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Releasable annuloplasty ring insertion — a novel experimental implantation model☆

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Abstract

Objective: Experimental testing of annuloplasty ring (AR) effects requires a control group if the AR is implanted conventionally. Our goal was to develop a reversible AR insertion method that allows for beating heart assessment with and without an AR, providing the ability to evaluate the effects of an AR in the same animal (internal control). We tested the feasibility of this technique in an *in vivo* ovine model using four-dimensional (4-D) radiopaque marker tracking. **Methods:** Before the operation, a rigid AR (Edwards Geoform®, Edwards Lifesciences, Irvine, CA, USA) was prepared by stitching the middle parts of eight double-armed sutures evenly spaced through the ring fabric using a Spring Eye needle. The resulting loops were 'locked' with polypropylene sutures. In addition, two drawstring sutures were attached to the AR. Using cardiopulmonary bypass and cardioplegic arrest, 12 adult sheep had 16 radiopaque markers sewn to the mitral annulus. The AR was implanted by stitching the eight sutures equidistantly in a perpendicular direction through the mitral annulus. The sheep were transferred to the catheterisation laboratory and 4-D marker coordinates were obtained using biplane videofluoroscopy (60 Hz) with the AR inserted (Geo-AR). The locking sutures were then released, the AR was pulled up to the atrial roof using the drawstring sutures and another dataset was acquired (control). Maximum and minimum mitral annular areas (MAA_{max}, MAA_{min}) during the cardiac cycle were derived from implanted markers. Data are provided from one representative animal. **Results:** AR insertion and release were uneventful in all animals. Whereas the mitral annulus was dynamic in the control state (MAA_{max}: 9.0 cm^2, MAA_{min}: 7.8 cm^2), mitral annular dynamics were abolished in the Geo-AR case (MAA_{max}: 6.2 cm^2, MAA_{min}: 6.0 cm^2). **Conclusions:** This novel releasable AR implantation method is feasible and permits *in vivo* assessment of AR effects in the same heart. The new technique should facilitate experimental AR testing and promote the development of ARs based on physical criteria.

Keywords: Annuloplasty ring; Reversible ring implantation; Novel insertion method; Ovine model

1. Introduction

Annuloplasty rings (ARs) are available in many shapes, sizes and material properties [1] and are commonly implanted during mitral valve repair procedures [2]. To evaluate the effects of ARs on the valvular—ventricular complex experimentally, quantitative comparisons must be made between different hearts with and without rings, thus comparing data from two groups of animals (an experimental group with the ring implanted and a separate control group treated identically, but without ring implantation). In order to avoid the need for a separate control group and strengthen statistical power, our goal was to develop an experimental AR insertion technique that allows the AR to be released in a beating heart, thereby enabling each animal to serve as its own control. To test the feasibility of this method, we assessed mitral annulus (MA) geometry and dynamics before and after release of an Edwards GeoForm® AR (a rigid, dog-bone-shaped AR with a 6-mm elevation of the P-2 segment; Fig. 1) in an *in vivo* ovine beating heart model using four-dimensional (4-D) radiopaque miniature marker tracking.

2. Materials and methods

2.1. Releasable AR preparation (Video 1)

In order to allow release of the AR on a beating heart, the ring was prepared before the operation as follows: the middle

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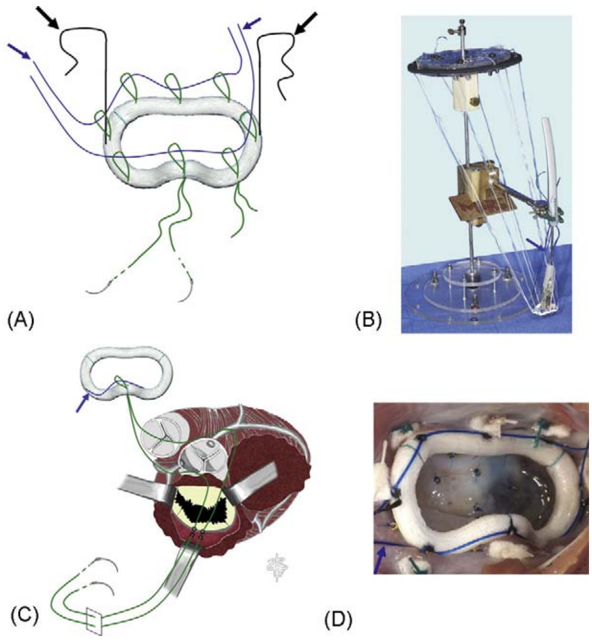

Fig. 1. Method of annuloplasty ring (AR) insertion in a releasable fashion. (A) Schematic of preoperative AR preparation: The middle part of eight 2/0 polyester sutures was sewn using a French needle through the AR (Edwards GeoForm®). The resulting loops on the upper side of the AR were 'locked' with two polypropylene sutures. Then, two drawstring sutures were placed near the commissural regions of the AR. (B) A self-made apparatus holding the prepared mitral annuloplasty ring was employed to facilitate ring implantation. The platform was sewn on top of the sheep's chest in the surgical field. The suture ends were subsequently taken from the black disc and sutured through the anatomical mitral annulus. (C) Schematic of the surgical insertion technique of the prepared AR: the needles of the 2/0 polyester sutures were first passed from the mitral annulus towards the left atrium and then through a Teflon felt pledget. (D) Intraoperative picture of the AR after insertion. Black and blue arrows denote the drawstring and locking sutures, respectively. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

part of each of the eight 2/0 double-armed polyester braided sutures was placed through the AR using a Spring Eye (French Eye) needle. These sutures were evenly spaced around the circumference of the AR (Fig. 1A). The resulting loops on the upper side of the annuloplasty ring were 'locked' with two polypropylene sutures (blue arrows, Fig. 1A). Two drawstring sutures were then placed at the commissural regions of the AR (black arrows, Fig. 1A). To facilitate AR implantation, the prepared AR was held by a self-made apparatus (Fig. 1B).

2.2. Surgical preparation

Twelve adult, Dorsett-hybrid, male sheep (48 ± 2 kg) were pre-medicated with ketamine (25 mg kg^{-1} intramuscularly), anaesthetised with sodium thiopental (6.8 mg kg^{-1} intravenously), intubated and mechanically ventilated with inhalational isoflurane (1.0—2.5%). A left thoracotomy was performed and the heart was suspended in a pericardial cradle.

Using cardiopulmonary bypass and cardioplegic arrest, 16 radiopaque markers were sewn equidistantly to the mitral annulus and two markers were sewn to the central edge of the anterior and posterior mitral leaflet, respectively.

2.3. Releasable AR implantation technique (Video 2)

The 2/0 polyester sutures from the prepared ring were first passed through the MA towards the left atrium (LA), in a perpendicular direction and then through a pledget as shown in Fig. 1C. The AR was then secured to the MA by tying these sutures. Fig. 1D shows the AR after insertion. The 'locking' thread and the drawstrings were exteriorised, and the LA was closed. The animals were weaned from cardiopulmonary bypass and transferred to the experimental animal catheterisation laboratory.

2.4. Data acquisition and analysis

Along with EKG signal and LV pressure, videofluoroscopic images (60 Hz) of MA markers were acquired using a biplane videofluoroscopy system (Philips Medical Systems, North America, Pleasanton, CA, USA) [3]. Images were first acquired under baseline conditions with the AR inserted (Geo-AR). The 'locking sutures' were then removed by pushing a tourniquet down towards the LA dome while pulling the sutures out to minimise traction on the AR. By pulling up on the drawstring sutures, the loops from the polyester sutures slipped back through the AR allowing the AR to be lifted away from the annulus into the LA (Video 2). After haemodynamic values returned to baseline, another data acquisition was performed (control).

Marker coordinates from each of the biplane views were merged to yield the 3-D coordinates of each marker centroid in each frame [3]. The MA area was plotted throughout the cardiac cycle around end-diastole (ED; defined as peak of the R-wave in the ECG). To determine MA shape, 3-D coordinates from annular markers were plotted at end-systole (ES, defined as frame preceding maximum $-dP/dT$) in a reference-free-coordinate system. In order to get an impression whether release of the AR into the LA affects atrial contraction, we plotted the distance between the anterior and posterior mitral leaflet edge markers (interleaflet distance) throughout the cardiac cycle, focusing particularly on late-diastolic leaflet dynamics reflecting A-wave flow into the LV. Data are shown from one representative animal.

All animals received humane care in compliance with the guidelines set forth by the National Institutes of Health (US Department of Health and Human Services NIH Publ. 85-23, Revised 1985). This study was approved by the Stanford Medical Center Laboratory Research Animal Review Committee and conducted according to the Stanford University policy.

3. Results

The Geo-AR was successfully released and lifted off the annulus in all animals. In one animal, atrial fibrillation occurred immediately after AR release, which was successfully treated by electrical cardioversion. Fig. 2A shows the MA area plotted around ED throughout the cardiac cycle with (Geo-AR) and without the ring inserted (control). As expected, MA area change was abolished with the AR insertion and MA contraction recurred after AR release.

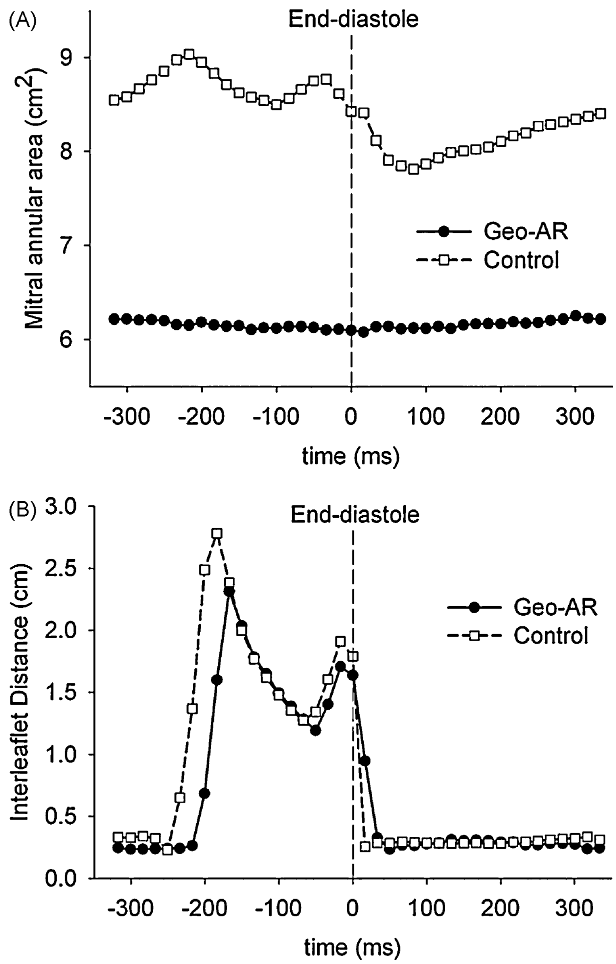

Fig. 2. Mitral annular area (A) and interleaflet distance (B) as a function of time plotted throughout the cardiac cycle centred around end-diastole (time = 0) with (Geo-AR) and without the annuloplasty ring inserted (control) in one representative animal.

Fig. 2B shows the plotted interleaflet distances for Geo-AR and control. The interleaflet distances of the two states (Geo-AR and control) are almost identical throughout the cardiac cycle. The curves show the typical late-diastolic A-wave resulting from left atrial contraction for both, Geo-AR and control. Fig. 3 shows the MA marker coordinates plotted at ES with (Geo-AR) and without the ring inserted (control). The MA conformed to the dog-bone shape of the AR in the Geo-AR state and returned to a physiologic saddle shape in the control state (Fig. 2B).

4. Discussion

Our main findings were that (1) this novel AR implantation technique was a feasible method and permitted AR removal in a beating heart animal model; (2) rigid AR implantation

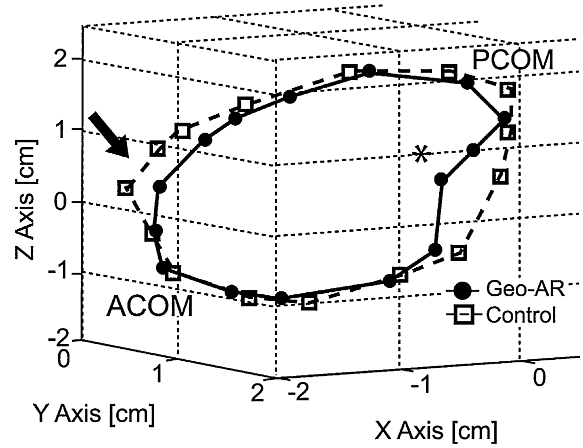

Fig. 3. Three dimensional mitral annular shape obtained from all annular markers from one representative animal in a reference-free-coordinate system at end-systole for control case and Geo-AR. The arrow points to the saddlehorn marker in the middle of the anterior annulus. The asterisk marks the mid-posterior annulus. ACOM: anterior commissure and PCOM: posterior commissure.

using this technique resulted in abolished MA dynamics as well as conformation of the AR to the 3-D AR shape; (3) release of the AR resulted in recurrence of MA dynamics and return of the MA to a physiological saddle shape; and (4) late-diastolic leaflet dynamics with and without AR were similar, which suggests that release of the AR into the left atrium did not affect left atrial contraction.

In conclusion, this novel releasable AR implantation method, for the first time, allows for AR deployment in a beating heart animal model and provides the ability to evaluate the effects of an AR in the same heart (internal control). This technique should prove useful in the future evaluation of ARs *in vivo* by reducing the number of animals required and strengthening the statistical power of the experiment. Ultimately, this novel AR implantation method may promote the development of ARs based on physical criteria.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejcts.2009.06.028.