Minimally Invasive Device for Rapid Urethrovesical Anastomosis

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1 Background

Radical prostatectomy is a common treatment for patients with prostate cancer [1]. The current surgical technique for radical prostatectomies requires dividing the urethra from the bladder in order to aid the removal of the prostate [2]. At the end of a prostatectomy, the urethra is reconnected to the bladder in a procedure known as urethrovesical anastomosis (UVA) involving suturing the urethra to the bladder with bio-absorbable sutures. This procedure is commonly done first by reconstructing the posterior aspect of the rhabdosphincter, using this reconstruction to bring together the bladder and the urethral stump and lastly performing a running suture to avoid multiple knot tying. UVA is the most challenging and time consuming of the radical prostatectomy procedure due to the constrained surgical field, the proximity of the external urethral sphincter, and the complexity of suturing on very small tubular structures. These have limited the surgical time for the UVA for an experienced surgeon to 15 min [3].

Most current suturing or stapling devices on the market are not designed for UVA and, therefore, lack crucial features necessary for performing the procedure, for example placing the urethra and bladder neck in contact to insert the sutures. One of the challenges in creating a device to automatically perform UVA is that no non-absorbable structures can remain in the urethra or bladder as interaction with urea in the urine can result in stone formation and further complications.

2 Methods

Based on interviews with clinicians, it became clear that a suturing system delivered through the urethra using only bio-absorbable sutures had potential to minimize procedural time, increase user-friendliness and enhance patient outcomes. Through an iterative design process a transurethral prototype was developed that is capable of suturing the urethra and bladder neck together by clamping, and deploying modified needles coupled to absorbable barbed-sutures.

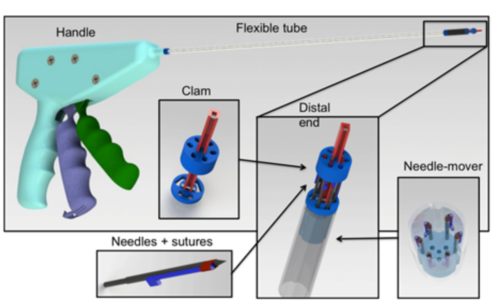

Fig. 1 Computer rendering of UVA device. Cup on distal end not shown for visualization purposes

Two actuating structures (one to bring the tissue together and a second to deploy the needles) are connected through flexible tubing to a handle that contains triggers that actuate the device (Fig 1). The two actuating structures and the tubing have an outer diameter of 5.8 mm to allow insertion into the surgical field through the patient's urethra. The steps of operation for this device are illustrated in Fig. 2.

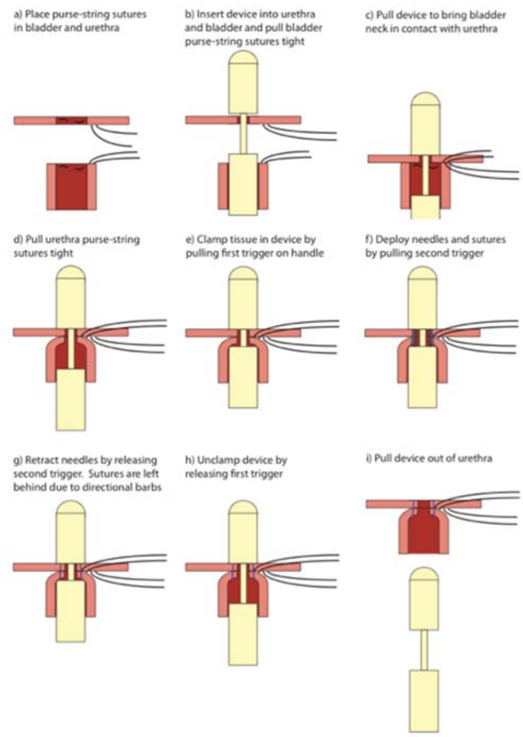

Fig. 2 Illustration highlighting the steps of operation of the device.

The surgeon places purse string sutures in the bladder neck and urethra (Fig. 2a) using the laparoscopic or robotic tools already in the body cavity from previous steps in the surgical procedure. The anastomosis device is then inserted through the urethra, and the top of the device is introduced into the bladder. The surgeon laparoscopically tightens the purse string sutures on the bladder, closing the tissue around the neck of the device (Fig. 2b). The bladder is pulled towards the urethra (Fig. 2c), and the purse-string sutures in the urethra are pulled tight, closing the tissue around the neck of the device in a similar fashion to the bladder (Fig. 2d). The surgeon next clamps the bladder and urethra tissue between the two ends of the anastomosis device by pulling a trigger in a proximal handle (Fig. 2e). If the surgeon is dissatisfied with the clamped tissue, the clamp can be released and the tissue readjusted by tightening the purse-string sutures before the anastomosis is performed. To deploy the sutures, the surgeon pulls a second trigger, causing the needles to be pushed along a linear path through the tissue (Fig. 2f). Upon releasing the trigger, the needles slide out of the tissue, leaving the sutures behind (Fig. 2g and Fig. 3). To remove the device, the clamp is released (Fig. 2h), and the device is pulled out through the urethra (Fig. 2i).

To simplify the operation of the device, the suture deployment method was designed so that it did not rely on knot tying or cutting steps, therefore simplifying the suturing to one step and a single degree of freedom for the suture placing mechanism. To eliminate the need for knot tying we employed barbed sutures that only allow unidirectional (distal) movement of sutures. A backstop prevents sutures from advancing too far. To avoid using a cutting mechanism to detach the sutures from the needles a simple release mechanism was designed that allows insertion of the sutures with the needle and detachment upon retraction (Fig. 3).

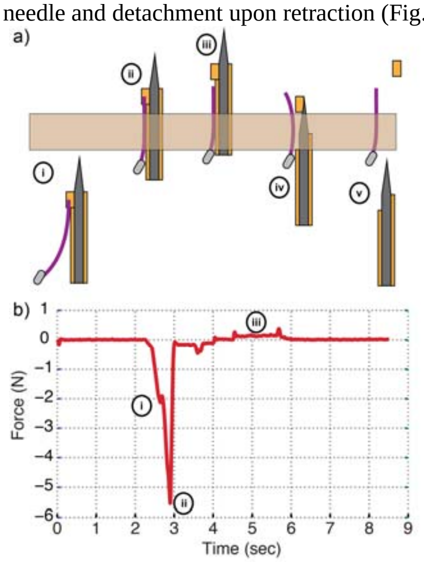

Fig. 3 (a) Schematic representation of the suturing process with the simple release mechanism (i) Suture is attached to needle through cuff. (ii) Needle and suture are inserted together. (iii) A backstop extracts the suture from the cuff. (iv) Barbed sutures are not extracted upon needle retraction. (v) The needle is retracted back to its original position, and the suture is left in the tissue, the cuff is removed with device. (b) Force profile for the procedure, (i) insertion of the needle, (ii) insertion of the suture and cuff and (iii) removal of the cuff.

3 Results

Testing of our device was performed on porcine tissue. To determine the forces that the device is subjected to during operation, the force profile for the deployment of the needle and suture was measured using a load cell (Fig. 3b). These tests show that the maximum force for a single needle to penetrate the bladder is 3.8 ± 0.8 N (*n=10*). By staggering the needles the peak force for each needle occur at different intervals. The force of penetration of the six needles is calculated from the force profile to be ~20 N at the maximum peak. Additionally the pull out force of a single barbed suture that had been inserted into porcine bladder was quantified using a load cell to pull on the suture in the opposite direction to insertion. A single barbed suture can withstand 4.5 N of tensile force before slipping out of the tissue.

Fig. 4 shows frames of motion from testing the final device mechanics, with the inset showing a close-up of the distal end of the device. The device is shown in the starting position (Fig. 4a), with the clamp opened and needles within the tube. The first trigger is pulled, moving the distal and proximal clamps together and clamping the urethra and bladder tissue (Fig. 4b). At this point, if the surgeon is dissatisfied with the clamping, the trigger can be released and the tissue readjusted and re-clamped. This trigger pull also sets the second trigger in position for deploying the needles. Pulling the second trigger pushes the needles out of the proximal clamp and through the tissue (Fig. 4c). The needles successfully move through both clamp plates without interference. This trigger is then released and a stretched retraction spring pulls the needles automatically into the tube without additional user input (Fig. 4d). Finally, the clamp trigger is released and the clamp relaxes (Fig. 4e) before the device is removed from the patient.

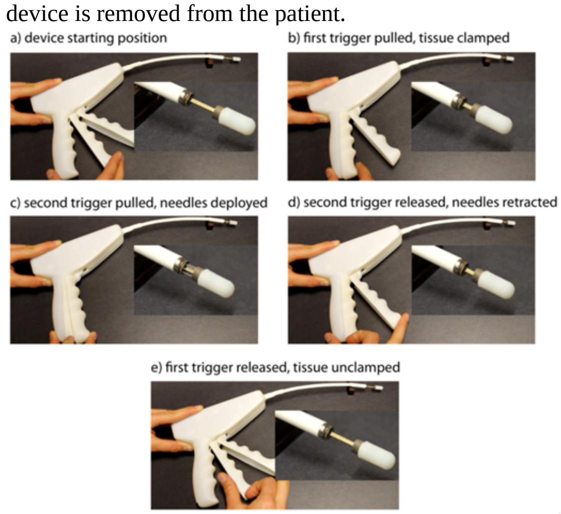

Fig. 4 Frames of motion for final device testing showing individual steps for the operation of the device.

4 Interpretation

Compared to current robotically-assisted anastomosis, this device exhibits potential improvements in procedure time, ease of surgeon training, and patient safety. Based on the similarities in procedural steps of this device and that of the bowel stapler, we estimate that the procedure time would be approximately 5 min compared with the 15 min of current procedures [3]. Furthermore, the simplicity of use will make surgeon training shorter and simplified. Lastly, in this design the needles move along a very predictable and repeatable linear path within the device and can only penetrate the very edge of the tissue that is clamped in the device, avoiding the external urethral sphincter and surrounding nerves and muscles thus potentially reducing the rate of complications from the UVA procedure and thus increasing patient safety.

References

[1] Lowrance, W. T., Eastham, J. A., Savage, C., Maschino, A. C., Laudone, V. P., Dechet, C. B., Stephenson, R. A., Scardino, P. T., and Sandhu, J. S., 2012, "Contemporary Open and Robotic Radical Prostatectomy Practice Patterns among Urologists in the United States," J Urol, 187(6), pp. 2087-92.

[2] Menon, M., Tewari, A., and Peabody, J., 2003, "Vattikuti Institute Prostatectomy: Technique," J Urol, 169(6), pp. 2289-92.

[3] Vallancien, G., Cathelineau, X., Baumert, H., Doublet, J. D., and Guillonneau, B., 2002, "Complications of Transperitoneal Laparoscopic Surgery in Urology: Review of 1,311 Procedures at a Single Center," J Urol, 168(1), pp. 23-6.