

# Balloon atrial septostomy in pulmonary arterial hypertension: Atrial flow regulator — New therapeutic option

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The article: “Balloon atrial septostomy in pulmonary arterial hypertension: A beneficial effect on the control of rhythm abnormalities” published in the *Cardiology Journal* (2016, Vol. 23, No. 5, 539–540) [1] which presents an important problem of patients with end-stage pulmonary arterial hypertension (PAH). The chronically elevated pressure in pulmonary circulation causes right ventricular failure with all its consequences. In the presented case, a 31-year-old patient was treated with treprostinil and sildenafil. Due to the supraventricular arrhythmia, two procedures of radiofrequency ablation were performed. As a consequence of clinical deterioration, the balloon atrial septostomy (BAS) was performed which improved the hemodynamic status and unexpectedly restored sinus rhythm.

The first report of blade BAS in patients with severe primary PAH was presented during the World Congress of Pediatric Cardiology in 1993. Authors reported a series of 15 children and adult patients with severe PAH in which BAS was performed. Interestingly, in 13 patients who survived BAS procedure, the long-term survival was essentially improved. In line with other reports, there was a significant increase in cardiac index, resulting in an increase in systemic oxygen transport [2–4]. Unfortunately, a subsequent size reduction or spontaneous closure of the defect has been observed in many reports requiring repeat BAS procedures [5, 6]. To avoid this problem, Micheletti et al. [7] implanted a custom-made fenestrated atrial septal device at the conclusion of BAS procedure to maintain the atrial septum opened. In 7 out of 20 children, the short-term spontaneous closure of the created defect was successfully avoided. This

approach has been implemented by other investigators [8, 9]. A fenestration was performed across the wire mesh and the waist of the device and the polyester fibers were subsequently removed. Platinum markers were placed on the right atrial disc of the device to reach the fenestration and to perform further procedures in the future. Also, the technique of implantation of the modified stent (“butterfly stent”) in created interatrial fenestration was reported [10].

The first factory-made fenestrated devices were offered by the Occlutech company. The atrial flow regulator (AFR) is self-expandable a double-disc nitinol wire mesh construction dedicated to create a communication and allow blood flow across the interatrial septum (Fig. 1). The disc diameter ranges from 16 mm to 23 mm, and fenestration diameter is from 4 mm to 10 mm. A 1–2 mm connecting waist exists between the two discs corresponding to the thickness of the atrial septum. The device has a very high flexibility and adaptability with unique braiding. It is repositionable and fully retrievable. The first-in-human use was performed by Vettukattil’s group in January 2015 [11]. After the implantation, there was an immediate hemodynamic and symptomatic improvement.

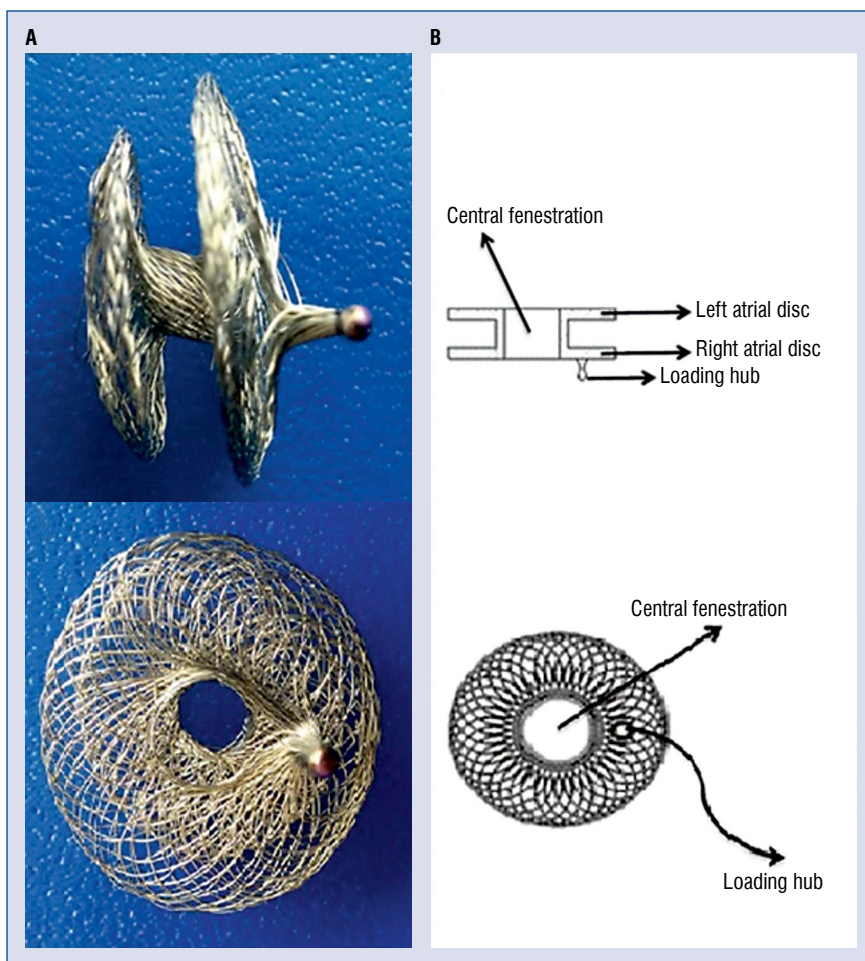
Besides its use, in PAH patients the future application of the AFR device may be extended to other heart failure populations especially those with severe diastolic dysfunction of the left ventricular and increased left atrial pressure. Implantation of the device may permit left heart decompression via the fenestration. Further clinical trials are still required.

**Conflict of interest:** None declared

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**Figure 1.** Atrial flow regulator-lateral view and technical drawing; **A.** Right atrial disc with loading hub; **B.** Technical drawing of right atrial disc with loading hub.

## References

1. Małaczyńska-Rajpold K, Araszkiwicz A, Mularak-Kubzdela T. Balloon atrial septostomy in pulmonary arterial hypertension: A beneficial effect on the control of rhythm abnormalities. *Cardiol J.* 2016; 23(5): 539–540, doi: [10.5603/CJ.2016.0075](https://doi.org/10.5603/CJ.2016.0075).
2. Kerstein D, Levy PS, Hsu D, et al. Blade balloon atrial septostomy in patients with severe primary pulmonary hypertension. Presented at the World Congress of Pediatric Cardiology and Pediatric Cardiac Surgery, Paris, France June 24. 1993.
3. Reichenberger F, Pepke-Zaba J, McNeil K, et al. Atrial septostomy in the treatment of severe pulmonary arterial hypertension. *Thorax.* 2003; 58(9): 797–800, indexed in Pubmed: [12947142](https://pubmed.ncbi.nlm.nih.gov/12947142/).
4. Law MA, Grifka RG, Mullins CE, et al. Atrial septostomy improves survival in select patients with pulmonary hypertension. *Am Heart J.* 2007; 153(5): 779–784, doi: [10.1016/j.ahj.2007.02.019](https://doi.org/10.1016/j.ahj.2007.02.019), indexed in Pubmed: [17452153](https://pubmed.ncbi.nlm.nih.gov/17452153/).
5. Kurzyna M, Dabrowski M, Bielecki D, et al. Atrial septostomy in treatment of end-stage right heart failure in patients with pulmonary hypertension. *Chest.* 2007; 131(4): 977–983, doi: [10.1378/chest.06-1227](https://doi.org/10.1378/chest.06-1227), indexed in Pubmed: [17426198](https://pubmed.ncbi.nlm.nih.gov/17426198/).
6. Sandoval J, Gaspar J, Peña H, et al. Effect of atrial septostomy on the survival of patients with severe pulmonary arterial hypertension. *Eur Respir J.* 2011; 38(6): 1343–1348, doi: [10.1183/09031936.00072210](https://doi.org/10.1183/09031936.00072210), indexed in Pubmed: [21349914](https://pubmed.ncbi.nlm.nih.gov/21349914/).
7. Micheletti A, Hislop AA, Lammers A, et al. Role of atrial septostomy in the treatment of children with pulmonary arterial hypertension. *Heart.* 2006; 92(7): 969–972, doi: [10.1136/hrt.2005.077669](https://doi.org/10.1136/hrt.2005.077669), indexed in Pubmed: [16278272](https://pubmed.ncbi.nlm.nih.gov/16278272/).
8. Fraisse A, Chetaille P, Amin Z, et al. Use of Amplatzer fenestrated atrial septal defect device in a child with familial pulmonary hypertension. *Pediatr Cardiol.* 2006; 27(6): 759–762, doi: [10.1007/s00246-006-1325-0](https://doi.org/10.1007/s00246-006-1325-0), indexed in Pubmed: [17111292](https://pubmed.ncbi.nlm.nih.gov/17111292/).
9. O'Loughlin AJC, Keogh A, Muller DWM. Insertion of a fenestrated Amplatzer atrial septostomy device for severe pulmonary hypertension. *Heart Lung Circ.* 2006; 15(4): 275–277, doi: [10.1016/j.hlc.2006.02.002](https://doi.org/10.1016/j.hlc.2006.02.002), indexed in Pubmed: [16857426](https://pubmed.ncbi.nlm.nih.gov/16857426/).
10. Prieto LR, Latson LA, Jennings C. Atrial septostomy using a butterfly stent in a patient with severe pulmonary arterial hypertension. *Catheter Cardiovasc Interv.* 2006; 68(4): 642–647, doi: [10.1002/ccd.20745](https://doi.org/10.1002/ccd.20745), indexed in Pubmed: [16969857](https://pubmed.ncbi.nlm.nih.gov/16969857/).
11. Patel MB, Samuel BP, Girgis RE, et al. Implantable atrial flow regulator for severe, irreversible pulmonary arterial hypertension. *EuroIntervention.* 2015; 11(6): 706–709, doi: [10.4244/EI-JY15M07\\_08](https://doi.org/10.4244/EI-JY15M07_08), indexed in Pubmed: [26477643](https://pubmed.ncbi.nlm.nih.gov/26477643/).