A permanent prosthesis for converting in situ muscle contractions into hydraulic power for cardiac assist

DENNIS R. TRUMBLE AND JAMES A. MAGOVERN
Cardiovascular and Pulmonary Research Center, Department of Surgery, Allegheny General Hospital, and Allegheny University of the Health Sciences, Pittsburgh, Pennsylvania 15212

Trumble, Dennis R., and James A. Magovern. A permanent prosthesis for converting in situ muscle contractions into hydraulic power for cardiac assist. J. Appl. Physiol. 82(5): 1704–1711, 1997.—The key to utilizing muscle power for circulatory support lies with the development of a practical scheme by which contractile energy may be collected and efficiently delivered to the bloodstream. This work describes initial in vitro testing of a prototype muscle energy converter (MEC) designed to transform the power of in situ muscle contractions into hydraulic form. The MEC resembles a simple piston pump and is designed for implant beneath the humeral insertion of the latissimus dorsi muscle. Bench tests were conducted to measure component function and to characterize device performance under various hydraulic loads. Under simulated muscle-pull conditions, MEC energy transfer capacity was found to be 170 mJ/stroke while operating at peak efficiencies (i.e., >98% of input power converted into hydraulic energy and preload work). Transfer efficiencies dropped from 96 to 38% as mean generated pressures increased from 23 to 36 N/cm² due to metal bellows flexion. These results demonstrate that a significant amount of contractile energy can be efficiently transformed to hydraulic power via this mechanism.

latissimus dorsi; muscle power; heart-assist device; burst stimulation; skeletal muscle

Scientists and engineers have been struggling for decades to develop a permanent prosthesis to assist the failing heart. Early work in the 1950s was sparked by the notion that the heart was, by virtue of its mechanical function, amenable to mechanical replication. At that time, replacement of the native heart by an implantable pump seemed not only possible but fairly straightforward. Expectations were further heightened in 1964 when the (then) National Heart Institute established The Artificial Heart Program in an effort to develop a completely mechanical replacement for the heart by the year 1970. Progress toward this ambitious goal, however, was soon slowed by technical and biological problems that exposed the true complexity of this endeavor. Twenty-seven years later, despite significant advances in implant technology, several obstacles to long-term circulatory support still persist.

Perhaps the most difficult problem facing researchers in this area is the need to develop an implantable power source to drive the device. Ventricular-assist devices (VADs) currently in use employ external power supplies with energy transmitted across the skin via tubes, wires, or electromagnetic fields (8, 19, 20). These schemes work well for short-term applications but may not be appropriate for chronic use because of problems with drive-line infection and concerns over the mechanical reliability and obtrusiveness of transcutaneous transformers. Clearly, an alternate means of power generation and delivery is needed to circumvent the problems caused by these extracorporeal power schemes.

The use of electrically stimulated skeletal muscle as an endogenous power source offers an attractive alternative to chronic drive systems currently in use. Muscular-powdered devices have the potential to greatly simplify cardiac implants by eliminating electromechanical components and by avoiding the need to transmit energy across the skin. This approach is especially appealing when one considers the substantial quality-of-life benefits to be derived from a self-contained system free from external components and daily maintenance. Moreover, the relative simplicity of such systems would drastically reduce the cost of long-term cardiac support, increasing its viability from a societal perspective.

In an effort to reduce this concept to practice, we have designed and patented a practical muscle energy converter (MEC) that is both biocompatible and highly efficient. This report summarizes our general approach and describes overall MEC operation, specific device components, and results from preliminary in vitro tests.

DEVICE OVERVIEW

The purpose of the MEC is to efficiently convert the power of in situ muscle contractions into a form that can be used by a wide variety of implanted hydraulic actuators. Although this device was originally conceived as a means to facilitate chronic circulatory support, other potential applications include actuation of prosthetic limbs, respiratory support via diaphragm displacement, augmentation of lymphatic flow, sphincter control, and so on.

Work to date has yielded a prototype device resembling a simple hydraulic piston pump (Fig. 1). This device is designed to be implanted along the axillary line, beneath the humeral insertion of the latissimus dorsi (LD) muscle (Fig. 2). The cylindrical 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 proximal tendon (humeral insertion) so that linear shortening pulls the piston into the cylinder, thereby transferring its contractile energy directly to the fluid supporting 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 (~1 cm) are employed to optimize device durability, minimize trauma to surrounding tissues, and reduce the kinetic components of muscle-power transmittal.

The internal piston shaft rides within the cylinder on a single low-friction bushing that provides radial stability and guides the piston shaft along the cylinder long axis (Fig. 3). Fluidic integrity is preserved via two edge-welded titanium bellows: the inner bellows provides a seal to contain the hydraulic fluid, whereas the outer bellows prevents biological debris from reaching the bearing surfaces. These bellows (with a predicted...
flex life $>10^{12}$ cycles) 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. Permanent magnets are incorporated into the piston head and outlet port to provide a passive magnetic bearing effect designed to limit stroke length and prevent piston-port impacts during forceful or prolonged contractions. Piston arm extension during periods of muscle relaxation is ultimately limited by the complete collapse of the inner bellows seal.

MEC function can be tailored to various applications via simple changes in bellows design. For this first prototype, thin bellows (0.002-in. diaphragm thickness) were chosen to create low preload forces and a stroke work capacity of 150 mJ. In this configuration, MEC stroke work capacity is limited by the deformation of the bellows diaphragms at high pressures ($>20$ N/cm$^2$) but offers the advantage that modest actuation forces (20–30 N) can be used to effect partial cardiac assist. Stroke work capacity can be readily increased for full circulatory support with the substitution of thicker bellows (0.0035 in.); however, in this case, more contractile energy would be needed to compress the stiffer bellows.

**DIMENSIONS**

The MEC readily lends itself to implantation beneath the LD muscle because of its compact size and short stroke length. The titanium housing, including the outlet port, is 8.3 cm long with a maximum outside diameter of 3.0 cm. The inner and outer diameters of both bellows measure 0.59 and 1.57 cm, respectively, yielding an effective pressure area of 0.92 cm$^2$. Stroke length is limited to 1.3 cm, corresponding to a peak stroke volume of ~1.2 ml. The maximum length of the MEC, including the outlet port and fully extended piston, is 12.9 cm. The entire device weighs 142 g and occupies a volume of 50 cm$^3$.

**BIOCOMPATIBILITY**

Tissue response to long-term MEC implantation will likely parallel pathobiological changes that typically occur with other titanium implants, cardiac pacemakers being the most common example. In most circumstances, wound healing and tissue repair begin immediately after device placement and progress through three distinct phases: inflammation, cell proliferation, and tissue remodeling (25). The initial inflammatory response serves to prevent bleeding and attract circulating macrophages and other leukocytes that remove damaged tissue, bacteria, and necrotic cells. The proliferative phase involves the migration of fibroblasts, endothelial cells, and epithelial cells to the wound site and is frequently accompanied by angiogenesis, reepithelialization, and biochemical changes in the extracellular matrix. The final phase (remodeling) involves the formation of a fibrotic capsule (i.e., scar tissue) formed via synthesis, deposition, and reorganization of large fibers composed primarily of type I collagen.

A flexible Teflon sheath will be used to prevent tissue infiltration of the outer bellows' folds during the early phases of wound healing. On the basis of the body's response to implanted materials (described above) and our experience with pacemaker implants, we believe the entire device will gradually become encapsulated by a layer of fibrous tissue that will act as a second, more permanent barrier against biological intrusions. Serous fluids secreted within this fibrous capsule should also protect against piston binding by acting as a natural lubricant.

**MEC CONTROL AND ADJUSTMENT**

The output characteristics of the MEC are governed by the contractile properties of the LD muscle. However, the timing and duration of these contractions are ultimately dictated by an implanted cardiomyostimulator (e.g., Medtronic 4710 Transform) that delivers a rapid succession of pulses to the muscle nerve. These commercial stimulators are fully programmable via transcutaneous telemetry and provide a wide variety of stimulation and cardiac synchronization modes, including nonsynchronous operation (5, 12). As a result, stimulation profiles can be easily modified to alter LD dynamics and control MEC function.

**USING THE MEC FOR CARDIAC SUPPORT**

The MEC may be used to drive a wide variety of ancillary devices designed to provide chronic circulatory support. The use of conventional blood pumps modified to accept low-volume hydraulic actuation is an attractive option that has been proposed elsewhere (2). This approach offers the shortest development periods due to reliance on well-established cardiac-assist techniques and hardware. However, it seems likely that devices specifically engineered to exploit MEC outputs will ultimately prove more effective than those originally designed for pneumatic or electric actuation.

Regardless of the terminal assist device used, every muscle-actuated ventricular-assist system (MAVAS) will comprise five main elements: an implantable myostimulator; in situ skeletal muscle; a muscle-energy conversion device; a power transmission conduit; and a pulsatile blood pump. Systems designed to provide partial assistance will employ a cardi synchronous stimulator to coordinate MEC actuation with the cardiac cycle. Possible blood pump options include intra-aortic balloons, extra-aortic compression devices, intraventricular balloons, cardiac compression devices, prosthetic ventricles, and total artificial hearts.

Given the inherent long-term nature of any MAVAS implant, system complexities should be minimized to increase reliability and reduce chronic maintenance concerns. Therefore, initial MAVAS development should focus on assist techniques that avoid the use of blood-contacting surfaces, valves, and compliance chambers. The two pumping schemes that meet these criteria are extra-aortic counterpulsation and direct cardiac compression. Mechanisms to realize both assist techniques are presently under development in this laboratory and...
will be refined to accommodate MEC outputs measured during chronic in vivo studies.

**MATERIALS AND METHODS FOR IN VITRO TESTING**

**Component testing.** Bellows spring rates were measured by using a thin-beam load cell (model LCL-010, Omega, Stanford, CT) mounted on a high-precision lead screw positioner (Velmex, East Bloomfield, NY) to quantify their individual contributions to muscle preload. The MEC was then completely assembled and placed in the same test apparatus to measure the overall preload characteristics of the device.

**Device testing.** A fully functional MEC prototype was tested in vitro to determine energy conversion efficiency and characterize device function under various load conditions. The experimental setup described below was designed to simulate the high-pressure pumping and low-pressure filling conditions anticipated in vivo.

Muscular compression was simulated on the bench by using a variable-speed rotary motor attached to a reciprocating rod guided by a Teflon bushing, as shown in Fig. 4. This rod was attached to the MEC muscle interface via a Teflon felt strip to simulate the asymmetric pull of the LD muscle on the piston head. MEC actuation rate and stroke length were set at 60 cycles/min and 1.05 cm, respectively. Hydraulic fluid expelled from the MEC [DC200 silicone oil (~12 mPa/s), Fluka Chemical, Ronkonkoma, NY] was channeled through a high-resistance needle valve to regulate pressure generation. Fluid pumped past this valve entered a graduated cylinder (for stroke volume measurement) and was returned to the MEC via a low-pressure reservoir connected to the outlet port through a check valve. A thin-beam load cell (LCL-040, Omega) 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. Pressures were measured with a stainless steel pressure transducer (MSP-300, Digi-Key, Thief River Falls, MN) positioned proximal to the needle valve.

All signals were digitized at a rate of 200 samples/s and stored in a Compaq 386/25 PC via a commercially available data-acquisition package (CODAS, Dataq Instruments, Akron, OH). These data were then postprocessed by using XANALYZE, a comprehensive waveform-analysis program developed at the National Institutes of Health (27).

**RESULTS**

**Preload characteristics.** Bellows return forces are plotted against stroke length in Fig. 5 along with the braking force supplied by the magnetic thrust bearing.

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**Fig. 4.** Schematic diagram of experimental setup. 1, Variable-speed rotary motor; 2, baseplate; 3, rotary-to-linear coupling; 4, reciprocating rod; 5, Teflon bushing; 6, displacement transducer/MEC coupling; 7, thin-beam load cell; 8, Teflon felt strip; 9, MEC; 10, anchor block; 11, inductive displacement transducer; 12, high-pressure tubing; 13, 4-way hydraulic coupling; 14, pressure transducer; 15, check valve; 16, high-resistance needle valve; 17, graduated cylinder; 18, low-pressure reservoir. Arrows indicate direction of fluid flow.

**Fig. 5.** A: preload forces generated by 2 bellows working individually. Inner bellows generates a negative force throughout much of stroke (meaning that its spring force is working against outer bellows to pull piston into cylinder). Both bellows work in compression to maximize durability. B: preload forces generated by bellows working in tandem, with and without magnetic thrust bearing in place. Note that force of magnets does not significantly retard piston motion until stroke length exceeds 10 mm.
Opposing bellows spring forces cancel at an outer bellows length of 35 mm (stroke length = 0), but their sum increases linearly to 8.03 N as stroke length approaches 15.5 mm. The magnetic thrust bearing adds no preload force at stroke lengths <5 mm and contributes only 3.6 N when stroke length equals 10 mm. However, as stroke length increases beyond 10 mm, the repulsive force between the magnets rapidly becomes dominant, adding 62 N of return force as stroke length approaches 14.5 mm.

Energy transfer efficiency. Typical displacement, force, and pressure waveforms generated during device testing are shown in Fig. 6. Work input and the various components of work output are displayed graphically as a function of mean generated pressure in Fig. 7. The energy required to compress the bellows (and thus provide preload to the muscle) was calculated to be 35 mJ for the stroke length used (10.5 mm). Total work output was taken to be the sum of the hydraulic and preload work performed by the MEC. Differences between input work and total output work represent dissipative energy losses due to friction, inertia, fluid viscosity, and bellows deformation.

For mean stroke pressures between 8 and 20 N/cm² [12–29 lb/in.² (psi)], 20–33% of input energy was converted to preload work, whereas the remaining 67–80% appeared as hydraulic power. Dissipative losses in this operating range were too small to be measured. As expected, mean pressures >25 N/cm² (36 psi) caused significant decreases in device efficiency and MEC stroke volumes (falling to 0.12 ml at mean pressures >36 N/cm²). These losses were due to bellows deformation caused by the increased pressure gradient across the thin bellows diaphragms (as evidenced by the gross reductions in stroke volume). These data strongly suggest that, for this particular prototype, mean output pressures should be kept <20 N/cm² to optimize energy transfer efficiency and preserve inner bellows durability.
DISCUSSION

The use of skeletal muscle as an endogenous power source affords a unique opportunity to bring a completely implantable, tether-free cardiac-assist system to fruition. Muscle-powered devices offer an attractive alternative to current long-term support schemes by eliminating the need to transmit energy across the skin, thereby reducing hardware requirements significantly. Through this mechanism, external battery packs, power-conditioning hardware, transmission coils, and internal power cells could all be replaced by natural biomechanical processes, serving to greatly enhance patient quality of life by improving reliability and eliminating all external components. Moreover, muscle-based blood pumps should be much less expensive to implement and maintain, resulting in wider availability and reduced costs for health care providers.

Of course, the feasibility of biomechanical circulatory support ultimately hinges on the ability of skeletal muscle to generate useful hemodynamic work on a continual basis. The persistent problem of muscle fatigue seemed to preclude such bioactuated systems until 1976, when Salmons and Sreter (23) demonstrated that skeletal muscle could be electrically “conditioned” to resist fatigue. Since that time, a number of investigators have quantified the chronic power output of trained skeletal muscle, both in theory and via direct experimentation (4, 22, 29; D. R. Trumble, W. L. Framboise, C. Duan, and J. A. Magovern, unpublished observations). Predictions of steady-state work capacity range from 2.0 to 15.0 mW/g of muscle tissue. Adopting the lowest figure, one can easily calculate that a trained muscle weighing 550 g could supply the 1.1 W required to move 5 liters of blood each minute across a pressure gradient of 100 mmHg. This muscle mass requirement is compatible with the use of human LD muscles that averages 600 g in the male (21). Actual power requirements will depend on the degree of circulatory support needed and the efficiency of muscle power conversion and transmission.

Questions concerning the long-term viability of muscle-powered systems have, to date, been addressed most effectively via chronic studies of skeletal muscle ventricles (15). In this “wrapped” configuration, stimulated LD muscles have been shown to maintain diastolic pressure augmentation for up to 836 days, thus proving that muscle fatigue and desensitization to electrical stimulation can be avoided indefinitely. These results, combined with data from ergometric studies of trained LD (described above), suggest that significant amounts of energy can be obtained from chronically stimulated skeletal muscle over long periods of time.

Given what is known about the energetic capacity of trained skeletal muscle, the main proviso to effective muscle-powered cardiac assistance is the development of a practical means by which this contractile energy may be harnessed and efficiently transmitted to the blood. To date, most attempts to harvest muscle power for circulatory assist have involved isolating the muscle (usually the LD) and wrapping it around the heart, aorta, or some other blood-filled vessel to provide direct energy transfer to the bloodstream (13–15, 17). Still others have chosen to use in situ LD contractions to compress a hydraulic pouch positioned between the muscle and rib cage (11, 16). These approaches are intuitive and direct but do not make efficient use of skeletal muscle power and have generally produced equivocal results.

The principal cause of this poor performance, aside from the ischemic effects of muscle mobilization, is the mechanical inefficiencies endemic to all muscle-wrap procedures. Skeletal muscles contain myofibers arranged linearly to produce shortening in one direction. Therefore, wrapping the muscle produces a pulling, twisting motion with much less compression than is achieved by a ventricle of similar mass. Likewise, compression devices placed beneath the muscle access only a small fraction of the available force because their movement is nearly perpendicular to the primary force vector of the muscle. It is apparent that these techniques are not the best way to harvest useful work from skeletal muscle and that alternative pumping schemes should be explored.

The most effective way to collect contractile energy is to station a compressive device at one end of an otherwise undisturbed skeletal muscle. This approach, first described by Guizzi and Ugolini (6) in 1979, allows the muscle to function at peak efficiency by preserving the biomechanics perfected through countless years of evolutionary adaptation. Of equal import is the fact that this scheme preserves the primary and collateral blood vessels needed to deliver oxygen and other chemical compounds that ultimately fuel the muscle. This is especially significant because trained muscles rely on oxidative metabolic processes to prevent fatigue during extended periods of activity.

Previous attempts to harvest in situ skeletal muscle for cardiac assist have employed a variety of mechanisms. The concept of powering a pump with linearly contracting muscle first appeared in the literature in 1964 when Kusserow and Clapp (10) used a canine quadriceps femoris to actuate a levered extracorporeal pump. Twenty-one years later, Spitzer (26) published a conjectural treatise describing a hydraulic implant comprising “a piston slidably disposed within a cylinder” designed for placement between the origin and insertion of the gracilis muscle. In 1992, Sasaki and colleagues (24) introduced a system that employed a flexible rod, sheath, crank, and cam to transmit muscle power to a pusher-plate blood pump. Later that same year, Farrar and Hill (2) reported the development of a “skeletal muscle-powered, linear-pull energy converter for powering . . . implanted devices,” which included a cylindrical housing and a piston-type actuator fixed to the thoracic wall beneath the LD muscle. Most recently, Takahashi et al. (28) described a linear-push actuator comprising a bellows supported by two interlocking cylinders designed to drive a muscle-powered dynamic patch for ventricular assistance. These studies have added much to the conceptual development of muscle-powered devices, but relatively little emphasis has
been placed on the detailed engineering needed to reduce these concepts to practice. As a result, efforts to date have failed to produce a practical means by which contractile energy may be collected and transmitted in vivo to perform work within the body.

This work was initiated in an effort to develop a realistic mechanism for harvesting and transmitting muscle power. Design considerations stressed durability, efficiency, and biocompatibility, resulting in a relatively simple device resembling a common piston pump. Bench tests have confirmed the efficacy of this device by demonstrating very high mechanical efficiencies (~98%) and dissipative losses that are vanishingly small. The impact of viscous and inertial effects on transmission efficiency was minimal due to the small volume of fluid displaced (~1 ml). Energy transmission losses became detectable only when pressures generated within the MEC exceeded the bellows’ rated capacity, causing more and more input energy to be diverted to bellows deformation as pressure overload increased. Although the energy-transfer capacity of this first prototype is limited (~170 mJ/stroke), it is important to note that thicker bellows can be readily substituted to achieve energy transmission levels compatible with full circulatory support.

Measurements of MEC piston recoil show that return forces supplied by the compressed bellows average ~4 N over a typical 1-cm stroke. Preload forces >70 N were recorded as stroke length approached 1.5 cm (due to the magnetic thrust bearing used to limit piston travel and prevent piston-port impacts). Although these return forces are comparable to human LD resting tensions (~3 N), long-term implant studies will be required to determine whether these preload levels are indeed adequate. If needed, additional preload force may be achieved by either shortening the MEC center shaft (to further compress the outer bellows) or by simply using a stiffer outer bellows.

The MEC was designed to utilize short stroke lengths (~1.0 cm) for several reasons: to enhance device durability, minimize trauma to surrounding tissues, improve transmission efficiencies, and reduce muscle fatigue. However, this raises a fundamental question, Can the human LD perform enough work over this short distance to power a blood pump? Anthropometric studies of the right LD muscles of 11 patients (3 female) before cardiomyoplasty at Allegheny General Hospital (Pittsburgh, PA) revealed an average muscle length of 41.2 ± 2.2 (SD) cm and a mean cross-sectional area of 19.4 ± 12.6 cm² (D. R. Trumble, unpublished observations). These findings confirm the left LD measurements of 10 human cadavers (5 female) performed by Perier et al. (18), which showed an average length of 35 cm and a cross-sectional area calculated at 19.3 cm². Because the maximum tetanic contractile strength of human muscle is known to be ~34 N/cm² (7), these data imply that a typical human LD can generate up to 656 N (147 lb) of force during an isometric contraction. Assuming, as several studies have shown, (1, 3, 9, 22), that the conditioning process reduces muscle force generation by one-half, and that another one-half is lost due to isotonic shortening (to be conservative), that leaves 164 N for chronic MEC actuation. This translates to 1.64 J of energy per 1-cm contraction, exceeding the combined output of both ventricles (typically 1.22 J/stroke) by 35% (4). According to these figures, a single trained LD muscle could (in theory) support the entire circulation, given a MAVAS operating at an overall efficiency of 74%.

Theoretical estimates notwithstanding, it should be noted that this amount of chronic work output has yet to be demonstrated in the laboratory. However, a MAVAS acting in a cardiac-assist role would not require this level of muscular performance. A muscle-powered device that employs direct cardiac compression need only restore the functional capacity lost due to infarction or other myocardial insult. The energy required to accomplish this task would be much less than the 1.22 J/stroke quoted above because even the sickest heart can generate enough pressure to open the aortic valve and eject a small volume of blood. Hence, properly timed MEC compressions could restore full cardiac function at a fraction of the energy required for total circulatory support.

Apart from LD function, other biological factors that may affect MEC performance remain to be studied, including rib cage fixation stability, MEC-soft-tissue interactions, and muscle preload requirements. These questions, among others, will be examined through a series of implant studies designed to test MEC function under in vivo conditions. Once these tests are complete, appropriate design modifications will be implemented and a second-generation device will be assembled.

Conclusion. In summary, this report describes our initial efforts to develop a practical implant for converting contractile energy into hydraulic power for potential long-term cardiac-assist applications. Prototype testing has yielded promising results but has thus far been limited to bench-top analyses. Further refinements are expected after implant studies. If successful, this device could be coupled to a hydraulic VAD to form a permanent MAVAS free of all external hardware. Such technology would provide a relatively inexpensive alternative to heart transplantation and enable patients to retain a high quality of life.

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