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***New Ideas** / Yeni Fikirler*

A novel device for technical standardization of valve-sparing aortic root reimplantation

Kapak koruyucu aort kök reimplantasyonunun teknik standardizasyonu için yeni bir cihaz

Ahmet Elibol

Department of Cardiovascular Surgery, University of Health Sciences, Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital, Istanbul, Turkey

ABSTRACT

Among valve-sparing aortic root replacement techniques developed for the treatment of aortic root aneurysms and aortic insufficiency, the reimplantation technique (the David procedure) has proved to provide excellent outcomes in experienced hands. However, it involves certain challenges in technical standardization, particularly for graft sizing, which is still far from standardization. A novel device was developed to facilitate and provide all the measurements in high precision and accuracy required for the David procedure. The device allows easy, rapid, and accurate acquisition of the patient's data and appropriate configuration of the aortic valve, irrespective of the surgeon's subjective evaluations. This all-in-one device provides all the major parameters including graft size, effective height, graft preparation, and simulation of the aortic coaptation. The device was successfully tested on a Devotini aortic root simulator and on a bovine heart *ex vivo*. The device proposed herein to be used for reimplantation has one explicit advantage: all valve geometry to be reconstructed and repaired can be simulated on the device with all its elements, in particular, the commissures and the cusps. Thus, all that is necessary can be clearly visualized in a manner whatever the configuration the surgeon prefers, particularly the creation of the effective height.

Keywords: Aortic insufficiency, David procedure, reimplantation, standardization, valve-sparing aortic root replacement.

ÖZ

Aort kök anevrizmaları ve aort yetersizliği tedavisi için geliştirilen kapak koruyucu aort kök replasman teknikleri arasında, reimplantasyon tekniğinin (David işlemi) deneyimli ellerde mükemmel sonuçlar ortaya çıkarabildiği kanıtlanmıştır. Ancak, başta standarttan uzak greft büyüklüğü olmak üzere, teknik standardizasyon açısından birtakım kısıtlılıkları mevcuttur. David işlemi için gerekli kesin ve doğru ölçümleri kolaylaştırmak ve sağlamak amacıyla yeni bir cihaz geliştirildi. Bu cihaz sayesinde cerrahın öznel değerlendirmelerinden bağımsız olarak hastaların verileri kolay, hızlı ve doğru bir şekilde alınabilmekte ve aort kapağı uygun bir şekilde konfigüre edilebilmektedir. Hepsi bir arada olan bu cihazda greft büyüklüğü, etkili yükseklik, greft hazırlığı ve aort koaptasyon simülasyonu dahil olmak üzere başlıca parametreler mevcuttur. Cihaz Devotini aort kök simülatörü ve *ex vivo* sığır kalbi üzerinde başarılı bir şekilde test edilmiştir. Reimplantasyon için kullanılmak üzere bu makalede anlatılan cihazın belirgin bir avantajı da vardır: yapılandırılacak ve onarılacak kapak geometrisi, komissür ve kusplar başta olmak üzere tüm komponentleri ile bu cihazda simüle edilebilir. Bu nedenle, gerekli olan her şey, bilhassa etkili yüksekliğin yaratılması, cerrahın tercih ettiği konfigürasyon ne olursa olsun, açıkça görüntülenebilir.

Anahtar sözcükler: Aort yetersizliği, David replasmanı, reimplantasyon, standardizasyon, Kapak koruyucu aort kök replasmanı.

Aortic root replacement surgery is performed in patients with aortic root aneurysms. Besides the threat of dissection, aortic root aneurysms may also cause aortic valve regurgitation due to dilatation of the base of the aortic valve (Figure 1). The most common practice is to perform the Bentall procedure, in which the aortic root aneurysm is removed along with the aortic valve. In this procedure, the native aortic valve is replaced with a mechanical or biologic prosthetic valve, even if the leaflets are not involved. However, both types of prosthetic valves are associated with severe complications.[1-3] Recipients of mechanical aortic valves are at risk for infections and thromboembolism, for which life-long anticoagulant therapy is indicated, with regular hospital visits and dose adjustment. In addition, mechanical aortic valves impose significant

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Correspondence: Ahmet Elibol, MD. Kartal Koşuyolu Yüksek İhtisas Eğitim ve Araştırma Hastanesi Kalp ve Damar Cerrahisi Kliniği, 34865 Cevizli, Kartal, İstanbul, Türkiye. Tel: +90 544 - 693 48 70 e-mail: elibol.md@gmail.com

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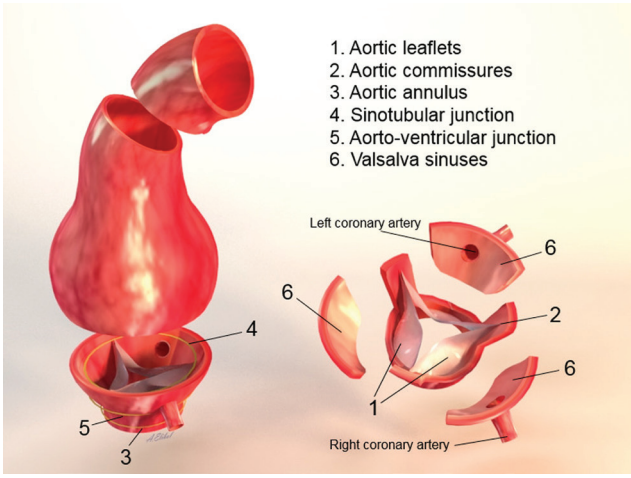


Figure 1. Anatomy of aortic root aneurysms.

limitations on the patients' lifestyle, restricting activity and for women, pregnancy. Although biologic prosthetic valves do not require anticoagulant therapy, structural deterioration is inevitable over time[4] and they have been shown to be associated with higher mortality and reoperation rates before 55 years of age.[3]

Due to these limitations, valve-sparing aortic root replacement techniques have been developed to preserve the native aortic root, including reimplantation and remodeling techniques.[5,6] The reimplantation technique (David procedure) has been progressively gaining interest owing to the wide range of indications it offers.[7] In this procedure, the aortic annulus is dissected and reimplanted into the replacement graft. However, it requires patient-specific anatomical measurements of the aortic root and valve, such as appropriate graft size, commissure height (height of the interleaflet triangle), and effective height, which are difficult to estimate and require experience.[5] Several techniques (e.g., echocardiography, computed tomography [CT], transesophageal echocardiography [TEE], valve sizers, or Hegar dilators) have been used to identify the appropriate graft size.[8] Commissure height is also used to estimate the graft size; however, this technique is highly based on visual inspection. Effective height, on the other hand, is determined using an aortic caliper, but accuracy depends on its vertical positioning on the aortoventricular plane. Therefore, the success of the David procedure highly depends on the skills and experience of the cardiothoracic surgeon. Thus, rather than leaving all these measurements to the surgeon's discretion and preference, which is highly dependent on the surgeon's skills and experience, there is an unmet need to develop a device and method to make standard and accurate measurements of the anatomical features of the aortic root and leaflet geometry.[9]

In recent years, a novel device has been developed to facilitate and provide all the measurements in high precision and accuracy required for the David procedure, specifically for David type I reimplantation. The device was patented to the developer (author AE) by No. TR/2016/18240 B. The device has three main advantages: *(i)* it provides the appropriate graft size based on an objective determination of the effective height; *(ii)* all measurements required for the David procedure can be obtained on the device, free from individual interpretations; and *(iii)* the device provides excellent guidance to graft preparation convenient for the patient's anatomy and to placement of the graft in position.

THE NEED FOR A NEW DEVICE FOR THE DAVID PROCEDURE

THE MAJOR ELEMENTS OF THE DAVID PROCEDURE

Valve-sparing aortic root reimplantation (VSARR) surgery requires an accurate measurement of the aortic valve and the root. The key to success for VSARR is the choice of appropriate graft size, which depends on the accurate measurement of the patient's anatomy. Miller DC, a distinguished cardiovascular surgeon with expertise in the David procedure, rightly commented on the procedure as follows: "This procedure remains more art than science and is most unforgiving of small technical errors in dynamic three-dimensional geometry."[10]

Graft sizing

The sizing of the graft, appropriate in diameter for the patient, is of utmost importance to achieve an optimal coaptation of the aortic leaflets and to avoid postoperative aortic insufficiency.[11] Several methods have been described for the selection and preparation of the graft.[12,13] Therefore, this stage is still far from standardization and remains mainly at the discretion of the operating surgeon. A graft of smaller than optimal size results in prolapse (collapse) with ensuing aortic regurgitation, while selection of a larger graft results in central aortic regurgitation.

The first step in choosing the right size of the graft is the measurement of the aortic annulus. Several methods have been described for this measurement, most of which are based on the measurement of the aortic annulus including pre- and intraoperative TEE, preoperative CT, sizing with Hegar rods to calculate the inner diameter of the aortic annulus, and sizing

with valve sizers, where a mechanical valve sizer is fitted around the annulus and a biological valve sizer is placed inside the aortic annulus.[11] If the selected method measures the inner diameter of the aortic annulus, the graft size is, then, often determined by adding 4 mm to the diameter.[11] However, David has objections to the use of anatomic measurements of the annulus made based on the assumption that the aortic annulus is already normal, since the anatomic components of the aortic valve are always disrupted due to aortic root aneurysms.[14] Due to the complexity of the measurements and the geometric variables of the aortic apparatus, David[14] proposed an indirect means of determining the graft size and estimated the graft size in relation to the average height of the cusps. Given that the radius of the reconstructed aortic root should be approximately two-thirds of the average height of the cusps, an addition of 6 mm is made to the two-thirds of the average height of the aortic cusps due to the placement of the graft outside of the aortic annulus. On the other hand, El Khoury[15] proposed the commissural height lying between the non-coronary cusp and the left coronary cusp to be used for determining the graft size, with the height of the commissure being equal to the external diameter of the sinotubular junction, equivalent to the graft diameter.

It is evident that the proposed measurement methods for the graft size are quite confounding and far from standardization.[16] The choice of the most optimal technique and the success of VSARR, therefore, often depends on the experience and individual preference of the surgeon.

Effective height

After reimplantation of the aortic valve inside the graft, it is important that all three cusps coapt at the same level, which should be at least 5 or 6 mm above the aortic annulus according to David. If the reimplantation does not provide coaptation at the same level, shortening of the free margin that disrupt coaptation may be needed.[14]

On the other hand, Schäfers and Aicher[17] introduced the use of an aortic caliper to measure the effective height and to check for the appropriate coaptation so that any residual or induced prolapse can be repaired. The use of an aortic caliper has been advocated by other cardiovascular surgeons, as well.[18] The recommended range for the effective height is 7 to 11 mm, depending on individual surgeons.[8,19]

A study which examined the effective height by transthoracic echocardiography in healthy adults found a mean effective height of 9.5 mm (range, 7 to 12) with a significant correlation with the body surface area, body weight, and body height.[20]

Subannular suture line and graft preparation

The placement of subannular sutures to fix the graft below the annulus has a significant role on leaflet configuration, coaptation, and effective height. The arrangement of these sutures is highly patient-specific, although there are variations in the preparation of the graft in relation to the site of the subannular sutures. As the subannular suture line does not lie in the same plane, the placement of the graft on the aortic root must match the alignment of the subannular suture line so that the corresponding points of the suture line can be determined on the graft.[21]

Reimplantation of the aortic commissures inside the graft

All three commissures should be positioned and reimplanted properly in the graft to form the new sinotubular junction, paying an attention to their spatial relationships with each other.[5] This part of the operation requires knowledge and experience to reimplant the valve exactly in the same position as it was before in the native aortic root.[11] If the commissures are fixed too low or high, this may lead to aortic insufficiency due to leaflet prolapse and oversuspension, respectively.

INNOVATION

The novel device, Elibol's David facilitator, measures the above-mentioned parameters, independent of the surgeon's subjective assessments, for the success of the David procedure. It also simulates coaptation at the very beginning of the procedure.

Once the device is seated on the aortic root, the surgeon will be able to obtain all data about these major parameters within only approximately 10 min and can proceed with the David procedure without having to choose from a wide variety of currently used methods or techniques.

Design of the device

The main components of the device include *(i)* an adjustable circle for graft diameter (26 to 34 mm), *(ii)* five legs for fixation outside the aortic annulus, each having a spring, *(iii)* three commissure holders attached to the circle, and *(iv)* two pins (central and peripheral) that serve as calipers to perform effective height measurement (Figure 2). The adjustable circle moves vertically on the legs to change the height of the commissure holders and horizontally

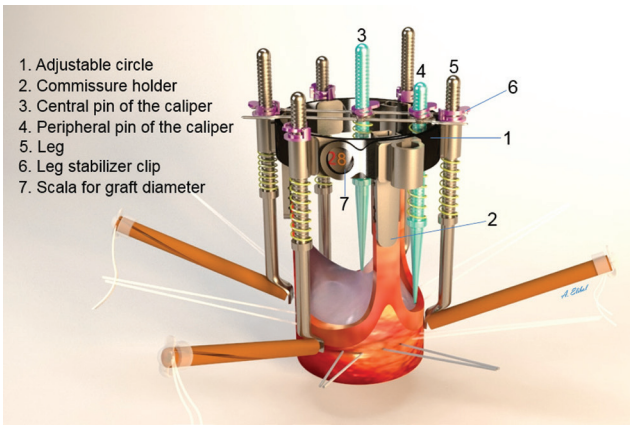


Figure 2. The appearance of device and its components.

(narrowing and widening) to change the distance of the commissure holders from each other. The legs are fixed to the aortic annulus at the subannular suture line using slit surgical tubes. The central and peripheral calipers measure the vertical heights from the coaptation tip and the nadir of each leaflet, respectively. The difference yields the effective height. The components and a step-by-step guide to the application of the device are provided in the supplementary material.

Functions of the device

The all-in-one Elibol's David facilitator was designed to eliminate the variability associated with diverse measurement techniques. *(i)* The device simulates optimum leaflet coaptation by modifiable resuspension through commissure holders on the adjustable circle. *(ii)* Once the optimal coaptation is achieved, the effective height for each leaflet (as the subtraction of the height of the coaptation tip from the height obtained at the nadir of each leaflet) is checked. At this stage and before graft selection, aortic cusp repair may be performed and/or effective height can be modified for individual leaflets in case optimal coaptation cannot be obtained. *(iii)* The device is locked and removed from the aortic annulus, at which time all measurements can be read on the device including the graft size as defined by the diameter of the circumference determined by the commissure holders. *(iv)* The graft chosen at the same diameter is inserted inside the legs of the device and attached to the commissure holders. *(v)* The subannular suture line and the resuspension points of the commissures are readily marked on the graft. *(vi)* The graft is cut just below the suture line. *(vii)* The remaining part of the reimplantation is merely tailoring.

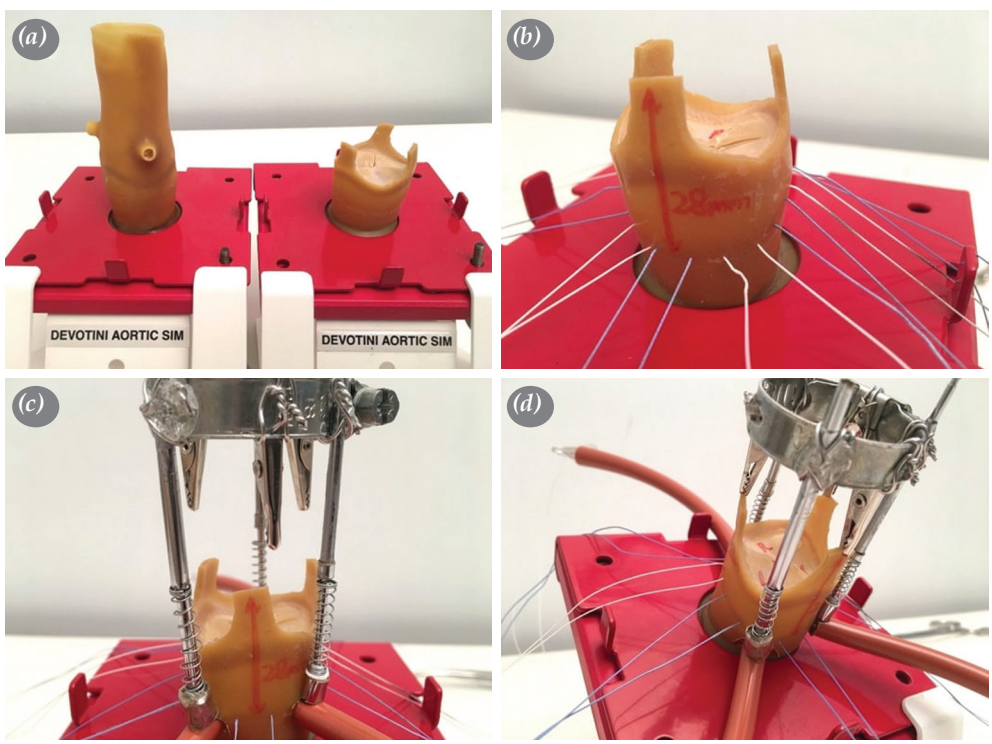


Figure 3. Placement of device on a Devotini aortic root simulator. **(a)** Preparation of aortic root. **(b)** Alignment of subannular sutures. **(c, d)** Fixation and positioning of device.

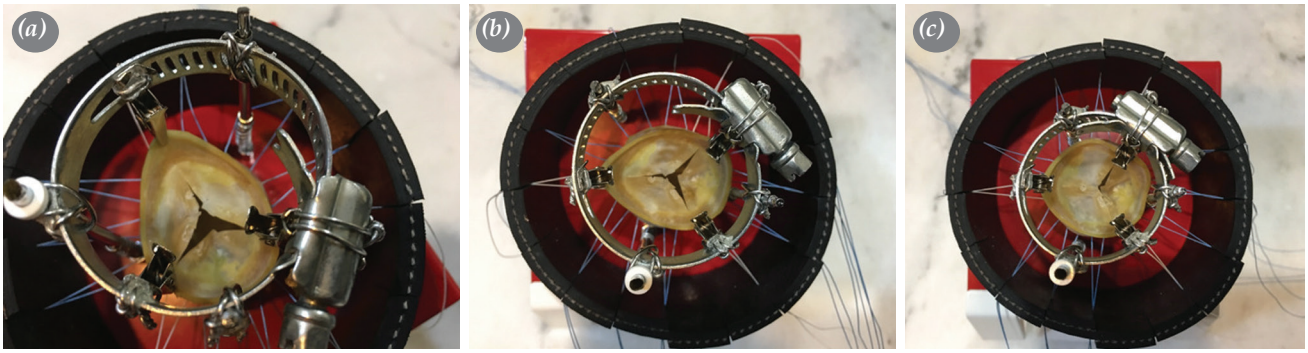


Figure 4. Simulation of coaptation. **(a, b)** Appearance of aortic leaflets at varying diameters of circle. **(c)** Optimal coaptation.

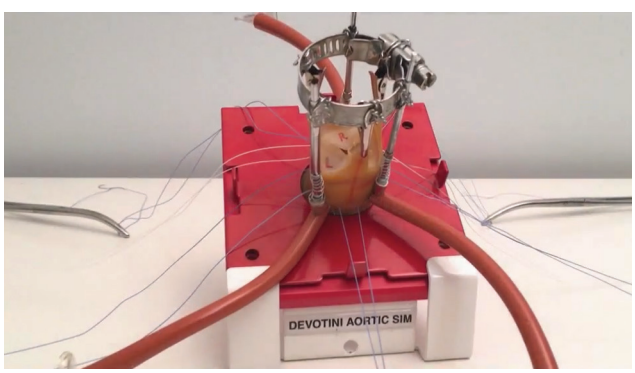
EXPERIMENTAL STUDIES

Testing the device on an aortic root simulator

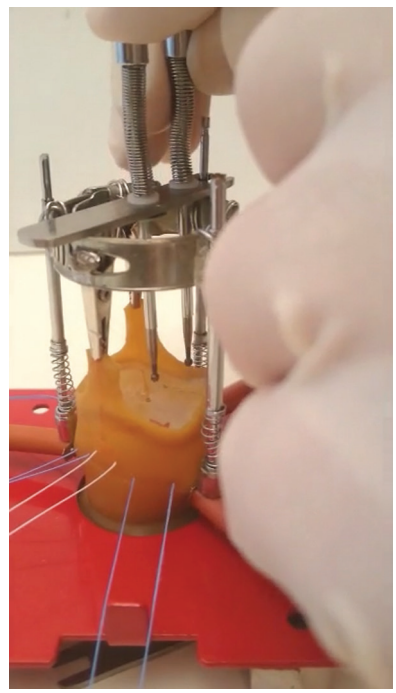
A three-leg prototype of the device was tested on a Devotini aortic root simulator. The ascending aorta and the sinuses of Valsalva were resected (Figure 3a). Subannular sutures that would form the subannular suture line were placed as in the David procedure, and the three aortic commissures were created with varying commissural heights in relation to the subannular suture line (Figure 3b). The device was, then, placed in the aortic root under the guidance of subannular sutures that corresponded to the three legs (Figure 3c). The commissure holders were attached to the three aortic commissures, above the commissural insertions of the leaflets (Figure 3d). While the springs on the legs pushed the legs downwards and the circle upwards, the commissure holders attached to the commissures limited the upward movement of the circle. This provided vertical positioning of the device on its own mechanics, which was observed to be stable (Video 1), in that its position returned to the initial state, even if an external force was applied to change the position. This fixed position provides a steady plane above the commissures (the new sinotubular junction), keeping the adjustable circle parallel to the subannular plane at each position of the heart. Simulation of coaptation was observed at varying diameters of the circle (Figure 4a, b). Once an optimal coaptation was observed (Figure 4c), the legs were locked and the effective height was obtained using the two (central and peripheral) pins (Figure 5a, Video 2). The device was, then, removed from the Devotini simulator with all the data required for the graft preparation available on the device (Figure 5b, c).

Ex vivo bovine heart study

A prototype device was designed according to the aortic root measurements of a 3-kg bovine heart



Video 1. Positioning prototype device.



Video 2. Positioning caliper.

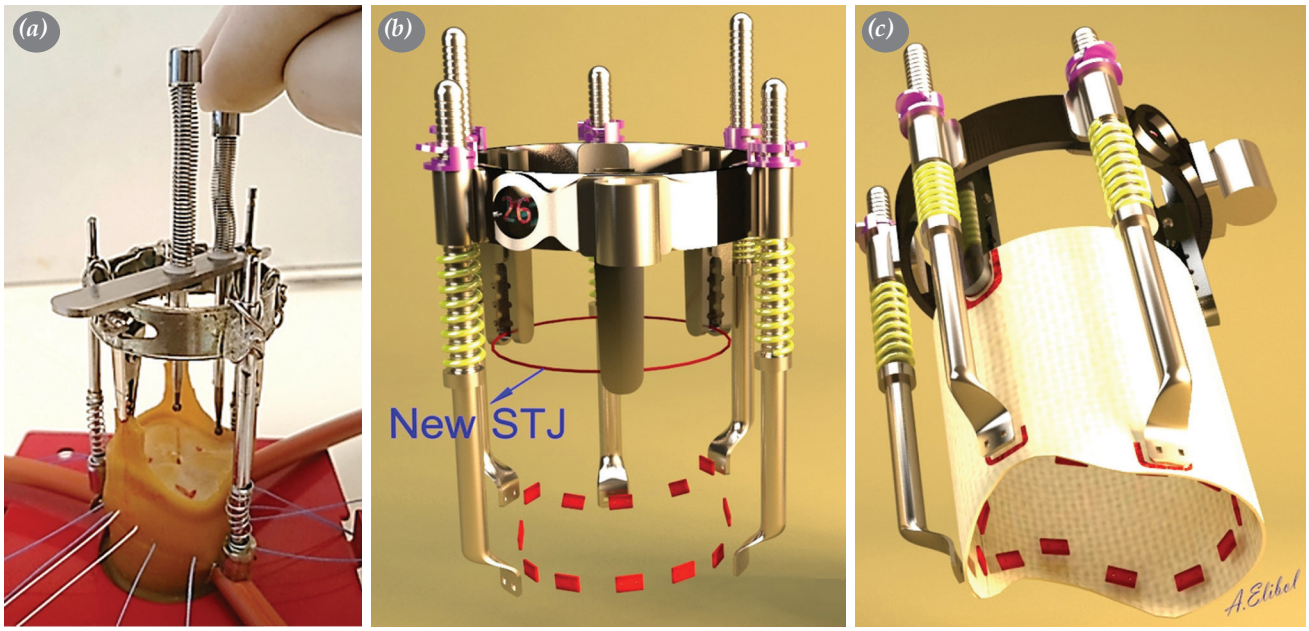


Figure 5. The appearance of device at optimal coaptation and graft preparation. **(a)** Positioning of caliper. **(b)** Locked device at an optimal coaptation. **(c)** Marking and preparation of graft.

(Figure 6a, b). The following steps were planned: *(i)* fixation of the device to the aortic root through the subannular sutures; *(ii)* by attaching commissure holders to the aortic commissures, positioning of the device and aortic resuspension; *(iii)* using an adjustable circle, the aortic coaptation simulation and through a stable (secured) adjustable circular frame, positioning of the aortic caliper perpendicular to the aortoventricular plane; *(v)* at an appropriate or inappropriate aortic coaptation created, water tests; and *(vi)* whether positioning of the device changes due to manipulations of the surgeon and gravity.

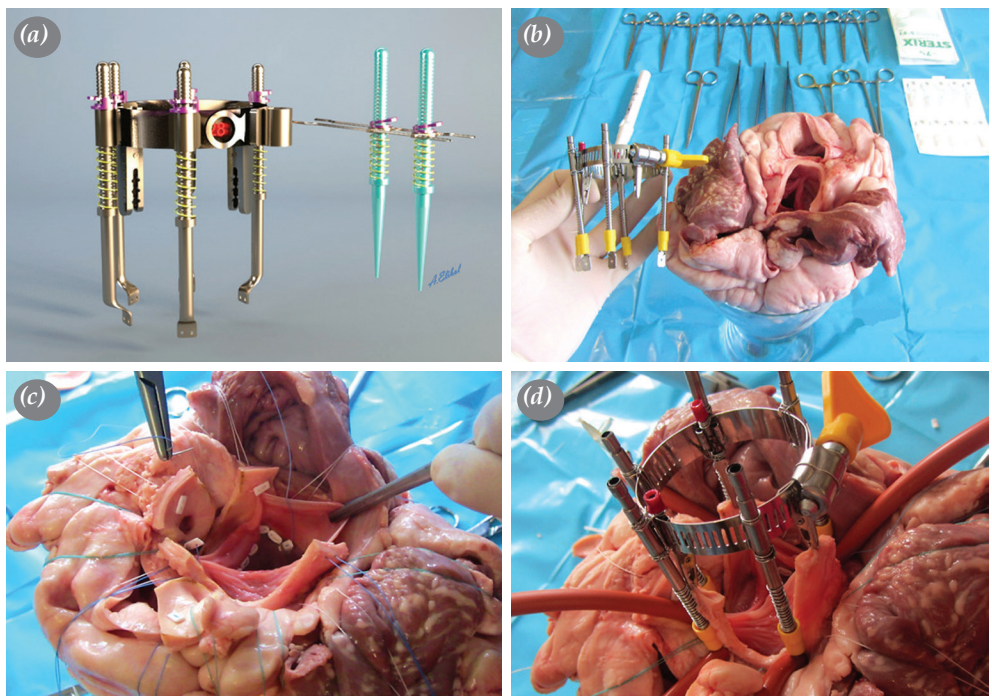


Figure 6. Implantation of the prototype device. **(a)** Three-dimensional modeling of device. **(b)** Prototype device appropriate for cattle's heart. **(c)** Preparation of aortic root. **(d)** Fixation of device.

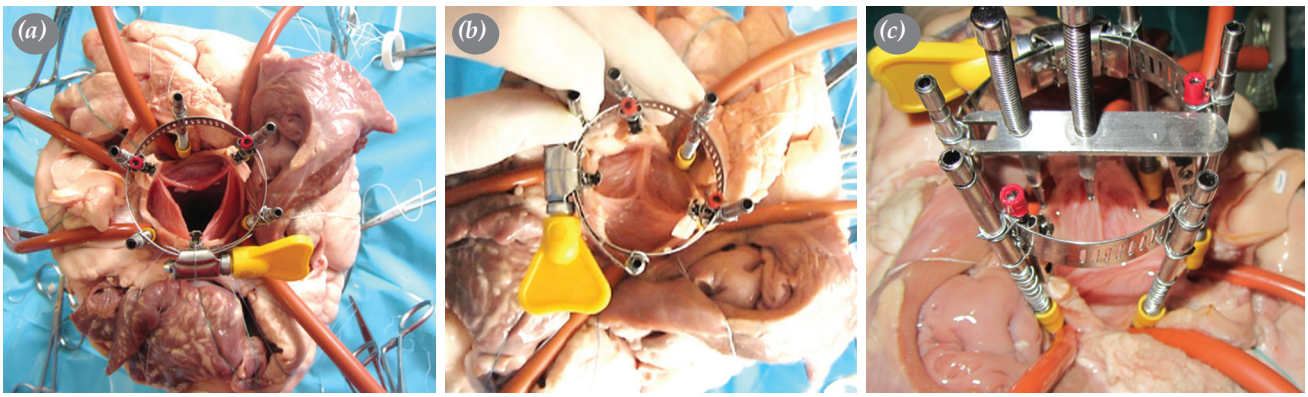


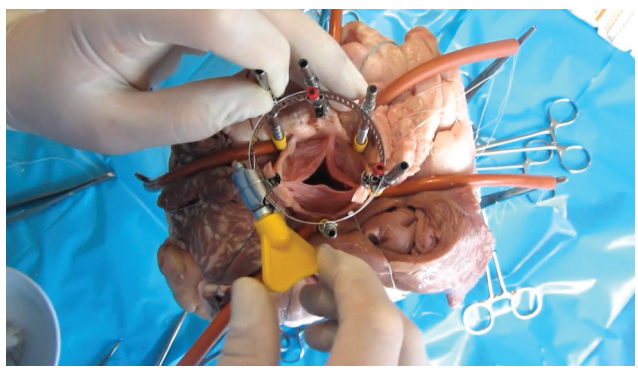
Figure 7. (a, b) Simulation of aortic coaptation and **(c)** positioning of caliper.

i) Preparation of the aortic root: As in valve-sparing aortic root replacement procedures, the three sinuses of Valsalva were resected, and the coronary buttons were prepared. Resuspension sutures were attached to the aortic commissures. Subannular sutures were placed (Figure 6c).

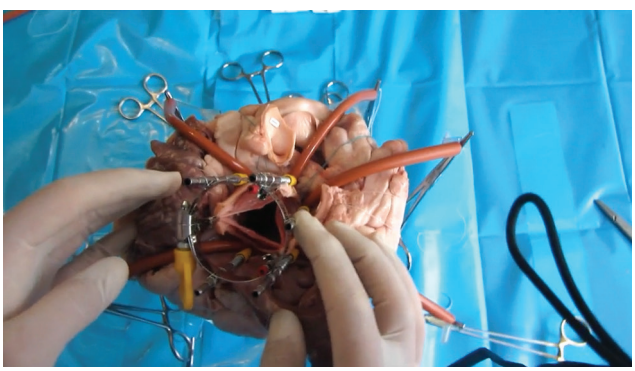
ii) Fixation of the device to the aortic root: Each pair of the subannular sutures were passed through the corresponding suture holes on each leg. The device was then advanced to the aortic root under the guidance of the sutures (Figure 6d). These five pairs of suture lines were then drawn into the slit surgical tubes to fix the device.

iii) Positioning of the device and the resuspension of the commissures: Aortic commissures were attached to the commissure holders. The adjustable circle was allowed to move upward until a point where the commissures became suspended. The aortic valve now stood with its three-dimensional structure, just as it does during its native functioning. Positioning of the device did not change and remained stable with manipulations of the surgeon, or when the plane was changed (Video 3).

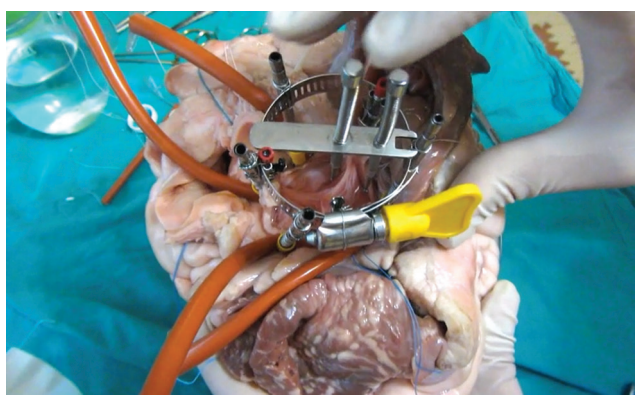
iv) Simulation of aortic coaptation and positioning of the caliper: Leaflet coaptation was obtained by gradually narrowing the adjustable circular frame (Figure 7a, b, Video 4). The pins were, then, placed on the adjustable circle and their contact with the insertion and free margin of the cusps was observed. (Figure 7c). The plane provided by the adjustable circle maintained stable perpendicular positioning of the pins (Video 5).



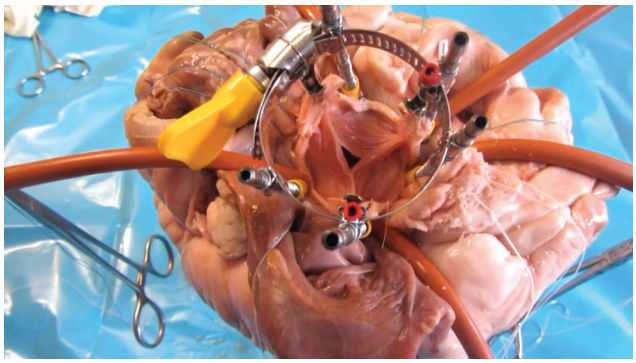
Video 4. Simulation of coaptation.



Video 3. Positioning prototype device and resuspension of the commissures.



Video 5. Positioning caliper.



Video 6. Water test.

v) Water test: When an appropriate aortic coaptation was obtained, water test was performed to test the resistance of coapting leaflets to water load (Video 6).

DISCUSSION

Compared with either mechanical or biological valve replacements, valve-sparing aortic root replacement has proved to be advantageous owing to its noninferior, even superior, perioperative mortality and follow-up reoperation rates, as well as lower rates of bleeding, and prosthesis-related complications, and improved quality of life.[22,23]

The aortic root is a complex anatomic structure with its components: the aortoventricular junction or aortic annulus, aortic cusps, aortic commissures, aortic sinuses, and the sinotubular junction, each of which having crucial roles for competent aortic valve function, particularly coaptation.[5] All aortic root dimensions, including the effective height, have been shown to be highly patient-specific and correlated with the body weight and size, and body surface area.[20]

To date, the proponents of the reimplantation technique have made valuable contributions to the aortic root and valve geometry not only to enhance our insight into valve anatomy, but also to improve surgical outcomes of the patients with aortic root aneurysms. A particular attention has been drawn to various aspects of the dynamic anatomical geometry of the valve apparatus, including the effective height, geometric height, commissure height, coaptation height, annulus diameter, and cusp repair.[5,8,10,14,17,20]

The device proposed herein to be used for the reimplantation technique has one explicit advantage. All valve geometry to be reconstructed and repaired can be simulated on the device with all its elements - in particular, the commissures and the cusps with mutual geometrical relations in concrete values - before proceeding with final reimplantation procedures. Thus, all that is necessary can be clearly visualized in a manner whatever the configuration the surgeon prefers, particularly the creation of the effective height.

As many authors emphasize about the reimplantation technique, there is a demanding need for standardization, which has an adverse effect on the operative time, particularly for older patients.[22] With the help of this device, the applicability of the David procedure may easily be extended to elderly patients with decreased times of myocardial ischemia and cardiopulmonary bypass.

Another feasibility of the device is that any necessary intervention for appropriate leaflet coaptation (patch repair, prolapse repair, leaflet repair, subcommissural annuloplasty) can be made during the simulation of coaptation, even before the graft size has been chosen.

The proposed device was specifically designed for David I procedures, for aortic root aneurysms with or without aortic insufficiency.[24] Yet, the use of this device can be extended to include the David IV and V procedures in which a larger graft is used.[5,25] Similarly, by adding minor modifications to the device, it can be also helpful in repair of bicuspid valves.

Limitations

The device was primarily designed for patients having a normal or near-normal aortic annulus. David et al.[26] found a mean graft diameter of 30.8 mm (range, 26 to 34 mm) in 167 consecutive patients undergoing aortic valve-sparing operations for aortic root aneurysms. The mechanism of the device was designed based on the reported range of graft size. Therefore, in case of a larger annulus, the adjustment of the device along with simulation would not be possible before downsizing the annulus. The author recommends placing slit surgical tubes through some of the sutures placed without pledgets, particularly those close to the commissures.

In conclusion, valve-sparing aortic root reimplantation technique has taken a long way since its first introduction in 1992 by Tirone David. However, its success largely depends on the experience and skills of the surgeon, which still is a limitation to its wider use and adoption. As emphasized by most authors, technical standardization is indispensable and remains the weakest aspect of this operation. The device presented herein may be a strong candidate to overcome limitations at the very beginning of the

David procedure, which in turn make the procedure more feasible and reproducible.

Declaration of conflicting interests

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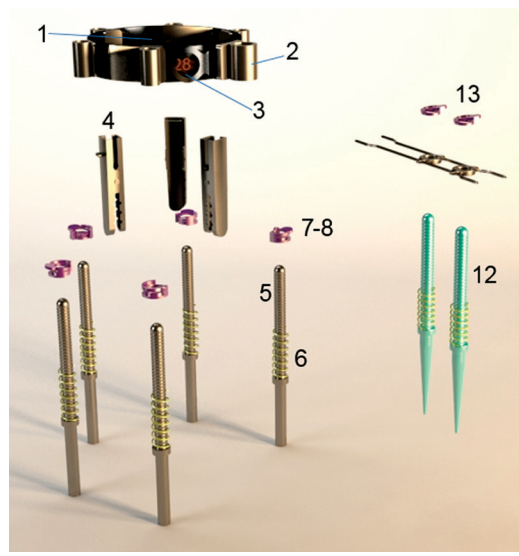
THE SUPPLEMENTARY MATERIAL Components of the device prototype	
1	**Adjustable circle:** It is attached to the aortic commissures by commissure holders, moving the aortic commissures (resuspension) to cause coaptation of the aortic valve and shows the graft diameter on a 26 to 34-mm scale.
2	**Circle screw:** It is used to adjust the diameter of the circle.
3	**Window to show the graft diameter:** It shows the graft size to be used, when an appropriate effective height is obtained during the simulation of aortic valve coaptation.
4	**Commissure holders:** Three commissure holders are attached to the aortic commissures.
5	**Legs:** Five legs are attached to the five subannular sutures (the same sutures for each operation, which include three commissural sutures and the mid sutures of the left and right coronary cusps). The stabilizers on each leg provide interpositioning of the legs that best correlates to the subannular suture line. By design, these legs do not measure the heights of the three commissures (as done with the other methods for graft preparation), as the purpose is to identify the positions of the legs in relation to each other. In the upper half of each leg, there are parallel notches with 0.25 mm intervals.
6	**Leg springs:** The springs push the adjustable circle away from the aortic valve. The force applied by the springs is somewhat equal to that exerted by the surgeon for resuspension of the commissures using forceps or sutures.
7	**Leg stabilizer clips:** They fix or release the legs at any level while the springs push the legs. This is accomplished by fitting of the clips into the parallel notches on each leg.
8	**Clip stabilizers:** They disable leg stabilizer clips, allowing the legs to move freely.
9	**Suture holes:** Holes placed at the lower end of the legs that correspond to each stitch of five subannular sutures.
10	**Leg connectors:** It connects each leg with the adjustable circle, allowing vertical sliding of the adjustable circle. It also allows precise horizontal arrangement of the legs to ensure perpendicular position to the respective sutures.
11	**Cusp caliper (effective height caliper):** It is placed on the upper edge of the adjustable circle with two measuring pins, enabling the pins to be positioned perpendicular to the aortic root. Thus, it allows an accurate geometric means of measuring the difference in height (effective height) between the lowest (leaflet insertion) and highest (midpoint of the free margin) of the aortic leaflets. This measurement is made thanks to the fixed horizontal plane provided by the adjustable circle. This precise measurement technique is unique to the device.
12	**Cusp caliper pins:** These pins have a millimeter scale. The difference in measurement between the two pins gives the effective height (coaptation height).
13	**Cusp caliper clips:** The pins are pressed so that they touch the aortic leaflets. The clip fixes the pin in that position, when the pressure is lifted. It also allows the pin to return to its initial position for a new measurement, when the clip is pressed.
14	**Pin-pulling springs:** They pull the cusp caliper pins away from the aortic leaflets.
15	**Pin endings:** The tapering part of the cusp caliper pins.
16	**Slit surgical tubes:** Due to the spiral slit that passes along the length of the surgical tube, each pair of the subannular sutures is inserted into the surgical tube together with the needles. Surgical sutures cannot be passed through standard surgical tubes with the needles. This slit allows easy insertion and removal of the sutures in the surgical tube.

A step-by-step guide to the application of the device

Before the device is placed in its position (in the patient), the adjustable circle is brought to maximum extension using the circle screw. By pushing the leg stabilizer clips and with a clockwise turning around its axis, each clip is fitted into its clip stabilizer notch. In this setting, the adjustable circle becomes movable. Each pair of five subannular sutures are passed through the corresponding suture holes on each leg. The device is advanced to the aortic root under the guidance of these sutures. These five pairs of stitches are drawn into the slit surgical tubes, which are advanced to the suture holes and, then, surgical tube stoppers are placed. At this point, each surgical tube is in contact with a suture hole, but the surgical tubes remain loose. The adjustable circle is gradually narrowed and, at the point where the holes of all the legs contact the aortic root tissue, the sutures are stretched, and all the surgical tubes are tightened. Thus, five legs are fixed with the use of the surgical tubes and sutures.

The adjustable circle is moved toward the aortic root and the commissural holders are attached to the aortic commissures. The device is gently released for positioning. The commissures move upwards until the movement of the device is limited at a point where the commissures remain suspended (manipulation routinely performed for surgery). This is the position at which the movement of the adjustable circle is locked with leg stabilizer clips.

Now, the aortic valve stands with its three-dimensional structure, just as it does during its native functioning. The central coaptations of the aortic leaflets are obtained by narrowing the adjustable circle. Once the optimal coaptation is achieved, the desired effective height for each leaflet (as the subtraction of the height of the coaptation tip from the height obtained at the nadir of each leaflet) is checked. The values are read on the millimeter scale on the cusp caliper pins. The effective height has been measured with precise accuracy and the graft diameter to be used can be read in the scale window of the adjustable circle.



With the legs of the device fixed, the device now shows the position of the five surgical sutures to each other. The commissure holders are released setting free the aortic valve structure. The surgical tube stoppers are removed, and the sutures are taken out from the surgical tubes. The sutures are removed, and the device is detached from the aortic root setting. At this point, the device has acquired all the vital data concerning the patient. The graft chosen at the same diameter as indicated by the device is inserted inside the legs and attached to the commissure holders at the same depth (5 mm). Using a marker pen, the suture holes on the legs are marked on the graft. In addition, the locations where the three commissures are to be resuspended are marked with reference to the lower points of the commissure holders. The graft is removed from the device to mark the subannular suture line on the graft.