catheter system for measuring arterial stiffness and pressure drops (Ramot)
code: 8-2013-562
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An innovative real-time, ultra-sensitive, Differential Pressure Catheter measurement and novel Arterial Stiffening assessment system during Renal Denervation (RDN) procedures.

A functional combined assessment system of stenosis severity and arterial wall stiffness variation for selection and deployment of stents during Coronary interventions.

The technology offers enhancement of procedure outcome and cost reduction by avoiding repeated hospital visits and length of recovery.

The Need

RDN is an endovascular catheter based procedure which uses thermal ablation for treatment of resistant hypertension. During the procedure, energy carrying Radiofrequency (RF) pulses are applied into the renal arteries wall at several locations, causing thermal damage aimed for denervation of nerves located in the vascular wall adventitia. The RDN procedure causes reduction of renal sympathetic afferent and efferent activity, which results in decrease of the systemic blood pressure. The success/failure of the procedure is currently evaluated only during follow-up, and there is no indication for the effect of the RF ablation in real-time during the procedure. Most importantly, there is no indication of the arterial stiffening during the procedure – a parameter critical to the success of the procedure.

The proposed technology facilitates real time monitoring of the stiffening of the renal arteries as a result of the RF ablation. The arterial stiffening is computed from changes in the blood pressure drop, measured from the artery lumen using a catheter. A critical requirement of the stiffening computation is that the pressure drop be measured with extremely high accuracy (~0.05 mm Hg). To the best of our knowledge the best accuracy available by commercial catheters for differential pressure (or pressure gradient) measurements is approximately 1.0 mmHg, which is too course for measurement of the required pressure drops during RDN. Our proposed technology makes such accuracy feasible without changing the pressure transducers owing to our in-house pressure restoration algorithm and monitoring system. The combination of pressure drop measurements with our proposed correcting algorithm brings the system to the required accuracy and enables the computation of arterial wall stiffening. The end result is the calculation of the effect and the potential damage of thermal ablation on the renal arteries.

The proposed technology and product is a differential pressure catheter measurement system comprised of a high precision differential pressure transducer connected to a fluid-filled multi-lumen, intra-arterial catheter, and a patented algorithm controller unit that computes the arterial stiffening from the acquired differential pressure measurements. The catheter is inserted into the renal arteries, which are subjected to renal denervation treatment, measures pressure drops in the location of the treatment, and diagnose and calculates the degree of arterial stiffening resulting from the treatment. Optionally, the catheter can be combined with a renal denervation technology (i.e. RF, laser ablation), or perform as a stand-alone system.

Potential Application

The potential field of application is Renal Denervation (RDN). The proposed technology offers monitoring in real-time the RDN procedure, and providing the interventionalists with important and critical information on the effect of their intervention. Currently the interventionalists do not get any feedback on how does the RF ablation affects the renal arteries, and whether the thermal ablation was efficient enough. Therefore any additional data to the interventionalists in real-time is essential, and can contribute to the successful outcome of the procedure.

Another field in which our technology can be applied is Coronary Intervention. The proposed technology can perform functional assessment of stenosis severity combined with assessment of the arterial wall stiffness variations. Such a combination is critical to the interventionalists as it provides the necessary and needed data for better decision making before stenting. Our proposed technology is specifically critical to border line patients where the arterial blockage is medium and the stent deployment is not considered fully. Using this technology in coronary intervention will require adaptation of the catheter system to the coronary artery tree.

Stage of Development

Ongoing research includes: (1) correlation of changes in the arterial stiffness to changes in the measured pressure drop. This step is investigated (a) in-vitro, on silicone mock arteries, and (b) in-silico, using fluid-structure interaction (FSI) computational simulations. (2) Calculating the technology sensitivity for sensing arterial stiffness changes during RDN procedure. This step is investigated using (a) in-vitro tests on ex-vivo porcine arteries, and (b) FSI computational simulations.

We have already shown a strong relation between changes in the pressure drop signal and changes in the arterial stiffness (in-vitro). We are now completing a series of tests for completion of the correlation between the two factors.

Recently we have performed a preliminary Proof Of Concept test in our catheterization simulator, using an ex-vivo carotid porcine artery. The goal of this test was to show that we can identify changes in the measured pressure drop when thermal ablation is applied to the arterial wall.

Pressure drops were measured using 5 french fluid-filled double-lumen catheter (18gauge/18gauge) and a differential pressure transducer. The pressure drop signal was corrected in real-time using our in-house restoration algorithm. Thermal ablation was applied to the outer side of the artery wall using a soldering iron. The soldering iron temperature is higher than what is used in RDN procedures, but we decided to use for the following two reasons: (1) starting the sensitivity tests with acute temperature condition, and (2) the thermal ablation was applied outside-in, in oppose to normal RDN procedure where the thermal ablation is applied inside-out: this fact reduces the sensitivity of the catheter to changes in the pressure drop as a result of arterial stiffening.

The results have successfully demonstrated that whenever we applied thermal ablation to the arterial wall, the pressure drop signal has changed, and remained different after the ablation was ceased.

Supporting Publications

Rotman, O.M., Zaretsky, U., Shitzer, A., Einav, S. Pressure Drop Measurement and Correction using Fluid-Filled Catheters and a Differential Pressure Transducer. Ann Biomed Eng, Nov 2013. Under review.

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