New insight in epicardial ablations: 3D-printed additive manufacturing as intra-procedural diagnostic and operative tool

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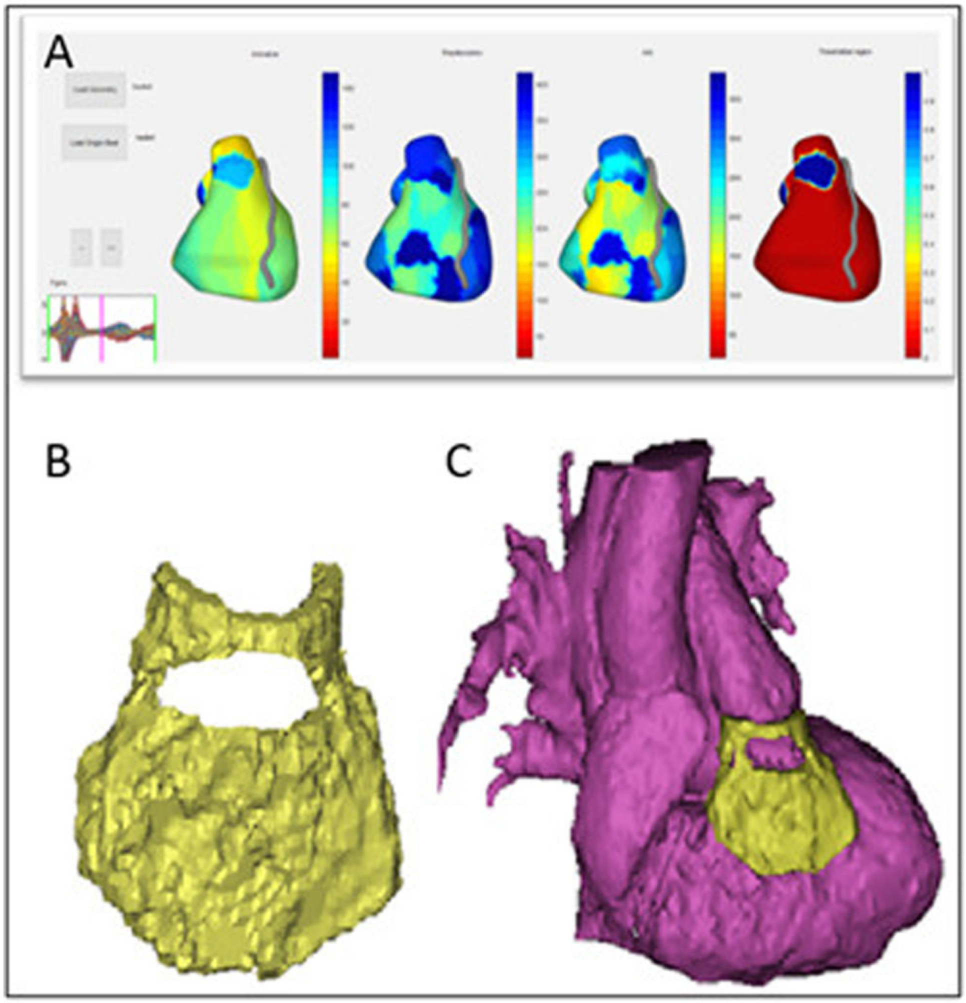
Background: The feasibility of additive manufacturings (AMs) as peri-procedural tools has already been established. In order to extend their use to intra-procedural tools for surgical, interventional, or electrophysiology procedures, AMs must be able to convey specific data from cardiac imaging and to come into contact with both biological tissue and energy sources.

Methods: A resin (MED625FLX) and a urethane thermoplastic elastomer (TPU) were chosen as materials for AMs, printed in a variety of thicknesses and configurations. Geometry test was conducted to compare the properties of materials before and after sterilization. In-vitro test was carried out in a wet lab to validate the safety related to propagation of energy underneath the material during application of power sources; three different sources (cryothermal, bipolar radiofrequency, unipolar radiofrequency) were tested. The release of debris derived from the AM on the biological tissue was verified both with electron microscopy and Raman spectroscopy.

Results: Geometries below 1 mm and above 2.5 mm did not pass the test after sterilization for both materials. A total of 100 energy applications were delivered during in-vitro testing. Temperature was kept constant. The type of material used for the AM, the energy-type delivered and the factorial combination of distance/material and distance/energy-type had a significant p-value for temperature changes on the tissue underneath the AM (Temperature*Material p=0,003; Temperature*Energy p<0,001; Temperature*Material*Position p=0,02; Temperature*Position*Energy p<0,001). Post-hoc test using Dunn's procedure showed significant p-values for distance (Temperature*Position p<.001) and energy-type erogated (Temperature*Energy*Cryo-biRF p<.001; Temperature*Energy*Cryo-uniRF p<.001; Temperature*Energy*biRF-uniRF p<.001), while there were no significant differences of temperature in relation to AM thickness and material. Raman spectroscopy on biological tissues revealed that no AM particles >1μm were released.

Conclusions: The use of AMs in intra-operative cardiac procedures may be feasible and safe, and it can be employed as a reliable integration of cardiological imaging into tangible localisation of certain specific structures or pathological substrates.

Example of AM 3D-printed prototype



Ablation in-vitro experiment