

**Summary: “Bipolar Vessel Sealing with the marClamp[®]/marCut[®]
Bipolar Instruments and the maXium[®] High-Frequency Generator in
Thyroid Operations, Tumor Operations, Flap Plasties, and Neck Soft
Tissue Interventions in the ENT Field”**

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Materials and Methods:

In this study, 90 patients were operated by different surgeons at the Otorhinolaryngology Clinic of the Tübingen University Hospital between April 4, 2007 and March 17, 2008, using the marClamp[®]/marCut[®] instruments in conjunction with the maXium[®] high-frequency generator. These patients were combined in the so-called "Martin group". A control group consisting of another 90 patients treated with the conventional method (ligation and suture) was set up for the same period.

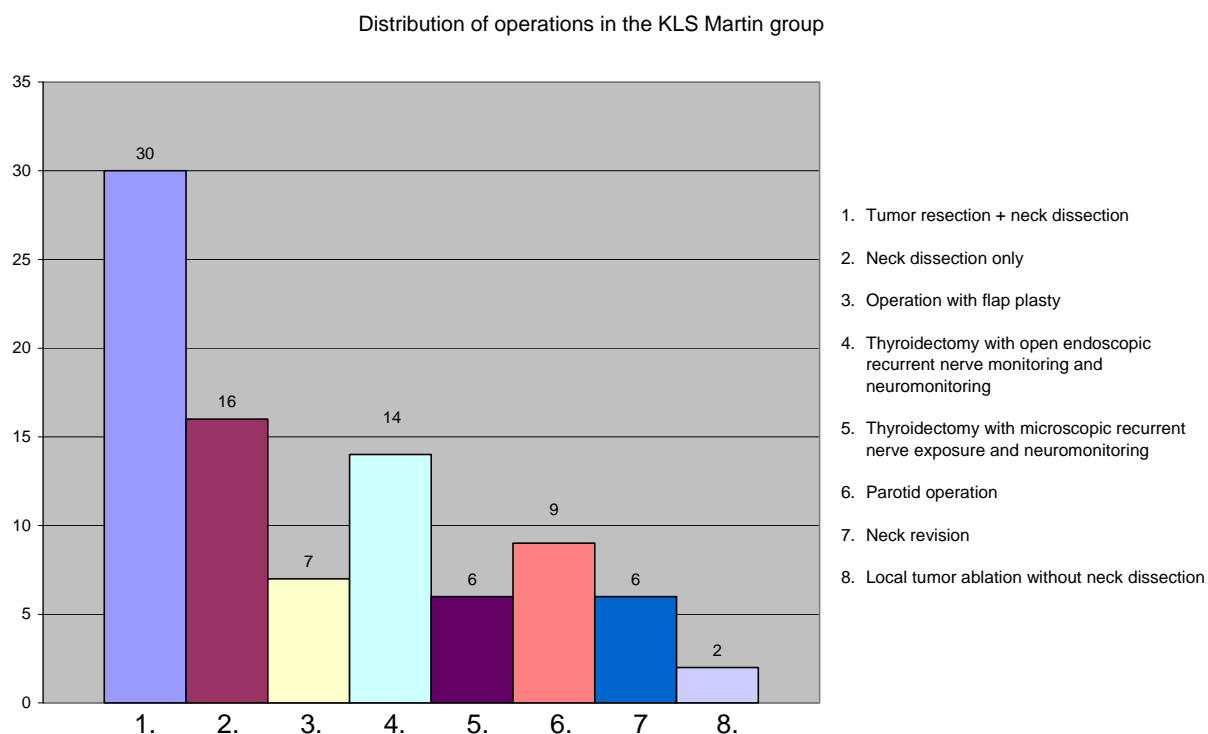
All operations were carried out under intubation anesthesia.

The surgeons of the Martin group recorded their application observations on a report document.

The following interventions were carried out with marClamp[®]/marCut[®]/maXium[®]:

- unilateral, bilateral, subtotal, nearly total or total thyroidectomies with microscopic or open endoscopic recurrent nerve exposure and neuromonitoring
- unilateral and bilateral neck dissections of I-V levels
- parotidectomies, parotid revisions
- removal of cervical fistulas, cervical fistula extirpations, neck revisions
- laryngectomies, hemilaryngectomies
- partial pharyngeal resections
- oropharyngeal carcinoma resections with enoral, lateral or combined approach
- tracheostoma operations and revisions
- oral cavity carcinoma resections
- submandibulectomies
- tonsillectomies
- wedge excisions in lower lip carcinoma cases
- carcinectomies in the main nasal cavity
- soft palate resections, soft tissue palate plasties
- flap plasties with pedicled pectoralis major flap, pedicled trapezius flap or thigh split-thickness skin graft
- combinations of the above-mentioned operations.

The operations were grouped as follows:



Objective parameters

The defined primary objective parameter for the study was the achievement of complete intraoperative vessel sealings.

Secondary objective parameters were a minimization of unwelcome results, especially secondary hemorrhages, a minimization of operating times, and a potential reduction in operating costs.

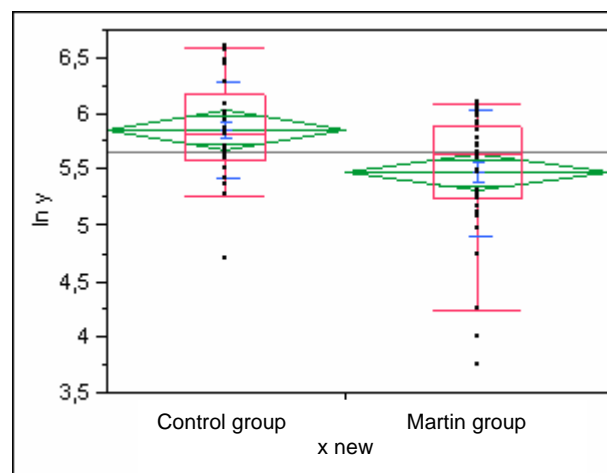
Results

The marClamp[®]/marCut[®]/maXium[®] system for bipolar vessel sealing represents a safe method for vessel occlusion in the fields of thyroid surgery, tumor operation and flap plasty, as well as across the entire range of neck soft tissue interventions performed in otorhinolaryngology. The primary objective parameter – “complete vessel occlusion” – was achieved consistently, compared with the ligature/suture standard procedure.

Secondary hemorrhages were assessed by using the Fisher Exact Test. The p-value determined (bilaterally) was $p = 1.00$ here. Consequently, it can be stated with statistical significance that the secondary hemorrhage rate for patients operated with

the marClamp[®]/marCut[®]/maXium[®] system is no higher than that of patients treated in the conventional way (by ligation/suture).

The t-test was carried out to compare operating times. In the “combined group” comprising tumor+neck dissection / flap plasties (including 11 thyroidectomies with neck dissection), i.e. the group with the especially time-consuming interventions necessitating a ligation of larger tissue bundles, the operations performed with marClamp[®]/marCut[®]/maXium[®] (Martin group) took place at a highly significant faster rate ($p < 0.005$) than was the case with the conventional technique using ligation and/or suture (control group). The p-value was 0.0028 here. The tumor resections with neck dissection and the flap plasty operations of the Martin group together had an incision-suture time of 271.51 minutes on average. In the control group, operating times amounted to 405.94 minutes on average. Consequently, the average operating time was 134.43 minutes (or 33.12%) lower in the Martin group than in the control group.



Statistical evaluation: t-test

In the thyroidectomies group there was also a significant evidence of operating time reduction due to the use of the marClamp[®]/marCut[®]/maXium[®] system. Even though the more time-consuming open endoscopic recurrent nerve identification using small incisions was performed in 70% of all operations in the Martin group (only 6% in the control group), the operating times of the Martin group turned out to be similar to those of the control group. According to the surgeons' opinions, time savings in the

range of 15–20% can also be expected for thyroidectomies when using bipolar vessel sealing, given that the same surgical technique is employed in both groups.

The scope of the study also included an assessment of the performance of the marClamp® and marCut® instruments. For marClamp®, the parameters vessel sealing, tissue adhesion, surface, form, ergonomics and handling were taken into account. For marCut®, the performance factors assessed by the surgeons included coagulation, tissue adhesion, ergonomics, handling and cutting.

The marClamp®/marCut®/maXium® bipolar coagulation system scored consistently good results in all of the above assessment categories.

Conclusion

1. Bipolar vessel sealing with the bipolar instruments marClamp®/marCut® and the high-frequency generator maXium® is a safe and efficient “OR system” for use in the surgically sensitive head/neck region.
2. The time savings achieved in the surgical interventions by using the bipolar vessel sealing technique in ENT surgery are of primary importance for the patients, due to a higher therapeutic quality.
3. The shorter operating time reduces the risk of infection significantly.
4. The anesthesia risk is lowered as a result of the shorter incision-suture times.
5. The significantly shortened operating times represent a substantial economic advantage (additional ligature and suture savings).