The BEST
Device Assessment
in THORACIC SURGERY
Best Seal: THUNDERBEAT® vs LiagSure® vs Harmonic®
Skeptik reviewer

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Case

• You have been asked to participate in a RFP (Request For Proposal) for your hospital’s selection of a preferred provider for a surgical vessel sealing device.

• To prepare for the clinical evaluation you search the literature and find this article
Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments

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Background

- Hemostasis is important for surgeons
- Modern surgical scissors use energy to cut and seal
- MIS tying is demanding and slow
- So we use staplers, clips, or energy devices
- “Why tie when you can fry?”
- Small vessels
  - Monopolar or bipolar electrocautery (Bovie®)
- Medium vessels
  - Bipolar or ultrasonic devices
William T. Bovie PhD

- Harvard
- Harvey W. Cushing MD
- 1st used October 1, 1926 Peter Bent Brigham
Ultrasonic scissors

- Uses vibration
- Seals up to 5 mm vessels
- Harmonic ACE® -Ethicon
- Seals and cuts simultaneously
- Fast
- Hot! Temperatures of >200°C
- Can cause lateral thermal damage
Bipolar

- Seals up to 7 mm vessels
- ENSEAL® -Ethicon
- LigaSure V® -Valleylab
- Pulsed bipolar energy and feedback control
- Temperature < 100°C
- Needs a cutting blade
- Needs 2 steps and takes longer
Research question

• What is the safety and efficacy of the THUNDERBEAT®, Harmonic ACE®, and LigaSure® energy devices in vivo in swine?
Population

- 8 German Landrace pigs
- 45-60 kg

- Carotid, splenic, femoral, iliac, popliteal, mesenteric, renal, axillary, brachial arteries

- 10 cm small bowel mesentery
Intervention device

- THUNDERBEAT®
  - Prototype
  - Olympus Medical Systems Corp., Tokyo, Japan
- Integrates both ultrasonic friction heat and electrical bipolar heat when using “seal-and-cut” mode
- Bipolar only works but does not cut
- Ultrasonic only can not be done

Fig. 2 Cross section of the jaws of the TB illustrating its mode of operation. Bipolar energy is delivered laterally (red arrows) and ultrasonic energy centrally (blue arrows), leading to additional sealing and simultaneous division of the tissue.
Comparison devices

• LiagSure V®
  • Valleylab Inc., Boulder, CO, USA

• Harmonic ACE®
  • Ethicon Endo-Surgery, Cincinnati, OH, USA
Outcomes

• Safety
  • Thermal profile
    • Infrared camera and thermosensor
  • Histologic damage
    • Width of tissue seal and small bowel damage

• Efficacy
  • Sealing capability
    • Seal failure
    • *Ex vivo* Burst pressures with saline infusion
  • Cutting speed
    • 10 cm of small bowel mesentery and across vessels
Author's Conclusions

• “The ultrasonic and bipolar technique of the THUNDERBEAT® has the potential to surpass the dissection speed of ultrasonic devices with the sealing efficacy of bipolar clamps.

• However, heat production that is comparable to conventional ultrasonic scissors should be minded for clinical use.”
Quality check list for device assessment
Are the results valid?

1. Did the study ask a clear focused question? ✔
2. Was the assignment of devices randomized? ✔
3. Was the randomization process concealed? ?
4. Were all tests that were done accounted for at the end? ?
5. Were all devices analyzed in the groups to which they were randomized? ?
Are the results valid?

6. Was the follow-up of subjects complete and long enough?  
   Crossed out.

7. Were testers and assessors “blind” to the treatment?  
   Checked.

8. Were the objects similar at the start of the trial?  
   Question mark.

9. Apart from the intervention, were the groups treated equally?  
   Checked.

10. Was the study free from industry support?  
    Crossed out.
IF YOU FIND IT IN MY DIAPER...

WE'RE DONE!
What are the results?

11. How large was the treatment effect?
   - 301 arterial vessels sealed
   - Seal failures were NOT different, but rates not explicitly reported “<10%”
   - Burst pressure was higher in larger arteries with TB than with HA
     - 734±64 mm Hg vs. 453±50 mm Hg
   - Cutting time was shorter with TB
   - Temperature was lowest with LS: < 100°C
   - HA and TB were hotter
Fig. 3  Burst pressure measured after in vivo sealing and division of arteries (p values significant by post-hoc comparison are indicated)
Burst pressure failures < 300 mmHg

Number Needed to Fail

5-7 mm vessels

- LS
- HA
- TB

Number Needed to Fail:
- LS: 9
- HA: 39.5
- TB: 10

5-7 mm vessels:
- LS: 11.1
- HA: 3
- TB: 10.2
Fig. 6 Time needed for sealing and cutting of a standardized length of 10 cm of small bowel mesentery (p values significant by post-hoc comparison are indicated)
Fig. 5  Time needed for division of arteries in both vessel categories (p values significant by post-hoc comparison are indicated)
<table>
<thead>
<tr>
<th></th>
<th>LS</th>
<th>HA</th>
<th>TB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(a) Thermosensor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum temperature ($^\circ$C) (95% CI)</td>
<td>86 ± 2$^c$ (81–91)</td>
<td>192 ± 7 (175–208)</td>
<td>172 ± 7 (158–187)</td>
</tr>
<tr>
<td>Time to decline to 60 $^\circ$C (s) (95% CI)</td>
<td>34 ± 3$^c$ (29–40)</td>
<td>54 ± 3 (48–60)</td>
<td>60 ± 3 (53–66)</td>
</tr>
<tr>
<td><strong>(b) Thermocamera</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum temperature ($^\circ$C) (95% CI)</td>
<td>85 ± 3$^c$ (80–90)</td>
<td>209 ± 7 (196–223)</td>
<td>229 ± 9 (209–241)</td>
</tr>
<tr>
<td>Time to decline to 60 $^\circ$C (s) (95% CI)</td>
<td>8 ± 1$^c$ (6–10)</td>
<td>33 ± 1 (31–35)</td>
<td>34 ± 1 (32–36)</td>
</tr>
<tr>
<td><strong>(c) Histological damage of small bowel (distance = 5 mm) (n)</strong></td>
<td>0/8</td>
<td>0/8</td>
<td>0/8</td>
</tr>
</tbody>
</table>

* (a) Thermosensor: Heat production measured by thermosensor after cutting 10 cm of the small bowel mesentery. (b) Thermocamera: Heat profile during single activation and division of mesenteric tissue determined by an infrared camera. (c) Histological damage of small bowel: Samples with histological damage to the small bowel after standardized division of the small bowel mesentery 5 mm distant to the bowel wall.

$^b$ After repeated activation, see Material and methods.

$^c$ $p < 0.05$ versus HA and TB.

$^d$ After single activation.
What are the results?

12. How precise were the results?
   - See above

13. Do you believe the results? ✅
Do the results apply to my patients?

13. Could the device be used on my patients? ✓

14. Were all clinically important outcomes considered? ❌

15. Are the benefits worth the harms and costs? ?
Key results

- All devices worked well for small vessels (<4mm)
- **THUNDERBEAT®:**
  - better sealing abilities i.e. burst pressures
  - Twice as fast as LigaSure (4s vs 8s for large vessels)
  - Hotter than LigaSure, same as Harmonic ACE

- No small bowel injury if energy device > 5 mm away
Skeptik BEST commentary

- Did have a priori hypothesis
- Sample sized calculations were done
- Did randomize devices and stratify for vessel size for burst pressures tests
  - Not clear how this was done.
  - No mention of concealment
- Statistical analysis appears correct
  - Adjusted for multiple comparisons
Skeptik BEST commentary

• How did they know to test large arteries (> 5mm) only for TB vs HA burst pressures?
• How did they know to compare speed only for TB vs LS?
• Appears they were maximizing positive results!
• 2 devices used on each animal, not all 3
  • Different animals...different results
Skeptik BEST commentary

- Burst pressure and histology evaluators were blinded
- Other measurements were not blinded.
  - Could they have concealed the instrument?
- Are burst pressures clinically meaningful?
  - Number of failures is a better metric
Skeptik BEST commentary

• Did not present the details of vessel size
  • Perhaps there were difference between devices
• Other clinical outcomes not tested:
  • Survival
  • Unrecognized delayed injury
  • Ergonomics of use
  • Sealing ability “under water”
  • Cost
• Are they really safe?
• Olympus funded the study
• Authors disclosed no conflict of interest
Comment on author’s conclusions vs BEST

- Overall agreement, but is it safe enough for Thoracic Surgery?
  - Esophagectomy
  - Dissection near trachea
Ed’s tweet home message

• THUNDERBEAT® may be better than the other energy devices for sealing and speed but beware of thermal injury!
Case resolution

• You participate in the RFP, fill out the feedback forms, and send them to HMMS

• You are still waiting for the verdict at LHSC.
TRUST NO ONE
NOT EVEN SKEPTIK RICK
What's the Best Batman?
CHEST is BEST™