# Creation of a Predefined Interatrial Communication with the Occlutech® Atrial Flow Regulator: Outcomes in a Porcine Model

Jacek Baranowski[1], Henrik Ahn[1,2], Joseph J. Vettukattil[3,4]
[1] Heart Center, Linköping University Hospital, Linköping, Sweden
[2] Department of Medical and Health Sciences, Linköping University, Linköping, Sweden
[3] Congenital Heart Center, Helen DeVos Children's Hospital of Spectrum Health, Grand Rapids, MI, USA
[4] College of Human Medicine, Michigan State University, Grand Rapids, MI, USA

## Background

- Permanent interatrial communication with a defined diameter is beneficial for palliation of congenital heart conditions with obstructive lesions, failing Fontan circulation, heart failure, and pulmonary hypertension.
- The predetermined atrial communication allows for shunting, maintaining adequate cardiac output.
- Although percutaneous stent implantation and balloon dilatation are well-established techniques to create an atrial communication, they often result in complications such as spontaneous closure of the fenestration, excessive desaturation, and stent embolization.
- The lack of a safe and effective interventional device for creating a sustainable atrial fenestration led to the development of the Occlutech® Atrial Flow Regulator (AFR) device (Figure 1).

## Objective

- To evaluate the safety, and efficacy of the AFR device in a porcine model.

## Methods

- Eight 2.5 month old piglets weighing 35-50 kg underwent AFR implantation.
- Hemodynamic changes, device position and patency were monitored using echocardiography and fluoroscopy for 3 months.
- Tissue reaction and histopathological changes were also studied.

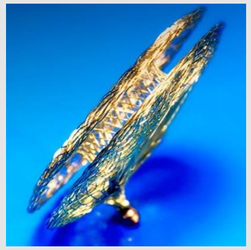

**Figure 1: Occlutech® Atrial Flow Regulator**

**Table 1. Pre- and post-implantation hemodynamics and fenestration patency at 3 months**

| Piglet | Device fenestration size (mm) | Pulmonary artery oxygen saturation (%) | | Mean pulmonary artery pressure (mmHg) | | Qp:Qs | | Fenestration patency |
|---|---|---|---|---|---|---|---|---|
| | | Pre- | Post- | Pre- | Post- | Pre- | Post- | |
| 1 | 8 | 54.2 | 53.0 | - | 17 | 1:1 | 1.16:1 | Patent |
| 2 | 10 | 55.6 | 42.4 | - | 25 | 0.9:1 | 1.2:1 | Excluded |
| 3 | 8 | 61.3 | 63.1 | - | 10 | 0.88:1 | 1:1 | Patent |
| 4 | 6 | 66.4 | 63.4 | - | 18 | 1:1 | 1.08:1 | Occluded |
| 5 | 10 | 67.8 | 58.0 | 13 | 11 | 1:1 | 1:1 | Patent |
| 6 | 4 | - | - | - | - | - | - | Excluded |
| 7 | 4 | 68.5 | 62.9 | 19 | 15 | 0.9:1 | 1:1 | Occluded |
| 8 | 6 | 62.3 | 60.7 | 14 | 11 | 1.08:1 | 1.08:1 | Patent |

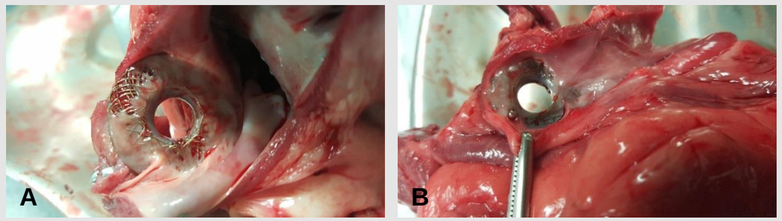


**Figure 2: Explanted device (Animal 5) with complete fenestration patency despite full endothelialization viewed from the A) left atrium and B) right atrium.**

## Results

- Eight animals were included in the study. The AFR was successfully implanted in 6 pigs; 2 were excluded from the study (Table 1).
- Device patency was demonstrable on echocardiography at 1 day after implantation (n=6).
- At 1-month follow-up, 2 pigs had spontaneous closure of the fenestration, but device patency was maintained in the remaining 4 piglets throughout the study period.
- Postmortem examination demonstrated patent shunts (Figure 2) with neoendothelialization (n=4), and slight decrease in pulmonary artery oxygen saturation 61.4 ±5.59 to 58.7 ±4.33 mmHg, but was not found to be significantly different at follow-up (p=0.3568). There was no statistically significant difference in the Qp/Qs before and after implantation (p=0.1881).
- No tissue reaction was noted at the implantation site (n=6).

## Conclusion

- The AFR device was found to be easy to deploy, safe, and effective in creating and maintaining a permanent atrial communication.

## References

- Bhamra-Ariza P, Keogh AM, Muller DWM. Percutaneous interventional therapies for the treatment of patients with severe pulmonary hypertension. J Am Coll Cardiol 2014;63:611-618.
- Stümper O, Gewillig M, Vettukattil J, Budts W, Chessa M, Chaudhari M, Wright JG. Modified technique of stent fenestration of the atrial septum. Heart 2003;89:1227-1230.
- Sivaprakasam M, Kiesewetter C, Veldtman GR, Salmon AP, Vettukattil J. New technique for fenestration of the interatrial septum. J Interv Cardiol 2006;19:334-336.