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Case In Point

Internal Form and Finish Critical to Manufacture of Heart Pump

The Project: Verify that geometry and surface texture of the housing for a heart pump will facilitate smooth functioning while not adversely affecting blood.

The Solution: Use extremely accurate instrumentation to measure form and surface to ensure they are compliant with specifications.

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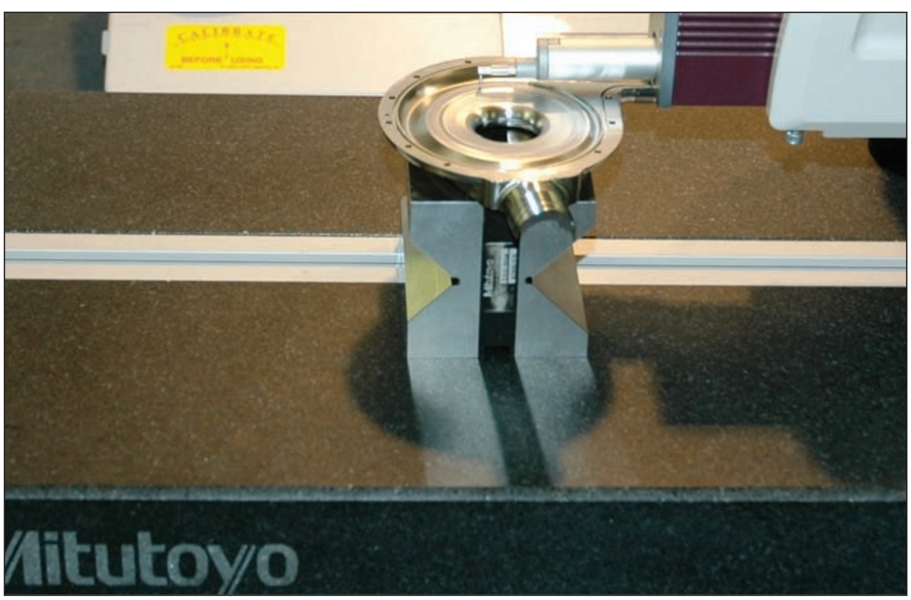

Profilometer measuring LVAD housing interior surface finish (R_a)

By Michael Cotton

The technology of heart transplants has been honed for almost 40 years now. Survival rates are constantly improving and great progress has been made on the problem of organ rejection. In fact, a challenge arguably tougher than surgery today is the ever-widening gap between the number of cardiac transplant candidates and the number of donor organs available to help them.

The good news is that a technological "bridge" solution to the donor shortage has emerged in recent years. It's called a ventricular assist device or VAD, and it holds great promise. A surgically-implanted pump designed to help a weakened heart circulate blood, the VAD is now being used as an effective and safe therapy to help those patients trapped in the transplant waiting line—and in the process, vastly improving their survivability and the quality of their lives. In the last few years, VADs are also being used to provide long term support to many non-transplant eligible congestive heart failure patients.

The VAD (or LVAD, when the pump is specifically implanted to assist the left ventricle—the heart's main pumping chamber) comes in two varieties. With the first, a device's pulsatile pumping action fairly closely emulates that of the heart itself. Developed somewhat later, the rotary (centrifugal) pump provides a continuous flow. The concept behind the

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Clinical Trial in Greece

On March 8, 2006, the rotary device developed by HeartQuest was implanted in a 67 year-old man at St. Luke's Hospital in Thessaloniki, Greece. The patient in question had been suffering for some time from congestive heart failure that would likely have eventually taken his life. With the assistance of his VAD, his heart should gradually grow stronger.

The operation, performed by a Greek surgical team specially trained at WorldHeart's Rotary Systems operations and at LDS Hospital (both in Salt Lake City), represented the first clinical implantation in a human of a bearing-free, fully magnetically levitated, centrifugal rotary heart pump. A key goal of the Greek clinical trial, aside from the benefit to the patient, has been to learn how the design of such pumps can be refined. Clinical trials in the U.S. will have to wait until sometime in 2007, due to the complexity of the FDA approval process. The greater time lag in this country is the reason many American biomedical advances have gotten their first clinical testing in Europe.

Ventricular assist devices are today being used as bridge therapy in the more than 100 clinical centers around the world. Before the HeartQuest device can be moved into full production, WorldHeart must finish clinical trials, complete pre-production stages like validation of the design and development of its manufacturing process, and get final FDA approval.

Says Robert Malone, QA Manager, Rotary Systems, WorldHeart, "Once the HeartQuest is on the market, we expect the volume for the first several years to be 50 to 100 pumps per year. A limiting factor that all VAD manufacturers face is that we've got to expand the market beyond just the hundred or so heart institutes now leading the way and get the product into mainstream hospitals and other facilities doing cardiac procedures."

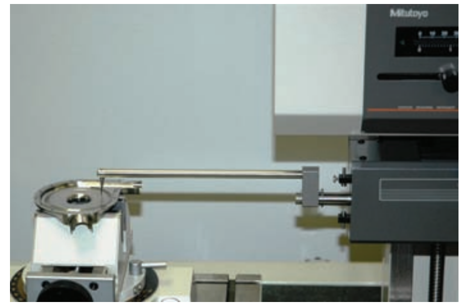
rotary pump is particularly ingenious because its rotor, silently sweeping blood along its path, is the only moving part in the device.

In traditional rotary models, the rotor turns on a mechanical bearing. In others, the bearing surface is lubricated by a thin layer of blood. However, the HeartQuest VAD from WorldHeart Corp., now in a European clinical trial, takes the technology one step further by eliminating the need for any bearing—blood-lubed or mechanical. The HeartQuest rotor is both levitated and spun by magnetic fields generated within the third-generation device—a principal benefit being that the clearance between the bottom of the titanium-alloy rotor and titanium-alloy housing in this device is large enough so that fragile blood components never experience destructive shearing forces.

The HeartQuest's proprietary MagLev technology uses a combination of passive magnetic fields (from permanent magnets embedded in the rotor and housing) and a single-axis of active magnetic control (from pulsed fields set up by stator windings in the housing) to both suspend and spin the rotor. A sensor inside the housing works with a feedback controller to keep the rotor centered in the housing. The result is a simple and efficient system. And with no bearing of any kind to wear, the useful working life of the implant should be greatly extended.

The Innovators

WorldHeart Corp., source of the innovative technology in the HeartQuest VAD, specializes in developing, manufacturing, and marketing implantable heart assist devices for late-stage and end-stage congestive heart failure. Their products enable recipients with otherwise poor prognosis to return to the normalcy of their homes, jobs, families, and hobbies. Established in 1986, the company expanded in August 2005 by acquiring MedQuest Products Inc. This strategic move added MedQuest's advanced rotary pump technology to WorldHeart's existing pulsatile device portfolio (their Novacor LVAS). As a result, WorldHeart is currently the only firm offering both types of pump to serve the needs of heart failure patients.



Measuring LVAD housing interior contour conformance

The Rotary VAD

The HeartQuest's housing is a small, well-radiused, titanium-alloy structure, almost round in shape, about 3 in. in diameter and about 1.5 in. in thickness. It consists of three parts match-machined during fabrication to ensure they fit together precisely. A large portion of the interior of the housing is a blood flow pathway designed to contain the rotor. Also in the blood path, on the downstream side of the rotor, is a critically-shaped cavity called a "volute," machined into the housing walls. Its shape helps control blood flow. The housing also includes a compartment for electronic circuitry, a sensor that can measure position of the rotor to within less than 1 mil of position, and magnet (stator) wiring; all electronic items are securely potted. Inlet and outlet cannulas are attached to the blood pathway. After assembly, the housing is sealed by laser-welding and then helium leak-tested.

During implantation, the HeartQuest's blood inlet cannula is sutured into the apex of the left ventricle. The outlet cannula is sewn to the ascending aortic arch, which sends oxygenated blood to the entire body. A lead wire extends from the pump out through the patient's skin to permit communication with an external controller and receipt of power from a rechargeable battery, both of which the patient can wear on a belt for mobility.

Critical Internal Surfaces

Several concerns are foremost in the design of the interior of a rotary blood pump:

• The need to optimize traditional per-

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Mock-up indicating LVAD orientation within body

Benefits of a Rotary VAD

The pulsatile VAD is still the most prevalent heart assist device in use today. One of its pluses is the fact that pulsatile pumping action probably emulates the natural pumping rhythm of the heart more closely than continuous flow. It has also been claimed that pulsatile pumps provide the highest degree of circulatory support needed by an end-stage heart failure patient.

However, a rotary pump may be more suitable for late-stage heart failure patients. It boasts its own impressive strengths. For example, it offers:

- **A smaller size** – A fact which facilitates implantation in a wider range of patients, including women, adolescents, and children
- **A quieter operation** – Pulsatiles typically emit a clicking noise
- **Less mechanical wear** than pulsatiles due to its MagLev operation (on this score, the bearing-free HeartQuest design should show the least wear of all) – The fact that rotary pumps usually have a lower RPM range than pulsatiles may also pay off in a longer device life.
- **A higher level of biocompatibility** – Since no lubricants are required in a magnetically-driven device, there is no need to introduce potentially toxic chemicals into the blood stream. What's more, the relatively smaller size of a rotary pump means the implantation pocket formed by the surgeon in the abdomen can be smaller, and therefore, possibly less prone to infection.
- **Versatility** – Rotaries generally provide a continuous blood flow, but under certain conditions they can be induced to provide a pulsatile pumping action. Says Malone, "If you lower the rotor RPMs and decrease the flow, you get a form of pulsing–it happens automatically as a reaction to systemic blood pressure within the body."

Neither the rotary or pulsatile approach represents the whole answer. In fact, they complement each others' roles in the treatment options they provide to the broad spectrum of patients suffering from heart failure.

formance specs that pertain to any rotary pump—parameters like pressure rise, flow rate, input torque, and rotational speed

- The need to assure viability of cellular components of the blood

In the HeartQuest pump, the 3D contoured volute on the downstream side of the rotor enhances hydraulic performance. It converts kinetic energy (arising from the blood's velocity) to potential energy (pressure or head), and straightens and equalizes flow coming out of the rotor. Properly designed, a volute can make a pump more efficient.

However, the contour must not encourage blood stagnation and the possibility of thrombosis or hemolysis. In general, a critical concern in an implantable pump is the avoidance of trauma to the cellular components of blood by assuring smooth surface transitions. Friction heating can also damage blood. Areas presenting angular changes in internal pump geometry must be avoided since they not only heat the blood but force it to take abrupt directional changes, mechanically working it. Another way to reduce friction and discourage blood stagnation is to create a surface "texture" which promotes/stimulates natural deposition of blood constituents to create a stable intermediary surface—with a low tendency to "break away"—and which keeps blood flowing smoothly over it.

Testing Form and Surface

To check the quality of surfaces in the interior of the titanium housing of the HeartQuest, both in the blood path and on the rotor, WorldHeart uses a Mitutoyo SJ-400 compact profilometer. Says Neal Maughan, a quality engineer at the company, "We supply roughness specs via CAD files to the outside supplier who does our machining—so we're simply checking their compliance."

The SJ-400 profilometer is mounted to a column on a granite block to isolate it from vibration. Then, as its probe moves across a machined region, the instrument provides Maughan with a figure called average surface roughness (R_a), the arithmetic average of the miniscule peaks and valleys in a surface. The actual value WorldHeart demands is proprietary.

Controlling this parameter allows the company to ensure that its pump's internal surfaces are such that blood will experience no abrupt transitions. Maughan explained, "Essentially, we want a surface that won't interrupt flow or cause any turbulence that could damage red blood cells."

The SJ-400 can measure roughness in two modes. In its skidded measurement mode, surface irregularities are detected with reference to a "skid," a radiused protrusion about as long as the stylus and located adjacent to it on the instrument's measuring arm. However, in this configuration, the instrument is not able to measure waviness and stepped features in an exact way.

In skidless measurement, on the other hand, surface irregularities are detected with reference to the guide on the drive unit in the instrument. In this mode, the unit can measure not only surface roughness but also waviness, straightness, and finely-stepped and hard-to-reach features on either a flat or curved surface.

The SJ-400 is capable of making as many as 36 kinds of roughness measurements to satisfy the various requirements of the latest standards issued by ISO, DIN, ANSI, and JIS. The instrument can provide

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Prototype LVAD configuration in pre-clinical testing

graphs of traces from the various measurements it makes, and offers a lab-quality measuring resolution of 0.000125 µ-m/0.005 µ-in., as well as a traverse range of 800 µ-m/0.032 µ-in. Surface roughness is analyzed and evaluated using SURFPAK-SJ, the SJ-400's roughness analysis software program.

To verify the conformance by the machining supplier to their specifications regarding the form (geometry) of the volute in their pump, Maughan says WorldHeart relies on a high-accuracy contour measurement instrument from Mitutoyo called a Contracer CBH-400. They use it to create entities (a type of geometry that can be created and edited as a single unit in a CAD program), as well as to measure small radii where the presence of an edge break could be a problem.

The Contracer captures surface form and profile details using a moving stylus, and processes and analyzes the data within a software package called FORMPAK. Measured profile geometry can be overlaid on a CAD model to check for deviations from the ideal design. According to Maughan, "We're especially pleased with the ability of our Contracer to amplify measurements as it creates a profile trace for us. That lets us make measurements on the volute and rotor that much more accurately." Using the dedicated software, it is possible to get precise contour readouts on all curved surfaces at any magnification up to 200X. The instrument has a measuring range of 4 in. for the X axis and 1.57 in. for the Z axis.

The Contracer features a digital scale on the X- and Y-axis, and a high resolution laser holoscale is incorporated into the Z-axis detection unit so it's possible to measure with 2 µ-in. (or better) resolution over the entire measuring range.