IMPLANTING AN ARTIFICIAL SKELETAL MUSCLE INTO THE HUMAN BODY: TOWARDS AN IONIC-STRENGTH BASED PROTOTYPE

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ABSTRACT
To implant an active artificial muscle inside the human body is still a dream due to the extreme difficulty of replicating natural muscular tissue. Present-day development of chemo-mechanical artificial muscles for robots could help to specify first prototypes of such active implants. Based on recent experiments made by the present authors on a “pH-muscle” functioning in an admissible physiologically pH-range, a global analysis is developed for a future “artificial muscle implant” both safe and efficient. A scheme of a possible future artificial muscle implant is shown associating our current prototype, whose skeletal muscle-like behaviour is provided by McKibben artificial muscle technology, with the use of a bio-compatible micro-organism, to be specified, which would be able to generate the necessary ionic-strength change to the swelling-deswelling of the ion-sensitive agent placed inside the McKibben structure. Preliminary experimental results are reported of a 10 cm long artificial muscle and 8 mm external diameter filled with a RCOOH commercial Amberlite resin generating a maximum force of 80 N with buffer solutions of pH between 4.5 and 8.4 in some tens of minutes with the hope of obtaining quicker responses by use of more specific ion-sensitive polymers.

KEY WORDS
Artificial muscle, pH-muscle, Active muscular implant.

1. Introduction
If it is relatively easy to design and insert bone implants into the human body as illustrated by hip replacements [1], no implementation technology is today available for muscular implants. Although skeletal muscles and bones are both physiological tissues, it is clear that the replication of muscular tissue is made impossible due to our technological inability to create flexible materials that can be put out of shape in response to a bio-compatible agent i.e. a kind of a rubber device whose spring-like elasticity properties would be controlled with low energy changes. While waiting for such a marvellous material to present itself, we think that efforts presently being made by some roboticians for developing new biomimetic artificial muscles could be applied to the design of active muscular implants in the near future. It is the relevance of this assumption that we wish to study in this communication. We do not claim in this paper to provide a “royal way” for the conversion from biomimetic robotics to a new physiology of robotic artificial actuators, but we hope through our limited analysis to help make a contribution to the general thinking of this future robotics-based implant physiology. This is why we have decided to initiate our analysis with the global question of the safety and efficiency of an implant (section 2). We then consider the opposition between micro and macro physiological devices (section 3) so as to emphasize the current interest in a macroscopic approach to the artificial muscle as a future implant. In section 4, we consider the difficult question of the choice of the implemented artificial muscle signal before, in section 5, reporting early experiments of a pH-muscle for a future embodiment, developed in our laboratory.

2. Safety and efficiency of the implant
Efficiency is the fundamental property to be expected for any technical apparatus, but in the case of a biomedical device aimed at being suitable for human use, efficiency cannot be developed without considering the safety issue. In the case of an implant, the safety consists of integrating the device without any damage into the surrounding organs and tissues. Safety can, however, be particularly difficult to set up due to the complexity of relationships between physiological systems. Moreover, the efficiency of a biomedical device might as well be useless if it cannot guarantee satisfactory safety levels. A consequence is that safety in fact determines the function of the implant. This idea can be illustrated in the case of the cochlear implant. In the 1980s, two technological approaches were concurrently considered: a single-channel technology which used a single electrode implanted at a relatively shallow depth into the cochlea, and a multi-channel technology characterized by the implementation of multiple electrodes along the cochlea. According to Garud and Rappa’s analysis [2], each previous approach corresponded to both a specific safety and efficiency level: safety is “reduce neuro-physiological trauma during use” and efficiency is “environmental sounds” in the first case when safety is
“reduce trauma of upgrading from single to multiple-channel” and efficiency is “speech recognition” in the second case (page 352). This example illustrates the large functional variation of any implantable bio-medical device defined from the safety-efficiency couple. However, it is not easy to characterize the safety of an implantable device. As emphasized in a paper about implantable brain chips [3], “it may prove difficult to develop nontoxic materials that will allow long-term use” of implants. Furthermore, according to the same authors, “it is also conceivable that there should be a higher standard for safety when technologies are used for enhancement rather than therapy” (page 11). This can be understood as the necessity to be safe both for the individual with the implant and people surrounding it.

What about artificial muscles? Artificial muscles can be considered either for an enhancement role, or for therapy. Implemented artificial muscles for enhancement would consist of substituting or combining more powerful artificial muscles to natural skeletal muscles, in a similar way to some present-day exo-skeletons. Beyond the efficiency and safety problems, this induces obvious ethical difficulties. We will not consider this futuristic and questionable proposition; consequently, our analysis is limited to a future integration of artificial muscles into the human body with the objective of being a substitute for a disabled muscle, or to a biomimetic actuator assisting a malfunctioning physiological activity, for example, urinary and/or faecal incontinence.

3. How to define an artificial muscle as an implantable active device?

According to the standard physiological view, skeletal muscle is typically defined as a hierarchy resolving itself into muscle fibres, and then into its smaller and smaller components [4]. At present no biomechanical device is able to reproduce the microscopic level of muscle contraction. How then is it possible to define an artificial muscle? One way of replying to this question is to note that the definition of any artificial organ can be characterized both microscopically and macroscopically. In the peculiar case of skeletal muscle, its static and dynamic behaviour can be characterized, respectively, by its so-called Tension-Length and Tension-Velocity [4],[5]. This phenomenological model of natural muscle can be the basis of a functional definition of artificial muscle – limited, however, to the skeletal muscle and not adapted to unstriped muscles. We consider it should be presented as follows:

A skeletal muscle is a contractile device whose generated force is, as far as possible, statistically related to the muscle length by a skeletal muscle-like Tension-Length relationship, and whose dynamic behaviour is as close as possible to the Hill Tension-Velocity relationship.

This definition which emphasizes the matchless originality of skeletal muscle as an actuator behaving like a variable-stiffness spring [4], must make possible the integration of an artificial muscle among a set of natural muscles or as a substitute for a natural muscle. However, this first definition does not take into account all constraints imposed by physiological systemic dependence. To return to the efficiency-safety issue, the weakness of such a phenomenological definition lies in the current absence of a general methodology combining a global functional organic definition with an exhaustive list of systemic requirements. As in the case of the cochlear implant, the conversion from the abstract implant definition to its efficient and safe alternative, remains empirical. This empirical research for the conversion towards realization can, however, be specified from a general anthropomorphic principle: giving a human-like form to the implant is helpful for its physiological integration. This argument completely renews the problem of actuator shape during its functioning: because the external form of the skeletal muscle is characterized by a global spindle shape modifying its dimensions during the contraction, for any artificial muscle a functioning depending on a shape changing and not on moving jointed pieces, is expected. This explains the prevalence of rubber and other polymeric materials in present-day artificial muscles’ development. Due to its linear actuator type, the spindle-shaped natural skeletal muscle imposes a significant constraint: keeping a constant volume during the full contraction. We can now complete the previous definition of the artificial muscle by the following specification of the contraction force:

The contraction force of an artificial muscle in accordance with the phenomenological-model skeletal muscle, is produced in such a way as to cause the actuator to change shape during the process in the way, as far as possible, of a spindle with a constant volume. The power-to-mass and power-to-volume ratios must be similar to corresponding physiological values.

Independently of the complementary question of the biocompatibility of materials, it appears that today no actuating device corresponds to this definition. Fig. 1 gives some examples of artificial-muscle shapes for an “external” use as robot or orthotic actuator which could prefigure future implanted artificial muscles. Let it first be noted that all considered examples are in accordance with the proposed definition of an artificial muscle as a “non-jointed” actuator, but are without a non-constant volume shape changing during contraction. Without taking into account the power issue, it could be thought that the too cumbersome shape of the recent pleated muscle [6] makes it poorly adapted for internal uses. Pending a definitive technology which perhaps could be based on electrically active rubber-based devices – whose shape changing could be made at constant volumes – as attempted through the roll-actuator [7], we favour so-called McKibben technology which is at present used as a robot bio-mimetic actuator, or as a prosthetic actuator [8],[9].
McKibben muscles in renewed versions can be characterized by a set of analogous properties with natural muscle, whose main characteristics can be listed as follows, in accordance with our previous analysis:

1. Static behaviour surprisingly analogous to natural skeletal muscle: McKibben muscle is like a variable stiffness spring whose inflation pressure analogously corresponds to neural activation;

2. Dynamic behaviour which can also be analogous, to a certain extent, with skeletal muscle accompanied by a judicious choice of external braided sheath, as we have tried to demonstrate in a previous work dealing with the compatibility of McKibben muscle with Hill’s model [10];

McKibben muscle – it is rarely emphasized – is a non-jointed fluidic actuator. Its functioning principle, illustrated in Fig. 4, is based on sheath “openings” characterized by an initial braid angle (see our paper [11] for details). The “mobile” part of the actuator – its braided sheath – is fully integrated into the actuator materials and, as a consequence, McKibben artificial muscle is naturally tight as opposed, for example, to a fluidic cylinder. As soon as it is possible to make safe the crimping of the end-tips between the inner tube and the braided sheath, this “closed” form of the actuating device is an important safety element for an implanted artificial muscle. However, this type of bio-mimetic non-jointed actuator cannot yet function in full accordance with the basic principle of a shape – changing at constant volume, since during contraction any fluidic artificial muscle consumes energy, its volume cannot be kept constant. Consequently, the efficiency of this artificial muscle is limited by the consequences of volume increases during contraction, i.e:

1. Muscle radius increases much more during contraction than natural skeletal muscle;

2. Maximum contraction ratio is acutely lower than natural skeletal muscle.

In the case of the McKibben muscle, it can be shown that an initial braid angle of about 20° leads to maintaining maximum external muscle radius to about 200% of the initial muscle radius, with a maximum contraction ratio of about 25%. This is about half the 50% natural skeletal muscle maximum contraction, but it is important to note that this 50% contraction ability is helped by the passive extension which is barely reproducible with a “mechanical” muscle. This latter point emphasizes the fundamental advantage of a material-based muscle over a mechanical-muscle: the perfect artificial muscle would be a spindle made of a stretchable material which can contract to about a maximum ratio of 40%, while keeping its volume constant, in response to a bio-compatible energy source. Because such bio-mimetic material is not yet available – rubber is mainly a stable material whose contraction necessitates high energies, we consider that a mini-cylindrical McKibben muscle could be a first step towards a material-like artificial muscle. A question, however, remains: what choice of an adapted control signal?

4. Choice of the control signal

4.1 Homeostasis and active implants control variables

It is well known that human physiology is based on a general homeostasis principle which maintains all physiological variables in strict limits: body temperature, blood pH, …etc. The acidic pH of the stomach is an exception to this rule which is used in drug delivery systems. As a consequence, any artificial muscle has to be controlled by a variable which must vary in accordance with this homeostasis principle. Here this is an important safety issue: even locally, an excessive variation of a physiological variable induced by the active implant can
lead to very serious consequences due to the inter-
dependence of physiological systems. Among the large
variety of available physical and chemico-physiological
variables which could be candidates for controlling active
implants, the difficulty is not to select one but to adapt the
control range imposed by the technology to a safe
physiological range. An amplifier of the control variable
can be a necessary consequence. This is in our view, a
new challenge for active implants. Amplifiers for
controlling robotic orthoses actuated by DC-actuators
already exist, and have shown their efficiency as
highlighted in recent experiments performed at the
Rehabilitation Institute of Chicago [12], and as illustrated
in Fig. 2. But, if such experiments show the possibility of
capturing the physiological signal to trigger a non-
biological actuator by means of an adapted amplifier, they
do not consider the peculiar problem of locating the
actuator and its amplification inside the body.

Fig. 2. Orthotic robot-arm associating natural neural
control to an external actuator (see text).

With respect to our safety-efficiency question, we can say
that the RIC-robot orthosis solves the safety-efficiency
problem by splitting it into an internal subproblem –
orthosis control – whose efficiency is obtained by re-
routing the nerves from the shoulder to the waist, and
safety is insured by non-invasion of technical devices, and
an external subproblem – the robot itself – whose
efficiency and safety are the consequences of a sound
mechanical device, and an adequate actuator-system
choice including amplifiers and energy supplies. If the
actuator becomes an implant, its efficiency depends
directly on the possibility of implanting the energy supply
it needs, and its safety mainly depends on the way of
controlling this energy without any risk to the body.

4.2 Colateral effects of a control variable

Another physiological characteristic must be taken into
account for the safety of implants controlled by external
signals: possible-signal “colateral effects”. It is well
known that electrical stimulation of neural tissue injects
charges into the biological environment using both
capacitive and faradic reactions. As a consequence,
although neural prostheses use charge-balanced biphasic
pulses with zero, uncharged pH changes potentially
harmful to tissue, can be induced. To reconsider the case
of cochlear implants, it has recently been shown that
marked pH changes can be produced close to the
electrodes performing electrical stimulation using charge-
balanced biphasic pulses at high intensities and rates [13].
It is clear that the induced pH effects, but also changes in
temperature could be dangerous for an implanted motor
requiring a relatively high energy level controlled by an
electrical variable. This is to avoid chemically and
physically undesirable effects induced by the electrical
control that we envisage to choose as a primary control
variable for the ionic strength of a solution irrigating the
muscle implant.

In following paragraph we report experimental results of
an original artificial muscle with the objective of
controlling it by a physiologically-compatible pH change.

5. Towards an ionic-strength based artificial
muscle

5.1 A safe structure inspired from McKibben muscle
structure

We have previously emphasized the relevance of adapting
McKibben external-use artificial muscle structure to a
future internal use. This can be made possible if the
production of pressure inside the rubber tube could be
obtained in a way other than the fluidic one, whose
required pressures are not admissible inside the body. A
bio-compatible agent is also necessary to generate the
“equivalent” fluidic pressure needed for artificial muscle
contraction. We have shown elsewhere that ion-exchange
resins were good candidates for reversible swelling and
deswelling in response to a pH-variation [14]. As also
emphasized earlier, the McKibben structure can appear
particularly safe as long as it can be ensured that the
rubber tube does not explode under pressure. This is
relatively easy to obtain by a judicious choice of inner
tube thickness [11], in accordance with the maximum
pressure or, in our case, the “equivalent” pressure of the
resin balls against the wall – estimated to about 3 bar in
later experiments. Fig. 3 illustrates the experimental set-
up devoted to highlighting the bio-mimetic static and
dynamic performances of a small 10 cm long and 8 mm
external diameter pH-muscle filled with a RCOOH
commercial Amberlite resin.

The two base/acid chemical reactions, respectively,
responsible for the swelling :

$$\text{RCOOH} + \text{Na}^+ \text{OH}^- \rightarrow \text{RCOO}^- \text{Na}^+ + \text{H}_2\text{O}$$  \hspace{1cm} (1)$$

and :

$$\text{RCOO}^- \text{Na}^+ + \text{H}^+ \text{Cl}^- \rightarrow \text{RCOOH} + \text{Na}^+ \text{Cl}^-$$ \hspace{1cm} (2)$$

of the deswelling correspond to a bang-bang control of
the artificial muscle between a high pH corresponding to
the full relaxation state, and a low pH corresponding to
the full contraction state. It is important to note that this
control mode is made possible by a bio-mimetic open-loop control of the artificial muscle: the application of basic pH obtains without the help of any force or position sensor, whether the production of a steady-state static force in isometric force, or a steady-state position in isotonic mode, as illustrated in Fig. 4. If, for the moment, the response-time question, which is discussed later, is not considered, the force efficiency of the artificial muscle is easy to obtain by associating a judicious choice of McKibben structure geometrical parameters with an adapted resin quantity inside the muscle inner tube. However, even if we assume to be able to design the McKibben structure using fully biocompatible materials, the question still remains of the safe use of basic-acidic reactive solutions.

5.2 Towards a control of the artificial muscle with a physiologically compatible pH-range

PH muscles are generally controlled using strong acid HCl-strong base NaOH. In the case of a pH-sensitive

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**Fig. 3.** Experimental set-up for determining static and dynamic performances of a polymeric McKibben artificial muscle fed alternatively by basic and acid solutions (see text).

**Fig. 4.** Open-loop control of the ion-exchange resin artificial muscle by bang-bang pH variations: (a) general control scheme, (b) experimental validation in isometric conditions – at zero-contraction state – in response to 0.1 NaOH and HCl solutions, (c) and in isotonic conditions against different loads (the position variation is represented as a contraction ratio defined by $\varepsilon = (l_0-l)/l_0$ where $l_0$ is the initial muscle length and $l$ its current length.
polymer containing acid groups such as the considered ion-exchange resins with COOH functional groups, resin swelling in basic pH is obtained by the exchange inside aqueous medium of Na$^+$ ions (from NaOH) with H$^+$ ions (from COOH functions), and the deswelling in acid pH by the exchange of H$^+$ ions (from HCl) with Na$^+$ ions (from the RCOONa$^-$ functions). When pH varies, the concentrations of Na$^+$ and H$^+$ ions also vary. In point of fact, although the term pH-muscle has been adopted for designating this kind of artificial muscle, it clearly appears that their pH-sensitivity is essentially an ion-sensitivity. This means that the true control variable of these artificial muscles is the concentration of reactive ions inside the aqueous medium while pH, in terms of control, is a secondary control variable. By splitting these two control variables, a high concentration of reactive ions in the reactive medium with a moderate pH would be maintained. The standard use of buffer solutions can thus be considered as a very simple and efficient method of reaching this goal. Consequently, we substitute a couple composed of a weak acid buffer-weak base buffers for the strong acid HCl-strong base NaOH, as pointed in Fig. 5.a’s scheme. One of these couples can be NaHCO$_3$ – CH$_3$COOH+CH$_3$COONa. Subsequently, we substitute a strong basic ion-exchange equation responsible for the polymer swelling expressed in Equ. (1) by the following equation in which it is assumed that the weak basic buffer is in excess, i.e. $a_{\text{weak}}>>1$:

$$
\text{RCOOH} + a\text{Na}^+ + a\text{HCO}_3^-
\rightarrow \text{RCOO}^-\text{Na}^+ + (a-1)\text{HCO}_3^- + (a-1)\text{Na}^+ + a\text{H}_2\text{CO}_3
$$

(3)

and the strong acid ion-exchange equation responsible for the polymer deswelling expressed in Equ. (2) by the following equation:

$$
\text{RCO}_2^-\text{Na}^+ + a\text{CH}_3\text{CO}_2^- + a\text{Na}^+
\rightarrow \text{RCO}_2\text{H} + (a-1)\text{CH}_3\text{CO}_2^- + (a+1)\text{Na}^+ + (a+1)\text{CH}_3\text{CO}_3^-
$$

(4)

In this way, it appears possible to control our artificial muscle prototype by a pH-range limited to about 4.5-8.4, as illustrated in different trials reported in Fig. 5. It is thus possible to experimentally determine some “optimal” buffer concentrations to generate the same maximum force as that obtained with NaOH 0.1 M solution with a close response time – which is 0.25 M in Fig. 5.b isometric response. As shown in Fig. 5.c, dynamic artificial muscle functioning is emphasized in isotonic response against loads between 0.25 kg and 10 kg.

![Fig. 5. Experimental validation of the control of artificial muscle by means of buffer solutions, (a) general control scheme, (b) isometric response for various concentration buffer solutions, (c) corresponding isotonic response against loads from 0.25 kg to 10 kg.](image-url)
5.3 A proposed scheme for a possible artificial muscle implant based on an ionic strength generator

As already mentioned, the closed and compact envelope of the considered artificial muscle appears to be particularly adapted for an implementation inside the human body whose materials (end tips and braided textile sheath) could easily be adapted to the physiological compatibility requirement. We have attempted in Fig. 6 to propose some speculative scheme of what this artificial muscle implant designed around McKibben artificial muscle technology might be: the ion-sensitive chemical agent is placed inside the McKibben structure, as in the case of our prototype. However, as can be seen in related experiments of Fig. 5.b and 5.c, the ionic version of McKibben muscle is appreciably slower than the pneumatic one on the same scale. Our choice of commercial resins non-specifically devoted to a quick swelling-deswelling, is one of the reasons for this power decrease, and we can hope in the near future to use quicker ion-sensitive agents. Furthermore the possibility of adapting slow muscles to physiological functions with relatively long biological rhythms will be discussed in the conclusion. Beyond this power issue, two major difficulties prevail for an efficient use of the implant: flow control on the one hand, energy ranges on the other hand.

Solution circulation needs a micropump. This kind of micro-device implantable into the human body has already been accomplished in laboratory conditions [15] and can be expected to be marketed in the near future with embedded low-consumption electric batteries, in comparison with what would be necessary for implanted electric actuators. By means of implanted microvalves, it is possible to realize a closed-cycle circulation of the basic solution until the swelling and, consequently, for the contraction to be effective. The deswelling phenomenon is obtained by switching to the acidic solution without a “washing” of the muscle content being necessary. In case of problems, a waste disposal device can be imagined to be mixed with the urinary one.

This switching process between a basic buffer solution and a acidic buffer solution can be adequate if some independent implantable “ionic strength generator” can be associated to the muscular implant. In our view, biocompatible micro-organisms would be able to produce the desired ionic-concentration changes: it is known, for example, that yeasts are able to significantly change extracellular pH during fermentation [16]. It is clear that there is still a gap between this well-known phenomenon and its integration into the human body with adapted time-response controlled by a suitable input. However, the challenge of adapting micro-organisms to the control of muscle implants seems reasonable. These ionic concentration changes are induced by a food supply peculiar to the micro-organism (sugar, O₂ …etc) but, as can be expected, in limited quantities with the hope in the near future of obtaining this nourishment directly from the blood. It is furthermore assumed that the general device controller will be able to select the food source either for basic or acidic change. To some extent, and by comparison with the performance of the RIC-robot, this is the pump feeding the muscle implant in combination with the ionic-strength generator, which would be interfaced to the corresponding motor nerve assumed to be healthy. A remote triggering of the muscular implant from an external controller can also be imagined.

6. Conclusion

From a general efficiency/safety principle and our experience in the design of “pH-muscle” for biomedical applications, we have tried to specify several conditions for a future implantation of an artificial muscle into the human body. The following four issues emerge corresponding to non-solved problems, but for each of them preliminary solutions can be proposed.

6.1 The artificial muscle as a constant volume changing-shape system

Any artificial muscle tries to capture the typical spindle shape of the skeletal muscle by controlling responsive materials in closed envelopes. By so doing it appears very difficult to maintain the actuator volume constant, as the natural muscle does. No controllable reversibly shape-changing material is today available. A kind of “magic” rubber device controlling chemical reactions in a spindle-like closed envelope such as the McKibben braided structure, provides the possibility of a relevant approach to this form requirement.

6.2 To control the artificial muscle by a bio-compatible agent: the search for the right control variable

Because of the homeostasis principle the choice of the control muscle-implant variable is a subtle problem. On the one hand, it can be hoped to connect the natural neural transmission to the implant controller. On the other, it is well known that the electrical energy transmitted by nerves cannot be directly used by standard electric actuators without the intermediary of amplifiers and batteries. Without trying to eliminate a complete electrical approach to the problem, we propose to consider alternative approaches and, in particular, a pH-based one employed for an experiment defining artificial muscles controlled by physiologically compatible pH variations. The problem is thus to find a way of reproducing this pH inside the body without the use of large buffer tanks! This question is directly linked to its supplying mode as discussed in next point.

6.3 To solve the energetic autonomy issue by incorporated micro-organisms generating pH variations

All embedded actuators need sufficient ranges to be efficient. This range issue is all the more crucial in the case of an active implant, its longevity and service life being critical for both its efficiency and safety. In
favouring an ionic responsiveness of the muscle implant, we propose to apply the established technology of micropumps for artificial sphincters to the circulation in a closed cycle of a buffer solution, whose ionic strength would be triggered by a micro-organism able to make its pH variable, like some yeasts do.

6.4 To generate the power adapted to the task

To implant an artificial muscle which would be an efficient substitute for a skeletal muscle involved in locomotion, is the ultimate aim of muscular implantation. Before reaching this goal, some easier-to-reach objectives could consist of favouring physiological functions involving muscular contraction with longer biological rhythms such as urinary and faecal functions. An artificial muscular implant could be very useful as a remedy to malfunctioning global musculature responsible for the well known difficulty of urinary incontinence, but also the much more socially destructive problem of faecal incontinence [17], [18]. Our future work will consist of attempting to convert our present prototype, shown in Fig. 6, into a pre-implantable prototype with a closed-cycle circulation of weak base and weak acid solutions generated by a yeast-type micro-organism.

Fig. 6. Speculative scheme of an ion-sensitive muscular implant.

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