Découverte fortuite d'un stent actif dans l'artère radiale après son déploiement.

Accidental retrieval of a drug eluting stent in the radial artery after its deployment. First case reported in literature.

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Résumé

Promus Element Plus est un stent actif référent de deuxième génération conçu pour aborder les lésions complexes. Ceci est dû à son profil de passage exceptionnel avec une meilleure flexibilité et conformabilité au dépend d'une perte significative de sa force longitudinale prédisposant à des déformations longitudinales. Nous décrivons une forme extrême de cette vulnérabilité: Le premier cas dans la littérature d'arrachement complet du stent lors du retrait de guide coronaire qu'on retrouvait au niveau l'artère radiale.

Un homme âgé de 65 ans admis pour un infarctus du myocarde sous endocardique. Après le déploiement du stent dans l'interventriculaire antérieure, nous étions surpris par sa disparition et sa découverte au niveau de l'artère radiale.

La conception du stent obéit à une balance de caractéristiques souhaitables. L'altération d'une propriété en vue d'améliorer sa performance requiert des compromis tel que la perte d'une qualité recherchée ou l'apparition d'un défaut. Nous pensions que des tests standardisés de la force longitudinale doivent être disponible pour les cardiologues afin de les aider à choisir le stent approprié pour chaque lésion.

Mots-clés

Angioplastie complexe, complication, conception du stent.

Summary

PROMUS ELEMENT PLUS is a leading second generation balloon expandable stent designed to aboard complex lesions thanks to his better crossing profile with enhanced stent flexibility and conformability , but with a significant loss of longitudinal strength leading to longitudinal deformation. We describe the extreme form of this longitudinal weakness: the first case in the literature of a complete stent snatching during the wire withdrawal which ends up in the radial artery.

A 65 year old male presented with a non ST elevation myocardial infarction. After deployment of the stent in the left anterior descending artery, we were surprised by its disappearance and its retrieval in the radial artery. Stent design is a balance of desirable characteristics. The alteration of one characteristic aiming at improving stent performance may lead to tradeoffs. Standardized testing of longitudinal strength should be available to cardiologists to aid in stent selection.

Keywords

Complex angioplasty; complication; stent design.

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INTRODUCTION

PROMUS ELEMENT PLUS is a leading second generation balloon expandable stent designed to aboard complex lesions thanks to his better crossing profile with enhanced stent flexibility and conformability, but with a significant loss of longitudinal strength leading to longitudinal deformation. To date, several published case series, and a more recent retrospective review of the Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) database for device malfunctions have highlighted this new phenomenon which appears to occur more often with PROMUS ELEMENT stent. We describe the extreme form of this longitudinal weakness: the first case in the literature of a complete stent snatching during the wire withdrawal which ends up in the radial artery.

CASE REPORT

A 65 year old male with a family history of coronary artery disease was admitted for non ST elevation myocardial infarction (NSTEMI). He had not diabetes and did not smoke. His physical exam was unremarkable. His electrocardiogram (ECG) showed sinus rhythm with non-specific T and ST changes. Troponin was elevated to 1.34 (nl 0-0.001 units). Coronary angiography showed a severe proximal left anterior descending (LAD) artery stenosis, a severe obtuse marginal branch stenosis with severe narrowing in the posterior descending artery (PDA).

After crossing the LAD lesion, a PROMUS ELEMENT PLUS 3.00*16 mm was deployed with a satisfactory result. Meanwhile, resistance was felt on the withdrawal of the wire. Relatively strong force was required to remove it from the vessel and we were even obliged to retire the catheter guide. We found difficulties regaining the radial artery that we thought owing to the spasm. So we change to the femoral approach. During the wiring of the circumflex artery, we were surprised by the reappearance of the LAD lesion and the disappearance of the stent.

The issues we encountered during the wire removal and to repass through radial artery suggest a wire entrapment between the stent strut that it pulled out and stucked in there. Fluoroscopy confirmed these assumptions. We proceed by restenting the proximal LAD deploying a PROMUS ELEMENT PLUS 3.5 * 16 mm then we deployed a PROMUS ELEMENT 2.25*12 mm in the PDA.

Finally, we decide to inflate a balloon in the stent lost in radial artery for better apposition and to avoid secondary embolism.

The patient suffered no adverse sequelae and remains well at follow-up.

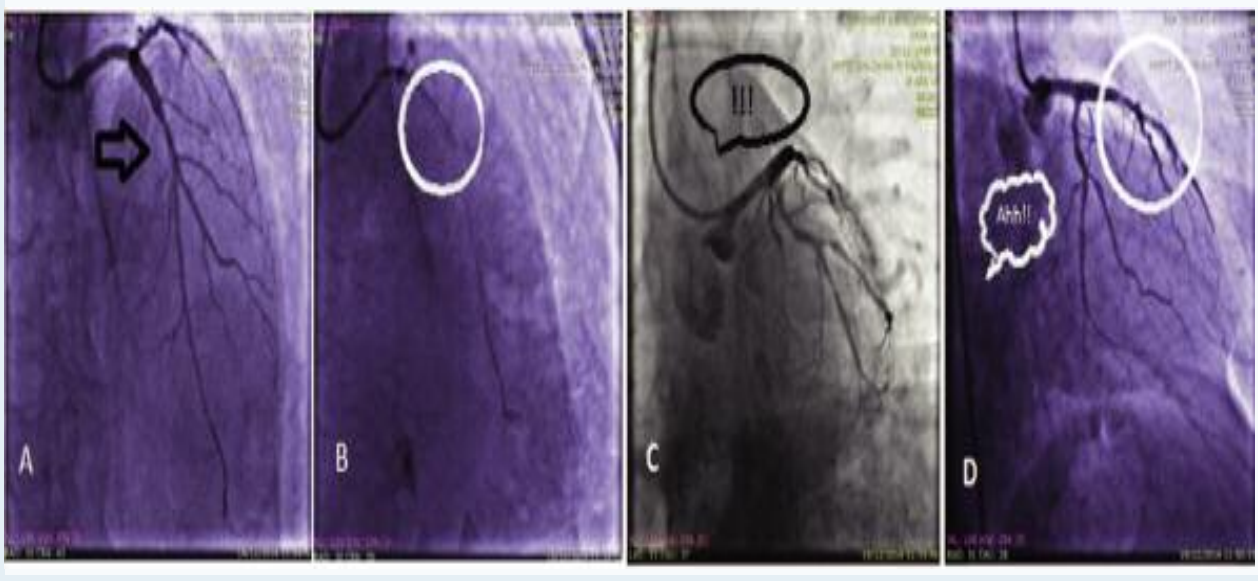


Figure 1 : Panel A: a severe proximal left anterior descending (LAD) artery stenosis, Panel B: a PROMUS ELEMENT PLUS 3.00*16 mm was deployed with a satisfactory result, Panel C and D: The reappearance of the LAD lesion and the disappearance of the stent.

Figure 2 the stent in the radial artery with the tip of wire entrapped in the proximal strut.

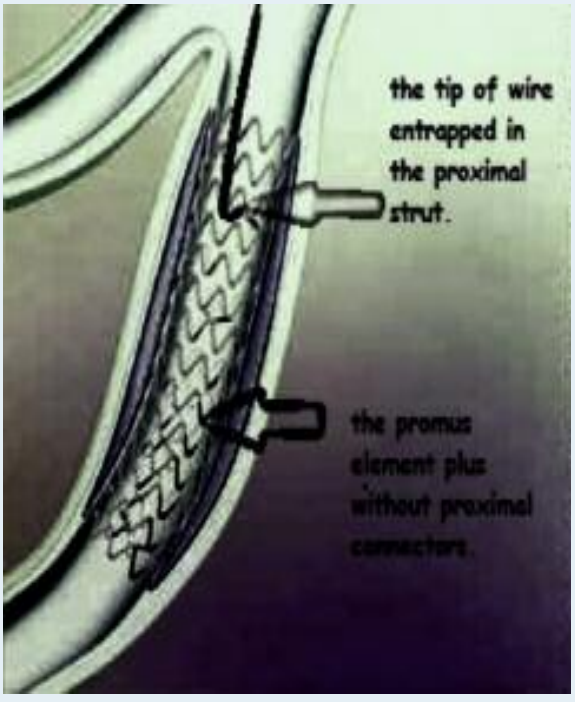
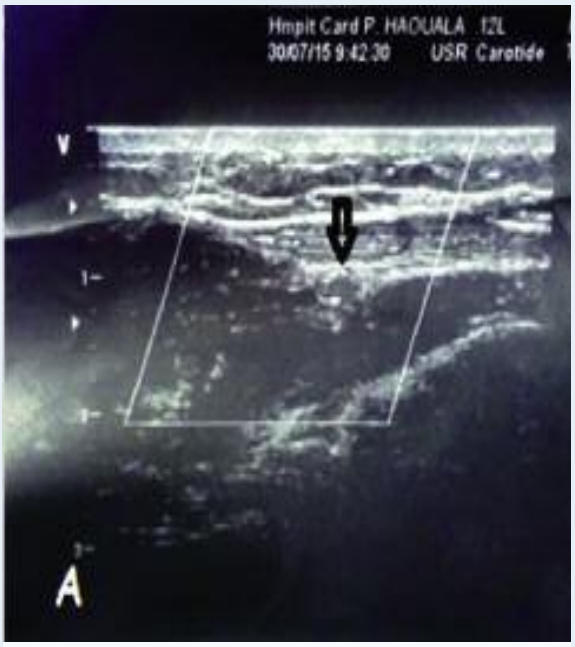


Figure 3 : the entrappement of the wire in the proximal strut.



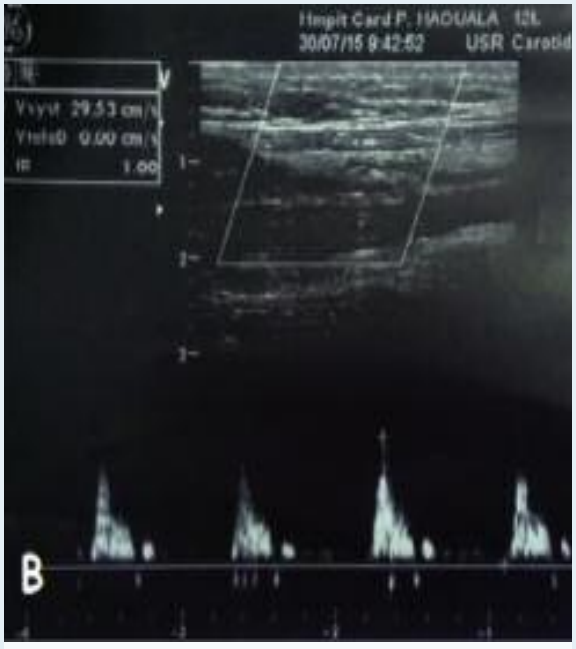


Figure 4 Panel A shows the perfect deployement of the stent in the radial artery. Panel B : normal flow velocity patterns through the stent.

DISCUSSION

In order to improve stent performance and overcome clinical issues, many engineering considerations are adopted to obtain an ideal stent that is highly deliverable, has a thin-strut, low-profile flexible design with high radiopacity, high radial strength, and minimal recoil. Unfortunately, altering any one feature of a stent platform will modify other aspects of how a stent performs. Whilst thinner struts and a lower metal to artery ratio aid stent delivery, the downside is to reduce radial strength. Reducing the number of fixed connectors between cells and altering the geometry of these connectors and their longitudinal distribution enhances flexibility and conformability, but at the expense of the longitudinal strength of the stent structure.

The Element stent was designed as a series of serpentine segments each joined to the next by two connectors, with the connector geometry arranged in a three-dimensional double helix–type configuration. This design allows forces to be balanced along the stent and allows each segment to operate almost independently of the others. The segment peaks are offset (nested), thereby reducing potential strut-to-strut contact when maneuvering the stent around a bend, enhancing deliverability. Furthermore, the peaks are widened and the length of each segment has been shortened to help redirect expansion strain longitudinally (contributing to increased radial strength) and to further improve conformability. The strut thickness is 81 µm, with a portfolio of stents being developed in diameters ranging from 2.25 mm to 4.0 mm and lengths from 8 mm to 38 mm.(1)

The major concern was the need to increase flexibility to facilitate safe delivery without compromising radial support. The Promus Element Plus (Boston Scientific), commercially available from late 2012, is identical to the Promus Element apart from the incorporation of latest balloon delivery technology. This new delivery system consists of a new dual-layer balloon, a strong outer layer, and a flexible inner layer, resulting in overall improved deliverability. (1)

Stent designs with 2 connectors between hoops have less longitudinal stability and are more susceptible to longitudinal distortion than those with more connectors. Distortion may involve bunching or separation of struts and protrusion of struts into the lumen with malapposition and potential obstruction of passage of devices. In our case the whole stent was carried out after deployment. In the bench test carried out by J Ormiston and al, the most easily deformed stents were the Omega and Driver. The force in Newtons to elongate stents by 1 mm was least for the Omega (0.19 _ 0.01N) and Driver (0.20 _ 0.03 mm, p=NS).

The earlier generation Cypher Select, a 6-connector design, had the greatest resistance to longitudinal distorting forces.(2) Besides connector number, the alignment of the connectors with the long axis of the stent may also be important for longitudinal integrity. The angulation of the connectors in the Element design where the connectors link the offset, in-phase hoop peaks may contribute to the lesser resistance to longitudinal distortion.

In order to overcome this issue, the Promus Element Plus was enhanced to a Promus Premier; it includes extra connectors on the proximal two segments of the stent which make the proximal stent end more robust to provide increased axial strength.

CONCLUSION

Stent designs should be more mindful of longitudinal integrity. Standardized testing of longitudinal strength should be available to cardiologists to aid in stent selection.

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