

## The use of the Ligasure™ Vessel Sealing System in head and neck surgery: a report on six years of experience and a review of the literature

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**Abstract.** *The use of the Ligasure™ Vessel Sealing System in head and neck surgery: a report on six years of experience and a review of the literature.* **Background:** The Ligasure Vessel Sealing System (LVSS) is a bipolar electro-surgical device with integrated active feedback control, sealing vessels up to 7 mm in diameter. It facilitates surgery by achieving the efficient haemostasis of blood vessels encountered during dissection, and allowing the rapid and secure division of vascularised tissues, while minimising thermal injury to adjacent tissues.

**Objective:** To report on our experience and review studies relating to the use of LVSS in Otolaryngology-Head and Neck Surgery.

**Type of review:** Retrospective series.

**Search strategy and evaluation method:** LVSS has been widely used in our department since 2002. All patient records relating to the use of LVSS were reviewed, and compared to surgical procedures done by our team without the use of LVSS, with special regard to operation time and post-operative complications. Furthermore, a Medline search and thorough review was conducted for all pertinent articles on LVSS in Otolaryngology-Head and Neck Surgery, and those articles were reviewed.

**Results:** In our department, LVSS is used for thyroidectomy, laryngectomy, neck dissection, parotidectomy, tonsillectomy procedures, congenital cysts, thyroglossal cysts, and excisions of submandibular gland and parapharyngeal space tumours. LVSS provided sufficient haemostasis, operating time was shorter, and post-operative complications did not differ compared to similar surgical procedures performed without the LVSS. The Medline search revealed 16 studies published by other colleagues regarding the use of LVSS in Otolaryngology Head and Neck Surgery procedures (15 studies in thyroid and 1 study in parotid surgery). The results published were similar to ours.

**Conclusions:** The use of LVSS in Otolaryngology-Head and Neck Surgery may have several advantages over standard methods. It is a reliable and safe device, providing sufficient haemostasis and reducing operating time.

### Introduction

The Ligasure™ Vessel Sealing System (LVSS) (Valleylab, Boulder, Colorado, USA) is a bipolar electro-surgical device with integrated active feedback control, sealing vessels up to 7 mm in diameter by denaturing collagen and elastin within the vessel wall and surrounding connective tissue. The LVSS facilitates surgery by achieving efficient haemostasis of blood vessels encountered during dissection, as well as by allowing the rapid and secure division of vascularised tissues. It consists of an electro-surgical generator, a

hand piece with a ratcheted scissor mechanism, and a footswitch. While the tissue is grasped by the hand piece, the response generator senses the density of the tissue bundle, automatically adjusting the optimal amount of energy to be delivered. The LVSS has been approved by the US Food and Drug Association for sealing vessels up to 7 mm in diameter and these seals can withstand a minimum of three times normal systolic pressure.<sup>1-4</sup> Experimental studies have demonstrated that the sealing power of the LVSS matches conventional ligatures and haemoclips, and is higher than

ultrasonic coagulation sears and bipolar coagulators.<sup>1-3</sup> Furthermore, many clinical studies have confirmed the sealing reliability of the LVSS. The LVSS delivers a precise amount of energy in accordance with the density of the grasped tissue, limiting thermal spread and injury to adjacent tissues. Experimental histological studies of vessels sealed with the LVSS demonstrated 1.5-3.3 mm thermal spread beyond the tissue within the forceps jaws.<sup>1-4</sup> Experimental and clinical studies have confirmed the role of LVSS as a safe and time-saving device providing sufficient haemostasis

in numerous surgical operations, including abdominal, urological, and gynaecological procedures.<sup>4-5</sup>

The LVSS has been widely used in Otolaryngology-Head and Neck Surgery procedures in our department since 2002. We report on our experience in our specialty. Moreover, we review the relevant studies published on the use of the device in Otolaryngology-Head and Neck Surgery. Emphasis is placed on the duration of the procedure, as well as on relevant post-operative complications.

### Patients and method

A retrospective study was conducted in an academic tertiary referral medical centre (Department of Otolaryngology, University of Crete School of Medicine, Heraklion, Crete, Greece), looking at patients who underwent surgery involving the use of LVSS from August 2002 to August 2008. All patient records relating to the use of the LVSS was used were reviewed and compared to similar surgical procedures performed by our team

without the use of LVSS, with particular emphasis on operating time and post-operative complications. Furthermore, a Medline search (December 2008) was conducted for all pertinent articles on LVSS in Otolaryngology-Head and Neck surgery in the English literature. The keyword "Ligasure" was used and the papers relevant to Otolaryngology-Head and Neck surgery procedures were selected from those available. All studies were thoroughly reviewed and compared to our results.

### Results

#### i. Thyroid Surgery

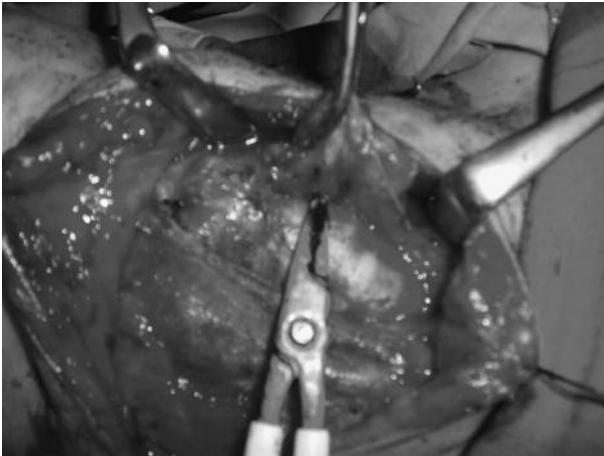
Since 2002, 174 patients (mean age 47.2 years), 35 males and 139 females (ratio 1/3.97), underwent total thyroidectomy in our department with the use of LVSS. The historical control group consisted of 559 subjects (mean age 48.4 years), 107 males and 453 females (ratio 1/4.22) who underwent total thyroidectomy without the use of LVSS after 1990 in our department (Table 1).

Recurrent laryngeal nerves and at least two parathyroid glands were identified in all individuals. In the LVSS group, the 'Precise' hand piece was used since it has thinner tips than the standard Ligasure instrument. Ligation of thyroid isthmus, middle thyroid vein, and superior and inferior poles was performed with LVSS in all cases, while the 'Precise' hand piece was used in many intra-operative steps for tissue dissection, including the dissection of parathyroid glands and recurrent laryngeal nerves in most cases (Figure 1). The mean operating time in the LVSS group was 52 minutes. There was a 33.8% reduction in operating time with the use of LVSS compared to our historical control group of patients without the LVSS. In the LVSS group post-operative complications included transient hypocalcaemia in 8 patients (4.59%), and transient unilateral paresis in 3 patients which resolved completely within 5 months. There was no bilateral vocal cord paresis or paralysis, no post-operative wound haematoma or wound infection. Post-operative

Table 1

Demographics of the Ligasure Vessel Sealing System (LVSS) group and historical group of patients undergoing total thyroidectomy, superficial parotidectomy and total laryngectomy with unilateral radical neck dissection

Procedure	Group	Patients (n)	Sex	Male/Female Ratio	Mean Age (years)
Total thyroidectomy	LVSS	174	35 male 139 female	1/3.97	47.2
	Historical control	559	107 male 452 female	1/4.22	48.4
Superficial parotidectomy	LVSS	56	14 male 42 female	1/3	53
	Historical control	129	30 male 99 female	1/3.6	56.4
Total laryngectomy with unilateral radical neck dissection	LVSS	26	26 male	–	54
	Historical control	132	132 male	–	59.7



*Figure 1*

Dissection of the left thyroid lobe from the anterior tracheal wall.



*Figure 2*

Coagulation of tissue bundle above the facial nerve in a superficial parotidectomy procedure.

complications did not statistically differ from our historical control group.

#### ii. Parotid surgery

In the period after 2002, 56 superficial parotidectomies were performed in our department using the LVSS (Figure 2). The LVSS group (mean age 53 years) consisted of 14 males and 42 females (ratio 1/3). The historical control group consisted of 129 subjects (mean age 56.4 years), 30 males and 99 females (ratio 1/3.6), who underwent superficial parotidectomy without the use of LVSS in our department (Table 1). In the LVSS group, the mean operating time (cut-closure time) was 86 min. Compared to our historical control group, there was a 40.27% reduction in operating time with the use of LVSS. Post-operative complications in the control group were as follows: seroma was observed in 3 patients, Frey syndrome in 4 patients, and transient facial nerve weakness in 16 patients, while post-operative bleeding and salivary fistulas were not observed. In the LVSS group,

there was no post-operative bleeding, seroma, or salivary fistula, and there were two cases of transient facial weakness, and one case of Frey syndrome.

#### iii. Total laryngectomy – Neck dissection

Overall, 33 total laryngectomies, 30 radical, 8 modified, and 7 elective neck dissections were performed in our department with the use of the LVSS (Figure 3). In 26 patients (mean age 54 years), all male, total laryngectomy was performed simultaneously with unilateral radical neck dissection. This group of patients was compared to our historical control group of 132 total laryngectomies with unilateral radical neck dissection performed without the use of LVSS. All subjects were male and the mean age was 59.7 years (Table 1). The mean operating time (cut-closure time) was 153 min in the LVSS group, and 196 in the control group (20.93%

reduction). A mean intra-operative estimated blood loss of 445 ml was measured in the LVSS group, while in our controls a mean of 1173 ml was observed. There was a 62.06% reduction in intra-operative blood loss in the LVSS group, indicating the excellent haemostatic properties of the device. No complications regarding haemostasis or other major complications were noted in the LVSS group, while in the historical control group chylous fistulas were observed in 6 (4.51%) patients, as well as skin flap necrosis in 3 (2.25%) patients, wound haematoma in 3 (2.25%) patients, and severe wound infection in 2 (1.50%) patients. It should be noted that, due to the policy of our department, we do not perform myotomy or place voice prostheses during the laryngectomy procedure, while drains are removed within 72 hours and oral feeding is initiated within 8–12 days post-operatively.



*Figure 3*

Ligation of tissue bundle in a radical neck dissection procedure

#### iv. Tonsillectomy

Ligasure tonsillectomy was performed in 538 patients (239 adults and 299 children) in our department (Figure 4). In all patients, the tonsillectomy was performed with the 'Precise' instrument, which was used both as a haemostatic device and dissection tool. The mean operating time was 7.5 minutes in children and 12 minutes in adults, and there was no measurable intra-operative bleeding during surgery in any cases. No early post-operative haemorrhage was observed, while late post-operative haemorrhage was observed in 8 adult patients. Control of bleeding under general anaesthesia was not required. No other post-operative complication was observed, with the exception of limited peritonsillar oedema in 95 patients (41 adults and 54 children), which resolved in all patients within 24 hours with no additional medication.



*Figure 4*

Dissection of the superior tonsillar pole



*Figure 5*

Dissection of thyroglossal duct cyst

#### v. Other Otolaryngology-Head and Neck procedures

In our department, LVSS has been also used in some congenital and thyroglossal duct cyst excisions (Figure 5), as well as in some excisions of submandibular gland and parapharyngeal space tumors. In these cases, it also provided sufficient haemostasis and reduced operating times without intra-

operative or post-operative complications.

#### Discussion

Similar results were found for 72 consecutive patients undergoing thyroid surgery in a previous prospective study in our department, with the use of LVSS device as the primary means of ligation,

where the LVSS also proved to be a safe device in thyroid surgery, resulting in sufficient haemostasis and a 28.4% reduction in operating time.<sup>6</sup> It should be noted that there is always a learning curve for each new surgical technique. As a result, this study found a further reduction of operating time associated with more experience with the device.

Our Medline search identified 15 studies published by other colleagues relating to LVSS use in thyroid surgery.<sup>7-21</sup> All the studies looked at operating time. Eleven studies reported significant reductions in operating time<sup>7-17</sup> with the use of LVSS compared to conventional thyroidectomy techniques, while four studies observed no significant difference.<sup>18-21</sup> All the studies also looked at post-operative complications. In all studies, post-operative complication rates were not higher with the LVSS than with conventional techniques.<sup>7-21</sup> Furthermore, three studies reported significantly lower transient post-operative hypocalcaemia in the ligasure group,<sup>8,10,20</sup> while Petrakis *et al.*,<sup>14</sup> in a prospective study (270 LVSS and 247 conventional total thyroidectomies), reported a significantly lower incidence of laryngeal nerve palsy, haematoma and transient hypocalcaemia in the LVSS group. Other parameters assessed by other colleagues were intra-operative blood loss, post-operative drainage, hospital stay and post-operative pain. In all the studies we looked at, intra-operative blood loss was not higher with LVSS than with conventional techniques,<sup>9,11,14,17-20</sup> while three studies<sup>9,11,17</sup> reported significantly lower blood loss. Three studies assessed post-operative drainage volume, and two of them observed

lower volumes in the LVSS group.<sup>11,14</sup> The third study found no significant difference between the LVSS and conventional thyroidectomy groups.<sup>19</sup> Six studies looked at length of hospital stay.<sup>7,9,12,13,14,16,19</sup> Three of them observed shorter hospital admissions in patients undergoing thyroidectomy with the use of LVSS,<sup>7,14,19</sup> while the other four studies observed no significant difference between the LVSS and conventional thyroidectomy groups.<sup>9,12,13,16</sup> One study looked at post-operative pain, finding less post-operative pain in the LVSS group than in patients undergoing conventional techniques.<sup>17</sup>

In a previous prospective study in our department, looking at 12 consecutive patients undergoing superficial parotidectomy performed using the LVSS device as the primary means of ligation, the LVSS proved effective in providing ligation and haemostasis, and there was a 35.8% reduction in operating time. It should be mentioned that, in all procedures, the 'Ligasure Precise' instrument was used as the primary means of ligation for all steps of the operating procedure, and in many intra-operative steps for tissue dissection, including facial nerve dissection. Furthermore, it proved to be a safe device for parotid gland surgery, since no post-operative bleeding, seroma, salivary fistula, or Frey syndrome were observed. There was one case of transient facial weakness, which resolved completely within 6 months.<sup>22</sup>

Colella *et al.*<sup>23</sup> published similar results in a prospective randomised study of the use of ligasure in superficial parotidectomy procedures. In their study, 17 patients underwent superficial lobe parotidectomy using the

ligasure, and 18 patients were operated with the conventional method. No statistically significant differences were noted between the 2 groups in adverse events during or after surgery, length of hospital stay, and time to return to work, while operating time was significantly shorter in the Ligasure group. We believe that LVSS is a safe device for parotid surgery, providing a bloodless surgical field, and reducing operating time, while the rate of adverse events during or after surgery is similar to the rate for conventional methods. We believe that this method is comparable to the conventional one.

The results from the group of patients undergoing total laryngectomy with or without neck dissection confirm the preliminary results of a previous study in our department,<sup>24</sup> while no studies published by other colleagues regarding this issue were found in English literature. We believe that the LVSS has a role to play in laryngectomy and neck dissection procedures, since the use of the device provides sufficient haemostasis and reduces both intra-operative blood loss and operating time, while the rate of post-operative complications seems to be comparable to conventional methods. We believe that further studies by other colleagues will confirm our results.

Ligasure tonsillectomy was assessed in earlier studies conducted in our department. No other studies on this issue have yet been published.<sup>25-28</sup> An earlier prospective randomised study in our department compared Ligasure tonsillectomy with cold knife tonsillectomy. Ligasure tonsillectomy proved to be

significantly superior in terms of intra-operative bleeding, operating time, and post-operative pain, while no significant difference was found in post-operative complications.<sup>25</sup> Another prospective randomised study in our department compared Ligasure tonsillectomy to thermal welding tonsillectomy and Ligasure tonsillectomy again proved to be a safe technique, providing sufficient haemostasis and minimising intra-operative bleeding, operating time, post-operative pain and post-operative complications.<sup>27</sup> We believe that LVSS tonsillectomy is a safe technique, providing sufficient haemostasis. Consequently it could benefit patients, especially those who cannot tolerate blood loss (e.g., children, patients with anaemia or factor VIII deficiency, and patients receiving anticoagulant therapy). Furthermore, it is associated with a reduction of post-operative pain.

### Conclusions

We believe that the LVSS is not another technical variation on a number of cutting coagulating instruments already used in head and neck surgery. Ligasure, in our practice, proved to be a reliable and effective device, providing sufficient haemostasis and reducing operating times. Furthermore, it is a safe device, since the rate of complications was the same as for other procedures performed with conventional techniques. Similar results have been published by other colleagues, particularly in thyroid<sup>7-21</sup> and parotid gland<sup>23</sup> surgery.

A number of hand pieces are available for the LVSS. The most suitable for Head and Neck surgery is the 'Precise' instrument.

Using the Precise instrument minimises thermal injury to the adjacent tissues and so it can be safely used close to (no more than 2-3 mm) sensitive anatomical structures such as the facial or laryngeal nerves, and it may be associated with less post-operative pain. Another issue of interest is the cost of the device. The 'Precise' instrument is a single-use instrument which costs approximately €300 in Greece. This cost could be offset by the overall reduction in operating time, which could raise the number of patients undergoing surgery.

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