# Linear muscle power for cardiac support: Current progress and future directions

Dennis R. Trumble

*The Gerald McGinnis Cardiovascular Institute, Allegheny General Hospital Pittsburgh, Pennsylvania, USA and The Department of Biomedical Engineering, Carnegie Mellon University, Pittsburgh, Pennsylvania, USA*

**Abstract**

A biomechanical implant has been developed to convert linear muscle power into hydraulic energy for the purpose of driving a circulatory support device. This implant—called a muscle energy converter or MEC—is designed to attach to the humeral insertion of the latissimus dorsi (LD) muscle so that stimulated contractions produce hydraulic power. The principle advantage of this approach over current methods is that it eliminates the need for external power sources and provides a reliable, low-cost, self-sustaining source of energy without immune compromise or loss of patient autonomy. This article summarizes the rationale for using muscle in a linear configuration, reviews the current status of device development, and examines three possible mechanisms by which to assist the failing heart using in situ skeletal muscle.

**Key Words**: skeletal muscle, cardiac assist, electrical stimulation, conditioning, linear contraction, prosthesis, latissimus dorsi

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The use of skeletal muscle as an endogenous power source is a promising means by which a completely implantable, tether-free cardiac assist system might be realized. This approach would obviate the need to transmit energy across the skin and so offers several important advantages over circulatory assist devices currently in use. Through this mechanism, external battery packs, power conditioning hardware, energy transmission coils, and internal power cells could all be eliminated. This would significantly 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 would be much less expensive to manufacture and easier to maintain, resulting in wider availability and reduced health care costs.

An important step toward achieving this goal has recently been accomplished with the development of a hydraulic muscle energy converter (MEC) designed for placement beneath the humeral insertion of the LD muscle (Figure 1). Implant tests suggest that LD power levels are sufficient to support the failing heart provided an efficient means can be devised to transmit this energy to the bloodstream [21].

The next phase in the development process is to design a prototype blood pump suitable for MEC actuation. Although the MEC has the potential to drive a wide variety of pulsatile blood pumps, the most attractive approach would be to squeeze or otherwise manipulate the heart from the outside. This method, 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 device weaning procedures.

This article briefly reviews the advantages of harnessing in situ muscle as an endogenous power source and details efforts to develop a practical means to capture and transmit this energy to aid the failing heart. Finally, three prospective configurations for MEC-based muscle-powered circulatory support are presented along with a critical appraisal of their various strengths and limitations.

### *Limitations of Muscle Wrap and Oblique Compression Techniques*

Refinements in muscle training and burst stimulation methods have spurred development of numerous techniques designed to utilize the transposition of conditioned contractile tissue for circulatory support. Methods employed to date include: wrapping the heart for direct mechanical assistance (cardiomyoplasty); wrapping the aorta for counterpulsation (aorto-myoplasty); shaping the muscle into a neo-ventricle to pump blood (skeletal muscle ventricle); and positioning a compressive device beneath the muscle. Low power production however, has proven to be a serious limitation common to all these approaches [11].

Although the causes of this poor performance are not completely understood, one likely contributor is the mechanical disadvantage that is created by wrapping skeletal muscle to form a compressive enclosure [22]. Unlike the spiral fiber orientation of the left ventricle, which allows the LV to contract concentrically, skeletal muscles myofibers are arranged in parallel and produce shortening in a single longitudinal direction. Muscles wrapped in this manner thus tend to provide far less compressive force than a cardiac ventricle of similar mass. Similarly, devices placed beneath the muscle belly utilize only a small fraction of the available contractile energy because their motion is nearly perpendicular to the muscle's primary force vector.

Another important factor likely to limit the effectiveness of these heterotopic methods is the trauma induced via muscle mobilization. Wrap-around techniques require isolation of the muscle from its surrounding structures, sacrificing collateral blood supply and depriving the muscle of its optimal orientation and preload. Indeed, surgical isolation of skeletal muscle has been shown to produce an immediate 37% decrease in contractile power due to trauma and physical separation from surrounding synergistic musculature [14]. Over the long term, reduced blood flow caused by the separation of collateral blood vessels can lead to ischemia and muscular atrophy thus lowering function still further [23]. In light of these limitations, it is apparent that current wrap-around methods for muscle-powered cardiac assistance are less than optimal and that alternative schemes for harnessing the contractile energy of skeletal muscle should be explored.

***Fig. 1*** *The seventh-generation muscle energy converter (MEC) pictured from above. This device features a rotary cam mechanism that compresses an internal bellows as the outer armature is rotated upward (90 degrees max). Machined into the actuator arm is a semi-circular channel designed to accommodate a looped artificial tendon (CardioEnergetics, Inc.) that connects the muscle to the MEC. The device is placed through a window created in the chest wall by removing a 6.5-cm segment of one rib. The housing is anchored to the adjoining ribs using steel suture wound around a ring of perforated tabs extending 0.7 cm from the device periphery.*

*Advantages of Using In Situ Muscle in a Linear Configuration*

Given the linear nature of muscular mechanics and the sensitivity of skeletal muscle to reductions in blood supply, perhaps the most practical way to harness muscle power would be to place a compressive device at one end of an otherwise undisturbed skeletal muscle. This approach was first proposed by Guizzi and Ugolini in 1979 [3] and allows the muscle to operate at maximum efficiency by preserving biomechanical mechanisms perfected through countless episodes of evolutionary adaptation.

This scheme also serves to preserve both the primary and collateral blood vessels needed to fuel the muscle and remove metabolic waste products. This is especially important in that conditioned muscles depend on oxidative metabolic processes to prevent fatigue during extended periods of activity.

This hypothesis was tested by Badhwar et al. [1] who studied the function of latissimus dorsi (LD) muscle in three orientations: sub-dorsi (compressive); circular (wrap); and linear-pull. Their results showed that linear actuation produced a three-fold improvement in work output over the wrap-type actuator and a five-fold increase over the compressive arrangement.

Another experiment completed by Geddes and associates at Purdue University [2] used isolated canine muscles contracting linearly to compress a valved pouch in a hydraulic model of the circulation (10-40 contractions/min). Dramatic increases in muscle blood flow were observed during periods of work, and fatigue was not a factor despite the fact that unconditioned muscles were used. Each of the three muscle groups—LD, gastrocnemius, and triceps—pumped over 1.5 L/min against a pressure load of 100 mmHg with an energy conversion efficiency approaching that of cardiac muscle (roughly 10%).

Based on these results, Geddes concluded that an energy conversion scheme should be sought in which linear shortening of skeletal muscle could be used to assist the circulation. Studies that have employed skeletal muscle in a non-isometric, linear configuration have generally isolated the muscle from its collateral circulation, leaving only the origin with its neurovascular supply intact.

This practice has clearly compromised the integrity of these muscles and diminished their performance. One notable exception may be found in a 1990 report by Salmons and Jarvis [12] on the force-velocity relationships of normal and trained rabbit tibialis anterior muscles. These tests, performed on fully vascularized muscles, led the authors to conclude, "Sustained work at a rate of 4 W/kg is not an unrealistic proposition for a suitably conditioned muscle." Another group examined the power output of in situ canine gastrocnemius-plantaris muscle contracting linearly against a "pneumatic muscle lever" [14]. Initial power levels of 19.0 mW/gram were reported for untrained muscle in these acute experiments. What's more, our own studies of linear in situ muscle power using normal and conditioned canine LD have yielded power levels of 5.76 and 2.06 mW/gram respectively [16,18]. These data support the hypothesis that certain skeletal muscles can produce mechanical power at levels sufficient for cardiac assistance and thereby validate the development of implants designed to harness this energy.

*An implantable muscle energy converter (MEC)*

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 LD muscle. The impetus behind this approach stems from two primary observations: first, that skeletal muscle can, with chronic activation, be trained to express fatigue-resistant muscle fiber phenotypes and second, that trained LD muscle can perform steady-state work at levels compatible with long-term cardiac assistance. 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 [19]. We believe the most effective way to capture this energy for cardiac assist purposes is to attach the LD humeral insertion to an implanted hydraulic pump that, in turn, can be used to actuate a pulsatile VAD.

*Physical and Functional Characteristics*

Seven 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 a means to maintain a low-friction hydraulic seal.

Owing to the importance of this key component and the severe life cycle 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.

*Muscle mechanics and MEC design*

The MEC is designed to operate at contractile force and velocity levels which correspond to peak power generation in fully conditioned human LD muscle. Anatomical measurements taken from cardiomyoplasty patients at this institution (n=11, 3 female) and cadaver studies performed elsewhere (n=10, 5 female) suggest average LD lengths of 35-40 cm and mean cross-sectional areas of 19-20 $cm^2$ in humans [10,17]. It is important to note that because these dimensions were taken from heart failure patients, they already account for skeletal muscle atrophy that typically occurs with CHF. Moreover, changes in skeletal muscle associated with CHF have been shown to be reversible via exercise training [8,9], so these muscles can be expected to respond to electrical conditioning as well.

Maximum force generation in normal skeletal muscle averages about 34 N/cm2 [4] and shortening velocities typically peak at five times total muscle length per second [13]. Maximum force and velocity levels for normal human LD muscles are therefore expected to be about 646 N and 175 cm/s respectively. Fully conditioned muscles, however, typically experience a 50% loss in force generating capacity and show a fivefold reduction in shortening velocity [12,18], which would lower these performance values to about 323 N and 35 cm/s. Because maximum contractile power production is known to occur near 0.3 Fmax and 0.3 Vmax [5,6], it is reasonable to assume that power from trained LD will be greatest when the muscle is allowed to generate about 95 N force while shortening at a rate near 11 cm/s. Given a contraction time of 0.25 seconds (corresponding to typical cardiac systolic durations) and a sinusoidal shortening trajectory centered around 11 cm/s (mean = 7.0 cm/s), LD shortening would total 17.5 mm, very near the maximum stoke length of the MEC. Taking the spring rate (137 N/cm) and effective pressure area (20.7 cm2) of the bellows into account together with the mechanical advantage of the cam and actuator arm (ca. 8), the forces required to actuate the MEC against peak rated pressures (30.9 N/cm2) range from 80 to 88 N. Hence, MEC actuation requirements are consistent with conditioned LD muscle operating near the peak of its power-velocity curve.

*Results from Animal Testing*

In the most recent animal trial the seventh-generation MEC device functioned well for 35 days after implant and generated the highest levels of power production observed to date [21]. Accumulator pressures (expressed as resting pressure over peak contraction pressure) ranged from a low of 181/267 mmHg on postop day 7 to a high of 478/710 mmHg on day 26. The peak driveline pressure generated in this last experiment was 1743 mmHg, which translates to a muscle pull strength of about 60 N (13.5 lbs). Steady state power generation was measured daily and trended upward as muscle training progressed. Mean stroke work levels reached 478 ± 21 mJ/stroke (mean ± std) on day 26 with a maximum value of 785 mJ being achieved on day 28 during a weekly pressure cycle test. MEC/LD stroke work was seen to vary linearly with accumulator preload pressure with peak values occurring at driveline pressures near 1000 mmHg. This is a sizable improvement over levels achieved in previous studies where stroke work and pressure levels topped out at 290 mJ and 430 mmHg respectively [20]. Because normal left and right ventricular stroke work levels in dogs this size (35 Kg) are roughly 700 and 150 mJ respectively, these data suggest that MEC/LD power levels, maintained in tandem with an appropriate cardiac assist device, are sufficient to provide significant long-term circulatory support.

### *Potential mechanisms for MEC-based circulatory support*

While the MEC has the potential to drive a wide variety of pulsatile blood pumps, the most attractive pairings are with a family of non-blood-contacting devices designed to squeeze or otherwise manipulate the heart or great vessels from the outside.

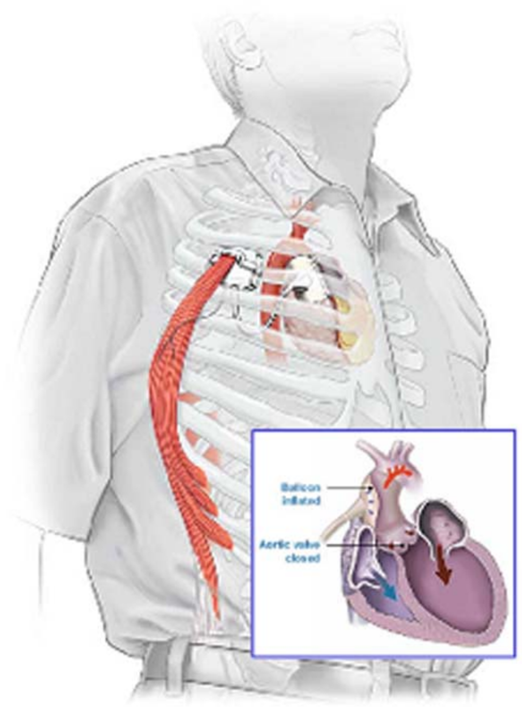


**Fig. 2** *Artist's conception of the MEC powering a C-Pulse extra-aortic balloon pump (Sunshine Heart). The balloon is inflated during diastole to reduce left ventricular afterload and increase coronary blood flow. Note that the right latissimus dorsi is used in this instance whereas most other MEC applications would favor using the left LD muscle.*

This approach, 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 device weaning procedures. Below are three possible configurations presented with a listing of their various strengths and limitations.

### *Extra-aortic counterpulsation*

Perhaps the most conservative approach to MEC-powered circulatory support is to use this pump to drive an extra-aortic counterpulsator similar to the C-Pulse device developed by Sunshine Heart Inc. (St. Leonards, Australia). This arrangement, shown in Figure 2, would involve inflating a balloon wrapped around the ascending aorta so that a 20 mL bolus of blood is displaced from the vessel between cardiac beats. Studies in patients have shown that extra-aortic balloon counterpulsation improves coronary blood flow and reduces left ventricular afterload [7].

The primary advantages of this approach are: 1) low power requirements, 2) no contact with the heart, 3) increased coronary perfusion, and 4) the fact that the target device has already been developed. Limitations include: 1) a relatively modest assist capacity; 2) the need for a clean, compressible aorta; 3) the need to boost MEC stroke volume from 5 to 20cc; and 4) the fact that the long-term effect of cyclic compression on aortic remodeling is not well understood.

### *Hydraulic contractile patch*

Another possible approach would be to use the MEC to actuate a hydraulic contractile patch sewn over a dysfunctional segment of the left ventricle [15]. This device, shown in Figure 3, is formed from a series of thin-walled tubes laid side-by-side and secured in tight approximation by a mesh of fine polyester filament. During diastole the tubes would lie flat against the epicardium and provide passive support to the ventricular wall. During systole the tubes would inflate to assume a circular profile, thus causing the width of the assembly to shorten by as much as 36 percent depending upon wall thickness and tube separation. Contractile force production would vary as a function of tube dimension (radius, length) and hydraulic pressure, both of which could be tailored to meet individual patient needs.

The main advantages of this device are: 1) moderate power requirements; 2) flexible volume constraints (i.e., no need to boost MEC volume output); 3) the ability to target a specific area of the heart; and 4) the ability to operate in conjunction with pericardial devices (e.g., the Paracor HeartNet) that act to lower ventricular wall stress. Potential difficulties include: 1) durability of the flexing elements; 2) stable fixation to the epicardium; and 3) potential impairment of diastolic filling.

***Fig. 3*** *Photograph of a prototype hydraulic contractile element formed from 34 thin-walled silicone tubes (0.147 cm ID, 0.193 cm OD) arranged in parallel and secured in tight approximation using fine polyester fiber. The fiber is woven in an over-and-behind fashion across the entire width of the assembly to a height of 4.3 cm so that a solid fabric surface is created. This allows the tubing to collapse completely when empty and to assume a full circular cross section when inflated. This also provides a means to support the tubing walls during high-pressure inflation while maintaining secure sidewall approximation throughout the contraction cycle.*

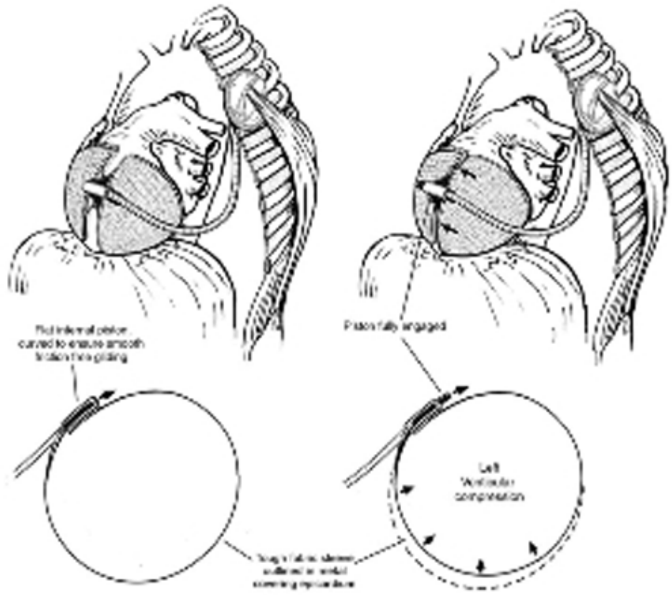

***Fig. 4*** *Drawing of a hypothetical "cardiac sling" powered by the MEC. During diastole (left) the wrap is allowed to open up as the ventricles fill. At the beginning of systole (right) the MEC actuates a piston that closes the wrap around the heart, preferentially pulling the left ventricular free wall toward the septum.*

*Dynamic Cardiac Sling*

The "cardiac sling" method involves the use of a flexible membrane wrapped around both cardiac ventricles. The MEC would actuate this device via a small hydraulic piston situated above the anterior intraventricular (IV) groove as shown in Figure 4. As the piston extends outward it moves the leading edge of the wrap across the IV groove toward the right ventricle, effectively pulling the left ventricular free wall toward the septum. This technique allows for the targeted compression of the LV with minimal right side involvement.

Advantages unique to this approach include: 1) the ability to move the entire LV free wall; 2) a wide force distribution to minimize epicardial trauma; and 3) the ability to provide passive restraint when not active. Issues that remain to be addressed are: 1) the level of support that can be provided via this method; 2) the long-term effect on the epicardium; and 3) whether diastolic filling would be significantly impaired.

*Summary*

This report summarizes our efforts to develop a functional prosthesis for transforming contractile energy into hydraulic power for chronic circulatory support. Results from animal testing of prototype devices are encouraging, but potential problems associated with long-term implantation have yet to be fully addressed.

Should the MEC prove to be a reliable means for transmission of contractile energy, this device could be paired with a hydraulic VAD to form a permanent muscle-powered ventricular assist device free of external hardware. Such a system could potentially represent an inexpensive alternative to heart transplantation and enable patients with heart failure to maintain a higher quality of life.

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## Address Correspondence to:

Dennis R. Trumble, Allegheny General Hospital; 8th floor, South Tower; 320 East North Avenue; Pittsburgh, PA 15212, USA; Phone: (412) 359-3660; Fax: (412) 359-5071; E-mail: trumble@wpahs.org

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