Coupling of Skeletal Muscle to a Prosthesis for Circulatory Support

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A durable bond between the end of skeletal muscles and prosthetic structures could, with appropriate linkage, allow circulatory support power by synchronous and/or sequential contraction of several in situ conditioned muscles. Potential advantages relative to a myoplasty wrap involve 1) less traumatic dissection, 2) efficient linear force development, 3) selectable contraction rate, 4) greater stroke work, 5) independent control of muscle pre-load and end diastolic pressure, and 6) independent control of duration of muscle tension and ejection time. However, no existing means of tissue-prosthetic bonding appears adequate. Practicality would demand that full tension bearing capacity by the bond take no longer than muscle conditioning. A prosthesis was developed to achieve those goals. As scaled for this study, it is made of 7,200–7,800 unspun, unplaited, 22 to 26 μm diameter polyester fibers swaged into four taper needles for weaving through distal muscle. The other end is formed into a polyurethane sheathed kemmantel cord for distal fixation. Devices were implanted in six 3 to 4 kg rabbits (unilateral posterior tibial tendon replacement, random side selection with contralateral dissection/closure controls), and their tensile strength was tested at 30 days. All healed well; leg movements were normal after 1 week. Limbs were frozen at −70°C between death and testing. Control failure occurred at 243 ± 94 N and experimental at 163 ± 44 N (p = 0.065, t-test); highest estimated requirement was 17.2 N. Interface strength was adequate by 30 days. Continued investigations, addressing other questions, are warranted. ASAIO Journal 1997; 43:M434–M441.

The appeal of skeletal muscle as a power source for circulatory support is the promise of forgoing both external power sources and skin penetrating power conduits.

Thus far, the only way in which skeletal muscle has been applied to clinical circulatory support is with the cardiomyoplasty operation. Electrical pre-conditioning to fatigue resistance, introduced and developed by Stephenon, Chiu and others,1 rendered this practical, and there are numerous encouraging reports. Nevertheless, there are potential difficulties:

1. Dissection and mobilization reduce collateral blood flow.
2. Force delivery by muscle belly pressure may be less efficient than end tension in contraction, and pre-stretching the muscle by belly pressure may compromise blood flow at rest.
3. A stable amount of work can be delivered only about every other beat, as effectiveness tends to deteriorate at stimulation rates over 30–35/min.
4. The contraction of a single muscle has generally not met cardiac stroke work requirements.
5. Diastolic ventricular pressure and muscle pre-stretch cannot be independently optimized.
6. Durations of muscle contraction and of blood ejection cannot be independently optimized.

There is documented symptomatic improvement in many individuals after cardiomyoplasty, and no theoretical concern can negate that. However, concomitant improvement in objective parameters of heart failure has been limited and far from consistent. Unless and until objective benefit reproducibly follows cardiomyoplasty, it seems only prudent to take these concerns seriously and to investigate procedures by which they might be addressed.

One idea with potential to address every one of these listed concerns has been suggested by a number of different investigators:3–5 leaving muscles in situ and delivering the force of linear shortening via some form of linkage to circulatory support devices. Only musculotendinous junctions would need be dissected. Contractile force would be delivered over the internal fibrous architecture, and there would be no lateral compression during relaxation. A group of muscles contracting synchronously should be able to provide total work for each supported stroke, and with activation of two or more groups in sequence, every stroke could be supported. Hydraulic or other mechanical linkages could provide adjustable trade-offs between velocity and force and between rates of energy input and output, thus freeing muscle pre-stretch force and end diastolic ventricular pressure, as well as the duration of muscle contraction and blood ejection, from any fixed relationships.

Force and displacement studies of linearly harnessed muscle, although usually done acutely on unconditioned muscles, have supported feasibility. A remarkably efficient (61–92% depending on force) hydraulic system6 and a means of rib fixation7 have been recently described. Optimal anchoring of linkage hardware to bone—to ribs for latissimus, to ilium for psoas, etc.—can draw on well developed orthopedic and oral surgical implant technology.5

What has not been solved is the problem of repeatedly and indefinitely transmitting contractile force from the muscle to artificial devices. At first glance, simply suturing or tying a cord, rod, or cable to a cut tendon would appear to suffice. It does in acute trials.2,3 But this delivers tremendous compressive force to a tissue with limited blood supply. Even for a 0.5 cm²
suture bearing surface, a modest 100 N of force would deliver 2 MPa or >15,000 mmHg. There is no direct experimental test of whether tissue integrity would be maintained with chronic repetition of such pressures. The frustrating century-long search for a truly artificial (rather than a tissue scaffold) tendon, held by sutures rather than healing from both sides, suggests that it would not.

This article's purpose is to review relevant prior work, to outline goals for an appropriate muscle-prosthesis bonding device, to present and defend a design concept we believe should meet those goals, and to describe an implantation study examining its early performance. The literature review section will be confined to 1) the rationale and experimental findings that have been advanced in support of linear pull methods of muscle harnessing, 2) some investigations of tissue-prosthetic interfaces, particularly as applied to attempts at artificial tendons and ligaments, and 3) practical requirements for muscle-prosthetic bonding to facilitate linear pull harnessing. There are many excellent reviews of the principles of skeletal muscle conditioning and stimulation as well as of its application to cardiomypolasty, and they will not be repeated. In Materials and Methods, we will 1) suggest practical requirements for a satisfactory tissue–prosthetic interface device, 2) give the principles that formed the basis of our device, and 3) suggest the type of computations that could be used to establish quantitative requirements. Then, we will 4) describe a simple embodiment of the device made of available materials and scaled to a small muscle (rabbit posterior tibial group). Finally, we will 5) present an experiment in which tissue–prosthetic bonding strength at 30 days (duration chosen as the shortest reasonable period during which electrical muscle conditioning would likely occur clinically) was tested for this simple trial model. Results will be given, and the discussion will focus on questions remaining for investigation.

**Literature Review**

Previous Investigations Related to Linear Pull Harnessing of Skeletal Muscle

We have examined the literature bearing on the purported advantages of linear pull harnessing of skeletal muscle for circulatory support. Three advantages cited by advocates of the approach are 1) minimization of dissection, 2) greater efficiency of contraction and consistency of capillary blood, and 3) potential for using two or more muscles or groups of muscles sequentially for every second or third stroke. One or more of these have been advanced by Farrar and Hill2 and Sasaki et al.3 in support of a linear latissimus model, by Spitzer4 for linear rectus femoris harnessing, and by Ugolini5 for a linear psoas major system, as well as by Salmons and Jarvis13 in a general review of skeletal muscle power. We believe there are three additional strong arguments for linear pull and will cite evidence supporting them as well: 4) the ability to use two or more skeletal muscles synchronously to meet power requirements for each stroke, 5) the ability to independently control muscle pre-stretch and end diastolic pressure, and 6) the ability to independently control duration of muscle contraction and of blood ejection.

Dissection and Translocation. The immediate risk of dissection of a muscle and moving it into the chest is vascular intreptum. Even the latissimus dorsi, with one dominant vessel pair, the thoracodorsal artery and veins, requires a “vascular delay” period for redistribution of interrupted collateral flow.10 Muscles without such a fortuitously isolated blood supply are at greater risk. Stainsby and Andrew11 measured >35% power reduction of a canine gastrocnemius muscle following only surgical isolation. A study by Ianuzzo et al.2 compared goat latissimus muscles that were dissected from surrounding structures, were paced for several months, or were both dissected and paced. They demonstrated that muscle degeneration associated with cardiomyoplasty was caused by surgical dissection and perhaps exacerbated by chronic stimulation, but not caused by stimulation alone.

Mechanical Effects of Linear Pull and of Wrap Constricting Configurations. All skeletal muscles suggested for circulatory support normally exert their force via a tendon. Internal architecture might be intuitively expected to have developed to efficiently transfer force linearly. Trumble and Magovern13 attribute mechanical inefficiency of wraps to the use of unidirectionally shortening myofibers to produce a pulling-twisting motion, a view shared by Tacker et al.14 Badhwar et al.13 sequentially harnessed the same muscles acutely by different modes and found three times the maximum power for linear pull as by wrap.

Similarly, the needed pre-stretch in a muscle wrap is received by belly pressure, raising tissue pressure, which could limit resting capillary blood flow. This was examined by Mannion and associates16 in skeletal muscle venousities using microspheres. There was a 25% reduction of inner layer (compared with outer layer) blood flow, but no overt ischemia. Achievable Rates of Repeated Contraction for Muscles. Salmons and Jarvis12 point out the intrinsic difficulty in synchronizing contractions to the cardiac cycle for which their velocity and frequency may not be suited. Experimental work shows no hemodynamic benefit in increasing to 1:1 from 1:2 pacing ratios in canine myoplasty.17 The predominant pacing mode of clinical cardiomyoplasty is every other beat.

Muscle Mass Related to Stroke Work. There are limited work/power data for muscle conditioned against fatigue, and data for fresh, unconditioned muscle vary wildly. Most reports give power ranging from five1 to seven1 to twenty6 mW/gm of muscle. Trumble and Magovern13 report 5.76 ml/gm for untrained 200 gm canine latissimus muscles, or >1 J/stroke, and suggest that this would extrapolate to >2 J in the human. After conditioning, stroke energy and mass may diminish,9 although some studies8,19 indicate this may be avoided. The stroke work delivered by a single conditioned muscle has thus far not reached the 0.7 to 0.8 J/contraction needed to meet an estimated 8.7 W baseline normal left ventricular power. This has suggested to some investigators20,21 that providing full stroke work by a single muscle was more realistic for the right than for the left ventricle.

Muscle Pre-Load and End Diastolic Pressure. Muscular work depends upon on pre-stretching.15 Stretching in a wrap configuration depends directly on end diastolic pressure. No studies were located that directly addressed the optimal pre-load for chronically conditioned skeletal muscles. Acker et al.10 addressed the optimal pressure pre-load in skeletal muscle ventricles, in which a canine latissimus was wrapped about a polymer sac. Extrapolating from the cavity pressures found optimal and the dimensional information given, the mid-thick-
ness tension resulting from those pressures would be roughly equivalent to those in a muscle around a dilated (end diastolic dimension 7 cm) human ventricle with an end diastolic pressure of 20 mmHg. Smaller ventricles would require higher pressures. In any given ventricle the pre-stretch of any wrapping muscle will be dictated by the end diastolic pressure for each beat, and independent optimization of the two cannot be achieved.

**Optimal Duration for Skeletal Muscle Tension and Ventricular Emptying.** The externally deliverable work of a contracting muscle occurs during shortening. If sustained isometric contractile element activity is required, metabolic work and expenditure of substrates still occur, with what could be considered a waste of energy. With work delivery via mechanical linkage, there is no need for continued contractile activity once initial shortening is completed. Valves, ratchets, or any of a number of adaptations of the linkage system could sustain the developed force throughout ejection, with no further metabolic demand.

**Investigation of Parallel Applications in Orthopedics**

There are clear and obvious similarities between this quest and the orthopedic challenges of artificial tendons and ligaments or of attachment of tendons to prosthetic bones. That work was extensively reviewed and will be briefly summarized.

**Tendon Fixation to Rigid Prostheses.** When total prosthetic femurs are placed, tendons not removed as part of the cancer operation are simply sutured to the prosthesis, where they become fixed only to a firm fibrous envelope—often allowing patients to walk, but giving no guidance as to true muscle–prosthetic bonding. Reported experimental study is restricted to acute tensile strength without investigation of tissue fixation durability. There is said to have been a European study of extraocular tendon ends inserted into holes in a porous ceramic prosthetic eye (P. Bajpai, personal communication, University of Dayton); no publication has been located.

**Artificial Tendons.** Early attempts at artificial tendons, dating from the beginning of the century, were reviewed by Hunter in 1965. Most of these efforts were troubled both by too little fixation to native tendon and/or bone and too much fixation to surrounding structures. The idea of a prosthetic material that would provide scaffolding for development of an autologus neotendon was evaluated with a number of materials. While there are encouraging experimental results and some reported clinical use, most of this work, whether using traditional absorbable suture materials or carbon fibers that gradually fragment, is not directly applicable to the current purpose, as, in the end, there is no bond from tissue to prosthetic material.

Polyester has also been used as a scaffolding, both as a weave and as plated, untwisted fibers. While the intention was simply to provide a mechanical framework onto which an autologous replacement of tendon or ligament would be formed of living tissue, the fibers did remain and, except in an application with likely high stress concentration, did not deteriorate. Of particular interest is a study by Amis et al. where a plated structure was used for tendon replacement. It was noted that in the periphery of the structure, where the plate was looser, the loosest fibers were surrounded by well vascularized tissue, with fibers appearing to be individually surrounded by healing tissue, and an absence of any thick fibrous capsule. This is completely consistent with basic work by Davila et al. and by Bruck on tissue–prosthetic interactions. Very small fibers (Davila et al.'s were about 50, Amis et al.'s were 15, and Bruck's were 5 μm) were "captured" by a collagen envelope compatible with the immediately adjacent blood supply. Amis et al. observed well vascularized and mature collagen that modeled into a tendon-like structure in response to repetitive stretching.

**Practical Requirements for a Useful Muscle–Prosthetic Bond.** While bonds must sustain expected force, that level of force is uncertain. Conditioned muscles may or may not contract with less force and velocity than unconditioned muscles. Khalafalla gives the maximum force of contraction for an unconditioned muscle as equivalent to 15 N/cm² of greatest cross-sectional area. Farrar and Hill cites studies showing forces of up to 4.5 kg (44 N) after 6 to 8 week training in latissimus dorsi tendons from 22 to 27 kg dogs and estimate 4–8 kg (40–80 N) as realistic from a human latissimus. From an estimated cross-sectional area (based on measurements of Sola et al.) of 20 cm², that would be 2–4 N/cm².

**Materials and Methods**

**Establishing Goals**

If such a fixation system is to function indefinitely, reasonable expectations include the following:

1. Ability to sustain an expected force of 6 N/cm² of greatest cross-section of the muscle being harnessed. This appears to offer an acceptable factor of safety relative to the above data.
2. Acceptable upper limits of compressive or shear stress on tissue. This is another unknown quantity. The general experience has been that constant pressures even slightly exceeding venous pressure are detrimental—witness decubitus ulcers in patients unable to change position in bed. In contrast, intermittent pressures of much greater magnitude are tolerated by some tissues. The soles of a runner's feet repeatedly receive an impact load of several times body weight on a very few square centimeters—easily several hundred pounds per square inch or many thousands of millimeters of mercury. The cartilage of a hip or knee joint is similarly loaded. However, these are tissues designed for impact loading. An admitted arbitrary limit for muscle was set far lower at 2,000 mmHg, sustained for <0.5 sec, and alternating with at least twice that duration of pressure in the subvenous range.
3. Freedom from major stress concentration in prosthetic structures, in view of extreme numbers of cycles to be sustained (about 16 million per year at a rate of 30/min).
4. Tissue contacting materials without known toxicity or excessive bioreactivity.

**Basic Concept for a Device**

1. The central idea underlying the present work is the use of very fine polymer fibers, placed in easily separable, untwisted, unbraided, and unplaited bundles or tows through a terminal portion of a skeletal muscle after sepa-
ration from tendon or origin. The total polymer cross-section would be small relative to that of muscle tissue, and yet surface area would be quite large due to small fiber size. Fibers would be formed in a sinusoidal pattern so that tension would effect lateral compressive forces against muscle (Figure 1, top) during contraction that would sum with the interstitial pressure developed during contraction.

2. Distribution and total length of the intra-muscular fiber would be such that shear forces (Figure 1, bottom), based on developed normal forces and estimated coefficient of static friction, would sustain expected tensile forces while maintaining normal forces below the arbitrary limit.

3. The continuing fibers, after exiting the muscle, would be organized—over a finite distance to lessen stress concentration—into a compact cord to transmit force.

4. A shape conforming non-adherent sheath over the cord and distal muscle would prevent lateral adhesions.

Calculations for a Hypothetical Prosthesis of Polyester Fibers

Quantitative considerations will be strictly dependent upon choice of materials and the particular muscle that is being harnessed. An example is given of the type of computations applicable to a prosthesis of arbitrary fiber dimensions, configuration, and load.

A fiber of 6 µm diameter, sinusoidal curvature of wavelength 0.5 π (1.5708) mm, and lateral amplitude ±0.125 mm is assumed. It is also assumed that, given the viscous behavior of muscle, the rapid onset of tension, and the presence of multiple nearby fibers with randomly opposing curvatures, deformity of muscle during force delivery will be negligible. An intramuscular length of 40 mm and a coefficient of static friction of 0.04 are modeled. An individual fiber end tension of 0.0005 N at muscle entry is assumed. This was modeled using a spreadsheet and both lateral compressive and shear forces computed for 0.1 mm segments. Lateral compressive force per unit length is the product of tension and local curvature, and shear force is the product of local compressive force and coefficient of friction. Each segment’s shear force reduces tension for the subsequent segment. For this example, only ~85% of the tension is dissipated, meaning that more fibers would be required to reduce each fiber’s entry tension.

A Specific Design and Its Fabrication

For guidance, a limited anatomic study was performed on five legs taken from 3 to 4 kg New Zealand White rabbits (following termination of unrelated other studies and death). The Achilles tendon and posterior tibial muscles were exposed through a longitudinal posterior incision and separated from surrounding tissue. Greatest muscle circumference was measured.

A prosthesis was designed and constructed of a commercially available bulk polyester fiber (Hoechst-Celanese, Charlotte, NC). Four tows of polyester fibers (scanning electron micrograph, ×200 and ×20,000; single fiber denier 5, or ~24 µm diameter) (Figure 2) were prepared with a total cumulative fibril cross-sectional area of ~3.5 mm² (~7,500 fibrils) and a total length of ~70 cm. The four tows were each swaged into

Figure 2. Scanning electron microscopy of the polyester fibers used. ×200 (top); ×20,000 (bottom).
dons of six 3 to 4 kg New Zealand White rabbits and left for 30 days so that tensile strength achieved could be measured. The tendon and the distal 1.5 cm of muscle were freed from surrounding tissue and most of the tendon removed. With the conical polyurethane sleeve inverted, each of the four polyester taws was brought from the cut end through the distal muscle obliquely three times in an “S” pattern (Figure 4) and out to the surface and cut. The sleeve was straightened to envelop the distal muscle and trimmed so that exposed fibers remained covered, the total remaining prosthetic surface was minimal, and the curved, trimmed edge meandered to minimize cicatrical effects of the scar at the margin. Interrupted (inverted knot) 8-0 sutures were used to “tack” the sheath margin to the muscular fascia (Figure 5). The cord was then measured, cut, and looped under and sewn to the posterior plantar fascia. Wounds were closed. Contralaterally, the tendon and distal muscle were similarly exposed, dissected, and closed without additional procedure. Animals were allowed unrestricted activity, and motion was observed daily for 30 days.

**Post Mortem Studies.** After death, the prosthesis and contralateral native tendon were dissected free of surrounding tissue and left attached to calcaneous and muscle. The muscle was in turn left attached to the tibia, and the hip was disarticulated. Location and extent of adhesions were noted. The legs were frozen at −70°C. They were then thawed by immersion in

**Experimental Evaluation**

**Mechanical Testing of the Prosthesis In Vitro.** Sample cords were tested for extensibility and tensile strength using a servo-hydraulic materials test frame. Thirty millimeter lengths were clamped and subjected to 10–90 N of force (sinusoidal at 0.5 Hz); cycles 31–40 were analyzed for tensile stiffness and hysteresis energy loss. Force was then applied at 180 N/sec until failure.

**Implantation and Post Operative Management.** The device was used as a unilateral replacement for excised Achilles ten-
out of tendon fibers from muscle. The 162.8 N mean experimental strength was 9.5 times the peak expected cyclic loading (17.2 N).

Discussion

The principal reason for this work was to see if early mechanical strength was sufficient to warrant expenditure of time and resources on an array of other questions, many quite complex. Several of these are questions that might be amenable to a simple model such as this, but for which the limited tools of the study as performed could not provide answers:

1. To what extent did cells and vessels surround and enclose individual fibers after this interval?
2. What was the extent of cell–polymer contact? Was it anything approaching the “osteointegration” that is sometimes achieved by hard tissue implants?
3. Did randomly opposing displacement forces from adjacent “wavy” fibers (plus tissue viscous behavior) actually ensure negligible lateral displacement during tension, as assumed in the computational model?
4. Did the true coefficient of static friction of individual fibers in healed tissue approximate the estimate on which computations were based?
5. At pullout, was the predominant plane of separation at the tissue–polymer interface or through the contiguous tissue?

There are additional questions that will require either longer studies or alternative animal models:

1. Does resistance to once applied high forces imply resistance to cyclically applied forces that are an order of magnitude lower? The pattern of healing in general is to remodel collagenous structures to meet applied forces,

Table 1. Mechanical Testing

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Tensile Stiffness (N/% elongation)</th>
<th>Tensile Strength (N)</th>
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<tr>
<td>Unimplanted prostheses: Cord of 7,500 24 micron fibers (combined cross section 3.4 mm²)</td>
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<tr>
<td>1</td>
<td>64.3</td>
<td>345</td>
</tr>
<tr>
<td>3</td>
<td>67.5</td>
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<td>4</td>
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<td>5</td>
<td>54</td>
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<table>
<thead>
<tr>
<th>Subject</th>
<th>Experimental Strength (N)</th>
<th>Control Strength (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant prostheses and contralateral controls:* Pullout strength at 1 mc, subjected to graduated force at 180 N/sec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>107.9</td>
<td>236.4</td>
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<td>1239</td>
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<tr>
<td>Mean</td>
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<td>243.1</td>
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<tr>
<td>Standard deviation</td>
<td>43.6</td>
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* $p = 0.849$ by one tailed t test for paired data.
as long as those forces are not sufficient to be injurious. Direct experimental study will be required.

2. What is the optimal fiber material? Possibilities include this or another type or size of polyester, Ultra High Strength Polyethylene (Spectra), and polypropylene. Besides mechanical behavior, cellular response may vary, as may availability in appropriate caliber.

3. What will be the responses observed after several months or years of in vivo loading?

4. Will a large polymer–tissue interface area in this configuration alter proteins or otherwise trigger autoimmune phenomena? This phenomenon has been documented for some experimental exposures to polymers and has been neither proven nor ruled out for clinical implants with large surface areas. An extensive contact area is the basis for mechanical function, but large contact areas will also amplify any unfavorable reactions. The device used in this experiment (24 mm, scaled to rabbit model) has 170 cm² of surface. The same device of 6 μm fibers would have 680 cm², while one scaled for a 750 gm human psos major might reasonably have twice the embedded fiber length and nine times the total fiber number, with a 12,224 cm² (1.224 m²) surface.

5. Will behavior be similar, except for scale, in larger animals and more massive muscles? Calculations indicate that the relationship of maximum expected tension (contractile force) to the maximum sustainable tension (bonding shear strength) will vary with muscle size. Peak contractile force varies with muscle cross-section. Shear strength varies with area of embedded fibers reasonably implantable in the distal muscle and thus roughly with total muscle mass. Generally, cross-section will vary as two-thirds power of mass. Therefore, the larger the muscle mass (if fiber caliber, frictional coefficient, proportional muscle dimensions, and normal forces are constant), the greater the ratio of sustainable to expected forces. For a human psos muscle, for example, a computational model similar to that used for the rabbit muscle indicates that a 60 mmHg intra-muscular contractile pressure alone would deliver over 1 ton of lateral force and, with a static frictional coefficient of only 0.02, would hold more than the expected 180 N (30 cm² cross-section and 6 N/cm² force assumed) maximum contractile force. Amplification of lateral force by tension curvature mechanisms would not be needed.

Conclusions

1. Mechanical behavior of the prosthesis as constructed is compatible with intended use.
2. There is no indication of biologic intolerance in this model for this duration.
3. Tensile strength of the tissue–prosthetic bond with this prosthesis at 30 days is sufficient that more extensive investigation is warranted.

References

26. Gottsaufer-Wolf F, Eggert EL, Markel MD, Schultz FM, Chao EYS:
Extracorporeal Life Support as a Post Left Ventricular Assist Device Implant Supplement

JAMES H. WUDEL, CHRISTOPHER C. HLOZEK, NICHOLAS G. SMEDIRA, AND PATRICK M. MCCARTHY

Extracorporeal life support (ECLS) is indicated following left ventricular assist device (LVAD) implant for right heart failure or pulmonary dysfunction. From December 1991 to December 1996, 100 patients were supported with the implantable HeartMate LVAD. Of these, 12 patients were supported with ECLS post LVAD implant. Pre-operatively, 10 patients (83%) were on an intra-aortic balloon pump, 9 patients (75%) were intubated, and 8 patients (67%) required ECLS bridge to LVAD implant. Six patients (50%) were men, and patient age ranged from 28 to 63 years (mean 46 ± 10 years). Duration of ECLS averaged 3 ± 2 days (range, 1-9 days). Eight patients (67%) required a right ventricular assist device (RVAD) with an ECLS circuit, three patients (25%) required peripheral veno-venous ECLS, and one patient peripheral veno-arterial ECLS. Forty-five percent supported with ECLS post LVAD survived to transplant compared with the 81% supported with LVAD only. Early in this experience, three patients had RVAD support only and all three patients died. RVAD support (with or without ECLS) was 11% overall and declined from 14% in the first 50 patients to 8% in the second 50. ECLS post LVAD is relatively uncommon and its use is associated with reduced survival, but helps salvage these critically ill patients. ASAIO Journal 1997; 43:M441-M443.

Extracorporeal life support (ECLS) is a temporary means of cardiopulmonary assistance following a variety of clinical situations. After left ventricular assist device (LVAD) implant, ECLS may be necessary for situations of perioperative right ventricular (RV) failure, respiratory insufficiency, or both. As no specific pre-operative indicators accurately predict who will require a RV assist device (RVAD) after LVAD, a versatile approach is needed in these critically ill patients.

To investigate the significance and influence of ECLS post LVAD implant, we retrospectively reviewed our clinical experience with patients who underwent LVAD implantation followed by ECLS.

Patients and Methods

Between December 1991 and December 1996, 100 patients were supported with the HeartMate (Thermo Cardiovascular, Woburn, MA) LVAD. A pneumatic LVAD was used in 64 patients, and vented electric left ventricular assist system (LVAS) in 36 patients.

Indications for Extracorporeal Life Support

ECLS was instituted secondary to refractory RV failure, respiratory insufficiency, or both. In all patients ECLS was initiated within 24 hr of LVAD placement. Early in our experience, RVADs were inserted only in those patients with RV failure and without signs of contributory pulmonary dysfunction. Recently, all patients requiring an RVAD were supplemented with an oxygenator as well. RVAD-ECLS was instituted only after the onset of refractory RV failure and not according to pre-operative RV indexes. Cannulation for RVAD-ECLS was via the common femoral vein and RV outflow tract. In three patients,