01
Less than 4	1.0 (referent)	—	1.0 (referent)	—
4–7	0.8 (0.3–2.3)	0.74	1.0 (0.2–4.6)	0.97
7–10	2.1 (0.9–4.8)	0.09	7.8 (2.0–30.8)	<0.01
10 or Greater	1.1 (0.4–3.1)	0.81	1.4 (0.3–5.7)	0.68
Combined repair	1.3 (0.7–2.6)	0.42	1.8 (0.6–5.3)	0.31
Flap width (cm):		0.05		0.39
Less than 2.0	1.0 (referent)	—	1.0 (referent)	—
2.0–2.2	2.2 (0.5–10.7)	0.32	2.5 (0.5–12.6)	0.97
2.2–2.5	4.1 (0.8–20.5)	0.08	4.7 (0.8–27.3)	0.25
2.5 or Greater	5.7 (1.3–25.4)	0.02	2.7 (0.5–15.2)	0.68

1.0–3.8, p = 0.04) and flap width 2.5 cm or greater (HR 5.7, 95% CI 1.3–25.4, p = 0.02) were predictive of failure on univariate analysis. On multivariate analysis smoking (HR 5.1, 95% CI 1.7–15.1, p <0.01), prior urethroplasty (HR 3.2, 95% CI 1.1–9.1, p = 0.03) and stricture length 7 to 10 cm (HR 7.8, 95% CI 2.0–30.8, p <0.01) were predictive of failure.

Univariate and multivariate Cox regression analysis of significant predictors of overall stricture-free survival can be found in table 4. No variables achieved statistical significance on univariate analysis. On multivariate analysis smoking (HR 4.0, 95% CI 1.2–12.9, p = 0.02), history of hypospadias repair (HR 4.4, 95% CI 1.3–14.6, p = 0.01), and stricture length 7 to 10 cm (HR 7.0, 95% CI 1.4–34.7, p = 0.02) were predictive of failure.

DISCUSSION

We have previously reported short to intermediate term followup on 54 patients undergoing FCF[9] as well as 25 patients who required a combined tissue transfer technique.[10] Success rates were 95% and 88%, respectively. In the current study of 124 patients median followup was 7.3 years with 33 patients at risk at 10 years or more. We used a statistically more rigorous method, ie K-M survival curves, to estimate our primary and overall 10-year stricture-free survival of 61% and 79%, respectively. We continue to judiciously use single dilation or DVIU of a recurrent short stricture web to achieve durable overall success. This is supported by the successful outcome in 50% of the 32 documented cases of treatment failure with a single DVIU. Median time to stricture recurrence was 1.6 years. However, the longest time to recurrence was 14 years. Although late instances of failure did occur we did not find the 5% per year failure rate seen in 1 series with a significant number of scrotal inlay flaps.[11]

Smokers were 4.0 times more likely than nonsmokers to experience overall treatment failure on multivariate analysis. Smoking also predicted higher primary failure rates. Younger age showed a trend toward predicting higher overall treatment failure rates on univariate analysis. We believe this is mainly because older patients were censored at time of death, leaving more young patients at risk for restricture. In addition, ascertainment bias might exist in that older patients may be more likely than younger patients to tolerate symptoms from mild recurrences of stricture disease.

Patients with a history of hypospadias repair were 4.4 times more likely to have overall stricture recurrence than those without this history. Cases with a history of hypospadias repair also showed a trend toward higher primary failure. Of note, the FCF was used to reconstruct a stricture within the prior hypospadias repair, not a de novo stricture more proximal to it. Similarly prior urethroplasty was a significant predictor of primary failure and these cases were 3.2 times more likely to experience recurrence. An additional trend toward overall failure was seen. In patients with a history of hypospadias or urethroplasty there is likely poor blood supply to the urethral plate, and significant scar tissue of the surrounding spongiosum, loose connective tissue and penile skin.

Compared with strictures 0 to 4 cm in length, strictures 7 to 10 cm had a 7.0 times higher failure rate when controlling for other variables. Longer strictures required a longer flap with a longer vascular pedicle which may put the flap at risk for failure. Additionally, longer strictures may be indicative of more aggressive disease. Given this hypothesis it is somewhat surprising that a dose-response effect was not seen, ie

TABLE 4. *Univariate and multivariate analysis of potential prognostic factors for overall stricture-free survival*

	Univariate		Multivariate	
	HR (95% CI)	p Value	HR (95% CI)	p Value
Age (quartile):		0.18		0.17
Younger than 35	1.0 (referent)	—	1.0 (referent)	—
35–48	0.7 (0.2–2.0)	0.49	0.8 (0.1–4.0)	0.16
48–59	0.3 (0.1–1.2)	0.09	0.2 (0.1–2.2)	0.37
Older than 59	0.3 (0.1–1.2)	0.08	0.1 (0.0–1.2)	0.11
BMI:		0.75		
Normal	1.0 (referent)	—		
Overweight	2.2 (0.3–17.8)	0.47		
Obese	1.8 (0.2–14.7)	0.60		
Smoking	2.2 (0.9–5.4)	0.09	4.0 (1.2–12.9)	0.02
DM	0.8 (0.2–3.4)	0.75	0.1 (0.0–15.9)	0.22
Vasculopathy	0.5 (0.1–2.2)	0.37	0.1 (0.0–1.3)	0.25
Trauma	1.6 (0.6–4.2)	0.30	10.5 (0.7–147.2)	0.19
Hypospadias	2.2 (0.8–6.0)	0.14	4.4 (1.3–14.6)	0.01
Prior urethroplasty	1.9 (0.7–4.8)	0.19	5.1 (0.8–38.1)	0.10
Stricture location:		0.65		0.31
Fossa	1.0 (referent)	—	1.0 (referent)	—
Penile	1.0 (0.3–1.5)	0.99	0.9 (0.1–17.5)	0.95
Bulbar-penile	1.5 (0.5–4.6)	0.45	0.2 (0.0–3.8)	0.25
Stricture length (cm):		0.38		0.03
Less than 4	1.0 (referent)	—	1.0 (referent)	—
4–7	0.7 (0.2–3.0)	0.61	0.5 (0.1–5.2)	0.57
7–10	1.4 (0.4–5.0)	0.59	7.0 (1.4–34.7)	0.02
10 or Greater	2.1 (0.6–7.6)	0.24	2.9 (0.6–13.5)	0.18
Combined repair	1.7 (0.7–4.2)	0.29	2.8 (0.3–24.8)	0.62
Flap width (cm):		0.69		0.51
Less than 2.0	1.0 (referent)	—	1.0 (referent)	—
2.0–2.2	3.4 (0.4–28.6)	0.25	7.6 (0.5–116.1)	0.17
2.2–2.5	2.4 (0.2–27.0)	0.47	0.5 (0.0–16.9)	0.34
2.5 or Greater	3.4 (0.4–28.9)	0.27	3.2 (0.0–88.6)	0.85

that the longest group of flaps, 10 cm or longer, were not predictive of treatment failure. It is certainly possible that an unrecognized confounder exists for which we did not adjust. On univariate analysis flaps 2.5 cm or longer were 5.7 times more likely to experience primary re-stricture. However, this relationship disappeared on multivariate analysis. Wider flaps are necessary when the native urethral plate is significantly narrower, consistent with more aggressive disease. In addition, wider flaps come closer to approximating a tubularized flap, which has significantly worse outcome than onlay.

Current debate may focus on the use of buccal mucosa grafts vs flaps to treat long anterior urethral strictures originating in the bulbar urethra or isolated to the pendulous urethra. In 1996 the use of penile skin free grafts was described in the pendulous urethra via dorsal onlay in 12 patients with strictures ranging from 1.5 to 5 cm.[12] Intermediate term results in these patients showed a deterioration with time.[13] Subsequently buccal mucosa has been used as the graft of choice. Table 5 presents a review of the literature of dorsal BMG in penile or panurethral strictures.[14–17] Many of these studies are reviews rather than original articles, some report outcomes including bulbar only strictures and most have short followup. Additionally, average stricture length in these studies was 4.7 cm, suggesting selection bias in performing 1-stage repair with BMG. The pooled overall success rate appears to be 91% at 3 years.

Other arguments may exist for the use of dorsal BMG performed in 2 stages in patients with complex anterior urethral strictures of any etiology. However, this technique appears to have no better results with a success rate of 87% at 3 years.[18] This comes with the further cost of 30% minor interval procedures between stages such that most authors acknowledge that the 2-stage repair can be more like a 3-stage repair.[19] In a single stage, with approximately 20% of patients needing single dilation or DVIU, the FCF is able to achieve a 79% long-term success rate at 10 years. However, this study does suggest that patients with prior hypospadias repair or urethroplasty are at significantly higher risk for failure, and these patients could be the ones who would benefit from a 2-stage repair.

We disagree with authors who have moved against penile flaps due to the complications of penile scar, torsion and ventral webbing.[19] The circumferential flap leaves only a circumcising incision scar. Penile torsion is seen only rarely when the flap is adequately mobilized. Ventral webbing is mainly a problem of tubularized FCF. We did see 3 patients with mild penile skin necrosis which re-epithelialized with conservative treatment. One patient experienced significant necrosis more than 2 years after surgery which did require operative débridement. Significant loss of sensation to light touch occurred in 2 patients. This is an important complication to discuss before using this method of repair. Finally, a moderate flap diverticulum occurred in 1 patient in this study. This is a technical error caused by not appropriately tailoring the flap and keeping it on stretch during the anastomosis. Overall we believe FCF complication rates compare quite favorably to those seen with BMG. One report shows that 51% of patients have donor site pain worse than expected, 26% have perioral numbness lasting longer than 6 months and 9% of patients have permanent changes in mouth opening.[20]

The limitations of this study involve all of those which are inherent to the retrospective design. Although it can be debated we believe it was appropriate to exclude those patients with LS from analysis because they have a unique disease process and because the distal penile skin may become involved by that process. We included patients who were lost to followup irrespective of followup time and allowed K-M analysis to estimate survival. Excluding these patients may underestimate or overestimate stricture-free survival as the influence of a good or bad outcome on the likelihood of followup is unknown in this population. Other weaknesses include those inherent to any large database such as missing data points. In this study except for BMI fewer than 25% of values were missing from any field. Arguments on the appropriate assessment of stricture recurrence in urethroplasty series will remain. We continue to use noninvasive means after the first 12 months to detect recurrence.

TABLE 5. *Recurrence after free graft urethroplasty in penile or panurethral strictures*

	No. Pts	Stricture cm (range)	% Success Mos	Followup (range)
Barbagli et al[12]	12	(1.5–5)	100	33 (18–56)
Asopa et al[6]	12	6 (2–10)	92	26 (8–40)
Gupta et al[14]	12	5 (3–16)	92	12 (10–16)
Dubey et al[15]	28		93	34 (8–72)
Barbagli et al[16]	18		81	34 (12–138)
Datta et al[17]	25	4.8 (3–9)	92*	48 (12–84)
All series	107	4.7	91	34

* This success rate is from an entire series that included 18 additional patients with bulbar only strictures.

CONCLUSIONS

Fasciocutaneous flap urethroplasty has good and durable success rates in the treatment of complex anterior urethral strictures. Predictors of failure included smoking, history of hypospadias repair and longer stricture length.

Abbreviations and Acronyms

BMG	=	buccal mucosa graft
BMI	=	body mass index
DM	=	diabetes mellitus
DVIU	=	direct vision internal urethrotomy
FCF	=	fasciocutaneous flap
K-M	=	Kaplan-Meier
LS	=	lichen sclerosus

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