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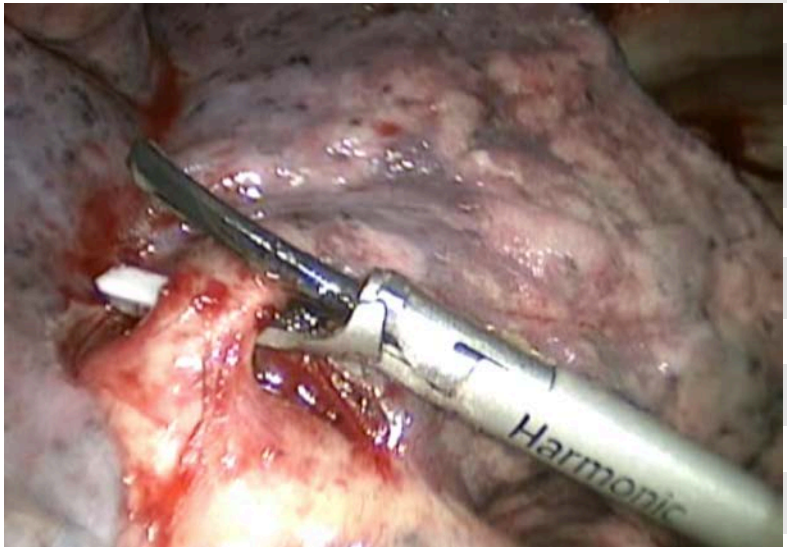
Energized VATS Lobectomy:
Evidence journey to seal small PA arteries and branches with advanced energy

Dr. Moishe Liberman, MD, PhD
Centre Hospitalier de l'Université de Montréal (CHUM)



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“Liberman Journey” - the data

Dr. Moishe Liberman, MD, PhD
Centre Hospitalier de l'Université de Montréal (CHUM)

Methodical approach evaluating small Pulmonary Artery (PA) vessel and branch sealing with HARMONIC®

	2014	2015	2016
	Pilot Study: Ex-vivo burst pressure of PA vessels from patients undergoing anatomical lung resection or lung transplantation	Ex-vivo burst pressure of PA vessels from patients undergoing anatomical lung resection	Animal survival study (dog): PA sealing in Video-Assisted Thoracoscopic Surgery Lobectomy
Comparator	HARMONIC ACE®, ENSEAL®, LigaSure™ and Thunderbeat	HARMONIC ACE®+ vs. Endopath ETS 35mm endocutter (white reload)	HARMONIC ACE®+ 7 (no comparator)
Conclusion	• Sealing was effective – high intraluminal burst pressures • Ultrasonic technology appeared superior but verification and further studies warranted	• Sealing was effective - high intraluminal burst pressures for ACE+ • Vessels sealed with ACE+ had mean bursting pressures ≥ vessels sealed with ETS	• Use of ACE+7 for PA branch sealing in VATS lobectomy was safe and effective • Human studies are recommended to evaluate clinical feasibility

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Methodical approach evaluating small Pulmonary Artery (PA) vessel and branch sealing with HARMONIC®

	2016	2017	2018
	Phase 1 Clinical Trial: PA sealing in open lobectomy (10 patients; 14 PAs sealed)	Phase 1 Clinical Trial: PA sealing in VATS lobectomy (20 patients; 31 PAs sealed)	Phase 2 Clinical Trial: PA sealing in VATS lobectomy
Comparator	HARMONIC ACE®+ 7 (no comparator)	HARMONIC ACE®+ 7 (no comparator)	HARMONIC ACE®+ 7 (no comparator)
Conclusion	• Phase 1 clinical trial positive (no seal failures) • Further studies recommended before widespread application in lobectomy, including VATS.	• Phase 1 clinical trial positive (no seal failures) • No intra- or post-operative bleeding related to ultrasonic sealing • Large-scale, prospective, multi-institutional studies recommended before widespread clinical application in VATS lobectomy.	*150 patients across 7 institutions in the U.S., UK and Canada* *Q4 2018 enrollment completed*

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Phase 2 Clinical Trial

Title: Ultrasonic Energy for Pulmonary Artery Branch Sealing During VATS Lobectomy (VATS PA-ACE)

Investigator initiated study sponsored by Ethicon: https://clinicaltrials.gov/ct2/show/study/NCT02719717

Primary Outcome Measures

- Technical success: Absence of intra-operative bleeding directly related to PA branch sealing with ACE+7 on vessels ≤7mm.
- All procedures were video-recorded to assess intra-operative vascular manipulation, vessel sealing & bleeding episodes

Secondary Outcome Measures

- Number of intra-operative transfusions
- Number of post-operative transfusions (up to 30 days)
- Number of conversion to open surgery
- Number of intra-operative mortality
- Length of stay (up to 30 days)
- Chest tube drainage per 24-hour period (in milliliters; time of surgery to chest tube removal)
- Number of operative take-back for bleeding, source of bleeding (up to 30 days)

Other Outcome Measures

- Number of morbidity and mortality (up to 30 days follow-up)

Institutions

Canada

1. **Centre Hospitalier de l'Université de Montréal** (PI: Moishe Liberman)
2. **Toronto General Hospital** (PI: Kazuhiro Yasufuku)
3. **St. Joseph's Hospital** (PI: Wael Hanna)
4. **London Health Sciences Centre** (PI: Richard Malthaner)

USA

5. **Jefferson University Hospital** (PI: Nathaniel Evans)
6. **Massachusetts General Hospital** (PI: Christopher Morse)

United Kingdom

7. **James Cook University Hospital** (PI: Joel Dunning)

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Prospective, Multi-Center, International Phase 2 Trial Evaluating Ultrasonic Energy for Pulmonary Artery Branch Sealing in VATS Lobectomy

Moishe Liberman[1], Eric Goudie[1], Chris Morse[2], Waël C. Hanna[3], *Nathaniel R. Evans[4], *Kazuhiro Yasufuku[5], Richard Malthaner[6], Joel Dunning[7], Edwin Lafontaine[1], *Pasquale Ferraro[1], *Cameron Wright[2], Hugh Auchincloss[2], *Michael Lanuti[2], Jocelyne Martin[1], *Harald C. Ott[2], *Henning A. Gaissert[2], John Sampalis[8]

[1]University of Montreal, Montreal, QC, Canada;[2]Massachusetts General Hospital, Boston, MA;[3]McMaster University, Hamilton, ON, Canada;[4]Jefferson University, Philadelphia, PA;[5]University of Toronto, Toronto, ON, Canada;[6]University of Western Ontario, London, ON, Canada;[7]James Cook University Hospital, Middlesbrough, United Kingdom;[8]McGill University, Montreal, QC, Canada

Objective: To evaluate the immediate, short- and medium-term efficacy and safety of pulmonary artery (PA) branch sealing utilising an ultrasonic vessel-sealing device in minimally invasive anatomical lung resection.

Methods: This study consists of a prospective, Phase II, multi-institutional, international clinical trial (clinicaltrials.gov: NCT02719717) which enrolled patients planned for VATS/robotic anatomical lung resection in seven centers (US, Canada, UK). Diameters of all PA branches requiring division were measured intraoperatively. PA Branches of 7mm or less were sealed and divided with an ultrasonic energy vessel-sealing device. The remainder of the lobectomy was performed according to surgeon preference. Intraoperative, in-hospital, and 30-day post-operative bleeding and complications were reported.

Results: A total of 150 patients with a minimum of one PA branch sealed and divided with an ultrasonic vessel-sealing device were prospectively enrolled and included in the trial. Anatomic resections included 139 lobectomies and 11 segmentectomies. A total of 424 PA branches were divided; 239 with the ultrasonic vessel-sealing device, 181 with endostaplers, and 4 with endoscopic clips. The mean and median PA diameters were 4.7mm / 5mm, 10.3mm / 10mm, and 6.5mm/6.5mm for each method, respectively. Three of the PA branches divided with the ultrasonic vessel-sealing device (1.3%) and four PA branches divided with endostaplers (2.2%) bled intraoperatively (p=0.47). Among the patients with seal failures, one patient required conversion to thoracotomy for vascular repair in the ultrasonic energy group. There was no postoperative bleeding from divided PA branches with either sealing method. One patient was re-operated for hemothorax from a bleeding bronchial artery. Mean and median length of stay was 4.1 and 3.8 days, respectively. There was no mortality at 30-days.

Conclusions: PA branch sealing with ultrasonic energy during VATS lobectomy is safe for vessels of 7mm or less. With appropriate training, the use of an ultrasonic vessel-sealing device is a reasonable alternative for vascular sealing in PA branches of 7mm or less.

Investigator initiated study sponsored by Ethicon: https://clinicaltrials.gov/ct2/show/NCT02719717