Research Article ISSN 2998-4513

International Journal of Cardiology and Cardiovascular Disorder

Minimally Invasive Laser Catheter Treatment of Cardiovascular Disorders

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Submitted : 30 Sept 2025 ; **Published** : 20 Oct 2025

Citation: Weber, H. et al., (2025). Minimally Invasive Laser Catheter Treatment of Cardiovascular Disorders. *I J cardio & card diso; 6*(4):1-14. DOI : https://doi.org/10.47485/2998-4513.1050

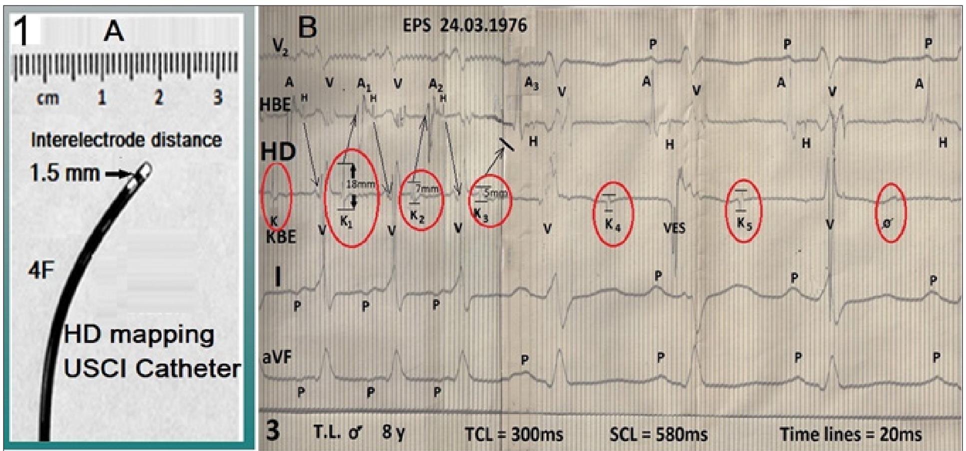
Abstract

*Based on key technology, the 1064nm laser, the **CardioVascLas®** System was tested for minimally invasive treatment of cardiovascular disorders including cardiac tachyarrhythmia, systemic and pulmonary hypertension, hypertrophic obstructive (HOCM) and parasitic (Chagas) cardiomyopathies and for side selective interatrial septal puncture Experimental and clinical tests. By evaluating over 1000 in-vitro and in-vivo experimental and clinical laser applications open-irrigated, non-contact laser applications under normothermic conditions showed unique and superior ablation effects and safety aspects. Research and study design, results achieved, unique aspects such as myocardial tissue selective laser wavelengths, high-density lasermapping are described. Significant outcome and further scope to continue research are indicated. It is concluded that laser ablation with the **CardioVascLas-System®** is a promising alternative for the treatment of cardiovascular disorders.*

Keywords: Catheter ablation, 1064nm laser, cardiac tachyarrhythmias, retrocardiac ganglion plexi, perivascular renal and pulmonary innervation, HOCM, Chagas, systemic and pulmonary resistant hypertension, side selective transseptal laser puncture.

Introduction

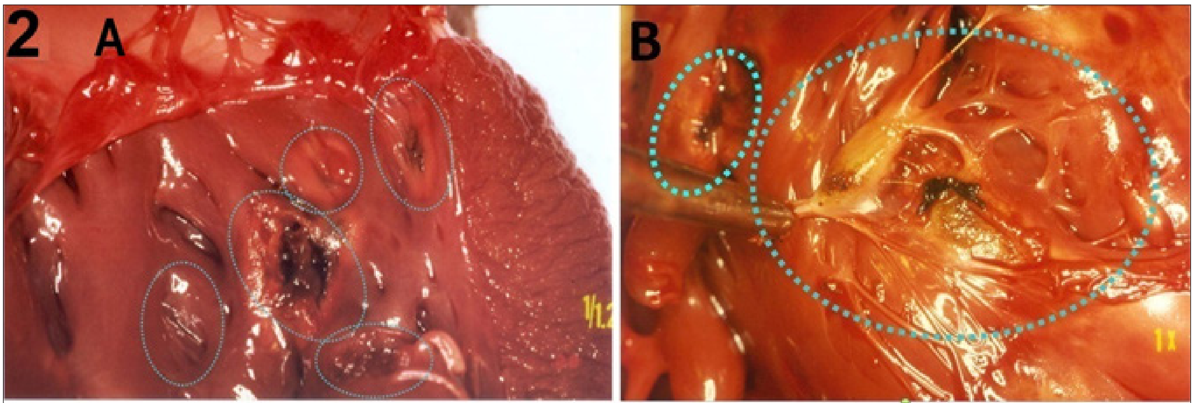
By using 4-6F USCI catheters with narrow interelectrode distances of ≤2.0mm catheter exploration of the heart chambers in pediatric patients during supraventricular tachycardia (SVT) electrical potentials suggesting specific accessory pathway (AP) potentials were recorded. AP potentials were recorded only during SVT and were localized to a very limited segment of the atrioventricular (AV) valve ring. During orthodromic SVT the AP potentials followed ventricular and proceeded atrial depolarizations in fixed intervals. Moreover, with gradual spontaneous dwindling or sudden disappearance of AP potentials in the High-Density (HD) electrogram the ORT ended simultaneously (Fig 1).



A Mapping Catheter B Spontaneous dwindling of AP potential K1-K3 Simultaneous SVT stop
HD KBE=High Density AP (K) and HBE=His-bundle electrograms, V2, I, aVF= Surface lead ECGs
A= atrial, V= ventricular potentials, H= His potential, VES= ventricular Extrasystole, P= p-waves

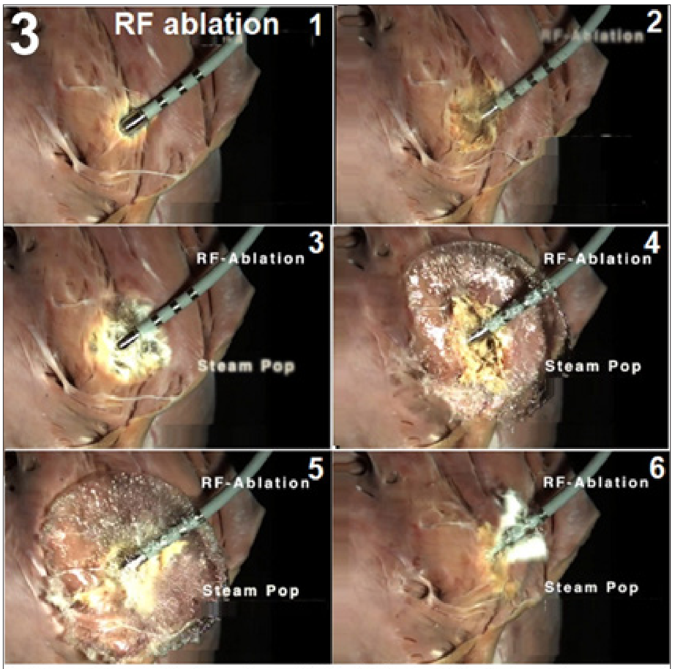
In 1979 inadvertent DC shock induced permanent intra-hisian block during a right electrophysiological study was reported (Vedel et al., 1979). Based on our experience with HD-cathetermapping we have tested the effects of DC-shock in a dog model and concluded that DC-shock of up to 300J/s are applicable without damaging anatomical structures of the heart (Weber et al., 1986). In August 1982 we cured a patient from its SVT with syncopal attacks by HD-mapping guided DC shock ablation of an antero-septal accessory pathway with bidirectional conduction properties (Weber & Schmitz, 1983).

After reports about severe lifethreatening barotrauma reported in the literature (Borggrefe et.al 1989) we have abandoned DC-shock ablation and focused our experimental tests on Radiofrequency (RF) ablation. However, in-vivo animal experiments in a dog model showed tissue vaporization with crater formation, mural thrombi and carbonization and lesions sizes were not reproducible (Fig. 2).



A Multipe endocardial RF lesions produced with the same Catheter technique and Level of energy
B Rupture of chordae, Detachement of endocardial layer, and mural Thrombus after RF ablation in dotted circles and ovals

In addition, severe pop with endomyocardial rupture and deep crater formation were reported (Fig. 3).

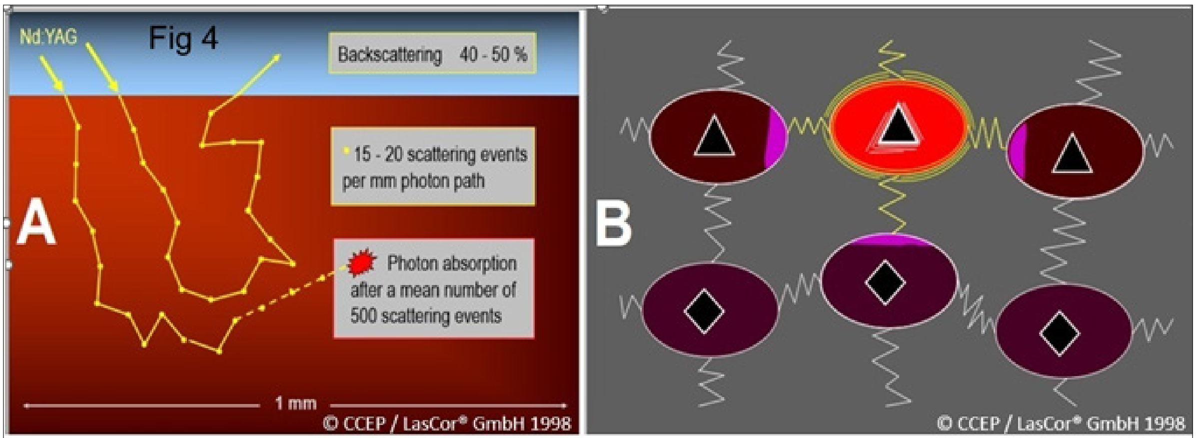


Video sequences during endocardial RF ablation resulting in Pop with rupture

The laser is a key technology with a high impact on medicine. With its low absorption in water and HbO_2 (Boulnois 1986) photons of the 1064nm laser are not absorbed by transparent or translucent tissue such as the endo- and epicardium. In myocardium 1064nm photons are mainly scattered and selectively absorbed by myocytes. Based on the tissue selective property of the 1064nm wavelengths we have started to develop the **CardioVascLas System**®.

Photon Scattering

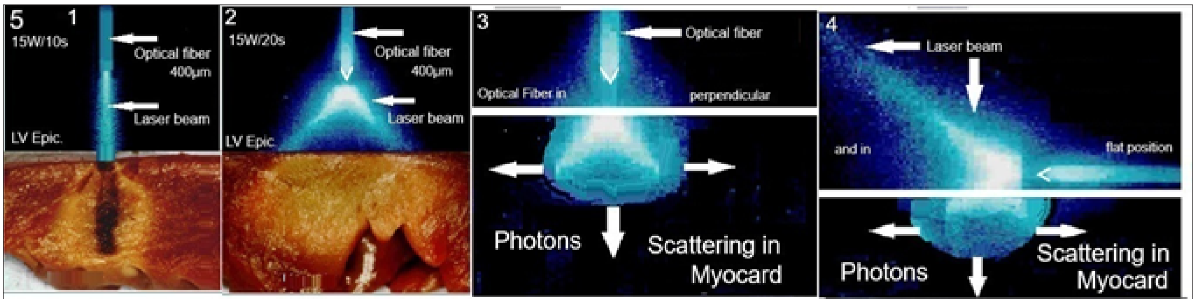
After frequent photon scattering in myocardium, photons are absorbed selectively by the corresponding molecules of myocytes transforming energy into molecular oscillation inducing heat by friction between molecules (Fig 4).



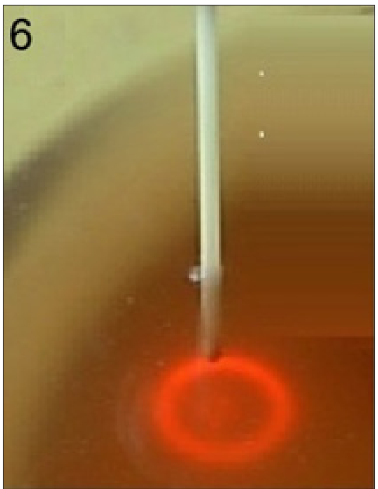
A Intense scattering of the 1064nm laser Photons in Myocardium and selective absoption of Photons of appropriate wavelength by the coresponding molecules of the myocites
B transforming energy into molecular oscillation inducing heat by friction between molecules

However, the catheter itself is not heated up - it does not transmit heat. It is rather cooled by saline irrigation at room temperature. Lesions are produced under normothermic conditions.

Laser effects on myocardium depend on radiation characteristics of the optical fiber tip. By applying the same power bare fiber with plan polished tip produces a higher power density with tissue vaporization and carbonization compared to fiber tips with a divergent laser beam with a lower power density (Fig 5).



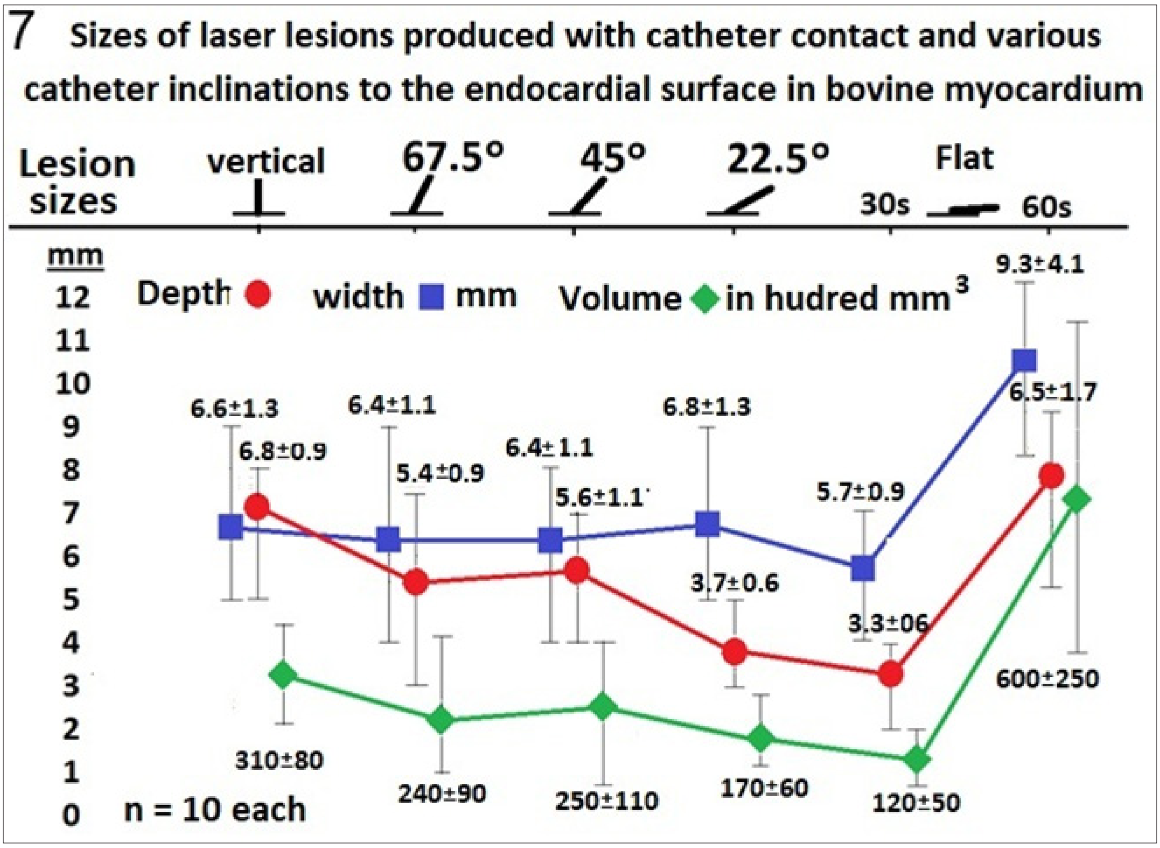
1 cw1064nm Laser Application in bovine Myocardium with a plan polished optical Fiber at a distance of 1.5mm
2 and by using a connically shaped optical Fiber with a divergent laser beam and a 5s longer Radiation time
By reducing the power density from 15.07 to 5.24/mm^2 dispite longer radiation time a carbonized channal could be avoided and a transmural homogenous coagulation necrosis without tissue vaporization with crater formation is achieved. 3, 4 Schematically: Photon scattering with the Fiber in perpendicular and flat position



Ring-shaped "Donut" like red pilot laser Illumination with a conically shaped fiber in water bath

Producing a "donut"-like ring-shaped radiation field in water (Fig 6).

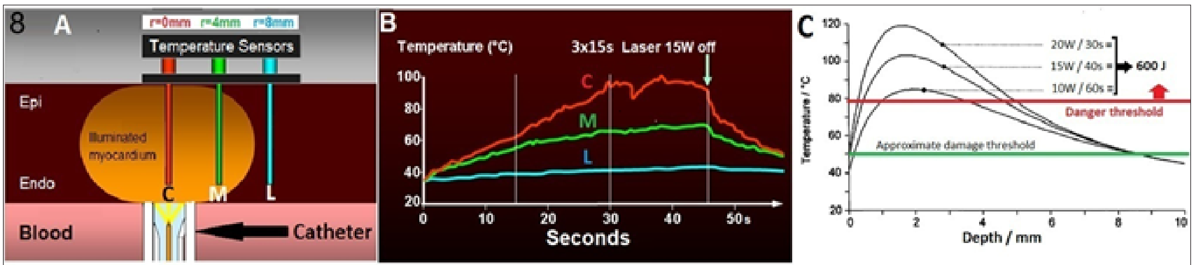
In myocardium photons are scattered diffusely regardless of angle incidence of the laser beam. With various catheter inclination toward the endocardial surface sizes of lesion produced may vary but even in flat fiber position large lesions can be achieved by lengthening radiation times with a few seconds only (Fig 7).



Catheter orientation is not a mayor determinant for lesion formation.

Temperature Measurement

For myocardial temperature measurement during laser application a special sensor array was inserted epicardially (Fig 8).

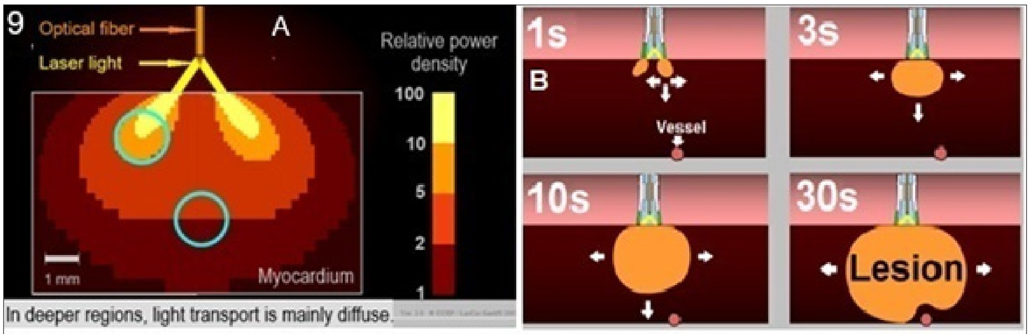


A Temperature sensor array inserted epicardially for temperature measurement during endocardial 1064nm laser application. Schematically
B Temperature curves registered during three consecutive laser impacts at 15W/15s each. Sensors placed at distances of 4mm from each other
C Temperature curves recorded during laser energy application at 600 Joule with various energy settings

During laser application intramural temperature increased gradually. Damage threshold was attained after application of an energy of 600J, however, energy settings with powers at 15W and 20W the danger threshold was exceeded. Energy settings are an important safety parameter.

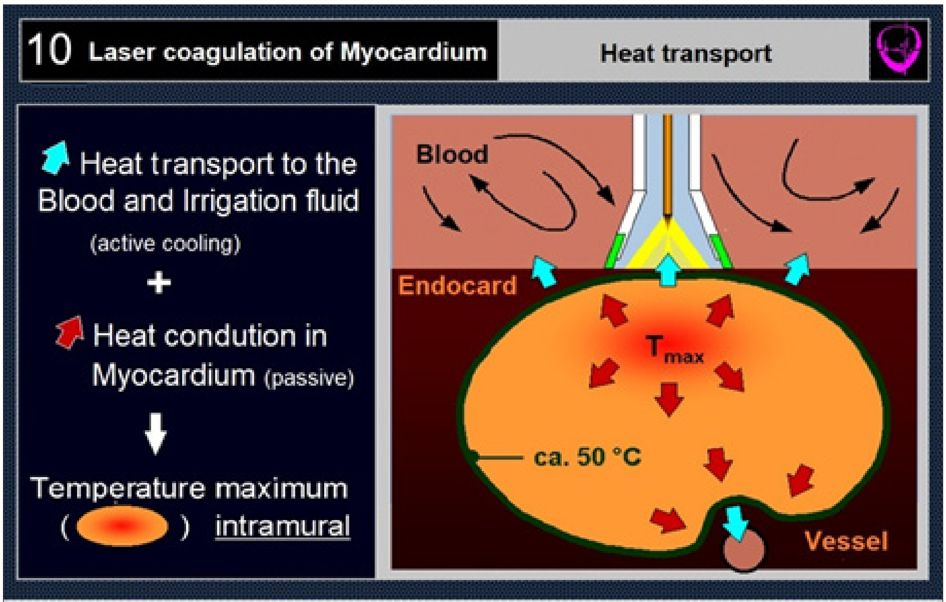
Lesion Formation

By absorption of photons lesion increase gradually (Fig 9).



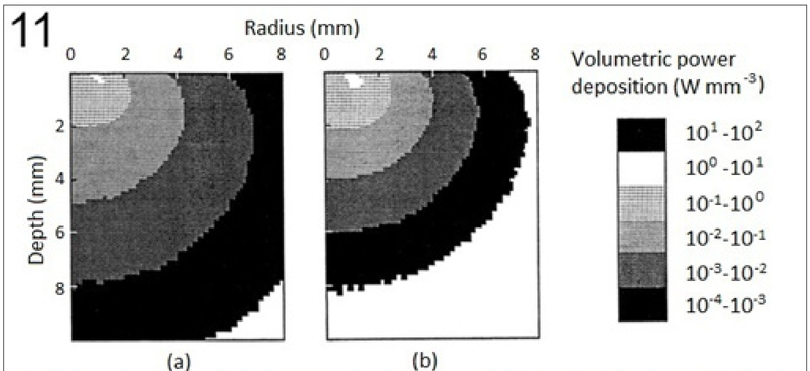
A Due to homogeneous distribution of photon energy in myocardium lesion is growing gradually resulting in a clear-cut solid volume of coagulation necrosis, B in general transmural after 30s in ventricular walls

Maximum temperature is induced deep intramurally and is spreading in the myocardial wall. Lesion is growing up to transmural or when steady state of temperature supply and offset is reached (Fig. 10).



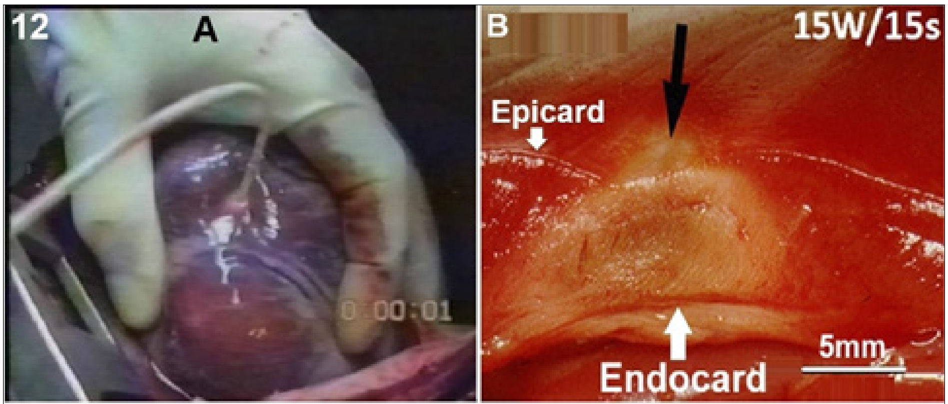
Maximum temperature is produced deep intramurally and is spreading by increasing the lesion

For investigation of laser lesion formation, a Monte-Carlo-simulation model was used (Heinze et al. 1994) to simulate distribution of volumetric power deposition in myocardium (Fig. 11).



Distributions of volumetric power deposition as a function of different optical tissue properties (a) Parameter set 2 versus (b) parameter set 4.
Both simulations were obtained with a rectangular ring profile with an outer diameter of 2mm and an inclination angle of 40°

Laser lesions are clear-cut, homogenous coagulation necrosis without tissue vaporization with crater formation (Fig 12).

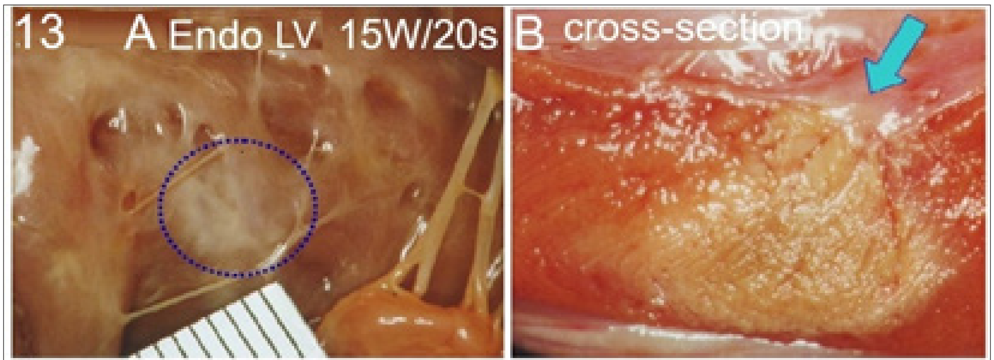


A Epicardial in-vivo laser application at 15W/10-15s demonstrate the stable Catheter Position, and
B The lesion is clear-cut homogenous without epi- or endocadial damage. Black arrow=catheter orientation

Laser ablation is a Low-power/Short-duration procedure.

Sizes of Lesions

Transmural ventricular lesion can be achieved within seconds (Fig 13).



A Coagulated myocardium glimmers through undamaged translucient endocardium (dotted circle).
B Transmural homogenous clear-cut lesion of coagulation necrosis. The arrow indicates the assumed catheter orientation during laser application

Sizes of lesion depend on the level of energy applied. For atrial lesions however, radiation time is shorter but of importance is the lesion area expansion. Transmural atrial lesions produced at 10W/8-12s covered an oval to circular area of dense fibrosis up to 12.0mm without damage to the atrial wall (Fig 14).

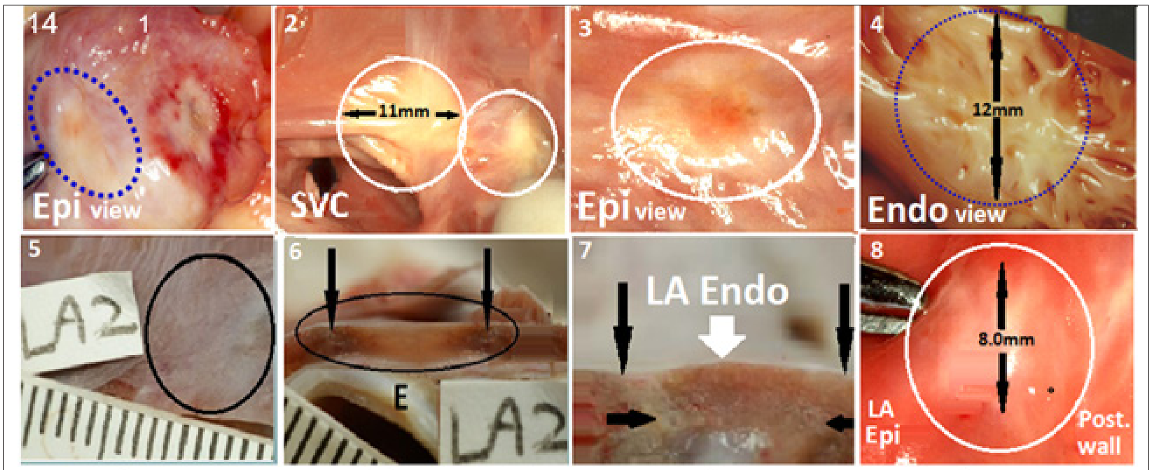
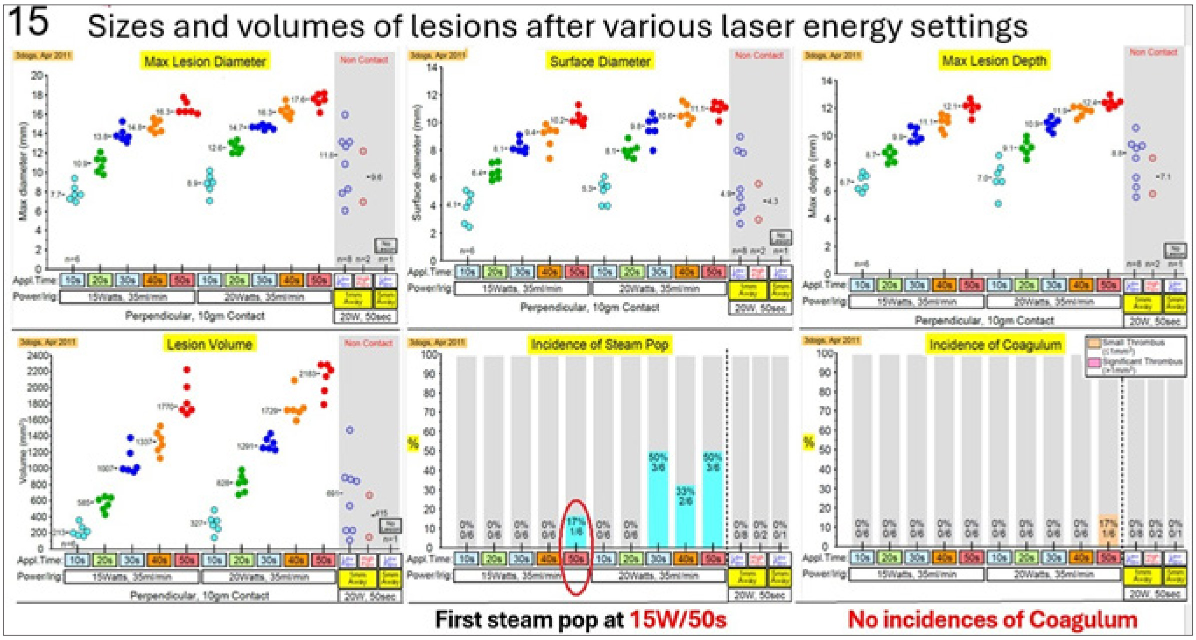


Fig 1 – 4 RA lesion **Fig 5 – 8 LA lesions**
Epi = epicardial, **Endo** = endocardial, **SVC** = superior vena cava **RA** = right atrium **LA** = left Atria **E** = Esophagus

In-vivo experiments in a thigh muscle model demonstrated a gradual increase of lesion sizes (Fig 15).



First steam pop occurred at 15W/50s. Thus, 15W applied up to 40s can be considered a safe range. In addition, lesions can be achieved even with the catheter endhole at 5.0mm distance from the target area. Lesions are of variable sizes most probably by the instability of the free floating catheter in the bloostream. Sizes of laser lesion depend on the level of energy applied in appropriate energy setting.

Energy Balance

Based on the amount of applied laser energy, the opto-thermal model is used to calculate:

- Fraction of laser energy absorbed in the tissue.
- Thermal energy is dissipated by catheter irrigation.
- Thermal energy is dissipated by the intracavitary blood.

Approx. 50% of the applied laser energy is absorbed in the myocardium and transformed into heat. The remaining fraction is mainly backscattered into the heart chamber. During irradiation, approx. 26 % of the induced heat is removed by the intracavitary blood stream. Due to the small endocardial area involved, catheter irrigation removes much less heat, only 3-4 % of the absorbed energy (Table 1).

Table 1: Energy balance

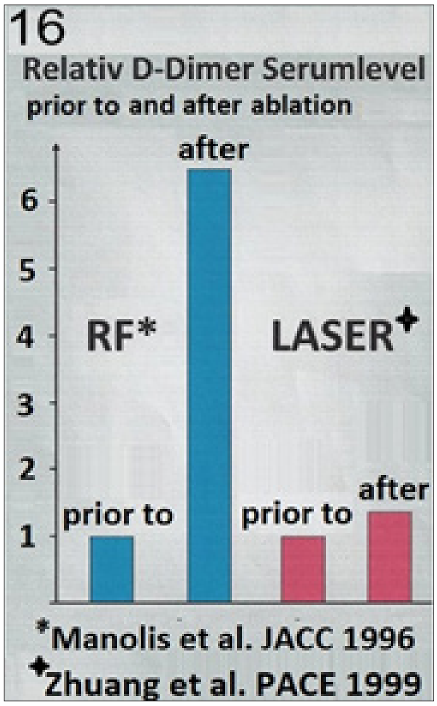
Pulse Duration (s)	Laser Energy (J)		Endocardial Cooling (J)	
	Applied	Absorbed	Catheter	Blood
1	15	7.5	0.1	0.2
5	75	37.5	0.9	3.4
10	150	74.9	2.1	10.8
20	300	149.9	4.9	32.0
30	450	224.8	7.8	58.3

Consequently, catheter irrigation plays a minor role for lesion dosimetry.

Thrombogenicity

To prove the possible thrombogenic effect of the 1064nm laser lesion serum d-dimer estimation was performed (Zhuang et al., 1999). As reflected by unchanged plasma D-dimer levels, laser ablation is without thrombogenic effect either immediately or at long term after the procedure (Fig 16).

This is a crucial and unique safety aspect of the 1064nm laser and may represent the major reason for the absence of thromboembolic events after cardiovascular laser application.

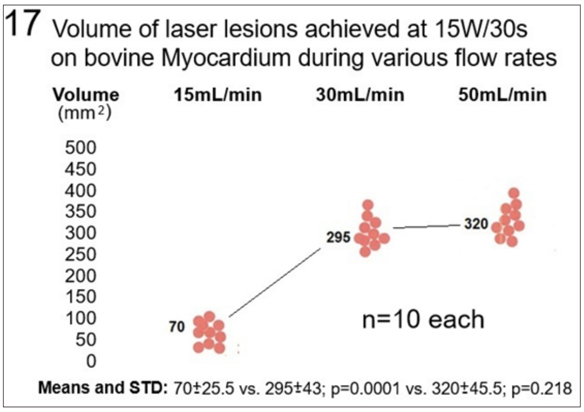


Catheter Irrigation

Catheter irrigation is a vital prerequisite for laser ablation. It washes away the blood avoiding its penetration into the catheter lumen and contact the optical fiber what would burn the fiber tip, destroy the catheter and endanger patients. A continuous flow rate of 10mL/min was performed during the study.

Laser lesions were produced at 15W (9.5 W/mm²)/30s (285 J/mm²), in stagnant blood (activated clotting time>350 s) at 18 °C, on bovine myocardium via an open-irrigated catheter **RytmoLas®**.

During flow rates of 15, 30, and 50 ml/min radiation was applied with the catheter end hole in contact with the endocardial surface (n=10). Lesions were evaluated morphometrically, and groups of lesions were compared by using the unpaired t-test (Weber & Sagerer-G, 2014).There was a significant increase of lesion volume from an irrigation flow of 15 to 30mL/min (Fig 17).



It is suggested that by using an open-irrigated laser catheter as described in this study, catheter irrigation at flow rates of 30 to 40 ml/min during laser application are optimal for myocardial coagulation.

Flow rate through 1-meter-long steel tubes with inner diameters of 0.5 1.0 mm was measured with, and without, an optical fiber fed through the tube (Table 2).

Table 2: Measured flushing rates, pump set to 60 ml/min.

Inner Diameter / mm	Flushing Rate / ml/min without optical fiber	Flushing Rate / ml/min with optical fiber
0.5	36	-
0.6	56	-
0.7	62	35
0.8	62	60
0.9	62	61
1.0	62	-

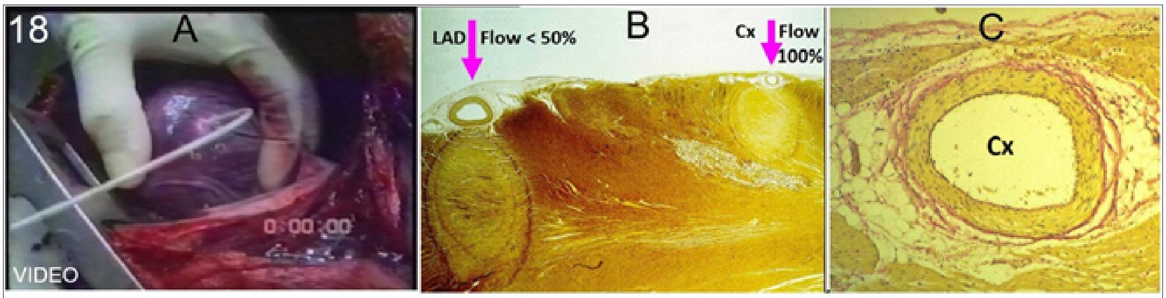
Minimum lumen width of the catheter hose = 0.8 mm. The RytmoLas® catheter hose has an inner diameter of 1.6 mm. Thus, the optical fiber can be fed through the lumen without compromising flow rate.

Contact Force

Catheter to tissue contact force is not needed for lesion formation (Sagerer-G & Weber, 2015). Even at distance of the catheter from the target surface, lesions can be achieved. The optical fiber is protected within the catheter lumen at 1.0-1.2 mm from the catheter endhole and shall never encounter tissue. Transmural laser lesion formation without contact force is unique and a special advantage for catheter ablation with magnetic navigation, where contact force is limited to magnetic field effect.

Effect on Coronaries

To determine the influence of laser coagulation of myocardium on coronary vessels, laser impacts at 10W/10s were aimed at epicardial coronaries (Weber et al., 1989; Weber et al., 1989). Sizes of myocardial lesions produced depend on coronary blood flow (Fig 18).

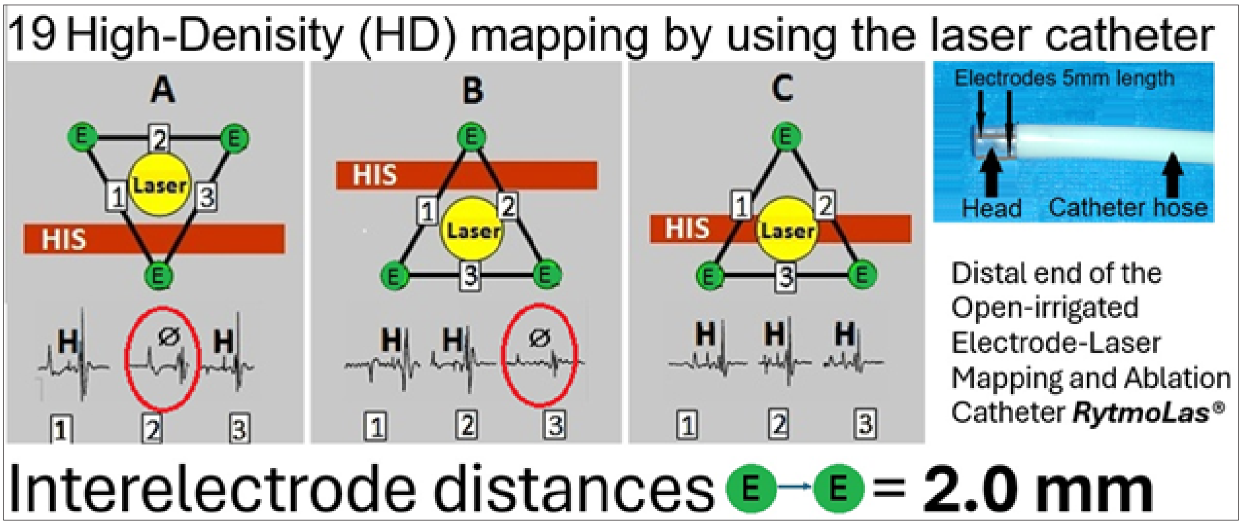


A Catheter position upon an epicardial coronary during laser application
B lesions produced through coronaries with various blood flow
C free lumen, no Thrombus, normal media and intima of the vessel

Coronary artery blood flow significantly reduces the volume of coagulated myocardium, whereas the vessels themselves remain undamaged (Weber et al., 1990). Laser ablation does not damage coronary arteries.

High-Density (HD) bipolar catheter mapping

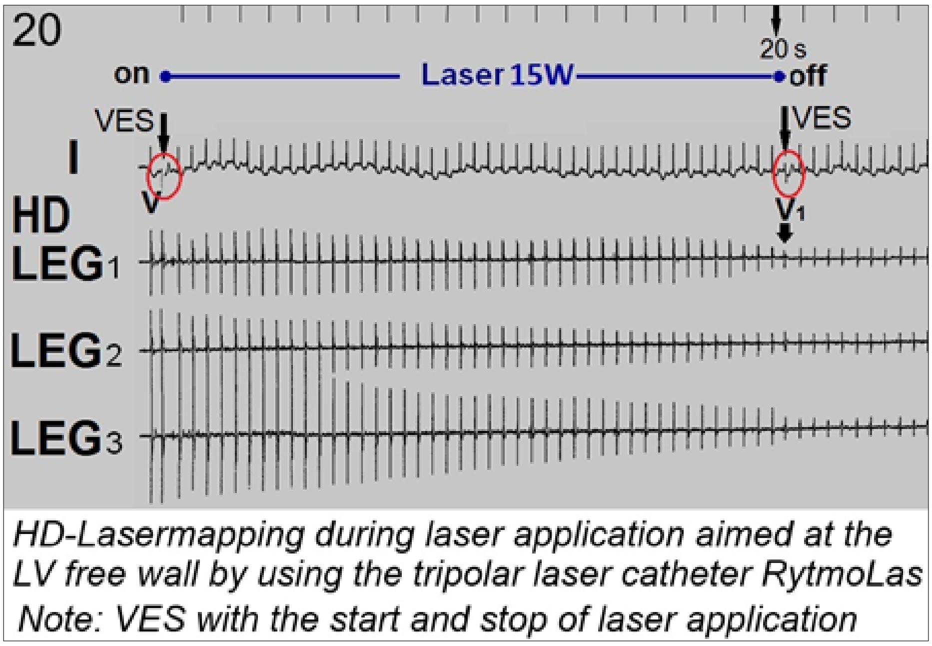
Based on our experience with SVT mapping by using ring-electrode catheters with narrow interelectrode distances (Fig 1) a laser catheter with three 4-5mm cable electrodes arranged equidistantly longitudinally in channels of the catheter head was used for HD catheter mapping (Fig 19).



With minimal lateral displacement from the His-bundle potentials were lost. Only when precisely overriding the His-bundle all the three recordings show H potential. Interelectrode distances ≤2.0mm, a unique technical feature for a precise localization of arrhythmogenic substrates in the heart.

HD-Lasermapping

HD catheter mapping during laser application a gradual dwindling of potential amplitudes is conspicuous without electrical hum because the laser light does not interfere with electrophysiologic monitoring principles (Fig 20).



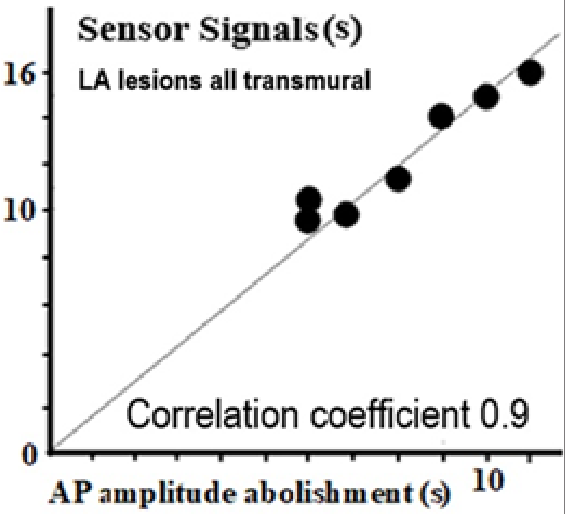
This allows for unique immediate real-time verification of success of treatment.

To control laser effects on the esophagus temperature sensors were placed behind the LA posterior wall. During various laser application times from 5 to 30s at 10W esophageal temperature sensor signals were registered three to 5s after permanent abolishment of electrical potential amplitudes in the HD-Lasermapping electrograms. Correlation coefficient was 0.9 (Fig 21).

21 A Time differences

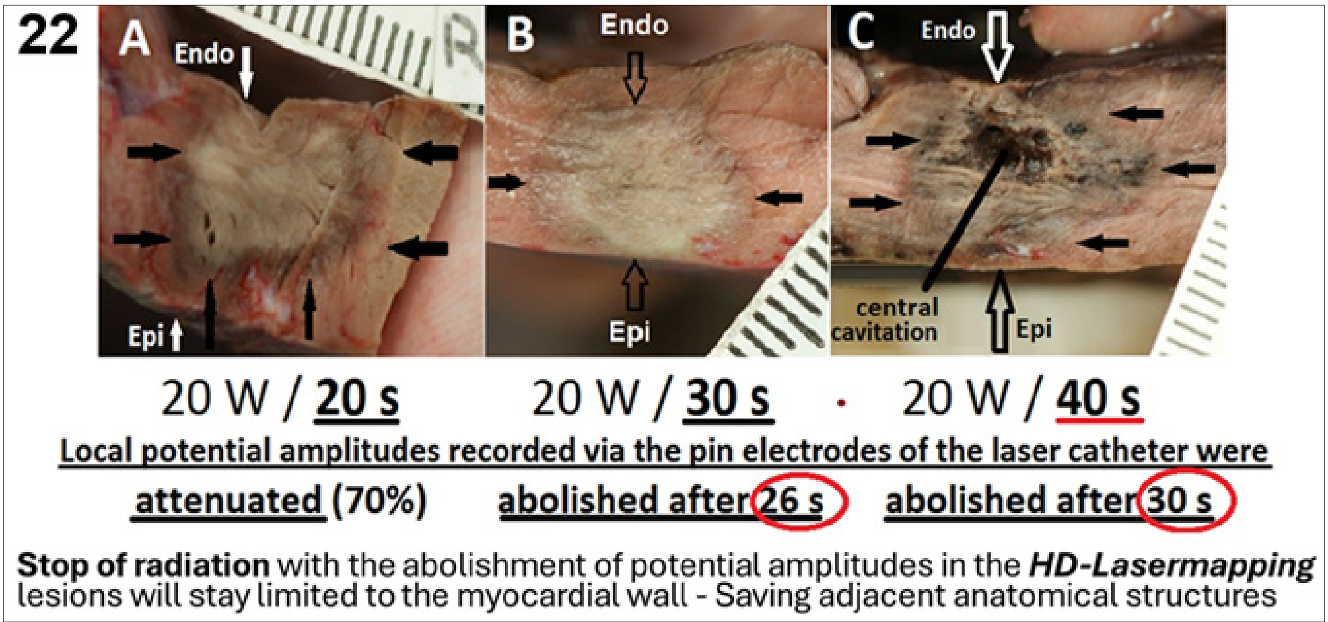
LA Laser time (s)	Permanent abolishment of AP amplitudes (s)	Esophageal sensor signal (s)	Time difference (s)
5	AP recurrence	ø	-
10	6	10	+4
10	7	10	+3
10	6	10	+4
20	10	15	+5
20	11	16	+5
30	9	14	+5
30	8	11	+3
at 10W	Mean 8.14 s SD = 1.95	Mean 12.3 s SD = 2.63	Mean 4.14 3-5 s
	P = 0.0058		

B Diagram

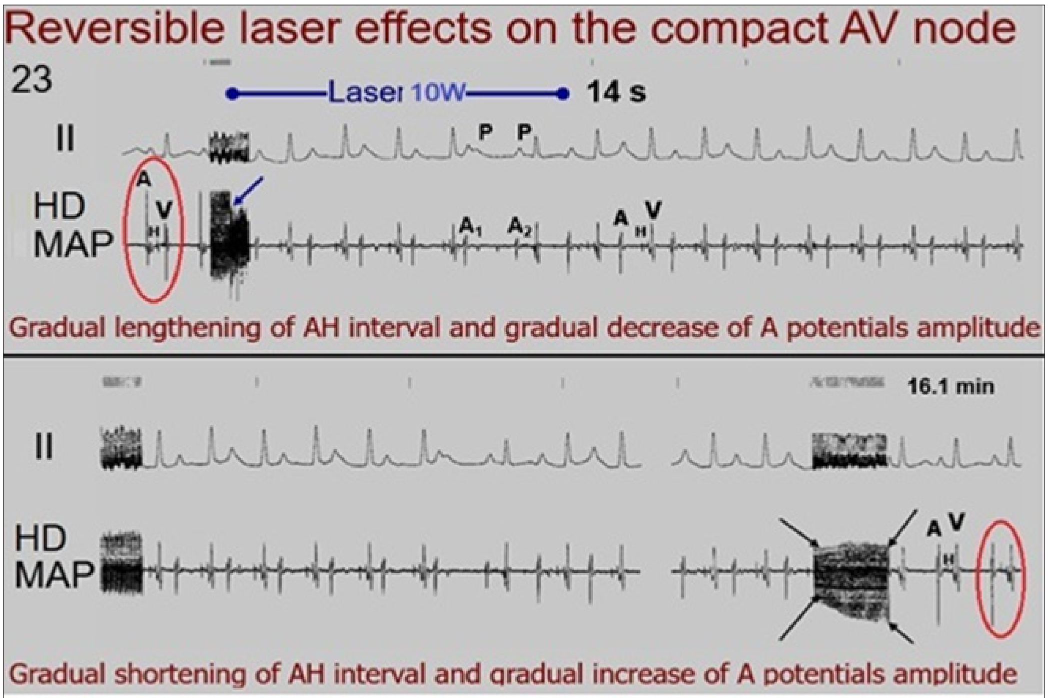


LA= left atrial, AP = atrial potential, s = seconds, SD = standard deviation, *p* = *p*-value
By conventional criteria, this difference is statistically very significant.

Thus, with timely stop of laser lesions will be limited to the myocardial wall saving adjacent mediastinal anatomical structures including the esophagus. HD-Lasermapping is a unique safety aspect of the laser method. In case of radiation times extending more than 5s after permanent abolishment of potential amplitudes in the HD-Lasermapping intramural pop may occur (Fig 22).



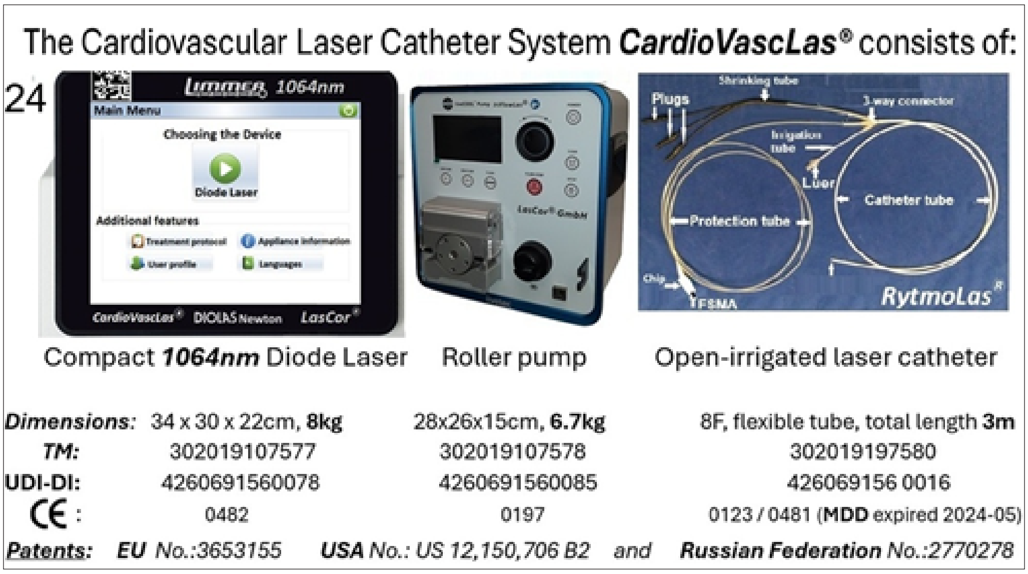
However, it never results in rupture with perforation of the myocardial wall. Central overheating is caused by the fact that in the central area maximum temperature is induced whereas the subendocardial and subepicardial layer are coagulated to dens rupture resistant fibrosis. Of crucial importance is also that premature stop of laser allows for complete reversible effects. Of crucial importance when AV-conduction is involved (Fig 23).



II=Surface lead ECG, HD=High density Lasermapping, A=atrial, V=ventricular, and H= His bundle potentials

The CardioVascLas-System®

Based on the numerous unique characteristics of the 1064nm laser, a multipurpose laser ablation system was developed. It consists of a compact 1064nm diode laser CardioVascLas® with its accessory the roller pump IriFlowLas® for catheter saline irrigation and a versatile laser catheter RytmoLas® with its variants (Fig 24).

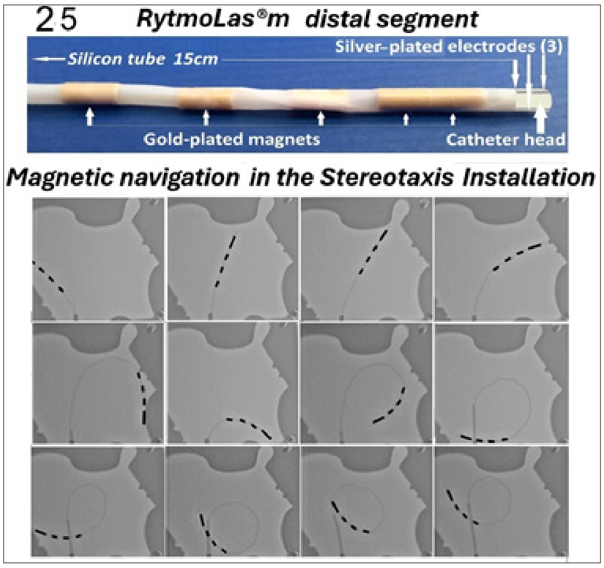


For user friendly and safe handling, the laser has treatment assistants. Initially, after all connections including the pump connections according to operating manuals are performed, you can start the laser and choose the language. For ablation procedures you have three assistants on the touch screens

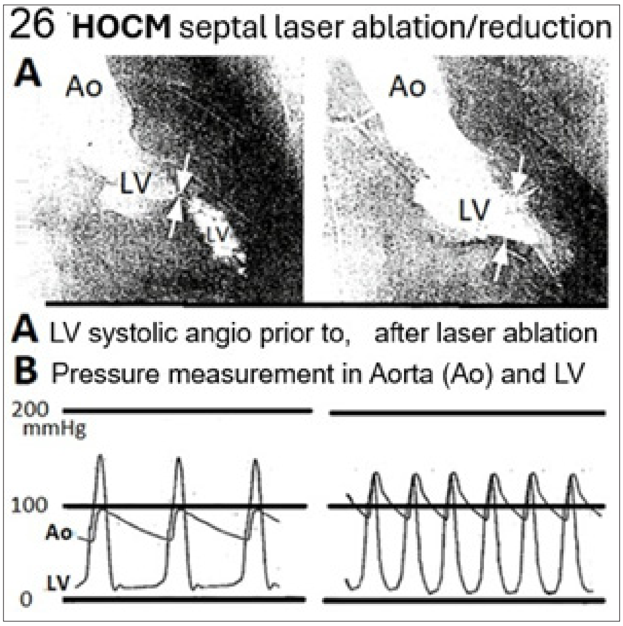
- Thin-walled myocardium <4.0mm: power 10W/10s e.g., for atrial myocardium (AF ablation)
- Thick-walled myocardium >4.0mm: power15W/15s
- Side selective transseptal puncture: 5W/5s

The parameters are preset, start and stop automatically and should not be changed. Catheter irrigation is 10mL/min continuously and increases automatically to 35mL/min via the footswitch during laser application. For transseptal puncture there is no irrigation. All the data can be stored on stick.

For vascular catheter access you need a long steerable sheath e.g., AGILIS, for manual, a robotic system e.g., Hanson Medical for robotically or Stereotaxis Genesis equipment for magnetic cardiovascular navigation. For the latter, the laser catheter variant RytmoLas®m, is provided with magnets at its soft distal end (Fig 25).



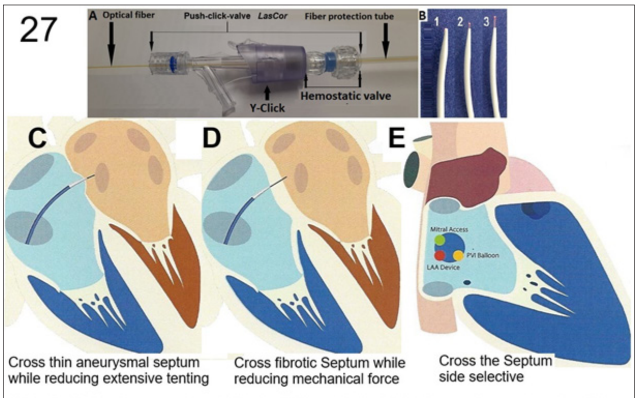
The flexible versatile ***RytmoLas***® can be used for ablation of all tachyarrhythmias regardless of type, ischemic or parasitic (D'Avila et al. 2002) or of side of the arrhythmogenic substrate in the heart chambers. Permanent release of subaortic obstruction form the RV side in HOCM is feasible with the RytmoLas®: (Fig 26).



Also, renal sympathetic denervation/modulation (Sagerer-G. et al. 2021) and pulmonary artery perivascular denervation (Condori Leandro et al. 2021) were successfully tested for resistant systemic and pulmonary hypertension with the variant ***HypertenoLas***®, All-in-One. In patients with systemic hypertension often associated with atrial fibrillation renal sympathetic modulation and atrial fibrillation ablation can be performed by using the same catheter during the same procedure reducing patients burden by avoiding repeat procedures.

ISPunctureLas®

For side selective interatrial septal laser puncture, a special optical fiber set was used. As a variant, it consists of the same components as the RytmoLas® but without the electrical and irrigation line, the catheter hose and the connector/distributer replaced by a Push-click-valve (Fig 27).

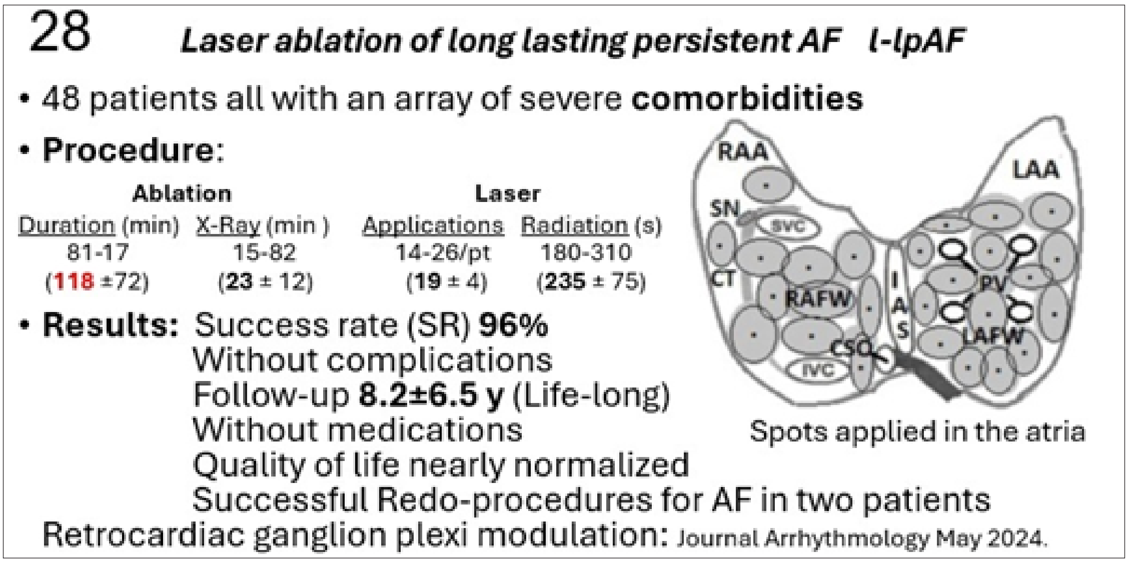


A Push-click-valve overview B Optical Fiber tip in 1 idle 2 pose 3 puncture Position
C D septal anatomy and E suggested points for side selective septal puncture

The ***ISPunctureLas***® was successfully used for side selective interatrial septal puncture in patients candidates for laser ablation of arrhythmias (Weber & Sagerer-G, 2013).

Laser ablation of long-lasting persistent atrial fibrillation (l-lpAF)

In 48 patients with l-lpAF laser ablation was attempted by using the ***CardioVascLas-System***®. Mean procedure duration time from vessel puncture to the removal of catheters was approximately two hours. X-ray exposure time 23min, mean laser applications 19/235s per patient (Weber et al., 2017). With a stepwise approach multiple laser spots of approximately 1.0cm in diameter (Fig 28) were aimed at the left and right atrial posterior walls, and if needed towards other atrial areas until sinus rhythm was achieved (Weber et al., 2017).



The high long-term success rate of 96% could probably be achieved by modulating the retrocardiac ganglion plexi during laser applications aimed at the left and right atrial posterior wall. Laser ablation on the posterior wall of the LA with a power of 15 W and duration <30 s did not lead to visible damage to the esophagus. However, laser ablation of atrial ganglion plexi (GP) zones is feasible and reduces the inducibility of AF. No change in atrial effective refractory period is detected following GP zones ablation, when performed from the right atrium (Vakhrushev et al., 2024).

Discussions

Already after our early publications of laser ablation, the laser was considered promising in the field of catheter ablation and was recommended as an alternative for arrhythmia ablation (Borbola, 1997). In an editorial comment of the J Innovations in CRM advantages of the laser method were emphasized (Mansour, 2019). Moreover, in an expert commentary of the Mayo Clinic the superiority of the laser method compared to other ablation techniques is described (Yasi et al., 2018), and other research publications (Condori-Leandro et al., 2021) just to mention a few.

In numerous aspects the 1064nm cardiovascular treatment is unique. As outlined most important are the unique tissue selective 1064nm laser wavelength for myocardium, normothermic application, and the High-Density laser mapping. These unique components represent milestones in cardiovascular treatment as compared to other methods including the recently all sides recommended Pulse Field Ablation. Short application time of PFA is too short and is overlapping HD-mapping electrograms with sudden not controllable results. In contrast HD-Lasermapping allows for gradual controllable increase of lesions limited to the target areas. And, if needed by immediate stop reversible effects. An important safety aspect.

Many of our results are confirmed by other research groups, e.g., contact force is not needed for laser lesion formation (Kimura et al., 2015). The ***CardioVascLas-System®*** 1064nm laser is also unique for implementation of Design to cost (DTC), procedural homogeneity, reproducible results, standardized data quality, evidence- based procedures, and it opens a large field of research opportunities (Splinter, 2025).

Conclusion

By using the 1064nm laser, the ***CardioVascLas-System®*** is a promising alternative for the treatment of cardiovascular diseases.

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