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1

STRUCTURE-BASED BIOMECHANICAL MODEL OF THE ARTERIAL WALL

Sylvain ROY, Alkiviadis TSAMIS, Gilles PROD'HOM, Nikos STERGIOPULOS

Earlier experimental work on decellularized arteries revealed the existence of significant residual stresses within the arterial wall, which are released upon chemical removal of vascular smooth muscle cells causing substantial radial expansion. Hence, the often-used Hill's model describing active and passive stresses within the wall does not hold true, because the existence of prestresses precludes the fundamental assumption of zero active stress when the vascular smooth muscle is inactive. We have, therefore, developed a new mathematical model based on a modified Hill's model, where compressive prestresses exist on the parallel elastic component and tensile prestresses apply on the series elastic component. Further, we developed a new constituent-based strain energy function to describe the pressure-diameter curves of normal and decellularized arteries. The model assumes that elastic constants of elastin and collagen and the statistical description of collagen engagement are not affected by decellularization. Excellent fits of the pressure-diameter curves of normal and decellularized arteries were obtained, suggesting that the model is a plausible one. We conclude that the correct biomechanical modeling of the arterial wall requires the knowledge of the zero stress state of both the series and parallel elastic components and that the constituent-based strain energy function is an appropriate means for the accurate description of the stress and strain field.

2

BIOMECHANICAL CHARACTERIZATION OF THE STENTED ARTERY. COMPUTATIONAL SOLID MECHANICAL ASPECTS

Gerhard A. HOLZAPFEL, Dimitrios E. KIOUSIS

Since stent design and the stent deployment technique are one cause for the success or failure of angioplasty treatments. Biomechanics has an important role in characterizing the solid and fluid mechanical environment that is achieved due to stent implantation. Supra-physiological loading conditions may lead to stress-induced wall damage, local interaction of the stent struts with the artery wall to focal vascular trauma, and the disturbed flow to non-physiological wall stresses. The mechanical changes that occur during and after dilation of the artery activate mechanobiological processes and may finally lead to in-stent restenosis characterized by a fibroproliferative response and by increased matrix production.

There are only a very few approaches documented in the literature that address the solid mechanical aspects of stenting. The present work summarizes one efficient methodology able to predict the changes in the mechanical environment of stenotic arteries that occur during the interaction with stents, while fluid dynamical aspects that may also drive clinical failures are not addressed here. The methodology is based on a computational strategy which allows a deeper insight in the development of mechanical strains and contact pressures during and after artery dilation.

In particular, the stent interaction with a patient-specific, atherosclerotic lesion of a femoral artery is modeled, and two different strut thicknesses of the stent are analyzed. The respective lumen gain and the pressure between the stent struts and the surface of the intima are visualized, and consequences discussed.

3

CHARACTERISATION OF THE FEMORO-POPLITEAL ARTERIAL AXIS DURING KNEE FLEXION

Marc LABROUSSE, Théodore OUEDRAOGO, Claude MARCUS,
Jean-François DELATTRE, Claude AVISSE

The dynamic anatomy of the vascular axes was underestimated for a long time. Since some years, this anatomical aspect gains more interest with the development of endovascular procedures. We report our experience in this field as a part of the studies we performed on the morphologic changes of the popliteal artery during the flexion of the knee. These studies involved arteriographies and dissections of 21 cadaveric lower limbs, angio-MRI studies of 5 healthy volunteers, and haemodynamic investigations performed on 60 young healthy volunteers. During knee flexion, we observed differences in behavior between the different segments of the popliteal artery. While the upper part demonstrated tortuosities of variable intensity, and on the other hand the middle and lower segments did not demonstrated major morphological modifications are more restricted. This arterial adaptation developed mainly between two fixed points: cranially, the adductor canal, caudally, the end of the popliteal artery at the level of the arch of the soleus muscle. This difference in behavior may allow understanding the physiopathology of popliteal artery traumatism and of popliteal entrapment syndrome. Other authors reported their experimental results on the behavior of the superficial femoral artery (SFA). While the SFA remains rather straight during knee flexion, the artery undergoes significant axial shortening with simultaneous torsion. The specific mobility of the femoral and popliteal artery explains certainly the failures and the poor results observed in some cases with femoro-popliteal stents. This should be taken into account for the development of material and for the indication of placements of stents in the femoro-popliteal region.

4

ARTERIAL SURFACE, STENTING AND ANTIPLATELET-THERAPY : A LOCAL CHALLENGE

Christian GACHET, François LANZA, Boris ALEIL

Stent implantation takes place at sites of atherosclerotic lesions with stenosis. It causes an acute thrombogenic and chronic inflammatory situation due to both the injured atherosclerotic plaque and the intravascular device. This is followed by neointima formation and ultimately, wound healing by coverage of the stented area by endothelial cells. To control the thrombotic response following vascular injury initiated by the intravascular device, immediate and long term antithrombotic therapy mostly based on antiplatelet drugs is required. The scope of our brief overview is to describe the general mechanisms of thrombus formation at sites of vascular injury, including stent-injured atherosclerotic lesions, and to recapitulate the rationale for efficient adjuvant antiplatelet therapy, its appropriate duration and the problem of re-thrombosis upon cessation.

5

DIFFERENCES AND COMMONS IN PATHOLOGY AND REACTION ON STENTS BETWEEN CARDIAC AND PERIPHERAL ARTERIES

**Frank D KOLODGIE, Gaku NAKAZAWA, Giuseppe SANGIORGI,
Elena R. LADICH, Allen P BURKE, Renu VIRMANI**

Although many factors related to the development, outcome, and prevention of atherosclerosis in aortic, carotid, and peripheral arterial territories are shared and in common with coronary atherosclerosis, there are distinguishing plaque features among various vascular beds. Since the underlying plaque morphology is critical to the overall performance of interventional devices, in particular stents, it becomes critical to gain a better understanding of phenotypic changes among various vessel types. Unfortunately, morphologic data in peripheral arteries is not as readily available as we base our findings on limited experience, since the opportunity for pathologic examination of peripheral arteries is not as frequent as for the carotid and coronary vasculature. In this review, we discuss similarities and morphologic differences in peripheral arterial disease guided by a more detailed knowledge of coronary and carotid atherosclerosis. Early to more advanced progressive lesions are identified based on descriptive morphology as originally cited for the coronary circulation. The histologic features associated with symptomatic and asymptomatic carotid and peripheral disease will also be addressed in the context of current stent based therapies for the prevention of major recurrent vascular events.

6

DOES THE LUMINAL SURFACE OF A BIOMATERIAL MODIFY ITS HEALING CHARACTERISTICS AND ENDOTHELIALISATION?

Sébastien FRANÇOIS, Karine VALLIERES, Gaétan LAROCHE

Morphology and chemical nature of the luminal surface of arterial prostheses influence their endothelialization and healing characteristics. On one hand, the microstructure of biomaterials can directly influence endothelial cells behaviour because these cells require growing on fairly flat surfaces to organize themselves in their natural 2D network. On the other hand, the surface of synthetic biomaterials is prone to activate the coagulation cascade. Consequently, many strategies such as surface modifications and in vitro cell seeding have been developed to improve vascular prostheses healing and patency. Surface modifications aim to provide specific chemical species on surfaces which can influence cell adhesion or protein adsorption. In vitro seeding is used to artificially produce a layer of endothelial cells on the luminal surface of prostheses, which should reduce graft thrombogenicity. Furthermore, new materials are in development to provide an optimal luminal surface for endothelialization.

This chapter is a review of scientific works aiming to characterize the effect of the aforementioned parameters on blood elements/biomaterials interactions.

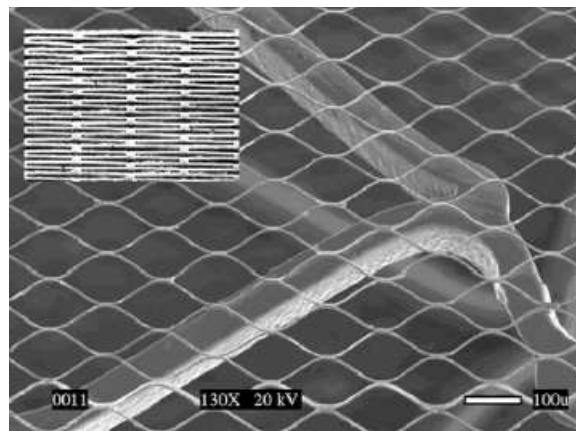
7

MANUFACTURING OF STENTS: OPTIMIZE THE STENT WITH NEW MANUFACTURING TECHNOLOGIES

**Andreas SCHUESSLER, Ullrich BAYER, Gerd SIEKMEYER, Rainer
STEEGMUELLER, Martin STROBEL**

We proposed a review of the different driving forces for further development of stent manufacturing technologies. Influences from the market, the clinics and the customers lead to manifold research and engineering activities.

We focused on developments in the area of materials development, including biodegradable stent materials, and on developments and optimization of manufacturing and surface modification technologies.



8

BENCH TESTING TO PREDICT FATIGUE FRACTURE OF STENTS IN THE SUPERFICIAL FEMORAL ARTERY

Scott ANDERSON

The use of nitinol stents in the superficial femoral artery (SFA) is becoming commonplace. The SFA is a tortuous biomechanical environment that has challenged the durability of these devices. A thorough understanding of the biomechanical loading environment is necessary to design and evaluate new stents. This paper reports recent methods for use of bench testing as a tool to predict fatigue fracture of stents in the SFA.



10

CLINICAL RESULTS OF THE NEW GENERATION BARE STENTS IN THE SUPERFICIAL FEMORAL ARTERY

Jos C VAN DEN BERG

Percutaneous treatment of stenotic and occlusive disease of the superficial femoral artery has recently evolved significantly with the advent of new generation nitinol stents. In this chapter, pathophysiology and functional anatomy of the superficial femoral artery is discussed. A brief overview of results of PTA and/or stent placement using old stent technology will be given. Results as obtained with new stent technology and its repercussions on the new TASC recommendations will be discussed in more detail.

11

COVERED STENT IN THE SUPERFICIAL FEMORAL ARTERY : DO WE NEED THEM ?

Yves ALIMI, Olivier HARTUNG, Mourad BOUFI, Pierre BARTHELEMY, Karim AÏSSI, Pierre CERQUETTA

Although surgical femoropopliteal bypass remains the gold standard technique for the treatment of superficial femoral artery (SFA) disease, new endovascular techniques (subintimal angioplasty, ..) and new technologies (nitinol self-expanding stents, stent-grafts, ...) has become widely available. These latter are perceived by many clinicians to be effective in treating the ever-greater numbers of elderly patients presenting with lower-extremity occlusive disease. When compared to conventional angioplasty alone or with bare stenting, appearance of covered stents offer the possibility of preventing or limiting myointimal ingrowth along the treated segment and then improving the mid-term patency of extensive and complexe SFA occlusive disease; they represent also an interesting tool to treat SFA aneurysms or SFA rupture during long transluminal or subintimal recanalization. However, the large delivery profile and obstruction of side branch access are still important drawbacks, and edge restenosis are not prevented.

Early studies, including our own experience, seem to confirm these potential advantages by reporting 3-years primary and secondary SFA patency rates of respectively 64 to 71 %, and 79 to 80 %, which can be favourably compared with above-knee femoro-popliteal saphenous vein or prosthetic bypasses, especially for TransAtlantic interSociety Consensus type C lesions (extensive but not total SFA stenosis and/or occlusion). Progressively, not only claudicants but also patients presenting with critical or moderate acute limb ischemia, and then more severe SFA lesions, are now included in the studies.

Modification of the TASC recommendations between 2000 and 2007 confirm the extension of endovascular treatment indications to more severe occlusive lesions. However, evaluation of long-term patency and assessment of potential superiority of these devices require further randomized studies with large patient populations, with establishment of recommendations for specific indications, strategy of postoperative surveillance and best medical therapy.

12

DRUG-ELUTING STENTS DEVICES : CLINICAL RELEVANCE AND PERSPECTIVE

Marinella SANDROS, Maryam TABRIZIAN

Drug-eluting stents (DES) are the predecessors of bare metal stents that have revolutionized percutaneous transluminal coronary angioplasty by reducing in-stent restenosis and repeat revascularization. This advancement is accredited to the ability of DES to elute drugs in a controlled manner at the target lesion site inhibiting smooth muscle proliferation which leads to in-stent restenosis. Despite the fact that in-stent restenosis rates are reduced by DES, it is important to recognize that it does not abolish it completely. For that reason research to enhance DES is still on-going. In this chapter, we will convey the biological factors that cause in-stent restenosis, as well as the various drug loading and delivery strategies available and evaluate their clinical efficacy. Furthermore, DES performance is also heavily dependent on implantation techniques and their challenges along with their limitations will be assessed and highlighted. On a final note, we will raise the reader's awareness on the latest efforts with commercially-available DES devices and their future prospect.

13

SECOND GENERATION DRUG-ELUTING STENTS. CLINICAL EXPERIENCE WITH NEW DRUGS AND DESIGNS

Lutz BUELLESFELD

The introduction of the first generation drug eluting stents resulted in a rapid acceptance of this new technology due to the remarkable efficacy benefit compared to conventional bare metal stents. However, with growing experience and availability of mid- and long-term follow up results, we know today that these first generation devices are probably less safe than expected. Multiple meta-analyses have shown that there is a small but definite increase in late stent thrombosis which might offset the clinical efficacy benefit over time. Stent design characteristics such as utilization of durable polymers might be related to that. Various new second-generation drug eluting stents are now developed and clinically tested which might have the potential to overcome this safety issue by 'smart' modifications with regard to one of the typical three drug eluting stent components: the drug, the carrier and the platform. The new drug eluting stents are using new specifically developed drugs, modified polymers, biodegradable polymers or polymer-free carrier models as well as specific stent platforms which address the needs for particular coronary lesion subsets.

This chapter is a review of the current clinical experience with these so-called second generation drug-eluting stents.

14

DRUG-ELUTING STENTS : REVOLUTION OR DOUBLE EDGE SWORD?

Jean-Pierre MONASSIER, Laurent JACQUEMIN, Olivier ROTH

The clinical benefits of drug-eluting stents (DES) in reducing the risk of restenosis are well established and have promoted a great hope for interventional cardiologists and patients. However, recently the safety profile of DES has become the focus of growing attention following presentations of data indicating an increased risk of late stent thrombosis. During the last 6 years, interventional cardiologists evolved from an great enthousiasm to a terrific doubt about the long-term results for their patients with one major question: in preventing intra-stent restenosis did they implant in their patients a device providing a good short-term result but a delayed thrombosis and mortality risk?

Now DES implantations represent more than 80 % of all implanted stents in USA and nearly 70 % in France. Facing the observations of stent thrombosis and their severity, the authors proposed to reassess the true clinical results and possible drawbacks of DES in order to try to answer three questions: Do DES really decrease the rates of restenosis and new revascularizations? What are the rates of DES thrombosis ? Do DES modify survival rate ?

15

SCIENTIFIC BASEMENTS FOR CRYOPLASTY

Yann GOUËFFIC, Philippe CHAILLOU, Alain COSTARGENT, Philippe PATRA

Percutaneous endovascular procedures are increasingly applied to treat peripheral arterial disease. However, restenosis and the need for repeated interventions remain major drawbacks limiting a widespread application of this minimally invasive technique. Cryoplasty as emerged as a promising novel technology with the potential to reduce the rates of restenosis. Cryoplasty combines simultaneous angioplasty and freezing of the artery. However few fundamental and clinical data are available to confirm the interest of this technology. Herein we report scientific and technical basements for cryoplasty, including an update on clinical trials our own clinical experience in the treatment of superficial femoral artery stenoses.



16

PACLITAXEL-COATED ANGIOPLASTY CATHETERS

Gunnar TEPE, Ulrich SPECK, Bruno SCHELLER

Treatment of restenosis after balloon angioplasty continues to be a challenge. Whereas there are no drug-eluting stents (DES) for use in renal and peripheral arteries except for below-knee vessels, DES are becoming more and more important in the coronary arteries. Nevertheless DES also have some major drawbacks such as inflammation due to the coating material and delayed endothelialization which might translate in a higher incidence of late thrombosis. Only recently have alternative modes of local drug delivery been proposed. Several animal studies showed that both paclitaxel coated balloon catheter and paclitaxel added to the contrast medium injected into the coronary arteries reduce restenosis rates. No major adverse effects were observed. Short exposure of the vessel for one minute during a single balloon inflation or infusion with the contrast medium was found to have a clear benefit over plain balloon angioplasty. The promising preclinical studies were followed by clinical trials.

18

ENDOVASCULAR TREATMENT OF FEMORO-POPLITEAL AND INFRA-POPLITEAL LESIONS: TECHNICAL RESULTS AND STENT CHOICE IN DAILY PRACTICE

**Thomas ZELLER, Aljoscha RASTAN, Sebastian SIXT,
Uwe SCHWARZWÄLDER**

Over the last decade considerable advances have been made in percutaneous technology for treatment of atherosclerotic diseases in the femoro-popliteal and infra-popliteal arteries. While treatment strategies are well defined in the iliac segment, where angioplasty and stenting perform well in appropriately selected lesions, the search for a durable transcatheter therapy for infra-inguinal arteries continues. While balloon angioplasty (PTA) is the accepted therapy for short lesions, long diffuse lesions are still recommended for surgical treatment. However, new stent technologies including more flexible self-expanding nitinol stents, covered stents and drug eluting stents have the potential to replace femoro-popliteal bypass surgery as treatment of choice for complex lesions. The major drawback of femoro-popliteal artery stenting is the issue of stent fracture which is still unresolved and the unknown impact on restenosis and vessel wall damage including pseudo-aneurysm formation. There is upcoming evidence that stent architecture is – besides the treatment of restenotic lesions - the strongest predictor of long-term treatment failure following stent-supported angioplasty of femoro-popliteal stenotic and occlusive lesions. For infra-popliteal interventions, there is still a lack of dedicated stent devices. Currently coronary stent devices including drug-eluting stents are used in the majority of the procedures in this vessel area. This chapter reviews the status of percutaneous endovascular stenting techniques for the treatment femoro-popliteal and infra-popliteal artery occlusive disease and the background of device selection.

19

WHICH OTHER FACTORS INFLUENCE PATENCY AND LIMB SALVAGE APART FROM THE CHOICE OF THE IDEAL BIOMATERIAL?

Jan MACIEREWICZ, David BECKETT, Jonathan BEARD

What is more important in trying to improve the results of stenting in peripheral arterial disease: to enhance the stent characteristics, or to medically optimise the patient?

This chapter explores these “non-stent” factors and their influence on clinical outcome.

20

DRUG-ELUTING STENTS AND ANTI-PLATELET THERAPY: CURRENT CLINICAL IMPLICATIONS

Jean-François TANGUAY

Coronary metallic stents have improved early angiographic success and reduced restenosis compared to conventional balloon angioplasty for the treatment of coronary de-novo lesions therefore transforming the field of coronary intervention. An even more significant revolution in the percutaneous management of coronary artery disease occurred with the development of drug-eluting stents (DES).

Recently, several meta-analysis of randomized clinical trials (RCT) reported a striking 50-70% reduction in restenosis or the need for recurrent target vessel revascularization with paclitaxel or sirolimus eluting stents (PES or SES) compared to bare metal stents (BMS). However, concerns may arise from delayed healing of the arterial wall and possible occurrence of late thrombosis in high-risk subsets. Indeed, it was initially reported that the cumulative incidence of stent thrombosis nine months after successful DES implantation in consecutive 'real-world' patients was substantially higher than the rate reported in clinical trials.

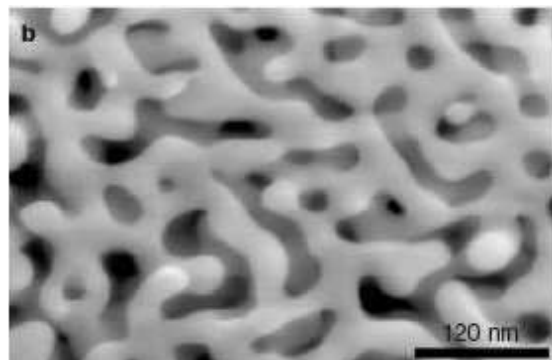
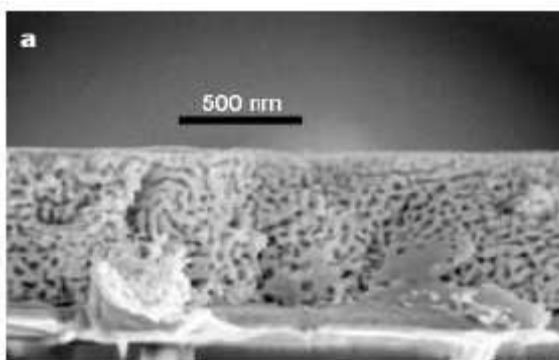
We will review the essential role of the endothelium after stenting as well as the current clinical implications for the clinicians using DES, the critical importance of patient selection, and the current clinical recommendations of long term dual anti-platelet therapy. The promise of using a pro-healing DES platform as a prevention strategy could potentially improve the clinical outcome in stabilizing a vulnerable plaque or in treating a high-risk patient population.

21

NANOTECHNOLOGY – WILL IT REVOLUTION STENT TECHNOLOGY ?

Devang N. PATEL, Steven R. BAILEY

Nanotechnology, is multidisciplinary field of utility and is based on principles derived from engineering, electronics, physical and material science. Manufacturing from these materials is on the molecular or submicron level. The distinguishing feature of nanotechnology is that the bulk properties of materials made from nano sized structures differ significantly from that of the original macro scale material. Endovascular stents potentially depend upon the nanoscale materials. Stent materials may be altered to improve stress and strain. Surface alterations may occur decreasing the inflammatory response or improving endothelialization. Nanodevices will allow the synthesis and control of materials in nanometer dimensions providing access to new material properties and device characteristics in unprecedented ways. Nanotechnology therefore represents the beginning of a revolutionary new age in our ability to manipulate materials and will revolutionize stent technology.



22

ROBOTICS AND VASCULAR BIOMATERIALS: THE FUTURE SURGICAL PROCEDURES

Fabien THAVEAU, Nabil CHAKFE, Jean-Georges KRETZ

Since the first laparoscopic aortofemoral bypass performed by Dion et al. in 1993, minimally-invasive surgical procedures have become more and more frequent. However the high level of technical skill requirement is a blockage for the standardization of these techniques. The introduction of robotic technology into the operating room may potentially transform vascular surgical practice. Robots have the potential to improve the performance of surgery and open up a new sphere of technical achievement.



23

NEWS FROM THE BIOABSORBABLE STENT: WHERE ARE WE TODAY?

Michael HAUDE

Unfortunately, the manuscript has not been received on time for its publication in the book.

24

DO WE NEED A DRUG-COATED STENT IN THE SUPERFICIAL FEMORAL ARTERY?

Goetz RICHTER

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