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 reliable thermofusion: compression and electrosurgical fusion of structures. The VIO 300 D and VIO 3 electrosurgery units generate the necessary current forms for optimal thermofusion with impedance-regulated current. The AUTO-STOP function stops the fusion process as soon as the tissue has achieved optimal coagulation.

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

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 150 C is suitable 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)
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 BiClamp seals arteries and veins reliably and effectively corresponding to the Ligasure instrument:¹ The bipolar thermofusion of the BiClamp is an effective method of sealing vessels which leads to a significant reduction of postoperative bleeding and reduces surgery time.²


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 reliably 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.


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

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 and visceral surgery (e.g. lymphadenectomy, liver surgery) gynecology (e.g. vaginal, abdominal or laparoscopic hysterectomy) and urology (e.g. cystectomy, partial nephrectomy).
<table>
<thead>
<tr>
<th>Cost-benefit analysis</th>
<th>BiClamp</th>
<th>Single-use vessel sealing instrument</th>
<th>Sutures and clips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material costs of instrument (incl. sterilization)</td>
<td>27.87 €</td>
<td>160.00 €</td>
<td>0.00 €</td>
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<tr>
<td>Suture materials</td>
<td>6.34 €</td>
<td>6.34 €</td>
<td>19.02 €</td>
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<tr>
<td>Costs of drainage incl. insertion of drains</td>
<td>7.67 €</td>
<td>7.67 €</td>
<td>14.49 €</td>
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<tr>
<td>Cost of materials per operation</td>
<td>41.88 €</td>
<td>174.01 €</td>
<td>33.51 €</td>
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| 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 € |      |      |