

Clinical evaluation of CoolSeal - a new, safe, and fast vessel sealing device in total thyroidectomy

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Objective. CoolSeal is a new vessel sealing system for dissection and hemostasis during surgery. No clinical studies have investigated safety, advantages or disadvantages regarding the use of this device. The aim of the present study was to investigate the safety of CoolSeal and compare it with conventional ligation technique or LigaSure during the total thyroidectomy. We hypothesized that the use of CoolSeal would reduce the operating time and bleeding without complications increase. Study design represents a retrospective cohort study with a tertiary reference center setting.

Methods. We analyzed total thyroidectomy data from January 2021 to June 2023. We recorded patients' characteristics, surgical information, and postoperative outcome.

Results. We performed 221 total thyroidectomies in the study period. Analysis was restricted to 171 patients operated by only two surgeons. Hemostasis was secured by conventional ligation in 117 patients (68%), LigaSure in 34 patients (20%) and CoolSeal in 20 patients (12%). Median thyroid weight and bleeding were 67 g and 50 ml, respectively. Procedures using LigaSure or CoolSeal were on larger glands (median 205 g) without increased bleeding (50 ml). Operating time was shortest with CoolSeal (96 min, $p=0.003$) compared with LigaSure (117 min) or conventional ligation (115 min). Bleeding was reduced with CoolSeal compared with LigaSure (45 vs. 100 ml, $p=0.003$). With CoolSeal, median hospitalization was one postoperative day, no patients required re-operation. There was no palsy of recurrent laryngeal nerves and no permanent hypoparathyroidism.

Conclusion. In our first clinical experience, CoolSeal was safe and efficient for total thyroidectomy. With a small sample size, we saw a clinical benefit with reduced operating time without post-operative complications increase.

Keywords: total thyroidectomy, vessel sealing system, CoolSeal, ligation technique, LigaSure

Vessel sealing devices are used with increased frequency in various surgical procedures. In contrast to development of new medical treatments, regulations for development of new surgical instruments are not equally strict (Bakkar et al. 2020). However, as surgeons, we rely on the claimed safety of these new devices. During total thyroidectomy (TT), many vessels of various size need to be dissected safely to complete removal of the thyroid gland. Traditionally, surgeons have used suture ligation and small clips to

seal vessels on the neck (Ferlito et al. 2006). However, with new vessel sealing devices, these standard techniques are being increasingly replaced with new instruments.

In all vessel sealing devices, some degree of heat development occurs around the instrument during use. In the neck during TT, this heat may increase the risk of damage to the recurrent laryngeal nerve, the parathyroid glands or other delicate structures around the thyroid gland (Garas et al. 2013; Dionigi

et al. 2016; Bakkar et al. 2020). Accordingly, any evaluation of a thyroid vessel sealing device should include not only operation time and bleeding, but also risk of damage to the recurrent laryngeal nerves and parathyroid glands. Hence, our aim in the current study was to evaluate the new CoolSeal device during TT and to compare with conventional suture tie technique and use of LigaSure small jaw (Medtronic).

Material and Methods

Cohort. This is a retrospective cohort study from Aarhus University Hospital, Department of Otorhinolaryngology, Denmark. We identified all patients who underwent TT (procedure code KBAA60) between January 2021 and July 2023. Patients were only included if the thyroidectomy was performed by one of two specific high-volume surgeons (>100 parathyroid procedures per year and >100 thyroid procedures per year), to reduce variation in operative technique and complication rates (Figure 1). We excluded patients if the TT was a large intrathoracic operation, included radical excision of lateral or central lymph nodes, use of intraoperative frozen section, patients under the age of 18, or operations where an extra surgeon was called intraoperatively. We anticipated that use of these exclusion criteria

would secure a more homogenous group of TT patients without any obvious increase in operation time or risk of complications.

Groups and time periods. The procedures were classified according to the etiology (Goiter/Graves/Cancer) based on the indication to undergo surgery and choice of device (conventional/LigaSure/CoolSeal). CoolSeal was only available in the last 9 months in the study period. Accordingly, we used LigaSure in all operations with a clinical need for a sealing device in the first 21 months. Allocation to CoolSeal or LigaSure in the last 9 months was based on surgeon's preference. Normally a sealing device would only be selected when operating on a large size thyroid gland.

Definitions. We recorded perioperative bleeding in milliliters based on estimates by the operative nurses and/or weight of the surgical napkins. The operation time of surgery in minutes was from the skin incision to end of wound closure. Further, hypocalcemia was defined as plasma levels of ionized calcium (Ca^{2+}) <1.18 mmol/L (lower reference limit). Our definition of hypoparathyroidism (hypoPT) was a postoperative condition with hypocalcemia in combination with low or normal plasma levels of parathyroid hormone (PTH) and a clinical need of treatment with activated vitamin D (alfacalcidol, calcitriol or similar) (Bollerslev et al. 2022). HypoPT

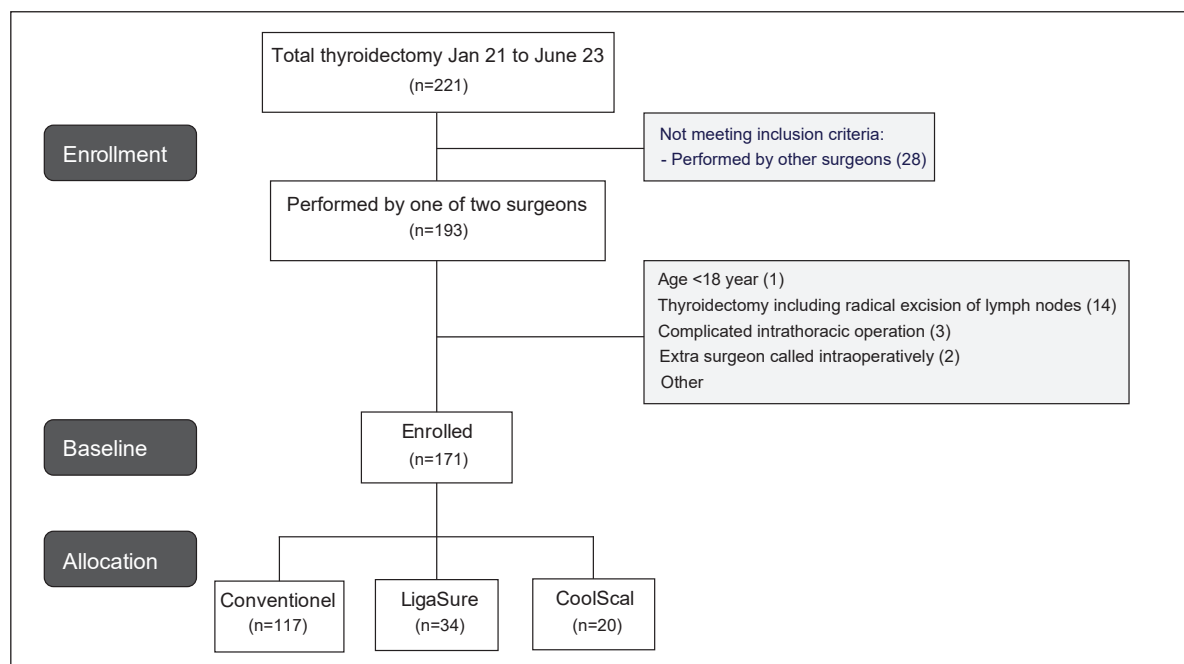


Figure 1. Patient enrollment and clinical allocation in the study period.

was either defined as transient when Ca^{2+} normalized within the first 6 months without medical treatment or permanent when treatment was needed beyond 6 months to normalize Ca^{2+} . Similarly, any palsy of the recurrent laryngeal nerves (RLN) was recorded with laryngoscopy at postoperative day one (POD1) and divided in transient or permanent depending on status after 6 months.

Sealing devices. The CoolSeal is a low energy (50 W), bipolar electrosurgical device, sealing vessels up to 6 mm in diameter. It measures resistance in connective tissues and automatically stops energy delivery when seal is complete with a reduced energy spread profile (<1 mm). Temperature reaches a maximum of 72°C, quickly reduced to 45°C, minimizing the thermal footprint.

The LigaSure vessel sealing device is a bipolar electrosurgical device, sealing vessels up to 7 mm in diameter, by denaturing collagen and elastin within vessel wall and surrounding connective tissue. It has a reduced energy spread profile (<2 mm) compared with unipolar cautery and potential decreased risk of injury to adjacent structures (Youssef *et al.* 2008; Konturek *et al.* 2020). Conventional suture tie technique secures hemostasis by ligation of vessels. Used as a standard technique in head and neck dissection described back to the 19th century (Ferlito *et al.* 2006). Currently, we supply with bipolar electrocautery of small vessels.

Approvals and ethical considerations. All patients had a clinical indication to undergo TT. Further, all patients were treated according to local and national guidelines. The use of different sealing devices was not specified for each patient before the operation. The selection of a sealing device was made on the day by the operating surgeon and based primarily on the size of the thyroid gland. Patients were included in a prospective study on TT and intraoperative fluorescence. Accordingly, all patients had both verbal and signed informed consent to be included in this TT project. The project was approved by the Central Denmark Regional Ethics Committee with case nr.: 1-10-72-28-21.

Statistics. Normally distributed data are presented as mean $\pm$ standard deviation and non-normally distributed data as median with interquartile range. Binary data are presented as n (%). Statistical differences between groups were analyzed using student's t-test or Wilcoxon Ranksum test, as appropriate and binary data were analyzed using Chi-squared test. All data will be analyzed using StataCorp 2023. A p value <0.05 is considered statistically significant.

Results

General results. A total of 221 patients underwent TT during the study period. Twenty-eight of them did not meet inclusion criteria and another 22 were excluded. Analysis was restricted to patients operated by only two surgeons (n=171) and secondarily allocated by vessel sealing method. Hemostasis was secured by conventional ligation in 117 patients (68%), LigaSure in 34 patients (20%) and CoolSeal in 20 patients (12%) (Figure 1). For included patients (n=171), indications for surgery were either cancer (n=29), goiter (n=62) or Graves (n=80) (Table 1). Median weight of resected thyroid gland was 67 g (range 8–703 g) and median perioperative bleeding was 50 ml (range 10–1000 ml) (Table 2).

CoolSeal vs. LigaSure. In patients operated without a sealing device, the median weight of resected thyroid gland was 53 g. These patients differed from patients operated with a sealing device. In the LigaSure and CoolSeal groups, median thyroid weight was 238 g (IQR 131; 360 g) and 140 g (IQR 68; 295 g), respectively (Table 3). The bleeding was reduced with CoolSeal compared with LigaSure (45 vs. 100 ml, p=0.003) and about the same as in conventional group (45 vs. 30 ml, p=0.990). The mean

Table 1
Baseline characteristics of all patients

Study population	
Patients [n (%)]	171 (100)
Age (years)	
Median (Range)	54 (18–83)
Female sex [n (%)]	135 (79)
Body mass index (kg/m ²)	
Mean (95% CI)	28 (27; 29)
Indication [n (%)]	
Cancer	29 (17)
Goiter	62 (36)
Graves	80 (47)
Anticoagulant treatment [n (%)]	24 (14)
PTH POD1 (pmol/L)	
Median	2.9
Interquartile range	1.8–4.4
Range	<0.5–13.7
Ca ²⁺ POD1 (mmol/L)	
Mean (95% CI)	1.21 (1.20; 1.22)

Abbreviations: PTH – parathyroid hormone; POD1 – post operative day 1.

duration of surgery was 113 min (range 60–240 min). The operating time was shortest with CoolSeal (96 min) compared with LigaSure (117 min, $p=0.003$) or conventional ligation (115 min, $p=0.002$). The median postoperative hospitalization was 1 day. In the CoolSeal group there were no hospitalizations longer than 2 days and in the LigaSure group none above 4 days.

Complications. We encountered a few complications in patients operated with a sealing device. One patient in the LigaSure group was re-operated during the first 24 h because of hematoma. Recurrent laryngeal nerve palsy was not seen in either the CoolSeal or LigaSure group. Three patients had permanent hypoPT after TT with LigaSure and in both groups a transient affection of calcium and PTH was common. These complications were not different between groups (Table 3).

Discussion

With the first clinical use of CoolSeal in TT, we have in a small series described reduced operation time

and a general safe use of this new device. Although we only operated a few patients with CoolSeal, it is reassuring that neither bleeding, hypoPT or nerve palsy seems to be a major concern when selecting CoolSeal.

The surgical time during TT is affected by many different circumstances. Both surgeons experience and technique, the size and weight of the gland, height and weight of the patient, and amount of assistance and surgical devices. To avoid comparison of unequal groups and different surgeons, we only included patients operated by one of two high volume thyroid surgeons (>100 parathyroid and >100 thyroid procedures per year). Further, with exclusion of cases with a need for other simultaneous procedures, we have a more homogenous group of patients. In these patients, we found a significantly reduced operation time around 20 min. Similarly, other studies have found reduced operative time when using energy-based devices (Pacilli et al. 2020). For different size of glands, it is not surprising that the operative time also changes. In our study, the median thyroid weight in the conventional group was 53 g vs. 238 g and 140 g in the LigaSure and CoolSeal group, respectively. Although the difference is not significant between the two groups with energy-based devices ($p=0.07$), there are clinical differences in median gland weight of about 100 g. Whether this difference in weight is the main reason for reduced operative time is unsure. From a surgical point, it is described that dissection is easier with CoolSeal due to improved jaws with thinner and smaller grip and with faster sealing. We did not find any previous publications with comparison between these devices.

With introduction of new operative devices for thyroid gland surgery, risk of bleeding, nerve damage, and hypoPT (Akgun et al. 2022) are relevant. Some studies have suggested that electrosurgical devices increase the risk of nerve damage because of the thermal footprint on surrounding tissue (Garas et al. 2013; Fundakowski et al. 2018). We did not have any nerve damage in the CoolSeal group and no bleeding with re-operation or permanent hypoPT. Accordingly, it is difficult in this series to describe clear differences. However, as we did not have any of these complications, it seems that there is no increase in complication risks. We will have to conduct larger studies to evaluate if risk of surgical complications is affected in comparison with other sealing procedures.

There is a wide selection of electrosurgical devices on the market (Harmonic Focus by Ethicon, Johnson and Johnson, Thunderbeat Open Fine Jaw by Olympus, and LigaSure by Medtronic). These

Table 2
Overall results from 171 operations

Operative Outcome (n=171)	
Thyroid weight (g)	
Median (Range)	67 (8–703)
Intraoperative bleeding (ml)	
Median (Range)	50 (10–1000)
Duration of surgery (min)	
Mean (Range)	113 (59–222)
Postoperative hypoparathyroidism [n (%)]	
Short (<6 months)	51 (30)
Permanent (>6 months)	10 (6)
Paresis recurrent laryngeal nerve [n (%)] (342 nerves at risk)	
Unilateral short (<6 months)	2 (0.6)
Unilateral permanent (> 6 months)	1 (0.3)
Postoperative bleeding with re-operation [n (%)]	10 (6)
Postoperative hospitalization (days)	
Median (Range)	1 (1–7)
Vessel sealing [n (%)]	
Conventional	117 (68)
LigaSure	34 (20)
CoolSeal	20 (12)

Table 3
Vessel sealing results

Parameter	CoolSeal	LigaSure	p-value
Number of procedures	20	34	
Thyroid weight (g)			
Median (IQR)	140 (68; 295)	238 (131; 360)	0.070
Duration of surgery (min)			
Mean (95% CI)	96 (87; 105)	117 (108; 127)	0.003
Perioperative bleeding (ml)			
Median (IQR)	45 (20; 75)	100 (50; 150)	0.003
Postoperative hypoparathyroidism (n)			0.170
Short	8	9	
Permanent	0	3	
Postoperative bleeding with re-operation (n)	0	1	NS
Recurrent laryngeal nerve paresis (n) ^a	0	0	NS
Hospitalization (days)			
1/2/3/4	13/7/0/0	18/13/2/1	0.350

^aNerves at risk was 108. Abbreviations: NS – non-significant.

devices are commonly used for TT around the world (Materazzi et al. 2017; Bakkar et al. 2020; Konturek et al. 2020). In Denmark, the use of LigaSure is common because of its reduced thermal spread, why we chose to compare LigaSure with CoolSeal. Multiple studies have compared energy-based devices with conventional ligation technique and different devices with each other (Calo et al. 2012; Hwang et al. 2014; Hammad et al. 2016; Canu et al. 2020, 2022; Pacilli et al. 2020). None of these publications have included CoolSeal. Overall, as a result of only few advantages/disadvantages between devices, the choice of device relies primarily on surgeon's preferences (Bakkar et al. 2020).

Limitations. This study has some limitations and the results reported must be interpreted while considering the known weaknesses of a retrospective cohort study. Size of thyroid gland and indication of surgery might have an impact on choice of equipment,

duration of surgery, bleeding, and other endpoints. With our inclusion and exclusion criteria, we have tried to reduce bias as described earlier. With at least 6 months of follow-up, we have tried to include both transient and permanent complications. However, with more numerous sample size, we will also be able to describe some of the rare complications in future studies.

Conclusion. Initial clinical evaluation of CoolSeal for the total thyroidectomy have been positive. In clinical evaluation, the device was safe and efficient in dissecting and sealing during thyroidectomy. The clinical benefit was a reduced operative time without any obvious increase in complication risks. Larger studies are needed to elucidate the risk of rare complications.

Conflict of interest: The authors declare no conflict of interest.

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