Homemade and Early Stent-Grafts

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18.1 The Beginning

In 1994, an international team [1] from Montefiore Medical Center, New York, and the Instituto Cardiovascular, Buenos Aires, aired the first report on the endovascular treatment of a popliteal artery aneurysm (PAA). The aneurysm had a diameter of 26 mm and a length of 15 mm, and harbored mural thrombus. The patient was a man, aged 63, with significant heart disease history. The procedure was performed through a cut down of the superficial femoral artery, in local anesthesia. A homemade device was used (Fig. 18.1) consisting on a 6 mm PTFE graft (stretch Goretex, W.L. Gore & Ass., Elkton, MD, USA) and two Palmaz stents (Johnson & Johnson Interventional Systems, Warren, NJ, USA): one stent was sutured to the proximal end of the graft, and the device was delivered through the superficial femoral artery; the stent was ballooned and fixed in the distal part of this artery; then, a second stent was passed through the graft and dilated to fix its distal end to the walls of the below-the-knee PA. After three months, ultrasound control demonstrated a thrombosed aneurysm sac around a patent graft. The Authors were very cautious in recommending the widespread use of this technique, but stressed its feasibility outlining the advantages of reduced invasivity, reduced need of blood transfusion and of major anesthesia, and, particularly, the obvious advantage of avoiding incisions around the knee.

The following year, the same group [2], in a review of their initial experience with endovascular treatment of complex arterial disease at different levels, reported on three cases of PAA treated with the aforementioned technique. The first case, i.e., the object of the previous report, was ok after 26 months, but the other two failed, one for technical problems and the other because the graft thrombosed on the sixth postoperative day: both were finally treated with open surgery. The Authors underlined that the available technology was primitive.

However, the feasibility of endovascular treatment of PAAs was really appealing: the interest (and the ingenuity) of both vascular surgeons and interventional angioradiologists was strongly stimulated, as was the interest of device producers.

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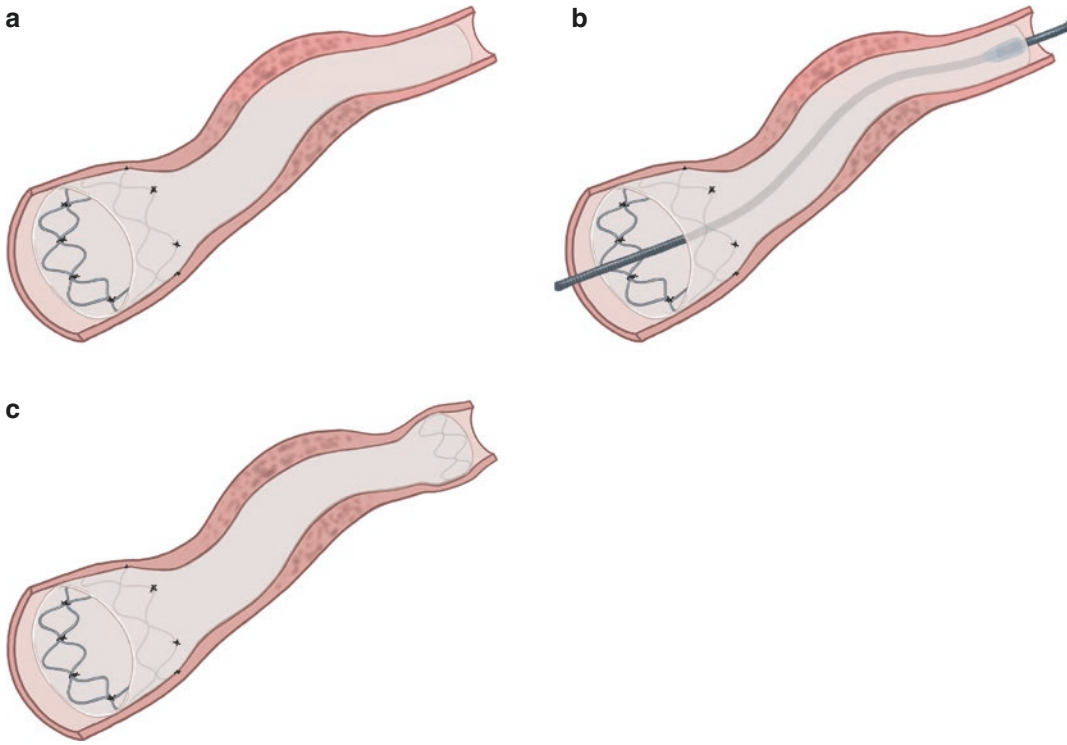

Fig. 18.1 Artist's conception of the homemade stent-graft used in 1994 by Marin et al. [1] (**a**) The PTFE graft with a Palmaz stent sutured at the proximal end has been delivered into the distal superficial femoral artery (the lower end reaching the distal popliteal artery) and the stent has been dilated. (**b**) A second stent is passed through the graft down to its distal end. (**c**) The distal stent has been dilated to fix the graft extremity in the below-the-knee popliteal artery

18.2 Home-Made Stent-Grafts

Mohan et al. [3], reviewing their experience in endografting of PAAs from 1994 through 2005, reported that a device similar to the one described by Marin et al. [1] was used in their first case: the graft occluded at 4 months and the limb was salvaged with an autologous vein femoro-peroneal bypass.

Spoelstra and Lesceu [4] (from Halle, Belgium) reported 11 cases of endovascular treatment of PAA, using a PTFE graft with two Palmaz stents (one proximal, one distal). In six cases, the clinical presentation was of critical ischemia from thrombosis/distal embolization and intra-arterial thrombolysis preceded the stent-grafting. The implanted graft (endo-bypass) measured in length from 10 to 28 cm. After 30 days and 6 months, primary patency was respectively 83% and 72%, with a secondary patency of 92%. Only one early failure was observed and was successfully treated with thrombolysis. A 6-month follow-up was available in 7/11 cases; an extended follow-up (2 years) was available only in one case.

Krajcer and Diethrich [5], in 1997, described the case of a 54-year-old man, with heavy ischemic heart disease, affected with a PAA 2 cm in diameter and 3 cm in length, containing thrombus. They used a 4 mm thin-walled PTFE graft (W.L. Gore & Ass., Flagstaff, AZ, USA) predilated to 8 mm and mounted over an 8 mm Wallstent (Schneider, Minneapolis, Min., USA). The Wallstent is a self-expanding stent made of a stainless alloy mesh, soft and flexible along its longitudinal axis, with good radial force and conformability; it was preferred to the Palmaz stent because this, in the Authors' experience [6], was

more easily damaged by compression and deformation; moreover, the Wallstent allows to fashion a low profile device, which may be implanted percutaneously. The Authors felt that stent flexibility was very important in their patient, who was a crane operator. At 8-month follow-up, the aneurysm was thrombosed and the stent-graft was patent with normal flow inside.

In 1999, Van Sambeek et al. [7], from Rotterdam, reported the endovascular treatment of ten aneurysms and pseudoaneurysms of the femoropopliteal tract. They used a PTFE graft sutured, at the proximal and distal ends, to a Palmaz stent. True PAAs were four: in two cases, technical problems obliged to turn to open surgery; in a third case, early thrombosis from graft kinking was treated with additional stenting, but rethrombosis occurred and the patient was finally treated with conventional surgery; only one case had a positive outcome, the stent-graft being patent after 13 months. The Authors concluded expressing a doubtful judgment about the validity of the technique.

18.3 The Cragg Endopro System 1– Passager

The first commercially available covered stent used to treat popliteal aneurysms was the Cragg Endopro System-1 (Mintec, Freepoint, Bahamas). From 1996, it was produced under the name of Passager by Boston Scientific (Watertown, MA, USA). The stent is formed by Nitinol wire annealed into a tubular zigzag configuration, the single elements being tied together with 7/0 poplypropylene. Nitinol (Nickel-Titanium Naval Ordinance Laboratory) is an alloy of Nickel and Titanium with an approximately equivalent atomic percentage of the two elements, known as shape-memory alloy: Nitinol stents recover their predetermined diameter at body temperature. The stent is self-expandable; in the Cragg stent-graft configuration, it is covered with a thin (0.1 mm) layer of woven dacron (Fig. 18.2).

The Cragg stent was used in several cases, particularly in the period 1995–2000 [8–21]. Formichi et al. [12] treated successfully four cases, with a follow-up of 4–21 months (mean 11.2 months). Henry et al. [8, 13, 14] reported on seven cases, observing three complications: one technical failure; one early occlusion (conversion to open surgery); one occlusion in the 3–6 month interval (treated conservatively). A detailed account of procedure and outcome is available for 19 cases from six European Centers [10, 11, 15–20] (Table 18.1).

Technical success was achieved in 18/19 procedures: in one case [18] it was not possible to cover the distal end of a large and tortuous aneurysm, and, owing to recurrence, or better persistence, the patient was submitted to conventional surgery. Early (<30 days) thrombosis occurred in four cases: two were converted to open surgery, one of these after rethrombosis following successful thrombolysis; one stent-graft was recanalized with thrombolysis, patency being maintained at 31 months; in one case,

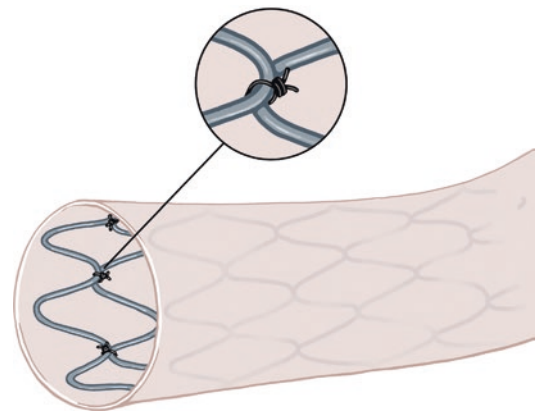

Fig. 18.2 Artist's conception of the Cragg Endopro System 1– Passager (see text)

Table 18.1 Outcome of stent-grafting with the Cragg Endopro System 1– Passager in 19 cases from six European centers

	1 month	3 months	6 months	12 months	24 months
Primary patency	14/19	12/14	8/10	6/8	4/5
Secondary patency	15/19	13/14	9/10	7/8	5/5

alcohol sympathectomy apparently assured limb salvage. One stent-graft occluded at three months, with diffuse involvement of leg arteries, leading to amputation. Finally, one occlusion was observed at 7 months, following prolonged squatting position while gardening and was successfully treated with thrombolysis (further follow-up of two months). All the other stent-grafts remained patent; the longest primary patency was of 26 months [20]; the longest secondary patency was of 31 months [16]. In all cases, different regimens of antiplatelet or anticoagulant therapy were followed. When specified, the number of outflow vessels, the number of stent-grafts used, the site of aneurysm distal end (above or below the articular line of the knee) did not apparently influence the outcome of the procedure.

Joyce et al. [22] proposed to deliver the Cragg stent in a retrograde way, through a transverse arteriotomy on the distal politeal artery: this, to avoid the risk of distal embolization (theoretically possible with the usual antegrade technique) and as well to achieve an easier progression through the aneurysm (especially in the presence of kinkings and tortuosity) by exerting a traction on the artery so as to straighten its course. They described one case, successful, with patent graft and thrombosed aneurysm at 1-year follow-up.

18.4 The Wallgraft Endoprosthesis

The Wallgraft endoprosthesis (Boston Scientific, MA, USA) consisted initially on a self-expanding elgiloy stent covered by a thin layer of PET (polyethylene terephthalate) bonded with siliconate adhesive.

Elgiloy is a super-alloy containing Cobalt 39–41%, Chromium 14–16%, Nickel 14–16%, Iron 11.3–20.5%, Molybdenum 6–8%, Manganese 1.5–2.5%.

In the second generation, the stent was bonded, throughout its entire length, to a covering graft of braided polyester, with Corethane (polycarbonate urethane) adhesive.

This endoprosthesis was used in several Centers in Europe and the USA to treat PAAs until 2005/2006, starting in 1997 [9, 21, 23–31]. The results are often mixed with those of other types of stent-grafts, but, in some cases, a detailed account of procedures and outcomes is available.

A consistent series came from the Texas Heart Institute [23, 26, 30], in cooperation with the Arizona Heart Institute and other USA Cardiovascular Centers. From October 1997 through April 2000, 12 cases were treated in the context of a trial project on endografting of peripheral arterial aneurysms [26]. Inclusion criteria were: atherosclerotic aneurysm located above the knee, reference vessel diameter between 7 and 11 mm, landing zones at least 1 cm from bifurcation or important branches. Exclusion criteria were: age <50 years, need for the stent-graft to cross the knee joint, life expectancy <1 year, no surgical candidate, contraindication to antiplatelet or anticoagulant or thrombolytic therapy. The diameter of the stent-graft was oversized of 1–2 mm and overlapping zone, when needed, was at least 2 cm. All the procedures were percutaneous. All the patients were submitted to lifelong antiplatelet regimen (Aspirin 325 mg). The primary patency was 77% at 6 months and 69% at 12 months, the secondary patency was 92.3%. The Authors commented the results observing a discorcenting incidence of thrombosis but as well an encouraging secondary patency rate, the lack of distal embolism, the uniform limb salvage. The work was updated in 2009 [30], the Wallgraft being used until 2006 (to end the trial), whence only the Viabahn was used. A follow-up of 5 years or more was reported for seven endografting procedures and, among these, the angiographic witness of the fair result (aneurysm excluded, graft patent) of the first case treated with Wallgraft [23] was included.

Another important experience was reported by the team at Insubria University (Varese, Italy): after a first series of seven cases treated from September 1998 through December 2001 [25], an updating was published in 2006 [29], totalling 12 cases available for follow-up. The outcomes are outlined in Table 18.2. There were six (50%) early failures: four cases were converted to open surgery; in two, secondary patency was gained

Table 18.2 Outcome of 12 Wallgraft endograftings, from Laganà et al. [29]

	30 days	6 months	12 months	24 months	36 months	48 months
Primary patency	6/12	6/8	6/8	6/8	3/4	2/2
Secondary patency	8/12	8/8	8/8	8/8	4/4	2/2

through mechanic thrombectomy and PTA; in one of the latters, following reintervention, the loss of overlapping caused reperfusion of the aneurysm, which was successfully treated with ultrasound guided thrombin injection. The Authors observed that occlusion affected 3/7 asymptomatic cases and 3/5 cases presenting with ischemia; 2/4 cases in which the middle PA was involved, and 4/8 cases involving the proximal PA.

Case reports on Wallgraft endografting were published by Henry et al. [24] and by Gerasimidis et al. [27].

The former reported the case of a trisaccular aneurysm treated with two stent-grafts for the total length of 22 cm; the graft acutely thrombosed after two months (following 1 week of unusual and prolonged knee flexions) and repeated thrombectomy allowed secondary patency at 14 months.

The latter reported two cases: one, presenting with claudication, occluded within 30 days and was managed conservatively; one, presenting with rupture, was successfully treated achieving a primary patency of 31 months. Both aneurysms were located above the knee.

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