Coronary anastomotic devices: Blood-exposed non-intimal surface and coronary wall stress

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Objective: This study compares the area of blood-exposed non-intimal surface in device-constructed anastomoses with the conventionally sutured anastomosis and examines the technical feasibility of 0 blood-exposed non-intimal surface anastomosis configurations.

Methods: In the device-constructed anastomosis, blood-exposed non-intimal surface was estimated in all anastomosis configurations identified in truly new (ie, nonduplicate and nonrelated) patent applications and in anastomotic devices recently introduced by several institutions. In the sutured anastomosis, blood-exposed non-intimal surface area was estimated by analysis of previously investigated anastomoses. In 0 blood-exposed non-intimal surface anastomosis configurations, finite element modeling was used to calculate coronary wall stress.

Results: By the end of 2001, 57 truly new applications for the distal coronary anastomosis had been published, categorized in 11 types of anastomosis configurations. The tissue blood-exposed non-intimal surface area (ie, non-intimal tissue surface area) ranged from 0 to 6 mm². Approximate total blood-exposed non-intimal surface areas (ie, sum of tissue blood-exposed non-intimal surface and foreign body surface area) in recent devices are 80 mm² (GraftConnector, Jomed, Helsingborg, Sweden); 33 mm² (Magnetic Vascular Positioner rings, Ventrica, Inc, Fremont, Calif); 4.3 mm² (distal connector of St Jude Medical, Inc, St Paul, Minn); and 0.3 mm² (Crinoline frame, University Medical Center Utrecht/Delft University of Technology, The Netherlands). The sutured anastomoses, in contrast, contained approximately 1.3 mm² blood-exposed non-intimal surface area. The mean peak porcine coronary wall stress in 0 blood-exposed non-intimal surface anastomosis configurations with greater than 90° arteriotomy edge eversion ranges from 0.4 to 0.8 N/mm² compared with the mean porcine coronary tear stress of 0.8 N/mm².

Conclusions: In recently introduced devices for clinical use, the total blood-exposed non-intimal surface area ranges from 4.3 to 80 mm² compared with 1.3 mm² in sutured anastomoses. The blood-exposed non-intimal surface area depends on anastomotic orifice size, wall thickness, and bonding components' location and size. Deforming the coronary wall to most of the 0 blood-exposed non-intimal surface anastomosis configurations leads to dangerously high stress concentrations in the coronary arteriotomy corners.

In off-pump coronary artery bypass grafting, some surgeons find suturing of the anastomosis demanding and time-consuming. In thoracoscopic coronary surgery on the beating heart, anastomosis construction by suturing is exceedingly demanding and time-consuming. To replace manual suturing by a facilitated and accelerated vessel wall-bonding process, various anastomotic devices for the distal anastomosis have been developed¹ and are being developed.²⁻⁶

In the year 2001 alone, 40 patents for end-to-side and side-to-side anastomotic devices were published in the patent literature (Figure 1). Although only 21 patents describe truly new ideas (ie, ideas that have not been published in duplicate or related patents), the total number of truly new patents that describe anastomotic designs, which can be used for the distal coronary anastomosis, exceeds 50. In the past 2 years, however, only 4 designs have evolved to prototype devices that have been reported in animal studies: the GraftConnector (Jomed, Helsingborg, Sweden),^{2,3} the Magnetic Vascular Positioner (MVP rings; Ventrica, Inc, Fremont, Calif),⁴ the St Jude Medical distal connector (St Jude Medical, Inc, St Paul, Minn),⁵ and the Crinoline frame developed in our institute (University Medical Center Utrecht/Delft University of Technology, The Netherlands).⁶ The first 3 devices are currently being tested in clinical trials.⁷⁻⁹ All 3 clinically tested devices display blood-exposed non-intimal surface (BENIS) within the anastomosis and thus conflict with the current surgical practice of intima-intima apposition in anastomosis suturing.¹⁰ BENIS may be the result of non-intimal wall layers exposed to blood (tissue-BENIS) or foreign body material (foreign-BENIS).

The first aim of this study was to quantify the area of BENIS (including both tissue and foreign body) in the anastomosis constructed with an anastomotic device and to compare this area with the BENIS area in the conventionally sutured anastomosis.

The perfect anastomosis would have 0 BENIS area. As a result, we further investigated the technical feasibility of anastomosis configurations without foreign-BENIS and tissue-BENIS. Zero BENIS area is obtained by proper deformation of both graft and recipient artery, necessary to expose only intima. We hypothesized that these deformations would induce wall stress that may exceed the threshold tear stress of the artery, leading to tears and leakage. Earlier, we studied deformation of the graft wall when it is everted around an anvil.¹¹ The second aim of this study was to estimate coronary wall stress in anastomoses with 0 BENIS and to compare this stress with the ultimate tear stress of the coronary artery.

Materials and Methods

Anastomosis Configuration

All invented anastomosis configurations for the distal anastomosis (both end-to-side and side-to-side) were categorized by searching

the patent literature (Figure 1). In each category, truly new patents were further identified. The area of tissue-BENIS in each configuration was calculated by the assumptions and formulas listed in Appendix I.

Because the surface of non-intimal tissue, that is, media or adventitia (tissue-BENIS), relates to the anastomosis configuration (anastomosis type and wall-apposition), tissue-BENIS was calculated for all anastomosis configurations found in the patent literature. Because the surface of foreign body materials, such as metal or synthetics (foreign-BENIS), relates to the choice of device (in dimensions and location of the bonding components), foreign-BENIS was only estimated in anastomoses constructed with anastomotic devices introduced by several companies and institutions in the past 2 years.

Anastomotic Devices

Tissue- and foreign-BENIS areas were estimated using reported and assumed frame dimensions; the formulas are listed in Appendix II. BENIS area in the sutured anastomosis was estimated from analysis of sutured anastomoses constructed in a previous study.¹²

Coronary Wall Stress

In anastomosis configurations with 0 BENIS area, coronary wall stress was estimated by finite element modeling (FEM) techniques. The modeled coronary dimensions (inner diameter: 1.8 mm; wall thickness: 0.6 mm) resembled the (porcine) coronary arteries from a study¹³ that was used to approximate the material model behavior (Appendix III). Distributed loads were applied to the edge of a longitudinal slit arteriotomy (length: 4.0 mm; slightly rounded corners to avoid nonrealistic stress values: 0.05 mm radius) in such a way that the coronary wall deformed to the shape required for 0 BENIS anastomosis configurations. Mean coronary wall peak stress was defined as mean principal peak Cauchy stress over the 6 FEM nodes with the highest stress values. The value for the threshold tear stress of the porcine coronary artery was derived from a previous study.¹⁴

To investigate the influence of the arteriotomy shape and the distribution of the loads that need to be applied to deform the coronary wall, 3 additional situations were analyzed for all 0 BENIS anastomosis configurations: initial longitudinal slit arteriotomy and intermittently applied loads along the arteriotomy edge that is connected to the graft (eg, anastomotic device pins); initial oval arteriotomy and distributed loads along the arteriotomy edge (cf, adhesive connection); and initial oval arteriotomy and intermittently applied loads along the arteriotomy rim.

Results

Anastomosis Configuration

By the end of 2001, 112 patents for distal coronary anastomosis had been published, 57 of which were truly new applications. The latter have been attributed to 11 categories according to the anastomotic configurations found in the patent literature (Figure 2).

Tissue-BENIS depends on the wall thickness of both graft and coronary artery and the circumference of the

Figure 1. Cumulative number of patent applications on coronary end-to-side and side-to-side anastomoses published in the patent literature during the last 30 years. Data were obtained from the database of the European patent office (esp@cenet, <http://nl.espacenet.com>). The search was restricted to United States and European patent applications and applications published by the World Intellectual Property Organization. Because ideas can be patented in a series of patent applications (continuations, divisions, or parallel applications in the United States, Europe, and at the World Intellectual Property Organization), a distinction was made between the total number of patent applications and the number of patent applications that describe truly new ideas.

anastomotic orifice. By definition, tissue-BENIS is 0 in intima-intima, intima-edge, and edge-edge appositions (Figure 2, A-E, J). It ranges from approximately 1 mm² in an intima-adventitia anastomosis (Figure 2, G) with a round orifice with a diameter equal to a small coronary artery (1.5 mm inner diameter) to approximately 6 mm² in an adventitia-adventitia side-to-side anastomosis (Figure 2, K) with a large (2 × 4 mm) oval anastomotic orifice.

Anastomotic Devices

In Figure 3, sketches of anastomoses constructed with 4 recently developed anastomotic devices are shown, along with 2 conventionally sutured anastomoses. The GraftConnector of Jomed (Figure 3, C) belongs to the intima-edge, end-to-side configuration (although direct contact between the walls is blocked by the sheet). Both the MVP rings of Ventrica, Inc (Figure 3, D) and the distal connector of St Jude Medical (Figure 3, E) belong to the side-to-side, adventitia-adventitia configuration, although in the former there is no direct tissue contact. The Crinoline frame of our own institute (Figure 3, F) cannot be categorized in only 1 single configuration. It uses a combination of appositions (intima-intima at the cheeks and intima-edge at the heel and toe). The estimated areas of tissue- and foreign-BENIS in each facilitated anastomosis and in the conventionally sutured anastomosis are listed in Figure 3 as well.

Wall Deformation

The FEM analysis of the coronary deformation of 0 BENIS anastomosis configurations is shown in Figure 4, A for a deformation with no eversion of the arteriotomy edge (Figure 2, A, D) and Figure 4, B-D for a deformation with 90° arteriotomy edge eversion (Figure 2, B, E, J). The remaining BENIS configuration with 180° arteriotomy edge eversion (Figure 2, C), showed (long before 180° eversion was reached) such a deformation that extreme luminal narrowing (sea-gull effect) occurred. For this reason, we stopped the FEM calculation. However, it is reasonable to assume that the peak stress in this configuration will exceed the calculated values for the intima-intima apposition 2 configuration (Figure 2, B). The mean peak stress values that occur in the corners of the arteriotomy are listed in Table 1.

Discussion

Anastomosis Configuration

Tissue-BENIS is present in the anastomosis configuration as soon as at least 1 media-adventitia edge is exposed to blood. It ranges from 0 to 6 mm². To our knowledge, the relation between tissue-BENIS and patency rate (in combination with variables such as coagulation factors, tissue type, tissue injury, and shear stress) has not been examined systematically. However, the presence of some tissue-BENIS in an anastomosis

Figure 2. Sketches of longitudinal sections and cross-sections of anastomosis configurations for the distal end-to-side and side-to-side coronary anastomosis found in the patent literature, categorized according to the obtained wall apposition. For each configuration, the number of patents containing truly new ideas is noted, together with the range of the media-adventia area exposed to blood (tissue blood-exposed non-intimal surface [tissue-BENIS]). A patent may be categorized in more than 1 configuration, because the elaboration of some inventions shows the applicability on different anastomosis configurations.

seems to be well tolerated. In the conventionally sutured anastomosis, for example, the estimated amount of tissue-BENIS was 1.0 mm², and those anastomoses show normal wall healing.¹² Furthermore, we recently observed surprisingly neat healing of the internal thoracic artery–left anterior descending artery anastomosis with an intentionally constructed adventitial

rim exposed to blood (tissue-BENIS ~3.5 mm²) (Figure 3, B), even when bypass graft flow was less than 15 mL/min.¹⁵

Tissue-BENIS in Recent Devices

The tissue-BENIS area in the anastomosis constructed with the St Jude Medical distal connector (~3.0 mm²) is larger

Figure 3. Tissue- and foreign-BENIS area in sketches of longitudinal sections and cross-sections of anastomoses constructed using the conventional running suture technique (A), an intentionally constructed adventitia rim¹⁵ (B), along with recently introduced anastomotic bonding frames: the GraftConnector (C), the MVP rings (D), the St Jude Medical distal connector (E), and the Crinoline frame (F). To obtain realistic dimensions of the graft, coronary artery, and bonding components, the dimensions were taken from published studies (C, E, F) or patent applications^{18,19} (D). For each anastomosis, the area of the media-adventitia edge (tissue-BENIS) was estimated, as well as the area of foreign body material (foreign-BENIS) exposed to blood. The anastomotic devices are drawn to scale.

than in the sutured anastomosis (1.0 mm²) but similar to the adventitia rim-exposure study (~3.5 mm²). Owing to its larger anastomotic orifice, the MVP-ring system yields a larger tissue-BENIS area (~6 mm²). The Crinoline frame of our institute and the GraftConnector result in an anastomosis with 0 tissue-BENIS, the latter because the polytetrafluoroethylene sheet covers the media-adventitia edge.

Foreign-BENIS in Recent Devices

A large foreign-BENIS area is present in the GraftConnector (80 mm²) because of the thin polytetrafluoroethylene sheet that covers the stent. The sandwich structure of rings in the MVP shows a fairly large foreign-BENIS area too (27 mm²). After implantation of both devices,^{3,4} anticoagulants were administered for a period. The foreign-BENIS area in the St Jude Medical distal connector (1.3 mm²) and the Crinoline (our institute) (0.3 mm²) are considerably smaller. Depending on the material properties, it is conceivable that

the larger the foreign-BENIS area, the more pronounced the anticoagulation needs to be. As with tissue-BENIS, however, the relation between foreign-BENIS area and patency rate remains to be determined. Unfortunately, no inferences on the effect of foreign-BENIS area can be drawn from in-stent restenosis studies. Stenting is associated with wall tears and other injury induced by the dilation of the stenosis. Wall tears, in combination with shear stress, are more likely to influence patency than the foreign-BENIS area of the stent itself. However, recent technologic developments with drug-eluting coatings on stents bear the promise that both thrombogenicity and intimal hyperplasia may become minor problems in anastomotic devices, irrespective of the foreign-BENIS area.

Wall Deformation

Although new developments in stent coatings, as well as a recent animal study,¹⁵ are challenging the assumptions un-

Figure 4. Finite element model (FEM) of bending the arteriotomy edge of differently shaped arteriotomies and boundary conditions: **A**, Longitudinal slit arteriotomy with no eversion of the arteriotomy edge and distributed loads along the cheek edge. **B**, Longitudinal slit arteriotomy with 90° arteriotomy edge eversion and distributed loads along the edge. **C**, Slit arteriotomy with 90° arteriotomy edge eversion and intermittent loads on the arteriotomy edge. **D**, Oval arteriotomy with 90° arteriotomy edge eversion and distributed loads along the edge. (The material model and boundary conditions used for the FEM are explained in Appendix III.)

derlying the gold standard of the sutured intima-intima apposition anastomosis, the most attractive anastomosis configuration remains the one with 0 tissue-BENIS and 0 foreign-BENIS area. In only 3 anastomosis configurations, BENIS might be avoided entirely: end-to-side intima-intima appositions 1, 2, and 3 (Figure 2, A-C). All other configurations have tissue-BENIS within the anastomosis or require bonding components that are at least partially located intraluminally (observation in patents).

The coronary deformation of the arteriotomy edge that is required in the end-to-side intima-intima apposition 2 (Figure 2, B) (and the side-to-side, edge-edge apposition, Figure 2, J) leads to a stress of at least 0.7 N/mm² in the case of both distributed (Figure 4, B) and intermittently (Figure 4, C) applied loads. This value nearly equals the threshold tear stress (0.8 N/mm²),¹⁴ leaving no safety margin. Reshaping

the arteriotomy to an oval shape will reduce the risk of tearing, because wall stress becomes lower (Figure 4, D). In some patients, however, the threshold tear stress may still be lower than the porcine mean value of 0.8 N/mm², because in the porcine study,¹⁴ tear stress ranged from 0.65 N/mm² to 1.10 N/mm².

Limitations to this Study

First, the tear stress threshold was based on experiments performed with healthy coronary arteries from young pigs.¹⁴ When 3 diseased human coronary artery segments were pressurized, they burst before 300 mm Hg was reached, whereas 8 porcine coronary arteries were challenged to 300 mm Hg without bursting (unpublished data). Unfortunately, in the literature, no tear stress values are available from diseased human coronary arteries. Second,

TABLE 1. Mean peak stress in the coronary arteriotomy corners in 0 BENIS anastomosis configurations

	Arteriotomy shape and type of load			
	Longitudinal slit arteriotomy		Oval arteriotomy	
	Distributed loads on the edge	Intermittent loads on the edge	Distributed loads on the edge	Intermittent loads on the edge
Type of wall deformation*				
No arteriotomy edge eversion (configuration A,D, Figure 2)	0.05 (Figure 4, A)	0.05	0.01	0.01
90° arteriotomy edge eversion (configuration B, E, J, Figure 2)	0.8 (Figure 4, B)	0.7 (Figure 4, C)	0.4 (Figure 4, D)	0.4

BENIS, Blood-exposed non-intimal surface; FEM, finite element model. All data in N/mm². Compare with mean porcine coronary threshold tear stress: 0.8 N/mm².

*180° arteriotomy edge eversion (0 BENIS configuration C, Figure 2) was not calculated as the FEM analysis shows an occluded lumen (sea-gulling) long before 180° eversion was reached.

the material model we used was based on compliant pig arteries.¹³ Human coronary arteries show more than 300% increase in stiffness when age increases from 8 to 19 to 60 to 80 years.¹⁶ Thus, in a diseased artery it is likely that relatively small wall deformation induces large wall stress. Third, owing to limitations in the FEM software package (Marc/Mentat; MSC Software Corporation, Palo Alto, Calif; see Appendix III), the model produced a stress that, at large deformations, is lower than would realistically occur. Fourth, we used dimensions from pig coronary arteries (inner diameter 1.8 mm, wall thickness 0.6 mm¹³) rather than dimensions from humans (inner diameter 1.0-2.5 mm, wall thickness 0.2-0.4 mm). The smaller the wall thickness, the lower the wall stress will be when bending the wall.

Taken together, true human stress values are likely to be higher than calculated in this study, whereas human threshold tear stress may be lower than observed in the pig. We infer that substantial deformation of the human arteriotomy rim without causing wall tears is unlikely.

Experience within our group with the One-Shot stapling device of US Surgical Corporation (Norwalk, Conn)¹⁷ illustrates the risk of arteriotomy edge eversion. Despite the favorable results of the FEM analysis shown in Figure 4, D (applicable to this device for which an oval arteriotomy is created), in the same porcine model, this 0 BENIS device created a local coronary dissection in 2 of 14 cases.¹⁷

In the remaining 0 BENIS configuration (end-to-side intima-intima apposition 1) (Figure 2, A), the coronary wall is only deformed slightly, resulting in acceptable stress (Figure 4, A). Results from a previous study,¹¹ however, in which we investigated graft eversion around an anvil, demonstrated that everting the graft to the shape (Figure 2, A) is likely to cause unacceptably high stress in the graft. Eversion can only be achieved properly around a small-rimmed anvil (GraftConnector) or around no anvil at all (Crinoline frame; developed by our institute).

Conclusion

In 4 anastomotic devices recently exposed in the literature, the total area of BENIS (tissue-BENIS and foreign-BENIS) depends on the size of the anastomotic orifice, wall thickness, and location and size of the bonding components. With the 3 clinically used devices, the estimated total BENIS area ranges from 4.3 to 80 mm² and exceeds the BENIS area in the conventionally sutured anastomosis (BENIS ~1.3 mm²). A major reason a 0 BENIS anastomosis is unlikely to be successful is that deforming the coronary wall to its required shape leads to stress concentrations in the corners of the coronary arteriotomy that are dangerously close to the threshold porcine coronary tear stress (0.8 N/mm²).

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Appendix I

Formulas Used to Calculate Tissue Blood-Exposed Non-Intimal Surface in Various Anastomosis Configurations (Figure 2)

Assumptions

- Wall thickness of coronary artery (t_{CA}) = 0.3 mm¹⁸
- Wall thickness of vein graft (t_{vein}) = 0.2 mm
- Wall thickness of internal thoracic artery (t_{IMA}) = 0.3 mm¹⁸
- Circumference of small (1.5 mm diameter) anastomosis orifice (C_{small}) = 4.7 mm
- Circumference of large (2 × 4-mm ellipse) anastomosis orifice (C_{large}) = 9.7 mm

Intima-intima (Figure 2, A-C),

Intima-edge (Figure 2, D),

Edge-edge appositions (Figure 2, E, J):

Tissue blood-exposed non-intimal surface (BENIS) = 0
(by definition)

Adventitia-intima (Figure 2, F):

$$\begin{aligned} (C_{small} + 2\pi \times \text{width}_{rim}) \times t_{vein} &< \text{tissue-BENIS} \\ &< (C_{large} + 2\pi \times \text{width}_{rim}) \times t_{CA} \\ (4.7 + 2\pi \times 0.3) \times 0.2 &< \text{tissue-BENIS} \\ &< (9.7 + 2\pi \times 0.3) \times 0.3 \\ 1.3 \text{ mm}^2 &< \text{tissue-BENIS} < 3.5 \text{ mm}^2 \end{aligned}$$

Intima-adventitia (Figure 2, G),

Edge-adventitia apposition (Figure 2, H):

$$\begin{aligned} C_{small} \times t_{CA} &< \text{tissue-BENIS} < C_{large} \times t_{CA} \\ 4.7 \times 0.3 &< \text{tissue-BENIS} < 9.7 \times 0.3 \\ 1.4 \text{ mm}^2 &< \text{tissue-BENIS} < 2.9 \text{ mm}^2 \end{aligned}$$

Adventitia-adventitia apposition (Figure 2, I, K):

$$\begin{aligned} C_{small} \times (t_{CA} + t_{vein}) &< \text{tissue-BENIS} < C_{large} \times (t_{CA} + t_{IMA}) \\ 4.7 \times (0.3 + 0.2) &< \text{tissue-BENIS} < 9.7 \times (0.3 + 0.3) \\ 2.4 \text{ mm}^2 &< \text{tissue-BENIS} < 5.8 \text{ mm}^2 \end{aligned}$$

Appendix II

Formulas Used to Calculate BENIS in Sutured and Device-Constructed Anastomoses (Figure 3)

Assumptions as in Appendix I

Conventional (Figure 3, A):

In histologic transversal sections (~15 sections/anastomosis) of 22 conventionally sutured anastomoses from a previous study,¹² the percentage of intima-intima apposition (X_{II}) along the anastomotic line was defined as the sum of anastomosis cheek sections with no medial edge exposed to blood divided by the total sum of cheek sections. X_{II} was 60% ± 20% (mean ± SD).

$$\begin{aligned} \text{Tissue-BENIS} &= (1 - X_{II}/100) \times t_{CA} \times \text{circumference}_{\text{studied anastomosis}}^{12} \\ &= (1 - 60/100) \times 0.3 \times 8.0_{\text{twice length arteriotomy}}^{12} \\ &= 1.0 \text{ mm}^2 \end{aligned}$$

$$\begin{aligned} \text{Foreign-BENIS} &= \text{number}_{\text{in lumen}}^{\text{suture loops}}^{12} \times \text{diameter}_{\text{suture}} \times \text{length}_{\text{loop}}^{12} \\ &= 13 \times 0.05_{\text{Prolene 8-0}} \times 0.5_{\text{assumption}} \\ &= 0.3 \text{ mm}^2 \end{aligned}$$

Adventitia-rim anastomosis (Figure 3, B):

$$\begin{aligned} \text{Tissue-BENIS} &= (\text{width}_{rim} + t_{CA}) \times \text{circumference}_{\text{studied anastomosis}}^{15} \\ &= (0.2 + 0.3) \times 7.0_{\text{twice length arteriotomy}}^{15} \\ &= 3.5 \text{ mm}^2 \end{aligned}$$

$$\begin{aligned} \text{Foreign-BENIS} &= \text{number}_{\text{lumen}}^{\text{suture loops}}^{15} \times \text{thickness}_{\text{suture}} \times \text{length}_{\text{loop in lumen}}^{15} \\ &= 11.3 \times 0.05_{\text{Prolene 8-0}} \times 0.5_{\text{assumption}} \\ &= 0.3 \text{ mm}^2 \end{aligned}$$

GraftConnector (Figure 3, C):

$\text{Tissue-BENIS} = 0 \text{ mm}^2$ (medial edge covered by sheet)

$$\begin{aligned} \text{Foreign-BENIS} &= \text{diameter}_{CA(\text{derived from published data})}^3 \times \pi \times \text{length}_{\text{stent (estimated from published figures)}}^3 - \text{Area}_{\text{anastomotic orifice}} \\ &= 2.7 \times \pi \times 10 - \frac{1}{4} \times \pi \times 2.5_{(\text{tube diameter})}^2 \\ &= 79.9 \text{ mm}^2 \end{aligned}$$

MVP rings (Figure 3, D):

(Ring dimensions estimated from sketches¹⁹ and assumptions are based on its use in arteries with a 2.5 mm inner diameter.)

$$\begin{aligned} \text{Tissue-BENIS} &= (t_{CA} + t_{MA}) \times \text{inner circumference}_{\text{ring}} \\ &= (0.3 + 0.3) \times 9.7_{\text{circumference } 2 \times 4 \text{ mm ellipse}} \\ &= 5.8 \text{ mm}^2 \end{aligned}$$

$$\begin{aligned} \text{Foreign-BENIS} &= 4 \times \text{thickness}_{\text{ring}} \times \text{inner circumference}_{\text{ring}} + 2 \\ &\quad \times \text{area}_{\text{ring}} + 2 \times \text{thickness}_{\text{ring}} \times \text{outer circumference}_{\text{ring}} \\ &= 4 \times 0.25 \times 9.7_{\text{circumference } 2 \times 4 \text{ mm ellipse}} + 2 \times \\ &\quad 5.5_{\text{area } 3 \times 5 \text{ mm ellipse}} - \text{area } 2 \times 4 \text{ mm ellipse} + 2 \times \\ &\quad 0.25 \times 12.8_{\text{circumference } 3 \times 5 \text{ mm ellipse}} \\ &= 27.1 \text{ mm}^2 \end{aligned}$$

St Jude Medical distal connector (Figure 3, E):

$$\begin{aligned} \text{Tissue-BENIS} &= (t_{CA} + t_{\text{vein}}) \times \pi \times \text{diameter}_{\text{orifice}}^5 - \text{Area}_{\text{frame body}} \\ &= (0.3 + 0.2) \times \pi \times 2.2 - 2.2_{\text{diameter}_{\text{orifice}}} \times 2_{\text{number}} \\ &\quad \text{of struts} \times 0.1_{\text{strut\_width (assumption)}} \\ &= 3.0 \text{ mm}^2 \end{aligned}$$

$$\begin{aligned} \text{Foreign-BENIS} &= \text{number}_{\text{clips}} \times 2 \times \text{length}_{\text{clipleg}} \times \text{width}_{\text{clipleg}} + \\ &\quad \text{Area}_{\text{frame body}} \\ &= 6_{\text{assumption}} \times 2 \times 0.7_{\text{assumption}} \times 0.1_{\text{assumption}} + \\ &\quad 2.2_{\text{diameter}_{\text{orifice}}} \times 2_{\text{number of struts}} \times 0.1_{\text{strut\_width}} \\ &\quad (\text{assumption}) \\ &= 1.3 \text{ mm}^2 \end{aligned}$$

Crinoline frame (Figure 3, F):

$$\text{Tissue-BENIS} = 0 \text{ mm}^2$$

$$\begin{aligned} \text{Foreign-BENIS} &= 4 \times \text{thickness}_{\text{hook}} \times \text{length}_{\text{exposed in lumen}} \\ &= 4 \times 0.15 \times 0.5_{\text{assumption}} \\ &= 0.3 \text{ mm}^2 \end{aligned}$$

Appendix III

Material Model and Boundary Conditions Used for Finite Element Model (Figure 4)

Finite element models (FEMs) require an adequate representation of material stress-strain behavior. By the assumption that the arterial wall is hyperelastic, incompressible, homogeneous, and isotropic, the material behavior can, of all functions available in the FEM software package (Marc/Mentat; MSC Software Corporation, Palo Alto, Calif), best be represented by the following strain-energy function:²⁰ $W = C_{10}(I_1 - 3) + C_{01}(I_2 - 3) + C_{30}(I_1 - 3)^3$

However, this model loses accuracy at large deformations. In reality, the wall stress will be higher than calculated, which would

only strengthen our conclusions. A least-squares fitting procedure was applied on the coronary circumferential stress-strain relation derived in a previous study on porcine coronary arteries,¹³ with the following results: $C_{10} = 0.0024$, $C_{01} = 0.0043$, and $C_{30} = 0.0063$.

All meshes were made of incompressible hexahedron elements. The proximal and distal ends of the coronary artery were restricted in the longitudinal direction. Because the coronary artery is embedded in surrounded tissue, the vertical movement of segments at the bottom of the artery was fixed. The loads on the arteriotomy edge were incrementally increased until the desired deformation (no arteriotomy edge eversion: orifice width = lumen diameter; 90° arteriotomy edge eversion: 90° rotation of the edge in heel/toe) was observed. This occurred under the following conditions:

1. No eversion + slit arteriotomy + distributed loads; no eversion + oval arteriotomy + distributed loads: A one-third segment of the cheeks is translated in a horizontal plane until the arteriotomy width equals the artery inner diameter.
2. No eversion + slit arteriotomy + intermittent loads; no eversion + oval arteriotomy + intermittent loads: Over the full thickness of the arteriotomy edge, on 3 locations at both cheeks, rows of elements are translated in a horizontal plane until the arteriotomy width equals the artery inner diameter.
3. Ninety-degree eversion + slit arteriotomy + distributed loads: Gradually increasing shear load (0.0035 N/mm² in cheek and 0.035 N/mm² in heel/toe) on the arteriotomy edge.
4. Ninety-degree eversion + slit arteriotomy + intermittent loads: Shear loads on clusters of elements (2 rows along the full thickness of the arteriotomy edge) on 8 locations along the arteriotomy edge (0.2 N/mm² on heel/toe, 0.015 N/mm² on cheeks, and 0.045 N/mm² on remaining locations).
5. Ninety-degree eversion + oval arteriotomy + distributed loads: Gradually increasing shear load (0.004 N/mm² in cheek and 0.04 N/mm² in heel/toe) on the arteriotomy edge.
6. Ninety-degree eversion + oval arteriotomy + intermittent loads: Shear loads on clusters of elements (2 rows along the full thickness of the arteriotomy edge) on 8 locations along the arteriotomy edge (0.085 N/mm² on heel/toe, 0.0085 N/mm² on cheeks, and 0.034 N/mm² on remaining locations).