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.1-9,11-14,16,20,22-27,29,30 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,10 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.16

Silicone-Coated Dacron. This material consists of a thin sheet of Dacron coated on each side with a silicone polymer.10 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.10,28 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

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†Collagen fabric-film laminate, prepared in 1962 and 1963, was supplied by the Medical Research Dept., Ethicon, Inc., Somerville, N. J.
‡Silicone-coated Dacron was furnished by The Holter Company, 3rd and Mill Streets, Bridgeport, Penn., as "Mediform Dura Substitute." Dacron is a synthetic fabric prepared by the Du Pont Co., Wilmington, Delaware.
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></td>
<td>3–6 wks</td>
<td>3 mos</td>
</tr>
<tr>
<td>Silicone-coated Dacron</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Collagen fabric-film laminate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light-tanned</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Dark-tanned</td>
<td>7</td>
<td>4</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 meningo-cerebral 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