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Improved Mechanism for Capturing Muscle Power for Circulatory Support

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Abstract

Although it is now understood that trained skeletal muscle can generate enough steady-state power to provide significant circulatory support, there are currently no means by which to tap this endogenous energy source to aid the failing heart. To that end, an implantable muscle energy converter (MEC) has been constructed and its function has been improved to optimize durability, anatomic fit, and mechanical efficiency. Bench tests show that MEC transmission losses average less than 10% of total work input and that about 85% of this muscle power is successfully transferred to the working fluid of the pump. Results from canine implant trials confirm excellent biocompatibility and demonstrate that contractile work of the latissimus dorsi muscle—measured to 290 mJ/stroke in one dog—can be transmitted within the body at levels consistent with cardiac assist requirements. These findings suggest that muscle-powered cardiac assist devices are feasible and that efforts to further develop this technology are warranted.

Keywords

Latissimus dorsi; Skeletal muscle; Muscle power; Blood pump; Energy; Power; Heart failure; Device; Biomechanical implant

INTRODUCTION

Congestive heart failure (CHF) is a highly debilitating and progressive illness that afflicts tens of millions of people worldwide. In the United States, over 4.8 million people currently suffer from this condition, and it is estimated that CHF will ultimately affect one in every five Americans (1,2). With over 400 000 new cases diagnosed each year in the United States alone, CHF is a rapidly growing public health problem that has proven difficult to treat. Current pharmacologic therapies can relieve symptoms in most patients but do not appreciably stem the course of the disease. Indeed, despite optimal pharmacotherapy and outpatient management, median survival times following initial diagnosis are alarmingly brief—just 1.7 years in men and 3.2 years in women (3). At present, heart transplantation remains the most effective treatment, but this approach is limited by a small donor pool and

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the serious side effects of immunosuppressive drugs. Mechanical circulatory support with a left ventricular assist device (VAD) has been shown to reverse the physiologic effects of severe congestive heart failure and improve both survival and quality of life when compared to medical therapy (4). In short-term use, as a bridge to cardiac transplantation, this approach has been particularly effective. When intended for permanent support, however, VAD technology has been plagued by problems associated with the complexities of transcutaneous power delivery and the complications of percutaneous drivelines (5,6). An alternative means of power generation that allows a completely self-contained form of mechanical circulatory support would therefore be a major advancement in the treatment of CHF.

The use of skeletal muscle as an endogenous power source represents a promising means by which a completely implantable, tether-free cardiac assist system might be realized. This approach—which uses commercial programmable muscle stimulators akin to cardiac pacemakers to elicit preset contraction patterns—would obviate the need to transmit energy across the skin and so offer several important advantages over circulatory assist devices currently in use. Through this mechanism, external battery packs, power conditioning hardware, transmission coils, and internal power cells could all be replaced by natural biomechanical processes. This would appreciably enhance patient quality of life by improving system reliability and eliminating all external hardware components. Moreover, due to their relative simplicity, muscle-powered blood pumps should be less expensive to manufacture and easier to maintain, resulting in wider availability and reduced costs for healthcare providers.

Work to create a practical muscle-powered VAD has focused primarily on developing an efficient, reliable means to capture and transmit energy from electrically stimulated latissimus dorsi (LD) muscle. The impetus behind this approach stems from two primary observations: first, that skeletal muscle can, with chronic activation, be trained to express fatigueresistant muscle fiber phenotypes (7); and second, that trained LD muscle can perform steady-state work at levels compatible with long-term cardiac assistance (8,9). Anatomically speaking, the key to optimizing muscle energy output is to allow the LD to contract normally with its blood supply intact so that performance limitations inherent to muscle mobilization techniques can be avoided (10). Perhaps the simplest way to capture this energy for cardiac assist purposes is to attach the LD humeral insertion to an implanted hydraulic pump—a device we call a muscle energy converter or MEC—that, in turn, can be used to actuate a pulsatile VAD.

Previous attempts to implement this biomechanical power scheme have used a variety of mechanisms. In 1992, Farrar and Hill introduced an implantable linear-pull energy converter comprising a simple piston-type actuator with sliding seals (11). A pair of guide shafts was added in subsequent versions to effectively counter the torque created by the offset between the muscle and piston shaft, but friction at the piston's o-ring seal limited energy transfer efficiency and presented inherent durability problems (12). Shortly thereafter, Takahashi et al. described a “linear-push actuator” with a bellows supported by two interlocking cylinders designed to drive a dynamic patch for ventricular assistance (13). This device worked well in acute trials using dogs, but issues of device fixation, tissue adhesion, and biomaterial leaks

were never addressed. Most recently, Sasaki and colleagues reported testing a “roller screw linear actuator” that transmits linear muscle power to a pusher-plate pump via a cable that is wound around a spool attached to a roller screw nut (14). In this case, questions regarding cable fatigue and stable tissue interfaces were left unresolved. These important pioneering studies have each served to advance the conceptual development of muscle-powered implants, but in their scope, none have fully addressed the key issues of biocompatibility and long-term durability. As a result, efforts to date have yet to produce a practical means by which contractile energy may be collected and transmitted in vivo to perform work within the body over an indefinite period of time.

At Allegheny, lessons learned through four previous design iterations (15–19) have now been incorporated into a fifth-generation device (MEC5) with significantly enhanced energy transfer capacity and tissue interface characteristics. This report details current improvements in the MEC design and summarizes results from in vitro mechanical tests. Results from a series of implant trials in dogs are also described wherein MEC/LD function was tested in isolation to assess anatomic fit, tissue interface stability, and the potential for maintaining long-term device function.

DEVICE DESIGN AND DEVELOPMENT

Five MEC prototypes have been designed and tested over the course of device development, each distinct in appearance but all designed to perform the same function, namely, to act as a muscle-powered hydraulic pump. At the heart of all these devices is an edge-welded metallic bellows used both as a pumping chamber and as a means to maintain a low-friction hydraulic seal. Owing to the importance of this key component and the severe cycle-life requirements of these pumps, pressure generation and volume displacement demands must be balanced against mechanical efficiency and stress reduction in order to create a bellows configuration suitable for these extreme operating conditions. This task is further complicated by design restrictions imposed by the functional limitations of trained LD muscle as well as anatomic size constraints.

The first three prototype devices share a common architecture and are pictured together in Fig. 1. Each was designed to operate as a linear piston-in-cylinder type pump with an eye toward keeping device complexity to a minimum. Despite numerous design improvements, however, stroke length demands raised concerns over long-term bellows performance, and the piston-in-cylinder design proved difficult to reconcile with certain anatomic constraints (15–17). Based on these findings, a radical design change was implemented in an effort to reduce bellows flexion stresses, lower the housing profile, and minimize the risk of tissue encumbrance to actuator motion (18). Unlike the long tubular bellows arrangement used in the three previous designs, the effective diameter of the bellows in this fourth-generation device (MEC4) was made nearly three times its expanded height to reduce stroke length requirements and allow fluid to be pumped from *inside* the bellows (tall bellows tend to “squirm” to one side when pressurized internally, a condition that can concentrate stress and reduce cycle life). This allowed the bellows to be cycled over a shorter distance (<4 mm) for improved durability while at the same time providing a spring-return force to reset the pump between contractions.

Because of its comparatively broad diameter (46 mm), the MEC4 bellows was made to lie flat relative to the chest wall, its axis of shortening perpendicular to that of the LD muscle (Fig. 2). This allowed the device to remain thin and unobtrusive but required that a mechanism be added to magnify the muscle force and redirect it against the top of the bellows. This was accomplished by means of a simple linear cam coupled to a shaft that crossed the housing through a spring-loaded Teflon seal. Device actuation was achieved by pulling a planar armature across the top of the housing that, by virtue of a direct mechanical coupling, advanced the camshaft to an equal distance. This action moved the cam across a pair of roller bearings mounted on the top termination of the bellows so that the free end was pushed toward the fixed (outlet) end. The bottom half of the housing was designed to pass through a window in the chest wall made by resection of a 6-cm length of one rib. This approach was adopted to further lower the profile of the muscle pump and to improve device stability. The housing was anchored to the chest wall using a thin rim of eight perforated tabs extending one-half inch from the device periphery, a method based on implant studies demonstrating the efficacy of device immobilization via fibrous tissue ingrowth (19).

Although bench tests showed the energy transfer capacity of the MEC4 to be more than double than that of the previous design, experiments also revealed that a large portion of the contractile energy used to actuate the device (up to 180 mJ per pump cycle) was lost due to sliding friction at the lip seal interface. Moreover, dynamic testing exposed a marked tendency for the bellows to tilt in the direction of cam motion—an inclination that increased in proportion to the pressure load. Thus, despite having achieved excellent anatomic fit, superior energy transfer capacity, and an overall mechanical efficiency of 80%, these observations raised concerns over long-term durability of both the bellows and camshaft seal.

To address these issues, the MEC4 was subsequently modified to include a rotary cam mechanism wherein the central shaft is turned rather than pulled by the muscle (Fig. 3). The principal advantages of this design are: (i) less friction (and hence wear) at the lip seal surfaces resulting in higher energy transfer efficiencies; (ii) lower stress on the bellows for increased cycle life; and (iii) lower risk of tissue encumbrance due to the elimination of the linearly reciprocating actuator arm. In addition, this actuation scheme allows broader latitude for device placement because the muscle no longer needs to lie perfectly parallel to the device surface in order to effect optimal performance.

In this configuration, two sets of ball bushings are used to support the camshaft as it rotates about its long axis. The camshaft passes through the upper housing via two spring-loaded lip seals and connects to an actuator arm that spans the width of the device. The muscle tendon is secured to the middle of the actuator arm via an artificial tendon interface (19). The current device, shown fully assembled in Fig. 4, allows the shaft to rotate 85 degrees while affecting a maximum bellows compression length of only 0.25 cm (note: with an effective pressure area of 20.7 cm², the stroke volume capacity of the bellows is 5.25 mL). Importantly, the bellows-bearing assembly now includes a central guidepost to ensure level compression profiles and even stress distributions. It should also be noted that cam profiles and rotation angles could be easily altered to fine-tune pump performance.

EXPERIMENTAL METHODS

In order to study MEC5 function apart from the confounding factors that would be introduced by coupling the device to an experimental blood pump, preliminary implant tests were designed to use gas rather than liquid as the medium for muscle energy transmission. The advantages of this approach are twofold. First, pneumatic operation allows pump output energies to be calculated from a single pressure waveform generated inside the sealed, flexing bellows. Second, this arrangement obviates the need to implant a separate chamber to receive fluid pumped from the bellows during device actuation.

In animal experiments, radio telemetry implants (model TL11M3-D70-PCP, Data Sciences International, St. Paul, MN, U.S.A.) were used to monitor pressure swings inside the bellows and the space between the bellows and housing (17). Remote pressure readings were then used to calculate volume changes and actuator displacement as described below. Actuator arm resistance was controlled in vivo by raising or lowering bellows resting pressure via a subcutaneous access port.

Bench testing

In preparation for extended in vivo trials, MEC5 function was tested on the bench to assess system function and overall mechanical reliability. In these experiments, muscular compression was simulated using a programmable linear actuator (SmartActuator, Ultramotion, Inc., Mattituck, NY, U.S.A.). The drive rod was attached to the MEC by a metal chain in order to simulate the pull of the LD muscle and allow the rocker arm to return to its home position without mechanical assistance. The chain was fixed to the MEC via a toothed clamping mechanism machined into the rocker arm, the clamped portion of the chain being encased in plastic tubing to allow for tight compression. Gas pressure within the bellows at the beginning (P_1) and end (P_2) of actuator arm motion was measured directly and changes in volume were calculated using Boyle's gas law ($P_1V_1 = P_2V_2$) where V_1 and V_2 are resting and post-contraction chamber volumes, respectively. A miniature load cell (ELH-TC401, Entran Devices Inc., Fairfield, NJ, U.S.A.) was mounted between the drive rod and MEC to measure the force applied to the muscle interface and piston motion was monitored using a linear potentiometer built into the actuator. Gas pressures were measured using two flush-diaphragm pressure transducers (EPX-V11-50P-/RS (housing) and EPX-V11-250P-/RS (bellows), Entran Devices Inc.), each fitted with a male luer connector. Pressure transducers were zeroed before each preload increment to minimize baseline drift. Stroke work input was calculated as the product of the mean actuation force and total stroke length. Stroke work output (i.e., the work done by the bellows in compressing the air sealed inside) was taken as the product of bellows volume change and mean pressure generation.

All waveforms were digitized at a rate of 250 samples/s and saved to a Compaq Armada E700 laptop computer (DI-720-P DAS with WinDaq/Pro+, Dataq Instruments, Akron, OH, U.S.A.). Data were post-processed using both Windaq and XANALYZE software. Datasets comprising five contiguous cycles were collected and waveforms averaged over this five-cycle period. All summary data were expressed as mean $\pm$ SD. Linear regression analyses were performed using the Marquardt-Levenberg algorithm for iterative, least squares estimation of curve-fit parameters.

Implant testing

The surgical procedures described below were performed in compliance with the *Guide for the Care and Use of Laboratory Animals* prepared by the National Academy of Sciences and published by National Academy Press (ISBN 0-309-05377-3, 1996). This project was also approved by the Institutional Animal Care and Use Committee of Allegheny-Singer Research Institute (Pittsburgh, PA, U.S.A.).

MEC5 pumps were implanted in three mixed-breed dogs (28–35 kg) to assess anatomic fit, tissue interface stability, and device function. Each animal was sedated with intramuscular injections of acepromazine (0.25 mg/kg) prior to induction of general anesthesia with intravenous Pentothal (20 mg/kg). Anesthesia was maintained with 1–2% isoflurane delivered through an endotracheal tube. A longitudinal incision was made over the lateral border of the left LD muscle, which was then freed from its humeral insertion and mobilized proximally with minimal dissection, leaving the muscle origin, intercostal perforators, and thoracic neurovascular bundle intact. A peripheral nerve stimulation lead (model 3987, Medtronic Inc., Minneapolis, MN, U.S.A.) was sutured over the main trunk of the thoracodorsal nerve and the LD was stimulated using an Itrel3 pulse train stimulator (model 7425, Medtronic Inc.). The LD insertion was then fitted with two artificial tendons (MyoCoupler, CardioEnergetics, Inc., Cincinnati, OH, U.S.A.) described previously (19). A 6.5-cm length of the second rib was removed adjacent to the sternum, and the actuator arm aligned perpendicular to the direction of LD shortening before being secured to the chest wall by tying four wire sutures around the ribs and through the perforated anchor plates. Finally, the terminal cords of the artificial tendons were fixed to the actuator arm via a clamping assembly and the muscle/pump system tested acutely to confirm proper alignment and full device actuation with muscle stimulation. A lateral chest X-ray (Fig. 5) was used to document device and hardware position immediately following surgery.

The dogs were allowed to recover up to 1 week prior to LD stimulation whereupon muscle contractions were induced using bursts of nine pulses delivered at a rate of 33 Hz. Because it normally takes about 6–8 weeks of electrical conditioning to convert skeletal muscles to mostly type-1 fatigue-resistant fibers (20,21), peak contraction rates were limited to 27 per minute over the 4-week study period to avoid muscle fatigue due to overstimulation. Historically, the preferred means of conditioning LD muscle has been to start with a single pulse (about one per second) then add 1–2 pulses per week to slowly build a functional pulse train. However, changes in muscle fiber type have been shown to depend more on the total activity imposed on the muscle than the pattern of stimulation, thus allowing for a variety of viable training regimens (22). In this application, the muscle must be made to contract forcefully from the very beginning to prevent adhesions around the muscle and the MEC actuator arm. We therefore opted to train the LD using a graded contraction rate (6–27 per minute) rather than slowly increasing the number of pulses per burst. Pulse trains of 240-ms duration were used to produce tetanic contractions that mimic the systolic duration of the heart. Because full LD conditioning could not be completed within the 4-week time frame of these studies, heart-like contraction rates were not attempted. Fully trained muscles, however, can be expected to work continuously at contraction rates of up to, and perhaps

exceeding, one per second (23). In comparison, resting heart rates in dogs weighing more than 30 kg (66 lbs) range from 70 to 100 beats per minute.

Throughout the course of the implant period, device performance was monitored on a daily basis and the pressure load was adjusted as required. At the conclusion of each study, the device and LD–MyoCoupler complex were removed for analysis and the dog recovered to document possible complications from device explanation. Because no major postoperative problems were encountered, all three dogs were released to adoptive homes.

BENCH TEST RESULTS

Tested in isolation, the spring-loaded lip seals held the camshaft motionless to a breakaway force of 3 N (0.67 lbs) with mean drag forces increasing from 1.8 to 2.1 N (0.40–0.47 lbs) in proportion to actuation speed (10–70 mm/s). Frictional losses at the lip seals varied from 33 to 39 mJ per full-length actuation cycle or roughly 2 mJ per millimeter of actuator arm rotation at peak shortening speeds.

Total energy output of the device is plotted against “muscular” work input in Fig. 6. This graph includes data collected for stroke lengths ranging from 2.3 to 17.5 mm (contraction speeds of 10–70 mm/s) and bellows resting pressures of 0–1200 mm Hg. Pull times were limited to 250 ms to mimic cardiac systole and total cycle time was set to 2 s. Under these conditions actuation forces peaked at 7–69 N, averaging 6–57 N during the active pull phase of the duty cycle. The mean energy transfer efficiency measured across the entire gamut of actuation conditions tested (taken as the slope of the fitted curve anchored at the origin) was just over 90%. At the maximum actuation speed and pressure load examined, a total of 1005 mJ of energy was required to drive the device, of which 85% (856 mJ) was transferred to the outlet port as bellows stroke work. An additional 9% (88 mJ) was lost to friction at the lip seal and bearing surfaces, the remainder being stored as potential energy in the bellows spring and housing vacuum—energy that is ultimately recovered between contractions to help reset the actuator arm.

IMPLANT RESULTS

Based on anatomic studies and prior implant experience, it was determined that the best location for MEC placement in dogs is adjacent to the sternum at the level of the second rib. This positioning preserves LD resting tension and moves the device away from the neurovascular bundle and stimulation lead while providing an optimum pull angle between the muscle and actuator arm (Fig. 7). This approach was used in all three experiments with consistently good results. Indeed, at the time of implantation, LD stimulation consistently brought the actuator arm to the full upright position in less than 0.1 s and generated up to 500 mm Hg pressure inside the bellows chamber. (Note: these muscles might have generated much higher pressures but were prevented from doing so to protect the tissue fixation surfaces, which typically require 5–7 days ingrowth time to stabilize.)

Questions regarding anatomic fit and tissue interface stability were both answered favorably. In all three cases, the MEC was securely seated in the plane of the chest wall with removal of just one rib. Four wire ties were sufficient to anchor the MEC acutely to the adjoining ribs

and allowed time for scar tissue to form around the mounting ring in the ensuing weeks to effect more permanent device fixation. No evidence of device migration was detected in any animal nor were there any instances where the muscle separated from the actuator arm. Mechanical tests performed on the explanted muscles measured tendon pullout strength at 162 ± 61 N, more than five times the peak force generated by these muscles.

The final aim of these early implant studies was to demonstrate that the MEC could be cycled in vivo over extended periods without becoming bound by adhesions to surrounding tissues. The first two trials were stopped prematurely due to deterioration in actuator arm motion. In both instances, the actuator arm itself was found to be completely free of adhesions and was able to be rotated manually without difficulty. The problem, however, was that the costal side of the LD became adherent to the MEC mounting ring and so was unable to shorten enough to effectively actuate the device. This problem was addressed in the ensuing (final) trial by applying a self-polymerizing liquid adhesion barrier (CoSeal Surgical Sealant, Baxter Healthcare Corp., Deerfield, IL, U.S.A.) over that portion of the mounting ring that lies beneath the muscle.

In this last dog, the MEC continued to cycle freely for 30 days without observable signs of tissue encumbrance or muscle fatigue before a gas leak in the external bellows port pressure line reduced muscle preload and immediately halved actuator stroke length—presumably because the actuator was no longer being returned to its “home position” at the end of each contraction cycle. Prior to this event, muscle stimulation had generated pump pressures over 430 mm Hg and produced muscle stroke work levels in excess of 290 mJ—the energetic equivalent of pumping 22 mL/stroke against 100 mm Hg blood pressure for left heart assist or 54 mL/stroke against 40 mm Hg for right heart support. Bellows pressure rise and fall times were 60 and 75 ms, respectively, on stimulation day 1 and 130 and 90 ms 30 days later. Stroke work production for this entire period is plotted in Fig. 8. Abrupt increases in stroke work production seen on postoperative days 26 and 35 are due to increases in bellows resting pressure created by the injection of air into the subcutaneous access port.

DISCUSSION

The development of a totally self-contained implantable blood pump has been a goal pursued by clinicians and engineers for over four decades now, yet this deceptively difficult undertaking continues to defy all attempts to solve its most enduring technical challenges. Indeed, despite the hundreds of millions of dollars that have been dedicated toward achieving this end, the principal problems of thrombosis and infection still persist—the latter being an unavoidable consequence of using percutaneous drive lines to effect long-term circulatory support.

Buoyed by the prospect of driving indwelling blood pumps without breaking the skin, wound-free energy delivery quickly became a prime motivation behind the development of electrically powered cardiac assist devices. There were, in fact, two important advantages to this approach. The first was that wearable battery packs would free patients from the worrisome prospect of being permanently tethered to a bulky air compressor and drive unit. The second and perhaps more compelling advantage was that electrical systems could

potentially be driven by inductive means using a pair of coiled wires—one applied externally and the other implanted just below the skin—to seamlessly bridge the dermal divide through the action of electromagnetic fields.

To that end, research initiated in the 1970s produced several transcutaneous energy transmission (TET) systems capable of driving both positive displacement and rotary blood pumps. Rather than being a turning point in the war on heart disease however, this technological TET offensive gave rise to a new set of problems. One major concern was the alarming increase in system complexity brought on by the newfound need to transform energy from direct current to alternating current and back again. The electronics needed to perform the last of these functions, in addition to handling the large currents induced in the implanted coil, had to be light, compact, durable, and implantable. Although technically achievable, the sheer complexity of this system not only raised the risk of device failure but also significantly increased system cost. Another less obvious worry stemmed from the fact that metal objects placed in the vicinity of the coils were found to detune the circuit by altering their mutual inductance and effective series resistance (24,25). This power scheme therefore requires a rigid metallic enclosure (offset several inches from the external coil) to shield the transformer coils against environmental interference that could lead to system failure.

One way to avoid the problems that underlie the use of extracorporeal power for circulatory assist would be to tap the energy stores that exist *within* the body, the most conspicuous source being skeletal muscle—the body’s largest biochemical engines. Yet despite the obvious allure of recruiting one muscle to help perform the work of another, this option was largely ignored in the early days of artificial heart development due to the assumption that fatigue-prone skeletal muscle was inherently ill-suited to perform cardiac work. Indeed, the extent to which skeletal muscle can adapt to altered work requirements was not recognized until 1976 (26), and it was not until several years later that skeletal muscle was seen to respond to chronic electrical stimulation to the degree necessary to be considered a viable power source for circulatory support (27).

Early efforts to harness muscle power for cardiac assist purposes sought to transfer the power of the latissimus dorsi muscle directly to the heart by means of direct cardiac compression. It was hoped that this four-square approach, called dynamic cardiomyoplasty, would obviate the need for implanted mechanical pumps and so eliminate the problems of thrombus and infection in one fell swoop. Unfortunately, the transplanted muscle was unable to provide significant cardiac compression for more than a few weeks owing to biomechanical inefficiencies and a compromised blood supply (28). In an effort to avoid these problems, we have modified this approach to allow the LD to remain in its natural anatomic position so that the native blood supply and natural contractile dynamics of the muscle could be preserved. The drawback, however, is that this scheme requires that a new mechanism be devised to capture and transmit this energy to the heart.

An important step toward achieving this goal has now been accomplished with the development of a novel hydraulic muscle pump designed for placement beneath the humeral insertion of the LD muscle. Bench tests show this device to be 85% efficient in transferring

muscle energy directly from the actuator arm to the outlet port where it can be used—in principle—to compress the heart or drive a blood pump. Implant trials in dogs confirm that tissue fixation sites are stable and that the device itself is anatomically unobtrusive. In terms of function, LD stroke work production of over 290 mJ was achieved in one dog after steps were taken to eliminate muscle adhesions found in the previous two animal implants. This level of stroke work far exceeds the normal output of the right ventricle in dogs this size (30–35 kg) and is well over half that of the left ventricle, indicating that significant cardiac support is possible via this mechanism given an efficient means to transfer this power to the bloodstream. Moreover, because device actuation drew no discernible response from these animals, it can be inferred that muscle pull and actuator motion produces no substantial discomfort and so suggests that this method of power production may indeed become forgettable with time.

While the MEC has the potential to drive a wide variety of pulsatile blood pumps, the most attractive pairings are with a family of direct cardiac compression devices (DCCDs) designed to squeeze the heart from the outside. This arrangement, apart from being extremely efficient from an energy transfer perspective, would eliminate the need for artificial valves and blood contacting surfaces while at the same time allowing for intermittent device activation as might occur during muscle training or weaning procedures. Of the DCCDs currently under development, the AbioBooster (manufactured by Abiomed, Inc., Danvers, MA, U.S.A.) seems to afford the most ready fit as it is specifically designed for low-volume hydraulic actuation (29). Because the ratio of hydraulic to physiologic stroke volume for this device rises with the number of tubes used to form the compressive sleeve, the AbioBooster can be tuned to operate in accordance with low MEC stroke volumes. Fewer than 45 tubular elements, for example, would be needed to amplify MEC volumetric outputs by a factor of 10, yielding a peak LV displacement volume of 52 mL (30). In practice, however, so voluminous a compression may not always be needed to provide significant circulatory support because a well-timed circumferential squeeze might act to lower myocardial wall stress enough to improve sarcomere shortening and therefore enhance the cardiac component of stroke work production.

Future work

While progress to date has been substantial, there are two essential tasks that remain to be completed before work to develop a muscle-powered VAD can proceed beyond the concept stage. The first is to quantify steady-state MEC power output in vivo and assess the physiologic adaptations that occur in skeletal muscle contracting under conditions of chronic circulatory support. This will be accomplished by extending MEC implant duration to 6 months and beyond in order to: (i) quantify the fiber type distribution and structural integrity of skeletal muscle following chronic MEC actuation; and (ii) determine the steady state work capacity of conditioned skeletal muscle contracting in situ against a terminal load. The second task is to meet heightened performance goals for energy transfer efficiency (95%) and minimum durability (300 million cycles) in order to provide the utmost cardiac support while ensuring reliable device function for up to 10 years of continuous use. Plans to optimize device efficiency and cycle life include: (i) minimizing friction at the two lip seal surfaces; and (ii) changing the bearings from ball to needle type and broadening their width.

Preliminary finite element analyses suggest that these upgrades are likely to achieve these performance goals, bringing muscle-powered cardiac assist another step closer to reality.

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FIG. 1.

First three MEC prototypes shown in chronological order, from left to right, oriented with muscle attachment points on top. Each functions as a straight piston-in-cylinder pump with an internal metallic bellows providing volume displacement and acting as a spring-loaded frictionless seal.

FIG. 2.

Artist's conception of MEC4 implanted beneath the latissimus dorsi (LD) muscle. Inset shows the device drawn in cross section: Numbered components include the linear cam (1), metallic bellows (2), spring-loaded lip seal (3), and sliding actuator arm (4).

FIG. 3. MEC5 shown in cross section at two stages of actuator arm rotation: 0 degrees (top) and 85 degrees (bottom). Note that as the actuator arm turns, the cam rotates downward against the central bearings and compresses the bellows.

FIG. 4. Computer rendering of MEC5 device shown with semitransparent housing (top) and in three-quarter cross section (bottom).

FIG. 5.

Top: Scale drawing showing anatomic placement of the MEC beneath the LD muscle of a 30-kg dog. Bottom: X-ray of MEC5 implanted in a dog with monitoring system and muscle stimulation hardware.

FIG. 6. MEC5 energy transfer efficiency plotted across the full range of stroke lengths, contraction speeds, and actuations forces tested. Overall device efficiency is 90%.

FIG. 7.
MEC fixed to the LD in a dog using an artificial tendon. Tissue ingrowth through the circumferential mounting ring securely anchors the MEC to the chest wall.

FIG. 8.

Stroke work of the LD muscle of dog #3 contracting nonstop for 30 days. Stimulator OFF times were reduced from 10 to 2 s over the first 16 days of in vivo device actuation (two seconds once every 4 days) to arrive at a peak contraction rate of 27 per minute.