Chapter 1:
Background and aim of this thesis

The Pulsatile Catheter (PUCA) pump is a transarterial blood pump that can be used as a Left Ventricular Assist Device (LVAD). The basic concept of the device was published by Hans Zwart in 1966, when he described in his thesis a closed-chest LV bypass in dogs. According to the original set-up, the inflow cannula is inserted into the LV via the right carotid artery. The blood is pumped back to the systemic circulation via the femoral artery with a roller pump. The system was tested in healthy animals as well as during experimental LV heart failure in dogs and sheep. The first clinical application of the device occurred in March 1970. Two patients received LV bypass due to intractable shock for respectively 11 hours and 5 ½ hours. The inflow cannula was inserted into the LV via the right axillary artery (first patient) or via the right subclavian artery (second patient). Although the circulation improved, both patients died from massive gastrointestinal bleeding.

Discussing the principle of Dr. Zwart’s assist device with Prof. Dr. W.J. Kolff at the Laboratory for Artificial Organs Research (Salt Lake City, Utah, USA) in 1990, Dr. G. Rakhorst sketched at the back of an envelope the concept of a new trans-arterial assist device (Fig. 1).

The device consisted of a single catheter with an integrated valve system that aspirated blood from the left ventricle and ejected it into the ascending aorta. A new concept for LVAD was born!

The PUCA pump project became a part of EUREKA project EU 68211 (formally 68210) “Trans-Arterial Blood Pumps”, accepted in April 1992 by the High Level Group at the Helsinki Meeting. The aim of this project was the development of specific blood pumps that can be applied under emergency conditions without the need for major surgery. Trans-Arterial Blood Pumps were defined as catheter-type blood pumps that can be introduced into the left ventricle, through a superficial artery, to support patients suffering from a heart failure. When this EUREKA project started two pump concepts were under investigation: the PUCA pump and the electro-magnetical axial blood pump (Helmholtz Institute Aachen, Germany). Because the last pump was in a rather premature state of development, the PUCA pump was selected as main target of this EUREKA project.
The PUCA pump project was financially supported by the Netherlands and Swiss governments, and by the Dutch Heart Foundation (Nederlandse Hartstichting). Although the German government had decided not to contribute to this project, some German universities and companies participated in this European research project.

The European cooperation between research institutions and industries allowed a multidisciplinary approach of this medical-technological project. The external driving system was developed by the Swiss experts (Ecole Polytechnique Fédérale de Lausanne), the membrane pumps were developed by the German participants (Helmholtz Institute Aachen; Berlin Heart GmbH, Free University of Berlin, Polymedica Aachen), and the valves and catheter were developed by the Dutch participants (Cordis Europe NV, Roden; Holland Biomaterials Group, Enschede; University of Groningen). All in-vitro and in-vivo tests for the various components have been performed by the research team of the BioMedical Technology Centre (BMTC) of the University of Groningen. Most of the partners from the feasibility phase (1992-1994) of the EUREKA project participated in the research phase (1994-1998).

The first dual valved PUCA pump prototypes were built in 1990-1992 by Prof. Dr. W.J. Kolff (University of Utah, Salt Lake City, USA) and by Prof. Hennig (Free University of Berlin, Germany). The American prototype was made from a standard reinforced venous cannula for extracorporeal circulation (ECC) with build-in valves and was driven by a single-port membrane pump connected to a pneumatic driver. The German prototype was made from a standard non-reinforced venous cannula
for ECC and was pneumatically driven as well. The first prototypes of thin walled catheters were produced in 1993 by the Cordis company (Cordis Europe NV, Roden, the Netherlands). These catheters were not flexible enough and were easy to kink. Fixation and cutting of the used stainless steel reinforcement wires (up to 64 per circumference) was difficult. Because of these complications the Cordis catheters were never tested in-vivo. When Cordis decided to leave the EUREKA project, because of the fact that it would take the company too much financial efforts to develop a large bore thin walled catheter, the faculty workshop produced from 1993 until 1994 catheter prototypes from commercially available non-reinforced PVC tubes with build-in valves. These prototypes were used in several acute animal experiments to test the functionality of the PUCA pump concept. Unfortunately, the PVC became rather soft after the introduction into the arterial system, which led to a difficult positioning of the catheter into the left ventricle.

The first thin walled valved polyurethane catheter was developed by Günther Brinckmann, a German student from the Fachhochschule Wilhelmshaven. With his manufacturing technique PUCA catheters were produced from 1995 until 1997 at the faculty workshop. All prototypes were made from stainless steel reinforced Estane 74 A (B.F. Goodrich, Cleveland, OH, USA) using a vertical dipping method (patent pending). Two versions were developed: relatively short (400 mm length) and large bore catheters (8 mm diameter) for aortic or axillary artery approach, and relatively long (1200 mm length) and small catheters (6 mm diameter) for femoral artery approach. Both versions had a wall thickness of 0.3 mm.

Since 1998 the latest version of the PUCA catheters have been produced at the Division of Artificial Organs, Department of BioMedical Engineering of the Faculty of Medical Sciences. The catheters that are made from Ni-Ti reinforced Tecothane® (Thermedics, Inc., Woburn, Mass., USA), are 40 cm long and have 7.4 mm inner diameter. The Ni-Ti alloy makes the catheter very flexible and easy to introduce. The catheter’s tip is coiled to prevent obstruction during blood aspiration and to allow easy introduction into the left ventricle. To avoid blood coagulation caused by interaction with the internal and external surfaces of the assist device, a special Heparin coating developed at the University of Twente (Enschede, the Netherlands) can be applied.

Until 1998 separate inflow and outflow valves were positioned in the PUCA pump prototypes (PUCA-I) to guide the blood from the left ventricle towards the membrane pump and from the membrane pump towards the aorta.

The single valve version of the PUCA pump (PUCA-II) was developed in 1998 by students from University of Twente and from the Hanze Hogeschool in Groningen.
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The PUCA-II has a miniaturized combined inflow/outflow valve (patent pending), positioned twelve centimetres from the tip. The proximal end of the catheter is integrated in a connector that enabled a tight connection between the catheter and a 60-ml stroke volume single-port membrane pump (Polymedica, Aachen, Germany). The pump can be pneumatically activated by the UTAH Heart driver (Artificial Heart Research Laboratories, Salt Lake City, USA), the Intra-Aortic Balloon Pump driver (Datascope Corp., Oakland, N.J., USA), or by the MEDOS VAD driver (MEDOS Medizintechnik, Stolberg, Germany). The PUCA pump is ECG-triggered. In case of severe cardiac arrhythmia or signal disorders, the pump driver switches automatically to an untriggered mode. Prof. Dr. M.H.J. Brouwer (University Hospital Nijmegen, The Netherlands) demonstrated in animal experiments that the device can be used not only as a LVAD during open chest conditions, but as a RVAD as well.

Aim of this thesis

The work described in this thesis started in 1994 as a part of the developments described above. At the onset of this thesis, the aim was defined as:

- To develop a good functioning PUCA pump prototype.
- To develop an easy, fast, and safe surgical introduction technique for the PUCA pump.
- To test the PUCA pump prototypes in vitro and in vivo (healthy animals).
- To develop a large animal model of acute ischemic left ventricular heart failure that can be used to assess the influence of the PUCA pump on the heart and circulatory system under realistic conditions.

References