Vessel Sealing Technology For Thyroid Surgery: Current Evidence

Sam Wiseman BSc, MD, FRCSC, FACS, Associate Professor, Department of Surgery, University of British Columbia
Endocrine Surgery / Head & Neck Surgery / Surgical Oncology / General Surgery
St. Paul's Hospital, Providence Health Care
Chair Endocrine Tumor Group
British Columbia Cancer Agency
Vancouver, British Columbia, Canada

SON Fall Update
Endocrine Surgical Oncology
November 2, 2013
Thoughts On Thyroid Surgery

The extirpation of the thyroid gland . . . typifies, perhaps better than any operation, the supreme triumph of the surgeon’s art. . . . A feat which today can be accomplished by any competent operator without danger of mishap and which was conceived more than one thousand years ago. . . . There are operations today more delicate and perhaps more difficult. . . . But is there any operative problem propounded so long ago and attacked by so many . . . which has yielded results as bountiful and so adequate?

Dr. William S. Halsted, 1920
Thyroid Surgical Technique

- Current thyroid surgical technique was pioneered by Kocher that led to a reduction in mortality from 12.8% in 1883 to less than 0.5% 15 years later.

- Thyroid has a rich blood supply (5.5 mL of blood/gram of tissue/minute).

- Operative field for thyroidectomy is small, readily obscured by a small amount of blood and requires meticulous surgical technique and hemostasis.

- Recurrent laryngeal nerve and/or parathyroid injury may be a direct consequence of an obscured (bloody) operative field.

- Postoperative hemorrhage may arise due to inadequate surgical hemostasis and lead to airway compromise and death.
Current Options For Hemostasis During Thyroid Surgery

• Ties/Sutures/Pressure
• Electrocautery (Monopolar or Bipolar)
• Clips
• Hemostatic Agents
• Novel Hemostatic Devices
  • Electrothermal Bipolar Vessel Sealing Systems
  • Harmonic Scalpel
Ties, Sutures, Pressure

• Classic technique for hemostasis during thyroid ORs

• Clamp and tie of all named and many smaller thyroid vessels

• Advantages:
  • ‘Tested and True’
  • No current created
  • No heat created

• Disadvantages:
  • Time consuming
  • Knot slippage
  • Foreign bodies (esp silk)
  • Leave a ‘stump’
Electrocautery

• **Monopolar Cautery**
  - Reliably seal vessels **2mm** in diameter
  - Lateral zone of thermal injury up to **2-8mm**
  - Especially useful for exposing surgical field

• **Bipolar Cautery**
  - Reliably seal vessels up to **3mm** in diameter
  - Lateral zone of thermal injury up to **2-8mm**
  - Especially useful for small vessel hemostasis

• Tysome et al. reported a retrospective series in which bipolar cautery was compared to clamp and tie in 153 thyroid surgeries- technique of triple sealing vessels – complication rates similar and earlier d/c in the bipolar group

(Tysome et al. Eur Arch Otolary 2009;266:1781-6)
Clips & Hemostatic Agents

• Clips can seal vessels well above physiologic BP

• Disadvantages
  • Clip slippage or bleeding
  • Foreign bodies – though absorbable clips available

• Hemostatic Agents
  • Thrombin, fibrin glue, collagen, soluable cellulose, absorbable gelatin sponge/gauze, hemostasis paper, hemostasis foam, gold foil, absorbable cotton, enbucrylate, methyl-2, alkyl or isobutyl cyanoacrylate
  • Fibrin, collagen, and fibrin and thrombin gelatin have been studied in thyroid surgery and reduce drainage volumes and hospital stay
  • Especially useful for controlling capillary oozing immediately adjacent to recurrent nerve (resorbable oxidized regenerated cellulose)

Vessel Sealing For Thyroid Surgery
In The O.R. At Noguchi Hospital In Beppu Japan

(Wiseman S. Bull ACS 2008:49-53)
Limitations of Current Literature Reporting Vessel Sealing For Thyroid Surgery

- Composed of many small retrospective case series
- Variable surgical expertise/volume/technique
- Variable patient populations
- Variable instrument generations studied
- Difficult to study uncommon events in thyroid surgery (ie RLN dysfunction, and hypoparathyroidism) in small studies with limited follow up
- Variable endpoints
- Variable definitions for different endpoints
- Variable costs from one center to another
- Instrument learning curves not considered
How To Overcome These Limitations?

• Large Multicenter Prospective Randomized Controlled Trial
  – Realistic? Necessary?

• Meta-Analysis:
  – Consolidates the results of several studies in order to address a set of related research hypotheses
Harmonic Scalpel

- Harmonic scalpel (Ethicon Endosurgery, OH, USA) – *Harmonic FOCUS* hand piece most useful
- Uses high frequency ultrasonic energy to enable vessel and tissue **coagulation and cutting** at the precise point of impact via vibration at **55.5 kHz** while using low temperatures ranging from **50 to 100 degrees celsius**
- Controls bleeding by coaptive coagulation at lower temperatures then electrosurgery or lasers

Harmonic Scalpel

- Uses high frequency mechanical energy to coagulate and cut vessels
- **No electrical energy transferred** to or through the patient (i.e., no neuromuscular stimulation)
- Vessels are tamponaded and sealed by disrupting protein structure and forming a protein coagulum

Harmonic Scalpel

• Able to seal vessels up to 5mm in diameter to well above physiologic blood pressure levels

• Mean arterial burst strength similar to clips/ligatures and equal to the LS for vessels 0.23-3mm

• Tip of device should be carefully positioned because with activation 10-20s can reach high temperatures (>100 degrees)

• Thermal spread is in a zone 0-2.2mm beyond the forceps (3-5mm safety zone recommended)

Harmonic Scalpel Application To Thyroid Surgery

• First reported for thyroidectomy in 1998 (Ultracision model)
• Currently > 80 published studies
• Harmonic Focus currently utilized
• Has been reported to:
  – Reduce operative time
  – Reduce transient hypoparathyroidism
  – Reduce intraoperative blood loss
  – Reduce postop drain output
  – Reduce postop hematoma
  – Reduce postop analgesia requirement
  – Reduce incision length
  – Reduce hospital stay
  – Reduce costs


Eligibility

- Undergoing total or subtotal thyroidectomy
- 18 years or older
- Only studies comparing HS to CH methods
- VATS/ETS excluded
- If additional procedures during OR study included if time of Thyroidectomy specified
- Prospective, randomized clinical trials
Harmonic Scalpel Meta-Analysis

• **Primary Outcome:**
  – Mean Operative Time (minutes) for total or subtotal thyroidectomy

• **Secondary Outcome:**
  – Incidence of transient RLN dysfunction and transient hypocalcemia

(Melck & Wiseman Int J Surg Onc 2010)
Harmonic Scalpel Meta-Analysis: Results

34 potentially relevant studies screened for retrieval

19 excluded
- 1 evaluated additional procedures
- 18 retrospective or non-randomized

15 retrieved for more detailed evaluation
- 6 excluded
  - 3 duplicate reports on same patient cohort
  - 3 relevant data not provided
- 9 included

(Melck & Wiseman Int J Surg Onc 2010)
### Harmonic Scalpel Meta-Analysis: Results

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Country</th>
<th>Industry funding</th>
<th>CH techniques</th>
<th># patients</th>
<th>Mean OR Time (min) for TT/ST (SD)</th>
<th>Transient RLND</th>
<th>Permanent RLND</th>
<th>Transient hypocalcemia</th>
<th>Permanent hypocalcemia</th>
<th>Postoperative hematoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallgrimson [11]</td>
<td>2008</td>
<td>Sweden</td>
<td>No</td>
<td>Electrocautery ligatures clips</td>
<td>CH = 24</td>
<td>CH = 168.8 (4.8)</td>
<td>CH = 1</td>
<td>CH = 0</td>
<td>CH = 7</td>
<td>CH = 1</td>
<td>CH = 0</td>
</tr>
<tr>
<td>Lombardi [5]</td>
<td>2008</td>
<td>Italy</td>
<td>No</td>
<td>Electrocautery ligatures</td>
<td>CH = 100</td>
<td>CH = 75.2 (23.5)</td>
<td>CH = 1</td>
<td>CH = 0</td>
<td>CH = 29</td>
<td>CH = 0</td>
<td>CH = 1</td>
</tr>
<tr>
<td>Yildirim [13]</td>
<td>2008</td>
<td>Turkey</td>
<td>No</td>
<td>Electrocautery ligatures</td>
<td>CH = 54</td>
<td>CH = 57.8 (16)</td>
<td>CH = 5</td>
<td>CH = 1</td>
<td>CH = 7</td>
<td>CH = 1</td>
<td>CH = 0</td>
</tr>
<tr>
<td>Kilic [6]</td>
<td>2007</td>
<td>Turkey</td>
<td>No</td>
<td>Electrocautery ligatures</td>
<td>CH = 40</td>
<td>CH = 46.7 (10.8)</td>
<td>CH = 0</td>
<td>CH = 0</td>
<td>CH = 5</td>
<td>CH = 0</td>
<td>CH = 0</td>
</tr>
<tr>
<td>Miccoli [12]</td>
<td>2006</td>
<td>Italy</td>
<td>Yes</td>
<td>Electrocautery ligatures</td>
<td>CH = 50</td>
<td>CH = 46.7 (10.8)</td>
<td>CH = 0</td>
<td>CH = 0</td>
<td>CH = 16</td>
<td>CH = 0</td>
<td>CH = 1</td>
</tr>
<tr>
<td>Frazzetta [8]</td>
<td>2005</td>
<td>Italy</td>
<td>No</td>
<td>Electrocautery ligatures</td>
<td>CH = 60</td>
<td>CH = 96 (17)</td>
<td>CH = 2</td>
<td>CH = 0</td>
<td>CH = 6</td>
<td>CH = 1</td>
<td>CH = 0</td>
</tr>
<tr>
<td>Cordon [9]</td>
<td>2005</td>
<td>Mexico</td>
<td>Yes</td>
<td>Electrocautery ligatures clips</td>
<td>CH = 12</td>
<td>CH = 136 (37)</td>
<td>CH = 0</td>
<td>CH = 0</td>
<td>CH = 9</td>
<td>CH = 0</td>
<td>CH = 0</td>
</tr>
<tr>
<td>Ortega [7]</td>
<td>2004</td>
<td>Spain</td>
<td>No</td>
<td>Ligatures</td>
<td>CH = 57</td>
<td>CH = 101 (16)</td>
<td>CH = 1</td>
<td>CH = 0</td>
<td>CH = 6</td>
<td>CH = 1</td>
<td>CH = 2</td>
</tr>
<tr>
<td>Defechereux [10]</td>
<td>2003</td>
<td>Belgium</td>
<td>No</td>
<td>Electrocautery ligatures clips</td>
<td>CH = 17</td>
<td>CH = 96.5 (28.9)</td>
<td>CH = 0</td>
<td>CH = 0</td>
<td>CH = 4</td>
<td>CH = 0</td>
<td>CH = 0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CH = 414</td>
<td>CH = 168.8 (4.8)</td>
<td>CH = 1</td>
<td>CH = 0</td>
<td>CH = 89</td>
<td>CH = 2</td>
<td>CH = 3</td>
</tr>
</tbody>
</table>

CH: conventional hemostasis; OR: operative; HS: harmonic scalpel; TT: total thyroidectomy; ST: subtotal thyroidectomy; SD: standard deviation; RLND: recurrent laryngeal nerve dysfunction.

Complications are uncommon. (Melck & Wiseman Int J Surg Onc 2010)
Results: Primary Outcome

Figure 2: Forest plot depicting individual and pooled weighted mean difference (WMD) in operative times with 95% confidence intervals.

HS reduced operative time by 23 minutes

(Melck & Wiseman Int J Surg Onc 2010)
Results: Secondary Outcomes

Transient Postoperative Recurrent Laryngeal Nerve Dysfunction (22/822 (0.03%))

Transient Postoperative Hypocalcemia (148/822 (18%))

(Melick & Wiseman Int J Surg Onc 2010)
Harmonic Scalpel Meta-Analysis: Conclusions

Use of the harmonic scalpel for thyroidectomy significantly reduces operative time and is associated with a reduction in postoperative hypocalcemia compared to conventional hemostasis techniques.

Electrothermal Bipolar Vessel Sealing Systems

- Electrothermal Bipolar Vessel Sealing System (Ligasure Covidien CO, USA)
- Computer controlled bipolar diathermy system that utilizes a combination of pressure and bipolar energy and incorporates impedance based feedback loops to modify bipolar energy
- During activation the response generator’s computer automatically adjusts the precise amount of energy to be delivered according to the density of the grasped tissue, sensed by the generator, in order to fuse the vessel wall and create a permanent seal by denaturing collagen and elastin fibers

Electrothermal Bipolar Vessel Sealing System

- Able to seal vessels up to 7mm in diameter to well above physiologic blood pressure levels (can tolerate up to 3x SBP)

- Mean arterial burst strength similar to clips/ligatures and higher than ultrasonic or bipolar sealed vessels when >3mm

- Thermal spread is in a zone 1.2 to 3mm beyond the forceps (5mm safety zone recommended)

Electrothermal Bipolar Vessel Sealing System (Ligasure) Application To Thyroid Surgery

• First Reported application in 2003
• Currently > 50 published studies
• ‘Precise’ and ‘Small Jaw’ hand pieces
• Has been reported to:
  – Reduce operative time
  – Reduce transient hypoparathyroidism
  – Reduce intraoperative blood loss
  – Reduce postop drain output
  – Reduce postop hematomas
  – Reduce RLN palsies
  – Reduce incision length
  – Reduce hospital stay
  – Reduce the need for general anesthesia (can do under local)
  – Reduce costs

• Articles ID’d from Cochrane/MEDLINE/EMBASE/Elsevier/SpringerLink/Ovid/Manufacturer (Jan 1/2006-July 31/2008)

• Eligibility
  – Undergoing total or subtotal
  – Only studies comparing LS to CH methods
  – Able to extract clearly complication rated for LS and HS groups
  – Prospective, controlled design (randomized and nonrandomized)
Ligasure Meta-Analysis

• **Primary Outcomes:**
  – Mean Operative Time (minutes)
  – Amount of intraoperative blood loss

• **Secondary Outcome:**
  – Length of hospital stay
  – Postoperative complications
    – Hypocalcemia
    – Recurrent Laryngeal Nerve lesions

Ligasure Meta-Analysis Results

• 9/27 studies met inclusion criteria (927 patients)
  • 4 randomized
  • 5 nonrandomized

<table>
<thead>
<tr>
<th>Source</th>
<th>Design</th>
<th>No. of Patients</th>
<th>Age, Mean (SD), y</th>
<th>No. of Men</th>
<th>Type of Thyroidectomy</th>
<th>Pathological Diagnosis of Lesions, B/M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LT</td>
<td>CT</td>
<td>LT</td>
<td>CT</td>
<td>LT</td>
</tr>
<tr>
<td>Kiriakopoulos et al, 2004</td>
<td>Non-RCT</td>
<td>40</td>
<td>40</td>
<td>48.2 (7.8)</td>
<td>46.4 (8.2)</td>
<td>7</td>
</tr>
<tr>
<td>Kirdak et al, 2005</td>
<td>Non-RCT</td>
<td>30</td>
<td>28</td>
<td>48 (13.9)</td>
<td>46 (12.9)</td>
<td>6</td>
</tr>
<tr>
<td>Manouras et al, 2005</td>
<td>RCT</td>
<td>94</td>
<td>90</td>
<td>51.8 (11.6)</td>
<td>54 (13.3)</td>
<td>20</td>
</tr>
<tr>
<td>Barbaros et al, 2006</td>
<td>Non-RCT</td>
<td>50</td>
<td>50</td>
<td>47 (11)</td>
<td>49 (13)</td>
<td>7</td>
</tr>
<tr>
<td>Kilic et al, 2007</td>
<td>RCT</td>
<td>20</td>
<td>20</td>
<td>45.1 (14.3)</td>
<td>41.4 (12.5)</td>
<td>3</td>
</tr>
<tr>
<td>Marrazzo et al, 2007</td>
<td>RCT</td>
<td>25</td>
<td>25</td>
<td>NM</td>
<td>NM</td>
<td>25</td>
</tr>
<tr>
<td>Saint Marc et al, 2007</td>
<td>RCT</td>
<td>100</td>
<td>100</td>
<td>49.5 (11.3)</td>
<td>54.1 (13.2)</td>
<td>10</td>
</tr>
<tr>
<td>Cipolla et al, 2008</td>
<td>Non-RCT</td>
<td>53</td>
<td>52</td>
<td>50.1 (11.4)</td>
<td>50.5 (14.3)</td>
<td>10</td>
</tr>
<tr>
<td>Youssef et al, 2008</td>
<td>Non-RCT</td>
<td>55</td>
<td>55</td>
<td>44 (11.4)</td>
<td>43.8 (10.7)</td>
<td>12</td>
</tr>
</tbody>
</table>

Abbreviations: B, benign; CT, conventional thyroidectomy; LT, LigaSure (Valleylab, Boulder, CO) thyroidectomy; M, malignant; NM, not mentioned; RCT, randomized controlled trial.

*a* No significant difference between patients undergoing LT vs CT.

*b* Significant difference between patients undergoing LT vs CT ($P<.05$).

### Ligasure Meta-Analysis Results

#### Table 2. Operative and Postoperative Parameters of the 9 Clinical Trials Comparing LT and CT

<table>
<thead>
<tr>
<th>Source</th>
<th>Operative Duration, Mean (SD), min</th>
<th>Operative Blood Loss, Mean (SD), mL</th>
<th>Length of Hospital Stay, Mean (SD), d</th>
<th>Postoperative Complications, No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LT (Mean)</td>
<td>CT (Mean)</td>
<td>LT (Mean)</td>
<td>LT (Mean) CT (Mean) LT (Mean) CT (Mean) LT (Mean) CT (Mean) LT (Mean) CT (Mean) LT (Mean) CT (Mean) LT (Mean) CT (Mean)</td>
</tr>
<tr>
<td>Kiriakopoulos et al, 22 2004</td>
<td>84 (6)</td>
<td>89 (7)</td>
<td>30 (5)</td>
<td>35 (8)</td>
</tr>
<tr>
<td>Kirdak et al, 23 2005</td>
<td>96.2 (22.2)</td>
<td>115.4 (19.1)</td>
<td>1.4 (1.2)</td>
<td>1.3 (0.7)</td>
</tr>
<tr>
<td>Manouras et al, 24 2005</td>
<td>87.3 (21.3)</td>
<td>101.6 (34.2)</td>
<td>2.1 (1.5)</td>
<td>1.8 (0.9)</td>
</tr>
<tr>
<td>Barbaros et al, 25 2006</td>
<td>58 (21)</td>
<td>75 (23)</td>
<td>1.4 (0.1)</td>
<td>1.6 (0.2)</td>
</tr>
<tr>
<td>Kilic et al, 26 2007</td>
<td>55.7 (12.7)</td>
<td>68.3 (19.9)</td>
<td>1.9 (0.4)</td>
<td>1 (NN)</td>
</tr>
<tr>
<td>Marrazzo et al, 27 2007</td>
<td>60 (14.8)</td>
<td>92.4 (27.5)</td>
<td>1.1 (0.3)</td>
<td>1 (NN)</td>
</tr>
<tr>
<td>Saint Marc et al, 28 2007</td>
<td>42.5 (11.2)</td>
<td>48.9 (6.8)</td>
<td>1.1 (0.2)</td>
<td>1 (NN)</td>
</tr>
<tr>
<td>Cipolla et al, 29 2008</td>
<td>104 (12.7)</td>
<td>110 (15.6)</td>
<td>58 (38.2)</td>
<td>61 (37.5)</td>
</tr>
<tr>
<td>Youssef et al, 30 2008</td>
<td>NM</td>
<td>NM</td>
<td>65.6 (14.8)</td>
<td>132.7 (28.4)</td>
</tr>
</tbody>
</table>

**Abbreviations:** CT, conventional thyroidectomy; LT, LigaSure (Valleylab, Boulder, CO) thyroidectomy; NM, not mentioned.

- **a** No significant difference between patients undergoing LT vs CT.
- **b** Significant difference between patients undergoing LT vs CT ($P < .05$).

Complications are uncommon.

**Ligasure Meta-Analysis Results**

### Unspecified Thyroidectomy

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinakopoulos et al. 2004</td>
<td>40</td>
<td>84.00 (6.00)</td>
<td>Kerlikowske et al. 2005</td>
<td>30</td>
<td>96.20 (22.20)</td>
</tr>
<tr>
<td>Mancuso et al. 2005</td>
<td>94</td>
<td>87.30 (21.30)</td>
<td>Vaccarino et al. 2006</td>
<td>50</td>
<td>68.00 (21.00)</td>
</tr>
<tr>
<td>Kric et al. 2007</td>
<td>60</td>
<td>56.70 (12.70)</td>
<td>Mann et al. 2007</td>
<td>25</td>
<td>60.00 (14.80)</td>
</tr>
<tr>
<td>Marzadori et al. 2007</td>
<td>100</td>
<td>42.50 (11.20)</td>
<td>Spaulding et al. 2008</td>
<td>53</td>
<td>104.00 (12.70)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>412</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 32.65, df = 7 (P < .01), I^2 = 78.8\%$

Test for overall effect: $z = 5.20 (P < .001)$

### Subtotal Thyroidectomy

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerlikowske et al. 2005</td>
<td>8</td>
<td>102.50 (16.70)</td>
<td>Kerlikowske et al. 2005</td>
<td>16</td>
<td>125.00 (19.70)</td>
</tr>
<tr>
<td>Vaccarino et al. 2006</td>
<td>94</td>
<td>87.30 (21.30)</td>
<td>Vaccarino et al. 2006</td>
<td>90</td>
<td>101.60 (19.70)</td>
</tr>
<tr>
<td>Mann et al. 2007</td>
<td>25</td>
<td>60.00 (14.80)</td>
<td>Mann et al. 2007</td>
<td>25</td>
<td>92.40 (27.50)</td>
</tr>
<tr>
<td>Spaulding et al. 2008</td>
<td>100</td>
<td>42.50 (11.20)</td>
<td>Spaulding et al. 2008</td>
<td>100</td>
<td>48.90 (8.60)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>206</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 157.01, df = 5 (P < .01), I^2 = 56.8\%$

Test for overall effect: $z = 2.94 (P < .003)$

### Total Thyroidectomy

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerlikowske et al. 2005</td>
<td>14</td>
<td>103.40 (23.50)</td>
<td>Kerlikowske et al. 2005</td>
<td>20</td>
<td>66.80 (46.00)</td>
</tr>
<tr>
<td>Kric et al. 2007</td>
<td>20</td>
<td>55.70 (12.70)</td>
<td>Vaccarino et al. 2006</td>
<td>29</td>
<td>101.20 (7.50)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>64</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 20.39, df = 2 (P < .001), I^2 = 90.2\%$

Test for overall effect: $z = 2.57 (P < .01)$

## Ligasure Meta-Analysis Results

### Intraoperative Blood Loss

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Random WMD (95% CI)</th>
<th>Weight, %</th>
<th>Random WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kirikoupolos et al. 2004</td>
<td>40</td>
<td>30.00 (5.00)</td>
<td>Cipolla et al. 2008</td>
<td>53</td>
<td>58.00 (38.20)</td>
<td>33.86 (-7.92 to -2.08)</td>
<td>33.67</td>
<td>(-17.48 to 11.48)</td>
</tr>
<tr>
<td>Youssef et al. 2008</td>
<td>55</td>
<td>65.60 (14.80)</td>
<td></td>
<td></td>
<td></td>
<td>33.47 (-67.10 to -58.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>148</td>
<td>147</td>
<td></td>
<td></td>
<td></td>
<td>100.00 (-25.13 to 18.18)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 186.08, df = 2 (P < .01), I^2 = 93.9\%$

Test for overall effect: $t = 1.14 (P = .26)$

### Length of Hospital Stay

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Source</th>
<th>No. of Participants</th>
<th>Mean (SD)</th>
<th>Random WMD (95% CI)</th>
<th>Weight, %</th>
<th>Random WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kirdak et al. 2005</td>
<td>30</td>
<td>1.40 (1.20)</td>
<td>Manouras et al. 2005</td>
<td>94</td>
<td>2.10 (1.50)</td>
<td>7.39 (0.10 to 0.60)</td>
<td>11.99</td>
<td>(0.30 to 0.66)</td>
</tr>
<tr>
<td>Barbaros et al. 2006</td>
<td>50</td>
<td>1.40 (0.10)</td>
<td>Marraze et al. 2007</td>
<td>25</td>
<td>1.90 (0.40)</td>
<td>30.79 (-0.26 to -0.14)</td>
<td>19.49</td>
<td>(-0.52 to -0.08)</td>
</tr>
<tr>
<td>Saint Marc et al. 2007</td>
<td>100</td>
<td>1.08 (0.30)</td>
<td></td>
<td></td>
<td></td>
<td>30.34 (-0.01 to 0.08)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>299</td>
<td>293</td>
<td></td>
<td></td>
<td></td>
<td>100.00 (-0.08 to 0.23)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: $\chi^2 = 24.31, df = 4 (P < .01), I^2 = 83.5\%$

Test for overall effect: $t = 1.01 (P = .31)$

---

Figure 3. Forest plots for the amount of intraoperative blood loss (A) and length of hospital stay (B). Squares indicate the point estimates of the treatment effect (weighted mean difference [WMD]) with 95% confidence intervals (CIs) indicated by horizontal bars. Diamonds represent the summary estimate from the pooled studies with 95% CIs. Ligasure is a vessel-sealing device manufactured by Valleylab, Boulder, CO.

Ligasure Meta-Analysis Results

Table 3. Quantitative Meta-analysis Results Based on the 9 Clinical Trials Comparing LT and CT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No. of Trials (N=9)</th>
<th>No. of Participants Included in the Meta-analysis</th>
<th>$P$, %</th>
<th>Pooling Model</th>
<th>Effect Size (95% CI)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td>8</td>
<td>412/405</td>
<td>78.6</td>
<td>WMD (rand)</td>
<td>-11.97 (-16.42 to -7.53)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Total thyroidectomy</td>
<td>6</td>
<td>295/291</td>
<td>96.8</td>
<td>WMD (rand)</td>
<td>-20.32 (-33.86 to -6.79)</td>
<td>.003</td>
</tr>
<tr>
<td>Subtotal thyroidectomy</td>
<td>3</td>
<td>64/58</td>
<td>90.2</td>
<td>WMD (rand)</td>
<td>-21.74 (-38.32 to -5.16)</td>
<td>.01</td>
</tr>
<tr>
<td>Intraoperative blood loss</td>
<td>3</td>
<td>148/147</td>
<td>98.9</td>
<td>WMD (rand)</td>
<td>-25.13 (-68.45 to 18.18)</td>
<td>.26</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>5</td>
<td>299/293</td>
<td>83.5</td>
<td>WMD (rand)</td>
<td>-0.08 (-0.23 to 0.08)</td>
<td>.31</td>
</tr>
<tr>
<td>Postoperative complications</td>
<td>9</td>
<td>63/467$^a$/467$^a$</td>
<td>0</td>
<td>OR (fixed)</td>
<td>0.91 (0.61 to 1.36)</td>
<td>.65</td>
</tr>
<tr>
<td>Transient complications</td>
<td>9</td>
<td>61/467$^a$/62/460$^a$</td>
<td>0</td>
<td>OR (fixed)</td>
<td>0.97 (0.65 to 1.45)</td>
<td>.87</td>
</tr>
<tr>
<td>Transient hypocalcemia</td>
<td>9</td>
<td>38/467$^a$/39/460$^a$</td>
<td>0</td>
<td>OR (fixed)</td>
<td>0.96 (0.59 to 1.55)</td>
<td>.87</td>
</tr>
<tr>
<td>Transient nerve lesions</td>
<td>8</td>
<td>18/467$^a$/17/460$^a$</td>
<td>0</td>
<td>OR (fixed)</td>
<td>1.05 (0.53 to 2.08)</td>
<td>.88</td>
</tr>
<tr>
<td>Permanent complications</td>
<td>2</td>
<td>2/467$^a$/5/460$^a$</td>
<td>0</td>
<td>OR (fixed)</td>
<td>0.49 (0.12 to 2.00)</td>
<td>.32</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; CT, conventional thyroidectomy; LT, LigaSure (a vessel-sealing device; Valleylab, Boulder, CO) thyroidectomy; OR (fixed), odds ratio (fixed effects model); WMD (rand), weighted mean difference (randomized effects model). $^a$Data are given as the number of patients with the complication/total sample size.

Ligasure reduced operative time by 22 minutes


Transient Postoperative Hypocalcemia (77/927 (8.3%))

Impacted due to inclusion of lobectomy cases

Transient Postoperative Hypocalcemia (77/927 (8.3%))

Impacted due to inclusion of lobectomy cases

(Total thyroidectomy: 96.8%)

(Recurrent Laryngeal Nerve Dysfunction (35/927 (0.04%)))
Ligasure Meta-Analysis Conclusions

Use of the Ligasure for thyroidectomy significantly reduces operative time but does not confer any advantage over conventional hemostasis techniques in terms of the amount of intraoperative blood loss, the length of hospital stay, and postoperative complication rates.

Any Head To Head Data?
# Ligasure vs Harmonic vs Conventional Hemostasis

Table 4. Literature review: operative time. LigaSure™ versus Harmonic Scalpel versus conventional hemostasis.

<table>
<thead>
<tr>
<th>Study (year)</th>
<th>Funding</th>
<th>Design</th>
<th>Procedure</th>
<th>Patients (n)</th>
<th>Conventional hemostasis (min)</th>
<th>LS™ (min)</th>
<th>Harmonic Scalpel (min)</th>
<th>Time saved by using LS compared with CH (%)</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective studies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dionigi et al. (2012)</td>
<td>Independent</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>LS: 90; HS: 92</td>
<td>73±9 (47–100)</td>
<td>76±10 (52–110)</td>
<td>NA</td>
<td>LS = HS</td>
<td></td>
</tr>
<tr>
<td>Rahbari et al. (2011)</td>
<td>Covidien (Dublin, Ireland)</td>
<td>Randomized</td>
<td>Total thyroidectomy, lobectomy</td>
<td>LS: 45; HS: 45</td>
<td>187.6±52.6</td>
<td>184.2±66.2</td>
<td>NA</td>
<td>LS = HS</td>
<td></td>
</tr>
<tr>
<td>Di Rienzo et al. (2010)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>CH: 31; LS: 31; HS: 31</td>
<td>72.7±13.6</td>
<td>68.9±7.4</td>
<td>62.7±14.1</td>
<td>5.20</td>
<td>HS &lt; LS = CH</td>
</tr>
<tr>
<td>Singh et al. (2010)</td>
<td>Independent</td>
<td>Randomized</td>
<td>Total thyroidectomy, lobectomy</td>
<td>LS: 14; CH: 14</td>
<td>68.5±14.53</td>
<td>68.6±27.47</td>
<td>NA</td>
<td>0</td>
<td>LS = CH</td>
</tr>
<tr>
<td>Goretzki et al. (2009)</td>
<td>Johnson &amp; Johnson and Covidien for presentation of data</td>
<td>Randomized</td>
<td>Total thyroidectomy, lobectomy, subtotal thyroidectomy</td>
<td>CH: 41; LS: 41</td>
<td>118</td>
<td>87</td>
<td>NA</td>
<td>26.20</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Oussoultzoglou et al. (2008)</td>
<td>Independent</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>LS: 40; BC: 46</td>
<td>170±57 (80–270)</td>
<td>NA</td>
<td>NA</td>
<td>BC 142±35 (75–265) &lt; LS</td>
<td></td>
</tr>
<tr>
<td>Sartori et al. (2008)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy, lobectomy, subtotal thyroidectomy</td>
<td>CH: 50; LS: 50; HS: 50</td>
<td>118±28</td>
<td>129±32</td>
<td>94±24</td>
<td>-9.30</td>
<td>HS &lt; LS = CH</td>
</tr>
<tr>
<td>Youssef et al. (2008)</td>
<td>Nondedicated</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 15; LS: 14</td>
<td>132.13±7.50</td>
<td>93.16±5.68</td>
<td>NA</td>
<td>29.50</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Cipolla et al. (2008)</td>
<td>NS</td>
<td>Nonrandomized</td>
<td>Total thyroidectomy</td>
<td>CH: 13; LS: 13</td>
<td>67.25±4.49</td>
<td>37.65±4.68</td>
<td>NA</td>
<td>44.00</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Klic et al. (2007)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>CH: 27; LS: 28</td>
<td>101.20±7.51</td>
<td>68.80±4.56</td>
<td>NA</td>
<td>32.00</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Minner et al. (2007)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy, lobectomy</td>
<td>CH: 77; LS: 73</td>
<td>117.6±36.1</td>
<td>107.4±35.2</td>
<td>NA</td>
<td>8.70</td>
<td>CH = LS</td>
</tr>
</tbody>
</table>

<: Faster than; =: No difference; BC: BiClamp; CH: Conventional hemostasis; HS: Harmonic Scalpel; Independent: Independent from industry; Randomized: Randomized groups; NS: Not specified; VANS: Video-assisted neck surgery

(Butskii & Wiseman Exp Rev Med Dev 10 (2013))
# Ligasure vs Harmonic vs Conventional Hemostasis

## Table 4. Literature review: operative time. LigaSure™ versus Harmonic Scalpel versus conventional hemostasis (cont.).

<table>
<thead>
<tr>
<th>Study</th>
<th>Funding</th>
<th>Design</th>
<th>Procedure</th>
<th>Patients (n)</th>
<th>Conventional hemostasis (min)</th>
<th>LS™ (min)</th>
<th>Harmonic Scalpel (min)</th>
<th>Time saved by using LS compared with CH (%)</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prospective studies (cont.)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saint Marc et al. (2007)</td>
<td>None reported</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>CH: 100; LS: 100</td>
<td>48.9 ± 6.8</td>
<td>41.5 ± 11.2</td>
<td>NA</td>
<td>15.10</td>
<td>LS &lt; CH (clinically irrelevant)</td>
</tr>
<tr>
<td>Marrazzo et al. (2007)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>LS: 25; CH(25)</td>
<td>92.4 ± 27.5</td>
<td>60 ± 14.8</td>
<td>NA</td>
<td>35.10</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Barbaros et al. (2006)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>LS: 50; CH: 50</td>
<td>75 ± 23</td>
<td>58 ± 21</td>
<td>NA</td>
<td>22.70</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Manouras et al. (2005)</td>
<td>NS</td>
<td>Randomized</td>
<td>Total thyroidectomy</td>
<td>CH: 90; LS: 94</td>
<td>101.6 ± 3.6</td>
<td>87.3 ± 2.2</td>
<td>NA</td>
<td>14.10</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Kirdak et al. (2005)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 9; LS: 8</td>
<td>128.89 ± 19.73</td>
<td>102.50 ± 16.69</td>
<td>NA</td>
<td>20.50</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lobectomy</td>
<td>CH: 10; LS: 8</td>
<td>99.80 ± 12.53</td>
<td>77.38 ± 13.7</td>
<td>NA</td>
<td>22.50</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subtotal thyroidectomy</td>
<td>CH: 9; LS: 14</td>
<td>119.33 ± 11.77</td>
<td>103.36 ± 23.48</td>
<td>NA</td>
<td>13.40</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total</td>
<td>CH: 28; LS: 30</td>
<td>115.43 ± 19.10</td>
<td>96.2 ± 22.21</td>
<td>NA</td>
<td>16.70</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Kiriakopoulos et al. (2004)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 40; LS: 40</td>
<td>89.7 ± 7 (74–102)</td>
<td>84 ± 6 (62–94)</td>
<td>NA</td>
<td>5.60</td>
<td>CH = LS</td>
</tr>
<tr>
<td><strong>Retrospective studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bove et al. (2012)</td>
<td>Independent</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 80; HS: 80; LP: 80</td>
<td>72.7 ± 13.6</td>
<td>68.9 ± 7.4</td>
<td>62.7 ± 14.1</td>
<td>5.20</td>
<td>HS &lt; LS = CH</td>
</tr>
<tr>
<td>Zarebszan et al. (2011)</td>
<td>American College of Surgeons</td>
<td>Case controlled</td>
<td>Total thyroidectomy Lobectomy</td>
<td>LS: 87; HS: 36</td>
<td>NA</td>
<td>74 ± 17</td>
<td>59 ± 11</td>
<td>NA</td>
<td>HS &lt; LS</td>
</tr>
<tr>
<td>Ignjatovic and Kostic (2011)</td>
<td>Independent</td>
<td>Prospective/retrospective case matched</td>
<td>Total thyroidectomy Lobectomy</td>
<td>LS: 23; CH: 33</td>
<td>70 ± 4</td>
<td>65 ± 3</td>
<td>NA</td>
<td>7.10</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Scilletta et al. (2010)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 112; LS: 144</td>
<td>170 (140–190)</td>
<td>140 (120–171.25)</td>
<td>NA</td>
<td>17.60</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Prokopakis et al. (2010)</td>
<td>NS</td>
<td>Retrospective</td>
<td>Total thyroidectomy</td>
<td>CH: 559; LS: 174</td>
<td>78.5</td>
<td>52</td>
<td>NA</td>
<td>33.80</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Cakabay et al. (2009)</td>
<td>Independent</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 217; LS: 41</td>
<td>98.2 ± 6.2</td>
<td>74.1 ± 4.5</td>
<td>69.8 ± 9.3</td>
<td>NA</td>
<td>24.50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subtotal thyroidectomy</td>
<td>CH: 116; LS: 27</td>
<td>77.4 ± 9.4</td>
<td>69.8 ± 9.3</td>
<td>9.80</td>
<td>9.80</td>
<td>LS &lt; CH</td>
</tr>
</tbody>
</table>

*Faster than; = No difference; BC: BiCamp; CH: Conventional hemostasis; HS: Harmonic Scalpel; Independent: Independent from independent samples t-test; LS™: LigaSure™; VANS: Video-assisted neck surgery.

(Butskiy & Wiseman Exp Rev Med Dev 10 (2013))
# Ligasure vs Harmonic vs Conventional Hemostasis

<table>
<thead>
<tr>
<th>Study</th>
<th>Funding</th>
<th>Design</th>
<th>Procedure</th>
<th>Patients (n)</th>
<th>Conventional hemostasis (min)</th>
<th>LS™ (min)</th>
<th>Harmonic Scalpel (min)</th>
<th>Time saved by using LS compared with CH (%)</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>McNally et al. (2009)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>LS: 59; HS: 15</td>
<td>NA</td>
<td>115 ± 38.3</td>
<td>88.0 ± 14.0</td>
<td>NA</td>
<td>HS &lt; CH</td>
</tr>
<tr>
<td>Goretzki et al. (2009)</td>
<td>Johnson &amp; Johnson and Covidien for data presentation</td>
<td>Retrospective</td>
<td>Total thyroidectomy</td>
<td>CH: 108; LS: 8</td>
<td>110 ± 17</td>
<td>88 ± 9</td>
<td>NA</td>
<td>20</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Inabnet et al. (2008)</td>
<td>NS</td>
<td>Retrospective</td>
<td>Total thyroidectomy, lobectomy</td>
<td>LS: 224</td>
<td>NA</td>
<td>77 (20–420)</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Manouras et al. (2008)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 90; LS: 148; HS: 144</td>
<td>93.3 ± 12.5</td>
<td>74.3 ± 14.2</td>
<td>73.8 ± 13.8</td>
<td>20.40</td>
<td>HS = LS &lt; CH</td>
</tr>
<tr>
<td>Musunuru et al. (2008)</td>
<td>NS</td>
<td>Retrospective</td>
<td>Lobectomy</td>
<td>CH: 99; LS: 51</td>
<td>92</td>
<td>52</td>
<td>NA</td>
<td>43.50</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Lepner and Vaasna (2007)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 121; LS: 143</td>
<td>104.8 ± 28.5</td>
<td>78.3 ± 34.4</td>
<td>NA</td>
<td>25.30</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lobectomy</td>
<td>CH: 52; LS: 50</td>
<td>75.3 ± 20.6</td>
<td>54.0 ± 27.2</td>
<td>NA</td>
<td>28.40</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subtotal thyroidectomy</td>
<td>CH: 26; LS: 11</td>
<td>106.0 ± 37.7</td>
<td>60.4 ± 19.2</td>
<td>NA</td>
<td>43.00</td>
<td></td>
</tr>
<tr>
<td>Franko et al. (2006)</td>
<td>NS</td>
<td>Retrospective</td>
<td>Total thyroidectomy, lobectomy</td>
<td>CH: 50; LS: 50</td>
<td>162 ± 32</td>
<td>127 ± 28</td>
<td>97 ± 30</td>
<td>NA</td>
<td>21.60</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lobectomy</td>
<td>CH: 30; LS: 22</td>
<td>100.6 (80–120)</td>
<td>135.3 (108–162)</td>
<td>NA</td>
<td>-34.50</td>
<td>LS = CH</td>
</tr>
<tr>
<td>Parmeggiani et al. (2005)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 120; LS: 70</td>
<td>91.35 ± 12.90</td>
<td>72.07 ± 12.49</td>
<td>NA</td>
<td>21.10</td>
<td>LS &lt; CH</td>
</tr>
<tr>
<td>Shen (2005) et al.</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 62; LS: 89</td>
<td>246 ± 6</td>
<td>192 ± 6</td>
<td>132 ± 6</td>
<td>NA</td>
<td>22.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lobectomy</td>
<td>CH: 37; LS: 46</td>
<td>162 ± 6</td>
<td>123 ± 6</td>
<td></td>
<td>NA</td>
<td>18.50</td>
</tr>
<tr>
<td>Dilek et al. (2005)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 25; LS: 15</td>
<td>97</td>
<td>75 ± 11</td>
<td></td>
<td>NA</td>
<td>22.70</td>
</tr>
<tr>
<td>Lachanas et al. (2005)</td>
<td>NS</td>
<td>Prospective compared with retrospective</td>
<td>Total thyroidectomy</td>
<td>LS: 72</td>
<td>NA</td>
<td>58</td>
<td></td>
<td>NA</td>
<td>28.40</td>
</tr>
<tr>
<td>Petrakis et al. (2004)</td>
<td>NS</td>
<td>Case controlled</td>
<td>Total thyroidectomy</td>
<td>CH: 247; LS: 270</td>
<td>86 ± 22</td>
<td>71 ± 14</td>
<td></td>
<td>NA</td>
<td>17.40</td>
</tr>
</tbody>
</table>

(Butskiy & Wiseman Exp Rev Med Dev 10 (2013))
35 Randomized trials: 2856 patients

- **HARMONIC > LIGASURE** or **CLAMP/TIE**
  - Hypoparathyroidism
  - Operative Time
  - Blood Loss
  - Drain Output
  - Neck Collection
  - Hospital Stay
  - Cost

- **CLAMP/TIE > LIGASURE > HARMONIC**
  - Recurrent Laryngeal Nerve Paralysis

**FIG. 3.** Ranking of hemostatic devices on all outcomes of interest represented in the form of a heatmap as the surface under the cumulative ranking curve (SUCRA). The heatmap represents the efficacy of surgical devices on all outcomes of interest based on SUCRA scores. SUCRA = 1 corresponds to an intervention that always ranks first and SUCRA = 0 to an intervention that always ranks last. Similarly, green represents the best device and red represents the worst for each individual outcome in a qualitative approach. Color images available online at www.liebertpub.com/thy
What About Currently Utilized Vessel Sealing Instruments?
• Prospective Randomized Study (182 thyroidectomy patients)
  • No difference between 2 groups:
    ▪ RLN dysfunction
    ▪ Bleeding
    ▪ Drainage
    ▪ Operative Time
    ▪ Postoperative Calcium Concentration
  
• However in the Harmonic group:
  ▪ Mean length of incision greater
  ▪ More likely to complain of pain with swallowing
  ▪ PTH measurements were lower (normal range)
  ▪ Oral calcium supplementation higher and longer

(Dionigi et al Langenbeck’s Arh Surg 397 (2012))
Prospective Randomized Study (245 thyroidectomy patients)

- No difference between 2 groups:
  - RLN dysfunction
  - Bleeding
  - Incision length
  - Length of hospital stay
  - Postoperative Calcium Concentration

However in the Harmonic group:
- Mean duration of operation was significantly shorter than the Ligasure group
  (Harmonic 16-70 min vs Ligasure 18-92 min)

(Teksoz et al Updates Surg Online 29 Aug (2013))
Head To Head Study Conclusions

- Clear time benefit when comparing HS or LS to CH

- Little difference between HS and LS in terms of time savings or postoperative complications

- Both HS and LS are safe, useful, and time saving alternatives to CH
Conclusions

• Vessel sealing technologies do represent an important technical advance for thyroid surgeons

• Both Harmonic Scalpel and Ligasure are faster (20 minutes for total thyroidectomy) than conventional hemostatic techniques

• These technologies are safe with complication rates similar to rates observed when utilizing conventional hemostatic techniques

• The choice of device is really based on the surgeon’s preference
Future Directions

• Evolving Vessel Sealing Technology
  • Further development of novel energy platforms that allow for shorter tissue fusion cycles and less thermal spread for LS
  • Cooling systems and auto cut-offs that ensure safe temperatures for jaws of HS
  • Re-usable instruments
  • New vessel sealing instruments/systems
Future Directions

• Surgical guideline/policy development

• Large multicenter randomized prospective study using *current generation* instruments

• Rigorous economic analysis
  – Center/Surgeon Specific

• Study of oncologic implications of vessel sealing
THANK YOU