Original Article

Stent dislodgement force of drug-eluting coronary stents: a bench test

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Background: Coronary stent dislodgement can cause critical complications. The dislodgement force of coronary drug-eluting stents (DES) remains unknown. This study aimed to compare the dislodgement force and pattern of contemporary DES.

Methods: Five DES designs which commonly used in clinical practice were tested. The force at which the stent dislodges relative to the balloon was measured. For the shim test, peak displacement force, defined as the first peak force that occurs during stent displacement and peak dislodgement force, defined as the peak force required to completely dislodge the stent from the delivery system, were measured. Three examples of each of the stents were tested using the shim test.

Results: The peak displacement force of Orsiro (3.1±0.8 N) was lower than that of Xience Sierra (5.8±0.5 N) [Firehawk 3.8±0.2 N, Resolute Onyx 4.5±1.5 N, Synergy 4.8±0.5 N (P=0.024)]. The peak dislodgement force was lowest in Orsiro (3.2±0.8 N) when compared to the other stents (Firehawk 6.6±0.6 N, Resolute Onyx 7.4±0.3 N, Synergy 11.8±0.4 N, Xience Sierra 11.1±1.6 N) (P<0.001); this remained significant in the multiple comparison analysis. During pullback of the stents, most stents buckled without removal. However, the whole Orsiro stent was completely removed from the delivery system.

Conclusions: The dislodgement force of DESs differed between stent designs. The Orsiro stent was lower than that of other DES; additionally, it easily removed the whole stent from the delivery system. During the coronary intervention, operators should consider stent design and be cautious when pulling DES back in lesions with calcifications or a previously implanted stent, which are at high risk for stent dislodgement.

Keywords: Stent dislodgement; drug-eluting stent (DES); complication

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Introduction

Stent dislodgement is a serious complication during percutaneous coronary interventions (PCIs). It can cause coronary artery embolization, stent thrombosis, and acute myocardial infarction (MI). Moreover, if a lost stent moves outside of the coronary artery, it may cause cerebral infarction or peripheral artery occlusion. Stent dislodgement is related to poor clinical outcomes, including death, emergency coronary artery bypass surgery, and bleeding complications requiring transfusion, and long-

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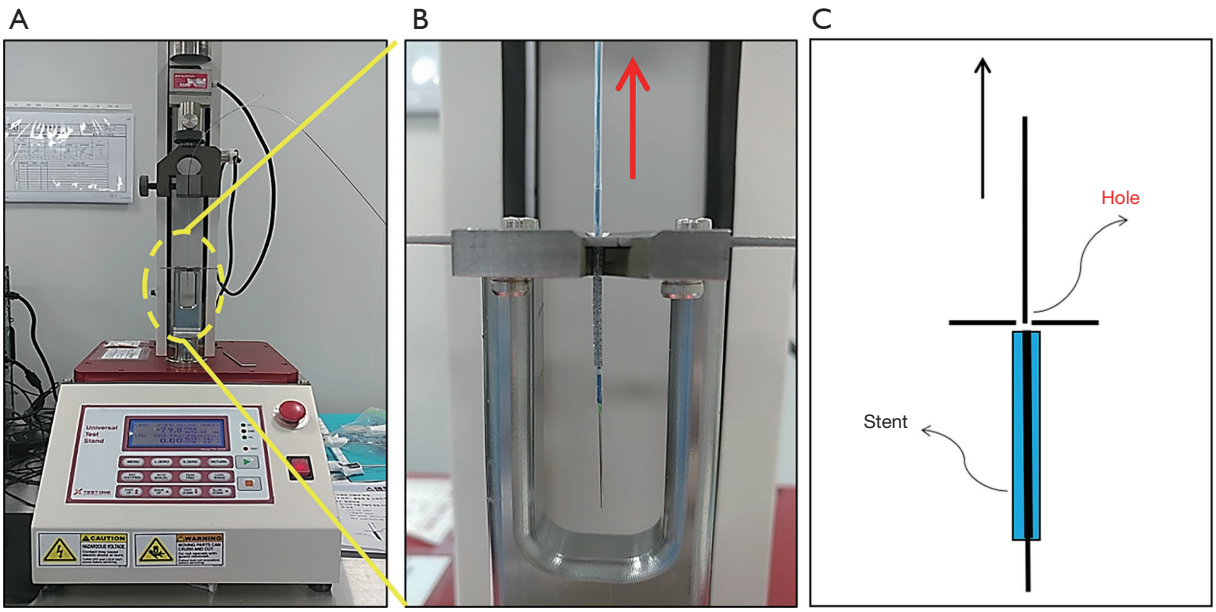


Figure 1 Stent dislodgement bench test. (A) Universal testing machine. (B) Expanded figure of yellow circle. The stents were dislodged from the proximal to the distal tip of the stent delivery system at a speed of 20 mm/min. For the shim test, the stent delivery system shaft fixed on the jig while the other segment captured the stent's proximal edge. (C) Schematic diagram of bench test. Arrow = pulling direction of shaft.

term target lesion failure (1-3).

In the drug-eluting stents (DES) era, the incidence of coronary stent dislodgement has decreased to <1% compared to that in the bare metal stent era (1.5–3%) (1,2,4-7). Several coronary lesion factors are related to stent dislodgement such as heavily calcified coronary lesions, severely tortuous vessels, long diffuse lesions, ostial lesions, and previously implanted stents (2,5). Unlike characteristics associated with the coronary lesion, the relationship between stent dislodgement and device factors, such as different stent designs, stent strut thickness, and metal platforms, is not well understood.

A recent study found that the use of thin strut stents is related to a higher incidence of stent dislodgement than thick strut stents (2). The thin strut stent improved crossability and trackability, however, it might increase the risk of stent dislodgement. To determine the relationship between stent dislodgement and coronary stent factor, this study aimed to evaluate the dislodgement force of DES using a bench test.

Methods

We performed the bench test to measure the force at which coronary stents were dislodged. Additionally, a movie was recorded to observe the stent dislodgement pattern during the test. This study was a bench test and thus did not include humans, therefore, it did not require institutional review board approval.

Measurement of dislodgement force

Dislodgment force is the force required to completely dislodge the stent from the balloon on delivery system. According to the American Society for Testing and Materials (ASTM) F2394-07 recommendations (Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System), we performed a guide-type stent securement test using the shim test. The stent system was mounted in a universal testing machine (UTM 5966, Instron, Norwood, MA) with a 50N force load cell (*Figure 1A*). The stent was dislodged from the proximal to the distal tip of the stent delivery system at a speed of 20 mm/min. The force at which the stent started to dislodge relative to the balloon was measured and recorded. The stent delivery system shaft was fixed on the jig while the other segment captured the stent proximal edge (*Figure 1B,1C*). To avoid affecting the contact between the stent and balloon

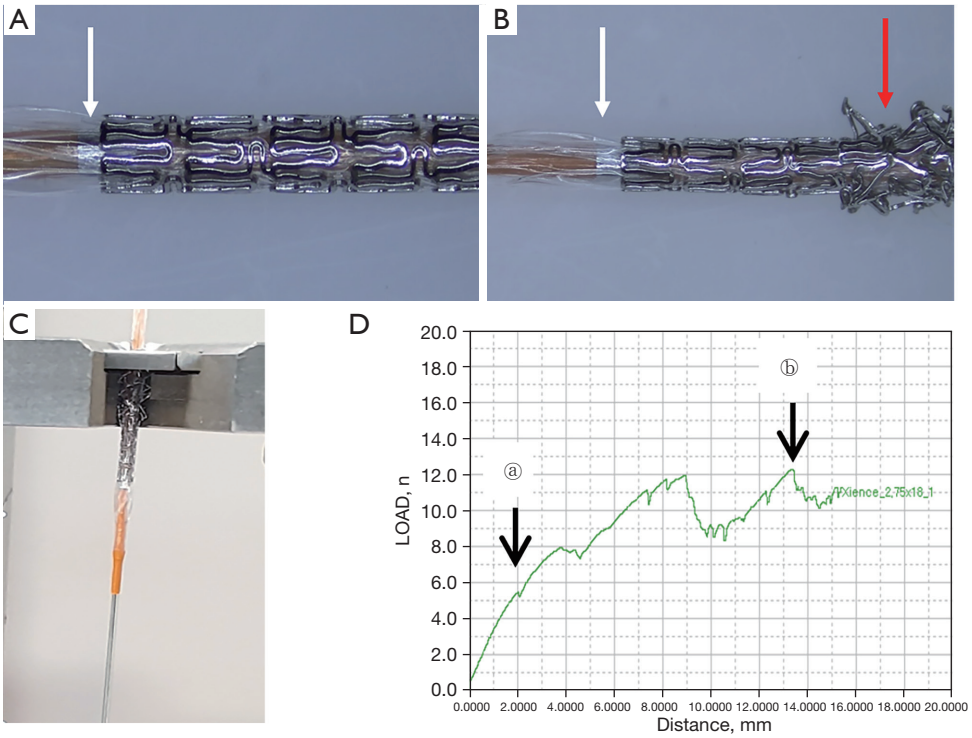


Figure 2 A demonstration of the bench test using Xience Sierra 2.75×18 mm. (A) The stent before the dislodgement test, and (B) after the dislodgement test. The silver marker on the left side (white arrow) represents the stent's distal marker, and that on the right side represents a dislodged stent (red arrow). (C) During the dislodgement test, the stent was pulled back from proximal site, and thus dislodged from there. (D) Measurement of the dislodgement force. The peak displacement force, which was the first sudden drop in force, was 5.5 N (ⓐ) and the peak dislodgement force was 12.3 N (ⓑ). N, Newtons.

during the measurement of stent dislodgment force, we measured the profile of the balloon catheter and adjusted the hole size according to each balloon diameter size. Also, we performed one sample test to confirm the force was not measured during withdrawal in the balloon part.

The initial peak displacement and peak dislodgement forces were measured in this study. Initial peak displacement force was defined as the first peak in force that occurred during or after stent displacement with respect to the balloon, and peak dislodgement force was defined as the peak or maximum force required to completely dislodge the stent from the delivery system balloon according to the ASTM F2394-07 recommendations.

Stent platforms

Five designs of the commercially available DES which were most commonly used in Korea were evaluated using Firehawk 2.75×18 mm (Shanghai Microport Medical Group, China), Orsiro 2.75×18 mm (Biotronik, Bülach, Switzerland), Resolute Onyx 2.75×18 mm (Medtronic, Santa Rosa, CA), Synergy 2.75×20 mm (Boston Scientific, Natick, MA), and Xience Sierra 2.75×18 mm (Abbott Vascular, Santa Clara, CA). Three examples of each of the stents were tested.

Statistical analysis

The data were presented as means ± standard deviations. The stents were compared using a one-way analysis of variance. Bonferroni multiple comparison test was performed for all pair-wise comparisons. All statistical analyses were performed using SPSS software (version 20.0, SPSS Inc., Chicago, IL). A P value of <0.05 was considered statistically significant.

Results

In total 15 DESs were tested using the shim test. *Figure 2* demonstrated the bench test results using Xience Sierra 2.75×18 mm. *Figure 2A*,*2B* were pictures of the stent before

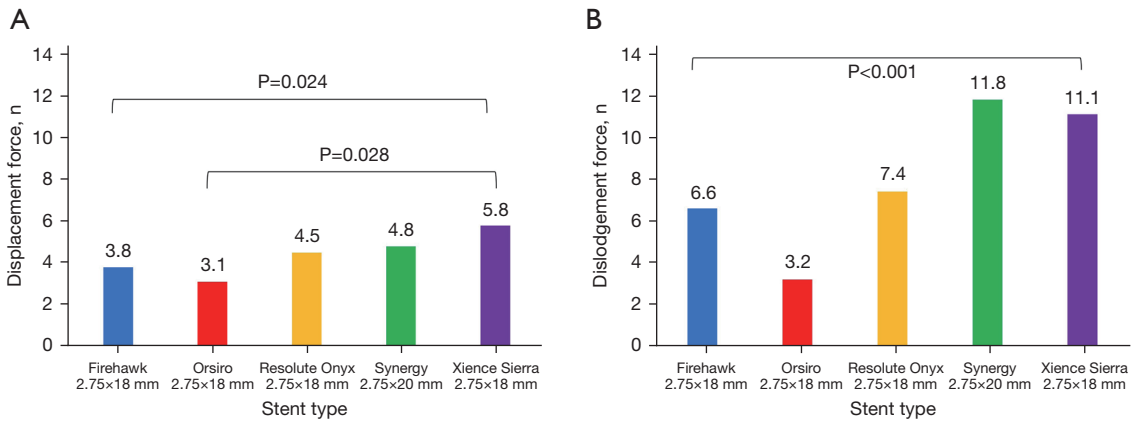


Figure 3 Shim test results. (A) Peak displacement force. The peak displacement force for the Orsiro stent was significantly lower than that for Xience Sierra. (B) Peak dislodgement force. The peak dislodgement force for the Orsiro stent was the lowest among the different stents evaluated (P<0.001). N, Newtons.

and after the dislodgement test. The white arrow on the left side was the distal marker of the stent, and the red arrow on the right side was the dislodged stent. *Figure 2C* displays the dislodgement test when the stent was pulled back from the proximal site, clearly showing that the stent was dislodged at the proximal site. *Figure 2D* showed the dislodgement force graph. The peak displacement force was 5.5 N, which was the first sudden drop of force (ⓐ), and the peak dislodgement force was 12.3 N (ⓑ).

Shim test

The results from the shim test are shown in *Figure 3*. The peak displacement forces were as follows; Orsiro 3.1±0.8 N, Xience Sierra 5.8±0.5 N, Firehawk 3.8±0.2 N, Resolute Onyx 4.5±1.5 N, Synergy 4.8±0.5 N (P=0.024). In the multiple comparison analysis, only the peak displacement force of Orsiro was significantly lower than that of Xience Sierra (P=0.028).

The peak dislodgement force was lowest for Orsiro (3.2±0.8 N) when compared to the other stents (Firehawk 6.6±0.6 N, Resolute Onyx 7.4±0.3 N, Synergy 11.8±0.4 N, Xience Sierra 11.1±1.6 N) (P<0.001). Additionally, the dislodgment force of Orsiro was significantly lower when compared to all other stents in the multiple comparison analysis (P=0.009 for Firehawk, P=0.002 for Resolute Onyx, and P<0.001 for Synergy and Xience Sierra).

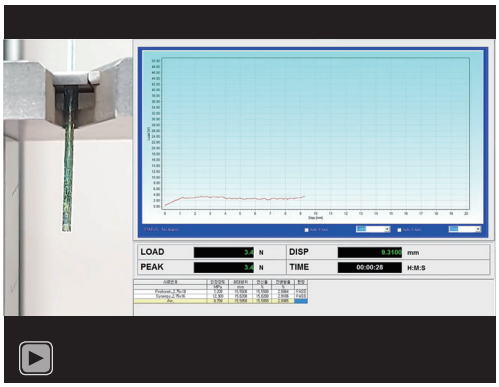
In addition to the dislodgement force itself, the pattern of the stent dislodgement differed. During the pullback of the stents, it was uncommon for the removal of the whole stent from the delivery system, but the stents were commonly buckled from the proximal site. This can be seen in *Video 1* (Xience Sierra 2.75×18 mm). In fact, a buckling phenomenon was observed in all stents except the Orsiro stent, which was easily removed from the delivery system (*Video 2*). *Figure 4* shows the stents after the shim test. The Orsiro stent was dislodged first at the stent's proximal site and then moved the whole stent to the outside of the distal marker (could not be seen distal marker) (*Figure 4A*), however, the other stents (Resolute Onyx, Xience Sierra, Synergy) buckled without moving whole stents, so the stents' distal marker could be seen (*Figure 4B-4D*).

The dislodgement force of most DESs was increased during pullback. The first pressure drop was observed when the proximal portion of the stent was dislodged, after that, the pressure rose again during continuous pullback (*Figure 5*). The force curve of most stents faced the right, upward direction. However, the force was decreased after the peak dislodgement force in the Orsiro stent, suggesting that the entire stent moved to the distal site without resistance (*Figure 5*, red lines for the Orsiro stent).

Discussion

This study evaluated the stent dislodgement force of five DES designs which were commonly used in clinical practice. It was determined that the dislodgement force of DESs differed between stent designs. The peak dislodgement force of Orsiro was the lowest among the tested DESs. Moreover, the whole Orsiro stent was easily removed from the delivery system without buckling, even though a small portion of the stent was broken.

Video 1 Pullback of Xience Sierra stent showed buckling phenomenon at the proximal site without removal of the whole stent from the delivery system.



Video 2 Pullback of Orsiro stent showed removal of the whole stent from the delivery system.

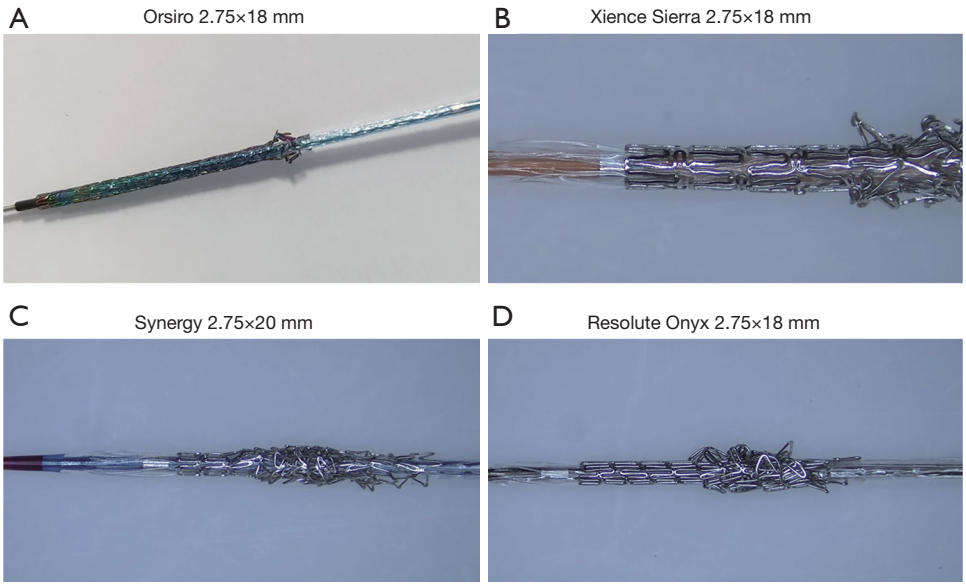


Figure 4 Stents after the shim test. (A) The Orsiro stent was dislodged from proximal site and the whole stent was moved outside the distal marker up to the balloon tip. (B-D) The other stents (Xience Sierra, Synergy, Resolute Onyx) did not move the whole stent; they caused buckling and the stent's distal marker was observed.

Coronary stent dislodgement during PCI is a rare but serious complication. Historically, the incidence of stent dislodgement for coronary stents has been 1.4–3.4%, however, this has decreased to 0.07–0.58% in the recent DES era (1,3,8-11). If stent dislodgement and loss occur within the coronary artery, there is a risk of MI or coronary artery perforation. If a lost stent migrates outside of the coronary artery, it causes cerebral or peripheral artery embolization. Lost stents are managed via retrieval using a gooseneck snare or other devices, crushing using a balloon or an additional stent, or surgical removal (12-14). Accordingly, this increases cardiovascular morbidity in addition to puncture site-related complications due to the long procedural times and increased device manipulation. Several previous studies identified that a severely calcified lesion, tortuous coronary artery, inappropriate pre-dilation, long lesion length, a previously implanted coronary stent, and inaccurate coaxial alignment of the guiding catheter were risk factors for stent dislodgement

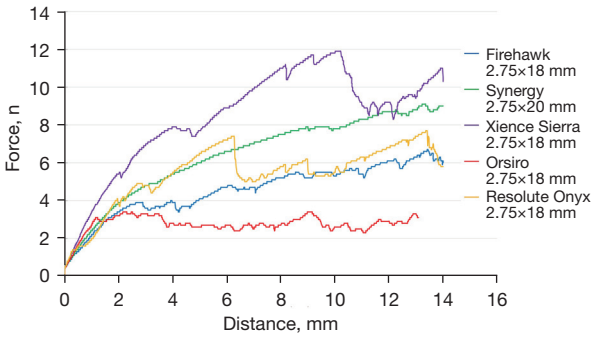


Figure 5 The dislodgement force. The dislodgement force of most stents was increased during pullback. The first pressure drop was observed when the proximal site of the stent was dislodged; thereafter, the pressure rose during continuous pullback. The force curve for most of the stents faces in the right upward direction. However, the force was decreased after the peak dislodgement force in the Orsiro stent. N, Newtons.

(1-3,5). However, the relationship between the device factor and stent dislodgement remains unknown.

It is important to pass through the complex lesion during PCI, likewise, it is also important to withdraw the stent system if it fails to cross the lesion. In clinical practice, stent dislodgement frequently occurs while withdrawing a stent in cases where there was a failure to cross a calcified or tortuous lesion or a previously implanted stent. The shim test simulates pulling while the tape test simulates pushing or pulling an undeployed stent delivery system. Using the shim test, we measured the peak displacement force and peak dislodgement force. There were no differences in the peak displacement force except that between Xience Sierra and Orsiro, but the peak dislodgement force was the lowest in the Orsiro stent among all the tested DESs. During pullback of the stents, other DESs except the Orsiro were not removed from the delivery system despite the stents being broken. The Orsiro stent was easily removed the whole stent if a strut was dislodged from the balloon. This means, if the Orsiro stent got stuck at a calcified lesion, previously implanted stent, or guiding catheter tip during stent withdrawal, the whole stent could be easily removed from the delivery system without buckling. Using the tape method, although the peak dislodgement force for Orsiro was lower than that of other stents, we could not obtain statistical significance since only one case of test was performed for each DES.

The stent dislodgement force and pattern are different according to the DESs, but the mechanism is unknown. One of the possible device factors for stent dislodgement is the crimping technique used when making stents. The crimping techniques or specific manufacturing methods were not public knowledge, so we were not able to compare these factors among the different stents in this study. However, we evaluated several Orsiro stent sizes (i.e., 2.5×15, 3.0×18, 3.0×23, and 4.0×12 mm), and all of them produced the same results. Additionally, we evaluated the Energy stent, which is a bare metal stent platform of Orsiro. This stent was dislodged in the same manner as Orsiro. The crimping methods used for Energy and Orsiro slightly differed, the Energy stent was crimped at a higher temperature than Orsiro. These findings suggest that the reason why the stent becomes dislodged is not due to the crimping technique but likely, due to the stent design.

Another device factor for stent dislodgement is the stent strut thickness. Rigatelli *et al.* reported on the relationship between stent strut thickness and dislodgement (2). They divided the stents into thick (>81 μm strut thickness) and ultrathin (≤81 μm strut thickness) strut stent groups. Stent dislodgement is more common in ultrathin than thick strut stents (0.28% *vs.* 0.78%, P<0.001). The ultrathin strut group included Resolute Onyx, Orsiro, Xience, and Coroflex. Although they did not report the incidence of each stent, approximately half of the stents were Orsiro stents which had the most thin strut, and this group displayed a higher rate of stent dislodgement. In the current study, thin strut stents were evaluated. The strut thickness was 60 and 81 μm for ≤3.0 and >3.0 mm for the stent diameter for Orsiro, respectively, 74–81 μm for Synergy, and 81 μm for Resolute Onyx. Although the data were not shown, Orsiro stents that were 3.5 and 4.0 mm in size could also be easily removed from the delivery system in contrast to other DES. In addition to stent strut thickness, stent dislodgement may be related to other stent design factors, including cell type, ring design, and the connecting link. Any of the above factors can influence the dislodgement force and should be evaluated in future studies.

Finally, stent platform and stent designs can influence stent dislodgement force. Previous bench test for stent longitudinal deformity has reported that longitudinal deformation was related to the number of connectors between hoops (15). Recently, DESs were developed with more thin struts and small connectors to increase flexibility, but reduced strength could affect the dislodgement force. Since stent dislodgement develops frequently when the stent gets stuck in calcium deposits or a previously implanted stent strut, the long axis of stent alignment

within the stenosis is also important. This may be related to the alignment of connectors, so the pattern of connectors such as peak to valley, peak to peak, offset, and mid-strut can influence stent dislodgement. Further studies on the relationship between stent design and dislodgement force will be needed.

The DES used in clinical practice must comply with the manufacturing guidelines. Although ASTM F2394-07 and International Organization for Standardization (ISO)-25539 recommend that a test for stent dislodgement should be performed, there are no clear cutoff values for the force, nor are there criteria for stent dislodgement. Thus, the findings from the current study can only be compared to DESs which have been evaluated in this study, it does not apply to all DES. Robust criteria for stent dislodgement should be determined in future evaluations.

Limitations

This study has some limitations. First, this was a bench test. Therefore, the obtained results might differ from those in the human coronary artery. Second, the number of included DES was small, and we did not evaluate all DES designs and all sizes, so it cannot be generalized. In the future, a large number of different-sized stents should be evaluated. Third, this study did not demonstrate the causal relationship between stent design and dislodgement, further studies investigating the biomechanical properties are required.

Conclusions

The dislodgement force of DESs differed between stent designs. Specifically, the dislodgement force of Orsiro stent was lower than that of other DES evaluated, and the whole stent was easily removed from the delivery system. Operators should consider stent design and be cautious when pulling DES back in a lesion with calcification or a previously implanted stent, which are at high risk for stent dislodgement. Further studies on the relationship between stent design and stent dislodgement will be needed.

Acknowledgments

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Footnote

Data Sharing Statement: Available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-49/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://cdt.amegroups.com/article/view/10.21037/cdt-22-49/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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