Connecting the Heart and Ear: 
A Novel LVAD Powered Through a Post-Auricular Pedestal

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Abstract

Objective: To evaluate the safety and efficacy of a novel method to power a Left Ventricular Assist Device (LVAD) in patients with advanced heart failure via a subcutaneous connection to a post-auricular, percutaneous, osseointegrated pedestal. This system was designed to improve patient mobility and function compared to traditional LVADs and expands on techniques commonly utilized for osseointegrated hearing prosthetics.

Study design: Case series from a prospective, randomized clinical trial

Setting: Tertiary-care, university hospital

Patients: Patients with heart failure refractory to medical management requiring LVAD

Intervention(s): Therapeutic and rehabilitative

Main outcome measure(s): LVAD use, rate of osseointegration, and post-auricular wound healing

Results: Three patients with NYHA class IV heart failure (average ejection fraction 18%, range 10-25%) were treated with the study device. Successful use of the external power supply, improved cardiac output, and temporal bone osseointegration occurred for all patients. No infections adjacent to the pedestal were encountered (average follow-up 7 months). One patient had a 4mm wound dehiscence adjacent to a rejected suture, and another patient had a pyogenic granuloma develop in the incision line. Both issues resolved with local wound care and did not impair use of the device.

Conclusions: This study has shown that a post-auricular, percutaneous pedestal housing subcutaneous connectors is a safe and effective way to deliver power to an LVAD. Minor post-auricular wound complications were encountered, but resolved with local wound care. This study also illustrates how otologic surgical techniques can be applied in a cross-disciplinary collaborative manner to foster prosthetic innovation.

Introduction

Left Ventricular Assist Devices (LVAD) are electromechanical circulatory devices that are used to partially or completely replace the function of a failing heart. The power supply for traditional LVADs is connected to the device via transcutaneous wires that enter the abdomen. We describe a novel LVAD (Jarvik 2000®, Jarvik Heart Inc, New York, NY) that is powered via subcutaneous wires that connect to a post-auricular pedestal. The pedestal is anchored to the temporal bone, similar to osseointegrated auditory prostheses.

Methods/Surgical Technique

Patients who met cardiac criteria for LVAD therapy were randomized to either the study arm with the post-auricular post or a traditional LVAD arm. Patients underwent the surgical procedure and were followed prospectively

Post-auricular Procedure in detail (see Figure 1)
1. Head CT scan is obtained to ensure adequate (6mm) of cortical bone thickness
2. An anteriorly-based C-shaped flap is planned with the center of the flap cut with a 5mm skin punch down to periosteum
3. Skin flap is raised and a cruciate incision is created in the periosteum, with subsequent elevation of periosteal flaps.
4. Subcutaneous wires are delivered via a plastic trochar tunneled from the thorax, through the neck, to the post-auricular incision.
5. Pedestal is secured with 4-6 6mm screws
6. Flap is sutured back over the pedestal

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age</th>
<th>Cause of heart failure</th>
<th>Ejection fraction</th>
<th>NYHA Class</th>
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<tbody>
<tr>
<td>1: Male</td>
<td>54</td>
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<td>10%</td>
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<tr>
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<td>76</td>
<td>20%</td>
<td>ischemic cardiomyopathy</td>
<td></td>
<td>III</td>
</tr>
</tbody>
</table>

Table 1. Patient demographics. NYHA = New York Heart Association Class of heart failure.

Figure 1. (from top left to right). A stair-step incision in the neck is shown. A 5mm punch is used to designate the site of the post. An anteriorly-based skin flap is raised. The pedestal is tunneled from the thorax and screwed into bone. The skin flap is brought back over the pedestal.

Figure 2. The external cable shown at about 1 month (left) and 3 months post-operatively

Figure 3. This patient had a delayed post-operative wound hematoma. This happened 4 months after surgery. The patient was anti-coagulated and, presumably, he had an exposed vessel at the skin-pedestal interface that caused subcutaneous bleeding.

Results

Three patients with NYHA class IV heart failure (average ejection fraction 18%, range 10-25%) were treated with the study device. Successful use of the external power supply, improved cardiac output, and temporal bone osseointegration occurred for all patients.

Complications

No infections adjacent to the pedestal were encountered (average follow-up 7 months). One patient had a 4mm wound dehiscence adjacent to a rejected suture, and another patient had a pyogenic granuloma develop in the incision line. Both issues resolved with local wound care and did not impair use of the device.

DISCUSSION

This study has shown the safety and efficacy of a novel LVAD powered through a post-auricular post. This device allows for greater patient mobility and was designed to decrease infections of the driveline that exits the abdominal wall. All patients were able to use their device with good stability of the post. This study highlights how otologist can collaborate in a multi-disciplinary fashion. Techniques that are familiar in otologic surgery, such as implanting osseointegrated temporal bone prosthesis can be employed in other disciplines, such as cardiothoracic surgery.

Minor wound complications were relatively common in this study. Of note, one patient develop a subcutaneous hematoma approximately 4 months post-operatively. The patient was anticoagulated. The delayed hematoma may have occurred because the percutaneous post does create a skin-soft tissue interface wherein there may be granulation highly vascularized and friable tissue. This tissue may be prone to bleed, particularly in anticoagulated patients. Meticulous surgical technique and hemostasis is recommended for all of these patients.