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THE EXPERIMENTAL USE OF POLYTETRAFLUORETHYLENE AS AN IMPLANT MATERIAL

by

A. H. MELCHER and C. J. DREYER

Joint Dental Research Unit of the C.S.I.R. and the University of the Witwatersrand, Johannesburg.

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The healing process in a circumscribed defect in the rat femur has been described [Melcher, 1960]. This type of defect is of value in assessing the effect of various implant materials on the healing of bone [Melcher, 1960]. In the present report the results obtained from implanting polytetrafluoreothylene are recorded.

MATERIALS AND METHODS

(i) *Materials*

"Fluon"* is the proprietary name for polytetrafluoroethylene, a plastic material which can be produced in moulded and extruded forms. It has a serviceable temperature range of from —100°C to 50°C. "Fluon" is a very inert material and is only affected by fluorine and the molten alkali metals. There are no effective adhesives for the material but it can be auto-welded using heat and pressure. It is non-wettable, has remarkable non-sticking properties and such a low coefficient of friction that it is virtually self-lubricating.

(ii) *Methods*

Circumscribed defects approximately 2 mm. in diameter were made in the lateral aspect of the femoral diaphyses of 15 albino rats of the Wistar strain weighing between 150 and 300 g., and these defects were each implanted with a piece of "Fluon". In addition, a rectangular piece of the material was implanted into the rectus abdominus muscle of each animal. The animals were sacrificed at periods varying from 6 days to 6 months postoperatively. The femurs were fixed in formol-Zenker's fluid. After decalcification they were serially sectioned and stained with haematoxylin and eosin.

OBSERVATIONS

(A) *"Fluon" implanted into bone*

(i) *The microscopic appearance of "Fluon"*

"Fluon" has a non-porous, light ground-glass appearance. The material has numerous black flecks in its substance and the three margins of the implant appear as a black line when viewed by transmitted light (Fig. 1).

(ii) *The reaction of the host tissues to "Fluon"*

No histological evidence of foreign body reaction or any other untoward host reaction to the "Fluon" could be recognised in any of the sections examined.

In the early specimens the haematoma intervening between the external aspect of a protruding implant and the overlying tissues was usually very narrow. The healing connective tissue which organised the haematoma was closely applied to the "Fluon" but not attached to it (Fig. 1). The bony callus, even after 6 months, also did not take attachment to the implant material and this was exemplified by the ease with which bone and "Fluon" were separated during histological preparation (Figs. 1, 2, 3, 4 and 5).

*Supplied by Imperial Chemical Industries (South Africa) Ltd., Johannesburg.

The healing bone was always separated from the "Fluon" by cellular connective tissue. This layer was similar in appearance to the osteogenic layer of the periosteum. Throughout the period of the experiment there was no evidence to suggest that the "Fluon" was being resorbed or that it was being invaded by healing connective tissue (Figs. 2 and 5).

(iii) *The effect of the "Fluon" implant on the healing of the defect*

The healing pattern in these defects followed that which takes place in ungrafted defects but the "Fluon" implant acted as a physical barrier to proliferation of the bony callus. The endosteal callus developed in the space between the graft and the wall of the defect and also covered the endosteal aspect of the "Fluon", often penetrating deep into the medullary cavity in order to do so (Fig. 1).

The subperiosteal callus could not bridge the defect when the "Fluon" protruded much above the surface of the femur (Figs. 1, 2 and 3). The bony proliferation, although obstructed by the protruding "Fluon", followed normal contours and did not grow over the external surface of the implant, which became covered by a thin layer of connective tissue. This connecting tissue ran in an arc from the surface of the external callus to the surface of the implant, forming a triangular area (Fig. 2). In many specimens, rather than the subperiosteal callus forming a butt-joint with the implant, a small trough filled with connective tissue separated the two at the bone surface (Fig. 2).

The resoprtion of the endosteal callus did not involve the bone lining the defect margins or that covering the "Fluon" implant. Eventually, the medullary aspect of the implant was covered by a thin incomplete layer of bone (Figs. 2 and 4). Remodelling of the callus was active up to three months postoperatively. At this time it was of mature compact appearance and the bone lining the medullary aspect of the implant was almost complete, much more substantial than that seen in the first few weeks of healing. In many places modelling resorption of this bone took place from the "Fluon" side. From 3 months postoperatively, new lamellae were laid down on the medullary aspect of this bone (Figs. 3 and 5).

Where the "Fluon" protruded through the subperiosteal bone in the outer part of the defect it was covered with mature connective tissue (Fig. 3). Where, however, it did not protrude externally, the defect was closed by subperiosteal bone (Figs. 4 and 5). In all specimens (up to six months) the internal aspect of the "Fluon" was almost wholly covered by bone even though the implant protruded far into the medullary cavity (Figs. 2, 3, 4 and 5).

B. *"Fluon" implanted into muscle*

The implanted "Fluon" became surrounded by loose connective tissue in which a few lymphocytes, plasma cells and histiocytes could be recognised. These inflammatory cells soon disappeared and the capsule gradually became more fibrous and acellular until, after six months, it was very narrow and consisted almost wholly of collagen fibres.

There was no histological evidence that the "Fluon" caused a foreign body reaction in the host tissues, or that any attempts were made to remove it. The "Fluon" did not induce the formation of heterotopic bone.

DISCUSSION

(i) *The relationship between the healing tissues and the "Fluon"*

Very few substances will adhere to "Fluon" and it neither absorbs nor is wetted by water. It is therefore not surprising that the healing connective tissue and bone do

not become attached to it and that there is always a layer consisting of osteogenic cells and connective tissue between the implant and the bone. By contrast, where bone or bone-like implant materials are used the bony callus is usually laid down directly on the graft [Melcher, 1960]. Non-adherance is a distinct disadvantage if "Fluon" is to be used as an implant material.

(ii) *The inability of the subperiosteal callus to cover "Fluon" protruding from the wound*

Even though the implant may penetrate deeply into the medullary cavity it is always surrounded by endosteal callus and after six months it is still separated from the medullary tissue by an almost unbroken layer of bone. On the external aspect of the defect, however, it is sufficient for only a slight protrusion of the implant beyond the external contours of the femur to prevent the "Fluon" from being covered by subperiosteal bony callus.

Murray *et al.* [1957] and Melcher and Dreyer [1961] have shown that external bony callus will develop in excess if the bone wound is covered by a shield. The latter authors believe that this may be a result of protecting the haematoma both from pressure and from invasion by non-osteogenic extra-skeletal connective tissue. In the present investigation the endosteal callus proliferated deeply into the medullary cavity, possibly because there was no extraneous pressure to distort the haematoma, which is colonised by osteogenic connective tissue alone. As a result, bone can be developed throughout the fibrous callus in the medullary cavity. The haematoma which develops on the external surface of the defect is subject to extraneous muscular pressure and this may determine its final shape, so that there may be very little haematoma covering a protruding implant. The haematoma may be colonised by either osteogenic connective tissue derived from osteogenic elements contained within the bounds of the fibrous periosteum [Pritchard, 1956], or by ext -skeletal non-osteogenic connective tissue. Bone formation will probably not take :e in areas colonised by the latter; instead, the part will be repaired by fibrous tiss.

It is thought that part of the haematoma on the surface of the femoral cortex is colonised by osteogenic connective tissue as it is otherwise unlikely that bony callus would develop in it. It is, however, possible that this area is very restricted for, even though the implant protrudes for only a short distance beyond the contour of the developing callus, the healing bone is not able to cover it. It has been observed that the protruding part of the implant becomes covered by fibrous connective tissue and that, in some cases, the wedge-shaped area between the implant and the femur becomes filled with the same tissue, which becomes less cellular as the healing period progresses. This dense collagenous tissue is characteristic of the scar tissue produced by extra-skeletal non-osteogenic connective tissue. It is therefore possible that the haematoma covering the external aspect of a protruding implant may be colonised by extra-skeletal non-osteogenic connective tissue rather than by osteogenic connective tissue.

It is not known why, in some specimens, a trough containing fibrous connective tissue is present on the surface of the bone between the implant and the subperiosteal callus.

(iii) *The endosteal trabeculae surrounding the implant*

The bone covering the medullary aspect of the "Fluon" is apparently not removed during resorption of the endosteal callus. It undergoes remodelling and, while it may be interrupted in places, there is evidence six months postoperatively that it is still being augmented by the deposition of circumferential lamellae. This bone possibly owes its existence to functional stress.

(iv) *The possible use of "Fluon" in bone surgery*

The results of this investigation indicate that "Fluon" hinders the healing of bone. "Fluon" might, however, be considered as a material for the restoration of damaged articular surfaces. This is suggested because it tends to be self-lubricating, because healing tissues do not become attached to it, because it does not appear to stimulate new bone formation and because it is apparently inert biologically. Furthermore, it can be manufactured in whatever shape or size may be required. The above problem requires further investigation as does the part, if any, played by "Fluon" in the development of malignant disease.

We are indebted to Mrs. A. Vorster, who produced the photomicrographs.

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LEGENDS TO PLATE (Opposite)

Fig. 1. 6 *Days Postoperatively* (Haematoxylin and Eosin x 30).

The implanted "Fluon" is of light ground-glass appearance and has black flecks in its substance. The healing tissues are closely applied, but not attached to the "Fluon" which has been displaced. The endosteal trabeculae have proliferated deep into the medullary cavity and have surrounded the implant. The fibrous callus lying between the periosteal aspect of the implant, which protrudes beyond the external contour of the bone, and the overlying muscle is very narrow.

Fig. 2. 28 *Days Postoperatively* (Haematoxylin and Eosin x 30).

The implant protrudes beyond the contour of the femur and is covered by a layer of connective tissue which extends from its surface to the surface of the bone, thereby forming a triangular area of connective tissue on its sides.

The medullary aspect of the implant is covered by a thin layer of bone. The "Fluon" has not been resorbed nor penetrated by connective tissue. It has been displaced and torn in histological preparation.

Fig. 3. 3 *Months Postoperatively* (Haematoxylin and Eosin x 30).

The implant protrudes from the defect and is not covered by bone but by mature connective tissue.

The bone covering the inner aspect of the "Fluon" is being thickened by the deposition of lamellar bone. The implant has been displaced during histological preparation.

Fig. 4. 28 *Days Postoperatively* (Haematoxylin and Eosin x 30).

The implant does not protrude externally but does penetrate into the medullary cavity. It is almost completely surrounded by bone.

Fig. 5. 6 *Months Postoperatively* (Haematoxylin and Eosin x 30).

The implant, which lies largely in the medullary cavity, does not protrude from the external aspect of the femur. It is almost wholly surrounded by bone which is being thickened on the endosteal aspect. There is no evidence that the "Fluon" has been resorbed or that it has been invaded by connective tissue. The implant has been displaced during histological preparation.

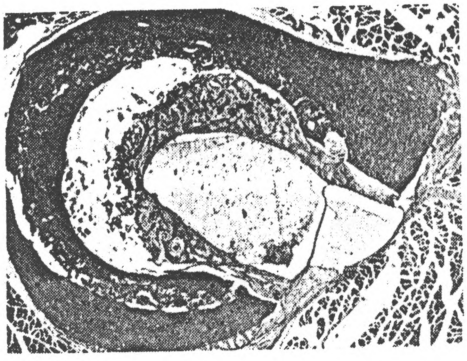

FIG. 1

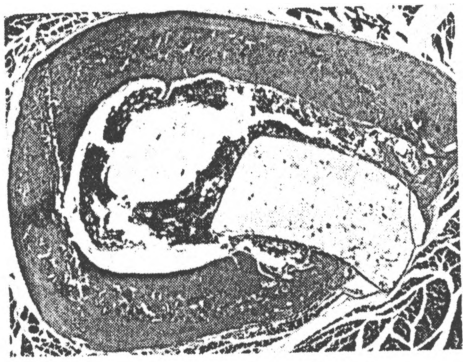

FIG. 2

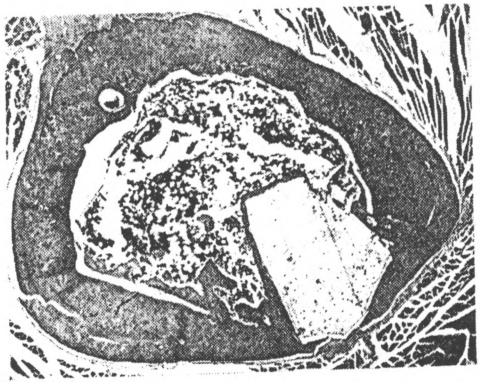

FIG. 3

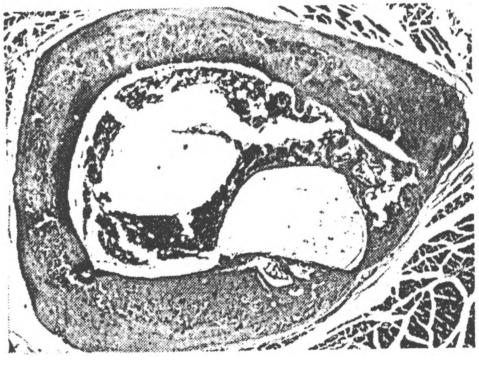

FIG. 4

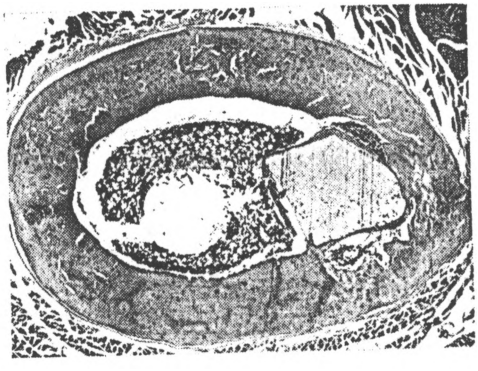

FIG. 5