Journal für
# Kardiologie
Austrian Journal of Cardiology
Österreichische Zeitschrift für Herz-Kreislauferkrankungen

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*Journal für Kardiologie - Austrian Journal of Cardiology 2001; 8 (12), 503-508*



Krause & Pachernegg GmbH • Verlag für Medizin und Wirtschaft • A-3003 Gablitz
P.b.b. 02Z031105M, Verlagsort: 3003 Gablitz, Linzerstraße 177A/21 Preis: EUR 10,–

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# Non-fluoroscopic catheter-based endocardial mapping and mapping-guided percutaneous transmyocardial revascularization

H. D. Glogar, M. Gyöngyösi

*Non-fluoroscopic catheter-based endocardial mapping is a new percutaneous catheter diagnostic intervention, which for the first time furnishes direct information on the myocardial viability online in the catheterization laboratory. Using an ultralow electrical magnetic field and steerable catheter, the NOGA mapping system reconstructs the 3D electrical and local shortening maps of the left ventricle. From the electromechanical information during systole and diastole, the NOGA system can provide accurate global and regional myocardial functional data that include end-systolic and end-diastolic volumes, ejection fraction, local endocardial shortening, electrical activation time, and unipolar and bipolar endocardial electrical signals, and can distinguish normal, viable and scarred myocardium.*

*Transmyocardial revascularization is designed to enhance the myocardial perfusion and function by creating a laser channel or by transplantation of plasmid encoding vascular growth factor in the ischaemic myocardium. Since surgical transmyocardial revascularization has a relatively high perioperative morbidity and mortality, percutaneous (catheter-based) myocardial revascularization was developed with the obvious advantage of avoiding surgery and general anaesthesia. Additionally, the mapping guidance allows the exact location of the catheter within the left ventricle, leading to more precise therapy with no or minimal use of fluoroscopy and angiographic contrast medium.*

*In summary, endocardial mapping allows the detection of myocardial viability online in the catheterization laboratory and is able to guide transmyocardial revascularization procedures.*

*Nonfluoroskopisches endokardiales Mapping stellt eine neue diagnostische Methode dar, die es erstmalig erlaubt, online mit einem perkutan eingebrachten Katheter Informationen über die Myokardvitalität zu erhalten. Mittels eines extrem schwachen elektromagnetischen Feldes und eines steuerbaren Katheters erstellt das NOGA Mapping-System Landkarten der elektrischen und mechanischen Aktivität des linken Ventrikels. Aus den gewonnenen Informationen kann das Gerät endsystolische sowie enddiastolische Volumina, die Auswurffraktion, die Verkürzungsfraktion des Endokards während eines Herzzyklus, elektrische Aktivierungszeiten sowie unipolar und bipolar abgeleitete endokardiale elektrische Signale berechnen und dadurch normales von ischämischem oder irreversibel geschädigtem Myokard unterscheiden.*

*Die chirurgische transmyokardiale Revaskularisation soll die Myokardperfusion und -funktion durch die Schaffung neuer Laserkanäle oder durch die Injektion von Plasmiden, die vaskuläre Wachstumsfaktoren produzieren, verbessern. Da diese Eingriffe jedoch mit einer relativ hohen perioperativen Morbidität und Mortalität verbunden sind, wurde eine entsprechende perkutane Methode entwickelt, die ohne chirurgische Operation oder Anästhesie durchführbar ist. In Kombination mit der diagnostischen Mapping-Prozedur wird die genaue Positionierung des Katheters im linken Ventrikel ermöglicht, was eine präzise Therapie bei minimalem Einsatz der Röntgendurchleuchtung erlaubt.*

*Endokardiales Mapping erlaubt die Online-Bestimmung der Myokardvitalität im Herzkatheterlabor und stellt gleichzeitig eine optimale Plattform zur Durchführung der perkutanen transmyokardialen Revaskularisation dar.* ***J Kardiol 2001; 8: 503–8.***

Although coronary artery bypass surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA) can be applied successfully to treat the majority of patients with symptomatic coronary artery disease, an increasing number of patients are refractory to medical treatment and can not be treated with these conventional revascularization techniques. These patients with diffuse coronary artery disease, small vessel disease, chronic myocardial ischaemia of microvascular origin or chronic total occlusion with poor distal target vessel, who are not amenable to further conventional revascularization need novel revascularization approaches, such as transmyocardial revascularization, formerly using laser, or recently, gene therapy.

Transmyocardial laser revascularization (TMLR) is designed to enhance the myocardial perfusion and function by creating a laser channel in the ischaemic myocardium, which provides myocardial blood flow directly from the left ventricular (LV) cavity to the ischaemic zones [1–3]. Since the reocclusion of at least some laser-created channels has been demonstrated histologically, the underlying mechanism of the clinical improvement of TMLR-treated patients is still an open question: it may be myocardial denervation and/or the laser-triggered neoangiogenesis leading to the development of new collateral channels within the ischaemic myocardium [4].

Animal studies have revealed improvements in mortality, decreases in infarct size and preservation of the LV contractile function [5–7] after TMLR. Early results of TMLR in humans, sometimes used in combination with CABG, have been encouraging [8–11]. On the basis of multicenter randomized controlled trials (one in the United Kingdom, two in North America), surgical laser revascularization significantly improves the frequency and severity of angina in patients with refractory angina [12–14]. However, in contrast with the results of animal studies, an improvement in the myocardial perfusion or overall survival could not be unambiguously confirmed in humans [15, 16]. The only clearly proven advantages of TMLR are the effectiveness in the treatment of angina and the better health-related quality of life [17–19]. Additionally, surgical TMLR, as an open-heart surgical method, results in a relative high perioperative morbidity and mortality; accordingly, the TMLR is recommended only for patients with end-stage coronary artery disease with no possibility of any other revascularization method [15, 20, 21].

Endocardial mapping-guided percutaneous transmyocardial revascularization avoids the operative, anaesthetic and perioperative complications and morbidity. Through utilization of the NOGA catheter-based endocardial mapping system, myocardial treatment regions can be well defined. Catheter-based percutaneous mapping-guided revascularization offers the potential to be as effective as surgical transmyocardial revascularization without the need for general anaesthesia and thoracotomy, and with no or minimal use of fluoroscopy and contrast medium.

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This review briefly summarizes the current state of the art on endocardial mapping, the mapping-guided percutaneous transmyocardial laser revascularization and gene therapy.

## Non-fluoroscopic catheter-based endocardial mapping

Endocardial mapping is a new percutaneous catheter diagnostic intervention, which for the first time furnishes direct information on the myocardial viability online in the catheterization laboratory. This information, together with functional information on the myocardial region in question, can be utilized online to plan further treatment strategies. The treatment strategies may consist in conventional revascularization procedures if possible, or in percutaneous transmyocardial revascularization, if no other option exists.

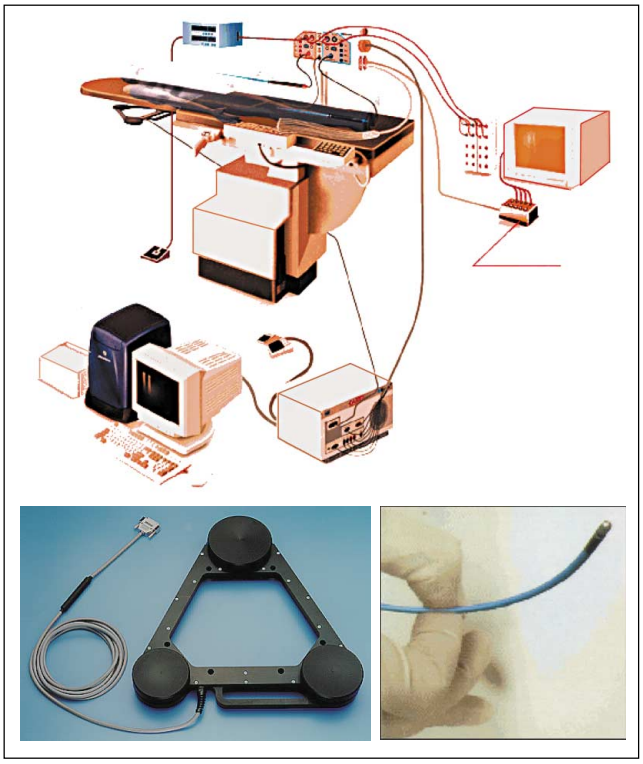

**Figure 1:** NOGA non-fluoroscopic catheter-based endocardial mapping system (above). Triangulation location pad (left buttom) detects the 3D location of the steerable catheter (right buttom).


**Figure 2**: NOGA silicon graphic monitor and processing unit.

The NOGA non-fluoroscopic cardiac electromechanical mapping system consists of a triangulation location pad interfaced with a deflectable tip catheter (Fig. 1), a NOGA silicon graphic monitor and a processing unit, as the work-station, which processes and exhibits the mapping data (Fig. 2). The triangulation location pad generates an ultralow magnetic field, and the sensor-tipped mapping catheter electrode precisely locates the catheter position in the LV in 3 dimensions. By steering the deflectable mapping catheter tip randomly to multiple LV endocardial sites, the NOGA processing system reconstructs the LV anatomy in 3 dimensions, presented in real time. The reconstruction of the LV proceeds step by step, and solid polygons are colored according to interpolation of the activation time using intracardiac electrogram recordings with a graded color scale (Fig. 3). For a good mapping quality, stable endocardial electrode location, stable heart rhythm cycle length and local electrical activity are required (Fig. 4). This system offers a unique method for measuring endocardial voltage potentials and simultaneously a regional myocardial contractility to distinguish between infarcted, ischaemic and normal myocardium. The normal myocardial cells exhibit at least a 15 mV resting unipolar potential; under 5 mV, scar tissue can be assumed; potentials between 5 and 15 mV suggest a viable

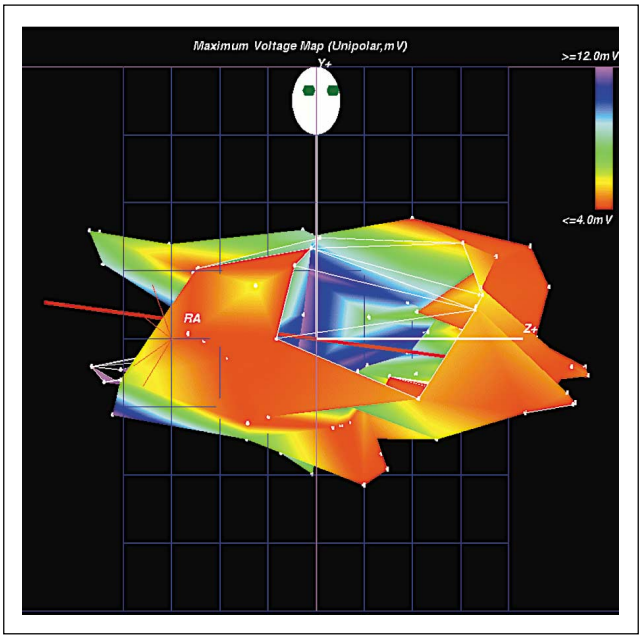


**Figure 3:** Color-coded polygons construct the 3D silhouette of the left ventricle.

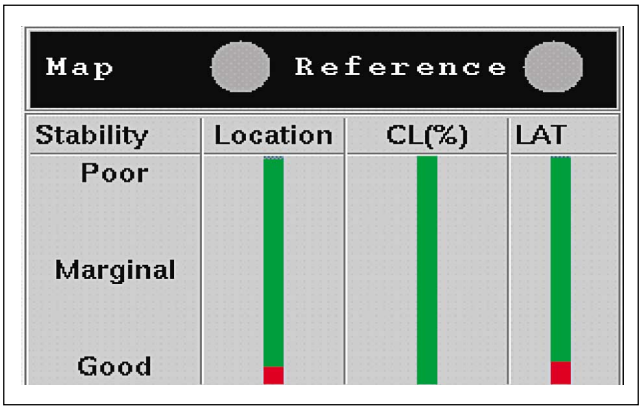


**Figure 4:** Three stability bars: location, cycle length (CL) and local activation time (LAT) show the catheter position stability.

myocardium with somewhat reduced tissue perfusion (Fig. 5). Similarly, the local shortening map provides information on the local mechanical activity of the LV. The color-coded scale allows a distinction of the normal, hypokinetic, akinetic and dyskinetic LV segments (Fig. 6).

### *Post-processing analysis of mapping data*

The reconstructed 3D endocardial map presents the myocardial local electrical activity and the LV local shortening maps. Both electrical and mechanical maps can be displayed as regional view images ("bull's-eye" maps). Such images allow the characterization of electromechanical functions in 12 different myocardial regions (septal, anterior, lateral, inferior/posterior; apical, mid and basal). An example of a regional view map (in comparison with a 201-Thallium perfusion scintigraphy polar map) is shown in Fig. 7. The electrical (voltage amplitudes) and mechanical (local shortening) functions are not necessarily concordant, especially when electrical activity is preserved despite an impaired mechanical activity.

### *Animal validation studies*

Endocardial electromechanical mapping as a new method was described for the first time *in vitro*, and then *in vivo* in pigs by Gepstein et al. in 1997 [22, 23]. The validation studies proved the high accuracy and reproducibility of LV mapping. The further development of the program led to the possibility of volumetric measurements and LV haemodynamics, including LV volumes, stroke volumes, and ejection fraction [23].

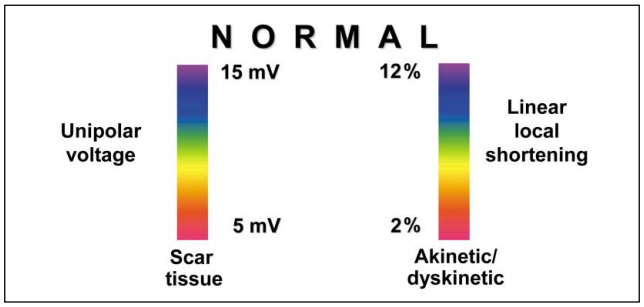


**Figure 5:** Graded color scale for the evaluation of myocardial voltage potential (left) and linear local shortening of the left ventricle (right).

Callans et al. utilized the NOGA CARTO electrophysiological system to investigate the 3D reconstruction of the LV from the intracardiac electrocardiograms. They observed that electrograms of infarct sizes had smaller amplitudes, longer durations and more frequent notched or late components than normal zones, and postulated that electroanatomical mapping allows accurate 3D characterization of infarct architecture [24].

On the basis of the 3D assessment of the electrical and mechanical properties of the LV with NOGA endocardial mapping, Kornowski et al. suggested that infarcted myocardium could be accurately diagnosed and distinguished from healthy myocardium by a reduction in both electrical voltage and mechanical activity [25].

### *Electromechanical mapping in patients*

The findings from animal experiments involving endocardial mapping, revealing the huge advantage of the mapping, e.g. the online myocardial viability assessment, were then quickly employed in humans, first by Kornowski et al. in 1998 [25]. In patients with myocardial ischaemia, LV mapping (as compared with myocardial perfusion imaging) showed mildly reduced endocardial voltage potentials and local shortening in segments with reversible perfusion defects and a profound electromechanical impairment in segments with fixed perfusion defects [25].

### *Present perspectives of endocardial mapping*

The main clinical indication of NOGA LV mapping is the provision of information on the myocardial viability in the catheterization laboratory. From the electromechanical information during systole and diastole, and by using a classical triangular reconstruction algorithm, the NOGA system can provide accurate global and regional myocardial functional data that include end-systolic and end-diastolic volumes, ejection fraction, local endocardial shortening, electrical activation time, unipolar and bipolar endocardial electrical signals and electromechanical delay. Thus, the non-fluoroscopic catheter-based endocardial mapping image provides simultaneous information regarding the cardiac mechanics, haemodynamics and electrical properties. Thus, an online diagnosis of the myocardial viability in the catheterization laboratory is possible for the first time.

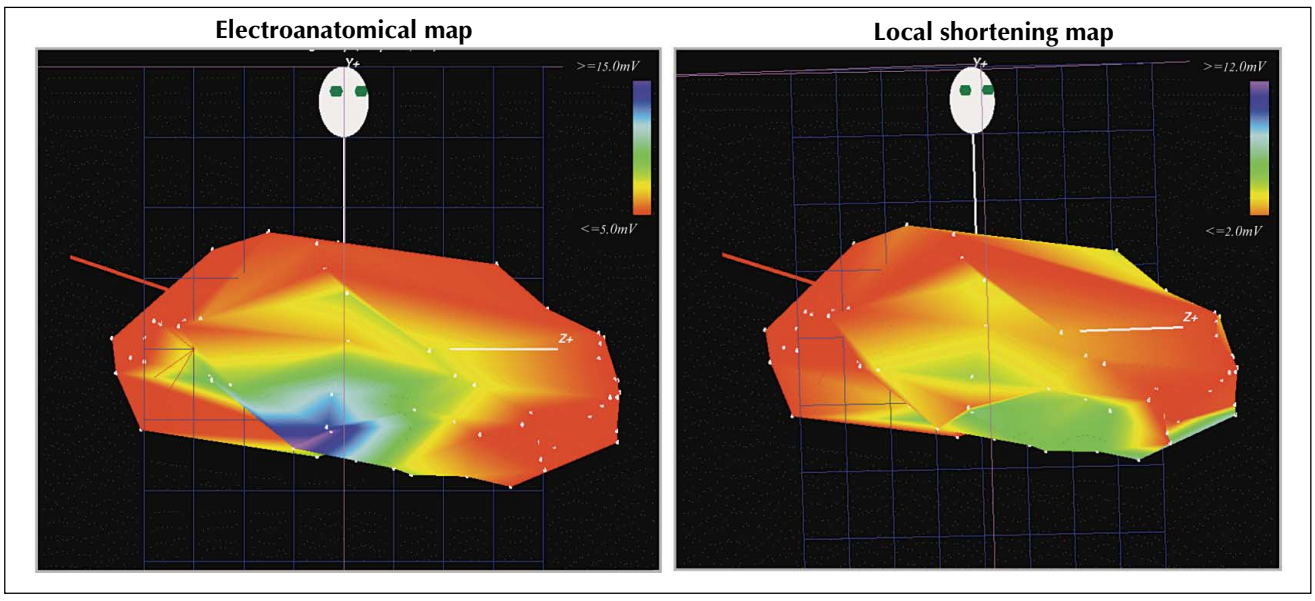


**Figure 6:** Impaired electrical and mechanical activity in the anterior, posterior and lateral wall with preserved electrical, but decreased mechanical activity at the anterior septum in a 54 year old patient with previous anterior and posterior myocardial infarction and ischaemic cardiomyopathy.

## Mapping-guided percutaneous transmyocardial laser revascularization (PMTR)

Since TMLR has a relatively high perioperative morbidity and mortality, the use of PTMR has the obvious advantage of avoiding surgery and general anaesthesia. Additionally, PTMR allows treatment of the ventricular septum, which is not accessible via a surgical approach. There is currently one laser system that can be operated without NOGA mapping (Eclipse Surgical Technologies or Cardiogenesis). However, it is extremely important to evaluate the patient carefully as concerns the viability of the treatment region and the myocardial thickness, using scintigraphic and echocardiographic methods. In contrast, the mapping guidance allows an exact location of the laser catheter within the LV, leading to more precise laser therapy with no or minimal use of fluoroscopy and angiographic contrast medium (Fig. 8).

Kornowski et al. published the first follow-up results on 77 patients treated with mapping-guided laser revascularization. The procedural success was 98.7 %, and an excellent immediately symptomatic improvement (74 %) and

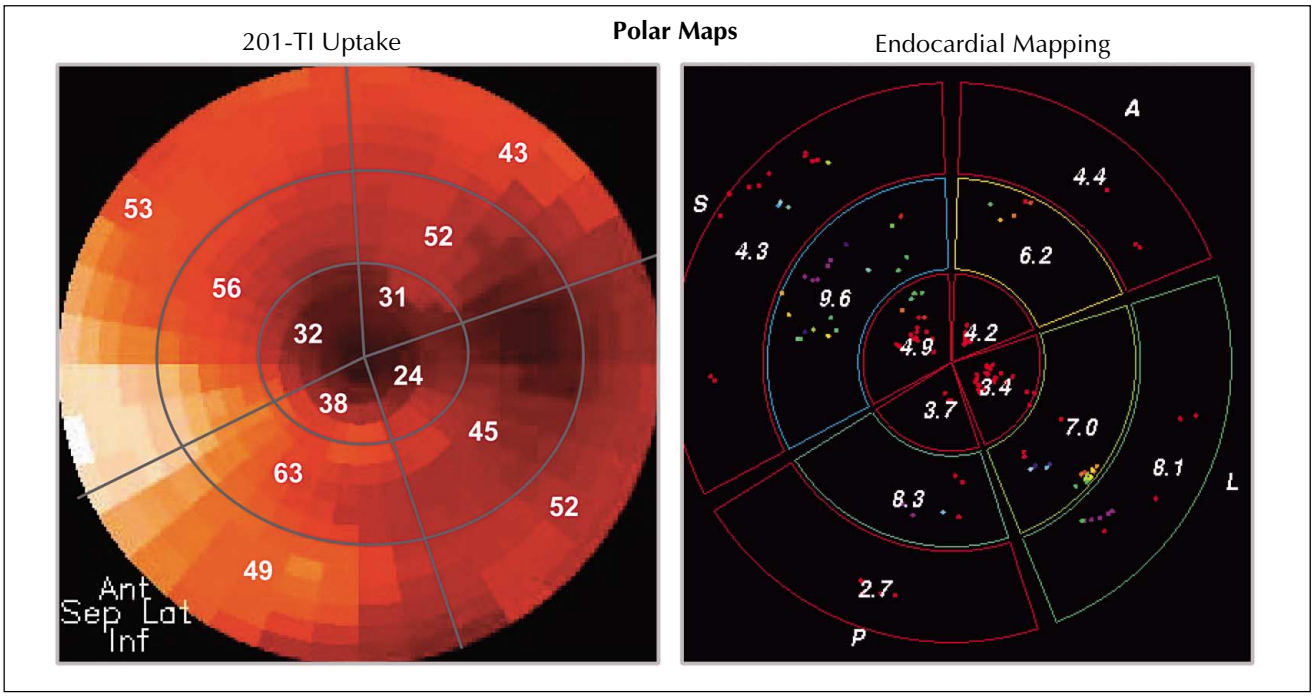


**Figure 7:** Polar maps of the 201-Thallium uptake and endocardial mapping present similarity in the evaluation of myocardial viability.

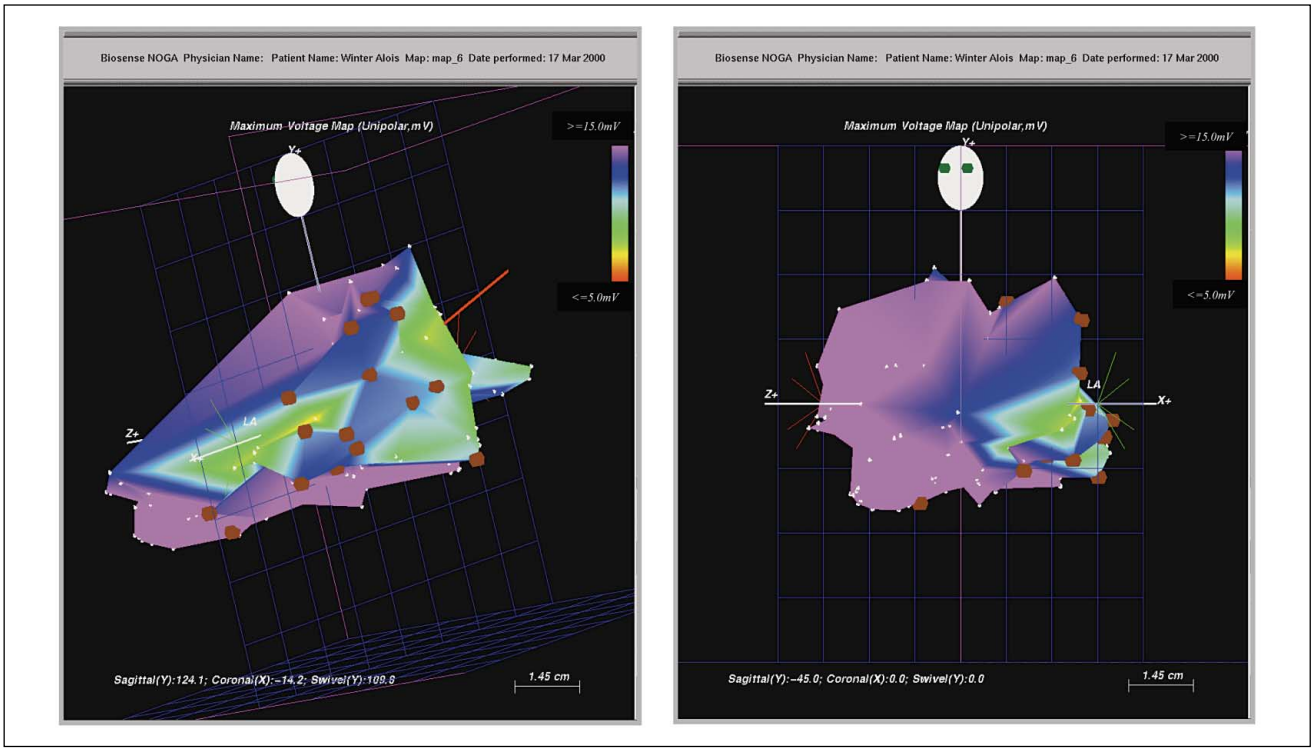


**Figure 8:** Endocardial mapping-guided direct myocardial laser revascularization. The points represent the laser channels in the lateral wall with decreased myocardial voltages.

very low in-hospital occurrence of major adverse cardiac events (2.6 %) could be documented. The 6-month follow-up revealed significant improvements in exercise duration (from 387 ± 178 to 491 ± 167 sec, p = 0.001) and angina severity (from 3.2 ± 0.5 to 2.0 ± 1.2 CCS class) [26]. However, on the basis of the direct myocardial revascularization in regeneration of endomycardial channel trial (DIRECT-Trial) showing that the PTMR has no benefit in comparison with the placebo treatment, the NOGA-guided PTMR has been stopped.

## Endocardial mapping-guided gene therapy

### *Intramyocardial gene therapy for myocardial angiogenesis*

Intramuscular transfection of genes encoding angiogenic cytokines may constitute an alternative treatment strategy for patients with extensive tissue ischaemia in whom contemporary strategies for antianginal medication or conventional revascularization fail or are not feasible. This strategy is designed to promote the development of supplementary collateral blood vessels that will constitute endogenous bypass conduits around occluded native arteries, a strategy termed "therapeutic angiogenesis" [27]. Animal studies have established that intramuscular gene therapy may be used for successful accomplish therapeutic angiogenesis [27]. Phase I clinical trials on human critical limb ischaemia confirmed the safety and efficacy of therapeutic angiogenesis, and this concept was extrapolated to the treatment of chronic myocardial ischaemia. The initial clinical results have supported the concept that the intramyocardial injection of naked plasmid DNA encoding vascular endothelial growth factor can lead to therapeutic angiogenesis, as demonstrated by the clinical improvement in patient symptoms and improved myocardial perfusion [28]. The phase I clinical study of the direct intramyocardial injection of angiogenetic factors as surgical myocardial gene therapy revealed a decrease in anginal frequency, a significant improvement in myocardial perfusion on both stress and rest images and improved collateral flow into ischaemic areas in coronary angiography [28–30]. Currently, however, it is unknown which agent (protein or plasmid) is the safest and most effective.

### *Mapping-guided gene therapy*

Although of potential clinical importance, the practical application of the transthoracic transepicardial strategy for therapeutic angiogenesis is clearly limited because of the risks and expense associated with the invasive nature of the procedure. Catheter-based transendocardial injection of angiogenic factors may provide equivalent benefit without surgery. However, the new approach of catheter-based endocardial mapping-guided gene therapy is currently still under investigation [30].

## Conclusions

1. Non-fluoroscopic catheter-based endocardial mapping images provide simultaneous information regarding cardiac mechanics, haemodynamics and electrical properties.
2. All this information is acquired with no or only minimal use of fluoroscopy and contrast medium.
3. Endocardial mapping allows the detection of myocardial viability *online* in the catheterization laboratory.
4. LV mapping is able to guide transmyocardial revascularization.
5. In patients with angina refractory to medical treatment, NOGA-guided transmyocardial revascularization might provide immediate and long-term symptomatic benefits.

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