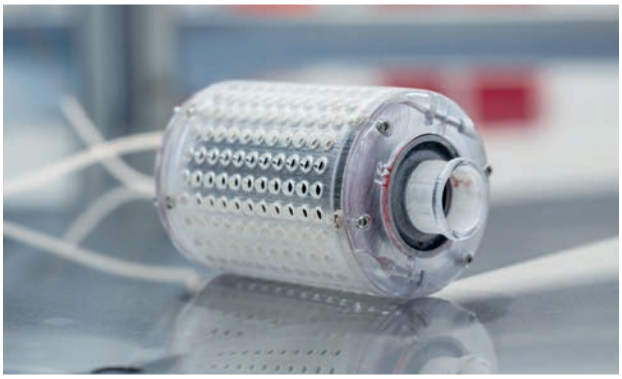
Center for Artificial Muscles
Report 2022

Center
for Artifical
Muscles

“A so great human adventure to perform and to succeed in creating these new medical devices”

PROF. YVES PERRIARD

Introduction



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After 4 years of development dedicated to research on a soft cardiac assist device, the Center for Artificial Muscles has opened its fields of application to facial reanimation and urology. Indeed, thanks to the additional CHF 8 million granted by the Werner Siemens-Stiftung, the collaboration with Nicole Lindenblatt from the department of plastic and reconstructive surgery of the University Hospital of Zurich and Fiona Burkhart from the department of urology of the University Hospital of Bern began in 2022.

The tubular actuator around the aorta designed to support the heart, has seen its development continued with the realization of new in-vivo tests in October 2022. A new design and a new approach seem to bear fruit since the energy provided has been multiplied by 4, meaning a more efficient actuator.

Finally, a new partnership has been set up with the European Children's Heart Center in Munich. An adaptation of the current system could make it possible to replace the right part of the heart, in particular for children presenting a congenital malformation. The lightness of Dielectric Elastomer Actuators (DEAs) is an undeniable advantage compared to current systems developed for adults, which are unfortunately not at all suitable for young patients.

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UNIVERSITÄT
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The European Children's Heart Center in Munich

ekhz europäisches kinder herzzentrum münchen

The European Children's Heart Center (EKHZ) in Munich is the result of a collaboration between the clinic for surgery for congenital heart defects and pediatric heart surgery at the German heart center of the Technical University (TU) and the section for surgery for congenital heart defects and pediatric heart surgery at Klinikum Großhadern of the Ludwig-Maximilians-Universität (LMU) in Munich. Both clinics provide pediatric heart surgery at the highest level of medicine and science, and together they are Germany's leading centers for the treatment of congenital and acquired heart defects.

"Children with congenital heart disease have a profound effect on us."

PROF. HÖRER

It goes without saying that the EKHZ needs to be kept updated on the health of young patients for many years after any medical procedure. Research towards achieving this goal is carried out on a consistent basis. They always find new ways to further improve the results of the therapy, thanks to the many years of experience they've gained performing many different procedures. For instance, the EKHZ is at the forefront of research regarding the treatment of univentricular heart disease. Important multicenter studies are being carried out at the EKHZ in collaboration with other large clinics in Europe and the United States in order to further advance the treatment of extremely uncommon congenital heart defects. Registers and databases, such as the German Ross Register and the European Pediatric Cardiac Surgery Database, are two examples of the kinds of projects in which they are involved in maintaining and analyzing data.

Research efforts are currently being focused on developing the ideal material that could be used to replace blood vessels or heart valves in the body. They are leading a project that is being carried out in collaboration with the ARTORG Center for Biomedical Engineering Research at the University of Bern with the intention of putting the newly developed materials to use in clinical settings. Moreover, it is possible that heart support systems will need to be implanted in patients who are born with extremely severe congenital heart defects, such as people with only a single ventricle. The pumps that are currently available held an important position in the field of surgical therapy. However, the future of this industry will see a transition away from mechanical pumps towards artificial muscles. That's why, the EKHZ is developing specialized systems for patients in collaboration with the École polytechnique fédérale de Lausanne.

https://ekhz-muenchen.de

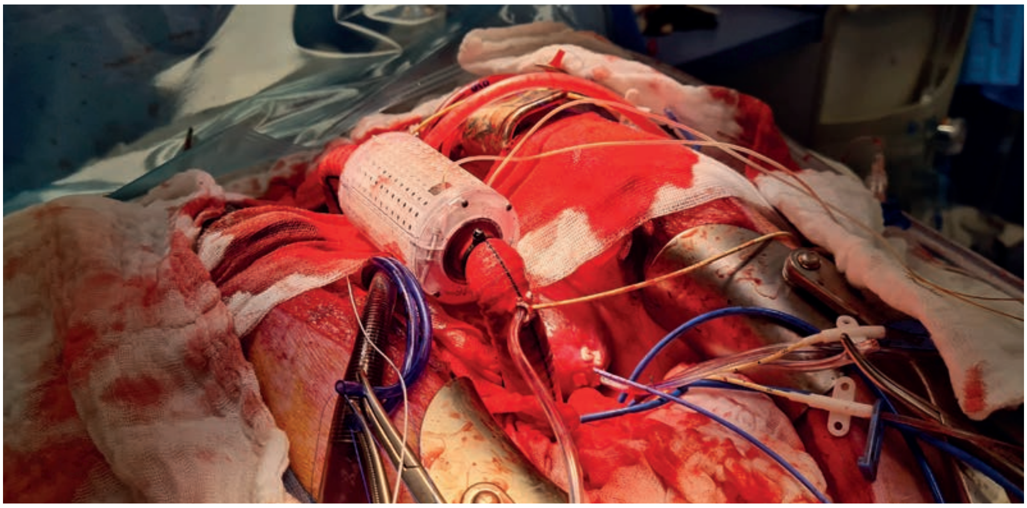
EPFL

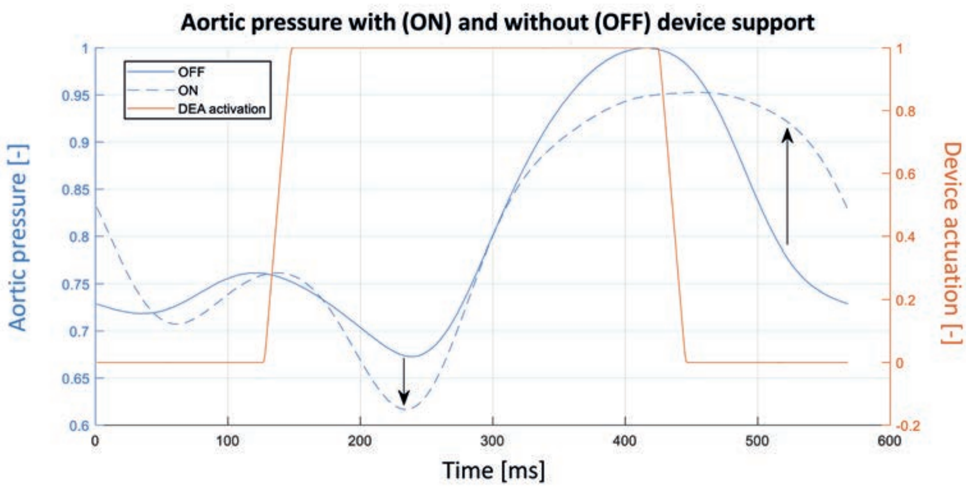
Scientific Highlights

Cardiac assist devices

In-vivo experiments of the augmented aorta

After last year's first successful implantation of the device in-vivo, in a pig, we have improved the technology and performed a new series of in-vivo experiments this year. The device was implanted in close proximity to the left ventricle via an aortic graft attached to the ascending aorta in pigs. The device performance was clearly improved compared to the in-vivo results last year. It was able to support the heart by lowering pressure during late diastole (before opening of the aortic valve) and increase pressure during early diastole (just after closure of the valve) by more than 10%. The non-obstructive design of the tubular device allows surgeons to fine tune the support by shifting the device actuation compared to the heart cycle to optimize the device performance. The device was functioning for up to 36'000 (average 10'000) heart beats and 8'400 activation and deactivations (average 2'000).

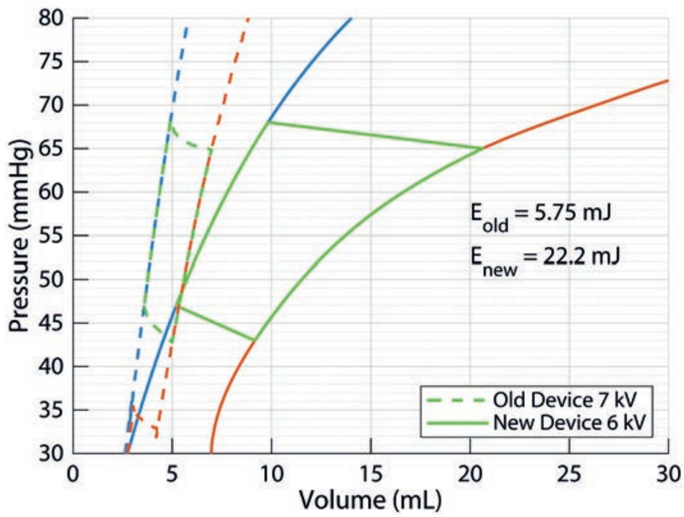




A better DEA for the in-vivo tests

Following the results from the 2021 pig experiments, one key challenge for the year was to increase the performances of the DEA, i.e. energy and displacement, to improve the cardiovascular parameters. The main change compared to the previous design was the addition of an axial pre-stretch. The original tube is 40 mm long and is stretched to reach a length of 60 mm thanks to the new housing. Adding this pre-stretch allows a more stable operation of the DEA by increasing the dielectric strength and lowering the risk of breakdown on the side of the electrode.

With the new design, we activated at 6 kV compared to the 7 kV from the previous one whereas we multiplied by four the energy provided by the DEA going from 5.75 mJ to 22 mJ. The displaced volume of blood is also increased going from 2.1 mL to 10 mL at deactivation. These better results translated into better hemodynamic results measured during the experiment as seen previously.

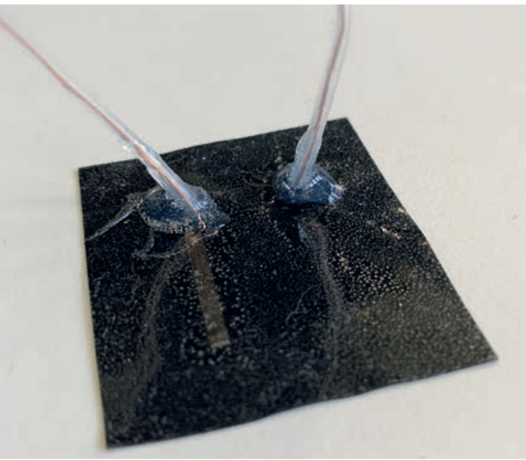


During clinical trials, several tubes are used. Until now, removing the tube from the aorta and connecting a new one took some time for the surgeon to complete. Moreover, with each change, a part of the aorta is lost. The idea of creating replaceable tubes was therefore explored and consists of a connector that would be permanently fixed to the aorta and an implant that would be hermetically connected to it.

Until the present, the implants are rolled and replace a part of the aorta. This requires removing part of the aorta and connecting the device in a tight way. We are also working on the possibility of creating an implant that is wrapped directly around the aorta. However, this induces some challenges. First, the use of silicone makes adhesion to any other material very difficult. Especially when it comes to living tissue. In addition, the fixation must be performed quickly because during surgery, the body can react in a negative way if the procedure takes too long.

Fully immersed membrane

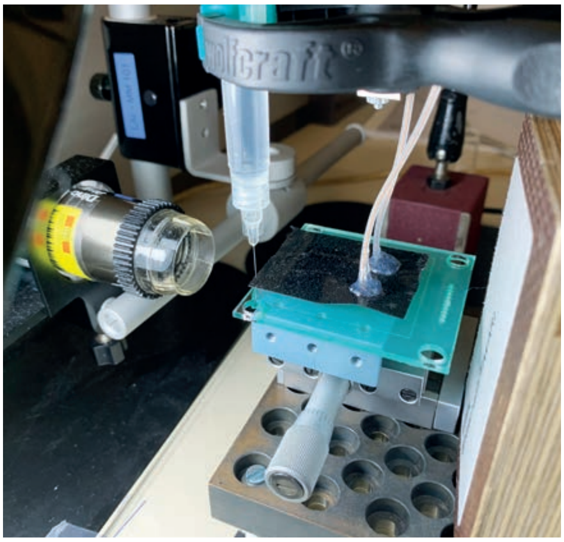
In the context of our ongoing work of making cardiac assist devices, DEAs are operating poorly when coming into contact with blood. Initial tests indicate that DEAs undergo early and irregular electrical breakdowns when it is subjected to operate in a saline solution (or blood like environment). This reduces the reliability of the device and so this challenge must be addressed. Thus, we are studying influence of ion diffusion when DEAs are placed in saline water. As a performance indicating parameter, we are measuring: electrical capacitance, resistance, contact angle, and breakdown voltage.

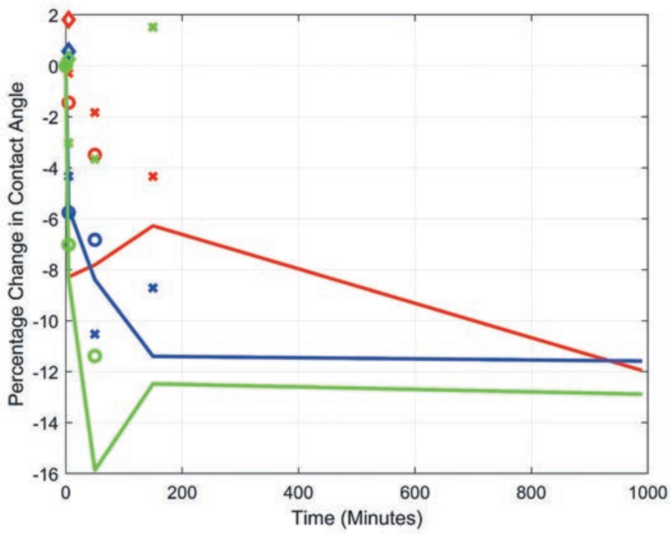


We used 20 mm x 20 mm samples composed of two 100 um thick active layers corresponding to the structure used during the animal experiments. We placed them in 3 different saline solutions S1 (9 g.L^{-1}), S2 (18 g.L^{-1}) and S3 (Deionized water) and monitored the mentioned parameters over a period of time (0, 5, 50, 150, 990 minutes).

No significant changes were observed in electrical capacitance and resistance. However, contact angle drop was recorded (about 13% over a duration of 990 minutes), which indicates clearly that diffusion is happening. Breakdown voltage showed minor changes (about 500-700 V) for a few samples, but breakdown irregularities were observed mainly due to manufacturing defects.

We are working towards analyzing ion diffusion with pre-stretched DEA samples when subjected to saline solution. In parallel, we have started to investigate using a coating that could avoid the abnormal breakdown.

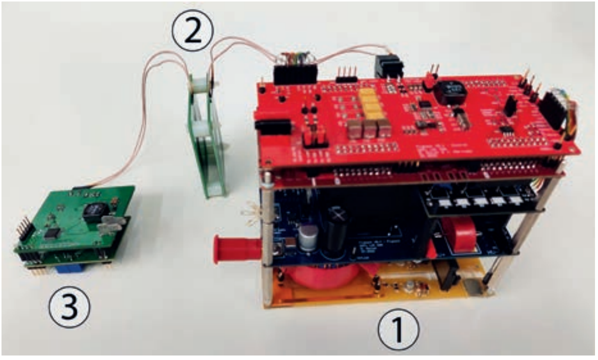




A fully autonomous high voltage generator driven through wireless power transfer

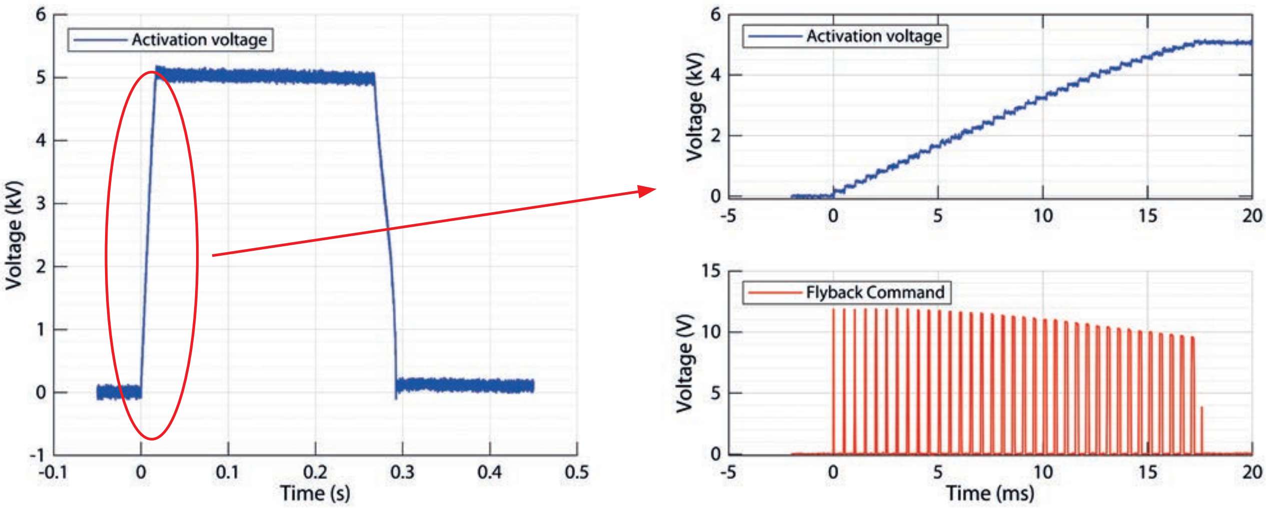
During the previous years, we developed a bidirectional flyback converter that could provide the high voltage required to activate the DEA. In order to open the possibility for this circuit to be implanted inside the body, it was required to be supplied without any wire that would go through the skin. During this year, we have worked on the combination of a wireless power transfer system with the flyback converter. The final prototype is composed of three main elements (see diagram below):

1. The flyback converter : to be implanted inside the body
2. The two coupled inductors made directly on printed circuit board that allow to transfer energy through the skin
3. The primary circuit, directly supplied from the battery, that controls the wireless energy transfer



As we can see on the picture, the flyback circuit is in one block and just requires the secondary side of the WPT to be plugged as an input and the DEA can be connected on the other side. The size of the flyback converter is 12 mm x 7 mm x 10 mm.

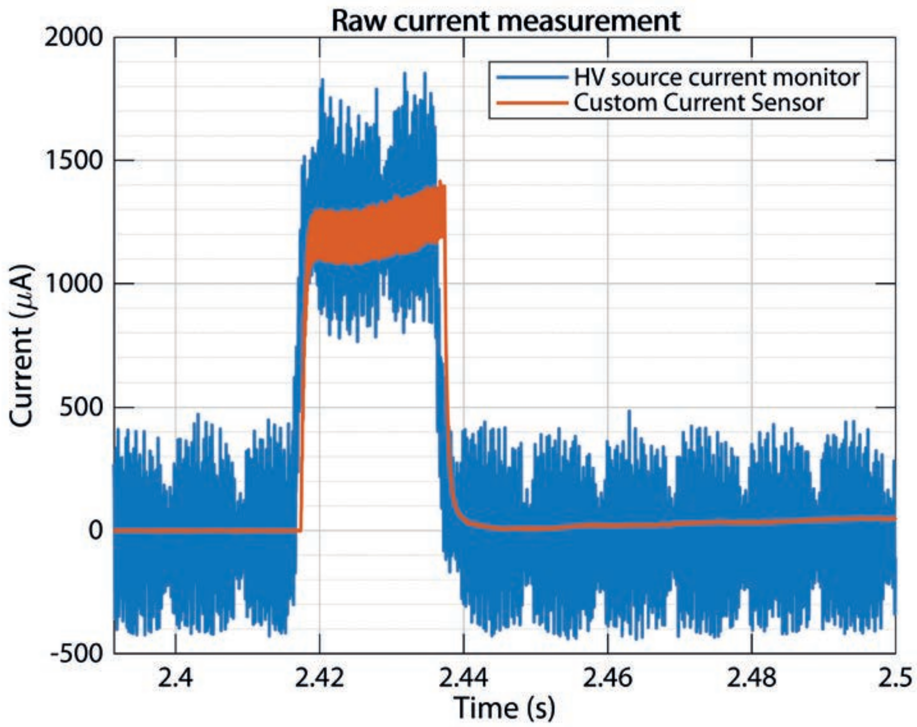
This device is still in development to optimize integration of the overall system and to minimize losses. Furthermore, we also work on the transfer of information between the inside and outside of the body through radiofrequency in order to control the activation of the DEA remotely or to have feedback on the proper working of the implant .



A new current sensor for estimation of the dielectric strength of DEAs

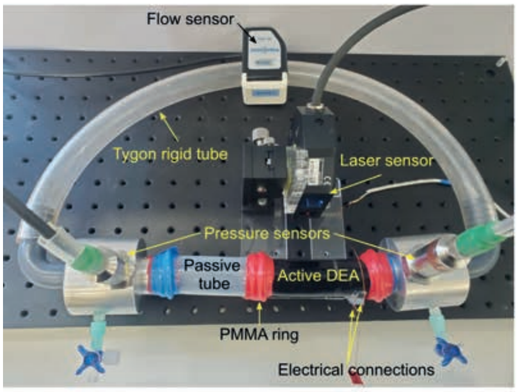
Estimation of the dielectric strength of DEAs is critical for the design of an optimized actuator and to compare different topologies. During this year, we developed a new technique to evaluate this maximum electric field that is only based on an electrical measurement. By measuring the current, we estimate the capacitance of the DEA that is then compared to a finite element model of the DEA to obtain finally the electric field inside the structure. This method allows us now to have a better overview of the performances of the actuator and notably to evaluate the influence of pre-stretch or saline water on the maximum electric field the DEA could reach.

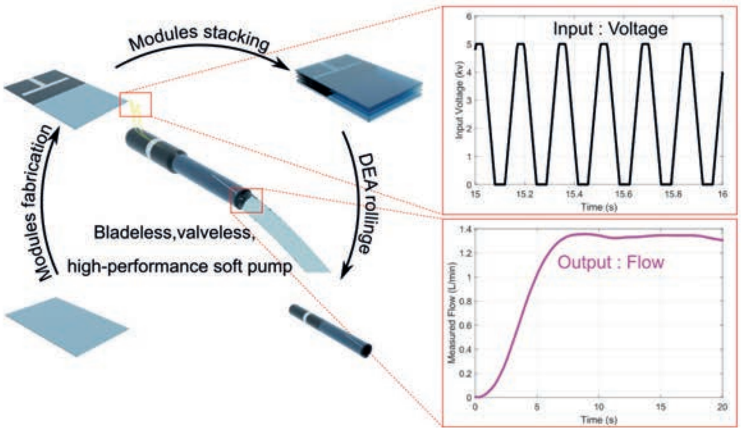
In order to have a more accurate measure of the current, we developed a portable current sensor that can measure current from 1 µA to 10 mA and that was used during the pig experiment in October 2022 to evaluate the capacitance of the implanted DEA.



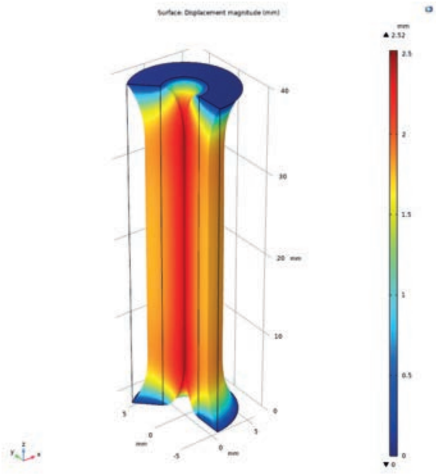
Impedance pump as an additional support mechanism

DEA based soft pumps could also be a solution for failing Fontan patients presenting a single heart ventricle. The Fontan procedure is a type of open-heart surgery performed to bypass the failing right heart so as to supply blood to the lungs. The requirements are quite different compared to the augmented aorta and the pumping principle must be thought out-of-the-box. Impedance pumps are simple designs that allow the generation or amplification of the flow. They are fluid-filled systems based on flexible tubing connected to tubing of different impedances. A periodic off-center compression of the flexible tubing causes the fluid to move so as to generate flow. Wave reflection at the impedance mismatch is the primary driving mechanism of the flow. Here, we present an approach to bladeless, valveless soft pumping via dielectric elastomer actuators. The soft pump design is inspired by the embryonic heart mechanism, also known as an impedance pump. It consists of three parts: an active DEA tube (pressure wave generator), a passive tube (pressure wave damper), and a decoupling ring connecting the two tubes. The decoupling ring ensures that the motion transferred between the two subsystems is conducted through the fluid only. By adjusting the input signal parameters (frequency, magnitude…), the flow properties can be controlled and tuned to the desired application requirements. The high performance of the proposed approach (up to 1.35 L.min^{-1}) has been demonstrated theoretically and experimentally. Future work includes optimizing the system's design to reduce the size, expand the working conditions, and improve performance. Additionally, conducting tests on a more anatomically correct setup (viscosity of blood, effect of soft tissues, the resistivity of the lungs…) is foreseen as well.





Urology

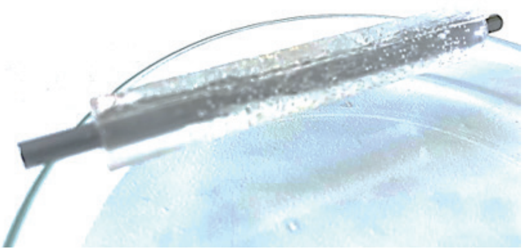


Artificial Urinary Sphincter

Urinary Incontinence is a common and embarrassing problem that affects hundreds of millions of people worldwide. Within the Center for Artificial Muscle, we are developing an Artificial Urinary Sphincter (AUS) based on DEAs.

Last year, an analytical model of the urethra as well as a finite elements analysis (FEA) has been developed in order to define the required pressure to close the urethra.

This year, our ambition was to perform ex-vivo tests on animal's urethra to validate our model. Preliminary tests on pig's urethra has been done and data analysis have allowed to extract mechanical properties of the urethra to be later used in the aforementioned models.

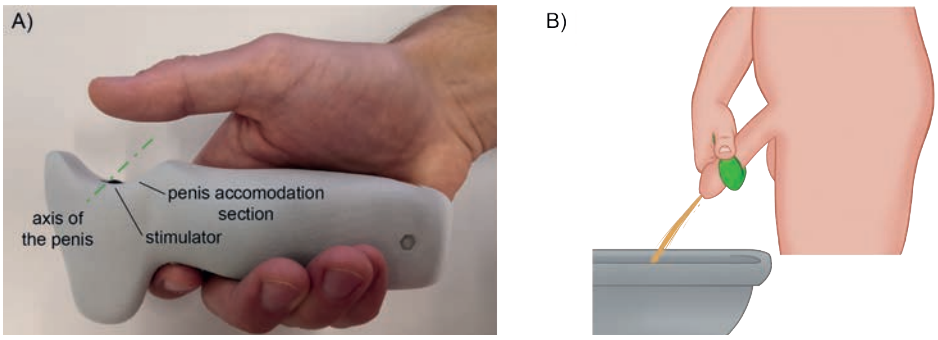


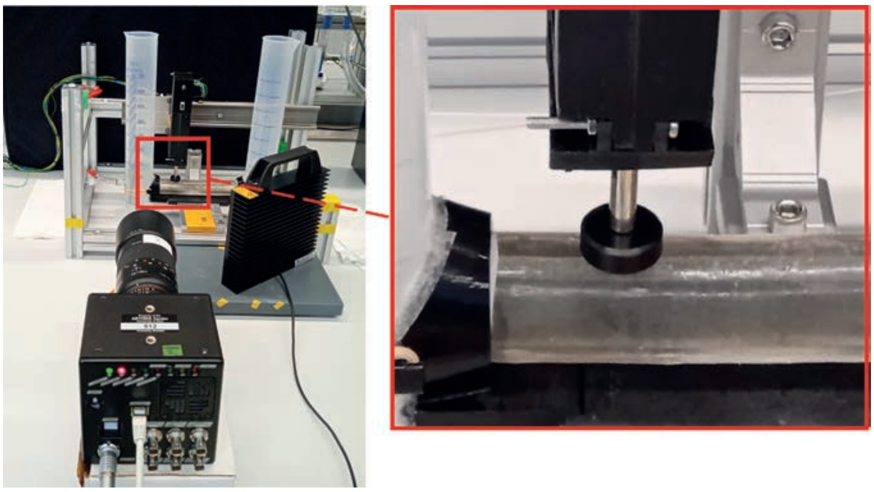
To limit tests on animal tissue, our team is also investigating the development of an artificial urethra. The difficulty of this challenge lies in the fact that the urethra is not a homogenous material and does not have a linear behaviour under stress. A new composite material has been used to manufacture a first prototype.

URODEA

The first prototype of a Non-Invasive Bladder Emptying Device (NIBED) has been developed and produced as a result of the research partnership between ARTORG Center for Biomedical Engineering Research (University of Bern), Department of Urology (Bern University Hospital) and the Center for Artificial Muscles (EPFL), funded by Innosuisse. The NIBED device is based on impedance pumping. It is designed for patients suffering from urinary retention who are unable to urinate properly and usually depend on catheters to empty their bladder. These catheters are uncomfortable, invasive and cause frequent urinary tract infections. Our device consists of an easy-to-use handheld medical device that is placed on the penis when the patient needs to empty the bladder. The unique value proposition is its non-invasive nature which can potentially eliminate the risks of urinary tract infections.

The first-in-man study was conducted between July 2021 and April 2022 in ten patients. The primary outcome of this study was the safety which was demonstrated in all patients. The NIBED device was accepted well by all patients and the feedback regarding device handling/usability were very positive. In this clinical trial, we could not prove the efficacy of the NIBED device in reducing the residual volume of urine after urination. Thus, in parallel, more in-vitro experiments are being conducted in our laboratories to improve the device performances.





Artificial Bio-Bladder

The human bladder is an expandable muscular organ which stores urine and helps in its flow control. Various diseases can occur that could prevent the bladder from a proper function. Some of the potential examples are: the inflammation of the bladder, bladder weakness, obstruction of the lower urinary tract by a hypertrophy of the prostate, congenital malformations or dysfunction caused by neurological diseases. In total, around 45 percent of the population worldwide suffer at least from one of these diseases and the trend is rising owing to the aging population. To develop new treatments, however, a better understanding and appropriate methods are needed.

Therefore, an in-vitro artificial bladder is under development which mimics the function of the bladder by stretching urothelial and smooth muscle cells cyclically. This artificial bladder will help to understand the behaviour of the bladder cells in an artificial environment and to investigate the influence of drugs and treatment methods on bladder cells without using animal testing.

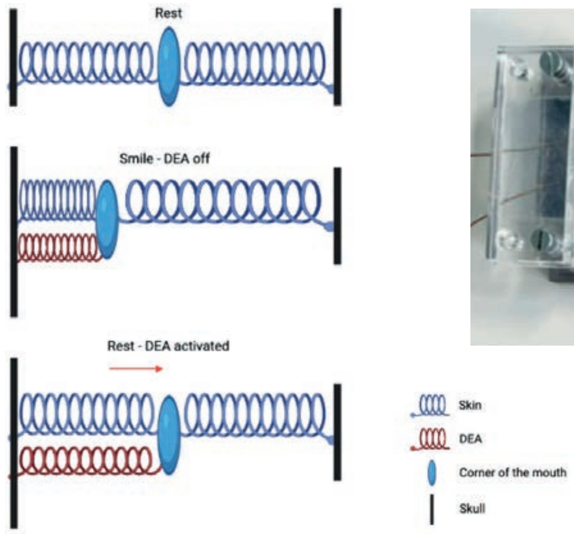
In contrast to the conventional actuators used to stretch cells, like linear motors, syringe pumps or magnets, a DEA allows to apply a huge and fast tensile and compressive strain, to reduce the number of external devices and enables sensing with the DEA during the actuation of itself (so called self-sensing).

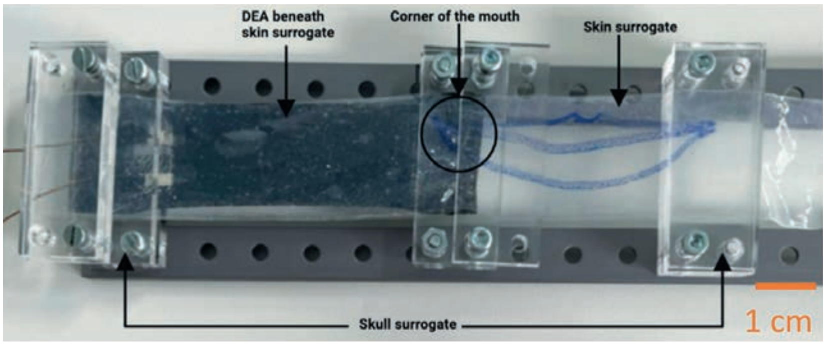
Facial Reanimation

Facial paralysis is a highly burdening situation, which is associated with emotional distress and overall reduced quality of life. The treatment plan varies depending on the aetiology and prognosis of the paralysis. In patients who still suffer from paralysis after a period of observation or following medication, surgical methods are taken into consideration.

Our team proposes a new, less invasive approach for dynamic facial reanimation post facial paralysis using soft artificial actuators. The proposed solution relies on the use of DEAs instead of biological muscles to restore mouth and more precisely smiling movement. The specifications of the actuator were obtained by comparing it with the characteristics of the facial muscles and the natural specifications of smiling and lip movements found in literature. The required force is of 2 N and the displacement of the corner of the mouth is of 7 mm.

However, implementing DEAs that mimic natural muscles has proven difficult, as DEAs provide in-plane expansion when actuated, while natural muscles contract upon stimulation. Our aim this year was to investigate the use of a normal configuration of DEAs to obtain a contractile movement for post paralysis facial reanimation, by inversing the actuation cycle: the voltage applied on the DEA will constantly be ON to keep the DEA stretched and will be turned OFF when a contraction movement is wanted, for instance for smiling. The consequence of this inverted behavior requires a setup where the non-activated DEA corresponds to a smiling position and the activated DEA corresponds to a neutral mouth.





The movement of facial muscles is controlled through the facial nerves. The traditional treatment for facial paralysis relies on a cross over neuronal transfer, taking the signal from the healthy side of the face to the paralyzed side and thus resulting in a symmetric movement of the mouth. A similar approach can be used to control the DEA, by implementing a neural interface on the healthy nerve to control the DEA placed on the paralyzed side.

Next steps

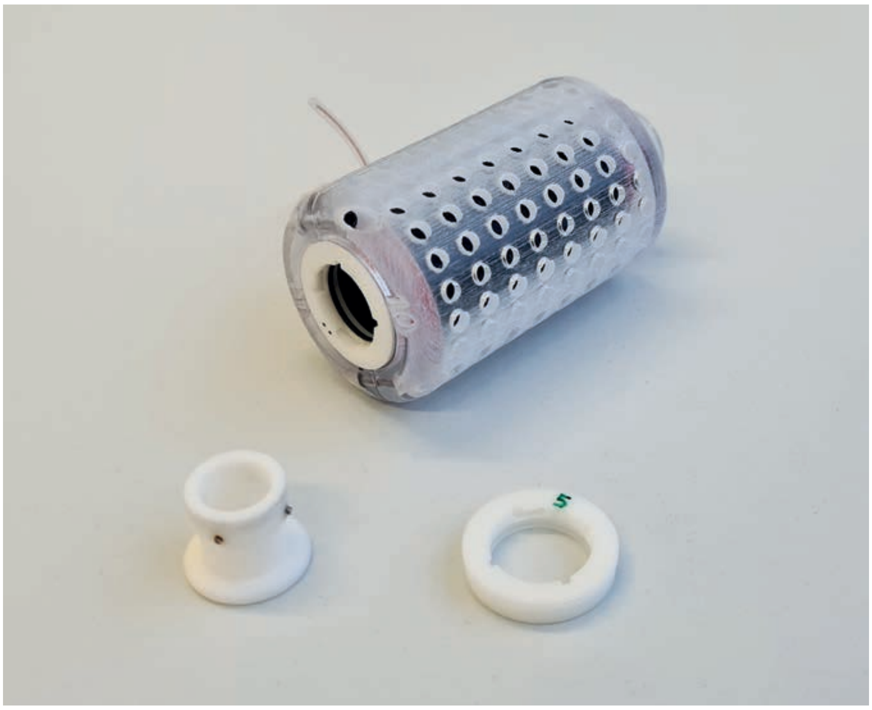
"Targeting chronic experiments..."

The latest in-vivo tests have confirmed our hopes for 2021. A flexible actuator can effectively modify the pressures seen by the heart and could, in all likelihood, allow it to recover its initial properties following a deficiency on its part. Nevertheless, the road to a viable solution for patients remains strewn with pitfalls which the CAM will strive to address in the coming months.

- **A stable material in contact with blood...**
  Laboratory tests show that DEAs can operate millions of cycles in contact with air. Unfortunately, blood and liquids in general modify the electromechanical properties of the active layer. A solution is being tested to enable our actuator to operate in contact with blood with performances similar to the ones obtained in air.

- **Minimally invasive...**
  Wrapping the actuator around the aorta remains a major challenge. The desire to help patients very early in their life requires offering a solution whose implementation will be simple for the surgeon and very undemanding for the patient.

- **Young patients...**
  The lightness and flexibility of DEAs make it possible to foresee solutions for children with right heart defects. Our first developments for the creation of a flexible pump operating at low pressure go in this direction. Tests under conditions similar to pulmonary circulation will be carried out quickly to validate the concept of a valve-less pump for failing Fontan.



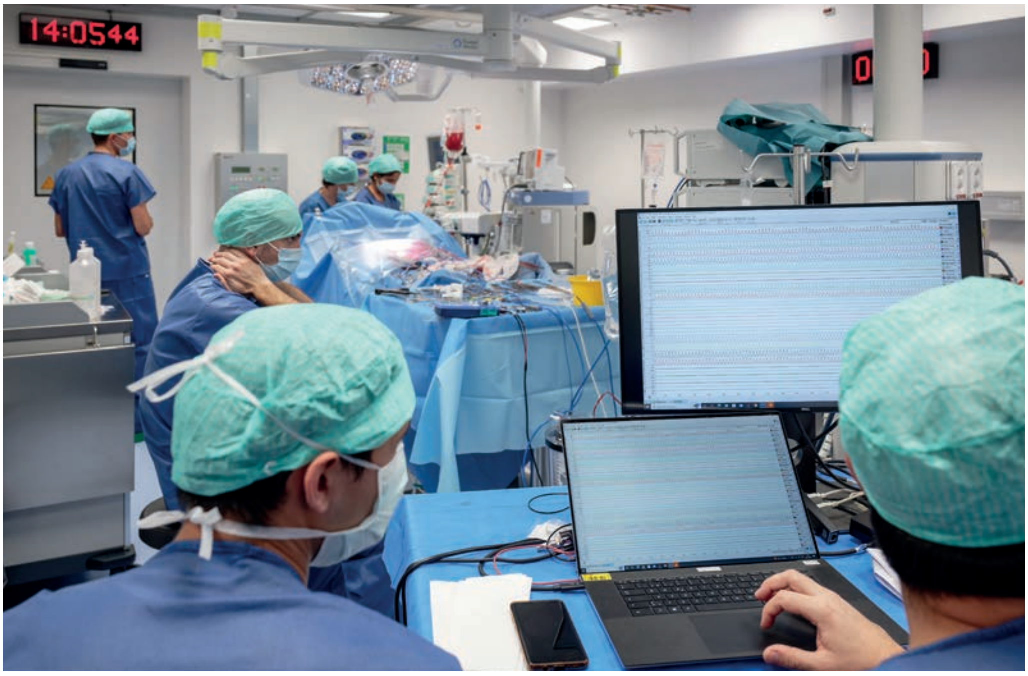
“A real center dedicated to the human body...”

The initial objective of the CAM created in 2018 was to offer alternative solutions to current systems based on flexible actuators, such as dielectric elastomer actuators, to relieve the human body. This is now a reality with no less than 6 ongoing projects. In addition to developments of cardiac assist devices, urological problems and facial reanimations are currently being studied.

- **Facial movements on rats...**
  After a little over a year of research, a flat actuator has met the specifications of doctors to bringing the faces of paralyzed patients back to life. 2023 will be a step further with the first in-vivo tests of the actuator on rats.

- **A miniature and robust DEA...**
  The constraints imposed by the genital tract (urethra, bladder) and the physiological parameters of the lower body (pressure, flow) imply the development of a miniature, robust and highly deformable actuator as an artificial sphincter. Next year should see the manufacture of such a DEA-based system after the design and modelling stages done in 2022.

- **A urological platform...**
  DEA-based actuators are not just a mechanical solution to the problem of incontinence. The development of drugs to treat various diseases related to the genital system requires a new platform capable of mimicking the cycles of the bladder. A planar DEA actuator will undoubtedly see the light of day and thus reduce the use of animals for the testing of new substances.

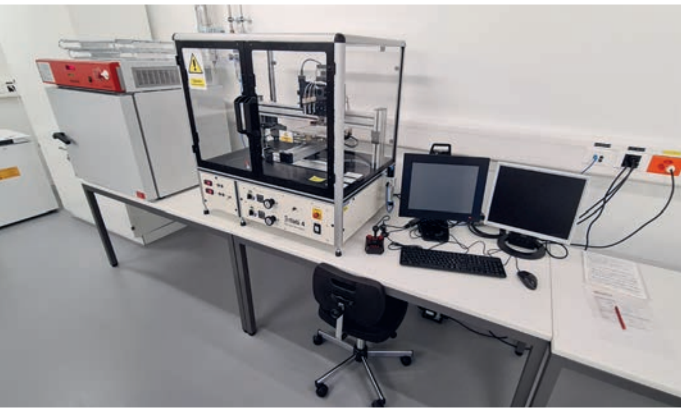


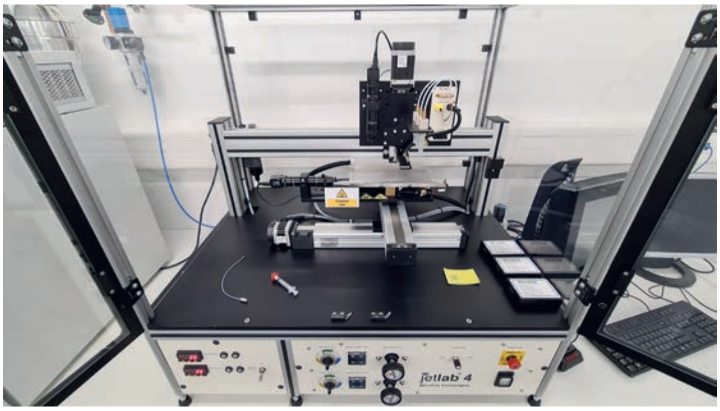
EPFL

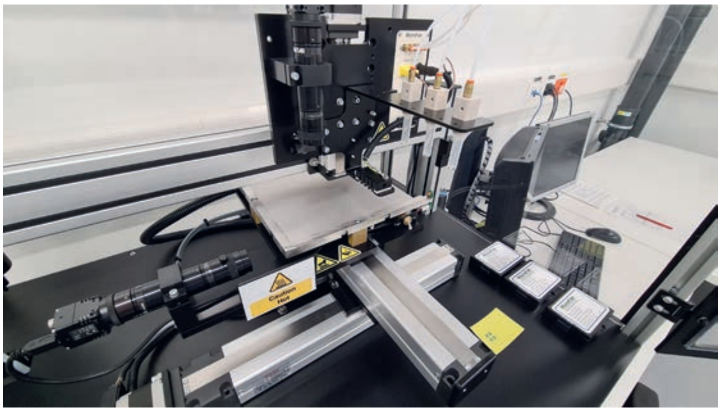
New Infrastructure in the Center for Artificial Muscles

Animal experiments require more and more prototypes. The need of high throughput while still achieving very accurate ink deposition has led us towards the acquisition of a pad-printer from Tecaprint™. This brand-new tool will ease the manufacturing of the tubular dielectric elastomer actuator for cardiac assist devices but will also reduce the thickness of the deposited ink. It will offer new opportunities as well regarding the development of planar actuators for the artificial bio-bladder. This tool will play a key role in the manufacturing process and will facilitate the various tests that need to be conducted before any medical implantation.

We also bought a 3D printing tool from Microfab™ which offers a highly accurate deposition method for the face reanimation and urological projects respectively. This tool enables the ability to depose lines of conductive ink of width down to a few microns. It allows to shrink the size of our actuators, which is mandatory for an easier integration and a high throughput platform for drug analysis.







Dissemination

Invited Talks

"The Artificial Muscle Center: a success among many innovative applications of electromagnetism in microtechnology", Yves Perriard, Sonceboz SA, Switzerland, Jun 9 2022.

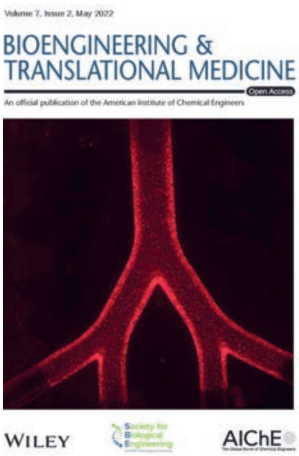
"A new cardiac assist device based on a dielectric elastomer augmented aorta", Yoan Civet, 36th EACTS Annual Meeting, European Association for Cardio-Thoracic Surgery, Milan, Italy, Oct. 5-8 2022.

"Artificial Muscles as assist device", Yoan Civet, Cardiology department, Universitätsspital Basel, Switzerland, Dec. 15 2022.

Thesis

Ultra-high voltage, low power and energy recovering electronics for dielectric elastomer actuators, Raphaël Mottet, 2022.

Journal papers



A novel soft cardiac assist device based on a dielectric elastomer augmented aorta: An in vivo study, T. Martinez, S.E. Jahren, A. Walter, J. Chavanne, F. Clavica, L. Ferrari, P.P. Heinisch, D. Casoni, A. Haeberlin, M.M. Luedi, D. Obrist, T. Carrel, Y. Civet, Y. Perriard, Bioengineering & Translational Medicine. 2022-08-22. P. 1-15

Adaptation of a solid-state-Marx modulator for electroactive polymer, M. Almanza, T. Martinez, M. Petit, Y. Civet, Y. Perriard, M. LoBue, IEEE Transactions on Power Electronics. 2022-06-16. Vol. 37, num. 11, p. 13014-13021

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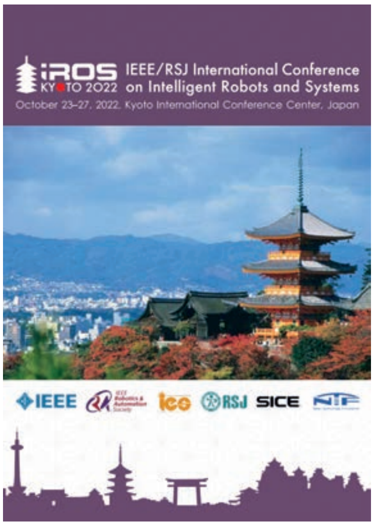

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“With the development of flat actuators, the engineering of artificial muscles for facial reanimation in patients has become a real possibility. This will provide new and less invasive reconstructive options for patients with facial paralysis.”

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