The safety and tolerability of the LOTUS torsion scalpel, a novel form of ultrasonic energy, in operative laparoscopic gynaecology

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Background:

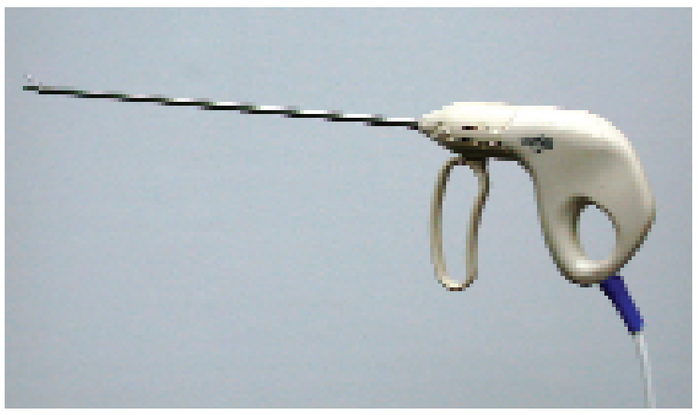
This is largest report into the safety and tolerability of the use of Torsional Mode Ultrasound cutting in operative laparoscopic gynaecology. The principle of currently used ultrasonic scalpels is to transform electric power into mechanical longitudinal movement of the working part of the instrument, by a piezoelectric transducer situated in the hand piece. The LOTUS (Laparoscopic Operation by Torsional UltraSound) Torsion Scalpel uses a different type of ultrasonic vibration (torsional shear wave down the waveguide) to turn the power through 90° and focus it into the target tissue as a compression wave. This allows secure coagulation and very fast cutting with lower risk of "distal drilling" (tissue damage at the tip of the waveguide).

LOTUS can be used in the following Gynaecological procedures:

- Salpingo-oophorectomy
- Hysterectomy
- Ectopic Pregnancy
- Adhesiolysis
- Excision of Endometriosis

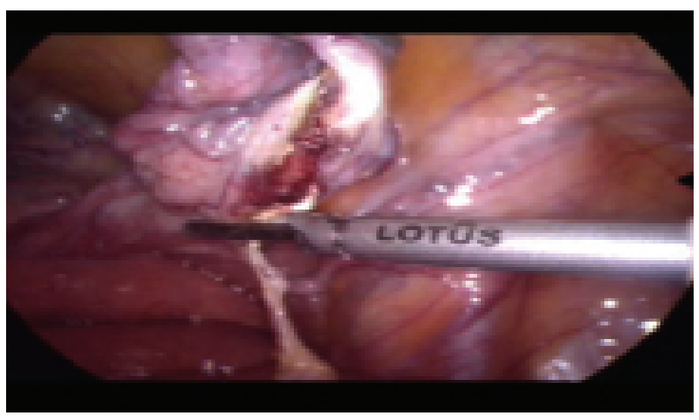
Rationale for the Project:

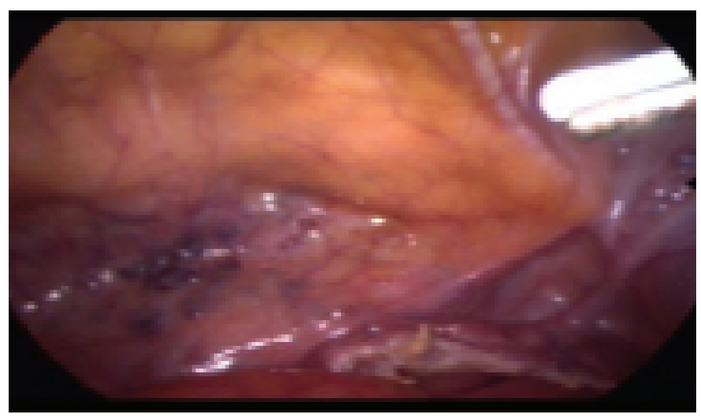
- To find out how effective the LOTUS Harmonic Scalpel is in Laparoscopic Gynaecological operations.
- To assess patient satisfaction.
- To evaluate the ease of use of the devise.



Methods/Design:

Retrospective clinical study of 25 operative laparoscopic cases, performed with LOTUS Torsion Scalpel during the period from October 2004 to September 2005, with telephone administration of follow-up questionnaire. Cases were identified from theatre records and patients contacted over the telephone with prior notification about recovery after discharge. There were 22 Salpingo-oophorectomy/oophorectomy cases, 1 salpingectomy for ectopic pregnancy, and 2 adhesiolysis procedures, all of which were successfully completed.





Results:

20 patients were discharged within 24 hours of the procedure, 3 of which went home on the same day. 2 patients were discharged on the second postoperative day. In 18 patients the operating time was less than 1 hour. There were no significant intraoperative complications related to the use of the LOTUS Torsion scalpel. In the follow-up period, of the 19 completed questionnaires 14 patients (73%) assessed their pain score in the first post operative week as less than 5 out of 10. 18 patients (94%) were happy with the procedure and would recommend it to others. The one patient not happy with the operation felt that at the time of the telephone call the procedure had not helped her chronic pain and dyspareunia.

Conclusions:

- Laparoscopic operations with LOTUS Harmonic Scalpel are effective, less time consuming and appear to be safe.
- Patient satisfaction is excellent.

We believe this early study has demonstrated that the LOTUS Torsion Scalpel is an effective, well tolerated and appropriate tool for operative laparoscopic gynaecology.

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