Intrinsic Structural Failure of Polyester (Dacron) Vascular Grafts. A General Review

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Abstract. Intrinsic structural failure of Dacron prostheses is a late exceptional complication, resulting from a loss of structural integrity of the graft. The authors report six cases of non-anastomotic false aneurysms in the mid-portion of a vascular Dacron graft, observed at a mean of 12 years after insertion. It concerns four femoro-popliteal bypass grafts, one cross-over graft and a branch of a bifurcated aorto-bifemoral graft, implanted between 1980 and 1990. This represents 0.2% of all vascular Dacron grafts implanted in authors’ department since 1980. The degenerated prosthesis was excised, and a new bypass graft was inserted. In three cases, histological analysis revealed a foreign body giant cell reaction against fragmented Dacron fibers. In none of the cases there was evidence of graft infection. The authors discuss the evidence and etiopathogenicity of this late, unusual complication, inherent to the Dacron graft material. The most probable causative factor is material fatigue, leading to gradual breakdown and fragmentation of individual fibers, and subsequent biodegradation of the basic material. Such an intrinsic weakness of prosthetic fabric has only be observed in first and second generation Dacron grafts.

Introduction

Dacron (polyethylene terephthalate,PET) prostheses are widely used as a durable and valuable vascular conduit, since its introduction in 1957 (1). Dacron, originally a trademark of DuPont (the first manufacturer of the yarn), has become common use in surgical language, and will be used throughout the text, rather than polyethylene terephthalate or polyester. Despite the proven reliability and acknowledged good long term performance of Dacron prostheses, structural defects, resulting in graft rupture or false aneurysm formation, have been sporadically reported (2-22). Such prosthetic failures have been observed in a variety of knitted Dacron grafts, manufactured by different companies. Modifications in the manufacturing process made Dacron grafts more resistant to cyclic pulsatile stretching and improved integration of the prosthetic material into the host tissue. Oppositely, only few reports concern Teflon (polytetrafluoroethylene, PTFE) prostheses (23-26). This graft inherent complication is observed after seven years or more of implantation. The frequency of this potential complication is very low (0.5% to 3%) (27).

The etiology of occasional structural textile failure is supposed to be multifactorial (13, 27). Possible causative factors, evoked in literature, are manufacturing flaws (errors in the production process), erroneous storage conditions, inappropriate surgical handling, material fatiguing and biodegradation.

An extensive review of the literature is made, based on a short series from author’s institution. The series concerns six defective prostheses in which holes and tears were observed more than 12 years following implantation, leading to huge midgraft pseudoaneurysms and perigraft haemorrhage. The authors discuss in detail the supposed mechanisms of loss of integrity of Dacron grafts.

Clinical series

During the last decade, the authors observed six cases of midgraft, non-anastomotic pseudoaneurysms in Dacron vascular prostheses (four femoro-popliteal 8 mm grafts, one 8 mm femoro-femoral cross-over graft and one aorto-bifemoral bifurcation graft). The patients presented a sudden pulsating, painful, tender mass at mid-thigh level (four degenerated femoro-popliteal grafts), at
suprapubic level (one degenerated cross-over graft) and at the right lower quadrant of the abdomen (a degenerated branch of a bifurcated aorto-bifemoral graft). There were no signs of focal inflammation. The diagnosis was readily apparent on clinical examination and on imaging studies, which revealed a false aneurysm along the course of the graft. In two cases the patient presented with hemorrhage and rupture of the pseudoaneurysm, requiring urgent repair.

The mean delay after implantation was 149 months (range: 13 to 180 months). The grafts were implanted between 1980 and 1990. It concerned three Microvel® Double Velour De Bakey (Meadox Medicals - Oakland, NJ, USA) prostheses, one Weaveknit Dacron (Vascular, USCI, United States Catheter and Instrument Company) prosthesis, one Sauvage Filamentous Vascular (USCI) prosthesis and one Cooley Double Velour Knitted Dacron (Meadox Medicals - Oakland, NJ, USA) prosthesis. Two of the defective grafts had been thrombectomised with a Fogarty balloon catheter 7 and 8 years earlier. None of the grafts was externally supported by rings. The six observations of intrinsic graft failure concern 0.2% of all Dacron grafts implanted at our institution since 1980. The defective graft was partially (n = 2) or entirely (n = 4) excised, and a new bypass graft was inserted. All patients had an uneventful postoperative course. The new prosthetic bypass functioned well for a mean of 41 months (range: 24 to 108 months).

Gross inspection of the defective graft revealed multiple, separate bleb-like saccular pseudoaneurysms (mean size: 25 mm) along three of the four explanted femoropopliteal grafts, corresponding to distinct fenestration holes inside the graft texture (Figs. 1 and 2). In the ruptured pseudoaneurysm of a limb of a bifurcation graft, a vertical rent of 12 mm was evidenced, 4 cm proximal to the femoral anastomosis, just underneath the inguinal ligament. This led to subtotal disruption of the graft and contained rupture. The remainder of the bypass graft had a normal aspect. The degenerated cross-over graft was surrounded by an encapsulated old haematoma, probably due to interstitial blood seeping throughout the dilated (35% increase in diameter) prosthesis. Two huge pseudoaneurysms of 45 mm and 50 mm diameter were close to both ends of the graft, where a 4 mm hole was evidenced (Fig. 3). One of the pseudoaneurysms was rapidly expanding, secondary to contained rupture. The anastomotic sites were intact. In two of the defective femoro-popliteal grafts, there was a concomitant, but independent anastomotic pseudoaneurysm, where the suture had pulled out of the fabric. Release of the suture line was due to unravelling of the prosthetic textile. Four grafts showed diffuse dilatation (mean of 28% increase in diameter, compared to manufacturer’s stated size).

Bacteriologic analysis of the retrieved prosthesis was negative in all cases. Histology was obtained on four retrieved defective grafts. The wall of the saccular pseudoaneurysm consisted of dense fibrous tissue, with complete absence of Dacron fibers. The defect inside the prosthetic wall contained broken filaments. In three cases, these prosthetic debris elicited a foreign body

Fig. 1
Angiographic image of a degenerated femoropopliteal Dacron bypass graft. Two non-anastomotic pseudoaneurysms are evidenced at the distal segment of the prosthesis. There is also an anastomotic pseudoaneurysm at popliteal level.
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Giant cell reaction, characterized by the accumulation of numerous multinucleated giant cells along the broken filaments (Fig. 4). Histo-enzymatic analysis revealed a pronounced activity of acid phosphatase inside the giant cells, suggestive for active digestion of Dacron fibers.

Discussion

Intrinsic structural failure of a fabric vascular graft is defined as the inability of the graft to retain its structural integrity after implantation (13). By definition there is no history of direct trauma in the area of the graft nor evidence of prosthetic infection. It is clinically evident as a pulsating mass along the course of the graft. The focal ectasia or pseudoaneurysm is secondary to a hole or tear in the body of the graft, outside the anastomotic areas. The first published case concerned a woven femoro-popliteal Dacron graft, and was reported by Knox in 1962 (9).

A short historical survey of prosthetic vascular conduits is useful (28, 29). The first vascular conduit was conceived by Voorhees (30) in 1952, and its textile was a Vinyon “N” polymer (used in parachute cloth) (Union

Fig. 2
Multiple bleb like pseudoaneurysms along a femoropopliteal Dacron graft, implanted 12 years ago. Angiographic (2A) and CT-scan (2B) image.

Fig. 3
Two mid-graft pseudoaneurysms in a femoro-femoral crossover Dacron bypass-graft. The left sided pseudoaneurysm shows a contained rupture.
the dark-green prosthetic fibres (insert). Numerous multinucleated giant cells are seen along the lumen (L), broken filaments of the defective saccular pseudoaneurysm consists of a dense fibrous tissue (F). Around the lumen (L), broken filaments of the defective prosthesis elicit a marked foreign body giant cell reaction. The grafts showed excessive dilatation secondary to loss of tensile strength and a decreased suture retention strength (17, 33). Their use was discontinued after some years. This lesson learned from the past should alert the manufacturers of endovascular graft devices covered with ultrathin textile. Structural failure, such as holes, tears and rents in the textile fabric near the bare springs or metallic scaffold, have been observed some years after implantation (34, 35).

Another innovative milestone in the original concept Dacron grafts was the velour coating, which gives a filamentous soft surface by an additional perpendicular pile of microloops of yarns, added to the knitted texture of ground yarns (36). Internal velour (1967) (36), external velour (1973) (37) and double velour (1977) (38) prostheses exhibit an enhanced trapping and adhesion of platelets and fibrin, favouring strong anchorage of neo-intima and outer capsule. A further step was the substitution of cylindrical velour filaments by trilobar ones, with a greater surface. It was an attempt to improve “heal ability” and to produce a velour of superior quality. However, trilobar filaments appeared to be less durable, and their use was discontinued in 1981. The pursuit of a completely endothelialised flow surface was elusive and a fault concept. The neo-intimal on the flow surface is mainly set up from fibrous tissue and is as far not antithrombotic, since almost devoided from endothelial cells. The strong tissue integration of knitted prostheses results in a reduced tendency to dilate and in an increased resistance to infection.

Actually, all knitted prostheses are coated or impregnated by a sealing (collagen, albumin or gelatine impregnation), making preclotting prior to implantation no longer necessary. The sealants do not interfere with the compliance of the knitted prostheses and the tissue ingrowth. As mentioned before, crimped knitted Dacron prostheses exhibit an inherent tendency to dilate after implantation, once pressurised. The mean dilatation is about 18% (39) and can vary enormously between grafts of a given or different trademarks.

Intrinsic structural graft failure occurs after a mean delay of seven years following implantation (2-22). In literature, extremes of 12 months (26) and 19 years (5, 14-16, 22) have been reported. The defective graft segment typically shows multiple fenestrations (8, 10, 19, 21, 27). Total disruption, with pseudoaneurysm formation at midgraft level, has also been reported (3, 16, 23, 25). It mainly concerns first generation knitted Dacron grafts have a porosity of 1500 ml/cm²/min, are more compliant and manifest superior handling characteristics compared to woven grafts. Later manufacturers fashioned ultra-light weight knitted Dacron fabrics (USCI), spacing the yarns, with large interstices and high porosity, in order to further promote graft incorporation within and anchorage to the surrounding tissue. The compliance of the knit trellis nor with the tissue ingrowth. As mentioned before, crimped knitted Dacron prostheses exhibit an enhanced trapping and adhesion of platelets and fibrin, favouring strong anchorage of neo-intima and outer capsule. A further step was the substitution of cylindrical velour filaments by trilobar ones, with a greater surface. It was an attempt to improve “heal ability” and to produce a velour of superior quality. However, trilobar filaments appeared to be less durable, and their use was discontinued in 1981. The pursuit of a completely endothelialised flow surface was elusive and a fault concept. The neo-intima on the flow surface is mainly set up from fibrous tissue and is as far not antithrombotic, since almost devoided from endothelial cells. The strong tissue integration of knitted prostheses results in a reduced tendency to dilate and in an increased resistance to infection.

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**Fig. 4**

Microscopic examination of a retrieved defective graft, H & E 50× (O.M.) and 200× (O.M., insert). The external wall of the saccular pseudoaneurysm consists of a dense fibrous tissue (F). Around the lumen (L), broken filaments of the defective prosthesis elicit a marked foreign body giant cell reaction (arrows). Numerous multinucleated giant cells are seen along the dark-green prosthetic fibres (insert).
grafts. Woven Dacron grafts are stronger and less prone for structural defects.

The incidence has been estimated at 0.5% to 3% in the earliest series (4, 19, 27). However, it is impossible to determine the exact frequency of structural degeneration of vascular prostheses. Not all observations are reported in the literature, possibly by fear for litigation. Another cause of underestimation of the incidence is that some cases of structural failure could lead to graft thrombosis and consequently, the prosthetic defect is ignored; hence the patency rate of the bypass grafts is variable at different levels, lower in femoro-popliteal than in suprarenal sites. Obviously only grafts patent for several years are susceptible to manifest loss of structural integrity. Finally, there has been a continuous evolution in the manufacturing process of vascular grafts and improvement of fabric design, making the comparison of sporadic case reports somewhat difficult. Even if the true incidence is not known, it seems that this complication is uncommon and rare.

For the most recently marketed vascular Dacron prostheses, reports on structural failure are exceedingly rare (3). Technological advances and improved quality of textile fabrics and graft design are claimed to yield better resistance to cyclic continuous hydrodynamic strain. But, a possible explanation could be that the changes are almost observed five or more years following graft insertion.

Manufacturers of vascular prosthetic fabrics should provide information on recent improvements in their graft-design or in the production process. The modified knitting pattern of Köper-interlacing of yarns (“sharkskin” stitches, Gelsoft, Sulzer - Vascutek - Inchinnan, Scotland) is relevant. Köper-knitted grafts have a greater burst strength and less tendency to dilate after implantation than warp-knitted Dacron grafts (18% increase in diameter versus 27% compared to manufacturer’s stated nominal diameter of the prosthesis) (40). For Albograft (Edwards Lifesciences, Biomateriali - Brindisi, Italy), the diameter of the yarn was increased and the number of filaments per yarn was decreased (n = 24) at the same time, in order to improve the burst, radial and longitudinal resistance of the fabric.

Almost all Dacron grafts dilate to a variable degree (from 5% to 84%, with average of 18%) shortly following insertion (39, 41). These dimensional changes early after implantation are inherent to the graft material and can be considered as a predictable phenomenon. Moderate (10% to 20%) dilatation of a pressurised Dacron graft is as so far not a matter of concern, is clinically irrelevant and cannot be defined as an intrinsic structural failure (28).

A uniform dilatation of Dacron grafts is secondary to flattening of the crimps once the graft is pressurised, to rearrangement and separation of the loosely interlaced knitted yarns (a phenomenon defined as gradual “yarn slippage” leading to enlargement and expansion of the interstices) and to progressive straightening of the yarns, submitted to pulsatile flow (4, 13, 14, 17, 22, 28, 39, 42). This results in loss of compactness and greater expansion of the knit, occasionally associated to interstitial blood seeping (19, 43). Cases of excessive dilatation up to 218% (10) and 367% (42) have been reported. Radial distensibility is typical for knitted Dacron grafts and is less observed with woven Dacron and with PTFE Teflon grafts, which are dimensionally more stable (13, 44, 45).

Prior dilatation is even not an essential prerequisite to late degenerative changes (13, 27, 29, 32, 33). There is clinical evidence that graft dilatation is unrelated to late structural graft failure, since midgraft pseudoaneurysms have been observed in externally supported ringed prostheses (2, 16, 25, 26). Ringed prostheses do not manifest generalised dilatation. Loss of structural integrity has also been observed in non-reinforced PTFE grafts, which exhibit less tendency to dilate (23). Many of the sporadic case reports do not mention generalised dilatation of the graft and only describe focal midgraft pseudoaneurysms, holes, tears or rents in the textile (8, 10-12, 16, 18, 21, 27).

Structural graft failure i.e. loss of integrity, occurs preferentially at the remeshing line of knitted Dacron prostheses (5). The remeshing line is the site where two textile bands are sutured together to create a tubular conduit. At that site, the yarns (a bundle of 27 to 54 Dacron filaments) are more stretched during the manufacturing process and have absorbed more tension. These filaments are more prone to breakage, resulting in a longitudinal tear. Another predictable area of weakness is the black guideline, allowing proper alignment during implantation (5). Thermal dye fixation could damage and weaken the yarns. Crimp ridges are more associated with fiber breakage, pleading for structural fatigue as underlying mechanism (27). On the peak of the ridges, the fibers are more elongated and exhibit reduced resistance to hydrodynamic strain. Material wear of Dacron filaments is the most probable cause of fiber breakdown and late degeneration of Dacron grafts (5, 25, 27). Repetitive hydrodynamic microtrauma, due to pulsatile blood flow, results in progressive stretching and thinning of the yarn filaments, with cracking or gradual rupture of some filaments. The ends of these distorted broken fibers appear as tapered and frayed (5, 27). All the load is then transferred to the remaining neighbouring filaments of the yarn, which will finally snap. On scanning electron microscopy the abrupt breaks appear as square ended (27).

The mechanical stress during manufacturing and after implantation is more important in small caliber straight tubes. This explains why tears are mainly observed in the branches of bifurcated grafts (6, 12, 15, 19, 22), in
femoro-popliteal (2, 3, 8, 10, 16, 20, 23, 24) and in axillo-femoral (19, 21, 25, 26) grafts.

The loss of structural integrity observed in externally supported ringed grafts, could be the consequence of a compliance mismatch between the inextensible plastic rings and the textile between the rings. Transversal rents have been observed at the junction of the rings, so the pseudoaneurysms protrude between the rings (2, 26). Moreover, the thermal fixation of the rings to the textile could fragilise the yarns and predispose them to breakage.

Additional external forces, such as compression and stretching of a prosthetic branch of a bifurcated graft underneath the inguinal ligament (7, 12, 15, 19), repeated bending at bone crossing (pelvic rim, ribs) or at the joint knee, or clot extraction by balloon catheter during graft revision (21, 24-27), could accelerate the degenerative process of graft wearing and fabric erosion. This fatigue in regions of high stress was noted in three of the six observations reported.

Biodegradation of the basic polymer is another probable contributing factor to fiber breakdown (46). Historically, Dacron and PTFE material were considered as ideal for vascular conduits, because of their inertness and minimal tissue reactivity. It is possible that, years after implantation, the macromolecular composition of polyethylene is modified by osmotic splitting or by hydrolytic fragmentation of weakened filaments. These subtle changes could provoke a foreign body giant cell reaction with recruitment of multinucleated giant cells in the vicinity of the defective graft segment (46, 47). This has been observed in three of the histologically analysed degenerated grafts of this series, and also by other authors (6, 7, 12, 16, 26, 27, 47).

Inappropriate rough handling of the graft by the surgeon and iatrogenic damage to the graft (i.e. application of unpadded clamps, overstretching during tunnelisation) is a possible but unprovable factor implicated in late structural failure of a graft. If structural graft failure would be the consequence of damage by surgical manipulation, then its frequency would be much higher (28).

Manufacturing flaws (such as excessive heating during yarn texturisation and crimping by thermo-fixation, excessive stretching of yarns during knitting, chemical cleaning, gamma or beta ray sterilisation (48)) are also questionable in relation to loss of structural integrity of a graft. The fabrication process is standardised and computer controlled. A meticulous quality control is performed before the graft is marketed. A cold method for compacting and crimping of the textile tubes has been introduced recently for the Albograft (Edwards Lifesciences, Biomateriali - Brindisi, Italy) to reduce weakening of the textile structure. Since ionising radiation has been related to molecular chain scission, the manufacturer of Albograft preferred gas sterilisation with ethylene oxide over radiation sterilisation, in order to preserve material integrity (48).

Chafke (5) and others (15, 17) make a plea for a cooperative clinical registry and retrieval program of defective grafts (an explant archive), in order to contribute to a better knowledge and in an effort to provide documentation on this rare phenomenon of late graft deterioration.

Today, Dacron prosthetic fabrics remain one of the most popular prosthetic conduits. Dacron prostheses can be considered as reliable and durable arterial substitutes, with a very low, unpredictable risk of structural failure or degenerative changes. Biological substitutes for arterial bypasses (umbilical vein, bovine carotid arteries) have not fulfilled the expectations and have been abandoned by many vascular surgeons, mainly because of their structural instability and aneurysmal degeneration (28, 49).

The ideal vascular prosthetic conduit should be “on shelf” available, durable and longstanding with a durability superior to the life-expectancy of the host, resist to dilatation, resistant to infections, and biocompatible. The ideal graft should exhibit and maintain a thromboresistant flow-surface and elastic properties, comparable to those of the original undiseased artery to which it is sutured, in order to approach the patency, compliance and flexibility of a normal artery. Such an optimal graft has not been produced. Some investigators work on the incorporation of molecular substances, such as growth factors, anticoagulants or antibiotics, and cellular layering (endothelial seeding or sodding), in order to resemble an endothelialised normal artery (47).

Finally, degeneration of Dacron textile fabrics is so sporadic and its probability is extremely low, that there is no evidence that regular periodic imaging by echoduplex scan of every graft is mandatory. This is opposite to the recommendation of serial echoduplex of the midgraft by other authors (7, 8, 11, 19-21, 39, 33, 42). However, since structural failure is linked with the duration of patency, limbs of an aortic bifurcated graft should be checked by ultra-sound every three year. Ultrasound surveillance of aortic bifurcated grafts is all the more justified since palpation of a pseudaneurysm at iliac level is rather difficult, if not impossible.

References

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