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◆HISTORICAL PERSPECTIVE ◆

The First Steps in Endovascular Aortic Repair: How It All Began

Nikolay L. Volodos, MD

Centre of Cardiovascular Surgery, Kharkov, Ukraine.

In my opinion, there were two main factors that contributed to my interest in the development of endografting of the aorta and its main branches. First of all, fate helped me to become one of the disciples of the founder of vascular surgery in the Ukraine, the academician Alexander Alekseevich Shalimov, who was a talented, very progressive man who strove for innovations. Dr. Shalimov determined my professional career; in 1962 he assigned me to work on the surgical treatment of ischemic heart disease, a therapy that had just started to develop all over the world. We performed coronary angiography and coronary artery surgery on dogs in very primitive conditions. But most importantly, we closely followed progress in that area abroad, mainly the work done by American doctors. We learned about, and enjoyed, the achievements of outstanding innovative physicians, such as Charles Dotter from Portland, Oregon, with his methods of coronary angiography, and the work of Donald B. Effeler from Cleveland, Ohio, on coronary artery surgery in dogs. In 1965, Dr. Shalimov founded the first specialized department of vascular surgery in the Ukraine, and I was its first chief.

The second main factor was the unusual conditions under which vascular surgery in our country developed. In the Ukraine, a vascular surgeon was both a surgeon and an angiography specialist at the same time. We personally performed all kinds of angiographic research. For example, in Kharkov, I performed the first 440 coronary angiographies, and later I operated on some of those patients. My 1971 PhD dissertation was dedicated to the topic: "Coronary Angiography and Surgery of Coronary Arteries." My second dissertation (1988) for a doctoral degree was on acute arterial pathology, in which one of the chapters was dedicated to the development of what we called at that time remote endoprosthetics (i.e., stent-grafting).

Before going into the specific details concerning the development of stent and stent-graft technology in the Ukraine, I would like to give credit to some of the co-workers who helped bring our ideas to fruition. In our early years together, we had developed productive, friendly relationships with the leading technical, scientific, and research institutes and large industrial enterprises in Kharkov. They helped us design and manufacture many medical tools and devices for cardiovascular surgery, since the domestic medical industry was unable to keep up with the scientific progress.

In the 1980s, Kharkov was the largest industrial center of the Ukraine, which is why I consider the design and manufacture of all elements for endovascular stent-grafting to be the result of a joint effort between the medical team under my leadership (Ivan Pavlovich Karpovich, Vladimir Ivanovich Troyan, and Julia Valentinovna Kalashnikova) and the industrial engineers of Kharkov to whom I am obliged: Vasily Egorovich Shehanin, aca-

Corresponding author: Nikolay L. Volodos, MD, Centre of Cardiovascular Surgery, ave. Lenina 64, flat 12, Kharkov 61103, Ukraine. E-mail: *volodos@ilt.kharkov.ua; nikolayvolodos@gmail.com; kalashnikova.jv@gmail.com*

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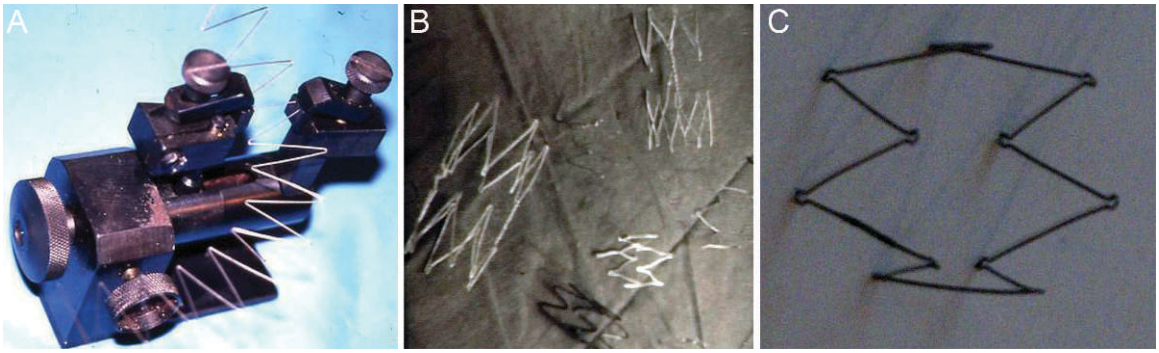

Figure 1 ◆ (**A**) The first special device for the manufacture of zigzag springs. (**B**) The first construction of the stent (1982). (**C**) Optimal variant of stent construction (1983).

demician Boris Ieremievich Verkin, Professor Nikolay Emmanuilovich Ternuk, Anatoly Semenovich Neoneta, Aleksander Aleksandrovich Aksenko, Leonid Fedorovich Yakovenko, Mikhail Semenovich Gurnak, Leonid Stepanovich Keremet, Nicholay Ivanovich Ustinov, and others.

LOOKING FOR A MINIMALLY INVASIVE THERAPY

The challenges associated with treating patients with serious comorbidities and ruptured abdominal aortic aneurysms (AAA) or acute thrombosis of the abdominal aorta pushed us to search for a less traumatic treatment method. We turned to Dotter's idea, which he reported in 1969,[1] and in 1982 started to look for a structure that could give a prosthesis a self-fixating quality, something that we considered to be the key to achieving a minimally invasive therapy.


СОЮЗ СОВЕТСКИХ СОЦИАЛИСТИЧЕСКИХ РЕСПУБЛИК
ГОСУДАРСТВЕННЫЙ КОМИТЕТ СССР
ПО ДЕЛАМ ИЗОБРЕТЕНИЙ И ОТКРЫТИЙ
АВТОРСКОЕ СВИДЕТЕЛЬСТВО
№ 1217402
"Протез кровеносного сосуда"
Авторы: Волосось Николай Леонтьевич, Лехкун Василий Егорович и Карпович Иван Иванович
15 ноября 1985г.

Figure 2 ◆ Our patent for a stent-graft (USSR Patent 1217402, issued in May 1984).

By the beginning of 1983 a strategy had been developed and directions were outlined. The main step forward was the design and manufacture of a Z-shaped stent. In searching for the most suitable material, we chose an elastic wire made of stainless steel (40KHN10MTYUVI; Bauman Moscow State Technical University, Moscow, Russia). To connect the ends of the wire, extensive mechanical studies were conducted, including various methods of welding, among which spot-welding proved to be the most suitable. We designed and produced a special device (Fig. 1A) for the manufacture of the zigzag stents. Over the course of our work, the device evolved from a primitive 2-level structure of bent wire (Fig. 1B) to the optimal version (Fig. 1C), which was protected by a USSR patent in May 1984 (Fig. 2), 5 months earlier than the Gianturco patent.

Since the stent was fundamentally a new geometric figure, it was necessary to study its properties. Firstly, the radial forces produced by the Z-shaped stent had to be calculated. To do this, we designed a special test apparatus that began as a primitive device with dead weights and evolved to precision instruments (Fig. 3), such as gramometers. Physicists calculated on a theoretical basis the elastic properties that the Z-shaped stents would need to hold the prosthesis: ~0.2 g/mm^2. A

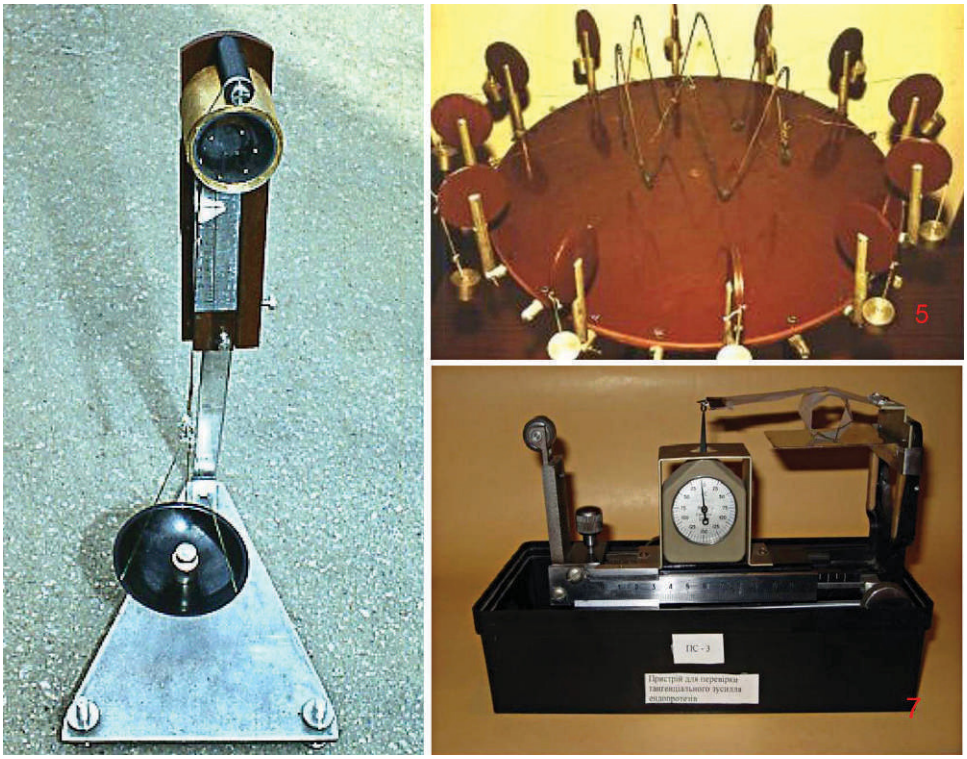

Figure 3 ◆ The evolution of devices for studying the radial forces produced by a Z-shaped stent.

nomograph was developed to help us choose the wire diameter and number and height of the zigzags in a stent depending on the diameter of the vessel. Based on this research, a self-fixating synthetic prosthesis was produced by placing a Z-stent in a standard Dacron synthetic graft (Sever, Leningrad, Russia). The crimps were removed by boiling and stretching the prosthesis. The Z-stent was placed into the lumen of the prosthesis and attached with thin atraumatic sutures (Fig. 4).[5]

The next major challenge was to determine the magnitude of the radial force necessary to hold the prosthesis in the aorta. We also needed to identify the behavior of the endoprosthesis under conditions of pulsatile flow, as well as study the reliability of its fixation and calculate the dislocation forces. For this purpose, a series of experiments (Fig. 5) were performed on cadaveric aortic segments in

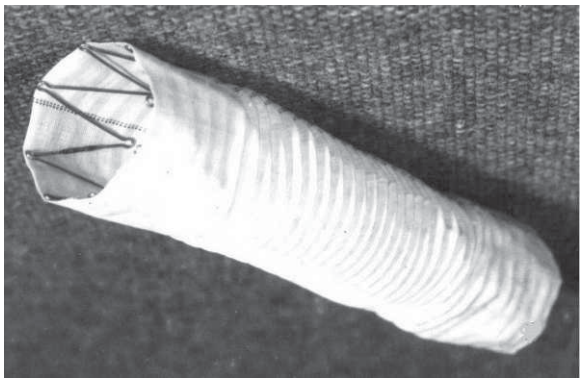

Figure 4 ◆ The first variant of the self-fixing endoprosthesis.

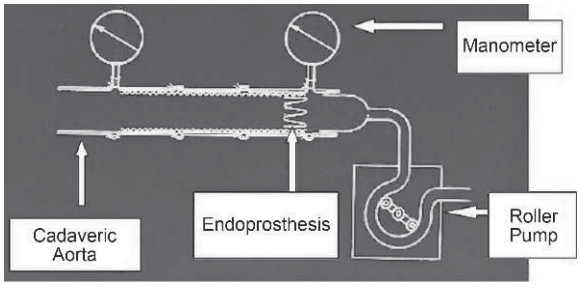

Figure 5 ◆ Schematic drawing of a pulsatile flow apparatus to study endoprostheses in cadaveric aortic segments.

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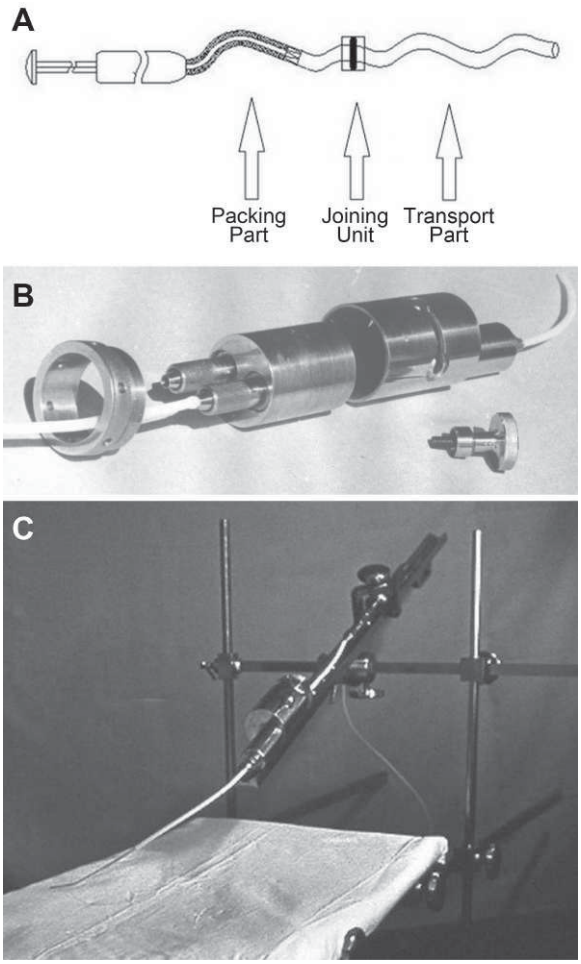

Figure 6 ◆ (**A**) Schematic drawing of our first delivery system. (**B**) One of the variants of the joining unit of our experimental delivery system. (**C**) Special metal frame attached to the operating table for fixation of the delivery system.

which endoprostheses had been placed; a heart-lung machine was used to achieve pulsatile flow under physiological conditions. The experiments confirmed the theoretical calculations; the stent must develop a radial force of 0.2 g/mm^2 in order to achieve stable fixation in the aorta.

About the same time, it became clear that delivering the endoprosthesis into the thoracic or abdominal aorta from the femoral artery would require a special delivery system. Our first delivery system (Fig. 6A), which was also patented, consisted of 3 parts: the loading part, the transportation component, and the docking device (Fig. 6B) to connect them.[6] The transportation component was made of polytetrafluoroethylene (PTFE), which was introduced using a guidewire and a catheter into the aorta through a peripheral artery. At the distal end of the transportation component, there was a docking device with a valve to ensure hemostasis. The loading component, also made of PTFE, compressed the endoprosthesis to several times its nominal diameter by means of special cone devices. The compressed endoprosthesis was then moved out of the loading component, through the docking device, and into the transportation component using a pusher, a flexible or rigid metal rod placed immediately behind the proximal stent. During the initial stage of our work, we attached great importance to rigid fixation of the delivery system, which was achieved by mounting the delivery system on a special metal frame attached to the operating table (Fig. 6C).[6,9,11] We felt that this would guarantee exact placement of the endoprosthesis in the aorta.

It was obvious that for a firmer contact, it was necessary to dilate the endoprosthesis from inside. For this purpose, a special balloon was developed and manufactured. It consisted of a dual channel radiopaque catheter connected at the end to a cylinder, the wall of which consisted of 3 layers: 2 outer ones made of latex rubber and a middle one made of a non-elastic fabric (Fig. 7A) that would guarantee a given diameter during balloon inflation (Fig. 7B), thus creating a non-compliant balloon.[7,8,12]

In those days, there were no computed tomography scanners, so to precisely measure the diameter of the vessels in which the stent-graft would be implanted, we designed and manufactured a special measuring catheter with graduated long metal markers placed 10 mm apart (Fig. 8).[6,55]

Having done the theoretical and experimental work, we decided that it was now possible to carry out experiments on animals. After making all of the above mentioned items between 1983 and 1984, experimental research was performed on big dogs (25–30 kg). The diameter of the aorta was determined using aortography and the measuring catheter. The endoprosthesis was introduced from the femoral artery and delivered into the

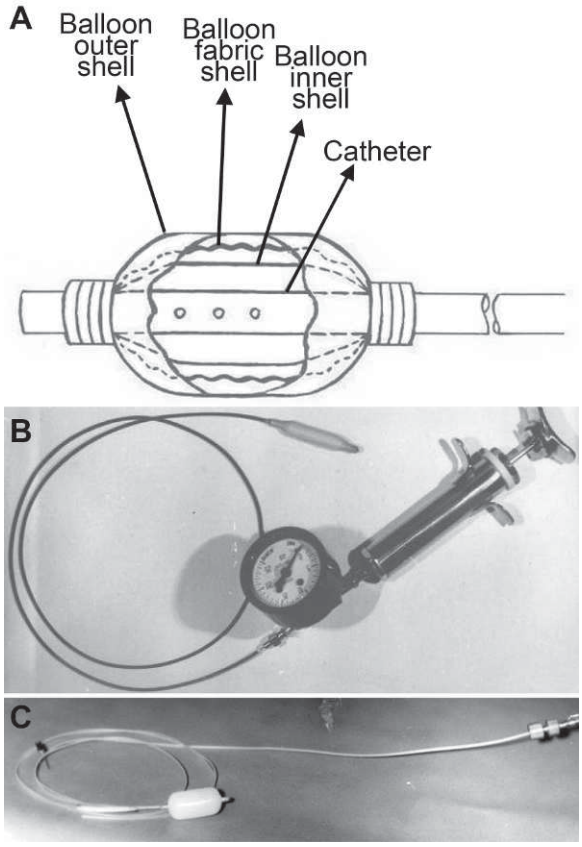

Figure 7 ◆ (**A**) Schematic diagram of our balloon catheter construction. (**B**) The balloon catheter is ready for use. (**C**) The balloon catheter is inflated maximally.

abdominal aorta using our delivery system. Finally, the endoprosthesis was seated with the help of our non-compliant balloon catheter. Fifteen experiments were performed; all the dogs survived and were monitored for 6 months. Every 2 months aortography was performed. There was no evidence that the endoprostheses shifted or dislocated (Fig. 9A) and all remained patent. After 6 months, the dogs were sacrificed. Macro- and microscopic examinations of the vessel wall were performed in the aortic segment in which the endoprosthesis was located. Macroscopically, the inner surface of the endoprosthesis along its entire length was covered with a grayish semitransparent tissue forming a kind of intima identical to the intima of an elastic-type vessel, with a smooth shiny surface that we tentatively called neointima. The Z-stent

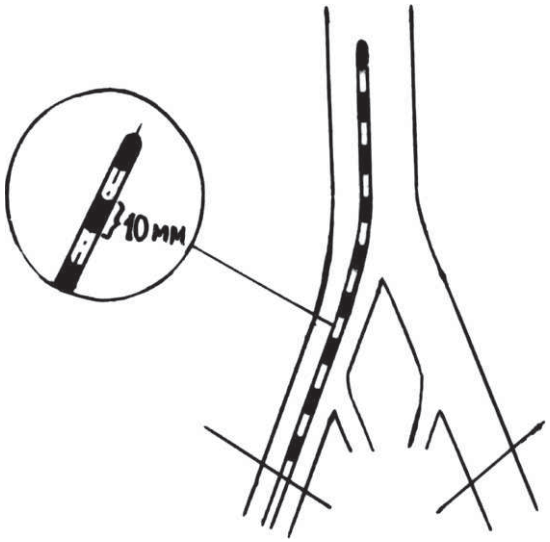

Figure 8 ◆ Our special measuring catheter.

was also submerged in a similar tissue, through which the wire struts could be seen (Fig. 9B).

With the new method of placing endoprostheses, we considered a thorough study of morphological changes in the vessel walls where the device was seated to be of paramount importance. The intima along the entire length of the endoprosthesis was inlaid with thickened endothelium and consisted of collagen fibers oriented concentrically on the cross section of the vessel, with spindle-shaped fibrocytes and smooth muscle cells enclosed between them (Fig. 9C). The neointima thickness was 0.25 to 0.65 mm. In the zone where the struts of the stent were located, neointima of the endoprosthesis was thicker: 0.39 to 0.58 mm. Under the prosthesis, the native intima of the aorta was thickened, and newly-formed vessels of a sinusoid type and capillaries were seen (Fig. 9D). In the media of the aorta, hyperplasia of elastic fibers was observed. The adventitia was somewhat thickened, the number of histiocytes was increased, and the elastic fibers were thickened. Thus, placing the endoprosthesis inside a vessel led to an anticipated reaction of the aorta, with the formation of neointima due to the growth of structural elements of the native intima in response to excitation.[3] These experiments demonstrated the functionality of the Z-stent

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