Flow dynamics of the St Jude Medical Symmetry aortic connector vein graft anastomosis do not contribute to the risk of acute thrombosis

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Background: The efficacy of the St Jude Medical Symmetry aortic connector (St Jude Medical, Inc, St Paul, Minn) for coronary artery bypass is currently debated. Potential drawbacks are the biocompatibility of the endoluminal device, the need for graft manipulation during the procedure, and the 90° offset of the vein graft from the ascending aorta, which may induce graft kinking and abnormal fluid dynamics. In this article, a computational approach was designed to investigate the fluid dynamics pattern at the proximal graft.

Methods: Four models of hand-sewn anastomoses and two models of automated anastomoses were constructed; a finite volume technique was used to simulate realistic graft fluid dynamics, including aortic compliance and proper aortic and graft flow rates. The anastomosis geometry performance was analyzed by calculating time-averaged wall shear stress and the oscillating shear index at the toe and heel regions of the proximal graft.

Results: Time-averaged wall shear stress was significantly lower in the hand-sewn anastomosis models than in the two models that simulated the use of the aortic connector (0.38 ± 0.07 Pa vs 1.32 ± 0.4 Pa). Higher oscillating shear index values were calculated in the hand-sewn anastomosis models (0.15 ± 0.02 Pa vs 0.06 ± 0.02 Pa).

Conclusions: Automated anastomosis geometry is associated with less critical fluid dynamics than with conventional hand-sewn anastomosis: the shape of the proximal graft induces more physiological wall shear stresses and less oscillating flow, suggesting a lower risk of atherosclerotic plaque and intimal hyperplasia as compared with conventional anastomosis geometry. Therefore, the reported early thrombosis and late failure of the St Jude Medical aortic connector anastomoses are not related to unfavorable fluid dynamics.

Automated anastomosis technology is widespread in surgery. Miniaturization of the devices and improved biocompatibility have allowed the recent introduction of anastomotic devices for coronary artery bypass grafting (CABG).¹⁻⁴ Theoretical advantages of automated anastomoses include standardization of the quality of the anastomosis, rapidity and ease of use, and, more interestingly, the possibility of performing a clampless proximal anastomosis on the ascending aorta.

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Figure 1. The six 3-dimensional models featuring the ascending aorta with the aorta-coronary bypass. The 4 models on the left represent the hand-sewn anastomoses, and the angle between the graft axis and the aortic conduit is 45°, 90°, 135°, and 180°. The 2 models on the right represent the anastomoses performed with the aortic connector with respect to a standard case and a critical one.

The St Jude Medical Symmetry aortic connector (St Jude Medical, Inc, St Paul, Minn) is a nitinol endovascular device that enables sutureless end-to-side anastomosis between a venous graft and the ascending thoracic aorta. Although easy to use and effective, the device has a number of limitations, including the presence of an endoluminal stent-like nitinol structure and the necessity of manipulation of the vein graft during preparation for delivery.² Another important procedural limitation of this device is the obligatory 90° offset of the venous graft from the aorta, leading to higher risk for kinking and compression of the graft from the mediastinal structures. Moreover, such a configuration may induce a drastic modification of the blood velocity profiles and wall shear stresses (WSS) as compared with conventional anastomosis designs, in which the saphenous vein is prepared with a cobra-head shape and the anastomosis has a 0° offset from the ascending aorta. Possibly related to this issue, although initial experience with the device has shown reliability and ease of use, are several reports of acute thrombosis of the vein graft, particularly at the proximal end of the graft.⁵⁻⁷

Local hemodynamic factors are involved in atherosclerotic plaque formation and development: disturbed flow may induce initial endothelial lesions (in case of too-high shear stress in association with excessive arterial wall strain) and inflammatory activation, with possible platelet aggregation and acute thrombosis.⁸ Low and oscillating

wall stresses contribute to atherosclerotic plaque growth by activation of both mechanical and biological pathways.⁹

To determine whether the proximal geometry of the offset of the anastomosis from the ascending aorta may induce flow disturbances that are responsible for accelerated atherosclerosis or acute thrombosis, we designed a computational approach to compare the flow and WSS patterns between conventional hand-sewn and automated proximal anastomosis geometries.

Materials and Methods

Figure 1 depicts the 6 models of proximal anastomosis used in this study. Four models reproduce the typical morphology of a conventional hand-sewn anastomosis and differ regarding the angle between the graft axis and the aortic conduit; angles of 45°, 90°, 135°, and 180° were considered. The other two models simulate the anastomoses performed with the aortic connector; they differ in the length of the straight portion of the graft upstream from the bending, which was 3 and 0.3 cm. The length of the straight portion before the bending is clinically correlated with the way the graft lies on the epicardial surface of the heart after implantation: the length of the straight portion is shorter for grafts directed toward the right coronary artery circulation (the graft is usually positioned in the right lateral aspect of the ascending aorta and is bent over the right appendage or the right ventricle to reach the diaphragmatic surface of the heart). In case of grafts directed toward the obtuse margin of the heart, the anastomosis is performed in the concave portion, on the lateral left side of the

Figure 2. Boundary conditions applied to the model. Q_{aor} , Aortic flow rate; Q_{bp} , coronary by pass flow rate; Q_{compl} , aortic flow rate in the radial direction due to aortic wall compliance.

ascending aorta, and the straight portion is longer because the graft bends only when it reaches the left atrial appendage. The straight portion is very short (0.3 cm in the simulation) in occasional cases in which the anastomosis is performed on the anterior surface of the aorta and there is no heart structure for it to be laid on (as is the case in patients with diffuse atherosclerotic plaques, in whom the anastomosis is obligatorily positioned where the aortic wall is free from disease).

For all models, the ascending aorta and graft diameters were assumed to be 3.5 and 0.5 cm, respectively; the graft was connected 2.3 cm downstream of the aortic inlet section, and the length of the proximal graft was set to 5.4 cm. To obtain stable boundary conditions (ie, uniform outlet pressures), the aortic conduit was assumed to be a 25-cm-long straight tube; for the same purpose, a 2.6-cm-long straight conduit was added at the end of the graft.

Boundary Conditions

The graft walls were assumed to be rigid, and no-slip conditions were imposed. This approximation was used because the assumption of compliant walls induces negligible changes in the fluid dynamics patterns as compared with those caused by changes of geometry and boundary conditions.¹⁰

The numeric simulations were obtained under unsteady flow conditions. The flow rate profile by Swanson and Clark¹¹ was used at the aortic inlet (Figure 2), with an average flow rate of 5 L/min; this corresponds to a maximum flow rate of 25 L/min at the systolic peak. At the graft outflow, the flow rate was calculated on the basis of the results obtained by a detailed numerically distributed nonlinear model of coronary bypass circulation.¹² The aortic outlet pressure was taken as the reference. To provide the correct diastolic graft inflow conditions, the aortic wall was assumed to be compliant; the Laplace law was used to calculate diastolic-to-systolic variation of the inner diameter of the aorta by assuming that the vessel thickness was 1 mm and the aortic elastic modulus was 1 MPa.¹³ Consequently, the aortic compliance was simulated by imposing a nonzero velocity normal to the aortic wall (v_n) according to the following relationship (Figure 2):

$$v_n = 1.74 \cdot 10^{10} \cdot t^8 \cdot (71.1 \cdot t^{0.9} - 9) \cdot \exp(-79 \cdot t^{0.9})$$

$$0 \leq t \leq 0.1$$

$$v_n = 0.023 \cdot [10(t + 0.000269) - 1] \cdot \exp[-10(t + 0.000269)]$$

$$0.1 \leq t \leq 0.8 \quad (1)$$

which is consistent to the calculated wall motion and whose time-varying behavior mimics the Swanson and Clark flow rate curve.

Simulation Setup

The fluid simulating the blood was assumed to be an isotropic, homogenous, incompressible, and newtonian fluid with a constant density (1060 kg/m³) and viscosity (0.0033 Pa · s). The finite volume method was adopted to solve the Navier-Stokes equations. This method requires the domain discretization; in this study, the hexahedral meshing technique was used, and the fluid domain was divided into approximately 230,000 cells. Preliminary simulations were performed to choose the discretization level that provided mesh-independent solutions. The Fluent software (Fluent Inc, Lebanon, Ill) was used for the calculation with a time step of 0.02 seconds each. The first- and second-order upwinding methods were used to solve the pressures and the velocities, respectively. Moreover, 2 cardiac cycles were performed for each simulation to obtain stable results independent from initialization.

Postprocessing Results

Two fluid dynamics indexes were used to evaluate the WSS at the anastomosis: the time-averaged WSS value (TAWSS) and the oscillating shear stress index (OSI). These indexes are used to identify low and oscillating WSS regions, which are usually associated with bifurcating flows and vortex formation that are strictly related to atherosclerotic plaque formation and fibrointimal hyperplasia.¹⁴⁻¹⁶

The TAWSS index is defined as

$$\text{TAWSS} = \frac{1}{T} \int_0^T |\text{WSS}| \cdot dt, \quad (2)$$

where T is the cardiac cycle time lapse.

The OSI value was calculated as follows^{17,18}:

$$\text{OSI} = 0.5 \left[1 - \frac{\left| \int_0^T \text{WSS} \cdot dt \right|}{\int_0^T |\text{WSS}| \cdot dt} \right] \quad (3)$$

According to this formulation, the OSI index ranges between 0 and 0.5.

Results

During the systolic phase, all the investigated models showed a vortex area downstream of the anastomosis (Figure 3). This vortex was the consequence of the rapid change of direction experienced by the fluid entering the graft; such

Figure 3. Fluid dynamics in the systolic phase ($t = 0.06$ s); a vortex occurred in the 6 models in this phase. The vortex is a consequence of the rapid change in direction of the fluid entering the graft. It is unavoidable in aorta-coronary bypass because of the necessity of executing the proximal anastomosis in the proximal aorta.

Figure 4. Fluid dynamics in the diastolic phase ($t = 0.65$ s); in the 4 models simulating the hand-sewn anastomoses, a vortex occurred close to the wall. This was not observed in the models that simulated the anastomoses performed with the aortic connector.

behavior is typical of small vessels originating from large vessels in which the blood flow is characterized by high velocities.

During diastole, the aortic valve is closed, and the inlet flow is the consequence of the elastic return of the aortic wall. The flow rate inside the graft reaches its maximum value because of the coronary pressure reduction, which depends on the cardiac muscle relaxation. In this case, the models show different fluid dynamics behaviors (Figure 4); in particular, the models simulating the hand-sewn anastomoses still showed a vortex area, whereas in the anastomoses performed with the aortic connector, the path lines were parallel, and no vortex occurred (Figure 5).

Figure 6 shows the WSS color maps at the diastolic maximum flow rate. Two views are provided for each model to show the heel and toe regions. In the models simulating the hand-sewn anastomoses, low and oscillating WSS occurred at the toe and heel regions, respectively; in particular, in the heel region, the oscillating WSS were due to the presence of the vortex area shown in Figure 4.

Tables 1 and 2 report the TAWSS and OSI indexes in the 2 regions. The tables also report their average value calculated with respect to an area of 0.1 cm^2 . In the toe region, in the 4 models of hand-sewn anastomoses, the numeric results show that low WSS were not associated with high OSI values, with the exception of the 45° configuration. Con-

Figure 5. Schematic view of the toe and heel regions for the 6 models in which the wall shear stresses have been collected.

versely, high OSI values were present in the heel region concomitantly with low TAWSS.

According to these results, the most critical model is the 45° model of hand-sewn anastomosis, in which the probability of pathologic thickening is high in both the toe and the heel regions. The most critical region is the heel; the models simulating the anastomoses performed with the aortic connector showed markedly improved fluid dynamics (TAWSS: 1.32 ± 0.4 Pa [mean $\pm$ SD] vs 0.38 ± 0.07 Pa; OSI: 0.06 ± 0.02 Pa vs 0.15 ± 0.02 Pa). Eventually, the configuration simulating the graft bending 0.3 cm downstream of the anastomosis was characterized by the highest TAWSS value (1.59) because of the skewness of the velocity profile and by an OSI value of 0.07, which is intermediate between the extremely low value of the 3-cm straight anastomosis (0.04) and the hand-sewn anastomoses (0.15 ± 0.02 Pa).

Discussion

From a purely geometric standpoint, the geometry of the proximal anastomosis obtained with the Symmetry aortic connector leads to more favorable flow patterns than the conventional cobra-head hand-sewn anastomosis. The 90° offset of the anastomosis is associated with more regular flow patterns, higher diastolic WSS values, and lower OSI values. As a consequence, a TAWSS value larger than 0.5 Pa is obtained throughout the cardiac cycle, and this is not correlated with the formation of fibrous plaques.¹⁴ Similarly, the OSI value, which is linearly related ($r = 0.6$) to the occurrence of atherosclerosis,¹⁶ is strongly reduced.

Initial clinical experience with the anastomotic devices has been associated with a notable incidence of early graft thrombosis and late occlusion.^{5,6} Shortly after clinical introduction of the device, Donsky and colleagues⁵ described occasional complete thrombotic occlusion of the aortic side of saphenous vein grafts for which the St Jude aortic connector was used to perform the proximal anastomosis. More

recently, Traverse and colleagues⁶ followed up 131 proximal vein graft anastomoses in a group of 74 consecutive patients who underwent automated anastomosis with the Symmetry Bypass System aortic connector at the time of CABG. Symptomatically significant stenosis or occlusion developed at the connector site in 11 of 74 patients within 1 year after CABG and necessitated multiple repeat interventions, including brachytherapy.

However, it should be determined whether the reported failures are caused by the automated proximal anastomosis itself or fall inside the already reported failure rate of vein grafts. The occlusion rate of vein grafts in the automated proximal anastomosis series was not significantly different from those published in previous angiographic studies in patients who underwent conventional CABG (13% vs 10%-20% for connector vs conventional anastomosis).^{19,20} The only comparative study, from Wiklund and associates,²¹ between conventional and automated anastomoses did not show significant differences.

The introduction of new technology is usually associated with unexpected and unpredictable problems and issues to be solved. Factors specifically involved in early and late failure of the aortic connector may include insufficient biocompatibility of the device, procedure-specific maneuvers (graft manipulation and the necessity of performing the proximal anastomosis first), and the geometrical conformation (90° offset of the vein graft from the ascending aorta), which has twofold implications: it may induce graft kinking and abnormal fluid dynamics.²

The presence of a nitinol structure inside the proximal anastomosis opens a number of questions about the biocompatibility of the St Jude Symmetry device and resembles the situation of a stent. However, because stent disease is inversely related to the size of the treated vessel²² and because the smaller size of the aortic connector device is 3.5 mm, a low risk of stentlike disease should be expected. Moreover, stent disease is also related to the underlying atherosclerotic

Figure 6. Wall shear stresses in the toe and heel regions during the diastolic phase ($t = 0.65$ s); in the 4 models simulating the hand-sewn anastomoses, both regions showed low wall shear stress values. The 2 models simulating the anastomoses performed with the aortic connection showed higher wall shear stress values in the heel region, as confirmed by the TAWSS and OSI index analysis (Table 2).

TABLE 1. Toe region

Bypass	Z _{tawss} (Pa)	zOSI	MinTAWSS (Pa)	MaxTAWSS (Pa)	maxOSI	minOSI
45°	0.60	0.25	0.35 (0.30)	1.19 (0.18)	0.41 (0.77)	0.05 (0.86)
90°	0.80	0.09	0.50 (0.09)	1.21 (0.13)	0.14 (0.95)	0.04 (0.89)
135°	0.99	0.04	0.59 (0.05)	1.25 (0.01)	0.08 (1.09)	0.01 (1.25)
180°	0.99	0.01	0.68 (0.01)	1.40 (0.06)	0.06 (1.40)	0.00 (0.98)
Connector (3 cm)	1.09	0.04	0.68 (0.09)	1.71 (0.03)	0.17 (0.71)	0.01 (1.39)
Connector (0.3 cm)	0.99	0.06	0.81 (0.08)	1.20 (0.05)	0.08 (0.83)	0.04 (1.09)

TAWSS and OSI values were calculated in the toe region; zTAWSS and zOSI are the average values for the region. The table also reports the maximum and minimum TAWSS and OSI values in the investigated region; for completion; the value of the other index calculated at the same point is reported in parentheses. Data of interest for the evaluation of atherosclerotic plaque formation and intima hyperplasia are reported in boldface (see text for details). TAWSS, Time-averaged wall shear stress; OSI, oscillating shear stress index.

TABLE 2. Heel region

Bypass	Z _{TAWSS} (Pa)	zOSI	MinTAWSS (Pa)	maxTAWSS[Pa]	maxOSI	minOSI
45°	0.40	0.16	0.26 (0.07)	0.82 (0.19)	0.38 (0.32)	0.04 (0.40)
90°	0.45	0.13	0.29 (0.09)	0.63 (0.02)	0.39 (0.33)	0.01 (0.53)
135°	0.39	0.12	0.25 (0.11)	0.62 (0.24)	0.42 (0.39)	0.01 (0.46)
180°	0.28	0.17	0.16 (0.35)	0.53 (0.04)	0.35 (0.16)	0.04 (0.53)
Connector (3 cm)	1.05	0.04	0.67 (0.03)	1.71 (0.02)	0.17 (0.71)	0.01 (1.39)
Connector (0.3 cm)	1.59	0.07	1.09 (0.08)	2.26 (0.01)	0.13 (1.43)	0.02 (2.06)

TAWSS and OSI values were calculated in the heel region; zTAWSS and zOSI are the average values for the region. The table also reports the maximum and minimum TAWSS and OSI values in the investigated region; for completion, the value of the other index calculated at the same point is reported in parentheses. Data of interest for the evaluation of atherosclerotic plaque formation and intima hyperplasia are reported in boldface (see text for details). TAWSS, time-averaged wall shear stress; OSI, oscillating shear stress index.

plaque, which is not present—at least in the early phase—in the vein graft. Nevertheless, to reduce the risk of early graft thrombosis, several groups advocate short-term aggressive antiplatelet therapy in patients who receive an aortic connector anastomosis.²³

The automated anastomosis procedure involves several manipulations of the vein graft, which is cannulated on a

mounting device in preparation for being deployed, with consequent contact of the endothelial surface with the device. Although the device has only smooth surfaces, this maneuver contradicts the no-touch technique of the vein graft.

The proximal anastomosis is performed before the distal one with the currently available connectors, and this may

lead to augmented risk of length misjudgment. Combined with the 90° offset of the graft from the ascending aorta, this increases the risk of proximal kinking of the graft if corrective measures are not undertaken.²

The 90° offset of the sutureless anastomosis, although it is a risk factor for kinking of the graft, offers a beneficial effect on blood fluid dynamics. Simulation results indicate that this conformation allows better flow dynamics conditions in the proximal portion of the vein graft, with possible advantages regarding the resistance to early thrombosis and late atherosclerosis. In particular, the 90° offset configuration avoids vortex formation in the heel region during the diastolic phase, thus enhancing the WSS and decreasing the OSI values throughout the entire cardiac cycle. These are both critical in the hand-sewn anastomoses. Also, in the case of a short, straight portion, the risk of occlusion is likely to be reduced compared with the hand-sewn anastomoses; although the OSI value is almost twice that observed in the model with the longer straight portion, it is still significantly smaller than in hand-sewn anastomosis models. Moreover, because of the skewness of the velocity profile, the TAWSS value is the highest observed in the investigated models. Consequently, it may represent the compromise between fluid dynamics requirements and a graft-kinking low-risk configuration.

In conclusion, this study indicates that the failure of sutureless anastomosis performed with the St Jude Medical aortic connector is not due to abnormal fluid dynamics. Other factors, such as graft kinking and biological factors (related to the endovascular nitinol device or to procedural graft manipulation), may be responsible for early graft failure and require further experimental and computational evaluation.

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