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D. W. Gregory

University of Aberdeen, Foresterhill

G. G. Youngson

University of Aberdeen, Foresterhill

D. Marshall

University of Aberdeen, Foresterhill

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IMPLANTATION FAILURE OF PERITONEAL DIALYSIS CATHETERS:
A SCANNING ELECTRON MICROSCOPICAL STUDY

D.W.Gregory^{1*}, G.G.Youngson² and D.Marshall¹

Departments of Bacteriology¹ and Surgery²
University of Aberdeen, Foresterhill,
Aberdeen AB9 2ZD, Scotland.

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Abstract

Patients with end stage renal failure may be treated by continuous ambulatory peritoneal dialysis. The transcutaneous portion of the catheters used in this treatment is covered with porous expanded polytetrafluoroethylene (PTFE) to provide a surface suitable for tissue infiltration. Following some instances where catheters failed to become fixed in the abdominal wall, a scanning electron microscopical study was carried out to compare the infiltration of catheters having successful or unsuccessful implantation.

The porous layer of a well-fixed catheter, removed after successful renal transplantation, was infiltrated with collagen fibrils and overlain by layered connective tissue composed of fibroblasts and collagen fibre bundles, sometimes linking to surrounding muscle fibres. The examination of four unsuccessful catheters revealed no evidence for infection being the cause of implantation failure. However the porous surface of these catheters was filled with blood components and products, sometimes apparently laid down in layers, suggesting that frequent bleeding resulting from repeated trauma may be responsible for the failure of catheter fixation.

These findings led to two changes in clinical practice with apparent patient benefit. The implantation site has been relocated to reduce chafing by clothing and the post-operative wound dressing technique has been altered to minimise catheter movement.

KEY WORDS: Renal support, Peritoneal dialysis catheters, Catheter implantation, Expanded polytetrafluoroethylene, Surgical procedure, Connective tissue, Tissue infiltration, Collagen, Blood components, Clot structure.

*Address for correspondence:

D.W.Gregory
Department of Bacteriology
University of Aberdeen
Foresterhill, Aberdeen AB9 2ZD
Scotland. Phone No.(0224) 681818 Ext. 2448.

Introduction

End stage renal failure, a consequence of many different disease processes, may require treatment by haemodialysis with subsequent renal transplantation. Because of geographical isolation from a dialysis centre or technical unsuitability for vascular access, a number of patients with this condition are considered ineligible for haemodialysis. For these patients renal support may be provided by continuous ambulatory peritoneal dialysis, a technique first described by Popovich and co-workers (1976 and 1978). This involves implantation of a catheter into the abdominal wall, through which dialysate is infused into the peritoneal cavity four or five times daily for periods between four and eight hours.

Following a change in the type of catheter used for this treatment at our hospital, a high incidence of failure (30%) of catheter fixation in the abdominal wall was encountered. This prompted a scanning electron microscopical study of the tissue infiltration of catheters in an attempt to identify the factors involved.

Materials and Methods

Peritoneal catheters

The catheters used during the period of this study were obtained from W.L.Gore & Associates (U.K.) Ltd.; their construction and the surfaces studied are illustrated in Fig.1. A catheter consists of a silicone rubber tube, the distal intra-abdominal portion of which is perforated to facilitate entry and efflux of dialysate to and from the abdominal cavity. The thickened transcutaneous portion is shaped into a collar, flange and cuff, and these latter two parts are covered with expanded PTFE ('GORE-TEX') which provides a porous surface suitable for tissue infiltration.

Unused 'GORE-TEX' vascular graft material was examined as a control for the appearance of expanded PTFE.

Catheter insertion

The catheter is inserted at operation through a midline abdominal incision below the umbilicus. The skin is dissected from

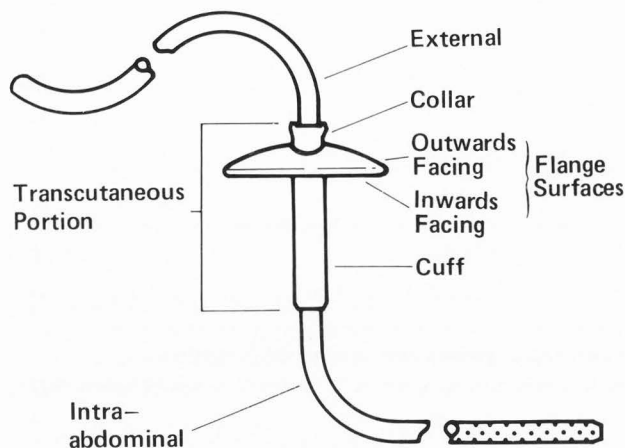


Fig.1. Diagram showing the constituent parts of a peritoneal dialysis catheter and the surfaces studied.

the abdominal wall and the catheter is implanted with the flange lying immediately under the dermis. The cuff is led through the muscular layers of the abdominal wall with the aid of an introducing stylette and the internal tubing placed to lie in the pelvis. The flange is fastened to subdermal tissues with absorbable sutures to provide early fixation and stability for the device. This allows immediate use of the catheter for dialysis purposes.

Patients and Samples

The catheters studied were from patients treated in the renal transplantation/dialysis unit of Aberdeen Royal Infirmary during 1983-84. A catheter with successful tissue infiltration was examined after removal from a patient when no longer required for therapy following successful renal transplantation. Four catheters with unsuccessful tissue infiltration were examined after removal for 'non-healing' and subsequent implantation site infection.

Scanning electron microscopy

The transcutaneous portion of each catheter removed was fixed in changes of neutral phosphate buffered 10% (v/v) formalin for 5-7 days. After fixation smaller samples were cut out to illustrate either superficial views of, or perpendicular profiles through, the outwards- and inwards-facing surfaces of the flange and the cuff surface (see Fig.1). These pieces were washed in distilled water, post-fixed in 1% (w/v) OsO_4 for 2½ - 4hr, washed in distilled water again and dehydrated through a graded series from 70% (v/v) to absolute ethanol. After critical point drying in CO_2 they were mounted with appropriate orientation using colloidal silver adhesive, sputter-coated with 15nm platinum, and examined in a JEOL JSM-35CF scanning electron microscope at 10kV. Pieces of unused 'GORE-TEX' vascular graft material were just mounted and sputter-coated prior to examination, using conditions as above.

Results

Fig.2 shows the appearance of unused 'GORE-TEX' expanded PTFE vascular graft material which has a similar structure to the 'GORE-TEX' layer on the transcutaneous portion of these peritoneal dialysis catheters. A complex lattice is formed by PTFE fibrils of varying thickness and irregularly branching pores between nodes of solid PTFE. An early description of this structure by Baker et al. (1976) provided the terminology used here.

Successful implantation

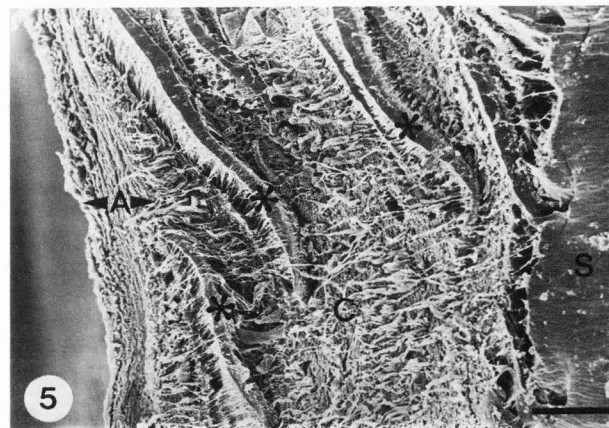
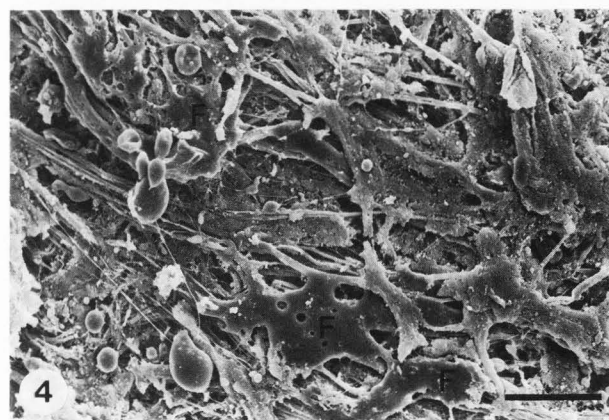
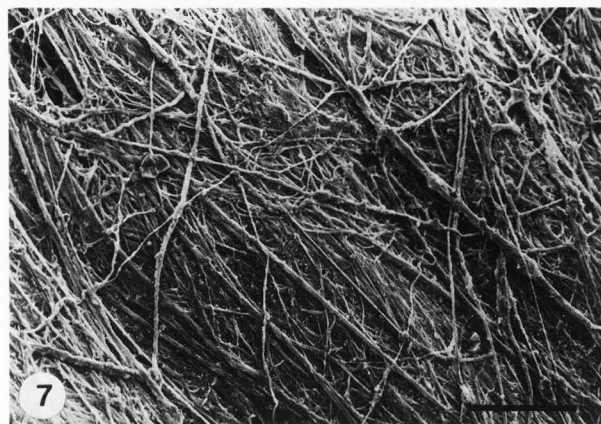
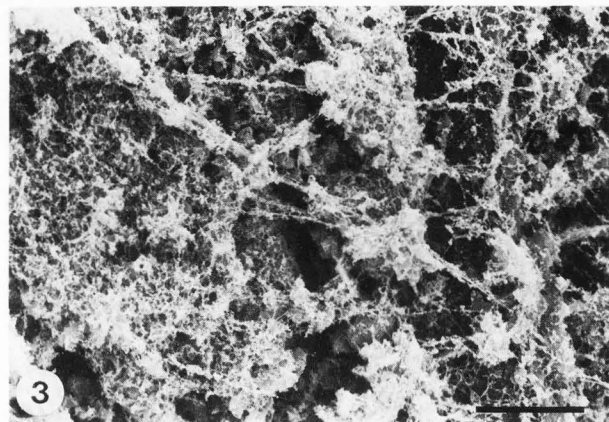
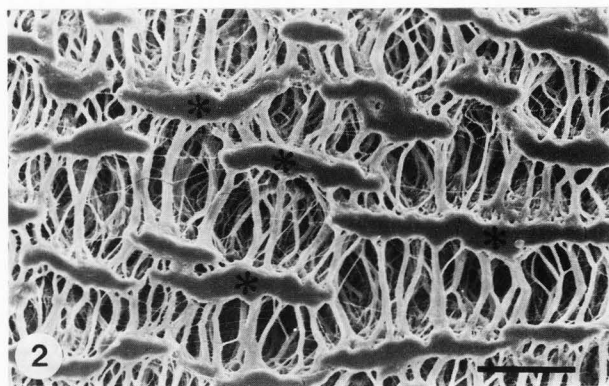
A catheter which had implanted successfully, but was no longer required after renal transplantation, was surgically removed and examined by scanning electron microscopy. With this catheter the outwards-facing surface of the flange (see Fig.1) was the least well infiltrated with tissue. Part of this surface is shown in Fig.3 where the pores appear to be filled with fibrin filaments and a fine granular material similar to that seen by Stewart et al. (1977) and suggested by those authors to be insoluble derivatives of fibrinogen. Other areas of this outwards-facing surface (Fig.4) were covered with fibroblasts forming collagen fibrils, similar to those shown by Kessel and Kardon (1979).

Fig.5 shows a radial profile through the entire 'GORE-TEX' layer on the inwards-facing surface of the flange (see Fig.1) of this successful catheter. Here layers of connective tissue can be seen overlying the 'GORE-TEX', with collagen fibrils penetrating the pores. At a higher magnification (Fig.6) the collagen fibre bundles in the overlying layers are clearly seen. A surface view of this inwards-facing surface of the flange is shown in Fig.7 and at a higher magnification (Fig.8) bundles of collagen fibres characteristic of dense irregular connective tissue (Kessel and Kardon, 1979) are clearly visible.

The most extensive tissue infiltration occurred around the cuff (see Fig.1) of this successful catheter. Pieces of cuff were mounted to enable both surface views and longitudinal profiles of the 'GORE-TEX' layer and adherent tissue to be examined. A longitudinal profile at one side of the cuff looked rather similar to Fig.5 but showed the 'GORE-TEX' layer to be overlain by approx. 1mm thickness of connective tissue, the surface appearance of which was like that shown in Fig.7.

Fig.2. Unused 'GORE-TEX' vascular graft material. PTFE fibrils of varying thickness stretch between nodes of solid PTFE (*) creating a porous lattice (bar = 20µm).

Figs. 3 & 4. Outwards-facing surface of flange of successful catheter. Fig.3 (bar = 10µm) shows fibrin filaments and a fine granular material filling pores in the expanded PTFE. Fig.4 (bar = 20µm) shows another area of this surface covered with fibroblasts (F) forming collagen fibrils.



Figs. 5-8. Inwards-facing surface of flange of successful catheter. Fig.5 (bar = 100 μ m) is a radial profile through the entire 'GORE-TEX' layer showing overlying layers of connective tissue (A), collagen fibrils (C) penetrating the pores between nodes of PTFE (*), and the underlying silicone rubber (S). Fig. 6 (bar = 5 μ m) is a higher magnification profile of the overlying connective tissue layers showing collagen fibre bundles. Fig.7 (bar = 100 μ m) is a surface view showing the mat of collagen fibre bundles whose fibrillar construction is clearly visible at the higher magnification of Fig.8 (bar = 10 μ m).

Fig.9 shows a longitudinal profile at the other side of the cuff surface where infiltrated connective tissue appears to have formed linkages between the cuff and surrounding abdominal muscle fibres.

Unsuccessful implantation

Four unsuccessful catheters which had to be surgically removed through failure of fixation to the abdominal wall were also examined. Scanning electron microscopy revealed no evidence of significant infection. Any putative microorganisms seen were scanty in number. However it was found that, unlike the successful catheters, the pores throughout the 'GORE-TEX' layer of the transcutaneous portion were almost completely filled with blood components and products.

The outwards-facing surface of the flange is shown in Fig.10. At a higher magnification (Fig.11) it can be seen that this surface is covered with red and white blood cells lying on an extensive fibrinous clot, similar in appearance to the cell-rich exudate covering a 1 day-old wound shown by Baur et al. (1981).

Fig.12 shows a profile through the entire 'GORE-TEX' layer on the inwards-facing surface of the flange. It can be seen that, unlike the successful catheter, here there are no cells or layers of connective tissue overlying the 'GORE-TEX' layer (compare Fig.12 with the equivalent profile shown in Fig.5). At higher magnification this profile showed that the pores were filled with blood cells and a fine granular material similar to that shown in Fig.3 in contrast to the collagen fibrils seen in Fig.5. The surface view of this inwards-facing surface of the flange appeared very similar to the surface shown in Figs.10 and 11 and consisted of erythrocytes, leucocytes and platelets lying on, and intermingled with, a matrix of fibrin filaments (in contrast to Figs. 7 and 8).

The surface of the cuff is shown at low magnification in Fig.13 where nodes of solid PTFE can be seen protruding through the clot which is filling the expanded zones. In Fig.14 the clot appears to have been laid down in layers which may relate to successive episodes of bleeding consequent upon repeated trauma. At a higher magnification the clot could be seen to consist of erythrocytes, leucocytes, platelets and fibrin filaments, with an appearance similar to that shown in Fig.11.

Discussion

The successful peritoneal dialysis catheter examined in this study showed a collagenous infiltration of pores in the expanded PTFE, sometimes linking to surrounding muscle fibres (Figs. 5 and 9). This finding is very similar to that described by Goldfarb et al. (1977) who showed expanded PTFE vascular grafts firmly incorporated into surrounding tissues by integration with periprosthetic dense collagen which extended directly into

the internodal spaces of the PTFE lattice structure. The layering of the collagenous tissue (seen clearly in Fig.6) may reflect the succession of collagenous laminae produced during wound healing as described by Baur et al. (1981).

The initial clinical impression prior to our investigation, i.e. that the failure of catheter implantation was due to local sepsis, was not corroborated by this study. Scanning electron microscopical examination failed to show any bacterial invasion of pores or adherence to the PTFE; indeed bacteria were not seen in significant numbers.

The presence of blood components and products throughout the pores in the 'GORE-TEX' layer of the flange and cuff of the unsuccessful catheters, sometimes laid down in layers (Fig.14), suggests that frequent bleeding resulting from repeated (perhaps minor) trauma may be responsible for the failure of catheter fixation. The high proportion of leucocytes seen in some of the clots (Fig.11) may provide further evidence for trauma being the cause of implantation failure because Stewart et al. (1977) showed leucocytes accumulate in thrombi as a response to leucotaxins released during tissue injury. The catheters studied had been implanted below the umbilicus, so it seems possible that the constant movement and chafing of clothing below the belt-line may have caused the repeated trauma.

These observations have led to two changes in clinical practice. Firstly, since these findings were noted, all such catheters have been implanted above the umbilicus (i.e., above the belt-line) and as yet there have been no failures of fixation in these patients (at present 7). Secondly, the dressing technique of the implantation site in the post-operative period has been altered so that movement of the catheter connecting tubing is kept to a minimum. Concurrent with these changes in practice the manufacturer has changed the catheter design to reduce chafing of clothing by creating a right-angle bend in the external tubing immediately outside the collar.

Conclusions

This scanning electron microscopical study suggests that implantation failure of peritoneal dialysis catheters is due to the bleeding caused by repeated trauma. These findings have led to changes in clinical practice with significant patient benefit.

Acknowledgements

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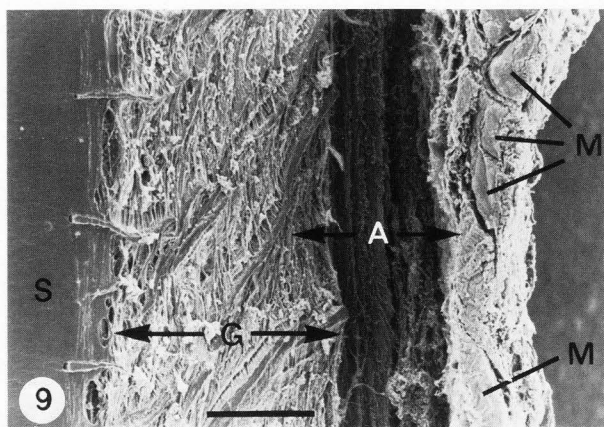


Fig. 9. Cuff surface of successful catheter. This is a longitudinal profile through the entire 'GORE-TEX' layer in an area where striated muscle fibres (M) overly connective tissue (A) itself overlying and infiltrating the 'GORE-TEX' layer (G) which is on the silicone rubber base (S) (bar = 200µm).

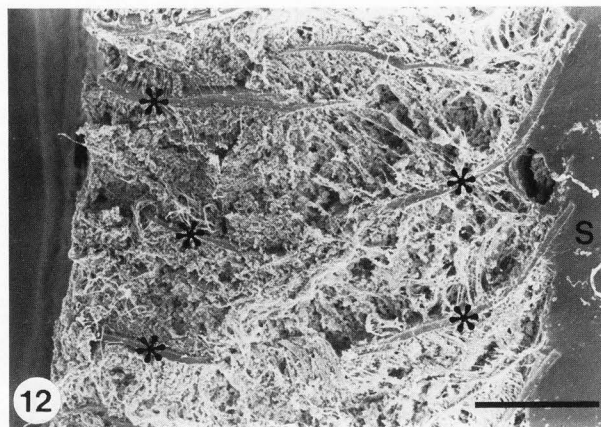
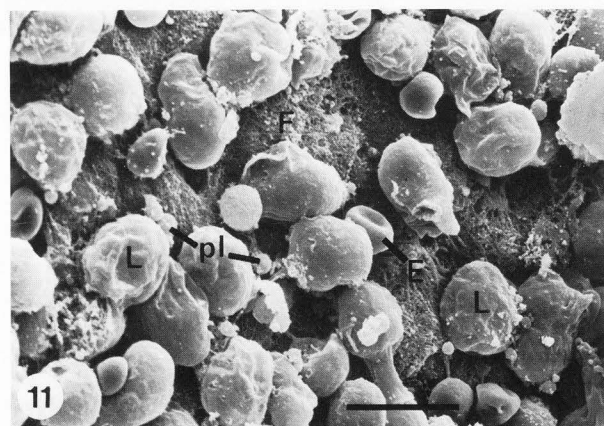
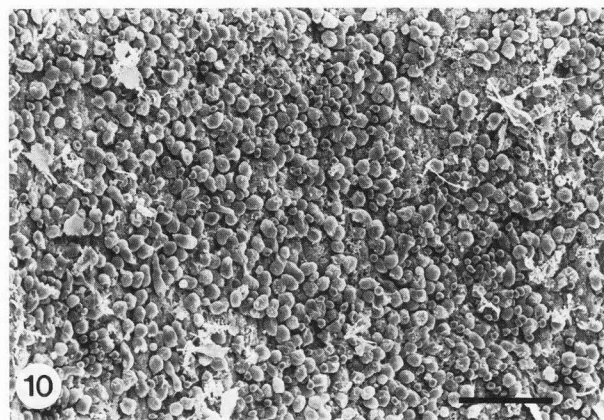
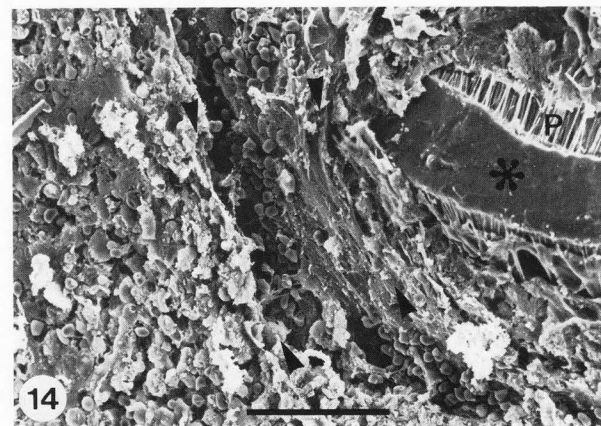
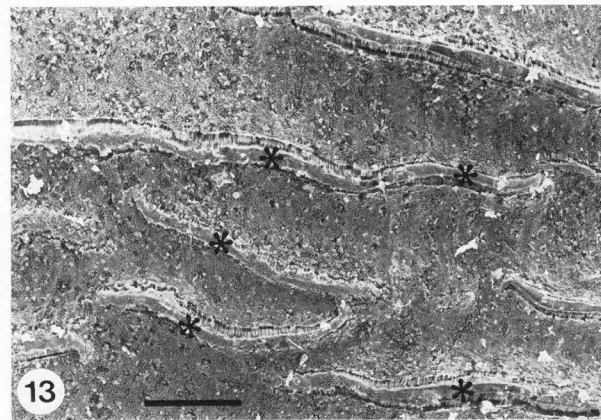


Fig. 12. Inwards-facing surface of flange of unsuccessful catheter. This is a radial profile showing the entire 'GORE-TEX' layer on its silicone rubber base (S). There is no overlying connective tissue (cf. Fig. 5) and a fine granular material fills the pores between nodes of PTFE (*). (bar = 300µm).



Figs. 10 & 11. Outwards-facing surface of flange of unsuccessful catheter. Fig. 10 (bar = 50µm) shows the uniform nature of this surface. Fig. 11 shows it consists of erythrocytes (E), leucocytes (L) and platelets (pl) lying on an extensive fibrinous clot (F). (bar = 10µm).



Figs. 13 & 14. Cuff surface of unsuccessful catheter. Fig. 13 (bar = 200µm) is a surface view showing nodes of PTFE (*) protruding through the clot which fills the surrounding pores. Fig. 14 (bar = 50µm) shows one such node (*) and its attached PTFE fibrils (P) protruding through clot which appears to have been laid down in layers (arrows).

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Discussion with Reviewers

R.M.Albrecht: Is it possible the unsuccessful as opposed to successful implantations, in the absence of infection, are due in part to individual differences in the level of the foreign body response rather than due solely to repeated trauma? In individuals with an unsuccessful implantation does moving the site and taking other measures to reduce trauma then result in a successful implant? Does reducing trauma to an 'unsuccessful' implant lead to a more 'successful' appearing implant?

Authors: We have not studied specifically the characteristics of the cells infiltrating the implantation site so cannot answer the first part of this question. Clearly light microscopy would aid clarification of the degree of foreign body response. However this can be answered indirectly by the response to the pertinent second part of the question in that a number of patients have had catheter implantation failure in the lower abdomen treated by catheter removal, a short period of haemodialysis and subsequent successful catheter implantation in the upper abdomen. These patients act as their own controls with respect to individual foreign body response and thus contribute to the thesis that trauma is funda-

mental in the aetiology of implantation failure. Once a catheter has failed, subsequent reduction in trauma does not salvage the implant.

R.M.Albrecht: Have the authors ever observed instances where infection may have played a role in implant failure?

D.B.Jones: Did bacteriologic cultures reveal any evidence of infection?

Authors: Infection, as indicated by positive bacteriological culture, was found in most of our failed catheters. We feel, however, that infection does not contribute primarily to catheter implantation failure but rather secondarily complicates the haematoma which forms around the traumatised implant. Our studies failed to show any impregnation of 'GORE-TEX' with organisms and indeed all catheters were initially clinically successful in use. Infection sufficient to induce catheter failure is likely to produce more clinical manifestations of sepsis than we have seen in these patients.

Other septic complications of continuous ambulatory peritoneal dialysis such as peritonitis, which occurs in approximately 10% of patients, does not correlate with implantation failure. For these reasons we feel that infection although a feature of implantation failure is not the fundamental cause.

S.R.Khan: Were the sites of catheter implantation different in successful and unsuccessful implants? If they were the same, why was there more bleeding in some patients and not others?

S.Goodman: Do the authors have any idea why one implant was successfully implanted? Is there any reason why less trauma occurred in this patient compared to the others?

Authors: The catheters are implanted by a standardised surgical technique using the same sites, initially below the belt line and more recently above the belt line. Clearly the transfer of location of implantation to the upper abdomen has been beneficial. However 70% of catheters implanted in the lower abdomen were successfully fixed. We presume those which fail are subjected to more trauma, e.g. by debilitated and/or partially-sighted patients. We have attributed the benefits of placing the catheters above the belt line to the reduced trauma from adjacent clothing.

R.M.Albrecht: Have the authors examined additional successful implantations and, if so, do they appear similar to the one described?

P.Frasca: Do you think that more than one successfully implanted catheter needs to be studied to conclude that clotting is the true cause of failure?

Authors: It is our intention to perform further scanning electron microscopical studies on successfully implanted catheters but the availability of such catheters is naturally low. However in light microscopy histological studies by the manufacturer, on catheters returned from patients throughout the world, similar findings have been noted and

similar conclusions have been drawn, leading to a re-design of the catheter's external tubing (J.Rominger (W.L.Gore & Associates, Inc.) personal communication).

S.Goodman: How long were the various catheters in place before excision? Could differences in connective tissue infiltration be due, in part, to differences in this time?

Authors: The times of removal ranged from three months to one year after implantation. The findings were independent of duration of catheter implantation prior to removal.

S.Goodman: Have any of the more recently implanted catheters been removed and examined? If so, does their morphology support your contentions?

Authors: We have not yet had occasion to remove any of our more recently implanted catheters as they have all remained in clinical usage and are functioning in a satisfactory fashion. They have now been in-situ for about six months and this indicates a successful implantation.

S.Goodman: Were all four of the unsuccessful implants similar or were there differences in morphology, such as in the amount or location of blood components or in the degree of connective tissue infiltration?

Authors: We were unable to detect any significant differences in the findings between the different implant failures.

P.Frasca: I am wondering, since your samples were coated with noble metal (platinum) and contrast seems to be no problem, why did you choose 10kV as the optimum voltage?

Authors: At 5kV resolution was poorer and contrast was lower resulting in less satisfactory images. There was no advantage in using an accelerating voltage higher than 10kV.

