A muscle-powered energy delivery system and means for chronic in vivo testing

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Trumble, Dennis R., and James A. Magovern. A muscle-powered energy delivery system and means for chronic in vivo testing. J. Appl. Physiol. 86(6): 2106–2114, 1999.—Electrically stimulated skeletal muscle represents a potentially unlimited source of energy for the actuation of motor prostheses. Devices to harvest and deliver contractile power have proven mechanically feasible, but long-term efficacy has not been demonstrated. This report describes recent refinements in muscle energy converter (MEC) design and details the development of an implantable afterload chamber (IAC) designed to facilitate implant testing. The IAC comprises a fluid-filled bladder housed within a titanium cylinder that connects directly to the MEC. A vascular access port allows percutaneous measurement and adjustment of air pressure within the housing and provides a means both to monitor MEC function and to control hydraulic loading conditions. Data from in vitro tests show that IAC pressure mirrors changes in MEC-piston displacement over a wide range of actuation speeds and stroke lengths. Stroke lengths and actuation forces calculated from IAC pressure readings were typically found to be within 5% of measured values. This testing scheme may yield important information in regard to the ability to harness energy from in situ muscle over prolonged periods.

motor prostheses; latissimus dorsi; muscle power; chronic circulatory assist; internal power source

The loss of contractile function within specific muscle groups is responsible for a wide array of disabilities, from incontinence to heart failure, for which treatment options are limited. Duplication of muscular function via artificial means would be an ideal solution, but the complexities of converting chemical energy into mechanical work within the confines of the human body have stymied this approach. The use of electrically stimulated skeletal muscle as an endogenous power source offers an attractive alternative, because muscle-powered implants would tap the body’s own energy supply to restore function to the patient. The technology needed to extract mechanical energy from muscle tissue has been readily available for years in the form of implantable myostimulators, but there are presently no efficient means to harness and transmit this energy for use elsewhere in the body.

The impetus to develop a means to harvest muscle power is based on the supposition that ample contractile energy can be made available for chronic use via artificial stimulation techniques. Although there is little doubt that this assumption is valid for low-power and intermittent applications, such as sphincter control and limb actuation, less is known about the feasibility of the use of muscle power for high-energy applications, such as cardiac assist. The ability of chronically stimulated skeletal muscle to perform continuous work is well established (7, 13). However, the effects of different training regimens and stimulation patterns on long-term muscle function remain to be fully explored because of the complexities of monitoring chronic in situ muscle function under controlled loading conditions. As a result, the extent to which skeletal muscle can perform chronic work to support the failing heart remains largely unknown. Energy balance calculations and short-term stimulation experiments have yielded promising results (4, 21, 24), but these findings have proved difficult to confirm in longer term studies (20). It is, therefore, important that development of a muscle energy-transfer mechanism be accompanied by a practical means to test such a device under long-term implant conditions.

Efforts to develop a practical muscle energy converter (MEC) have recently been initiated in this laboratory and elsewhere (11, 22). Results from bench tests and acute implant trials suggest that collection and transmission of contractile energy is feasible from a mechanical standpoint, but long-term efficacy has yet to be demonstrated. The dearth of information about chronic in vivo device performance and the steady-state work capacity of in situ skeletal muscle can be attributed, in large part, to technical difficulties involved in the control of subcutaneous loading conditions and the monitoring of MEC function during extended implant trials.

These problems have been overcome with the development of an implantable afterload chamber (IAC) designed to provide both a regulated pressure load to the MEC and a simple means to monitor device performance in conscious animals. This in vivo testing scheme
requires no percutaneous connections and allows the animal to remain unencumbered between data sessions; thus the risk of infection is minimized while the MEC is allowed to function normally throughout the implant period. Through this mechanism, long-term studies of skeletal muscle function, tissue responses to MEC implantation, and the efficacy of biological attachment sites may now be pursued.

This report summarizes the principles that govern IAC operation and describes device assembly, IAC calibration techniques, and results from preliminary in vitro testing of the MEC-IAC system. Recent refinements in MEC design and functional capacity are also described.

**MEC-IAC DESIGN AND OPERATING PRINCIPLES**

**MEC Function and Current Configuration**

The MEC is an implantable device designed to transform the mechanical energy of in situ muscle contractions into hydraulic form and efficiently transmit this energy for use elsewhere in the body. Although this energy transmission scheme may potentially be configured to drive a variety of implanted motor prostheses, work to date has focused on ventricular-assist applications. The ultimate objective is to eliminate the need for external power supplies that are obtrusive, expensive, and contribute to infection and device failure rates.

Basically, the MEC comprises a sliding piston housed within a hydraulic cylinder (Fig. 1). This device weighs 91 g, occupies a volume of 26 cm³, and is designed to be implanted along the axillary line, beneath the humeral insertion of the latissimus dorsi (LD) muscle. The stainless steel housing is fixed to the rib cage, with its outlet port located distally and its long axis aligned with the primary force vector of the LD. The muscle is attached to the top of the piston via its humeral tendon so that linear shortening pulls the piston into the cylinder, and its contractile energy is thereby transferred directly to the fluid that supports the piston. As the muscle shortens, hydraulic energy is transmitted from the MEC under conditions of high pressure and low flow (a scheme chosen to minimize viscous and inertial losses). Short stroke lengths are employed to optimize device durability, minimize trauma to surrounding tissues, and reduce the kinetic components of muscle-power transmittal.

The central piston shaft rides within the cylinder on a single low-friction bushing that provides radial stability and guides the piston shaft along the cylinder’s long axis. Fluidic integrity is preserved via two edge-welded stainless steel bellows. These bellows also provide an axial force that extends the MEC during muscle relaxation to refill the pump and preload the muscle. Internal air vents are stationed around the bearing site to prevent piston damping caused by pressure swings within the bellows seals. MEC compression length is ultimately limited by the total collapse of the outer bellows, whereas piston arm extension is restricted by the complete collapse of the inner bellows seal. Each bellows comprises 80 convolutions, with a nominal spring rate of 1.2 N/mm and maximal stroke length of 67 mm. Actual stroke length is limited to 18 mm, however, to accommodate optimal LD shortening speeds and to minimize flexion stresses that can lead to bellows failure. A flexible polyester sheath (formed from a collagen-coated vascular graft) is used to prevent tissue infiltration of the outer bellows folds during the early postimplant period.

As described in a previous report, MEC function can be tailored to various applications via simple changes in bellows design. Initial prototype devices featured thin titanium bellows with low spring rates and a modest stroke-work potential (150 mJ). For this second prototype, stainless steel bellows were chosen to increase maximal pressure capacity by 750% (to 1,034 kPa) and, hence, significantly improve energy transmission capability to 1,125 mJ per 1.8-cm stroke. These high-pressure bellows have an effective pressure area of 0.6 cm² and thus serve to limit MEC stroke volumes to 1.08 ml or less.

The MEC is similar in function to another implantable energy transmission device presently under development at the California Pacific Medical Center and Thoratec Laboratories. Both are piston-based hydraulic pumps designed for attachment to the LD.
muscle near its humeral insertion. Design details, however, differ considerably. The California Pacific Medical Center-Thoratec pump features a central cylinder that houses a piston with a sliding O-ring seal. Two slide bars flank this cylinder and serve to counter the moment created by the offset between the muscle and central piston shaft. Four linear bushings are used to stabilize the slide bars and to center the piston shaft. The muscle attaches to a central slider that is fixed to the slide bars and moves with the piston. Moving parts are isolated from the body by two tapered rolling sheaths. This device measures 12.9 × 4.8 × 2.0 cm and has been tested successfully in acute implant trials (in goats) with the use of an external loading system. At 2 wk after implant, hydraulic pressures of 200 psi and energy-transfer levels of 1 J/stroke were achieved, and the device continued to cycle freely throughout the course of the 6-wk implant period.

Despite encouraging results from in vitro and short-term implant trials, however, neither device has been rigorously tested under the extreme operating conditions for which they were designed (i.e., chronic in vivo cycling against physiological loads). To facilitate such testing, we have devised an implantable loading system compatible with the high-pressure, low-volume hydraulics used by these devices.

IAC Design and Operation

The implantable afterload chamber is a small pressurized vessel designed to provide both a continuous, controlled load to the MEC and a reliable means to monitor long-term device performance in conscious animals. This device is an adaptation of an implantable mock circulation system originally developed by Acker et al. (1, 2) to study chronic function of skeletal muscle ventricles in free-running dogs. As the name suggests, this mock circulation device was originally designed to mimic arterial pressure loads for the purposes of evaluation of chronic skeletal muscle ventricle function. Recently, efforts to harness the power of in situ skeletal muscles have created an impetus to refine this technique for use with high-pressure, low-volume muscle energy transfer schemes. System modifications include significant reductions in housing and internal bladder volumes (tailored to accommodate small MEC stroke volumes), development of high-pressure subcutaneous-access port fittings, and the formulation of specific calibration techniques needed to correlate IAC pressure readings to MEC function and muscle performance.

The IAC comprises a thin titanium cylinder machined to accept insertion of a fluid-filled bladder that connects directly to the inlet-outlet port of the MEC via noncompliant polyvinylchloride tubing (Fig. 2). This air-tight housing communicates with a vascular access port (left) that allows percutaneous measurement and adjustment of air pressure between the housing and the latex bladder. A second subcutaneous access port (top) is used to adjust bladder filling volumes and to measure fluid pressures generated by MEC compression.

Before system implantation, the MEC, conduit, and bladder are completely filled with silicone oil, and the access ports are vented to air; this allows the 3.25-ml latex bladder to assume its preformed shape. A 1.5-ml bolus of fluid is then removed with a syringe to ensure that fluid pumped from the MEC will not expand the bladder beyond its resting volume (a condition that would complicate force calculations, due to the elastic properties of the bladder). Under these circumstances, fluid is ejected from the MEC only after LD contraction generates fluid pressures sufficient to overcome IAC...
resting pressure (P<sub>1</sub>). Once fluid pressure exceeds P<sub>1</sub>, bladder volume increases in proportion to MEC fluid displacement. This causes the volume of air within the IAC housing to decrease by an equal amount and thus to increase housing air pressure in accordance with Boyle’s law. At the end of LD shortening, which corresponds to maximal fluid volume displacement, air volume within the IAC is minimized (V<sub>2</sub>) and air pressure is maximized (P<sub>2</sub>). On LD relaxation, high air pressure acts in conjunction with bellows spring forces to collapse the bladder and return fluid to the MEC.

MEC stroke volume is calculated on the basis of changes in IAC air pressure (which are directly proportional to the amount of fluid pumped into the bladder). Because P<sub>1</sub> and P<sub>2</sub> are measured directly, and V<sub>1</sub> (initial air volume) is known at the time of IAC fabrication, V<sub>2</sub> can be readily calculated by using Boyle's law (P<sub>1</sub>V<sub>1</sub> = P<sub>2</sub>V<sub>2</sub> at constant temperature). Once V<sub>2</sub> has been established in this manner, MEC volume displacement is simply taken as V<sub>1</sub> − V<sub>2</sub>. This technique eliminates the need for an implanted flow probe (and its attendant percutaneous connectors) and allows the MEC-IAC system to function indefinitely with minimal risk of infection.

IAC pressure readings, together with known values of bellows spring rate and effective pressure area, can be used to calculate MEC actuation force, stroke length, compression rate, displacement volume, stroke work, and both instantaneous and mean power production. Moreover, MEC-loading conditions can be adjusted in vivo to optimize steady-state power output by simply injection of or removal of gas from the IAC via its terminal access port. In this way, hydraulic resistance can be incrementally adjusted until muscular contractions produce maximal MEC stroke work (as determined from IAC-pressure waveforms). These conditions can be maintained throughout the implant period, and data collected on a regular basis can be used to document changes in MEC performance. This will help to identify conditions under which maximal work levels are achieved and will help to establish the time course of contractile changes with muscle conditioning.

**MATERIALS AND METHODS**

A fully functional MEC-IAC system was tested in vitro to determine the accuracy of this percutaneous monitoring scheme. IAC pressures were measured under various contraction profiles and loading conditions and subsequently were used to calculate MEC performance parameters. The accuracy of this technique was determined by comparison of these figures with concurrent measurements of MEC actuation force and piston displacement. The experimental setup described below was designed to simulate actuation and loading conditions anticipated in vivo.

Muscular compression was simulated on the bench by using an instrumented pull bar that was activated manually (Fig. 3). This bar was attached to the MEC-muscle interface via a thin cable to simulate the asymmetrical pull of the LD muscle on the piston head. MEC actuation rate and stroke length were varied to cover a wide range of fluid-ejection profiles. Hydraulic fluid expelled from the MEC [DC200 silicone oil (~12 mPa/s), Fluka Chemical, Ronkonkoma, NY] was channeled through a 30-cm length of high-pressure polyvinylchloride tubing (4.8-mm inner diameter) to the inlet port of the IAC. A miniature load cell (model ELH-TC401, Entran Devices, Fairfield, NJ) was mounted between the drive rod and MEC to measure forces applied to the muscle interface. Piston motion was monitored with an inductive displacement transducer (DCT-500C, RDP Electrosense, Pottstown, PA) attached to the MEC piston head. IAC pressures were measured with an EPX-series subminiature pressure sensor (Entran Devices) mounted on a Huber-point needle as shown in Fig. 4.

All signals were digitized at a rate of 200 samples/s and were stored in an IBM 300PL personal computer via a commercially available data-acquisition package (Windaq, Dataq Instruments, Akron, OH). These data were then post-processed by using XANALYZE, a comprehensive waveform-analysis program developed at the National Institutes of Health (19). The data presented are typical results from multiple trials that showed no measurable variability among runs. Linear regression analyses were performed using Mathcad software (MathSoft, Cambridge, MA). Summary data are expressed as means ± SD.

**RESULTS**

Typical force, displacement, and pressure waveforms generated during tests of the device are shown in Fig. 5. As expected, oscillations in IAC pressure closely mirror changes in MEC-piston displacement over a wide range of actuation speeds and stroke lengths. The degree to which IAC air pressure follows MEC-piston position can be seen in Fig. 6, where these two waveforms are plotted one over another. These data demonstrate that MEC motion can be accurately monitored via percutaneous pressure measurements and that no significant waveform damping occurs with this method.

The accuracy of stroke-length calculations computed from IAC pressure port readings is shown in Fig. 7. Piston displacement was calculated for stroke lengths that ranged from 0.5 to 17.9 mm and was found to be in substantial agreement with measured values. Linear-regression analysis of these data yielded a correlation coefficient (r) of 0.994 and a slope close to unity (0.98).

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**Fig. 3.** Schematic diagram of experimental setup (drawn to scale except for tubing length). 1, baseplate; 2, displacement transducer-MEC coupling; 3, tendon attachment site; 4, MEC; 5, inductive displacement transducer; 6, miniature load cell; 7, high-pressure polyvinylchloride tubing; 8, pull bar; 9, IAC; 10, percutaneous access port (fluid); 11, percutaneous access port (gas).
Absolute differences between measured and calculated values averaged 0.44 ± 0.32 mm. Relative differences averaged <5%.

Similarly, estimates of MEC-actuation forces were found to approximate closely those forces measured directly at the LD tendon attachment site. Forces were calculated on the basis of changes in IAC air pressure, taking into account MEC piston area and effective bellows spring rate. These data are shown in Fig. 8, plotted against peak force measurements (range, 24–144 N). Again, linearity was found to be high (r = 0.995) with a slope close to unity (0.95). Initial calculations were slightly higher than were measured forces by an average of 5.4 ± 3.3 N (8.9 ± 6.9%). Force calculations adjusted to this offset factor differed from measured values by 0.02 ± 3.3 N (0.6 ± 4.4%).

**DISCUSSION**

Skeletal muscle is the most abundant tissue in the human body, accounting for ~25% of total body weight in women and 40% in men (15). These biological engines convert chemical energy into mechanical work with a proficiency unequaled by artificial means and, hence, skeletal muscle represents an attractive source of power for implanted devices. However, implementation of muscle-powered implants has been hindered by technical difficulties associated with 1) measurement of...
the energy available from skeletal muscle under actual working conditions, and 2) means to harness and deliver this energy for use elsewhere in the body. This report summarizes our efforts to provide a simple means to both monitor the long-term function of electrically stimulated skeletal muscle in situ and efficiently convert contractile power into hydraulic form for mechanical actuation of implanted prostheses.

Numerous studies suggest that certain large skeletal muscles have the potential to generate steady-state (aerobic) power at levels sufficient to support even the most energy-intensive applications (i.e., circulatory assist). For example, in 1986, Ugolini (24) published a conjectural treatise based on the energetic limits of the human psoas major muscle and predicted a steady-state power capacity of 5.19 W (6.92 mW/g). Five years later, Geddes and Badylak (4) used the rate of muscle O₂ consumption to place the chronic power available from working skeletal muscle at 6.03 mW/g. With the use of a muscle the size of a human LD (600 g), these power levels would be more than sufficient to drive an artificial heart (typical power output, 1.3 W) if a means could be devised to efficiently convert this energy into pumping power. However, these estimates of chronic work potential have yet to be confirmed experimentally under actual cardiac-assist conditions. As a result, the extent to which skeletal muscle can perform chronic hemodynamic work has not been fully established.

In principle, the most effective way to harness muscular work is to employ a linear arrangement, with the muscle tendon detached from its natural insertion point and reconnected to a pulsatile energy converter. This hypothesis has been tested by Sakakibara et al. (12), who evaluated the performance of LD muscle in three orientations: wrap type, compressive type, and linear type. This study showed that linear actuation produced a sixfold improvement in work output over the wrap type and a 50% increase over the compressive arrangement.

Despite the apparent advantages of linear actuation, most studies of muscle power for cardiac assist have either employed wrap configurations or isolated the muscle from its collateral circulation; this leaves only its insertion and neurovascular supply intact (2, 5, 10, 18). These techniques have clearly restricted muscle performance and have, therefore, yielded little information in regard to the ultimate capacity of skeletal muscle to pump blood. One notable exception can be
found in a 1988 publication by Stainsby and Andrew (17), which describes the power output of in situ canine gastrocnemius-plantaris muscle that contracted linearly against a pneumatic muscle lever. In this study, power levels of 19.0 mW/g were recorded for muscles tested under minimally invasive conditions. These data, however, cannot be used to predict the long-term performance of trained skeletal muscle, because only normal (untrained) muscles were studied under brief periods of activation (range, 30 s to 4 min).

An analogous study was recently performed in this laboratory by using trained LD muscles in dogs (20). In that experiment, a custom ergometer was used to measure the external work of electrically stimulated skeletal muscle that contracted once per second over four contiguous hours. Contraction lengths were limited to 10 mm, and hydraulic-loading conditions were adjusted to optimize LD stroke work. Results suggest that fully trained skeletal muscle left in situ can provide as much as 2.06 mW/g of steady-state mechanical power at contraction rates compatible with cardiac assist applications. Due to the limited duration of these tests, however, there remains a need to confirm these findings via chronic implant studies.

Among the most comprehensive studies of the steady-state working capacity of skeletal muscle have been those of Jarvis (7) and Salmons and Jarvis (13, 14). They designed and built a novel apparatus to measure the dynamic properties of rabbit tibialis anterior muscles in situ. This apparatus comprises a digitally controlled electrohydraulic system that allows muscle force to be measured at preset velocities of shortening. This system can also be arranged so that muscles contract cyclically around a known point on their power-velocity curves while work output is monitored on a continual basis. With the use of this apparatus, complete sets of force-length, force-frequency, force-velocity, and power-velocity curves were compiled for tibialis anterior muscles and were used to design endurance studies. For fatigue testing, both conditioned and control muscles were made to contract at velocities that generate maximal instantaneous power and at such repeat frequencies that their time-averaged initial power outputs were the same. Fatigue tests were performed with comparable initial work outputs (10 mW/g) for up to 7 contiguous hours to relate steady-state work output to that required for circulatory support. Having studied muscles trained for 11 wk via continuous 10-Hz stimulation, Salmons and Jarvis (13) conclude that “sustained work at a rate of 4 W/kg is not an unrealistic proposition for a suitably conditioned muscle.”

Although these prior studies provide important information about contractile characteristics of trained and normal muscle, there are several reasons to suspect that these constant-velocity experiments do not accurately predict the sustainable power available from a muscle under cardiac-assist conditions. First, it is probably rare for muscle-shortening velocity to be both constant and optimal for power output throughout the shortening phase. In fact, for many sequentially activated muscles, shortening trajectories are close to sinusoidal (8). The maximum power available from a muscle that shortens with this trajectory is expected to be 10–20% less than would be obtained were the muscle to shorten only at optimum velocity. Second, muscle activation and relaxation are not instantaneous processes. A muscle does not become immediately and fully active at the onset of shortening nor instantly relaxed at the end. The extent to which muscle activation is incomplete as it shortens reduces muscular work. Moreover, the degree to which the muscle remains active into the lengthening phase increases the work required to reextend the muscle and reduces the net work performed over a full cycle. Finally, these experiments set the period of activation to correspond with the time taken for full excursion (~30% of in vivo muscle length). It is unlikely that muscles that operate under cardiac-assist conditions would be able to shorten to this extent due to the short cycle times required to keep pace with the heart. Clearly, future studies of muscle performance must be conducted under more realistic circumstances to accurately assess the feasibility of muscle-powered cardiac assistance.

We have attempted to address these shortcomings with the development of an implantable afterload chamber designed to provide both a regulated pressure load and a simple means to monitor long-term MEC performance in conscious animals. Data from in vitro tests have demonstrated the efficacy of this approach by confirmation of the accuracy of MEC actuation force and stroke length estimates based solely on IAC pressure measurements. Because these pressure waveforms closely follow changes in MEC piston position (see Fig. 6), displacement curves can be reliably reproduced from pressure readings by simple calibration of pressure-waveform amplitudes with corresponding displacement calculations. Displacement and pressure data can then be combined to determine other performance parameters such as shortening speed, stroke work production, and instantaneous power levels.

It is important to note that MEC-IAC dynamics should always be evaluated in vitro before implantation, both to verify proper device function and to optimize system accuracy. Once preliminary bench tests are completed, small discrepancies between measured and estimated values can be minimized by adjustment of estimated device constants (e.g., initial IAC air volume) to more accurately track MEC performance parameters. Correction factors can also be introduced if bench-top calibration measurements reveal consistent differences between measured and calculated values (used here to reduce mean errors in force estimates from 8.9 to 0.6%).

This method of monitoring chronic muscle function may open new avenues for research in the fields of biomechanics and tissue engineering. For instance, long-term studies could be conducted to determine the stimulation patterns and loading conditions that best preserve the strength and speed of fatigue-resistant muscle. Experiments could also be performed to document the time course of functional changes brought...
about by chronic muscle conditioning, 2) measure the steady-state work capacity of stimulated skeletal muscle, 3) quantify the effects of pharmacological interventions on muscle mechanics, and 4) study the effects of myoblast transfer and gene therapies on contractile function. The ability to study in vivo muscle mechanics over prolonged periods could thereby improve our understanding of skeletal muscle energetics and help to establish the limits within which biomechanical prostheses may safely function.

Tissue Interactions and Device Attachment Issues

Apart from questions that concern the steady-state work capacity of skeletal muscle, several important feasibility issues that involve chronic MEC function have yet to be addressed. One important question is whether such dynamic implants might eventually become mired in scar tissue and cease to function. These concerns are based on biological healing and encapsulation processes known to occur with long-term metallic implants; cardiac pacemakers are the most common example (16, 22). On the basis of extensive clinical experience with chronic pacemaker implants, we believe that the MEC will inevitably become encapsulated by a layer of fibrous tissue that comprises mostly type I collagen fibers. Whether this encapsulation process can be prevented from substantially restricting MEC piston motion is largely unknown. We suspect, however, that repeated cycling of the device during the early stages of implantation may prevent fibrous attachments from adhering to the kinetic portion of the implant. This supposition has recently been tested by Reichenbach et al. (11) through short-term (6-wk) implantation of a similar device in goats, with the use of an external loading system. They report that “upon explant, a fibrous layer was encapsulating the implanted [energy] convertor; however, the layer was not adherent to [the] device surface and did not appear to hinder device function.” Chronic implant trials (now made possible with development of the IAC) will be needed to determine whether unencumbered device actuation can be maintained over the long term.

Another problem that could severely limit the efficacy of this device involves potential difficulties in establishment of stable tissue attachments. There is no doubt that development of a secure tendon attachment scheme is essential to the viability of harnessing in situ muscle power via the MEC. Numerous methods to effect a secure bond between the device and muscle tendon are presently being considered. In addition to the tendon-loop method described previously (see Fig. 1), a tendon-clamp mechanism has been devised, whereby the tendon is inserted into a toothed clamp attached to the piston head. This fixation scheme was recently tested (in dog) in an acute implant trial in which stable LD tendon attachment was maintained against repeated isometric contractions that generated >100 N force (unpublished observations). Future trials may also include the use of tendon-bone blocks (6) and porous metallic surfaces designed to induce biological fixation via tissue ingrowth (3). Another possible method of LD fixation involves fine, unbraided polymer fibers sewn into the muscle tendon, with the braided end used for device fixation, as described by Melvin et al. (9). These fixation schemes may all be enhanced by the use of fibrin glue or medical-grade adhesives applied to the attachment site.

In addition to development of stable tendon-fixation techniques, we are presently considering several methods to secure the MEC to the rib cage. Work continues in conjunction with Encore Orthopedics (Austin, TX) to develop a simple means to screw, bolt, clamp, wire, or otherwise affix the MEC housing to the ribs. A prototype scheme that uses a single plate secured with bone screws was recently implanted in a dog for 35 days. On explant, the MEC was found to be firmly fixed to the ribs due, in large part, to fibrous tissue ingrowth at the attachment site. However, because of the thin periosteum of the ribs, cortical bone screws proved difficult to tighten, and they eventually came loose in most instances. This initial experience suggests that stable rib cage attachment might be achieved if purely mechanical attachments can be maintained long enough to allow fibrous ingrowth through a porous substrate. Plans to refine rib cage attachment include the replacement of bone screws with bolts that clamp and/or the substitution of tantalum wire mesh for the main anchor plate to maximize fibrous tissue adhesions around the MEC housing.

Conclusion. In summary, this report describes refinement of an implantable MEC and development of a means for chronic implant testing. This in vivo monitoring scheme eliminates the need for percutaneous connections, minimizes the risk of infection, and allows the MEC to function against realistic, controlled loading conditions. In vitro studies have shown that important device parameters can be monitored via pressure measurements made through a single percutaneous access port. This method of monitoring MEC function may yield important information concerning the work capacity of chronically stimulated skeletal muscle, tissue responses to long-term kinetic implants, and the degree to which in situ muscle power may be used to assist the failing heart.

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