Patient-specific analysis help to develop a stent for percutaneous valve implantation

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Introduction
Every year about 600 patients only in UK require surgical treatment to replace their dysfunctional pulmonary valve. Since 2000, percutaneous insertion of a valved stent (Melody™, Medtronic Inc, Minneapolis, USA) avoided surgery to more than 1100 patients worldwide1 and Melody recently received the FDA approval.

Despite the success of a minimally invasive technique, the implantation site of patients with congenital heart disease who require pulmonary valve replacement is highly variable in size, geometry and dynamics. This limits the suitability of the current device to approximately 15% of patients who require pulmonary valve replacement, thus committing 85% of patients to surgical treatment options2.

A new valved-stent-graft, which would potentially increase the number of patients who could benefit from this minimally-invasive procedure, has recently been designed in collaboration with Medtronic. A hourglass shape stent-graft was developed as made of six super-elastic alloy wires interwoven with polymeric fabric. In January 2009, this new device was successfully implanted in the first man3 (Figure 1).

To establish whether potential new device designs would safely fit the wide implantation site morphologies, thus increasing the number of patients who might benefit from percutaneous treatments, we used patient-specific finite element (FE) simulations to assess the prospective applicability of new devices in a group of patients who require treatment. The FE analyses mimicked virtual percutaneous pulmonary valve implantation (PPVI) to provide morphological and structural information useful both for the development of the device design and for the clinicians in the decision-making process.

Materials and methods
62 consecutive patients who had undergone surgical pulmonary valve replacement at our centre between 2006 and 2008 were retrospectively selected. Magnetic resonance (MR) images of these patients before surgery were processed using imaging software (Mimics Inc. Materialise, Belgium) to reconstruct the volumes of each patient's implantation site. These 3D datasets were then converted into FE models. (Figure 2)
Three device designs were modelled and tested using FE simulations (Abaqus Explicit, Simulia, Providence, RI, USA): stent-graft SG1 resembles the first device tested in animals; stent-graft SG2 a custom device specifically tailored for the first patient morphology; and, stent-graft SG3 is a hypothetical larger device.

One-dimensional beam elements were chosen to mesh the stent wires. The graft fabric was meshed by membrane elements. A tight, rigid contact was assumed to simulate the suture between stent and graft.

The shape memory alloy model implemented in ABAQUS was used to describe the Nitinol material of the stent wires. A hyperelastic, isotropic constitutive model based on a reduced polynomial strain energy density function was applied for the fabric graft material. These material models were validated with experimental tests carried out for the Nitinol and fabric samples.

The implantation of each device (SG1, SG2, and SG3) was simulated inside every patient-specific anatomical model.

The analysis which mimics the clinical procedure into the 62 patients’ outflow tract models was divided in 2 steps. First, the stent was crimped down to 7 mm diameter using displacement control conditions. Second, the displacement constraints were removed under quasi-static conditions and the stent-graft tended to recover its original shape. In this step, a general contact algorithm was defined to allow interaction between the device and the RV, RVOT and pulmonary trunk internal wall.

Diameters at various sections of the devices, areas of contact with the arterial wall and strains affecting stent wires were analyzed to evaluate the success of a virtual implant.

**Results and discussion**

The different phases of a virtual deployment of SG2 into a specific anatomy are shown in Figure 3. Figure 3a illustrates the initial crimped positioning of the device inside the RVOT. The stent-graft, once the displacement conditions were released, adapted its shape to the arterial wall of each specific patient (Figure 3b). Figure 3c proves the area of contact between device and implantation site at the end of the simulation.

![Figure 3. Deployment phases of SG2 inside a patient’s implantation site model: a) crimped SG2 positioning; b) final configuration of the implant; and c) section of the internal wall where areas of contact are highlighted in red.](image)

All simulations (3x62) of implants of stent-grafts inside RVOT/PA patient-specific models were successfully carried out. Many examples of virtual implants into a variety of morphologies are shown in Figure 4. Measures of diameters and analyses of contacts showed that a safe anchoring was ensured in 37% of patients for SG1, 42% for SG2 and 63%.

![Figure 4. Ten examples of device implants](image)
Conclusion
In this study, we used realistic patient-specific data to demonstrate the utility of a new percutaneous pulmonary valve device. We have shown that by varying the dimensions of the device, the number of patients that could potentially benefit from this new treatment can be increased. Furthermore, once devices are developed, the methodologies presented could offer tools to help clinicians in the decision-making process for planning treatment with the correctly sized device.

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References