Hyperion™
CLINICAL INFORMATION

The interventional approach has become increasingly preferred for the treatment of many congenital and structural heart defects, including atrial septal defects (ASDs), ventricular septal defects (VSDs), patent ductus arteriosus (PDAs) and patent foramen ovale (PFO). Some severe sequelae that may affect the outcome of the interventional approach (CSI) are receiving increased attention from researchers, clinicians and physicians, for pediatric and adult treatment.

The short- and intermediate-term results achieved with these devices have been documented. Please find an overview of publications of the SHSMA occluder (Shanghai Shape Memory Alloy Co., Ltd.; Shanghai, PRC), marketed as Hyperion™ Occluders and Vascular Plugs by Comed BV, The Netherlands.

The Hyperion™ Occluder and Vascular Plug range is made out of pre-oxidized Nitinol wires, formed into a highly functional and elastic wire mash, providing a high level of anatomical compliance. The short hub design and screw housing are made out of oxidized stainless steel. The wire thickness differs per size and type to ensure:

- Functional elasticity
- Enhanced shape memory
- Easy positioning
- Optimal deployment

- High bio-compatibility
- Fast endothelialisation
- Minimized nickel release

The patch lining within the discs and connecting waist is made out of PET, fixed by a suture wire, ensuring a fast endothelialisation.

• Comed BV, The Netherlands, Hyperion™ Occluder, under CE-0535 is marketed by Lepu Medical Technologies as MemoStar™ Occluder
• All Hyperion™ Occluder are designed and manufactures by SHSMA Corporation, Shanghai, China
A New Pan-Nitinol Occluder for Transcatheter Closure of Ventrical Septum Defect in a Canine Model.
Zhong-Ru Ding, M.D., Young-Wen Qin, M.D., Jian-Qiang Hu, M.D., Xian-Xian Zhao, M.D., Zhi-Hong, M.D., and Jiang Cao, M.D.
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Background
The Amplatzer ventricular septal defect (VSD) occluder has a fixed stainless steel pin bottom protruding out of the surface at the center of the discs on both sides. Theoretically, this protruding bottom may interfere with epithelialization or, in some cases, cause thrombosis.

Objective
To evaluate a new type of pan-nitinol VSD occluder without the protruding stainless steel pin bottom on both sides in a canine VSD model designed to ensure safety, effectiveness, and feasibility.

Methods and Results
VSDs were successfully created by transseptal ventrical septal puncture with a Brockenbrough needle and dilation with an 8 mm diameter balloon via the right jugular vein in 9 out 12 canines. The new type VSD occluder was successfully implanted in 8 of the 9 canines. No procedure- or device related complication was observed. Transthoracic echocardo-graphy and MRI 2 months after device implantations showed that there was no device dislocation or heart valve dysfunction in 6 out of 8 tested canines. In addition, gross and pathological examinations 3-6 months after implantation showed no corrosion of the devices or serious inflammatory reactions in the modeled animals. Complete endotheliazation was seen over the surface of the discs.

Conclusion
The new pan-nitinol VSD device can be successfully implanted in a canine VSD model via a trans catheter approach featuring high success rate, low risk of procedure-related complications, and sound biocompatibility. The results suggests that this new VSD occluder could be used safely in future clinical trials for further test.
Clinical Study of Trancatheter Closure of Patent Ductus Arteriosus with Occluder Device.

Abstract Objective
To evaluate the efficiency of transcatheter closure of patent ductus arteriosus (PDA) using occluder device.

Method
25 patients with PDA were treated with transcatheter closure with duct occluder device. Each PDA was occluded through the percutaneous procedure. Aortographies were made to evaluate the efficiency immediately after the procedure. Echocardiographies were performed 72 hours, 1 month and 3 month after the closure to find whether there was a residual shunt or recanalization.

Results
The smallest diameter of PDA measured by aortography was 5.9±1.2 (1.5-11)mm, and the mean diameter of duct occluder device measured by aortography was 11.8±1.5 (6-16)mm. The technical successful rate was 100%. Aortography showed that 25 patients had been completely closed 10 minutes after operation, the mean pressure of pulmonary artery declined significantly after operation (P < 0.05). No complications happened during operation. Residual shunt, the place of duct occluder device, hemolysis, embolism and aortic stenosis didn't happen during 3 months follow-up.

Conclusion
Transcatheter closure of PDA using duct occluder device is safe and efficient. The success rate if high, and there is less trauma.

• SHSMA Corporation, Shanghai, China, Occluders and Vascular Plugs have been CE-Certified by Comed BV, The Netherlands under CE0535., as Hyperion™ Occluders and Vascular Plugs. Hyperion is a trademark of Comed BV, The Netherlands.
Safety and Efficacy of Transcatheter Closure of Large Atrial Septal Defect

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International Journal of Cardiovascular Disease 2008, 35 (3).

**Objective**

This study was to evaluate the safety and efficacy of transcatheter closure of large atrial septal, by analyzing the treatment of 12 cases of ASD defined as > 30mm in diameter.

**Method**

Twelve patients with secondary LASD (Sex: 5 male and 7 female; age 36.3±10.6) years old; ASD diameter: (33.1±4.5) mm; 4 with stump of top atrium cordis < 3 mm; 3 with stump AO < 3 mm or absence; PAMP: (36.2±13.1) mmHg, 7 with moderate pulmonary hypertension or worse; 6 with heart enlargement in X-Ray check, accepted interventional therapy with Chinese-made occluder devices (diameter: 36~42mm), and were assessed with ECG, transthoracic echocardiography (TTE) and X-Ray check before and after the procedure at the follow-up of 1 week, 3 month, 6 month and 1 year.

**Results**

In 12 patients treated by methods of right superior pulmonary vein release, LASDs were successfully closed in 10 patients (83.3%). Immediate residual shunt was found in 2 patients and vanished in one week. Device dislocation occurred in one case with stump of top atrium cordis < 3 mm and emergency surgical intervention was conducted. No death cases. Pulmonary pressure decreased obviously after device implantation in 5 cases with moderate pulmonary hypertension, and hearts deflated in 6 heart-enlarged cases. No split stream occurred on atrium cordis level. No other complications such as embolization, infective endocarditis, cardiac perforation, Purkinje system abnormality and migraine was observed.

**Conclusion**

Transcatheter closure of large atrial septum defect with Chinese-made occluder device is safe and efficiency, so long as the indications of procedure are in attention.
Comed Clinical Information
Hyperion™ Occluders & Vascular Plugs

Simultaneous transcatheter therapy of perimembranous ventricular septal defect combined with atrial septal defect.
Zhao Xian-xian, Qin Yongwen, Xiong Wenfeng, et al. Department of Cardiology, Changhai Hospital, Second Military Medical University, Shanghai 200433, China.

Objective
To evaluate the possibility, methods and efficiency of simultaneous transcatheter therapy of perimembranous ventricular septal defect (VSD) combined with atrial septal defect (ASD).

Method
Four patients with PM VSD combined with ASD, including 3 males and 1 female, age ranging from 12 to 16 years; underwent simultaneous attempted transcatheter therapy.
The diameter of PM VSD were 3-6 mm and the distances from the defect rim to aortic valve were 2-6 mm by echocardiography before the procedure, the stretched diameter of ASD was 6-10 mm. PM VSD were occluded using homemade (Chinese) two disc PM VSD occluder first and the ASD were occluded later on.

Report
All patients were treated successfully at one time. The diameter of ASD was 6-10 mm and the occluder diameter was 6-12 mm. No residual shunt was found by the transthoracic echocardiography and left ventriculography after the occluders deployed. No complications occurred.

Conclusion
Simultaneous transcatheter therapy of PMVSD combined with ASD is feasible, safe and effective.

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Transcatheter closure with use of the SHSMA occluder in 180 patients with congenital heart defects; preliminary results.
Wang-Feng Sun, Zhi-Feng Dong, Kaizheng Gong, Guo-pei Zhang, Ting Cui, Yu-Dong Xia, Jing Dong, Yuan Shen. Tex Heart Inst J 2010; 37(5):531-7

Transcatheter closure of congenital heart defects with the use of septal occluders has been widely accepted as a preferred treatment; however, the high cost of these devices limits their clinical application in some countries. Few clinical data are available regarding lower-cost products. Accordingly, we evaluated the efficacy and safety of the Chinese-made Shanghai Shape Memory Alloy (SHSMA) occluder in patients with congenital heart defects.

From December 2001 through December 2008, a total of 180 patients with congenital heart defects (ages, 3–68 yr; mean age, 17.35 ± 13.22 yr) underwent transcatheter closure with use of the SHSMA occluder: 73 had atrial septal defects; 64, ventricular septal defects; 40, patent ductus arteriosus; and 3, complex congenital defects. The mean diameters of the defects were 20 ± 7.6 mm (atrial septal), 4.9 ± 2.1 mm (ventricular septal), and 5.6 ± 2.2 mm (patent ductus arteriosus).

The procedural success rates were 98.6% for atrial defects, 98.4% for ventricular defects, and 100% for patent ductus arteriosus and for complex defects. The overall incidences of sequelae were 5.5%, 9.4%, 2.5%, and 0, respectively. Six months postprocedurally, complete occlusion was associated with a significant decrease in the right ventricular Tei index in atrial septal defect patients (P <0.05) and with improvement of body mass index in 11 children.

These results suggest that the SHSMA occluder is a safe, effective device for the transcatheter closure of congenital heart defects. For confirmation, a randomized controlled trial with more patients and a longer follow-up period is warranted.
Transcatheter closure of multi-hole perimembranous VSD with aneurysm: 3-year follow-up study.

Abstract
The majority of ventricular septal defects (VSDs) are perimembranous, accounting for 75-80% of all VSDs.

The objective of this study was to investigate occluder selection and transcatheter closure technique for multi-hole perimembranous VSD with aneurysm, and to evaluate clinical efficacy and safety. Patients with multi-hole VSDs and aneurysm (n = 64) were selected for the procedure using transthoracic echocardiography. Double-disc symmetrical, small-waist double-disc asymmetrical and zero eccentricity occluders were selected based on left ventricular angiography.

The closure was successful in 63 of 64 patients (98%). The double-disc symmetrical occluder was used in 16 cases, the small-waist double-disc asymmetrical occluder in 42 cases, and the zero eccentricity occluder in 8 cases (2 occluder types were used in 2 cases). Fifteen minutes after the procedure, 52 cases had no residual shunt and 12 had a trace amount of residual shunt. The residual shunt disappeared in five cases 5-7 days post procedure, with a trace amount of shunt remaining in seven cases. Transient conduction abnormalities related to the procedure occurred in six patients; however, none required permanent pacemaker implantation. At the 1-month, 6-month, 1-year, 2-year, and 3-year follow-up visits, echocardiography indicated that the position of the occluders was fixed, and there were no complications including residual shunt, newly developed atrioventricular block, thromboembolism, or bacterial endocarditis.

The study results indicate that left ventricular angiography is useful in selecting the most appropriate device for transcatheter closure of multi-hole perimembranous VSD with aneurysm. The transcatheter closure procedure is safe and effective with little residual shunt and no major complications for up to 3 years of follow-up.
A New Coated Nitinol Occluder for Transcatheter Closure of Ventricular Septal Defects in a Canine Model

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Abstract
This study evaluated feasibility and safety of implanting the polyester-coated nitinol ventricular septal defect occluder (pcVSDO) in the canine model.

Methods and Results
VSD models were successfully established by transseptal ventricular septal puncture via the right jugular vein in 15 out of 18 canines. Two types of VSDOs were implanted, either with pcVSDOs ( ) as the new type occluder group or with the commercial ventricular septal defect occluders (VSDOs, , Shanghai Sharp Memory Alloy Co. Ltd.) as the control group. Sheath size was 10 French (10 Fr) in two groups. Then the general state of the canines was observed after implantation. ECG and TTE were performed, respectively, at 7, 30, 90 days of follow-up. The canines were sacrificed at these time points for pathological and scanning electron microscopy examination. The devices were successfully implanted in all 15 canines and were retrievable and repositionable. There was no thrombus formation on the device or occurrence of complete heart block. The pcVSDO surface implanted at day 7 was already covered with neotissue by gross examination, and it completed endothelialization at day 30, while the commercial VSDO was covered with the neotissue in 30th day and the complete endothelialization in 90th day.

Conclusion
The study shows that pcVSDO is feasible and safe to close canine VSD model and has good biocompatibility and shorter time of endothelialization.

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Use of a Patent Ductus Arteriosus Occluder in the Treatment of a Renal Artery Inferior Vena Cava Fistula

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Renal artery inferior vena cava fistula Treatment

Abstract

We report a case where an 8-mm mushroom patent ductus arteriosus occluder was used in a 59-year-old woman to resolve a renal artery inferior vena cava fistula that occurred following a right nephrectomy performed 27 years earlier. Complete occlusion of the fistula was achieved. This case highlights the novel use of a PDA occluder and provides evidence that this may be a viable technique for the management of arteriovenous fistulas with similar vessel relationships, anatomical characteristics and occlusion demands as the fistula described in this report.
Transcatheter Versus Surgical Closure of Perimembranous Ventricular Septal Defects in Children
A Randomized Controlled Trial

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(Transcatheter Closure Versus Surgery of Perimembranous Ventricular Septal Defects; NCT00890799) (J Am Coll Cardiol
2014;63:1159–68) a 2014 by the American College of Cardiology Foundation

The objective of this study was to evaluate the safety and efficacy of the surgical versus transcatheter approach to correct perimembranous ventricular septal defects (pmVSDs) in a prospective, randomized, controlled clinical trial.

pmVSD is a common congenital heart disease in children. Surgical closure of pmVSD is a well-established therapy but requires open-heart surgery with cardiopulmonary bypass. Although the transcatheter approach is associated with significant incidence of complete atrioventricular block, it may provide a less invasive alternative. Critical comparison of the safety and efficacy of the 2 interventions necessitates a prospective, randomized, controlled trial.

Between January 2009 and July 2010, 229 children with pmVSD were randomly assigned to surgical or transcatheter intervention. Clinical, laboratory, procedural, and follow-up data over a 2-year period were compared.

Neither group had mortality or major complications. However, statistical analysis of the 2 groups demonstrated significant differences (p < 0.001) in minor adverse events (32 vs. 7), quantity of blood transfused, duration of the procedure, median hospital stay, median intensive care unit stay, median hospitalization cost, and median blood loss. During a median follow-up of 2 years, the left ventricular end-diastolic dimension of both groups returned to normal and there was no difference in closure rate, adverse events, and complications between groups.

Transcatheter device closure and surgical repair are effective interventions with excellent midterm results for treating pmVSD in children. Transcatheter device closure has a lower incidence of myocardial injury, less blood transfused, faster recovery, shorter hospital stay, and lower medical expenses.
Transcatheter Closure of Atrial Septal Defects Improves Cardiac Remodeling and Function of Adult Patients with Permanent Atrial Fibrillation

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Background: Permanent atrial fibrillation (AF) is the most common form of dysrhythmia associated with atrial septal defects (ASDs) in patients older than 40 years. However, little is known about cardiac remodeling after transcatheter closure in patients with permanent AF. This study was designed to compare cardiac events and remodeling effects after transcatheter closure in such patients.

Methods: Clinical data of 289 adult patients older than 40 years who underwent ASD closure at our center were analyzed retrospectively. Of them, 63 patients with permanent AF were assigned to the case group, and the other 226 patients without permanent AF were assigned to the control group. Cardiac events and changes in left and right cardiac cavity dimensions before the procedure and 6 months after the procedure were compared between the two groups.

Results: Patients in the case group were significantly older than those in the control group. The right ventricular (RV) volume and right atrial (RA) volume were decreased significantly in both the groups during a median follow-up period of 6 months after closure ($P < 0.001$). The left atrial dimensions, left ventricular end-systolic dimensions, left ventricular end-diastolic dimensions and left ventricular ejection fraction showed no significant change before and after the procedure in both the groups. Changes of the RV volume and RA volume in the case group were significantly smaller than those in the control group ($P = 0.005$ and $P < 0.001$). The New York Heart Association cardiac function was improved in both the groups during the 6 months follow-up period.

Conclusions: The transcatheter closure of ASD can improve the cardiac remodeling and cardiac function in patients with or without AF.

Key words: Atrial Fibrillation; Cardiac Catheterization; Heart Septal Defects; Atrial
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Huang Guoming1, Ding Zhongru1, Tu Xiaowen1, Qiao Huaiyu1, Wang Hongru1, Yu Yanli1, Han Qingping1, Wen Ping2. International Journal of Cardiovascular Disease 2008, 35 (3).

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6) Transcatheter closure of multi-hole perimembranous VSD with aneurysm: 3-year follow-up study.

7) A New Coated Nitinol Occluder for Transcatheter Closure of Ventricular Septal Defects in a Canine Model
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10) Transcatheter Closure of Atrial Septal Defects Improves Cardiac Remodeling and Function of Adult Patients with Permanent Atrial Fibrillation.
Liang Chen1, Yuan Bai1, Fei-Yu Wang1, Zhi-Gang Zhang2, Xing-Hua Shan3, Tao Chen1, Xian-Xian Zhao1, Yong-Wen Qin1

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