

Thermofusion for total thyroidectomy with BiClamp

1. Overview

Introduction/Importance

With more than 100,000 annual cases, thyroid procedures are among the most frequently performed surgical interventions in Germany. These interventions are carried out in highly visible areas (i.e. at the front of the throat); for cosmetic reasons they are therefore performed through the smallest possible opening. Preferred approaches include endoscopic techniques, minimally invasive video-assisted techniques (MIVAT) and minimal incision techniques (Kocher transverse collar incision).

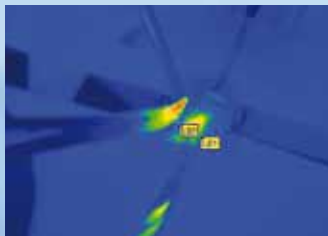
Areas of application

Prior to resection the points of access and the organs are exposed; vessels and tissue structures are thermofused with an ergonomic instrument, the BiClamp 150 C. The geometry of the BiClamp's jaws offers good visibility, even when the points of access are narrow. Clips or sutures are generally not required.

Function

Two aspects are important for safe thermofusion: compression and electro-surgical fusion of structures. The VIO 300 D electro-surgery unit generates the necessary current forms for optimal thermofusion with impedance-regulated, dynamic current (Bi-Clamp current). The AUTO-STOP function stops the fusion process as soon as the tissue has achieved optimal coagulation. The fused area can withstand pressures amounting to three times systolic blood pressure.

The fusion is permanent; within a few days the parchment-like fused area has changed into scar tissue.



► Low temperature levels



► Thyroid surgery with a BiClamp 150 C

The advantages at a glance

- ✦ As the BiClamp 150 C can be reused up to 30 times, the instrument costs are calculated proportionately based on the number of operative procedures (see cost-benefit analysis)
- ✦ The BiClamp procedure has been FDA approved for sale in the United States for the thermofusion of vessels with diameters of up to 7 mm
- ✦ The instrument's geometry was especially designed for thyroid surgery and ensures good visibility, even during minimally invasive procedures
- ✦ Using the BiClamp 150 C it is possible to largely dispense with exogenous materials such as clips and sutures
- ✦ The temperatures created by the BiClamp 150 C are not high, thereby limiting the risk of lateral thermal damage to tissue (e.g. to vocal cord nerves)

2. Innovation

Technical description of the innovation

The vessel or tissue bundle requiring sealing is grasped by the reusable instrument BiClamp 150 C and compressed. A defined current is applied to the tissue via the two jaws of the instrument so that the collagenous and elastinous tissue components fuse together. The following studies have proved that thermofused areas can withstand burst pressures amounting to three times the blood pressure of a healthy person.

Richter, Sven, Kollmar, Otto, Neunhoeffler, Eva, Schilling, Martin K., Menger, Michael D., Pistorius, Georg: Differential Response of Arteries and Veins to Bipolar Vessel Sealing. Evaluation of a Novel Reusable Device. In: Journal of Laparoendoscopic & Advanced Surgical Techniques, Vol. 16, No. 2. (April 2006), pp. 149-155.

Richter, Sven, Kollmar, Otto, Schilling, Martin K., Pistorius, Georg: Efficacy and quality of vessel sealing. Comparison of a reusable with a disposable device and effects of clamp surface geometry and structure. In: Surgical Endoscopy, Vol. 20, No. 6. (June 2006), pp. 890-894.

Novelty content

In the past, the safe and rapid treatment and closure of vessels and tissue bundles with ligatures, particularly in difficult to access operative areas, was one of the biggest surgical challenges.

Today, using the new thermofusion technique, vessels and tissue bundles can be sealed safely under good visibility. Various systems are available on the market; the major difference between systems is that some are single-use and others are reusable.

An article published in the World Journal of Surgery in 2008 by Oussoultzoglou et al. demonstrates that the ERBE BiClamp 150 C significantly reduces operating times compared to operations with a single-use instrument. An additional saving of operating time results from the fact that it is possible to almost completely dispense with clips and ligatures.

Oussoultzoglou, Elie, Panaro, Fabrizio, Rosso, Edoardo, Zeca, Ion, Bachellier, Philippe, Pessaux, Patrick, Jaeck, Daniel: Use of BiClamp Decreased the Severity of Hypocalcemia after Total Thyroidectomy Compared with LigaSure. A Prospective Study. In: World Journal of Surgery, Vol. 32, No. 9. (September 2008), pp. 1968-1973.

Qualitative benefits (for patients, physicians, hospitals, cost-bearers)

- ✦ Reduces operating times and thus operating costs
- ✦ Operations are less tiring for physicians
- ✦ Better compliance for patients because less drainage required
- ✦ Reduced material costs for sutures and drainage

3. Cost-benefit analysis

Potential cost savings with the BiClamp are presented below for total thyroidectomy procedures. The BiClamp procedure is compared with standard "suture and clip" procedures and with procedures using single-use vessel sealing instruments. Cost savings result from the lower instrument costs, the reduced consumption of materials and shorter operating times (Oussoultzoglou et al.).

The material costs for the BiClamp are calculated based on a proportion of the acquisition costs (with the instrument being used in 30 procedures) and the costs of sterilization (which amount to 1.20 € per intervention).

The purchase costs for the electrosurgical unit have not been included in the evaluation of either the single-use vessel sealing instrument or of the BiClamp, as such units are standard in most operating rooms. The sterilization costs for the BiClamp, the costs of suture materials, drainage and personnel are based on empirical values from clinics.

Statements regarding the percentage of total thyroidectomies performed out of more than 100,000 annual thyroid procedures vary widely. Based on these figures it was assumed that 35 percent of these procedures are total thyroidectomies. Sutures and clips are used in around half of these procedures (17,500). Single-use vessel sealing instruments are used in approximately 40 percent of total thyroidectomy procedures (14,000). Only 10 percent of procedures are performed using the BiClamp (estimate by ERBE).

This indicates that the BiClamp could provide total potential savings of more than 11 million € per year in total thyroidectomy procedures in Germany. The BiClamp offers additional potential savings in interdisciplinary procedures, for example, general surgery (e.g. lymphadenectomies), gynecology (e.g. vulvectomies) and visceral surgery (e.g. hepatic surgery).

Cost-benefit analysis	BiClamp	Single-use vessel sealing instrument	Sutures and clips
Material costs of instrument (incl. sterilization)	27.87 €	160.00 €	0.00 €
Suture materials	6.34 €	6.34 €	19.02 €
Costs of drainage incl. insertion of drains	7.67 €	7.67 €	14.49 €
Cost of materials per operation	41.88 €	174.01 €	33.51 €

Operating time (minutes)	142 min	170 min	180 min
Cost of operating time	1,269.48 €	1,519.80 €	1,609.20 €

Decreased personnel costs		250.32 €	339.72 €
Decreased cost of materials		132.13 €	-8.37 €
Potential savings per operation		382.45 €	331.35 €

Number of annual operations per procedure		14,000	17,500
Potential annual savings for each type of procedure (rounded)		5,354.000 €	5,799.000 €
Sum of potential annual savings (rounded)		11,153.000 €	

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