DETECTION OF STRUCTURAL FAULTS IN CORONARY ARTERY-IMPLANTED STENTS THROUGH NON-INVASIVE TECHNIQUES OF MICROWAVE RADIATION

Oriol Rodríguez Leor

Institut d'Investigació Hospital Universitari Germans Trias i Pujol

Javier Tejada Palacios

Facultat de Física – Universitat de Barcelona

1. Summary of the project

Cardiovascular diseases are the leading cause of morbidity and mortality in our society. Coronary artery disease, in its various clinical manifestations (stable angina, unstable angina, myocardial infarction, sudden death), often requires endovascular treatment using a coronary stent implant. Coronary stents are metal structures with a tubular, reticular shape, implanted inside the coronary arteries in the presence of significant obstructions, to restore coronary flow and improve symptoms and the prognosis of patients.

Stents may present a variety of problems when implanted at the coronary artery level. This is relatively infrequent but when clinical problems are present they can be severe, being mainly intrastent restenosis (proliferation of the intima of the vascular wall inside the stent that can cause a reocclusion of the vessel); lack of contact between the stent surface and the vascular wall (mainly due to vascular remodeling that results in dilation of the artery and may predispose to intrastent thrombosis); fracture of the stent (the metal structure of the stent may be affected by corrosion or be subjected to constant shear forces that cause fracture); stent recoil (the pressure exerted by the vascular wall on the structure of the stent may cause a partial collapse of the stent). Currently the methods for monitoring or detecting implant stent alterations are invasive and / or ionizing techniques such as costly coronary angiography, intravascular ultrasound or optical coherence tomography and their use cannot be generalized to all coronary stent patients. However, these are techniques that require very specific machinery that is not available outside high-tech centers.

Coronary stents have a metallic structure with characteristic electromagnetic resonance in a frequency range between hundreds of megahertz (MHz) and tens of gigahertz (GHz). This electromagnetic resonance can be detected by a frequency scanning procedure involving a broadband signal that excites the resonance frequencies in the stent. Scattered radiation analysis can provide insights into the stent environment (related to intrastent restenosis or vascular wall remodeling and lack of contact with the stent surface) and stent geometry (related to structural damage to the stent).

The project hypothesis is that since the stent is a metallic structure with a characteristic electromagnetic resonance in a frequency range between hundreds of MHz and tens of GHz, electromagnetic resonance of stents can be detected by broadband frequency scanning that excites stent resonance frequencies. Scattered radiation analysis can provide insights into the stent environment (related to intimal proliferation and intrastent restenosis phenomena, delayed vascular remodeling, and poor wall apposition phenomena) and the geometry of the stent (related to fracture or recoil of the stent).

The specific objectives of the project are the development of a device that allows non-invasive and non-ionizing characterization of coronary stents once implanted and validation of its use in an animal model in terms of ability to detect restenosis, structural damage and / or lack of stent apposition to the vascular wall.

2. Results obtained

The results of the work done over the last 4 years are summarized in the following points:

a) Experimental simulation of the electromagnetic properties of stents. We characterized basal stent electromagnetic resonance phenomena with different lengths, diameters, and structural designs. We also characterized in vitro model changes in resonance parameters when there are structural alterations (deformation, recoil, fracture) or when the stent medium changes (simulation of restenosis or incomplete apposition).

b) Development of a prototype microwave measuring system for the study of stents in vitro and in vivo. This system is easy to use, based on probes and antennas, and allows the capture of data synchronously with the electrocardiogram, to always measure at the same time in the heart cycle. This is essential to be able to make measurements in vivo.

c) Validation and evaluation of the prototypes in vitro (in air and immersed in water).

d) Validation and evaluation of in vivo prototypes in a pig model. Stenting at the circumflex coronary artery as well as the femoral (more superficial) artery was implanted in 10 pigs, with follow-up and measurement for 30 days. The antenna-based prototype allowed stent detection in all cases, while the probe-based prototype only allowed stent detection in some cases, due to a measurement depth limitation.

e) The implementation of the project has resulted in an initially unplanned application of the technology, such as the characterization of the stent during the manufacturing process. This application can be very useful because in the manufacturing process the quality control of the stents is carried out manually, and the technology developed can allow it to be done automatically by characterizing the optimal signal of each stent once manufactured.

3. Relevance with possible future implications

The results of this project open two fields of application of the developed technology:

a) Characterization of the stents once implanted

Stents are metal structures that have a characteristic resonance when subjected to a microwave source. This resonance has an initial pattern and is modified by changes in the structure of the stent (fracture or recoil) and in the tissue surrounding the stent (intrastent restenosis or lack of attachment to the vascular wall). We have shown that these phenomena can be adequately characterized by the technology developed and that it may allow application in stent monitoring. Currently prototypes are being refined to ensure penetration capacity greater than 5 cm from current devices. We have also started a human study to monitor carotid stents, where depth is not a limitation.
Once the prototype has been refined, it will allow monitoring of the stents once implanted. A basal reading of the resonance spectrum will be required, immediately after the implant, and later readings may be performed which will give information on what happens to the structure of the stent and the tissues surrounding it during follow-up, allowing non-invasive and pre-clinical diagnoses of phenomena related to the development of late stent complications such as intrastent restenosis and stent thrombosis.

The final measuring device must be portable and of use at the patient's bedside, with the intention that its use may be generalized not only in large hospitals or high-tech centers but also in primary care centers or outpatient clinics, within the routine monitoring of patients who have a stent implanted.
In addition, this technology may be useful for monitoring peripheral vascular stents.

b) Characterization of stents during the manufacturing process

We are currently working on the development of a device (hardware and software) that can be added to the stent manufacturing chain and allows for systematic quality control. The stent manufacturing industry has welcomed the possibility of using this technology, as in many cases the control is manual and unsystematic.

4. Generated scientific bibliography

Publications

Gálvez-Montón C*, Arauz-Garofalo G*, Rodriguez-Leor O*, Soler-Botija C, Amorós García de Valdecasas S, Gerez-Britos FD, Bayes-Genis A, O'Callaghan JM, Macià F, Tejada J. Ex vivo assessment and in vivo validation of non-invasive stent monitoring techniques based on microwave spectrometry. Sci Rep. 2018 Oct 4;8(1):14808

Communications in scientific meetings

Carolina Gálvez-Montón, Oriol Rodriguez-Leor, Gianluca Arauz-Garofalo, Carolina Soler-Botija, Susana Amorós García de Valdecasas, Juan Manuel O'Callaghan, Javier Tejada, Antoni Bayes-Genis. Espectrometría de microondas para la monitorización no invasiva de stents. SEC2018-Congreso de las Enfermedades Cardiovasculares. Seville, 25-27 October 2018

S. Amoros Garcia De Valdecasas, G. Gonzalez-Lopez, I. Jimenez Cuesta, LL. Jofre, A. Bayes-Genis, J. Tejada, JM. O'Callaghan Castella, O. Rodriguez-Leor, C. Galvez-Monton. Novel microwave technique for coronary stent monitoring. Frontiers in Cardiovascular Biology 2020. Budapest, 24-26 April 2020.

Oriol Rodriguez-Leor. Espectrometria de microones per a la caracterització no invasiva d'stents coronaris en el model porcí. V Reunió CardioNet, Grup de Treball de Recerca

Bàsica i Traslació Clínica de la Societat Catalana de Cardiologia. Centre de Medicina Comparativa i Bioimatge (CMCiB), Badalona, 13 March 2020

Doctoral thesis

Amorós Garcia De Valdecasas, Susana. Design of planar probes for stent monitoring. Master thesis (pre-Bologna). Univeristat Politècnica de Catalunya (UPC). http://upcommons.upc.edu/handle/2117/93073