Evaluation of clinical studies of laser catheter ablation in patients by using the ***RytmoLas***®

1988-2003 Clinical Study in the Laser and Applied Technologies Centre Harlaching, ***Prof. St. Jockenhövel***
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1994 Ludwig-Boltzmann-Institute, Wilhelminen Hospital, Vienna. ***A Kaltenbrunner, W Steinbach***
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2004 EP Laboratory German Heart Center Munich. ***C Schmitt, B Zrenner***
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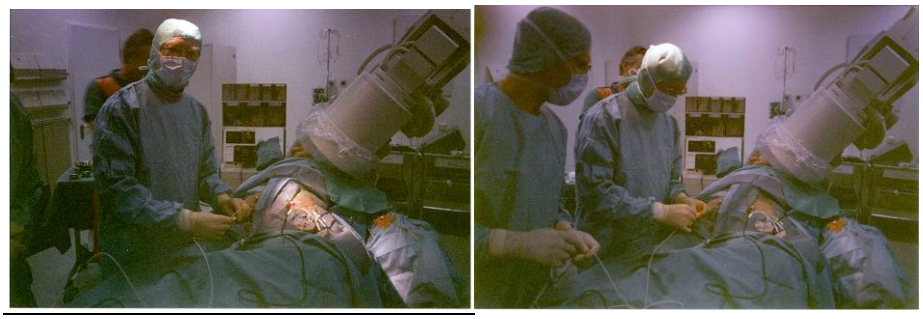

Laser treatment **during the clinical study** conducted by H. Weber in the EP laboratory, Cardiac Department, and Laser and the Applied Technologies Centre Hospital Harlaching, Teaching Hospital of the LM University of Munich

Kurzzusammenfassung des Standes der Technik, Aachen, den 15.04 2019

Exzerpt: Das Standardtherapieverfahren Radiofrequenzablation hat sich in den letzten Jahren u.a. durch kraftsensitive sowie temperaturkontrollierte Kathetersysteme weiterentwickelt. Auch neue Strategien wie die „high-power short-duration“ , ballonbasierte Ablationstechnologien, nichtthermische irreversible Elektroporationsverfahren und gepulste elektrische Felder wurden klinisch erprobt.
Nach den vorliegenden tierexperimentellen und klinischen Daten zum ***RytmoLas®*** und mit Blick auf den aktuellen Stand der Technik, konnte keines der beschriebenen Verfahren vergleichbar gute Ergebnisse erzielen. ***Der RytmoLas®*** scheint zumindest dem Stand der Technik ebenbürtig, wenn nicht **in verschiedenen technischen und klinischen Aspekten überlegen.**

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2 Evaluation of the clinical study by the expert of the Notified Body

Excerpt: Based on the results of the animal experimental studies and the clinical data presented, and considering the actual state of the art, the ***RytmoLas®*** laser therapy is still at least an up-to-date, and, in some **technical and clinical *aspects**** superior.

*- it is a **high-density** mapping/pace mapping guided, **low** power **short** duration (10-15W/4-30s) ablation procedure, performed under normothermic conditions (the catheter **is not heated up**).
- Produces **clear-cut** homogenous transmural lesions of coagulation necrosis, **limited** to the targeted arrhythmogenic substrate, the sensitive myocardium,
- under **monitoring** for immediate success: the abatement and eventually abolishment of potential amplitudes, without tissue vaporization with crater formation,
- healing in **dense fibrous scars** without shrinking or aneurysm formation; lesions are **not thrombogenic**, and are **not arrhythmogenic**,
- can be achieved **without pressure**, even at a distance of 1-3mm from the irradiated field, regardless of catheter **orientation to** and the **anatomy of** the irradiated field.
- can be used also for selective sympathetic laser modulation and varicose ablation. **“all-in-one”**

Summary: In the above-mentioned EP laboratories a total of 843 laser catheter applications were performed in 103 patients with various mechanisms of arrhythmias without complications, with a long-term ≥5 years success rate of ≥90% by using the open-irrigated ELMA catheter ***RytmoLas***®.