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ORIGINAL ARTICLE

Artificial Valve

Mechanical properties of a new thermally deformable mitral valve annuloplasty ring and its effects on the mitral valve

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Abstract

Ideally, an annuloplasty ring's shape should be changed intraoperatively if mitral valve repair is unsuccessful because of a short coaptation length or systolic anterior motion. Several post-implantation adjustable rings have been developed, but they are not freely deformable and are unsuitable for asymmetric repair of the valvular annulus. We developed a novel thermally deformable mitral annuloplasty ring to address these problems and assessed the ring's mechanical properties and its effect on the mitral valve anatomy. This ring was made of polycaprolactone. Tensile and bending tests were performed to evaluate the ring's mechanical properties. The ratio of the transverse and septal–lateral length was determined as 4:3. Using 10 pig hearts, we measured the post-deformation coaptation length and minimum distance from the coaptation to the ventricular septum, which is a factor of abnormal systolic anterior motion of the mitral valve. In the mechanical tests, the ring's yield point was greater than the deformation force of the annulus in humans. In pigs with deformation from "4:3" to "4:2", the coaptation length was significantly increased in each mitral valve part. In pigs with deformation from "4:3" to "4:4", the minimum distance from the coaptation to the ventricular septum was significantly increased. Asymmetrical ring deformation increased the coaptation length only at the deformed area. In conclusion, this new thermally deformable mitral annuloplasty ring could be "order-made" to effectively change the coaptation length in all parts of the mitral valve and the distance from the coaptation to septum post-deformation via intraoperative heating.

Keywords Mitral valve · Mitral valve annuloplasty ring · Polycaprolactone

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Introduction

Over the past decades, after Carpentier et al. introduced the completely rigid Carpentier Classic mitral valve annuloplasty ring in 1971, more than 40 mitral valve annuloplasty rings with various shapes have become commercially available [1–3]. Mitral valve annuloplasty has mainly been performed to increase leaflet coaptation and avoid future annular dilatation after mitral valve repair. Nonetheless, the mitral valve coaptation length is usually not uniform. Furthermore, systolic anterior motion (SAM), which can cause obstruction of the left ventricle's outflow [4], might occur after mitral repair. To achieve a longer coaptation length and avoid SAM, we sometimes change the mitral valve ring size or perform additional plasty procedures [5]. However, exchanging the mitral valve annuloplasty ring would be traumatic for the mitral annulus and requires longer cardiopulmonary bypass time and higher cost due to the need for a new ring. Several post-implantation adjustable rings have been reported to solve these problems [6, 7]. However, these rings are not freely deformable and are unsuitable for asymmetric repair of the valvular annulus. We developed a thermally deformable ring that can be bent freely many times. In this study, we have assessed the mechanical properties of this device and its effects on the mitral valve anatomy.

Materials and methods

Ring design

The thermally deformable ring is made of polycaprolactone (PCL) (3 mm in width) [8], with a nickel–chromium alloy wire core, polyvinyl chloride tube coating, and polyester sewing cuff (Fig. 1a). The melting point of PCL is 60.0 °C. We heated the nickel–chromium alloy wire core with a direct current of 3.0 V for 75 s using a dry cell (Fig. 1b). Finally, the wire was cut with a length of 1 cm and bent along the ring. Figure 2a shows the temperature change determined using a digital multimeter Sanwa-CD772 (Sanwa Electric Instrument Co., Ltd., Tokyo, Japan). A thermography, Infra-Eye 3000 (Fujitsu Japan, Tokyo, Japan), was used to show temperature change. The ring was opened and unbent. The polyester sewing cuff was partially removed at the center of the band. The polyvinyl chloride tube was further removed and PCL was uncovered in the center (Fig. 2b). The ring has now been patented in Japan (JP 2018-416A).

Mechanical property test

Tensile and bending tests were performed on the PCL bar and the ring-shaped PCL, using Instron 3365 (Instron, Norwood, MA, USA). For the tensile test, the pulling force and rate were set at 1 N and 5 mm/min, respectively. Three rings were tested, and the average Young's modulus value was calculated. For the bending test, the PCL bar was 17 mm in thickness, 10.5 mm in width, and 40 mm in length. The three-point method was adopted. The bending force started at 0.1 N. The maximum deformation and expansion rates were 3 mm/min and 5 mm/min, respectively.

Finite element analysis of stress on the mitral annuloplasty ring

To simulate stress on the mitral annuloplasty ring in vivo, a computer model was developed. A basic ring shape, with a width of 3 mm, was traced on a 24-mm Physio ring (Edwards Life Science LLC, Irvine, CA, USA). The

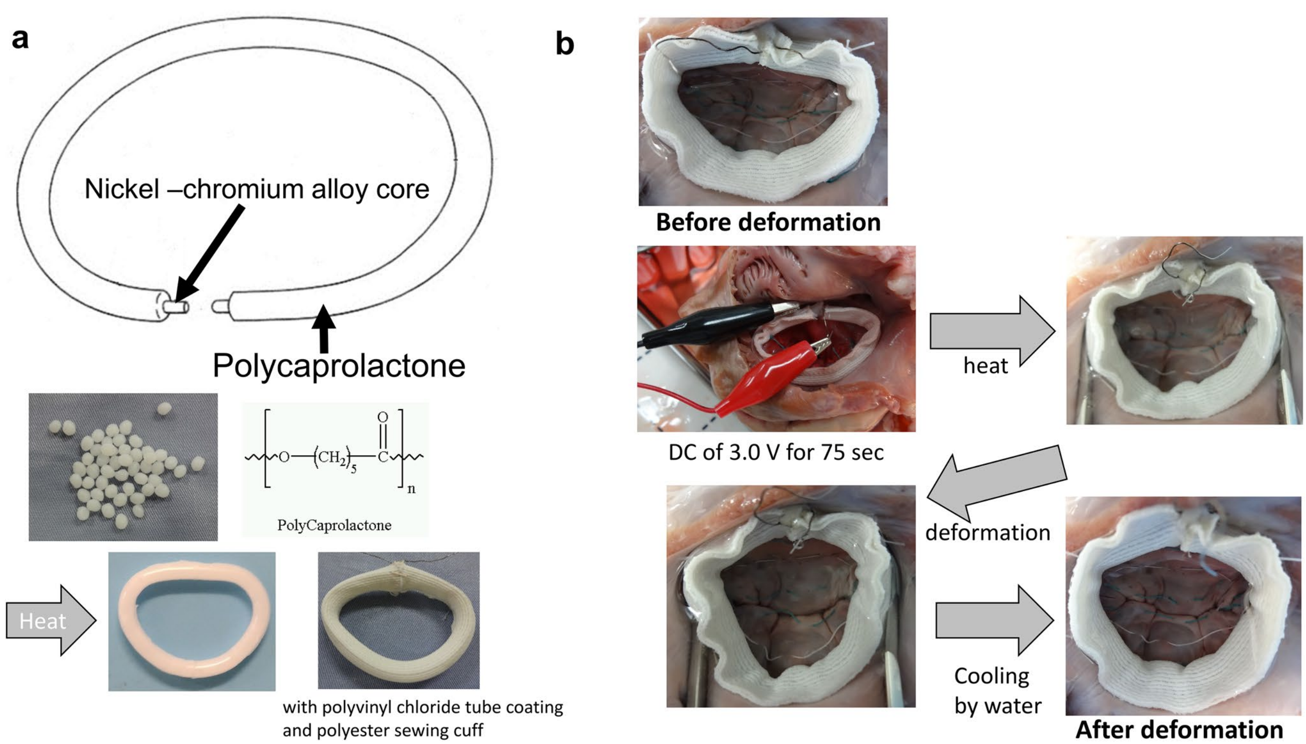

Fig. 1 **a** Thermally deformable mitral valve annuloplasty ring. The ring was made of PCL (3 mm in width) with a nickel–chromium core, polyvinyl chloride tube coating, and polyester sewing cuff. PCL can be deformed by heat (60 °C). **b** Schema of how to deform the ring. *DC* direct current, *PCL* polycaprolactone

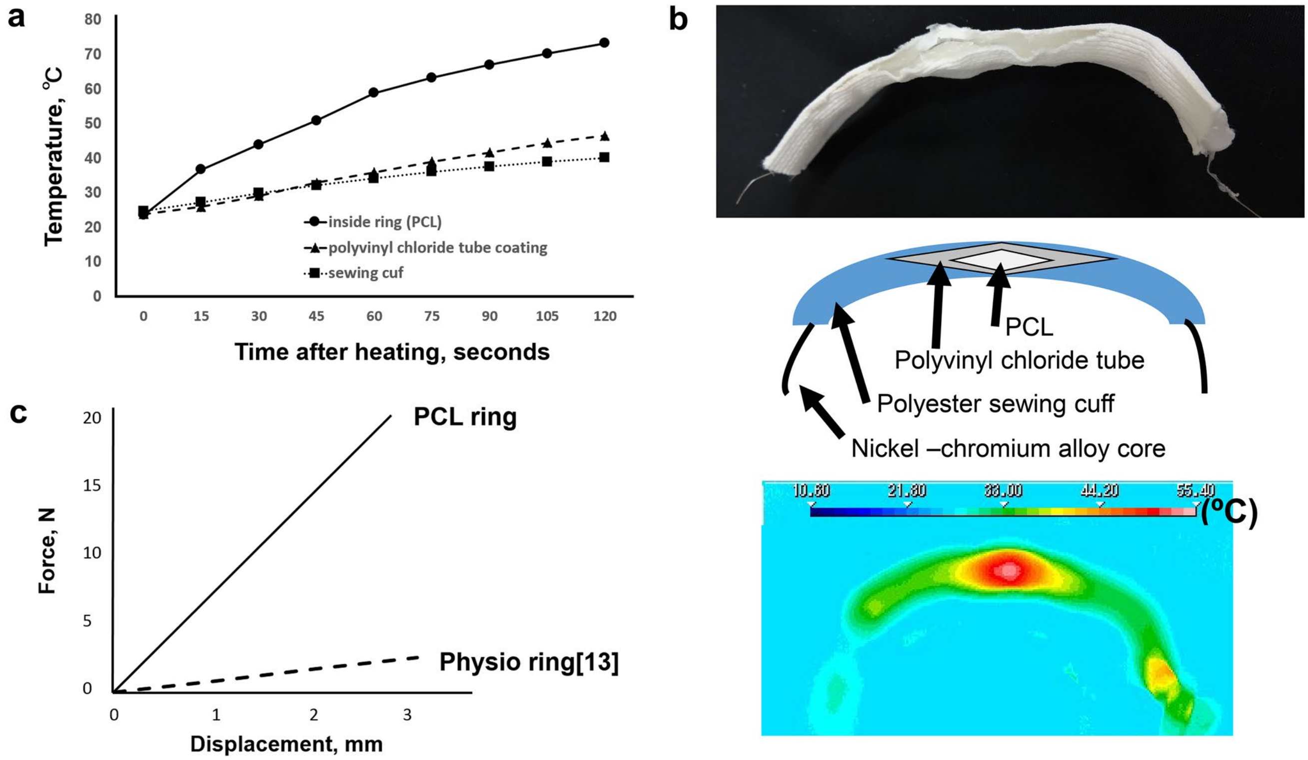

Fig. 2 **a** Temperature elevation inside the ring, polyvinyl chloride tube coating, and sewing cuff after heating. The temperature was the average of three rings. In 75 s, the temperatures of the ring, polyvinyl chloride tube coating, and sewing cuff were elevated to 63.0 °C, 39.1 °C, and 36.1 °C, respectively. **b** Thermography of the ring after direct current 3.0 V 75 s treatment. The ring was opened and unbended. The polyester sewing cuff was removed in the central part. The polyvinyl chloride tube was removed and PCL was uncovered in the center. **c** Relationship between force and displacement of the PCL ring in the tensile test. The result of the Physio ring is also shown according to the report of Purser et al. [13]. *PCL* polycaprolactone

surface of this ring was discretized into tetrahedron meshes with 22,145 elements for a finite element analysis using ANSYS™ Release 15.0 software (Canonsburg, PA, USA). The Young's modulus was set at 0.35 GPa, determined using the above-mentioned bending test. The Poisson ratio was set at 0.42. The contractility of the mitral valve annulus was set at 0.1357 MPa [9]. Displacement of the mitral annuloplasty ring due to annular motion was hypothesized to be radial. The von Mises method was used to assess the average ring stresses as absolute values. The movement of the ring was also simulated in systole and diastole.

Assessment of the mitral valve structure with ring deformation

The ring's baseline configuration was adjusted to that of a commercially available ring, the Physio ring (Edwards Life Science LLC), i.e., the ratio of the transverse and septal–lateral distance was 4:3, with a flat plane. The ring was deformed into three types: in type A deformation, the ratio of the transverse and septal–lateral distance was changed from "4:3" to "4:2" (decrease in the septal–lateral distance); in type B deformation, it was changed from "4:3" to "4:4" (increase in the septal–lateral distance); and in type C deformation, the septal–lateral distance at A1–P1 (Carpentier's classification [10]) was decreased (asymmetric deformity) (Fig. 3a).

Figure 3b shows an apparatus to test the change in the mitral valve structure because of deformations of the ring. We performed mitral valve annuloplasty in 10 adult pig hearts (330 ± 50 g). The aortic valve was excised, and the ostium of the coronary arteries was tied. The ascending aorta was then connected to a cylinder. The afterload, which corresponded to pressure on the mitral valve, was maintained at 100 mmHg (136 cmH_2O) throughout the measurement period. The ring's size was adjusted to the area of the anterior mitral leaflet (true size). The ring was sutured on the mitral valve annulus using 4-0 polypropylene in an interrupted fashion. An Aloka SSD-2000 ultrasound machine (Aloka Co., Ltd., Wallingford, CT, USA) with a 7.5-MHz ultrasound probe was positioned on the left atrium. Each leaflet coaptation length (A1–P1, A2–P2, and A3–P3) was measured. The minimum distance from the coaptation to the ventricular septum (C-sept) [4] was also measured, by

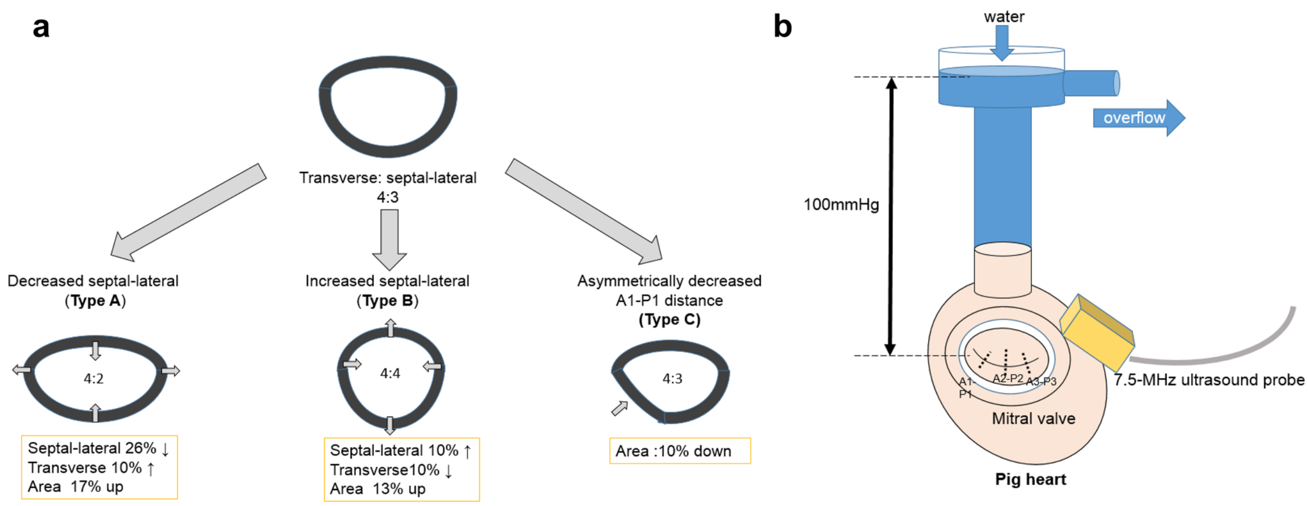

Fig. 3 **a** Deformation pattern of the ring. **b** Apparatus to test the change in the mitral valve structure. The mitral valve was pressurized by 100 mmHg

which we could estimate the risk of SAM. An ink test was performed using Pyoktanin blue to examine the area of coaptation [11]. Mitral regurgitation was insignificant in all 10 hearts. The use of laboratory animals was consistent with the Guide for the Care and Use of Laboratory Animals published by the US National Institutes of Health.

Pathological assessment for heat injury

The pathological examination was performed for detecting heat injury to the left atrial myocardium of a pig. Three rings were tested: no heating, 5 times heating, and 10 times heating. Hematoxylin–eosin (HE) and Masson's trichrome (MT) stain were used.

Statistics

Continuous variables are presented as mean ± standard deviation, and categorical data are presented as numbers and percentages. The Mann–Whitney *U* test was used to compare continuous values. The χ^2 test was used for categorical variables. Statistical analysis was performed using JMP 12.0.1 (SAS Inc., Cary, NC, USA). The significance threshold was set at 0.05.

Results

Ring temperature

After heating the nickel–chromium alloy wire core with a direct current of 3.0 V for 75 s using a dry cell, the temperature was elevated to 63.0 °C, 39.1 °C, and 36.1 °C for the PCL, polyvinyl chloride tube coating, and sewing cuff, respectively (Fig. 2a). Thermography showed that the temperature of the sewing cuff was under 40 °C (Fig. 2b).

Mechanical property test

In the bending test of the PCL bar, the Young's modulus of the ring was 0.35 GPa. Figure 2c shows the relationship between force and displacement of the ring in the tensile test. At a displacement of 3 mm, which has been shown to be the average displacement of the mitral valve annulus [12], our ring's force was 10 times greater than that of the Physio ring [13].

Finite element analysis of stress

Figure 4 shows the simulated stresses on the ring. The ring's stress was the highest at the commissural part in all deformation models. The highest stress (11.7 MPa) was observed in type A (Fig. 4b) and the lowest (3.3 MPa) in type B deformation (Fig. 4c). These values were lower than the previously reported tensile yield strength for PCL (14.68 MPa) [14]. The ring was moved to anterior–posterior direction in 0.1 mm (Fig. 4e) and transverse direction in 0.2 mm (Fig. 4f) in systole.

Effect of ring deformation on the mitral valve

In type A deformation, the changes from baseline at the septal–lateral distance, transverse distance, and ring area were − 26%, + 10%, and + 17%, respectively. In type B deformation, the changes were + 10%, − 10%, and + 13%, respectively. In type C deformation, the ring's area was

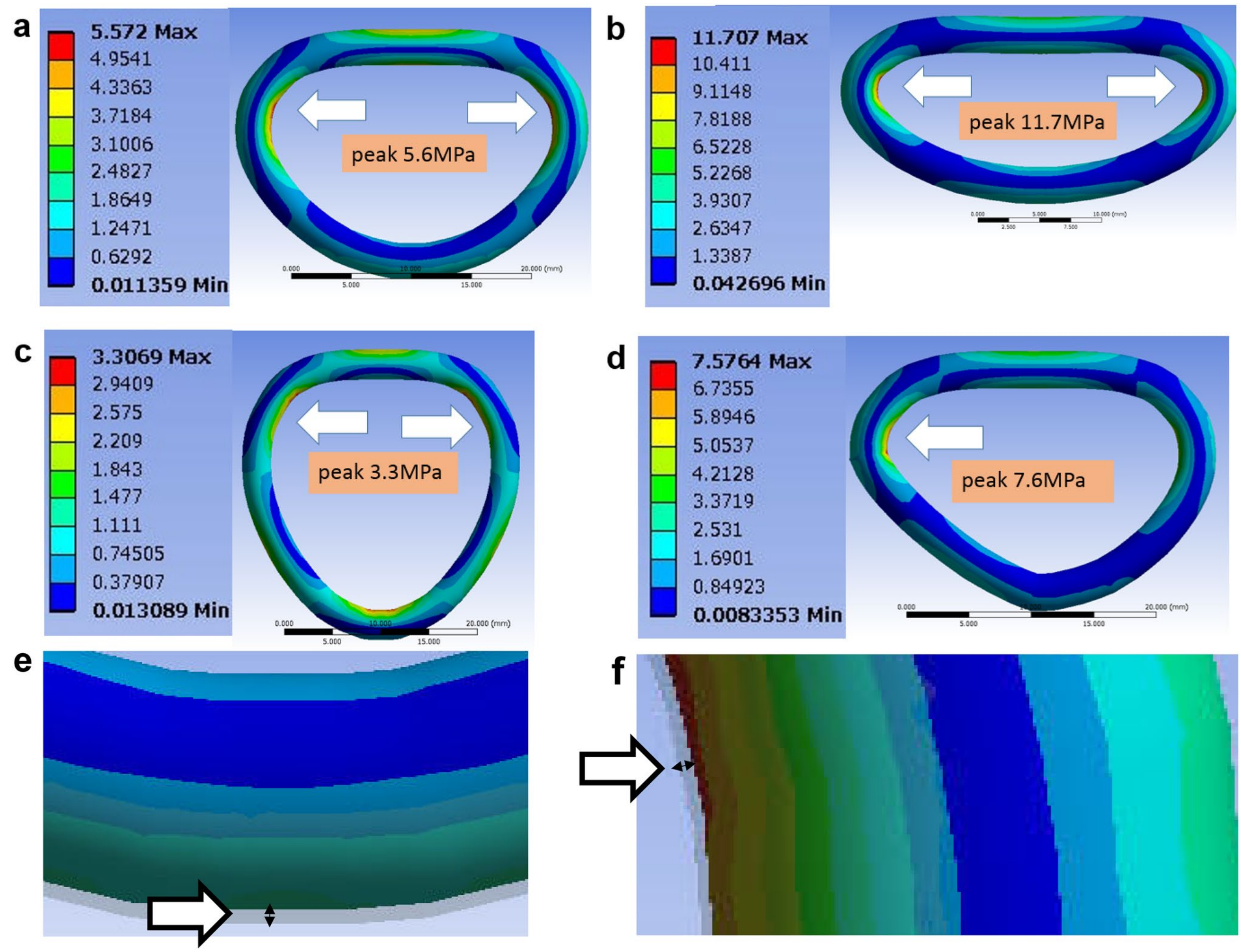

Fig. 4 Simulated stresses on the ring after deformation. The color bar indicates the stress force, which was calculated using the von Mises method (red, high; blue, low). **a** Pre-deformation, **b** type A deformation, **c** type B deformation, **d** type C deformation. The white arrows indicate the strongest point of stress. **e** The ring was moved to the anterior–posterior direction in 0.1 mm and **f** the transverse direction in 0.2 mm in systole. The gray part indicates the ring position in diastole (arrows)

decreased by 10%. Figure 5a–d shows the ink test of the mitral valve pre- and post-deformation. Type A deformation of the annuloplasty ring increased leaflet coaptation. However, type B deformation decreased leaflet coaptation. Type C deformation increased coaptation only in A1–P1. Table 1 shows coaptation and the C–sept length after ring deformation. Type A deformation increased coaptation in all areas and decreased the C–sept length compared with the baseline value. However, type B deformation decreased coaptation in all areas and increased the C–sept length. Type C deformation increased coaptation only in A1–P1 and did not change the C–sept length.

Assessment of heat injury

Figure 5e shows the pathological findings of the left atrial myocardium after heating. There was no necrotic findings in control, 5 times heating and 10 times heating in the HE and MT stain. This ring could be thus deformed at least 10 times without injury in the subendocardium.

Discussion

The mechanical properties of a new thermally deformable mitral annuloplasty ring and its effects on the mitral valve were confirmed with a ring property test and simulation with a finite element analysis. Furthermore, we demonstrated that free deformation of the ring was useful for changing leaflet coaptation and the C–sept length in a pig heart model.

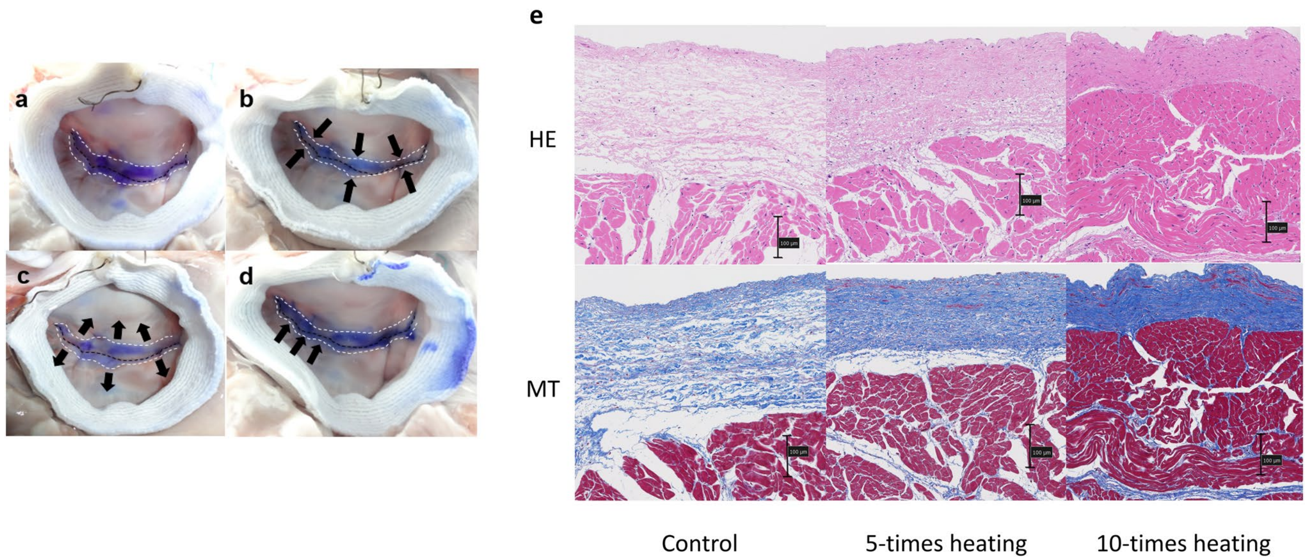

Fig. 5 Ink test of the mitral valve after ring deformation. **a** Pre-deformation, **b** type A deformation, **c** type B deformation, **d** type C deformation. **e** Pathological findings of the left atrium after heating: HE (upper) and MT (lower) stain in control (no heating), 5 times heating, and 10 times heating. Black bar indicates 100 μm. *HE* hematoxylin–eosin, *MT* Masson's trichrome

Table 1 Coaptation length of the mitral valve leaflets and C–sept length after deformation of the ring

	Before annuloplasty	Pre-deformation	Type A deformation	*P* values	Type B deformation	*P* values	Type C deformation	*P* values
A1–P1 (mm)	9.0 ± 1.6	10.7 ± 1.6	12.4 ± 1.2	< 0.001	8.0 ± 2.0	< 0.001	12.9 ± 1.5	< 0.001
A2–P2 (mm)	10.4 ± 1.9	11.0 ± 2.3	14.1 ± 1.9	< 0.001	7.8 ± 1.7	< 0.001	10.8 ± 2.4	0.32
A3–P3 (mm)	8.9 ± 1.5	9.6 ± 1.2	11.9 ± 0.9	< 0.001	7.4 ± 1.6	< 0.001	9.5 ± 1.2	0.2
C–sept (mm)	30.8 ± 4.2	30.9 ± 3.9	29.1 ± 4.2	0.003	33.8 ± 4.9	< 0.001	31.6 ± 3.9	0.91

Values are reported as mean ± SD; the differences between pre-deformation and type A, B, and C deformation were examined

SD standard deviation, *A1–P1* coaptation length at the A1–P1 line, *A2–P2* coaptation length at the A2–P2 line, *A3–P3* coaptation length at the A3–P3 line, *C–sept* the minimum distance from the coaptation to the ventricular septum

PCL as an artificial ring material

The core part of this ring was made of PCL, which is a biocompatible and commercially available synthetic biodegradable polymer. The properties of PCL were as follows: molecular weight, 40,000–80,000; Young's modulus, 0.21–0.44 GPa; tensile strength, 4–785 MPa; melting temperature from 56 to 65 °C; and glass transition temperature from − 65 to − 60 °C [8, 15–17]. Shandas et al. reported that the deformation and reaction forces of the mitral annulus in the cardiac cycle were 2.7–8.0 N and 4.4–13.9 N (1 N/mm^2 = 1 MPa), respectively [18]. Thus, our new ring had sufficient strength to serve as a mitral annuloplasty ring and undergo any type of deformation. The heat developed by the nickel–chromium alloy was conducted to PCL and could be blocked by the polyvinyl chloride tube and sewing cuff. The temperature of the sewing cuff was lower than 40 °C when the ring was deformed by heat.

Coaptation length of the mitral leaflet

Carpentier et al. reported that the normal mitral valve has a 7–9 mm coaptation length in the middle line of the valve, and it should be maintained at more than 5 mm after mitral valve plasty [10]. Tozzi et al. reported that inadequate coaptation (< 2 mm) might lead to failed repair [7]. Not only primary, but also functional mitral regurgitation could be reduced to some extent by shortening the septal–lateral distance of the mitral annulus [19, 20]. Thus, modifying the septal–lateral diameter would be useful when residual mitral regurgitation is encountered after repair [6]. We demonstrated that our current deformable ring further increased the coaptation length in A1–P1, A2–P2, and A3–P3. In a clinical setting of inadequate coaptation after mitral valve repair [6, 7], our ring can change the coaptation length in an asymmetrical fashion intraoperatively according to the valve's pathology.

SAM and the C–sept length in mitral valve repair

SAM of the anterior leaflet of the mitral valve can occur in up to 14% of patients after mitral repair and cause mitral regurgitation and hemodynamic compromise [1]. The pathology of SAM is either a large posterior leaflet that pushes the coaptation point toward the ventricular septum or elongated leaflets with small annuloplasty rings [4]. One of the risk factors of SAM is a short C–sept length. Although intraoperative SAM can usually be managed with fluid administration and discontinuation of inotropic drugs, another repair technique or mitral valve replacement is sometimes necessary [21]. There are various additional techniques for the mitral leaflet to prevent SAM [5, 22–24]. Another approach to SAM is to exchange the annuloplasty ring with a larger one [25] or another ring with a different design [26]. We showed that our current deformable ring can increase the C-sept length after deformation without the need to exchange the sutured annuloplasty ring. In a clinical setting of SAM, the ring's shape can be adjusted after implantation. The sutured ring does not need to be explanted, which would otherwise damage the annular tissue, prolong the cardiopulmonary bypass time, and increase the cost due to the need for a new ring. Langer et al. have reported the same concept of a post-implant adjustable ring. However, their ring is not reversible and has a limited deformation length [6].

Limitations

The current study has several limitations. First, the PCL we used in the core part of the mitral valve ring is biocompatible and can be degraded in the human body. Although there is a risk of deterioration of the ring in the long term, we were able to cover the PCL with polyvinyl chloride easily. We have started an experiment using another material for the ring. Second, our ring was examined using the same configuration as the Physio ring. The ring stress would be different in other 3-dimensional rings. Third, in the finite element analysis used in this study, we hypothesized that the annulus would move concentrically in all parts of the mitral valve. Lansac et al. and Rausch et al. reported that the annulus's motion in sheep was not simply concentric, especially in the commissure-to-commissure part [27, 28]. Therefore, our hypothesis might not be accurate in this respect. It is difficult to simulate real motion of the heart perfectly; therefore, the feasibility and durability of the ring should be tested in a moving heart. Fourth, it would be ideal to deform under the trans-esophageal echocardiography guide for the beating heart. However, for the current ring, we need cardiac arrest and deformation of the ring by hands or forceps. Lastly, the durability of the ring was not tested in vivo. We have planned a durability test using pigs.

Conclusion

This newly designed thermally deformable mitral annuloplasty ring could be "order-made" and effectively change the coaptation length in all parts of the mitral valve and the distance from the coaptation to the septum after the ring is deformed due to intraoperative heating.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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