Experimental Evaluation of Silicone-Coated Dacron and Collagen Fabric-Film Laminate as Dural Substitutes*

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A number of investigative studies have been conducted in the search for a satisfactory substitute for the dura mater. Such materials as metal foils, biological tissues, rubber sheets, and synthetic fabrics have been tested both experimentally and clinically for possible human use. The results of these studies have, in general, been disappointing in that the proposed materials either provoked tissue response or possessed undesirable physical characteristics.

The present study was designed to evaluate the tissue response toward two materials, collagen fabric-film laminate† and silicone-coated Dacron,‡ implanted in the subdural space of dogs. Each product appeared to have favorable physical characteristics, and an experimental evaluation of each material as a potential dural substitute seemed warranted. Silicone-coated Dacron has been used previously for duraplasty, but studies in which the tissue reaction to this material has been evaluated in experimental animals and patients have not been reported.

Materials

Collagen Fabric-Film Laminate. This substance is prepared from bovine collagenous tissue. After enzymatic purification and dispersion in an acid media, collagen strands are formed and woven into a fabric. A thin collagen film is coated onto both sides of the fabric which is then treated chemically (tanned) to provide the desired strength and rate of absorption. The finished product is sealed in a plastic envelope and then sterilized by irradiation. Two types of collagen fabric-film laminates, differing in the extent of tannage (light or dark), were tested in this study. Details concerning the physical characteristics, method of preparation, tanning, and sterilization of the collagen fabric-film laminate have been previously published by Kline.

Silicone-Coated Dacron. This material consists of a thin sheet of Dacron coated on each side with a silicone polymer. Silicone-coated Dacron is highly electrostatic and, because of this characteristic, small particulate matter such as dust, lint, or powder will adhere to its surface. To obviate this problem in the present study, the precleaned material, supplied by the manufacturer in sealed plastic envelopes, was handled entirely with instruments. Small squares measuring approximately 3×3 cm which were cut from the larger sheet were placed in clean Petri dishes and autoclaved immediately before implantation.

Method

The experimental studies were performed in 74 adult mongrel dogs. The animals were anesthetized intravenously with sodium pentobarbital. The scalp was shaved, prepared with antiseptic solutions, and draped as a sterile field. With aseptic surgical technique, a midline incision was made in the scalp, exposing the bone on each side. Bilateral parietal trephine openings were made, and each was enlarged into a craniectomy which measured 2 cm in diameter. The dura mater within the area of exposure was excised from each side.

In 60 animals (Group 1), the rest of the procedure was as follows. On the right (control) side the excised dura mater was placed directly on the cortical surface. On the left
Experimental Dural Substitutes

TABLE 1

Method of investigating silicone-coated Dacron and collagen fabric film as dural substitutes

<table>
<thead>
<tr>
<th>Material Implanted</th>
<th>No. of Dogs (Group 1)</th>
<th>No. of Dogs (Group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Period of Evaluation</td>
<td>Period of Evaluation</td>
</tr>
<tr>
<td>Silicone-coated Dacron</td>
<td>3–6 wks 3 mos</td>
<td>6 mos 3 mos (Lacerated Cortex)</td>
</tr>
<tr>
<td>Collagen fabric-film laminate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light-tanned</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Dark-tanned</td>
<td>7</td>
<td>9</td>
</tr>
</tbody>
</table>

side, the material being evaluated was cut to the size of the defect in the dura mater and laid on the surface of the brain. The replaced dura mater and each material being tested remained in place without the use of sutures. In every animal, the arachnoid membrane on each side was disturbed as little as possible. To make the collagen film laminate more pliable, it was soaked in physiological saline solution for several minutes before application.

Of the 60 dogs, silicone-coated Dacron was implanted in 21, light-tanned collagen fabric-film laminate in 19, and dark-tanned collagen fabric-film laminate in 20. The scalp wounds were closed. At the end of the procedure, each animal was given an intramuscular injection of 400,000 units of penicillin G procaine and 0.5 gm of streptomycin.

As shown in Table 1 (columns 1–3), the animals in Group 1 were further divided into three smaller groups depending on whether they were sacrificed between 3 and 6 weeks; at the end of 3 months; or at the end of 6 months. At the time of sacrifice, the gross tissue reaction to both the graft and the control dura mater was graded on the basis of adhesions to the subjacent pia-arachnoid and cerebral cortex on a 0 to 4 scale as follows:

0 = No adhesions
1 = Filmy adhesions which separated easily
2 = Filmy adhesions which separated with minimal dissection
3 = Moderately dense adhesions which required sharp dissection
4 = Adhesions so tenacious as to produce cortical tearing during removal.

After gross evaluation of control and graft sites in each animal, the brain was removed, fixed in 10% formalin for a period of 14 days, and prepared for microscopic study. The histologic techniques included Hematoxylin-eosin, and Masson and Mallory's phosphotungstic acid hematoxylin stains.

In the remaining animals (Group 2, Table 1), the procedure described for Group 1 was altered in that the cerebral cortex beneath both the graft and control sites was lacerated in several places with a 20-gauge needle to a depth of approximately 5 mm before implant of the graft and excised dura mater. These animals were sacrificed at the end of 3 months. Gross and microscopic evaluation of the tissue response at the control and test sides was carried out as with Group 1.

Results: Gross Tissue Reaction

The data in Table 2 were obtained by averaging the grade of gross meningeal adhesion for each group at each period. For example, the six animals in the silicone graft group that were sacrificed between 3 and 6 weeks showed adhesions ranging from Grade 0 to Grade 2, with an average value of 1.2; whereas, an average value of 1.8 was obtained on the control side.

Silicone-Coated Dacron. The gross tissue response to the silicone graft was minimal. In the animals sacrificed between 3 and 6 weeks and at 3 months, the tissue reaction associated with the graft was actually less than that on the control side. The average
adhesion grade at 3 to 6 weeks was 1.2 for the silicone graft and 1.8 for the control; at 3 months, 1.6 for the graft and 2.9 for the control. At 6 months, there was no difference between control and graft sides.

**Collagen Fabric-Film Laminate.** In six animals sacrificed between 3 and 6 weeks, the light-tanned collagen provoked more reaction than occurred on the control side. The average grade was 3.0 on the test side and 1.4 on the control side. There was no difference between control and graft sites at 3 months. At the end of 6 months, there was more gross reaction to the collagen graft (average grade, 3.8) than on the control side (average grade, 2.5).

The dark-tanned collagen during each of the three time periods produced gross adhesions that were similar to those on the control side.

**Gross Reaction Over Damaged Cortex.** The average grade of adhesion for each material placed over experimentally traumatized cortex is shown in Table 3. The silicone graft provoked fewer gross adhesions than occurred on the control side. In five animals, the average grade for silicone was 2.9, while that on the corresponding control side was 3.9. Both types of collagen fabric-film laminate produced more gross adhesions than were observed with the silicone graft. There was no difference in the degree of tissue reaction between the controls and either of the two varieties of collagen tested.

**Results: Microscopic Observations**

**Control Side.** The replaced dura mater stimulated only a minimal cellular response (Fig. 1). The degree of cellular reaction was approximately the same at each of the periods of evaluation. Microscopically, adhesions between the replaced dura mater and the subjacent pia-arachnoid were slight to moderate.

### Table 2
*Average grade of gross meningoencephalocerebral adhesions observed with dural substitutes. (Group 1, 60 animals)*

<table>
<thead>
<tr>
<th>Material Implanted</th>
<th>Grade of Adhesions—Period of Evaluation‡</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>3 to 6 wks</td>
</tr>
<tr>
<td></td>
<td>No. Animals</td>
</tr>
<tr>
<td>Silicone-coated Dacron</td>
<td>6</td>
</tr>
<tr>
<td>Collagen fabric-film laminate:</td>
<td></td>
</tr>
<tr>
<td>Light-tanned</td>
<td>6</td>
</tr>
<tr>
<td>Dark-tanned</td>
<td>7</td>
</tr>
</tbody>
</table>

* C=control side.
† T=test (graft) side.
‡ See text for grading system.

### Table 3
*Gross meningoencephalocerebral adhesions observed with dural substitutes over damaged cortex. (Group 2)*

<table>
<thead>
<tr>
<th>Material Implanted</th>
<th>No. Dogs</th>
<th>Gross Reaction over Damaged Cortex (3 mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Control*</td>
</tr>
<tr>
<td>Silicone-coated Dacron</td>
<td>5</td>
<td>3.9</td>
</tr>
<tr>
<td>Collagen fabric-film laminate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light-tanned</td>
<td>5</td>
<td>4.0</td>
</tr>
<tr>
<td>Dark-tanned</td>
<td>4</td>
<td>3.9</td>
</tr>
</tbody>
</table>

* Control side.
† Test (graft) side.
Silicone-Coated Dacron. In those animals sacrificed between 3 and 6 weeks, the silicone graft was encapsulated by a thin smooth fibrous envelope which contained small numbers of round cells and was continuous at its edges with the dura. There were slight to moderate adhesions between the fibrous envelope and the pia-arachnoid.

At 3 months the fibrous envelope was well-developed with an associated minimal cellular response (Fig. 2). There were moderate adhesions between the envelope and the pia-arachnoid. The microscopic appearance at 6 months was similar to that observed at 3 months.

Collagen Fabric-Film Laminate (light-tanned). At 3 weeks, an intense foreign-body reaction was present. There was varying, but generally heavy, infiltration of lymphocytes, plasma cells, and macrophages. The tissue reaction was most pronounced about the individual collagen fabric fibers but also involved the subjacent pia-arachnoid. At 6 weeks, only small fragments of the collagen fabric remained, with an associated residual cellular response. There was no glial reaction in the adjacent cerebral cortex. A dural neomembrane encapsulating the residual collagen fabric was present in all specimens.

At 3 months, there was a well-formed dural neomembrane replacing the collagen graft. There were occasional small fragments of the graft, with minimal numbers of round cells. The dura was moderately adherent to the underlying pia-arachnoid (Fig. 3). The microscopic appearance at 6 months was similar to that seen at 3 months.

Collagen Fabric-Film Laminate (dark-tanned). The cellular response about the collagen graft at the 3-to-6-week interval was marked. This was more pronounced than that seen with the light-tanned collagen film but included the same cellular elements. At 6 weeks, the graft was surrounded by a neomembrane from which fibrous tissue projected into the interstices of the fabric. There were moderate meningocerebral adhesions.

At 3 months, the graft was still intact and was associated with a moderate cellular infiltration about the individual fibers. There was slight infiltration of round cells in the

Fig. 1. Control side (replaced dura) at 3 months. There is a well-formed dural layer, and a minimal cellular reaction about the replaced dura. Adhesions between the dura and the underlying pia-arachnoid are slight to moderate. H. & E., X105.

Fig. 2. Silicone-coated Dacron, 3 months. The silicone graft has been removed before fixation for microscopic study. The fibrous envelope is well-developed. The associated cellular response is minimal. H. & E., X70.
Scattered fragments of collagen remain along with minimal numbers of round cells. Moderate adhesions are present between the dura and the underlying pia-arachnoid. H. & E., x70.

Fig. 3. Light-tanned collagen fabric-film laminate, 3 months. A well-formed dural neomembrane is present. Scattered fragments of collagen remain along with minimal numbers of round cells. Moderate adhesions are present between the dura and the underlying pia-arachnoid. H. & E., x70.

Pia-arachnoid, but no foreign body giant cells were seen (Fig. 4). In each specimen, there was a well-formed dural neomembrane which encapsulated the collagen graft. There were moderate adhesions between this layer and the underlying pia-arachnoid. At 6 months, remnants of the graft were still contained within the dural neomembrane. Cellular response to the remaining fragments of the graft was variable with moderately heavy infiltration of small round cells in some specimens. There were moderate adhesions between the pia-arachnoid and dural membrane.

Microscopic Reaction over Damaged Cortex. The silicone-coated Dacron and both varieties of the collagen fabric-film laminate placed over the experimentally traumatized cerebral cortex were associated with a cellular response similar to that described with untraumatized cortex.

Over the cortical wounds, the pia-arachnoid showed thickening and extended into the needle tract in the brain in all wounds greater than 2 mm in width. However, the adhesions between the meninges and the cerebral cortex were less marked beneath the silicone graft than with either variety of the collagen graft or even with the animal’s own replaced dura mater.

Discussion

One of the primary purposes of any material used as a dural substitute should be the reduction or prevention of adhesions between the cerebral cortex and the overlying soft tissues. This, in turn, lessens the possibility of postoperative or posttraumatic seizures. Such a substitute assumes particular importance in patients with an operative or traumatic dural defect. In evaluating potential dural substitutes, various authors have listed the properties which the ideal material should possess. These include: inertness in tissue, nontoxicity, favorable tensile strength, availability in various sizes, ease of sterilization, and soft consistency. Moreover, the substitute should remain intact long enough to prevent the ingrowth of fibrous tissue in the period before regeneration of the pia-arachnoid.

Of the materials tested in the present study, only silicone-coated Dacron satisfied these criteria. The gross and microscopic tissue reactions to the silicone graft were minimal. Some adhesions could be expected between the inner layer of the fibrous envelope surrounding this graft and the subjacent pia-arachnoid. But at each stage the silicone material actually stimulated less tissue reaction than did the replaced dura mater on the control side. The collagen fabric-film laminate, on the other hand, provoked a moderate-to-marked cellular reaction about each fiber strand similar to that observed during absorption of catgut sutures. With the light-tanned collagen, the gross tissue reaction was more severe at 3 to 6 weeks and 6 months than at the 3-month interval (Table 2). We have no explanation for this biphasic tissue reaction.

Because of the degree of tissue reaction associated with the collagen graft, we feel that this material should not be used as a dural substitute in clinical practice. This is contrary to the conclusions of Kline and Jannetta and Whayne, who studied the tissue response to collagen film laminate.
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Fig. 4. Dark-tanned collagen fabric-film laminate, 3 months. The fabric remains intact and is associated with a moderate cellular infiltration about the individual fabric fibers which extends into the pia-arachnoid. A well-formed dural neomembrane is present and adhesions are moderate. H. & E., X70.

implanted into a dural defect in dogs. Kline observed that resorption of the implanted material was slow and attended by a round-cell response, while Jannetta and Whayne noted a transient mild foreign-body reaction as the collagen resorbed. Despite these cellular reactions, however, these investigators felt that the collagen product showed promise as a dural substitute.

An undesirable feature of silicone-coated Dacron is its electrostatic property, which causes small particles of lint, dust, and talc to adhere to the material.\textsuperscript{10,28} Unless the material is handled with care, it is possible to carry foreign particles with the implant. Our experience was that appropriate handling eliminated this hazard.

Summary

Silicone-coated Dacron and collagen fabric-film laminate were evaluated as possible dural substitutes in a total of 76 dogs.

The silicone graft was associated with a minimal gross and microscopic reaction at the time periods studied. The gross tissue reaction to this material in the animals sacrificed at both 3 to 6 weeks and 3 months was less than the reaction evoked by the replaced dura mater on the corresponding control side.

Both the light- and dark-tanned collagen fabric-film laminates stimulated a moderate-to-marked gross and microscopic tissue reaction. On the basis of these findings, it is our feeling that this material should not be recommended for clinical use.

The results of this study indicate that the properties of silicone-coated Dacron justify its consideration for use as a dural substitute in patients.
References


