REVIEW ARTICLE JSLS

Clinical Use of a Cordless Laparoscopic Ultrasonic Device

Fernando J. Kim, MD, David Sehrt, BS, Wilson R. Molina, MD, Alexandre Pompeo, MD

ABSTRACT

Objective: On April 25, 2012, the first laparoscopic cordless ultrasonic device (Sonicision, Covidien, Mansfield, Massachusetts) was used in a clinical setting. We describe our initial experience.

Methods: The cordless device is assembled with a reusable battery and generator on a base hand-piece. It has a minimum and maximum power setting controlled by a single trigger for both coagulation and cutting. A laparoscopic radical nephrectomy was performed on a 56-year-old man with a 7-cm right renal mass. A laparoscopic pelvic lymphadenectomy was performed in a 51-year-old man with high-risk prostate cancer. Data on surgical team satisfaction, operative time, number of activations, and times the laparoscope was removed as a result of plume were collected.

Results: The surgical technician successfully assembled the device at the beginning of the cases with verbal instructions from the surgeon. Operative time for nephrectomy was 77 minutes, with 143 total activations (minimum = 86, maximum = 57). The operative time for the pelvic lymphadenectomy was 27 minutes, with 38 total activations (minimum = 27, maximum = 11). One battery was used in each case. The laparoscope was removed twice during the nephrectomy and once during the lymphadenectomy. Surgical staff satisfaction survey results revealed easier and faster assembly, more space in the operating room, ergonomic handle, and comparable cutting/coagulation, weight, and plume generation with other devices (**Table 1**).

Conclusion: The first clinical application of the pioneering cordless dissector was successfully performed, resulting in surgeons' perceptions of comparable results with other devices of easier and safer use and faster assembly.

Key Words: Laparoscopy, Surgical instrument, Cordless, Ergonomics.

INTRODUCTION

Laparoscopic techniques and instrumentation are continually being refined to improve patient outcomes and ease the learning curve of laparoscopic surgery.[1] The introduction of the ultrasonic dissector has been widely accepted into the surgical arena as a reliable cutting and coagulating device. The ultrasonic energy is initiated by a vibrating piezoelectric crystal couple to a vibrating blade to transect soft tissue and occlude vessels up to 5 mm.[2] Contemporary ultrasonic systems involve a hand-piece connected to an external generator and a foot pedal. These systems occupy a copious amount of space and congest the operating room (OR). The Sonicision Cordless Ultrasonic Dissector (SCUD) (Covidien, Mansfield, Massachusetts) delivers comparable clinical effectiveness to conventional ultrasonic systems while achieving unique benefits as the first cordless instrument.[3] Our objective is to present the first clinical application of a cordless laparoscopic energy-based dissector and the benefits of this novel technology.

METHODS

The Device

The SCUD is a cordless energy-based dissector designed for laparoscopic surgery. It operates similarly to conventional dissectors but with a number of innovations. The SCUD is assembled with a reusable battery and generator on a base hand-piece (**Figure 1**). The assembly may be performed autonomously and in the sterile surgical field. The instrument requires a quick systems check of the minimum and maximum mode before each use. The instrument has a 39-cm shaft length with a 5-mm diameter. It is activated by a dual-mode energy button, which is

Division of Urology, Department of Surgery, Denver Health Medical Center, Denver, CO (all authors).

Division of Urology, Department of Surgery, University of Colorado, Aurora, CO (Drs. Kim, Molina, Pompeo).

Address correspondence to: Fernando J. Kim, MD, Division of Urology, Department of Surgery, Denver Health Medical Center, 777 Bannock St., MC 0206, Denver, CO 80204. Telephone: (303) 436-6558, Fax: (303) 436-6572, E-mail: Fernando.kim@dhha.org

DOI: 10.4293/JSLS.2014.001153

Table 1.
Survey of Operating Room Staff[a]

		Easy/Yes	Difficult/No
Ability to assemble the device		7 (100%)	0
Ability to hand the device over to other members of the surgical team		7 (100%)	0
Efficiency in saving space in the operating room		7 (100%)	0
Overall satisfaction	Unsatisfactory	Indifferent	Satisfactory
	0	0	7 (100%)

[a]Operating staff consisted of 4 surgeons and 3 scrub technicians and/or registered nurses.

Figure 1. Assembly of the SCUD. **Left,** the disassembled SCUD is composed of a hand-piece, battery, generator, and torque wrench. **Right,** the assembled and activated SCUD.

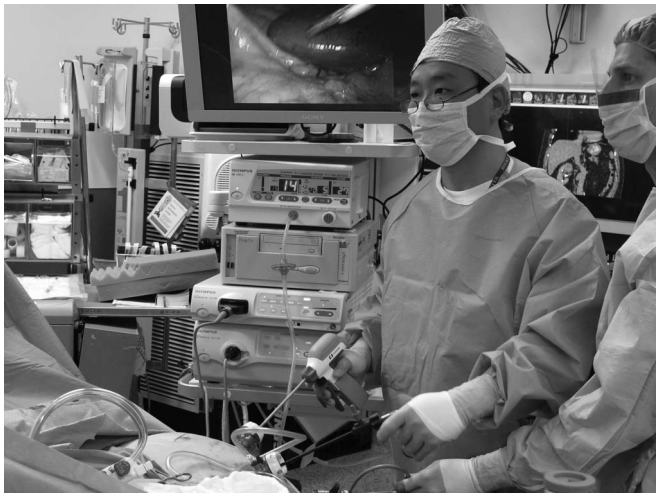

Figure 2. Use of the cordless ultrasonic dissector.

pressed to the first level for the low-power setting (coagulation) and to the second level for the full-power setting (cutting). Feedback for each level is proved with distinct audible tones produced by the SCUD. This activation method contrasts with conventional ultrasonic dissectors, which use either a 2-button hand trigger or a foot-pedal system (**Figure 2** and **Figure 3**). The power of the SCUD is driven by a battery pack that also functions as part of the handle of the instrument. The battery packs are rated to last for an entire surgery; however, it is recommended that

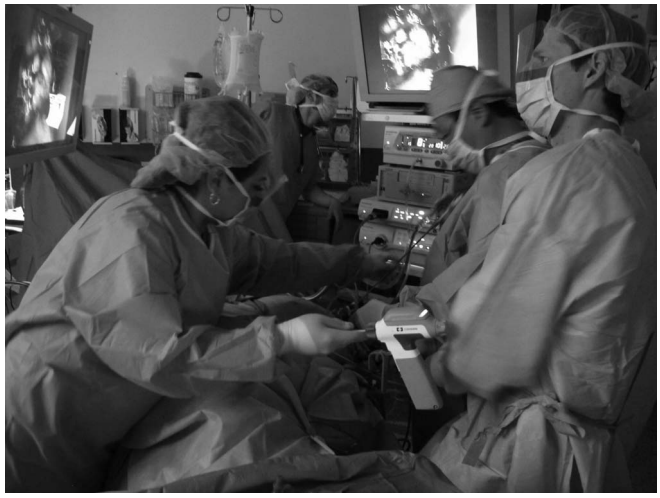

Figure 3. The surgical technician passing the cordless ultrasonic dissector to another member of the surgical team.

a back-up battery remain available. The device indicates the power level through a series of lights on the generator. A green light means the system is ready. A yellow light on the instrument is generated when there is 20% battery power remaining. A red light indicates that the battery needs to be charged. The charger enables 4 batteries to be charged simultaneously, and each battery can be fully charged within 2 hours.

First Clinical Use

The first clinical procedures using the SCUD were performed April 25, 2012 at Denver Health Medical Center after all regulatory Food and Drug Administration process approval was obtained for clinical use. The initial case using the SCUD was a laparoscopic radical nephrectomy performed on a 56-year-old man who had a 7-cm right renal mass. The following procedure was a laparoscopic pelvic/obturator lymphadenectomy performed in a 51-year-old man diagnosed with high-risk prostate cancer.

Objective and Nonvalidated Subjective Survey

The overall surgical performance of the device was evaluated by subjective and objective methodologies. The surgical team (5 surgeons, 3 registered nurses, and 2 surgical technicians) was queried about their overall satisfaction of the device, the ability to assemble the device, the ability to hand the device to the surgeon, and the efficiency in saving space in the OR.

The battery's capabilities were studied by the number of activations in each power setting and the number of battery packs used in each procedure. The clinical effectiveness was evaluated by comparing operating time to average institutional cases and complications from the procedure, and by evaluating the number of times the laparoscope was removed because of plume adhesion to the scope.

RESULTS

The surgical team successfully assembled the device at the beginning of the cases with verbal instructions given by the team leader surgeon. The generator and battery were both securely assembled and remained in this fashion for the entirety of the procedures.

The total operative time for the laparoscopic radical nephrectomy was 77 minutes. The total operative time at the institution for laparoscopic radical nephrectomy ranges from 73 to 245 minutes using similar corded devices. In total, 143 activations were applied, with 86 on minimum mode and 57 on maximum mode. The SCUD was used to release the column and the attachments of the abdominal wall and to coagulate some of the small perirenal vessels. No seal failure occurred on any vessels coagulated. However, the renal vasculature and ureter were sectioned after Hem-o-Lok ligation application (Teleflex Medical, Research Triangle Park, North Carolina) per our standard practice.[4] The laparoscope was removed twice during the procedure because of plume adhesion. No acute or long-term complications were observed. The surgical margins were found to be negative.

The pelvic lymphadenectomy was performed in 27 minutes. Our institutional operative time ranges from 37 to 59 minutes for this procedure. In total, 38 activations with 27 on minimum mode and 11 on maximum mode were used. Hem-o-Lok clips were used during the lymphadenectomy on the proximal and distal ends of the nodes as our standard practice.[4] After clamping, the nodes were dissected with the SCUD. The laparoscope was removed once during the procedure because of plume adhesion. Likewise, no acute or long-term complications with the procedure were observed.

One battery was used in each case. Neither battery provided a warning at the 20% low battery level. There was no noticeable difference observed in the operation of the device throughout each procedure. Both procedures used less than 50% of the battery energy reserve.

The ergonomic interface of the trigger was evident. The dual-mode energy button was successfully implemented. Both the low- and high-power settings were triggered when they were needed. There was no inadvertent cutting during coagulation of blood vessels on any of the 181 activations. The activation of the device was performed intuitively by surgeons, meaning they did not need to visually verify that they were triggering the correct activation button, which would have taken focus away from the surgical visual field (i.e., as with foot-pedal or cumbersome device handles with less ergonomic activation system).

The weight of the device is approximately 14 oz and was reported subjectively by the surgeons as insignificant and not fatiguing. The standard 39-cm length of the SCUD shaft was appropriate for both procedures.

A nonvalidated OR staff survey of (5 surgeons, 2 scrub technicians, and 3 registered nurses) was performed to evaluate overall satisfaction with the device, the ability to assemble the device, the ability to hand the device over to other members of the surgical team, and the efficiency in saving space in the OR. The results revealed unanimous positive responses for: easy ability to assemble the device, easy ability to hand the device over to other members of the surgical team, and efficiency in saving space in the OR. Moreover, there was 100% overall satisfaction of the OR staff in using the device.

DISCUSSION

Medical technologies and techniques have always been evaluated in terms of patient safety and benefit and, in this respect, surgery is not an exception.[5] Nonetheless, it is not sufficiently appreciated that practicing surgeons are also at risk of safety concerns. New technological innovations have made modern surgical practice safe; however, the equipment required in the modern OR also occupies a sizable amount of space. The laparoscopic arena is renowned to be more crowded than an open procedure,[6] but now that the cornerstone of laparoscopic instruments has been established, emerging technology has been directed toward minimizing their size and improving their

ergonomics. The most widely accepted example of this modernization is the adoption of liquid crystal display (LCD) screens into the operative arena. Older ORs were equipped with cathode ray tube (CRT) monitors, which were large, immobile, and placed away from the surgical field. The introduction of the LCD monitor enabled screens to be hung closer to the surgical field. The result was improved visibility of the field, better posture of the surgeon, and less stress imparted on the surgical team.[7] The development of cordless devices may likewise be revolutionary. With the introduction of the SCUD, the laparoscopic technology may address the need for a safer environment to prevent tripping over electrical cords, obstruction of movement of mobile instruments and generators, and faster assembly of instruments, thus decreasing OR setup time.

The National Institutes of Health has been funding the development of cordless energy-based technology since the late 1980s.[8] Eliminating cords would unquestionably improve the ergonomics of laparoscopic and open surgery. Like the benefits of using LCD monitors closer to the surgical field, a cordless design would improve the space in the OR, the mobility of the instrument, and thus the efficiency of the laparoscopic procedure. Surgeons would be able to focus more on the patient and less on the instruments surrounding them. Cordless instruments do not tangle or have a limited working area like their corded counterparts. Devices can be passed from member to member much more easily, and there is no risk of contaminating the surgical field with cords or dragging other instruments into the surgical field. The ergonomic and cordless features were appreciated by the surgical staff and a nonvalidated survey was obtained. The portable battery was not changed during the duration of the surgeries, decreasing the skepticism that one may have during a pivotal part of the surgery. Further, the minimal nature of cordless devices also enables easy transportation from hospital to hospital because there is no need for bulky generators.

Efficacy of the ultrasonic technology was investigated by us and by others. A study comparing the SCUD with the ACE evaluated the transection time of 10 cm of small-bowel mesentery.[3] The SCUD required 24.8 seconds, which was significantly faster than the ACE 33.8 seconds. Our experience with this device also confirms the enhanced cutting feature, especially noted during the nephrectomy while we were transecting Gerota's fascia. Vessel sealing is another attribute to consider, and the ACE and SCUD have shown to be comparable. The average seal times of the SCUD and ACE were 5.2 seconds and 4.8 seconds, with an average burst pressure of 578 and 605 mm Hg, respectively.[3] The seal failure rates were similar between the devices, but we did not see any seal failures in our two surgeries when the device was applied correctly for vessels <5 mm.

Although ultrasonic dissectors produce high temperatures, thermal spread was seen as comparable with the ACE, with a mean spread of 1.08 mm for the ACE and 1.06 for the SCUD.[3,9] We saw no iatrogenic injury to proximal tissue when using the device. The visual obstruction from plume by these devices also varies. A recent study showed that the average plume generated by the SCUD, ACE, and SonoSurg (Olympus, Center Valley, Pennsylvania) in the maximum setting were 12.65%, 8.76%, and 9.46%, respectively ($P = .026$). On the coagulation setting, the obstructions for the devices were 4.8%, 26.63%, and 0.21% ($P < .001$).[10] Plume was described as minimal during surgery, and the laparoscope was only removed to clean the optics once during surgery. The efficacy of the SCUD during the initial two procedures was comparable with other conventional ultrasonic instruments.

Our initial two cases of a cordless energy-based device revealed the advantages of the cordless instrument (less crowded OR because of the lack of generators or foot pedals, efficient single hand-piece mobility, and shaft rotation without hindering the instrument's range of motion). In addition, the device was passed easily between team members, without unsafe dragging of other instruments, sponges, etc., as may happen with corded instruments. The weight of the device was not noticeable compared with other ultrasonic dissectors. Moreover, we believe that the absence of cord decreases the possibility of cord contamination. Certainly, more laboratory, economic, and larger randomized clinical studies are needed to learn more about the SCUD and the impact of a cordless energy-based instrument in laparoscopic and open surgery, but this initial experience sets a higher standard for a better, safer, and more efficient surgical space and ergonomics in the era of cordless devices and minimally invasive surgery.

CONCLUSION

The first clinical application of the pioneering cordless dissector was successfully performed, resulting in fast assembly and easy, safe use. The cordless technology may affect how ORs may be designed, to increase efficiency, staff satisfaction, and the safety of both patients and staff.

References:

1. Heinrich WL, Lukoff B, Younblood P, et al. Criterion-based training with surgical simulators: proficiency of experienced surgeons. *JSLS*. 2007;11:273–302.

2. Cimino WW, Bond LJ. Physics of ultrasonic surgery using tissue fragmentation: part I. *Ultrasound Med Biol*. 1996;22:89–100.

3. Tsirline VB, Lau KN, Swan RZ, et al. Evaluation of an innovative, cordless ultrasonic dissector. *Surg Innov*. 2012; 20:1–6.

4. Wein AJ, Kavoussi LR, Novick AC, Partin AW, Peters CA. *Campbell-Walsh Urology*. 10th ed. Philadelphia, PA: Saunders; 2012.

5. Wetter PA, Rovira IK. Do no harm—ORReady initiative aims to improve safety and outcome for 6 million patients. *JSLS*. 2011;15:131–132.

6. Alarcon A, Berguer R. A comparison of operating room crowding between open and laparoscopic operations. *Surg Endosc*. 1996;10:916–919.

7. Berguer R, Rab GT, Abu-Ghaida H, Alarcon A, Chung J. A comparison of surgeons' posture during laparoscopic and open surgical procedures. *Surg Endosc*. 1997;11:139–142.

8. Schmidt RS, Hudson WR. A miniature, rechargeable, cordless electrocautery for neurosurgery. *J Neurosci Methods*. 1990; 32:71–73.

9. Kim FJ, Chammas MF, Gewehr E, et al. Temperature safety profile of laparoscopic devices: Harmonic ACE (ACE), Ligasure V (LV), and plasma trisector (PT). *Surg Endosc*. 2008;22:1464–1469.

10. Kim FJ, Sehrt D, Pompeo A, Molina WR. Comparison of surgical plume among laparoscopic ultrasonic dissectors using a real-time digital quantitative technology. *Surg Endosc*. 2012;26:3408–3412.