AmnioFix® SURGICAL

CASE EXAMPLE

Challenges in Urethral Stricture Disease

Doctor/Practitioner Information
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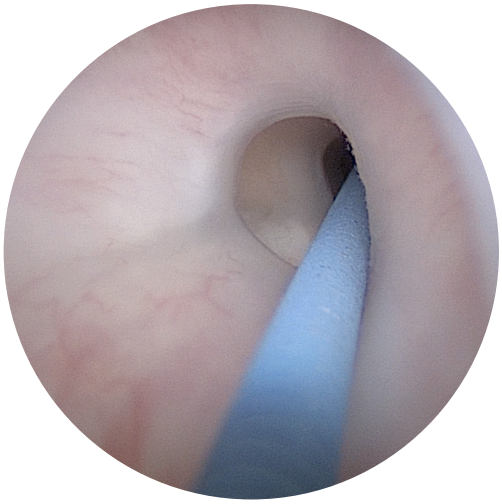
URETHRAL STRICTURE



MiMedx

PATIENT CASE EXAMPLE

AmnioFix® Injectable Used During DVIU for Urethral Stricture Disease

CHALLENGE: HIGH RISK PATIENT WITH RECURRENT STRICTURE IS A POOR CANDIDATE FOR URETHRAL RECONSTRUCTION

Patient age, comorbidities, and underlying disease are known to impair wound healing.[1] Consequently, certain patients are not viable candidates for complex surgical procedures due risk of the surgery, as well as post-op complications. In this case, the patient's significant cardiac history and comorbidities, the placement of the patient in high lithotomy position, and the nature of the procedure put the patient at risk for complications associated with anesthesia, cardiac stress, blood clots, strokes, rhabdomyolysis, and nerve injury. While reconstruction was not an ideal option in this patient, he was seeking a longer-term solution to address the recurrent strictures, which have high reported treatment failure rates of up to 35%.[2]

CLINICAL HISTORY

71-year-old male with a significant cardiac history, including atrial fibrillation and cardioversion, a history of prostate cancer status post-external beam radiation, benign prostatic hyperplasia, and urethral stricture disease presents with difficulty urinating and a weak stream due to recurrent urethral stricture. This is further compounded by anticoagulation therapy.

The patient was previously treated three years prior for prostate cancer and at that time received intensity modulated radiation therapy (IMRT) resulting in bulbar stricture disease. Over the previous three years, the patient has received treatment for his strictures with recurrences approximately every six months, including three urethral dilations in the most recent 18 month period.

This patient, frustrated with his current treatment protocol, consulted with a Reconstructive Urologist, who recommended Direct Visualization Internal Urethrotomy (DVIU) over urethral reconstruction due to the high risk of morbidity associated with the patient's age and poor health status. (See cover for stricture image before 1st DVIU.)

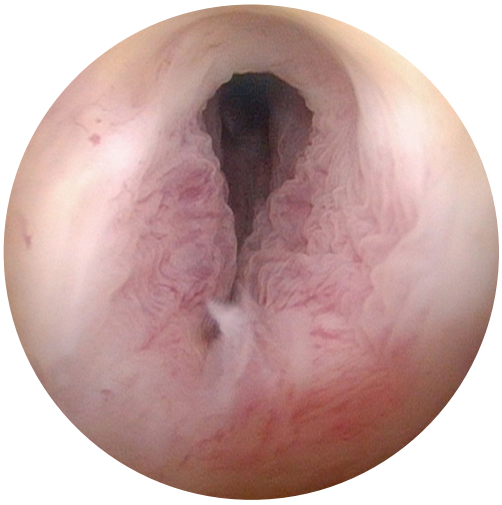


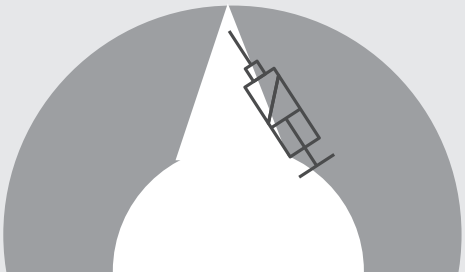
Figure 1
Stricture prior to 2nd DVIU and AmnioFix in January 2016

SURGICAL INTERVENTION

The patient underwent a standard DVIU procedure and returned with a recurrent stricture approximately four months later. The patient was scheduled for 2nd DVIU, but due to the high likelihood of recurrence, AmnioFix Injectable was added to help enhance the healing and reduce scar tissue formation (Figure 1). 100 mg of AmnioFix Injectable was mixed with 1 mL of normal saline and injected at the apex of the cut with an endoscopic needle through a ridged cystoscope following DVIU. A 22 French Foley catheter was left in place for 7-10 days. The goal is to allow for scar expansion, dilation, and enhance the speed of epithelization versus over wound contraction.

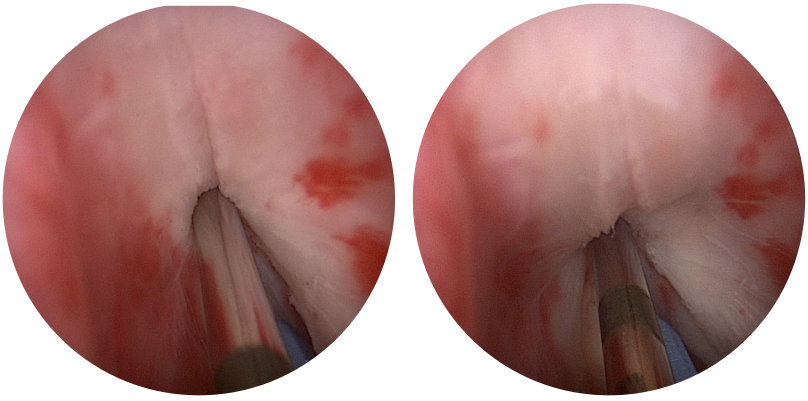
The patient was seen again three months later with early symptoms of recurrent stricture, however upon examination, the tissue in the area of the stricture showed significant signs of improvement. The recurrence was at least 50% larger than previous interventions, the urethral scarring was softer, and there were indications of increased vascularization in the previous radiated scar field. The patient was again treated with DVIU and AmnioFix, following the same protocol as described above (Figures 2-4).

TECHNIQUE SPOTLIGHT*



- 100 mg diluted in 1 cc of normal saline
- Injected at the apex of the cut following a DVIU with a 21 gauge endoscopic needle
- Placement of a 22 French Foley catheter that is left in place for at least 7-10 days

Figure 2
DVIU and AmnioFix Injectable technique description



Figures 3 & 4
Submucosal injection of AmnioFix into apex of cut

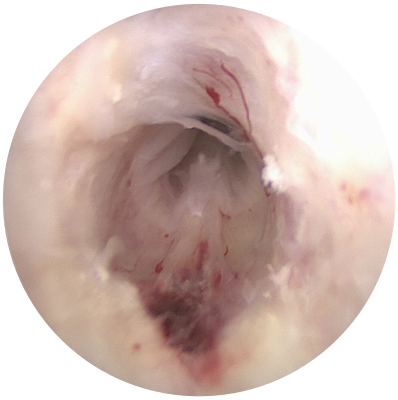


Figure 5
April 2016 follow up - View of prior stricture 3 months after 2nd AmnioFix injection. No evidence of stricture recurrence. Mild scope trauma visible after passing 24 French scope without difficulty.

FOLLOW UP

The patient was seen for follow up three months post DVIU and 2nd AmnioFix treatment with no indications of stricture recurrence. Upon examination, the dense scar site appeared more viable and friable (Figure 5). A 24 French cystoscope passed freely into the bladder and thus far the patient has shown no indications of voiding difficulty to date.

PATIENT TIMELINE

2012 — IMRT for prostate cancer leading to bulbar stricture

2013 — 3 dilations approximately every 6 months

2014

2015 — DVIU for severe pin point stricture

2nd DVIU with 1st AmnioFix injection for a pinpoint stricture

2016 — 3rd DVIU with 2nd AmnioFix injection for a stricture recurrence. Est. size ~10 French, but tissue with increased vascularity

No stricture recurrence, able to pass a 24 French scope with ease

CONCLUSION

I have several years of experience with both EpiFix® and AmnioFix in various wound and surgical applications, including prostatectomy, stricture repair, and fistula repair, where I have anecdotally observed enhanced healing and improved clinical outcomes using these grafts. Similarly in this case example, AmnioFix Injectable appears to have helped enhance healing and minimize scar tissue formation in a challenging patient with a history of recurrent stricture disease. Longer-term follow up for this patient is required, but the short-term observations are promising. In addition, the DVIU with AmnioFix offered a more conservative treatment option and significant upside for a patient that was too high of a risk for traditional urethral reconstruction surgeries.

To find out more about MiMedx® products or to start an evaluation:

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REFERENCES

1. Guo S, Dipietro LA. Factors affecting wound healing. J Dent Res. 2010 Mar;89(3):219-29.
2. Stormont TJ, Suman VJ, Oesterling JE. Newly diagnosed bulbar urethral strictures: etiology and outcome of various treatments. J Urol. 1993 Nov;150(5 Pt 2):1725-8.

*Technique description is based on Dr. Storey's personal, clinical experience and preference.
† As of April 1, 2016
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