Implantation Technique for the HeartSaver Left Ventricular Assist Device

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The development of the HeartSaver Ventricular Assist Device (VAD) (WorldHeart Corporation, Ottawa, Canada) was begun in 1984 at the University of Ottawa Heart Institute under the direction of Dr Wilbert Keon with the preparation of a grant proposal outlining the design of a totally implantable, electrohydraulic VAD. The components of the device, including the unified pump (containing the blood sac, motor, and volume displacement chamber), the internal battery and external power supply, the transcutaneous energy, and signal system (TESS), were developed separately by specialized groups over the next 6 years.

With a primary design objective to have an intrathoracic positioning of the device, planning for the ultimate implantation technique of the VAD in humans has occurred during the development stages of the project. At the same time, an alternative implantation technique was developed for use in the calf model to allow for animal studies, which is described elsewhere. The rationale for an intrathoracic placement was to allow the inflow and outflow cannulae length to be minimized to reduce risk of thromboembolism, to provide a neutral pressure in which the volume displacement chamber would reside, and to minimize compression of any internal organ while reducing the length of incisions and amount of dissection needed for implantation. Placement of the TESS secondary coil and internal battery was to be done using standard technique developed for pacemakers and implantable defibrillators.

There have been concerns expressed by some over the intrathoracic location with fear of potential compression of the lung. However, it was felt that the dilated, failing heart would create a potential space that would be left once the heart was decompressed by the VAD and that the anterior compression of the lung would be minimal considering that most of the left lung resides infero-posteriorly. In addition, a potential space exists between the chest wall and diaphragm antero-laterally to the heart that is routinely developed for implantation of the current generation of VADs. This space could be developed for the HeartSaver device and tailored for ideal positioning with the decompressed heart. Displacement of abdominal contents would be minimized by this technique, which has created some problems with other devices in terms of early satiety and limitations in movement.

Numerous human cadaver fit trials have been performed with the different configurations of the device as it was developed. At the time of this writing, the HeartSaver VAD was undergoing final animal testing before regulatory approval, and, to date, no human has been implanted with the device.

Device Description

The resultant HeartSaver VAD consists of 3 implantable components: the HeartSaver VAD unit, the internal battery and the internal transcutaneous energy and signal system (TESS), as well as connecting cables (Fig 1). The VAD unit uses electrohydraulic actuation and combines the blood sac, volume displacement chamber (VDC) (containing silicone oil), electrohydraulic axial flow pump, and control electronics into a single unit capable of being implanted into the thoracic space. Power to the device may be from external batteries or an internal lithium ion battery that gives patients the potential to be disconnected from the external battery for 45 to 60 minutes, thereby allowing patients the freedom to move, shower, and perform unrestricted physical activities. The external controller may be connected to a remote monitor that may communicate by telephone, internet, or satellite to other centers for remote assessment of device function.

Anatomic Considerations

With each of the 3 components, there are considerations for anatomic placement of this device. The first is the positioning of the TESS primary coil. It may be placed in 1 of 3 locations in order of preference: axillary, pectoral, or on the lower anterior chest. Because of its pear shape and length of 14.8 cm, it would be advantageous to identify the position of the TESS preoperatively to optimize its location in each individual patient.

The second consideration is for the position of the internal battery. This should likely be placed in the preperitoneal space below the rectus muscle similar to the position of the early ICDs. However, if the patient...
seems to have a generous amount of subcutaneous tissue, then a supra-rectus sheath position may be considered, which should facilitate the replacement of the battery if needed in the future.

The third consideration is the intrathoracic position of the HeartSaver blood pump. The device was designed to be in the left pleural cavity for reasons mentioned above. However, the exact position will depend on a number of factors: (1) chest width, (2) angulation of the chest wall lateral to the sternum in the horizontal axis, (3) position of the left ventricular apex in the pericardium, (4) amount of displacement of the right ventricle, and (5) length and angulation of inflow cannula chosen for use.

FIG 1. HeartSaver VAD system components including (left to right) (1) Transcutaneous Energy and Signal System, (2) blood pump consisting of a volume displacement chamber, blood sac, motor, and silicone hydraulic fluid, and (3) lithium ion internal battery.
**Surgical Technique**

1A Axillary location of TESS. 1B Pectoral location of TESS. The TESS pocket is made first. A 9 cm horizontal incision is made in the axilla, pectoral or lower chest region and carried down through subcutaneous tissue to pre-muscular fascia. A subcutaneous pocket of appropriate size (8.75 × 14.5 cm) to accommodate the TESS is made using provided sterile models as guides.

2 Internal battery with connector may be positioned either horizontally or vertically in a supra- or sub-rectus sheath position. A median sternotomy skin incision is made and carried down to midway between the xiphisternum and umbilicus. A preperitoneal pocket is made by incising the anterior rectus sheath just lateral to the linea alba and lifting the rectus sheath anteriorly. A plane above the posterior rectus sheath is made to accommodate the internal battery model in either a horizontal or longitudinal orientation, depending on preoperative measurements.
Intrathoracic placement of HeartSaver VAD in the left pleural space with inflow and outflow cannulae connected to left ventricle and aorta, respectively. The sternum is divided, and the pericardium is opened as far right as possible to create a pericardial flap that can be used to cover the outflow cannula at the end of the procedure. The left pleural cavity is opened to allow positioning of the VAD model. If needed, a plane between the left anterior chest and diaphragm can be created to allow for the inferior displacement of the VAD. An appropriate inflow and outflow cannula are selected to optimize VAD placement to prevent excessive rightward displacement of the heart.

Once the VAD position is determined, the TESS and internal battery are implanted with their cables and connectors brought through to the location of the VAD using subcutaneous tunnelers provided with the implant kit. This is done before heparinization of the patient.

The cannulae are implanted with the patient anticoagulated with heparin and placed on cardiopulmonary bypass to facilitate this part of the procedure. A sidebiting clamp is placed on the left side of the ascending aorta and an aortotomy is made. The outflow graft is cut to an appropriate length and anastomosed to the aorta. The heart is supported out of the pericardium with sponges, and a site for left ventricular cannulation is determined based on VAD model positioning. Approximately 10 interrupted pledgeted sutures of 1 or 2 braided material are placed around the apex of the left ventricle or just adjacent to it. A ventriculotomy is made with a punch or scalpel and the cored apex is sent for histologic examination. The left ventricle is inspected internally to ensure the absence of thrombus or potential obstruction to inflow. The cannula is placed into the ventricle, and sutures are brought through the sewing ring and tied.

The HeartSaver VAD is placed into the chest in its predetermined position, and the cannulae are attached to the appropriate ports after filling the blood sac with heparinized saline or albumin. The gland nuts are left loose to facilitate de-airing. A catheter is placed into the outflow graft, and suction is applied with the outflow graft occluded distally.
4 Final configuration with HeartSaver VAD in left chest connected to TESS and internal battery. The TESS and internal battery are connected to the HeartSaver VAD. The connectors are aligned and screwed together with tools provided in the implant kit. The clinical engineer/perfusionist performs a check of the appropriate powering and communications with the device to ensure proper connection and alignment between components (TESS and battery). The VAD is actuated with single beats and de- aired with some movement of the VAD to displace air.

Once de-airing is complete, the VAD is turned on to pump at a fixed rate of 60 bpm and the patient is slowly weaned off cardiopulmonary bypass with the outflow graft on continuous venting and suction to remove any residual air. When stable, the VAD can be turned on full-fill/full-eject mode.

5 Patient after chest closure with TESS primary coil in place and 3 chest tubes draining left chest and pericardial space. The chest, abdominal, and TESS pocket incisions are all closed with standard techniques used in the institution. The primary coil of the TESS is placed and secured with a harness over the secondary coil.
Postoperative Course and Follow-Up

Patients will remain in the intensive care unit until stable. The following most common medications can be anticipated:

- Inotropic agents for right ventricular support, which can usually be weaned slowly over the first few postoperative days.
- Anticoagulation will start approximately 8 hours after surgery provided chest tube losses are less than 50 mL/h. This will include intravenous heparin to maintain the partial thromboplastin time in the range of 60 to 90, followed by clopedigrel, 75 mg per day, beginning on day 1. Heparin can be changed to coumadin when the patient is stable and ambulatory with the International Normalized Ratio target between 2.5 to 3.5.

Patients will undergo routine cardiac rehabilitation while in the hospital. Device function will be closely monitored with attention paid to pump filling and response to exercise. Preparations for discharge will include device education by a VAD nurse or clinical engineer. Major issues will be to determine comfortable fit of the primary coil in the axilla/pectoral area with support appliances, the adequacy of communication and power transfer with the positioning of the subcutaneous TESS coil, the proper operation of the internal battery as a stand-alone power supply, the function of the alarms and patient awareness of appropriate actions if an alarm sounds, and the outfitting of the patient’s home for a battery charger. Follow-up will be done through the heart failure/VAD clinic on a regular basis to ensure proper device function and patient status.

Comments

The HeartSaver VAD is a pulsatile, totally implantable VAD that should have the benefit of no percutaneous connections, which should translate into fewer infections compared with older-generation VADs. The importance of pulsatility long-term remains to be seen, but the high-volume, low-velocity pumping action may have its benefits compared with the lower-volume, high-velocity output of nonpulsatile VADs. Compared with other totally implantable pulsatile systems, the volume displacement chamber design prevents the need for periodic refilling, and the system components are more compact. The power supplies are designed to allow a high degree of mobility without restricting daily activities. The VAD allows for the heart to be left in situ, thereby resulting in a permanent backup in case of device failure, which is an advantage compared with total artificial hearts.

The HeartSaver VAD has been under development since 1989 and is currently undergoing formal animal testing before regulatory approval for human use. The device has been proven to be reliable in in vitro testing and preliminary in vivo experiments but requires further optimization. It is hoped that the advantages of this system are proven in the initial clinical trials, which should be underway once optimization is complete.

REFERENCES


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