ORIGINAL ARTICLE

Aortic Root Surgery with David Procedure. Initial Report.

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The aortic valve preservation surgery with the David procedure is a technique that has proven to be as effective as the classic Bentall surgery for the surgical treatment of aortic root aneurysm. Although it has a higher reoperation rate, it offers the advantage of avoiding complications related to prosthetic valves and oral anticoagulation. We present our initial casuistry. *Material.* From September 2013 to May 2019, 14 patients with aortic root aneurysm, ascending aorta, or dissection underwent David procedure. There were 5 women and 9 men with a mean age of 42 years (from 17 to 62 years). Eight patients had Marfan syndrome. One patient presented Stanford B aortic dissection, nine had mild aortic insufficiency and the remaining 5 had a moderate degree, one patient had moderate to severe mitral regurgitation due to prolapse. The left ventricular ejection fraction was normal in 86% of the cases. The diameter of the aortic root was 56.7 mm (range, 48mm - 61.3 mm). *Results.* The David procedure was performed in all cases. The cause of aortic insufficiency in all cases was by alteration of its geometry due to the present dilation. One patient underwent concomitant mitral valve repair. We had a re-operation for bleeding. The average of days on mechanical ventilation were 1.6 and the in-hospital stay was 6.7 days. There were no other complications. At a 12-months follow-up, the freedom from moderate or severe (≥3+) aortic regurgitation was 100%. Only two patients remained with mild aortic valve regurgitation and all were asymptomatic and free from oral anticoagulation. *Conclusions.* The David procedure is a viable option with excellent results. It avoids complications related to anticoagulation and the presence of mechanical aortic valve prostheses. It is imperative to know the anatomy and physiology of the aortic root in order to achieve an adequate functional result. We must broaden the surgical horizon in young patients with aortic root aneurysm to give a better quality of life in the long term.

Key words: **Aortic Valve Reimplantation; Aortic Root Aneurysm; Aortic Valve Sparing; David Procedure; Tijuana; México.**

La cirugía de preservación de válvula aórtica con la técnica de David es un procedimiento que ha demostrado ser igual de eficaz que la cirugía clásica de Bentall en el tratamiento quirúrgico de aneurismas de la raíz de aorta. A pesar de que tiene mayor índice de re-operación, ofrece la ventaja de evitar las complicaciones relacionadas a las prótesis valvulares y la anticoagulación oral. Presentamos nuestra casuística inicial. *Material.* De septiembre de 2013 hasta mayo de 2019 fueron sometidos a cirugía de David 14 pacientes con aneurisma de raíz aórtica, aorta ascendente o disección. Fueron 5 mujeres y 9 hombres con una media de edad de 42 años (de 17 a 62 años), 8 pacientes tuvieron síndrome de Marfán. Un paciente presentó disección aórtica Stanford B, Nueve de los pacientes tenían insuficiencia aórtica leve y los restantes 5 de grado moderado, un paciente presentó insuficiencia mitral moderada a severa por prolapso. La fracción de expulsión del ventrículo izquierdo fue normal en 86% de los casos. El diámetro promedio de la raíz aórtica fue de 56.7 mm (48-61.3 mm). *Resultados.* En todos los casos se pudo realizar la cirugía de David. La causa de insuficiencia aórtica en todos los casos fue por alteración de su geometría debido a la dilatación presente. Un paciente ameritó plastia mitral concomitante. Tuvimos una reoperación por sangrado. Los días promedio de ventilación mecánica fueron de 1.6 y de estancia hospitalaria de 6.7 días. No hubo otro tipo de complicaciones. En el seguimiento a 12 meses solo dos pacientes permanecen con insuficiencia valvular aórtica leve y todos se encuentran asintomáticos y libres de anticoagulación oral. *Conclusiones.* El procedimiento de David es una opción viable con excelentes resultados. Evita las complicaciones relacionadas a la anticoagulación y a la presencia de prótesis valvular aórtica mecánica. Es imperativo conocer la anatomía y fisiología de la raíz aórtica para lograr un adecuado resultado funcional. Debemos ampliar el horizonte quirúrgico en pacientes jóvenes con aneurisma de raíz aórtica para dar una mejor calidad de vida a largo plazo.

Palabras clave: **Aneurisma de raíz de aorta; Procedimiento de David; Preservación de Válvula aórtica; Reimplante de Válvula Aórtica; Tijuana; México**

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Aortic root surgery still is a surgical challenge due to several factors that influence both the decision for surgery as well as the evolution and follow-up. Etiology, age, associated comorbidities and lifestyle are some of the main variables to consider in the election of the surgical technique that offers the greatest benefit for our patients; furthermore, to know and reproduce this technique in order to avoid anticoagulants and the complications associated to mechanical prosthesis, is the main challenge to the surgeon.

Since 1968 Bentall et al. [1] described the aortic valve and ascending aorta replacement using a graft with a mechanical prosthesis attached and has been since then the standard treatment for aortic aneurysms affecting the aortic root, with excellent and reproducible results. However, in this technique, even when the native valve is morphologically normal it is always replaced by a mechanical valve requiring anticoagulant for life. Magdi Yacoub and Tirone David [2,3] described techniques that preserved the native valve when the morphology is normal in the context of aortic root aneurysm or dilation, procedures currently used in aortic root preservation surgery and over time have shown good results. Reimplantation, described by David, and the aortic root remodeling, described by Yacoub, constitute currently the main known techniques for these patients; the former recommended in young patients, the latter in older patient with a normal aortic valve annulus [4].

The David procedure has been widely described [3,4]. It consists of reimplantation of the native aortic valve within a graft replacing the damaged aorta. This technique has been modified several times over the years. Thus, generating up to six different variants described by different authors [5-9] (**Fig. 1**).

In the last 6 years, we have performed the David technique on 14 patients, eight of them with Marfan Syndrome, one with Stanford type B aortic dissection, the rest with root or ascendant aorta aneurysm. The present article describes the initial experience in our institution.

MATERIAL

From September 2013 to May 2019, aortic valve sparing surgery has been carried out using the technique described by David [3] in 14 patients, 13 with aortic annulus ectasia or aneurysm of sinuses of Valsalva, and 1 with Stanford type B aortic dissection. Eight patients with Marfan syndrome. The average age was 42 years (17-62 years), five female patients, three patients with systemic arterial hypertension and two with type 2 diabetes mellitus (**Table 1**).

Transthoracic echocardiogram was the initial test for all the patients with the main objective of assessing the cardiac function, measuring the diameter of the aortic valve ring, sinuses of Valsalva, sinotubular junction, proximal aorta and distal ascending aorta. Valve function, leaflets motility and regurgitation severity were carefully evaluated. In 8 patients, an outpatient transesophageal echocardiogram was additionally performed, and in the remaining 6 patients was performed in the operation room just before starting the surgery. Aortic angio-tomography was used as a secondary study in all the patients with purpose of assessing the complete root and ascending aorta anatomy and as a complement to transthoracic echocardiogram. Coronary angiogram was not a routine study and was only performed in a 62-year-old patient, with cardiac risk factors obtaining a normal result. In a 56-year-old patient with aortic dissection we decided not to perform a cardiac catheterization due to the high risk of complications. The mean sinuses of Valsalva diameter were 56.7mm (48.0-61.3mm). Nine of the patients had mild aortic regurgitation and five moderate regurgitation. A patient with bicuspid aortic valve with no regurgitation or stenosis was included for aortic valve reimplantation.

Surgical technique

In our report we use the technique initially described by David et al. [3], having the required clinical and paraclinical data, considering the surgical criteria [10] for valve preservation in those patients with sinuses of Valsalva diameter of more than 45mm and aortic root dilation of more than 50mm with adequate valve morphology (leaflets of normal appearance without prolapse or perforation). A transesophageal ultrasound probe was placed in all the patients for postoperative echocardiogram. Through median sternotomy, aortic and right atrium cannula was placed for extracorporeal circulation, aortic clamping and cardiac arrest using Del Nido cardioplegic solution every 90 minutes; an aortotomy 1cm above the sinotubular junction was performed, carefully assessing the aortic valve morphology and leaflets quality, prolene 4-0 was placed on each commissure pulling up together until the leaflets have adequate coaptation in the center, this being higher than 4mm in all the cases. Having decided to preserve the valve due to favorable anatomy we proceed with a wide dissection of the aortic root, as deep as possible beyond the aortic annular plane and avoiding damage to surrounding structures. Once the above is finished, we proceed to harvest the coronary buttons and removal of the abnormal aortic tissue leaving 3 to 4 mm of aortic wall attached to the valve. (**Fig. 2**).

Table 1. Demographic Characteristics

VARIABLE	Total population, n= 14
Gender	
Female	05
Male	09
Age (years)	
17 - 45	12
46 - 60	01
> 60	01
Aortic regurgitation	
Mild	09
Moderate	05
Left ventricle ejection fraction	
> 50%	12
< 50%	02

Although several methods have been described for choosing the graft diameter [11], we opted to use Dr. David's formula [10] which in summary considers the average height of the 3 cusps multiplied by 2 offering a correct diameter; to achieve this we performed simultaneous traction with clamps at the commissure of the cusps until full extension, then measuring the distance from the insertion to the free margin of Arancio´s nodules.

In horizontal direction to the aortic annulus, and in the fibrous portion, 9 to 12 "U" stitches with 3-0 polyester suture, where placed starting below the leaflets and heading outside of the root (sub annular region) and then to the graft; the 3 stitches initially placed at the valve commissures are passed inside the graft in order to locate the native valve within it. The graft is then pulled down and adjusted. The aortic ring measuring device is placed at the annular region which gives support while tightening the sutures.

We proceed with the valve reimplantation, the first step is to re-suspend the commissures at the predetermined height which is desired by having a valve coaptation surface of at least 4 mm and with this ensure a valve sufficiency; this is achieved placing the three 4-0 prolene at the commissures on the graft at the same distance avoiding distorting the shape of each commissure and they are knotted thus leaving the desired height; using 4-0 prolene we reimplanted the graft with continuous suturing of the edges of the aortic wall adjoining the valve (**Fig. 3**). The procedure is completed reimplanting the coronary buttons using 5/0 prolene by the Bentall and Bono technique [1]. In all cases it was applied biological glue Tisseel Baxter NDC 0944 type in the anastomoses of the coronary buttons. Next, we partially clamp the graft only allowing a catheter into the root and cardioplegia is administered to assess bleeding.

We finished with the distal anastomosis of the graft in the ascending aorta by unclamping the aorta and weaning the extracorporeal circulation. The transesophageal echocardiogram is performed evaluating the surgical result.

RESULTS

During the mentioned period we performed a total of 22 ascending and aortic root surgeries; 5 Bentall procedures, 3 using interposition tube graft and 14 using David technique. The patients who underwent to Bentall procedure had annular dilation larger than 27mm and cusps lesion (retraction or perforation) and those where the main exclusion criteria for valve preservation. The ascending aorta interposition graft was used only in cases of aneurysm without valve or aortic root disease.

Of the 14 selected patients, lesion or retraction of the leaflets was not found, so in all the cases the etiology of aortic valve regurgitation was due to abnormal geometry by dilation. One patient with Marfan´s Syndrome also had severe mitral valve regurgitation associated to posterior leaflet prolapse and required quadrantectomy, sliding, and a Carpentier-Edwards prosthetic ring was placed.

In eight patients the diameter of the graft was 28mm they were all female, in the remaining six it was 30mm. The transesophageal echocardiography showed adequate cardiac function in all cases, twelve of them without residual aortic valve regurgitation and two patients who previously had moderate regurgitation presented mild regurgitation; given that there was no evidence of valve abnormalities or hemodynamic repercussion, we decided not to modify it.

Table 2. Postoperative Results

VARIABLE	Total population, n= 14
Aortic cross-clamping time	128 min, (98 – 195)
Cardiopulmonary bypass time	157 min (108 -208)
Graft diameter	
28 mm	08
30 mm	06
Intensive care unit stay	3.7 days (3 – 6)
In-hospital stay	6.7 days (5 –10)
Residual aortic valve regurgitation	
none	12
mild	02
Moderate	00

One patient was reoperated due to bleeding due to a leak at the left coronary button anastomosis. Our first patient presented a complete atrioventricular conduction block and to achieve extracorporeal circulation removal a transitory epicardial pacemaker was placed and intravenous anti-inflammatory drugs were used every 8 hours until manage to reverse the AV block 24 hours after the surgery. Prior to hospital discharge, a 24-hour Holter showed sinus rhythm.

The mean aortic clamping was 128 min (98-195 min) and extracorporeal circulation 157 min (108-208 min). Duration of mechanical ventilation was 1.6 days (range 1 to 3), the stay in the intensive care unit was 3.7 days (range 3 to 6) with a mean in-hospital stay of 6.7 day (range 6 to 10). There were not infections or other type of complications (**Table 2**).

Oral anticoagulation with coumarins was administered for a period of 8 weeks in the patient who underwent mitral valve repair and prosthetic ring placement. Aspirin was used rigorously for at least 6 months in all patients. All patients were reviewed with transthoracic echocardiography one month, sixth months and one year after surgery. The two patients with mild aortic regurgitation remain the same and without functional or hemodynamic repercussions. All patients are in functional class I of the New York Heart Association.

DISCUSSION

Dilation of the aortic root and bicuspid valve are the most common causes of aortic valve regurgitation in western countries [12,13]; in such a way that the knowledge and mastery of the anatomy and physiology of this region is essential for an adequate surgical decision-making in order to achieve good outcomes.. Tirone David has quoted "was the development of

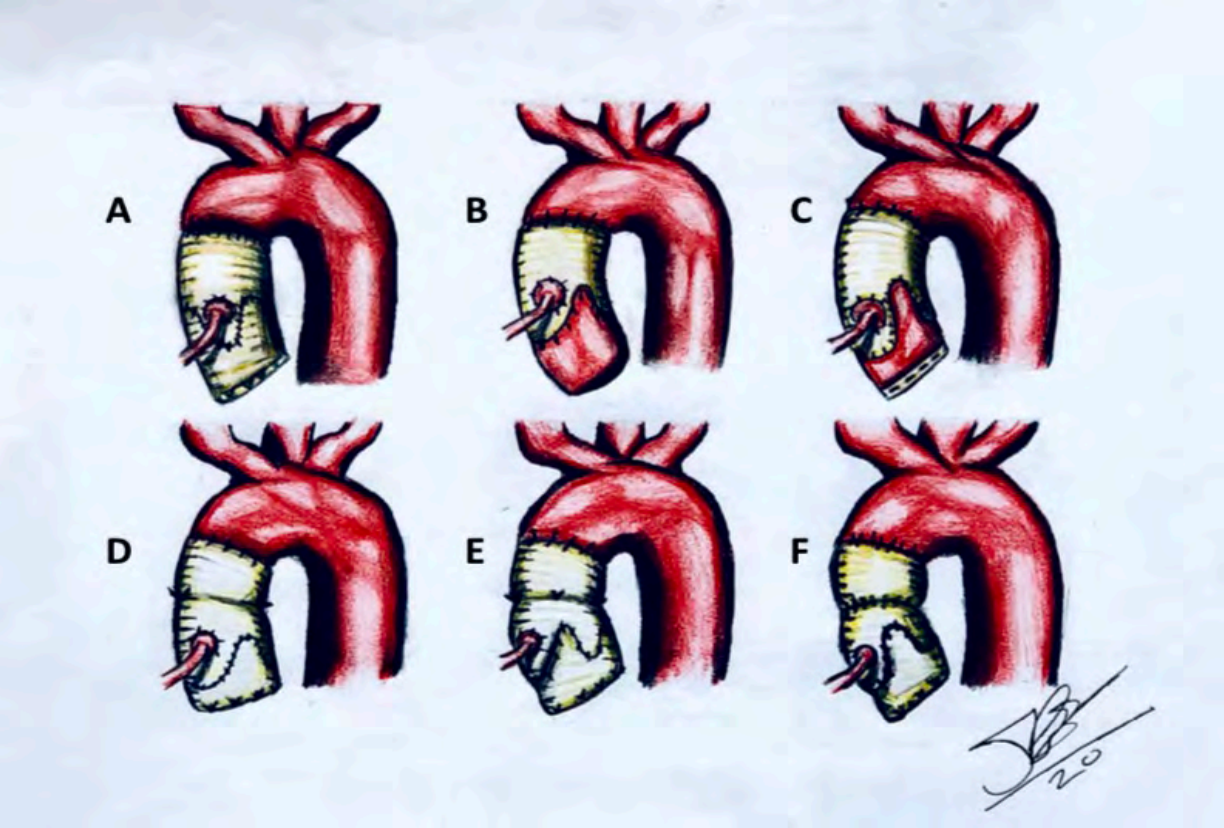

Figure 1. Variants of the technique in the aortic valve sparing surgery. A. Original (David I), B. Yacoub procedure or Remodelation (David II), C. Modified Yacoub procedure with annular prosthesis (David III), D. Straight graft plication (David IV), E. Valsalva graft (David V), F. David V with two grafts.

this operation a stroke of surgical genius? No, is the result of the accumulation of knowledge of anatomy, physiology, pathology and surgical experience" [14].

The aortic root is a geometric functional unit constituted by the ventricle-arterial junction or aortic annulus, the leaflets or cusps, the commissures, the inter- commissural triangles, coronary sinuses, coronary arteries and sinotubular junction. [15,16]. For this reason, any alteration of the root components causes failure in the valvular mechanics, for example, abnormal dilation of the sinotubular junction pulls the commissures outward, which precludes adequate coaptation of the leaflets and causes valve regurgitation, such that prompt intervention is one way to prevent the aortic leaflets from becoming thin and damaged by the stretching [16]. All patients with reimplantation in our report presented coaptation abnormalities due to sinotubular union dilation, which was confirmed by the absence of injury of the cusps and adequate coaptation when performing commissure traction in the initial surgical evaluation.

Having patient with an aortic root aneurysm who is a candidate to preserve the valve, has generated controversy regarding the decision to perform reimplantation or root remodeling. Reports indicate that for patients older than 50 years with ascending aortic aneurysm and dilation of the sinotubular junction, with normal cusps and aortic annulus, and with moderate or severe valve regurgitation, with simple replacement of the ascending aorta and consequent reduction of the union sinotubular for a better coaptation of the cusps is sufficient [17]. On the other hand, younger patients with aortic root aneurysms associated to collagen abnormalities syndromes, may have associated annulo-aortic ectasia or dilation years after remodeling with increase of aortic regurgitation. By this reason, the reimplantation of the valve is indicated because it stabilizes the annulus [18]. Furthermore, we described echocardiographic evidence that opening and closing speed of the cusps is increased when the valve is reimplanted within a cylindrical graft without neo-aortic sinuses [19]. In addition, the compliance of the root also plays an important role in modulating the mechanical cusps stress. In these terms, the remodeling of the root is superior to reimplantation. The modifications that have been made to the root reshaping such as graft placement on the outside of the aortic annulus [6] or the annular stabilization with Polytetrafluoroetheylene (PTFE) suture described by Schneider and Schäfers [20] , has allowed young patients to be brought in for remodeling of the root with lower incidence of long-term reoperation. Twelve of our patients were in the age range of 17 to 45 years, eight with Marfan Syndrome, one more with bicuspid valve and three with aortic annulus diameter > 25 mm. On the other hand, the patient with aortic dissection had

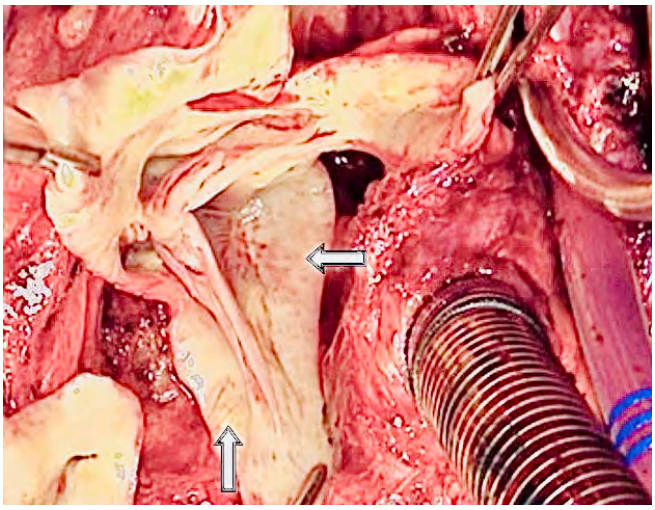

Figure 2. Native aortic valve with 3 to 4 mm of aortic wall (arrows).

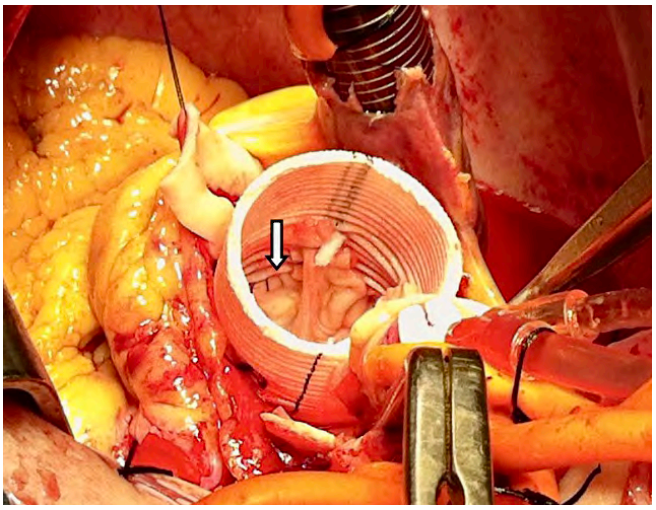

Figure 3. Aortic valve implanted within the graft with running suture (arrow).

a 27 mm diameter ring and the dissection flap very close to the right coronary artery, and our last patient 62-year-old had an annular diameter of 27 mm.

For all the above, we decided to perform aortic reimplantation in all cases. The graft that was chosen was Dacron without preformed sinuses and we used the formula described by Dr. David to determine the correct diameter. If a graft is chosen too large may not reduce the annular diameter and not allow adequate coaptation of the cusps, or if the graft is too small the cusps collide with it during systole with subsequent abrasion [21]. In order to avoid the aforementioned alterations, sinuses grafts have been made preformed with favorable results [6,7]. However, Dr. David's observation is that these have spherical sinuses and normally the aortic root is a cylinder with three sinuses of non-spherical characteristics [21]. In case of not using a preformed graft, and to improve the mechanics of the cusps, it is possible to create aortic sinuses using a Dacron tubular graft selecting a diameter 2 to 4 mm larger than necessary and then plicate the corresponding graft areas in the commissures [4]. We did not perform the plication of the graft and in the control studies of up to one year, no alteration of the cusps has been reported nor valvular mechanics.

A key factor for successful aortic reimplantation is that the cusps must be reasonably normal, especially for surgical groups that are beginning to develop this technique. Transesophageal echocardiography is the best diagnostic tool for these cases and all components of the aortic root must be evaluated for decision making [21]. Our protocol included this study in all cases complementing the values obtained by transthoracic echocardiogram and obtaining the complete morphology of the root; operative findings were compared to those previously described and there was only a minimal variation of the measurements of anatomical structures. To obtain an adequate assessment echocardiography we must be familiar with the anatomical findings of according to patient age, the above is justified since all the components of the aortic root are elastic in children and young people but with aging they lose elasticity due to the replacement of elastic fibers by fibrous tissue [22]. The geometric relationships between the components of the aortic valve change with age, for example, the transverse diameter of the aortic annulus is 15 to 20% larger than the diameter of the sinotubular junction in children, this due to that during systole the ascending aorta increases in diameter; likewise, with the aging of these structures the diameter of the sinotubular junction increases and may become equal to or even greater than the annular diameter, but the valve remains competent as long as they have adequate central coaptation [23].

The typical configuration of a normal aortic valve is not only characterized by the dimensions of the root, also the configuration of the cusps is important. Schäfers et al. [24] described the importance of the cusps coaptation height as "effective height" and defines this term as the difference in height between the free margins of the cusp and the insertion line in the annulus; to obtain this measure, they designed a device or caliper that is positioned in each one of the valves to get the height in millimeters (**Fig. 4**). In their report, they find that the effective height range in normal aortic cusps between 8 and10 mm. Therefore, they concluded that an aortic valve reimplantation or repair with a low effective height leaves regurgitation and will require reoperation. Particularly in our casuistry the caliper to determine the height is not available; however, as described in the surgical technique section, we measured each one of the cusps and obtained the diameter of the graft and also assessed the geometric height that assures a central coaptation of at least 4 mm. We should not confuse the effective height with the geometric height; the latter has been described [24] as the set of the dimension of the sinuses, length of the line of insertion of each cusp and the length of the free margin and is obtained by pulling each commissure to leave the cusp well extended so we are able to place a ruler from the insertion point and up to the free edge. Schäfers et al. [25] reported a study conducted in Germany with 615 patients that included geometric height of the leaflets in 286 bicuspid aortic valves and 329 with tricuspid

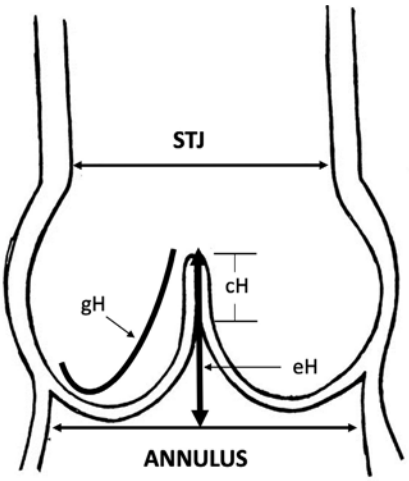

***Figure 4.** Schematic drawing of the aortic root with graphic description of effective high, geometric high, coaptation high, and sino-tubular junction.*
cH = coaptation high; eH = effective high; gH = geometric high; STJ = sino-tubular junction.

valve, the average for the tricuspid leaflets was 17 mm and 20 mm for the bicuspids. Thirteen patients in our report had a tricuspid valve with an average geometric height of 13.9 mm and the patient with two leaflets was 16.5 mm, in all cases the coaptation surface was 4 mm or more; we can infer that the geometric height difference from the German study and the found in our report could be related to body surface which is different in our population.

Preservation of the aortic valve in patients with aortic root aneurysm it is a promising alternative in select patients; Saczkowski et al. [26] in a systematic review of the literature reported a hospital mortality of 2.6%, low incidence of complications and a recurrence of regurgitation or stenosis that required reoperation with a mean of 2.4% patient-years in 17 centers with a total of 2,800 patients. On the other hand, there are reports [27-29] comparing David and Bentall operations where the result and common denominator is that the Bentall procedure has a lower re-operation incidence than David procedure; however, the latter gives us a greater long-term survival and free of oral anticoagulant. Continuing with the various techniques, Gaudino et al. [30] conducted a study comparing the use of a valved graft with a biological prosthesis, a valved graft with mechanical prosthesis and aortic valve preservation surgery (remodeling and reimplantation). The incidence of re-intervention was lower in patients undergoing Bentall with a mechanical prosthesis, re-intervention was greater in the preservation of the aortic valve in patients undergoing remodeling; however, long-term survival is greater in those undergoing David peocedure.

The casuistry that we report only shows 5 patients undergoing Bentall with mechanical prosthesis, all with good cardiac function, free of complications and with normal prosthetic function. However, all of them are on permanent oral anticoagulation.

In one report at 30 years of follow-up, Dr. David presented 465 patients who had reimplantation of the aortic valve from 1989 to 2018. The operative mortality was 1% (5 patients). In total, 15 patients had reoperations on the aortic valve from 2 days to 23 years after the reimplantation, aortic valve dysfunction appears to be progressive but at a slow rate, after a mean follow-up of 10 years, only 28 patients developed moderate or severe AI. Of note, the cumulative proportion of reoperations at 20 years was 6.0% [31]. The reimplantation of the aortic valve is associated with an increasing incidence of regurgitation over time. Better definition of its mechanisms is necessary to hopefully improve long-term results [32]. A year since our report, we do not have late re-operations and survival is 100% with 85.7% without moderate or severe aortic regurgitation. In the follow-up time we have not found major complications inherent to the technique such as those described by Van Dick et al [33] requiring reoperation such as aortic regurgitation due to poor coaptation, perforation or cusp retraction, patch dehiscence, hematomas, anterior mitral leaflet.

In our country there is only one publication that reports a successful case resolved with David V surgery [34]. Mexico does not have reference cardiology surgical centers for aortic surgery, so a greater experience of all the variants of procedures of this anatomical region can be achieved. Our hospital is no exception, it is even a general hospital not exclusive to cardiac surgery; however, we began to develop aortic surgery with satisfactory results.

As a conclusion, the operation to repair aortic root aneurysm, with or without aortic valve insufficiency using the David procedure represents a viable option with excellent results. Like other similar techniques, it avoids the implantation of mechanical prosthesis which require the permanent use of anticoagulants. After all, an operation should be reproducible and ideally should be applicable to a larger number of patients. We must thus focus on failures, since we learn more from failures than from successes. The intervention requires careful implementation of the technique, as well as complete knowledge of the aortic root.

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