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ORIGINAL ARTICLE

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A clinical evaluation of the LOTUS ultrasonic shears in gynaecological surgery

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Abstract A prospective quasiexperimental single blind study was conducted to test the hypothesis that the LOTUS (laparoscopic operation by torsional ultrasound) shears have significant advantage over conventional cutting bipolar forceps when used to divide and coagulate pedicles in gynaecological surgery. Ten university teaching hospital patients between 35 and 51 years of age were recruited. They all underwent elective abdominal hysterectomy and bilateral salpingo-oophorectomy for nonmalignant indications such as fibroids and menorrhagia. The round and infundibulopelvic ligaments were divided with the LOTUS shears or the Power Blade cutting bipolar forceps at open hysterectomy, and the time taken to complete the division was recorded. Two hundred histological samples were examined for thermal damage by the blinded histopathologist. The main outcome measures were the degree of thermal damage on histology, the time taken to divide each structure, and the need for additional haemostasis. Thermal damage was present in 99/200 slides. The LOTUS shears caused thermal damage in 47 sections. The cutting bipolar forceps caused thermal damage in 52 sections. The degree of thermal damage was less with the LOTUS shears. The mean times taken by the LOTUS shears to divide the round ligaments and infundibulopelvic ligaments were 9.24 s and 20.02 s, respectively. The corresponding times for the bipolar forceps were 9.69 s and 27.53 s, respectively. The LOTUS shears were associated with shorter bisection times and less thermal damage in this pilot study. These results were not statistically significant.

Keywords Torsional ultrasound · Bipolar forceps · Thermal spread · Hysterectomy

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Introduction

Electrosurgery has become a common energy modality in laparoscopic surgery. It is, however, associated with certain specific hazards, such as bowel injury that can lead to significant morbidity or even mortality from faecal peritonitis [1, 2]. The tissue temperature generated by ultrasound is less than 80°C, much lower than that associated with electrosurgery, which can be as high as 200°C [3]. Thermal spread is therefore expected to be less with ultrasound sources. In animal experiments, the extent of lateral thermal spread is four times less with ultrasound compared with electrosurgery [3], which is associated with charring and smoke formation [4, 5]. Charring may also lead to the coagulum becoming detached, resulting in problems with bleeding [5].

The first ultrasonic scalpel was introduced in 1991. Traditionally, the older shears such as the harmonic scalpel have applied longitudinal ultrasound waves down the shaft of the instruments. This invariably concentrates the energy at the tip of the instrument instead of between the blades, thereby reducing efficacy. The acronym LOTUS stands for laparoscopic operation by torsional ultrasound. The LOTUS shears (SRA Developments, Devon, UK) are the first ultrasonic scalpel to use torsional rather than longitudinal mode ultrasound to produce a cutting and haemostatic effect. They achieve focussed energy transmission into the target tissue; torsional waves are applied directly to the target tissues, thereby enhancing the efficacy of the shears. The torsional mode is a rotational oscillation whereby the tip (and equally spaced points along the waveguide) vibrates back and forth in a short arc around the waveguide axis. It is generated by applying a harmonic torque about the proximal end of the waveguide axis. The unique blade comprises two grooves side by side in the edge of the waveguide, at the distal end. The sides of the grooves are in fact planar, near-radial facets that lie normal to the direction of torsional vibration. Any tissue contacting these facets experiences a direct mechanical force. The waves cause denaturation of proteins by the breakage of hydrogen bonds in tissue, cutting and coagulating them with maximum efficiency.

The Power Blade cutting bipolar diathermy forceps (Mantis Surgical, Hampshire, UK) has a retractable blade, which is activated to divide pedicles following initial coagulation. Both the LOTUS shears and the cutting bipolar forceps have been in regular use in our institution for several years. We have on occasion used both instruments in the same patient during operative laparoscopy. Our impression was that the LOTUS shears appear to have an edge over the bipolar forceps. To date, there has been no published data of in vivo human studies directly comparing the efficacy of bipolar diathermy energy and ultrasonic energy as well as the spread of thermal injury on identical structures.

Materials and methods

Ten women between 35 and 51 years of age were recruited. They all underwent elective abdominal hysterectomy and bilateral salpingo-oophorectomy for nonmalignant indications such as fibroids and menorrhagia.

At open surgery, the left or right round ligaments and infundibulopelvic ligaments were divided by one or the other instrument selected by a randomisation envelope. All the trial procedures were performed by a single surgeon (G.A.), after which the rest of the hysterectomy was performed in the standard way for the lead surgeon. The LOTUS shears were applied across each pedicle in turn, and the power activated until complete division took place. The pedicles were then secured with sutures as normal. The corresponding structures on the contralateral sides were then divided using the cutting bipolar forceps. The pedicle was grasped between the forceps blades, power was applied until coagulation took place, and then the blade was activated to complete the division. The time taken to divide each structure was noted using a stopwatch. The standard power setting for the bipolar forceps was 40 W. With the LOTUS shears, the standard power setting (35 W) was used to divide the infundibulopelvic ligaments, and the high power setting (50 W) was used for the round ligaments. The excised structures were sent dry to the blinded histopathologist (A.O.). Serial sections were taken at 2, 4, 6, 8, and 10 mm from the point of application of each instrument on each structure and examined under a light microscope for thermal damage. The data collected were entered into an Excel spreadsheet for analysis.

LOTUS trial results

Results regarding operating times and thermal damage are shown below.

Operating times (seconds)

Round ligament	No.	Mean	Median	Range	*p*-v–value (Wilcoxon signed rank test)
LOTUS	10	9.24	6.71	5.22–29.65	0.1688
TRIPOL	10	9.69	9.13	5.78–17.09	

Infundibulo pelvic ligament	No.	Mean	Median	Range	*p*-value (Wilcoxon signed rank test)
LOTUS	10	20.02	17.5	6.62–41.47	0.1688
TRIPOL	10	27.53	29.2	4.75–54.35	

Thermal damage

Round ligament	2 mm	6 mm
LOTUS (mean, SD)	12.9 (4.4)	1.6 (1.8)
TRIPOL (mean, SD)	14.4 (2.8)	1.8 (2.3)
p-values (Wilcoxon signed rank test)	0.5319	0.9178

Infundibulopelvic ligament	2 mm	6 mm
LOTUS (mean, SD)	10.2 (4.66)	2.2 (3.19)
TRIPOL (mean, SD)	12.8 (5.27)	4 (5.56)
p-values (Wilcoxon signed rank test)	0.2802	0.4105

Round ligament	2 mm		6 mm		10 mm	
Thermal damage	Yes	No	Yes	No	Yes	No
LOTUS	10	0	5	5	0	10
TRIPOL	10	0	5	5	0	10

Infundibulopelvic ligament	2 mm		6 mm		10 mm	
Thermal damage	Yes	No	Yes	No	Yes	No
LOTUS	10	0	5	5	1	9
TRIPOL	9	1	5	5	0	10

Need for additional haemostasis

Both instruments were equally effective in securing haemostasis in all the pedicles.

Discussion

In total there were 200 histological slides from the serial sections. Thermal damage was defined by the presence of all of the following: coagulation necrosis of collagen, smudging of collagen/muscle nuclei, fat necrosis, and fibrillation/fragmentation of collagen. A formula was devised to grade the severity:

Degree of damage $(D) = I \times A$

where I is the intensity and A is the area.

The magnification settings on the light microscope were as shown below.

Intensity of damage (I)	Area of damage (*A*)
4+ LP (×4)	≥4 10 mpf (×10)
3+ MP (×10)	3 5–10 mpf (×10)
2+ MP (×20)	2 < 5 mpf (×10)
1+ HP (×40)	

Thermal damage was maximal at 2 mm for both instruments. At 6 mm, the degree of damage was significantly less for both instruments. In the bipolar slides, there was extensive coagulation necrosis and fragmentation of collagen fibres as well as smudging of the nuclei, as shown in Fig. 1. The degree of thermal damage was less with the LOTUS shears, as seen in Fig. 2. No thermal damage was seen at 10 mm in any slide but one (LOTUS). This may have resulted from a double attempt to divide a large infundibulopelvic ligament in a patient with a 20-weeks'-sized fibroid uterus. It is noteworthy that the standard power setting was used for the infundibulopelvic ligament when the LOTUS shears were used to divide these structures. We chose the lower power setting because our previous experience had shown that the high power setting was associated with less effective haemostasis.

Conclusion

Both instruments were equally effective in securing haemostasis. The LOTUS shears were associated with shorter bisection times and less thermal damage at 2 and 6 mm on histological sections. Although the differences were not statistically significant in this pilot study of only 10 patients, they do mirror findings in animal studies [4] and also support the subjective impression that LOTUS shears are safer than diathermy, particularly when working around delicate structures such as bowel and ureters. In addition, the study has provided information (Table 1) that would be required to make a helpful statistical sample size calculation for a larger trial.

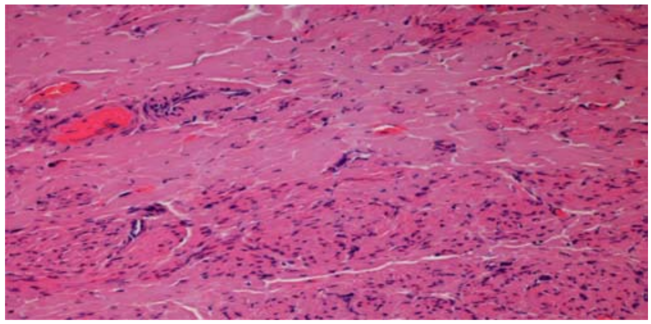

Fig. 1 Section of round ligament cut at 2 mm with Power Blade cutting bipolar forceps. There is marked coagulation necrosis and fragmentation of collagen fibres and smudging of nuclei

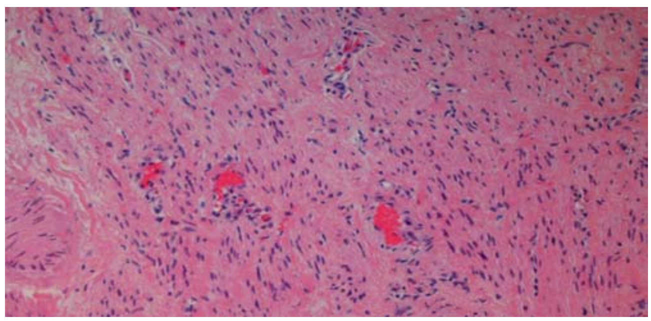

Fig. 2 Section of round ligament cut at 2 mm cut with LOTUS shears, showing only mild coagulation necrosis and smudging of collagen fibre nuclei

Table 1 Sample size calculation for a large trial (*RL* round ligament, *IPL* infundibulopelvic ligament)

	Delta	Sigma	Sample size	+5% inflation
Times (s): IP ligament	7.5	15.3	35	37
RL thermal damage: 2 mm	1.5	6.2	136	143
RL thermal damage: 6 mm	0.2	3.8	2835	2977
IPL thermal damage: 2 mm	2.6	7.6	69	73
IPL thermal damage: 6 mm	1.8	6.1	92	97

Sample size calculation: alpha =0.05 (5%); power 80%; delta = difference in group means; sigma = standard deviation of difference in the response of matched pairs

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