

*mar*Clamp®



Seal
Safe

180

max. Watt

PROSPECTIVELY RANDOMIZED STUDY COMPARING
LIGASURE AND MARCLAMP® IN HYSTERECTOMIES

STUDY OF JENA UNIVERSITY HOSPITAL / GERMANY

Prospectively randomized study comparing LigaSure and marClamp® in hysterectomies

Objective:

This first pilot study aimed at assessing the KLS Martin marClamp®/maxium® bipolar, reusable vessel sealing system on the basis of 30 female patients due to receive a vaginal or abdominal hysterectomy. To this end, a quantitative and qualitative comparison between conventional ligatures (10 patients), the Valleylab LigaSure system (10 patients) and KLS Martin's marClamp® system (10 patients) was to be carried out.

Answers sought:

In specific, the following issues were examined:

Is the marClamp®/maxium® system basically suitable for vaginal and abdominal hysterectomy?

- Does it allow to perform bipolar sealing of vessels and tissue bundles without any specific tissue dissection or preparation?
- Is sealing safety guaranteed with the system (quality, uniformity, comparability with conventional methods)?
- How about safety with regard to secondary hemorrhages?
- Are conventional ligatures usually unnecessary with the system?
- Is the pressure applied with the marClamp® instrument an essential parameter for successful sealing?
- Do arteries and veins respond differently to the sealing action?
- How about the histopathologic examination? How does the system compare with Valleylab in this respect?
- How about the thermal damage done to the sealed tissue?
- How does the reusable instrument compare to the disposable instrument in terms of intraoperative application?
- How about tissue adhesion to the instrument?
- How about the quality of the instrument's jaw surfaces?
- What vessel sizes are to be expected in gynecology?
Is it possible to seal even the largest vessels encountered in hysterectomy procedures safely and reliably?

The parameters to be assessed included carbonization, the degree of transparency of the sealed zone (description of its consistency due to collagen transformation), the thermal spread of the sealed zone (demarcation), etc.

Key study topics:

- Assessment of the suitability of the system for use in gynecology (vaginal and abdominal hysterectomy).
- First direct comparison between the LigaSure/Valleylab system and KLS Martin's maxium®/marClamp® system, based on a defined number of female patients.
- Histologic data for the above-mentioned first comparison, plus assessment of the data.

Basic situation:

In conventional hysterectomy procedures, clamps are used in the process of removing the uterus, followed by ligation of the vessel-tissue bundle with surgical suture materials. Electrosurgical procedures offer advantages in terms of shorter operating times, reduced blood loss and lower postoperative morbidity, but are so far considered disadvantageous with regard to the histopathologic assessment of the resection margins and in terms of cost relative to the standard ligature technique. The study was designed to compare two of the currently available electrosurgical techniques – LigaSure and marClamp® – in order to determine the differences between the two methods.

Materials and methods:

10 patients awaiting hysterectomy were prospectively randomized to each of the three groups (operation with LigaSure vs. marClamp® vs. conventional ligature). The evaluation data for the three study groups was gathered from the patient files (operating times, day of discharge, postoperative consumption of painkillers, intra- and postoperative complications), the operation report sheet (specific questions to be answered by the surgeon) and the histologic report. The results obtained were entered into an Excel spreadsheet and subsequently analyzed.

Results:

Between March 2006 and July 2006, 10 female patients were randomly assigned in each case to marClamp®, LigaSure and the conventional ligature technique and were subsequently operated according to the respective method. 21 patients were hysterectomized due to benign findings (uterine myoma, prolapse, hypermenorrhea and adenomyosis). The remaining nine patients had malignant tumors (ovarian carcinoma, cervical carcinoma, ovarian borderline tumor, endometrial carcinoma, vulvar carcinoma).

With each of the two systems, vessel sealing was carried out twice side by side in order to achieve a broad sealing zone. The macroscopically visible extent of the thermal demarcation within the sealing zone was quite similar for both vessel sealing techniques, amounting to 1–2 mm. The resection margins were comparably easy to assess for the pathologist for all three procedures. The histologic sections showed local circulatory disorders in the tissue in the sense of hemorrhages caused in blood vessels and surrounding tissues. However, this had no adverse effect on the assessability of the section margins of the histologic specimens. Operating times were noncomparable due to the different diagnoses and surgical interventions, and the same applies to painkiller consumption, drain application times and draining volumes.

Evaluation/discussion of results:

The marClamp®/maxium® system was found to be suitable for vaginal as well as abdominal hysterectomy, both for benign and malignant findings. Bipolar sealing of vessels and tissue bundles could be performed without any special tissue dissection or preparation and as safely as with the disposable competition product or the suture technique. Moreover, safe sealing was usually possible with marClamp® with regard to all the vessel calibers encountered in the hysterectomies performed. In this first study based on a small number of cases, the sealing performance of the marClamp® system was found to be reliable and comparable with LigaSure. Due to the heterogeneity of the hysterectomy indications involved, the intra- and postoperative complication risks, the postoperative draining volumes and postoperative pain were comparable only within the same group (benign/malignant indications). Regarding intraoperative application, the comparability of the study groups – and thus the three techniques – was good.

The risk of postoperative hemorrhages is very low for the marClamp® system, just as it is for Liga-Sure and conventional sutures. This hemorrhage rate was in line with historical data, well within the range of the surgical standard. Conventional vessel ligation was usually unnecessary with the system. From the histologic point of view, arteries and veins responded in the same way to the sealing action. All three techniques produced local hemorrhages in vessels and their surrounding tissue due to blood backpressure caused by clamping off the blood flow. The histopathologic assessability of the specimens was equally good for all three techniques.

In the case of both electrosurgical techniques, the thermal demarcation of the sealed tissue extends 1–2 mm macroscopically into the tissue surrounding the sealing zone. This should be taken into account intraoperatively in order to protect surrounding structures, keeping the thermal impact to a minimum. However, this has no adverse influence on the histologic assessability of the resection margins. A distinct advantage of the electrosurgical procedures might be seen in the prevention of suture granulomas.

The reusable vessel sealing instrument of the marClamp® system has a clear price advantage over the disposable product, while no disadvantages could be observed in the present study as regards handling, safety or pathological assessability. Tissue adhesions and instrument incrustations were rare for both electrosurgical techniques, provided the jaw surfaces were adequately cleaned between applications. However, the LigaSure instrument showed a stronger tendency for sealed tissue sticking to the working ends. While this can have an adverse effect on operating times, this parameter was not the subject of the study.

By way of summary, it can be said that the marClamp® system is comparable to the LigaSure system in terms of intraoperative handling, safety/ reliability and assessability of the resection margins by the pathologist. No statements were made with regard to operating times, postoperative pain and hospitalization times, due to the heterogeneity of the cases included in the study (see above).



Fig. 1: Vessel and tissue bundles during the sealing process using marClamp® during vaginal hysterectomy.



Fig. 2: Sealing zone after completion of the marClamp® sealing process and dissection during vaginal hysterectomy.

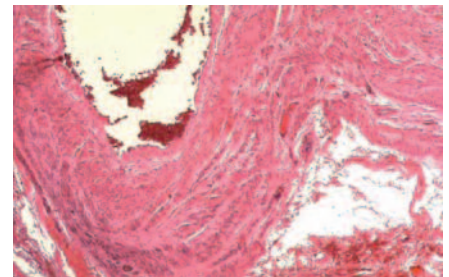


Fig. 3: Histologic image of the resection margin. A vessel wall can be recognized. The margin is easy to assess histologically.

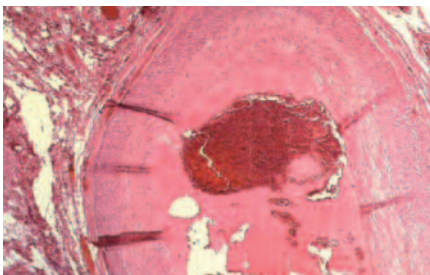


Fig. 4: Histologic image of the resection margin with vessel cut surface. Numerous erythrocyte clusters point to a local circulatory disorder in the sense of a hyperemia. The margin as such can be well assessed according to the usual histopathologic criteria (e.g. in-sano resection).

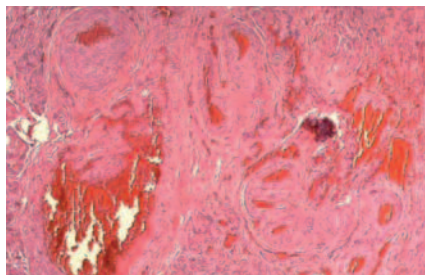


Fig. 5: Histologic image of the resection margin with numerous vessel cut surfaces. Inside the vessels again erythrocyte clusters indicating a local circulatory disorder in the sense of a hyperemia. The margin can be well assessed in this case again.

KLS Martin Group

Karl Leibinger GmbH & Co. KG

78570 Mühlheim
Germany
Tel. +49 74 63 838-0
info@klsmartin.com

Stuckenbrock Medizintechnik GmbH

78532 Tuttlingen
Germany
Tel. +49 74 61 16 11 14
verwaltung@stuckenbrock.de

KLS Martin GmbH & Co. KG

79224 Umkirch
Germany
Tel. +49 76 65 98 02-0
info@klsmartin.com

Rudolf Buck GmbH

78570 Mühlheim
Germany
Tel. +49 74 63 99 516-30
info@klsmartin.com

KLS Martin France SARL

68000 Colmar
France
Tel. +33 3 89 21 66 01
france@klsmartin.com

Martin Italia S.r.l.

20059 Vimercate (MB)
Italy
Tel. +39 039 605 67 31
italia@klsmartin.com

Martin Nederland/Marned B.V.

1270 AG Huizen
The Netherlands
Tel. +31 35 523 45 38
nederland@klsmartin.com

Nippon Martin K.K.

Osaka 541-0046
Japan
Tel. +81 6 62 28 90 75
nippon@klsmartin.com

Gebrüder Martin GmbH & Co. KG

Representative Office
121471 Moscow
Russia
Tel. +7 (499) 792-76-19
russia@klsmartin.com

KLS Martin L.P.

Jacksonville, FL 32246
USA
Office phone +1 904 641 77 46
usa@klsmartin.com

Orthosurgical Implants Inc.

Miami, FL 33186
USA
Office phone +1 877 969 45 45
sales@orthosurgical.com

Gebrüder Martin GmbH & Co. KG

A company of the KLS Martin Group
KLS Martin Platz 1 · D-78532 Tuttlingen
Postfach 60 · D-78501 Tuttlingen
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com