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Original Article

In vitro modeling of crimped Dacron vascular grafts for aortic root replacement

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Abstract: Objective: To objectively quantify the effect of flattening the crimps in Dacron tube grafts on the radial compliance under pulsatile pressure. We aimed to minimize the dimensional changes in woven Dacron graft tubes by applying axial stretch to the graft. We hypothesize this might reduce the risk of coronary button misalignment in aortic root replacement. Methods: In an in vitro pulsatile model that delivered systemic circulatory pressures to Dacron tube grafts, we measured oscillatory movements in 26-30 mm Dacron vascular tube grafts before and after flattening the graft crimps. We also describe our surgical methods and clinical experiences in replacing the aortic root. Results: Flattening the crimps in Dacron tubes with axial stretching significantly reduced the mean maximal oscillation distance measured radially during each balloon pulse (3.2 ± 0.8 mm, 95% CI: 2.6, 3.7 mm vs. 1.5 ± 0.5 mm, 95% CI: 1.2, 1.7 mm; $P < 0.001$). Conclusion: The radial compliance of woven Dacron tubes was significantly reduced after flattening the crimps. Applying axial stretch to the Dacron grafts prior to determining the coronary button attachment site can help maintain dimensional stability in the graft, which may reduce the risk of coronary malperfusion in aortic root replacment.

Keywords: Dacron, aortic root replacement, crimping, radial compliance

Introduction

In 1954, Dr. DeBakey introduced Dacron™, a proprietary polyester fabric made from polyethylene terephthalate (PET), as a synthetic substitute for repairing aneurysmal blood vessels. Since then, Dacron has become the standard synthetic graft material for both surgical replacement and endovascular repair of aortic aneurysms [1]. Its high tensile strength, long durability, low thrombogenicity, and inert chemical properties have made Dacron ideal for use as a synthetic graft substitute in the aorta and its major branches. Dacron vascular grafts with woven sets of PET filaments oriented at 90° tend to have a smoother surface, less permeability, and less radial compliance than grafts with knitted PET filaments [2]. Thermal crimping treatment is used to induce a wavy shape in the textile of the Dacron graft. Crimping of Dacron contributes to the maintenance of Its tubular shape with bending flexibility and axial compliance [3].

Aortic root replacement (ARR) has evolved to become the standard treatment for significant structural disruption at the origin of the thoracic aorta. This part is referred to as the aortic root and includes the following components: Sinuses of Valsalva, inter leaflet triangles, sinutubular junction, leaflet attachments, leaflets, and annulus [4]. Common indications for ARR are: Aneurysmal dilatation of the aortic root with coronary displacement, type A aortic dissection with underlying root dilatation, aortic valve endocarditis with aortic root abscess, and other miscellaneous indications, such as aortic root injury or excessive calcification. ARR is contraindicated if the coronary ostia are not displaced. Also given the complexity and dexterity of this operation, it is contraindicated in patients with severe ventricular dysfunction or other high risk comorbidities that can make the surgery taxing on heart. Originally described in 1968 by Bentall and De Bono, ARR surgery, was performed with the use of a prefabricated composite valve-graft conduit. The coronary arteries were

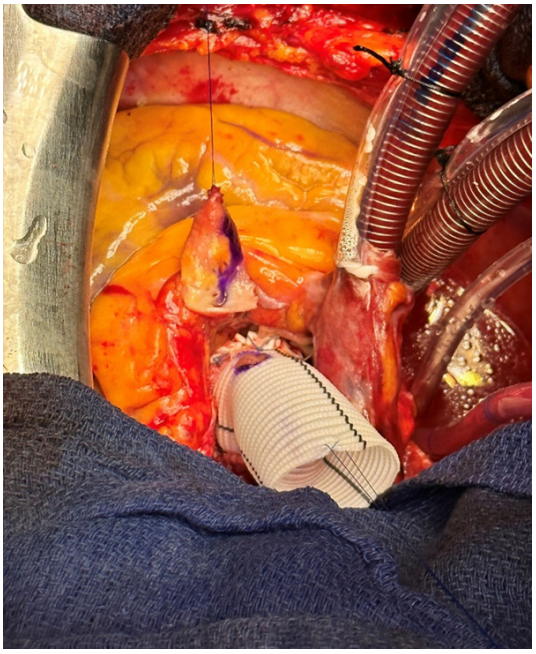

Figure 1. In aortic root replacement (modified Bentall), the coronary ostia are mobilized by fashioning a button of aortic tissue around the ostium. Then, an opening is created in the Dacron to which the button is sewn in an end-to-side fashion.

then sutured to the sides of the synthetic graft, with circumferential sutures around the coronary peri-ostial area, then the aortic aneurysmal wall was wrapped over the graft [5]. This technique was later modified to the current preferred choice of ARR procedures (with or without sparing the native aortic valve). In this modification, a full thickness "button" of the aorta surrounding the coronary ostium is mobilized. After the coronary artery is aligned appropriately with an opening created in the Dacron graft, each button is abutted against the Dacron opening for an end-to-side reimplantation (**Figure 1**) [6]. Currently, ARR procedures are associated with low (2% to 6%) mortality and excellent long-term benefits [7].

During the ARR, mobilization and reimplantation of the coronary buttons represents a technical skill that requires delicate care and fine dexterity. Coronary button misalignment can adversely affect the immediate outcome of the procedure if it goes unrecognized. Coronary insufficiency due to technical issues can lead to ventricular arrhythmias, pump failure, and death [8]. The prevention of coronary button misalignment and malpositioning involves two technical skills: proper coronary button mobilization/reimplantation technique, and ensuring the synthetic graft maintains the proper geometric configuration when it is subjected to systemic pulsatile blood flow [9]. In the context of ARR, few studies have investigated the in vivo dynamics of synthetic vascular grafts and how they affect coronary button alignment after reimplantation. Without specifically modeling and anticipating the configurational changes that may occur in the vascular prosthesis under systemic blood flow conditions, the procedure could result in coronary button tension, buckling, or torsion which may lead to acute pump failure. This can lead to immediate and devastating effects on the surgical outcome (**Figure 2**) [8, 10, 11].

The purpose of the present study was to use in vitro pulsatile oscillation to measure the radial dimensional changes in Dacron tube grafts when its crimps are flattened. We also summarized our clinical outcomes in flattening the Dacron graft crimps prior to determining the site of coronary reimplantation in AAR.

Patients and methods

In vitro pulsatile model

After approval from our local hospital ethics board, an in vitro study was conducted with an improvised pulsatile model using standard instruments and equipment in the cardiac operating theater. The experimental setup included an intra-aortic balloon pump (IABP) console (Cardiosave®, Maquet, Rastatt, Germany), a 30-cc fiber-optic intra-aortic balloon catheter (Sensation Plus®, Maquet, Rastatt, Germany), Dacron tube grafts of three different sizes (26, 28, and 30 mm; Gelweave™, Terumo Aortic, Scotland, UK), an 8-mm polytetrafluoroethylene (PTFE) vascular graft (Gore-Tex®, Flagstaff, Arizona, USA), saline tubing, 50-mm syringes, a cardioplegia aortic root cannula (DLP®, Medtronic, Minneapolis, USA), a laser distance sensor with 0.5-mm accuracy, and a Scanlan® manual caliper for direct measurement (**Figure 3**).

Using standard vascular instruments, we grafted an 8-mm PTFE tube to the side of each Dacron tube graft. The IABP catheter was introduced through the PTFE side-arm, and the balloon segment was placed inside each Dacron

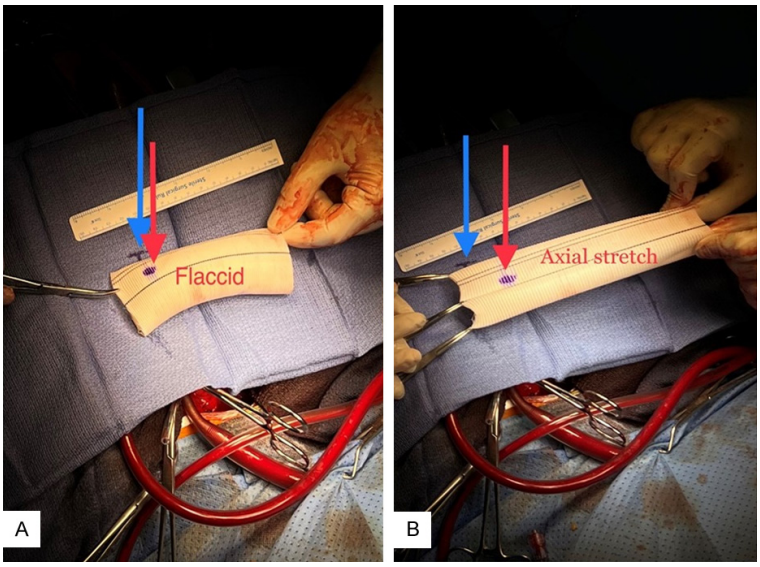

Figure 2. The effects of Dacron vascular graft stretching on coronary button landing site displacement. A. When the Dacron graft is in a flaccid state both the blue arrow (representing the coronary button site) and red arrows (representing the button landing site on the graft) are in direct alignment. B. When the Dacron graft is subjected to mechanical axial stretch the red arrow (landing site) is further displaced from the blue arrow (coronary button site).

tube graft. The graft was filled with a saline-glycerin solution (60% 0.9% normal saline; 40% glycerin) to simulate the kinematic viscosity of whole blood (3.5 mm^2/s). A cardioplegia needle was used as a port to inject the saline-glycerin fluid into the Dacron tube. Next, the tube was de-aired and sealed with vascular clamps at both ends. Four points were marked on opposite sides of the Dacron graft as reference points. Laser measurements were taken at each point, as the IABP pulsated inside the graft at 80 beats/min with a mean pressure of 60-65 mmHg according to a pressure sensor at the tip of the balloon catheter. The graft's maximum radial oscillation movements were measured in millimeters by the laser beam at each marked point. Each measurement was validated by direct means using the Scanlan® caliper tool (**Figure 4**).

The tested Dacron tube grafts had diameters of 26, 28, or 30 mm, but were all 30 cm in length. Two sets of trials were done for each graft size, with each set consisting of four measurements (one measurement for each of the four points on the graft) during 80 oscillations per minute; one set was taken with the Dacron crimps preserved, and the other set was taken with the crimps completely effaced after axial stretching (see Supplementary Video).

Patient cohort retrospective analysis

With permission from the ethics board, we retrospectively collected anonymized clinical data on all consecutive patients who underwent ARR at our local institution between January 2014 and June 2020. Individual consent was waived. Only ARRs performed by a single surgeon (RN) were selected to eliminate variability in the surgical technique. Patients who were operated on by other surgeons or who did not have ARR with two coronary reimplantations were excluded. We reviewed a total of 42 patients. All of the data related to patient presentation, operative intervention, and in-hospital mortality were collected from the hospital charts. The need for rescuer coronary artery bypass grafting (CABG) during or immediately after ARR was used as an indicator of coronary button malposition or misalignment.

Operative technique

Surgically, the aortic root and ascending aorta were approached via a median sternotomy. The arterial cannulation site for cardio-pulmonary bypass (CPB) was chosen based on the arterial anatomy in the chest and diagnosis at the time of presentation to the hospital. For patients with aneurysms that extended up to the distal ascending aorta, the proximal aortic arch was cannulated. For patients with an aneurysm beyond the ascending aorta or with an acute type A aortic dissection, but were hemodynamically stable, an 8-10-mm Dacron graft was sewn end-to-side to the right axillary artery for arterial access. For patients with type A aortic dissections that were not hemodynamically stable, arterial access was gained through the femoral artery. Venous access was gained centrally via the right atrium.

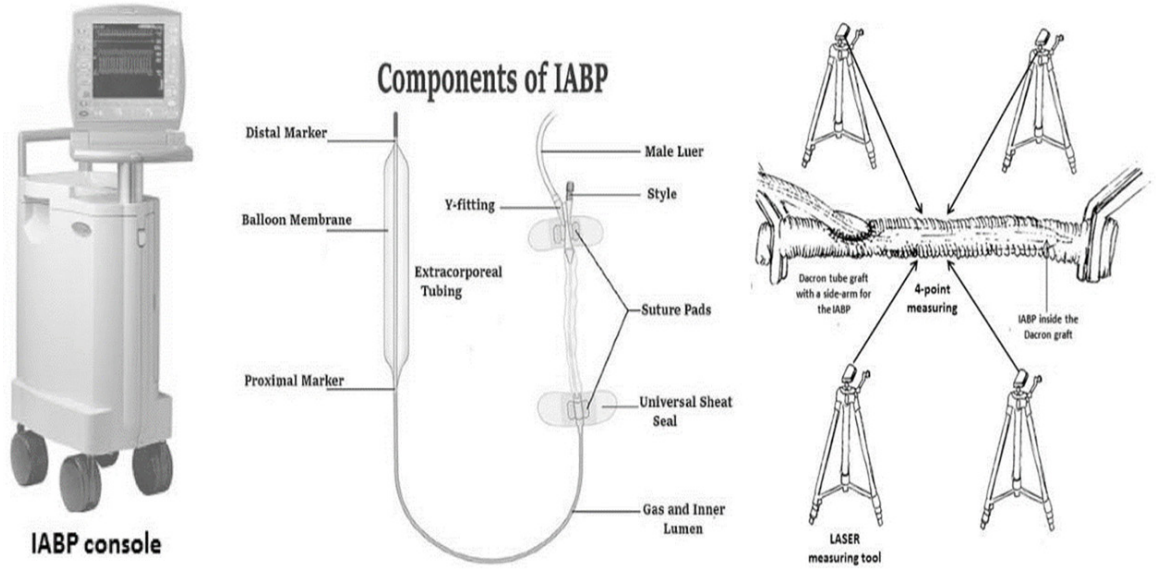

Figure 3. In vitro model of a pulsating aortic graft. A commercially available intra-aortic balloon (IABP) console (*left*) was connected to an IABP catheter (*middle*). A fiberoptic pressure sensor was on the tip of the catheter. The balloon part of the catheter was advanced through a sidearm (*right*) in the test Dacron vascular graft. The graft was filled with a saline-glycerin solution. During pulsation, radial compliance of the graft was measured with lasers fixed at four points located on opposite sides of the graft.

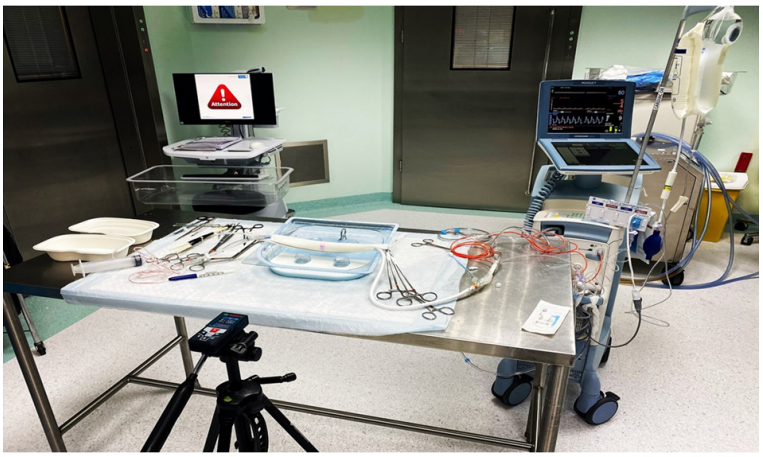

Figure 4. Experimental model set-up.

Patients were subjected to deep hypothermic circulatory (DHCA) arrest at 18°C when they required an "open" distal aortic anastomosis, a hemi-arch replacement, or a total arch replacement. Antegrade cerebral blood flow was intermittently administered at 10-12 ml/kg/min through the neck vessels or axillary artery to protect the brain during DHCA. For procedures limited to the proximal ascending aorta and aortic root, patients underwent moderate (32°C) systemic hypothermia. Myocardial protection was achieved with antegrade cardioplegia induction via coronary ostial infusion, combined with retrograde intermittent cold blood-potassium (4:1) cardioplegia.

During core cooling, an aortic cross-clamp was applied at the distal ascending aorta, and the left ventricle was vented through the right superior pulmonary vein. Next, a longitudinal incision was made in the ascending aorta to gain visual access to the aortic root and coronary ostia. After ensuring adequate myocardial protection, the aortic root was carefully dissected down to the ventricular myocardium, and the aortic valve commissures were suspended with traction sutures to maintain the semilunar architecture of the aortic annulus. The right and left coronary buttons were separated from the corresponding sinuses of Valsalva, with a 3-4-mm rim of aortic wall tissue. The coronary arteries were mobilized just enough to reach the graft wall once it was anchored and secured to the aortic root. Care was taken to mark the anterior portions of each coronary button with a surgical marking pen to

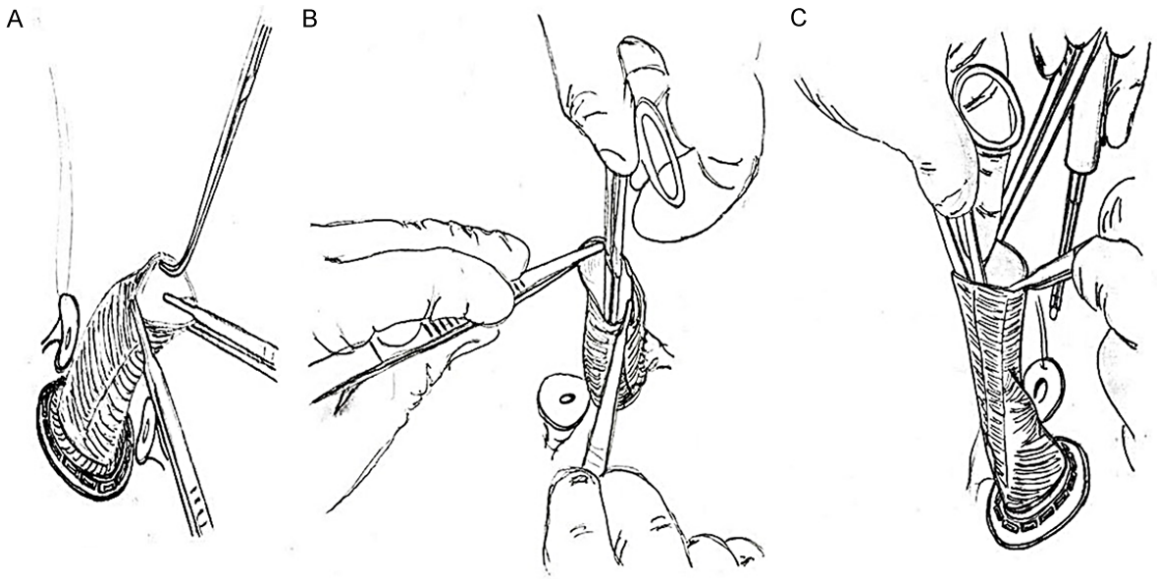

Figure 5. Preparing a Dacron graft for coronary button reimplantation in aortic root replacement. A. The Dacron graft is anchored to the aortic annulus and axially stretched in an anatomic orientation to eliminate all crimps. B. Right-angled forceps inserted inside the graft is pressed against the wall to make an indent at the site of coronary button attachment. C. A surgical coil burner is used to make an opening in the side of the graft at the coronary button attachment site for an end-to-side anastomosis.

avoid malrotation during attachment to the Dacron graft.

After the Dacron graft was secured in place at the aortic root, either as a composite valve-conduit or a native aortic valve-sparing root replacement, attachment sites were identified for coronary button reimplantation. The attachment site for each coronary button was marked on the graft in a specific sequence. First, the Dacron graft was oriented to the anatomic position it would assume after constructing the distal anastomosis to the aortic arch. Second, all axial crimps in the Dacron tube were effaced by pulling the graft walls in the axial direction. The corresponding coronary button was then brought into contact with the graft without tension, and the landing site was marked with a surgical marker or by making an indentation (**Figure 5**). The right coronary button required an extra step: The perfusionist had to temporarily impede venous return to the pump and allow the right ventricle to fill prior to marking the attachment site on the graft. This distention prevented the right coronary from kinking upward when the cardiopulmonary bypass was ceased and the right ventricle filled with blood and started pumping.

Statistical analysis

Statistical analyses were performed with SPSS 21.0 software (SPSS Inc., Chicago, IL). Categorical data are expressed as absolute numbers and percentages. Numerical data are expressed as the mean and standard deviation (SD) or median and interquartile range. Continuous variables were evaluated with the Student t-test, Mann-Whitney U test, or one-way ANOVA test as appropriate. A two-tailed *p*-value < 0.05 was considered significant for all statistical tests.

Results

Experimental in vitro findings

The effacement of crimps in all three sizes of Dacron grafts (**Table 1**) resulted in a significant reduction in the mean maximal oscillation distance measured radially during the balloon pulsation (3.2 ± 0.8 mm, 95% CI: 2.6, 3.7 vs. 1.5 ± 0.5 mm, 95% CI: 1.2, 1.7; P < 0.001; **Figure 6**). There were no significant differences in the changes in oscillation distance between the three graft sizes either before or after flattening the crimps as determined by one-way ANOVA [F

Table 1. Oscillation distance (in mm) measured using the in vitro Dacron graft model

Graft size	*Crimped*	*Effaced*	*P-value*
26 mm	2.7 ± 0.6	1.4 ± 0.5	0.014
28 mm	3.1 ± 1.0	1.4 ± 0.5	0.027
30 mm	3.6 ± 0.5	1.6 ± 0.5	< 0.001

The maximum oscillation distance was measured at 80 beats/min with a perfusion pressure of 60-65 mmHg. Values are given as the mean of the four measurement points on each graft ± SD.

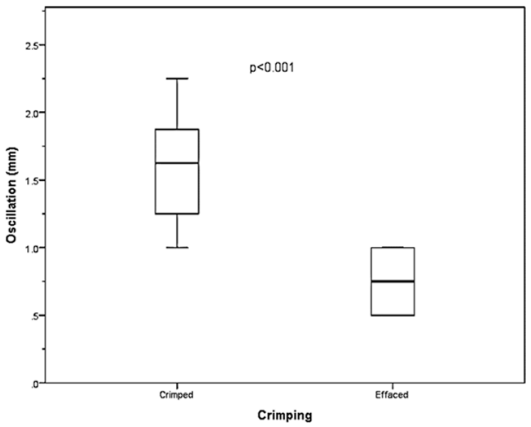

Figure 6. Radial oscillation distances measured in grafts (four measurements in each of the three graft sizes) in crimped and flattened (effaced) states.

(2, 9) = 1.2, P = 0.336; F (2, 11) = 0.439, P = 0.655] (**Figure 7**).

Clinical cohort

Between January 2014 and June 2020, 42 consecutive patients underwent ARR (**Table 2**). The median patient age was 48 years. Aortic root aneurysm was the most common pathology (54.8%), followed by acute aortic dissection and aortic root abscess. Most patients had mechanical composite valve-graft conduits placed (76.2%), followed by a homograft bioprosthesis and an aortic valve-sparing procedure. The mean CPB time was 127 min, and the mean cross-clamp time was 85 min. Nearly half of the patients required open distal anastomoses under DHCA. The mean time under DHCA was 24 min. Two patients died in hospital (4.7%); one died due to a stroke that resulted in neurological injury, which led to a prolonged post-operative course in the intensive care unit, and the other died due to recurrence of infection and sepsis in the aortic root after primary surgery for an aortic root abscess. No patients required rescue CABG due to coronary button malposition or misalignment.

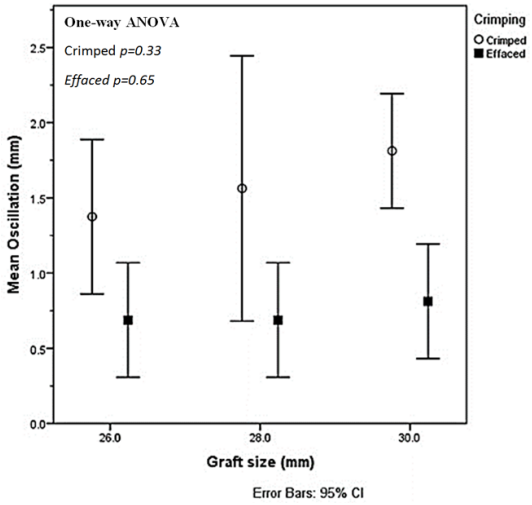

Figure 7. The mean radial oscillation distances measured in each of the three sizes of Dacron grafts. The maximum oscillation distance was measured at 80 beats/min with a perfusion pressure of 60-65 mmHg at four points (4 opposite spots) in both the crimped and effaced (flattened) state. Comparison of grafts in the crimped (open symbols) and flattened (filled symbols) states.

Discussion

In this study, we used an improvised in vitro model to determine whether effacing the crimps in Dacron grafts commonly used for ARR could improve performance. By measuring the maximum oscillation distance with each impulse, we found that, after the crimps in the grafts were effaced, the radial compliance of the woven Dacron was significantly reduced to a constant 1.5 ± 0.5 mm. This suggests that flattening the crimps in the Dacron graft prior to marking the coronary button attachment site improves the dimensional stability of the graft under systemic pressure. Thus, reducing the early structural changes in graft dimensions could mitigate the consequences of choosing an improper coronary button landing site. In addition, this strategy could reduce the risk of coronary malperfusion due to coronary button misalignments that can occur with changes in graft geometry under the stress of systemic blood flow. The small case series in which we applied this technique yielded acceptable in-hospital outcomes with no reported case of any

Table 2. Clinical experiences with aortic root replacement surgeries performed in 2014-2020

Characteristic	Data *n = 42*
Median age, years	48
Aortic root pathology (%)	
Root aneurysm	54.8
Aortic dissection	38.1
Aortic root abscess	4.8
Miscellaneous	2.4
Aortic valve intervention (%)	
Mechanical prosthesis	76.2
Bioprosthesis	14.3
Valve-sparing	9.5
Cardio-pulmonary bypass time, min	127 ± 42
Cross-clamp time, min	85 ± 23
DHCA (%)	48
DHCA time, min	23.75 ± 8
In-hospital operative mortality (%)	4.8

Values are given as mean ± SD unless indicated otherwise.
DHCA: deep hypothermic circulatory arrest.

patient requiring rescuer CABG or exhibiting obvious signs of coronary malperfusion or ischemia requiring urgent re-intervention.

Initially, knitted Dacron grafts were appealing as a vascular substitute due to their inherent radial compliance. However, long-term dilatation developed in the thoracic aorta due to fatigue in the material [12]. Currently, the more structurally stable woven Dacron graft is the prosthesis of choice for thoracic aortic replacement in most centers [13]. In an effort to determine whether the stated size of the Dacron graft reflects the actual internal diameter, Reid et al. [14] used standardized metal probes to test graft capacities. They found that each tested graft size could easily accommodate a probe 1 mm larger than the stated diameter and, when stretched, they could accommodate a probe 2 mm larger than the stated diameter. They also documented a 12% increase in diameter measured by Doppler within 3 months of vascular implantation. Etz and colleagues retrospectively reviewed 2000 postoperative computerized tomography scans to evaluate the early and late diameter measurements of woven Dacron grafts in both the ascending and descending aorta [9]. They documented a 17% increase in diameter from the manufacturer's measurement in the ascending aorta and a 21% increase in the descending aorta within the first 7 days of implantation. They also found that grafts continued to dilate after the initial expansion at a median rate of 2.8% and 2.3% per year in the ascending and descending aorta, respectively, for up to 18 months post-implantation. After 18 months, the median graft expansion diminished to 1% per year. They also found that arterial hypertension was the only factor significantly associated with graft expansion in the ascending aorta. The authors recommended anticipating an up to 20% expansion in woven Dacron grafts shortly after implantation when selecting the prosthesis size and structure for operations such as valve-sparing ARR and endovascular stenting.

After implantation, vascular prostheses are exposed to several longitudinal and radial forces that deform a graft in different ways. In the aortic root, changes in blood pressure and the different phases of the cardiac cycle can impact the graft architecture and shape. Finite element models have demonstrated that, due to the textile structure of Dacron, changes in the graft crimping height and width can impact the graft's longitudinal elasticity and bending stiffness [3]. Another in vitro mechanical study by Khoffi et al. analyzed the compliance of a collagen-coated Dacron vascular prosthesis [15]. They found that the radial compliance depended on the wall thickness and crimping geometry of the prosthesis. Our results demonstrate that eliminating the crimps in the graft with axial stretching could greatly reduce the compliance in the grafts. The amount of compliance reduction was similar for all graft sizes tested.

Our clinical experience in ARR was consistent with previous reports. Among 42 patients, we observed a mortality of 4.7% and no need for rescue CABG due to coronary button misalignment. In a previous study of 139 patients who underwent a modified Bentall ARR, Shahriari et al. [8] reported a 30-day mortality of 4.3%. In addition, 3 (2.2%) patients required rescue CABG due to presumed coronary button misalignment. They speculated that the mechanism of coronary button malpositioning might be tension, buckling, or torsion, which led to myocardial ischemia, ventricular arrhythmia, myocardial infarction, and pump failure. Because this condition is typically life threatening, the authors advocated early recognition of

these signs and prompt rescue by performing CABG with a saphenous vein segment. A newer generation of Dacron vascular grafts specifically designed for use as an aortic root substitute (Gelweave™ Valsalva, Terumo Aortic, Scotland, UK) was made to mitigate the structural changes in the crimped grafts under hemodynamic tress. Instead of having crimps equally embedded axially along the graft length, these novel grafts come with a bulging proximal segment devoid of crimps that cannot be axially or radially stretched. This rigid segment of the graft is where the potential coronary button can be reimplanted without needing to flatten the graft and efface its crimps. These particular grafts are not widely available and are more expensive to purchase. The axial stretching technique prior to coronary button reimplantation described in our series helps address this issue when using the more widely available standard crimped Dacron vascular grafts.

The present study aimed to validate the merits of the surgical technique by conducting bench testing with an improvised in vitro model. Our findings contributed to understanding factors that affect the properties of vascular prostheses after in vivo implantation and how to avoid the possible early structural changes that occur in these vascular prostheses.

This study had some limitations. The in vitro model used in this study was not validated by other methods. Models described by other researches to evaluate the dynamic properties of vascular grafts may have been more precise or accurate [10]. In addition, we only tested three sizes of Dacron grafts, and they were made by the same manufacturer. Therefore, the results are not generalizable. Finally, the clinical experience we described included a small cohort treated in a single center with only in-hospital mortality and absence of coronary malperfusion as clinical outcomes.

Conclusion

In conclusion, we showed that flattening the crimps in synthetic Dacron grafts reduced the dimensional changes in grafts caused by pulsatile oscillations. This technique may improve the outcome of ARRs by avoiding detrimental changes in graft structure after the restoration of systemic blood flow.

Acknowledgements

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As the patients' relevant data was anonymous and retrospective, no patient-specific consent was required. Ethics approval for the study was provided by the King Saud University Ethics Board for Clinical Research.

Disclosure of conflict of interest

None.

Abbreviations

PET, Polyethylene terephthalate; ARR, Aortic root replacement; IABP, Intra-aortic balloon pump; PTFE, Polytetrafluoroethylene; CABG, Coronary artery bypass grafting; CPB, Cardiopulmonary bypass; DHCA, Deep hypothermic circulatory arrest.

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Supplementary Video. Demonstration of the Dacron graft pulsation model.