Device for Extravasal Correction of the Function of Vein Valves Based on Nitinol Shape Memory and Its Clinical Application

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1 Introduction

Lower extremities varicosity is widely spread. Statistical data presented by various authors show that in Japan, 8–9% of adult population suffer from varicosity, in Africa 7–10%, in the USA 20–30%, in England 10–17%, in Europe 20–30% [1–8]. In accordance with Goldmann (1990) [9], only in the USA 80 million of adults have varicosity.

Side effects, namely, trophical ulcer, chronic dermatitis, thrombophlibitis, bleeding from expanded veins, bring to the temporary disability that sometimes can result in total disability, where the patients become invalid. 0.2–3.9% of population [10–12] have the lower extremities trophical ulcer, 75–90% of these cases are caused by varicosity and post-thrombophlibitis [13, 14]. In accordance with Smith et al. (1990) [15] 500,000 in the United Kingdom and 800,000 in the USA suffer from chronic venous insufficiency complicated by trophic ulcers. Trophic ulcers resulted in significant loss of working days: 500,000 working days and 2 million working days were lost in England and Wales, and USA, accordingly [12]. Until recently, the chronic venous insufficiency progress was connect- ed to the pathological expansion of hypodermic veins or thrombic occlusion of deep main veins. But researches conducted during the pass twenty years have revealed that the venous blood flow along deep veins requires correction or reconstruction.

As we can see from the materials of the Ninth World Congress on phlebology (Kyoto, Japan, 1986); 15th World Congress on angenology (Rome, Italy, 1989) and 12th World Congress on phlebology (London, England, 1995) the main idea was underlined that only high level of diagnostics of disturbance of venous blood flow in the system of hypodermic and deep veins can allow to discontinue standard operations and to begin to make operations based on pathogenic reasoning specific for every patient. All the above-mentioned conditions are of high social significance in research and would improve the treatment of the veins diseases.

Problem of elimination of pathological retrograde blood flow in the deep main veins constitutes the most significant moment of operative treatment of varicosity. This allows to reduce venous hypertension and to cut down the probability of further pathological changes in the system of veins [16]. In case the deep veins valves are certified to be in the normal state, it is reasonable to make a
Varicotomy of hypodermic veins with perforant ligation [16]. But it has been revealed that 80–94% of the patients have ectasia of deep veins and relative insufficiency of their valve [17–20], which requires a correction of their function.

In case of the hypodermic vein removal and perforants ligation without further reconstruction of abnormal valve, severe misfunctions of microcirculation and tissues trophism [21, 22] in distal sections of lower extremities stay in force. Trophic ulcers treatment does not bring any reliable results [23, 24]. In accordance with Hopkins et al. (1992) [25] the stable venous pressure in the veins of the foot above 60 mmHg increases the risk of ulcers formation higher than 50%.

A variety of methods of venous valvular correction apparatus are known and still under permanent development. Today the methods of extravasal correction of valves are widely used because they are lowing traumatic and technically available. This method lies in the fact of vein narrowing in the valve area, which allows the closing of the cusps and the correction of the valve function. Zelenin and Kurakov (1979) [26], Kuo-Hau Zhang et al. (1993) [27] used muffs from auto-vein to correct valve functions through vein narrowing. Askerkhanov (1984) [28] used muffs from broad fascia; Raju et al. (1991) [29] used artificial muffs. But artificial muffs can cause the vein cicatrization and narrowing [30]. Automuffs do not cause such cicatrization but the veins become narrower [30]. Moreover, these materials are not flexible and they are skeleton-free, which makes it difficult to monitor the extent of vein narrowing.

Tsukanov [31] proposes to narrow the vein in the valve area by using fascial paravasual structures, while Zuev with co-authors (1986) [32] propose to perform peryvenous muscular plastic. But most patients do not have pronounced fascial structures and the muscles suturing leads to cicatrization. It is difficult to monitor the vein narrowing and the skeleton function is not reliable.

Lavsan skeleton spirals do not present limitations [19]. Lavsan is inactive and is not subjected to destruction. Correction techniques are simple. Spaces between loops provide quick revascularization of the vein wall. But the valve cusp anatomic defectiveness in 20–25% of the cases does not allow to perform complete correction of their function.

Moreover, the spiral positioning is time and labor consuming process. The vein should be mobilized along a significant length, which complicates cicatrization and requires to apply turnstiles. At the same time, the vein can be traumatized by the sharp ends of the spiral in the reeling process in the area of abnormal valve, which further prolongs the post-operative period. The most negative factor of any spiral (and any muff) circular in section is that it significantly reduces the vein lumen, which has negative impact on its passage capacity.

In 1975, Kistner [33] performed the first intravasal direct reconstruction of the valve cusps (valvuloplastic) in clinic. Positive results of valvuloplastic (VP) were certified by other authors [34–39]. Raju and Sottiurai [40] modified and simplified these operations techniques. They performed VP through transverse incision and valve cusp suturing through the vein wall. But this method of VP has not gotten a wide application in common surgical practice because of high-risk of post-operative thrombosis and technical complication. In accordance with Perrin [41], 10–13.8% of thrombosis were observed within 36 h after operation.