

A Monitoring Catheter for Dynamic Cardiomyoplasty

Norbert W. Guldner, Peter Klapproth, Thomas Fischer, Ralf Noel and Hans-H. Sievers

Clinic of Cardiac Surgery, Medical University of Lubeck, Germany

Abstract

Measurement of the pressure developed between a dynamic Cardiomyoplasty (DCMP) wrap and the myocardium was evaluated as a possible method for monitoring skeletal muscle contractile force and the synchronization of the myostimulator-induced DCMP contraction in relation to the heart cycle. A newly designed implantable monitoring catheter was tested in goats ($n = 3$) for a six-month duration.

A small fluid-filled balloon attached to a monitoring catheter was placed between the myocardium and the DCMP wrap. The catheter ended in a subcutaneous access port used for pressure monitoring. Sharp pressure signals produced by the contracting DCMP were obtained in all animals at the beginning of the study. An 86% reduction of the initial amplitude of the pressure curve occurred after six months of stimulation in two goats. In the third goat, no contraction could be verified, and the DCMP was considered failed. Pressure signals transferred from the contracting myocardium could be characterized into defined segments of contraction, ejection and filling. This information allows mechanical synchronization of the DCMP contraction with the desired period of the heart cycle.

The DCMP monitoring catheter successfully transferred signals relating to the functional state of the DMCP wrap and its mechanical coupling to the heart cycle. We expect that with the use of this catheter we can better understand and optimize DMCP as a therapy for end-stage heart failure.

Key words: latissimus dorsi muscle, FES, cardiac assistance, monitoring.

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Twelve years after the first clinical application of dynamic Cardiomyoplasty [2] and after more than 600 patients, knowledge and understanding of the mechanisms for this procedure are poor [4, 5, 8, 11, 12]. Nevertheless, clinical improvement with a significantly lower demand for intensive care, mainly in dilated cardiomyopathies, has been observed. A functional improvement of the failing myocardium following DCMP has been demonstrated [9, 14]. The purpose of this study was to test the feasibility of a newly designed catheter for evaluating the skeletal muscle contractile force and the timing of the myostimulator-induced contraction in relation to the heart cycle.

Material and Methods

The implantable DCMP monitoring catheter was made of polyurethane. It had a double lumen, length of 45 cm, and diameter of 1.3 mm (Figure 1). A polyurethane balloon, 4 mm in diameter and 30 mm in length, was attached to the catheter tip. It communicated with both lumen of the catheter (Figure 1a). The other end of this catheter led into two tubes: one entered a small measuring chamber, a Port-a-Cath (Figure 1b) used for pressure monitoring, and the other was sealed after filling and de-airing the catheter

and balloon with hyperosmolaric saline solution (Figure 1c).

Three female boor goats weighing 38 to 45 kg and aged between 3 and 5 years were used in this study. They were kept under veterinary care at the Animal Department of the Medical University of Lubeck. They were supervised by a representative of the Society for the Prevention of Cruelty to Animals from the government of Schleswig-Holstein, Kiel, Germany.

Xylazinehydrochloride 2% (Rompun®) 0,2 mg/kg and Ketamin (Ketanest®) 5 mg/kg were used to induce general anesthesia. After endotracheal intubation, the animals were ventilated with oxygen and anesthesia was maintained with a continuous application of 4 to 6 mg Propofol (Disoprivane®) per hour through a central intravenous line via the internal jugular vein. Intermittent intravenous boli of Ketamin (Ketanest®) of 1 to 2 mg/kg were administered. There was no use of a muscle relaxant.

The goats were placed in the right lateral decubitus position, and an oblique incision from the left axilla to the left iliac crest was made. The left latissimus dorsi muscle (LD) was dissected free from its insertion and surrounding fascial attachments. Two muscular electrodes (Model

A monitoring catheter for dynamic cardiomyoplasty

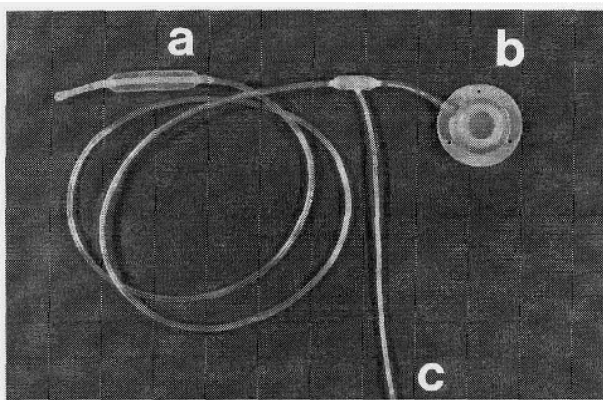


Figure 1. The implantable cardiomyoplasty monitoring catheter with a diameter of 1.3 mm has a double lumen. Around its tip, a polyurethane balloon was attached with a diameter of 4 mm and a length of 30 mm (a) communicating with both lumen of the catheter. The other end of this catheter led into two tubes: one into a small measuring chamber, a port-a-cath (b), the other sealed (c) after filling and de-airing the catheter with hyperosmolaric saline solution.

IML-2, Teletronics Pacing Systems, Inc., Denver, Colorado, USA) were inserted and weaved around the branches of the thoracodorsal nerve, 6 cm apart. The third rib was partially resected (5 to 6 cm), and the LD was transferred into the intrathoracic cavity. The free edge of the humeral tendon was attached to the second rib. The animal was then placed in the supine position. Through a median sternotomy, a left LD cardiomyoplasty was performed in the standard posterior-to-anterior fashion. The catheter was filled with saline solution and de-aired, and its balloon was placed under the diaphragmatic posterior wall of the left ventricle, near its base (Figure 2). Before completing the DCMP wrap using a pericardial flap (Figure 2, right), pressure signals of the catheter were tested to be optimal (Figure 2, bottom). The cardiac sensing electrode (Model 033-572, Teletronics Pacing Systems, Inc.) and the myoelectrode were then connected to a myostimulator (Model 7220, Teletronics Pacing Systems, Inc.).

The typical two-week healing period was omitted. The myostimulator was programmed immediately after surgery with the following stimulation variables: amplitude 2.5 to 5 Volts, bursts of 2 pulses at a frequency of 50 Hz, a pulse width of 120 microseconds and a synchronization mode of 1:20 (Figure 3). The stimulation pattern was progressively increased by increasing the pulse number from two to twelve pulses per burst and by increasing the synchronization ratio from 1:20 to 1:2 in goat one and to 1:8 in goats two and three. Pressure signals from the monitoring catheter were registered by piercing the subcutaneous implanted Port-a-cath and recorded via an electro-mechanical pressure transducer (Hewlett Packard, Model 78342A, Boblingen, Germany) into a personal computer (AT 486, 33 MHz).

Figure 2. The DCMP catheter is placed between the wrap of latissimus dorsi muscle and the base of the posterior wall of the left ventricle. A recording from the DCMP-catheter is shown with heart actions and with three contractions of the dynamic cardiomyoplasty in a 1:20 stimulation ratio.

Stimulation protocol DCMP

	pulses per burst	stimulation ratio
week 1+2	2	1:20
week 3+4	5	1:15
week 5+6	8	1:12
week 7+8	10	1:10
week 9+10	10	1:8
week 11+12	10-12	1:8

Figure 3. Stimulation protocol for dynamic cardiomyoplasty of goat 2 and 3: amplitude 5 V, pulses per burst 2-12, pulse width 120-280ms, burst frequency 50 Hz, stimulation ratio 1:20-1:8, R-wave delay 200-250 ms.

In goats two and three, a conductance catheter (7 french, Cardiodynamics Leiden, The Netherlands) was introduced by the Seldinger technique into the carotid artery and placed along the longitudinal axis of the left ventricular cavum to record the real-time pressure-volume relationship. The pressure signals as measured by the

DCMP-monitoring catheter were compared to the pressure-volume data in order to correlate DCMP catheter measurements to cardiac events. Pressure measurements via the monitoring catheter were performed twice a week.

Results

During the electrical conditioning of the LD wrap, prominent pressure spikes caused by LD contraction were recorded (Figure 2, bottom and Figure 4). Good contraction of the LD was monitored in all three goats during the first eight postoperative weeks. During this time period, a synchronization of 1:20 to 1:10 was delivered by the myostimulator with an increasing number of pulses per burst, 2 to 10. Goat one reached an end stage synchronization mode of 1:2, and no pressure signals associated with LD contraction were recognized after the twelfth postoperative week. In goats two and three, reaching a final synchronization mode of 1:8, pressure signals verifying LD contraction were evident up to 6 months.

The pressure signals sensed by this DCMP-catheter showed significant temporal changes over the course of the study (Figure 4). The amplitude of the peak pressure during LD contraction decreased to about 14% of its original value. The pressure rise time (dP/dt) decreased as expected with the decreasing contraction velocity of the muscle (Figure 4, right).

Simultaneously recorded ECG, pressure signals measured by the DCMP monitoring catheter (MON), and the pressure and volume signals measured by the conductance catheter are shown in Figure 5. The "heart-curve" monitored by the DCMP catheter showed an ascending and a descending curve (Fig. 5, MON). Two phases could be distinguished from the descending part: an ejection phase and a relaxation phase.

Discussion

Signals from the DCMP-catheter provided information about the synergetic muscle contraction relating to a large area of the posterior wrap, rather than just a small region of the muscle as do other more focal measurements. The balloon was placed in the region of the DCMP wrap which has the most important influence on the heart, and at the location of the heart's largest circumference. In the classic left LD DCMP, the posterior wall of the left ventricle is always covered with the most valuable muscle tissue. Accordingly, a balloon of 30 mm of length at that location should give representative information of the functional state of this important part of the muscular wrap.

The DCMP monitoring catheter can aid in identifying the optimal synchronization ratio of muscle contraction to heart rate. This is one important factor in preserving latissimus dorsi muscle viability. A skeletal muscle overstressed by a high contraction frequency and high energy delivery might become damaged. We believe that this happened in goat one which underwent stimulation at a synchronization mode of 1:2.

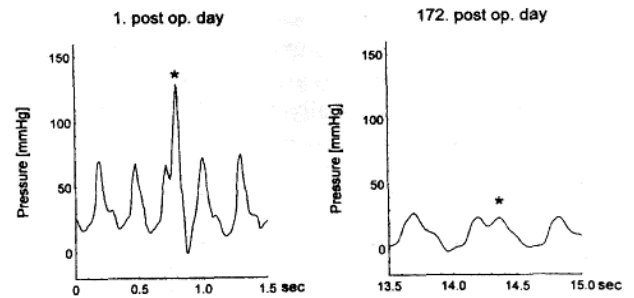


Figure 4. Example pressure recordings as sensed through the DCMP-catheter are shown. Heart actions and one contraction of the LD (*) are clearly recognized on the first postoperative day (left) as measured in goat three with a R-wave delay of 200 ms. On the 172nd postoperative day (right) heart actions and LD contraction (*) are still evident but with a greatly reduced amplitude associated with LD contraction and a decreased pressure rise time (dP/dt).

Catheter signal in relation to heart cycle

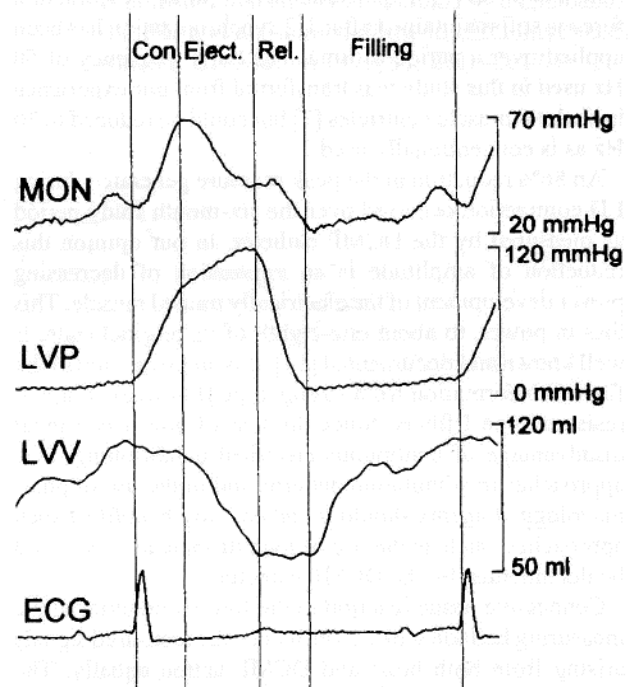


Figure 5. Heart signals registered via the DCMP-Monitoring catheter (MON) were correlated to the heart cycle by comparing left ventricular pressure (LVP) and left ventricular volume (LW) measurements taken by a conductance catheter placed in the cavity of the left ventricle. From the monitored signals of the heart (MON), contraction (Con), ejection (Eject), relaxation (Rel) and filling phases can be distinguished.

The conditioning protocol used in this study (Figure 3) was based on our experience in developing "functionally adapted" stimulation patterns in skeletal muscle ventricles [7]. In practicing functionally-adapted stimulation, the stimulation demand is only increased when pressure measurements indicate that the muscle can sustain a new level of demand without fatigue. By carefully incrementing the stimulation only after the muscle has "functionally adapted" to a new level of demand, the final power capacity of the muscle can be improved and the muscle viability preserved. The 1:8 mode used in goats two and three was associated with sustained function and preserved muscle tissue. This finding supports the good clinical outcome, reported by Chekanov, in fourteen DCMP patients after more than five years of using a chronic stimulation ratio of 1:6 [3].

The purpose of the present experiment was to test the catheter and to evaluate a stimulation protocol. In further studies the DCMP-catheter can be used as a tool to determine the synchronization mode that is optimal for clinical use. Monitoring the LD contraction using the DCMP catheter should be performed during and after the conditioning period, which conventionally uses a final stimulation ratio of 1:2 [2,4,5], in order to determine if contraction force is still maintained after 1:2 synchronization has been applied over a period of time. The burst frequency of 50 Hz used in this study was transferred from our experience in skeletal muscle ventricles [7] but could be reduced to 30 Hz as is conventionally used.

An 86% reduction in the peak pressure generated during LD contraction occurred over the six-month study period as measured by the DCMP catheter. In our opinion this reduction of amplitude is an expression of decreasing power development of the electrically trained muscle. This loss in power, to about one-eighth of its original state, is well known and documented [13]. It is an expression of the fiber transformation from strong, type II to weak, fatigue-resistant type I fibers. Since the loss of power is a great disadvantage of continuous electrical conditioning, new approaches in stimulation patterns and in the use of pharmacological agents should be taken. Any benefit of such approaches, such as the use of hypertrophic agents, could be documented by the DCMP catheter.

Connective tissue reaction to the foreign material of the measuring balloon will also influence the measured signals arising from both heart and DCMP action equally. The relationship between the DCMP signal and the heart signal can be studied to account for any dampening of the signals due to encapsulation rather than actual LD power loss.

The pressure signal associated with the mechanical activity of the base of the left ventricular posterior wall (Figure 5, MON) was characterized by an ascending curve, a peak and a descending curve. The descending part was divided by a small peak, which separated the ejection phase from the relaxation phase. The relation to the heart cycle was verified by conductance catheter measurements. Based on these signals, the DCMP catheter can be used to

synchronize the DCMP contraction with the heart cycle. If the goal of DCMP is to increase the ejection fraction directly, contraction should occur during the ejection phase. If a girdling effect leading to reverse remodeling is the goal [9, 14], perhaps stimulation during the relaxation phase would be logical. We have proposed a "walk behind" contraction to achieve a dynamic training effect during electrical conditioning of skeletal muscle ventricles. This training was found to maintain or increase muscular power in skeletal muscle ventricles and may be worthwhile in DCMP [6].

In clinical application, the risk of complications associated with an extravasal catheter can be minimized. Risk of infection can be diminished by removing the DCMP catheter early, or surrounding the catheter near the Port-a-Cath with Dacron felt for better in growth of tissue, preventing the spread of infection from the Port-a-Cath to the heart.

While this monitoring catheter gives information about the functional state of DCMP, investigations by a conductance catheter [1,9, 10, 14] should elucidate any improvement of the myocardium. In conclusion, this DCMP-monitoring catheter provides information as to whether the LD is still contracting, how effective is the power development of the muscular wrap, and what is the optimal mechanical coupling to the heart cycle. In our opinion this monitoring catheter should be helpful in understanding and optimizing clinical DCMP.

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Address correspondence to:

Dr. Norbert W. Guldner, Klinik für Herzchirurgie, Medizinische Universität zu Liibeck, Germany, tel. 0049 4512108, fax 0049 451 2051.

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