

Intraoperative Ureteral Identification Utilizing StimSite™ Technology during Robotic-Assisted Sacral Colpopexy Procedure: A Case Report

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Abstract

Identification of the pelvic ureter location is crucial during robotic-assisted sacral colpopexy procedures to avoid iatrogenic injury. In this case study, StimSite™ technology (Allotrope Medical; Houston, TX) was used to assist with ureter identification. StimSite is a novel, minimally invasive surgical device designed to facilitate ureter identification by delivering on-demand mild electrical impulses to stimulate visible ureteral peristalsis. Visualization of the ureter can help prevent inadvertent injury which can cause significant patient morbidity, and in some cases mortality. The use of StimSite permitted ureter mapping along the pelvic sidewall and assisted with creating the proper peritoneal dissection for synthetic mesh placement. StimSite provides a minimally invasive, time-conscious option for real-time ureter identification during robotic-assisted sacral colpopexy procedures.

Keywords

Robotic-Assisted, Sacral Colpopexy, Ureteral Injury

1. Introduction

Ureter identification during robotic-assisted sacral colpopexy and pelvic surgical procedures is imperative to avoid iatrogenic injuries. Iatrogenic ureteral injury is a potential complication of all surgical procedures performed in the pelvis [1]. It occurs mainly during female pelvic surgery and can result in devastating consequences and even mortality in the short-term and potential loss of organ function in the long term [2]. The rate of clinically apparent iatrogenic ureteral injuries during routine gynecologic pelvic operations ranges from 0.2% to 2.5% and can increase to 10% to 30% with radical procedures for malignant conditions

[3]. Until recently, methods for ureter identification included direct visualization, tactile ureter stimulation, ureter stent placement, ureterolysis, and Infrared Illumination System (IRIS). Limitations include reproducibility, time investment, and invasive nature depending on the modality chosen.

This is the first case report in the literature describing the use of StimSite technology, which was FDA cleared in 2020 to assist with ureter identification. StimSite elicits on-demand ureteral contraction by way of low-powered electrical stimulation which enhances visualization and pelvic mapping. StimSite is minimally invasive and there has been no reported patient morbidity associated with on-demand stimulation of the pelvic ureter for enhanced visualization and pelvic mapping. In addition, setup requires a negligible time investment, as it integrates with routinely used surgical instrumentation.

2. Case Report

A 65-year-old female presented for consultation with a 6-month history of a bulging sensation in the vagina associated with pelvic pressure and vaginal dryness. The patient was able to see and feel vaginal tissue beyond the introitus. The symptoms began after a heavy lifting episode. The patient's past medical, family, and psycho-social history was non-contributory. Her past surgical history was relevant for a previous transvaginal hysterectomy with bilateral salpingo-oophorectomy for abnormal uterine bleeding. Pertinent physical findings include a BMI of 25.6, atrophic vaginal mucosa secondary to exposure and lack of hormone therapy, and right paravaginal defect with a stage 3 cystocele. The patient was offered conservative and surgical options and provided informed consent for robotic-assisted sacral colpopexy.

At the beginning of the case, the robotic adapter was connected to the StimSite signal box and kept in standard electrical surgical unit (ESU) mode until ready to visualize the ureter (**Figure 1**).

StimSite was placed in "STIM" mode upon noting the patient had a right-sided-colon-to-sidewall adhesion obscuring visualization of the ureter. The bipolar grasper jaw was placed at the right pelvic brim on the peritoneum in the suspected area of the ureter. Once the location was confirmed, the dedicated StimSite foot pedal was depressed briefly to deliver fixed-signal electrical stimulation to the ureteral smooth muscle.

Peristalsis of the ureter was visualized until it was obscured by the colon adhesion (**Figure 2**).

The peritoneum was then sequentially dissected using the robotic monopolar scissors, freeing the colon from the right pelvic sidewall. The ureter was mapped incrementally during this dissection until the bowel was free from the right pelvic sidewall. The remainder of the ureter was mapped using StimSite until its descent into the parametrial tunnel. With the bowel safely removed from the right pelvic side wall and the ureter location identified, the peritoneum was opened from the sacral promontory to the vaginal cuff as part of the standard



Figure 1. StimSite signal box connected to surgical instrumentation. STIM button is pressed when ready to visualize the ureter, and dedicated foot pedal used to deliver the fixed signal.

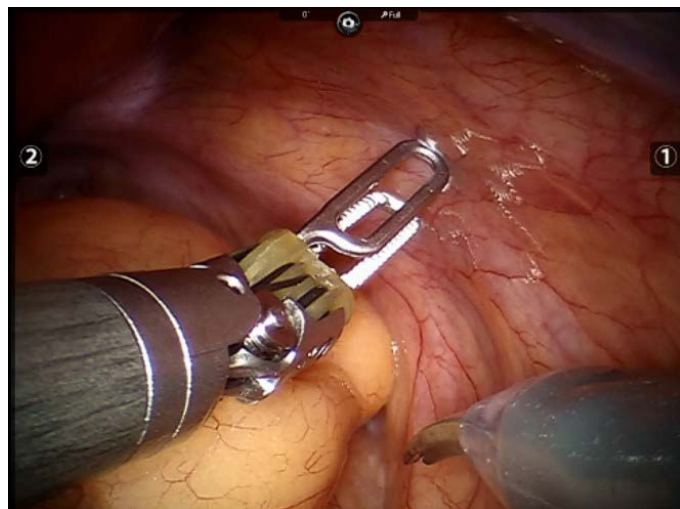


Figure 2. Bipolar instrument tip applied to the tissue or sidewall at anticipated ureter location with tips placed at the proximal ureter to allow distal mapping of ureter.

sacral colpopexy procedure. Once the surgical mesh was secured, the peritoneum was reapproximated with periodic checks of the ureter location using StimSite until the closure was complete. The left ureter location was also confirmed at the beginning of the procedure, during, and at the end.

The patient had an uneventful postoperative course and was discharged to home on postoperative Day 1. At 6 weeks postoperatively, follow-up examination revealed excellent apical support and correction of the paravaginal defect. The patient reported being pleased with the surgical result. She remained free of signs and symptoms of iatrogenic ureteral injury, and there were no adverse or unanticipated events resulting from intraoperative use of StimSite.

3. Discussion

A urologic injury is one of the most feared complications for pelvic surgeons and can result in significant patient morbidity or even mortality [4]. Healing from a ureteral injury can take several weeks to several months depending on the severity and need for staged interventions. Accurate identification of the ureters is vital to preventing iatrogenic ureteral injuries [3] [5]. Good surgical technique, preventive measures, early diagnosis, and evidence-based management are also key to reducing morbidity [6].

In this case report, StimSite was integrated with current OR instrumentation to visualize the ureters during robotic-assisted sacralcolpopexy. Postoperatively, the patient remained free of signs and symptoms of ureteral injury. There are no clinical trials examining modalities and techniques available to reduce the incidence of urinary tract injuries beyond imaging, stents, or scopes, all of which require additional cost and time [7] [8] [9]. Preoperative imaging has been used to locate the ureters, but also necessitates an additional procedure for the patient, and does not provide real-time visualization during the surgery. Alternatively, intraoperative insertion of ureteral stents has been used to locate the ureters, but can potentially misshape or injure the ureter, and does not significantly decrease the risk of injury. Likewise, cystoscopy is routinely used to assess for urinary tract injury, however, a normal intraoperative cystoscopy is not necessarily predictive of urinary tract injury, as it can still remain undetected [10]. StimSite provides an adjunct preventive measure which can be seamlessly integrated into the procedure to mitigate risk of ureteral injury.

Several studies have reported a higher incidence of ureteral injuries in gynecology and urology procedures [11] [12]. As reported in the literature, ureteral injuries can be difficult to identify intraoperatively and costly to correct if undetected [12]. Iatrogenic ureteral injuries in post-hysterectomy cases can result in additional costs and sequelae such as hospitalization, nephrostomy tube placement, urinary fistula, acute renal failure, and sepsis. Although not typical, these injuries can be significant and burdensome for the patient and surgeon. A recent study examining iatrogenic ureteral injury litigation found most of the verdicts favored the defendant (339/470, 72%), with a median award of \$552822.96 (USD) [13]. Increased award amount was associated with factors such as duration of temporary drainage, inadequate workup claims, and failure to supervise trainees. [13] Another review of 20 iatrogenic injuries found 70% of injuries were diagnosed after discharge, 50% had a complicated post-op course and 45% resulted in unfavorable legal outcomes (settlement or trial loss) [14]. In comparison, the cost of incorporating this modality into practice may outweigh the costs of litigation and patient burden. Further research and cost analysis is necessary to evaluate the projected benefit and cost-effectiveness of this modality in conjunction with other preventive measures.

A strength of this case report is the introduction of StimSite as a novel, complementary modality for ureteral identification during robotic-assisted sacral

colpopexy procedures. Additionally, the use of StimSite may be extrapolated to other pelvic or colorectal surgeries in which there is an increased risk of ureteral injury. Some factors associated with a higher risk of injury include the presence of adhesions, laparoscopic or robotic mode of access, and low-volume surgical practice [10]. StimSite may offer preventive benefits to facilities where a Urology consult is not readily available. This could have meaningful implications for facilities, given hospital charges for delayed ureteral injuries can nearly double without significantly more reimbursement [15]. A noted limitation of this case study is there is only one patient and further research in a larger population is needed to determine if the incidence of ureteral injury could be reduced with this technology. It should also be noted, that this case study was not designed to discourage currently used methods such as ureteral stenting or cystoscopy, but rather to introduce an adjunct measure to enhance prevention. Given there are still injuries that go unrecognized, it is clear there is still room for improvement and preventative action.

4. Conclusion

StimSite provided on-demand visualization of the ureter allowing it to be mapped from the pelvic brim to the parametrial tunnel, which could help mitigate the risk of ureteral injury. StimSite can be integrated with current surgical instrumentation and requires minimal setup time making it a convenient, user-friendly modality to assist the surgeon with intraoperative pelvic ureter identification.

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Conflicts of Interest

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