Periodica Polytechnica
Mechanical Engineering

57(1), pp. 41–44, 2013
DOI: 10.3311/PPme.7016

RESEARCH ARTICLE

Simulated extraction of stent stabilized coronary sinus leads

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Received 2013-04-30

Abstract

Cardiac resynchronization therapy (CRT) is an effective non-pharmacological therapeutic method for the treatment of selected patients with chronic heart failure with a wide QRS complex and mechanical dyssynchrony of cardiac ventricles. A new technique is used to stabilize the implanted coronary sinus lead in an appropriate position with an expanded coronary stent to maintain synchronous pacing of the left ventricle. The extraction of the previously stented lead might be indicated for any medical or technical reason. Neither the capability to stabilize the lead, nor the lead removal procedure and the necessary physical activity of extraction have been evaluated yet. The aim of our study is to simulate the extraction of a stent stabilized coronary sinus lead in in-vitro experiments. We evaluated the additional stabilization capability of the technique, as well as the extraction force needed to pull out the CS lead using stabilizing stents with different diameters and lengths.

Keywords

extraction · stent stabilized coronary sinus lead · resynchronization therapy

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1 Introduction

Cardiac resynchronization therapy (CRT) is an effective non-pharmacological therapeutic method for the treatment of selected patients with chronic heart failure with a wide QRS complex and mechanical dyssynchrony of cardiac ventricles. The recently published MADIT CRT trial showed that 7.5% of the coronary sinus (CS) lead implantations were unsuccessful and 5-10% of patients required re-operation during the follow-up period, due to CS lead dysfunction [1–3].

Stent implantation may improve the stability of the lead position stabilizing the CS lead to the wall of the CS side branch. A stable lead position may improve the implantation success rate and decrease postoperative complications. The long-term results of the technique are promising, however, it is still not known whether the implanted coronary sinus lead can be easily and safely extracted without damaging the lead in case of system infections or potential CS lead replacements [4].

The aim of our study is to simulate the acute extraction of a stent stabilized coronary sinus lead in in-vitro experiments. We evaluated the additional stabilization capability of the technique as well as the extraction force needed to pull out the CS lead using stabilizing stents with different diameters and lengths.

2 Methods

A special system was developed and constructed to simulate the realistic conditions under which the implanted CS lead is extracted. The heart's anatomy and the requirements of a resynchronization were considered in the constructions. An 8 mm thick wood element with a curved, open channel (45 mm bending) was prepared. The suitable silicon tube was selected as an appropriate replacing material with similar physical properties as the coronary veins that can serve as a reliable model of the anatomic situations. A silicon tube that is having similar elastic properties like the coronary vein (with a wall thickness of 1 mm and an inner diameter of 5 mm) was inserted into the prepared curved channel. This model has similar structural qualities as in the anatomy of the coronary sinus on the atrio-ventricular border and capable to simulate the acute lead extraction [5].

Six Attain OTW 4193 leads (Medtronic) and one Corox OTW

75 UP (BIOTRONIK) lead were used and extracted in our experiments. The thickness of the electrode tip of Corox OTW UP was 5.8 Fr (1.914 mm), and the Attain OTW 4193 lead was 5.4 Fr (1.782 mm). Different stents were available for the fixation (Pro-Kinetic, Orsiro, manufacturer: BIOTRONIK). We performed 11 extractions with different CS leads and stent combinations to evaluate the force needed to pull out the lead. The relation of extraction force and stent size was also assessed using different lead types (Tab. 3.

Zwick Z005 tensile test equipment was used to model the extraction and to record the required pulling force. This machine has a fixed lower clamp and a moving upper clamp. The wood element was fixed in the lower clamp and the tube was filled with a physiological solution. The stent was introduced into the silicone tube and positioned with a 2-5 mm distance from the lead tip. According to the clinical routine the stent was expanded at 14 atmosphere inflation pressure maintained for at least 6 seconds. Thereafter, the CS lead was stabilized with the introduced coronary stent positioned beside the lead, as it is used in the daily practice of physicians implanting CRT systems (Fig. 1).

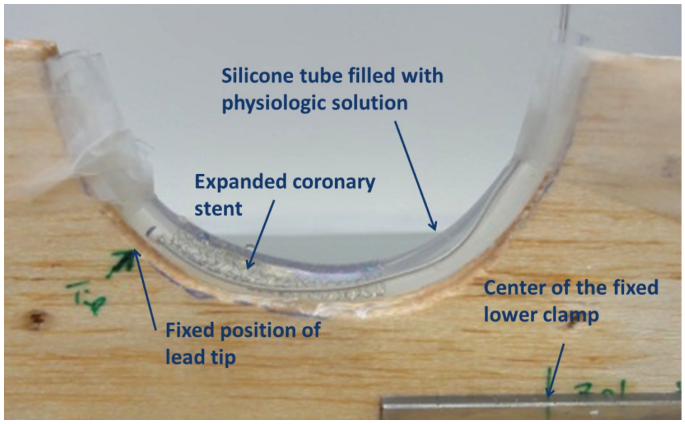

Fig. 1. Wood element modelling the coronary sinus with an already implanted CS lead and expanded stent at the lead tip

The proximal part of the lead was fixed in the upper clamp at 10 cm from the connector. This is the length of the lead that is available for the extraction, as it is freely movable in the pacemaker pocket. With the same position of the wood element and the same position of the leads, they were fixed and positioned in the wood element similarly in all experiments.

The extraction of the lead was performed with a fixed 100 mm/min pulling speed which is realistic and comparable with the speed of extraction that physicians use when removing the lead. Extraction force of the leads is defined as the maximum force that is applied during the pulling out process and that is continuously measured until the leads are completely extracted from the silicone tube.

Extraction of non-stented leads was performed with a Corox and an Attain lead inserted in the silicon tube under the same conditions as for the removal of the stented leads in order to evaluate the pulling force of a lead without additional stent stabilization.

Examination of the force required to tear the lead can give an idea of the maximum pulling force that can be applied during a lead extraction in clinical practice. Measurement of the real extraction force of the lead is almost impossible during the medical procedure under realistic conditions.

A Corox and an Attain lead were examined after the extraction with the tensile test equipment to define the force required to tear the lead. The tip of the lead was fixed in the lower clamp and the connector of the lead was fixed in the upper clamp. Due to the internal lead design, during the tensile test, the lead length could be extended to several times its own length before the lead was disrupted. Rupture of the outer silicone or polyurethane insulation was considered as the indication of lead fracture.

3 Results

The extraction forces of all 11 samples were successfully recorded and the Force-Displacement curves are summarized in Fig. 2. In one case, the lead fixed with a 5× 40 Pro-Kinetic stent could not be removed. The recorded force displacement curve was not analyzed because the effective extraction force applied was outside the range of usable removing power.

The characters of the curves were identical when the maximum extraction force exceeded the limit of 2N. At the first stage of the applied removing procedure, the lead gets strained in relation to the increasing tensile force without moving the lead tip. If the pulling force overcomes the stent stabilizing fixation, lead displacement next to the stent may result. The lead passes along the stent and the rate of applied pulling force gradually decreases. When the tip reaches the outer shoulder of the stent, it suddenly jumps out of the tube of the vein model and the tensile force almost immediately drops to zero-level.

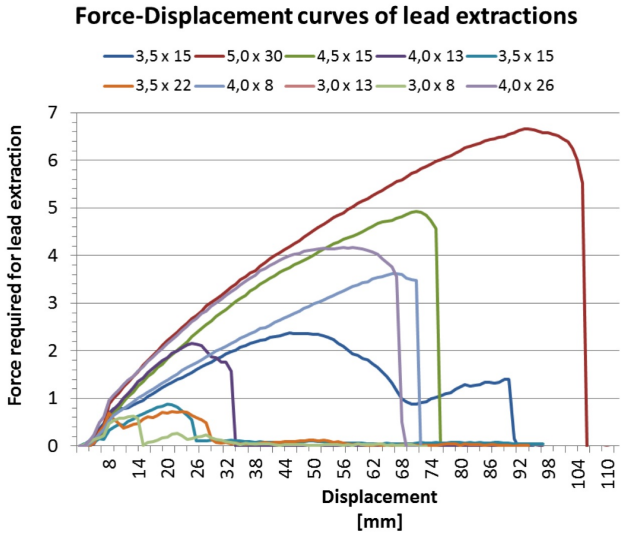

Fig. 2. Diagram of Force-Displacement curves of extracted leads (in-vitro experiments)

If the lead was stabilized with a 3.5 × 15 Pro-Kinetic stent, we found that after the maximum tensile force was reached, the force decreased gradually, and after that a second increase of force was observed. The character of the curve was different

Tab. 2. Coronary sinus leads and stents to simulate lead extraction

Sample	Coronary sinus lead (Type, manufacturer)	Type of stent	Dimensions of stent (Diameter × length)
1.	Corox OTW 75 UP, BIOTRONIK	Orsiro	3.5 x 15
2.	Attain OTW 4193, Medtronic	Pro-Kinetic	5.0 x 30
3.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.5 x 15
4.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.0 x 13
5.	Attain OTW 4193, Medtronic	Orsiro	3.5 x 15
6.	Attain OTW 4193, Medtronic	Orsiro	3.5 x 22
7.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	4.0 x 8
8.	Attain OTW 4193, Medtronic	Pro-Kinetic	3.0 x 13
9.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	3.0 x 8
10.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.0 x 26
11.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	5.0 x 40

Tab. 3. Maximum extraction force in combination with different leads and stents.

Sample	Coronary sinus lead (Type, manufacturer)	Type of stent	Dimensions of stent (Diameter × length)	Maximal extraction force [N]
1.	Corox OTW 75 UP, BIOTRONIK	Orsiro	3.5 x 15	2.39
2.	Attain OTW 4193, Medtronic	Pro-Kinetic	5.0 x 30	6.69
3.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.5 x 15	4.96
4.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.0 x 13	2.17
5.	Attain OTW 4193, Medtronic	Orsiro	3.5 x 15	0.9
6.	Attain OTW 4193, Medtronic	Orsiro	3.5 x 22	0.75
7.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	4.0 x 8	3.64
8.	Attain OTW 4193, Medtronic	Pro-Kinetic	3.0 x 13	0.01
9.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	3.0 x 8	0.64
10.	Attain OTW 4193, Medtronic	Pro-Kinetic	4.0 x 26	4.19
11.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	5.0 x 40	8.3
12.	Corox OTW 75 UP, BIOTRONIK	Pro-Kinetic	5.0 x 40	9.27

than observed in other experiments. The extraction force first reached 2.39N and then began to decrease. After approx. 67–72 mm displacement, it increased again. The explanation for this is that if the pulling force reaches the extraction force, the Corox OTW lead starts to move out in the direction of the pulling force, and the stent is deformed by the shifting lead. After a moderate deformation of the stent, the lead was held back by the strut of the stent and the two implants could only be removed from the vein model at the same time with an increasing pulling force.

The stent deformation was too high during the measuring procedure when the Corox OTW lead was stabilized with a 4.0×8 ProKinetic stent. We assume that the length of the stent was too short and it turned over in the vein model during the removing procedure. If a 3.0 mm diameter stent was used for fixation, the lead could be removed easily without any deformation or dislodgement at an extraction force lower than 1N. We observed that the stent requiring an extraction force less than 1N was not adequate for the evaluation because the stent did not affect the extraction process at all, and it did not generate an additional fixation force on the lead. For that particular reason, only the stabilized cases were evaluated with the extraction force exceeding the limit of 2N.

The forces for 12 extractions obtained from the recorded Force-Displacement curves are summarized in Tab. 3. In the case of sample no. 11, the maximum force was applied, but the stented lead could not be removed at all even in the repeated experiments (no. 12) and the extraction procedure had to be terminated.

The evaluation of the pulling force of leads without stent stabilization was successful. The Corox OTW UP lead had a maximum pulling force of 0.33N and the Attain OTW 4193 lead had a maximum force of 0.15N during the removal procedure.

The maximum working length of the tensile test equipment was reached for both lead types when the tensile tests of the Corox and Attain leads were performed and the test system stopped automatically. The maximum force applied was 9.75N for the Corox OTW lead and 14.21N for the Attain OTW leads. Surface insulation rupture or damage was not observed even at these high-force loading levels.

4 Conclusions

In our study we were able to simulate the stabilization and the acute extraction of a coronary sinus lead (when no tissue growing can be observed) and we could evaluate the extraction force needed to pull out the CS lead using stabilizing stents.

The following observations were made in our experiments:

1 In our study, we demonstrated a reliable additional lead stabilization by means of a stent implantation in a vein-simulating system in comparison to standard lead positioning without stenting.

2 We evaluated the extraction force needed to pull out the CS lead using stabilizing stents with different stent diameters and lengths.

3 We proved that if an adequately sized stent is selected for the fixation, the lead can be removed safely and extracted for any medical or technical reason without risk of damaging or fracturing the lead.

4 Stabilization was defined as an "optimal fixation" if the lead could be extracted without any damage or complication. The "optimal fixation" could be achieved with a carefully selected, appropriately sized stent.

5 Optimal stent stabilization can be achieved if the extraction force is higher than 2 N but lower than 6-7 N.

5 Limitations

Our observation was obtained during in-vitro simulations of the realistic medical procedure. However, we can not simulate the interaction of leads and organic structures and tissue reactions to the biological environment (for example, inflammatory reactions, endothelization processes, etc.). This acute extraction model can not be used to simulate lead extractions after years of implantation when the extraction is highly depending in fibrous process because in that case a tissue layer is covered the lead and the stent as well. Our results show a realistic relationship between the applicable extraction forces and different stent sizes and can probably offer guidance to physicians who have to select a suitable stent size for coronary sinus lead stabilization. Stent fixation of CS leads is not a frequently used method and may not be necessary in the future if alternative techniques will be available that supports the stabile positioning of the implanted CS leads.

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