The Device Selection of VSD Closure

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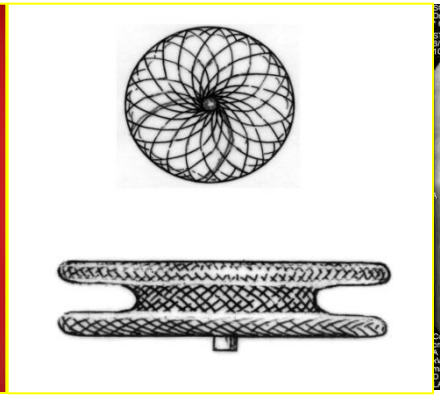
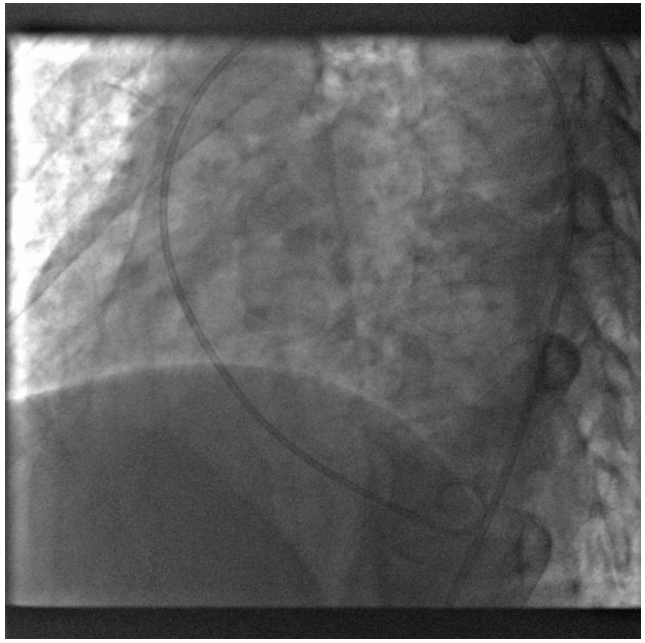
VSD device in China

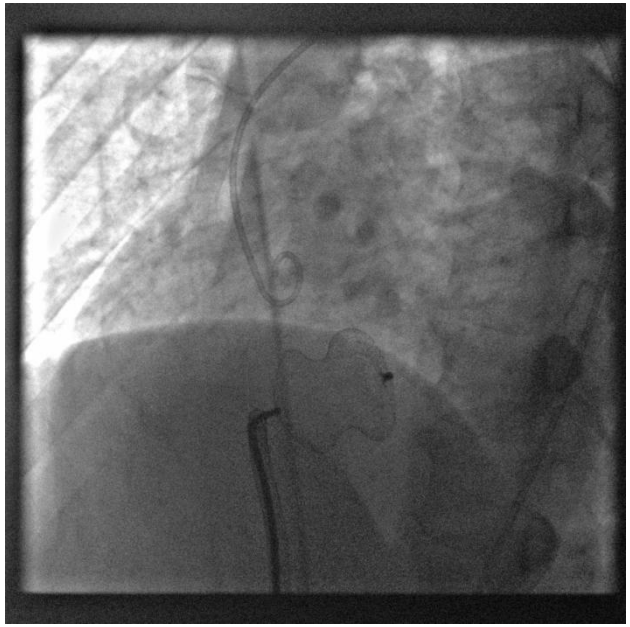
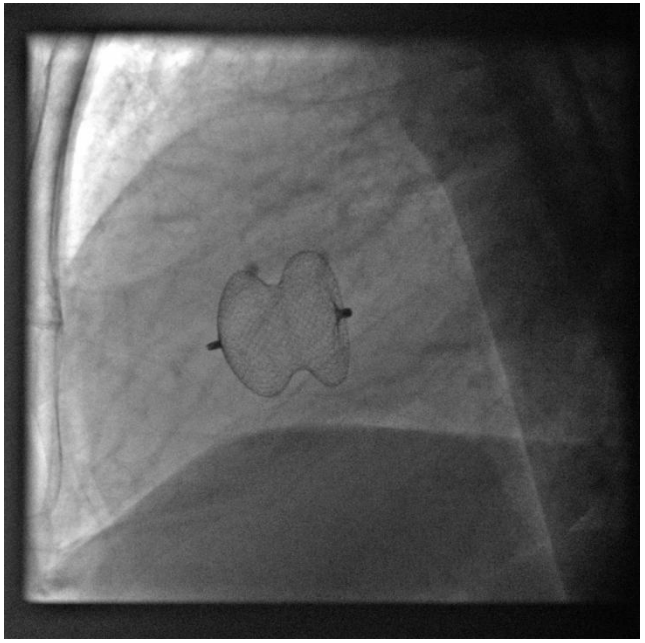
- **2001: Amplatz**
- **2002: Device made in china, 7 companies, mainly 3 companies**

Symmetric device

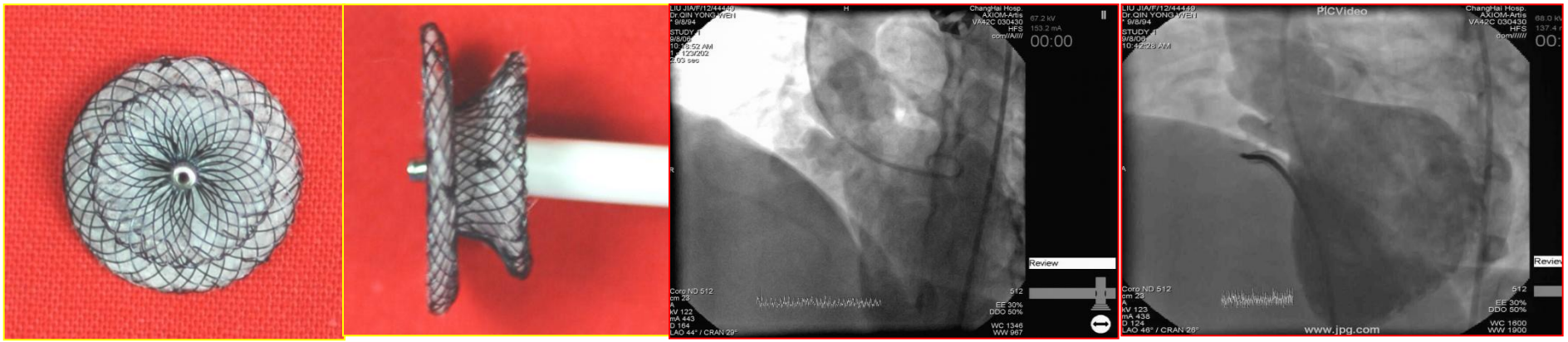


- **Symmetric device:** Disc is 4 mm bigger than waist in diameter. The length of the waist is 2 mm.
- **Candidate:** Rim to the aortic valve and the tricuspid valve is more than 2 mm.

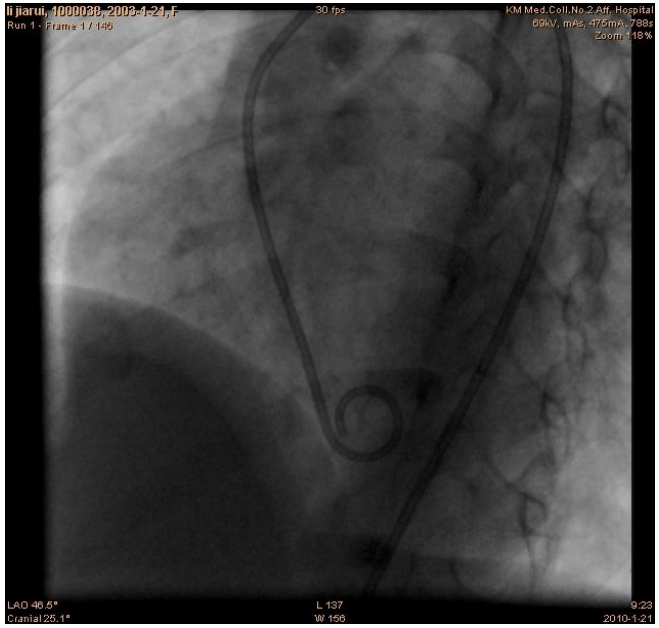


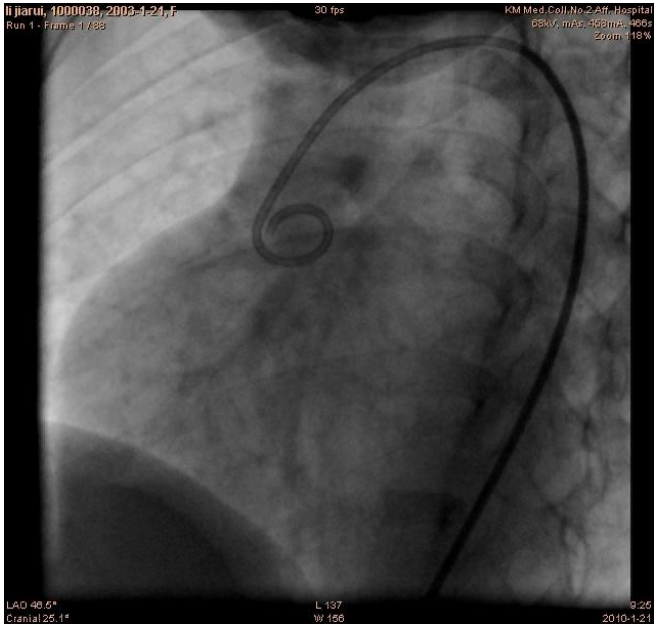



Modified symmetric device



- **Modified symmetric device:** Left disc is 6 mm bigger than waist in diameter and the right is 4 mm bigger. The length of the waist is 2 mm.
- **Candidate:** VSD with aneurysm formation, more than 2 holes


li jiarui, 1000038, 2003-1-21, F
30 fps
KM Med.Coll.No.2 Aff. Hospital
Run 1 - Frame 1 / 146
69kV, mAs, 475mA, 788s
Zoom 118%
LAO 46.5°
Cranial 25.1°
L 137
W 156
9:23
2010-1-21


li jiarui, 1000038, 2003-1-21, F
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Run 1 - Frame 1 / 88
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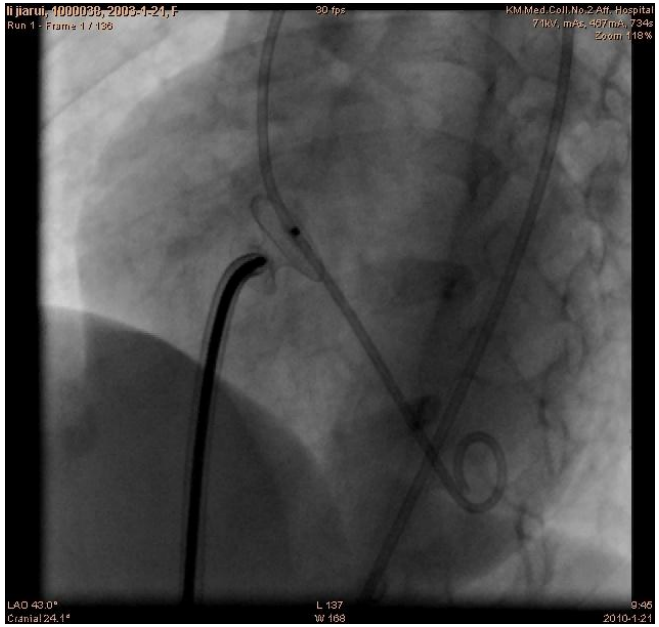
Cranial 25.1°
L 137
W 156
9:25
2010-1-21


li jiarui, 1000038, 2003-1-21, F
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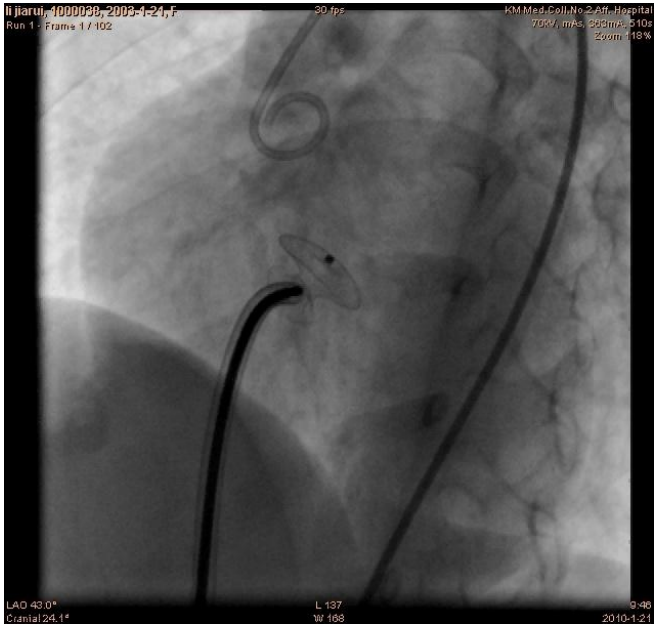
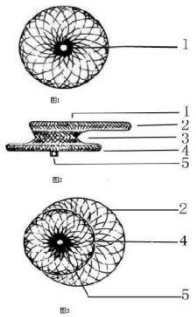
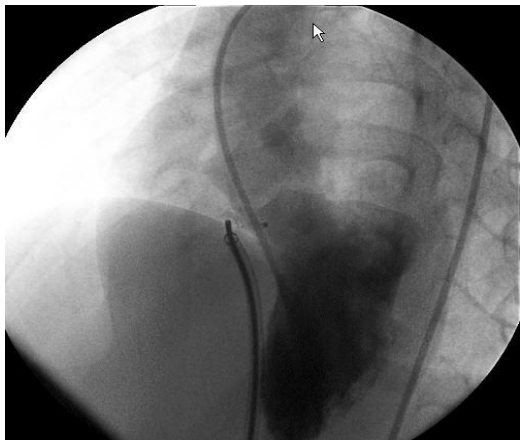
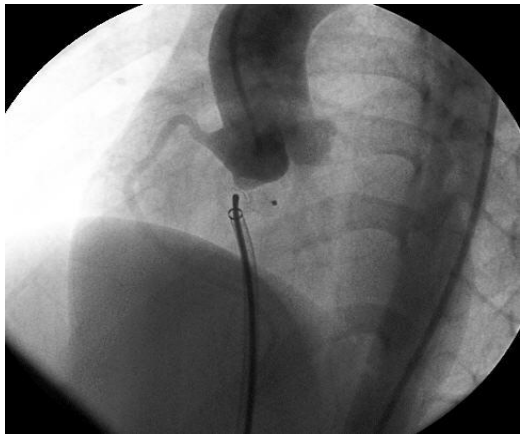
KM Med.Coll.No.2 Aff. Hospital
Run 1 - Frame 1 / 136
71kV, mAs, 497mA, 734s
Zoom 118%
LAO 43.0°
Cranial 24.1°
L 137
W 168
9:46
2010-1-21


li jiarui, 1000038, 2003-1-21, F
30 fps
KM Med.Coll.No.2 Aff. Hospital
Run 1 - Frame 1 / 102
LAO 43.0°
Cranial 24.1°
L 137
W 168
9:46
2010-1-21

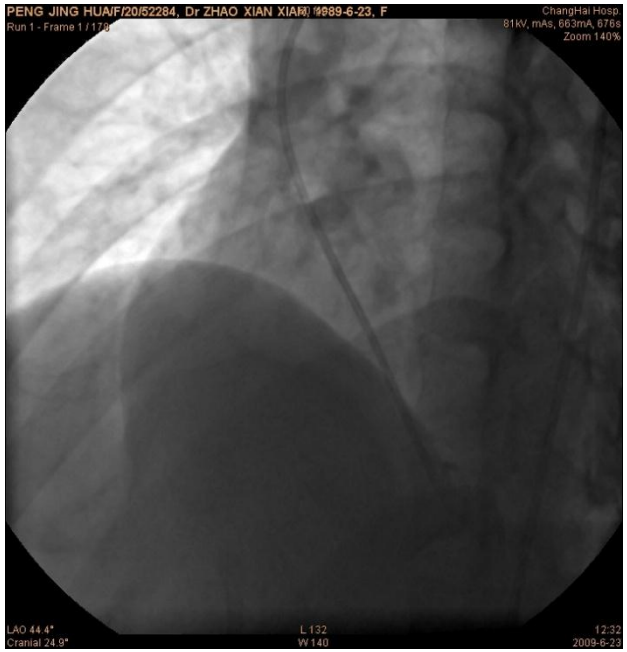
Asymmetric device

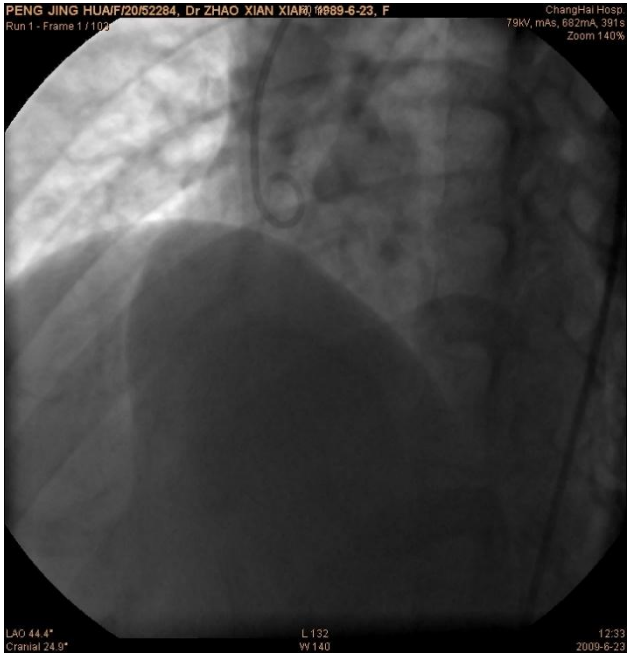


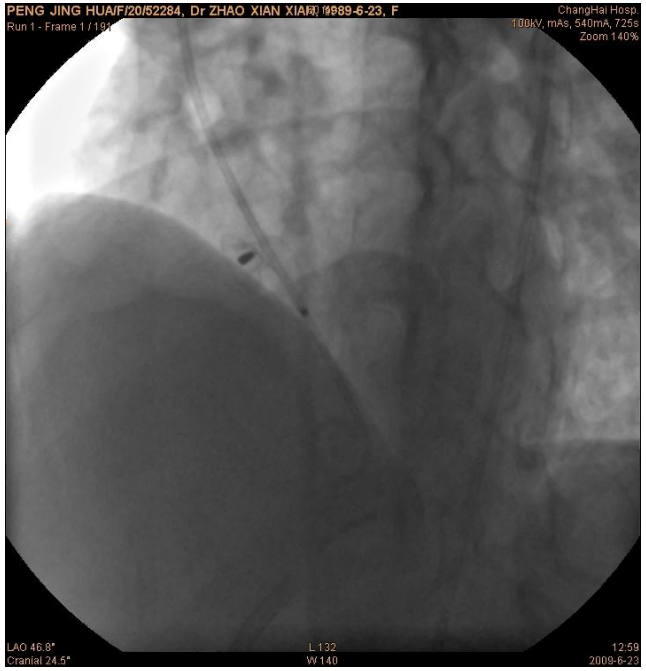


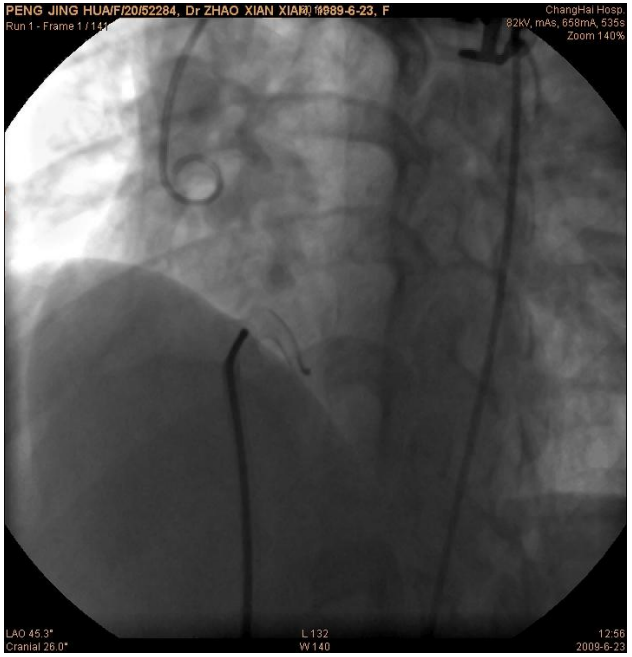


- **Asymmetric device：** **left disc is irregular and right disc is 4 mm bigger than the waist in diameter.**
- **Candidate:** **Rim to the aortic valve is less than 2 mm.**


PENG JING HUA/F/20/52284, Dr ZHAO XIAN XIAN
Run 1 - Frame 1 / 178
ChangHai Hosp.
81kV, mAs, 663mA, 676s
Zoom 140%
LAO 44.4°
Cranial 24.9°
L 132
W 140
12:32
2009-6-23


PENG JING HUA/F/20/52284, Dr ZHAO XIAN XIAN
Run 1 - Frame 1 / 102
ChangHai Hosp.
79kV, mAs, 682mA, 391s
Zoom 140%
LAO 44.4°
Cranial 24.9°
L 132
W 140
12:33
2009-6-23


PENG JING HUA/F/20/52284, Dr ZHAO XIAN XIAN
Run 1 - Frame 1 / 181
ChangHai Hosp.
100kV, mAs, 540mA, 725s
Zoom 140%
LAO 46.8°
Cranial 24.5°
L 132
W 140
12:59
2009-6-23


PENG JING HUA/F/20/52284, Dr ZHAO XIAN XIAN
Run 1 - Frame 1 / 141
ChangHai Hosp.
82kV, mAs, 658mA, 535s
Zoom 140%
LAO 45.3°
Cranial 26.0°
L 132
W 140
12:56
2009-6-23

Compare of 2 devices

- **Multiple pilot study**
- **509 patients:**

  291 male, 218 female
- **compared asymmetric with symmetric device**
- **Follow-up period: 12 months**

VSD characteristics

	Asymmetric group	Symmetric group	P value
cases	266	243	
Qp/Qs	1.69±0.46	1.72±0.61	0.68
VSD (mm)	4.12±0.72	3.86±1.04	0.46
To AV (mm)	**3.5±0.7**	**5.2±1.2**	**0.01**
device (mm)	7.4±4.3	6.6±1.4	0.08

Result of closure

	Asymmetric	Symmetric	P value
success rate	95.5%(254/266)	96.8%(235/243)	0.98
instant complete closure rate	87.0%(231/266)	97.1%(235/243)	0.001
complete closure after 12 month	99.0%(198/201)	100% (195/195)	0.83
new AR	2.6%(7/266)	1.3%(3/243)	0.21
new TR	16%(39/266)	12%(29/243)	0.67

Complications

	Asymmetric	Symmetric	P value
hemolysis	4(1.5%)	0	0.06
III AVB	4(1.5%)	1(0.4%)	0.31
severe AR	1(0.4%)	2(0.8%)	0.95
severe TR	1(0.4%)	1(0.4%)	0.98

Complications

	Asymmetric	Symmetric	P value
arrhythmias	60(22.5%)	33(13.2%)	<0.001
mild AR	6(2.3%)	1(0.4%)	0.172
mild TR	38(14.3%)	28(11.5%)	0.502
femoral thrombosis	1(0.4%)	1(0.4%)	1.0
transfusion	1(0.4%)	1(0.4%)	1.0

Conclusions

- **Both asymmetric and symmetric device are equally effective for VSD closure.**
- **Both asymmetric and symmetric device had similar risk for major complications.**
- **Asymmetric device had increased risk of minor complications, such as mild arrhythmias and instant residual shunt.**
- **Device selection must be individualized.**

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PEDIATRIC AND CONGENITAL HEART DISEASE

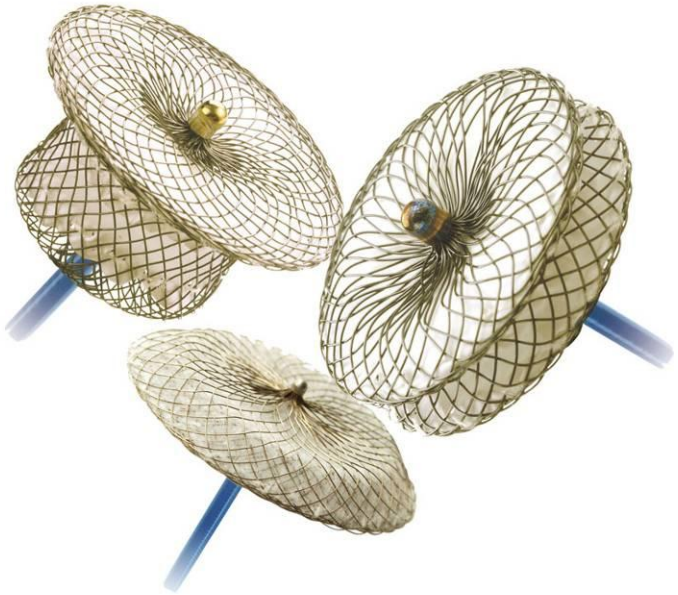
Original Studies

Transcatheter Closure of Perimembranous Ventricular Septal Defect in Children: Safety and Efficiency with Symmetric and Asymmetric Occluders

Rong Yang,* MD, Yanhui Sheng, MD, Kejiang Cao, MD, Xiangqing Kong, MD, Di Xu, MD, Yonghong Yong, MMS, Lei Zhou, MD, Hao Zhang, MD, Linmei Qian, MD, Wei Sun, MD, and Zhengnan Gu, BS

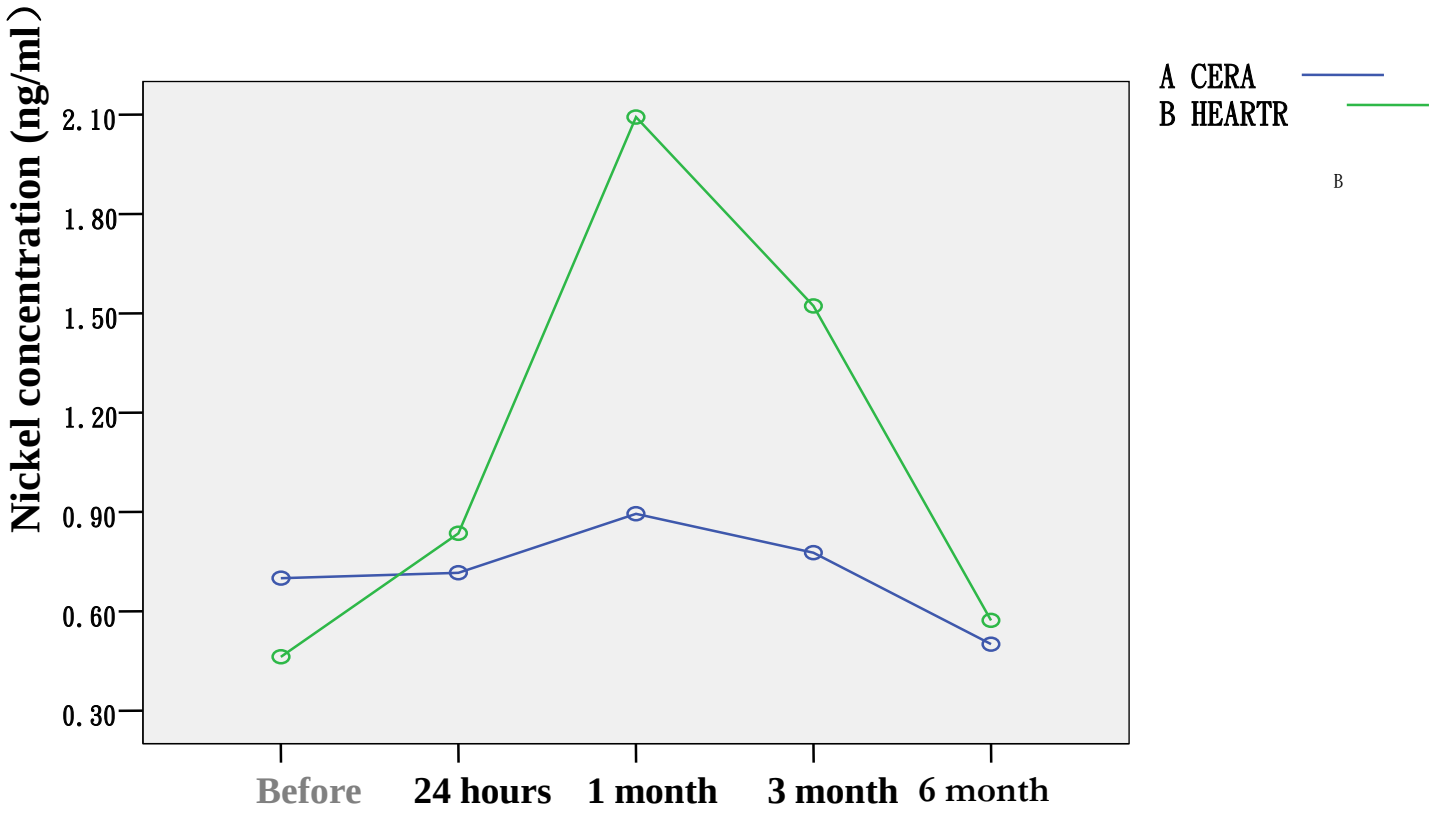
Objectives: This study was designed to determine the safety and efficiency of asymmetric and symmetric ventricular septal occluders (AVSDOs and SVSDOs, respectively) for closure perimembranous ventricular septal defect (PMVSD) in children. **Methods:** Between January 2003 and December 2007, 142 children with PMVSD were treated with occluders (64 with AVSDOs and 78 with SVSDOs). **Results:** The defect diameter was 5.3 ± 1.1 mm in the AVSDO group and 5.4 ± 1.3 mm in the SVSDO group ($P > 0.05$). The success rates were similar between two groups [93.8% (AVSDO) vs. 94.9%

Cera device



- Titanium nitride coated
- Decreased Ni release
- Better and faster endothelium coverage
- Lowered risk of thrombus formation

Serum Nickel Release



Serum Nickel concentrations —pediatric patients

Time	CERA (ng/ml)	HEARTR (ng/ml)	*P*-VALUE
Before	0.827±0.665（n=46）	0.586±0.518 （n=47）	0.054
24-hours	0.654±0.444 （n=45）	0.974±0.512 （n=45） ＊	0.002
1 month	0.937±0.495 （n=45）	1.982±0.694（n=40） ＊ #	0.000
3 months	0.824±0.468 （n=39）	1.401±0.918 （n=42）＊ #	0.001
6 months	0.486±0.176（n=43）	0.617±0.421 （n=43）☆&	0.065

Summary

- In china, at least 3 kinds of devices are commercially available. Specifically designed device is increasingly used in china.
- Different device is similar in the closure efficacy and safety.
- Device selection must be individualized.


Thank you