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248 Clinical Cases of G-K Mechanical Heart Valve

Liao Chongxian, Li Zengqi, Chen Daozhong, Chen Jianping, Lai Tianjie, Weng Qingyong

From Jan 1988 to Jan 1994, we have performed 248 valve replacement procedures with the use of 268 Hook-port (G-K) tilting disk valves. The report of these cases is as follows.

Clinical data

There were 248 patients in this group, including 112 males and 136 females. The average age was 35.4±12.6 years of age, with a range from 7 to 66 years of age. These cases included 2 cases of congenital aortic valve insufficiency (AI) with ventricular septal defect (VSD), 2 cases of mitral incompetence (MI), 2 cases of ruptured aneurysm of Valsalva sinus with AI, 2 cases of Marfan syndrome, 1 case of incompetence caused by traumatic rupture chordate tendineae mitral valve, 2 cases of incompetence caused by myxoid transformation of mitral valve, 23 cases of rheumatic mitral stenosis (MS), 15 cases of MI, 93 cases of MS + MI, 14 cases of AI, 13 cases of AI + aortic valve stenosis (AS), 23 cases of MS + MI + AI, 31 cases of MS + MI + AI + AS, 13 cases of postoperative MS + MI after closed mitral commissurotomy, 4 cases of bioprosthetic valve failure and 8 cases of infective endocarditis. The average disease course was 11.2±5.8 years, with a range from 4 months to 35 years. 14 patients were of grade II preoperative heart function (NYHA), 153 patients were of grade III and 81 patients were of grade IV. The average cardiothoracic ratio was 0.65±0.05, with a range from 0.5 to 0.9. The cardiothoracic ratio was more than 0.7 in 44 cases (18.1%). 116 patients (63.7%) experienced the complication of atrial fibrillation. 116 patients underwent mitral valve replacement (MVR); 44 patients underwent aortic valve replacement (AVR) and 38 patients underwent MVR + AVR (18 using imported bileaflet valves in AVR and 20 using G-K valves in AVR). 12 aortic valves were of Model 25, 30 of Model 23 and 22 of Model 21 of all the aortic valves. 19 mitral valves were of Model 25, 123 of Model 27 and 62 of Model 29.

Operation method

We performed cardioplegia perfusion with 4°C cold cardioplegia solution containing potassium at 10 ml/kg through the aortic root or left or right coronary artery after performing cardiopulmonary bypass under a medium to low temperature (22~28°C). Half amount of cardioplegia perfusion was repeated every 30 minutes. Pericardial cavity was surrounded with flake ice or placed in an icebag. Mitral valve replacement was performed using the interatrial groove path more frequently. However, if the patient needed to undergo tricuspid valvuloplasty or replacement reoperation, we would choose the right atrium -
interatrial septum path. During aortic valve replacement, the impaired valve was resected through oblique incision in the ascending aortic root. The subvalvular structures under the mitral valve would be partially or totally reserved in patients with a larger left ventricular chamber (all of the 3 cases in this group using this method had a good outcome after the operation). After the measurement of the actual size of mitral annulus, we chose to use a one size smaller artificial valve. We used everting mattress suture with a pad in all valve fixation.

**Result**

(1) There were 13 cases (5.24%) of early deaths (within 30 days after the operation) in this group. Causes of deaths included seriously low cardiac output in 4 cases, serious cardiac dysrhythmia in 2 cases, respiratory failure in 2 cases, renal failure in 2 cases and mycotic endocarditis in 1 case and advanced pericardial tamponade in 2 cases. Of all these 13 early deaths, 9 were of grade IV preoperative cardiac function and 4 grade III. None of early deaths was directly related to artificial valves. (2) There were 3 cases (1.22%) of late deaths (later than 30 days after the operation). Of these 3 cases, 2 cases with mycotic endocarditis died in month 2 and 6 postoperation, respectively, 1 with excessive anticoagulation died of cerebral hemorrhage in year 1 postoperation. (3) Postoperative cardiac function recovery: 218 cases were followed for 6 months to 6 years, with an average of 29.6±13.1 months. 68 cases of grade IV preoperative cardiac function changed to grade I postoperative in 18 cases, grade II in 36 cases and grade III in 14 cases. 140 cases of grade III preoperative cardiac function changed to grade 0 in 22 cases, grade I in 86 cases and grade II in 30 cases, and no change in 2 cases. 10 cases of grade II preoperative cardiac function changed to grade 0 in 6 cases and grade I in 3 cases and no change in 1 case.

**Discussion**

G-K valves are hook-port disk valves. After 6 years of clinical application and following-up observation, we concluded that G-K valves are advantageous because of: (1) Excellent hemodynamics. In this case group, postoperative cardiac function was significantly improved. Echocardiogram showed the disks can normally open or close with a larger valve orifice and lesser gradient pressure, which is in accordance with domestic reports [1,2]. (2) G-K valves with one lesser column in comparison with similar importing tilting disk valves as Medtronic valves may consequently reduce the chance to destroy formed elements in blood and lesser chance of thrombogenesis or serious haematolysis with larger effective orifice area. In our experience, no artificial valvular thrombogenesis was observed so far, but the long-term still needed to be followed up. (3) G-K valves can rotate around suture ring. At surgery, the disk opening position can rotate until satisfying opening and closing is observed. (4) G-K valves have lower valve frame, which can less frequently cause left ventricle rupture. In this group, no case of left ventricle rupture was observed. (5) Reliable quality and excellent abradability. (6) The price is suitable and
it may be easily accepted by patients in the extensive impoverished area.

G-K valves have the following restrictions: (1) Some patients were not easily adapted to the undesirable sound when the disk opened or closed. (2) Doctors might feel a sense of nonfluency inserting the needle into the aortic valvular suture ring. (3) Some suture rings might become deformed after ligature, while deformation of the suture ring may cause the knot plugging into the orifice, which should be noted in surgery.

References


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Author affiliation: Heart surgical department, The Union Hospital Affiliated to Fujian Medical University, 350001
Animal experiments of GK bileaflet prosthetic heart valve
ZHONG Jiug, TANG Yue, MENG Liag, et al
(Department of Cardio-thoracic Surgery, General Hospital of Air Force, Beijing 100036, China)

Abstract: Objective To observe and evaluate the long-term existence result of a new type of bileaflet mechanical prosthetic heart valve (GK bileaflet valve) after its implantation to the animal bodies. Methods Seven sheep were operated upon with either mural valve or pulmonary valve under the extracorperal circulation, totally 7 GK bileaflet valves were implanted. Through animal general appearance observation, circulation and the breath system monitor, the blood biochemical and bacteriologies examination, pathologic histology check, long-term existence time and existence quantity, we analyzed and evaluated the general function of GK bileaflet valves and their effect on the each main organs. Results One animal died during the surgical operations; and 6 animals had long-term existence (over 30 d), the longest existence time was 378 days. Over a long period of time existent animals, did not appear any infection and valve-related complications. According to the plan S animals were sent to autopsy in 1, 3 and 6 months respectively, the prosthetic valvular had smooth surface, opened and closed freely. The embolisms and abnormalities were not found in the main organs including the lung, kidney, liver, spleen, and myocardium during general and histological examinations. Conclusion GK bileaflet prosthetic heart valve exhibits good biological consistency, satisfied durability, and excellent hemodynamic properties. Implanting into the animal body can acquire the satisfied long-term existence result.

Key words: Heart valve prosthesis; Animals; Survival rate

GK bileaflet prosthetic heart valve is a new type of valve developed jointly by General Hospital of Air Force and Beijing Beijing Star Medical Devices Co., Ltd. After in vitro performance and fatigue test, it was applied to animal long-term survival testing from March 2001 to March 2003 in the current study, and a desired result was achieved.

1 Materials and Methods
1.1 Preoperative preparation Seven Small-tailed Han sheep (1 to 2 years, male, weighted 37~67 (47.9 ±7.3kg), in accordance with the experimental animal requirements after 1 week quarantine). A 24-hour fasting was undertaken preoperatively. The blood was collected from the same specie of sheep for intraoperative use.

1.2 Anesthesia and position: Ketamine (20~30mg/kg) and diazepam (2~2.5mg/kg) intramuscular injection and systemic induction of anesthesia. After Secoverine (1mg/kg) intramuscular injection, artificial ventilation was established by endotracheal tube (ET), and ketamine (8~10mg/kg) and diazepam (0.8~1mg/kg), or only fentanyl (2~4μg/kg) for
maintenance of anesthesia through intermittent intravenous injection. Either left- or right-lateral position was acceptable. The arterial pressure and central venous pressure were monitored with Limb lead ECG, transcutaneous oxygen saturation continuous monitoring, and internal carotid artery and internal jugular vein cannulation. At the same time, nasopharyngeal temperature, hemoglobin, hematocrit, serum electrolytes, blood gas analysis, blood activated clotting time (ACT), urine output and other indicators were recorded.

1.3 Extracorporeal Circulation (EC) Methods: Sans 7000 artificial heart-lung machine, Xijing Bubble Oxygenator, whole blood as priming fluid, 706 plasma substitute and crystal fluid were used to establish EC. Arterial perfusion tube was inserted at the root of ascending aorta; superior and inferior vena cava tube or atrioventricular tube was implanted through right atrium. Heparin (dosage: 3mg/kg) was used to maintain an ACT above 400s. The whole operation was conducted under room temperature and without heart arrest. The nasopharyngeal temperature was kept at between 36°C ~ 37°C during EC. Protamine was used to neutralize heparin after it was completed.

1.4 Surgical Methods: The left fourth intercostal thoracotomy approach was applied to three sheep, and right approach to other sheep. Systemic heparinization after opening of pericardium. Double purse-string was sutured at the ascending aorta, and aortic perfusion tube inserted. The purse-string suture was applied at right atrium, in which superior and inferior vena cava tube or 1 atrioventricular tube was implanted. Afterwards, EC was started under mildly low-temperature. During the replacement of mitral valve, after sectioning along the long axis of the left atrial appendage, the mitral valve was exposed and removed. Afterwards, continuous 2-point 4.0 Prolene suturing was carried out and prosthetic mitral valve was implanted. The prosthetic mitral valve was sutured on the completely-reserved mitral valve, in only one case. In the pulmonary valve replacement, transverse incision was performed on the main pulmonary artery, and three 4.0 Prolene suture was used to continuously sew up the prosthetic valve, with partial pulmonary valve leaflets as pad. After the replacement completed, the opening and closing of valve leaflets were examined. The incisions were sewed up on the left and right atrium and pulmonary artery. Gradually in experimental animals the extracorporeal circulation was reduced, piping was removed and pericardial incision was left open. Intrathoracic drain tube was placed at the lower intercostal position, sutured incisions and closed thoracic cavity in sequence.

1.5 Postoperative Care After closure of thoracic cavity, breathing machine was used for mechanical ventilation. After the removal of endotracheal intubation, the animals changed into standing position. The arterial and venous pressure and ECG were monitored continuously for 24~48h to maintain a stable circulation. The vasoactive drugs were utilized if necessary. Blood would be transfused in accordance with the volume of drainage fluid and the
concentration of hemoglobin. The homeostasis should be maintained and blood pH and electrolytes be kept in the normal range.

1.6 Antibiotics and anticoagulant therapy Postoperatively intravenous administration of antibiotic was continued for 5~7d. Cefazolin sodium was applied to No. 12 and 13 animals while Penicillin to others. Continuous venous injection of heparin was started with micro pump to maintain ACT at about 200s. After the removal of endotracheal intubation and moving to the recovery room, triple anticoagulation was continuously utilized on animals. While the sheep left the recovery room, the increased dosage of warfarin was administrated but heparin and aspirin were discontinued. INR should be kept at 3.0 ~ 4.0 in the first week. For long-term survived sheep, INR was examined once each one or two weeks and adjusted to 2.5~3.0. Three months later, the anticoagulant was discontinued on schedule.

1.7 Observed Indicators: For long-term survived animals, the quality of their life (including eating, drinking, characteristics of stool and urine, metal state, and daily activities, etc.), hemorrhage, embolism, infection and other abnormalities, should be closely observed and strictly recorded. The autopsy and pathological examinations should be carried out in the animals that died postoperatively and were executed regularly on schedule, to gain a comprehensive understanding of the abnormal changes on their lung, kidney, liver, spleen, heart, brain and other main organs.

1.8 Statistical analysis: SPSS 10.0 software was used for data analysis. All data was expressed as mean±standard deviation (x±s). t test was applied to group comparison, and \( P < 0.05 \) are statistically significant. Kaplan-Meier Regression method was for survival and event correlation analysis while Log-Rank test for the comparison of overall difference.

Tab 1 A variety of laboratory indicators and results of seven animals implanted with GK bileaflet valves

<table>
<thead>
<tr>
<th>No.</th>
<th>Animal s under Study</th>
<th>Weight (kg)</th>
<th>Implant position</th>
<th>Types of valves</th>
<th>Size of valves (mm)</th>
<th>EC time (min)</th>
<th>ET time (h)</th>
<th>ICU duration (d)</th>
<th>Survival Time (d)</th>
<th>Cause of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>sheep</td>
<td>51</td>
<td>pulmonary valve</td>
<td>AV</td>
<td>21</td>
<td>65</td>
<td>10</td>
<td>5</td>
<td>201</td>
<td>executed</td>
</tr>
<tr>
<td>2</td>
<td>sheep</td>
<td>46</td>
<td>pulmonary valve</td>
<td>AV</td>
<td>21</td>
<td>49</td>
<td>8</td>
<td>6</td>
<td>91</td>
<td>executed</td>
</tr>
<tr>
<td>3</td>
<td>sheep</td>
<td>48</td>
<td>pulmonary valve</td>
<td>AV</td>
<td>21</td>
<td>58</td>
<td>11</td>
<td>4</td>
<td>40</td>
<td>executed</td>
</tr>
<tr>
<td>4</td>
<td>sheep</td>
<td>43</td>
<td>mitral valve</td>
<td>MV</td>
<td>25</td>
<td>80</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>ventricular dilatation, low cardiac output</td>
</tr>
<tr>
<td>5</td>
<td>sheep</td>
<td>67</td>
<td>mitral valve</td>
<td>MV</td>
<td>27</td>
<td>72</td>
<td>9</td>
<td>4</td>
<td>378</td>
<td>trauma</td>
</tr>
<tr>
<td>6</td>
<td>sheep</td>
<td>40</td>
<td>mitral valve</td>
<td>MV</td>
<td>25</td>
<td>51</td>
<td>12</td>
<td>5</td>
<td>41</td>
<td>executed</td>
</tr>
</tbody>
</table>
2 Results

Seven GK bileaflet valves were implanted in seven animals (See Table 1). The operation was successfully performed in six with normal size, filling level, and opening and closing of valves in atrium and ventricle, however, the hyperdistension of heart or errhysis of incisions made one survive only on bypass machine. Six survived for over 1 month, in which three over 3 months, and one even successfully for 378d. The mean survival time was 130. 2 ±71.5 d respectively. In the six long-term survived animals, five were executed at the end of 1st, 3rd, and 6th month in line with study plan, respectively, and the other one died of trauma. Six animals, successively getting rid of bypass machine, kept stable hemodynamic with their blood pressure at 90/60~130/70 mmHg. A small amount of dopamine (2~5μg•min^-1•kg^-1) was administrated to two sheep during perioperative period with their heart rate at 140~150/min in sinus rhythm. Sinus tachycardia appeared in No. 1 animal postoperatively with their heart rate at 140~150/min, and returned to normal after symptomatic treatment. Blood routine test, plasma free hemoglobin, blood biochemistry and blood culture were regularly examined and all kept in normal range, except for a low hemoglobin concentration observed in No. 1 sheep. The regular blood culture and prosthetic valve bacterial culture after execution were negative.

Triple anticoagulant was applied in the study to maintain an ACT at 200s and INR at 3.6±0.9 (2.5~6.1), respectively, when the animals stayed in ICU. After they moved out, INR was measured once one or two weeks and kept at 3.1±0.6 (2.3~5.1) with the daily dosage of warfarin at 9~21 mg and its mean at 13.9 ± 4.5 mg. No thrombosis, embolism and bleeding were observed.

The autopsy and pathological examinations were undertaken in all long-term survived animals, executed on schedule or died unexpectedly. The smooth surface of prosthetic valves was observed without thrombosis. No embolism and other abnormal change were observed in the lung, kidney, liver, spleen, heart, brain and other organs.

3 Discussion

Chronic animal survival test should be conducted for the new prosthetic heart valve before clinical application, however, there were few studies documented on the survival test for its considerable difficulties, long observation period, various factors involved and high expenses [1,2]. China-made bileaflet mechanical valve, though having been developed for many years, failed to be utilized clinically, mainly due to the strict national standards formulated in accordance with

<table>
<thead>
<tr>
<th></th>
<th>sheep</th>
<th></th>
<th>mitral valve</th>
<th>MV</th>
<th></th>
<th>83</th>
<th>7</th>
<th>5</th>
<th>31</th>
<th>executed</th>
</tr>
</thead>
<tbody>
<tr>
<td>total</td>
<td>7</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td>65.4±5.9</td>
<td>4.8±1.3</td>
<td>130.2±7</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>-</td>
<td>6.8</td>
<td></td>
<td></td>
<td></td>
<td>9.5±3.1</td>
<td>5.1</td>
<td>1.5</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

MV: mitral valve prosthesis; AV: aortic valve prosthesis
international standards, in which animal long-term survival test was a key rate-limiting step [3]. In the recent two years, we conducted such an animal test on GK bileaflet valve, and achieved an increasing success rate and satisfactory results via continuous improvement of test strategies and techniques.

3.1 Experimental standard of prosthetic mechanical valve: In line with National Standards in 1990, implantable prosthetic heart valves include mechanical and bioprosthetic valve. Before clinical application, heart valves should be implanted into at least three animals, and their survival time over 30 days. Furthermore, according to the latest standards of FDA (ISO 5840296), it is required that there are at least three experimental animals surviving more than three months, in order to gain a comprehensive understanding of the relative characteristics of implanted prosthetic heart valves [3]. In the present study, the prosthetic valve replacement had been conducted in seven animals, in which six survived over one month, three over three months, and one even over one year. In this sense, the survival time in the study was far longer than that required by national standard.

3.2 The choice of experimental animals: Animal model has been applied to the clinical evaluation of mechanical heart valve for many years, but a variety of animal models have their own advantages and disadvantages. Dog is light-weighted and difficult to manage. Pig is not suitable for long-term animal model due to the difficulties in endotracheal intubation and postoperative management. The rapid growth of calf will lead to relative stenosis of the implanted valve several months after operation, so it is not an ideal animal model, either. Sheep, with the similar characteristics of hemodynamic and laboratory indicators with man, is often selected as animal model in valve replacement. General anesthesia and extracorporeal circulation are enough for operation, and its postoperative treatment is relatively simple, too. Besides, other factors, such as docile temperament, easy management, little postoperative infection, easy long-term feeding and high long-term survival rate, make sheep an ideal choice for chronic test of heart valve replacement.

3.3 Choice of implant position of prosthetic valve Tricuspid valve was mostly chosen in the previous long-term survival animal test with valve replacement for its easy exposure. There are rare reports on pulmonary valve replacement. However, as an implant position, pulmonary valve possesses many advantages that makes it an ideal position worth recommending to evaluate the long-term survival of mechanical valves, if the survival of experimental animal is taken into account, such as enlarged visual operative field, easy operation, the whole replacement under room temperature and without heart arrest, no need for cold delivery tube inserted at the aortic root occlusion clamp, simplified surgery steps, shorten operation time and reduced various surgical complications. However, as a pre-clinical experiment of new type prosthetic valve, the experimental position should be that most commonly
used in valve replacement. In this sense, the mitral valve replacement was chosen in the latest four animals, and No. 25 or 27 mitral valve was selected to match the weight of animal. All operations were successfully completed. It indicated that mitral valve could be chosen as position for replacement in accordance with clinical practice.

3.4 Experimental techniques of prosthetic valve implantation under extracorporeal circulation: To date, the animal experiment abroad of valve replacement were mostly completed via left atrial appendage or right atrium under heart arrest [4], in which the leaflet was removed first, the suture was separated at the level of valve ring and there prosthetic valve was implanted. However, mitral implant in the current study is completed via left atrial appendage without occlusion of ascending aorta and heart arrest, under the support of extracorporeal circulation. The strength of this operation type is that the operation at aortic root could be left out and the possibility of myocardial ischemia is avoided. Furthermore, the opening and closing of valves could be observed under direct vision after implantation, to detect whether there is abnormal paravalvular blood flow, which could be found as two returning blood flow jetting out of the bileaflet valve axis. In the study we also kept whole mitral valve untouched, sutured the prosthetic valve above the mitral valve ring with the needle sewing into from atrial wall and out from valve ring. The above suture technique ensured the successful implantation of the prosthetic valves with suitable size or type.

3.5 The significance of long-term survival: In six long-term survived animals, five were executed on schedule, and autopsy indicated the good properties of opening and closing of heart valves without paravalvular leakage, thrombosis, and embolism or bleeding on main organs. The other died of trauma 378 days after operation, in which no complications related to valve implantation were observed via autopsy. It is reasonable to consider that GK bileaflet valve can achieve an ideal effect of anticoagulation through early, active postoperative treatment after implantation in animals with its good blood compatibility and anti-thrombotic properties.

Seven GK bileaflet prosthetic valves was implanted in seven animals in the present study, in which six survived for over one month in good conditions, normal mental state, feeding and drinking, and activities. No structural abnormalities and mechanical failure were observed on all seven GK bileaflet valves. Anatomical and histological examination indicated that the prosthetic valves had smooth surface and no thrombosis, embolism and other abnormalities in major organs. In conclusion, the present study indicated that China-made GK bileaflet valve had achieved a satisfactory long-term survival effect for its stable application safety, ideal hydrodynamic properties, good biocompatibility and reliable durability.

References:


Comparison of Clinical Effects between Native GK-double-leaflet Mechanical Heart Valve and Edward


(the second affiliated Hospital of Harbin Medical University, Harbin 150086, China)

Abstract: Objective To evaluate the clinical effects of native GK-bileaflet mechanical heart valve. Methods From April 2003 to August 2003, 20 patients with heart valve disease were performed on heart valve replacement with native GK bileaflet mechanical heart valve (group I). The postoperative outcome was compared with another 20 patients who underwent heart valve replacement with Edward bileaflet valve (group II). Results a suicide was committed and 2 cases of leaking around the valve occurred in group I 7d, 2d, 23d respectively after the operation; 1 case of leaking around the valve happened 2 months after the operation in group II. All the three patients came back to health through the second repair surgery, and the operative courses of the other patients were fee and smoothly. There was no significant difference between both groups in their ICU stay, hospital stay after operation and assistant time of hypertension drug (P>0.05 respectively), while the cost in group I was much lower than that in group II (P< 0.005). There were no mistakes prosthesis-related occurred in both groups during follow-up period and no statistically significant difference was observed in the ratio of postoperative relief of cardiac function in the corresponding period. Conclusion The homemade GK bileaflet prosthesis could be taken as an ideal alternative for native heart valve for its safety, reliability, high quality and low price in our undeveloped area at present.

Key words: Cardiovascular surgery; heart valve replacement; Mechanical heart valve' comparison

Beijing Star Medical Devices Co., Ltd is responsible for the researching, development and manufacturing of GK – double – leaflet prosthesis which is the first generation of native double – leaflet valves. Our institute was submitted to perform valve replacement on 20 patients in comparison with 20 patients in the control group who were performed valve replacement with importing double – leaflet prosthesis (Edward valves) from April, 2003 to August, 2003 in order to further evaluate the clinical quality and efficacy of GK – double – leaflet prosthesis. The trial report is as follows.

1 Clinical Data

Patients were divided into two groups of 20 patients. Clinically all of the patients experienced palpitation, chest distress and short breath after exercises. Patients with infectious endocarditis were experiencing or had experienced long-term febrile diseases. Before...
inclusion, we examined all patients for their medical history, and all of these patients underwent physical examination, electrocardiographic examination, chest X-ray and echocardiogram diagnosis.

1.1 Native valve group (group I): There were 20 patients in this group, including 8 males and 12 females. The average age was 47.1±9.94 a with a range from 21 to 60 a. The average weight was 60.3±10.6 kg with a range from 44.5 to 94.0 kg. There was 1 case of grade II preoperative cardiac function, 17 of grade III and 2 of grade IV. Preoperative diagnosis: 15 cases of rheumatic heart disease including 2 cases of combined valvular heart disease, 9 cases of left atrioventricular valve disease, 2 cases of infectious endocarditis, 2 cases of degenerative aortic valve disease and 1 case of patent ductus arteriosus. We performed double valve replacement on 6 patients (2 patients using GK – double – leaflet valves both and 4 patients using GK – double – leaflet valves and GK – single – leaflet valves simultaneously). 12 patients were performed on left atrioventricular valve replacement and 2 patients underwent aortic valve replacement. Intraoperative procedures concluded 2 cases of left atrial thrombectomy, 1 case of ligation of patent arterial duct, 3 cases of right atrioventricular Devega plasty and 1 case of left atrial volume reduction surgery.

1.2 Importing valve group (group II): There were 20 patients in this group, including 11 males and 9 females. The average age was 46.0±12.73 a with a range from 13 to 62 a. The average weight was 64.58±13.49 kg with a range from 43 to 98 kg. There were 18 cases of grade III preoperative cardiac function and 2 of grade IV. Preoperative diagnosis: 13 cases of rheumatic heart disease including 6 cases of combined valvular heart disease, 7 cases of left atrioventricular valve disease, 4 cases of degenerative aortic valve disease and 3 cases of infectious endocarditis including 1 case of combined patent ductus arteriosus. We performed double valve replacement on 6 patients, left atrioventricular valve replacement on 10 patients and aortic valve replacement on 4 patients. Importing Edward – double – leaflet valves were applied on all of the patients in this group. Intraoperative procedures included 2 cases of left atrial thrombectomy, 1 case of patent arterial duct, 3 cases of right atrioventricular Devega plasty and 1 case of left atrial volume reduction surgery.

2 Operation procedures

Both group underwent conventional cardiopulmonary bypass cannulating under general anesthesia, and anterograde perfusion with cold blood or modified Thomas cardioplegia (once for single valve replacement and twice for double valve replacement). Continuous suture was applied in both left atrioventricular and aortic replacement. Mural thrombectomy, right atrioventricular valve Devega plasty ligation of patent arterial duct or left atrial volume reduction surgery were performed on part of the patients simultaneously. The average blocking time was (36.4±9.08) min and (3.83±12.40) min for the two groups respectively. The average connecting time was (65.45±10.46) min and (67.65±15.64) min for the two groups.
3 Statistical methods

All values were designated as ±s. T test and \( t \) test were used to compare measurement data and enumeration data respectively.

4 Results

No intraoperative death occurred in both groups. 1 case of suicide was committed in group I after oral application of valium. 2 cases of leaking around the valve occurred in group I 2d and 23d after the operation, respectively. 1 case of leaking around the valve occurred in group II in an car accident two months after the operation. These three patients recovered from leaking around the valve after reoperation and were then discharged.

4.1 Preoperative data

The preoperative data of group I and II shown in Table 1 and 2, respectively, was comparable with each other.

<table>
<thead>
<tr>
<th>Table 1 General preoperative data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>Age (a)</td>
</tr>
<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>Disease course (y)</td>
</tr>
<tr>
<td>EF%</td>
</tr>
<tr>
<td>C/T</td>
</tr>
<tr>
<td>Native valve group (group I)</td>
</tr>
<tr>
<td>47.1±9.94</td>
</tr>
<tr>
<td>60.3±10.6</td>
</tr>
<tr>
<td>7.05±7.78</td>
</tr>
<tr>
<td>55±11</td>
</tr>
<tr>
<td>0.67±0.08</td>
</tr>
<tr>
<td>(n=20)</td>
</tr>
<tr>
<td>(21~60)</td>
</tr>
<tr>
<td>(44.5~94)</td>
</tr>
<tr>
<td>(42~70)</td>
</tr>
<tr>
<td>(0.54~0.77)</td>
</tr>
<tr>
<td>Importing valve group (group II)</td>
</tr>
<tr>
<td>46±12.73</td>
</tr>
<tr>
<td>64.5±13.5</td>
</tr>
<tr>
<td>6.57±9.10</td>
</tr>
<tr>
<td>49±13</td>
</tr>
<tr>
<td>0.62±0.06</td>
</tr>
<tr>
<td>(n=20)</td>
</tr>
<tr>
<td>(22~66)</td>
</tr>
<tr>
<td>(43~98)</td>
</tr>
<tr>
<td>(32~68)</td>
</tr>
<tr>
<td>(0.54~0.80)</td>
</tr>
</tbody>
</table>

Table 2 Preoperative cardiac function data

<table>
<thead>
<tr>
<th>Group</th>
<th>grade II</th>
<th>grade III</th>
<th>grade IV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (n=20)</td>
<td>1 (0.05)</td>
<td>17 (0.85)</td>
<td>2 (0.1)</td>
<td>20</td>
</tr>
<tr>
<td>Group II (n=20)</td>
<td>0</td>
<td>18 (0.9)</td>
<td>2 (0.1)</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>35</td>
<td>4</td>
<td>40</td>
</tr>
</tbody>
</table>

The ICU stay, postoperative hospital stay and duration of taking pressor agent showed no significant difference for the two groups (\( P \) > 0.05 for all of the three parameters). Mean hospital cost was significantly lower in group I than group II (\( P \) < 0.005). There were no mistakes prosthesis-related occurred in both groups during follow-up period and no statistically significant difference was observed in the ratio of postoperative relief of cardiac function in the corresponding period (at the discharge time and 3 months to 1 year after the operation). The detailed data is listed in Table 3 and 4.
4.2 Postoperative results

Table 3 Postoperative data

<table>
<thead>
<tr>
<th>Group</th>
<th>ICU stay (h)</th>
<th>Hospital stay after the operation (d)</th>
<th>Pressor agent administration time</th>
<th>Hospital cost (Y)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native valve group (group I)</td>
<td>18.52±25.81</td>
<td>01.57±2.8/0</td>
<td>46/2 28.05</td>
<td>41 417-42 03 32/3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importing valve group (group II)</td>
<td>14.23±10.70</td>
<td>02.02±1.52</td>
<td>45-50 24.42</td>
<td>6/ 6’5 74 07 256-75</td>
</tr>
</tbody>
</table>

Table 4 postoperative relief of cardiac function in the short – term and long – term (cases%)

<table>
<thead>
<tr>
<th>Group</th>
<th>At discharge</th>
<th>3 months to 1 year postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 grade in relief</td>
<td>2 grades in relief</td>
</tr>
<tr>
<td></td>
<td>7’/31(</td>
<td>00’/47(</td>
</tr>
<tr>
<td></td>
<td>04’/-64(</td>
<td>4’/-14(</td>
</tr>
</tbody>
</table>

* 1 suicide was committed after the operation and was excluded.

5 Discussions

Valve replacement remains the main treatment method for all types of cardiac valvular diseases currently\cite{1}. Mechanical valves is the first choice in China for its simplicity in manufacturing, excellent durability (about 40 ~ 50 years) and relatively low costs (about ¥ 4 000 ~ 5 000 for a native valve). Mechanical valves can be grouped into double – leaflet valves and single – leaflet valves in design. Studies have proven that double – leaflet valves are more consistent with human natural structures because of their center– type blood flow and lower transvalvular pressure gradient, which make the patients have more evident improvement in postoperative hemodynamics and more satisfactory relief in cardiac shape and functions\cite{2}. Besides, this type of valves are biaxial, so if the valve in one side gets jammed, the other valve in the opposite can still function to prevent sudden death and to save time for emergent treatment and reoperation. In view of this, most of the importing mechanical valves have changed into double – leaflet currently. However, the exorbitant price of importing valves is too high to be accepted by some patients (around ¥ 15 000). Native GK – double – leaflet valves manufactured by Beijing Star Medical Devices Co., Ltd are of no significant difference from the importing
long-term therapeutic effect, while the hospital cost is significantly lower in native valves. Given the domestic economic conditions at present, the homemade GK – double – leaflet prosthesis could be taken as an ideal alternative for its safety, reliability, high quality and low price.

References:


(Editor: Xuezhen Liu) (Accepted date: 2004 – 12 – 07)
Primary clinical application of
new (GK) bileaflet mechanical heart valve

ZHONG Jing, WAN Shi-jie, WANG Wei-xin, et al
(Department of Cardiovascular Surgery, General Hospital of Air Force, Beijing 10036, China)

Abstract: Objective to introduce a new type of bileaflet mechanical prosthetic heart valve (GK bileaflet valve) and evaluate clinically the early hemodynamic effect and short term follow up after its replacement. Methods 20 patients were operated upon with a mean age of 44.5±10.74 years. 85 percents (17/20) had NYHA class III and IV heart function. The mitral valve replacement was performed in 14 patients, aortic valve replacement in 4 patients and double valve replacement in 2 patients. Follow-up is 100% and extended 1 to 2.5 years. Result There was no any early or late mortality. Without valve-related complications all patients have lived for more than 1 to 2.5 years. Conclusion Early clinical results and short-term followup demonstrate that GK bileaflet prosthetic heart valve exhibits excellent hemodynamic properties, satisfied blood consistency and a low incidence of valve-related complications.

Key words: heart valve prosthesis; heart valve diseases/surgery

GK bileaflet mechanical heart valve (GK bileaf valve in abbreviation below) is a new bileaflet mechanical heart valve, which is developed by Air Force General Hospital and Beijing Star Medical Devices Co., Ltd together. It was applied clinically from Sep 2002 after the completion of extracorporeal tests and animal experiments, and 20 bileaflet valves were applied in 22 heart valve replacement surgeries during one and a half years. The conditions of clinical application and recent follow-up results are summarized as followings.

1 Materials and methods

1.1 Mechanical heart valves GK bileaflet valve is a kind of mechanical valves which are low in valve support with three-channel central flow and bileaflet. Graphite acts as the base of valve support and valve (leaf), and surface is covered by pyrolytic carbon. Opening angle of leaflet (in one-direction) is 85\(^{\circ}\), a sella peak structure which owns a pair of processes at inflow side is adopted in appearance, ball-socket design is applied into joint-twisting structure in valve hub, and sewing cuff is filament fabric.

1.2 Patient data Among 20 patients, 9 were male and 11 female. Age ranged from 31 to 60 years old (44.5±10.74 years old in average), weight from 43 to 83 kg (57±12.4 in average), and history from 0.6 to 36 years, 8.78 years in average. Symptoms of palpitation, brachypnea, dyspnea, and so on were clinically available after activity, and coronary diseases were excluded by pre-operative examination, ECG, chest film, echocardiography, and alike. Pre-operative diagnosis: 50 cases for rheumatic heart disease, among
which 18 cases for joint valvular disease, 2 for mitral disease, 13 for restriction after closed mitral commissurotomy, 1 for degenerative disease of aortic valve, and 1 for infective endocarditis. 7 cases were accompanied by chronic atrial fibrillation, with 4 cases for left atrium thrombosis. 3 cases for cardiac function of level II, 13 cases for cardiac function of level III and 4 cases for that of level IV.

1.3 Surgical methods: Surgeries were all conducted on patients under moderate hypothermic general anesthesia and extracorporeal circulation, with application of antegrade cold blood or cold crystal cardioplegia for sole valve replacement and that of both antergrade and retrograde cold blood cardioplegia for bileaflet replacement. Continuous suture along right atrium-interventricular septum routine was adopted for mitral valve replacement; Interrupted mattress suture was mostly placed by 2-0 Ethicon stitches with shims for aortic valve replacement, and 3-stitch Prolene continuous suture was applied in few patients. Partial patients were also conducted on by left atrium wall mechanical thrombectomy, tricuspid De Vega plastic surgery or left atrium volume-reduction. Warfarin was initially administrated orally 48hs after operation, to regulate prothrombin time (PT) to 1.5 times of contrast value, and international standardized value (INR) was 1.5-2.5 (when international sensitive index was 1.2).

1.4 Hemodynamic and hemocompatibility observing parameters Such index was observed dynamically as routine blood test, routine urine test, liver function and changing process of free serum hemoglobin. Those parameters were examined, like cardiothorax rate (chest film), measurement of all atriums and ventricles, effective area of mechanical valve opening, flow velocity at valve opening, transvalvular pressure gradient (echocardiography) and so on during follow-up.

1.5 Follow-up Patients were followed half a year and one year later respectively, and follow-up ways were inclusive of letter, call, outpatient visit and so on. Cardiac function grading, valve-related complications and alike were judged according to activity, administration, examination results and so on, referred to American Cardiothorax Association Standard which was set up in 1996 by Edmunds and others [2].

1.6 Statistic analysis SPSS 10.0 software was applied, data was expressed in $\overline{x} \pm S$, t-test was conducted

Kaplan-Meier regression was applied into correlation analysis of survival rate and incident, with Log-Rank test to compare population difference.

2 Results

2.1 Early results Among 20 cases in this group, 14 cases receiving mitral valve replacement, 4 receiving valve replacement, 2 receiving both mitral and aortic valve replacement, 4 cases also receiving left atrium thrombectomy and
5 also receiving tricuspidoplasty. Blocking time for sole valve replacement was 29-112 (64.75±27.5) minutes with CPB time of 46-163 (96.35±38.52) minutes. That for bivalve replacement was 67-146(78.66±22.36) minutes with CPB time of 85-176(106.16±23.29) minutes. Total number of GK bileaflet implanted was 22, among which there were 16 mitral valves (25M 5, 27M 10, 29M 1), and 6 aortic valves (21M 2, 23M 4). No death was existent in through group (within 30 days). Tubes intubated in patients were all pulled out within 24 hours after operation, and their consciousness was clear with stability of hemodynamics and absence of severe arrhythmia. Mild low cardiac output syndrome occurred on 2 cases, and another open heart surgery was conducted on one case due to poststernal blood oozing at 6 hour after the operation. Such parameters recovered to preoperative level 3-7d after surgery (as seen in chart 1), as hemochrome, blood platelets and hemocompatibility related index. All of the patients left hospital with complete recovery within 25 days after operation.

2.2 Follow-up results: Those 20 survival patients were followed up periodically, and it indicated that the longest survival time was 2 years and a half with the shortest time of 12 months, 15.3 months in average. All of the patients were followed up periodically (Follow-up rate was 100%), with the transfer of cardiac function from preoperative level III-IV to level I-II, which meant possibility of physical work to different degree and excellent living quality. Reexamination of chest film and echocardiography showed cardiothoracic ratio and measurement of all atriums and ventricles downsized noticeably, and both valve opening area and transvalvular pressure gradient were improved dramatically half a year after operation (Chart 2). Such index was normal, which referred to routine blood test, routine urine test, liver function and free serum hemoglobin. No complications related to valves were found, including failure of valvular structure (disorder or dysfunction), nonstructural dysfunction (periphery valve leakage), thrombosis of valve, thromboembolism, anticoagulation bleeding, mechanical valve infectious endocarditis and so on.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Preoperative</th>
<th>Operation</th>
<th>Postoperation (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Hb (g/L)</td>
<td>135</td>
<td>102</td>
<td>106</td>
</tr>
<tr>
<td>Free Hb (g/L)</td>
<td>30.1</td>
<td>38.6</td>
<td>34.4</td>
</tr>
<tr>
<td>Blood platelets (10^9.K(</td>
<td>243</td>
<td>103</td>
<td>134</td>
</tr>
<tr>
<td>Sum serum bilirubin (μmol/L</td>
<td>11.6</td>
<td>23.2</td>
<td>10.9</td>
</tr>
</tbody>
</table>

Chart 1 Observing results of hemocompatibility index after valve replacement
Chart 2 Comparison of observing index between pre-replacement and post-replacement of valve

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Preoperation</th>
<th>Postoperation</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inside diameter of left ventricle at end diastole (mm)</td>
<td>72.3±13.4</td>
<td>54.6±12.5 *</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Long diameter of left atrium (mm)</td>
<td>64.5±10.2</td>
<td>55.3±9.32 *</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Flow velocity at valve opening (m/s)</td>
<td>2.6±0.8</td>
<td>1.5±0.4 *</td>
<td></td>
</tr>
<tr>
<td>Transvalvular pressure gradient (mm Hg)</td>
<td>34.6±8.3</td>
<td>12.3±5.2 * *</td>
<td></td>
</tr>
<tr>
<td>Effective area at valve opening (cm²)</td>
<td>0.9±0.5</td>
<td>2.1±0.5 * *</td>
<td></td>
</tr>
<tr>
<td>Cardiothorax rate (%)</td>
<td>0.64±0.17</td>
<td>0.61±0.12</td>
<td></td>
</tr>
</tbody>
</table>

Attention: Comparison between two groups P<0.01 P<0.05

3 Discussion

Mechanical heart valve is essential for cardiac valve disease which couldn’t be repaired by plastic surgery. In 1960, the birth of caged ball valve marked the stepping of mechanical valve research into clinical application stage. In 1969, the study of tilting disc prosthesis won success, and pyrolytic carbon was selected as valve making material, as well as not only a leap of mechanical valve design but also a myth that the applied pyrolytic carbon material held up clinical tests and has been still applied into several types of valves till present. In 1977, the turn-up of bileaflet valve resulted in realization of central flow which was close to physiological state, advancing further in terms of mechanical valve hemodynamics. Currently, the number of bileaflet valve accounts for 60%-70% among that of all mechanical heart valves clinically applied [3].

Domestic tilting disc prosthesis has been developed in 70s last century, while the development and preparation of bileaflet valve is still relatively weak. There was only a single report about clinical application of Home-made bileaflet valve in 1992 [4]. We collaborated with Beijing Star Medical Devices Co., Ltd, embarked on developing GK bileaflet mechanical heart valve from 1998, passed extracorporeal test conducted by National Institutes for Drug and Biological Products Control, and pursued clinical application in several domestic hospitals from Sep 2002 after a series of both acute and chronic animal experiments. 22 GK bileaflet valves have been implanted into 20 patients in our department during more than one year, who were observed and analyzed in terms of peri-operative stage and recent follow-up.

Assessment of a new mechanical heart valve is mainly to observe hemodynamics, security and endurance as well as biocompatibility. Hemodynamic effect could be judged by measuring cardiac output, transvalvular pressure gradient and other index directly, speculated through valve opening area and flow velocity by ultrasonography, and also estimated by maintenance of circulatory function after operation and forward cardiac function state. It was vital for extracorporeal
accelerated fatigue test to reckon endurance. Clinical observation of valve-related incidence not only indicated whether it was endurable or not but also reflected its safety generally. Such index was rather significant for assessment of mechanical valve function, as evaluation of biocompatibility after valve implantation and clinical observation of thrombosis, embolism, hemolysis, as well as hemolytic anemia.

Three aspects above were observed systematically and analyzed generally during primary clinical application. It was observed during surgery that surface of valve was smooth, both opening and closing of valve were flexible, twisting was free, conforming to basic requirements of clinical application. Patients in this group broke away from extracorporeal circulation successfully, and circulatory system was stable after operation without severe low cardiac output syndrome, passing peri-operative stage safely. Cardiac function was all improved dramatically, as shown in the follow-up of 1-2 years later after operation, indicating excellent hemodynamic effect was present for 89 bileaflet valves in patients. All of such index backed to normal range within one week, which referred to hemochrome, blood platelets, bilirubin, free serum hemoglobin. No complications were available, like thrombosis and embolism, even under anticoagulation with low intensity, as demonstrated that short-term hemocompatibility was good and forward effect remained to be seen.

No complications correlated to valves follow-up. Although it was still years away for assessment of valve endurance, observation of infection and periphery valve leakage lasted for over one year for the whole group without noticeable hemolysis, thrombosis and embolism, and complications concerning anticoagulation. Reexamination of ultracardiography indicated that such parameters were all among normal range, as maximum flow velocity at valve opening, transvalvular pressure gradient, effective area of valve opening and so on, showing there was no significant difference between this kind of valves and other imported bileaflet valves which were usually applied clinically.

4 Summary

This type of heart valve was excellent in function, stable in hemodynamics, easy in suture, low in valve noise, reliable in function, through clinical application of 22 GK bileaflet valves into 20 cases and short-term follow-up observation after operation. No death was existent in this group both recently and forwards without valve-related complications during follow-up, inclusive of valve structure failure, valve thrombosis, embolism, bleeding, mechanical valve infectious endocarditis and so on. Given that the number of surgery cases was not large and follow-up time was not long, further follow-up and observation were still essential for judgment of forward effect.

References:

Circulation Journa , 2003,18(4):303-305


Clinical Application of New (GK) Bileaflet Mechanical Heart Valve

Zhong Jing, Yi Ding-hua, Jiang Shulin, Li Tong, Han Zhen, Wan Shi-jie

(1. Department of Cardiovascular Surgery, General Hospital of Air Force, Beijing 10036, China; 2. Department of Cardiovascular Surgery, Xijing Hospital, the Fourth Military Medical University, Xi’an 710032, China; 3. Department of Cardiovascular Surgery, the second Clinical College, Harbin Medical University, Harbin 150086, China)

Abstract: Objective To introduce a new type of bileaflet mechanical prosthetic heart valve (GK bileaflet valve) and evaluate clinically the early hemodynamic effect and short term follow-up after its replacement. Methods Sixty-one patients with heart valve diseases were operated upon. The mitral valve replacement was performed in 34 patients, aortic valve replacement in 16 patients and double valve replacement in 11 patients. A total of 72 GK bileaflet mechanical valves were implanted, 45 in mitral position, and 27 in aortic positions. Blood consistency and hemodynamics were monitored. Follow-up was carried out routinely to check whether there were some valve-related complications. Results There was no early mortality (<30d). Only one patient died of trauma 2 months after the operation. Follow-up was 100% and extended 1 to 2.5 years. Without valve-related complications all patients have lived for more than 1 to 2.5 years. In 98% (60/61) of survivors heart functional performance have improved to New York Heart Association class I or II. Conclusion Early clinical results and short-term follow-up demonstrate that GK bileaflet prosthetic heart valve exhibits excellent hemodynamic properties, satisfied blood consistency and a low incidence of valve-related complications. Midterm and long-term results should be observed further.

Key words: Heart valve diseases; Prosthetic hear valve; Implantation of heart valve prosthesis

GK bileaflet mechanical heart valve (GK bileaf valve in abbreviation below) is a new bileaflet mechanical heart valve, which is developed by Air Force General Hospital and Beijing Star Medical Devices Co., Ltd together. It was applied clinically from Sep 2002 after the completion of extracorporeal tests and animal experiments, and 61 bileaflet valves were applied in 72 heart valve replacement surgeries during one and a half years. The conditions of clinical application and recent follow-up results are summarized as followings.

1 Materials and methods
1.1 Mechanical heart valves

GK bileaflet valve is a kind of mechanical valves which are low in valve support with three-channel central flow and bileaflet. Graphite acts as the base of valve support and valve (leaf), and surface is covered by pyrolytic carbon. Opening angle of leaflet (in one-direction) is $85^\circ$, a sella peak structure which owns a pair of processes at inflow side is adopted in appearance, ball-socket design is applied into joint-twisting structure in valve hub, and sewing cuff is filament fabric.

1.2 Clinical data

61 cases of valve replacement were completed by three hospitals (21 by Second Clinical Institute of Harbin Medical University, 20 by Xijing Hospital affiliated to The Fourth Military Medical University, 20 by Air Force General Hospital), among which 29 were male and 32 female. Age ranged from 18 to 60 years old (41.5±10.74 years old on average), weight from 38.5 to 90.4 kg (54.2±12.4 on average), and history from 0.6 to 36.0 years, 8.8 years on average. Symptoms of palpitation, brachypnea, dyspnea, and so on were clinically available for all cases after activity, whose diagnosis was proved by physical examination, ECG, chest x-ray, echocardiography and alike prior to operation. Coronary angiography served cases over 50 years old to exclude coronary disease. Pre-operative diagnosis: rheumatic heart disease in 47, among which joint valvular disease was in 11, mitral disease in 34, restriction after closed mitral commissurotomy in 1, bio-valve degeneration in 1, degenerative disease of aortic valve in 5, and infective endocarditis in 6. 23 cases were accompanied by chronic atrial fibrillation, with left atrium thrombosis in 8, cardiac function of level II in 9, cardiac function of level III in 40 and cardiac function of level IV in 12.

1.3 Surgical methods

Surgeries were all conducted on patients under moderate hypothermic general anesthesia and extracorporeal circulation, with application of antegrade cold blood or cold crystal cardioplegia for sole valve replacement and that of both antergrade and retrograde cold blood cardioplegia for bileaflet replacement. Continuous suture along right atrium-interventricular septum routine was adopted for mitral valve replacement; Interrupted mattress suture was mostly placed by 2-0 Ethicon stitches with shims for aortic valve replacement, and 3-stitch Prolene continuous suture was applied in few patients. Partial patients were also conducted on by left atrium wall mechanical thrombectomy, tricuspid De Vega plastic surgery or left atrium volume-reduction. Warfarin was initially administrated orally 48hs after operation, to regulate prothrombin time (PT) to 1.5 times of contrast value with international standardized value (INR) of 1.5-2.5 (when international sensitive index was 1.2).

1.4 Hemodynamic and hemocompatibility observing parameters

Such index was observed dynamically as routine blood test, routine urine test,
liver function and changing process of free serum hemoglobin within 2 weeks after operation. Those parameters were examined during follow-up, like cardiothorax rate by chest X-ray, measurement of all atriums and ventricles by echocardiography, effective area of mechanical valve opening, flow velocity at valve opening, transvalvular pressure gradient (echocardiography) and so on.

1.5 Follow-up

Patients were followed half a year and one year later respectively, and follow-up ways were inclusive of letter, call, outpatient visit and so on. Cardiac function grading, valve-related complications and alike were judged according to activity, administration, examination results and so on, referred to American Cardiothorax Association Standard which was set up in 1996 by Edmunds and others [2].

1.6 Statistic analysis

Conducted on intergroup contrast, and it was significant statistically when $\chi^2 / \sqrt{4}$-Kaplan-Meier regression was applied into correlation analysis of survival rate and incident, with Log-Rank test to compare population difference. SPSS 10.0 software was applied for statistics.

2 Results

Chart 1 Observing results of hemocompatibility index of 61 cases after valve replacement

<table>
<thead>
<tr>
<th>O</th>
<th>Q</th>
<th>C</th>
<th>X</th>
<th>Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>1c</td>
<td>2c</td>
<td>6c</td>
<td>03c</td>
<td></td>
</tr>
</tbody>
</table>

2.1 Early results

Among 61 cases in this group, 34 cases receiving mitral valve replacement, 16 receiving valve replacement, 11 receiving both mitral and aortic valve replacement, 4 cases also receiving left atrium thrombectomy and 5 also receiving tricuspidoplasty. Blocking time for sole valve replacement was 29-112 (64.75±27.5) min with CPB time of 46-163 (96.35±38.52) minutes. That for bivalve replacement was 67-146 (78.66±22.36) min with CPB time of 85-176 (106.16±23.29) minutes. SnS/knut/adq/neF J ahk/des hikok/ran/ was 72, among which there were 45 mitral valves (25M 8, 27M 24, 29M 3), and 27 aortic valves (21M 11, 23M 5, 25A 1). No death was existent in through group (within 30 days). Tubes intubated in patients were all pulled out within 24 hours after operation, and their consciousness was clear with stability of hemodynamics and absence of severe arrhythmia. Mild low cardiac output syndrome occurred on 5 cases, and 2 cases received surgeries again on 2nd and 21st day after operation respectively, due to periphery valve leakage. Another open heart surgery was conducted on one case due to poststernal blood oozing at 6th hour after operation. All of the patients left hospital with complete recovery within 25 days after operation. Hemocompatibility related index of 61 cases backed to normal range during 3-7 days after operation.
2.2 Follow-up results

Those 61 survival patients were followed up periodically with 100% follow-up rate, and it indicated that the longest survival time was 2 years and a half with the shortest time of one year, 15.3 months in average. All of the patients survived long term except one case dying of wound two months after operation (not valve-related death), with the transfer of cardiac function from preoperative level III-IV to level I-II, which meant possibility of physical work to different degree and excellent living quality. Reexamination of chest film and echocardiography showed cardiothorax rate and measurement of all atriums and ventricles downsized, and both valve opening area and transvalvular pressure gradient were improved dramatically at 6th month after operation (Chart 2). Such index was normal, which referred to routine blood test, routine urine test, liver function and free serum hemoglobin. No complications related to valves were found, including failure of valvular structure (disorder or dysfunction), nonstructural dysfunction (periphery valve leakage), thrombosis of valve, thromboembolism, anticoagulation bleeding, mechanical valve infectious endocarditis and so on.

3 Discussion:

Mechanical heart valve is essential for cardiac valve disease which couldn’t be repaired by plastic surgery. In 1960, the birth of caged ball valve marked the stepping of mechanical valve research into clinical application stage. In 1969, the study of tilting disc prosthesis won success, and pyrolytic carbon was selected as valve making material, as was not only a leap of mechanical valve design but also a myth that the applied pyrolytic carbon material held up clinical tests and has been still applied into several types of valves till present. In 1977, the turn-up of bileaflet valve resulted in realization of central flow which was close to physiological state, advancing further in terms of mechanical valve hemodynamics. Currently, the number of bileaflet valve accounts for 60%-70% among that of all mechanical heart valves clinically applied [3].

Domestic tilting disc prosthesis has been developed in 70s last century, while the development and preparation of bileaflet valve is still relatively weak. There was only a single report about clinical application of Home-made bileaflet valve in 1992[4]. Beijing Star Medical Devices Co., Ltd collaborated with Air Force General Hospital, embarked on developing GK bileaflet mechanical heart valve from 1998, passed extracorporeal test conducted by National Institutes for Drug and Biological Products Control, and pursued clinical application in our three
hospitals from Sep 2002 after a series of both acute and chronic animal experiments. 72 GK bileaflet valves have been implanted into 61 patients in our department during more than one year, who were observed and analyzed in terms of peri-operative stage and recent follow-up.

Chart 2 Comparison of observing index between pre-replacement and post-replacement of valve

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Preoperation</th>
<th>Postoperation 10d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inside diameter of left ventricle at end diastole (mm)</td>
<td>72.3± 13.4</td>
<td>54.6 ± 12.5**</td>
</tr>
<tr>
<td>Long diameter of left atrium (mm)</td>
<td>64.5± 10.2</td>
<td>55.3± 9.3**</td>
</tr>
<tr>
<td>Flow velocity at valve opening (m/s)</td>
<td>2.6± 0.8</td>
<td>1.5± 0.4*</td>
</tr>
<tr>
<td>Transvalvular pressure gradient (mmHg)</td>
<td>34.6± 8.3</td>
<td>12.3± 5.2**</td>
</tr>
<tr>
<td>Effective area at valve opening (cm(^2))</td>
<td>0.9± 0.5</td>
<td>2.1± 0.5**</td>
</tr>
<tr>
<td>Cardiothorax rate</td>
<td>0.64± 0.17</td>
<td>0.61± 0.12</td>
</tr>
</tbody>
</table>

Assessment of a new mechanical heart valve is mainly to observe hemodynamics, security and endurance as well as biocompatibility. Hemodynamic effect could be judged by measuring cardiac output, transvalvular pressure gradient and other index directly, speculated through valve opening area and flow velocity by ultrasonography, and also estimated by maintenance of circulatory function after operation and forward cardiac function state. It was vital for extracorporeal accelerated fatigue test to reckon endurance. Clinical observation of valve-related incidence not only indicated whether it was endurable or not but also reflected its safety generally. Such index was rather significant for assessment of mechanical valve function, as evaluation of biocompatibility after valve implantation and clinical observation of thrombosis, embolism, hemolysis, as well as hemolytic anemia.

Three aspects above were observed systematically and analyzed generally during primary clinical application. It was observed during surgery that surface of valve was smooth, both opening and closing of valve were flexible, twisting was free, conforming to basic requirements of clinical application. Patients in this group broke away from extracorporeal circulation successfully, and circulatory system was stable after operation without severe low cardiac output syndrome passing peri-operative stage safely. Cardiac function was all improved dramatically, as shown in the follow-up of 1-2.5 years later after operation, indicating excellent hemodynamic effect was present for 89 bileaflet valves in patients. All of such index backed to normal range within one week, which referred to hemochrome, blood platelets, bilirubin, free serum hemoglobin. No complications were available, like thrombosis and embolism, even under anticoagulation with low intensity, as demonstrated that short-term hemocompatibility was good and forward effect remained to be seen.

No complications correlated to valves
were present after relatively close follow-up. Although it was still years away for assessment of valve endurance, observation of infection and periphery valve leakage lasted for over one year for the whole group without noticeable hemolysis, thrombosis and embolism, and complications concerning anticoagulation. Reexamination of ultracardiography indicated that such parameters were all among normal range, as maximum flow velocity at valve opening, transvalvular pressure gradient, effective area of valve opening and so on, showing there was no significant difference between this kind of valves and other imported bileaflet valves which were usually applied clinically.

This type of heart valve was excellent in function, stable in hemodynamics, easy in suture, low in valve noise, reliable in function, through clinical application of 72 GK bileaflet valves into 61 cases and short-term follow-up observation after operation. No death was existent in this group for short term but one due to wound forwards, without valve-related complications during follow-up, inclusive of valve structure failure, valve thrombosis, embolism, bleeding, mechanical valve infectious endocarditis and so on. Given that the number of surgery cases was not large and follow-up time was not long, further follow-up and observation were still essential for judgment of forward effect.

References:


806. The preliminary clinical report about the domestic GK bileaflet mechanical heart valves

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Abstract Objectives To observe the clinical therapeutic effect and long term follow-up result of GK type artificial bileaflet heart valves(GK BHV). Methods We followed up 61 cases of artificial heart valve replacement surgery regularly and checked for related complications, 34 of which were mitral valve replacement surgery(MVR), 16 of which were aortic valve replacement surgery(AVR), and 11 of which were double valve replacement surgery(DVR). Results No operative mortality was observed (within 30d from surgery). And there was only one case of trauma death in the long term. From the follow-up lasting 1 year to 2.5 year, the condition of the rest patients survived have all improved, with elevated cardiac functions from III~IV to I~II, better hemodynamic performances, good biocompatibility, and improved quality of life. Conclusions The preliminary application of GK BHV has obtained a satisfactory therapeutic effect and the recent follow-up result didn’t show any complications related to the valves.

GK type artificial mechanical bileaflet heart valve is a new domestic artificial bileaflet heart valve developed and produced by the Beijing Star Medical Devices Co. Ltd. To further evaluate its therapeutic effect, we applied GK BHV on 61 cases of heart valve replacement surgery. And the results of the clinical application and long term follow-up are as follows.

1. Materials and methods

1.1 Patients: The 61 patients, 29 of which were male and 32 of which were female, aging 18 to 60 years old (41.2±9.8 in average), and weighting 28.5 to 90.4 kg (54.2±10.8 kg in average), all presented a symptom of heart palpitations, shortness of breath and chest distress after physical activities. Before the surgery, we confirmed the diagnosis through examination, electrocardiograph, chest film and echocardiogram, and ruled out the possibility of coronary artery disease by running coronary arteriography on elder patients over 50 years old. The preoperative diagnosis were as follows: 47 cases of rheumatic heart disease, among which 11 cases were combined valvular disease, 34 cases were mitral lesions, 1 case was mitral stenosis after closed mitral commissurotomy,
5 cases were degenerative aortic valve disease; and 6 cases were infective endocarditis. 23 cases were complicated by chronic atrial fibrillation, and 8 cases were complicated by left atrial thrombus. 9 out of the 63 patients reached the cardiac function grades of II, 40 out of 61 were III, and 12 out of 61 were IV.

1.2 Operation methods: The surgery was performed with a cardiopulmonary bypass at moderate hypothermia using general anesthesia. We chose cold blood cardioplegia cis irrigation during univalve replacement surgery, and combined cold blood cardioplegia cis irrigation with trans irrigation during double valve replacement surgery. To replace the mitral valve, we adopted continuous suture through the right-sided atrial septum pathway. To replace the aortic valve, we adopted interrupted mattress suture with a gasket using the 1—0 Ethicon on most patients, continuous suture using 1 or 3 needles. We also performed thrombectomy of mural thrombus in the left atrium on 8 patients and De Vega’s tricuspid valve angioplasty or left atrium volume reduction surgery on 5 patients at the same time.

1.3 Anticoagulant therapy: when taking Warfarin per oral at 48 hours after surgery, the prothrombin time (PT) increased 1.5 times comparing to the control value, while the international normalized ratio(INR) reached 1.5~2.5(when international sensitive index is 1.2), in which range the INR of aortic valve replacement can be relatively low while the mitral valve replacement and double valves replacement can be relatively high.

1.4 Outcome measures of hemodynamics and blood compatibility: The size of atriums and ventricles, the area of valves and the gradient of transvascular pressure were measured respectively at preoperative period, early postoperative period(when discharged) and follow-up(after half year and one year). And the fluctuation of the result of routine blood examination, routine urine examination, liver function and free-haemoglobin in plasma were also followed closely.

1.5 Postoperative follow-up: Further consultations were demanded at 3 months, half year and 1 year postoperatively to acquire the information of medical record, physical examination, echocardiography, electrocardiography and some laboratory examinations. The important task was to get to know the quality of life, recovery of cardiac function and whether there emerged the valve-related complication.

Statistical methods: All of the numerical value should be expressed using the form of mean ± standard deviation. The comparison of measurement data should use t test, while the comparison of enumeration data should use x2 test.

2. Results

2.1 Early result
Among the 61 cases, 34 cases were mitral valve replacement, 16 cases were aortic valve replacement and 11 cases were double valve replacement. The clamping time of univalve replacement and double valves replacement were 29~132 (43.62±21.31) min, and 67~146 (72.66±22.31) min respectively, and the bypass time were 46~163(74.23±32.51) min and 85~176(98.14±28.41) min respectively. The GK BHV implanted totaled 72, among which 45 were mitral valves (18 25M, 24 27M, 3 29M), 27 were aortic valve (11 21A, 15 23A, 1 25A).

No operative mortality occurred(within 30d from surgery). Tracheal incubations were all withdrawn in 24 hours after surgery, with patients being conscious, stable in hemodynamics. No serious arrhythmias occurred, while mild low cardiac output syndrome appeared on 8 cases, reoperation due to paravalvular leak at 2dd and 21d postoperatively occurred on 2cases, and re-thoracotomy due to retrosternal bleeding at 6h postoperatively occurred on 1case. There was no case of mechanical valve failure or malfunction observed. The related outcome measurement index such as haematochrome, blood platelet and blood compatibility index restored the preoperative level only 3~7d after surgery(see Fig.1), and all patients recovered and left the hospital within 30d after surgery.

2.2 Follow-up results

We did regular follow-up of the 61 patients, lasting from 1 year to 2.5 years: except for 1 patient died from trauma (not valve-related death) after 2 months from surgery, the other patients all enjoyed a long-term survival, the longest of which lasted 2 years and 6 months and the average of which lasted 1.83 years. And the cardiac function of these patients had changed from III~ IV to I~ II. Hence, they became able to undertake physical labor of varying degrees, and enjoyed a satisfying quality of life. The chest film and echocardiograph obtained from the reexamination half year from the surgery showed that the cardiothoracic ratio and the size of atrium and ventricle significantly decreased, and the area of the valve and the gradient of the transmembrane pressure improved remarkably (Fig 3,4). We didn’t discover any valve-related complications in the follow-up, including valve structure damage (mechanical failure or valve malfunction), non-structural dysfunction, valve thrombosis, embolism, drug withdrawal or hospitalization due to bleeding from anticoagulant drug, and artificial valve infective endocarditis, etc.

From the reexamination results in the follow-up, including routine blood examination, routine urine examination, liver function and free plasma haematoglobin, only one patient was low in the red blood cell counting, hematocrit, and haematoglobin level and normal in the other tests.

3. Discussion

Artificial heart valve replacement surgery is often performed on patients whose heart valve diseases can’t repaired using general surgery. The invention of caged-ball valve in 1960 marked the research of artificial heart valve’s heading into clinical application stage. Then in 1969, the creation of single tilting disc valve using pyrolytic carbon as material was very successful, which led to the wide use of this material. With the invention of bileaflet heart valve, the hemodynamic
character of artificial heart valve was further improved to a level more analogous with the physiological situation. At present, the bileaflet heart valve takes up 60~70% of the total artificial heart valve applied in the clinics. In China, the manufacture of single tilting disc valve has begun since 1970s, but the invention and manufacture of bileaflet heart valve is not fully developed and there was only one case-report of clinical application in 1992. The GK type artificial mechanical bileaflet heart valve produced by the Beijing Star Medical Devices Co. Ltd has passed all the tests of the National Institute for Food and Drug, a series of animal experiment, stepped into clinical application in Oct. 2002, during which 72 GK BHV were implanted into 61 patients, and obtained a satisfying recent therapeutic effect.

When evaluating a new type of artificial heart valve, people often consider these three aspects: hemodynamics, safety and durability, and biocompatibility. The effect in hemodynamics can be judged through measuring the heart output and transmemberane pressure gradient directly, or deducing from the valve area and blood velocity using ultrasound indirectly, or assessing the preservation of circulation at and after surgery and also the long-term cardiac function postoperatively. As for the safety and durability, in-vitro accelerated fatigue test can reflect the durability indirectly, while the clinical observation and valve-related complications can only tell part of the durability but reflect the safety comprehensively. To evaluate the biocompatibility which is especially significant for the evaluation of mechanical character of valve, what we usually do in the clinics is observing the occurrence of thrombosis, embolism, haemolysis and hemolytic anemia, which not complete but very principal.

During the clinical validation, we did systematic observation and comprehensive analysis of all of the three aspects. What we observed in the surgery was that the surface of the valve was smooth, the open and shut of the valve was flexible, and the suture of the valve ring was convenient. After the surgery, 61 patients all got off the bypass successfully, had stable circulation systems postoperatively with no serious low cardiac output syndrome, and pulled through the perioperative period. The postoperative follow-up in 1~2.5 years from surgery showed that their cardiac function were all significantly elevated, which suggested that the hemodynamic effect of the GK BHV in vivo was very good.

We monitored the related measurements of the patients after surgery including haematochrome, platelet, bilirubin, and free heamatoglobulin in plasma. The result indicated that the index all restored the normal level in one week. And no thrombosis or embolism appeared, which suggested a good blood compatibility in short term, but the effect in long term remained to be discovered.

Through the intensive follow-up, we didn’t find out any valve-related complications. Though the durability still remained to be evaluated, the observation of infection and paravalvular leak already lasted over 1 year, which showed that, same as the other bileaflet valves applied in the clinics, there was no thrombosis and embolism, or any anticoagulation-related complication.

4. Conclusions
From the implantation of 72 GK BHV into 61 patients and short-term postoperative follow-up, we concluded that this heart valve has excellent in performance, stable in hemodynamics, easy to be sutured, low in valve noise, and reliable in safety and quality. We observed no operative mortality in the short time, no valve-related death in the long time, no valve-related complication in the follow-up, including valve structure failure (mechanical failure or valve malfunction), valve thrombosis, embolism, bleeding from anticoagulant drug, and artificial valve infective endocarditis, etc. Considering the number of the cases and the time of the follow-up is still limited, we suggest a further follow-up and observation to determine its therapeutic effect in the long term.
GK-2 prosthetic heart valve: twenty-year experience

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Abstract: Objective The GK-2 mechanical heart valve was introduced in 1985. We firstly implanted it in 1986. The purpose of this study was to analyze our 20-year clinical experience. Methods Between March 1985 and June 2004, 402 valves were implanted in 301 patients, 113 men and 188 women with a mean age of 37.59±10.23 years. Ninety-one percents had NYHA class III or IV heart function. The single valve replacement was performed in 92 patients. Follow-up is 89% and extended 1 to 20 years with cumulative 2252.3 patient-years. Results The early mortality was 3.32% (10/30). The main cause of death included low cardiac output syndrome (LCOS) in 5 patients, operated vascular endocardics, bleeding and arrhythmia. There were 17 late deaths (1.39% per patient-year). The congestive heart failure, arrhythmia and bleeding were the major reasons. In 92.3% of survivor’s heart functional performance had improved to NYHA class II or class I. Conclusion Early and long-term results demonstrated that the GK-2 prosthetic heart valve exhibits us excellent hemodynamic properties, mechanical durability and a low incidence of valve-related complication.

Key words: Heart valve prosthesis; Heart valve surgery; follow-up studies.
1.2 Surgical methods Operations were all performed under moderate hypothermia and extracorporeal circulation, with incision at medium of sternum (Two cases were of right anterolateral incision). Apart from three cases of valve replacement without heart arrest, 53 cases were infused by 4°C potassium cold cardioplegia, 10ml/kg with repeat infusion of half amount every 30 min, through aortic root or left and right coronary artery directly, and flake ice was added into pericardium to protect myocardium. 148 cases received infusion of myocardium-protective liquid with the approach of lasting cold blood antegrade infusion or retrograde infusion through coronary sinus, and received terminal warm blood in fusion at fifth minute prior to opening.

The main surgical routine of mitral valve replacement was right atrium-interatrial septum route, with 27 cases (27/301) of interatrial groove path. Excision of abnormal valve by oblique incision along the root of ascending aorta served aortic valve replacement. Since 1993, subvalvular structure of mitral valve was partially or thoroughly retained for cases with large cavity in left ventricle, with maintenance of posterior valve and chordae tendinae in 43 and reservation of utter mitral structure in 2. Continuous suture was performed for all cases except those with severe valve ring of calcification or with node and rigidity, for which interrupted suture was vital [1]. A continuous circle of suture should start from 6th point for mitral valve, while one Prolene thread was demanded to stitch continuously and terminated at commissure for aortic valve. Surgical procedure included mitral valve replacement (MVR) in 183 (60.8%), mitral valve with aortic valve replacement (DVR) in 92 (30.56%), aortic valve replacement (AVR) in 21 (6.98%), and tricuspid valve replacement (TVR) in 5 (1.66%), with thrombectomy on left atrial wall in 34, tricuspid valve plastic surgery in 43, left atriotipication in 7, malformation correcting for all sorts of congenital diseases in 15, transection of abnormal bundles in pre-excitation syndrome in 2, excision of left atrial aneurysm in 1, CPB in 1 and ascending aorta replacement in 2. Blocking time for sole valve replacement was 21-114 (51.90±19.32) min with CPB time of 52-147 (91.16±27.05) min; That for bivalve replacement was 61-125 (95.03±19.81) with CPB time of 91-201 (139.32±30.19) min. Number of cases with automatic heart self-recovery was 187 (62.13%), and assist circulatory time was 1/3-1/2 times of aortic blocking time after heart self-recovery. After operation, warfarin or other new anticoagulation tablets were administrated after thoracic catheter was pulled out. Prothrombin time was maintained at 1.5-2 times of normal prothrombin time range (PTR). In the group, 290 GK-2 mitral valves were implanted with aortic valves in 112 (including 51 wave-suture aortic valves of self-design).

2 Results

2.1 Early results Early death (within 30 days after operation) reached 10 with mortality rate of 3.32% (10/301), among which MVR death was in 8 (5.26%), with DVR death in 1
(1.67%), TVR death in 1 (25%), and absence of AVR death. Death reasons included low cardiac output syndrome in 5, and intraoperative hemorrhage, infectious endocarditis, obstructive ventricular arrhythmia, respiratory failure and deep coma in 1, respectively. Other main complications were inclusive of blocking for a second or third time or transfer in 6 (difficult resuscitation in 1, resewing of aortic incision, hemmorhage of pulmonary artery in 1, respectively), acute and chronic pericardial tamponade in 1, respectively, severe ventricular arrhythmia in 4 (multiple defibrillation in 2), severe low cardiac output syndrome [dopamine>10ug (min-kg), lasting more than 6h] in 11, respiratory failure (ventilator assist over 72h), coma in 4, hemiplegia in 3 (transient occurrence in 2), severe psychotic symptoms in 2, renal failure in 1, and multiple organ dysfunction in 1. Periphery valve leakage and mechanical valve disorder and other valve-related death were absent early after operation. Mean transvalvular pressure difference of mechanical valve was 21.23mm by echocardiography examination after operation, with that of aortic valve of 12.3, 11.2mm Hg; 25, 27, 29mm and mitral valve of 7.8, 5.2, 4.8mm Hg.

2.2 Late results The period of survived 291 cases ranged from 31 days to 20 years with an average of 10.48±4.35 years. Death number of interviewees was 17, and the chief reasons of late death included heart failure in 9, arrhythmia in 2, cerebral hemorrhage in 1, cerebral infarct in 1, pulmonary infection and infectious endocarditis in 4 and so on, with no record of mechanical valve disorder. Severe complications were inclusive of muscular hemorrhage of lower limbs due to excessive anticoagulation in 2, peritoneal hematoma in 1, venous thromboembolism of lower limbs due to insufficient anticoagulation in 1, and cerebral infarct and hemiplegia in 1. All of above cases administrated anticoagulant orally without detection of prothrombin time according to requirements with other main complications of transfusion related hepatitis in 6. Cardiac function was improved to different extent after operation, with survived cases of 232 within current follow-up, whose cardiac function recovered to level I, II mostly, with merely 16 cases of level III, IV. Cardiothorax rate and all atrial and ventricular sizes downsized dramatically after operation, compared with those prior to surgery. K-P survival curve was not cited to describe year-mortality rate of patients in this paper, by virtue of the effect of follow-up rate and basic medical conditions of our nation, while the real follow-up data was listed in chart 1.

3 Discussion:

3.1 Technical traits of GK Tilting Disc Prosthesis

This kind of valves was found to be advantageous in many aspects, and reliable in clinical application after 20-year clinical application and postoperative follow-up observation. Short-term mortality rate of the group was only 3.32% with long-term mortality rate of interviewee of barely 2.2%.
0.38%, lower than that in domestic multiple similar reports. None of the dead 27 cases were caused by valve-related factors, and none of both short-term and long-term complications were associated with valve quality.

<table>
<thead>
<tr>
<th>Period of follow-up(year)</th>
<th>Number of targeted follow-up cases</th>
<th>Visit rate(%)</th>
<th>Survival rate of interviewees(%)</th>
<th>Complication rate of interviewees(%)</th>
<th>Rate of cardiac function of level III, IV for survived cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5~1</td>
<td>291</td>
<td>91.11(265)</td>
<td>96.98</td>
<td>0.75</td>
<td>0.75</td>
</tr>
<tr>
<td>1~5</td>
<td>198</td>
<td>79.29(157)</td>
<td>89.91</td>
<td>3.18</td>
<td>0.64</td>
</tr>
<tr>
<td>5~10</td>
<td>156</td>
<td>86.54(135)</td>
<td>84.44</td>
<td>11.11</td>
<td>2.22</td>
</tr>
<tr>
<td>10~20</td>
<td>76</td>
<td>46.78 33</td>
<td>81.82</td>
<td>13.33</td>
<td>3.95</td>
</tr>
</tbody>
</table>

3.1.1 Reasonable structure of GK mechanical valve Abrasion performance and hemodynamics were excellent. Hook-hole design was adopted for GK-2 heart valve, enhancing valve activity, increasing effective area of valve opening, and its hemodynamics was fine with noticeable improvement in cardiac function after operation. Echocardiography examination indicated both opening and closing of disc were good, with large area of opening and small pressure gradient, consistent with abroad reports [3]. Endurance of such valves was fine, with the longest survival time of nearly 20 years and over 76 cases surviving for more than 10 years. However, longer-term effects were still to be seen with further observation.

3.1.2 Reduction of complications by refinement of aortic valve suture border Aortic valve ring of human being went like wave, and was not on the same plane, while mechanical aortic valve was a simple circle ring of symmetry. Aortic valve ring was lifted onto the same plane during surgery, making superior and inferior shrinkages of aortic sinus close to each other, downsizing diameter of primitive aortic root, increasing tension of valve ring at sinus root. Thus, suture border of mechanical aortic valve was refined by us, and three symmetric suture borders (1mm thick, 2mm wide) like sinusoidal valve were sewed. “Wave peak” of mechanical valve was connected with conjunction of “wave trough” and sinus root during surgery. Aortic sinus didn’t shrink when falling valve was stitched by interrupted or continuous suture. No tension was existent for “in-situ” knotting, with which knots were beyond valve ring, avoiding obstructing valve and reducing tension of perivalvular tissue [4]. 51 wave-suture-border aortic valves were implanted in the group with satisfactory effect.

3.1.3 Low density anticoagulation, reducing anticoagulant amount properly Total occurrence rate of hemorrhage and embolism was 2.66% patient/year without formation of mechanical valve embolus, among which terrible anticoagulation history was existent in 5 cases with severe hemorrhage and embolism. It was emphasized that
prothrombin time should be maintained at 2 times of normal value years before, and hemorrhage incidence was much higher than that of embolism. Postoperative anticoagulation could not only prevent embolus formation effectively but also avoid complication of hemorrhage. From dimension of valve manufacturing, reduction of its activation to blood system was the key for elevation of hemocompatibility and antiembolism ability, which was dependent on treatment on surface coating and smoothness of mechanical valve. Identical carbon deposition technology was adopted for GK mechanical valve with higher level of smoothness, whose hook-hole design reduced destruction of formed elements in blood and adhesion of fibrin, lessened embolus formation and occurrence of severe hemolysis. In the recent five years, previous method of large amount to reach anticoagulation standard was transferred to that of smaller amount to achieve anticoagulation standard gradually, and prothrombin time was maintained at a level a little higher than 1.5 times of normal value. Postoperative hemorrhage rate declined, while embolus occurrence rate didn’t increase noticeably. Low intensity anticoagulation was also adopted by some abroad scholars [5], and their conclusion was similar to that of the group.

3.2 Consequence of long-term follow-up
Beside higher requirement of mechanical valve, enhancement of intraoperative care, logical surgery mode and selection of surgery time, and assertion of postoperative cardiac function and anticoagulation were also equally significant for effect of valve replacement [6]. Heart was arrested under oxygen by the way of lasting oxygenated cold blood infusion and warm blood infusion prior to opening of aorta for patients in the group with large hearts, severe disease, double-valve replacement or valve replacement once again, beneficial for automatic heart self-recovery. Retaining of posterior valve and subvalvular structure as well as detection and treatment of tricuspid valve (De Vega or Kay plastic surgery) were performed during operation with satisfactory effect.

K-P survival curve was not utilized to describe year-mortality rate of patients in the group, because larger difference between interviewed group and missed group would influence precision of survival curve greatly, due to patient resource in the group from multiple social classes and the difference between current medical level and personal health consciousness in our country [7]. According to the real follow-up data of the group, follow-up rate lessened gradually and also did survival rate of interviewees with the prolonging of follow-up period. It was difficult to explain effect coefficient of mechanical valve as a result of longer follow-up period of the group and the presence of other death factors beside hearts of patients as well as heart failure and ventricular remodeling in cases with rheumatic heart disease. The number of cases with cardiac function of level III, IV didn’t increase dramatically during follow-up, for survived patients over 10 years in the group, as indicated indirectly that the main related factors of cardiac function during late follow-up of
patients were preoperative conditions of cardiac function, and reliability and endurance of mechanical valve in long-term application. 7 cases went with severe anticoagulation related complications, and 5 with terrible anticoagulation history (7.15%), as demonstrated that logical publicity and education as well as supervision, and long-term anticoagulation were rather significant.

3.3 Future of single-leaf disc valve
Bileaflet mechanical valve was clinically widespread in recent years, but it was found that thrombosis occurrence rate and mechanical disorder rate of single-leaf disc valve were lower than those of bileaflet valve according to comparison between single-leaf and bileaflet conducted by some research centers, and some other researchers studied and deemed single-leaf valve could elevate coronary blood flow. Advantage of single-leaf valve could also be seen in terms of mechanical security and anticoagulation from cases in the group. Traditional study held that single-leaf valve was small in opening area, louder in noise, and eccentric in blood flow, compared with bileaflet. Except eccentric blood flow which couldn’t be altered, actual effective area of single-leaf valve was enough to cater to demands of ventricular filling and ejection, although its effective opening area was relatively smaller. It could be seen that left atrium and ventricle of most patients with valve replacement downsized, based on research of the group. The tested transvalvular pressure difference was also ideal, and the problem of valve noise was believed to be improved gradually with the development of material science and manufacturing technology.

Reference


Visualization Of Cavitation On Mechanical Heart Valve

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Abstract: Cavitation has been documented fo GK mechanical heart valve in an in vitro flow system simulating the closing event in mural position. From picture taken with digital camera: cavitation clouds moved outwards along the seat stop on the occlude surface after closure. Cavitation on was investigated and explained by squeezing flow from the impact between occlude and seat stops at the closure of mechanical heart valve. Its mechanism is vortex cavitation from wall jet. Velocity of squeezing flow was estimated to be up to 9 m/s causing local low pressure contributing much to cavitation. Closing velocity of occlude was an important factor for cavitation potential of UK valve. Cavitation duration varied with the ventricular loading rate and was up to 440fcs at loading rate of 2750mmH}/s. The loading rate threshold of cavitation was 420mmH}/s. This value was lower than that normal physiological condition of 750mmH}/s in animal test. It was concluded that there was possibility of cavitation for UK mechanical heart valve.

Key words: Mechanical heart valve; Cavitation visualization; Squeezing flow; Wall jet

0 Introduction

Cavitation erosion pits were observed on pyrolytic carbon occluder of mechanical mitral valve removed by valve replacements, therefore, it was suspected that there was cavitation on the in vivo mechanical mitral valve. Furthermore, that could lead to potential risk of thrombosis and mechanical valve damage[1]. In recent years a number of studies on mechanical heart valve cavitation were undertaken, most of them indicated that the squeezing flow between mechanical valve occluder and seat stops or valve ring was the main underlying mechanism [2-4], however, the causes of cavitation and its specific process still remain unclear. To date, in China, no study has been carried out on the cavitation of China-made mechanical valve. To fill gaps in this field and gain certain understanding of the characteristics or trends of China-made mechanical valves, the cavitation visualization of GK valve was conducted in the present study. The foreign and domestic products have quite similar constructures, however, their influence on cavitation was still under study at home and abroad.
1 Methods

1.1 Simulation System

The duty cycle of mechanical mitral valve can be divided into three stages: 1, open; 2, stay completely open; 3, close. When ventricular diastole begins, mechanical mitral valve opens, blood flows into cardiac ventricle from the atrium via ventricular valve; while ventricle contracts, the blood backstreaming will make mechanical mitral valve close, at the time, cavitation sometimes occurs on the surface of occluder. The mitral valve closing is hydrodynamical results, thus, it is assumed that the backstreaming in the mechanical mitral valve closing exerts major influences on cavitation and the effects of forward flow might be ignored. In accordance with the hypothesis, simulating single closure of mechanical mitral valve was selected as the cavitation study method, which was used in the previous studies and indicated to be rational [3, 5].

The study device is shown in Figure 1. It is divided into two parts: Hemodynamic simulation and pneumatic drive. Hemodynamic simulation part consists of valve seat, atrial and ventricular chamber. Atrial chamber is a plexiglass square box, with the glass window opened on one side, the valve installed on the other side, and in connection with ventricle through an circle hole on the upper side. Ventricular chamber is a horizontal plexiglass cylinder with one side connected to a cylindrical flow channel, then in connection with the atrial wall through a hole, and with the upper part of the other side leading to an air inlet. Two pieces of splints clip closely the sewing ring of mechanical heart valve, and are tightly fixed with bolt in the hole between atrium and ventricle, shown in Figure 2. Moreover, pneumatic drive consists of pump, air tank, electric valve, control valve, pressure gauge and exhaust valve and other components. In the test, when the pressure of air injected into air tank by pump reaches a certain degree, electric valve will be turned on, air compressed into ventricle, fluid driven back into atrium, and the backstream would close the mechanical valve. During each closure, the valve begins to close from fully open state, and the ventricular loading rate is controlled by control valve or gas pressure. China-made GK27 mechanical valve, with a 27 mm-diameter sewing ring, was selected in the current study. A 35% v/v concentration of glycerol-water mixture was used as simulating blood, with 3.3cP viscosity coefficient and 1100kg/m^3 density measured at room temperature. The atrial solution surface was open to the atmosphere, and the central pressure of valve kept at about 6mmHg. The standing time of the solution under study should be at least 2 days, in order to release undissolved air from the solution, and no special degassing was conducted.
1.2 The control of physiological conditions

Transvalvular pressure \( p(t) \) is the driving force of the close and open of mechanical mitral valve. During its closure, \( \frac{dp}{dt} \) – the rate of change of \( p \) over time - was selected as the indicator of ventricular loading rate[3]. To date, the physiological transvalvular pressure in the patients with mechanical mitral valve replacement had no published data, however, in adult goats into whom Medtronic-Hall mechanical mitral valve was planted, the \textit{in vivo} study indicated that their appropriate physiological conditions were \( \frac{dp}{dt} = 700\sim2300\text{mmHg/s}[5] \), in which the lower and upper bounds corresponds to the normal state and ultra-high-strength motion state, respectively. The \( \frac{dp}{dt} \) was chosen as the indicator of physiological state of ventricular drive, to control and evaluate the closing process of the mechanical mitral valve. In the simulation system, the atrial surface was open to the atmosphere, therefore, the pressure of inflow side of the valve kept stable. A pressure tap was installed in the outflow-side wall, at 40mm-distance from the valve, to measure ventricular pressure. It should be noted that the transvalvular gradient pressure here is not strictly the differential pressure between both sides of the occluder during closing, but reflects the pressure at a certain distance away from valve-side, which is more easily measured and more convenient for comparison with the results of other studies.

The response time of the Pressure Sensor (EGG ICSENSORS 0096-015G) is for 1 ms. The measured curve of the transvalvular pressure during its closure is shown in Figure 3. Assuming that the pressure began to increase at the initial valve closure, the measured ventricular pressure curve and calculated loading rate during the closure of occluder were indicated in Figure 3. In cavitation visualization test, the loading rate was gradually decreased from high level to low until no cavitation appeared, then, the lowest loading rate of cavitation was defined as the loading rate threshold of cavitation of mechanical valve.
0-2 B ‘shn’ shn ‘ly’ shn

Flash-trigger technology [3,6,7] is used for the cavitation visualization of mechanical mitral valve, Figure 4 shows the diagram of Cavitation Visualization System. A camera, placed at atrium window, is used to shoot cavitation at the inflow-side of mechanical valve when the occluder is closed. A laser beam passes through from the mechanical valve-side along the surface (shown in Figure 2), on the other side a photodiode is set to receive beam. While the mechanical valve stays open, the occluder would block the laser beam, however, while the valve begins to close, the occluder would permit laser beam to transmit, then photodiode level conversion occurs. The signal is used to trigger flash after time delay, the flash lights up the mechanical valve in the dark, and the film or CCD in the opened camera will finish exposure imaging. The flash would last for about 70μs. Olympus C-1400L digital camera with a resolution of 1280 × 1024 was used in the study. The retardation time was adjusted and gradually prolonged so that the sequence of photos of cavitation would basically reflect the cavitation during the closure of mechanical valve[6], with its shooting interval at 40μs or less. After the test, the cavitation photos were downloaded to computer, the digital image processing technology was used to photo processing, and its screen resolution reached 0.04mm/pixel. Ventricular pressure and flash signals were recorded simultaneously. The cavitation inception was defined as the moment of the collision of occluder with seat stop.  Olympus C-1400L camera comes with LCD display itself, and could realize a real-time observation of the newly taken pictures. The criteria of cavitation existence during one delay is defined as follows: if cavities appeared on 2 of 3 photos, it is considered as cavitation.
2 Results

The study of cavitation visualization was conducted on the China-made GK27 mechanical heart valve at the loading rate of dp/dt = 450, 570, 790, 1120, 1660, 2750 mmHg / s, respectively. At each above rate the cavitation appeared in the vicinity of the seat stop during closure. When the loading rate was less than 420mmHg/s, cavitation disappeared, therefore, 420mmHg/s was defined as the threshold loading rate of cavitation of GK27 mechanical heart valve, even lower than 750mmHg/s - the normal physiological value of man[5]. A series of cavitation photos, taken at the inflow-side of GK27 valve with its loading rate at 1660mmHg/s, were shown in Figure 5. As indicated, the Photo 4 in Figure 6 was taken at t=1.85ms, on which the cloud-like cavities appeared close to the seat stop on the surface of occluder. The photograph of t=18.5ms showed cavitation inception at the time when the occluder impacted seat stop. The cavities moved outwards from the edge of seat stop at high speed in fan-shape radial movement, and the radial bright line was the trajectory of the cavity moving at high speed during relatively long flashing period. The cavity movement velocity was calculated by its moving distance during the effective flashing period. And the calculated maximum velocity of cavity movement was about 9m/s, tremendously different from150m/s - the measured results of MH27 valve[3]. According to Bernoulli equation, this velocity will bring down the water flow pressure by 4 atm. On the basis of our observation, the cavitation can be considered as the result of high-speed jet resulted from the impact of occluder on seat stop and the squeezing of fluid between their gap during the closure of valve. The squeezing flow numerical simulation by Makhijani and Bluestein indicated such a high-speed flow did exist [2,4] . After cavitation inception, fan-shape radial movement of cavitation clouds, mixed up with the flowing fluid around, slowed down rapidly, and the slowly-moving or relatively-static cavitation cloud generated around the seat stop, as
shown in photograph (4) in Figure 6. According to the volume of cavitation cloud, it was reasonable to consider that the cavitation reached the maximum and the cavity expansion basically completed. Afterwards, the cavitation cloud entered collapse stage. The cavities close to the valve ring collapsed first, and the residual cavities at the final stage of collapse gathered together at the about 2 mm-distance of valve ring into griddle-shape cavity cloud, as shown in photo (4) and (5) in Figure 5. It could not be seen under the seat stop. At that time, the cavity clouds looked like white powder, and finally changed into a linear shape and disappeared. The maximum lifetime of the cavity was about 450 μs, if the flash time is considered. The collapse process seemed to be longer if complete disappearance of powder cavity cloud was considered, about extra 100 μs.

Table 1 The relationship of the maximum cavitation duration and intensity with ventricular loading rate

<table>
<thead>
<tr>
<th>dp/dt mmHg/s</th>
<th>The maximum cavitation duration (μs)</th>
<th>Cavitation level (visualized cavity area)</th>
</tr>
</thead>
<tbody>
<tr>
<td>420</td>
<td>&lt;70</td>
<td>Slight</td>
</tr>
<tr>
<td>570</td>
<td>110</td>
<td>General</td>
</tr>
<tr>
<td>790</td>
<td>150</td>
<td>General</td>
</tr>
<tr>
<td>1120</td>
<td>370</td>
<td>Moderate</td>
</tr>
<tr>
<td>1660</td>
<td>450</td>
<td>intense</td>
</tr>
<tr>
<td>2750</td>
<td>440</td>
<td>the most intense</td>
</tr>
</tbody>
</table>

With the area of cavities as indicator, the valve cavitation intensity under varied loading rates were compared in Figure 6, in which the photographs of cavities at the maximum intensity under various loading rates were showed. With the increase of ventricular loading rate, the size of cavity enlarged, cavitation intensified, and cavity clouds generated more distantly from seat stop. The photograph taken at 420 mmHg/s (dp/dt) was not shown since it was so small that cavities were unclear, however, these cavities could be identified on the computer screen. When dp/dt was lower than 420 mmHg/s, no cavity could be observed, therefore, it was defined as the threshold state of mechanical valve cavitation. For a series of pictures of cavitation, the period from the appearance of cavity to its disappearance was defined as visualized cavitation duration. For flash time of cavitation visualization system lasted about 70 μs, the maximum cavitation duration was the sum of visualized cavitation duration and flash time. The relationship between the maximum cavitation duration and intensity as well as ventricular loading rate was shown in Table 1. Cavitation duration increased with loading rate disproportionately. The correlation between cavity lifetime and loading rate was indicated in Figure 7, and as shown in it, with the increase of loading rate, cavitation inception appeared earlier.

3 Discussion and Conclusions
When valve is closed, the end of occluder rotates at the highest linear velocity and collides with seat stop, during which local squeezing flow generates. The primary location shape of cavitation inception is consistent with squeezing contact surface during the impact of occluder on seat stop, thus, it is known that, for GK mechanical valve, the jet, generated in the squeezing between occluder and seat stop during valve closure, is the main cause of cavitation. On the basis of the mechanism, some one considered it as Venturi cavitation, for the cavity movement speed is 9m/s, calculated by its movement trajectory, which could cause a drop of 4 atm. If the potential energy of the flow provided by the squeezing is not enough to make up such a drop, the pressure in the jet would be less than cavitation threshold pressure. In addition, the severe vortex of high-speed jet can intensify the conversion of the heat energy to kinetic energy, the local pressure would lower, and the gas nucleus in the jet will expand in the high-speed movement. When the jet with growing-up cavities rushes out and squeezes the gap between valve and seat stop, the cavities can be observed to move outwards on the taken pictures. However, the author proposed vortex cavitation mechanism, that is, this cavitation is a vortex cavitation caused by jet. This squeezing jet is a kind of wall jet according to jet environment. The surface of discontinuity, formed at the free mixing zone of the jet, might lose its stability and develop into a vortex. The fluid surrounding the vortex will be entrained and absorbed into the jet, at the same time, turbulence will come into being after continuous moving, deforming, and separating. The turbulence generated great pulse pressure, and made the core pressure of vortex decrease less than cavitation threshold pressure in a flash. The gas nucleus enlarged in high-speed movement, and cavities can be observed to move outwards at the jet free mixing area outside of the squeezing gap exit. This is the mechanism of vortex cavitation caused by wall jet. The drop of the fluid pressure resulted from dilatation wave generated during the closure of valve, generally speaking, is not enough to lead to cavitation [3], for the cavities generated by dilatation wave are only separate ball-shape cavities [6] with unstable position. Furthermore, according to the shape and distribution characteristics of the cavities, the cavitation observed in the study is not produced by such a dilatation wave, however, the pressure drop here could strengthen the trends of jet cavitation, and delay cavity collapse, and prolong cavitation lifetime [8]. The enlargement of cavitation cloud volume in the squeezing jet is the interaction results of cavity development and continuous low-pressure. With the slow-down of mixing up of jet with surrounding fluid, as well as the reflection of dilatation wave, the pressure began to recover and the cavities developed into collapse stage. The collapse duration of cavity cloud seems to be longer than its development period, which can be explained by cavity kinetic. For the collapse location of cavity clouds, the last cavities disappeared at 2-mm distance from the valve ring. Further studies are required on the damage degree of this cavity collapse. To date, there are no clinical reports related to the evidence of cavitation at the above location of mechanical valve. Some cavities collapse at the near end of occluder might be the underlying reason of the cavitation at the edge of valve and occluder. Lee had indicated that, for MH mechanical valve and other similar products, the threshold loading rate of cavitation was only half the normal loading rate.
of man. GK mechanical valve might have the same characteristics as MH for their similar structures. The result provides support for the explanation of squeezing jet as the underlying reason of mechanical valve cavitation, however, for the cavitation mechanism, Lee proposed that this was a kind of vortex cavitation caused by wall jet.

According to Figure 7, cavitation duration prolonged with, but out of proportion to, the increase of loading rate. It might be caused by the experimental system error. The cavitation duration might be a little shorter at 1120 and 1660mmHg/s, and at the same time, the collapse time of cavities is disperse. The collapse stage seemed to be a little longer. At the end stage of collapse, no obvious change could be observed of the volume of cavities in powder state, therefore, it is difficult for the naked eye to accurately determine the time of complete cavity collapse. However, it is relatively easy to determine the starting time of cavitation, for the sudden growth of cavity at the cavitation inception would make the change of its volume obvious. With the increase of the loading rate, the time of cavitation inception will occur earlier. The position of occluder, used for the measurement of starting time in delayed timing, is immovable, and the cavitation duration is the period from the time when the occluder at initial reference location to its impact on seat stop, on the basis of which the closing rate of valve could be evaluated. With the increase of loading rate, the time of the impact of occluder on seat stop will be earlier, furthermore, the impact velocity will rise, too. It shows that the impact velocity of occluder has a greater effect on the cavitation, which is a support that the squeezing jet is the underlying reason of cavitation.

According to this study, the following conclusions could be drawn:

(1) The loading rate under normal physiological state is about 750mmHg/s. The present study indicated that the threshold loading rate of cavitation of GK27 mechanical heart valve was 420mmHg/s, similar to that of Medtronic Hall mechanical valve, but far less than that under normal physiological state.

(2) Cloud-like cavities appeared in the vicinity of seat stop, moved radially outwards. Therefore, the cavitation is caused by the local squeezing jet generated during the impact of occluder on seat stop during the GK mechanical valve closure. As for cavitation mechanism, the author think it is a vortex cavitation caused by wall jet.

(3) With the rise of loading rate, the closing velocity of valve is increased, and the GK mechanical valve cavitation is intensified, too. Therefore, the closing velocity of valve is a key indicator to evaluate the cavitation trend GK mechanical valve.

(4) Modify the design of valve, for instance, to reduce appropriately the squeezing contact area of seat stop, or to decrease the velocity of occluder at the final stage of closing, etc, so as to decrease squeezing jet velocity and improve the cavitation trend of mechanical valve.
4 Reference


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