A silicone rubber tendon for extraocular muscle
An experimental study

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In 14 dogs' eyes, silicone rubber prostheses strengthened with Dacron mesh were successfully inserted as partial tendon substitutes for the lateral rectus muscles. Although preparations tended to have fewer adhesions to the globe after longer periods in vivo, in all but one case some adhesions remained. These probably would prevent the prostheses from functioning perfectly as tendons, even though a sheath were formed around the prosthesis in each case.

Various inert materials have been used as substitutes for ocular tissue. A recent addition to the list is a silicone rubber made by compounding a silicone polymer with a finely powdered filler of pure silica as a reinforcing agent.

The present study was undertaken to determine if silicone rubber would be suitable as an artificial tendon for extraocular muscle.

Review of the literature

No report of an attempt to create an artificial tendon for ocular muscle with inert material was found. However, several materials have been used in attempts to produce tendonlike subcutaneous prostheses in other parts of the body. Lange lengthened a human quadriceps tendon with silk strands and 2½ years after the procedure found that a "tendon" as thick as a lead pencil had formed in the subcutaneous fatty tissue. Microscopic examination revealed no elastic fibers or blood vessels. The silk threads were not destroyed but had become infiltrated with new growth. Sevier used silk tendons in the extremities of cats. Microscopically, the silk was found to act as a matrix around which fibrous tissue was laid down. Unless the tendon sheath was left, the regenerated structure was not true tendon but simply fibrous tissue. Delbet reported upon the use of a form of rubber tendon in dogs; it was unsuccessful because the attachments to tissues came loose. Grau used polyethylene-covered silk or wire for prosthetic tendons in the extremities of dogs; he was unsuccessful in maintaining fixation of soft tissues to the prostheses. Williams implanted strips of Teflon in extremities of the dog without deleterious effects. Micro-
scopic examination of his preparations revealed well-developed pseudosheaths composed of fibrous tissue. A thin layer of cells which looked like mesothelium lined the pseudosheath. Moderate infiltration of round cells was the only evidence of reaction.

Use of silicones in eye surgery. Leib and co-workers implanted a silicone (Silicone B 695-106-1 Dow-Corning) in the anterior chambers of the eyes of rabbits. Microscopic examination revealed that the implanted silicone was well tolerated and was covered with a single layer of endothelial cells. Ellis implanted silicone tubes in the anterior ocular chambers of rabbits without seriously affecting the health of the eyes. Stone injected a silicone into the vitreous of rabbits without apparent injury to the eyes. Clinically, Schepens and co-workers used silicone rubber for scleral buckling procedures without serious effects on the eye due to the rubber.

Use of silicones for other types of surgery. Silicone rubber has been used extensively in other fields of surgery, both clinically and experimentally. They have been used for heart valves, urethras, ureteral valves, bile ducts, hydrocephalus shunt tubes, parts of heart-lung machines, and in various other ways.

Materials and methods

The rubber used in this study was Silastic X-30146. Because sutures tended to tear out, the material was strengthened with a Dacron mesh (Fig. 1). Prostheses were formed by calendering the rubber on both sides of the Dacron mesh so that essentially none of the Dacron would be in contact with tissue. The prostheses, 0.02 inch thick, were elastic and would stretch enough to provide sufficient pliability to avoid damaging ocular tissue during and after placement in the vicinity of the eye. Because the silicone used is a soft rubber compound, the prostheses easily conformed to the curvature of the globe.

Experimental procedure. The silicone rubber prostheses were boiled for 15 minutes in Ivory soap flakes, rinsed in clear water to remove any lint, placed in a glass dish, and autoclaved. They were cut to size at the operating table.

Healthy mongrel dogs weighing about 10 kilograms were anesthetized with intravenous pentobarbital. The regions about the eyes were cleansed with pHisohex, and the eyelids and lid margins were painted with aqueous Merthiolate. After the animals were draped, the conjunctiva and fascia bulbi over the lateral rectus muscles were opened. The lateral rectus muscles were isolated, carefully cleaned, and stripped of check ligaments. In 3 cases a small piece of muscle (about 5 mm.) was resected; however, this procedure was abandoned because of technical difficulties in handling the small extracocular muscles of the dog. Subsequently, the muscles were simply cut at about the musculotendinous junction. The prosthesis, about 4 mm. wide and 5 to 10 mm. long, was sutured to the distal end of the muscle with No. 5-0 double-armed black silk. A suture was run in a lock stitch over the width of the muscle, passed through the prosthesis, and tied on it.

Two methods were used to suture the prosthesis to the proximal end of the tendon. The first method was the same as that used on the distal end. The second method consisted of pulling the tendon through a hole cut in the prosthesis and suturing the tendon back on itself with No. 5-0 black silk. The incision in the conjunctiva and fascia bulbi was closed with a running No. 4-0 catgut suture, and Neosporin ointment instilled in the eye. The dogs were returned to their cages and observed for varying lengths of time before being sacrificed.

Specimens were removed and examined grossly and microscopically at the end of 10 and 20 days, about 40 days and about 2 months, 4 months, 5 months, and over 6 months.

Results

The procedure was successful in 14 cases: 7 by the first method and 7 by the second. Because there was no difference in the response of tissue or the fixation of prostheses attributed to either method, the two groups were combined in Table I.

No manifest tropias were noted. There appeared to be normal motility as far as could be told by observing the eyes. This was true even though the prostheses lengthened the total tendon-muscle mass by different amounts.

At the end of 10 days gross examination revealed that the prostheses were in place and firmly fastened to the globes and rectus muscles. Adhesions were distributed generally about the entire area. The prostheses were strongly adherent to the globes
Fig. 1. Postmortem specimens. Prosthesis in eye on left was in vivo for 39 days; that in eye on right, for 61 days. Sheath around each prosthesis is transparent enough to reveal Dacron mesh through silicone rubber. In specimen on left continuity of sheath over preparation can be seen well. Proximal end of sheath on right was disrupted in dissection.

Microscopic examination revealed that the prostheses were surrounded by a cellular layer about 6 to 10 cells thick. The cells of this layer had round to spindle-shaped, dark-staining nuclei. No definite endothelium-like layer could be seen, but in a few places an occasional small segment contained a few endothelium-like cells. Beyond the immediate layer of 6 to 10 cells, there was loose, moderately cellular areolar tissue. Many mononuclear cells and a few polymorphonuclear were seen; no giant cells were noted. The muscle tissue in the various sections was observed to be hypercellular because of infiltration with mononuclear cells. Around the suture material infiltration with mononuclear cells was moderate.

At the end of 20 days, similar gross findings were noted except that there were fewer widespread adhesions and there was less distortion of tissue. A sheath surrounded each prosthesis, but it contained no fluid.

Microscopic examinations of 20 day specimens revealed that each prosthesis was surrounded by a capsule of two layers. The inner layer was composed of cells, 2 to 3 deep, which had deeply staining nuclei, and which were relatively ovoid compared with the cells of the outer layer. The latter was 8 to 10 cells thick and was composed of cells with spindle-shaped nuclei and large, slender cell bodies. The surrounding tissue was much less cellular than in the 10 day specimens; however, extensive mononuclear cell infiltration around the sutures remained apparent wherever sutures were seen in the sections.

At about 40 days, gross examinations revealed less tissue reaction. There were fewer adhesions, and dissection of the tendon-prosthesis-muscle mass was quite simple. Microscopic examination revealed that the two-layered sheath now was fairly well developed: nuclei of some of the cells bordering the prosthesis bulged into the space surrounding the prosthesis, and the outer cell layer was well organized. There
was minimal cellular response in the remainder of the sections, except for a few mononuclear cells in the tissue around the sheath—much fewer in number than in the 20 day specimens.

At about 2 months similar findings were noted. Dissection was quite easily performed, but there still were adhesions to the globe at the suture lines.

Microscopic examination revealed a two-layer sheath about the prosthesis. In one specimen (in vivo for 79 days) many histiocytes and a moderate number of mononuclear cells were seen around the entire prosthesis. No gross evidence of active infection or inflammation was noted in this animal either during life or at necropsy. Sclera, ciliary body, and retina were included in the section; all appeared normal.

In specimens examined at the end of 4 and 5 months and more than 6 months gross findings were similar; the major difference was in the extent of the adhesions which bound the prosthetic sheath to the globe. In general, the longer the prosthesis remained in the body, the fewer were the adhesions. In the specimens, there were still adhesions at the suture lines; these were easily broken with a spatula or blunt instrument.

Microscopy continued to show the sheath with the two layers of cells. No giant cells were observed, but mononuclear cells were found around the silk sutures in all sections, even those examined after 6 months in vivo.

### Table I. Results

<table>
<thead>
<tr>
<th>Dog No.</th>
<th>Days prosthesis was in body</th>
<th>Fluid inside sheath</th>
<th>Adhesions</th>
<th>Microscopic evidence of inflammation</th>
<th>Remarks†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td>Yes</td>
<td>+4</td>
<td>Many mononuclear cells, few polymorphonuclear leukocytes</td>
<td>See Fig. 2</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>Yes</td>
<td>+4</td>
<td>Many mononuclear cells, few polymorphonuclear leukocytes</td>
<td>—</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>No</td>
<td>+3</td>
<td>Few mononuclear cells</td>
<td>See Fig. 3</td>
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<tr>
<td>4</td>
<td>20</td>
<td>No</td>
<td>+3</td>
<td>Few mononuclear cells</td>
<td>—</td>
</tr>
<tr>
<td>5</td>
<td>39</td>
<td>No</td>
<td>+2</td>
<td>Very few mononuclear cells</td>
<td>See Fig. 1, left eye</td>
</tr>
<tr>
<td>6</td>
<td>43</td>
<td>No</td>
<td>+3</td>
<td>Few mononuclear cells</td>
<td>Surgical specimen; new prosthesis inserted</td>
</tr>
<tr>
<td>7</td>
<td>61</td>
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<td>+2</td>
<td>Very few mononuclear cells</td>
<td>See Fig. 1, right eye</td>
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<tr>
<td>8</td>
<td>79</td>
<td>No</td>
<td>+2</td>
<td>Many mononuclear cells, no polymorphonuclear leukocytes</td>
<td>Retina in slide</td>
</tr>
<tr>
<td>9</td>
<td>139</td>
<td>No</td>
<td>+1</td>
<td>Very few mononuclear cells</td>
<td>Retina in slide</td>
</tr>
<tr>
<td>10</td>
<td>144</td>
<td>No</td>
<td>+1</td>
<td>Essentially none</td>
<td>—</td>
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<tr>
<td>11</td>
<td>154</td>
<td>No</td>
<td>+1</td>
<td>Essentially none</td>
<td>—</td>
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<td>164</td>
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<td>0</td>
<td>Essentially none</td>
<td>—</td>
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<td>Essentially none</td>
<td>See Fig. 4</td>
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<td>14</td>
<td>210</td>
<td>No</td>
<td>+1</td>
<td>Essentially none</td>
<td>Sutures removed from globe end of preparation at 71 days. Retina in slide</td>
</tr>
</tbody>
</table>

*Adhesions were graded as follows: 0, No adhesions. +1, Adhesions at suture lines only. +2, Adhesions at suture lines and beneath prosthesis. +3 and +4, Adhesions at suture lines, beneath and above also.

†In each instance a sheath formed around the prosthesis.
The muscle-prosthesis preparation was at least as strong as normal dog extraocular musculature. When each preparation was dissected, it was hooked with a muscle hook and tugged on vigorously. In no case did the prosthesis tear loose.

No detailed study of the underlying globe was made; however, no gross abnormalities were noted. In 3 microscopic sections, in vivo from 79 to 210 days, portions of the underlying sclera, ciliary body, and retina were seen; no abnormalities were noted.

Comment
At the outset of the study we thought the animal tissue might have a tendency to pull away from the prosthesis if necrosis

Fig. 2. Tissue layer surrounding prosthesis after 10 days in vivo. Two layers of sheath are not yet evident. (Hematoxylin and eosin. x600.)

Fig. 3. Tissue layers around prosthesis in vivo for 20 days. Two layers of sheath are beginning to be apparent. (Hematoxylin and eosin. x600.)
Fig. 4. Tissue layers around the prosthesis at the end of 179 days. Two layers are well developed and quite evident. (Hematoxylin and eosin. ×600.)

...occurred around the sutures. Therefore, two methods of securing the prosthesis to the globe were used. As the specimens were examined, it soon became apparent that the prosthesis became ensheathed very quickly in a connective tissue covering lined with endothelium-like cells. Even preparations examined after only 10 days in vivo showed the beginnings of the sheath. Sutures, then, were not essential to long-term fixation; the body provided physiologic fixation. In one case, at re-operation for observation 71 days after the insertion of the prosthesis, the preparation was isolated and the sutures at the globe end were removed. When examined again at the end of 210 days, the prosthesis was still in place.

We were unable to tell which method had been used to fix prostheses to the globe end of the tendon without splitting the preparation and finding the hole through which the tendon had been pulled before suturing.

In all microscopic sections containing suture material, an inflammatory response occurred about the sutures. We postulate that this response resulted in adherence of the preparation to the sclera along the suture lines. Prostheses in all cases retained the qualities of the soft pliable rubber material composing them; no calcification was observed. All the eyes operated on became white and quiet, usually within 2 weeks. This suggests that no deleterious effect on ocular or orbital tissues occurred.

The motility of dogs' eyes is difficult to evaluate. However, no manifest squints resulted, nor did the animals act as if they experienced diplopia. They ate, played, and, generally, acted as normal animals.

REFERENCES

Silicone rubber tendon