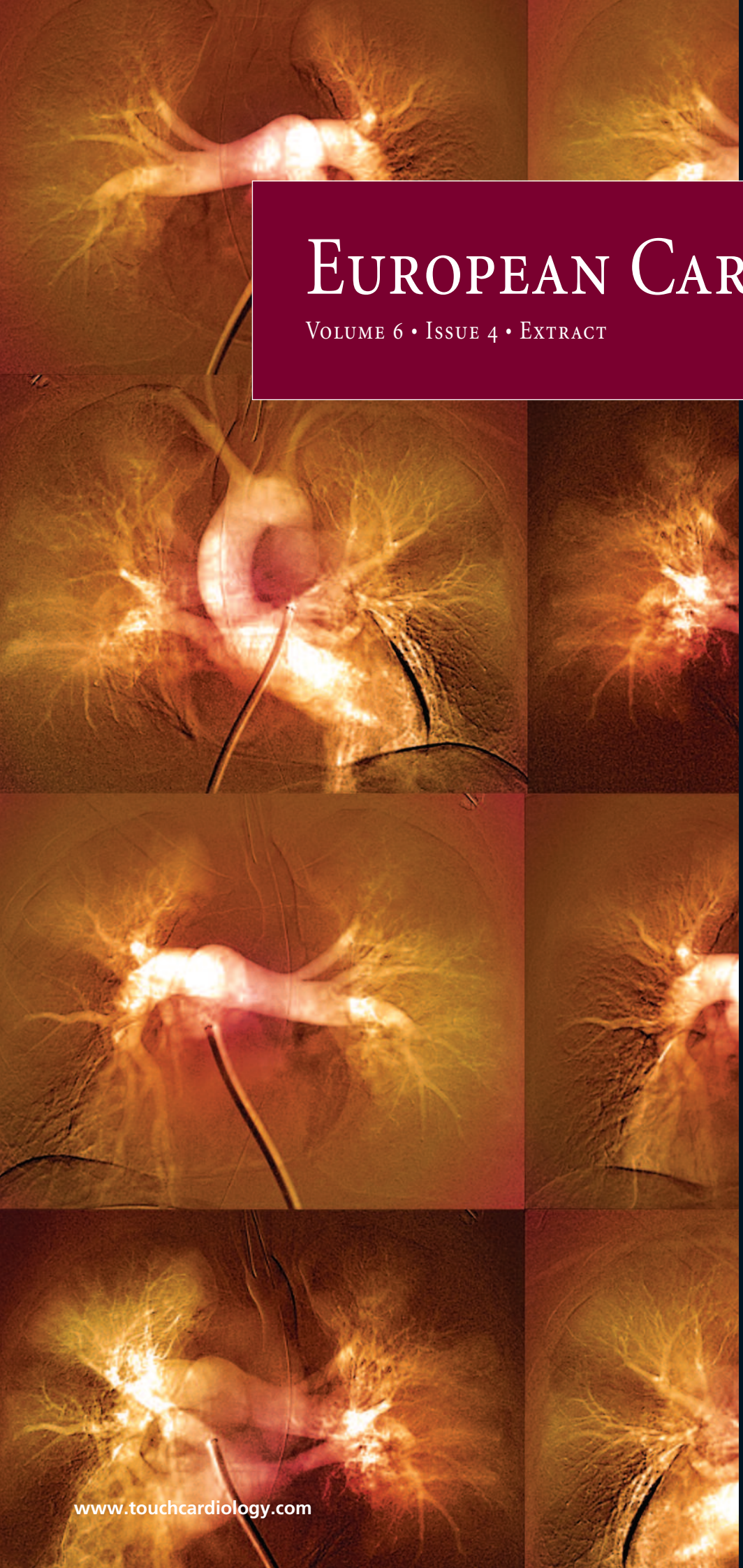

European Cardiology

Volume 6 • Issue 4 • Extract

Svelte™ Acrobat Stent-On-A-Wire Coronary Stent System

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Abstract

Direct stenting may reduce local vessel trauma, minimise 'geographical miss', prevent distal embolisation and save time/money during percutaneous coronary interventions. However, direct stenting is currently performed in ≤50% of most cathether laboratories worldwide. Among the main reasons to pre-dilate, vessels anatomy (tortuosity and amount of calcification) play a central role in the operator's decision. The recently developed Acrobat Stent-On-A-Wire (SOAW) coronary system combines a very thin (81µ) L605 CoCr stent mounted on a delivery system with a 0.012-inch integrated guidewire tip (distance from the tip of the wire to the stent is 22mm). This is a balloon-expandable stent and the nylon balloon is also directly mounted onto the wire. The Acrobat SOAW may potentially facilitate percutaneous coronary intervention by reducing time/cost and minimising peri-procedural complications and therefore benefit a large number of patients in daily practice who are currently labelled as unfavourable for direct stenting.

Key words

Percutaneous coronary intervention (PCI), direct stenting, Acrobat Stent-on-a-Wire, balloon-expandable stent

Disclosure: The authors have no conflicts of interest to declare.
Received: 8 September 2010 **Accepted:** 28 October 2010 **Citation:** *European Cardiology*, 2010;6(4):36–9
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Acknowldegements: Patrick W. Serruys, MD, Erasmus Medical Center, Rotterdam; Pieter R. Stella, MD, PhD, Utrecht Medical Center, Utrecht; Alexander Abizaid, MD and Jose de Ribamar Costa Junior, MD, Instituto Dante Pazzanese de Cardiologia, Sao Paulo; Andres Fernandez, MD and Juan Granada, MD, Instituto Cardio-Neuro-Vascular CORBIC, Medellin.

Support: The publication of this article was funded by Svelte Medical Systems, Inc.

Coronary stenting is a percutaneous procedure intended to regain coronary artery patency overcoming the major limitations of balloon angioplasty: acute recoil and negative vessel remodelling.[1–3] The first contemporary balloon-expandable stent was the Palmaz, immediately followed by an articulated variant known as the Palmaz-Schatz, the first stent to be tested in large multicentre trials (the Stent Restenosis Study [STRESS] and the Belgium–Netherlands Stent [BENESTENT]).[4–6] However, initial stent designs were large, rigid devices that made implantation difficult. In addition, these stents were crimped by hand in the balloon catheter, resulting in precarious safety of the device inside the implantation system.[5,6] As a consequence, pre-dilatation of the target lesion used to be routine prior to stent deployment. While percutaneous treatment of coronary artery disease with stent implantation is associated with high rates of clinical success and low rates of procedural morbidity, the risks of exposure to radiation, administration of contrast dye, haemorrhaging at the access location and cost are not insignificant. These risks of percutaneous coronary intervention (PCI) are incrementally greater in older patients, disease in multiple vessels that require phased procedures, chronic kidney disease and peripheral arterial disease,[7–12] making minimisation of these risks very important. Direct stenting may potentially reduce local vessel trauma, minimise 'geographical miss', prevent distal embolisation and save time and money during PCIs reducing patient and operator exposure to radiation. Direct stenting has been compared with conventional stent implantation with pre-dilation in several observational studies and randomised trials using bare-metal stents (BMS).[13–27] In selected lesions (low degree of calcification of the lesion with minimum blood vessel tortuosity), there have been high technical and procedural success rates. In addition, significant reductions were attained in procedure time, radiation dose, administration of the contrast dye and costs, with similar clinical results for six to 12 months.[22–27] Nevertheless, direct stent implantation is currently utilised in about 30–40% of PCI procedures.[28,29] Among the main reasons to pre-dilatate, vessel anatomy (tortuosity and amount of calcification) plays a central role in the operator's decision.

The recently developed Acrobat Stent-on-a-Wire (SOAW) coronary stent system (Svelte™ Medical Systems) is a coronary stent system that uses a fixed-wire catheter platform. The system combines a very thin (81µm) cobalt–chromium (L605) stent mounted on a delivery system with a 0.012-inch integrated guidewire tip (distance from the tip of the wire to the stent is 22mm; see *Figure 1*). Besides the facility to directly deploy the stent, this novel device should also potentially facilitate treatment of small vessels and distal lesions. The current publication addresses in more details the Acrobat SOAW system.

Description of the Device

The Svelte™ Acrobat SOAW coronary stent system consists of a balloon-expandable stent pre-mounted on Svelte's SOAW single-lumen fixed-wire implantation catheter platform. The stent is made of cobalt–chromium alloy (L-605) and is available in diameters ranging from 2.5 to 4mm and lengths of 8 to 28mm. The Acrobat

Figure 1: Magnified View of the Very Low Profile, Cobalt–Chromium Acrobat Stent-on-a-Wire Coronary Stent System

Figure 2: Visual Comparison of a Regular Balloon-expandable Cobalt–Chromium Stent (Left) and the Novel Svelte™ Acrobat Stent-on-a-Wire (Right)

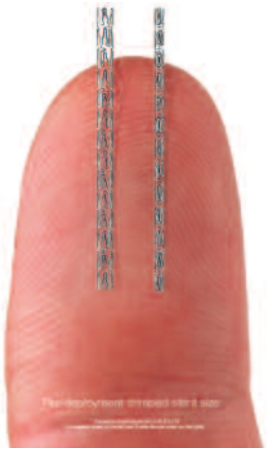
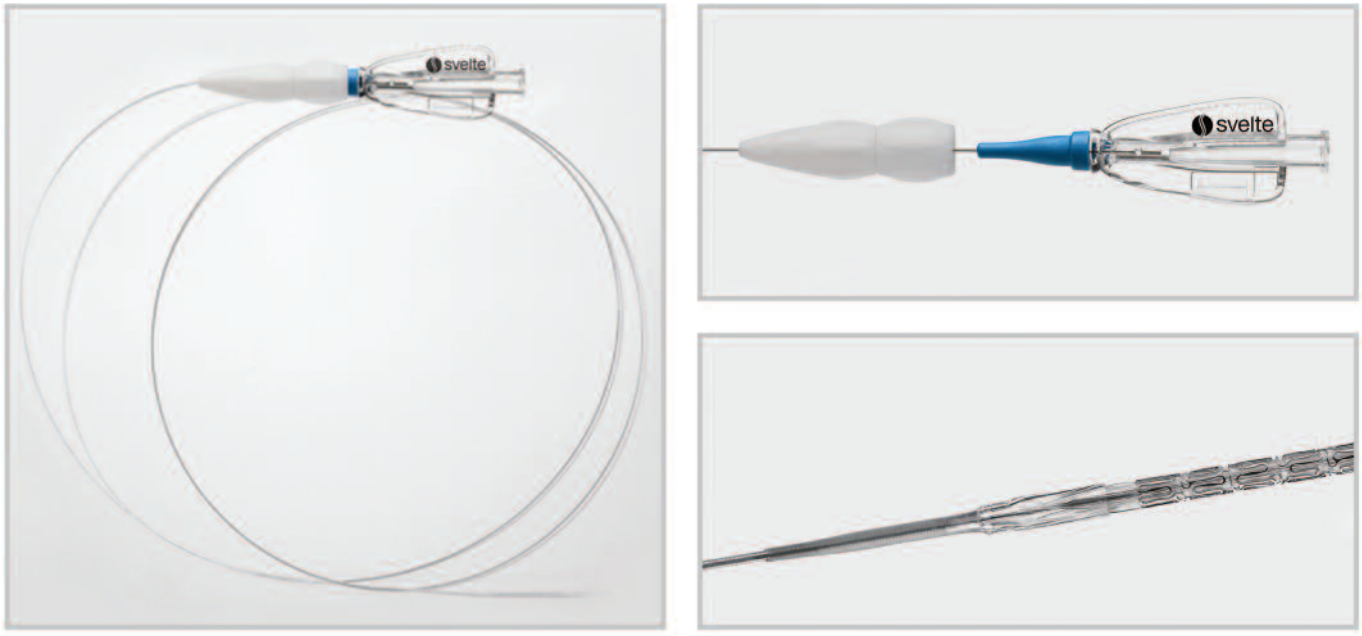


Figure 3: Illustrative Representation of all Components of the Novel Svelte™ Acrobat Stent-on-a-Wire



SOAW system is compatible with 5 French (Fr) guiding catheters (minimum internal diameter 0.056 inches).

The lesion entry profile of the formable radiopaque wire tip is 0.012 inches (see *Figure 2*). The SOAW implantation catheter's operational extension is 145cm, and includes two proximal axis markers (90 and 100cm) to indicate the relative position of the implantation system up to the extremity of a radial or femoral guide catheter. Proximal and distal radiopaque markers are located under the balloon to indicate the operational extension of the balloon and the diameter of the expanded stent under fluoroscopy. There are balloon control bands on each end of the balloon to control expansion and deflation. An integral torquer device is located on the proximal axis (see *Figure 3*).

The basic steps to deploy the Acrobat SOAW coronary stent system are represented in *Figure 4.* This innovative stent system was recently evaluated in a first-in-man (FIM) study. The Svelte FIM trial was a multicentre (four sites), international (Brazil, The Netherlands and Colombia), prospective, non-randomised, single-arm registry of the novel Acrobat SOAW for the treatment of *de novo* coronary lesions. A total of 46 patients were enrolled with planned angiographic evaluation at six months. For a pre-specified cohort of 15 patients, serial intravascular ultrasound (IVUS) assessments right after stent implantation and at six months will be performed while for a cohort of 19 patients, optical coherence tomography (OCT) assessment at similar time points will be performed. The primary end-point of the study is the survival-free rate of combined major adverse cardiac events (MACE; cardiac death, myocardium infarction and target-lesion revascularisation) at 30 days. As secondary end-points it will analyse the following: device success rate; lesion success rate; procedure success rate; (individual) incidence of cardiac death, myocardium infarction and target-lesion revascularisation; binary restenosis and in-stent/in-segment late luminal loss at six months; stent thrombosis rate (according to ARC definition) up to six months. *Figure 5* displays two examples of patients treated in the FIM series. The enrollment phase of this study

Figure 4: Schematic Representation of the Main Steps in the Svelte™ Acrobat Stent-on-a-Wire Deployment

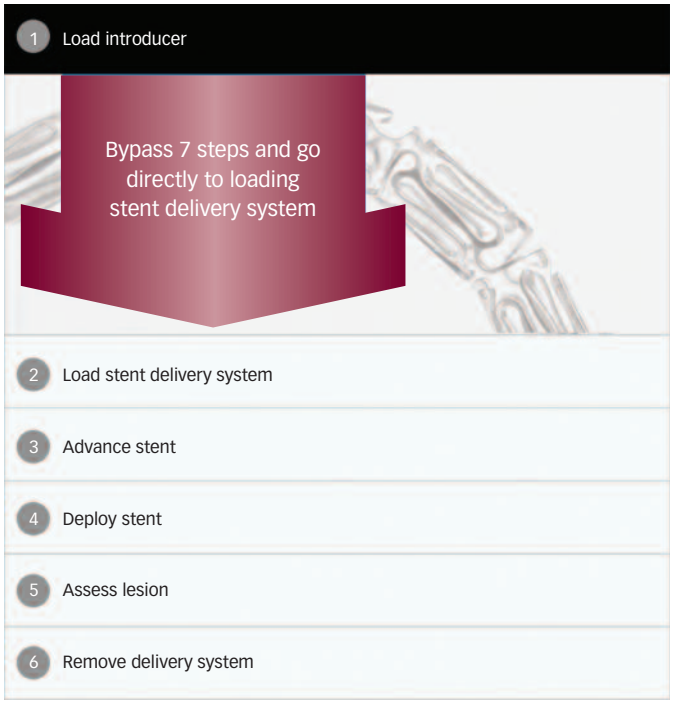
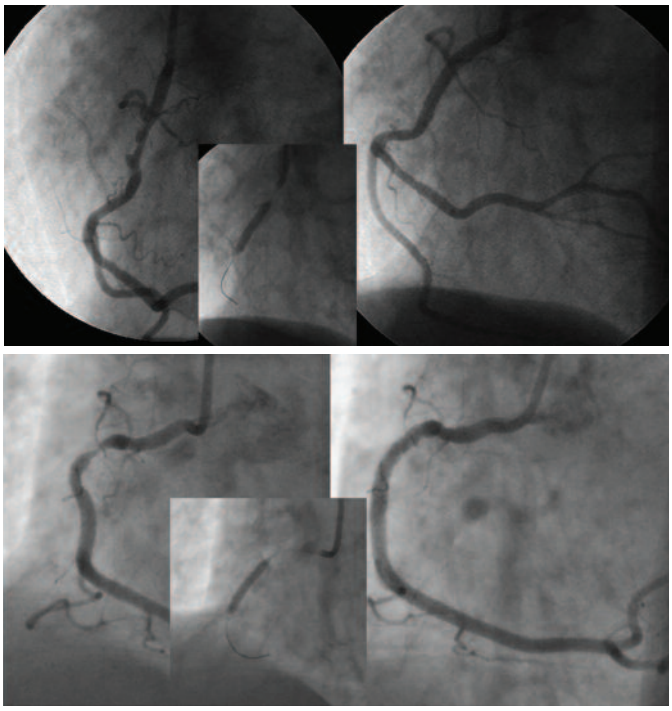


Figure 5: Two Cases in the First-in-man Evaluation of the Svelte™ Acrobat Stent-on-a-Wire (Brazil)



was recently completed. The Acrobat stent was deployed in 100% of the cases (89.1% of direct stenting) achieving a procedure success rate of 97.8%. Up to 30 days there were no deaths, Q-Wave MIs or urgent target lesion revascularisation (TLR). In cases without imaging (IVUS, OCT), fluoroscopy times were extremely low with a median of 4.5 minutes. Six-month invasive follow-up is ongoing and results will soon be presented. *Figure 5* displays two examples of patients treated in the FIM series. In both cases, the Svelte™ stent was directly deployed and fluoroscopy time did not exceed five minutes with an average of 50ml of contrast.

Future Perspectives

CE Mark was granted to Svelte Medical for the BMS Acrobat SOAW on 20 August 2010. With this approval, Svelte will now focus on the release of the drug-eluting stent (DES) version of the Svelte™ Acrobat, which is under development and will use a novel non-inflammatory carrier for the drug. The company also plans to initiate US clinical trials on the Svelte™ Acrobat SOAW technology in 2011.

Conclusions

The Svelte™ Acrobat SOAW has the potential to significantly improve PCI by reducing time and cost and minimising peri-procedural complications. With improved access and a potential reduction in complications, the Acrobat allows for application in patients who are currently labelled as unfavourable for direct stenting. Its innovative concept has completed enrollment in a FIM study, secured CE Mark for the Acrobat BMS product and the next-generation DES version is highly anticipated. ■

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