

Long-term *in vivo* Alterations of Polyester Vascular Grafts in Humans

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Objectives: To examine the influence of *in vivo* hydrolysis on the physical properties of polyester grafts and their correlation to the period of implantation in the human body.

Materials and methods: Sixty-five explanted vascular grafts were obtained after 0–23 years of implantation due to suture aneurysms (18), occlusion (12), graft infection (12), failure of graft material (7) and post-mortem (16). The surface was examined by scanning electron microscopy, the molecular integrity by infra-red spectroscopy and physical strength by probe puncture.

Results: Scission of macromolecular chains and loss of strength were shown. It was demonstrated that hydrolytic degradation of polyester takes place with increasing time of implantation in humans. Analysis by linear regression showed that polyester grafts lose 31.4% of their bursting strength in 10 years and 100% in 25–39 years after implantation.

Conclusions: Regular follow-ups of patients with aged vascular grafts and the precise documentation of implanted materials are necessary to estimate graft degradation.

Key Words: Polyester; Vascular grafts; Degradation; Hydrolysis.

Introduction

Polyester vascular grafts have been implanted in human beings since nearly 40 years. Early experiences made by military surgeons with parachute textiles led to the choice of polyethylene terephthalate (polyester) as a vascular graft material.¹ Dacron® fibres from E.I. DuPont de Nemours & Company, Inc. were the first polyester fibres to gain acceptance by the Food and Drug Administration (FDA) in the U.S.A. This resulted in their almost exclusive use by all graft manufacturers.² Various alterations of textile structure led to improvement of healing characteristics, tissue in-growth, suture retention and reduction of graft dilation. Today, warp-knitted and woven polyester grafts are used world-wide for replacement of the aorta and iliac arteries.

Reports of graft rupture leading to surgical intervention are rare.^{3–10} The hydrolytic degeneration of

polyester vascular grafts has been mentioned in literature since the mid 1970s.^{11–14} In 1979 Rudakova *et al.* predicted complete degradation of polyester fibres after 30 years of implantation in both humans and dogs.¹⁵ The initial filament strength decreases by 50% in 10 years under similar conditions.¹⁵ Graft manufacturers confronted with this problem emphasise that alterations to the polyester have been made in the last 15 years in order to improve its resistance to hydrolytic degeneration.

In 1992 we started a project in co-operation with engineers, technicians and vascular surgeons in order to investigate explanted grafts. We were interested in the chemical and physical aspects of material alteration leading to the observed failure of polyester vascular grafts and their correlation to the period of implantation in the human body.

Materials and Methods

Until the end of 1995, 170 explanted polyester vascular grafts were obtained from 29 clinics in Germany, Austria and Great Britain. So far, 65 of these explants have

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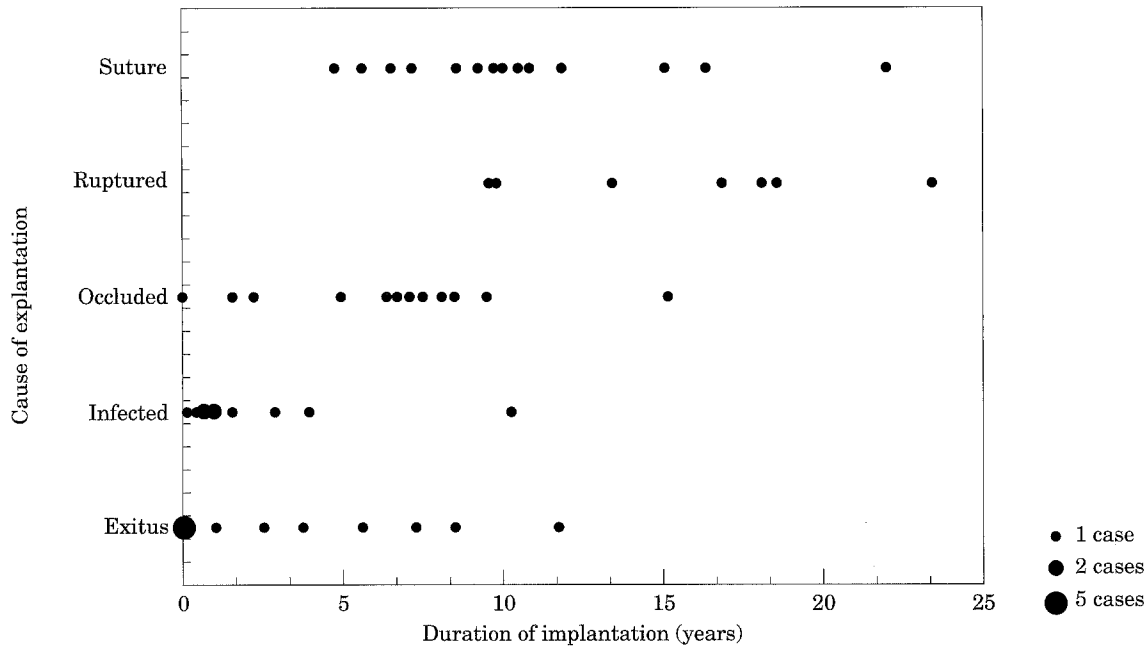


Fig. 1. Relationship between the cause of graft explantation and the duration of implantation for the 65 examined explants.

been examined by the methods explained below. The majority of grafts (63) were warp-knitted, one graft was woven and one weft-knitted. The examined 65 grafts had been implanted between 1971 and 1994, the time of implantation ranging between 0 and 23 years. They were explanted because of anastomatic aneurysms in 18 (28%), occlusion in 12 (18%), graft infection in 12 (18%), rupture of graft material in seven (11%) and post-mortem in 16 cases (25%). Figure 1 shows the relationship between the cause of explantation and the duration of graft implantation for the 65 examined explants. Most graft infections occurred within the first years of implantation. The majority of occlusions were seen between 5 and 10 years. Anastomatic aneurysms reached a peak frequency at around 10 years, whereas graft ruptures were scattered between 9 and 23 years after implantation. The graft ruptures mostly contained pseudoaneurysms. Figure 2 shows such a graft aneurysm after enzymatic removal of tissue. The remains of the polyester material show a mosaic-like structure. The exception was one case in which the transverse rupture of a 10-year-old aortic Dacron® tube graft lead to vast retroperitoneal bleeding, shock and sudden death.

Grafts explanted in our hospital were immediately stored without fixation in a refrigerator at +5°C before being cleaned. Explants from other clinics were sent by mail. Seven were fixed in formalin, 58 were without fixation. All grafts were cleaned immediately on arrival. An enzyme-detergent TERG-A-ZYME (Alconox,

NY, U.S.A.) was used. The cleaning procedure was as proposed by Berger and Sauvage.³ As recommended, 3.75 g detergent were dissolved in 500 ml of water. The grafts were left in this solution at 45°C for 5 days. The clean specimens were thoroughly rinsed in cold water and dried at room temperature for at least 24 h.

Electron microscopy

Scanning electron microscopy (SEM) allowed the observation of filament surfaces of the explanted grafts. Images were acquired on a Hitachi S-4500 cold field emission instrument (Hitachi, Kobe, Japan) using an accelerating voltage of 1 kV. Several filaments were retrieved from every cleaned, dried graft and separately placed on self-adhesive carbon platelets on aluminium tables. Gold coating was not necessary. Multiple random photographs were obtained at several magnifications.

Mechanical examination

The probe puncture test, described in ISO 7198-2 for cardiovascular implants and tubular vascular prostheses,²⁰ is used by graft manufacturers to assess material quality. Due to the circular penetration hole and the hemispherical indenter, the orientation of textile yarns is irrelevant and damage of the textile structure

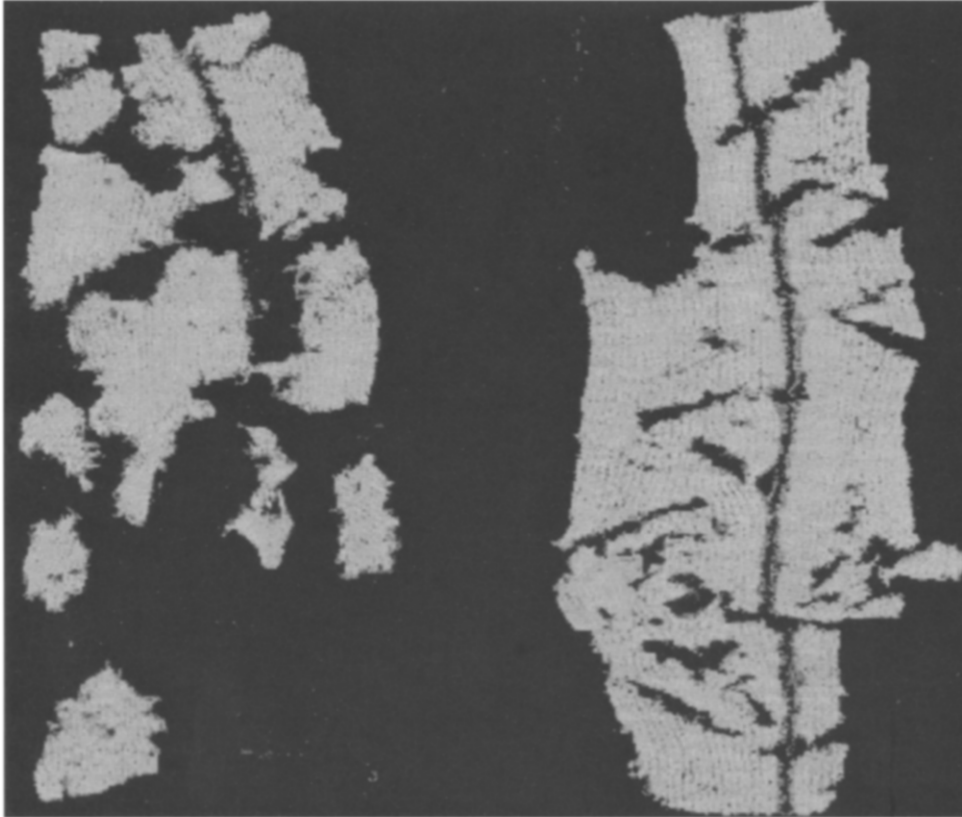


Fig. 2. Photo showing the mosaic-like appearance of an 18-year-old dilated femoropopliteal Dacron® bypass after enzymatic removal of tissue.

by sample cutting is prevented. This test was modified for use on a Bionix 858 MTS hydraulic testing machine (MTS Systems, Berlin, Germany) and reduced to half the original size in order to cope with the small pieces of explanted grafts (Fig. 3). The indenter measured 48 mm in diameter with a polished, hemispherical ending. The samples were cleaned as described above. Their size ranged between 10 mm and 45 mm width and at least 10 mm length. The circular specimen holder was equipped with a polyvinylchloride ring to prevent slipping of material. Specimens were manually stretched whilst clamping to remove crimping. The indenter penetrated the material with a velocity of 70 mm/min. A minimum of three tests were performed; five tests were preferred if the sample permitted this. In 11 cases of the 65 explants discussed in this paper mechanical testing was not possible, due to insufficient size of explanted material.

Chemical examination

Polyester consists of monomers of terephthalic acid and ethylene glycol. The synthesis of such a linear

chain of carbonyl groups by extraction of water is called polycondensation. Hydrolysis, the reversed reaction, leads to chain scissions due to water uptake (Fig. 4). This re-exposes the carboxylic acid end groups of the monomers. The characteristic absorption of infra-red light allows the identification of carbonyl groups and carboxylic acid end groups by infra-red spectroscopy. Fourier-transformed infra-red spectroscopy (FTIR) was performed using a BioRad 650 instrument (Bio-Rad Laboratories GmbH, U.S.A.). All specimens were cleaned as described above and dried in a vacuum oven at 50 °C. Minute pieces of graft material were pulverised at -196 °C, mixed with potassium-bromide (KBr) powder and pressed into tablets. These tablets were scanned in transmission mode between 1800 cm^{-1} and 1400 cm^{-1} wavenumber of IR-light, with a resolution of 2 cm^{-1} . The mean of three values was attained.^{16,17} Differences in the quantity of examined material explain the different intensities of absorbance of the entire IR-spectra. It was therefore necessary to set the measured intensities of absorbance of infra-red light of the carboxylic acid end group at 1640 cm^{-1} and the carbonyl groups at 1710 cm^{-1} in relation to the stable benzol group peak at 1510 cm^{-1} in order to obtain comparable, normalised intensities.

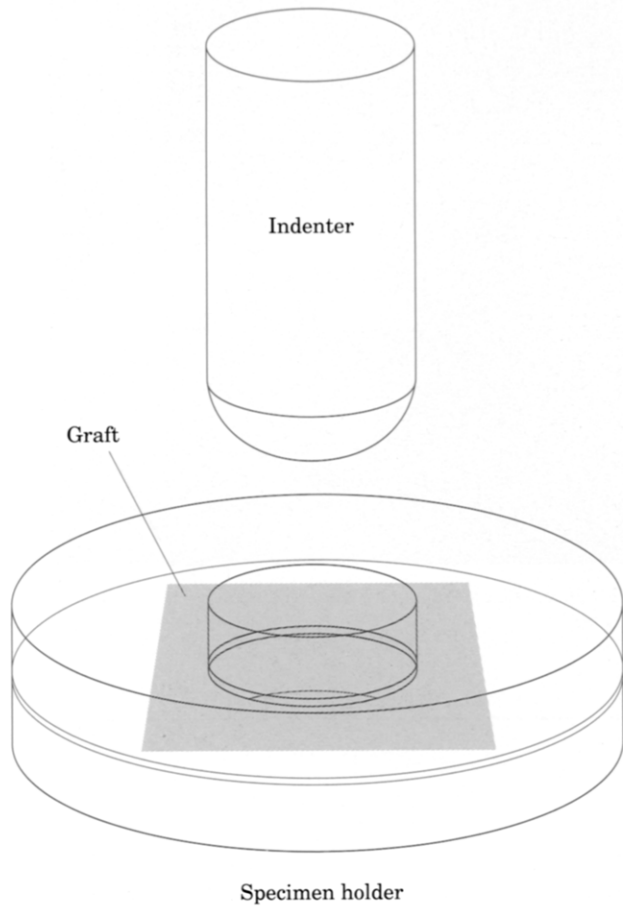


Fig. 3. Probe-puncture test (simplified). The hemispherical indenter passes through the graft material suspended between the circular specimen holder. The maximum burst strength is recorded.

In order to confirm the interaction of polyester and water, experimental hydrolysis was carried out. The experiment was performed for 5 weeks with amorphous polyester foil and a new, un-implanted segment of a Meadox Cooley Doublelevelour graft at a constant temperature of 70°C and in a buffer solution consisting of Na₂HPO₄ and NaH₂PO₄ stabilising a pH of 7.3 in order to prevent catalysation of hydrolysis by acids or bases. Parts of the specimens were retrieved weekly and examined by FTIR as described above.

Statistics

The data gained from the examinations of explants were analysed by linear regression analysis with time of implantation as independent variable using SPSS for Windows (Version 6.0). All tests were performed with an α-level of 0.05.

Results

Electron microscopy

Figure 5 shows an SEM image of a 13-year-old filament. The aortobifemoral graft had to be explanted because of rupture in the iliac segment, away from the anastomosis. This image is representative of the observations made on the 25 more than 7-year-old specimens of the 65 examined grafts. In the centre of the picture a typical brittle fracture with torsion of the

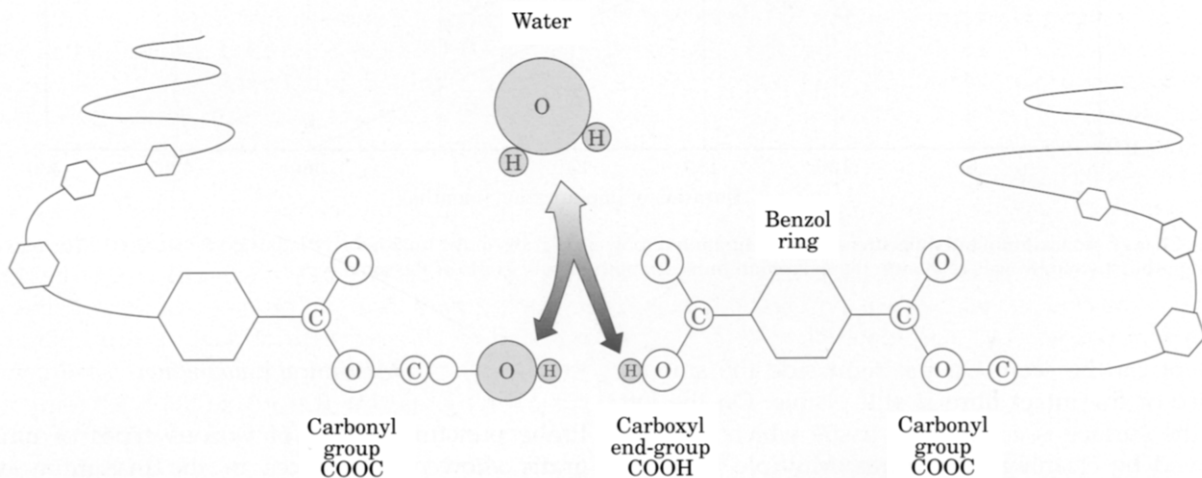


Fig. 4. Simplified model of the chain-like polyethylene terephthalate (polyester) macromolecule showing the extraction of water during synthesis (polycondensation) and the reversed reaction (hydrolysis), causing chain-scission. Hydrolysis creates a new carboxyl end-group (COOH) which absorbs a different wave-length of infra-red light than the carbonyl group (COOC) of the intact molecule.

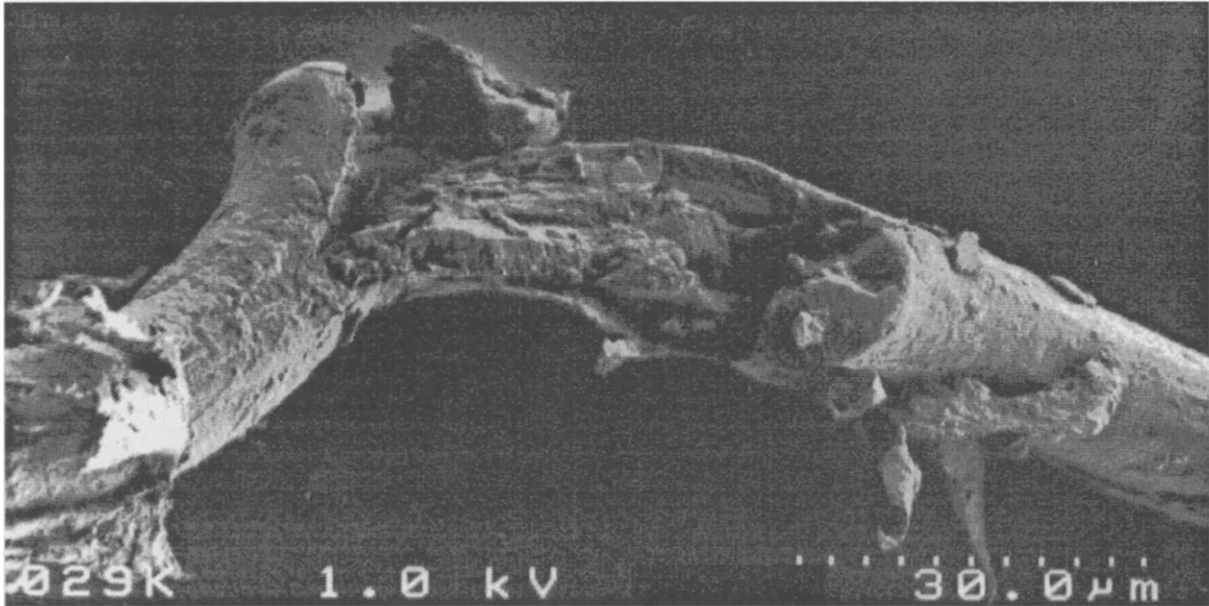


Fig. 5. Filament of a 13-year-old vascular graft showing a fracture in the centre and the relatively smooth surface of the filament on the right side.

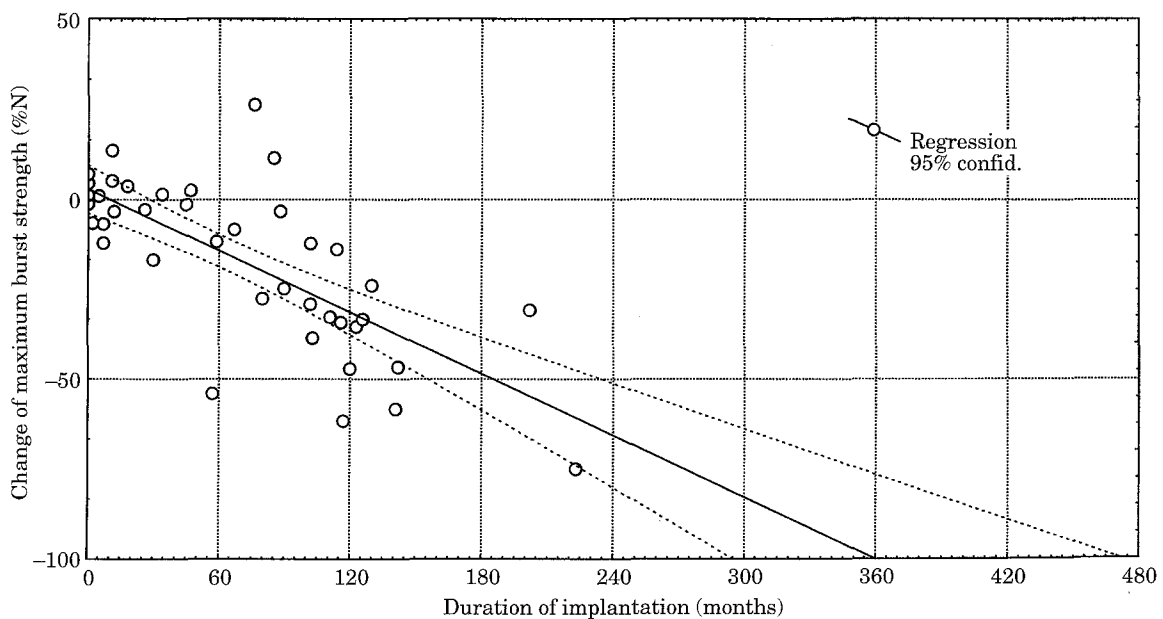


Fig. 6. Change of maximum bursting strength with duration of polyester-grafts in the human body (adjusted $R^2=0.52092$). The measured maximum burst strength was related to the maximum burst strength of new grafts of the same type.

filament can be seen. On the right side the smooth surface of the intact fibre is still visible. On the left side the surface is covered by tissue which was not removed by cleaning procedures. Multiple fractures of filaments seen in SEM of elderly grafts were accompanied by general loosening of the textile structure.

Mechanical examination

Probe puncture testing of various types of unused grafts showed differences in the maximum burst strength between graft-types and manufacturers ranging from 95 to 215N. Mechanical testing of 54 explanted grafts revealed a decrease of maximum

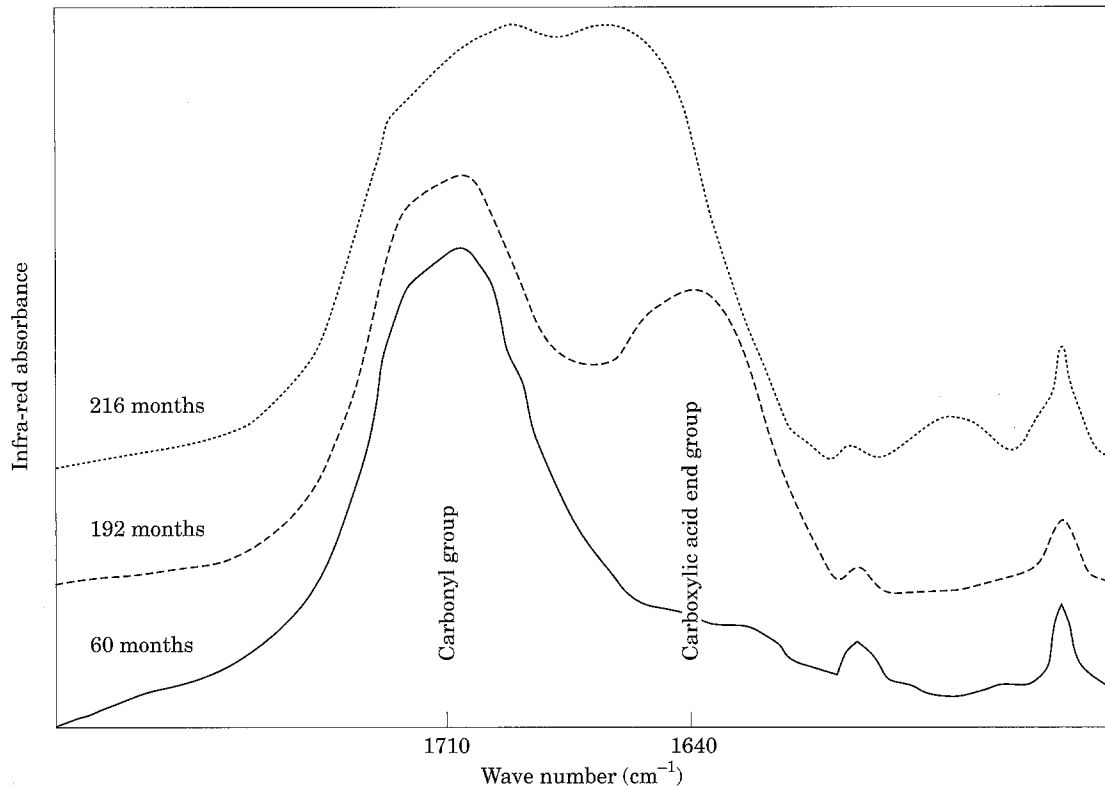


Fig. 7. Infra-red spectra of three grafts after 60, 192 and 216 months of implantation showing an increase of the carboxylic acid peak at 1640 cm^{-1} , whereas the carbonyl peak at 1710 cm^{-1} does not change with duration of implantation.

bursting strength with duration of implantation. Regarding the differences between unused grafts, the maximum burst strength of explants has to be compared with the results of new grafts of the same type. The calculated change of maximum burst strength was plotted against the time of implantation in Fig. 6, showing the normalised loss of strength with duration (adjusted $R^2=0.52052$). The change of bursting strength could only be calculated in 45 of the 65 cases. In 11 cases the explanted amount of material was not sufficient to be tested by probe puncture. In a further nine cases either the manufacturer or the type of graft implanted remains unknown, or an unused graft of the same type could not be obtained for testing.

Chemical examination

In the polyester macromolecule the carbonyl groups connect the chain segments, whereas carboxylic acid groups and alcohol groups terminate the chains (Fig. 3). The comparison of IR-spectrograms of the 65 explanted grafts showed an increase of the peak of the carboxylic acid end-group at 1640 cm^{-1} , whereas the peak of carbonyl group at 1710 cm^{-1} did not change. The comparison of the spectras of a 60, 192 and 216 months-old explant emphasises this in Fig. 7. The

normalised intensities of the carboxylic acid end-groups increase with duration of implantation as shown in Fig. 8 ($R^2=0.223$). The increase of carboxylic end groups is due to chain scission of carbonyl groups. The normalised intensity of the carbonyl peak did not decrease considerably ($R^2=0.005$).

The experimental simulation of hydrolysis also showed an increase in the normalised intensity of infra-red absorbance of the carboxylic acid end-groups in contrast to the constant intensity of the carbonyl group in 5 weeks of observation (Fig. 9).

Discussion

Hydrolytic degradation of polyester in watery mediums is well known.¹⁹⁻²¹ Despite the apparent simplicity of the basic mechanism shown in Fig. 4, the hydrolysis of polyesters is a very complex process, which is still not fully understood. In an infra-red spectrogram the characteristic peaks of IR absorption of undissected carbonyl groups at 1710 cm^{-1} and carboxylic acid end groups at 1640 cm^{-1} allowed the observation of the outcome of the hydrolytic chain scission. Our experimental simulation of hydrolysis confirmed this, showing an increase of carboxylic acid

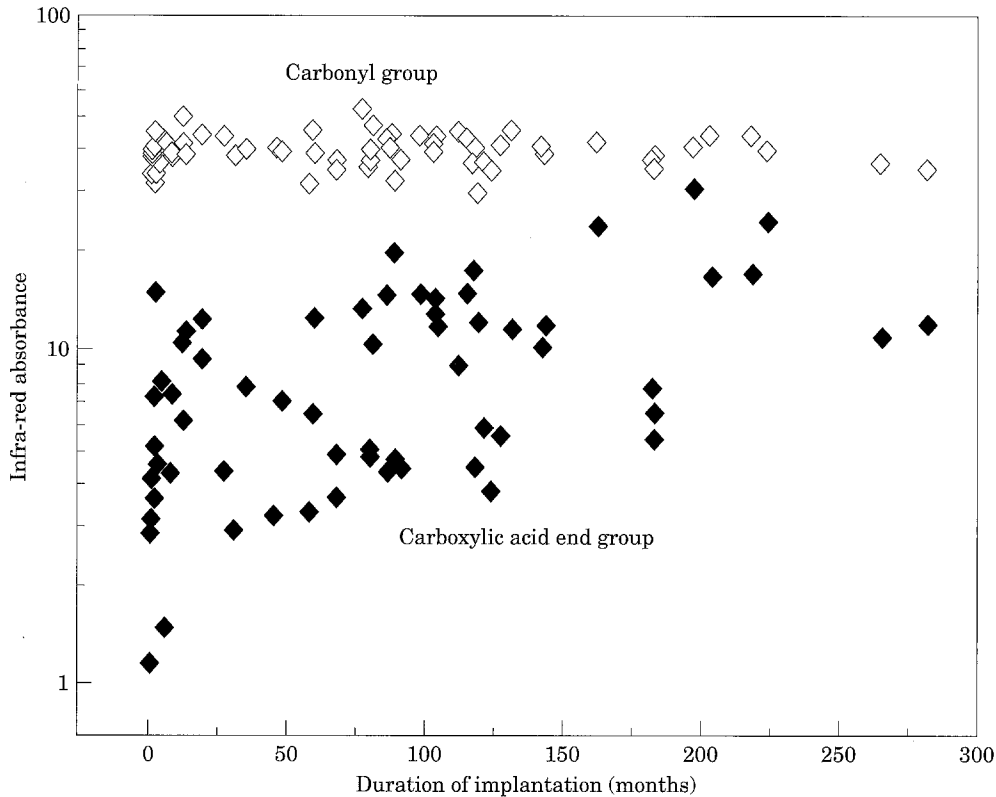


Fig. 8. Increase of normalised intensity of absorbance of infra-red light by carboxylic acid groups ($R^2=0.223$) and no change of normalised intensity of absorbance by carbonyl groups ($R^2=0.005$) with duration of polyester grafts in the human body.

end-groups with extended exposure to the severe hydrolytic conditions. Despite the loss of one carbonyl group for each acid end-group, no noticeable change in the amount of carbonyl groups was evident. This is explained by the great amount of carbonyl groups in the polyester macromolecules. The examination of explanted grafts by FTIR showed similar results, correlating to the duration of implantation (Fig. 8).^{16,17}

The reason of hydrolysis remains unknown. Autocatalytic mechanisms as well as catalysation by metal ions are described *in vitro*.^{19,21} Which role may enzymes and lymphatic cells play *in vivo*? Attenuated total reflection (ATR) FTIR presented advanced hydrolysis on the luminal surface of grafts, the region in close contact to blood. Further pharmacological and histological evaluations are being undertaken.

The chain scissions, as the product of hydrolysis, lead to a shortening of macromolecules. *In vitro* examinations proved the predominance of terminal group scissions (with extraction of short chain segments rather than internal chain scissions).¹⁹ The shortening of macromolecules results in change of physical properties.¹⁹ These are evident in the brittleness of the material, leading to fractures as seen in SEM. The change of physical properties is demonstrated by the

probe puncture test. Although this test has little resemblance to physiological loading, it has the advantage of being a reproducible method of examining graft materials, independent of the orientation of yarns in the textile structure. Unimplanted grafts from different manufacturers show differences in maximum burst strength, ranging from 90 to 215N. The results of implant examinations needed to be related to measurements of unused grafts of the same type. Due to the lack of unused specimens for all graft types and missing information of graft origin, normalised mechanical data could only be evaluated for 45 explants. The observed change of maximum burst strength in these cases shows a decrease of strength with duration of implantation.

Because of the small number of specimens available from different manufacturers, a comparison of graft types was not possible in this paper. Furthermore, we were not able to match explants with unused grafts of the same batch number. This may explain the variation of the results in this paper. Further prospective studies may permit this in the future. More precise mechanical evaluations such as the examination of single filaments and dynamic testing of entire tubes are necessary and are being developed.

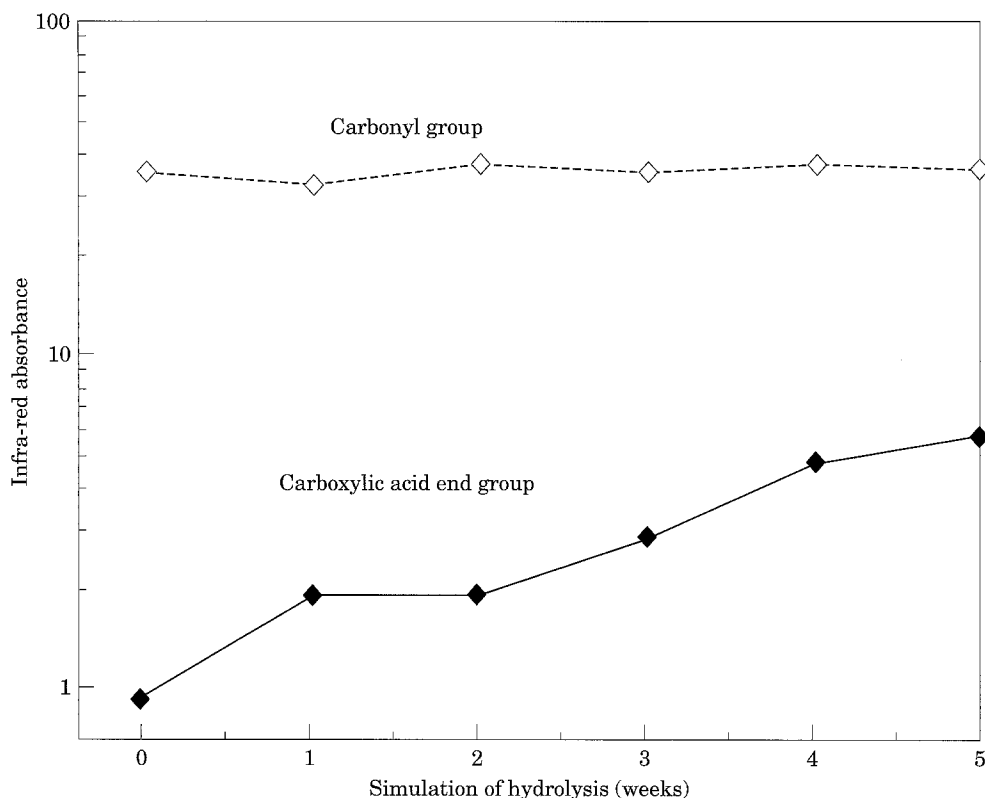


Fig. 9. Increase of normalised intensity of absorbance of infra-red light by carboxylic acid groups and no change of normalised intensity of absorbance by carbonyl groups during simulation of hydrolysis on an unused polyester graft in water at 70°C for a period of 0–5 weeks.

Clinically relevant material deterioration presumably only occurs in 2–3% of patients.^{3,10} The earliest graft failure observed in our group was after 19 years, the latest after 23 years. The rareness of graft failure may be due to the reduced life expectancy of elderly patients with arteriosclerotic disease. The great majority of vascular patients needing artificial grafting is older than 60 years. Today the increase of younger vascular patients receiving polyester grafts increases the possible length of implantation and hence increased the risk of rupture.

Hydrolysis effects the surface of polyester grafts. The quotient of surface and volume is proportional to the progress of degeneration. This allows the presumption that thinner grafts, such as those newly developed for endovascular use, will degenerate quicker than the thicker, conventional ones. Clinically relevant ruptures might therefore be expected much earlier in endovascular prostheses. Furthermore, acceleration of degeneration may be caused by the surgeon, e.g. clamping, stitching and dilating intraoperatively or by storage and resterilisation preoperatively.

The variation of results in this paper may be explained by numerous unknown biological, chemical and mechanical influences in individual patients. A

prospective study involving human patients is not possible, as the occurrence of failure is too seldom and the necessary observation time too long. A far larger number of retrieved explants is necessary for further studies. The co-operation between the laboratories of vascular surgery in Strasbourg and our vascular department assisted by the French and the German Societies of Vascular Surgery has already proved to be a promising approach.

The knowledge that degeneration may occur many years after implantation suggests that long-term follow-up is required, preferably by vascular surgeons themselves. Precise documentation of implanted graft material by the surgeon is also necessary. Perhaps these patients should also be supplied with some form of material passport as carried with pace-makers. For the meantime we still employ polyester grafts in the aortic and iliac segments but take care not to use artificial grafts where possible, especially in younger patients. This also effects the number of endovascular operations we have performed. Thrombendarterectomy and interventional techniques performed by a team of surgeons and radiologists have gained much more attention in our hospital due to the results of our research.

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