A new coating for medical implants: Polyzene®-F

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Introduction: Polyzene®-F is a ultra-pure form of a high molecular weight, inorganic polymer with a -[P=N]$_n$- backbone and soft rubber-like properties[1]. The trifluoroethanol side groups result in hydrophobic surface properties of polymer films (advancing water contact angle at 112°). Trifluoroethanol groups can impart anti-inflammatory properties and stabilize proteins in solution against thermal denaturation. Here we summarize the biocompatibility results of Polyzene®-F and focus on preclinical animal studies and their translation into clinical results for CeloNova´s Polyzene®-F coated embolization particles (Embozene™ Microspheres) and the CATANIA™ Coronary Stent System.

Results: Polyzene®-F is a custom-made ultra-pure polymer that can be applied to metal, ceramic, and plastic devices. In a comparative study with other polymers used in medical applications, Polyzene®-F exhibited exceptional properties. The hydrophobic Polyzene®-F surface can adsorb thick layers of proteins from blood, absorbing human serum albumin (HAS) and human immunoglobin (HIgG) in preference over fibrinogen (HFb), fibronectin (HFn), and von Willebrand factor. Furthermore, a film of surface proteins, most importantly including the coagulation-cascade proteins, can to a large extent adsorb reversibly and maintain their molecular conformation and biological activity as probed by Circular Dichroism spectroscopy and specific antibodies, respectively. These observations suggest that Polyzene®-F does not activate the complement system[2].

Polyzene®-F was found to be exceptional resistant to platelet adhesion and surpasses, in this respect by far, medical grade poly(tetrafluoroethylene) (platelet adhesion reduced by 93%) and polyethylene (platelet adhesion reduced by 99 %) surfaces. Similar results were obtained in a dynamic "Chandler Loop" model. A further indicator for excellent biocompatibility and use as a coating for stents is that Polyzene®-F treated surfaces show significantly improved endothelial migration as compared to bare metal surfaces.

Polyzene®-F is currently incorporated into several CeloNova's products as an anti-inflammatory and anti-thrombotic coating, e.g., in embolization particles (Embozene™ Microspheres) and a new generation of cardiovascular stents (the CATANIA™ Coronary Stent System). Embozene™ Microspheres have been successfully applied for the local treatments of liver cancer and metastases uterine fibroids, meningioma, arteriovascular malformations, and hypertrophic obstructive cardiomyopathy. Because cell anoxia and consequent death are the aim of embolization, a complete and long-lasting shutdown of blood supply must be achieved. Host responses to foreign materials are known to influence the biological performance of implants. In comparative minipig studies it was found that all embolic materials triggered a mild inflammatory reaction after liver embolization. As compared to small Embosphere particles, which caused a pronounced inflammatory and giant cell reaction after 4 weeks, treatment with Embozene™ Microspheres resulted in a very mild inflammatory and foreign body reaction, which underscores its good biocompatibility. Recent clinical results confirm the superior performance of Embozene™ Microspheres[4].

The CATANIA™ (CAT) stent is flexible, cobalt chromium, balloon expandable stent. Its surface is treated with a 40- nm-thick Polyzene®-F film to reduce peri- and postprocedural platelet activation and agglomeration, and to prevent tissue reactions that lead to restenosis. Results at 6 months showed that an historical cohort of patients treated with bare metal stent had a statistically significant higher risk of major cardiac and cerebrovascular events in comparison to patients treated with CATANIA™ stent. The CATANIA™ stent treated with Polyzene®-F exceeded not only those for bare metal stents (BMS), but rivaled or exceeded results for drug-eluting stents (DES) in a separate study[5].

Conclusions: Embozene™ microspheres tested in clinical trials show significant improvement in the treatment of liver cancer metastases and uterine fibroids as compared with other embolization particles. The clinical trials with the CATANIA™ coronary stent demonstrate results comparable to, and in some cases better than, many drug-eluting stents, but without multiple complications resulting from the use of drug-eluting stents. Out to 18 months, there has been no death, no heart attack, and no thrombosis reported with the CATANIA™ stent in the ATLANTA clinical trial.

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