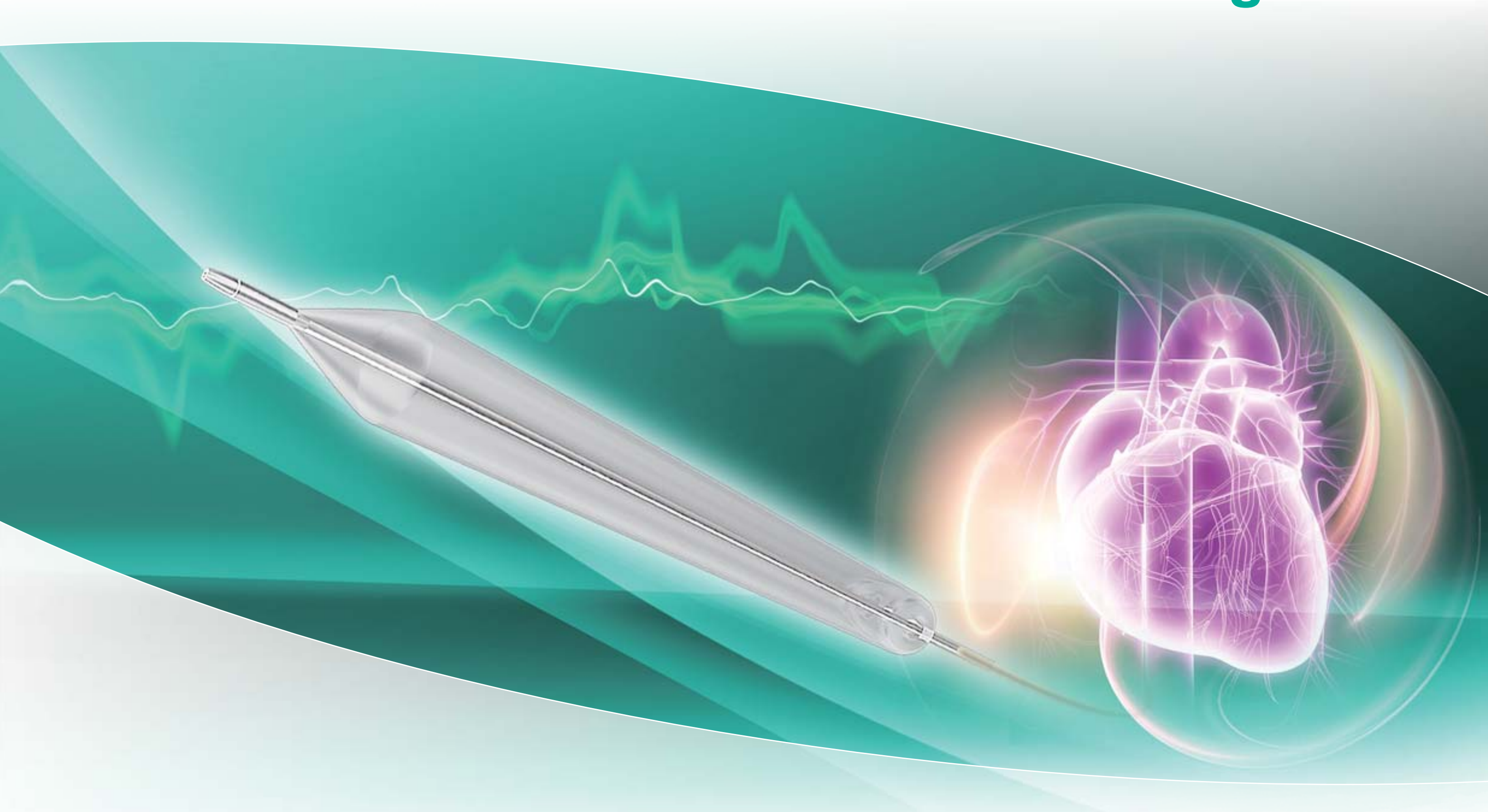
Comparing the Performance of Intra-Aortic Balloon with a Different Design



Abstract

Intra-Aortic Balloon Pump (IABP) therapy is widely used as quick, easy and economic heart assist therapy. Several recent reports have shown that a long balloon which has no optimal stability to stay in place during operation can cause severe complications. The newly developed "XEMEX IABP Balloon Plus, Short Balloon" from ZEON MEDICAL INC. Japan has a different design from other balloons in terms of the relationship between balloon length, diameter and stiffness of the catheter shaft.

This laboratory trial compares pump performance of conventional balloons and "XEMEX Short Balloons" in a mock circuit. We can show under different conditions that a shorter balloon with less volume is able to perform equal to or better augmentation than a conventional balloon.

Key Words:
Intra-Aortic Balloon Pump, Short Balloon, Augmentation

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Background

Intra-Aortic Balloon Pump is the oldest, most easily available and most economic kind of mechanical circulatory support. Although the use of other circulatory support techniques like ECMO and VAD have made their result, IABP is still very useful in the therapy of cardiogenic shock. The question "How long is the optimal balloon" arose first in Asia and notably in Japan. Mr. Soeda, chief engineer in the Department of Medical Engineering at Hoshi General Hospital, Fukushima, Japan started researching the aortic length, diameter and the design of IABP balloons in 1986. His main findings were:

- **There is a positive correlation between patient height, BSA and aorta length**
- **Tortuosity was not observed above the diaphragm**
- **The arterial diameter showed thinning under the diaphragm notably thinning of the artery below the renal artery**
- **The distance to the bending point at the diaphragm from the left subclavian artery is more than 170mm**

In 1992, Mr. Soeda subsequently started developing a balloon catheter for the Japanese population.
The main questions during development of this balloon were:

- **How long is the optimal balloon?**
- **What is the best diameter?**
- **What is the best ratio between aortic length and diameter?**
- **How do aortic length and diameter depend on patient height?**

A balloon was produced and became well established in the Japanese and Asian markets from the middle of the 1990s. Some publications showed that XEMEX Short Balloons worked very effectively.

A paper was published in 2010 in the journal Circulation that showed very clearly that even in a European population there was a mismatch between length of the IABP balloon and the length of the descending aorta. This population demonstrated that in up to 25% of cases the balloon was too long and occlude the visceral and renal arteries if the recommendations of the companies producing the IABP balloons were followed. Other information from Asia pointed out that the bigger balloons can cause critical complications in their directions for use.
After the first clinical trials in Europe, the question of "how can a smaller balloon with lower volume more or less produce the same augmentation?" arose.

Aim of this study

- How effective is a XEMEX Short Balloon in tall patient pumping?
- From patient monitoring, does a 35mL XEMEX Short Balloon show the same or more augmentation as a conventional 40mL balloon?
- How can the smaller balloon produce more augmentation?
- Does a 35mL XEMEX Short Balloon have the same augmentation power as a 40mL conventional balloon?

- Does a 40mL XEMEX Short Balloon have the same augmentation power as a 50mL conventional balloon?
- If so, how does this work?
- Which factor has the most influence on augmentation? Balloon volume, balloon size, balloon design, diastolic pressure or inflation time?

Material and Methods

Test Equipment

Driving Consoles

- Maquet CS 300 1: 3
- XEMEX D/C 908 1:4

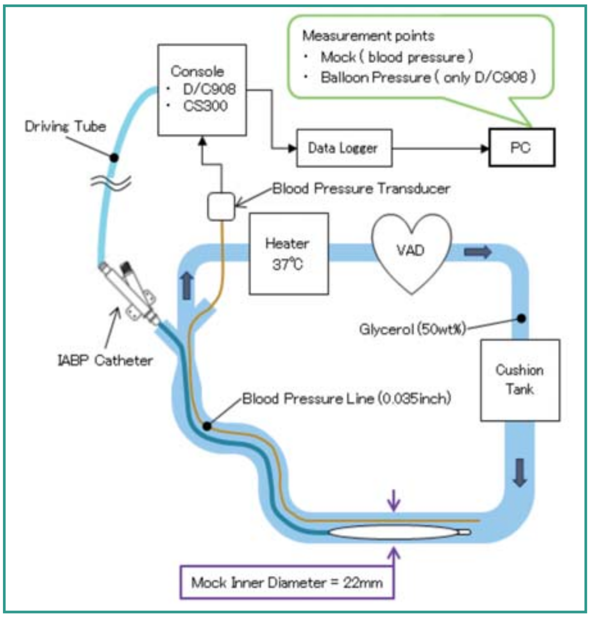
VAD Conditions

- Thoratec console and ventricle – H.R. 100 bpm
- 1 beat per 600msec
- Stroke volume depends on circulation conditions

Mock Conditions

- Tube diameter 22mm
- Solution 50 % glycerol
- Temperature 37°C
- Total mock volume 4800mL

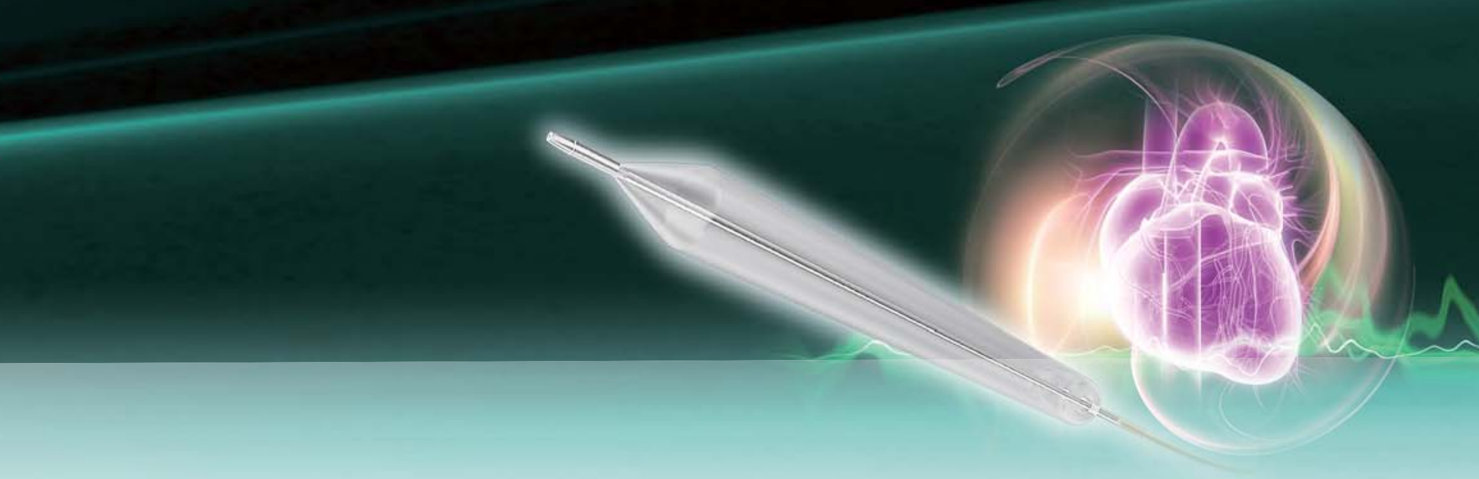
The Mock circuit



Tested Balloon

Sample Name	Brand	Model	S/N	Catheter Size	Balloon Volume
Z8F35	XEMEX	BPGL3580SH	304050865	8F	35mL
Z8F40		BPGL4080SH	24SH	8F	40mL
M7F40	MAQUET	Sensation7F40	27960302	7F	40mL
M8F50		SensationPlus8F50	28270170	8F	50mL

Fig.1 Tested Balloon



Test Condition

Mock Conditions	Mock inner Diameter	22mm
	Filling Fluid	Glycerol 50 wt%
	Set Temp.	37°C
	Total Volume	4.8L
VAD Conditions	HR	100bpm
	Duration 1 beat	600msec
	Blood Pressure	See the Test condition
	Flow Rate	See the Test condition
CS300 Conditions	Supported Beats	1:3
	Inflation Timing	3.1
	Deflation Timing	1.2

Fig.2 Test condition

Test condition

Test 1	Blood Pressure	60-80mmHg
	Flow Rate	4.5L/min
Test 2	Blood Pressure	60-80mmHg
	Flow Rate	3.0L/min
Test 3	Blood Pressure	40-60mmHg
	Flow Rate	3.0L/min

Fig.3 Mock condition

Points of measurement

Following the procedure shown above, measurements are taken on average every 20 beats according to the following parameters.

1: Maximum pressure at the balloon inflation
2: Augmentation area at the balloon inflation
3: Occupancy of balloon membrane in the Mock circuit

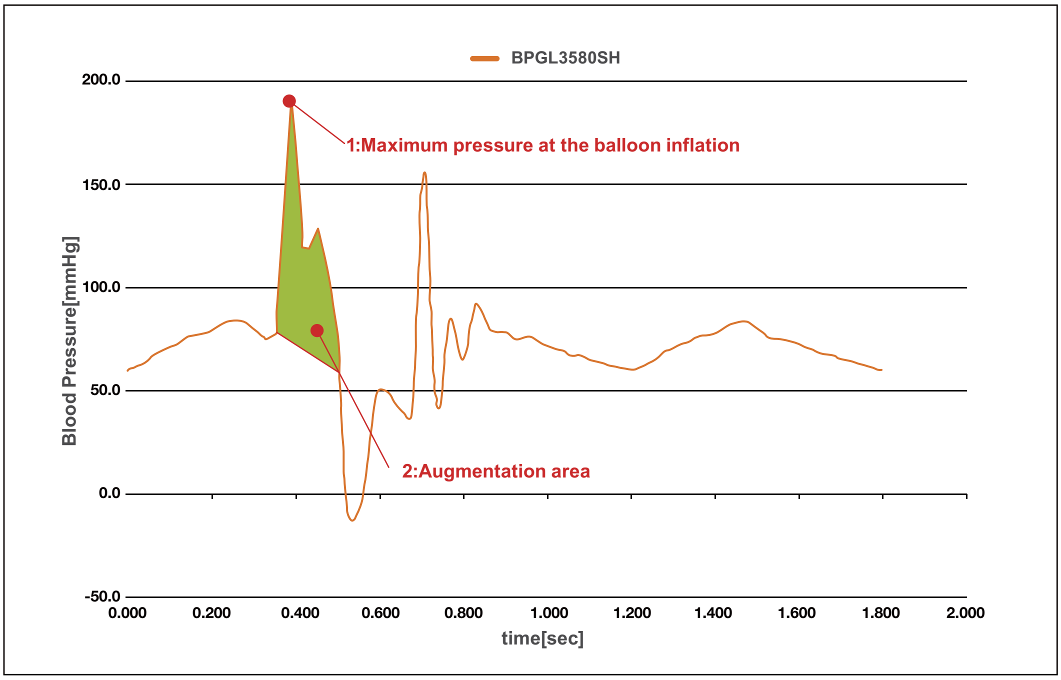
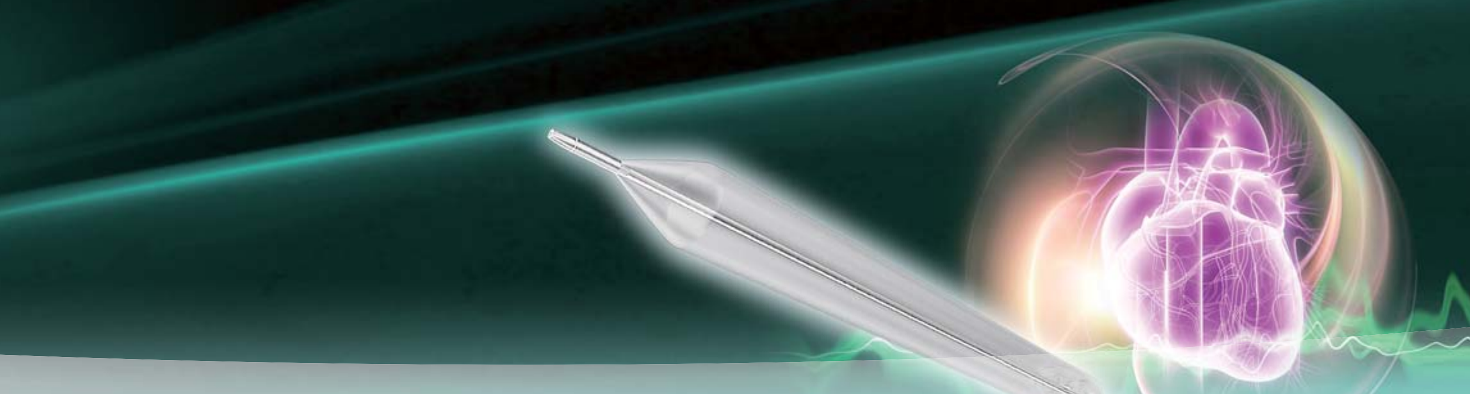


Fig.4 Measurement Points on the Pressure Curve

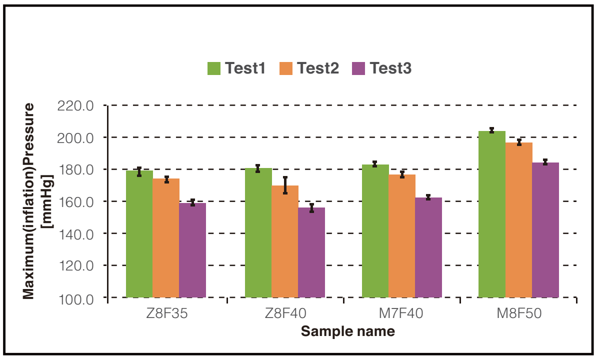


Results

1: Maximum pressure at the balloon inflation

		Maximum(inflation) pressure mmHg			
		Z8F35	Z8F40	M7F40	M8F50
Test 1	Ave	179.0	180.9	183.6	204.7
	σ	2.4	1.7	1.1	1.5
	MAX	181.8	184.5	185.7	208.1
	MIN	171.0	177.7	181.9	202.7
Test 2	Ave	174.6	170.6	177.3	197.6
	σ	1.2	4.7	0.9	1.5
	MAX	177.5	180.6	178.9	200.0
	MIN	172.6	163.1	175.2	194.1
Test 3	Ave	159.5	156.5	163.1	184.3
	σ	1.3	2.4	0.9	1.4
	MAX	161.9	160.0	165.3	186.6
	MIN	157.2	150.3	161.5	180.6

Maximum(inflation)Pressure [mmHg]



The maximum pressure at the balloon inflation was as below.

Under Test 1:

High M8F50 ＞ M7F40 ≧ Z8F40 ≧ Z8F35 Low

Under Test 2 and 3:

High M8F50 ＞ M7F40 ≧ Z8F35 ≧ Z8F40 Low

2: Augmentation area at the balloon inflation

Results of measurement Augmentation area

	Augmentation area [mmHg・sec]			
	Z8F35	Z8F40	M7F40	M8F50
Test 1	8.00	8.81	6.67	9.25
Test2	8.79	10.39	7.49	10.13
Test3	10.11	11.98	8.54	11.01

Under Test 1 condition:

High M8F50 ＞ Z8F40 ＞ Z8F35 ＞ M7F40 Low

Under Test 2 condition:

High Z8F40 ≧ M8F50 ＞ Z8F35 ＞ M7F40 Low

Under Test 3 condition:

High Z8F40 ＞ M8F50 ＞ Z8F35 ＞ M7F40 Low

Balloon diameter is strong correlated to Augmentation area, bigger Augmentation area is higher Augmentation. Balloon volume has less influence than balloon diameter.

3: Occupancy of balloon membrane in the Mock circuit

Mock circuit spec.

I.D. [mm]	I.D. Area [mm²]
22.0	380.1

Occupancy ratio of balloon membrane in the Mock circuit

Sample Name	Balloon outer diameter (mm)	Balloon length (mm)	Diameter occupancy	Area occupancy
Z8F35	17.1	162	77.7%	60.4%
Z8F40	17.5	177	79.5%	63.3%
M7F40	15.0	258	68.2%	46.5%
M8F50	17.4	258	79.1%	62.6%

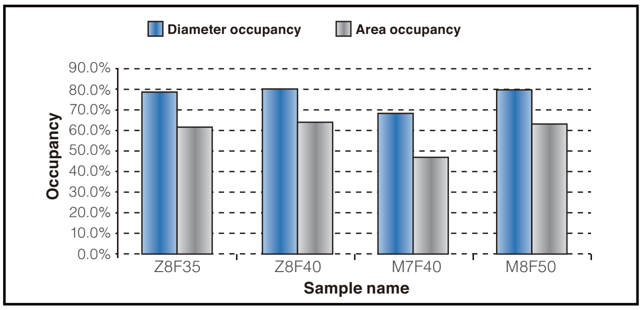
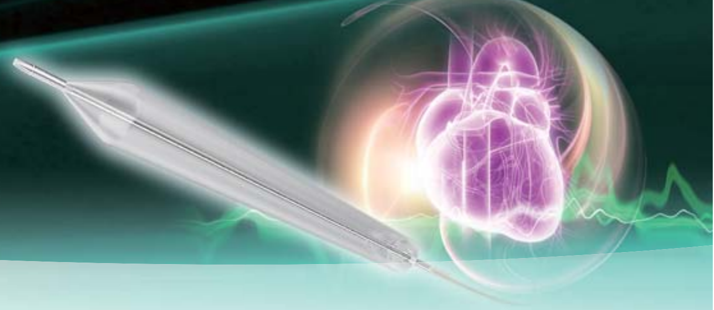


Fig.5 Balloon occupancy in the Mock circuit



Conclusions

The area under the pressure curve during diastolic augmentation is the product of diastolic augmented pressure and time. This value is the most suitable to evaluate the augmentation performance of a balloon.
In a total of three test conditions, augmentation performance may be shown as; High Z8F40SH ≧ M8F50 ＞ Z8F35SH ＞ M7F40 Low.
This is laboratory evidence for what can be seen on a real curve on a patient monitor in an ICU. The XEMEX Short Balloons from ZEON MEDICAL INC. Japan pump the same or more than the bigger and longer products from the competitor. In summary, in a European patient of average height the 35mL XEMEX Short Balloon will produce very good augmentation and with its length of 162 mm nothing is occluded under the diaphragm. In every situation, this kind of balloon is a safer choice for the patient. In fact, the 50mL balloon with its length of 260 mm is not needed and is rather more dangerous than helpful.
The augmentation by the 40mL XEMEX Short Balloon is less than that of the 50mL balloon from a competitor. The reasons are the similar diameter and shortness of the XEMEX balloon. However, the augmentation is perfectly suited to the patient, especially under conditions of poor circulation that we tried to mimic. There is no reason to have a balloon length of 260 mm.
Another reason for the impressive performance of the Short Balloon could be the higher stiffness of the catheter shaft. In high velocity films taken during these trials, we can see how the balloons of the competitor move in the test circuit during pumping according to flow and pressure changes. The XEMEX Short Balloon does not move.
We consider that both XEMEX Short Balloons from ZEON MEDICAL INC. Japan are able to produce the same or better augmentation than much longer devices from the competitor. There is no reason to use a balloon longer than the XEMEX Short Balloon.

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