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Towards a fully absorbable percutaneous ASD closure device

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Introduction:
Transcatheter closure of hemodynamically significant atrial septal defects (ASDs) with adequate rims has become the standard treatment modality. While this treatment is generally safe and effective, there are several reports of complications of a chronic foreign body. In addition, the permanent implant hampers transseptal access to the left atrium should this be required during alter life. We investigated the feasibility and biological short-term effects of a fully absorbable septal occluder in an animal model.
Methods:
ASD were created interventionally in a sheep model by transeptal puncture and subsequent balloon dilatation of the defect (n=12). Using a 12F sheath, the defects were closed under fluoroscopic and intracardiac echo control using a (patially) radio-opaque, fully retrievable and repositionable septal occluder consisting of a completely absorbable polymer. Residual leakage was assessed by color Doppler and bubble contrast studies and devices explanted for gross pathology and histology after 1, 3 and 6 months.
Results:
Transcatheter ASD closure was possible in all animals. In 4 sheep the device was either repositioned or retrieved and replaced without problems. Devices showed excellent echogenicity and good visibility under fluoroscopy. All defects were closed effectively and showed no or small residual shunting immediately after implantation. No residual leaks were observed after 1-6 months follow up. Histology showed a very benign healing response with less cellular response compared to permanent implants and first signs of polymer resorbtion.
Conclusions:
Transcatheter ASD closure using fully absorbable, completely repositionable and retrievable ASD occluder is feasible. In an experimental sheep model the devices showed an excellent echogenicity and good radiopacity. During short-term follow-up there were no residual or recurrent leaks. Histology showed a favorable and remarkable inert healing response. While longer term results are awaited, the material and technology holds promise for percutaneous ASD closure without permanent foreign material.