Newsletter

GEPROVAS

European Group for Research on Protheses
Applied for Vascular Surgery

JANUARY 2017

Edito

Nabil CHAKFÉ
Prof. MD, PhD - President of GEPROVAS

A year of transition

In our previous newsletter, we presented you with the main areas of development of GEPROVAS.

Over the past six months, we have redesigned our development strategy. This development is included in the projects of the local authorities and especially the NEXTMED project. It also fits in with the development of the IHU, specialised in image-guided minimally invasive surgery, which opened last October.

In 2017 GEPROVAS will truly look to the future. In the fall, we hired Nathalie Couvreur who joined as administrative assistant and Delphine Dion, a textile engineer who will be responsible for explant analysis.

We have drawn up an ambitious business plan aimed at allowing us to move into new premises in 2017 and to prepare for an even more ambitious development project in the next five to six years.

Thank you for your interest in and support for our project.

INFORM | ANALYSE | IMPROVE

Leading actor in public health

The GEPROVAS is an independant and certified structure in charge or research, monitoring and aging characterisation in the field of cardiovascular implantable medical devices.
The GEPROVAS is also involved in the training of surgeons and medical teams.

GEPROVAS'S activities are certified NF EN ISO 9001. GEPROVAS' test plateform is certified NF EN ISO 13485.

LLOYD'S REGISTER LRQA ISO 9001

LLOYD'S REGISTER LRQA ISO 13485

PORTRAIT

Nathalie Couvreur

Administrative Assistant

Qualified in administrative management and human resources, Nathalie has a solid experience of six years as an administrative and human resources assistant in a biotechnology start-up.

Dynamic and rigorous, Nathalie will bring all her know-how to GEPROVAS. She will also be involved in event coordination, communication and marketing.

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Education 2016-2017

The Education department continued its development in 2016 with the organisation of 8 simulation workshops lasting 4 days.

These workshops were aimed at developing the acquisition of technical gestures and the automating of the steps of an operation, in order to secure and improve patient care.

Moreover, GEPROVAS in collaboration with the vascular surgery and renal transplantation department of Strasbourg hosted 4 international fellows for stays of one month.

These visits allow the participants to take part in simulation courses and to observe medical practice in France. They are based on common bonds of trust between hospitals.

Finally, our team was awarded a Strasbourg University Excellence Initiative funding budget (IDEX) to launch a new university training course for graduate students in medicine from February 2017.

The focus will be on the initiation, training and evaluation of surgical and technical gestures in simulation, supported by a strong model validated in prestigious North-American universities. This innovative training will take place using e-learning and simulation.

In 2017, GEPROVAS wishes to continue to organise training courses for different publics; residents, surgeons and students. Furthermore, a new offering for sales forces and operating room nurses is planned for the second half of the year.

2ND ENDOVASCULAR SIMULATION BOOTCAMP

The second "Endovascular Simulation Bootcamp" took place from October 20 to 21.

This event, opened by a lecture by Professor Granry, head of the anesthesia and revival and emergency medicine departments at the University Hospital of Angers, allowed 18 young vascular surgery residents to be introduced to the practice of simulation in suture and endovascular surgery and also to practice sizing. The workshops, led by our team of supervisors from all over France and supported by our industrial partners (WL Gore, Bard, Medtronic, Cook and Vascutek), were a great success, with participants expressing a satisfaction rate of 95%.

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Clinical research

The clinical research activity launched in 2013 in the department of vascular surgery continues to grow.

Five new studies are currently being carried out in the hospital.

Two studies are led by the CHU of Angers and by the CHU of Bordeaux and three are led by industrial promoters (Jotec, Medtronic, Vascutek).

The department of vascular surgery enjoys world-wide recognition in the Valiant-Evo international clinical trial led by Medtronic. This study is aimed at demonstrating the security and the efficacy of the Valiant-Evo thoracic stent-graft among patients who have a descendant thoracic aorta aneurysm and who are eligible for endovascular treatment.

We are the leading world recruiter with 5 patients selected and operated with this endo-graft! We are thus positioned ahead of the United-Kingdom and Canada which demonstrates that in Strasbourg we too are able to offer the latest technologies in terms of care.

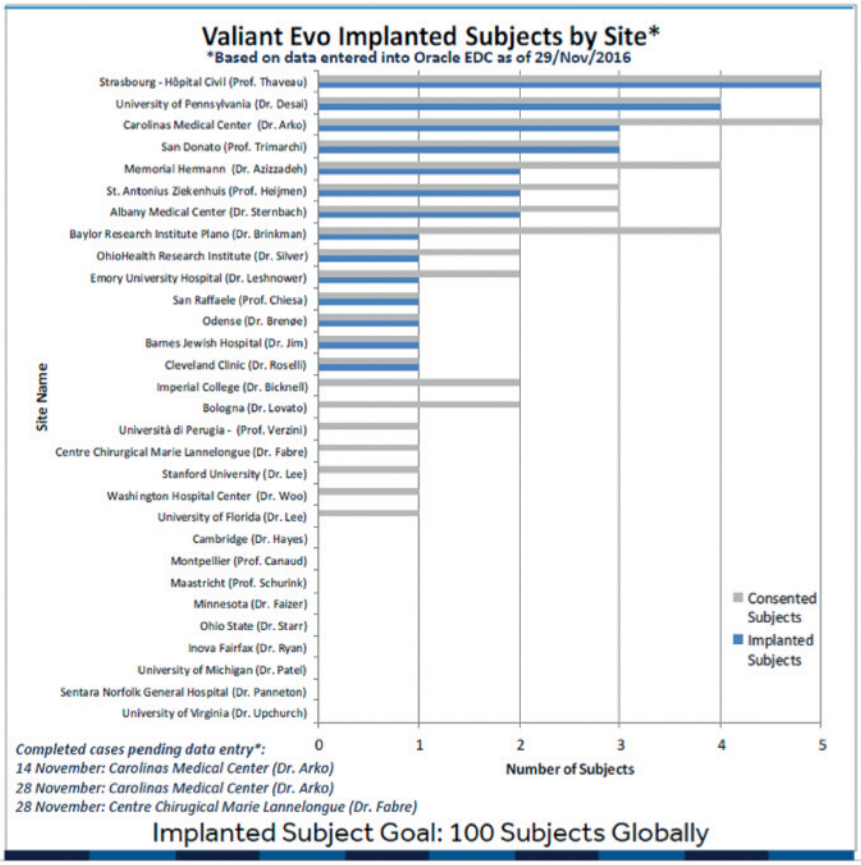
VALIANT EVO INTERNATIONAL CLINICAL TRIAL

ENROLLMENT FLASH
#8 DD 18 NOV 2016

Site	Site activation	# enrolled	# included	Enrollm. Rate (pt/wk)	Inclusion Rate (pt/wk)
Strasbourg, France	5-Jul-16	5	5	0.26	0.26
Milano (San Donato), Italy	17-Jun-16	4	3	0.18	0.14
Nieuwegein, Netherlands	17-May-16	3	2	0.11	0.08
Odense, Denmark	27-Jul-16	1	1	0.06	0.06
Milano (San Raffaele), Italy	21-Jun-16	1	1	0.05	0.05
Bologna, Italy	26-Jul-16	2		0.12	
London (Imperial), UK	31-May-16	2		0.08	
Paris, France	11-Jul-16	1		0.05	
London (St-George), UK	20-Sep-16				
Montpellier, France	9-Aug-16				
Cambridge, UK	4-Aug-16				
Maastricht, Netherlands	18-Jul-16				
Perugia, Italy	11-Jul-16				
London Ontario, Canada					
Quebec, Canada					

Medtronic
Further, Together

PATIENTS TREATED WITH VALIANT EVO:
31 SUBJECTS GLOBALLY (18 US, 13 OUS)*



Follow

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We also provide good results in the clinical study of the CHU of Bordeaux. The principle of this study is to compare three treatments of peripheral intra-stents restenosis.

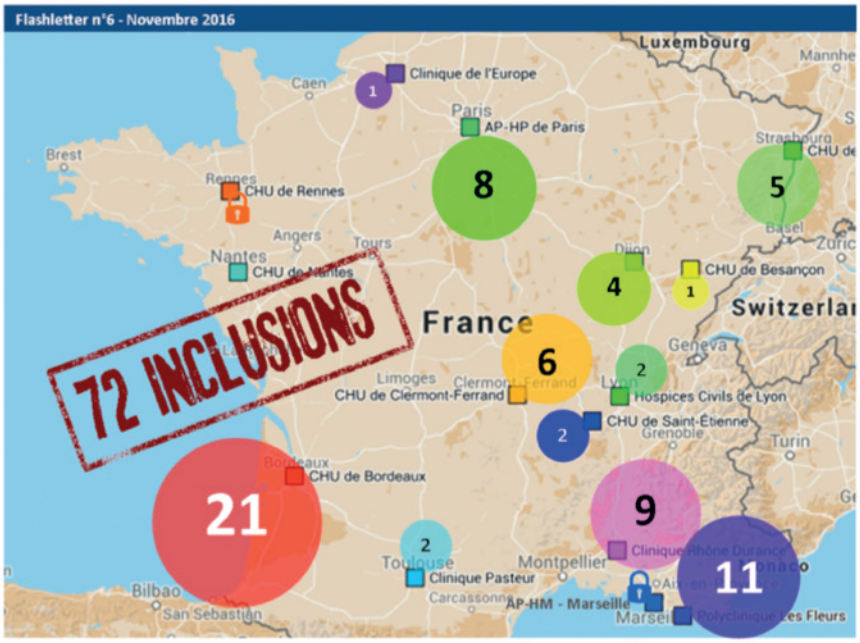
The aim is to calculate the costs of these three techniques and to link them with their efficacy in order to optimize the budget impact on health insurance.

In terms of participation, the department of vascular surgery in Strasbourg is in 5th position nationally.

INTACT

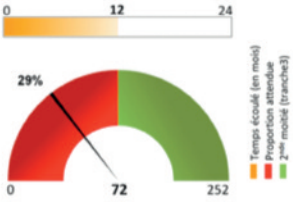
State of progress
November 2016

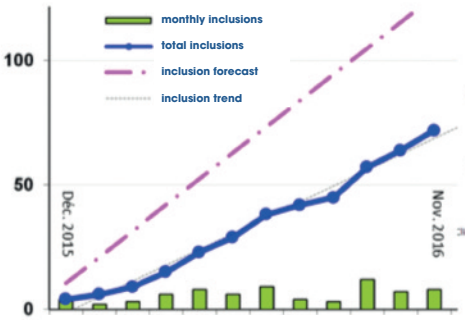
CHU Hôpitaux de Bordeaux



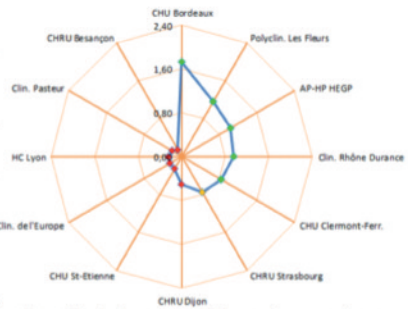
Key figures

12/15 recruiting centers
2 closed centers
72/124 patients included/expected
41 EIG notified since INTACT begin
6/12 centers with inclusion rates >0.8
12 months left to include 252 patients





Cumulated inclusion curve



Recruiting centers inclusion rate (monthly)

In 2017, the vascular surgery department will receive new clinical research studies.

One of them will concern the comparison of the efficacy of different versions of stents in the treatment of the femoral and/or the popliteal artery. New medical and economical perspectives will be at stake next year!

Explant and analyze

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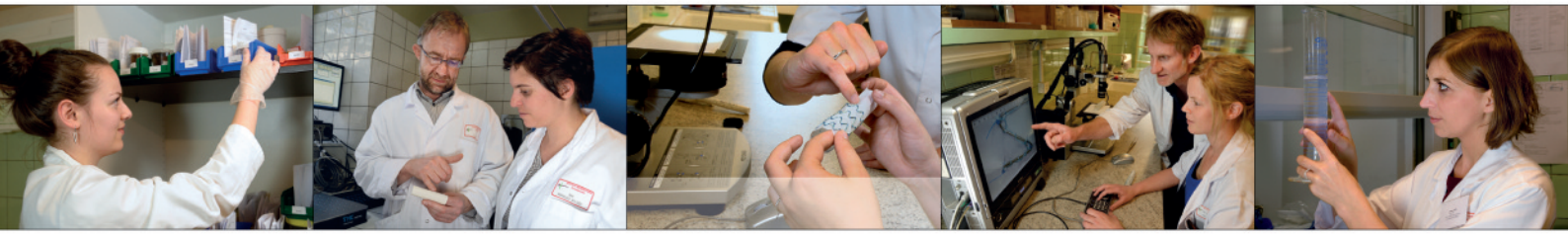
Vascular explant analysis platform

The present European context is right for the development of our vascular explant analysis platform. Indeed, a new European draft regulation for medical devices was published in June 2016 to replace the existing directives (90/385/CEE-93/42/CEE-98/79/CE).

One of the most important objectives of this revision is to ensure a high level of human health protection and patient safety in reinforcing post-market surveillance and vigilance activities. These new regulations should be adopted in the next few years and will mean GEPROVAS will become of considerable importance. Indeed, thanks to the analysis of the 506 explants that we have received since 2011, we have a unique collection of data in the field of vascular medical devices.

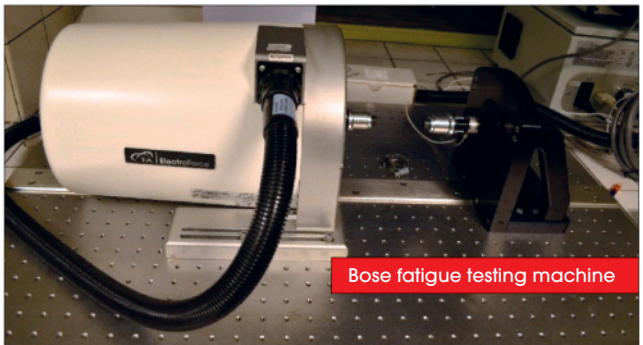
So please continue to support us by sending your explants so that we might together be an actor in the evolution of vascular medical devices!



Test platform – R&D

As part of its research activities, GEPROVAS has acquired two new machines: a radial force test machine to evaluate the radial stiffness of stents and endopotheses (Blockwise) and a fatigue test machine (Bose). Test have already been realized for the company PROTIP thanks to this equipment.

Blockwise machine model TTR2 to calculate radial force



Bose fatigue testing machine

PORTRAIT

Delphine Dion

Engineer

A young graduate of the "Ecole Nationale Supérieure des Arts et Industries Textile de Roubaix", with a master in Medical Devices and Biomaterials from the university of Lille, Delphine has the dual textile and clinical competencies required for vascular explant analysis.

Rigorous and exact, she is very keen to apply her enthusiasm to the development of an innovative tool which would improve the follow up and analysis of vascular implants.

Analyze and innovate

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- **From January 2017,** GEPROVAS in collaboration with the LPMT of the University of Haute Alsace will be a partner of the research team of **Prof. Saber Ben Abdessalem** at the ENIM in Monastir (Tunisia) for the development of braided stents.
- **From December 2016 onwards, Dr. Elie Girsowic**z of Strasbourg University Hospital, will undertake a thesis in partnership with the LPMT of the University of Haute Alsace on the mechanical behavior of peripheral stents under the direction of Pr Nabil Chakfé and Pr Frederic Heim.
- **Dr. Yannick Georg** will defend his thesis on January 6, 2017 on the interactions between endoprostheses and vessels.
- **Prof. Frédéric Heim** held a conference entitled "Textile Heart Valve Prosthesis: State of the Art" at the New Jersey Institute of Technology in New York in October 2016, invited by Professor Michael Jaffe.
- **Jérémie Jayet**, a surgery student, has been a trainee at GEPROVAS since November 2016 as part of a Master's Degree in Surgical Sciences on the theme of fenestration of endoprostheses.
- **Prof. Nabil Chakfé** was invited and represented GEPROVAS at several meetings related to cardio-vascular surgery: ESVS, Copenhagen, 16/09; Carlo Settaci, Sienna, 16/09; CHORUS, Seoul, 16/10; MUC, Munich 16/12; How to do it, Milano, 16/12…

Partnership

ID NEST MEDICAL

In addition, GEPROVAS has signed a partnership agreement with ID-NEST Medical, which has just raised € 450 000 in funds to pursue the development of a new stent concept. GEPROVAS is responsible for developing specific tests to evaluate the performance of prototypes.

Permanent members of GEPROVAS:

Nabil Chakfé | MD, PhD - President
Bernard Durand | PhD - Vice President
Frédéric Heim | PhD - Head of R&D
Fabien Thaveau | MD, PhD - Treasurer, Head of Clinical Research
Yannick Georg | MD - Head of Education
Anne Lejay | MD, PhD - Associate
Julie Papillon | PhD - Head of Operations
Camille Schmidt | Study Coordinator
Delphine Dion | Engineer
Nathalie Couvreur | Administrative Assistant

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Vascurisq
esvs
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Our partners,

Alsace BioValley L'innovation santé
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