Papers and Posters published on Lotus Series 2, Series 3 and Series 4.

1. Ching S.S., McMahon M.J.: Randomised Clinical Trial of Longitudinal versus Torsional Mode Ultrasound in Laparoscopic Cholecystectomy. **(POSTER)**

2. Ching S.S., Sarela. A, Hayden J., McMahon M.J.: Randomised Clinical Trial of Torsional versus Linear Mode Ultrasonically Activated Devices for Laparoscopic Cholecystectomy.

3. Ching S.S.: Good Vibrations: Longitudinal versus Torsional Ultrasonic Shears in Surgery- Clinical Study. **(POSTER)**

4. Ching S.S.: Good Vibrations: Longitudinal versus Torsional Ultrasonic Shears in Surgery-Laboratory Study. **(POSTER)**

5. Ching S.S., McMahon M.J.: Comparison of Linear and Torsional Mode Ultrasonic Coagulating Shears for the Sealing of Medium to Large Sized Arteries. *Surgical Endoscopy* , 2006

6. S.S. Ching, C. Verbeke, Prof. S. Homer-Vanniasinkam, Prof. M.J.McMahon: Comparison of Torsional and Linear Mode Ultrasonic Coagulating Shears for Sealing Veins. *Journal of Laparoendoscopic & Advanced Surgical Techniques* **18**, No.6, 2008 DOI: 10.1089/lap.2008.0066

7. S.S.Ching, M.J.McMahon: Comparison of Heat Dissemination from Longitudinal and Torsional Mode Ultrasonic Shears using Infrared Thermal Imaging and Thermocouples. **(POSTER)**

8. S.S.Ching, M.J.McMahon: “Tissue Welding” by Ultrasound: Is Torsional Mode Superior to Longitudinal Mode for Sealing Blood Vessels? **(POSTER)**

9. G.Awadzi, J.Frappell, A.Oriolowo, T.Sibanda: A Clinical Evaluation of the Lotus Ultrasonic Shears in Gynaecological Surgery. *Gynecological Surgery* (S2005) **2**: 183-186. DOI 10.1007/s10397-00509197-7

10. G.Jain, J.Parmar, M.M.Mohammed, T.Bryant, L.Kitteringham, N.Pearce, M.Abu-Hilal: Stretching the Limits of Laparoscopic Surgery: Two-Stage laparoscopic Liver Resection. *Journal of Laparoendoscopic & Advanced Surgical Techniques***20**, No.1, 2010 DOI:10.1089/lap.2009.0061

11. E.J.Noble, K.B.Hosie: Ex-Vivo Comparison of Efficiencies of Lotus and Ethicon Ultrasonic Instruments. **(POSTER)**

12. E.J.Noble, K.B.Hosie: Porcine Ex-Vivo and In-Vivo Vessel Sealing Experiments to Compare Lotus and Ethicon Ultrasonic Instruments with LigaSure Bipolar Vessel Sealing Device. **(POSTER)**

13. E.J.Noble,N.J.Smart, C.Challand, K.Sleigh, A.Oriolowo, K.B.Hosie. Experimental Comparison of Mesenteric Vessel Sealing and Thermal Damage Between One Bipolar and Two Ultrasonic Shears Devices. *British Journal of Surgery 2011;* **98**: 797-800

14. N.J.Smart, E.J.Noble, C.Challand, K.Sleigh, A.Oriolowo, K.B.Hosie. A Comparison of the Ability of Lotus Ultrasonic Device, Ethicon Ace Harmonic Scalpel and LigaSure Bipolar Device to Seal Mesenteric Blood Vessels During Colorectal Surgery. **(POSTER)**

15. Sinha S, Tkacz Z, Robinson M, Morris E. The Safety and Tolerability of the Lotus Torsion Scalpel, a, Novel Form of Ultrasonic Energy, in Operative Laparoscopic Gynaecology

16. M.Abu-Hilal, T.Underwood, M.Taylor, N.Pearce. Reducing the Risk of Bleeding in Laparoscopic Liver Surgery.

17. Widdison, A.L., Barns, V., Prescott, O. and Pollard, A., 2016. A cost-minimization analysis of first intention laparoscopic compared to open right hemicolectomy for colon cancer. *Annals of medicine and surgery*, *5*, pp.23-28.

18. Berrisford, R.G., Wajed, S.A., Sanders, D. and Rucklidge, M.W.M., 2008. Short-term outcomes following total minimally invasive oesophagectomy. *British Journal of Surgery: Incorporating European Journal of Surgery and Swiss Surgery*, *95*(5), pp.602-610

19. Baltatzis, M. Sheen, A., et al Comparison of Outcomes Between Open Major Hepatectomy Using CUSA and Laparoscopic Major Hepatectomy Using “Lotus” Liver Blade. A Propensity Score Matched Analysis

LOTUS Clinical Publication Summary

Subject of Clinical Paper	Qty
Thermal Spread / Tissue temperature	5
Vessel seal burst pressure	4
Haemostasis / Blood Loss	3
Dissection time	5
Instrument temperature	2
Patient satisfaction	1
Cost Benefit	1
LOTUS Being used	

1. **Poster** Ching S.S., McMahon M.J.:
"Randomised Clinical Trial of Longitudinal versus Torsional Mode Ultrasound in Laparoscopic Cholecystectomy"

AIMS	DATA	RESULTS
• Compare Lotus to Ultracision in Lap Cholecystectomy for: • Haemostasis (blood • Gallbladder dissection time • Postop complications	• 20 patients randomised by instrument. • Cystic Artery sealed and divided with shears. • Blood loss measured	• Blood loss less for Lotus. • Gallbladder excision time faster for Lotus.

2. Ching S.S., Sarela. A, Hayden J., McMahon M.J.:
"Randomised Clinical Trial of Torsional versus Linear Mode Ultrasonically Activated Devices for Laparoscopic Cholecystectomy"

AIMS	DATA	RESULTS
• Compare Lotus to Ultracision in Lap Cholecystectomy for: • Haemostasis (blood loss) • Gallbladder dissection time • Postop complications	• 151 patients randomised by instrument. • Cystic Artery sealed and divided with shears. • Blood loss measured	• Blood loss less for Lotus. • Gallbladder excision time faster for Lotus.

3. **Poster** Ching S.S.: Good Vibrations: Longitudinal versus Torsional Ultrasonic Shears in Surgery.– Clinical Study

AIMS	DATA	RESULTS
• Haemostasis (blood loss) • Gallbladder dissection time • Strength of seals in blood vessels • Lateral thermal spread	• 47 patients randomised by instrument. • Cystic Artery sealed and divided with shears. • Blood loss measured	• No difference in blood loss. • No difference in Gallbladder excision time.

4. Ching S.S.:Good Vibrations: Longitudinal versus Torsional Ultrasonic Shears in Surgery.– Laboratory Study

AIMS	DATA	RESULTS
• Compare burst pressure of seals made by Lotus or Harmonic Scalpel used to divide porcine carotid artery In-vitro	• 104 seals made in 50 vessels. Vessel diameter and burst pressure measured.	• BP (321 - 378mmHg) independent of vessel diameter up to 7.4mm for Lotus. • BP inversely proportional to vessel diameter for H/S (479 – 317mmHG) up to 5.2mm vessel diameter but 203mmHg for vessel diameter 5.3mm up to 7.4mm
• Compare lateral thermal spread in cuts made by Lotus and H/S in chicken muscle In-vitro	• Thermocouples placed in tissue at various distances from cut edge	• Rise of 15ºC 2mm and 10ºC 4mm from edge cut with Lotus. • Rise of 12 ºC 2mm and 8ºC 4mm from edge cut with H/S. • Thermal spread beyond 5mm from cut edge insignificant for Lotus and H/S
• Compare cut time and blade and tissue temperatures of Lotus and H/S while cutting bovine muscle In-vitro	• Cut durations timed • Infrared thermal images taken during energization to quantify temperatures	• Lotus mean cut time 5s. • H/S mean cut time 10s. • No significant difference in blade or tissue temperatures during cutting with the two devices

Key Message: Lateral thermal damage the same for LOTUS and H/s and insignificant beyond 5mm for both. No significant difference in blade temperature.

5. Ching S.S., McMahon M.J.: Comparison of Linear and Torsional Mode Ultrasonic Coagulating Shears for the Sealing of Medium to Large Sized Arteries. *Surgical Endoscopy* , 2006

AIMS	DATA	RESULTS
• Compare burst pressure of seals made by Lotus or Harmonic Scalpel used to divide porcine carotid artery In-vitro	• 104 seals made in 50 vessels. Vessel diameter and burst pressure measured.	• BP (321 - 378mmHg) independent of vessel diameter up to 7.4mm for Lotus. • BP inversely proportional to vessel diameter for H/S (479 – 317mmHG) up to 5.2mm vessel diameter but 203mmHg for vessel diameter 5.3mm up to 7.4mm

Key Message: Both Longitudinal and torsional devices can seal 5mm vessels but Torsional has extended ability to seal 7.4mm vessels with same degree of confidence. Increasing vessel size correlates with a lower burst pressure for longitudinal systems.

6. S.S. Ching, C. Verbeke, Prof. S. Homer-Vanniasinkam, Prof.M.J.McMahon: Comparison of Torsional and Linear Mode Ultrasonic Coagulating Shears for Sealing Veins. *Journal of Laparoendoscopic& Advanced Surgical Techniques* **18**, No.6, 2008 DOI: 10.1089/lap.2008.0066

AIMS	DATA	RESULTS
• Compare vessel sealing capability of Lotus and Harmonic Scalpel in Ex-vivo human veins	• Varicose veins harvested from 15 patients • Seals either tested for BP, or • Examined microscopically for mural thickness, seal length, extent of coagulation and lateral thermal effect.	• Burst pressures Vein mm / Lotus mmHg / H/S mmHg 2.0-3.0 / 245 / 133 3.5-4.5 / 149 / 94 5.0-6.0 / 82 / 76 • 517③m seal length by Lotus. 316③m seal length by H/S. • 467③m tissue coagulation by Lotus. 335③m tissue coagulation by H/S • 1.5mm lateral thermal effect by Lotus. 1.1mm lateral thermal effect by H/S

Key Message: Torsional mode ultrasonic shears produced more secure seals on veins up to 4.5 mm in diameter. This can be explained by the greater seal length produced by torsional mode shears.

7. **Poster** S.S.Ching, M.J.McMahon: Comparison of Heat Dissemination from Longitudinal and Torsional Mode Ultrasonic Shears using Infrared Thermal Imaging and Thermocouples.

<table>
<tr><th>AIMS</th><th>DATA</th><th>RESULTS</th></tr>
<tr><td>• Compare lateral thermal spread from cut edge while cuts made by Lotus and H/S in chicken muscle In-vitro</td><td>• Thermocouples placed in tissue between 0.5 and 7.0mm from blade</td><td>• Mean rise of 10ºC with Lotus.
• Mean rise of 8ºC with H/S.
• Median tissue temperature at cut edge immediately after cut was 69®C with Lotus.
• Median tissue temperature at cut edge immediately after cut was 78®C with H/S.</td></tr>
<tr><td>• Compare blade temperatures of Lotus and H/S during and after cutting bovine muscle In-vitro</td><td>• Infrared thermal images taken during energization to quantify temperatures with time</td><td>• Mean blade temp’
<table><tr><th></th><th>T (®C) LOW</th><th>T (®C) HIGH</th></tr><tr><td>Lotus</td><td>130</td><td>95</td></tr><tr><td>H/S</td><td>100</td><td>90</td></tr></table>• Temp’ ranges overlap.
• Both blades took 25s. to cool to 50®C and a further 20s. to cool to 33®C</td></tr>
</table>

Key Message: Lotus has comparable lateral thermal spread as Harmonic but Lotus has a cooler cut surface (69®C) compared to Harmonic (78®C) as Lotus is in contact with the tissue for less time.

8. **Poster** S.S.Ching, M.J.McMahon:
“Tissue Welding” by Ultrasound: Is Torsional Mode Superior to Longitudinal Mode for Sealing Blood Vessels? **Repeat of 4.**

AIMS	DATA	RESULTS
• Compare burst pressure of seals made by Lotus or Harmonic Scalpel used to divide porcine carotid artery In-vitro	• 104 seals made in 50 vessels. Vessel diameter and burst pressure measured.	• BP (321 - 378mmHg) independent of vessel diameter up to 7.4mm for Lotus. • BP inversely proportional to vessel diameter for H/S (479 – 317mmHG) up to 5.2mm vessel diameter but 203mmHg for vessel diameter 5.3mm up to 7.4mm

9. G.Awadzi, J.Frappell, A.Oriolowo, T.Sibanda:
A Clinical Evaluation of the Lotus Ultrasonic Shears in Gynaecological Surgery.*Gynecological Surgery* (S2005) **2**: 183-186. DOI 10.1007/s10397-00509197-7

AIMS	DATA	RESULTS
• Test hypothesis that Lotus has significant advantage over conventional bipolar forceps when coagulating and dividing gynaecological pedicles.	• 10 patients having elective open hysterectomy and bilateral salpingo-oophorectomy were recruited. • Round and Infundibulo-pelvic Ligaments were divided with Lotus on one sideand Power Blade on the other. • Time taken for ligament division measured. • 200 histological samples examined for thermal damage by blinded histopathologist.	• Thermal damage was present in 99/200 samples; 47 in Lotus sections, 52 in bipolar forceps sections. • Degree of damage less with Lotus compared to Bipolar but not statistically significant. • Mean time for Lotus to divide Round Ligament was 9.24s. andInfundibulo-pelvic Ligament was 20.02s. • Times for Bipolar were 9.69s. and 27.53s. respectively. Longer times not statistically significant.

Key Message: Thermal damage by Lotus less than bipolar and restricted to within 10mm of cut edge.

10. G.Jain, J.Parmar, M.M.Mohammed, T.Bryant, L.Kitteringham, N.Pearce, M.Abu-Hilal:
Stretching the Limits of Laparoscopic Surgery: Two-Stage laparoscopic Liver Resection. Journal of Laparoendoscopic& Advanced Surgical Techniques

AIMS	DATA	RESULTS
• First reported case of totally laparoscopic two-stage liver resection. • Specialist Lotus Liver Resector used. • Six weeks between two stages.	•	• totally laparoscopic two-stage liver resection is safe and effective

11. **Poster** Noble EJ, Hosie KB
Ex-vivo Comparison of Efficiencies of LOTUS® and Ethicon® Ultrasonic Instruments

AIMS	DATA	RESULTS
• Compare efficiency of energy transfer from longitudinal and torsional mode ultrasonic blades into Polyethyleneglycol • Dissection speed of Lotus and H/S compared. • Rate of dessication of porcine tissue in-vitro by Lotus and H/s compared.	• Temperature rise of mass of glycol recorded and compared to generator output power for Lotus and H/s. • Speed of dissection of in-vitro porcine tissue measured. • Volume and mass of porcine tissue dessicated per minute measured for Lotus and H/S	• Temperature rise of 3ºC in glycol energized by Lotus. [energy calculation in poster questioned] Temperature rise of 1.4ºC in glycol energized by H/S.[energy calculation in poster questioned] • Lotus twice as fast through porcine loin and liver as H/S • Tissue dessication rate greater for Lotus

12. **Poster** E.J.Noble, K.B.Hosie:
Porcine Ex-Vivo and In-Vivo Vessel Sealing Experiments to Compare Lotus and Ethicon Ultrasonic Instruments with Ligasure Bipolar Vessel Sealing Device.

AIMS	DATA	RESULTS
• Compare the vessel sealing ability of S3 Lotus, Harmonic Ace and Ligasure bipolar using ex-vivo and in-vivo porcine models.	• Ex-vivo: porcine renal vessels harvested from recently slaughtered pigs and divided/sealed by one of the three devices. • In-vivo:porcine mesenteric, renal, splenic and inguinal vessels were dissected/sealed by one of the three devices during midline laparotomy in two anaesthetised pigs • Vessel diameter measured with verniercalipers. • Seal burst pressure measured	• Ex-vivo For mean vessel diameters shown, Burst Pressure Ligasure mmHg: 1231; 4.5mm Lotus mmHg: 963; 3.4mm Ace mmHg: 1399; 3.6mm • In-vivo For mean vessel diametersshown, Burst Pressure Ligasure mmHg: 2416; 2.2mm Lotus mmHg: 2244; 2.7mm Ace mmHg: 2626; 2.2mm

Key Message: All three instruments seal small vessels in-vivo sufficiently to withstand at least 7x systolic blood pressure and medium vessels ex-vivo sufficiently to withstand at least 2.5x systolic blood pressure. Ace seals are more secure than S3 Lotus seals (significantly for ex-vivo) due to tapering of S3 blade compared to S2.

13. E. J. Noble, N. J. Smart, C. Challand, K. Sleigh, A. Oriolowo and K. B. Hosie
Experimental comparison of mesenteric vessel sealing and thermal damage between one bipolar and two ultrasonic shears devices

AIMS	DATA	RESULTS
• Compare ability of CV3 Lotus, Harmonic Ace and Ligasure Atlas at sealing harvested mesenteric vessels ex-vivo	• 18 patients having elective lap or open colorectal surgery were recruited and allocated to one of the three devices. • After removal of colorectal specimen, up to 8 mesenteric arteries and veins were dissected out with the allocated device. • 93 vessels were assessed in total. • Vessel seal Burst Pressure was measured. • Depth of thermal damage was measured from histological samples byblinded histopathologist along with vessel type, diameter and wall thickness.	• For mean vein diameter of 1mm, Burst Pressure Ligasure mmHg: 1295; Lotus mmHg: 1145; Ace mmHg: 1113 • For mean artery diameter of 1mm, Burst Pressure Statistically significantly lower for Lotus but 6-10x Ligasure mmHg: 2005; Lotus mmHg: 1206; Ace mmHg: 1704 systolic blood pressure. • Depth of thermal damage significantly greater with Ligasure compared with Lotus or Ace. • No clinically relevant differences in BP or thermal damage

Key Message: All three instruments were equally good at sealing blood vessels, with bursting pressures well above physiological blood pressure levels.

14. N.J.Smart, E.J.Noble, C.Challand, K.Sleigh, A.Oriolowo, K.B.Hosie. A Comparison of the Ability of Lotus Ultrasonic Device, Ethicon Ace Harmonic Scalpel and Ligasure Bipolar Device to Seal Mesenteric Blood Vessels During Colorectal Surgery. (**Poster)**

AIMS	DATA	RESULTS
To compare blood vessel sealing by 3 surgical instruments (LOTUS, ACE and LigaSure). Primary outcome Bursting pressure of sealed blood vessel. Secondary outcomes Success/failure to seal vessel and collateral (thermal) damage sustained to vessel.	Inclusion criteria - all patients over 18 years undergoing any elective colorectal resection. Patients were randomized into one of 3 treatment groups. Up to 8 blood vessels were dissected from the mesentery of the specimen after removal from the patient. Vessels were then sealed using the allocated instrument.	All three instruments sealed mesenteric blood vessels safely and effectively with no sealing failures. LigaSure caused significantly more thermal damage to blood vessels than ACE or LOTUS.

15. Sinha S, Tkacz Z, Robinson M, Morris E.
The Safety and Tolerability of the Lotus Torsion Scalpel, a, Novel Form of Ultrasonic Energy, in Operative Laparoscopic Gynaecology. (**Poster)**

AIMS	DATA	RESULTS
• Assess effectiveness of Lotus in laparoscopic gynaecological surgery. • Assess patient satisfaction with procedure done by Lotus. • Assess ease of use of Lotus.	• Retrospective study by telephone interview of 25 patients October 2004 to September 2005. • 22 Salpingo-oophorectomy/Oophorectomy • 1 ectopic salpingectomy • 2 adhesiolysis	• 25/25 procedures successful • 20/25 patients discharged within 24 hours, 3 within 8 hours. • 14/19 completed questionnaires rated pain during first week post-op < 5/10. • 18/19 patients were happy with procedure and would recommend it to others. • 1/19 patients felt procedure had not improved chronic pain and dyspareunia. • 18/25 operating times < 1 hour.

16. M.Abu-Hilal, T.Underwood, M.Taylor, N.Pearce. Reducing the Risk of Bleeding in Laparoscopic Liver Surgery. (**Poster)**

AIMS	DATA	RESULTS
• Retrospective review of laparoscopic liver resections to assess overall success rate and weaknesses of the procedure.	• Retrospective study of 80 laparoscopic liver resections between 2003 and 2007. • Patient age. • Malignancy rate • Operating time • Blood Loss • Blood transfusions	• Lap liver resection is safe and effective • Bleeding is the major risk/weakness. • Haemostasis is reliant on modern laparoscopic technologies to allow safe parenchymal transaction (Lotus and CUSA)

17. Widdison, A.L., Barns, V., Prescott, O. and Pollard, A., 2016. A cost-minimization analysis of first intention laparoscopic compared to open right hemicolectomy for colon cancer. *Annals of medicine and surgery*, *5*, pp.23-28.

AIMS	DATA	RESULTS
The cost of a longer operating time and consumables may offset savings from a shorter length of stay (LOS). A cost minimization study was undertaken to compare the relative costs.	Elective right hemicolectomies for colon cancer performed over 5 years by two teams One team performed an open operation (OG), the other intended to perform all operations laparoscopically (LG) using the Lotus scalpel. Clinical outcomes and relative costs were evaluated.	Laparoscopic right hemicolectomy is oncologically equivalent but less costly 62% probability that a laparoscopic right hemicolectomy was cheaper than an open operation.

18. Berrisford, R.G., Wajed, S.A., Sanders, D. and Rucklidge, M.W.M., 2008. Short-term outcomes following total minimally invasive oesophagectomy. *British Journal of Surgery: Incorporating European Journal of Surgery and Swiss Surgery*, *95*(5), pp.602-610

AIMS	DATA	RESULTS
This study documented the morbidity, mortality and challenges of adopting MIO (Minimally invasive oesophagectomy) in a specialist unit in the UK.	A prospective group of 77 patients was listed consecutively with the intention of performing MIO. Three other patients underwent open oesophagectomy during the study period. Oesophageal aortic branches were clipped with Ligaclip (10-M/L; Ethicon EndoSurgery, Cincinnati, Ohio, USA) and thicker tissue was divided with a LotusTM torsional scalpel.	MIO was attempted in 77 patients, completed successfully in 70, abandoned in six patients (8 per cent) with unsuspected metastatic disease. There was one in-hospital death (1 per cent). Complications occurred in 33 patients (47 per cent), including nine gastric conduit-related complications (13 per cent). Median lymph node harvest was 21 (range 7–48) nodes. Mean overall and disease-free survival times were 35 and 33 months respectively. Median disease-free survival for patients with stage III disease was 26 months.

19. Baltatzis, M. Sheen, A., et al Comparison of Outcomes Between Open Major Hepatectomy Using CUSA and Laparoscopic Major Hepatectomy Using "Lotus" Liver Blade. A Propensity Score Matched Analysis

AIMS	DATA	RESULTS
The study aims to explore the efficacy and safety of laparoscopic vs. open major liver resection.	Between January 2016 to May 2018, Lotus ultrasonic energy device was used for parenchymal transection in laparoscopic cases vs. CUSA in open procedures 82 consecutive patients.	There was no difference in the intraoperative and postoperative transfusion rates. Patients after laparoscopic surgery were discharged 2 days earlier on average. The use of the Lotus ultrasonic energy device appeared to be efficient and safe for parenchymal transection in the laparoscopic procedures.

Summarized by Dr. S.M.R. Young