# Effect of Fixed Position on Critical Performance of Aortic Valve in Vitro Testing

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**Abstract:** Objective — To determine the optimal fixation position by studying the effect of valve and valve fixation position on the key performance during in vitro hydrodynamic testing. Methods — Two self-expanding transcatheter aortic valves were fixed in three different ring positions, tested according to ISO 5840 standard method, and the key performance results were compared and analyzed. Results — When the fixed position of valve and valve ring was aligned with the bottom edge, the mean arterial pressure and regurgitant fraction were the smallest and the effective orifice area was larger. Conclusion — The fixed position of the valve and valve ring has a certain influence on the key performance of the hydrodynamic testing during in vitro testing. The lower fixed position will lead to the smaller effective orifice area. The higher fixed position will lead to the higher regurgitant fraction. Therefore, the optimal fixed position should be determined before the in vitro testing of the aortic valve.

***Keywords*:** aortic valve, in vitro testing, mean pressure difference across the valve, regurgitant fraction, effective orifice area

## 1. Introduction

Heart valve refers to the valve between the atrium and the ventricle or between the ventricle and the artery, whose function is to ensure the one-way flow of blood in the heart and the effective delivery of blood throughout the body. Heart valves are divided into atrioventricular valve and semilunar valves. The atrioventricular valves include the mitral valves and tricuspid valves. The semilunar valve includes the pulmonary valve and the aortic valve. The aortic valve is located between the left ventricle and the aorta, allowing blood to maintain a one-way flow from the left ventricle to the aorta. Aortic valve disease is a common clinical cardiovascular disease. The incidence of aortic stenosis caused by calcification and degeneration of the aortic valve increases year by year[1-5], especially with the increase of age. The treatment of aortic valve disease includes surgically implanted and transcatheter heart valve, among which transcatheter aortic valve is one of the common treatment methods nowadays. It has the advantages of no need for large incision, fast postoperative recovery, and low risk for some high-risk patients[6-9]. Cardiac valve products should be tested in vitro to verify their hydrodynamic properties before clinical use, and hydrodynamic data is an important basis for clinical selection of valve specifications. During in vitro testing, the fixed position of aortic valve and valve ring has a great impact on test results. At present, there are few studies on in vitro testing of heart valve, and this paper takes transcatheter aortic valve as the research object. Different fixed positions of valve and ring during testing were studied, and the influence of valve and ring on the key performance of fluid dynamics was analyzed through the test results.

## 2. Test sample and method

### 2.1 Test sample

At present, the common structures of transcatheter aortic valve include balloon dilated valve, self-dilated valve and mechanical dilated valve. The self-expanding valve was selected as the research object in this experiment. The stent of the self-expanding valve was made of nickel-titanium memory alloy, which was flexible under the cold salt water, and rigid and restored at high temperature (body temperature). After cooling, the valve was compressed into the delivery sheath and sent to the implant site. The valve stent is automatically deployed after encountering warm blood and is fixed at the expected site[10-12]. For the two self-dilatating transcatheter aortic valves (Figure 1) selected in this study, the deployed diameter of sample 1 is 29mm, and the applicable valve ring diameter ranges from 23mm to 26mm. A valve ring with a diameter of

23mm is selected for testing. The deployed diameter of sample 2 is 29mm, and the applicable valve ring diameter ranges from 24.5mm to 26.5mm. A valve ring with a diameter of 26.5mm is selected for testing. The valve ring was made of addition vulcanized silicone rubber material and solidified by custom mold casting. Fixed position 1 was for the valve to be aligned with the lower edge of the valve ring and then bonded; fixed position 2 was for the lower edge of the valve to be glued 3mm below the lower edge of the valve ring; fixed position 3 was for the lower edge of the valve to be glued 3mm above the lower edge of the valve ring.

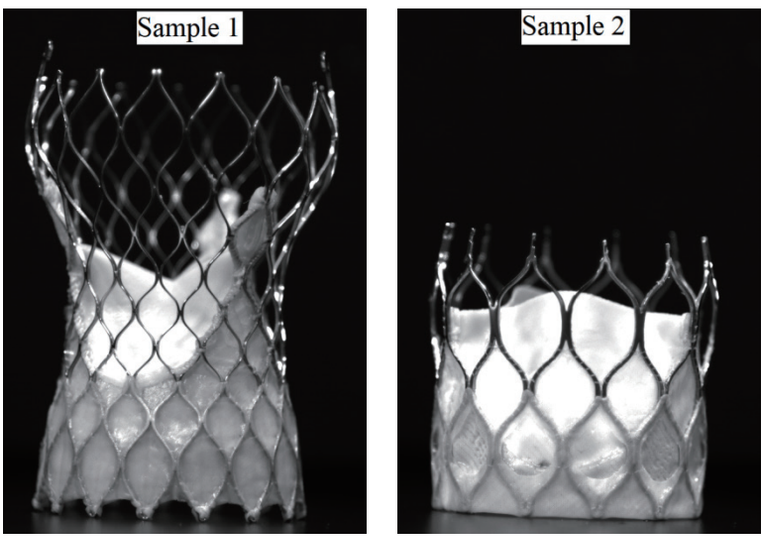


**Figure 1. Transcatheter aortic valve for testing**

## 2.2 Test method

The in vitro hydrodynamics tests of transcatheter aortic valves mainly include steady forward flow test, steady back flow leakage test and pulsating flow test, the principle and test results of which will greatly help clinicians understand the performance of artificial heart valves. The pulsating flow test is to simulate the operating environment of the valve in the natural heart, and reproduce the state of the artificial heart valve after implantation in the human body as true as possible[13]. The key of pulsating flow test is to simulate human pulsating blood flow field under different physiological and pathological conditions, and simulate the operation of valve under different physiological and pathological conditions by changing the circulation rate of pulsating flow, systolic proportion, arterial pressure difference and other parameters[14,15]. The test conditions required in the ISO 5840 standard are heart rate 70 beats /min, forward flow time period 35%, mean arterial pressure 100mmHg, and cardiac output 2L/min, 3.5L/min, 5L/min, and 7L/min respectively. The pulsation flow test results mainly include the average flow rate and RMS flow rate through the valve, the mean pressure difference across the valve, the effective orifice area, the regurgitant volume (including the closing volume and the leakage volume), and the regurgitant fraction. In this study, according to the test conditions of ISO5840, key performance including the mean pressure difference across the valve, effective orifice area and regurgitant fraction were selected for testing, and the influence of different fixed positions of valve and valve ring on key performance was studied.

# 3. Test results

## 3.1 Mean pressure difference across the valve test results

When the cardiac output was 2L/min, 3.5L/min, 5L/min and 7L/min, sample 1 was tested at fixed position 1, and the mean pressure difference across the valve test results were 3.3mmHg, 3.8mmHg, 4.6mmHg and 8.1mmHg, respectively. The mean pressure difference across the valve test results were 4.2mmHg, 5.8mmHg, 8.1mmHg and 11.0mmHg, respectively, when tested at the fixed position 2. The mean pressure difference across the valve test results were 3.8mmHg, 6.1mmHg, 8.6mmHg and 12.0mmHg, respectively, when tested at fixed position 3. Sample 2 was tested at fixed position 1, and the mean pressure difference across the valve test results were 3.2mmHg, 3.9mmHg, 5.1mmHg and 7.1mmHg, respectively. The mean pressure difference across the valve test results were 3.4mmHg, 4.3mmHg, 5.5mmHg and 7.9mmHg, respectively, when tested at the fixed position 2. The mean pressure difference across the valve test results were 3.3mmHg, 4.7mmHg,

5.7mmHg and 7.6mmHg, respectively, when the test was carried out at the fixed position 3. The results showed (Figure 2) that when the two samples were tested at three fixed locations, the mean pressure difference across the valve was the smallest at fixed position 1, while the mean pressure difference across the valve was larger at fixed position 2 and fixed position 3.

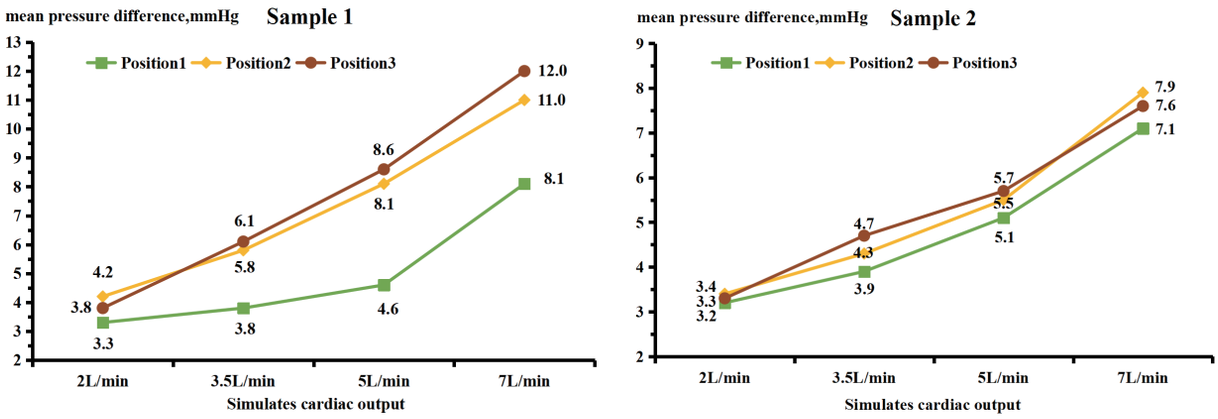


**Figure 2. Effect of different fixation positions on mean pressure difference across the valve**

## 3.2 Test results of effective orifice area

When the cardiac output is 2L/min, 3.5L/min, 5L/min and 7L/min, sample 1 is tested at the fixed position 1, and the effective orifice area test results are 1.68cm$^2$, 2.21cm$^2$, 2.88cm$^2$ and 3.27cm$^2$, respectively. The effective orifice area test results were 1.36cm$^2$, 1.98cm$^2$, 2.47cm$^2$ and 2.73cm$^2$, respectively, when tested at the fixed position 2. The test results of effective orifice area are 1.70cm$^2$, 2.17cm$^2$, 2.96cm$^2$ and 3.38cm$^2$, respectively, under the state of fixed position 3. Sample 2 was tested at fixed position 1, and the effective orifice area test results were 1.86cm$^2$, 2.39cm$^2$, 2.81cm$^2$ and 3.39cm$^2$, respectively. The effective orifice area test results were 1.56cm$^2$, 1.79cm$^2$, 2.28cm$^2$ and 2.87cm$^2$, respectively, under the state of fixed position 2. When the test was carried out at the fixed position 3, the effective orifice area test results were 1.98cm$^2$, 2.44cm$^2$, 2.88cm$^2$ and 3.35cm$^2$, respectively. The results showed (Figure 3) that when the two samples were tested at three fixed locations, the effective orifice area results showed that the effective orifice area at fixed position 2 was the smallest, and the effective orifice area at fixed position 1 and fixed position 3 was larger.

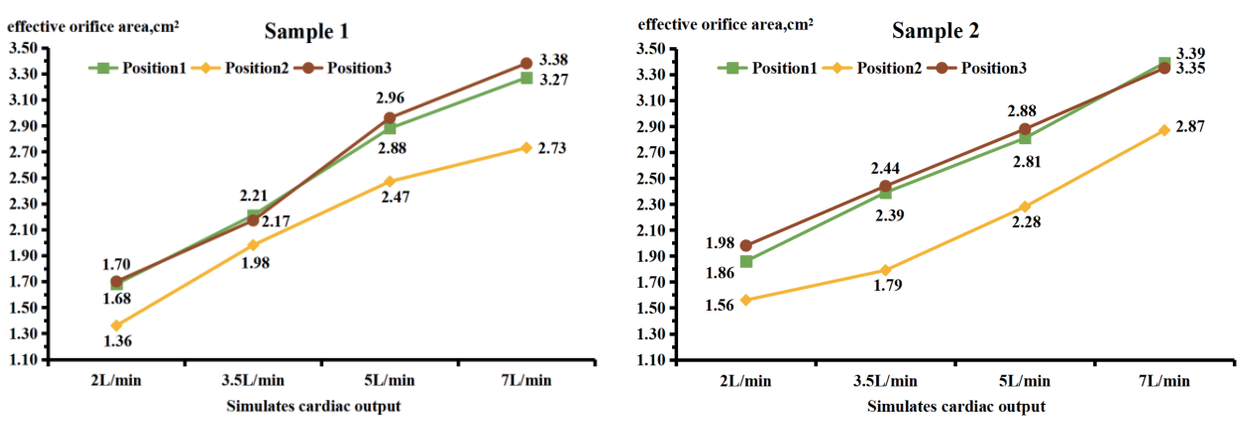


**Figure 3. Effect of different fixation positions on effective orifice area**

## 3.3 Regurgitant fraction test results

When the cardiac output was 2L/min, 3.5L/min, 5L/min and 7L/min, sample 1 was tested at fixed position 1, and the test results of regurgitant fraction were 14.31%, 7.77%, 5.37% and 2.87%, respectively. The results of regurgitant fraction were 15.84%, 8.81%, 5.73% and 3.68%, respectively under the state of fixed position 2. The test results of regurgitant fraction were 17.12%, 10.03%, 6.97% and 4.27%, respectively, under the state of fixed position 3. Sample 2 was tested at fixed position 1, and the results of regurgitant fraction were 12.16%, 5.55%, 3.85% and 3.19%, respectively. The test results of regurgitant fraction were 15.44%, 8.12%, 6.41% and 5.08%, respectively under the state of fixed position 2. The test results

of regurgitant fraction were 19.87%, 11.62%, 9.19% and 7.56%, respectively, under the state of fixed position 3. The results showed (Figure 4) that when the two samples were tested at three fixed locations, the regurgitant fraction results showed that the regurgitant fraction at fixed position 1 was the smallest, and the regurgitant fraction at fixed position 3 was the largest.

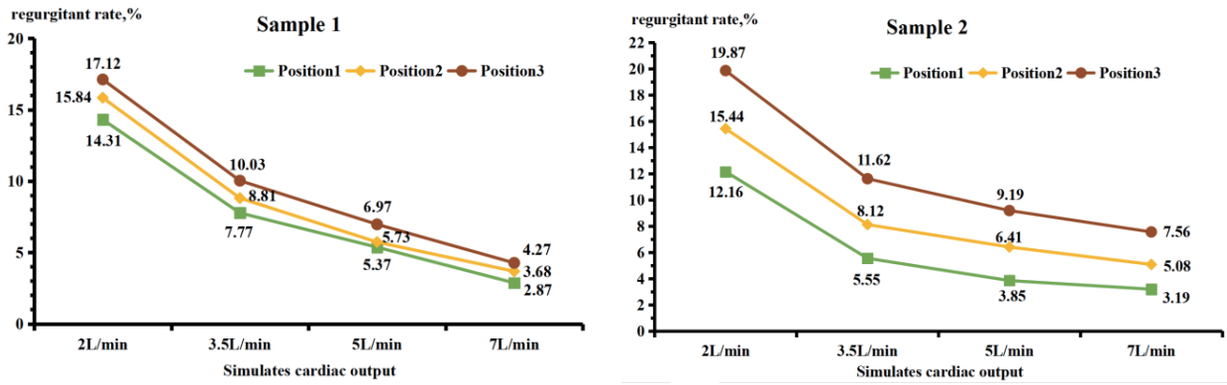


**Figure 4. Effect of different fixed positions on regurgitant fraction**

## 4. Discussion

It can be seen from the test results that different fixed positions of valve and valve ring have certain effects on the mean pressure difference across the valve, effective orifice area and regurgitant fraction of key performance during the in vitro fluid dynamics test of aortic valve. When the test was conducted at fixed position 2, the effective orifice area in the test result was the smallest. The reason might be that due to the lower fixed position, the valve ring affects the opening and closing of the valve orifice, resulting in a smaller opening area. When the test was performed at the fixed position 3, the regurgitant fraction was the highest in the test results. The reason might be caused by the upward fixed position leading to a smaller compression effect of the valve ring, which resulted in the increase of regurgitant fraction due to the loose closure of the valve orifice. At the fixed position 1, the mean pressure difference across the valve and regurgitant fraction are the smallest, and the effective orifice area is larger, which is the best position among the three positions.

In this study, it was found that the fixation position of the valve and valve ring had a certain influence on the key performance test results during the in vitro fluid mechanics test of the aortic valve. The lower fixation position would lead to the smaller effective orifice area, and the higher regurgitant fraction would result from the lower fixation position. Therefore, the optimal fixation position should be determined before the in vitro test of the aortic valve. At the same time, due to calcification or myocardial tissue fixation of the valve stent during clinical use, the risk of displacement or detachment is relatively small. However, in the in vitro simulation of pulsation flow test, although the valve ring has certain compliance, there is still a risk of displacement or even detachment. Therefore in order to better simulate clinical use conditions when conducting in vitro simulated fluid mechanics tests, necessary fixation treatment should be carried out if necessary to prevent unexpected displacement or detachment during the test. In this study, the valve and valve ring were fixed by adhesive method, which avoided the influence of paravalvular leakage during the in vitro hydrodynamic test. However, in the clinical stage, paravalvular leakage in the early stage is inevitable, and the influence of fixation and fixation method on key performance should be further studied in subsequent studies.

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