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Histopathology of 56 human explanted atrial septal defect (ASD) closure devices

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Objective: To evaluate and characterize tissue reactions within and at the surface of devices for interventional closure of atrial septal defects.

Materials and methods: Explants were processed using a uniform protocol after surgical removal from humans. Devices were fixed in formalin and embedded in methylmethacrylate. Serial sections were obtained by sectioning with a diamond cutter and grinding, thus saving the metal/tissue interface for histological evaluation. Immunohistochemical stainings were performed using conventional protocols.

Results: 56 devices were analysed (Amplatzer n = 28, Cardioseal/Starflex n= 9, Biostar n= 5, Helex n= 4, others n= 10). Implants had been in the human body for 1 day to 15 years (mean 3.2 years). Main reason for explantation had been residual shunting in 19, thrombi and/or emboli in 10, heart surgery otherwise indicated in 8, device dislocation in 7, deformity of the device in 5, damage to the right atrial wall in 3 and other reasons in 4 patients, respectively. Endothelialisation and cellular organisation of tissue within the devices was present in all specimen with implantation times > 6 months. Lymphocytic infiltrations and local foreign body reaction related to textile components were found in almost all explants. Calcifications and partial corrosion or even loss of "permanent" materials (metal wires, ivalon foam) were seen in explants with implantation time > 7 years.

Conclusion: This is the largest cohort on ASD occlusion devices with complete histology work-up after surgical explantation. We demonstrate timely endothelialisation and tissue organisation, a typical pattern of chronically persisting inflammation. Calcifications and material alterations were seen in long-term explants. We conclude that patients with ASD occlusion devices should be followed life-long for detection of potential implant-related complications. Our findings may be relevant for development of new devices.