Artificial Muscle for Reanimation of the Paralyzed Face

Durability and Biocompatibility in a Gerbil Model

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**Background:** Current management of permanent facial paralysis centers on nerve grafting and muscle transfer; however, limitations of those procedures call for other options.

**Objectives:** To determine the durability and biocompatibility of implanted artificial muscle in a gerbil model and the degree of inflammation and fibrosis at the host tissue–artificial muscle interface.

**Methods:** Electroactive polymer artificial muscle (EPAM) devices engineered in medical-grade silicone were implanted subcutaneously in 13 gerbils. The implanted units were stimulated with 1 kV at 1 Hz, 24 h/d via a function generator. Electrical signal input/output was recorded up to 40 days after implantation. The animals were euthanized between 23 and 65 days after implantation, and the host tissue–implant interface was evaluated histologically.

**Results:** The animals tolerated implantation of the EPAM devices well, with no perioperative deaths. The muscle devices created motion for a mean of 30.3 days (range, 19-40 days), with a mean of $2.6 \times 10^6$ cycles (range, $1.6 \times 10^6$ to $3.5 \times 10^6$ cycles). Histologic examination of the explanted devices revealed the development of a minimal fibrous capsule surrounding the implants, with no evidence of bacterial infection or inflammatory infiltrate. No evidence of device compromise, corrosion, or silicone breakdown was noted.

**Conclusions:** Artificial muscle implanted in this short-term animal model was safe and functional in this preliminary study. We believe that EPAM devices will be a safe and viable option for restoration of facial motions in patients with irreversible facial paralysis.


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**Analysis of the Facial Nerve and Associated Sequelae:**

**Introduction:** Facial paralysis is a common condition affecting the facial nerve and associated structures, including the eyelid, external ear, and parotid gland. It can result from a variety of causes, including trauma, Bell’s palsy, tumors, and infections.

**Epidemiology:** Facial paralysis affects an estimated 40,000 patients in the United States each year.1 Most of these cases are self-limiting Bell’s palsy; patients with permanent paralysis require surgical rehabilitation. Patients experience psychologically debilitating disfigurement and impaired communication ability, as well as functional impairments, such as oral incompetence to food and saliva, the inability to smile, brow ptosis, nasal obstruction, and eyelid complaints, such as extropion and eye irritation (exposure keratopathy). Chronic facial paralysis often requires surgical management. Corneal protection is paramount to avoid exposure keratopathy and visual impairment. In the acute setting, eye lubrication regimen is used. Paralytic eyelid rehabilitation may involve gold weight eyelid loading and lower eyelid tarsorrhaphy or canthoplasty. The drawbacks of these procedures include potential gold weight extrusion, eyelid ptosis, and creation of dysyssynchronous slow, gravity-assisted eyelid closure.2 The potential for using an artificial muscle to recreate facial motion in the setting of permanent facial paralysis may restore facial movement, including eyelid blinking.

Traditional rehabilitation in patients with facial paralysis involves static and dynamic surgical procedures that seek to mimic the function of the paralyzed facial musculature.3 Nerve grafting, when possible, can restore tone and function but can be limited by synkinetic facial movement and spasms. In the setting of permanent facial paralysis, the state of the science has evolved to free microvascular muscle transfer to create facial motion. Significant advances in the technique and outcomes of smile restoration have occurred since Harii et al.4 first described the gracilis muscle transfer for facial reanimation in 1976. The motor innervation of a free...
Dielectric elastomers can grow by as much as 300% of their nonactivated size, creating an efficient, powerful artificial muscle. In general, greater voltage results in greater expansion until electrical breakdown. In addition, the EPAM devices can operate at a very low current, which creates little heat or noise.11

We have been developing an artificial muscle–powered eyelid device to recreate blinking for adults and children with facial paralysis12 (Figure 1). We developed the eyelid blink and smile sling concepts by using an amalgam of current surgical procedures and philosophies to create a dynamic, controllable, and permanent alternative to more-invasive surgical options. The current reconstructive paradigm could benefit from the addition of artificial muscle because there are several shortcomings related to facial reanimation around the eye. For one, the gold or platinum eyelid-loading procedure results in a dysynchronous and slow eyelid blink that relies on gravity to pull the eyelid closed. This can affect cosmesis but can also prevent the instinctive blink reflex to protect the cornea. A second shortcoming is that facial paralysis affects lacrimal function in several ways, including lacrimal oversecretion, eyelid ectropion, meibomian gland dysfunction, and absence of a normal tear film.14
Finally, the creation of eyelid blinking with free tissue transfer has not shown great success.15 Unfortunately, current reconstructive methods fail to address all of these issues.

To our knowledge, there have been no studies examining implantation of artificial muscle in a biological model. We seek to further develop a permanently implantable medical device that can create facial movement, such as a smile or opening and closing the eyelids. The device would ideally be interfaced to contralateral normal facial movement—allowing voluntary and symmetric eyelid control—and have a battery that is externally rechargeable without wires or connectors. This module would contain the artificial muscle actuator that would pull on a mechanical sling. We theorize that the EPAM device could be synchronized to the normal side of the face, but this has not been demonstrated. A myoelectric

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**Figure 1.** Conceptual illustration demonstrating a possible artificial muscle and power source design. A, Illustration of the potential applicability of a novel eyelid sling procedure using electroactive polymer artificial muscle (EPAM) to recreate eyelid blinking. The left upper eyelid sling is attached to the EPAM device, powered by a battery, and signaled by a myoelectric sensor (green wire) to the normally functioning orbicularis oculi muscle to coordinate eyelid blinking. B, An electroactive polymer device (*) includes an actuator (†) having an electroactive polymer (‡) in a biocompatible sheath (§). The electroactive polymer is attached to the eyelid sling (¶) and energized by a power supply (¶). A myoelectric sensor (#) is in electrical contact with the actuator to provide a signal from the contralateral orbicularis oculi muscle to coordinate eyelid blinking. Reprinted with permission from Senders et al.12
sensor threaded over the normal side could detect the voluntary facial impulse or involuntary blink and fire the artificial muscle at the same time. A previous study showed that a sling device coupled to an EPAM actuator could be implanted in the upper and lower eyelids to create eyelid closure when the sling was activated.

The objectives of the current study were 2-fold: (1) to determine the durability and biocompatibility of the implanted EPAM device in a gerbil model and (2) to determine the degree of inflammation and fibrosis at the host tissue–artificial muscle interface. The gerbil was chosen because of its tolerance for implantation and our laboratory’s experience with successful application of the head mount to safely direct the wires from the external power source to the EPAM device. A wireless, battery-operated system does not exist. The general hypothesis is that an artificial muscle actuator has the potential to be an effective solution for restoring motion to non-functioning facial movement in children and adults with permanent facial paralysis. The estimated number of eyelid blinks that the potential EPAM eyelid sling would need to generate can be calculated by considering a normal 6 to 15 blinks/min for 16 waking hours a day for 365 days, equaling up to 5 million cycles of motion per year.

METHODS

DEVICES AND POWER SUPPLY

Gerbils received implanted EPAM devices that were stimulated by an external power supply, which allowed for adjustment and monitoring of electrical input. The connection between the power supply and each gerbil was devised using experience by our laboratory in the gerbil model in other applications. In brief, the technique for external power connection to the gerbil involved screw fixation of a 3-mm spring to the posterior skull, bone cement to protect the attachment, and an electroconductive swivel connection (commutator) between the spring and the top of the cage. This allowed the animal to move about the cage without applying torque to the EPAM device. A function generator created a square wave input into the EPAM device, generating movement of the implant that could be palpated under the skin of the gerbil.

SURGICAL IMPLANTATION PROCEDURE FOR THE GERBIL MODEL

The surgical procedure for this experiment was derived from previous studies on surgical implantation in gerbils. In brief, the animals were anesthetized with a mixture of ketamine hydrochloride, 80 mg/kg, and xylazine hydrochloride, 20 mg/kg. The fur over the skull was removed from the anterior limit of the eyes to the middle of the neck. The area was disinfected with povidone-iodine solution followed by alcohol, 70%; this was repeated 3 times. A parasagittal scalp incision was created, exposing the skull. A 1.0-cm-diameter section of periosteum was removed posterior to the coronal suture. A 1.2-mm-diameter burr hole was made lateral to the sagittal sinus for placement of a stainless steel anchoring screw (size 0-80, 0.32 cm). The free ends of the insulated EPAM stimulation wire were passed through a 3-mm-diameter stainless steel spring (to prevent chewing by the gerbil), one end of which was attached to the screw. Dental cement was then applied to the cranium to cover the stimulation wire and screw spring. The free end of the spring was connected to the electroconductive swivel (commutators) at the top of the cage to afford the gerbil free range of motion. These wires were connected to the signal function generator (271-U; Fluke Inc) and external high-voltage power supply amplifier controller (Model 610E; Trek, Inc).

The implanted EPAM devices were activated on initial implantation until euthanasia at 1 KV, 60 contractions per min-
Figure 3. Duration of electroactive polymer artificial muscle (EPAM) device function. Device failure was attributable to electrical wire connections between head mount and commutator unit in all cases. Kaplan-Meier curve illustrating time to EPAM device motion detection failure. Mean duration was 30.3 days.

Cumulative Implant Survival

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<th>Days After Implantation</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
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<tr>
<td>NUMBER OF ANIMALS</td>
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This study represents the first evaluation of the biocompatibility and durability of EPAM devices in an animal model. The results showed that implanted EPAM devices were safe, without stimulating a significant immune response or predisposing animals to infection. The implanted EPAM devices were stable within the subcutaneous site, and no obvious violation of the integrity of the devices was seen. The devices could be continuously stimulated without adverse effects on the animal for up to 40 days. The EPAM devices functioned for as many as $3.5 \times 10^6$ cycles, which would be equivalent to providing more than a year of continuous eyelid blinking for a patient with facial paralysis.

The next phase of experiments will aim to measure (using tensiometry and videography) the strength, durability, and reproducibility of movement created in vivo by artificial muscle. We seek to understand how the fibrotic wound healing process and fibrous capsule, which we observed in this preliminary experiment, will affect the functional movement of the eyelid sling mechanism and EPAM device function during a longer study.

Patients with facial paralysis experience significant functional and psychological impairment. Currently, several nerve grafting and muscle transferring surgeries are available; however, limitations in the quality of the results and the morbidity of the procedures demand that a better option be established. Artificial muscle to recreate facial movement is an exciting new concept that has drawn attention from multiple research forums, national news sources, and even family support groups. This study begins the process of understanding the long-term potential of these devices.
term interactions between host tissue and artificial muscle. By ensuring the safety of these implanted devices, we hope to move forward in determining the functional abilities of these implants.

We had 1 animal death due to a hemorrhage after the sagittal sinus was exposed when the head mount detached from the skull on day 23. There did not appear to be any evidence of infection in this animal at necropsy. None of the other animals developed evidence of infection at the site of implantation, despite the wires exiting the skin from the implant.

This study has some important limitations. The EPAM devices, as designed for this study, did not impart any measurable actuation of anatomic structures. The life span of these units when increased stroke and force are created needs to be measured. We do not believe that this limitation affects the interpretation of the findings in light of the project’s aims. Previous work with EPAM showed no detriment of effect with repeated stimulation while imparting force on a load ex vivo. This short-term implantation period may not reflect the fibrotic reaction to the EPAM device and possible sling material. Determining the functional capabilities of the implanted EPAM devices with regard to the life span while performing their expected functions will be accomplished in a study in a larger mammal (Yucatan pig) model being developed to test the eyelid sling mechanism. These studies will also shed light on the effects of fibrosis and scarring that will envelop the implanted devices and evaluate how detrimental these processes are on their function. Additionally, a self-contained battery-operated EPAM device has not yet been created.

The technology for long-lasting, implantable artificial muscle devices in humans is still in its infancy and needs considerable advancements in engineering before such devices are readily available. The eyelid sling, on
which our laboratory has previously published data,12 provides an avenue for the use of such implantable devices in humans, although this represents only one of many potential applications. Studies are under way to establish an entirely implantable eyelid sling in a cadaver model. Before EPAM devices can be developed for use in humans, several obstacles must be overcome, including the need for smaller, more efficient EPAM device specifications, an internal power source, electromyographic sensors, and the interface between the EPAM device and sling mechanisms. Such devices would require implanted batteries with long life spans. Recent work23 in the nanotechnology field could make this a reality in the near future. Other recent work24-27 suggests that electromyographic signals can be used to control devices, such as intelligent wheelchairs and advanced prostheses. In addition, recent studies28 have shown the feasibility of stimulation for a paralyzed face after detection of electromyographic signals from the normal side of the face.

In conclusion, we have shown in this study that implanted artificial muscle devices can function to create motion. The devices did not stimulate a significant inflammatory response or produce adverse effects. Further studies will be developed to explore the applicability of EPAM devices for restoration of facial motions in the population with irreversible facial paralysis. We believe this will be a safe and viable option, but further engineering designs and adaptation for use in humans remain obstacles to be overcome.

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REFERENCES


