A Highly Flexible Slotted Tube Stent Design Coated with a-SiC:H First Clinical Experiences

J. KOOLEN, C. HANEKAMP, H. BONNIER
1Catharina Hospital, Eindhoven, Netherlands

Summary

A new stainless steel slotted tube stent design, TENAX, with circular tantalum markers at both ends, was coated with hypothrombogenic hydrogen-doped amorphous silicon carbide (a-SiC:H). The hypothrombogenic properties of this semiconducting coating are due to its electrochemical characteristics and very smooth surface. The new stent design has extreme flexibility, a low profile and optimal radiopacity values, facilitating simple and safe delivery. The yielding stent structure enables side branch access. TENAX coronary stents have been implanted since June 1997. Stent properties and procedural outcome were assessed.

Key Words

Tubular slotted, 316L, coronary stent, semiconductor coating, TENAX

Introduction

A spirited race for modified stent designs has ensued with the rapid growth of the coronary stenting field-reaching 25 to 50 % in interventional cardiology catheter labs and even higher at leading centers [1]. It is clear that none of the original stent designs were optimal under all clinical circumstances. The optimal or "ideal" stent should be delivered simply and safely to various locations in the coronary vasculature. Therefore, it should be flexible, have a low strut thickness, and form smooth contours with the delivery system. In addition, the stent must be capable of sustaining sufficient radial strain to resist the external force that compresses it centrally toward the lumen.

A good hemocompatibility is mandatory since the surface of the stent comes into direct contact with blood for the first 2 to 4 weeks after stent implantation and into contact with the growing intimal proliferation tissue afterwards. Each of the stent design materials used today is thrombogenic to some extent and instigates some inflammatory response in the tissue. While it is clear that metals cause an intense proliferative response, the question remains which metals have the best biocompatibility in clinical applications. Whether there is an optimal surface treatment or not that makes the stent more hemocompatible and/or biocompatible is an important research subject today. The purpose of this article is to address the fundamental and clinical functionality and handling characteristics of the TENAX coronary stent, a 316L highly flexible slotted tube coated with a-SiC:H.

Stent design affects short- and long-term performance

The precise correlation between the design and clinical performance of stents is currently under investigation. Mechanical characteristics of stent designs, such as longitudinal flexibility, the ability to resist radial force, and scaffolding properties, are relatively easy to assess by using finite-element analysis. In contrast, the long-term performance of different stents in their ability to reduce restenosis is more difficult to evaluate. Acute clinical performance of a stent is strictly dependent on its ability to be delivered to the target lesion and to scaffold plaque against the vessel wall effectively. With these properties there is a tradeoff between stent length and the deliverability. Delivery can be influenced by stent length; in general, longer stents (especially tubular) are less easy to deliver through tortuous segments of the vasculature. Although there is a consensus that coil stents are more flexible than tubular ones, owing to their design differences, their scaffold-

ing properties are inferior. The possibility of plaque protruding between the coils is also more likely, which may adversely influence late restenosis rates. This space between the coils may, however, be an advantage if a vessel needs to be stented over a major side branch. Stent deformation has occurred in some of the coil stents; this problem has been partially solved by providing the stent with a longitudinal backbone structure. The earlier slotted tubular stent designs [2] required a bridge joint to provide the stent segments with flexibility over its length. Such bridges are a site of possible plaque protrusion into the stent and may also be a common site for restenosis [3]. This problem is reduced with the new tubular slotted design of the TENAX coronary stent by using shorter articulations and cross-over segments at the articulation sites.

The issue of sufficient pressure for stent deployment remains controversial. The general rule of high pressure deployment has been considered the optimal method of deployment for the earlier slotted tube designs, such as the PALMAZ-SCHATZ and TENSUM [4][5]. However, transferring this rule to all coronary stent designs is problematic. For some of the new designs, it has been suggested that optimal deployment may be achieved with less pressure, thereby also minimizing the risk of vessel trauma and distal dissections.

Stent visibility is another important factor: the more visible the stent, the easier the procedure and the more accurate the stent positioning. However, a highly radiopaque stent, e.g. the TENSUM might interfere with the qualitative and quantitative analysis of stenting by angiography, both during inflation and during post-procedure assessment. Compromise solutions have been considered to overcome this problem, such as thicker (more radiopaque) material, gold stent markers, and even gold-plating the surface of the stents.

The cross-sectional area of metal covering a stent is another variable, ranging between values as low as 8% and as high as 23%. It is assumed that as long as the metal content is below a certain threshold, its effect is minor. The percentage of metal coverage of a stent is related to some extent to its scaffolding properties.

Stent thrombogenicity is a decisive disadvantage which can occur within hours and days after implantation. It is well known that stent materials currently used, i.e., metals, are thrombogenic. It has not been proven that among the classic metals used for stenting any particular metal is more or less thrombogenic in a clinical intracoronary environment. However, it has been shown that the amount of thrombus adhering to the stent [6] is determined by the degree of smoothness of the stent surface, which may, in turn, influence the intimal proliferative response [7]. Stent thrombogenicity depends on multiple factors, including stent surface characteristics, the level of wall injury caused by primary angioplasty and stent deployment, as well as physical or mechanical interference with the field of flow within the artery. It has been well recognized that to minimize stent thrombogenicity in patients, the single most important parameter is its assimilation into the wall [8][9].

Surface characteristics of a stent have been shown to be a factor affecting the rate of platelet deposition on the wall and may have an important effect on the long-term outcome after stenting [7]. It has been established that metallic surface modification may have an effect on two interrelated components of thrombosis, platelet adhesion and aggregation, and factor XII activation. Any method which inhibits absorption of protein to the stent should interfere with the process of thrombosis through one or both of the above mechanisms. Other actions to alter the physical properties of the surface may involve modification of the ionic charge or coating the stent with a thin film of a biocompatible material [10][11].

Coating with a-SiC:H improves hemocompatibility

Hemocompatibility of coronary stents is still limited due to thrombogenicity of the artificial surface. A new concept for avoiding thrombosis is to improve the hemocompatibility of the materials. Thrombogenesis at artificial surfaces can be described by means of an electron transfer process, in which electrons transfer from the fibrinogen to the solid (Figure 1). This process stimulates the release of fibirinopeptides and the subsequent polymerization of fibrin [12]. During recent years, a physical model was developed which allowed electrochemical requirements for a hemocompatible surface to be derived [13]:

- To prevent degeneration of blood proteins, the solid must have empty electronic states at the transfer level, a prerequisite met by a semiconductor with a sufficiently large band gap.
- The electronic transfer current must be minimized; therefore, a low density of states within the semiconductor band gap is necessary.

A material that satisfies the electronic requirements mentioned above is silicon carbide in an amorphous

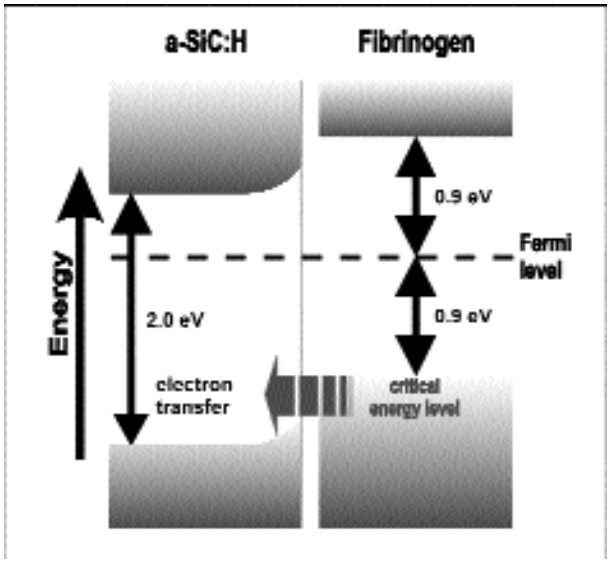

Figure 1. Potential distribution at the fibrinogen/semiconductor phase boundary (with a band gap of 2.0 eV).

hydrogen-rich modification (a-SiC:H). The a-SiC:H is deposited onto the stent surface by the plasma-enhanced chemical vapor deposition technique (PECVD). The process parameters regulating both the biocompatibility and the hemocompatibility of amorphous silicon carbide were investigated and optimized.

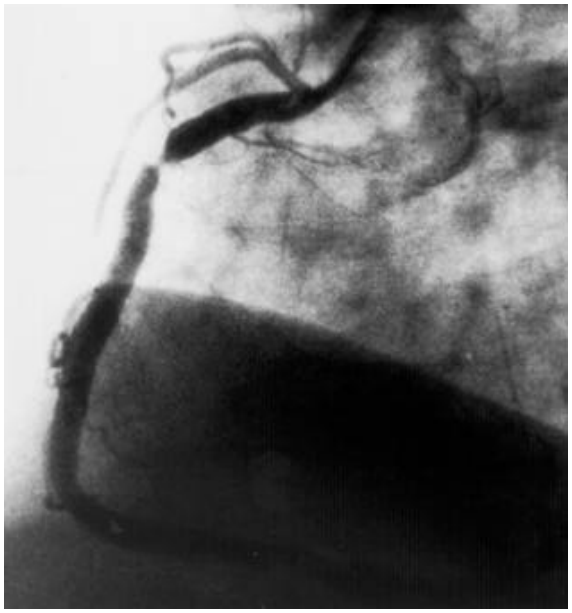

Figure 2. Severe stenosis in proximal RCA. The lesion was pre-dilated with a Supreme 3.0 x 20 mm balloon dilatation catheter using an inflation pressure of 10 bar.

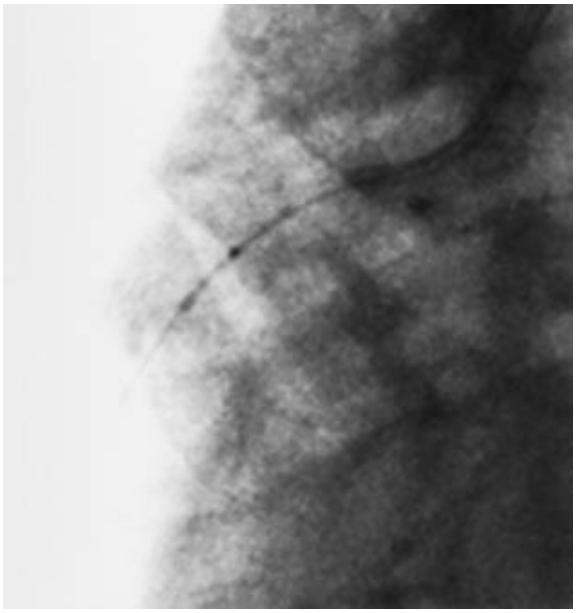

Figure 3. TENAX 15 mm stent, pre-mounted onto a Supreme 3.0 x 20 mm balloon dilatation catheter. Both the radiopaque tantalum stent markers and the radiopaque central balloon marker are visible, enhancing accurate and precise positioning.

The a-SiC:H layers were deposited with a band gap of 2.0 eV and a low state density. By applying plasma prior to the deposition of a-SiC:H, adhesion of the coating was improved, thus preventing spalling and defect formation during the dilatation of the coronary stent.
With its defined electronic properties, amorphous silicon carbide is characterized by excellent hemocompatibility and biocompatibility. Extensive in vitro investigations of cytotoxicity, hemolysis (analyzed under dynamic conditions using a modified Chandler system), mutagenicity, as well as the growth behavior of human endothelial cells showed ideal behavior.

Materials and Methods

In the course of this study, 44 TENAX coronary stents were implanted. Figure 2 shows an example of severe stenosis before stent implantation. Stent properties and procedural outcome were assessed [14].
The stent applied is TENAX, a stainless steel 316L, balloon expandable stent with a tubular slotted design coated with the hypothrombogenic semiconducting a-SiC:H. To facilitate exact stent placement and deployment, the stent has two radiopaque tantalum rings at both ends of the stent. Due to the yielding stent design, the TENAX stent resembles a coil stent and is

very flexible, thus offering side branch access. The low profile of the stent favorably influences the handling characteristics. The pre-mounted version of TENAX, TENAXCOMPLETE is pre-mounted on a low shaft rapid exchange balloon expandable system (Figure 3). The material properties of the specially designed balloon guarantee secure fitting of the stent to the system and optimal radial expansion of the stent during deployment.

The 44 TENAX coronary stents total were implanted in 39 patients with a mean age of 57 years. Of the patients, 72% had stable angina, 13% unstable angina, and 15% underwent rescue percutaneous transluminal coronary angioplasty (PTCA). Indications for stent implantation were dissection in 30% of the patients, sub-optimal results after angioplasty in 11%, and elective surgery in 59%.

The diameter of the TENAX stents implanted ranged from 3.0 mm to 4.0 mm; implantation pressure varied from 10 to 12 bar. Intracoronary ultrasound was performed in 4 patients. In these patients, complete radial stent deployment and sufficient stent apposition against the arterial wall were achieved with expansion pressures ranging from 8 to 12 bar.

Results

The TENAX stents were successfully implanted in 42 cases (Figure 4). In 2 cases, stent implantation could not restore coronary flow due to severe dissection. One patient underwent coronary artery bypass graft, one patient underwent minimally invasive direct coronary artery bypass.

In all cases, the target lesions were reached and crossed within tortuous segments and through tortuous arteries without difficulties. The radiopaque tantalum markers made precise and accurate positioning simple and safe.

No hospital complications were reported for 33 patients. One stent thrombosis occurred 1 day after the intervention but was successfully re-opened by angioplasty. Three patients suffered from a non Q-wave infarction.

A 30-day clinical follow-up was performed in 23 patients. Of this group, 78 % were free of angina, 22 % had stable angina of a CCS class 1 to 3. None of the patients were admitted to the hospital for major events or for additional interventions. The 6-month clinical and/or angiographical follow-up is pending.

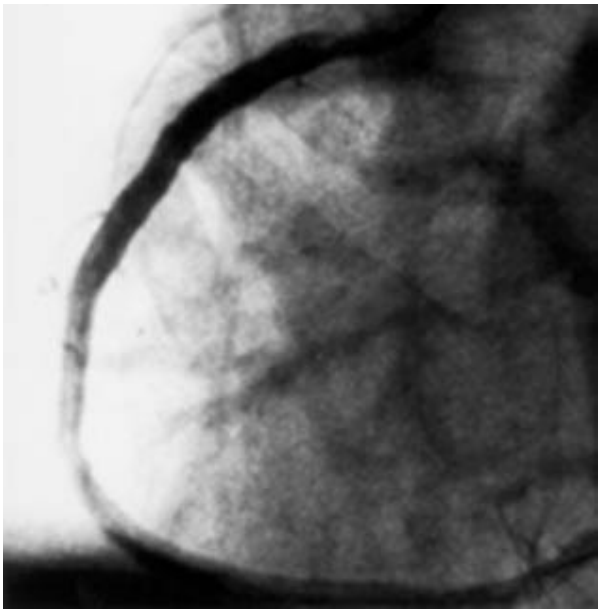

Figure 4. Angiography after stent implantation, showing fully restored flow.

Conclusion

In this study, a hybrid coronary stent design is proposed in which the surface coating was optimized for hemocompatibility independently of mechanical properties of the stent body. In vitro results confirm reduced thrombogenicity of stents coated with a thin a-SiC:H film as compared to uncoated stents.

The initial trial with the TENAX coronary stent confirms the expected performance. This stent is easy to deliver, has a high functionality and excellent handling characteristics, and shows promising initial clinical results. Intracoronary ultrasound displayed full radial expansion and stent apposition against the arterial wall with moderate deployment pressures. A multicenter feasibility trial is scheduled to investigate short- and long-term clinical and angiographic outcomes [14].

References

[1] Meyer BJ, Meyar B, Bonzel T, et al. Interventional cardiology in Europe 1994. Eur. Heart J 1996; 17:1318-28.

[2] Schatz RA, Baim DS, Leon M, et al. Clinical experience with the Palmaz-Schatz coronary stent. Initial results of a multicenter study. Circulation 1991; 83:148-61.

[3] Dussaillant GR, Mintz GS, Pichard AD, et al. Small stent size and intimal hyperplasia contribute to restenosis: A volumetric intravascular ultrasound analysis. J. Am Coll Cardiol 1995; 26:720-4.

[4] Goldberg Sl, Colombo A, Nakamura S, et al. Benefit of intracoronary ultrasound in the development of Palmaz-Schatz stents. J. Am Coll Cardiol 1994; 24: 996-1003.

[5] Colombo A, Hall P, Nakamura S, et al. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1995; 91: 1676-88.

[6] De Scheerder IK. Stent coating. XVIII Congress of the Eur Soc Cardiology; Birmingham, UK, August 25-29, 1996.

[7] De Scheerder IK, Wilczek KL, Verbeken EV, et al. Biocompatibility of polymer-coated oversized metallic stents implanted in normal porcine coronary arteries. Athero sclerosis 1995; 114:105-14.

[8] Rogers C, Kamovsky MJ, Edelman ER. Inhibition of experimental neointimal hyperplasia and thrombosis depends on the type of vascular injury and the site of drug administration. Circulation 1993; 88: 1215-21.

[9] Rogers C, Edelman ER. Endovascular stent design dictates experimental restenosis and thrombosis. Circulation 1995; 91: 2995-3001.

[10] Bolz A, Schaldach M, Heublein B, et al. Hybrid coronary stents with a hemocompatible amorphous silicon carbide coating. Poster presentation TCT, Washington 1997.

[11] Bolz A, Amon M, Özbek C, et al. Optimization of hemocompatibility and functionality by a hybrid design of cardiovascular stents. Progress in Biomedical Research; Spring 1996: 8-12.

[12] Sawyer PN, Brattain WH, Boddy PJ. Electrochemical criteria in the choice of materials used in vascular prostheses. in: Biophysical mechanism in vascular hemostasis and intravascular thrombosis. Sawyer PN (ed.), New York: Appleton-Century Crofts; 1965: 337-348.

[13] Bolz A. Physikalische Mechanismen der Festkörper-Protein-Wechselwirkung an der Phasengrenze a-SiC:H-Fibrinogen. Dissertation. University of Erlangen, Germany (1991).

[14] Hanekamp C, Koolen J, Pijls N, van Gelder LM, Bonnier J. A new flexible amorphous hydrogenated silicon carbide, a-SiC:H, coated stainless steel slotted tube coronary stent. Poster presentation TCT, Washington 1997.