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Implantation Forces and Anatomical Fit of Medtentia Annuloplasty Ring in Porcine Hearts

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Medtentia annuloplasty ring (MAR) is an implant for mitral valve repair using a helix ring concept developed by Medtentia International ltd. This helix ring implant takes on mitral annuloplasty with a new perspective as it utilizes the anatomy of the valve and is easier to implant compared to regular annuloplasty rings. As the implantation procedure takes less time and can be performed with minimal invasive surgery, it brings a potential treatment form for patients for whom surgery is considered too risky today.

This bachelor's thesis was a part of Medtentia's research and development project to gain knowledge about the forces linked with the implantation of MAR. The initial problem had to with knowing when an expanded MAR should be implanted instead of the regular MAR. The measurement data was gathered by implanting various MARs and testers into porcine hearts while being attached to a digital force meter. The hearts used in the measurements were from pigs weighing from 180 to 250 kg. The measurements were performed at the Hospital district of Helsinki and Uusimaa in Meilahti research and development unit during the time period of 11/2012 and 1/2013. There were a total of 41 recorded measurements done on 6 porcine hearts.

The findings in this research are used in the ongoing development of MAR, its accessories and their implantation procedures. These include giving recommendations on the limit of the implanted mitral valves width when switching to an expanded option of MAR. Implantation procedure trouble spots and possible new solutions were added to the summary as well. The most concrete improvement was the calibration of the helix tester to simulate regular MAR better. An implantation slide that reduced implantation friction led to patenting.

Keywords	Mitral valve, cardiovascular system, force measurement, annuloplasty ring

Contents

Abbreviations

MAR	Medtentia annuloplasty ring
RBC	Red blood cell
WBC	White blood cell
RA	Right atrium
RV	Right ventricle
LA	Left atrium
LV	Left ventricle
SAN	Sinoatrial node
DLC	Diamond like carbon
MA	Moving average
SD	Standard deviation

1 Introduction

1.1 Backround

The mitral valve is a complex apparatus in which several structures work in synchrony to open during diastole and close in systole. Changes in just one of these structures caused by a congenital or acquired disease can lead to abnormal valve function and regurgitation of blood back into the left atrium causing loss of ventricular pressure and forward flow. In other words a leakage occurs in the mitral valve and every time when the heart tries to pump blood to the body a portion of it goes in the wrong direction. [1]

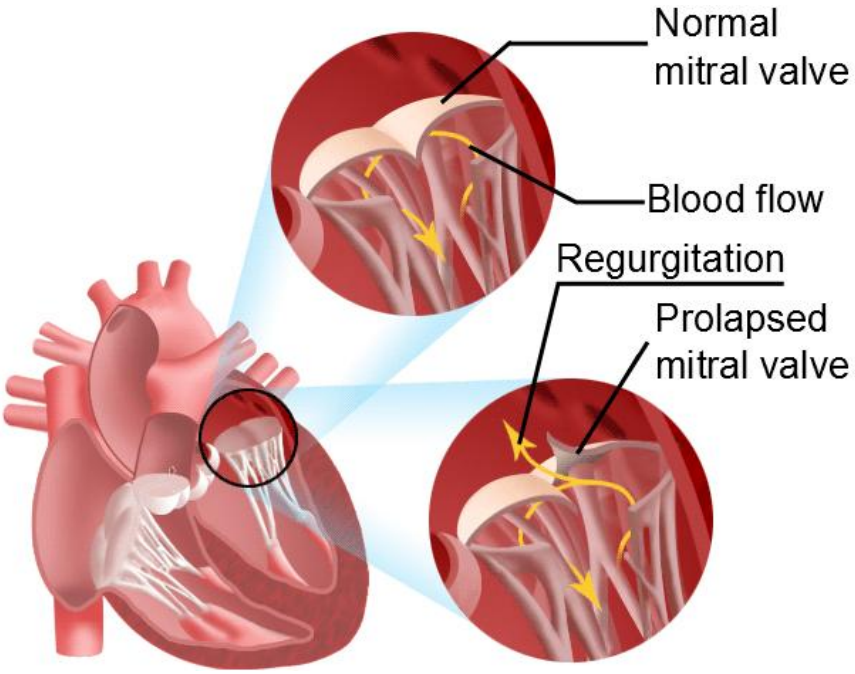

Fig.1 Normal and prolapsed mitral valve [2]

Mitral valve regurgitation is the second most frequent heart valve disease after aortic stenosis and it is increasingly prevalent. It can be caused by rheumatic fever or a heart attack in the muscle attached to the heart valve. Simply put a regurgitating mitral valve decreases the efficiency of the pumping action of the heart. When the blood flow does not meet the body's needs, the heart starts to compensate this by increasing the size of the left ventricle (LV); this means that the heart enlarges the cavity where the blood is before being pumped to the body. This can cause a downward spiral as a relatively common reason for mitral regurgitation is the enlargement of the LV. Other reasons for dilation can be caused by years of untreated high blood pressure, alcohol abuse or simply by a chronic leakage of the mitral valve. [3]

It is widely accepted that surgical repair for severe mitral regurgitation is the optimal treatment and should be performed when it is feasible. When compared with valve replacement, surgical repair has a lower perioperative mortality rate, improved survival rate, better preservation of postoperative LV function and lower long-term morbidity. The results of valve repair are also highly dependent on the experience of the surgeon. [4]

Medtentia International ltd. developed a helix-shaped mitral valve ring that is used for fixing regurgitation of a mitral valve. The implant's function and use are easy to learn as it is shaped so that the anatomy guides the implantation procedure. Simply put the Medtentia annyloplasty ring (MAR) reshapes and enhances the mitral valve without the need to dissect it. This entire procedure can be performed in a mini-invasive surgery that also implies shorter and safer surgery.

1.2 Research goals and methods

This research study was conducted to find out more about the forces needed to implant the MAR and what components contribute to the resistance. The secondary goals were to calibrate a testing tool to match the actual implant in friction wise and to determine the maximum mitral valve width when the regular MAR can be implanted. Additionally all improvements and trouble spots in the implantation procedure were identified. These measurements were conducted by implanting various Medtentia developed implants and testing tools into mitral valves of porcine hearts. The implantation of MAR and other implants were done while being attached into torque force meter, thus collecting the information of required force to perform the procedure.

Porcine hearts were chosen for the research as there is a general acceptance in literature that their anatomy is similar to the human heart. A form of pig-to-to-human xenotransplantation research has been taking place since the 1960's as bio prosthetic heart valve replacement. In this research the most important difference had to do with the very coarse trabeculations in porcine ventricles, which were much broader than those observed in human ventricles. This difference in the porcine hearts left ventricle wall had an effect on some of the measurements, but all noticed anomalies and other adverse factors were taken into consideration in the results. [5, 6]

1.3 Medtentia annuloplasty system

MAR and its accessories are developed to enable minimally invasive annuloplasty repair for humans on their native mitral valve. The technology is based on a helical ring with a shape that corresponds and utilises the mitral valve anatomy. The implantation is done by placing it to the posterior commissura and rotating it 360°.

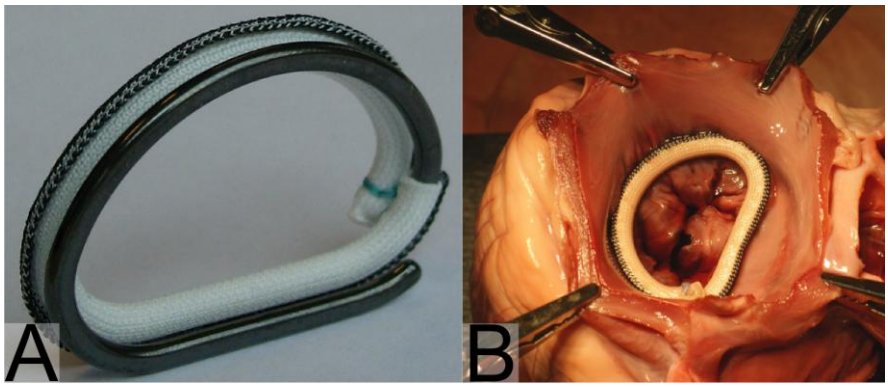

Fig.2 A.Regular MAR B.MAR implanted in a porcine heart.

Due to its straightforward functionality the implantation is easy to learn and perform as well as to suture into place. This means a shorter cardiopulmonary bypass time is required, which makes it possible to treat patients for whom surgery is considered too risky today.

Table 1. MAR technical data

#	Component	Description
1.	Medtentia Annuloplasty Ring	Sizes: 26, 28, 30, 32, 34, 36, 38, 40
2.	Helix Ring	Titanium (Ti6Al4V)
3.	Coating	Diamond-Like-Carbon (DLC)
4.	Fastening Textile	Polyester
5.	Sterilization	Ethylene Oxide
6.	Weight variation	3 g size 26 – 5 g size 40
7.	Width variation	30,9 mm size 26 - 40,9 mm size 40
8.	Orifice area variation	364,4 mm^2 size 26 – 855,3 mm^2 size 40

There are two types of MAR, the regular and the expanded. The difference between these implants is that the regular is for patients with normal leaflet thickness and the expanded is for thickened leaflets. Both of these rings come in eight different sizes which are chosen on the basis of the patient's annulus size. The Medtentia annuloplasty system is delivered in a tray which consists of the helix tester, sizer, leaflet measurement tool, handle and a nerve hook. The implants are delivered separately because of sterilization validation. Note the accessories shown in figure 3 are prototypes.

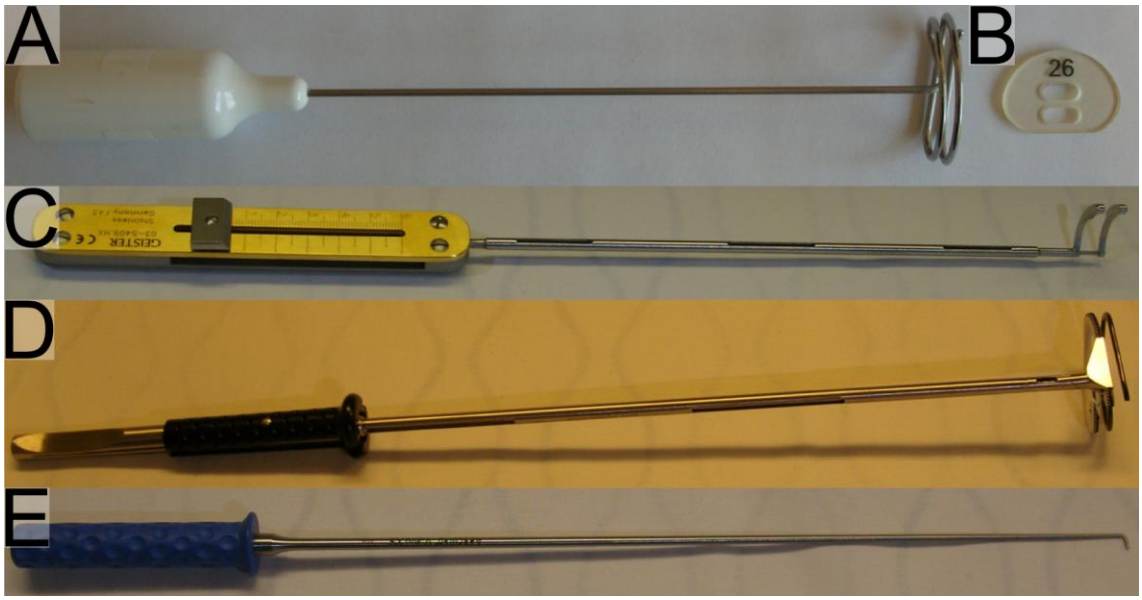

Fig.3 A.Helix tester B.Sizer C.Leaflet measurement tool D.Handle with new tester E.Nerve hook

The implantation of MAR can be done by using a median sternotomy, where the rib cage is opened from the middle or with a less invasive approach of minithoracotomy. In this minimally invasive surgery the operation is performed through a 5 cm incision on the right side of the rib cage with the help of endoscopic video-assistance. [7]

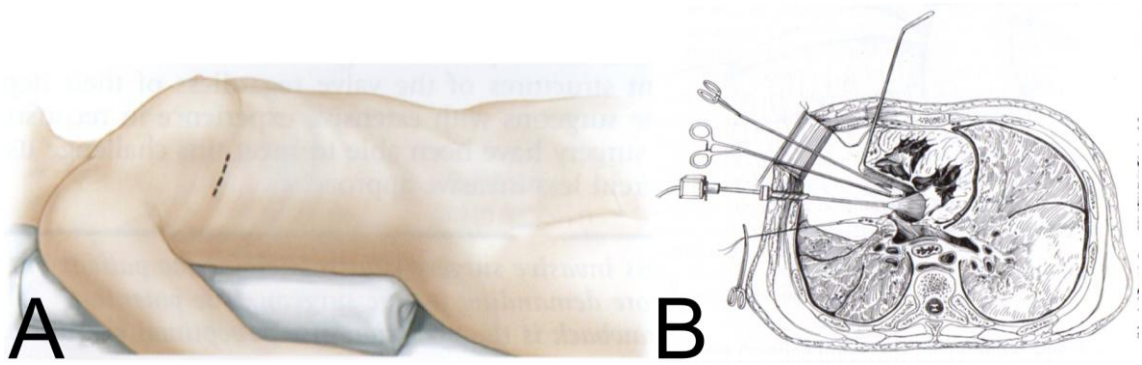

Fig.4 A.Right lateral minithoracotomy incision [7] B.Video-assisted micro mitral operation: Thoracic cross-section [8]

The mitral valve size is measured using the sizer and a regular surgical clamp. This gives the surgeon the size of the MAR to be used. When making the decision to apply a regular or an expanded MAR, the leaflet measurement tool or the tester can be used. After this the correct MAR is attached to the handle and positioned to the posterior commissura. MAR is inserted carefully by turning it 360° while making sure that none of the tendinous chords are left outside of the ring. The nerve hook can be used to help with the chords guidance.

When the implant is in its correct position the leaflets are pulled towards the center. This downsizes the annulus and adds more boundary surface between the leaflets. After this the annulus is fixated to the implant's textile with 12 to 14 sutures and the procedure is done.

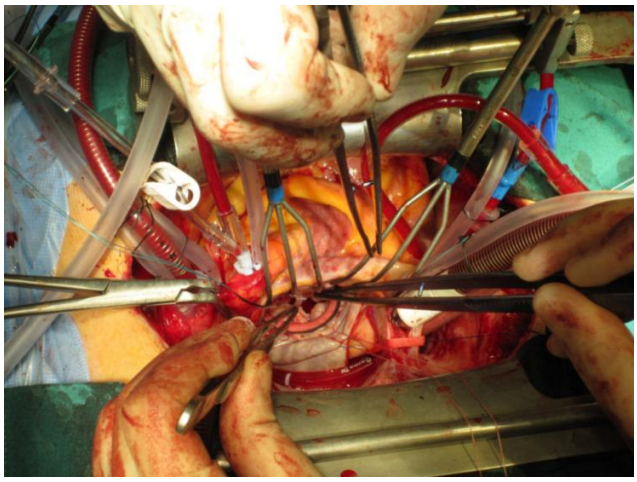

Fig.5 First human patient try out through median sternotomy. Meilahti, 30.06.2011

2 Literature review

2.1 Brief introduction to the cardiovascular system

In a multicellular organism such as a human being, different cells form tissues and organs, thus creating optimal life conditions for other cells. All cells require continuously energy for example to transfer nutrients, keep up their structure, grow and divide. When the supply of energy of a cell ends, it dies immediately. Only organisms with a diameter of a few millimeters can exchange nutrition through diffusion with its surrounding environment. This nutrition diffusion through the exterior surface does not work fast enough with larger organisms due to the longer distances to cells within the organism. For example nutrition to pass its way from the human intestines to the brain by diffusing through each cell on the way would take several years. Humans and other developed organisms have specialized systems to take care of the interaction with the body and environment as well as nutrition exchange. These include skin, digestive, urinary, and respiratory systems. For transferring substances between these systems and body's other cells, developed organisms have their own transfer system, which is the cardiovascular system. The autonomous pumping of the heart keeps blood flowing in the vessels transferring nutrition, substances and waste products within the human body. So if a substance becomes absorbed into the blood stream, it takes less than a minute for it to reach any organ in the body. Aside the fact that blood transfers nutrients and removes waste products, it plays an important part in regulating the temperature and the pH levels of the body as well. [9, 10]

An important part of understanding this system is knowing not only how it functions but also why it functions the way it does. This will give an understanding of the crucial parts of the system and what will happen when blood circulation ends. As said before all organisms require energy to be able to do mechanical work. For instance microorganisms need it to engulf food and humans to walk around. In a nutshell, we are powered by the oxidation of biomolecules made mainly off carbon, hydrogen and oxygen. The end products of the catabolism of food molecules are carbon dioxide, water and energy. Photosynthesis, the process where plants convert CO_2 and H_2O to glucose and O_2, is the reverse of the oxidation of glucose in humans. Basically oxygen is the chemical energy source to for us as solar energy is to plants. [11]

From an engineer's point of view the cardiovascular system could be described as a hydraulic system. This way of explaining will give a straightforward description of the system's functions rather than in dealing with anatomical and biochemical approaches. The main parts of this system are a double pump (the heart) and a pipeline (blood vessels) for the transfer medium (blood) to flow through.

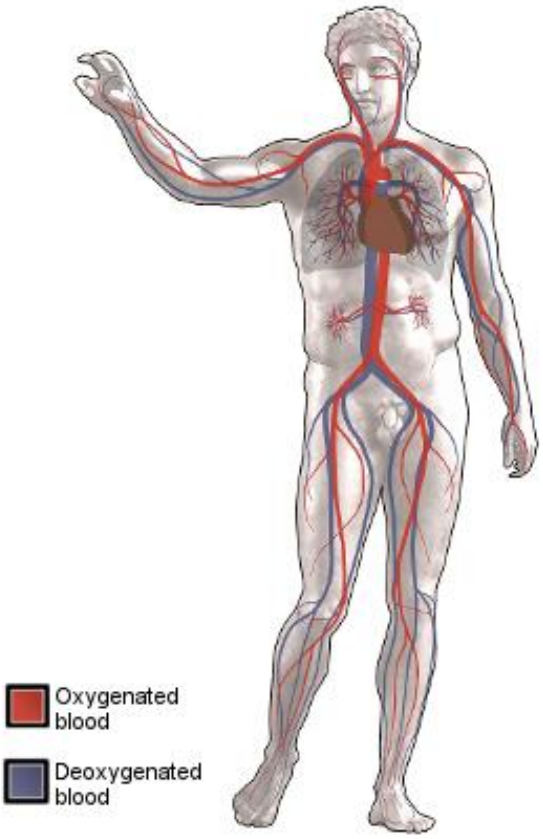

Fig.6 Circulatory system [12]

The entire system is broken down into three smaller circulations; pulmonary, systemic and coronary. The pulmonary circulation is the part where blood gets pumped from the right side of the heart into the lungs where it releases the CO_2 and receives O_2. After this the oxygenated blood drains into the left side of the heart.

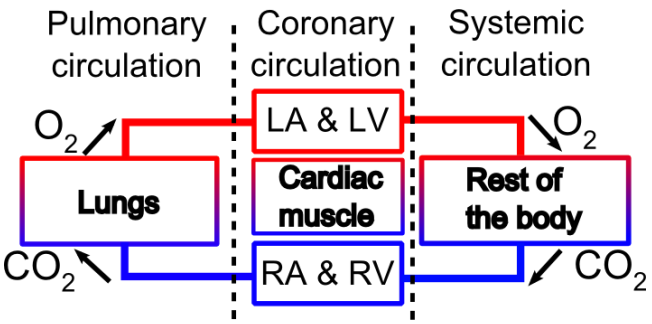

Fig.7 Three circulations simplified

The systemic circulation starts when the oxygenated blood gets pumped from the left side of the heart into the aorta. Since all of the “fuel” for the cells is pumped through the left side of the heart it is a very critical part of the entire system. From the aorta the blood gets divided through arteries to the body where it releases O_2 and receives CO_2, which drains through the veins into the right side of the heart and the cycle can start again. [9, 10]

The coronary circulation could be considered the most crucial of the circulations as it takes care of the heart muscle’s substance exchange, which then enables the other circulations to perform. As the heart keeps contracting all the time, it requires a continuous feed of nutrition and other substances. This feed comes through left and right coronary arteries which branch off from the root of the aorta. [9, 10]

2.2 Blood

There are approximately four litres of blood in an adult woman and five or more in a man. This volume of blood makes can make up 8% of the total weight of a human. Blood itself could be described as liquid tissue, as only a bit less than half of it is blood cells and the rest is plasma, which is 92% water. Plasma is the blood’s liquid transfer medium and because of its high percentage of water it also carries 70% of the carbon dioxide and other substances that cannot attach to red blood cells as well. [13, 10]

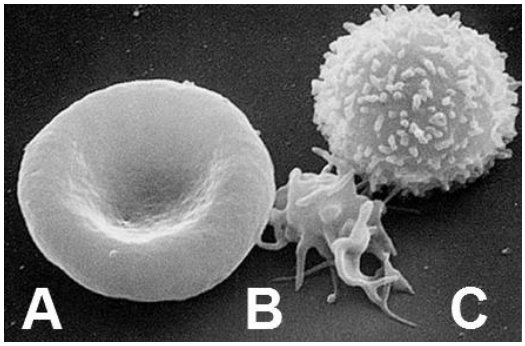

Fig.8 A. Red blood cell B. Platelet C. White blood cell (14)

Blood cells divide into three main groups; red blood cells (RBC), white blood cells (WBC) and platelets. RBCs duty is to carry oxygen (O_2) to cells and a part of the carbon dioxide (CO_2) back to the lungs for removal. Almost 99% of the oxygen intake is attached to the iron containing haemoglobin of the RBC. Hemoglobin makes up to 90% of the dry weight of a RBC and also gives blood its colour.

WBCs have important tasks involving the immune system of the human body. They only use the blood circulation as a transfer method to get into the parts of the body where an inflammation has occurred. Platelets are a part of the hemostasis process where they coagulate and clog the bleeding mechanically. [13, 10]

2.3 Blood vessels

Blood vessels could be placed into three categories; veins, arteries and capillaries.
Each type of these vessels has a unique physique and specific duty to perform in the cardiovascular system. Blood vessels that transfer blood away from the heart are called arteries and vessels that bring blood towards the heart are veins. Capillaries are the middle point between arteries and veins, where the particle exchange occurs with tissues. [9, 10]

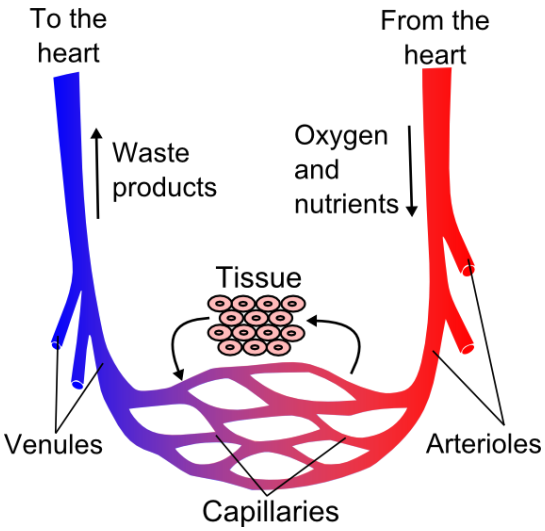

Fig.9 Blood vessel types

Each artery branches out into smaller and smaller blood vessels, thus creating a system which covers the body´s entire feed of oxygen. The smallest artery and vein are called an arteriole and a venule. Arterioles are made of three layers, in which the middle one is made of smooth muscle tissue. These sphincters control the blood flow into capillaries by expanding or contracting depending on the autonomic nervous system. [9, 10]

Veins and venules on the other hand do not contract or expand, but instead have an anatomical feature which allows the blood to flow only in one direction. This nature's check valve with the use of skeletal muscles creates a pump, which pushes blood towards the heart. This skeletal-muscle pump's function is shown in figure 10. Veins also work as a reservoir for 60% of the blood's total volume due to their low blood pressure. [9, 15]

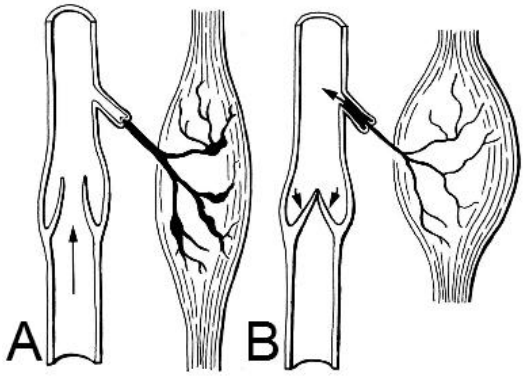

Fig.10 A.Muscle relaxed and valve open B.Muscle contracted and valve shut [15]

2.4 The heart

The human heart is basically a hollow muscle with four chambers and its main duty is to keep up the pressure inside the cardiovascular system. All mammals have this similar basic structure of the heart being a four chambered double pump. Left and right atrium (LA, RA) are the first chambers where the blood goes when entering the heart. Next and the last chambers for the blood to go are left and right ventricles (LV, RV). The right side receives deoxygenated blood from the body and pumps it back into the lungs. The left side on the other hand, receives oxygenated blood from the lungs and pumps it back to the body. [9, 10]

The heart beats regularly because it generates action potentials in the sinoatrial node (SAN) located in the wall of right atrium. This so called “pacemaker” generates itself action potentials that conduct to other parts of the heart through its electrical conduction system, thus contracting the heart muscle in a certain order. The autonomous nervous system controls SAN by delaying or speeding up its cells membrane potential depolarization. In other words.it controls the frequency of the action potential generation but not the order or speed of the heart muscle’s contraction. The action potential first makes the atriums contract and after a little pause the ventricles. In a normal situation the atriums contract 1/6 second earlier than the ventricles. This gives time for the ventricles to receive enough blood from the atriums. [9, 10]

Oxygenated blood comes from the lungs through the pulmonary veins and drains into the LA. On the right side deoxygenated blood comes through vena cava and drains into RA. When the atriums contract their size decreases and cause the blood to flow into the ventricles. Separating RA and RV is the tricuspid valve and between LA and LV is the mitral valve.

Before the blood is pumped away from the heart to the lungs or the entire body, it passes by the last valves. When RV pumps blood to the pulmonary artery, it passes by the pulmonary valve and when LV pumps blood to the aorta, it goes through the aortic valve. [9, 10]

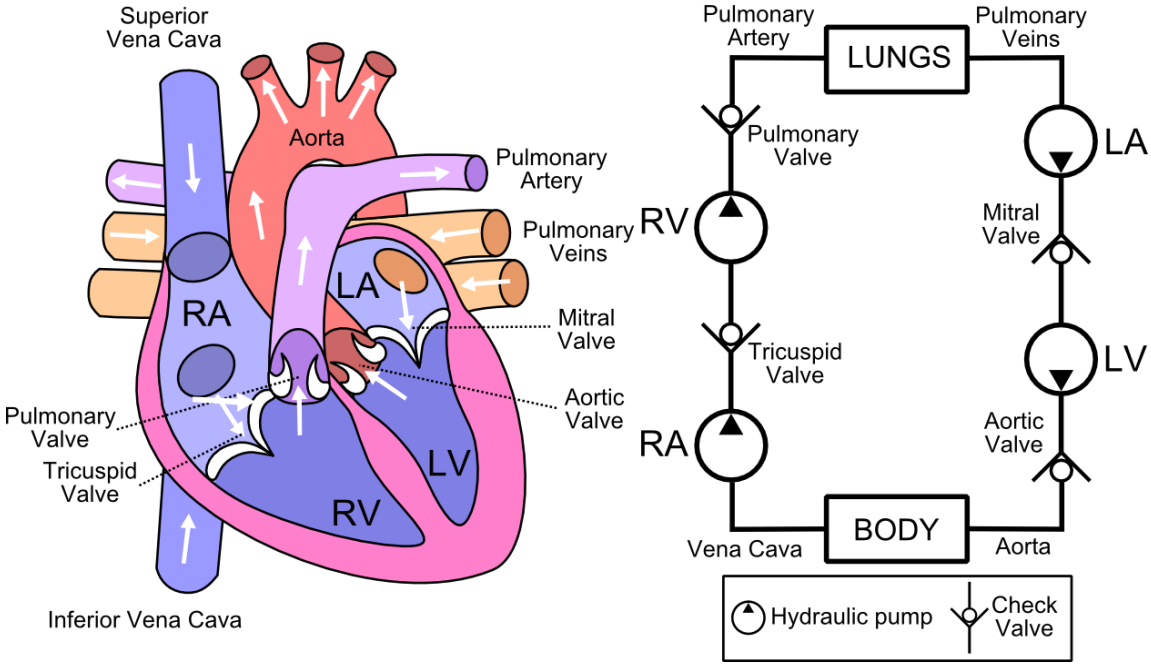

Fig.11 Anatomy of the heart [16] and its function presented with hydraulic symbols.

The valves are meant to prevent blood from being pumped in the wrong direction. Their anatomy is such that they open and close in accordance to blood pressure. An example of this mechanism could be a barn door closing on a windy day.

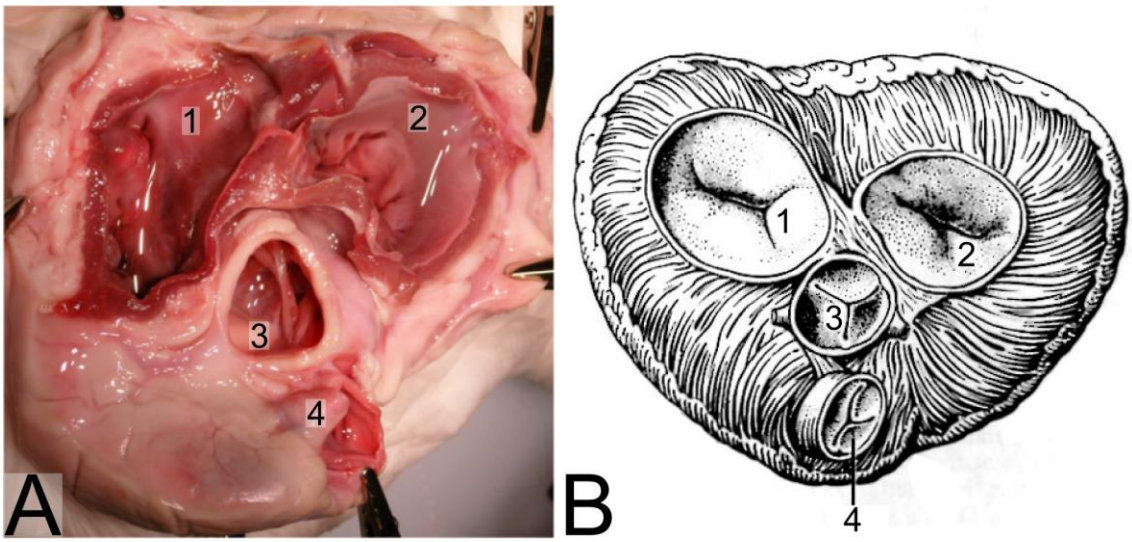

Fig.12 Fibrous base of heart without atria. A. Porcine heart from measurements B.Human heart [17] 1.Tricuspid valve 2.Mitral valve 3.Aortic valve 4.Pulmonary valve

Tricuspid and mitral valves prevent the blood flowing back in the atriums when the ventricles contract. Pulmonary and aortic valves prevent back flow from the arteries back to ventricles during the contraction of the atriums. [9, 10]

2.4.1 Mitral valve

The mitral valve's function in the heart is to prevent blood flowing back into the left atrium when the left ventricle contracts. This valve is very important because all oxygenated blood goes through the left side of the heart.

Mitral valve comprises of four basic components, which are annulus, leaflets, tendinous chords and papillary muscles.

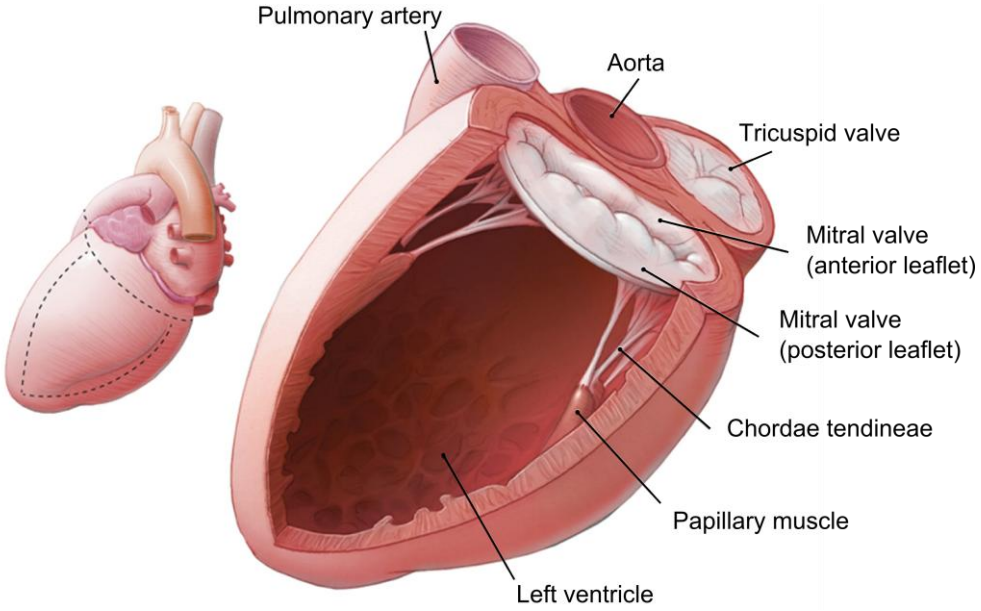

Fig.13 Components of mitral valve

Mitral annulus could be considered to be a fibrous hinge around the valve, which supports the mitral valve leaflets. The annulus shape and hinge position has shown noticeable variations, not only from heart to heart but also within the same heart. In an average mitral valve the annulus shape could be described as a "bean" shape and the hinge position right between LA and LV. [18]

The mitral valve consists of two leaflets which cover the entire surface of the passage way from LA to LV. There is no clear indication of the separation of the leaflets, thus there is no precise definition to distinguish leaflet clefts from commissures. The anterior leaflet takes up to 1/3 of the circumference of the annulus but still covers a half of the valve surface. In figure 14 the approximation of anterior leaflet is marked. [18]

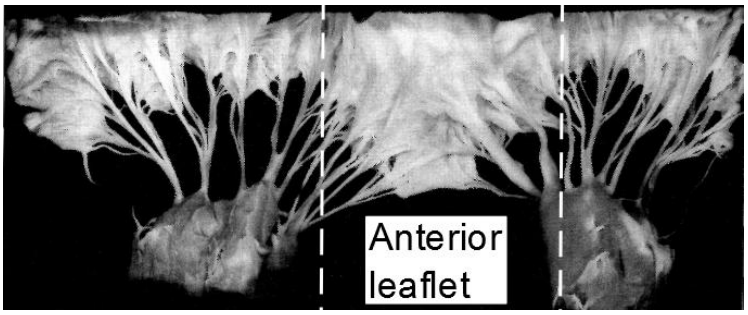

Fig.14 Human mitral valve spread open and viewed from the ventricular aspect [18]

The papillary muscles emerge from opposite sides of the ventricle septum and viewing from the atrium they are beneath the commissures. They divide into a variable number of heads, each working as an anchor for the tendinous chords. Normally these chords insert into the edge of leaflets but in some cases to the base, in which they are called basal chords. Together the papillary muscles and chords create the mechanism which closes the leaflets together when the LV is contracting. During ventricular systole the ventricle contracts and the papillary muscles shorten, thus pulling the leaflets and closing the valve. The figure 15 presents a normal mitral valve´s function. [18]

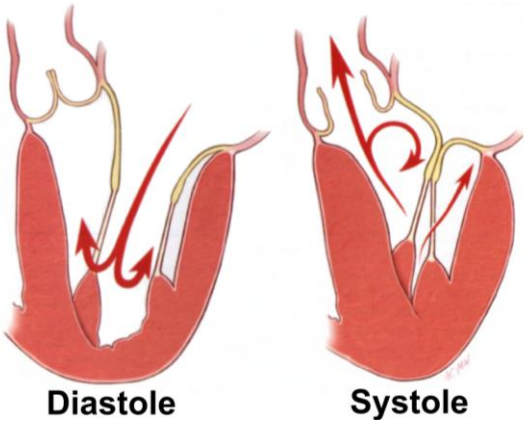

Fig.15 Mitral valve function during diastole and systole [7]

2.4.2 Mitral valve dysfunctions

Mitral regurgitation is a common valvular disorder which can arise from abnormalities of any part of the mitral valve apparatus. These abnormalities can arise for example from birth defects, heart's transient ischemic attack or from a rheumatic fever. The disease leads to a lesion in the valve, which enables blood to leak from LA back to the LA during a systole. This leakage starts to burden the heart as it starts to compensate for the loss of oxygenated blood in the body by increasing the size of the left ventricle. [19]

Diseases like congenital malformations, inflammatory diseases, trauma, tumors, myocardial infarction, endomyocardial fibrosis and many more can cause lesions affecting one or several components of the heart valves.

These lesions can be leaflet thickening and calcification, papillary muscle rupture and ventricular dilatation. Valve analysis is simplified with the functional approach, since it is necessary only to determine whether the motion of each leaflet is normal (type I), prolapsed (type II), or restricted (type III). This classification is helpful in recognizing the lesions that produce this dysfunction. [7, 20]

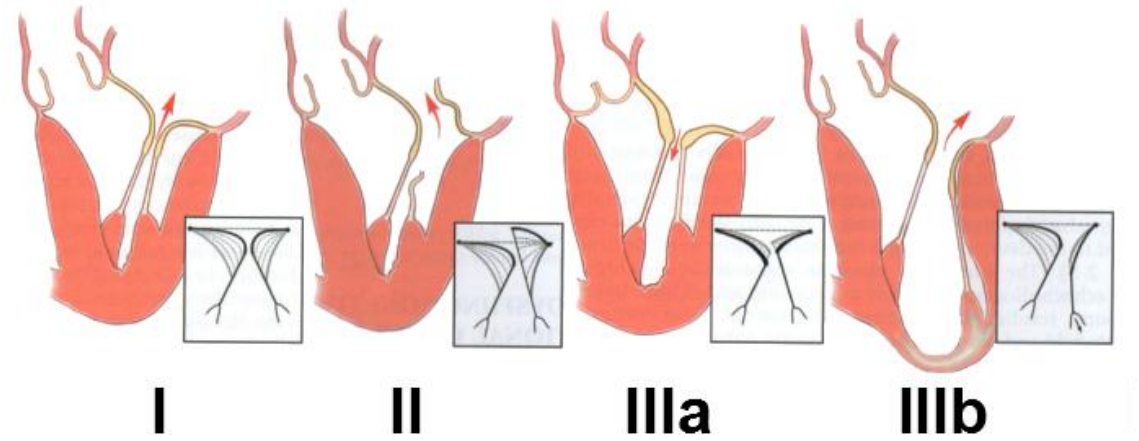

Fig.16 Carpentier's functional classification. I. Normal leaflet motion II. Excess leaflet motion IIIa. Restricted leaflet opening IIIb. Restricted leaflet closure [7]

2.4.3 Mitral valve repair

Alain Carpentier's "A new reconstructive operation for correction of mitral and tricuspid insufficiency" released in January 1971 set the standard for mitral valve repair that is still used today. Depending on the mitral valve condition the repair could be leaflet re-section, annulus downsizing with the use of an annuloplasty ring or both of these. In a leaflet resection the leaflet is re-shaped to cover the valve properly. The annulus down-sizing could be performed with a classic annuloplasty ring. The rings are usually kidney or oval shaped titanium rings with a textile covering them intended for suturing. The most noticeable differences compared to MAR is that the ring is put to the atrium side and attached by using a parachute suturing technique. This suturing technique takes more time and requires a skilful surgeon. [21]

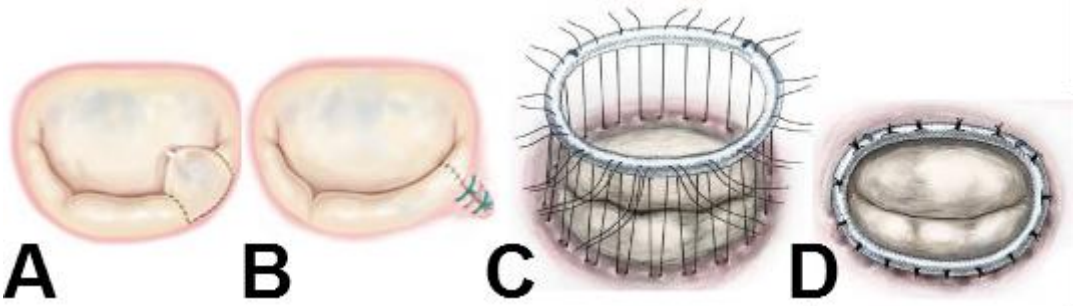

Fig.17 A.Quadrangular resection of posterior leaflet B.Leaflet edge reapproximation C.Parachute suturing technique D.Remodeling annuloplasty with a ring. [7, 22]

3 Physical theory

3.1 Torque

Torque, also known as moment, is the tendency of force trying to rotate an object about an axis from a perpendicular distance. So basically it is the turning force on an object such as a bolt but when examining this momentarily, it could be thought of as the force of leverage at the pivot point. The strength of torque comes from three quantities; the applied force, length of the lever arm and the angle between the force and the lever arm. The unit of torque is newton metre [Nm]. One newton metre is equal to one newton of force applied perpendicularly to a one meter long lever arm. In this thesis the measurements are done in newton centimetre [Ncm]. The measurement results vary around 10 Ncm, what is a 10 N applied to a 1 cm lever arm. To understand this force a little better, it could be explained as holding a 100g weight on your extended index finger. [23]

Cross product of force and length of lever arm

$$\vec{M} = \vec{r} \times \vec{F} \tag{1}$$

$\vec{M}$ Moment vector

$\vec{r}$ Lever arm length

$\vec{F}$ Applied force

In scalar form

$$M = rF \sin \emptyset \tag{2}$$

$\mathrm{F} \sin \emptyset$ Perpendicular force from the lever arm

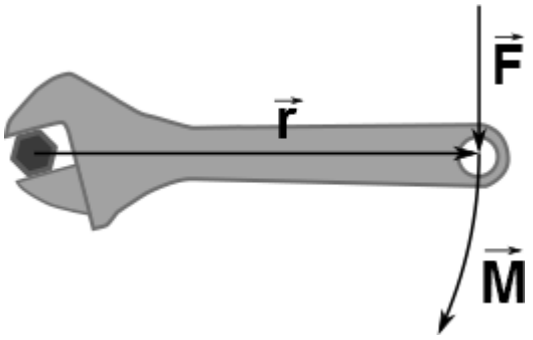

Fig.18 Illustration of torque and vectors

3.2 Friction

Friction is a force that prevents the sliding of two surfaces on each other and slows the sliding down. This force is calculated by multiplying the applied force perpendicular to the surface and the material's coefficient of friction. In these measurements the two surfaces were leaflet tissue and MAR textile, which were moistened with saline solution to reduce friction. [23]

3.3 Forces in measurements

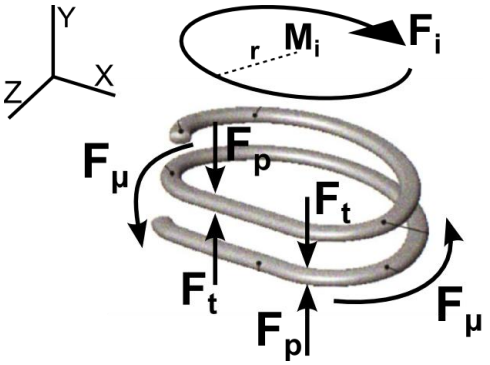

Fig.19 Force map of implantation procedure

Moment converted into force where lever arm length is the longest length from the center of MAR.

$$F_i = \frac{M_i}{r} \tag{3}$$

M_i implantation moment

r length from MAR's center to its most furthest part

Equation of when static friction is defeated in horizontal and vertical directions.

$$\begin{matrix} F_{xz} \\ F_{yz} \end{matrix} \begin{cases} F_i - F_\mu = 0 \\ F_p - F_t = 0 \end{cases} \tag{4}$$

F_i implantation force

F_μ friction between leaflets and MAR textile

F_p MAR's pressuring force

F_t leaflet tissue's pressuring force

MAR and mitral valve were in the same level in all of the measurements. Since there were so many variables in each measurement, a correlation between leaflet thickness and force was not calculated.

4 Implantation torque measurement

4.1 Introduction

The measurements were performed at the Hospital district of Helsinki and Uusimaa in Meilahti research and development unit during the time period of 11/2012 and 1/2013. There were a total of 41 recorded measurements done on 6 porcine hearts.

The hearts used in the measurements were from pigs weighing from 180 to 250 kg. The implantations were done with different size 30 MAR setups. This size was chosen for the measurements since it fits the mitral valve size of the porcine heart. Different MAR setups will be the regular MAR, helix tester, helix tester with textile and other prototypes. The collected data is used to research and identify factors that have an effect on the implantation forces and how to make the helix tester to correlate better with the regular MAR

4.2 Measurement plan

The data is gathered using a digital force meter, which is attached to the MAR holder during the implantations. The implantation procedure is ideally performed by a 360° turn of the ring into the valve annulus structure, but in these measurements the implantation is phased into two 180° turns. A simplified idea of the measurements can be seen in figure 20.

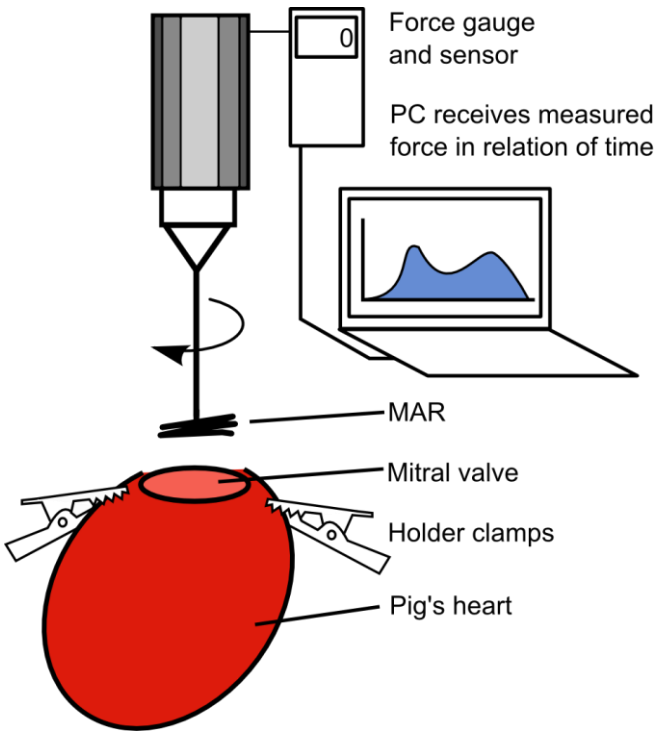

Fig.20 Measurement setup

4.3 Parts and tools

Table 2. Tools used in measurements and implantation

Part	Details
Digital torque gauge MARK-10 series M5i	sn: 3499454 calibrated: 25.10.2012
Torque sensor MARK-10 MR50-100	sn: 350021 calibrated: 25.10.2012
Mituytoyo Caliper CD-15CPX	sn: 09055237 calibrated: 11.05.2012
Laptop with MESURgauge software	-
Measurement table	prototype
Basic surgical equipment	-

Table 3. Parts used in implantation

Part	Name used	Details	Revision No.
MAR regular size 30	MAR regular	Regular MAR, w/o DLC	1
MAR regular holder size 30		sn: 14-30-007	1
Size 30 helix tester	Tester	Gap 2,1±0,1 mm	-
Modified size 30 helix tester	Modified tester	Gap 1,6±0,1 mm	-
Implantation slide		15 mm x 30 mm plastic sheet	-

The holder is attached to the force gauge using a ⌀2mm metal bar, which is wedged to the MAR holder. Figure 21 shows the metal bar wedged to holder.

Fig.21 Size 30 holder with the attachment bar

The regular MARs used in the measurement have not been tumbled and do not have diamond like carbon coating (DLC). These differences in the regular MAR are predicted to have a slight increment in friction but it will have an insignificant effect on the result.

4.4 Measurements

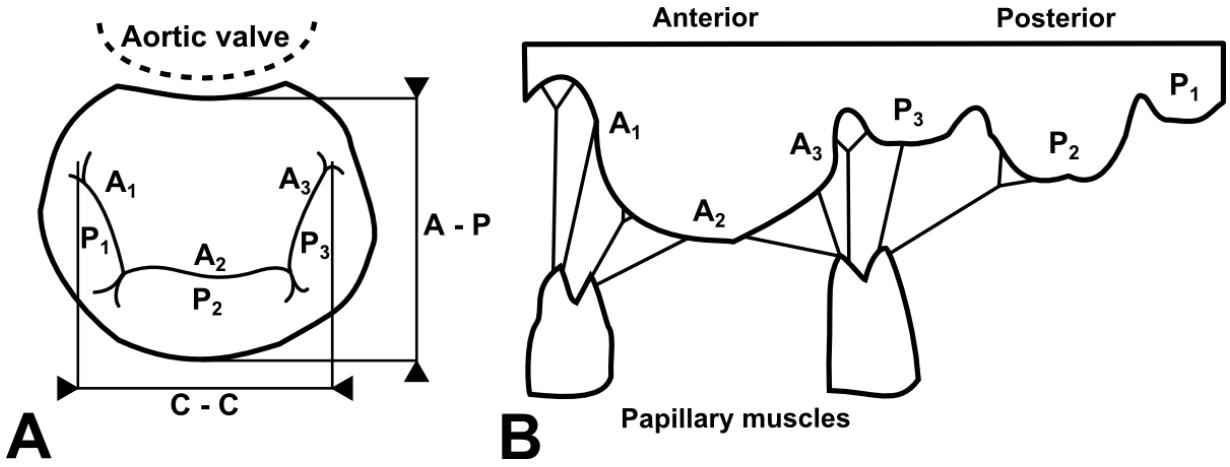

Fig.22 A. Mitral valve cross section B. Leaflets spread out

4.4.1 Annulus size

1. Measure lengths A – P and C – C from mitral valve
2. Size annulus and confirm the correct MAR size

4.4.2 Implantation

1. Position the implant´s starting point below P_3. See figure 22-A
2. Turn the implant into the mitral valve in phases listed below. After turn the implant in opposite direction while preventing the movement
    a. 0° to 180°
    b. 180° to 360°
3. Ensure that the implantation is done properly and all chords are inside the implant
4. Unscrew the implant from the mitral valve

4.4.3 Leaflet thickness

1. Measure leaflet thickness from positions A_2, P_2 and P_3. See figure 22-B

4.5 Procedures

4.5.1 Pre-preparations

1. Open up the left atrium and clean the mitral valve from coagulated blood.
2. Attach the heart to the measurement table's clamps
3. Connect the force gauge to the laptop and setup MESURgauge software.
4. Moisten the textile around MAR with saline solution.

4.5.2 Measurement

1. Measure the annulus
2. Proceed with the implantation
3. Save the measured data in accordance of data handling

4.5.3 Post-preparations

1. Dissect open the left ventricle open and search for anomalies.

4.6 Data handling

The main data is gathered with two implantation procedures because the implementation can sometimes be difficult due to anatomical changes in the porcine hearts. These phases are marked in the data as a big negative score and the implantation is normally done in two 180° phases but can be done also in four 90° phases. The data received from torque gauge will be Newton centimeters (Ncm) in the relation of time.

Each measurement will be first grouped in accordance to the mitral valve and then after implant setup. All collected measurement data should be saved in separate files and named individually. The data regarding leaflet thickness, annulus size and miscellaneous information of measurements or heart anomalies is written down in the measurement table.

4.7 Data evaluation

4.7.1 Tolerances

Table 4. Tolerances of parts and tools

Part	Details
Digital torque gauge MARK-10 series M5i	± 0,1% of full scale ± 1 least significant count
Torque sensor MARK-10 MR50-100	± 0,35% of full scale ± 1 least significant count
Mituytoyo Caliper CD-15CPX	± 0,02mm
MAR ring pitch	+ 0,1mm
MAR ring width	± 0,15 mm

The torque gauge and sensor are highly accurate but the digital torque gauge resolution is 0,5 while using Ncm. This is the biggest error in the measurements so the main tolerance is chosen to be ± 0,25 Ncm.

4.7.2 Heart anomalies

The physical changes and anomalies in porcine hearts made significant alterations in the measured data. All collected data is evaluated on the basis of noticed anomalies in the implanted heart. These include basal chords and muscle folds below the leaflets. Figure 23 presents quite normal findings in the implanted porcine hearts.

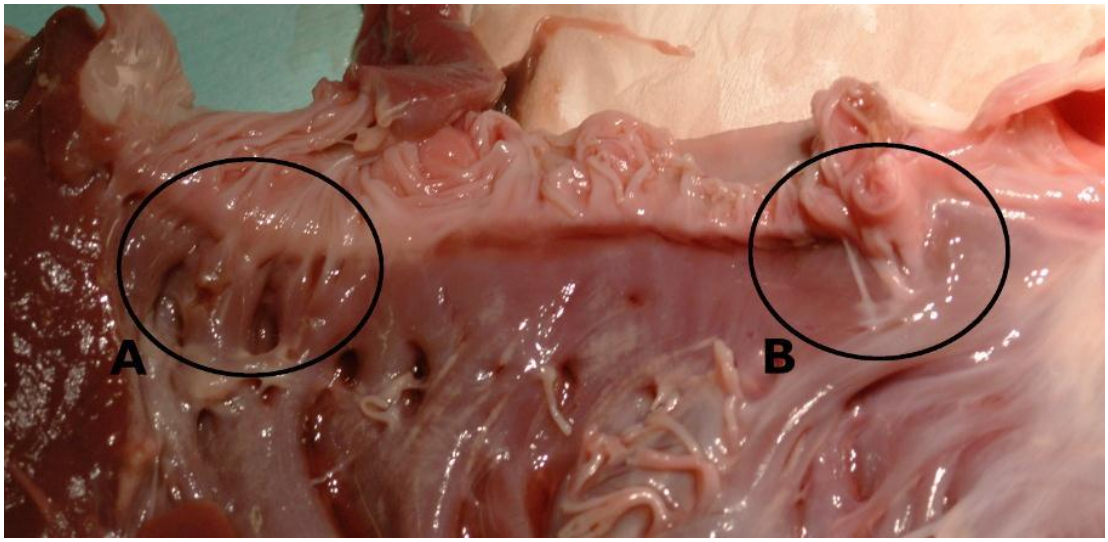

Fig.23 Below posterior leaflet of the 5th heart used in measurements. A. Muscle folds and nodules B. Basal chords

These anomalies were noticed in the repeated patterns in the graph as an increment of the required implantation force or as a complete halt to the procedure. For an example of implantation difficulties see figures 24 and 25. Other variables included for instance the moisture of the annulus and valve tissue which also increased the friction but did not halt the procedure.

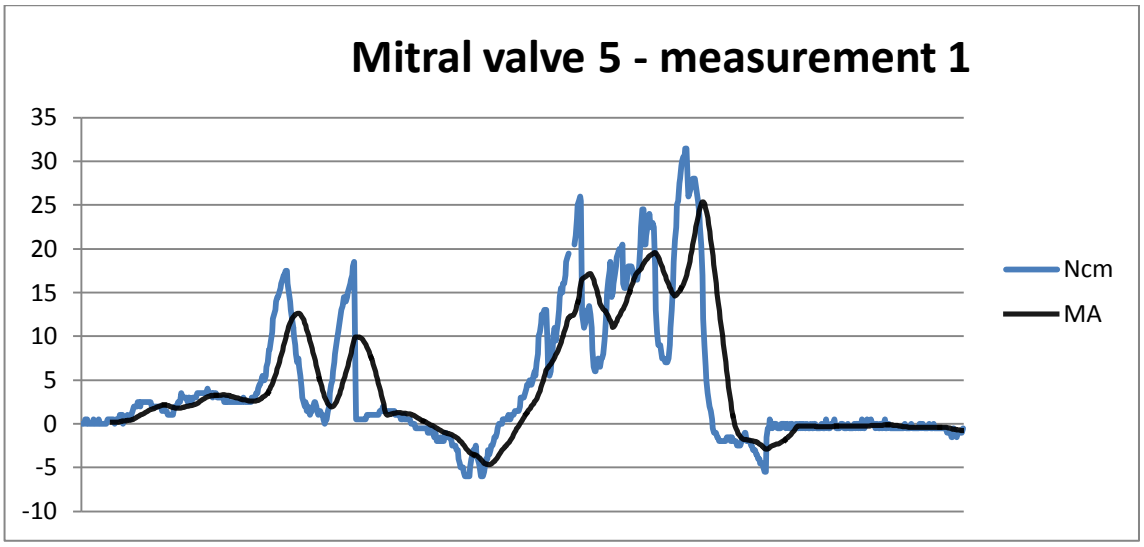

Fig.24 MAR regular, 31,5±0,25 Ncm

The measurement was stopped due to complications at ¾ of the implantation. Dissecting the heart revealed basal chords below the posterior leaflet shown in figure 23.

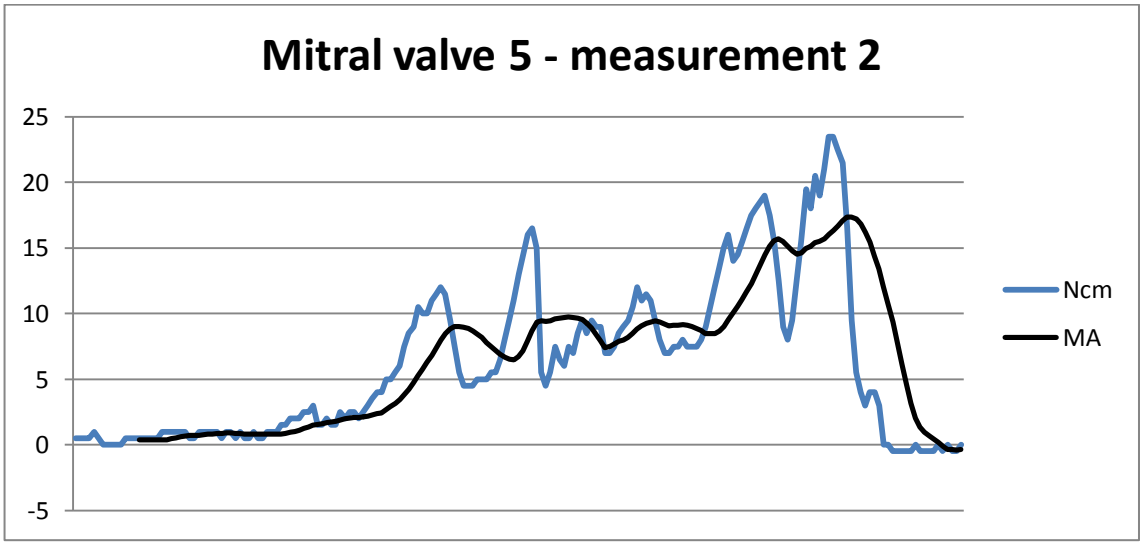

Fig.25 MAR regular, max force 23,5±0,25 Ncm

Heart anomalies and high friction between the MAR textile and dry valve tissues caused the implantation force to increase with an almost linear correlation.

5 Measurement data (porcine hearts)

Graphs that have some exceptional trait are shown in this section of the thesis. Regular implantations were performed on mitral valves 1 and 2 but due to changes in the measuring procedures, only the maximum forces of the second mitral valve's measurements are comparable data.

5.1 Mitral valve 2

Table 5. Measurement table of the 2th mitral valve

#	MV	MAR setup	Max (Ncm)	Misc.
1	2	MAR regular	11	No phases.
2	2	MAR regular	5	See above.
3	2	MAR regular	9	See above.
4	2	MAR regular	9	See above.
5	2	MAR regular	6,5	See above.
6	2	MAR regular	9,5	See above.

5.2 Mitral valve 3

Table 6. Measurement table of the 3rd mitral valve

#	MV	MAR setup	Max (Ncm)	Misc.
1	3	MAR regular	16	MAR textile got stuck in the posterior leaflet. Holder attachment bar failed to grip. Implantation was not completed.
2	3	MAR regular	5	Holder attachment failed again. Implantation not completed
3	3	Tester	5	OK
4	3	Tester	2	Lifted upwards while implanting to try reducing friction.
5	3	Tester	4	OK
6	3	Tester	3,5	The implantation feels "loose".
7	3	Tester & textile	9,5	Textile started to rise while implanting.
8	3	Tester & textile	13,5	Textile started to rise while implanting. Implantation not completed.
9	3	Tester, textile & slide	4,5	OK
10	3	MAR regular & slide	5,5	OK

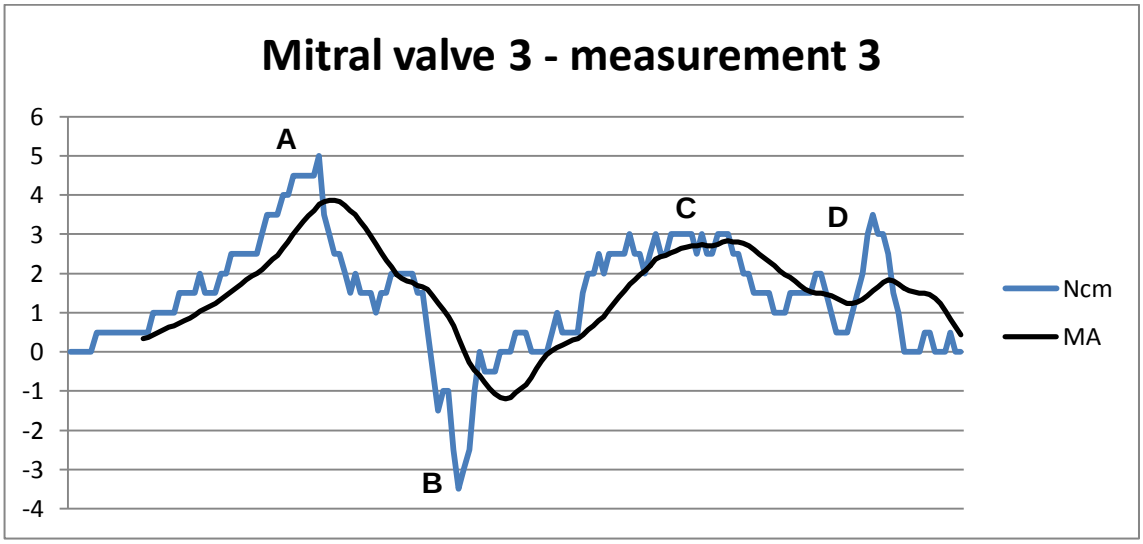

Fig.26 Tester, max force 5±0,25 Ncm. A.First half peak B.Half way mark C.Second half peak D.Irregularities

Figure 26 shows regular patterns seen in the force graphs. The first noticeable thing is the maximum force peak marked with A, which is followed by the implantation half way mark B. In the second half there is a peak, roughly 70% of the maximum force marked with C. The irregular peak marked with D is estimated to be caused by an anomaly in the heart.

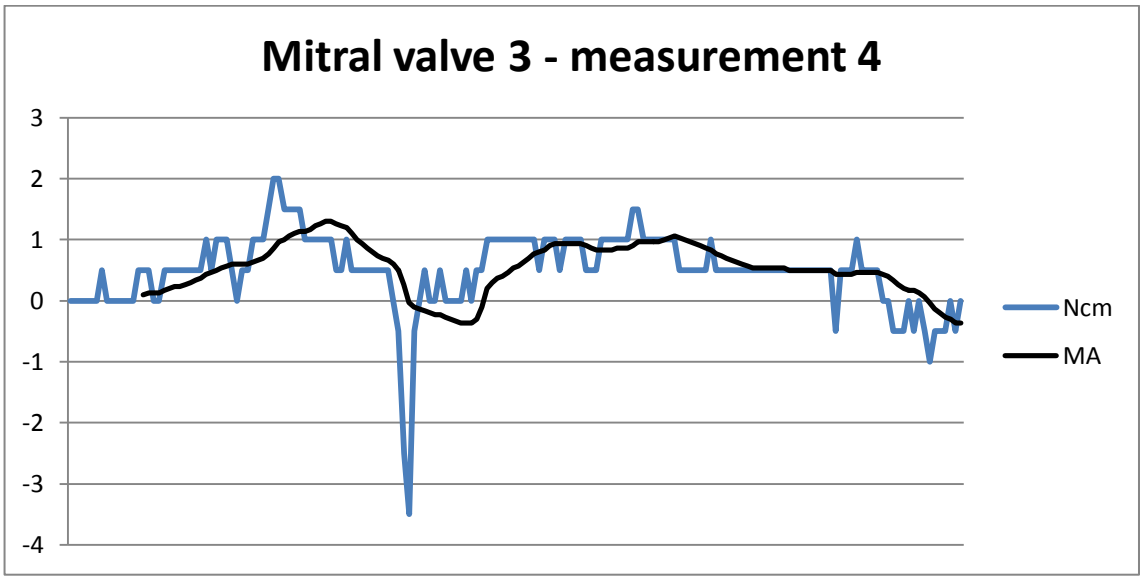

Fig.27 Tester, max force 2±0,25 Ncm

In this measurement the implantation technique was changed slightly in accordance with the noticed anomalies. The same patterns as in figure 26 can still be seen but the required force decreased over 50%.

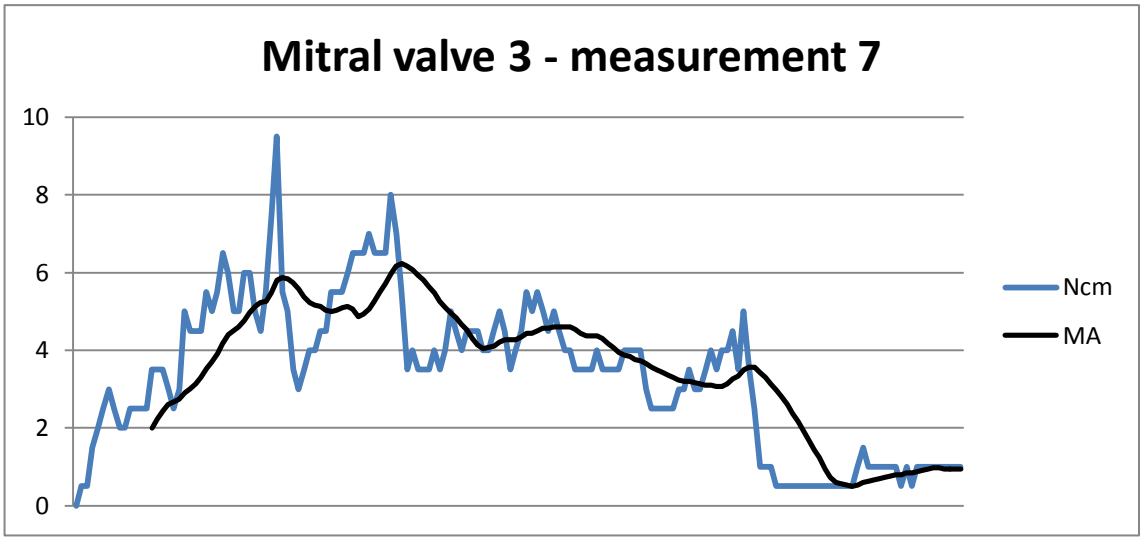

Fig.28 Tester with textile, max force 9,5±0,25 Ncm

A regular MAR's textile was inserted on to the tester and the measurement was performed again. The regular maximum peak is in the expected place, but after this the increased difficulty of the implantation is noticeable.

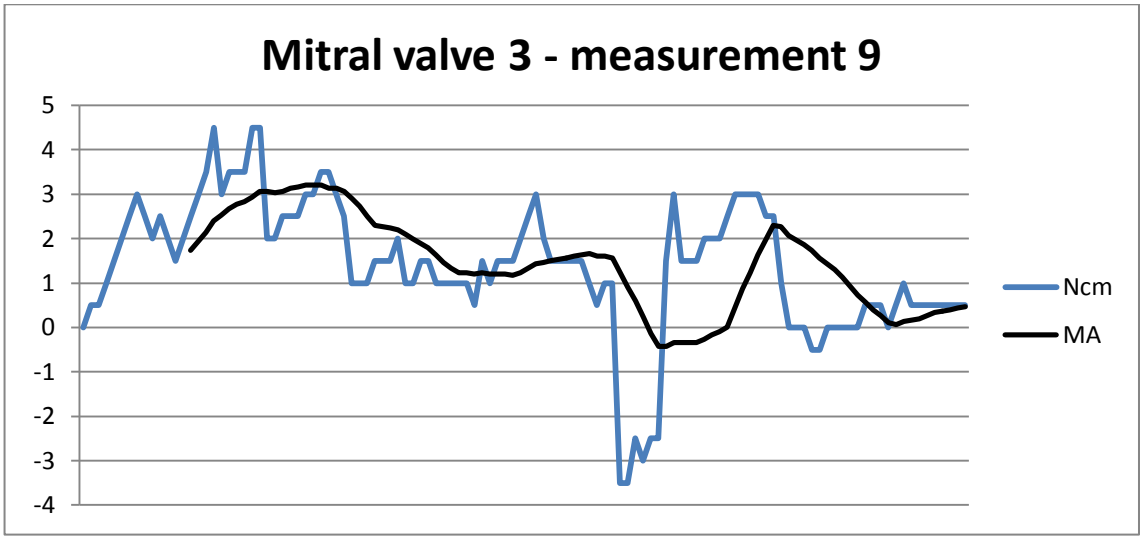

Fig.29 Tester with textile and plastic implantation slide, max force 4,5±0,25 Ncm

In this measurement as a test to reduce friction between textile and tissues a small plastic "slide" was placed where the textile begins. When comparing figures 28 and 29, the slide decreased friction almost by a half. The implantation technique might be the reason why the regular patterns on the graph are not clearly visible.

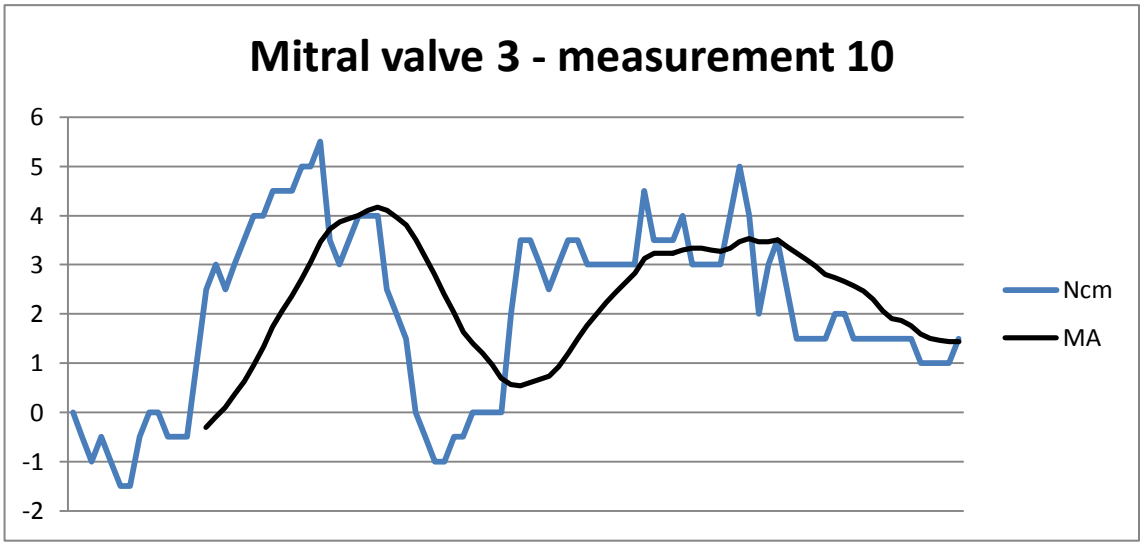

Fig.30 MAR regular with an implantation slide, max force 5,5±0,25 Ncm

When examining figure 24's the MA (moving average) graph, it is very much similarly shaped as the one in figure 30. This MA graph shape of two curvatures could be assumed to be the ideal force graph of a phased implantation.

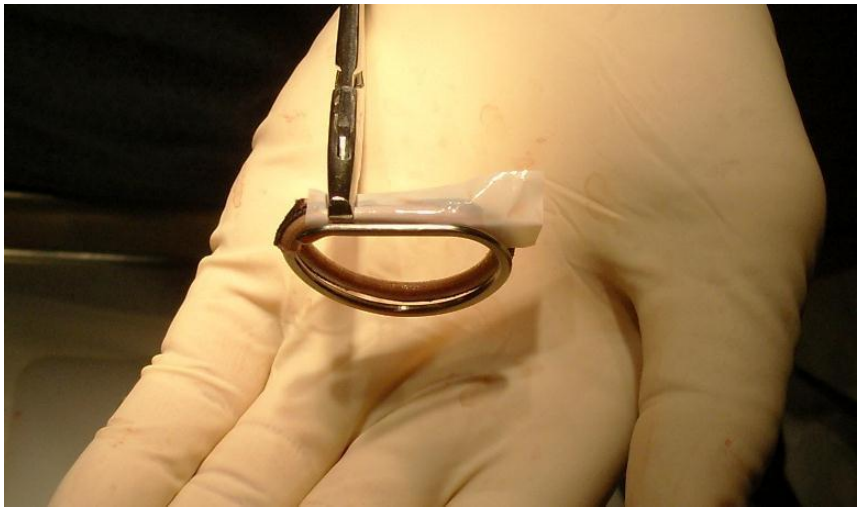

Fig.31 The implantation slide on MAR regular

The slide was made of 0,1 mm thick regular medical grade plastic and was placed to cover the start of the textile. This was to ease the tissue´s transition from the metal to textile.

5.3 Mitral valve 4

Table 7. Measurement table of the 4th mitral valve

#	MV	MAR setup	Max (Ncm)	Misc
1	4	Tester & textile	4,5	OK
2	4	Tester & textile	7,5	Difficulty to implant.
3	4	Tester & textile	4	Difficulty to implant and all chords did not go inside MAR
4	4	Tester & textile	5	Tissues had dried a bit.
5	4	MAR regular	11,5	Implantation not completed.
6	4	Tester	2	OK
7	4	MAR regular	7	OK

Basal chords were found below the posterior leaflet in the dissection of the heart.

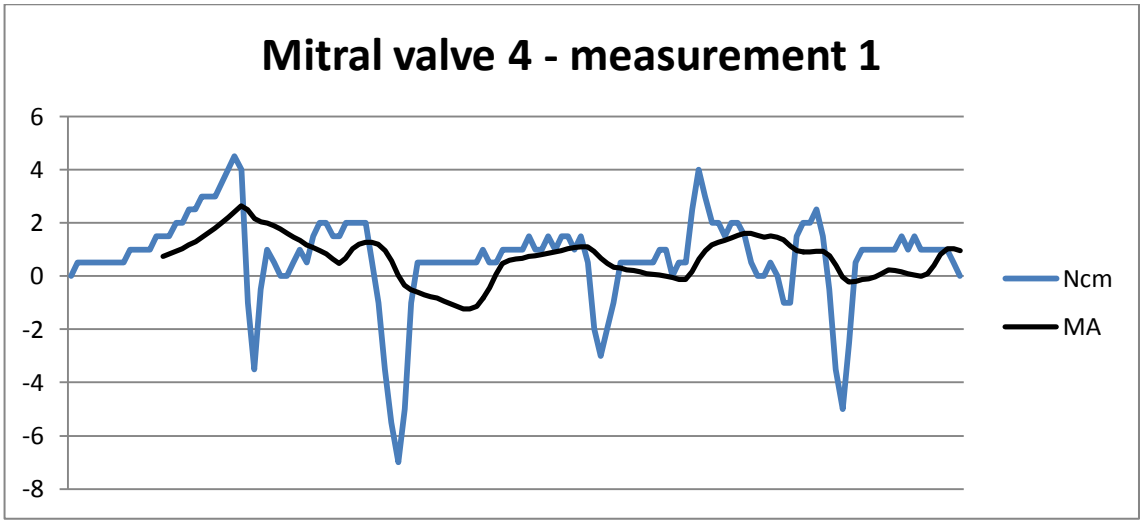

Fig.32 Tester with textile, max force 4,5±0,25 Ncm

The lowest peak presents the half way mark. Many low peaks present implantation backtracking which came from difficulties in the implantation, not that the measurement would have been phased in quarters.

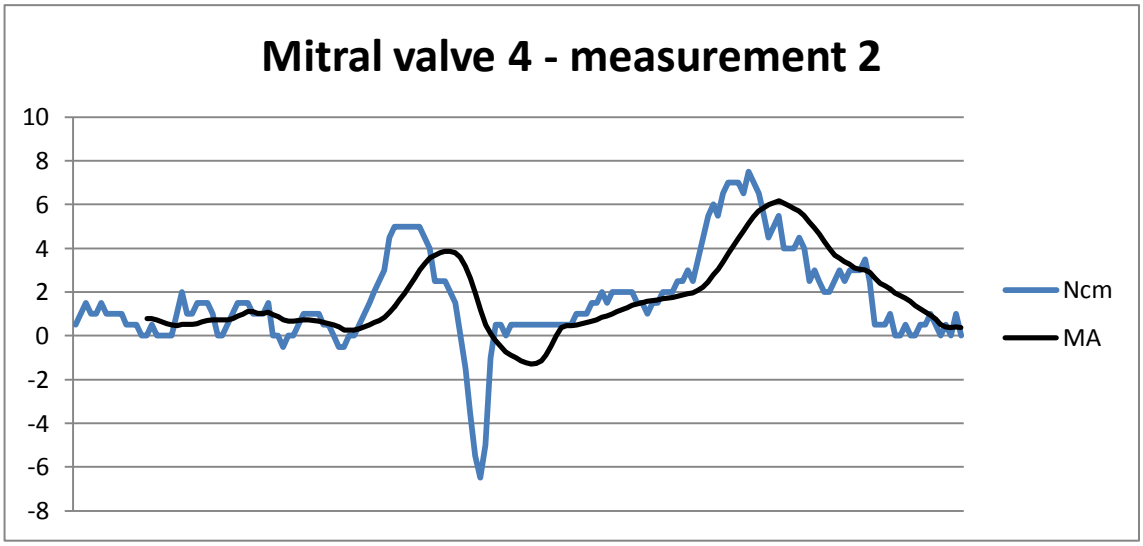

Fig.33 Tester with textile, max force 7,5±0,25 Ncm

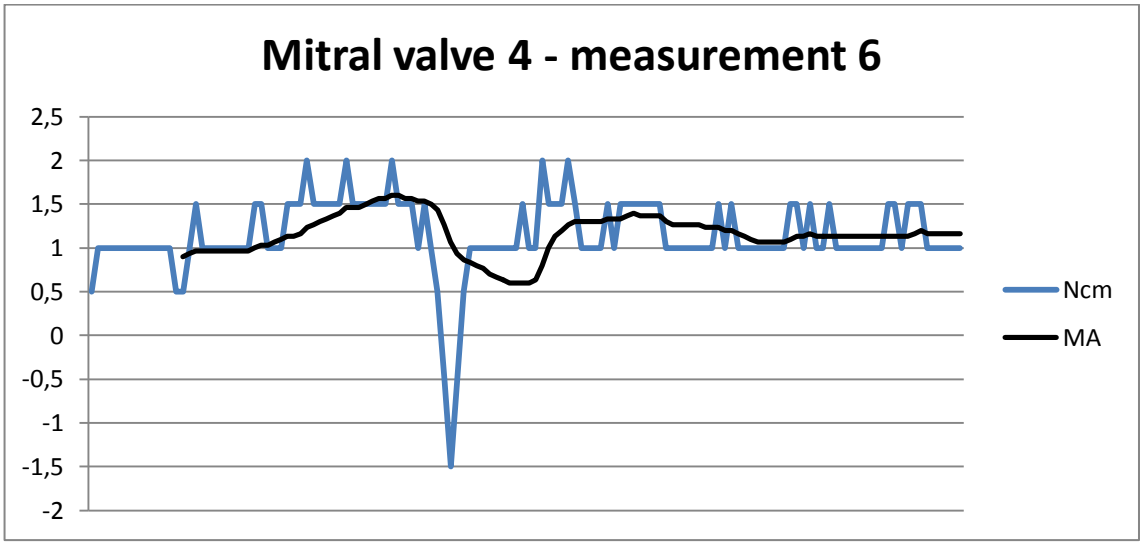

Fig.34 Tester, max force 2±0,25 Ncm

Comparing figure 32 to figures 31 and 30, the textile's friction increasing effect can be seen even more clearly. These graphs also give an example of the implantation route's effect on the required force in a heart with anomalies. Another factor could be the tissue stretching effect of the measurements conducted previously on the mitral valve.

5.4 Mitral valve 5

Table 8. Measurement table of the 5th mitral valve

#	MV	MAR setup	Max (Ncm)	Misc.
1	5	MAR regular	31,5	Implantation did not go over 180 degrees
2	5	MAR regular	23,5	Implantation felt “sticky”.
3	5	MAR regular	25	Phased at 180° and 270°
4	5	MAR regular	17	Phased at 90°, 180° and 270°
5	5	MAR regular	30	Phased at 90° and 180°. MAR fell of holder at about 180°. Implantation not completed.
6	5	MAR regular & plastic slide	3,5	Phased at 90°, 180° and 270°. Chords left out
7	5	MAR regular & textile - 6mm	7	Phased at 90°, 180° and 270°.
8	5	MAR regular & textile - 6mm	5	Phased at 90°, 180° and 270°.

Anomalies shown in figure 23 were found in the dissection of the 5th heart. Figures 24 and 25 are measurements representing difficulties of implantation in this mitral valve.

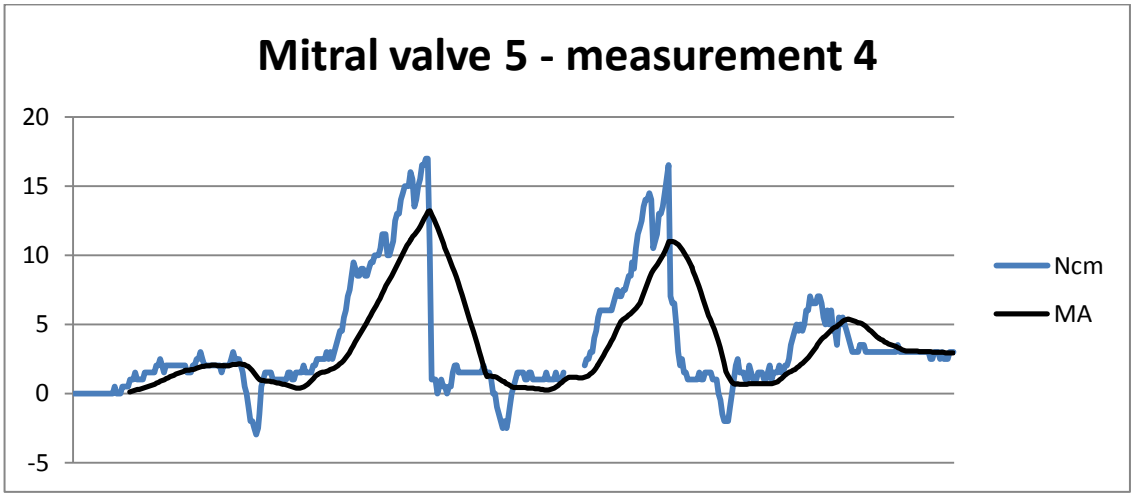

Fig.35 MAR regular, max force 17,5±0,25 Ncm

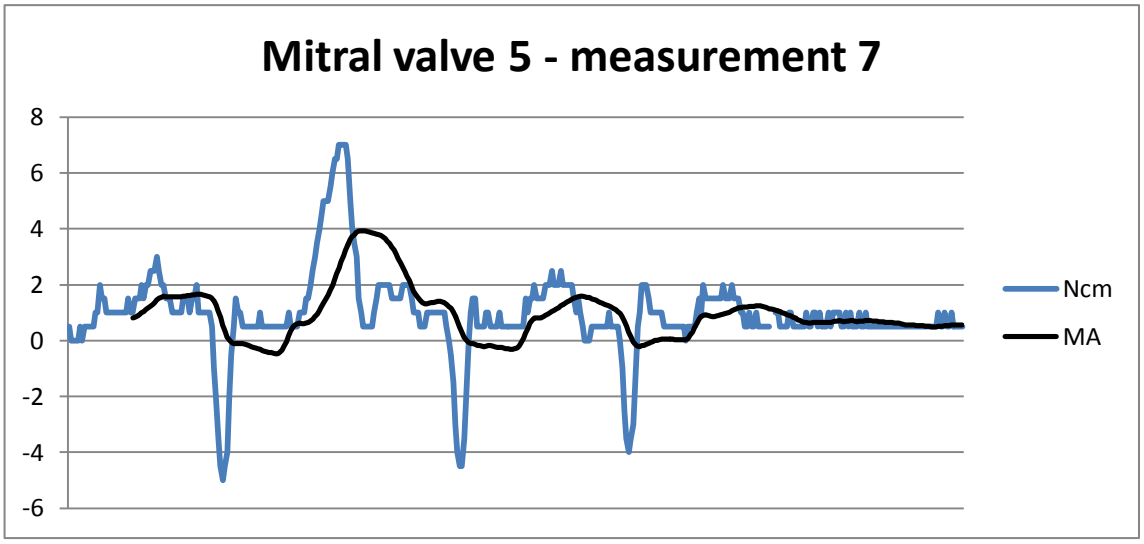

Fig.36 MAR regular with 6mm less textile, max force 7±0,25 Ncm

This measurement was phased in quarters due to difficulties in the implantation. This graph shows which part of the implantation procedure required more force than others.

Between measurements shown in figures 35 and 36 the only difference was that the tolerance of +6 mm overlap of the MAR textile was removed. This possibly cannot be the single reason for the decrease in the needed force. The change is estimated to be the tissue stretching effect of the measurements conducted previously on this mitral valve.

From this we can assume that the +6 mm tolerance of textile length does not have a noticeable increase in implantation friction.

5.5 Aorta tissue 1

Table 9. Measurement of implantation on the 5th heart's aorta tissue

#	AT	MAR setup	Max (Ncm)	Misc.
1	1	MAR regular & textile -6mm	9,5	MAR implanted in to stretched aorta tissue. Phased at 90°, 180° and 270°.
2	1	MAR regular & textile -6mm	10	See above.
3	1	MAR regular & textile -6mm	10	See above.

These measurements were conducted on dissected aorta tissue of the fifth porcine heart. The tissue was cut, cleaned, soaked in saline for a short while to soften it up and spread open on the measurement table as seen in figure 37. After this measurements were conducted by the normal rotating way by inserting more and more tissue into the MAR.

The thickness of the aorta tissue 1 was 2,3±0,2 mm.

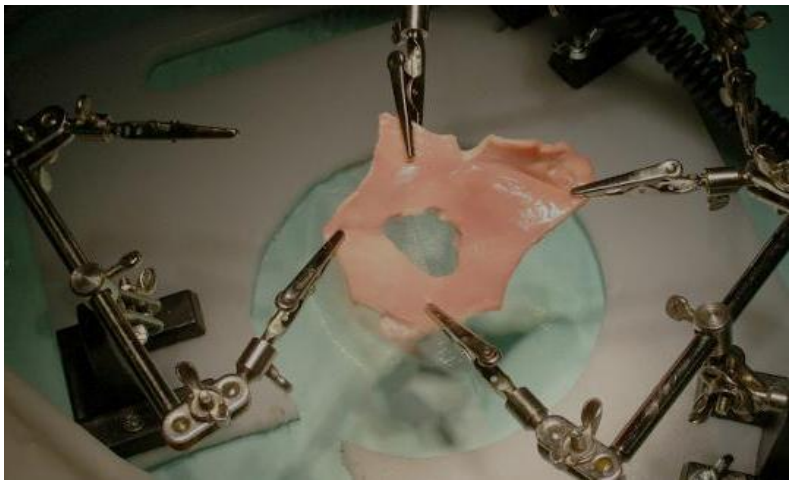

Fig.37 Aorta tissue measurement setup

Note that in figure 37 the dissected part in the middle of the aorta tissue is smaller than the implanted MAR. This way it was possible to implant by increasing the tissue amount steadily inside MAR.

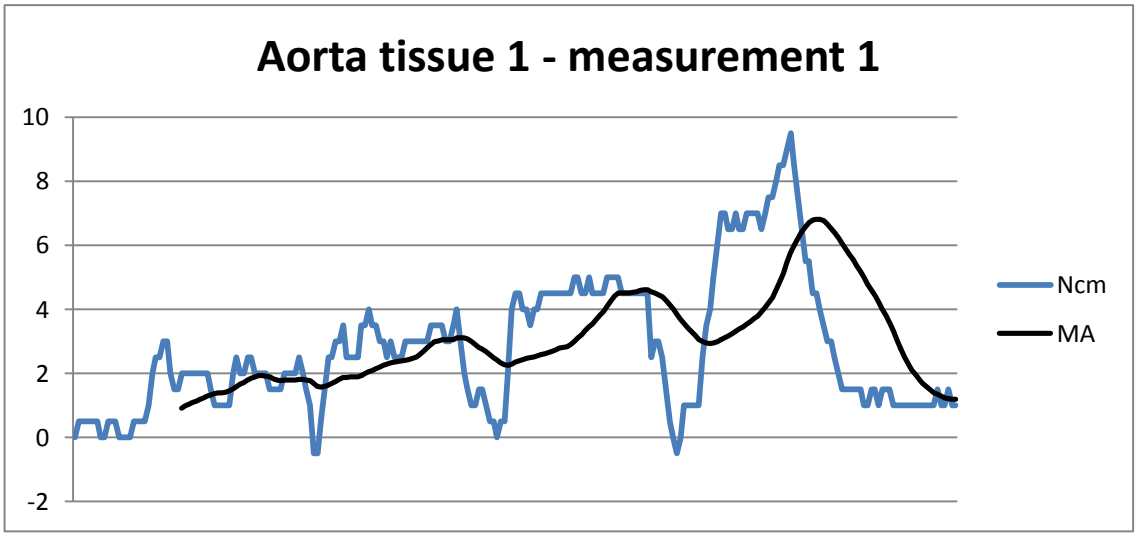

Fig.38 MAR regular with 6mm less textile, max force 9,5±0,25 Ncm

The measurement was done three times and the friction rose similarly to the same level on each occasion.

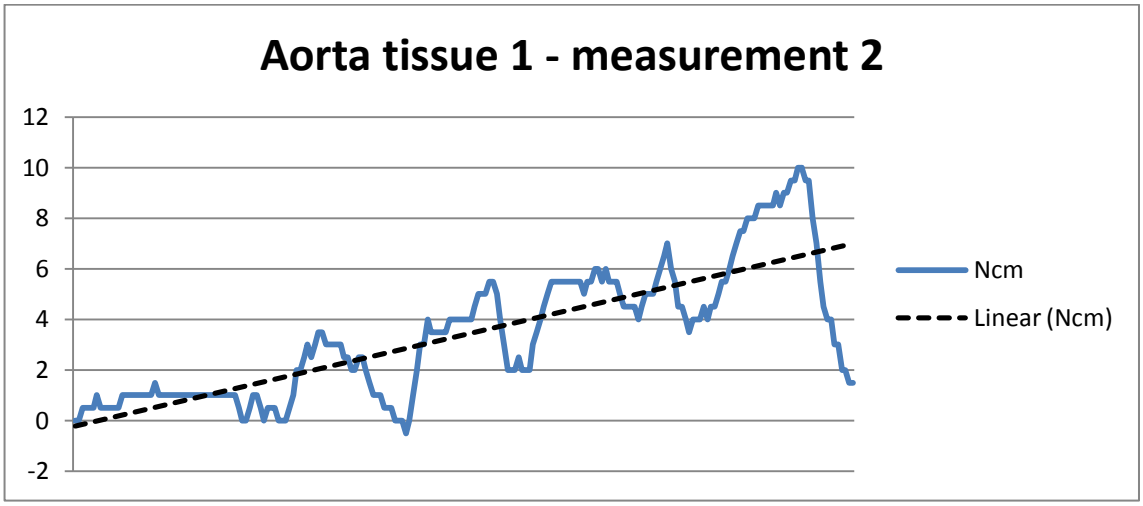

Fig.39 MAR regular with 6mm less textile, max force 10±0,25 Ncm

In figure 39 instead of moving average a linear trend line was added to show the friction rise more distinctly.

The outcome of these measurements gives instructions of limitations on maximum valve width for the regular MAR. On the basis of this for example if 10 Ncm was kept as the maximum force for a safe implantation the mitral valve width should be below 2,5 mm.

5.6 Aorta tissue 2

Table 10. Measurement table of the 6th aorta tissue

#	AT	MAR setup	Max (Ncm)	Misc (saline use, etc.)
1	2	MAR regular	-	Implantation on aorta tissue not completed due to width. Tissue width: 2,67 mm SD:0,17
2	2	Tester	3,5	Sizer movement difficult but implantable.
3	2	Modified tester	5,5	Sizer movement difficult and tissue starts to move.

These measurements were conducted on dissected aorta tissue of the sixth porcine heart. The tissue was prepared as in the measurements of aorta tissue 1.

Regular MAR was tried to implant on aorta tissue with the thickness of 2,7±0,2 mm. The regular MAR could not be inserted into the aorta tissue with safe implantation forces. This means that the aorta tissue did not start going inside the implant and the tissue started to fold.

The tester was implanted the same route and no specific difficulties were noticed. This would lead to the conclusion that the tester a gap of 2,1±0,1 mm does not simulate the regular MAR on this matter. Since the tester has the same surface as MAR it will only simulate accurately the stretching effect on the annulus and help to choose the correct implant size.

The modified tester's gap had been narrowed to 1,6±0,1 mm as a test to simulate the regular MAR better. The modified tester was implanted into the tissue fine but the tissue moved slowly while rotating the tester. While choosing between regular and expanded MAR, this narrowed tester would help better than the regular tester. This would happen so that if the valve tissue would start following the narrowed tester while implanting, an expanded MAR should be chosen for the implantation.

This narrowing should be done by increasing the tester material thickness and by this way achieving the gap to 1,6±0,1 mm. Adding a textile to the tester would increase the width and friction, but the textile could cause unnecessary tissue abrasion.

5.7 Data summary

The summarized data is comprised of measurements which did not involve noticeable implantation difficulties due to anomalies. The MAR regular group in table 11 includes regular and MAR with 6 mm less textile, since the slight change in textile length had almost no impact on the measurements. Moreover the measurements where the implantation slide was used are combined.

Table 11. Summary of measurements on mitral valves

MAR setup	Mean of max (Ncm)	SD	n
MAR regular	7,7	2,1	9
Tester	3,3	1,3	5
Tester & textile	5,7	1,6	3
MAR regular & slide	6,0	1,4	2

The outcomes of the measurement results correlates well with the expected conclusion. The thickest setup has the highest mean of maximum force and the thinnest setup has the lowest.

Table 12. Summary of measurements on aorta tissue

MAR setup	Mean of max (Ncm)	SD	n
MAR regular	9,7	0,6	3
Tester	3,5	-	1
Modified tester	5,5	-	1

6 Conclusions

6.1 Phased implantation

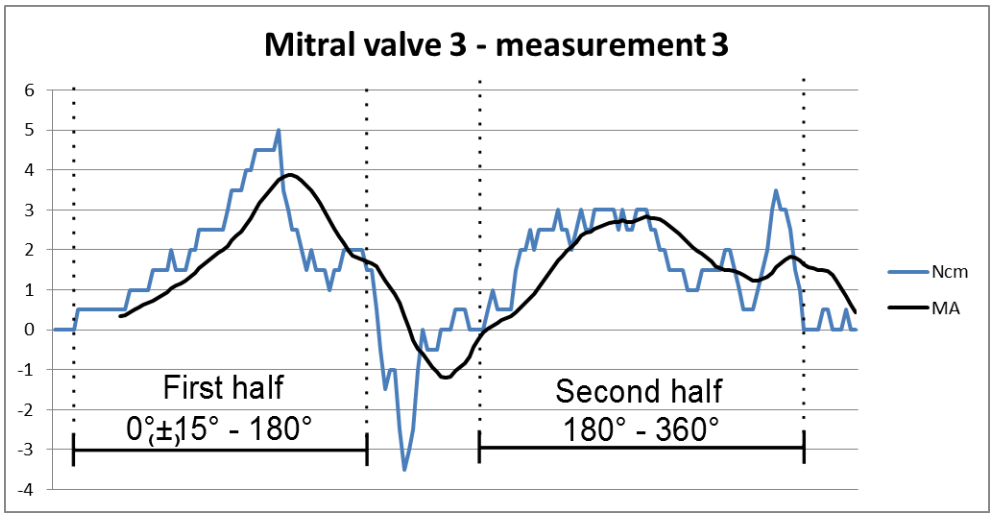

Fig.40 Tester, max force 5±0,25 Ncm

Figures 26 and 40 show the same measurement graph but in figure 40 the graph is divided into first and second half of the implantation procedure. In actuality the posterior leaflet takes up to 2/3 of the overall valvar circumerence, thus the posterior leaflet's area in the graphs extends a bit to both ends of the second half. The second half represents anterior leaflet including tolerances. The distinction between anterior and posterior leaflet is quite vague and each valve has individual variability in formation of the fibrous annulus of the mitral valve. In this report these halves are thought as the first half being posterior leaflet and the second half as anterior leaflet. On the basis of anatomical variability a start positioning tolerance of +15° is added to the start and as well all the tolerances in the graphs are estimated slightly high.

As noted before, the highest implantation force is on the posterior leaflet side and is followed by the anterior side, which seems to require roughly 30% less force to implant. The peak right in the end of the second half is assumed to be caused by an anomaly and when considering tolerances concerning the valvar leaflet circumference, the last spike could be estimated to be caused in the start of the posterior leaflet. This estimation is also supported by the amount of anomalies found below the posterior leaflet.

Phased implantation figures explained.

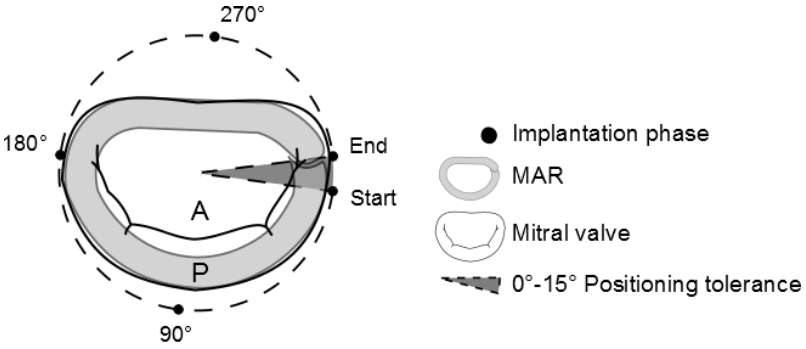

Fig.41 Explanations of phased implantation figures. Leaflets A: anterior, P: posterior

Since the implantation is not conducted with a constant speed and the angles of implantation are approximations, the angles are placed in the graph with a ±30° tolerance. These angles are only to give an approximation of the position and help to analyse the force graph.

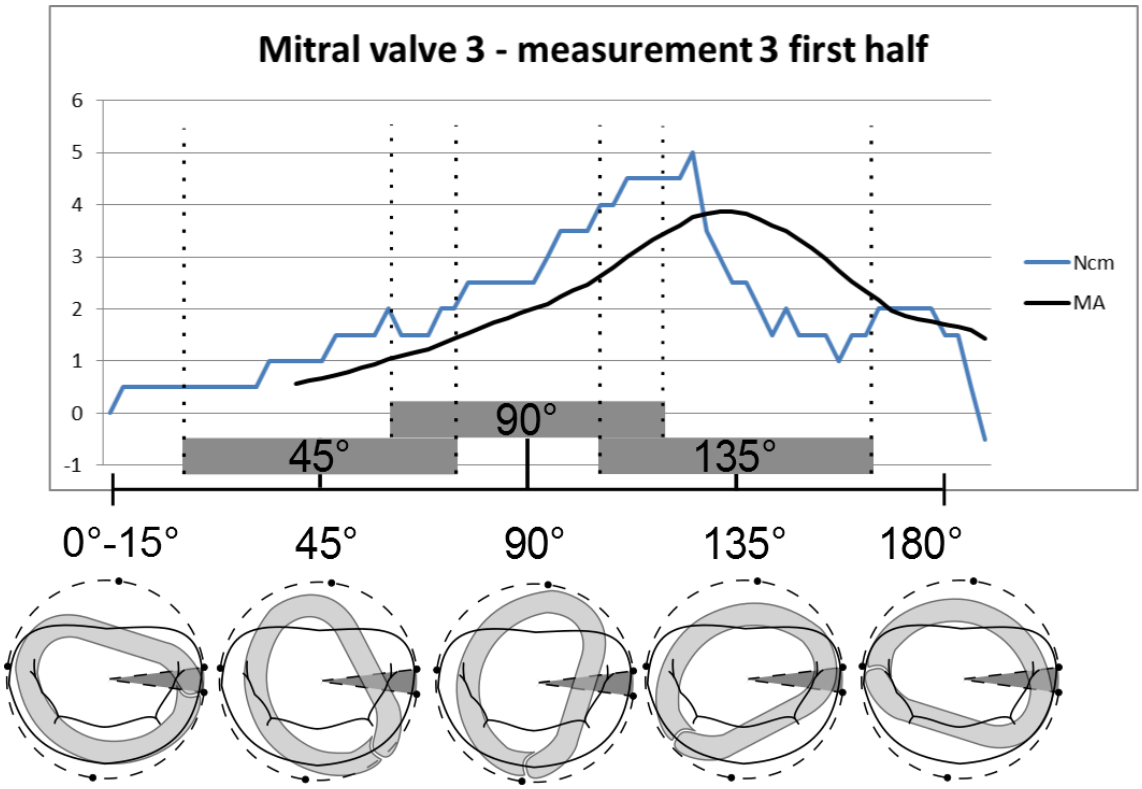

Fig.42 Phased first half implantation of MAR

The maximum required force of the implantation is between 90° - 135°. This is estimated to be caused mainly by the complexity of the posterior leaflet anatomy and that MAR reshapes the annulus at these angles as seen from figure 42.

The posterior leaflet is divided by slits into three or more scallops which are approximately 1 mm thinner and 40% shorter than the anterior leaflet. Due to the small size of the scallops they can start moving sideways and finally folding if they don't slide inside the MAR. The position and fast decline of the maximum force can be assumed to happen because the scallops moving along the implant and finally sliding into the MAR. This occurs due to high static friction between leaflet tissue and MAR textile.

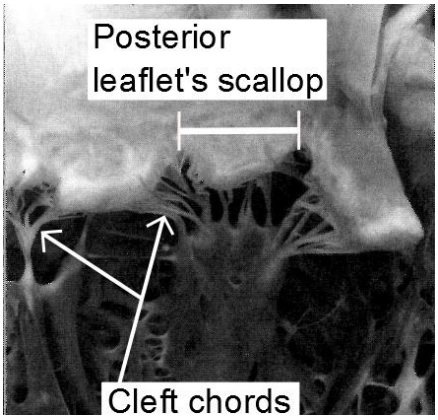

Fig.43 Posterior leaflet scallops and cleft chords [18]

As seen in figures 14 and 43, the cleft chords get closer to the ventricle wall and can get in the way or get on the wrong side of the implant. In addition as they are closer, but there are also more chords for this area than below the anterior leaflet. For this reason the first part of the implantation is quite normally done by scraping MAR along the ventricle wall to be sure that all chords get inside MAR. In the implant position between 90° - 135° the annulus is stretched and pushes commissural corners of the MAR towards the atrium wall. As seen in figure 44 the ventricle wall below posterior valve can be very uneven, with basal chords and abnormal papillary muscles.

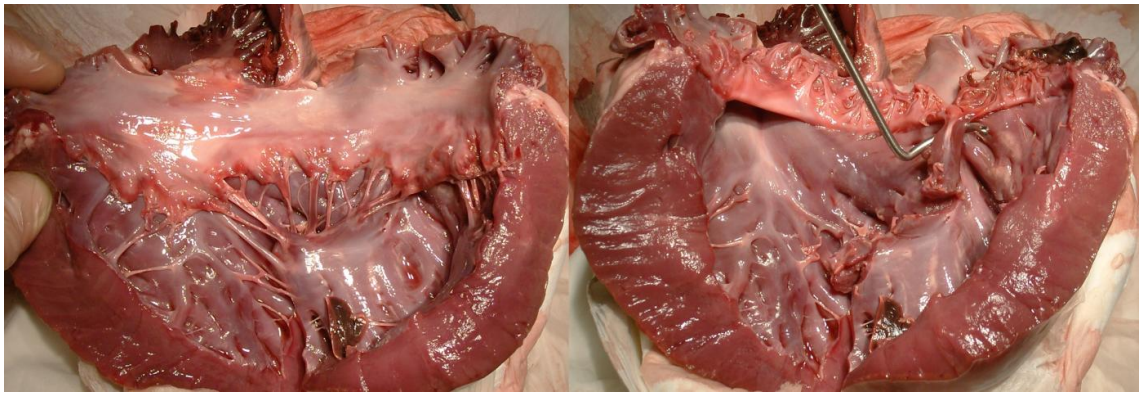

Fig.44 Left ventricle of the 6th porcine heart dissected open. Abnormal papillary muscle pointed out.

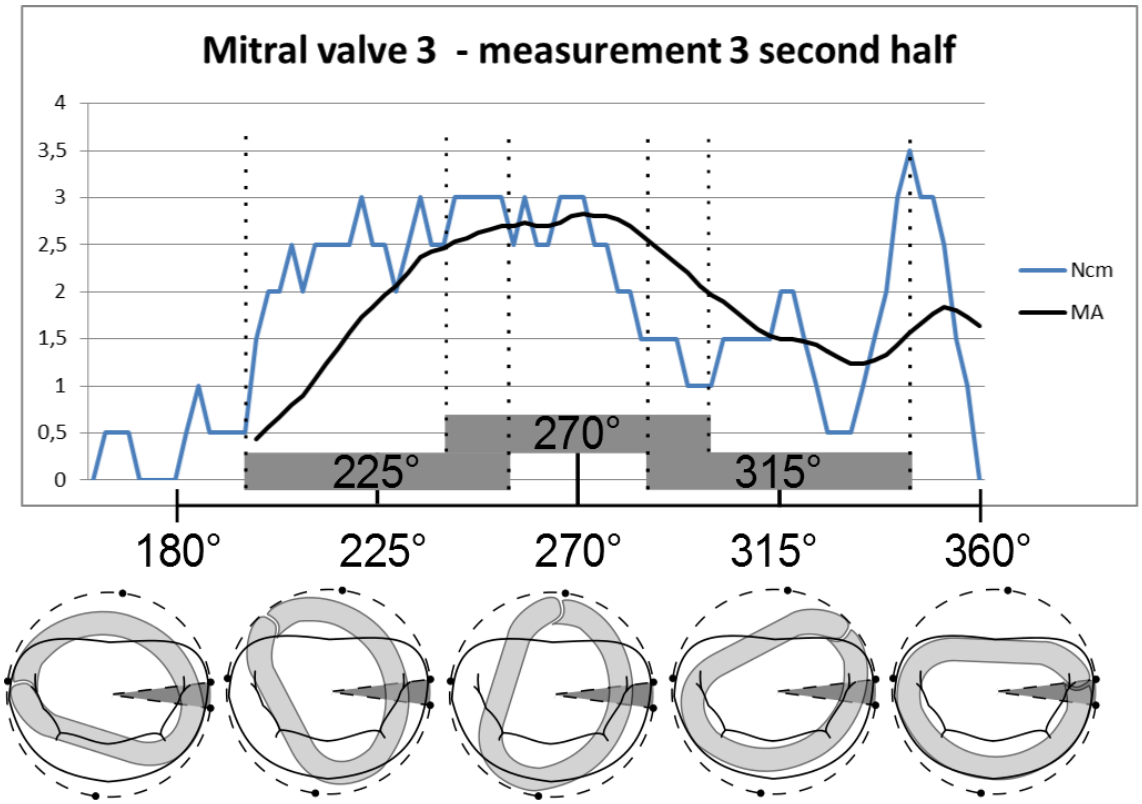

Fig.45 Phased second half implanation of MAR

The annulus is stretched most between 225° - 315° but force is required more in the start, rather than being divided equally in this area. In this half of implantation the MAR is already behind posterior leaflet's chords and is moving more in accordance with the anatomy of the annulus. The anterior side of ventricle septum wall is smoother and does not contain basal chords which could create implantation obstacles. The difference between leaflet and ventricle septum can be seen in figure 44, as well as the fact that below the middle of the anterior leaflet there are no chords at all due to the aortic valve outflow track.

The posterior leaflet cleft chords are stretched most between 180° - 270° and are released after this. The ending of this force working against MAR implantation can be seen also in the force graphs as a start of decline at 270°. This also means that basal chords and abnormal papillary muscles that don't stretch well can also complicate the second half of the implantation.

The anterior leaflet can be in some cases 1 mm thicker than the posterior leaflet but it does not start moving or folding as easily as posterior leaflet due to its large size. Clear start and an end for the anterior leaflet cannot be seen clearly in the graphs.

6.2 Summary

The most noticeable pattern in the graphs was the peak force of the implantation at the first half of the procedure. This is estimated to happen when the posterior leaflet scallops do not go inside the MAR gap and start moving or folding. MAR with the gap too small can cause this problem due to a higher compressing force and there is increasing friction between the textile surrounding the implant and leaflet tissue.

The first half of the implantation has an anatomy which needs to be done with more precision and caution than the second half. This does not mean that the second phase would be easier to install due to simpler anatomy. The reason is that the basal chords and other anomalies passed in first half can create tension towards MAR in the second half and even halt the implantation. In accordance with the measured data the highest forces occur between 90° - 270°.

The bigger the size of MAR, the bigger the tension towards the annulus will get in the implantation angles 45° to 135° and 225° to 315°. In particular the second half will get more difficult when MAR is too big for the mitral valve because both ends of the annulus are being stretched.

When implanting a regular MAR instead of when an expanded MAR should have been chosen, the posterior leaflet scallops will start to move or even fold. The regular gap size is estimated not to cause additional problems when implanting the complex anatomy of the posterior leaflet. The textile surrounding MAR thickens the implant and creates more friction.

Creating a tester to match regular MAR´s implantation force would require a very small gap. This gap would be so small that it would be difficult to implant and could even cause damage to the leaflets. Therefore a tester with a gap of 1,6±0,1 mm could be used as a guidance in choosing should an expanded MAR be used rather than the regular.

Measuring the mitral valve's anterior to posterior (A – P) and commissure to commissure (C – C) values did not give unambiguous information of the suitable MAR size. Therefore the valve area should be measured using a tester to stretch the annulus in a comparable shape.

6.3 Techniques to ease the implantation

1. Filling the ventricle with saline solution to lift the leaflets and reduce friction on tissues.

2. Decreasing the force pushing MAR towards posterior ventricle wall can ease implantation difficulties with muscle folds.

3. The posterior leaflet implantation can be done slightly sideways to reduce stretching of the annulus.

4. Lifting MAR slightly while rotating in placed can reduce tension and ease getting chords inside MAR especially in the posterior leaflet.

5. Going through the route with a helix tester can ease to find the path for MAR implantation.

6. Pulling leaflets towards the center while implanting reduce the chance of folding.

7. Decreasing static friction between MAR textile and tissue will ease the posterior leaflet implantation.

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Measurement summary

Measurements on mitral valves

MAR setup	Mean of max (Ncm)	SD	n
30 MAR regular	7,7	2,1	9
Size 30 Sizer	3,3	1,3	5
Size 30 Sizer & cloth	5,7	1,6	3
MAR 30 regular & slide	6,0	1,4	2

***This group includes regular MAR and MAR -6mm cloth.**

***This group includes all setups used with implantation slide**

Measurements on aorta tissues

MAR setup	Mean of max (Ncm)	SD	n
30 MAR regular	9,7	0,6	3
Size 30 Sizer	3,5	0,0	1
Modified size 30 sizer	5,5	0	1

Data table							
	Mitral valve				Aorta tissue		
Group	30 MAR regular	Size 30 Sizer	Size 30 Sizer & cloth	MAR 30 regular & slide	30 MAR regular	Size 30 Sizer	Modified size 30 sizer
Max Ncm	11	5	4,5	7	9	3,5	5,5
	5	2	7,5	5	10		
	9	4	5		10		
	9	3,5					
	6,5	2					
	9,5						
	7						
	7						
	5						

Used porcine heart information

Hearts used in measurements

Heart	Date used	A-P	C-C	MAR x	A2	P2	P3	Aorta	Misc
1	14.11.2012			x	1,70	2,30		3	
2	14.11.2012			x	1,46	1,27			
3	21.11.2012	22	34,5	28	1,16	1,30	1,28	2,6	
4	23.11.2012	25,9	28	29	0,97	2,06	1,75		Under P1-P2 a muscle rinkle and thirtiary cord
5	5.12.2012	20,6	21,7		1,60	2,50	1,00	2,3	SD: 0,2
6	15.1.2013							2,677	Under posterior muscle rinkles and basal cords. Post. Implantations on valve failed due to amount of anoma-lies. Aorta SD: 0,17

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