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# Characterization of Atrial Septal Defect Occluders by right and left atrial pull-out forces

**Abstract:** Occluders made of the shape memory alloy Nitinol are commonly used to close Atrial Septal Defects (ASD). Until now, standard parameters are missing defining the mechanical properties of these implants. In this study, we developed a special measuring setup for the determination of the mechanical properties of customly available occluders (i.e. Occlutech Figulla® Flex II 29ASD12 and AGA AMPLATZER™ 9-ASD-012)

**Keywords:** atrial septal defect (ASD), device closure, septal occluder device, mechanical properties.

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## 1 Background

Cardiac defects are the most common congenital organ defects and occur in about 11 in 1000 newborns [1]. Atrial Septal Defects (ASD) are the second most common defects and make up to 17.0 % of the congenital heart diseases [2]. If ASD closure is indicated the use of implants made of the shape memory alloy Nitinol, so called occluders, is the method of choice today. Unfortunately, until now there are no standard parameters defining the mechanical properties and allowing an interindividual comparison of these implants.

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## 2 Aims

The occluders maintain their position in the heart by clamping forces determined by the shape of the device and the material properties. The aim of this study was to determine the maximum force, which is needed to dislocate ASD occluders by pulling at the right or left atrial side and thereby overcoming the clamping forces as an indicator of the stiffness of the occluders. All measurements were performed on occluders of different brand and model under clinical relevant conditions with the aim to compare their mechanical properties.

## 3 Methods

The occluders examined in this study were 12 mm in size, i.e. the 9-ASD012 AGA AMPLATZER™ Septal Occluder (AGA Medical Corporation, Plymouth, USA) and the 29ASD12 Figulla® Flex II ASD (Occlutech, GmbH, Jena, Germany). Both are shown in figure 1.

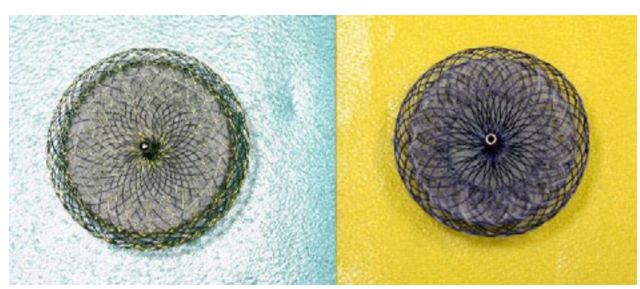

**Figure 1:** Examined occluder models: Occlutech occluder (left) and AGA occluder (right)

To simulate the clinical peri- and postoperative conditions, measurements were performed in 37 °C isotonic saline solution and in air at 21 °C. These environmental conditions represent on one hand the body temperature of the patient and on the other the circumstances during the physicians' preoperative occluder selection by manually testing its mechanical properties.

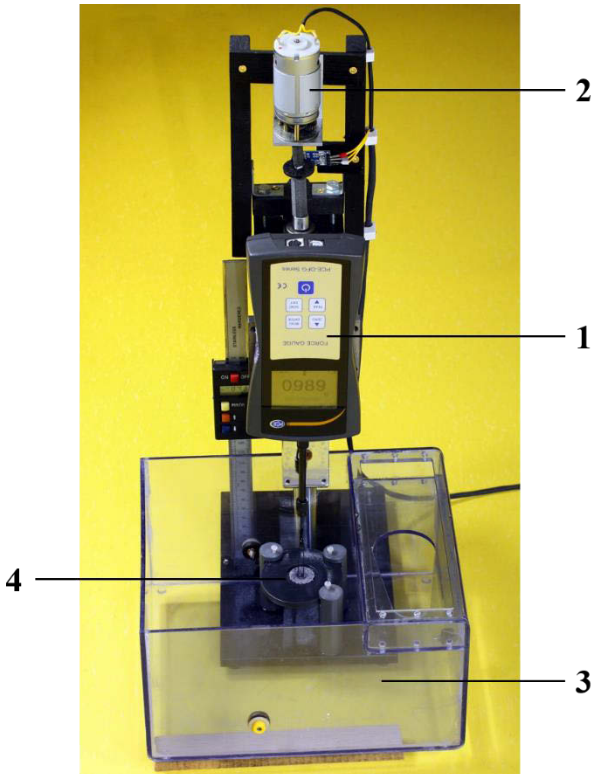


**Figure 2:** Measuring setup for the determination of pull-out forces

A special measuring setup (figure 2) was developed and constructed. It consists of a digital force gauge (1), a gear motor (2), a wet-lab (3) and the atrial septal model with the occluder (4) to be investigated. The digital force gauge PCE-LFG 10 (PCE Deutschland GmbH, Meschede, Germany) with USB connection has a measurement range up to 10 N. The measurement values can be exported via USB to a PC. The motor provides a 50:1 gear reduction. It ensures that the occluders are pulled out consistently. The wet-lab can be filled with isotonic saline solution and heated to 37 °C. The temperature is measured permanently and the target temperature is hold by a self-made control device (missing on the figure).

The atrial septal model is a 3D-printed disk with a circular hole in it. The size of the hole matches the size for which the occluders are suitable according to the manufacturers' specifications. It is flexible with a shore A hardness of 50, which is similar to heart tissue [3]. The pull-out measurements are each repeated five times.

To evaluate the measured data an unpaired T-test for independent samples was performed. The level of significance was chosen to be 1 %.

# 4 Results

All force measurements were successfully completed. Results are displayed in table 1 as mean values in Newton (N) with the standard deviation. The measuring setup was successfully used and the functional capability proven.

**Table 1:** Pull-out forces under various conditions

| | To the left atrial side | | To the right atrial side | |
|---|---|---|---|---|
| | **AGA 9-ASD-012** | **Occlutech 29ASD12** | **AGA 9-ASD-012** | **Occlutech 29ASD12** |
| **21 °C air** | 4.906 ± 0.041 N | 5.534 ± 0.142 N | 3.447 ± 0.032 N | 3.582 ± 0.277 N |
| **37 °C NaCl** | 4.375 ± 0.051 N | 4.670 ± 0.038 N | 3.305 ± 0.002 N | 2.999 ± 0.058 N |

## 4.1 Comparison of make and model specific pull-out forces

Comparing the forces that were needed to dislocate the implants, our measurements show that it takes significant ($p < 0.01$) more force to dislocate the Occlutech occluder under both environmental conditions by pulling at the left atrial side. It also needs more force to pull out the Occlutech occluder by pulling at the right atrial side in air. However, this difference is not significant ($p \approx 0.36$). In isotonic saline solution, significant more force ($p < 0.01$) is needed to dislocate the AGA occluder by applying the force at the right atrial side. These differences can be explained by the different constriction of the occluders. The AGA occluder has a hub on both sides, the Occlutech occluder only on the right atrial side. This affects directly the stiffness of the implant.

## 4.2 Influence of environmental conditions on pull-out forces

Comparison of the pull-out forces needed in the different environmental conditions demonstrates that it takes significant more force to dislocate the occluders in air at 21 °C. An explanation for that is that the blood simulating isotonic saline solution causes decreased friction between the implant and the septal model. Furthermore, the material behaviour of Nitinol depends on the environmental temperature.

### 4.3 Comparison of left and right atrial pull-out forces

Despite the fact that the right atrial occluder disks are smaller than the left ones, it takes significant ($p < 0.01$) more force to dislocate the occluders by pulling at the left atrial side. This can be observed for both environmental conditions. It can be explained by the fact that because the right atrial disks are smaller, the Nitinol mesh is denser and as a result of that the disks are stiffer.

## 5 Conclusion

Our findings demonstrate that different forces are needed to pull out ASD occluders from the left and right atrial side. Respecting the pressure differences in the atria, both left and right pull-out forces in various environments combined with the manufacturers tolerances could be standard parameters allowing comparison of different makes of occluders. These differences may result in a different stiffness of the occluders whilst in place, i.e. a stiffer right atrial side as compared to the left and a softer left atrial side of the Occlutech occluders as compared to the AGA occluders. Its differences should be individually considered in selecting and by implanting atrial septal occluders or may play a role if side effects do occur.

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