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Review of Current Actuator Suitability for Use in Medical Implants

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Abstract—**This paper presents an initial formal review of the suitability of currently available actuation technologies for use in fully implantable medical devices, with a focus on applications requiring linear motion. Examples of such applications are a mechatronic hydrocephalus shunt and implantable insulin pumps. Some general basic requirements for fully implantable devices are discussed, followed by an overview of potential actuators. Possible design concepts are presented for electromagnetic and shape memory technologies, including a comparison of their respective pros and cons. Methods of modeling and analysis are given to aid early decision-making processes for general design applications. Finally, other more complicated but attractive actuation possibilities are discussed.**

I. INTRODUCTION

SINCE the development of the first intra-aortic balloon pump by Moulopoulos in 1962 [1], actuators have been considered for use in medical implants. Nevertheless, outside of cardiac assist devices, total artificial hearts, drug delivery devices, and discontinued insulin pumps [2]-[4], the majority of implants in use today are passive devices incapable of independent and active mechanical work production.

Due to demographic trends and improved healthcare, the percentage of people over the age of 65 in many developed nations is increasing, causing healthcare costs to rise. The further development of autonomous medical implants may help to reduce these costs by allowing patients to receive the care they require at home or with less utilization of medical resources (i.e., doctor visits, hospitalization, etc.) [5].

To be capable of actively observing the patient's health condition as well as providing immediate treatment, autonomous implants require at least a microcontroller, integrated sensors, and an actuator.

For example, in the case of a mechatronic shunt that may be used to better treat hydrocephalus patients, a suitable actuator is required to adjust a valve, which regulates the patient's intracranial pressure. Shunt implantation (Fig. 1) is the most common treatment for hydrocephalus, which allows the drainage of excess cerebrospinal fluid (CSF) from the skull to another part of the body, typically the peritoneum.

Due to various limitations of current passive shunts, a mechatronic shunt would be preferred. Through a control algorithm, pressure and flow sensors, and an actuator, such a shunt could determine the need for drainage and regulate the amount of flow through the valve [6], [7].

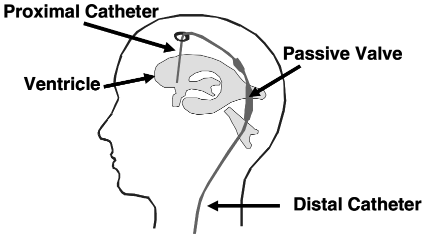

Fig. 1. Example of a shunt used to treat hydrocephalus. The CSF flows though the proximal catheter implanted in a brain ventricle, and passes though the passive pressure valve on its way to the peritoneum.

The purpose of this paper is to present an initial formal review of the suitability of currently available actuators for use in fully implantable medical devices, with a focus on applications requiring linear motion (e.g., mechatronic shunt). To the authors' knowledge, a documented critical and comprehensive investigation of this nature does not exist.

Our discussion is an initial attempt at such an undertaking, and will begin with overviews of some general requirements for fully implantable devices and of possible actuators. This will be followed by a more in-depth analysis of two simple, and therefore, attractive technologies, namely electromagnets and shape memory alloy actuators. In order to aid decision-making for general design purposes, the respective pros and cons of each are discussed, along with a presentation of modeling and analytical methods. Finally, actuation possibilities using electric and ultrasonic motors are briefly considered.

II. MEDICAL BACKGROUND AND ACTUATOR TECHNOLOGY

A. *Medical Requirements and Considerations*

Medical implants impose a unique set of requirements for the design engineer. Some of these are listed in Table I.

TABLE I
GENERAL ACTUATOR REQUIREMENTS FOR FULLY IMPLANTABLE MEDICAL DEVICES[A]

Bio- and hemocompatible	
Long and stable operational lifetime	> 3 yrs
Excellent reliability and/or failsafe	Failure < 5% / yr
Compact/implantable size	~ 10^{-6} m^3
Daily energy consumption	< 1 W·h
Compatible with other medical equipment (e.g., MRI)	
Temperature and heat limitations	< 50 °C

[A] Fully implantable medical device refers to any medical device, which, along with all of its components (e.g., energy supply, energy transfer mediums), is entirely surgically implanted within the body.

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Note that the definition and relative importance of each requirement is dependent on the specific application. The values listed should be used only as guidelines and may vary significantly. For example, the actual maximum temperature of the actuator depends on the biological tissue contacting the implant, the materials, components and thermal insulation used, and the usage pattern of the actuator.

Biocompatibility is a broad term used to describe the various toxicity, reactivity, immunological, and mechanical requirements of a material in a particular biological environment. The daily energy consumption is based on a rechargeable lithium-ion battery, and depends on the other energy consuming components (e.g., sensors, microprocessor), and the desired lifetime of the implant. Additionally, the patient's ability to undergo common medical procedures, as well as the effects of these procedures on the actuator performance, must be considered.

B. *Potentially Suitable Actuators*

A complete review of every actuator available today is beyond of the scope of this paper, and a general overview can be found in [8]. Still, depending on the specific functional requirements, there are several actuators that may be considered reasonable candidates for a fully implantable device (see Table II).

TABLE II
POTENTIAL ACTUATORS FOR FULLY IMPLANTABLE MEDICAL DEVICES

1. Electromagnetic
2. Shape memory alloys
3. Electric motors
4. Ultrasonic motors
5. Thermal (bimetal or wax)
6. Electrostatic
7. Electrochemical
8. Piezoelectric, magneto- and electrostrictive
9. Magnetoelastic

Listed grossly in order of likely application suitability.

Although each technology listed in Table II is a conceivably possible actuation choice, many are suitable for only specific applications (e.g., electrostatic) or possibly require relatively complex control circuitry (e.g., electric and ultrasonic motors). Therefore, for this initial investigation we will focus on the two simplest options for fully implantable devices requiring linear motion. Further information on each listed technology can be found in [8]-[13].

III. ELECTROMAGNETS

A. *Design Concept*

Electromagnetic actuators typically consist of a resistive or superconducting coil and a permanent magnet. Since the magnet's optimal position is just outside the coil and the force-displacement relation is non-linear [14], it is often advantageous to use a design shown in Fig. 2.

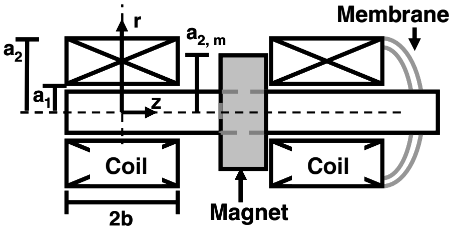

Fig. 2. Possible design for electromagnetic actuator.

A single permanent magnet lies between two conducting coils, whose inner radii act as a bearing for a rod supporting the magnet. A membrane attached to the rod and the outer housing of the coils may, if necessary, seal the system from its surroundings, and may also act as a mechanical return in case of electrical failure. Other failsafe methods (e.g., capacitive discharge, external devices) may also be used.

B. *Pros and Cons*

The main strengths of an electromagnetic actuator are its simplicity and versatility. Although the calculations may be difficult, the physics of these actuators is well documented [9] and analytical programs are available. Furthermore, electromagnets directly accept DC current as an input and output linear force, which allows for a very simple integration with other electrical components.

Other advantages include relatively few components, quick response times, and long lifetimes. Due to the magnet, an implanted electromagnet may be adjusted noninvasively, which can be both helpful and dangerous. MRI compatibility is indeed a concern given the possibility of inductive heating and unintended powering of the conductive coils.

Position control is fairly difficult, making electromagnets more suited for binary applications. Tolerance and alignment difficulties, especially for small actuators ($<10^{-6}$ m^3), can be problematic, and may cause relatively large friction forces. These losses, in addition to diameter, voltage, and current constraints, may unacceptably reduce actuation efficiency.

C. *Modeling and Analysis*

To aid early design decisions, the following modeling techniques may be used with an understanding of the associated errors. More refined methods may be necessary later in the design process.

From electromagnetic theory, the force on the magnet from a single coil, F_z, can be written as

$$f_z(r,\theta,z) = B_{rem,z} \cdot (\partial \vec{H} / \partial z) \tag{1}$$

$$F_z = \int_{V_{mag}} f_z dV \tag{2}$$

where f_z is the force density (N/m^3), $B_{rem,z}$ is the magnet's remanence along the z-axis (T), H is the magnetic field strength (A/m), V_{mag} is the magnet volume (m^3), and A is the magnet's cross-sectional area (m^2). Rather than calculating the vector quantity H at each point in the magnet's volume, (2) can be simplified by using only the magnetic field strength on the coil axis, H_z.

$$F_z = B_{rem,z} A \cdot \int_z (dH_z / dz) dz \tag{3}$$

According to [9],

$$H_z(z/a_1) = G(z,\alpha,\beta) \cdot [(W\lambda)/(\rho a_1)]^{1/2} \tag{4}$$

where G is a geometry factor of the coil, $\alpha = a_2/a_1$, $\beta = b/a_1$, W is the power consumed by the coil (W), λ is the "space factor" of the solenoid, and ρ is the resistivity of the wire ($\Omega\cdot$cm). Since λ and ρ are primarily defined by wire choice, and the factor G reaches an optimum when α and β are 1.75 and 0.75, respectively [14], (3)-(4) demonstrate that the force on the magnet is dependent only on the supplied electrical power, coil inner radius, and magnet properties.

The major error associated with this analysis results from the usage of the derivative of the magnetic field strength on the coil axis to approximate that for the actual field strength within the magnet's entire cross-sectional area. It is therefore reasonable to assume that the error is greater for a magnet with a greater outer radius. More work is necessary to confirm this.

A large-scale electromagnet (a_2 = 0.02 m), shown in Fig. 3, was built and tested.

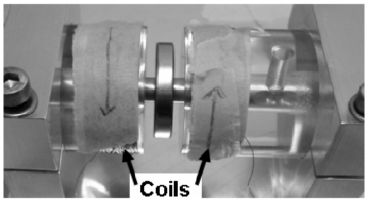

Fig. 3. Large-scale electromagnet, similar to that shown in Fig. 2.

With a ratio $a_{2,m}/a_2$ = 0.74, the error between the force calculations based on (3), (4) and the actual measured force was 130%. This is an unacceptable error for final design calculations; however, the results from the above analysis may still provide an accurate order-of-magnitude estimate useful for early design decisions.

IV. SHAPE MEMORY ALLOYS

A. Background

Although shape memory effects were first observed over 65 years ago, actuators based on this principle have had only limited practical use. Reference [10] is an excellent resource for more information about shape memory alloys (SMA).

The basic principle for thermally actuated SMA is a change in the alloy's microstructure. At high temperatures an austenitic phase is stable, whereas at low temperatures the alloy persists in a martensitic phase. Among other electrical and mechanical properties, the elastic moduli of both phases differ significantly. When a resisting force (e.g., weight or bias spring) is applied to the SMA and the temperature is cycled (e.g., electrically resistive heating), a change in shape of the SMA, and hence a positive work output, is possible.

B. Design Concept

A common form for an SMA actuator is shown in Fig. 4.

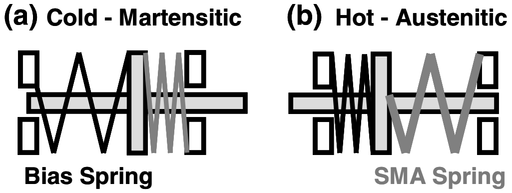

Fig. 4. Possible design for SMA actuator. (a) Inactivated condition when SMA spring is "cold," hence in martensitic state, and compressed. This is also failsafe position; (b) Activated condition when SMA spring is "hot," in austenitic phase, and extended.

A helical compression spring made from an SMA (typically Ni–Ti) is placed in parallel with a standard stainless-steel spring. As martensite, the SMA spring is compressed by the bias spring. Then, as the SMA is heated until austenitic transformation, the SMA spring extends and moves the assembly. Work output is achieved by attaching a payload to the system, and by properly designing both springs. Note that this design has an automatic failsafe feature, which is activated once the SMA spring re-cools and is compressed.

The so-called "two-way shape memory effect" allows for a similar motion as that described above, without the need for a bias spring to compress the martensite. However, due to processing difficulties, property variations, and significant performance instabilities, the "one-way effect," as shown in Fig. 3, is normally preferred [10], [15].

C. Pros and Cons

The main advantages of SMA are simplicity and strength. To actuate, one must only apply DC current through the material and heat it to its transformation temperature. Like electromagnets, this allows for easy system integration and even fewer components. Even at small sizes, SMA actuators are capable of relatively high forces (~ 5 N) limited only by the material's yield stress and fatigue. Another important advantage of SMA, at least for Ni–Ti, is that it is completely nonmagnetic (i.e., it is not affected by MRI) and is biocompatible. Although binary actuation is simpler, proportional control is also possible [10].

However, SMA actuators have severe limitations. First, SMA design is necessarily a trial-and-error process because the material properties and behavior are very sensitive to composition, thermo-mechanical processing, stress-strain history, and thermal environment. Second, due to inherent material hysteresis and heat losses to the environment, SMA tend to be inefficient and have slow response times (> 1 s). Third, to maintain a stable amount of recoverable strain over even a few thousand cycles, total material strains are limited to about 1-2%. Efficiency is further reduced because the SMA spring (see Fig. 4) must fight a rather strong bias spring, which requires the strength to compress the SMA in its martensitic condition. High temperatures (~ 70 °C) can also be a concern. Some of these problems can be alleviated with alternative materials (e.g., Ni–Ti–Cu) or designs.

D. Modeling and Analysis

Although it is generally difficult to calculate several performance parameters like power consumption, efficiency, and actuation time, it is possible to make some simple force, stress-strain, fatigue, and size analyses. From [16], general design calculations are possible with linear approximations of the austenitic and martensitic stress-strain characteristics, obtained either experimentally or from manufacturers [15].

Using general spring equations and, for a fatigue lifetime of about 100,000 cycles, limiting the maximum shear stress to 60 MPa [15], basic force and dimensional parameters can be calculated. The general procedure is different depending on one's requirements and application. For example, given a maximum outer diameter, desired work output, and appropriate spring index, one can find the necessary dimensions and parameters (e.g., turns, spring constant, etc.) for the SMA spring. Furthermore, given a desired stroke, the spring constant of the bias spring is found, from which the spring's other parameters can be calculated. Although an iterative and rough analysis, this process can be a suitable "reality check" for early design ideas.

V. OTHER ACTUATORS

A. Electric Motors

The ubiquity and versatility of electric motors demand their consideration for medical implants. A full review of all electric motors is far beyond our present aim. For some examples of current uses in medical devices, see [2] and [3].

Given the variety of electric motors, it is difficult to make a general evaluation of their performance. Nevertheless, electric motors typically can be used as binary, discrete, or continuous actuators, have long operational lifetimes, and are relatively efficient (~ 50%) at small sizes [17].

Disadvantages of electric motors include misadjustment, inductive heating, and demagnetization difficulties with MRI equipment [18], and necessary power conversions (i.e., transmissions) for linear motion and greater torque. Although DC motors offer simple electrical operation, brushless and stepper motors require somewhat complicated circuitry.

B. Ultrasonic Motors

Piezoelectric actuation has not been suitable for medical implants mainly because of their high voltage requirements. However, a few companies have been able to overcome this obstacle with ultrasonic motors [11], [19].

The main advantages of ultrasonic motors are MRI compatibility, large force production (~ 2 N), excellent efficiency and simplicity (few components). However, they are friction-driven actuators, and therefore, have potentially shorter lifetimes (100,000 cycles). Ultrasonic motors also require complicated circuitry to generate the necessary input signals. Although only a few companies offer such devices for medical applications, they are a novel attempt to offer greater actuation possibilities for implants.

VI. CONCLUSION

It is clear that there is no single best actuator for use in a fully implantable device. Still, based on our investigation electromagnetic and shape memory devices seem to have rather significant disadvantages. It is our hope that the presented modeling techniques may provide some insight into their appropriate usage and limitations, and aid engineers with early design decisions. Despite their greater complexity, electric or ultrasonic motors may be the better choice.

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