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## **Summary of PhD dissertation**

# **Investigation of stent stabilised devices for pacemakers**

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## ***Introduction***

Cardiac diseases have a leading role among causes of death all over the world and also in our country. One of their common forms is the cardiac heart failure affecting 2-3% of the adult population, however, in elderly its occurrence can be as high as 10%. Properly indicated Cardiac Resynchronization Therapy applying pacemakers considerably improve the quality of life and the life expectancy of patients suffering from cardiac heart failure. [1]

Cardiac Resynchronization Therapy (CRT) is one of the proven non-pharmacological treatments of chronic cardiac failure. During resynchronization therapy the mechanical dissynchrony between ventricles is reduced with synchronous biventricular stimulation. Three leads (right atrial, right and left ventricular leads) are implanted and positioned in the heart and connected with a biventricular pacemaker. [2-4]

Implantation of a biventricular pacemaker is technically more difficult than that of a traditional dual chamber pacemaker, because the access of the left ventricle through coronary sinus is more difficult than an implantation of a lead into the right ventricle. Approximately 20-30% of patients receiving resynchronization therapy are non-responders (therapy without any effects), which can be explained with the dislodgement of the lead due to the instable lead position. [2-7]

In order to prevent lead dislodgement, a new method was introduced at the Heart Centre of Semmelweis University for the stabilization of the left ventricular lead within the coronary vein with a coronary stent introduced into the vein and expanded beside the positioned lead. [8-15]

## ***Literature Review***

A metallic implant, a stent is positioned beside the left ventricular lead placed into the coronary sinus, and the lead is stabilized with the expansion of the stent. However, as a result of the continuous motion of the heart, the two implants, presumably will be rubbing to each other. The function of the lead can significantly be influenced by the extent of the damage on its insulation coating that can result the failure of the stimulation and sensing function of the lead. In addition, if the lead extraction is indicated - because of a life threatening bacterial infection - the stent fixation can obstruct the removal of the lead. If the lead is ruptured during its extraction, the remaining fragment within the heart can maintain infection, or if the lead is ruptured the free metallic end can cause dangerous injuries of the heart.

More issues of the technique have been criticized, on the basis of patient safety. The most important two questions are discussed below: [1, 11-15]

- 1.) Will the lead remain in function after its implantation and stabilization with a stent for a long period of time? In other words, will the stent cause any damage on the external insulation coating surface of the lead because of the continuous

load and friction that can affect the pacing and sensing properties of the lead?  
Will it threaten the function of the lead?

- 2.) Is the removal of the system (extraction of the device and the leads) possible without any complications if it is indicated because of an infection? Is extraction of the lead possible if it has been stabilized with a stent without the rupture of the lead?

Answers to these questions, will support the improvement of the efficacy and safety of the therapy with the reduction of the potential risk of therapeutic intervention for the patients' benefit.

## **Objectives**

The aim of my research work is to work out appropriate experimental methods and testing procedures of medical device in order to answer the arising questions concerning particularly the left ventricular pacemaker leads stabilized with stents.

- 1.) Elaboration of a method to analyse the functional characteristics (surface damages and electric integrity) of the lead to investigate left ventricular leads stabilized with a stent and extracted from the heart of the patient. Investigation of the stability of left ventricular lead fixed with a stent for a longer period of time.
- 2.) Elaborating an in-vitro system for modelling of the extraction of the lead, Examination of the damages of the lead and deformation of the stent with an experimental simulation of the lead extraction.

## **Summary of the Research Work**

| <b>Research Work</b>   |   |
|--|---|
| <b>Issues related to the extraction of the lead</b>  | <b>Examination of the damages of the lead</b>   |
| 1.) Measurement of strength and strain characteristics of coronary veins   | 1.) Examination of samples obtained from modelling of the extraction of leads.  |
| 2.) Selection of material substituting coronary vein   | 2.) Investigation of left ventricular leads stabilized earlier with a stent, obtained from real environments; extracted from the heart of the patient |
| 3.) In-vitro modelling of the extraction of the leads with standard manual extraction, with measuring extraction force |   |

### **Experiments Performed on Human Heart removed during transplantation**

**Table 1: Experiments performed in my research work**

My experiments can be divided into two groups; the first one focuses on long-term stability of the leads, and the second one is related to the investigation of procedure of extraction of the leads with its consequences. (Table 1)

## Possibility of the Extraction of the Leads

I made two types of testing with the prepared veins in order to use the results to find an appropriate material for my model experiments to substitute veins. In the first case, I tested the stress and the strain characteristics of a piece of a vein, maintaining its original geometrical properties. In the second series of my experiments I made further, longitudinal and transversal excisions from the prepared vein and I determined the strength and strain at strength of dissected vein samples.

I looked for the most appropriate material to substitute veins on the basis of the result of tensile tests of several plastic tubes.

Having had the strength and also the strain at strength of coronary veins, on the basis of geometrical deduction calculation I completed a recommendation for the physicians to determine the optimal stabilizing stent diameter in the function of the diameter of the site of the placement in the vein. Using this method, the size of the implanted stent can be determined depending on the diameter of the vein. Consequently the selected stent will provide the appropriate stability, but it makes the safe removal of the lead possible without any complications if its removal is indicated (Figure 1).

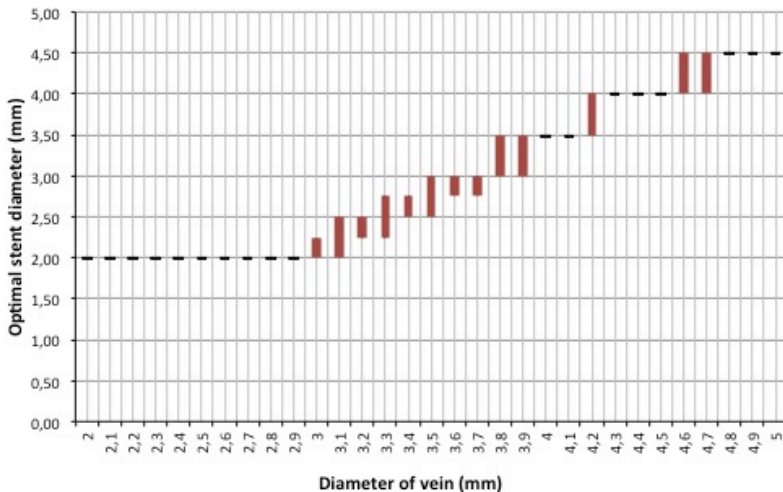


Figure 1: The recommendation for selection of the optimal stent-size depending on the diameter of the vein

In-vitro modelling of the extraction of the leads was performed on two different type of extraction model. During these experiments the recommendation of the optimal stent in function of the vein diameter was also evaluated with the diameter of 5 mm. In case of the first type of experiments I tested the removal of 6 pieces of Corox OTW 75 UP type leads with the usual manual extraction. I modelled the extraction of 5 pieces of Corox OTW 75 UP and 7 pieces of Medtronic Attain OTW 4193 type leads in the second type of extraction model with the registration of the extraction force measured by my developed experimental measuring system.

The size of the shortest stents tested with simple extraction was 3.5×10 mm. One of these stents turned over during the extraction and the other stent was pulled out from the tube together with the extracted lead. The tested 4.5×13 mm stent showed less deformation during the extraction of the lead.

The aim of registration of the extraction force was to measure the additional stability of the lead fixed with a stent. In case of a 3,0 mm stent-diameter with Attain-lead the required extraction force did not deviate (0,15 N vs. 0,01 N). In case of a Corox-lead, the force was a little bit stronger (0,64 N vs. 0,33 N) than the force measured during the extraction of a lead without any stent-stabilization. I considered the stabilization appropriate and it is providing an additional fixation if at least 2 N force was needed for the extraction of the stent fixated lead, and this condition was fulfilled at stent-diameters above 4,0 mm.

Testing Attain OTW leads, I established that in case of two stents with the same 4,0 mm diameter but with different lengths (13 mm vs. 26 mm) the required extracting forces were also different (2,17 N vs. 4,19 N). I also determined that a 4,5×15 mm stent provided nearly the same stabilisation as that was achieved with 4,0×26 mm stent (4,19 N vs. 4,96 N).

I succeeded in testing and proving that lead fixation with an optimal sized stent will provide an additional stabilization for a left ventricular lead in comparison with the traditional way of lead implantation. Besides, I proved that in case of applying an optimal size stent, the lead could be extracted safely, without any ruptures.

### **Long-term Stability of the Leads**

I investigated the surface of extracted leads with microscope to define damages and the functional integrity of the lead was also evaluated. I constructed an expert system in two modules, including all tests required for the analysis of the integrity, injuries and functional state of the leads in a comprehensive way (table 2).

| Examinations under microscope  | Functional investigations   |
|--|---|
| <ul style="list-style-type: none"> <li>- <b>Stereomicroscope</b>: to find injuries on the surface</li> <li>- <b>Metallic microscope</b>: to determine main sizes of injuries</li> <li>- <b>Confocal microscope</b>: to determine depth of the injury</li> <li>- <b>Electron microscope</b>: to analyse surface morphology</li> </ul> | <ul style="list-style-type: none"> <li>- <b>Measuring serial resistance</b>: to prove functional operation</li> <li>- <b>Measuring with X-ray microscope</b>: to analyse the integrity of the inner spiral</li> </ul> |

**Table 2: Expert System to Test Leads**

For further testing, I received four pieces of extracted leads (extraction was indicated because of PM infection) and four leads removed during heart transplantation (I received two removed heart together with the leads). I could investigate on these leads the consequence of the mechanical load caused by the heart motion during the long-lasting, continuous operation of the system. I also investigated the injuries and damages of the leads developed due to the extraction. Moreover, 6 pieces of Corox-leads were at my disposal, removed during the first series of modelling the lead extractions.

On the samples obtained from modelling of the extraction of leads I did not find any damages on two leads. Steroid collar of the leads had several damages and, I found three injuries on one sample with electron microscopy. In one case, an about 400 µm long surface scratch could be seen on the insulation coating of the lead. The character of the damages was the same in all cases: long-shaped forms, deeper scratches having sharp contours in comparison with damages caused by friction. The leads could be extracted without ruptures in all cases. On the basis of the structure of the surface injuries, it can be concluded whether the observed damage is the result of the extraction of the lead or that is caused by stress of the heart motion.

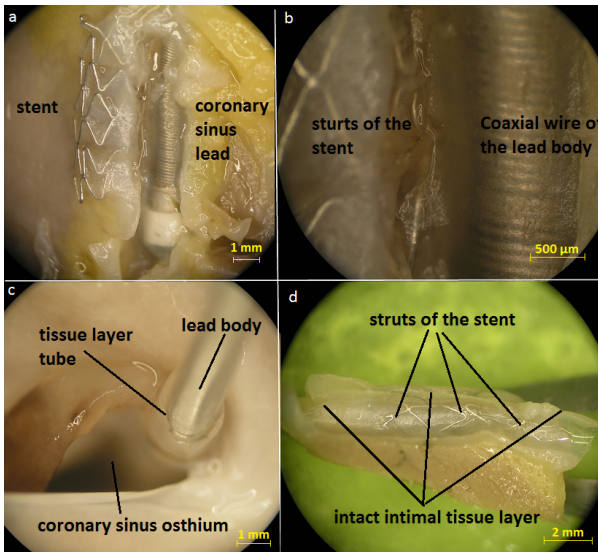
I found deeper injuries on the silicon insulation coating on two leads extracted from their real surroundings, indicating the effect of the extraction of the leads. In case of the Corox OTW 75 UP lead, 34 µm, while in case of the Attain OTW 4193 lead, 47 µm depth of injury could be measured. Only minimal surface damage could be observed after a longer time with implanted stent, due to the continuous friction only on the surface structure of the insulation coating of leads. Injuries on the steroid collar of leads, could not be observed.

### **Experiments Performed on Hearts removed during transplantation**

Having had the support of the Heart Centre of Semmelweis University, I had the opportunity to investigate two hearts removed during transplantation, together with implanted left ventricular lead (Corox OTW and Attain 4193) stabilized with stents. Aim of the investigation was to analyse intravascular tissue reactions developing as a result of the stented stabilization of coronary sinus lead.

Corox-lead had been functioning for 26 months and Attain-lead for 15 months after the CRT implantation. I carefully dissected the wall of the coronary sinus on the outer surface of the heart, along its longitudinal axis and I removed the lead manually. I observed the procedure under microscope, and then I investigated the injuries on the lead.

The coronary lead and the stent were fully embedded into their surrounding area with an intact tissue layer. In both cases, a thin tissue layer developed between the stent and the lead, separating the two implants from each other (figure 2). Morphological alterations referring to some tissue scarring or presence of some proliferative tissue could not be discovered.



**Figure 2: Endothelial tissue layer around the coronary lead stabilized with a stent: a)** microscopic image taken after excising of the vein, it is distinctly visible that the stent and the lead are without contacting each other; they are in a distance from each other; **b)** An enlarged microscopic image to determine the distance between the lead and the stent ; **c)** the lead is covered with an endothelial layer up to the orifice of the coronary sinus; **d)** cross-sectional image of the vein section after the extraction of the lead. A covering tissue layer can be found on the struts of the stent, proving that the stent really is not in contact with the lead.

Tissue layer found in between the lead and the stent formed tissue coverage (sheath) around the lead that presumably prevented the development of injuries during the extraction of the lead. The stent was not deformed because that was embedded into the structure of the tissue layer.

We assume that the stabilizing mechanism of the stent is remarkable important in the early period after the implantation, until the full development of the local endothelization process is completed. In the early stage of implantation the stent fixation itself can maintain the appropriately positioned lead on its optimal place. Later the developing tissue stabilizes the lead and it can keep it in its earlier fixed position as a result of the endothelization tissue reaction. Subsequently, the

stabilizing function of the stent will be taken over by the covering tissue layer developed around the lead and the stent.

My conclusions of the investigation on human hearts are limited because I made my statements on the basis of studying two human samples only. However it should also be considered, that, receiving removed heart during heart transplantation for research studies is very difficult. Even the observations on two cases have outstanding importance and valuable conclusions.

## ***New Scientific Achievements***

### **Examination of extracted left ventricular pacemaker leads**

I developed an expert system that is applied for the damage assessment of pacemaker leads. With applying this system the nature and extent of injuries can clearly established. The test system is based on two modules, performing functional tests and microscopic analyses damage and functional properties of the lead. Based on the examination of explanted leads in the expert system of testing, I concluded that:

**Thesis 1:** In case of stent stabilization of the left ventricular lead the stent didn't cause any damages in the lead that could endanger its functional operation neither during the 24 months' implantation period, nor during the extraction procedure of the lead. The method of stabilization with stents is secure and efficacious. [18, 19, 21, 22, 23, 24]

### **Measurements of mechanical characteristics of veins**

On the basis of testing coronary veins of swines, I have gained new scientific results in relation to the strength and the strain at strength of veins. I have concluded that in case of longitudinal samples of the coronary vein, strength is  $2,55 \pm 0,46$  MPa; in case of transversal samples it is  $1,06 \pm 0,07$  MPa, while strain at strength is  $137 \pm 37\%$  and  $323 \pm 79\%$ , respectively.

**Thesis 2:** Samples of the coronary veins from swines are anisotropic to such an extent that, between their longitudinal and transversal strain characteristics are different they exceed the double value. [16, 17]

Having measured the strain at strength of coronary veins, I worked out two theoretical models for the calculation of, the optimal stent size that can be determined depending on the diameter of the vein. The stabilization of stented pacemaker lead is efficient, preventing the dislodgement of the lead. In the case if the extraction of the lead is indicated, it can be removed without any rupture or damage. On the basis of the models, I defined my recommendations for the clinical practice how to choose an optimal stent diameter for stabilizing the coronary lead:

**Thesis 3:** In the case of 2–3 mm vein diameter the optimal stabilization of the left ventricular pacemaker lead can be achieved with the use of a stent 10–15 mm in length and with diameter of 2–3 mm.

**Thesis 4:** In case of vein diameter exceeding 3 mm, the stent size must be adjusted to the diameter of the vein. The nomogram of my model can be applied for the selection the optimal size of the stent.

### **In-vitro modelling of the Extraction of Leads**

I have worked out two test procedures for in-vitro modelling of the extraction of leads. On the basis of these procedures, I have the following conclusions:

**Thesis 5:** In case of the application of a stent with appropriately selected size for the stabilization of a pacemaker lead, the stent will provide an additional fixation in comparison with the traditional implantation technique. However, if the removal of the lead is indicated, the force that is applied to the extraction of the lead will not cause its rupture and the lead can safely be extracted. [19, 21, 24]

**Thesis 6:** The stents are significantly deformed during the extraction of the pacemaker lead: In my in-vitro model I observed that stents with smaller size than the optimal value turned around crosswise during the lead extraction. This can cause injury of the vein and its surroundings within the heart of the patient, particularly if the lead must be extracted soon after the implantation before the protecting tissue forming process is completed. [21, 24]

### **Investigation of the relations between the lead, the vein-wall and the stent on removed human heart obtained at transplantation.**

I examined human hearts removed during transplantation. Histological examination of the contact between the lead, the vein-wall and the stent showed the development of a tissue sheath surrounding the pacemaker lead. The time elapsing after the implantation was at least 15 months until my attempts to extract leads and this time was enough for the endothelization process. This endothelial layer separates the lead from the stabilizing stent. In case of one of the heart transplant patients, the thickness of the tissue layer around the implanted Corox-lead tip was 110 micrometre, while at the thinner body part of the lead it was 370 micrometre. In case of the other patient I measured 96 micrometre thickness of tissue layer beside the implanted Attain-lead between the external surface of the stent and the lead.

**Thesis 7:** The stabilization of the pacemaker lead with a stent positioned in the coronary sinus is remarkable essential only in the early period after the implantation, until the development of the sheath by the endothelization tissue is completed. [23]

**Thesis 8:** The developed tissue sheath separates the lead from the stent physically at least 15 months after the implantation. During the extraction of the pacemaker lead, the developed tissue sheath can diminish the risk of damages of the implanted stent and the lead. [23]

### ***Application and Utilisation of the Results***

Observations during clinical work and the practical experience of physicians performing cardiac interventions arise questions demanding medical technological approach. The results of my research work are not only a conclusion of a medical technology, but the results of my research work with the conclusive view of an engineer, provide a useful and relevant information for the physician and my observations can directly be utilized and applied in clinical practice.

The summary of the theoretical and practical utility of my study results in an engineer's work and in medical practice is reviewed below.

The applied in-vitro methods can be used for the quality control of the manufactured products, the leads;

- Special characteristics of medical products can be compared and evaluated.
- Certain quality requirements (e.g. tensile strength, stretching, etc.) can be defined for determination of limits of ranges of physical and mechanical properties
- My results can be considered and utilized in the innovative research development of devices.

The results of my simulation measurements and other observations have valuable conclusions to the physicians

- Useful information concerning the application of the device (e.g. level of the extraction force when the lead is being extracted)
- I have worked out recommendations and guide for the selection of the optimal sized stent for the stabilization of the lead on the basis of the obtained results of objective measurements, which can be utilized in clinical practice.

Finally in my research work I have proved how the professional co-operation of engineers and physicians can help mutually and successfully the co-operative research work in the field of medical technology and in the clinical practice.

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