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Mechanical modifications of soft actuators for the use as a dynamic iris implant

S. Martin, J. Schwab, P. Caballero López, E. Benke, S. Reitelshöfer and J. Franke

Abstract— **Aniridia is a condition characterized by defects or absence of the iris. Since the eyes are a central point of attention in the human face, these deformities are often covered with cosmetic implants. However, patients suffer from the static pupil diameter of these implants, resulting in high light sensitivity or inadequate night vision. Therefore, we present a functional iris implant based on dielectric elastomer actuators. These electric drives are characterized by a silent and continuous adaptation as well as a small construction volume and a low heat emission. Since they normally exhibit in-plane uniaxial motion, this displacement must be focused to operate similarly to the iris sphincter. Therefore, we investigated possible mechanical modifications of the setups to generate a directional motion. The results of the study are presented and discussed.**

Clinical Relevance— **The proposed system design enables the functional treatment of aniridia and other accidental iris defects. In addition, the system serves as a basis for later developments of e.g. functional lenses that allow focus adjustment.**

I. Introduction

Aniridia, recognizable by the absence of the iris, is a disease that affects most of the eye structures and can have significant effects on vision. Its appearance is mainly caused by mutation of the PAX6 gene and patients often suffer from deficiencies of the whole visual system. [1] Cosmetic prostheses are implanted to give them a normal appearance of the eye that is inconspicuous in everyday life. For this purpose, a disc-shaped silicone layer can be inserted under the cornea to cover the malformation. Custom-made implants can be individually color-matched to the healthy eye to create an optimal covering. [2] However, the diameter of such implants is fixed, resulting in limited night vision or severe light sensitivity. This problem is addressed in this work by presenting a concept for a functional iris implant that allows the pupil diameter to be adjusted depending on the current light situation.

Dielectric elastomer actuators (DEA) are used to enable the activation of the implant. Their advantageous drive characteristics, including the absence of stiff mechanical parts, no heat emission, and silent operation, make them a good choice for a functional iris implant. In the following section, the operating principle of these actuators is presented. Then, adaptive optical setups based on DEA proposed in the literature are outlined. In addition, different mechanical adjustments of DEA are presented. Finally, first tests of the drives are performed and the results are discussed.

II. Fundamentals

A. Working principal of dielectric elastomer actuators

DEA belong to the group of smart materials and represent a subdivision of electrically active polymers. Their functional principle, shown in Fig. 1, is based on the Maxwell stress effect between two electrodes that are oppositely charged. Between them is a dielectric layer made of an elastomeric material that exhibits incompressible mechanical properties. This causes the two electrodes to move toward each other, reducing the thickness of the internal structure, which displaces perpendicular to the applied force. [3, 4]

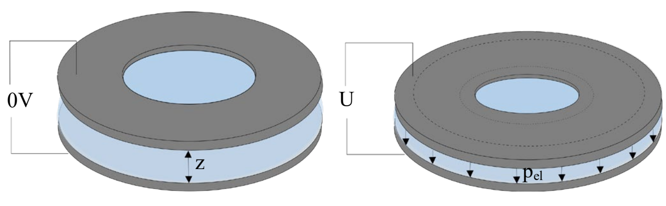

Fig. 1 Operating principle of DEA, which expands radially due to the Maxwell pressure p_{el} while reducing the thickness z of the dielectric

The advantageous aspects of these actuators are a silent, fast and continuous movement with no need for additional rigid mechanical structures. In addition, the system has negligible heating effects and can be made from certified medical grade silicones. [5] However, in order to generate the desired motion, high driving voltages are required, which should not exceed the dielectric strength of the elastomer in order to avoid damage to the system. From (1) the relationship between the resulting Maxwell pressure p_{el} and the required driving voltage U can be derived. [3]

$$p_{el} = \varepsilon_0 \varepsilon_r \frac{U^2}{z^2} \qquad (1)$$

Equation (1) shows that the Maxwell pressure p_{el} and the driving voltage U are directly dependent on each other and can be varied by adjusting the thickness of the dielectric layer z or

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the material-specific permittivity ε_r, since ε_0 is the dielectric constant. In order to reduce the required voltage, which is usually in the range of several kV, we have modified an aerosol jet printing process that allows the deposition of thin dielectric structures that can be driven with lower voltages below the kV range [6]. Thus, dielectric layers of 10 µm are targeted, which, depending on the dielectric strength of the elastomer used, can lead to driving voltages of less than 500 V. However, the currents that occur do not exceed 2.5 mA, which is crucial for patient safety.

B. Current state of the art of DEA-based optical systems

One of the most studied topics using DEA are optical systems. Continuous motion can achieve precise stepless adaptation of lenses and apertures. In the following, the current findings of DEA based optical systems inspired by human anatomy are presented, which serve as a reference for the functional iris implant under investigation.

Most research articles describe setups for adaptive lenses that can adjust focal length and focus. DEA work in a similar way to the ciliary muscle [7] or the sphincter of the iris [8], while the lenses vary in appearance from elastomeric to liquid lenses. A common working principle of the various setups is that the outer shape of the lens is manipulated by activation of the DEA, resulting in greater or lesser curvature of the surface and therefore an adjustment of the focal length. A system that represents a human-machine interface as required for the iris implant is the setup by Li et al [7]. They presented a system capable of adjusting the focal point of the lens by dielectric elastomers controlled by electro-oculogram signals. However, DEA are attached to rigid frames and form a volumetric assembly, which is not suitable for an implant with small dimensions. In contrast, the setting proposed by Carpi et al [9] has the potential to act as a compact structure of a conformable lens, that can be further improved to develop a medical implant. It consists of two adhesive elastomeric sheets encapsulating a liquid lens between them. Flexible electrodes are attached to both sides, surrounding the lens and causing deformation when a voltage is applied. In addition to the findings discussed, further research regarding DEA based lenses and irides can be found in [8, 10] and [11], respectively.

In contrast to the approach from Carpi et al [9], the present work is focused on the iris motion rather than a lens accommodation. The absence of material in the center on the one hand influences the driving behavior, on the other hand further modifications to regulate the movement are investigated.

C. Comparison of the human iris and artificial muscles

The human iris consists of two muscle groups, the radial dilator muscle and the concentric sphincter muscle, and protects the retinal cells by rapidly contracting and attenuating the amount of incoming light. The size range of the inner diameter of the human iris is between 1.5 - 8.0 mm to regulate the amount of light entering the eye and improve the depth of field. In elderly people, the aperture is reduced to a maximum of 4.0 - 5.0 mm. [12] An area adjustment of the iris opening of 1:16 allows up to 80 times more light to enter the eye. [13]

In comparison, the actuation potential for non-pre-stretched DEA is given as 10-20 % surface expansion [3]. This corresponds to a diameter reduction of the pupil from 8.0 mm to 7.34 mm or 6.62 mm respectively. However, this theoretical value indicates that the deformation of the DEA is fully directed toward the center rather than an uniaxial deformation. To achieve higher movement amplitudes, several adjustments can be made. First, pre-stretching the silicone layer significantly increases the actuation potential [14]. In addition, stacking multiple electrodes with alternating dielectrics improves the performance of the system [6]. Second, modifications must be made to focus actuation on the inner diameter of the DEA. For this purpose, various design modifications are carried out, which will be presented and evaluated in the following.

III. MATERIALS AND METHODS

In analogy to the biological iris, we use two concentric round electrodes with a circular space in the middle, similar to the setup of Carpi et al [9]. In contrast to their setup, ours consist only of one silicone film as dielectric, namely a 20-µm film made of Elastosil® from Wacker Chemie AG. The electrodes are applied on both sides by aerosol jet printing, which is described in detail in [6]. This allows uniform distribution of the reduced graphene particles, which serve as a flexible electrode. To enable double-sided printing of the silicone film, it was placed in a metal frame, while attention was paid to not introduce stresses into the material. For practical testing the actuators have printed contact wires that are contacted with aluminum strips and graphene grease to ensure electrical conductivity.

A. Modifications of the DEA

As mentioned in chapter two, the working principle of the DEA usually is a uniform surface expansion perpendicular to the electric field between the two electrodes. In order to focus the motion on the inner diameter, modifications of the structure have to be made. Possible options to create a non-isotropic actuator motion from the literature include the use of pre-stretch [15], partial curing of the silicones resulting in different material properties, the so-called interpenetrating networks (IPN) [16], or a stiff mechanical manipulation [17]. Because the implant is designed to be rolled and injected like state-of-the-art cosmetic implant, the rigidity of the frame is limited [18]. In the following, the studied modifications are presented in detail.

First, the transparent dielectric is cut in the center of the circular electrode with a laser to give the actuator room to expand, otherwise the forces from the opposite sides of the inner circle would compensate each other. A schematic drawing of the changes can be found in Fig. 2 (a). The diameter of the cut circle d_h is investigated in relation to the inner diameter of the electrode. To prevent the system from breaking through at the cut dielectric, a minimum distance d_{min} is maintained between the electrode and the hole.

Second, the expansion of the outer diameter must be limited without restricting implantation through the injector. Therefore, the use of additional silicone material applied by aerosol jet printing and the attachment of a 100 µm thick Polyethylene terephthalate (PET) layer, which still allows flexibility but no extensibility, is investigated. The modified parameters can be found in Fig. 2 (b), which are tested separately and combined in practical tests. In the evaluation section the results are shown and discussed. Therefore, images of the DEA are taken with and without voltage applied and compared. In the following it is briefly introduced how the expansion of the system was observed and evaluated.

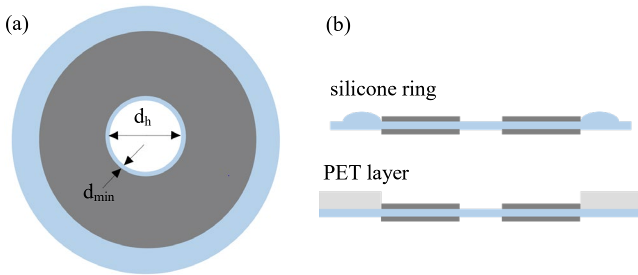

Fig. 2 Schematic overview of the adaptations performed through a hole in the center (a) and rigid frames (side view) (b)

B. *Movement analysis method*

The printed samples are analyzed for their motion amplitude as a function of the adjustments made. For this purpose, images are taken at 0 V and in the activated state at 1500 V, just before dielectric breakdown. Both images are converted to a grayscale image and filtered with a fixed threshold to determine the electrode region, as shown in Fig. 3. Thus, the image is divided into the electrode area (black) and the surrounding area (white). Histogram analysis and automated wrapping of the image to the edges of the geometry can be used to quantitatively evaluate the difference between the activated and static states. Although the contacts for the electrode region are included, they do not act as a capacitor and remain identical in both states.

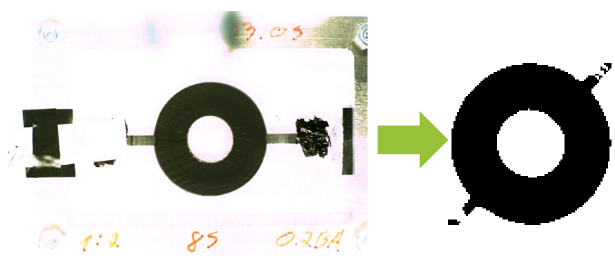

Fig. 3 Image transformation operations for expansion analysis from captured camera image (left) to filtered and cropped image (right)

IV. Results

Following the described procedure, five printed patterns were analyzed. The modifications and their effect on the motion amplitude are analyzed separately to find the adaption with the largest contraction of the inner diameter (pupil). Table 1 shows the parameters of the unmodified DE.

From Table 1 it can be clearly seen that the surface expansion is not evenly distributed between an expansion of the outer diameter and a contraction of the inner diameter. Rather, it can be seen that most of the expansion occurs around the outer diameter because the radial forces in the center block each other. Therefore, a hole is cut in the center to reduce the material stress and allow the DEA to move freely. The results can be found in Table 2.

TABLE 1. MOVEMENT AMPLITUDE OF FIVE ANALYZED SAMPLES WITHOUT MODIFICATIONS AT 1500 V

Sample N°	**1**	**2**	**3**	**4**	**5**
Electrode area [%]	9.2	6.7	7.9	7.8	6.7
Outer diameter [%]	4.0	3.3	2.9	2.9	1.9
Pupil diameter [%]	-0.5	-0.05	-0.5	-1	-0.5

TABLE 2. MOVEMENT AMPLITUDE OF FIVE ANALYZED SAMPLES WITH 6 MM HOLES AT 1500 V

Sample N°	**1**	**2**	**3**	**4**	**5**
Electrode area [%]	8.8	6.1	7.7	6.9	6.4
Outer diameter [%]	3.5	2.5	3.1	2.7	2.6
Pupil diameter [%]	-1.9	-1.4	-1.5	-1.5	-0.5

When modifying an expansion space in the center, it was found that larger holes lead to larger displacements of the inner diameter. An example is given using specimen N° 1, which showed a contraction of the pupil diameter of 1.0 % with a 4 mm hole, which increased to 1.9 % with a 6 mm diameter hole. It can be seen from Table 2 that the movement of the inner diameter increased significantly due to the absence of the silicone material in the center. Only sample N° 5 showed no increase in contraction of the inner diameter and even a decreased expansion behavior. This can be explained by the placing of the silicone layer in a metal frame for double-sided printing. This allows stresses to be applied to the silicone sheet, resulting in a pre-stressed condition that increases the amplitude of movement of the system. Cutting a hole in the center reduces this stress and therefore the higher actuation potential.

However, the higher percentage of expansion still acts around the outer diameter and expands the system outward. To address this, the surrounding material needs to be stiffer, which is achieved by placing a non-elastic material layer around the DEA and increasing silicone deposition. The results for both parameters are shown in Table 3 below.

TABLE 3. MOVEMENT AMPLITUDE OF FIVE ANALYZED SAMPLES WITH STIFFENING MODIFICATIONS AT 1500 V

Sample N°	**Modification**	**1**	**2**	**3**	**4**	**5**
Electrode area [%]	**Silicone**	8.0	6.8	7.9	5.2	5.2
	PET layer	5.5	5.1	6.2	5.8	3.5
Outer diameter [%]	**Silicone**	3.1	2.7	2.9	2.1	2.1
	PET layer	2.0	2.0	1.8	2.3	1.2
Pupil diameter [%]	**Silicone**	-0.5	-0.5	-1.5	-0.0	-0.0
	PET layer	-1.0	-0.05	-0.5	-0.5	-1.0

The results presented show that the application of stiffer zones surrounding the DEA reduces the overall actuation potential compared to the unconstrained design evaluated in Table 1. This reduction of the motion amplitude is greater using the inelastic PET material, as the silicone causes an increase in stiffness but still can be deformed and thus only dampens the motion.

Finally, the combination of modifications is to be evaluated. For this purpose, a silicone ring of 2.5 mm plus 10 mm PET layer is placed around the DEA and an expansion area of 6 mm is cut in the center. The results are shown in Table 4.

TABLE 4 MOVEMENT AMPLITUDE OF FIVE ANALYZED SAMPLES WITH HOLES AND STIFF RIM AT 1500 V

Sample N°	1	2	3	4	5
Electrode area [%]	4.3	4.0	3.3	2.7	2.4
Outer diameter [%]	1.2	1.0	1.0	0.8	0.6
Pupil diameter [%]	-1.9	-1.4	-1.5	-1.9	-1.5

Compared to the modification with only one hole in the center, the expansion of the outer diameter is significantly reduced, while the pupil diameter contracts similarly and shows increased performance. Due to the mechanical stiffening at the outer diameter, part of the motion amplitude is damped and differences could be observed for the distance between the rigid frame and the electrode, which have to be evaluated in detail in the future.

V. DISCUSSION AND OUTLOOK

The presented work discusses the use of DEA as a functional iris implant. Since the actuator exhibits uniform motion behavior under normal conditions, various mechanical adjustments were made to achieve non-isotropic behavior with focused deformation in the inner circle. Therefore, mechanical stiffeners around the outer diameter and a hole in the center were investigated for modified actuation behavior. The practical test showed that large diameters for the cut hole lead to larger expansions of the electrode area and that it has the greatest influence of the investigated modifications on the pupil movement. In combination with the second modification the pupil contraction can be further improved. However, by applying passive materials, the system experiences damping that limits overall performance.

Although the DEA based iris does not achieve the same amplitude of motion as the biological reference, a reduction in light input was observed, which needs to be quantified in subsequent studies. Furthermore, stretched elastomeric films increase motion amplitude, as do stacked electrodes, which remains to be investigated for the intended use as an iris. As a result, higher motion amplitudes are expected, ranging from 10-20 % [3]. For use as an implant, various safety aspects must be taken into account. To ensure patient safety, medical device specifications must be considered, such as reliability or a biocompatible encapsulation that can be printed in the same process device. In addition, electrical safety aspects must be fulfilled by the system, as specified in IEC 6061-1, which requires, among other things, a closed control loop.

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VI. REFERENCESREFERENCES

[1] H. T. Lim, D. H. Kim, and H. Kim, "PAX6 aniridia syndrome: clinics, genetics, and therapeutics," *Current opinion in ophthalmology*, vol. 28, no. 5, pp. 436–447, 2017, doi: 10.1097/ICU.0000000000000405.

[2] T. M. Yildirim, R. Khoramnia, M. Masyk, H.-S. Son, G. U. Auffarth, and C. S. Mayer, "Aesthetics of iris reconstruction with a custom-made artificial iris prosthesis," *PloS one*, vol. 15, no. 8, e0237616, 2020, doi: 10.1371/journal.pone.0237616.

[3] R. Pelrine and R. D. Kornbluh, "High-field deformation of elastomeric dielectrics for actuators," *Materials Science and Engineering*, vol. 2000, pp. 89–100.

[4] R. Pelrine *et al.*, "Dielectric elastomer artificial muscle actuators: toward biomimetic motion," in *Smart Structures and Materials 2002: Electroactive Polymer Actuators and Devices (EAPAD)*, San Diego, CA, 2002, pp. 126–137.

[5] S. Martin *et al.*, "Electrical and mechanical characterization of medical grade silicones as dielectric layers in aerosol jet printed dielectric elastomers," in *Electroactive Polymer Actuators and Devices (EAPAD) XXIII*, Online Only, United States, Mar. 2021 - Mar. 2021, p. 58.

[6] S. Reitelshöfer, S. Martin, F. Nendel, T. Schäfer, D. Pham, and J. Franke, "Accelerated aerosol-jet-printing of stretchable rGO-electrodes for stacked dielectric elastomers by using a new hybrid atomizer," in *Electroactive Polymer Actuators and Devices (EAPAD) XXII*, Online Only, United States, Apr. 2020 - May. 2020, p. 61.

[7] J. Li *et al.*, "A Biomimetic Soft Lens Controlled by Electrooculographic Signal," *Adv. Funct. Mater.*, vol. 4, p. 1903762, 2019, doi: 10.1002/adfm.201903762.

[8] M. Pieroni, C. Lagomarsini, D. de Rossi, and F. Carpi, "Electrically tunable soft solid lens inspired by reptile and bird accommodation," *Bioinspiration & biomimetics*, vol. 11, no. 6, p. 65003, 2016, doi: 10.1088/1748-3190/11/6/065003.

[9] F. Carpi, G. Frediani, S. Turco, and D. de Rossi, "Bioinspired Tunable Lens with Muscle-Like Electroactive Elastomers," *Adv. Funct. Mater.*, vol. 21, no. 21, pp. 4152–4158, 2011, doi: 10.1002/adfm.201101253.

[10] L. Maffli, S. Rosset, M. Ghilardi, F. Carpi, and H. Shea, "Ultrafast All-Polymer Electrically Tunable Silicone Lenses," *Adv. Funct. Mater.*, vol. 25, no. 11, pp. 1656–1665, 2015, doi: 10.1002/adfm.201403942.

[11] C. G. Tsai and J. A. Yeh, "Circular dielectric liquid iris," *Optics letters*, vol. 35, no. 14, pp. 2484–2486, 2010, doi: 10.1364/OL.35.002484.

[12] J. François and F. Hollwich, *Augenheilkunde in Klinik und Praxis: Band 1*. Stuttgart [u.a.]: Thieme, 1977.

[13] J. François and F. Hollwich, *Augenheilkunde in Klinik und Praxis: Band 2*. Stuttgart [u.a.]: Thieme, 1981.

[14] R. Pelrine and R. Kornbluh, "Electrostriction of polymer dielectrics with compliant electrodes as a means of actuation," *Sensors and Actuators A: Physical*, vol. 1998, no. 64, pp. 77–85, 1998, doi: 10.1016/S0924-4247(97)01657-9.

[15] Y. Xiao *et al.*, "Anisotropic electroactive elastomer for highly maneuverable soft robotics," *Nanoscale*, vol. 12, no. 14, pp. 7514–7521, 2020, doi: 10.1039/d0nr00924e.

[16] Y. Jin, X. Gao, and Y. Luo, "Dielectric elastomer film with anisotropic actuation deformation on film plane," *J Appl Polym Sci*, vol. 137, no. 23, p. 48795, 2020, doi: 10.1002/app.48795.

[17] S. Rosset, O. A. Araromi, and H. R. Shea, "Maximizing the displacement of compact planar dielectric elastomer actuators," *Extreme Mechanics Letters*, vol. 3, pp. 72–81, 2015, doi: 10.1016/j.eml.2015.04.001.

[18] C. Mayer, T. Tandogan, A. E. Hoffmann, and R. Khoramnia, "Artificial iris implantation in various iris defects and lens conditions," *Journal of cataract and refractive surgery*, vol. 43, no. 6, pp. 724–731, 2017, doi: 10.1016/j.jcrs.2017.06.003.