Optimal alignment of the Figulla® Flex Occluder (FFO) to the atrial septum before release in patients with atrial septal defects

(1): Department for Congenital Heart Disease; (2): Department for Surgery of Congenital Heart Disease, Heart and Diabetes Centre, Bad Oeynhausen, Germany

Introduction: Closing atrial septal defects (ASD’s) may be challenging for several reasons including deficient or floppy rims, abnormal anatomy of the ASD, the absolute ASD size in correlation to the atrium or the proximity to other relevant intracardiac structures such as coronary sinus or the AV-valves. Optimal alignment is those cases is crucial to visualize the presumed final position of the device. The Figulla® Flex device has a mobile joint connecting the delivery cable in a tilted angle of 45 degrees without significant stress on the implant. We report the results of the change in orientation before and immediately after device release.

Patients: Over the past 2 years we implanted 85 FFOs in our patients for interventional ASD closure (age 1 to 48 years, weight 6 to 100 kg). All investigations were performed under deep conscious sedation under TEE and/or TTE guidance (below 10 kg bw). Standard fluoroscopy included a strict lateral projection during the release process of the device (see pictures). The angles of the left and right atrial discs before (A and B) and after (C and D) the release of the device were measured and the difference (A-C and B-D) calculated thereafter.

Examples in 2 patients: note the minimal changes of the angles before and after release of the device

Results: The angles before release were A: 28,2° (±7,2°) and B: 42,6° (± 7,2°) before and C: 18,1° (±5,3°) and D: 26,5° (± 6,6°) after release, resulting in a change of the left atrial disc in 10 ° (±4,3°) and the right atrial disc in 16,1° (±6,4°) only.

Discussion: Whereas other devices with a simple screw system to connect the delivery system with the device cause a significant torsion and tension of the device, the delivery system of the FFO allows with the tilt of 45° an ideal adaptation to the septal tissue. All devices could be placed in the final position without adverse tension or stress caused by the delivery wire. We think that this device offers superior anatomical adaptation even in challenging anatomy.