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Delphi Consensus Study Toward a Comprehensive Classification System for Angioplasty-Induced Femoropopliteal Dissection

The DISFORM Study

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ABSTRACT

OBJECTIVES The aim of this study was to seek expert consensus regarding the features that predict adverse outcomes in order to develop a dedicated angiographic classification system for femoropopliteal artery dissection.

BACKGROUND Dissection of the femoral and popliteal arteries is common after percutaneous angioplasty. Its classification is important. However, all current classification systems have significant limitations.

METHODS Delphi consensus methodology was performed over 3 rounds, using an expert panel of 17 interventionalists. Each was asked to rank dissection features with the potential to lead to acute technical failure and/or early restenosis and then which combination of features would require the placement of a metallic scaffold to avoid those outcomes. Results were used to develop a novel grading system and dissection treatment algorithm.

RESULTS Four main characteristics were identified from a comprehensive preliminary list. There was a good level of agreement between panelists from 773 responses (48 combinations). All panelists recommended scaffolding if a dissection produced a ≥50% diameter reduction (100%). Most recommended scaffolding if the dissection had a spiral shape (73%-100%), was severely flow limiting (93%-100%), or had complex morphology defined by long and multiple dissections (65%-100%). Multiple combinations of those features were more likely to receive a recommendation to scaffold.

CONCLUSIONS Scaffolding of a postangioplasty dissection is recommended in the presence of significant diameter reduction, spiral shape, flow impairment, or adverse morphology (DISFORM). The DISFORM classification system has been developed as a tool to provide uniform language to standardize reporting and for discussion of dissection treatment and prognosis. (J Am Coll Cardiol Intv 2021;14:2391–2401) © 2021 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

DISFORM = diameter reduction, spiral shape, flow impairment, or adverse morphology

FLIPI = flow limitation in peripheral intervention

IVUS = intravascular ultrasound

PTA = percutaneous transluminal angioplasty

Percutaneous transluminal angioplasty (PTA) remains the cornerstone of endovascular treatment for peripheral artery disease. Despite rapid technological advancements providing an expanding list of adjunctive technologies, it is PTA-mediated luminal gain that is fundamental to successful revascularization of the ischemic lower extremity (1).

The mechanism of balloon angioplasty is dissection: overall stretching of the external elastic lamina and plaque shift without plaque compression (2,3). Evidence of this is seen on histopathological studies that demonstrate a degree of dissection and arterial wall disruption after every angioplasty (2,4,5). Although it is the goal of PTA to increase the vessel lumen, the resulting dissections, especially if deep, uncontrolled, or flow limiting, might lead to deleterious clinical consequences such as acute occlusion and restenosis (3,6).

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The classification of angioplasty-induced femoropopliteal dissection is important to aid treatment planning, evaluation, prognosis derivation, standardized reporting, and ongoing investigation of the condition. However, there is currently no dedicated and comprehensive system for the classification of those dissections. All previous systems used for peripheral arteries have limitations (7-10). Some were developed for the coronary arteries and include features with little relevance to those of the leg (7). Some are overly simplistic, with insufficient detail to serve their purpose (10), and others are based on intravascular ultrasound (IVUS), an excellent modality to image dissection but one that is not available to all interventionalists (8,9,11). The aims of this study were to achieve consensus from an expert panel in identifying significant clinical features of peripheral artery dissection and to develop a dedicated, comprehensive angiographic classification system.

METHODS

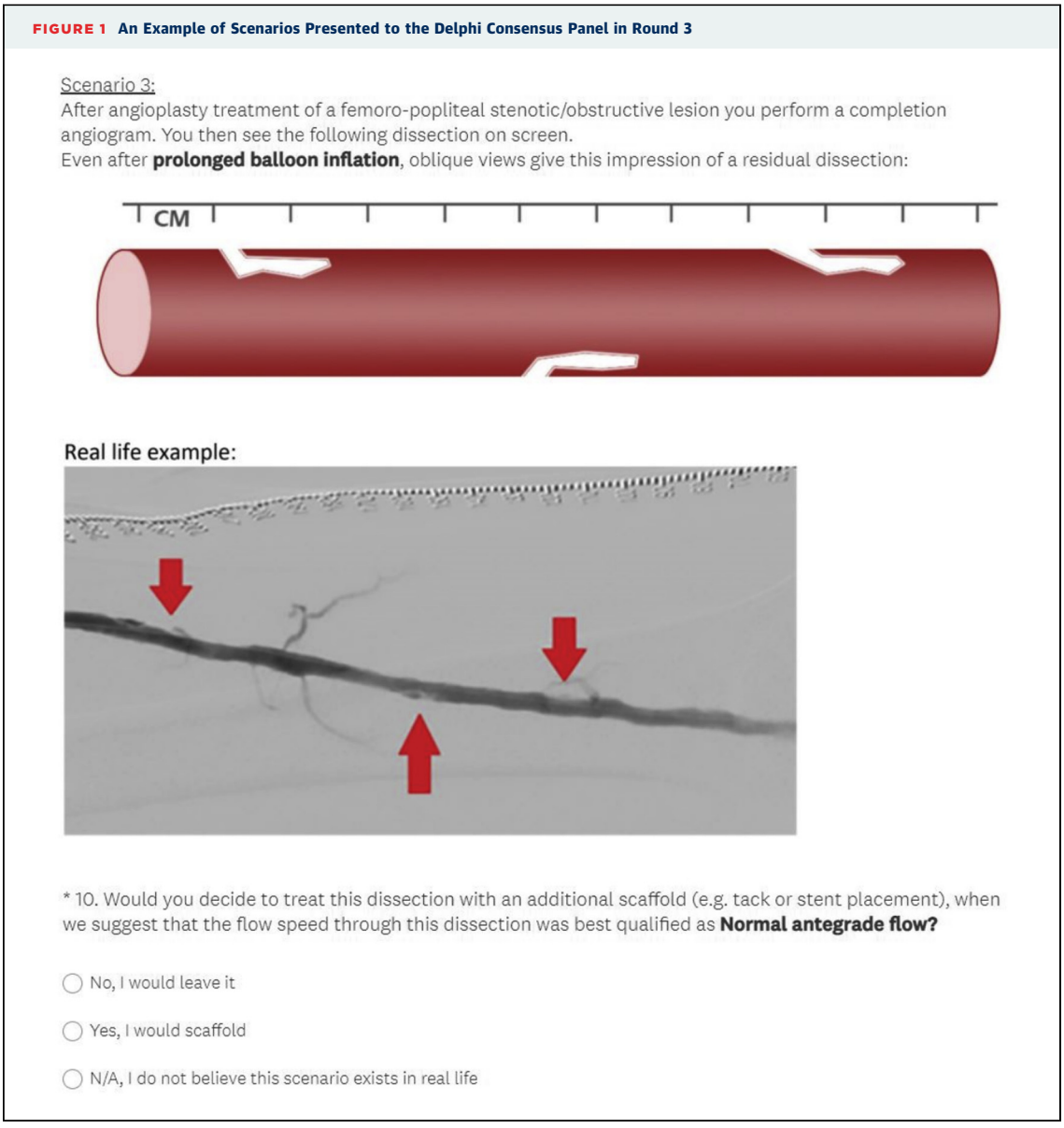
A series of questionnaires based on Delphi consensus methodology were distributed using online software (SurveyMonkey) and/or e-mailed to avoid unintentional guiding of feedback (12). Approval was granted by the local research ethics committee (South Eastern Sydney Local Health District Research Support Office: 2021/ETH00699). To eliminate bias and increase the representability of the panel, invitations were extended to specialists from multiple regions and different fields of vascular medicine. An expert panel was formed with equal proportions of vascular surgeons (n = 5), interventional cardiologists (n = 5), and interventional radiologists (n = 5), supplemented by a smaller sample of vascular medicine specialists (n = 2) (Supplemental Appendix).

The consensus process comprised 3 rounds. In the first round, an executive committee of 2 vascular surgeons and 2 cardiologists were asked to list potential features of angioplasty-induced dissection of the femoral and popliteal arteries (superficial femoral artery origin to third part of the popliteal) that may predict adverse clinical outcomes (defined as acute target lesion failure within 24 hours or early restenosis at <6 months). Those outcomes were chosen as the most significant physical and inflammatory consequences of dissection, respectively. Acute failure results from the extreme shear forces that are created by the dissection flap, known to limit flow and result in occlusion. Restenosis is the immunoinflammatory mechanism that occurs after vessel wall trauma.

In the second round, the Delphi panel was presented with that entire list of features and asked to score each of them individually (on a scale from 1 to 9) for their predictive value toward those 2 adverse clinical scenarios. Panelists were provided with graphic representations for those selected features and instructed to consider this as the most accurate depiction after orthogonal angiographic views. Each included an angiographic image with ruler to provide morphologic clarity, as well as length and diameter reduction. For the morphologic features, several cutoff definition options were provided, and free-text recommendations were accepted to determine the panel recommendations for those cutoffs. A score of 1 represented no predictive value and 9 the strongest predictive value. Significant panel consensus was defined as a mean score of 6 or higher, with at least 70% of scores within a 3-point bandwidth. Those most predictive features and the preferred methods for adjudicating morphology and flow impairment were short-listed for the subsequent round.

For the third round, a graphical illustration was paired with an angiographic image (where available) and presented for all possible combinations of short-listed factors (**Figure 1**). Flow rates were given, using the preferred method determined in round 2. The panel was instructed to assume that each image represented the most accurate representation possible (again on the basis of orthogonal views) of the remaining dissection after prolonged balloon inflation. In this round, the panelists were asked a single question: "Would you treat this dissection with an additional scaffold (eg tack or stent placement)?" The possible answers were "No, I would leave it," "Yes, I

FIGURE 1 **An Example of Scenarios Presented to the Delphi Consensus Panel in Round 3**



would scaffold," and "I believe this scenario does not exist in real life." A consensus of >80% was considered an absolute recommendation and >50% to 80% a moderate recommendation to use a scaffold. We considered a consensus not to scaffold if ≤20% of panelists believed that one was required and a moderate recommendation to avoid a scaffold if that number ranged from >20% to 50%.

STATISTICAL ANALYSIS. Scores for clinical relevance are presented as mean ± SD or median (interquartile range) if data had a nonparametric distribution. Dichotomous variables and proportions are presented as counts and percentages. Three-point agreement was expressed as a percentage, which was calculated by dividing the number of responses for the 3 consecutive scores with the greatest number of responses by the total number of responses. If a panelist believed that a given scenario could not exist, that panelist's vote was removed from the sample size for that question only.

RESULTS

Questionnaires were delivered and responses received between April 2020 and January 2021. Each round of questionnaires had a 100% response rate. Three panelists (18%) responded by e-mail and 14 (82%) used the online survey platform.

TABLE 1 Second-Round Panel Scores to Evaluate Predictive Value of Dissection Features for the Outcomes Acute Failure and Early Restenosis Ranked by Mean Value

	Predictive Value	Score ≥6 Agreement	3-Point Agreement
Acute failure (<24 h)			
Diameter reduction ≥50%	7.9 ± 0.8	100	94
Flow rate reduction	7.6 ± 1.0	94	88
Spiral shaped dissection	7.1 ± 1.5	88	82
Length of dissection	6.2 ± 1.8	65	59
Pressure gradient	5.8 ± 1.9	71	65
Multiple separate dissections	4.9 ± 1.8	47	71
Double lumen lucency	4.9 ± 1.9	35	53
Extravasation	4.5 ± 1.8	24	65
Early restenosis (<6 mo)			
Diameter reduction ≥ 50%	7.8 ± 1.3	94	76
Flow rate reduction	7.5 ± 1.1	88	88
Spiral shaped dissection	7.3 ± 1.2	94	82
Length of dissection	7.0 ± 1.5	82	71
Pressure gradient	6.6 ± 1.4	76	76
Multiple separate dissections	6.3 ± 1.9	82	76
Double lumen lucency	5.8 ± 1.7	65	76
Extravasation	4.2 ± 1.9	29	53

Values are mean ± SD or %. Features were considered predictive if the mean was ≥6.0 with ≥70% 3-point agreement.

ROUND 1. The executive committee listed features of angioplasty-induced dissection they determined to be of potential relevance to peripheral arteries. These were: 1) reduction in luminal diameter; 2) length of dissected artery; 3) multiplicity of dissections; 4) contrast extravasation; 5) a spiral shape; 6) double lumen lucency (contrast behind the lamella or in the wall); 7) degree of flow; and 8) translesional pressure gradient measured by pressure wire or catheter-based manometer system.

The committee suggested 3 methods of measuring flow impairment for adjudication during the second round: 1) comparing flow through the dissected target artery to flow in profunda femoris collateral vessels on the same angiogram; 2) measurement of the time for contrast filling and subsequent washout; and 3) using a flow grading model modified from the TIMI (Thrombolysis In Myocardial Infarction) flow grading system used in coronary artery interventions (13,14).

TABLE 2 The FLIPI Score for Peripheral Artery Dissections

Score	Descriptor
FLIPI 0	Normal antegrade flow
FLIPI 1	Mild reduction in antegrade flow
FLIPI 2	Minor antegrade contrast penetration, faint flow beyond the dissection
FLIPI 3	No flow-through, only collateral filling distal to the dissection

Modified from the TIMI (Thrombolysis In Myocardial Infarction) score for coronary arteries (13,14).
FLIPI = Flow Impairment in Peripheral Intervention.

This was redefined as the FLIPI (flow limitation in peripheral intervention) grading system (Table 2).

ROUND 2. In the second round, features were presented and adjudicated for their ability to predict clinical outcomes of acute occlusion and early restenosis. Each was assessed with a separate question. The features considered predictive of acute failure (mean score ≥6 with ≥70% 3-point agreement) were diameter reduction ≥50%, flow impairment, and a spiral-shaped dissection (Table 1). For the outcome of early restenosis, those same 3 factors were considered predictive as well as 3 additional factors: dissection length ≥2 cm, translesional pressure reduction, and multiple (vs single) dissections.

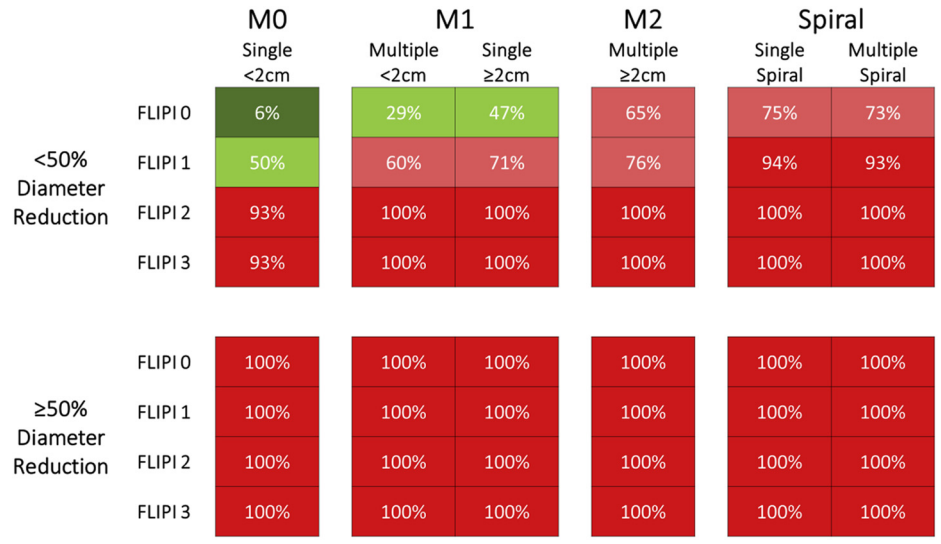
Most of the panel preferred the FLIPI method (53%) of evaluating flow impairment (Table 2). The remainder of panelists were evenly split between comparing flow with adjacent collateral vessels and timing contrast filling and then washout. There was consensus that the best method to assess flow impairment was real-time cine angiography.

Although the panel believed that translesional pressure gradient may be a useful method of predicting adverse outcomes, there was no consensus as to what constituted a significant pressure drop and whether its use had been validated in clinical trials. To satisfy the major objective of developing a classification system that was universally applicable, independent of specialized equipment and on the basis of angiography alone, it was decided that pressure gradient would be excluded from the classification system.

ROUND 3. The final features chosen for the model were: 1) diameter reduction ≥50%; 2) length ≥2 cm; 3) number of dissections (single vs multiple); and 4) presence of a spiral shape. Each was a dichotomous parameter, producing 16 independent dissection combinations. However, there was consensus that a spiral-shaped dissection of <2 cm was not possible to visualize on angiography, necessitating the removal of those 4 combinations. This left 12 possible scenarios, each with 4 flow grade possibilities (FLIPI 0-3), giving 48 final image, illustration, and flow combinations for adjudication.

There were very few scenarios the panel believed were nonexistent, with no more than 4 for any given scenario. However, when this was the chosen response, that panelist was excluded from that scenario calculation. The panel determined that each of the characteristics chosen in the second round was a strong independent predictor of an adverse outcome. Scaffolding was strongly recommended for any dissection that had any of the following: diameter

FIGURE 2 Percentage and Color Coding for Delphi Panel Recommendation to Place a Supporting Scaffold



Red and pink boxes represent a recommendation to scaffold (**red**, strong recommendation, >80% agreement; **pink**, moderate recommendation, >50%-80% agreement). **Green boxes** represent a recommendation against scaffolding (**dark green**, strong recommendation, ≤20% agreement to scaffold; **light green**, moderate recommendation, >20%-50% agreement to scaffold). FLIPI = flow impairment in peripheral interventions; M = morphology classification grade.

reduction ≥50%, a spiral shape with any flow impairment, or severe flow reduction of FLIPI grade 2 or 3. For dissections that did not compromise the lumen ≥50%, were linear, and where flow had mild or no impairment (FLIPI 0 and 1) the combination of flow and morphologic features became important in the decision-making algorithm. For those with normal antegrade flow (FLIPI 0) there was consensus that no scaffold was required if there was a single dissection of <2 cm. If there were multiple linear dissections (<2 cm) or a single long linear dissection (>2 cm), the use of scaffolding was a moderate-strength recommendation in the presence of minor flow impairment (FLIPI 1) but not in the presence of normal flow (FLIPI 0). If there were multiple long linear (>2-cm) dissections, there was a moderate-strength recommendation to scaffold for both FLIPI 0 and 1. Scaffolding was still recommended for single or multiple spiral dissections with no flow impairment, but the strength of that recommendation was moderate.

Final scaffolding recommendations are given in Figure 2.

THE DISFORM CLASSIFICATION SYSTEM FOR PERIPHERAL ARTERY DISSECTION. The DISFORM (diameter reduction, spiral shape, flow impairment, or adverse morphology) classification system was developed to incorporate the features identified in this Delphi consensus study (Table 3). It was designed to aid treatment planning and evaluation, prognosis prediction, information exchange, and the ongoing investigation of peripheral artery dissections. It provides each individual dissection a morphologic and pathophysiological classification ($D_xS_xF_xM_x$). Examples of peripheral dissections classified using DISFORM are given in Figure 3. In the final Delphi round, the results of all possible $D_xS_xF_xM_x$ combinations were collated and analyzed to validate its use as a decision-making tool and provide an algorithm for treatment (Central Illustration). Four DISFORM dissection types (I-IV) were defined on the basis of an incremental severity of adverse prognosis in the opinion of the expert panel (Table 4).

DISCUSSION

This study was designed to reach consensus on angioplasty-induced femoropopliteal dissection by polling experts in the field of peripheral intervention. Its objective was to create a classification system to facilitate discussion around treatment options and prognosis. Its final product, the DISFORM classification system, combines the angiographic features thought to be of greatest significance and provides a descriptive framework for communication that may assist in the conduct of clinical trials. Moreover, it

TABLE 3 The DISFORM Classification System for Peripheral Artery Dissection

	Parameter	Description	
D	Diameter reduction	D_0	Diameter reduction <50%
		D_1	Diameter reduction ≥50%
S	Spiral shape	S_0	Nonspiral (linear) configuration
		S_1	Any spiral configuration
F	Flow impairment	F_0	FLIPI 0: normal antegrade flow
		F_1	FLIPI 1: reduced antegrade flow
		F_2	FLIPI 2: minor antegrade penetration
		F_3	FLIPI 3: no flow through dissected segment, only collateral filling
M	Morphology	M_0	One single dissection <2 cm in length
		M_1	Multiple dissections <2 cm in length or a single dissection ≥2 cm in length
		M_2	Multiple dissections ≥2 cm in length

Modified from the TIMI (Thrombolysis In Myocardial Infarction) score for coronary arteries (13,14).

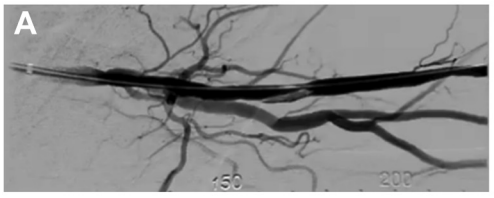
DISFORM = diameter reduction, spiral shape, flow impairment, or adverse morphology; FLIPI = flow impairment in peripheral interventions.

facilitates a decision-making algorithm to aid physicians when they are faced with dissections in their everyday practice. The strengths of DISFORM are that it is applicable to all peripheral angiographic procedures and does not rely on the availability of adjunctive imaging methods such as IVUS. It is designed by peripheral interventionalists specifically for use in femoropopliteal arteries and requires little additional training to incorporate into clinical practice.

Although several other classification systems have been used for arterial dissection, each has had its limitations. Some were developed as tools to guide coronary interventions, and although translation to the peripheral circulation is possible, experts agree that there are distinct and important differences between peripheral and coronary arteries that make several features of coronary dissection less relevant. The National Heart, Lung, and Blood Institute percutaneous transluminal coronary angioplasty classification system has been used to describe angioplasty-induced dissection of peripheral arteries since it was first described in 1985 (7). It distinguishes 6 categories (A-F), ranging from simple linear to spiral morphologies. It includes contrast extravasation as a separate category, as well as persistent filling defect and total occlusion of the target vessel. Although progression from A to F is often considered to be of incremental severity, it was not intended to be used as a guideline for additional therapies or as a treatment algorithm. Some suggest the National Heart, Lung, and Blood Institute classification is too complex to be applied in routine daily practice and that several of its coronary features are not relevant to femoropopliteal arteries, which have distinct differences, including length, diameter, burden of disease, and exposure to significant external forces during mobilization. This led to the simplified classification system developed by Kobayashi et al (10) specifically for peripheral artery interventions (10). It consists of 3 categories that are based on digital subtraction angiography: group A, in which there is no angiographic dissection; group B, in which there is mild dissection (the width of the dissection is less than one third of the lumen); and group C, severe dissection, in which the width of the dissection is more than one third of the lumen. Spiral dissection is included in group C. This system's simple design was intended to facilitate wide adoption in everyday practice, but its lack of detail limits its utility in differentiating features experts recognize as having prognostic value and its use in clinical research as a method of categorization.

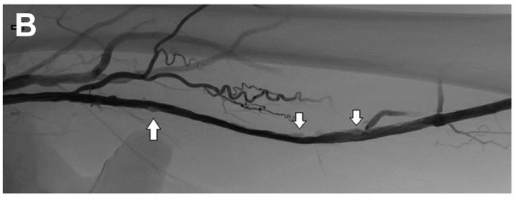
The use of IVUS as an adjunct to angiography for the evaluation of dissection has grown in popularity, as it provides information that may accurately determine both the depth and degree of arterial injury, as well as differentiating among plaque, thrombus, and intramural hematoma. A Dutch study performed both qualitative and quantitative analyses investigating the use of IVUS (9). The qualitative analysis evaluated vascular wall damage, classifying the degree of injury as atherosclerotic plaque radial tear of the intimal surface, dissection (a radial tear separating the lesion from the underlying arterial wall), and/or medial rupture. The extent of dissection was then quantified and classified into 1 of 4 groups (absent, minor, moderate, and severe) as determined by 30° incremental arcs of the blood vessel circumference in cross section. Although this system provides a framework to classify the degree and extent of dissection, it is limited in its description of other features thought to be clinically important, including length, luminal diameter reduction, and spiral morphology. The more contemporary iDissection grading system is an alternative IVUS-based method proposed by Shammas et al (8). It consists of 6 dissection grades that combine depth of injury (from intima to adventitia) with circumference of dissection (<180° or ≥180°), features known to influence clinical outcomes. However, iDissection also failed to consider the length of the dissection, presence of thrombus, spiral morphology, and flow. Although IVUS has been shown to identify dissections at higher frequency and in greater detail than conventional angiography, it is not available to all interventionalists, it is more challenged in evaluating flow patterns, and its interpretation requires both skill and experience (11,15). It is therefore not universally applicable and is likely to remain an

FIGURE 3 Examples of the DISFORM Classification System for Femoropopliteal Artery Dissection



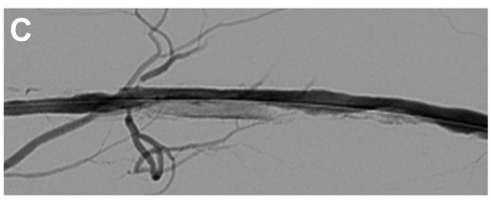
Diameter Reduction ≥50%	Yes
Spiral Shape	No
FLIPI Grade	0
Morphology	Single <2cm

$D_1S_0F_0M_0$



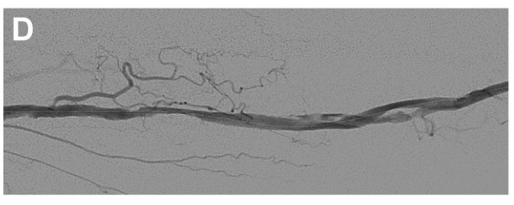
Diameter Reduction ≥50%	No
Spiral Shape	No
FLIPI Grade	0
Morphology	Multiple <2cm

$D_0S_0F_0M_1$



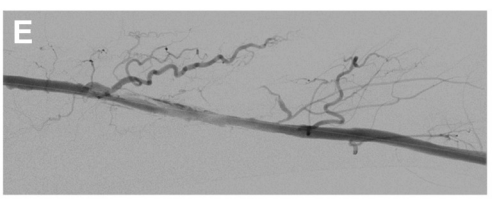
Diameter Reduction ≥50%	Yes
Spiral Shape	No
FLIPI Grade	1
Morphology	Single ≥2cm

$D_1S_0F_1M_1$



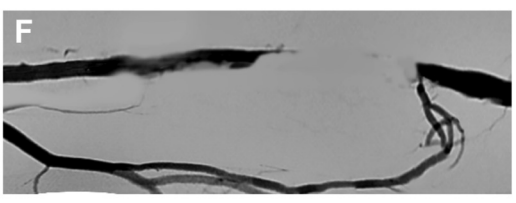
Diameter Reduction ≥50%	Yes
Spiral Shape	Yes
FLIPI Grade	1
Morphology	Multiple >2cm

$D_1S_1F_1M_2$



Diameter Reduction ≥50%	Yes
Spiral Shape	Yes
FLIPI Grade	2
Morphology	Single ≥2cm

$D_1S_1F_2M_1$



Diameter Reduction ≥50%	Yes
Spiral Shape	No
FLIPI Grade	3
Morphology	Single ≥2cm

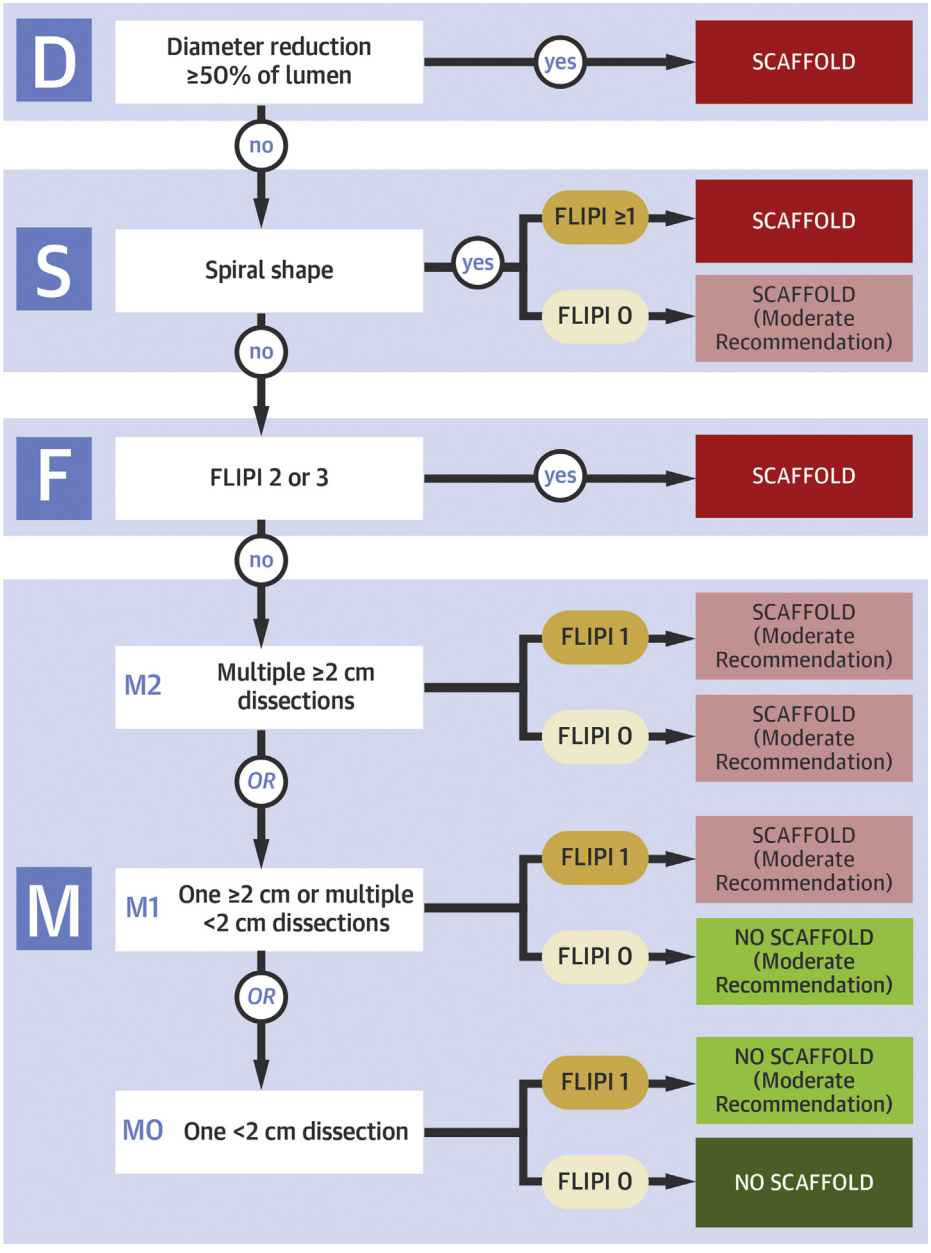
$D_1S_0F_3M_1$

Dissections increase in severity from **A to F.** DISFORM = diameter reduction, spiral shape, flow impairment, or adverse morphology; FLIPI = flow impairment in peripheral interventions.

adjunctive imaging modality for the foreseeable future. It is our view that a grading system for peripheral artery dissection must rely on angiographic imaging, be specific to the arteries of the periphery, and be underscored by expert opinion if it is to be universally accepted.

The newly proposed DISFORM classification system satisfies those criteria and can be used in several ways. The first is as a descriptive classification tool. Akin to CEAP (clinical, etiologic, anatomical, pathophysiological) for chronic venous insufficiency (16) and the TNM (tumor, node, metastasis) system

CENTRAL ILLUSTRATION **Flowchart for Management of Postangioplasty Dissections of the Femoral and Popliteal Arteries**



Voûte, M.T. et al. J Am Coll Cardiol Intv. 2021;14(21):2391–2401.

Red and pink boxes represent a recommendation to scaffold (**red**, strong recommendation, >80% agreement; **pink**, moderate recommendation, >50%-80% agreement). **Green boxes** represent a recommendation to not scaffold (**dark green**, strong recommendation, ≤20% agreement to scaffold; **light green**, moderate recommendation, >20%-50% agreement to scaffold). FLIPI = flow limitation in peripheral intervention.

commonly used for the classification of malignant tumors (17), DISFORM gives each individual dissection a morphologic and pathophysiological classification ($D_xS_xF_xM_x$). This provides a checklist of critical dissection features that conveys complex detail to the physician while requiring only a modest understanding of system definitions. The second is as an incremental ranking tool that provides a framework

TABLE 4 DISFORM Recommendations for the Classification and Treatment of Peripheral Artery Dissections of Femoropopliteal Arteries

Dissection Type	Description	DISFORM Grade	Panel Scaffold Recommendation	Recommendation to Scaffold
DISFORM I	• Short (<2-cm), linear dissection and • No diameter reduction and • No flow impairment	$D_0S_0F_0M_0$	No	≤20%
DISFORM II	• No diameter reduction ≥50% and • Linear dissection and Either: • 1 long or multiple short (<2-cm) dissections with no flow impairment or • 1 short (<2-cm) dissection with minor flow impairment	 $D_0S_0F_0M_1$ $D_0S_0F_1M_0$	No (moderate strength)	>20 to ≤50%
DISFORM III	• No diameter reduction ≥50% and Either: • A single short (<2-cm) spiral dissection without flow impairment or • 1 long or multiple short (<2-cm) linear dissections with minor flow impairment or • Multiple long linear dissections with either no or minor flow impairment	 $D_0S_1F_0M_0$ $D_0S_0F_1M_1$ $D_0S_0F_{0\text{-}1}M_2$	Yes (moderate strength)	>50 to ≤80%
DISFORM IV	Any of: • Diameter reduction ≥50% or • Severe flow impairment or • Spiral morphology with any flow impairment	Any D_1 or F_2-F_3 S_1 if associated with F_1-F_3	Yes	>80% to 100%

DISFORM = diameter reduction, spiral shape, flow impairment, or adverse morphology.

to consider the potential of any dissection to result in adverse clinical outcomes, such as acute occlusion or restenosis. It uses the panel's expertise to rank those risks and recommend guidance around the use of additional scaffolds to prevent those outcomes. This is given in the form of a pragmatic treatment algorithm designed for clinical application. The final intended use of the system is to use the grading system (I-IV) as a tool in the conduct of clinical trials. It is designed to separate dissection categories according to perceived severity and risk for adverse outcomes in a simple and intuitive way that can be easily understood and interpreted during an enrollment procedure within a clinical study.

It is important to stress that DISFORM remains a descriptive classification only. This contrasts with measures of patency, target lesion revascularization, and quality of life, which are designed to be objective outcome assessment instruments for longitudinal research. Like any classification system, DISFORM requires validation studies to evaluate it against conventional efficacy endpoints to determine its accuracy in predicting the risk for adverse clinical outcomes. Future research may take the form of natural history studies that follow patients over time to determine whether DISFORM grade is truly predictive of restenosis and target lesion failures that result in reintervention. Such studies may be retrospective, whereby dissections left without scaffolding are subsequently evaluated, or longitudinal prospective studies designed to follow a cohort of dissection outcomes over time.

STUDY LIMITATIONS. First, as with all studies using Delphi consensus methodology, our data are subjective by nature. However, although not directly supported by clinical data, expert opinion is frequently used to define and develop classification systems. Delphi consensus studies should be viewed as a method of expert opinion gathering prior to further scientific validation.

Second, adverse outcomes such as acute failure and restenosis are influenced by more than the angiographic features of dissection. Arterial inflow, runoff, cardiac output, hypercoagulability, elastic recoil, blood vessel calcification, and resistance to heparin and/or antiplatelet agents are just a few factors that may affect outcomes in the short term and mid-term. DISFORM does not take account of those.

Third, flow across a dissection is difficult to quantify and can be dynamic. A dissection may not limit flow in a resting state but become significant upon exercise. Another dissection may have a mobile flap that is unrecognized during procedural angiography

but lifts to cause acute occlusion after the completion of the intervention. Moreover, although most interventionalists can recognize flow reduction on cine angiography, all are challenged when it comes to providing a clear and objective definition. The panelists favored the use of a modification of the well-established TIMI system used in coronary arteries. Although all methods of flow determination are imperfect, the panelists believed that this provided the best general description of flow across the lesion with the least risk for subjective interpretation.

Fourth, we removed translesional pressure gradient from our model, as the panelists raised concerns around limited availability, demonstrated validity, and the definition of a significant gradient. However, most agreed that it was likely to have value in predicting adverse outcomes. Although not ultimately included in the DISFORM system, pressure gradient may be used to complement it for those interventional laboratories that have access.

Finally, nonstent technologies such as drug-coated balloon therapy and atherectomy may affect outcomes. These may affect early restenosis and have not been considered in DISFORM, which is focused solely on features of dissection.

CONCLUSIONS

The Delphi consensus panel determined that significant diameter reduction, spiral morphology, flow impairment, and the length and number of dissections were key features to consider when evaluating a dissection following angioplasty of the femoral and popliteal arteries. The combination of these is critical to determine which dissection is likely to lead to adverse clinical outcomes. DISFORM provides a universally applicable, common language to describe those dissections on the basis of a morphologic and pathophysiological description method, an incremental risk rating grade, and a pragmatic treatment algorithm.

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Dr Schneider is a medical advisory board member for Medtronic, Boston Scientific, and Philips; and consultant for Surmodics, Silk Road Medical, Medtronic, Cardiovascular Systems Inc, Cagent, CTI Vascular Ag, Illuminate, Intervene, Limflow, and Devoro. Dr Thomas is a consultant for Abbott Vascular, Medtronic, and Philips Healthcare. Dr Brodmann is a consultant for BD Bard, Philips, Medtronic, Boston Scientific, Biotronik, Cook Medical, Cagent, Shockwave, MedAlliance, Soundbite, Reflow Medical, and Bayer Healthcare. Dr Armstrong is a consultant for Abbott Vascular, Boston Scientific, Cardiovascular Systems, Medtronic, Philips Healthcare, PA Bypass, and Shockwave. Dr Holden is a medical advisory board member for Gore, Boston Scientific, Philips Healthcare, and Medtronic; and is a clinical investigator for Cook, BD Bard, Shockwave, Intact Medical, Surmodics, Cagent, and Trireme Medical. Dr Varcoe is a consultant for Abbott Vascular, Intact Medical, Shockwave, Medtronic, BD Bard, Philips Healthcare, Surmodics, and Intervene. All paid honoraria were modest. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

WHAT IS KNOWN? When treating peripheral atherosclerotic disease, postangioplasty dissections are commonly encountered. Current classification systems of such dissections are nonspecific to the peripheral arteries, are overly simplistic, or require adjunctive intravascular imaging. There is no femoropopliteal-specific, angiography-based classification system for postangioplasty dissections and no treatment algorithm for clinicians to refer.

WHAT IS NEW? Key features of postangioplasty dissections were identified using the Delphi consensus method, interrogating a multidisciplinary, international panel of 17 interventional specialists. These data were used to develop a novel pathophysiological classification system (DISFORM) that is based on angiography alone. Furthermore, recommended management strategies were developed for lesion scaffolding over conservative treatment.

WHAT IS NEXT? The DISFORM classification system is a new uniform reporting standard for describing and comparing dissections for both scientific and practical clinical applications. It now requires validation studies to establish its utility for that purpose.

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APPENDIX For a list of Delphi panelists, please see the online version of this paper.