

## Evaluation of the early and one-year clinical outcomes of venous endothelial protective solutions on graft patency in patients undergoing coronary artery bypass grafting

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### ABSTRACT

**Objectives:** This study aims to evaluate the effects of DuraGraft®, an endothelial protective solution, in comparison to heparinized normal saline, on the patency of saphenous vein grafts (SVGs) in patients undergoing coronary artery bypass grafting (CABG).

**Patients and methods:** Between December 2019 and May 2021, a total of 30 male patients (mean age: 41.7±3.2 years; range, 33 to 45 years) who underwent CABG with at least one SVG were included in the study. Saphenous veins were harvested using the open technique and stored at room temperature in either DuraGraft® or heparinized saline. At one-year follow-up, symptomatic patients underwent coronary computed tomography angiography (CTA). The patients were divided into two groups based on their admission dates. Those who received the DuraGraft® were assigned to the intervention group (Group 1, n=14), while patients who received heparinized normal saline solution were assigned to the control group (Group 2, n=16). A total of 67 grafts from 30 patients were analyzed.

**Results:** One-year angiographic evaluations showed no significant difference in graft patency between the two groups ( $p>0.05$ ). There was no significant difference in segmental diameter reduction ( $p=0.483$ ). However, venous wall thickening was significantly less in the DuraGraft® group, whereas diffuse wall thickening was observed in the control group ( $p=0.020$ ).

**Conclusion:** The reduction in venous wall thickening in the DuraGraft® group in our study suggests a possible long-term benefit. However, due to the lack of extended follow-up data, these findings should be interpreted with caution.

**Keywords:** DuraGraft®, graft patency, graft preservation, saphenous vein.

Surgical treatment options for ischemic heart disease date back to the 1930s. In 1968, Favaloro<sup>[1]</sup> published his coronary artery bypass grafting (CABG) using the great saphenous vein (GSV), and over time, this approach became widely adopted in cardiovascular surgery.<sup>[1]</sup>

The most effective and long-lasting treatment method for coronary artery disease is surgical revascularization of the myocardium. However, graft failure is one of the most critical factors influencing long-term clinical outcomes. In aortocoronary bypass surgery performed using the GSV, graft patency rates within the first year range from 81 to 98%.<sup>[2]</sup> Long-term studies have shown that 10-year graft patency rates decrease to around 55 to 60%.<sup>[3,4]</sup>

The GSV is commonly preferred in CABG owing to its advantages, such as ease and speed of

harvesting, ability to provide adequate blood flow, and low risk of spasm.<sup>[5]</sup> However, factors such as the duration of graft harvesting, the time spent outside the body, and the composition of the storage solution directly affect long-term graft patency. Damage to the venous wall triggers the development of intimal hyperplasia, becoming one of the main causes of early graft occlusion. Endothelial damage arises from various factors, including mechanical trauma

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during surgery, storage in unsuitable solutions, the generation of free oxygen radicals during prolonged storage, and related ischemia.<sup>[6]</sup>

In this context, DuraGraft® (Somahlution Inc., Florida, USA) has become one of the most widely accepted solutions for intraoperative protection and treatment of the saphenous vein graft (SVG) endothelium during ischemic storage. Developed on the basis of a physiological saline solution, DuraGraft® contains antioxidants such as glutathione and L-ascorbic acid, as well as arginine, which serves as a substrate for nitric oxide synthase in endothelial cells. These components ensure systematic protection of the graft against ischemic damage during the storage process. Some studies have demonstrated that DuraGraft® outperforms saline and blood-based solutions and can preserve endothelial structure and function for up to 24 h.<sup>[6,7]</sup> However, despite these favorable *ex vivo* findings, systematic data confirming the clinical efficacy of DuraGraft® in preventing intimal hyperplasia, vein graft disease, and related vein graft failure still remain insufficient.<sup>[8]</sup>

In the present study, we aimed to assess the early and one-year clinical and radiological outcomes of DuraGraft® versus standard heparinized saline in patients undergoing CABG using SVGs.

## PATIENTS AND METHODS

This single-center, prospective, controlled study was conducted at the Cardiovascular Surgery Department of the University of Health Sciences Ankara City Hospital between December 2019 and May 2021. Only patients under the age of 45 years who presented to our center with a diagnosis of coronary artery disease and underwent isolated CABG using at least one venous graft were included in the study. Inclusion criteria were as follows: age <45 years, undergoing open-heart surgery for the first time, undergoing isolated elective CABG, and use of at least one venous graft during the operation. Exclusion criteria were as follows: reoperation, undergoing emergency surgery, patients without venous grafts or with grafts deemed unsuitable for use, patients over 45 years of age, requiring coronary endarterectomy, undergoing combined procedures along with CABG, and using only arterial grafts. Finally, a total of 30 male patients (mean age: 41.7±3.2 years; range, 33 to 45 years) were included in the study. Written

informed consent was obtained from each patient. The study protocol was approved by the Ankara City Hospital Clinical Research Ethics Committee (Date: 28.04.2021, No: E1-21-1761). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient data, including demographic characteristics, comorbidities, pre- and postoperative laboratory results, and radiological findings, were collected by designated researchers from the hospital's digital database and archival records.

The patients were divided into two groups based on their admission dates. Those who received the endothelial protective solution (DuraGraft®) were assigned to the intervention group (Group 1, n=14), while patients who received heparinized normal saline solution were assigned to the control group (Group 2, n=16).

Following the diagnosis of coronary artery disease, all patients underwent preoperative evaluations, including echocardiography, chest X-ray, electrocardiography (ECG), and laboratory tests such as biochemistry, complete blood count, and coagulation parameters. During the postoperative hospital stay, patients were monitored through routine ECGs, chest X-rays, and biochemical assessments until discharge.

Patients were followed at one, three, six, and 12 months postoperatively with laboratory parameters and ECG assessments. In the first postoperative year, symptomatic patients underwent advanced cardiac imaging (echocardiography, coronary computed tomography angiography [CTA]) to evaluate graft patency and cardiac function. Patients who presented to a healthcare facility with chest pain or angina-equivalent symptoms at least once within the three months prior to their final outpatient clinic visit were considered symptomatic.

### Operative procedure and graft preservation solutions

All CABG procedures were performed under general anesthesia via median sternotomy, using standard aorta-right atrial cannulation, under on-pump and cross-clamp conditions. Cardiac arrest was achieved with a single dose of del Nido cardioplegia and topical cooling.

All great saphenous vein grafts were harvested using an open technique, with care taken to avoid

overdistension, excessive handling, and distortion in order to minimize endothelial damage. In both groups, the grafts were rinsed at room temperature with their respective solutions and stored in the same solution within at least 15 min of harvesting. Until the distal anastomoses were completed, the grafts were kept in their respective storage solutions, and intraoperative flushing was also performed with the same solutions to evaluate the anastomoses.

In Group 1, the graft preservation solution used was DuraGraft®, a buffered solution containing glutathione (G), ascorbic acid (A), and L-arginine (L) (GALA). It is stored at a temperature between +2°C and +8°C. During surgery, 12,500 IU of heparin was added to 250 cc of DuraGraft®, which was then used at room temperature. The composition of DuraGraft® is presented in Table 1.

In Group 2, a 250-cc room-temperature saline solution containing 0.9% sodium chloride (154 mmol/L sodium chloride) was used as the storage solution. Heparin was added intraoperatively at a concentration of 40 U/mL.

#### Imaging methods and evaluation

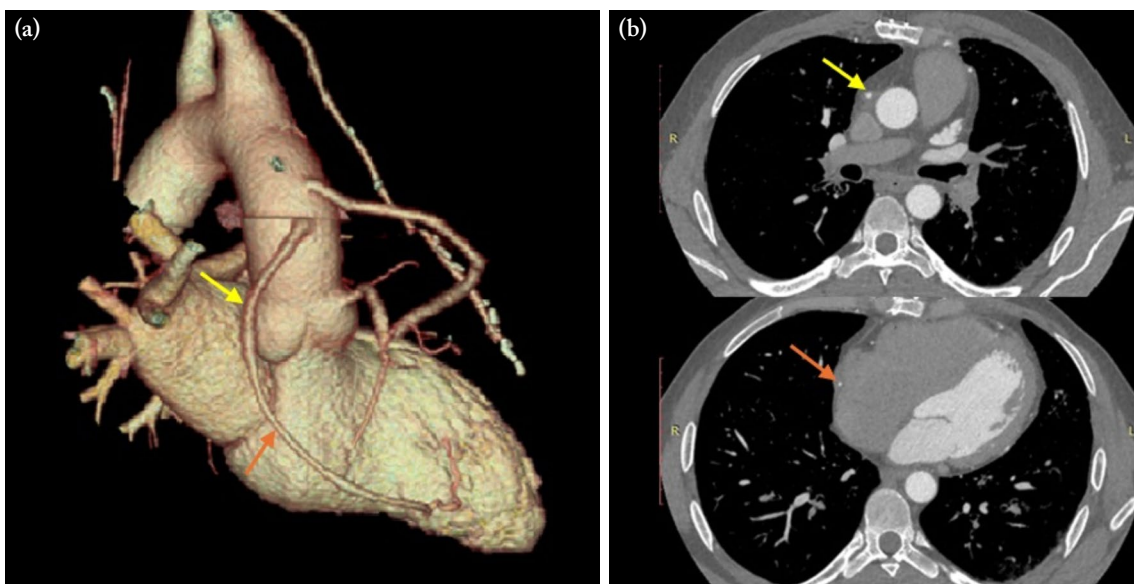
Coronary CTA protocol was adapted from studies by Lau et al.<sup>[9]</sup> and Perrault et al.<sup>[10]</sup> In both

groups, a total of 67 anastomoses from 30 patients with SVGs were evaluated. Imaging was performed using a multi-detector CT (MDCT) scanner with at least 64 slices. To lower the heart rate below 60 beats per min, 50 to 100 mg of oral metoprolol was administered prior to scanning. Imaging was performed with ECG and contrast synchronization, and all scans were acquired during a single breath-hold. The evaluated parameters were as follows: total vessel diameter (TVD) and lumen diameter; TVD measured from pre-contrast scans (if image quality was insufficient, post-contrast scans were used); lumen diameter measurements obtained from post-contrast images; grafts classified as totally occluded or patent; patent grafts further divided into two subgroups based on whether they had greater or less than 50% stenosis; and saphenous vein wall thickening assessed as either diffuse thickening or minimal change.

Saphenous vein wall thickening was categorized as either minimal or diffuse based on the visual assessment of axial and multiplanar reconstructed coronary CTA images. This classification was performed by a single experienced radiologist blinded to group allocation, who assessed the entire length of the SVGs. Although no strict

**Table 1**  
DuraGraft solution content

| Function                            | DuraGraft®                         |
|-------------------------------------|------------------------------------|
| Ion balance                         | Calcium chloride dihydrate         |
|                                     | Potassium chloride                 |
|                                     | Magnesium sulfate                  |
|                                     | Magnesium chloride                 |
|                                     | Sodium chloride                    |
|                                     | Sodium bicarbonate                 |
|                                     | Anhydrous dibasic sodium phosphate |
| pH control-Buffer molecules         | Monobasic potassium phosphate      |
|                                     | Sodium bicarbonate                 |
|                                     | Anhydrous dibasic sodium phosphate |
| Anaerobic metabolism support agents | Monobasic potassium phosphate      |
|                                     | D-glucose                          |
|                                     | Dibasic sodium phosphate anhydrous |
| Antioxidants                        | Monobasic potassium phosphate      |
|                                     | L-glutathione                      |
| NO synthesis substrate              | L-ascorbic acid                    |
|                                     | L-arginine                         |



**Figure 1.** (a) The segment with normal saphenous graft diameter and minimal wall thickening in the same patient is indicated with a yellow arrow; (b) the segment with diffuse wall thickening and the narrowing in the lumen of that segment is indicated with an orange arrow.

quantitative threshold was used, the assessment was guided by consistent visual criteria, including concentric wall thickening, luminal narrowing, and contrast dispersion patterns. Figures 1a, b show marked three-dimensional (3D) MDCT images of patent and stenotic SVGs.

### Endpoints

The primary endpoints were graft patency, mortality, and recurrent angina. Secondary endpoints included coronary events requiring reintervention, major adverse cardiovascular and cerebrovascular events (MACCEs), deterioration in cardiac function, and SVG wall thickening.

### Statistical analysis

Study power analysis and sample size calculation were performed using the G\*Power version 3.1.9.7 software (Heinrich Heine University Düsseldorf, Düsseldorf, Germany). With  $n_1=31$ ,  $n_2=36$ ,  $\alpha=0.05$ , and effect size ( $d$ )=0.74, the power of the study was calculated as 85%.

Statistical analysis was performed using the IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA) and MedCalc 15.8 software (MedCalc Software Ltd., Ostend, Belgium). Descriptive data were presented in mean  $\pm$  standard

deviation (SD), median (min-max) or number and frequency, where applicable. The chi-square test was employed for the comparison of categorical variables. Normality was evaluated using Kolmogorov-Smirnov and Shapiro-Wilk tests, skewness-kurtosis values, and graphical methods (histogram, Q-Q Plot, stem-and-leaf, boxplot). Independent samples t-test was used to compare normally distributed continuous variables between the groups. A  $p$  value of  $<0.05$  was considered statistically significant.

## RESULTS

Of a total of 30 patients, all underwent surgery at the time of data collection. The demographic and preoperative characteristics of the study population are summarized in Table 2. No statistically significant differences were observed between the groups except for body mass index (BMI) and hypertension, which were higher in the control group ( $p=0.048$ ). No patients had a history of stroke, peripheral arterial disease, carotid stenosis, renal or pulmonary disease in either group.

### Procedural data and graft-specific characteristics

In all patients, the left internal mammary artery (LIMA) was used to bypass the left anterior

**Table 2**  
Patient characteristics

|                                      | Group 1 (n=14) |       |            | Group 2 (n=16) |       |            | <i>p</i> |
|--------------------------------------|----------------|-------|------------|----------------|-------|------------|----------|
|                                      | n              | %     | Mean±SD    | n              | %     | Mean±SD    |          |
| Age (year)                           |                |       | 41.2 ± 2.7 |                |       | 42.1 ± 3.6 | 0.478    |
| Sex                                  |                |       |            |                |       |            | -        |
| Male                                 | 14             | 100.0 |            | 16             | 100.0 |            |          |
| Female                               | 0              | 0.0   |            | 0              | 0.0   |            |          |
| Body mass index (kg/m <sup>2</sup> ) |                |       | 25.4±2.6   |                |       | 28.5±4.1   | 0.028    |
| Smoking                              | 13             | 92.9  |            | 15             | 93.8  |            | 1.000    |
| Diabetes mellitus                    | 3              | 21.4  |            | 4              | 25.0  |            | 1.000    |
| Hypertension                         | 11             | 78.6  |            | 7              | 43.8  |            | 0.048    |
| LVEF (%)                             |                |       |            |                |       |            | 0.972    |
| ≤30                                  | 1              | 7.2   |            | 1              | 6.3   |            |          |
| 30-50                                | 3              | 21.4  |            | 4              | 25.0  |            |          |
| ≥50                                  | 10             | 71.4  |            | 11             | 68.7  |            |          |

SD: Standard deviation; LVEF: Left ventricular ejection fraction.

descending (LAD) artery. All LIMA grafts were found to be patent and were excluded from the statistical analysis due to the study's focus on comparing SVGs.

A total of 31 distal bypasses were performed in the 14 patients in the intervention group using SVGs, while 36 distal bypasses were performed in the 16 patients in the control group. Within-group comparisons showed no statistically significant differences between patent and occluded grafts in

the intervention group in terms of all measured variables ( $p>0.05$ ).

There was no statistically significant difference between the two groups regarding the location of the target vessels and graft patency ( $p>0.05$ ); however, the target coronary artery diameters in the intervention group were found to be significantly larger ( $p=0.027$ ). In the control group, there was a statistically significant relationship between graft patency and the duration of time the graft remained

**Table 3**  
Operative characteristics and surgical data

|                                            | Group 1 (n=31) |                | Group 2 (n=36) |                 | <i>p</i> <sub>1</sub>    | <i>p</i> <sub>2</sub>    |
|--------------------------------------------|----------------|----------------|----------------|-----------------|--------------------------|--------------------------|
|                                            | Patent (n=24)  | Occluded (n=7) | Patent (n=24)  | Occluded (n=12) |                          |                          |
|                                            | n              | n              | n              | n               |                          |                          |
| Target coronary arteries                   |                |                |                |                 | 0.557 <sup>b</sup>       |                          |
| Diagonal                                   | 7              | 4              | 5              | 2               |                          |                          |
| Circumflex                                 | 8              | 2              | 10             | 4               |                          |                          |
| Ramus intermedius                          | 2              | 1              | 1              | 1               |                          |                          |
| Left posterolateral                        | -              | -              | 1              | -               |                          |                          |
| Right coronary system                      | 5              | -              | 5              | 4               |                          |                          |
| Right posterior descending                 | 2              | -              | 2              | 1               |                          |                          |
| Target coronary artery mean size (mm)      | 1.5±0.3        |                | 1.3±0.3        |                 | <b>0.027<sup>a</sup></b> |                          |
| Solution exposure mean time (min)          | 69.2±18        | 67.1±22.1      | 65.7±16.9      | 83.1±21.8       | 0.564                    | <b>0.012<sup>a</sup></b> |
| Cross clamp mean time (min)                | 65.6±16.7      |                | 71.5±20.1      |                 | 0.216                    |                          |
| Cardiopulmonary bypass mean duration (min) | 105.2±39.6     |                | 116.2±48.3     |                 | 0.318                    |                          |

*p*<sub>1</sub>: Intergroup comparison (Group 1 - Group 2), *p*<sub>2</sub>: Intragroup comparison (patent-occluded); <sup>a</sup> Independent Samples t test; <sup>b</sup> Chi-square test.

| Table 4                                                                             |                |      |                |      |            |
|-------------------------------------------------------------------------------------|----------------|------|----------------|------|------------|
| Intergroup comparison of graft occlusion percentages (in all distal bypass targets) |                |      |                |      |            |
|                                                                                     | Group 1 (n=31) |      | Group 2 (n=36) |      | <i>p</i> * |
|                                                                                     | n              | %    | n              | %    |            |
| Graft occlusion percentage                                                          |                |      |                |      |            |
| <50                                                                                 | 20             | 64.5 | 18             | 50.0 | 0.483      |
| >50                                                                                 | 4              | 12.9 | 6              | 16.7 |            |
| Total occluded                                                                      | 7              | 22.6 | 12             | 33.3 |            |
| * Chi-square test.                                                                  |                |      |                |      |            |

| Table 5                                                               |                |      |                |      |            |
|-----------------------------------------------------------------------|----------------|------|----------------|------|------------|
| Intergroup comparison of saphenous vein graft wall thickness increase |                |      |                |      |            |
|                                                                       | Group 1 (n=31) |      | Group 2 (n=36) |      | <i>p</i> * |
|                                                                       | n              | %    | n              | %    |            |
| Wall thickness increase                                               |                |      |                |      |            |
| Minimal                                                               | 15             | 62.5 | 6              | 25.0 | 0.020      |
| Diffuse                                                               | 9              | 37.5 | 18             | 75.0 |            |
| * Chi-square test.                                                    |                |      |                |      |            |

in the storage solution ( $p<0.05$ ); occluded grafts were kept in the solution for a longer period. Target vessels for distal bypasses, their diameters, and other intraoperative data are detailed in Table 3.

### Medication and whole graft analysis

All patients received 100 mg of acetylsalicylic acid and a beta-blocker at discharge. Clopidogrel was prescribed to 85.7% of patients in the DuraGraft® group and to all patients (100%) in the control group. Similarly, atorvastatin was administered to 64.3% of patients in the DuraGraft® group and 87.5% in the control group. There were no statistically significant differences in postoperative medication regimens between the groups ( $p>0.05$ ).

No in-hospital mortality or MACCEs were observed in either group. The mean follow-up duration was  $11.9\pm2.9$  months in the DuraGraft® group and  $12.1\pm2.5$  months in the control group, with no significant difference between them ( $p=0.847$ ).

Based on coronary CTA data, grafts were classified as totally occluded or as having <50% or  $\geq 50\%$  segmental luminal stenosis. In the intervention group, seven of the 31 saphenous vein bypass grafts (22.6%) were found to be totally occluded. Among

the patent grafts, 20 (64.5%) showed <50% luminal narrowing, and four (12.9%) had  $\geq 50\%$  segmental stenosis. In the control group, 12 of the 36 SVGs (33.3%) were totally occluded. Among the patent grafts, 18 (50.0%) showed <50% luminal narrowing, and six (16.7%) had  $\geq 50\%$  segmental stenosis. Comparisons between the groups revealed no statistically significant difference in graft occlusion rates ( $p=0.483$  and  $p>0.05$ ) (Table 4).

When the patent SVGs were evaluated for changes in vessel wall thickness, 15 of the 24 patent grafts (62.5%) in the intervention group showed minimal thickening, while nine (37.5%) had diffuse wall thickening. In the control group, six of the 24 patent grafts (25.0%) had minimal thickening, while 18 (75.0%) showed diffuse wall thickening. Comparison between the groups revealed a statistically significant difference in saphenous vein wall thickening ( $p=0.020$  and  $p<0.05$ ), with the intervention group showing less wall thickening (Table 5).

## DISCUSSION

Coronary artery bypass grafting remains a widely practiced surgical treatment for cardiovascular

disease. Long-term graft patency is a key determinant of surgical success. Although arterial grafts are preferred due to their superior long-term patency, SVGs are still frequently used because of their anatomical suitability, ease of harvesting, and adequate length. However, it is well known that venous grafts are more susceptible to endothelial injury and hemodynamic stress compared to arterial grafts.<sup>[11]</sup>

In the present study, we evaluated radiologically the impact of DuraGraft® solution on SVG patency. While comparing the SVGs in the intervention and control groups, no statistically significant difference was observed in graft failure rates at the one-year follow-up. Assessment of SVG wall thickening revealed a significantly higher rate of diffuse thickening in the control group. This finding suggests that longer-term differences in graft failure may emerge over time. Additionally, in the control group, a significant association was found between longer storage times in solution and graft failure. Furthermore, larger target vessel diameters and shorter cross-clamp times were positively correlated with graft patency. These observations are consistent with the literature.<sup>[10]</sup> Target vessel diameter is known to have a direct impact on graft patency.<sup>[12]</sup> The larger target vessel diameters observed in the intervention group were not intentionally selected. However, this difference may have influenced the flow patterns within the SVGs, potentially affecting the nature of wall thickening. Additionally, the longer duration of solution exposure in the control group may have contributed to the development of intimal hyperplasia. Despite these differences, the rate of total graft occlusion did not significantly differ between the groups during the study period. The long-term impact of wall thickening on graft occlusion should be evaluated through extended follow-up.

This finding contrasts with the clinical study by Harskamp et al.,<sup>[13]</sup> which demonstrated favorable patency outcomes with buffered solutions. Although other studies have reported lower incidences of MACCEs, repeat revascularization, myocardial infarction, and mortality in favor of DuraGraft®,<sup>[14]</sup> no such events were observed in either group in this study. This discrepancy may be due to the small sample size and short follow-up period. To determine the long-term clinical effects of DuraGraft®, studies

with longer follow-up periods and larger patient cohorts are certainly needed.

Ongoing multi-center randomized-controlled trials are currently evaluating the efficacy of endothelial protective solutions in SVG preservation.<sup>[8,15]</sup> These studies are critical for understanding the clinical relevance of such solutions and validating their use. Our study represents one of the early clinical evaluations conducted in Türkiye following the inclusion of DuraGraft® in the reimbursement list, and it is significant for prospectively examining graft patency and clinical outcomes.

An important factor in interpreting our results is the study population, which consisted exclusively of males under the age of 45, primarily due to national reimbursement policies in effect during the study period. While this homogeneity may reduce confounding, it limits external validity, as older individuals and women comprise a significant portion of the real-world CABG population. Although the reimbursement criteria required patients to be under 45 years of age, there was no restriction on sex; however, no female patients under 45 were admitted during the study period.

Furthermore, graft patency was assessed only in patients who exhibited clinical symptoms such as chest pain or angina equivalents in our study. The reason for performing control coronary CTA only in symptomatic patients was to avoid unnecessary diagnostic burden and healthcare costs associated with screening all patients. However, subclinical graft occlusion is a well-documented phenomenon, and this methodological limitation may have led to an underestimation of the true rate of graft failure in both groups.

The main limitation to our study is its relatively small sample size, being conducted at a single center with patients exclusively under the age of 45 years. Therefore, the findings of this study cannot be generalizable to older patients or those with multiple comorbidities. Of note, the decision to include only patients under 45 years was based on the availability of the solution under specific reimbursement indications at the time of the study, without any conflict of interest from the authors. Another limitation is the one-year follow-up period, which may be considered too short for fully assessing long-term graft patency. Furthermore, the study

design included only male patients younger than 45 years of age, based on the regulatory criteria for access to the DuraGraft® solution at the time. This demographic limitation restricts the applicability of our results to the general population, particularly elderly and female patients with higher comorbidity burdens. Another limitation involves the selective use of coronary CTA solely in symptomatic patients. Asymptomatic graft occlusions may have gone undetected, introducing potential bias into the reported graft patency rates. A more robust evaluation would involve systematic imaging follow-up, regardless of clinical symptomatology.

In conclusion, coronary artery disease continues to rise globally, and improving the long-term success of surgical revascularization remains a key objective. As the most commonly used graft after the internal mammary artery, the saphenous vein holds promise when combined with endothelial protective strategies to enhance long-term patency. The reduction in venous wall thickening in the DuraGraft® group in our study suggests a possible long-term benefit. However, due to the lack of extended follow-up data, these findings should be interpreted with caution. Further multi-center, large-scale studies with extended follow-up periods are warranted to establish more reliable conclusions on this subject.

**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

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