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Complications and Failure Modes of Polymer-Jacketed Guidewires; Insights From the MAUDE Database

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Complications and Failure Modes of Polymer-Jacketed Guidewires; Insights From the MAUDE Database

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ABSTRACT

Background: The modes of failure of coronary polymer-jacketed guidewires have received limited study.
Methods: We queried the Manufacturer and User Facility Device Experience (MAUDE) database between January 2011 and December 2020 for reports on coronary polymer-jacketed guidewires and retrieved 254 reports.
Results: The most common failure mode was failure of the guidewire to cross (36.2%), followed by guidewire fracture (35%), peeling of the polymer jacket (13.8%), failure to retrieve the guidewire (13.8%), and guidewire unraveling (4.7%). Guidewire fracture was more common with soft (37.3%) compared with stiff (23.8%) guidewires. Failure of retrieval was only reported with soft guidewires (9%). Coronary perforation and dissection occurred in 19.7% and 7.9% of the reports, with more reports with stiff as compared with soft guidewires (45.2% vs. 14.6% for perforation and 21.4% vs. 5.3% for dissection).
Conclusions: The most common failure modes of polymer-jacketed guidewires during percutaneous coronary intervention are failure to cross the lesion, guidewire fracture, and peeling of the polymer jacket. Coronary perforations were more common with stiff whereas wire fracture was more common with soft polymer-jacketed guidewires.

1. Introduction

Polymer-jacketed guidewires are widely used in percutaneous coronary intervention (PCI) to facilitate advancement through tortuous and severe lesions. They are frequently the first guidewire utilized for crossing chronic total occlusions (CTOs) [1,2]. The first polymer-jacketed guidewire was introduced in 1995 (Choice® PT (Boston Scientific, MA, USA)) followed by multiple guidewires of different tip stiffness by various manufacturers. Polymer-jacketed guidewires may increase the risk of perforation but there is limited data on their limitations and complications. We used the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) registry to examine the mode of failure and complications of polymer-jacketed guidewires.

2. Materials and methods

The FDA's MAUDE database is a database of adverse events caused by an approved medical device. The MAUDE is an online database with either mandatory (for manufacturers and device user facilities) or voluntary (for healthcare professionals, patients, and consumers) reporting. We searched the database from January 2011 to December 2020 for reports on coronary polymer-jacketed wires [soft non-tapered wires (Whisper, Pilot 50 (Abbott Vascular)), Fielder FC, and Sion black (ASAHI Intecc, Japan)], [soft tapered wires (Fielder XT, Fielder XTA, Fielder XTR (ASAHI Intecc, Japan)), Bandit (Teleflex, USA), and Fighter (Boston Scientific, USA)], and [stiff non-tapered wires (Pilot 200 (Abbott Vascular, USA)), Gladius or Gladius Mongo (Asahi Intecc, Japan), and Raider (Teleflex, USA)].

The database was last accessed on January 2nd, 2021, by two independent reviewers (RM and MM). The MAUDE database is publicly

Abbreviations: MAUDE, Manufacturer and User Facility Device Experience database; PCI, percutaneous coronary intervention.

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available and de-identified; therefore, no institutional review board approval was required for this study. We compared the mode of failure between soft and stiff polymer-jacketed guidewires and between soft tapered and soft, non-tapered guidewires.

2.1. Outcomes and statistical analysis

The primary outcome of this study was the mode of failure of coronary polymer-jacketed guidewires. Secondary outcomes included clinical consequences of device failure. Categorical variables were described as numbers and percentages and compared using Pearson's chi-square or Fisher's exact tests. A value of $p < 0.05$ was considered significant, and p-values are two-sided where possible. All statistical calculations were performed with IBM SPSS Statistics for Mac, Version 26.0. Armonk, NY: IBM Corp (2020).

3. Results

We found a total of 423 reports during the study period. After excluding non-coronary ($n = 145$), duplicate and irrelevant cases ($n = 24$), our final cohort included 254 reports of coronary polymer-jacketed guidewire failure. Of those, 42 were for stiff and 212 for soft guidewires (tapered wires $n = 76$, non-tapered wires $n = 136$). The study flow chart is shown in Fig. S1. The number of events reported for each category per year is shown in Fig. S2.

3.1. Modes of failure and clinical outcomes

The most common failure mode was failure to cross (36.2%), followed by wire fracture (35%) and peeling of the polymer jacket (13.8%) (Table 1, Fig. 1). Failure to retrieve the guidewire was reported in 13.8%, and guidewire unraveling in 4.7%. Guidewire fracture was more commonly reported with soft (37.3%) as compared with stiff guidewires (23.8%). Retrieval failure was exclusively reported with soft guidewires (9%). There was no difference in wire unraveling or peeling of the polymer jacket between soft and stiff guidewires. Snaring was used in 11.8% of the reports, and the wire was covered by a stent in 10.6%. The wire was left inside the patient in 9.1% of the reports. There was no difference in the mechanisms of failure reported for the tapered vs. non-tapered soft wires (Table S1).

Coronary perforation and dissection occurred in 19.7% and 7.9% of the reports, and were more common with stiff guidewires (45.2% vs. 14.6% and 21.4% vs. 5.3%, respectively). Pericardial effusion occurred in 3.9% of the reports with a higher incidence with stiff wires. Covered stents were used in 49 out of 50 reports of coronary perforation. Surgical intervention was needed in 7.9% of cases, and death occurred in 7.9% of the reports. Failure mechanisms and clinical outcomes of each wire are shown in Table S2.

Specific wire failure modes are shown in Table S3. For the Pilot family, wire fracture represented 41% of Pilot 50 reports and 23% of Pilot 200 reports. Peeling of the polymer jacket was reported in 12.5% of Pilot 50 reports and 23% of Pilot 200 reports. No guidewire unraveling was reported for the Pilot family. There were no reports of coronary perforation with Pilot 50 and only one report with Pilot 200. Within the Fielder family, wire perforation was most common with the Fielder XT (18%) with 0% incidence in the Fielder XTA or XTR. Fracture of the Sion black wire occurred in 38% of the reports and peeling of the polymer jacket in 23.8%. The incidence of coronary perforation with the Sion black guidewire was 19%.

Table 1
Reports of polymer-jacketed guidewire failure in the MAUDE registry classified according to tip stiffness.

	Overall ($n = 254$)	Soft ($n = 212$)	Stiff ($n = 42$)	P-value
Vessel treated				
LAD, n (%)	86 (33.9)	70 (33)	16 (38.1)	0.525
LCX, n (%)	42 (16.5)	38 (17.9)	4 (9.5)	0.181
OM, n (%)	8 (3.1)	7(3.3)	1 (2.4)	0.755
RCA, n (%)	91 (35.8)	74 (34.9)	17 (40.5)	0.492
PDA, n (%)	9 (3.5)	8 (3.8)	1 (2.4)	0.656
LIMA, n (%)	1 (0.4)	1 (0.5)	0 (0)	0.656
Unknown, n (%)	17 (6.7)	14 (6.6)	3 (7.1)	0.898
Lesion characteristics				
Calcified, n (%)	144 (56.7)	112 (52.8)	32 (76.2)	0.005
CTO, n (%)	96 (37.8)	62 (29.2)	34 (81)	<0.001
Tortuous, n (%)	76 (29.9)	67 (31.6)	9 (21.4)	0.188
Modes of failure				
Failure to cross, n (%)	92 (36.2)	67 (31.6)	25 (59.5)	<0.001
Wire fracture, n (%)	89 (35)	79 (37.3)	10 (23.8)	0.095
Peeling of the polymer jacket, n (%)	35 (13.8)	31 (14.6)	4 (9.5)	0.381
Failure of retrieval, n (%)	19 (7.5)	19 (9)	0 (0)	0.044
Wire unraveling, n (%)	12 (4.7)	9 (4.2)	3 (7.1)	0.419
Complications				
Perforation, n (%)	50 (19.7)	31 (14.6)	19 (45.2)	<0.001
Dissection, n (%)	20 (7.9)	11 (5.3)	9 (21.4)	<0.001
Pericardial effusion, n (%)	10 (3.9)	6 (2.8)	4 (9.5)	0.042
Hemodynamic collapse, n (%)	8 (3.1)	4 (1.9)	4 (9.5)	0.010
Tamponade, n (%)	4 (1.6)	2 (1.5)	0 (0)	0.541
Myocardial infarction, n (%)	4 (1.6)	4 (1.9)	0 (0)	0.370
Stroke, n (%)	3 (1.2)	1 (0.4)	2 (0.8)	0.019
Wire embolization, n (%)	2 (0.8)	2 (0.9)	0 (0)	0.527
Stent thrombosis, n (%)	1 (0.4)	1 (0.5)	0 (0)	0.656
Arrythmia, n (%)	2 (0.8)	2 (1.5)	0 (0)	0.417
Management				
Wire exchange, n (%)	67 (26.4)	60 (28.3)	7 (16.7)	0.118
Covered stent, n (%)	49 (19.3)	30 (14.2)	19 (45.2)	<0.001
Observation, n (%)	36 (14.2)	33 (15.6)	3 (7.1)	0.153
Snare, n (%)	30 (11.8)	27 (12.7)	3 (7.1)	0.305
Wire jailed with a stent, n (%)	27 (10.6)	24 (11.3)	3 (7.1)	0.422
Left inside patient, n (%)	23 (9.1)	21 (9.9)	2 (4.8)	0.289
Unknown, n (%)	17 (6.7)	12 (5.7)	5 (11.9)	0.139
Change of CTO technique, n (%)	2 (0.83)	2 (0.9)	0 (0)	0.527
Outcome				
No adverse events, n (%)	194 (76.4)	165 (77.8)	29 (69)	0.221
Procedure aborted, n (%)	20 (7.9)	16 (7.5)	4 (9.5)	0.664
Surgical conversion, n (%)	20 (7.9)	20 (9.4)	0 (0)	0.038
Death, n (%)	20 (7.9)	11 (5.2)	9 (21.4)	<0.001

LAD = left anterior descending artery; LCX = left circumflex artery; OM = obtuse marginal artery; RCA = right coronary artery; PDA = posterior descending artery; LIMA = left internal mammary artery; CTO = chronic total occlusion.

4. Discussion

Our study is the first to report the modes of failure of coronary polymer-jacketed guidewires. The main findings can be summarized as follows: 1) the most commonly reported failure modes of coronary polymer-jacketed guidewires were failure to cross the lesion followed by guidewire fracture and peeling of the polymer jacket, and 2) as compared with soft guidewires stiff guidewires were often associated with coronary perforation, dissection, pericardial effusion, and need for covered stents.

Polymer-jacketed guidewires are frequently used in complex PCI, as they are lubricious and can often negotiate significant tortuosity and advance through highly stenosed or 100% lesions. [3] In this study, they were further categorized as stiff or soft wires. Stiff polymer-jacketed guidewires have high tip-load with high penetration power. They are non-tapered and mainly used for CTO PCI. The soft polymer-jacketed wires are designed to track microchannels and navigate tortuosity, and are often the first guidewires used for antegrade CTO crossing. They can be either tapered or non-tapered.

In our analysis, the most common mode of failure was failure to cross the lesion, which is not an adverse event. Failure to cross was reported in 59.5% of the stiff wires reports and 31.6% in the soft wires reports. Failure to cross is not unexpected and is likely related to high lesion complexity (76.2% calcified lesions, 81% CTOs).

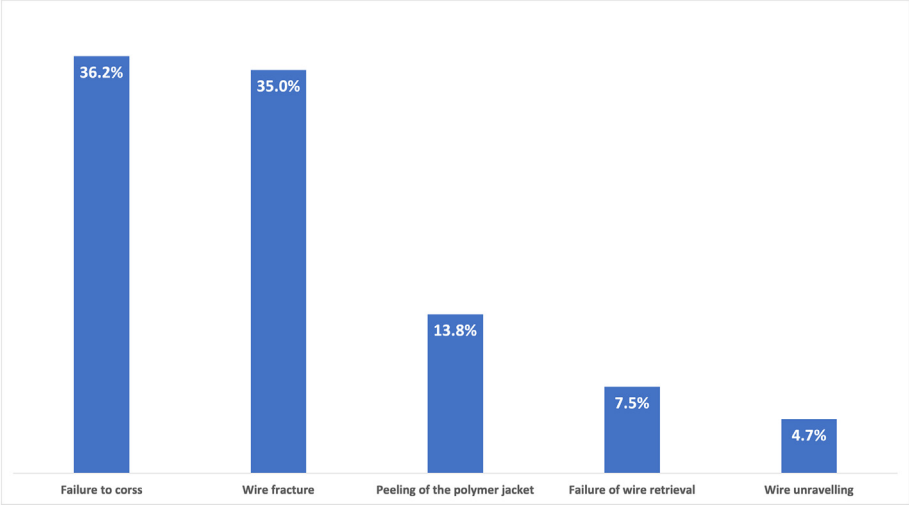

Fig. 1. Failure modes of coronary polymer-jacketed wires as reported to the MAUDE registry.

Guidewire fracture occurred in 35% of the reports and was more common with soft guidewires. It may be related to aggressive guidewire manipulation (polymer-jacketed guidewires are often knuckled to facilitate extraplaque CTO crossing). Sometimes leaving the guidewire fragment within the coronary artery and covering it with a stent may be safer than attempting retrieval, which however may be necessary if the guidewire fragment fratgprotrudes into the aorta [4].

Given the nature of the polymer-jacketed wires, abrasive surfaces such as severe calcification at bends and stent struts jailing polymer-jacketed wires can strip the polymer of the guidewire. In our analysis, peeling of the polymer jacket was reported in 13.8% of cases. The peeled off polymer may embolize into the microvasculature, causing myocardial infarction [5]. Pan et al. reported that during bifurcation stenting, jailed polymer-jacketed wires were more resistant to retrieval damage and more efficient in crossing the side branch ostium than non-polymer-jacketed wires [6]. The question of whether to jail polymer-jacketed vs. non-polymer-jacketed wires during bifurcation stenting is beyond the scope of our study.

In our analysis, the occurrence of coronary perforation or dissection was high with the use of stiff polymer-jacketed wires (45.2% of the reports). In contrast, perforation with soft wires was reported in 14.6%. Although polymer jacketed guidewires are considered safer than non-polymer jacketed stiff guidewires they can still cause coronary perforations, especially if a balloon or microcatheter is advanced over the guidewire after it exits from the vessel architecture [7,8]. The perforation site was not consistently reported, and therefore, could not be analyzed. In our analysis, covered stents were used in 49 out of 50 reports of coronary perforations caused by polymer-jacketed wires. Use of orthogonal projections to verify the guidewire course before advancing equipment over it is critical. The polymer-jacketed guidewire should be replaced by a workhose guidewire after successful crossing to minimize the risk of distal coronary perforation.

4.1. Limitations

Our study is limited by selection bias resulting from the retrospective analysis from the MAUDE and selective optional reporting by healthcare professionals. Second, the incidence of each device's mode of failure cannot be determined as the study lacks a denominator. Third, details on the sites of perforation (e.g., vessel body, distal vessel, etc.) and microcatheter-induced perforations are not consistently reported and therefore could not be analyzed. Finally, a correlation between the device failure and clinical adverse events cannot be accurately determined (e.g., coronary perforation requiring covered stents can be due to microcatheter advancement rather than the wire itself).

4.2. Conclusions

The most common failure modes of polymer-jacketed guidewires during percutaneous coronary intervention are failure to cross the lesion, guidewire fracture, and peeling of the polymer jacket. Coronary perforations were more often reported with stiff polymer-jacketed guidewires.

CRediT authorship contribution statement

Michael Megaly: conceptualization, Development or design of methodology, statistical analysis, writing the initial draft.

Ramez Morcos: data curation, development or design of methodology.

Michael Kucharik: data curation.

Mariam Tawadros: data curation.

Mir B. Basir: critical review, commentary, and revision.

Ashish Pershad: critical review, commentary, and revision.

Brijeshwar Maini: critical review, commentary, and revision.

Houman Khalili: critical review, commentary, and revision.

Khaldoon Alaswad: critical review, commentary, and revision.

Emmanouil S. Brilakis: Conceptualization oversight and leadership responsibility for the research activity planning and execution. critical review, commentary, and revision.

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Declaration of competing interest

Khaldoon Alaswad: consulting/speaker honoraria from Boston Scientific, Cardiovascular Systems Inc., Abbott Vascular, Teleflex.

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Emmanouil Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Asahi Intecc, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), ControlRad, CSI, Ebix,

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Appendix A. Supplementary data

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