Section V
Applications
VI

Biomedical, Haptic and Micro-scale Applications
A NEW FRONTIER FOR ORTHOTICS AND PROSTHETICS: APPLICATION OF DIELECTRIC ELASTOMER ACTUATORS TO BIONICS

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Abstract

Dielectric elastomer actuators (DEAs) whether used as artificial muscles or as replacements for traditional actuators show great potential for use in modern active orthotic and prosthetic therapeutic applications. Such actuators are roughly similar in function and biomechanics to natural muscle, including the ability to produce the high peak power density needed for muscle-like actuation that can simplifying biomimetic and bio-inspired design. Furthermore, DEAs are also capable of multidirectional actuation, enabling novel external and implantable designs not as suited to traditional actuation technology. Examples include artificial muscle-powered prosthetic arms, active ankle-foot orthoses, and ventricular assist devices. While challenges currently exist in using dielectric elastomer-based actuators for biomedical use, this technology shows great potential for the development of advanced orthoses and prostheses, leading to a substantial benefit for those with physical impairments and disabilities.

Keywords: Artificial muscle, biomechatronics, biomedical electroactive polymer applications, biomimetics, bionics, dielectric elastomer actuators, dielectric elastomer-powered ventricular assist devices, electroactive polymer bicep, orthotics, powered ankle-foot orthosis, prosthetics.

19.1 INTRODUCTION

An ancient Egyptian stele slab 1 located in the Carlsberg Sculpture Museum in Copenhagen, Denmark dating from approximately 1500 BCE depicts a patient suffering from polio using a very long wooden stick as a mobility aid to vault over his non-functional limb. In many parts of the world, similar assistive aids are still used to treat the same disability, in a nearly identical manner. While this method’s longevity is a testament to the robustness of the ancient approach, current and emerging technology allows for the creation of more advanced and functional orthoses and prostheses. In this chapter, we explore the use of dielectric elastomer actuators (DEAs) for use in such external and implantable biomedical applications.

As defined in Chapter 1 of this book, DEAs are novel, muscle-like actuators that operate based on the electromechanical response of a polymeric material to the application of an electric field [1]. Commonly referred to as ‘artificial muscles’, these actuators have demonstrated good performance over a wide range of parameters and configurations.

While no single, consensus definition for ‘orthotics’ and ‘prosthetics’ exists [2], we chose to define a prosthesis as a device which replaces the function of a natural limb, while an orthosis serves by augmenting the function of an existing natural-body system. 2 In other words, a prosthetic can be thought of as a series attachment to the body, as in for example a treatment for limb amputation, while an orthotic

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1 Stele slabs are traditional ancient Egyptian markers constructed in a variety of shapes, usually formed from stone or wood and usually bearing inscriptions, reliefs, or paintings, generally used as boundary markers, tombstones, or for commemorative purposes.
2 Semantic note: ‘Prosthetics’ refers to the field of study, while ‘prosthetic’ is an adjective. The noun form is ‘prosthesis’ with ‘prostheses’ as plural. The same convention holds true when referring to orthoses.
is attached in parallel to a body organ, such as in treatment of limb dysfunction [3]. For the purposes of
this discussion, we will focus on three distinct bionic domains: active prosthetic limbs, external orthotic
therapeutics, and implantable orthoses and prostheses.

To familiarize the reader, we begin with a concise background on orthotics and prosthetics, first
reviewing the history of orthotic and prosthetic technology, then exploring general considerations for
orthotic and prosthetic device design, and finally briefly discussing contemporary design paradigms
and methodologies.

We then explore some of the competitive advantages over traditional actuation technologies of using
DEAs as artificial muscles, and as regular actuators with respect to therapeutic orthotic and prosthetic
applications. These advantages are illustrated by way of case study.

The first study takes the artificial muscle label literally and explores the use of DEAs in actuating
an arm skeletal system in a biomimetic, agonist/antagonist manner. The second case study explores
using DEAs to power an ankle-foot orthosis currently actuated by more traditional means. The final
case study presents a situation where dielectric elastomer’s novel ability to actuate out-of-plane is har-
nessed for cardiac ventricular assistance.

We conclude by considering limitations on the use of DEAs in orthotics and prosthetics, and implica-
tions for near-term adoption.

19.1.1 Historical background

A need for orthoses and prostheses has existed as long as humankind has had to deal with the loss of limb
utility through injury or dysfunction. Simple walking sticks must certainly have been used as basic canes
since the earliest days of humanity and indeed, as demonstrated by the Egyptian stele slab previously
mentioned, rudimentary walking aids are shown to have been used for much of recorded human history.

The art of orthotics can be traced back to the study of practical splint and brace making [4, 5].
Primitive orthoses and prostheses were generally simple devices constructed out of materials on hand,
usually bone, wood, leather, and in time metals. Historically, the study of prosthetics has been closely
associated with that of limb-amputation surgery performed as a critical-care measure in response to
trauma and injury from warfare and battle [6]. While historical accounts exist attesting to ingenious
artificial joints designed by armor-makers as early as the 15th or 16th century [7], the development
and invention of the prosthetic padded peg-leg served reliably as the gold standard of treatment for
centuries [8].

Credited with inventing ligatures, which replaced the contemporary method of searing the ends of
residual limbs to stop blood loss, as well as pioneering the use of site selection to produce limbs that
were as functional and useful as possible, French army surgeon Ambroise Paré (1510–1590) is con-
sidered by many to be the father of amputation surgery and prosthetics.

In modern times, major periods of warfare, and the resulting numbers of grievously wounded soldiers
have had a catalytic effect on orthosis and prosthesis development [9]. The large number of amputations
resulting from the American Civil War established the prosthetics industry in the United States towards
the end of the 19th century. Advances in the brutality of warfare in the 20th century required appropri-
ate advances in orthotics and prosthetics technology to keep pace with the multitude of injured soldiers
returning home.

While enormous progress has been made since the days of the peg-leg – using a modern prosthetic
racing foot, the current world record for the 100 m sprint for a below-knee amputee is within 1.5 s of
the mark set by an able-bodied sprinter [10], frustration still exists within the disabled community as to
the pace of prosthetic and orthotic development, relative to general, technical progress [11].

19.1.2 General considerations for orthotic and prosthetic design

While the specific design criteria for orthoses and prosthesis vary based on the application, user, oper-
ating environment, and exact disability being treated, several common considerations must be taken
into account in designing such rehabilitative systems. The ultimate goal of such orthotic and prosthetic
devices is, at a minimum, to match the performance of the natural limbs and body systems that are
being replaced or augmented. Fundamentally, such devices must be functional, reliable, safe [12], and
ideally comfortable enough for routine, sustained use.
From an engineering standpoint, such orthotic and prosthetic bionic devices must be capable of operating in a highly constrained design space. One of the most important considerations faced in device design is weight. A therapeutic bionic system must ultimately be light enough to be used by the user – for example, an ambulatory foot orthoses must be light enough for the foot to be easily raised while walking. Furthermore, the biodynamic considerations of the additional weight on the body must be taken into account. A very heavy full-arm prostheses strapped far to one side of the body’s center of mass could create problems with balance.

In addition to functional concerns, issues of user comfort must be addressed. The noise signature and the heat produced by the device must be accounted for in a manner that does not cause undue discomfort to the user and those around them. With active or semi-active devices, the energy density of the active element must be high enough to power the device without undue penalty. Another approach is to minimize energy expenditure by maximizing energy recovery.

A final, yet equally vital consideration in the design of orthoses and prostheses is that of the physical appearance of the device (cosmesis) – in the case of external prosthetics, more natural-looking devices are preferred when possible.

All these factors must ultimately be balanced against the final cost of the resulting device to the end user. Ideally, the long-term costs of maintenance and ownership should also be economical, an especially important consideration considering the high level of use advanced orthoses and prostheses might see.

19.1.3 From passive to active: current directions in orthotic and prosthetic development

While entirely passive contemporary devices such as the Össur company’s Flex-Foot Cheetah® prosthetic sprint-foot can perform their single, chosen function remarkably well [13], they do not possess the versatility and adaptability for every day use in a multitude of real-world situations. In order to enable increased functionality and more life-like behaviour, advances in orthotics and prosthetics must be towards active or semi-active devices. Active devices offer a level of control and adaptability not found in passive devices, yet are more complex, requiring sources of power and complicated control hardware and software.

Passive orthoses and prostheses are powered solely by passive elements, such as springs which are generally coupled in such a way that body motion provides them with the elastic deformation required to perform mechanical work in the device. In walking prostheses, springs are usually used to store elastic energy during one portion of the motive cycle, and return it later on in the cycle to aid in ambulation. However, dynamic tasks such as walking, running, or climbing stairs benefit from at minimum the ability to control the apparent stiffness of spring elements used. Such quasi-passive elements, defined as those which cannot apply a non-conservative force, include but are not limited to variable-dampers, and clutches, including combinations of variable-dampers and clutches that function in conjunction with, or supplement other passive elements.

Active systems are capable of providing an even more robust functionality [14]. Currently, modern orthotics and prosthetics are in general powered through the use of a combination of springs, electric motors, pneumatics [15], and more recently shape memory alloy (SMA) actuators [16–18]. The majority of these active devices are lab prototypes or developmental proof-of-concept test-beds, and have not yet been incorporated into commercially available orthotic and prosthetic therapeutics.

19.2 COMPETITIVE AND DEVELOPMENTAL ADVANTAGES OF DEA USE

DEAs have many inherent properties that make them well suited for use in orthotic and prosthetic applications, key among them being the similarity of DEAs in function to the body’s own actuation system – natural muscle, and the fundamental stand-alone technical benefits afforded by such polymer actuators.

Colloquially referred to as ‘artificial muscles’, actuators based on dielectric elastomers are uniquely suited to orthotic and prosthetic development due to their rough similarity in function to natural muscle [19]. Fundamentally, both DEAs and natural muscle are compliant viscoelastic actuators that provide a linear contractile force and are capable of both isometric and eccentric actuation. The magnitude of the
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Figure 19.1 Comparison between natural muscle and direct-drive electric actuation technologies: (a) scale-invariant stroke and force comparison and (b) energy power and speed comparison and bandwidth for various actuators (adapted from [20]).

force and the displacement of the actuator can equal or exceed that of human skeletal muscle on a per mass basis as shown in Fig. 19.1. As a result, elastomeric actuators similarity to natural muscle allows for more biomimetic and bio-inspired design and construction of orthoses and prostheses.

Like natural muscle, DEAs are force controllable (not strictly binary actuators) allowing for fine movement and position control. This allows for orthoses and prostheses that can potentially replicate precise, nuanced natural function.

Modelled in first order as an integrated spring-dashpot system, DEAs exhibit viscoelastic properties similar to natural muscles, further simplifying orthotic and prosthetic design. This feature is useful because a separate damping element no longer has to be included to modulate the output of a mechanical actuator. The inherent compliance of DEAs could make orthotics and prosthetics designed using such actuators more comfortable to the end user. Furthermore, DEAs can be used to modulate the effective viscoelastic behaviour of a joint, without the need for complex engineered structures or feedback loops. This property is explored in more detail in Chapter 14 of this book.

During level-ground running, energy is stored transiently in the elastic deformation of the stretched natural leg muscles – by being able to mimic this behaviour, dielectric elastomer–powered lower-extremity orthotics could allow for more energy-efficient ambulation [21].

Furthermore, such actuator’s natural-muscle-like properties could lead to more anthropomorphic designs. If DEAs advance to the point where their physical form-factor becomes very similar to natural muscle, natural-looking orthoses and prostheses with superficially realistic-looking musculature could be created.

While DEAs are especially promising for orthotic and prosthetic applications due to such actuator’s similarity to natural muscle, their use simply as a replacement for traditional linear or angular actuation mechanisms also show great potential. The potential advantages of DEAs compared to traditional actuator technologies include:

- **Lightweight**: Elastomeric actuators capable of the same peak power weigh significantly less than competing electrical actuation technologies, allowing for more comfortable and natural bionics, as well as use of the actuators in orthotic systems augmenting body locations/limbs traditionally unable to support system weight.

- **Out-of-plane (multidirectional) actuation**: Flat-sheet polymer dielectric actuators are capable of taking on complex (curved) conformations and can expand in two planar directions or actuate out-of-plane relative to the sheet, generating force normal to the curve. This capability may be well-suited for implantable devices where, for example it is desired to mimic the behaviour of non-planar musculature, such as cardiac or respiratory diaphragm muscles.
Scaling and modularity: DEAs are relatively unique in that stacks of several actuators can practically be used in parallel to increase the output force while maintaining a given output displacement. (Force scales in parallel, displacement in series.)

Low cost: Actuators are potentially cheap enough to be easily replaced and commoditized, moderating reliability requirements.

Noise: Elastomer actuator-powered devices can operate silently, an important concern for usability and quality of life on the part of the wearer.

Biocompatibility: The similar physical properties of DEAs in comparison to the body’s natural soft tissues could help with biocompatibility in relation to implantable orthotics and prosthetics. Additionally, dielectric elastomer materials such as silicones have already been shown to be both bio-safe and biocompatible and have a proven track record for both internal and external use [22].

19.3 CASE STUDIES: POSSIBLE APPLICATION OF DEA TECHNOLOGY TO ORTHOTICS AND PROSTHETICS

While there are a multitude of orthotic and prosthetic applications where electroactive polymer-based DEAs could make a substantial difference, we have chosen to highlight three specific applications which are uniquely, or most effectively enabled by dielectric elastomer actuation technology.

19.3.1 An electroactive polymer bicep: a dielectric elastomer-powered arm orthotic/prosthetic

Introduction

DEAs have been compared to natural muscles due to the similarity in their function, physical properties, and behaviour. In this case study, we extend that analogy and use DEAs in place of natural muscle in actuating a biomimetic skeletal arm system. Such a use highlights DEAs suitability for use in balanced agonist/antagonist systems.

The human musculoskeletal system features a load-bearing skeletal system consisting of mineralized bone which is actuated by natural voluntary contractile muscles. Muscles are attached to their connection points by tendons, tough yet flexible bands of collagen-based fibrous connective tissue that apply the tension of the muscle to the bone attachment point. The human arm consists of the humerus bone, which connects at the elbow joint to the paired radius and ulna bones, which continue on to attach the wrist. The humerus, the long bone of the arm runs from the shoulder to the elbow, fitting between the scapula (shoulder blade) and the ulna. The distal end of the humerus forms a hinge joint with the ulna at the elbow, allowing for flexion and extension. There also exists a pivot joint between the capitulum of the humerus and the head of the radius, which allows for pronation and supination motions.

In this example, we focus on the musculature and movement about the elbow. The elbow is bent and the forearm brought up (acute angle between ulna and the forearm) through the action of the bicep muscle. The origin, or fixed skeletal attachment of this muscle is at the scapula and the glenoid cavity (the inside hollow of the shoulder joint), and its insertion (tendon attachment to the bone that is to move) is near the elbow on the radius. When the bicep contracts, the arm is flexed at the elbow due to the tension applied by the bicep pulling the radius bone closer to the shoulder.

The elbow is straightened out by the action of the tricep muscle. The tricep originates in the shoulder and has its insertion on the ulna. The tricep functions by pulling its insertion point on the ulna closer to the shoulder, resulting in an increasingly obtuse angle between the humerus and forearm.

The bicep and tricep function as an antagonistic pair, with the antagonist tricep acting in opposition to the agonist, which in this case is the bicep, the prime mover responsible for generating the range of movement in the joint through contraction. The antagonist functions as an extensor, ‘opening’ the joint while the agonist functions as a flexor, ‘closing’ the joint. Another example of such a pair is the quadriceps and the hamstrings.
Biomimetic application of dielectric elastomer artificial muscles

Biomechanically speaking, such antagonistic pairs are necessary in the body because natural muscles are only capable of contraction, and therefore can only exert a pulling force. This behaviour is similar to the functional mode of simple strained DEAs in their most basic configuration.

At first glance this might appear to be an area where traditional electromechanical linear actuators are of superior utility to natural or dielectric elastomer artificial muscles. Electromechanical linear actuators are generally capable of both pulling and pushing, providing an additional degree of freedom compared to their muscular competition. A single actuator capable of both pulling and pushing could functionally replace a system requiring antagonist actuators. While various dielectric elastomer configurations such as the spring roll are also capable of applying both a pushing and pulling force, not all applications are ideally suited to such function. Antagonist systems, especially as implemented with the specific physiology of the elbow allows for a level of very precise motor control not necessarily easily achieved by a single push–pull actuator. It is now understood that human motion control relies on not just the ability to apply a given force or move to a desired position, but to tune the impedance of the joint in order to achieve the desired behaviour for a given task [23].

DEAs are well suited to such a biomimetic role. In order to function correctly, antagonistic systems must be fine-tuned in order to maintain the balance between the agonist and the antagonist. This balance is potentially difficult to achieve with traditional electromechanical linear actuators. The elasticity inherent in DEAs simplifies antagonistic pairing by providing the ability to damp dynamic perturbations to the pairing, allowing for more robust and versatile actuated assemblies.

DEAs also show promise for such biomimetic applications since, like muscles, they are naturally linear actuators. Electric motors typically generate linear motion by using gearing to translate the motors natural rotational output motion to linear form. Such gearing adds an unnecessary size, weight, and potentially a noise penalty to motors used as linear actuators. While linear electric motors can be used for position control, they require complex electric signalling, such as multiple phase trains and/or translation steps.

As shown in Fig. 19.2, Kornbluh et al. have demonstrated a model of a life-sized human skeletal arm powered by a dielectric elastomer artificial muscle [1]. The muscle consists of a rolled actuator connected between the humerus and the radius that takes the place of the bicep. While the resulting actuator is smaller than would be desired for true natural performance, proof-of-concept functionality has been demonstrated [24].

Other researchers have begun to develop more practical DEA-powered arm prosthetics and orthotics. Recently, Carpi et al. have demonstrated a DEA-powered orthotic hand splint that is capable of modulating the joint impedance of the wrist for more effective rehabilitation [25].

While practical DEAs presently have not been scaled up to match the force levels of larger natural muscles such as the bicep, these examples serve as a demonstration of possible bio-inspired applications.

Figure 19.2 Mockup of a dielectric elastomer-rolled actuator on a full-size human skeletal arm model. Future prosthetic devices may use DEAs as muscles to closely mimic both the form and function of a natural arm.
which could result in more natural and usable orthotics and prosthetics. Further, DEAs may find their first utility as the smaller muscles of the wrist or hand, where the ability to provide for fine motion control is critical in producing a prosthetic with improved dexterity.

19.3.2 A powered ankle-foot orthosis to treat a drop-foot gait pathology

Introduction

In this case study, we explore the use of DEAs in an external, powered orthosis used as a treatment for the drop-foot gait pathology commonly associated with stroke, cerebral palsy, or multiple sclerosis.

Starting in the 1970s, Flowers et al. began research aimed at advancing the prosthetic knee joint from a passive non-adaptive mechanism to an active device with the ability to vary its damping [26–29]. The Flowers knee was capable of exhibiting a wide range of joint damping throughout the walking cycle. High knee joint damping during ground contact prevented buckling. Low damping during the leg-swing phase allowed the prosthetic to swing naturally and freely with damping smoothly increased to decelerate the prosthesis just prior to heel strike.

While the variable-damper Flowers knee was never released commercially, manufacturers have developed a knee orthosis system consisting of a computer-controlled variable-clutch. While only offering locking and unlocking controllability, a variable-clutch design improves the metabolic economy of level-ground ambulation in comparison to more traditional fully locked-knee designs [30].

In contrast to those available for the knee, commercially available ankle-foot orthotic and prosthetic devices are currently completely non-adaptive and passive while in contact with the ground surface. Such devices such as the Össur company’s recently released the Proprio Foot™ are capable of actively changing their position during the swing phase, but remain passive during stance [31]. Such devices usually consist of carbon-composite leaf springs or elastomer bumper springs that function by storing and elastically releasing energy throughout the gait cycle. Compared to non-compliant or damping-only (dissipative) ankle-foot devices, passive elastic devices afford greater heel, toe, and vertical compliance to a below-knee amputee, which has been shown to increase the amputee’s comfort and ambulation speed [32]. While progress has been made, contemporary passive ankle-foot orthoses cannot match and do not perform as well as their biological counterparts in many key metrics, including balance and stability, power generation, efficiency, and life cycle [3].

Research has shown that powered ankle-foot orthoses that are capable of variable damping can overcome many of the existing shortcomings of contemporary ankle-foot orthoses [21].

Current state of technology

To demonstrate the clinical and functional importance and efficacy of a powered ankle-foot orthosis, Herr et al. developed a powered orthosis (Fig. 19.3) to treat the dominant complications of drop-foot, a gait pathology that results from a muscle impairment in the anterior compartment of the leg, as a result of which a patient is unable to dorsiflex the ankle or lift the foot. This leads to slapping of the forefoot after heel strike and dragging of the toes at the beginning of the leg-swing phase of walking.

The developed ankle-foot orthosis is comprised of a variable-force actuator controlled by algorithms tied into models of natural biomechanical ankle function. The actuation system consists of a spring placed in series with an electric motor, similar in concept to the series arrangement of natural tendon with muscle [33]. As a result, the series elasticity enables the modulation of force instead of position, with output force of this spring-electric motor system being proportional to the length-change across the series elasticity multiplied by the spring constant. Therefore, by controlling the position/length of the spring, force and torque can be controlled across the joint of the orthoses.

To counteract the gait complication of drop-foot, the controller commands the actuator to apply a torque proportional to joint position when needed. Therefore, the stiffness of the ankle is actively modulated to minimize forefoot collision after heel strike and the position of the foot is adjusted by dorsiflexing the ankle, providing sufficient toe clearance during the late swing phase. Clinical data from a comparison of two drop-foot afflicted participants wearing both the described powered orthosis and a conventional, constant stiffness orthosis indicated that a powered orthosis that actively modulates both impedance and motive torque may present certain clinical benefits for the treatment of the drop-foot gait pathology in comparison to conventional constant joint stiffness ankle-foot orthoses [34].
However, this resulting powered orthosis is heavy enough to impede walking, unnatural in shape, and noisy. The use of DEA technology has the potential to overcome these present limitations, and by allowing for the integration of joint impedance and motive force controllability, the possibility of considerable advantage to the challenged.

**Application of DEAs to current technology**

Field-activated polymer actuators such as those composed of dielectric elastomers show great potential for adoption in such an orthotic as described above. Since orthotic therapeutic approaches tend to draw inspiration from natural biomechanics, it would simplify the therapeutic approach to incorporate an actuation technology that best mimics natural muscle, the motive actuator for the natural body.

In such an application, a DEA would be used to replace the spring-electric motor system that is used to provide the active control of the ankle and foot during ambulation. A DEA would function as a linear actuator with the ability to dynamically tune its stiffness and modulate its output force on demand. Such a system has the potential to be more functional, usable, and robust than one powered by a spring-electric motor assembly.

As noted, the viscoelastic behaviour of dielectric elastomer-based actuators is similar to that of natural muscle [19], allowing for inherently easier control and a more robust response to high-frequency shocks or disturbances. Considering the demonstrated impact that limb/orthotic stiffness has on ambulation, an actuator with the ability to dynamically modulate its stiffness is preferable. Since such polymer actuators are capable of fast, controllable responses, the force and strain of these actuators can be used to electronically modulate and control apparent stiffness [35].
Usability concerns are addressed by the low-weight and bulk of a dielectric elastomer-powered orthosis and the noise-free operation of such a system. Such considerations would make an orthosis powered by dielectric elastomers eminently more practical, and therefore usable.

As an added benefit, the high electromechanical coupling demonstrated by field-activated polymer actuators could allow for the dielectric elastomer powering the orthosis to be operated in reverse, as a generator, while at the same time providing integrated damping and energy absorption functionality. Such an operational mode could potentially be used to recapture some of the electrical energy applied to the muscle-actuator for actuation. This approach not only allows for a more natural model of muscle function, but could potentially be harnessed to extend battery life – a non-trivial concern.

The benefits and advantages of using DEAs in place of a spring-electric motor system that we have illustrated make such polymer-based actuators very promising for orthotic applications.

19.3.3 An orthotic dielectric elastomer-powered ventricular assist device

Introduction

In this third case study, we explore a potential use of DEAs for an implantable device which cannot be duplicated by more traditional actuation technology. We consider using a DEA as an out-of-plane actuator to actuate against the natural human heart, functioning as a ventricular assist device (VAD). In addition, we explore some of the considerations involved in using DEAs in orthotics or prosthetics implanted into the body.

Assisting a failing heart has been under consideration since the early 20th century. Early efforts focused primarily on replacing the entire heart or the technically simpler solution of supporting and augmenting the function of the left ventricle. Limited progress was made till the development of reliable cardio-pulmonary bypass systems. Such a procedure allows for the circulation and oxygenation of the blood by diverting the blood from the heart and lungs through a heart–lung machine and returning the blood to the aorta. While effective in the short term, such a procedure ultimately resulted in high mortality rates for patients who did not regain normal natural cardiac function [36].

The first attempts at implanting a 'modern' VAD in 1964 resulted in the deaths of most of the test patients within a few hours of implantation [37]. Another early attempt involving a left heart bypass through use of cannulation techniques resulted in the deaths of three out of four patients [38]. The most successful of the early assist attempts was the intra-aortic balloon pump. An inflatable balloon pump in the lumen of the thoracic aorta assists the heart by displacing blood volume from the inside of the chamber itself [39]. Vascular complications, particularly vascular trauma and aortic perforations resulted, causing this to ultimately be a less than ideal therapy [40].

To date, there has already been substantial investigation in the cardiac assist device field. The current state of the art of implantable cardiac assist technology consists of either a cannula-coupled pump which bypasses the left ventricle entirely, or an implantable inter-aortic balloon.

Most therapeutic efforts focus on the left ventricle of the heart as it is required to produce considerably more pressure for the same volume of flow compared to the right ventricle of the heart [41]. As such, left ventricular assistance usually provides a more noticeable return to normal cardiac function. Most patients with heart failure do not undergo a course of right ventricle mechanical assistance, as such a procedure has not proven to be very clinically effective [42].

A major problem facing pump-type VADs that makes contact with flowing blood is the formation of clots. Surface imperfections as small as 10 μm can induce platelet clumps to form. This problem was partially addressed by lining the inner part of the pump with a layer of biological cells [43]. Fibers that encouraged the growth of a cellular layer were attached by a procedure called flocking. To prevent these from breaking off, an over-coating was used in the flock process [44], however, coatings only proved effective for 2–3 months.

When a VAD is implanted in a patient with end stage heart failure it can restore blood pressure and cardiac output back to near normal levels. The VAD boosts the patient’s pumping power by feeding blood into a battery-powered pump and out through a tube connected to the main artery. Furthermore, the relief of pressure in the left ventricle appears to induce reverse structural remodelling [45]. Both the cells and the structure of the heart have been shown to recover after a VAD is put in place [46, 47].
While ongoing work has focused on VAD miniaturization [48], the current generation of VAD devices unfortunately proves too bulky for implantation in small adults and some children. Smaller individuals just do not have the volume within their thoracic cavity for the placement of a pump and the associated electrical control hardware. Furthermore, many children have not physically developed to the point where their thoracic cavity can hold the weight of such devices [49]. This presents a major clinical limitation to the use and adoption of such devices.

Furthermore, current VADs require complicated surgical installation. Patients with VADs that rely on the cannulation of the heart face an increased risk of death due to complication from the surgery and infection [50]. In addition, most modern pump-based VADs simply replace the function of the entire ventricle. Current therapies do not allow the physician to selectively assist parts of the cardiac tissue. Recent efforts have focused on providing a cardiac assist through direct compression of the heart. Such efforts have primarily relied on pneumatic methods of supplementing heart actuation [51]. Such efforts have proven to be effective [52] in laboratory animal studies [53] and show potential for use in humans. Furthermore, a VAD which directly contracts the heart could potentially provide the patient with improved recovery times and reduce damage to cardiac tissues.

**Mechanical actuation of natural cardiac tissue**

We postulate a novel left ventricular assist device (LVAD) that functions by mechanically actuating the heart's own natural tissue in order to provide short term, localized relief for the heart muscle as it regenerates and regains full cardiac function.

At the heart of this device will be a multi-layer DEA. The actuator alternately squeezes and relaxes against the natural ventricle, pumping blood through compression of the ventricle.

The VAD will consist of the DEA surrounded by a stiff ring for structural support (Fig. 19.4). The entire device will be coated by a flexible, impermeable polymer membrane. This membrane will keep the electroded active region of the actuator free from fluid or moisture, while at the same time serving as insulation between the heart, the device, and the body at large. This membrane would be flexible and highly compliant.

**Figure 19.4** Illustration of a possible dielectric elastomer-based VAD. Such a system could be composed of a DEA supported by a stiff structural frame sandwiched between biocompatible and impermeable polymer coating membranes. This would sit over the left ventricle of an ailing, semi-viable heart, actuating in sync with, and providing contractile assistance to the heart.
The VAD would be affixed on and around the left ventricle of a semi-viable and functional heart. Regular diastolic filling of the ventricle would coincide with dielectric elastomer electrode activation, deforming the diaphragm as the ventricle filled with blood. Systole would coincide with the cessation of electrode activation and the elastic return of the actuator to its natural state. This would serve to enhance and augment the natural contraction of the ventricle and provide contractile assistance to the ailing heart.

Future iterations might feature an actuator that is segmented into several discrete, individually addressable and controllable sections allowing for an overall expansion and contraction cycle that more closely mimics the path of the electric depolarization wave in the heart.

This example is presented as a potential example of a novel use for DEAs, and does not take into account the many difficulties involved in such an endeavor from power, to tissue bruising, and the compliance of the organs against which this device will be actuating. Such a concept is not necessarily achievable with current technology, but is presented as an example of a unique actuation modality not easily or practically achieved by traditional actuation technologies in a biomedical context.

Specific issues pertaining to implantable orthotics and prosthetics

While many of the same engineering challenges that face designers of external orthotics and prosthetics are encountered in designing an implantable therapeutic, the task of designing an implant is complicated by the specific requirements posed by the body’s internal environment. At the very minimum, implants must be bio-safe and biocompatible, which includes being both non-toxic and also of such a construction that it will not trigger an immune reaction. Implants must, beyond almost all other considerations be highly reliable. Once implanted, it must be able to safely function without intervention for the entire life of the device, without servicing or outside intervention.

19.4 LIMITATIONS AND DESIGN CONSIDERATIONS OF ORTHOTIC AND PROSTHETIC USES OF DIELECTRIC ELASTOMER

While dielectric elastomer-based actuators have remarkable potential for use in orthotic and prosthetic applications, the technology as it stands at the time of this writing is not without its limitations. Some of these limitations can be alleviated, or even eliminated with more research, while others are fundamental and inherent in this actuation technology. Limitations include:

- **Performance**: While the performance of practical DEAs has increased by several orders of magnitude over the life of the technology and continues to show steady improvement, there is still room for growth as current performance with sufficient lifetime at large size scales is not enough for certain applications. Improvements in materials engineering will likely produce higher-performance dielectrics, while advances in structures will better harness and turn those dielectrics into actuators.
- **Reliability**: An especially crucial aspect for biomedical/bionic applications. Again improving, but current DEAs are primarily hand-made laboratory devices, with rampant sample variation. The more integral the actuator becomes to the functioning of an orthotic or prosthetic, and the more crucial the orthotic and prosthetic becomes to a person’s way of, or very life, the more reliable the actuator must be.
- **Reverse operation compared to natural muscle**: While not necessarily a shortcoming, it must be recognized that dielectric elastomer artificial muscles have an opposite active state compared to natural muscle. Natural muscle contracts when energized, while dielectric elastomer artificial muscles contract when de-energized. However, research in this area is ongoing and Carpi et al. and others have demonstrated dielectric elastomer designs that are capable of operating in a contractile mode like natural muscle.
- **Electrical safety**: Dielectric elastomer-powered orthoses and prostheses must ultimately be safe for the user and those around them. While normally operating at low currents, dielectric elastomers require a high voltage to operate. Orthotics and prosthetics designed using dielectric elastomers must take this into account, ensuring adequate electrical safety conventions are followed. Chiefly, the device must be suitably shielded so that there is no risk of creating a pathway for potentially dangerous current leakage. Care must also be taken to ensure that the device limits the maximum leakage current and electric field that can occur under a worst case scenario.
can be addressed with proper packaging and intelligent electronic driver circuit design, public perception can still be a potential issue. Many might be uneasy with the thought of being, in the case of implantable devices, so intimately connected with and in such close proximity to a nominally ‘high-voltage’ device. External devices must be ruggedized to survive wear-and-tear, as well as changing environmental considerations while still maintaining electrical integrity and safety. Both devices targeted for internal and external use must be rigorously tested and proven.

19.5 CONCLUSION

Just as the digital revolution produced the computer as an updated analogue for the Egyptian stele slab discussed in the introduction, a similarly updated bionic analogue must be developed to replace the simple passive vaulting pole depicted on that stele slab. We stand at the threshold of an age in which current work in bioengineering and biomechatronics can be readily translated into potentially revolutionary orthotic and prosthetic devices that are capable of producing tangible and practical benefits for the physically challenged or those suffering from impairment.

The advanced limbs and engineered therapeutic devices of tomorrow will not necessarily be enabled by discoveries in a single field, but from the integration of advances in materials, mechanics, actuators, sensors, and control systems. While actuators based on dielectric elastomers are just one potential solution to a particular subset of issues in such a broad domain, we strongly believe that the potential of dielectric elastomers with respect to such applications warrants further study, development, and exploration. While limitations do exist with the current state of the technology, DEA’s similarity to natural muscle, benefits as a traditional actuator and ability to actuate in non-traditional ways present a compelling case for their inclusion in the development of the next generation orthotics and prosthetics.

References

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