

## HOMOGRAFT HEART VALVE BANK

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### ▶ Donor Criteria

- Valves are retrieved from donors of solid organ transplant in whom the heart as an organ is not suitable for transplant.
- Donors may also include people who have died at home, any hospital ward or in a hospice.
- Consent from next-of-kin is necessary.
- Removal should be performed within 48-72 hours of death.
- Age range up to 60 years.
- A medical history questionnaire is completed by Bank staff.

### ▶ Contraindications

- More than 72 hours since death.
- Age over 60 years.
- Cardiovascular and related disorders: cardiac valvular diseases or predisposing conditions, endocarditis, connective tissue disease (Marfan's), autoimmune disorders, or more than 3 months use of steroids.
- Transmissible viral diseases: HIV positive, hepatitis (B/C) positive.
- Sepsis, tuberculosis and syphilis positive.
- Malignancies excluding: primary CNS tumor, basal cell carcinoma, carcinoma in situ of cervix if smears are negative 1 year after treatment.
- Diseases of unknown etiology (e.g. Creutzfeldt Jacoub, Huntingdons Chorea, Parkinson's, Alzheimer's and other forms of dementia).

### ▶ Retrieval

#### *(a) from beating heart donors*

- Retrieval is performed as the last procedure, following the harvest of other organs by other teams.
- Heart is removed under sterile conditions in theater. Blood testing is normally carried out prior to retrieval, however, a blood sample is still requested.
- The valve is processed in theatre following the standard protocol.

#### *(b) from post-mortem examination*

- Valves are retrieved from cadaveric donors who require post-mortem examinations.
- Retrieval must not interfere with post-mortem examination, and therefore should follow the examination of the heart by the pathologist.
- Two 10ml clotted blood samples are obtained.
- The heart is retrieved by the pathologist, washed in sterile Hartmann's solution and placed in a white plastic container filled with sterile Hartmann's solution at 4°C along with the blood sample.
- The donor information form is completed by the Bank staff, and collected together with the heart.
- If dissection is not to take place immediately, the container should be placed in the refrigerator at 4°C. Dissection should be performed as soon as possible.

- *Blood Sampling*

Two clotted blood samples, approximately 10 mls each, are collected during retrieval and sent for screening of :

- HIV antibody
- HBsAg
- Anti-HCV
- Syphilis

▶ **Valve Preparation**

- *Environment*

- Dissection is performed in a certified microbiological safety cabinet to ensure a high air quality environment. This is available in the Lee Hysan Laboratory on the 7th floor. Sterile drapes and dissecting instruments are used to prevent cross contamination. Operator should scrub and wear sterile gown and gloves.
- Valve is submerged in cold (4°C) sterile Hartmann's solution during dissection.

- *Dissection method*

- Place the heart in the anatomical position.
- Remove the adventitia, starting at the aortic arch and moving towards the root.
- Expose the right coronary artery and remove the surrounding adventitia.
- Expose the left coronary artery at the level of the bifurcation and dissect it back towards the aorta.
- Cut both coronary arteries 10-20mm distal to origin. Inspect the opened coronary arteries for atheroma and report it on valve assessment sheet.
- Continue dissecting the adventitia off the aorta until the ventricular muscle is reached.
- Remove the pulmonary artery and right ventricle out of the heart.
- Incise the inferior surface of the left ventricle down to the apex and open it like a book exposing the anterior leaflet of the mitral valve.
- The mitral valve chordae are cut, and a half moon-shaped superficial incision is made in the ventricular wall which is deepened to remove the valve.
- A band of ventricular muscle is retained at the base of the aorta. This muscle band is trimmed to a depth of 3-4mm and 1-2mm in thickness.
- Approximately 3-4mm of both left and right coronary arteries remain attached to the homograft and as long a length of aorta as possible up to the subclavian/carotid branches.

- *Measurement*

- The valve is measured in order to determine valve ring diameter, aorta internal diameter and the length of the aorta.
- A set of standard sizers and a ruler are used.
- Measurements are only possible with accuracy of  $\pm 1$ mm.
- Details are recorded on valve description form.

- *Valve Grading and Description*

- Valve leaflets are gently inspected with a forceps for any large patches of atheroma, calcification, fenestration or damage during death or the process of dissection.
- Valve competence is tested by filling with Hartmann's solution and monitoring leakage.
- Overall grade (*very good, good, fair*) is allocated after completion of inspection and testing.
- All details regarding valve abnormalities are recorded on valve description drawings.

- *Rejection Criteria*

- Congenital defects (e.g. bicuspid, quadricuspid valves).
- Damage (e.g. rupture, bruising during death/resuscitation).
- Excess atheroma.
- Large fenestrations.
- Calcium in leaflets or wall.
- Dissection/retrieval faults.

- *Sterilization and Disinfection*

- Since many valves are obtained from non-sterile mortuary environment, all valves are immersed in a strong antibiotics-nutrient medium immediately following dissection. This medium is designed to provide maximum disinfection within a short incubation time, whilst minimizing toxicity to remaining viable cells and maintaining osmolarity balance.

- The sterilization/nutrient solution consists of:
 

Hank's solution with 40mM HEPES (125ml)	50%
Sterile water for injection (90mls)	50% (including antibiotics)
Amphotericin	0.05 mg/ml
Ciprofloxacin	0.20 mg/ml
Vancomycin	0.05 mg/ml
Gentamicin Sulphate	4.00 mg/ml
NaOH (1N) - (to pH 7.3-7.4)	3 mls
  
- The medium is prepared by Pharmacy on request and is supplied in 250ml containers. These can be stored at 4°C for up to 7 days. Upon preparation of a valve, Amphotericin is added to the solution Perrier to valve immersion.
- Valve is incubated at room temperature for 24 hours in the dark (cover with foil). This is due to the photolabile nature of Amphotericin, which degrades in the presence of ultraviolet light.
- After this time sterilization is considered to be complete and valve is transferred to a 4°C refrigerator.
  
- *Microbiological Testing*
  - Ten samples of aortic wall are removed at the end of dissection for microbiology. Five are placed in a sample tube with antibiotics solution and the other samples are placed with the valve in its container.
  - Both valve (in its container) and samples (in a tube) are treated identically (i.e. placed at room temperature for 24 hours).
  - Samples are then sent for microbiological screening, using donor name and identification number.
  - The Microbiology Department will test the samples for:
    - aerobic bacteria      -anaerobic bacteria      -fungal contaminants      -other low temperature organisms (typically found in mortuary environment)      -mycobacterium tuberculosis
  - Normally after 9 days a report is issued from the laboratory confirming lack of bacterial growth after sub-culturing. Once this is issued, the valve can be designated "sterile". A prolonged fungal culture is monitored for a further 3 weeks and a TB culture continues for up to 6 weeks. The surgeon using the valve is warned that these cultures are continuing, but accept that the report after 9 days is sufficient.
  - The details of valve microbiological screening are recorded and if the results are negative, the valve may be considered for releasing for use (provided blood testing is also negative).
  - If any result is positive, valve is discarded.
  
- *Storage*
  - Valves can be kept in their sterilization mixture in the refrigerator at 4°C for 6-10 weeks. Valves unused after 10 weeks must be discarded.