CARDMI ASSIST DEVICES
and the Application of Data Analysis,
Modelling and Information Processing

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Contents:
1. History of the mechanical cardiac assist and replacement
2. Pump systems:
   - Pulsatile systems
   - Rotary blood pumps with conventional bearings
   - Rotary blood pumps with touchless bearings
3. Controllers and monitoring of Card. Assist Devices
4. Research (selected examples):
   - Control for physiological adaptation
   - Interaction of Pump and Cardiovasc Sys.
   - Flow simulation in the carotic artery

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A blood pump has to:

- generate sufficient blood flow (5-8 L/min) at physiological pressures (up to 150mmHg ~ 25 kPa);
- to treat the blood particles gently (otherwise the destruction of erythrocytes and the activation of platelets occur);
- avoid thrombus formation, which can occur due to stagnation points, recirculation areas, heat generation or improper material transitions;
- require minimal traumatization during and after implant (Size of surgical field, diameter and flexibility of tubings, cables);
- depending on the indication be failsafe up to several years, easy replaceable, to adapt to the flow request, to be small and silent;
- be inexpensive in acquisition, implant and postoperative care.

Application:

for TOTAL ARTIFICIAL HEART as orthotopic heart replacement (TAH)
for VENTRICULAR ASSIST for left (LVAD), right (RVAD) or biventricular (BiVAD) application;

Pump type:

PULSATILE PUMPS, with membrane and valves driven pneumatically or electrically;

ROTARY PUMPS
Roller pumps with squeezed tubing
Centrifugal pumps with conventional or touchless bearings
Axial pumps with conventional or touchless bearings;

Duration of Application: SHORT TERM, BRIDGE to transplant or recovery
LONG TERM (Destination Therapy)
Milestones of Mechanical Cardiac Assist (I):

1934 Roller pump for cardiopulmonary bypass (DeBakey - USA)
1957 First animal implant with Total Artificial Heart (Kolff, Akatsu – Cleveland)
1963 First clinical implant of a cardiac assist system (Liotta - Houston)
1968 First clinical implant of a balloon pump (Kantrowitz - USA)
1968 Rotary pumps for blood transport (Blackshear, Kletschka, Rafferty - Minneapolis)
1975 Clinical use of an industrially produced rotary pump for the heart lung machine (Biomedicus, Minneapolis)
1982 First clinical use of a Total Artificial Heart for destination therapy (Kolff, Jarvik, De Vries – Salt Lake City)

Milestones in Mechanical Cardiac Assist (II):

1984 First clinical application of an electrically driven cardiac assist device (Portner - Stanford)
1986 First clinical implants of TAH as bridge to transplant (Unger - Salzburg, Wolner - Wien, Hetzer - Berlin)
1988 First clinical application of high speed axial pumps (Wampler, Fraser - Houston)
1993 First discharge to home with a pulsatile pump (Loisance, Portner - Paris)
1999/2000 First discharge of a patient with rotary pump (Wolner - Wien)
2007 Patient on device for 7 years (Jarvik, Westaby, London)
The expectations have changed:

1986: "The safety standards as in animal experiments are sufficient, otherwise the patient will be dead tomorrow", patient stays in intensive care

1990: Implant for several weeks seems to be sufficient, mobilization of the patient in the standard ward

1993: Full mobilization of the patient for several months must be possible, temporary discharge from hospital

2000: The system must be small and silent, at low anticoagulation and freedom of infection

2003: Implantation of devices for destination therapy, as final solution for several years.

2008: The heart should be particularly protected or even recover during cardiac support

Schematic of a pneumatic blood pump:
Example: Artificial Heart in Vienna - Phase 1

Clinical Use 1986
On the right side the driving unit, on the left side the spare unit

1972 Development of the “Elliptic Heart”
1979 Clinical use for Assist
1884 Start of the clinical transplantation program
1986 First implant of the elliptic heart as bridge to transplant

Left Ventricle of a TAH
Patient during 2-week bridge to transplant and after transplant


Driving and Monitoring System

1985 Start of Construction and anatomical studies;
1987 Animal experiments up to 180 days;
1988 Clinical use as TAH and VAD, 60% are transplanted;
1991 Industrial transfer does not work out, production has to be stopped due to limitations in the old laboratory.

Patient, 1990 on TAH support, 1 year after transplantation
Frontpanel of a pneumatic drive with microcontrolled Alarm System; The two pumps are balanced via a Master-Slave-Adjustment, the necessary Flow was determined via venous oxygen saturation.

Pulsatile Membran-Blood pumps as assist device in LVAD and BiVAD-Configuration (Thoratec):
Electromagnetically driven pulsatile pump: NOVACOR, fully portable support since 1993

Arrow-Lionheart als Final-Therapie:
**Arrow-Lionheart als Final-Therapie:**

- **Outlet Cannula**
- **Inlet Cannula**
- **Internal Coil**
  - 2 7/8" dia x 5/8"; 0.3 lb
- **Compliance Chamber**
  - 3" dia x 1/2"; 0.2 lb
- **Access Port**
- **Motor Controller**
  - 4" x 3.75" x 1 1/8"; 1.1 lb
- **Blood Pump**
  - 2 7/16" dia. x 2 13/16"; 1.5 lb

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**Arrow-Lionheart als Final-Therapie:**

- **Compliance Chamber**
  - 3" dia x 1/2"; 0.2 lb
- **Access Port**
- **Motor Controller**
  - 4" x 3.75" x 1 1/8"; 1.1 lb
- **Blood Pump**
  - 2 7/16" dia. x 2 13/16"; 1.5 lb

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The Total Artificial Heart
with integrated Motor
ABIOCOR®

Classification of Rotary Blood Pumps

<table>
<thead>
<tr>
<th>Axial Pumps</th>
<th>Radial Pumps</th>
<th>Diagonal Pumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemopump</td>
<td>Biopump</td>
<td>Capiox SP</td>
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<tr>
<td>Jarvik 2000</td>
<td>Delphine</td>
<td>Isoflow (Lifecare)</td>
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<tr>
<td>Sun Weska (IVP)</td>
<td>DelBakey</td>
<td>DeltaStream</td>
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<td>HeartMate II</td>
<td>Impella</td>
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<tr>
<td>Axipump</td>
<td>CosAide</td>
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<tr>
<td>Valvo Pump</td>
<td>Streamliner</td>
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<td>RotaFlow</td>
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<td>HiFlow</td>
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<tr>
<td></td>
<td>Sikkaio Pump</td>
<td>AB-180</td>
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<td></td>
<td>Vienna Centrifugal</td>
<td>EVAheart</td>
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<tr>
<td></td>
<td>Abiomed CF</td>
<td>Kritter Pump</td>
</tr>
<tr>
<td></td>
<td>MSCP</td>
<td>HeartMate III</td>
</tr>
</tbody>
</table>
Rotary Blood pumps: The bearing of the rotor is crucial for blood trauma and thrombus formation:

Mechanical bearings include areas of high shear stress, heat and low washout. These factors contribute to blood trauma (hemolysis) and thrombus formation (via platelet activation and stagnation).

Classification of Rotary Blood Pumps depending on the Bearing Technology:

First Generation:
Mechanical Bearing, sealed or blood immersed:
Area of high shear at the bearing rim, heat and stagnation.

Second Generation:
Magnetic bearing, actively controlled by electromagnets

Third Generation:
Magnetic bearing combined with hydrodynamic stabilization
**Rotary Pumps for short term Assist: Biomedicus®**

The discs forward the blood by adhesion and centrifugal force: CFD of shear stress
(Keyhani et al.)

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**Impeller Pumps for short term Cardiac Assist:**

Example: Cobe®: Pump for extracorporeal circulation and short term assist
Impella Miniature Axial Pump

Ø 6.4 mm, 4.5l/min, with pressure sensors for placement and flow monitoring

Second Generation:
Magnetic bearing, actively controlled by electromagnets; The control is done based on magnetic sensors and the voltage in the coils (so called Back ElectroMagnetic Force) with a high speed signal processor.
CentriMagR Bearingless Pump

- First disposable centrifugal blood pump based on bearingless motor design
- No bearings, No seals, No wearable components
- Magnetically levitated rotor
Underside of pump after 11 days of support

Terumo Duraheart: actively controlled rotor position
Berlin Heart Incor:
Axial Flow pump with actively controlled rotor

Third Generation:
Magnetic bearing combined with hydrodynamic stabilization
The VentrAssist RBP

- radial flow device
- no seals, shaft or contact bearings
- hydraulically suspended impeller Ø40 mm
- specific speed = 18.4

HeartWare® - HVAD
HeartWare® - HVAD

Controller with monitoring and trend data storage (up to 1 months of trends and event loggings (current, flow pattern, supply voltage etc); Battery with loading status and history storage.

HeartWare® - HVAD

Monitoring Laptop for pump adjustment and alarm setting, trend data display
In 1998, fully implantable rotary blood pumps became available in the clinical arena for long term clinical use. The new situation of small, implantable, valveless systems with continuous flow brought up a boom of questions, which could only partially be answered before in animals, concerning:

- implant technique,
- optimal pump adjustment and postoperative management,
- physiological compatibility of “pulseless” flow,
- rehabilitation of patients and requirements for discharge from hospital
- diagnostics and procedures specific for rotary pumps.

**Micromed-DeBakey:**
**Fully implantable rotary Pump, 1st Implants in Berlin and Vienna 1998**

The Micromed™/De-Bakey Axial Blood Pump

- Titanium pump with inflow and outflow guide vanes, apical inflow cannula, implanted subdiaphragmatically
- Driven by a brushless DC-motor, which couples directly magnetically to the pump rotor, with manually adjustable speed.
- Pump flow measured with an implantable ultrasound flow probe.
Micromed™/De-Bakey – LVAD:
Arrangement of pump, flowprobe, controller and power supplies

With axial pumps, the operating field can be kept small!

Continuous Flow ≠ nonpulsatile flow!

Pump flow stays somewhat pulsatile due to remaining heart contractility. Pulsatility usually increases during recovery.
Low aortic pressure pulsatility:

We proudly came up to the standard ward with the first patient. He was the worldwide first recipient of a rotary blood pump without any catheters!

But after only two hours, we got a call of the nurse:

**How should a measure blood pressure?**
**The cuff method does not work, I do not hear a pulse!**

Solution: Distal measurement of arterial flow with a handheld ultrasound probe (like in vascular diagnostics of peripheral perfusion).

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Blood Pressure Monitoring at low arterial Pulsatility with a Wristwatch Blood-Flow-Detector

**Wrist-Watch Ultrasound Detector**

**Arrangement for Riva-Rocci-Cuff-Measurement**
**Automatic System with Microcontroller**

(Prototype with external Ultrasound System)

**Signal Analysis:**

1. Cuff inflation
2. Slow cuff deflation
3. Determination of flow recurrence point and flow signal validity…
4. …results in determination of systolic pressure
5. Cuff pressure release
Results:

Correlation of Pressure with invasively measured systolic pressure:
\[ \Delta P = 2.6 \text{mmHg}; \quad r = 0.93 \]

Correlation of Heart rate with rate measured by ECG:
\[ \Delta HR = 2.5 \text{ bpm}; \quad r = 0.98 \]

......343 steps to the top of St. Stephan’s Cathedral......
Back to nearly normal life:

Data Reported by Home Patients:

**Hemodynamics:**
- AoP
- Heart frequency

**Pump:**
- Performance (flow, power, speed)
- Alarms (caused by pump and handling)

**Anticoagulation:**
- INR (either home or laboratory data)

**Others:**
- Body temperature (indicator for infection)
- Body weight (indicator for fluid balance)
- Subjective feeling (ranking 1-5)

* Noted twice daily; & daily; * On demand; # by E-Mail

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Do we still need physiologically responsive control?

Yes, we do:
- to adapt to changes in aortic pressure,
- to adapt to changes in fluid balance and circadian rhythm,
- to adapt to sudden changes in homeostasis (sitting up, standing up, coughing, Valsalva-Maneuver),
- to maximize available flow in case of impaired right heart contractility, without impeding the right heart functionality,
- to react to persistent suction, which may not only damage blood and the intra-ventricular wall, but additionally cause right heart failure due to septum shift and subsequent tricuspid insufficiency.

A control system has to provide:
- proper adaptation to venous return and physical activity;
- safe and robust performance,
- adaptation to special conditions in the pathologic patient (such as arrhythmia, collapsible septum),
- minimal sensor requirements, limited to long-term stable signals,
- minimal and simple settings by the physician to adapt to individual patients should be necessary.

We chose an approach, which is based on determination of venous return and on heart rate. Additionally, a very reliable detection system for eventual suction was developed.
Analysis of flow patterns for eventual suction:

1. Extraction of pattern properties in the time domain;
2. Design of a decision system, which uses these properties like a human expert.

MeanMinMax Criteria

Mean-, Min- and Max-Pump Flow are evaluated between two local minima.

Low Flow Criteria

- Mean Flow < $a_1$ [l/min]
- $P2P < a_2$ [l/min]
- $a_3$ [l/min] < Flow < $a_4$ [l/min] for more than 300 ms
- $a_1, a_2, a_3, a_4$ … Threshold values
**Plateau Criteria**

A flow decrease after a plateau situated at the top of a flow peak will be detected as suction if a consecutive increase in pump flow can be observed.

**Saddle Criteria**

A significant flow decrease followed by a phase of low flow changes will be assessed as suction if a consecutive flow decrease occurs.

**Asymmetry Criteria**

The calculation of the asymmetry criteria is based on the determination of local flow minima. Suction will be assessed if the falling arch of one flow peak is much steeper than the rising one.

**SlewRate Criteria**

Suction is assumed if the slew rate of a falling edge exceed a threshold level of 60 l/min/sec. Certainly the slew rate criteria and the asymmetry criteria yield to the same result.
Development of a reliable suction detection system based on beat-to-beat analysis of the pump flow signal

- Definition of distinct indicators for Suction Based on Clinical Experience
- Approx. 1000 data records from 100 patients
- Calculation of Algorithm Results for all Data Records
- Classification of Data Records
- Selection of the most efficient algorithm combination based on numerical optimization

Classification of Data Records

- Snap 1
- Snap 2
- Snap 3
- Snap n-2
- Snap n-1
- Snap n

Algorithm n
Algorithm n-1
Algorithm 2
Algorithm 1

Threshold Values = 
\[ \begin{array}{cccc}
1 & b1 & \ldots & h1 \\
b2 & \ldots & e2 & \ldots & f2 \\
\vdots & \ddots & \ddots & \ddots \\
b5 & \ldots & e5 & \ldots & f5 \\
b6 & \ldots & e6 & \ldots & f6
\end{array} \]

Evaluation of the algorithm results for the whole data set at different threshold levels

Results of the individual algorithms at different threshold values
Algorithm Combination:

\[
\begin{array}{cccccc}
\text{ALGO 1} & \text{ALGO 2} & \ldots & \text{ALGO n-1} & \text{ALGO n} \\
0 & 0 & \ldots & 0 & 1 \\
0 & 0 & \ldots & 1 & 0 \\
1 & 1 & \ldots & 1 & 0 \\
1 & 1 & \ldots & 1 & 1 \\
\end{array}
\]

Evaluation of the Optimization Criteria for all threshold combinations of the involved algorithms.

Results of the individual algorithms at different threshold values.

Evaluation of the optimization criteria for all permutations of the threshold values at every algorithm combination.

Algorithm combination and related threshold values, which are best concerning the Optimization Criteria.

Applied Optimization Criteria:

\[ \text{Opt}_1 = \text{FalsePositive} + \text{FalseNegative} \]

\[ \text{Opt}_2 = (a_1^*\text{FalsePositive}) + (a_2^*\text{FalseNegative}) \]

\[ \text{Opt}_3 = \text{FalsePositive} \]

\[ a_1, a_2 \ldots \text{weighting factors} \]

ROC-Diagram of the Optimization Results

In the chosen optimum compared to the expert decision of the 784 relevant pattern 4 were classified false positive and 6 false negative.

From the set of the certain expert decision (Type 1,5) only 1 file was classified false positive.

Mal-detection distribution of four different algorithm combinations.
- Adjusts speed to obtain a desired flow;
- In case of sufficient venous return, a target desired flow depending on heart rate is achieved;
- In case of lack of venous return (suction indicated, too low flow P2P-amplitude), the maximal possible flow is achieved.
- If the maximal possible flow falls below a certain level, a fail-safe mode is activated.

Vienna-Micromed-Control: Physician Settings:

The physician sets (depending on patient condition, on venous oxygen saturation, lactate etc., eventual weaning) a desired flow level for rest and exercise, and the heart rate for rest and exercise.

He further sets a certain minimal acceptable flow level, at which automatic control should be left.

Finally he may set a level of ventricular unloading in case of diminished venous return.

Further preset boundary safety conditions include minimal/maximal speed and maximal power.
- In the ICU, maximal possible cardiac output may be desired, independently of heart rate: Just set one heart rate and a high desired flow;

- To protect the right ventricle, flow may be desired limited: Just set a low desired flow value;

- To allow maximal exercise capacity, just set a high desired flow level at exercise;

- To train the ventricle for weaning, just set a low desired flow level.

This setting can be easily done to fit to all patient conditions!

The “Landscape of control”:

Depending on speed, time, subjective changes like exercise, coughing, pressing etc. the relation of speed and P2P-Amplitude of waviness changes. The system should try to stay in the optimal working point, where some peak-to-peak-flow waviness remains at the “good side”. This is done by efficiency optimization.
The limited Observability of the “Landscape of control”:

Due to the limited number of speed modifications and the necessity of filtering, only a small part of the control landscape is known to the system. It must therefore rely on local changes of the environment and react proper to local alterations.

Implementation:

Algorithms were developed in Matlab®, implemented in a PC-Environment with dSpace® signal processor card. For control, the PC uses only the information available in the pump controller (flow, speed, current) and generates a speed signal, which is transferred to the controller.

For safety reasons, beside other measures, the system could be switched immediately to standard manual mode by a clinically experienced supervisor.
Clinical Feasibility Study:

To prove the safety and functionality of the system, 57 tests were done at three different settings for up to 3 hours:

a) During ICU stay at rest and standard routine like mobilization, cleaning of respiratory tract, change of bed-linens;

b) At the standard ward and after hospital release mimicking daily life conditions for 3 hours: Laying, sitting standing, coughing, Valsalva, eating, walking around. This series included also repeated bicycle exercise (5 minutes bicycling, 5 minutes rest) with blinded evaluation of the subjective reactions to control/non-control.

c) At right-heart catheterization (required for pretransplant evaluation), spiroergometry with non-controlled versus controlled load cycles was performed.

Results of the feasibility study:

- The system remained stable also under conditions of extreme arrhythmia (up 240% variation), very thin septum and suddenly diminished venous return.

- The system did take proper action in case of sudden events like Valsalva, coughing, and change of position.

- No switchover to manual mode was required in any test.

- Suction did occur very rarerly and short, and was never identified by the patient himself.
Various bicycle exercises at 40 W during 5 minutes

Research Group on Cardiovascular Dynamics, Univ. of Vienna, Austria

MicroMed, Houston TX, USA

Constant Speed Physiological Control System

Nonfiltered data at arrythmia:

Zentrum für Biomedizinische Technik und Physik

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Test Protocol, Catheter Ergometry

Four patients received right heart catheter exercise tests, one in constant speed mode and one in controlled mode with a break of 45 minutes between:

1) Preparation for exercise and recording of baseline parameters
2) Warm up: 5 minutes bicycling without load
3) Exercise: 5 minute steps of 25 Watt, 50 Watt, 75 Watt, until Respiratory Quotient RQ ≥ 1.1
4) Cool down: 2 minutes bicycling without load
5) Recording of final haemodynamic values at rest after 5 minutes

Patient Monitoring for catheter-ergometry:

1. Swan-Ganz-Catheter: CVP; PA; PCWP; CO
2. Invasive Arterial Blood Pressure Measurement
3. Spiro-Analysis: Oxygen uptake, Respiratory Quotient
4. DeBakey VAD®: Flow; Speed; Current
5. ECG
Conclusions:

- The algorithm proved safety, reliability, stability and functionality also in patients with massive arrhythmia, very thin septal wall, and intensive care conditions;

- The system did properly react to physical exercise, with a massive increase of flow, compared to the low intrinsic flow increase at constant speed.

- In catheter-ergometry, pulmonary arterial (mean -26%) and wedge pressure (mean -50%) could be significantly reduced.

- In catheter-ergometry, the control system could increase the physical capacity up to 17% (mean 10%).

- In first blinded tests (which already exceeded the feasibility scope of the study) patients did report some subjective increase of wellness even in short exercise periods.
Assessment of cardiac contractility during rotary blood pump support using an index derived from pump flow

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Background

With the increasing number of clinical applications of rotary blood pumps (RBPs), the remaining contractile function of the heart comes into the focus of interest. This is particularly important for approaches to recovery and explants of RBP, but also for cardiac protection in long term implants.

Determination of cardiac function under ventricular support is challenging: Standard contractility indexes can only be partially applied (due to continuous unloading), and can be determined only from time to time (due to complexity of the measurement procedures).
Aim of the Study

To develop a parameter for assessing contractility of the heart, which is independent on preload and afterload, and which can be determined frequently from already available data.

A good contractility index has to be:

• sensitive to changes in myocardial properties
• insensitive to changes in preload, afterload, heart rate
• simply accessible
Selected classical cardiac contractility indexes

- Preload-recruitable stroke work (stroke work vs end-diastolic volume):
  \[ PRSW = \frac{SW}{EDV - b_0} \]  
  (Glower D et al. Circulation 1985)

- Left ventricular dP/dt_{max} vs end-diastolic volume:
  \[ \frac{dP}{dt_{max}} \cdot EDV = \frac{dP}{dt_{max}} \frac{EDV}{c_0} \]  
  (Little WC Circ Res 1985)

Disadvantage of these indexes:
Additional (invasive) measurement required

Proposed pump flow derived index (IQ)

Values accessible from flow signal:
1. Maximal derivative of pump flow (dQ/dt_{max})
2. Peak to peak pump flow (QP2P)

Advantage of IQ-index:
*Moderate speed variation required for a_0
A flow signal (either measured or derived) is available in most of the pumps. It can be easily assessed continuously in RBP recipients.
Computer simulation

Cardiac contractility
(100% 60% and 30% of E_max)

Preload conditions by increasing end-diastolic volume (EDV)

Afterload conditions by increasing systemic vascular resistance

Rotary blood pump
(8-12krpm)

Cardiovascular model
with rotary blood pump

LV-pressure
LV-volume
Pump flow

Model Inputs → Simulation → Model Outputs

Indexes from simulations in different preload, afterload, and contractility during RBP support (mean ± SD)

Step1: Normal contractility (100%)
Step2: Reduced contractility (60%)
Step3: Reduced contractility (30%)

Conditions: afterload (1x, 1.5x, and 2x of systemic vascular resistance), and preload (110, 120, and 130 ml, EDV) with different contractility (100%, 60% and 30%)

→ Similar trends of the new flow pattern index (I_Q) as classical indexes
% change of indexes in different preload, and afterload (computer simulations)

Conditions: afterload (1x, 1.5x, and 2x of systemic vascular resistance), and preload (110, 120, and 130 ml, EDV)

→ Index changes less than 20% in different preload/afterload conditions

Acute animal experiments

- Implant MicroMed DeBakey VAD © in 7 healthy sheep.
- Adjust pump speeds:
  - 7.5-12 krpm
- Use pharmacological interventions to reduce and increase cardiac contractility.
  - Normal contractility
  - Reduced contractility (Verapamil)
  - Increased contractility & afterload (Noradrenalin)
Results: Cardiac contractility indexes from animal experiments (n= 7, mean ± SD)

Step1: Normal contractility  
Step2: Reduced contractility (Pathological case)  
Step3: Increased contractility (Recovery case)

→ Similar trends of the new flow pattern index ($I_Q$) as classical indexes

% change of indexes after heart rate change by pacemaker in animal experiments

→ $I_Q$-index is less sensitive to heart rate change than other classical indexes
Discussion (I)

• The I_Q-index was sensitive to contractility changes and only slightly sensitive to preload and afterload during RBP support in a similar manner as other classical contractility indexes.

• The I_Q-index was less sensitive than classical contractility indexes to heart rate changes induced by pacemaker.

• The I_Q-index does not rely on any geometric or volumetric assessment. It is not affected by artifacts created from LV-volume measurement.

Discussion (II)

• The I_Q-index can be easily continuously assessed in RBP recipients.

• However, for accurate determination of I_Q-index a sufficient frequency response of the flow signal is necessary.

• In the next step clinical data shall be analyzed.
Conclusion

The flow derived index, $I_Q$, is a useful parameter to continuously indicate cardiac contractility changes in patients with RBP support without additional measurements.
BACKGROUND:

In angiology, deadwater and stagnation areas particularly in vascular branches are considered to be at high risk for depositions and plaque growth.

Particularly the carotid bulb has been investigated in detail for flow conditions and risks of atherosclerosis.

With low-pulsatile flow as occurring in rotary pump recipients, recirculating areas may even persist during the whole cycle - as predicted by older twodimensional studies. This may have detrimental consequences particularly for patients with atherosclerotic preconditions.

Methods (I):

- Surface grids from carotid arteries provided by anatomical casts;
- Flow patterns derived by Ultrasound from standard patients and pump recipients, with interpolation for various degrees of assist;
Methods (II):

Numerical Simulation using:

• 49536 elements, with 420081 velocity nodes and 55601 pressure nodes
• Time-dependent, three dimensional Navier Stokes Equations;
• Assuming incompressible Newtonian Fluid;
• Boundary conditions with fully developed flow-field and no-slip-condition at the surface;
• Solver using a Finite Element Galerkin Method, with Picard relaxation, based on a biconjugate gradient solvation, assuming a convection dominated problem, Stabilization, upwind method: streamline upwind Petrov-Galerkin.

Local velocity profiles without support:
Local velocity profiles at high support:

Peak wall shear stress:
Summary of Results:

• The maximal extent of the recirculation area depends on the waveform;
• Secondary flow patterns in the transversal plane provide considerable washout also at low pulsatile conditions: This effect is even more pronounced in non-planar bifurcations;
• Particle residence time does not differ considerably between pulsatile and supported conditions;
• Peak wall shear stress values differ considerably between the different degrees of pump support;
• Mean wall shear stress is very similar for all conditions at all locations.
Many thanks to:

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- our department head: Prof. Wolner
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- Micromed Company, particularly Dallas Anderson, Bob Benkowski, and Gino Morello
- the Patients and their Relatives
  and last not least my Family!