Thyroid surgery with the new harmonic scalpel: A prospective randomized study

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Background. Despite their safety and effectiveness in thyroid surgery, the previous harmonic scalpel instruments are considered large and cumbersome by several surgeons. An innovative technical improvement of the device has been made available since 2008. The objective of this study was to compare the results of total thyroidectomy using the new harmonic scalpel (FOCUS) with that with the previously available device (HARMONIC ACE).

Methods. A prospective randomized study of all total thyroidectomies between February and July 2008 was conducted. Patients (n = 90) were randomized to undergo total thyroidectomy with FOCUS (group A, n = 45) or HARMONIC ACE (group B, n = 45).

Results. No significant differences were identified between the 2 groups in terms of demographics, reoperative thyroid surgery, thyroid gland weight and diameter, pathologic diagnosis, preoperative and postoperative serum PTH and calcium levels, postoperative complications, duration of hospital stay, and final outcome. The mean operative time was less in group A than group B (63 ± 7 min vs 76 ± 8 min, P = .009).

Conclusion. The new harmonic scalpel is a useful adjunct to the armamentarium of the thyroid surgeon. It is safe, effective, and hand friendly, offering great capabilities for delicate tissue grasping and dissection. Use of this device decreased operative time compared with the previously available instrument. (Surgery 2011;149:411-5.)

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Operative resection is the treatment of choice for many thyroid disorders.1-3 Meticulous hemostasis is one of the first priorities of thyroid surgeons to prevent potential complications.4-7 In addition, time-saving modifications in operative treatment are becoming an increasingly important issue. Until recently, hemostasis was most often performed by clamp-and-tie maneuvers, diathermy, or clips. Ties and sutures are time consuming, carry the risk of knot slipping, and rarely might cause inflammation and poor wound healing.8 In addition, clips may be dislodged and necessitate leaving foreign material in the patient, and diathermy produces remarkable thermal spread to adjacent tissues.9-11

Harmonic scalpel is an innovative hemostatic device designed as an alternative to conventional techniques, which offers adequate hemostasis with minimal thermal spread.9-11 Its use in laparoscopic12 and open surgical procedures13 has proven to be safe and effective regarding hemostasis, complications, and operative time. Despite its safety and efficacy in thyroid surgery,14-18 several surgeons consider the previously available instruments large and cumbersome, especially in terms of dissection capabilities.13,17,18 A novel technical improvement in the harmonic device for thyroid surgery has been available since 2008. Its use has not been evaluated thoroughly and a comparison between this new (FOCUS) and the previous device (HARMONIC ACE) has not been performed. We hypothesized that FOCUS will decrease operative time as a result of its greater tissue grasping and dissection capability. The objective of this study was to compare the results of total thyroidectomy using FOCUS to that with HARMONIC ACE.

METHODS

Study design and population. All patients who underwent total thyroidectomy for benign or malignant disease in our department by the same...
endocrine surgeon between February 2008 and July 2008 were included in this prospective randomized study. Approval by our Institutional Review Board was obtained prior to study initiation. Written, informed consent was obtained preoperatively in all cases. No funding or financial support was received from the company of the harmonic scalpel devices/instruments. Patients submitted to a hemithyroidectomy and those who underwent additional surgical procedures together with the total thyroidectomy (ie, parathyroidectomy or cervical lymph node dissection) were excluded.

Patients were randomized preoperatively into 2 groups according to the harmonic scalpel device used during the surgical procedure: Group A patients underwent total thyroidectomy with the use of the new device (FOCUS; Ethicon Endosurgery, Cincinnati, OH) and group B underwent total thyroidectomy with the use of the previously available instrument (HARMONIC ACE; Ethicon Endosurgery). Randomization was performed at the time of admission to the hospital ward on the day of surgery using Bernoulli tables. Both devices were used solely for hemostasis during the whole procedure, that is, for ligation of all vessels including the superior thyroid artery and of all tissue bundles. Suture ligations, ties, electrocautery, or clips were not used in any patient in any operative step. Low power setting (level 3) and short activation times (less than 10 s) were used for both instruments in all cases to maximize safety.

Serum calcium and parathormone (PTH) levels were determined at 12 and 24 h postoperatively (normal range, 8.5–10.5 mg/dL and 15–68.3 pg/mL, respectively). Uncomplicated cases were discharged on the first postoperative day. Patients were followed at 1, 2, and 4 weeks and at 3, 6, and 12 months postoperatively with oral calcium supplementation in all patients. No other complication, including transient or permanent laryngeal nerve palsy, permanent hypoparathyroidism, hemorrhage, hematoma, wound infection, skin burn, or mortality occurred. The mean uptake obtained in postoperative follow-up radioiodine scans performed in the 19 thyroid cancer patients is 0.4% (range, 0–0.8%) and the mean postoperative serum thyroglobulin levels measured in these 19 patients are 0.5 ng/mL (range, 0–0.9 ng/mL).

Forty-five patients composed group A (FOCUS) and 45 patients composed group B (HARMONIC ACE). Demographic and clinical data of the 2 patients’ groups and the results of the comparison between these groups are shown in the Table. No statistically significant differences between group A and group B were identified in respect to age, sex, reoperative thyroid surgery, preoperative and postoperative serum calcium and PTH levels, weight and diameter of the thyroid specimen, pathologic diagnosis, postoperative complications, duration of hospital stay, and the final outcome (Table). The papillary and follicular thyroid carcinoma subgroups of patients in group A and group B were also comparable in terms of tumor size and stage (data not shown). In addition, no differences were found between group A and group B regarding mean postoperative radioiodine scan uptake and thyroglobulin (0.3% vs 0.4%, $P > .1$, and 0.4 ng/mL vs 0.5 ng/mL, $P > .1$, respectively). Use of the FOCUS device, however, resulted in a significant decrease in operative time of approximately 17%. In particular, the mean operative time was

RESULTS

During the 6-month period, 90 consecutive patients were submitted to total thyroidectomy and composed the study population (mean age, 52 ± 9 years, females: 77%). Eight patients (9%) had temporary postoperative hypoparathyroidism; 6 of these patients (7% of the total group) presented asymptomatic biochemical hypocalcemia, whereas 2 (2%) patients sustained clinical (symptomatic) hypocalcemia. Hypocalcemia subsided within 2 months postoperatively with oral calcium supplementation in all patients. No other complication, including transient or permanent laryngeal nerve palsy, permanent hypoparathyroidism, hemorrhage, hematoma, wound infection, skin burn, or mortality occurred. The mean uptake obtained in postoperative follow-up radioiodine scans performed in the 19 thyroid cancer patients is 0.4% (range, 0–0.8%) and the mean postoperative serum thyroglobulin levels measured in these 19 patients are 0.5 ng/mL (range, 0–0.9 ng/mL).

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Innovative advances have occurred recently regarding technology, instrumentation, and energy sources and devices leading to the rapid development of energized dissection and coagulation systems and their application tools that facilitate surgical procedures in terms of hemostasis, tissue dissection, and ligation, as well as reduction of operative time. Such technological advancements are enabling new ways to achieve effective hemostasis and tissue dissection, adding to the surgical options available. Ultrasonically activated shears constitute such a newly developed, novel system that uses high-frequency ultrasonic energy to enable simultaneous vessel and tissue coagulation and cutting at the precise point of impact via vibration at 55.5 kHz while using low temperatures of approximately 100°C. As a result, the harmonic scalpel offers adequate hemostasis with minimal thermal spread and, thus, minimal adjacent tissue destruction. This technology has been used in cardiac, thoracic, urologic, gynecologic, and general surgical procedures with satisfactory results regarding safety and efficacy. Moreover, it has been made available to thyroid surgery recently and has been shown to be safe and effective.

The first harmonic scalpel device made available for thyroid surgery was the Ultracision CS-14C, and the first report of its results was published in 1998. The U.S. Food and Drug Administration (FDA) has approved Ultracision CS-14C for ligation of vessels up to 3 mm in diameter. The need for a smaller and more user-friendly hand piece was, to some extent, satisfied by the development of a newer instrument (HARMONIC ACE) that was available until recently. The HARMONIC ACE, as well as the more recent FOCUS device, has been approved by the FDA for ligation of vessels up to 5 mm in diameter. Another improvement of the device was that whereas Ultracision CS-14C was activated by a foot pedal, the HARMONIC ACE and FOCUS instruments alternatively offered hand activation, providing ergonomic function and enhanced comfort and control. Several studies have shown that thyroid surgery with the use of Ultracision CS-14C as well as HARMONIC ACE is safe, effective, and time saving compared with the traditional technique of suture ligation. Despite these results and the ergonomic improvement of the HARMONIC ACE hand piece, several surgeons consider both Ultracision CS-14C and HARMONIC ACE to be large and cumbersome for use in the neck, especially in terms of tissue dissection or fine-grasping capabilities. This deterrent has led to an innovative technical improvement of the device for thyroid surgery made available in 2008. The FOCUS device is a small (9 cm), lightweight, clip-like instrument with a curved tip. These properties may make this hand piece useful for tissue delicate grasping and dissection, and facilitate additional decreases in operative time. Use of the FOCUS device, however, has not been evaluated thoroughly, whereas to the best of our knowledge, a comparison between FOCUS and HARMONIC ACE has not been performed.

The aim of the current study was to compare total thyroidectomy performed with the new harmonic scalpel hand piece to that performed with the previously available device with respect to operative time, hemostasis, and perioperative complications. The results of our study are promising. Both instruments were reliable, safe, and efficient. In addition, both devices were used solely for hemostasis in all steps during the operation in all cases; thus, no foreign bodies (ie, ligations or clips) were left behind. Moreover, the FOCUS device was particularly hand friendly and useful for dissection in several intraoperative steps. It might be a bit bulky for the dissection in the area of the recurrent laryngeal nerve and ligament of

### Table. Comparison between group A (FOCUS) and group B (HARMONIC ACE) patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (n = 45)</th>
<th>Group B (n = 45)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>51 ± 8</td>
<td>52 ± 7</td>
<td>NS</td>
</tr>
<tr>
<td>Pathologic diagnosis†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multinodular goiter</td>
<td>30 (67%)</td>
<td>32 (71%)</td>
<td>NS</td>
</tr>
<tr>
<td>Hashimoto thyroiditis</td>
<td>3 (7%)</td>
<td>2 (4%)</td>
<td></td>
</tr>
<tr>
<td>Graves disease</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td></td>
</tr>
<tr>
<td>Papillary carcinoma</td>
<td>8 (18%)</td>
<td>6 (13%)</td>
<td></td>
</tr>
<tr>
<td>Follicular carcinoma</td>
<td>2 (4%)</td>
<td>3 (7%)</td>
<td></td>
</tr>
<tr>
<td>Operative time (min)*</td>
<td>65 ± 7</td>
<td>76 ± 8</td>
<td>.009</td>
</tr>
<tr>
<td>Transient hypocalcemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(total)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>4 (9%)</td>
<td>4 (9%)</td>
<td>NS</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Hospital stay (days)‡</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>NS</td>
</tr>
</tbody>
</table>

*Data are presented as mean ± SD.
†Data are expressed as the number of patients and percentage (parentheses).
NS, not significant.

No statistically significant differences were noted regarding sex, reoperation, preoperative and postoperative serum calcium and PTH, thyroid gland weight and diameter, other complications (transient or permanent laryngeal nerve injury, permanent hypoparathyroidism, hemorrhage, hematoma, wound infection, and skin burn), and mortality (P > .1).

### DISCUSSION

Innovative advances have occurred recently regarding technology, instrumentation, and energy sources and devices leading to the rapid development of energized dissection and coagulation systems and their application tools that facilitate surgical procedures in terms of hemostasis, tissue dissection, and ligation, as well as reduction of operative time. Such technological advancements are enabling new ways to achieve effective hemostasis and tissue dissection, adding to the surgical options available. Ultrasonically activated shears constitute such a newly developed, novel system that uses high-frequency ultrasonic energy to enable simultaneous vessel and tissue coagulation and cutting at the precise point of impact via vibration at 55.5 kHz while using low temperatures of approximately 100°C. As a result, the harmonic scalpel offers adequate hemostasis with minimal thermal spread and, thus, minimal adjacent tissue destruction. This technology has been used in cardiac, thoracic, urologic, gynecologic, and general surgical procedures with satisfactory results regarding safety and efficacy. Moreover, it has been made available to thyroid surgery recently and has been shown to be safe and effective.
Berry in some cases, in which a clip should be used instead. In contrast, the HARMONIC ACE hand piece was found relatively cumbersome.

No significant differences were identified between the 2 groups compared in demographics, clinical data or morbidity, but the FOCUS device in total thyroidectomy decreased the operative time by approximately 17% (mean difference, 13 min) compared with that performed with HARMONIC ACE. Because the 2 groups of patients in this prospective randomized study were similar with respect to all other analyzed parameters, this decrease in operative time was most likely attributed to the greater capability for fine-tissue grasping and dissection offered by the FOCUS, confirming our initial hypothesis.

An important issue regarding the use of these modalities is the extent of lateral thermal spread and associated tissue injury. Several experimental studies proved that thermal damage is limited to 0–2 mm beyond the tissue grasped within the forceps of the device.9,31,32 The decreased propensity for collateral thermal damage is an important advantage of the harmonic scalpel, particularly when compared with monopolar and bipolar diathermy,9-11 because it allows safe vascular ligation with minimal risk for damage to the parathyroid glands, the recurrent laryngeal nerve, and the external branch of the superior laryngeal nerve. Although the temperature of the harmonic scalpel is approximately 100°C with short activation times (less than 10 s), the tip of the device must be checked carefully because it can reach greater temperatures (>100°C) with prolonged activation (10–20 s) that may result in injury to adjacent structures.33,34 As heat production is directly proportional to the power setting and the activation time, high-power use (power levels 4 and 5) and long activation are hazardous.34 Thus, a safety margin of 3–5 mm is required between the active curved blade and these structures. The device should be placed in such a manner so that the inactive blade is closer to the surrounding structures, and the shears should always be used on a low power setting (level 3) and with short activation times (less than 10 s) to maximize safety and avoid collateral damage.33,34 With these precautions, the harmonic scalpel can be used safely in thyroid surgery with no increase in complication rate.14,18,24,30,33,34 The safety of using either the HARMONIC ACE or the FOCUS device in thyroid surgery, using these precautions, was also shown in our study. Meticulous dissection is crucial to establish this safety margin of at least 3–5 mm between the tip of the device and the laryngeal nerves or the parathyroid glands; if this distance cannot be achieved, then one should not use the harmonic scalpel but should employ other hemostatic methods, such as suture ligations, ties, or clips to ensure a total thyroidectomy and avoid thermal damage to these structures. Such a safety margin was achieved with meticulous dissection in all patients in this study.

The use of the harmonic scalpel in thyroid surgery is more expensive than the conventional technique. This increase in overall cost is its major disadvantage; however, the potential added cost to the procedure should be compared with the substantial benefit in operative time savings and the elimination of clips and sutures use for hemostasis. The decrease in operative time and the increased comfort for the surgeons should also be taken into consideration. In our previous study, it was found that in the same time that 4 total thyroidectomies were performed using the clamp-and-tie technique, 5 thyroidectomies were conducted with the Ultracision CS-14C harmonic scalpel.14 Moreover, the decrease in operative time with the use of the FOCUS instrument along with the enhanced comfort provided by its design and improved tissue grasping and dissection capability should be emphasized. These benefits obtained with FOCUS might make this device cost effective for thyroid surgery. This potential cost effectiveness is likely more important for total thyroidectomy, compared with lobectomy, as time savings are greater in the first scenario.

In conclusion, both harmonic scalpel devices were found to be reliable, safe and effective in this study. They simplified total thyroidectomy, eliminating the need for clamp-and-tie maneuvers while achieving efficient hemostasis. Furthermore, the new hand piece was even more easy to use, hand-friendly, and offered substantially improved tissue delicate grasping and dissection capabilities. Our results show that utilization of this device in total thyroidectomy significantly reduced operative time compared to the previously available instrument. The new harmonic scalpel device can therefore be a very useful adjunct to the thyroid surgeon’s armamentarium. Further studies are needed, however, to evaluate the results of its utilization in thyroid surgery.

REFERENCES


