SILICONE IMPLANT TO EXTRA-OCULAR MUSCLES*

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A PROCEDURE which would allow the lengthening of an extra-ocular muscle beyond that which is usually obtained from the conventional surgical techniques would be of definite advantage in large-angle strabismus and strabismus fixus. Since silicone rubber is well tolerated by ocular and non-ocular tissues, the implantation of a small, thin sheet of this material to lengthen an extra-ocular muscle is a logical approach in this situation. The purpose of this paper is to report an experimental study, using rabbit eyes, and clinical observations in two patients with strabismus, in which this surgical procedure was applied. A long-term follow-up of these two patients and a report of several other clinical cases will be published at a later date.

Material and Methods

Silicone rubber sheet‡, 0.010 in. thick, was used in the experiments. The material was sterilized either by immersion in 70 per cent. alcohol or by autoclaving. Twelve adult rabbits weighing 3–4 kg. were used. In each rabbit only one eye was operated on. The silicone was always attached to the superior rectus muscle because it is relatively strong and accessible. The rabbits were anaesthetized with intravenous sodium Nembutal (30 mg./kg.) and ether drip. The hairs and lashes of the side to be operated on were shaved, and the skin was painted with 2 per cent. iodine solution. The eye was anaesthetized with drops of Ophthaine (0.5 per cent. Proparacaine hydrochloride, Squibb) and disinfected with a few drops of Neosporin solution (Burroughs Wellcome).

The conjunctiva and fascia bulbi overlying the superior rectus muscle were cut. The muscle was carefully isolated by cutting adhesions with scissors. A muscle forceps was applied close to the insertion and the tendon was transected. A piece of silicone sheet 5 or 6 mm. long was cut in a trapezoidal shape in order to fit the width of the tendon stump anteriorly and the narrower width of the muscle, over the forceps, posteriorly. The implant

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was sutured to the sclera by means of two U-shaped, 6-0 in. silk or catgut sutures (Fig. 1). Trimming the corners of the plastic and preventing these from curling up was an important step, otherwise the conjunctiva would be perforated, particularly if the flap was very thin. At the free end of the plastic, two similar U-shaped sutures were passed upwards from below and tied over the muscle (Fig. 2). The U-shaped sutures were used in order to avoid cutting the implant or the muscle, as could happen if they were sutured edge to edge. The clamp was released and the resistance of the sutures at the proximal and distal ends of the

FIG. 1.—The silicone implant is sutured to the sclera by means of two U-shaped sutures.

FIG. 2.—Two U-shaped sutures have been passed through the silicone sheet and the muscle tendon.

FIG. 3.—The implant has been fixed to the sclera and the muscle, and resistance of the sutures is tested.

implant was tested by gently pulling with a muscle-hook passed under the implant (Fig. 3). The conjunctiva was closed with a continuous suture which was removed ten days later.

The eyes were enucleated after the animals had been killed with intravenous Nembutal and examined microscopically and macroscopically at 1, 2, 3, and 5 months after surgery. These eyes were fixed in 10 per cent. formalin, then embedded in paraffin, and sectioned at 5 μ . The sections were stained with haematoxylin and eosin. Two eyes were processed in celloidin.

Results

Results were satisfactory in all twelve eyes. Conjunctival reaction in the post-operative period was minimal. Macroscopically, the appearance of the eye was similar in all cases. The silicone tendon seemed to form a continuous body with the muscle as shown in Fig. 4 (from a case two months old). The implant was strongly fixed to the sclera at its insertion and anterior portion. The posterior portion of the implant was free from adhesions.

FIG. 4.—Two months after surgery, the silicone implant seems to form body with the muscle. S, Silicone implant. M, Muscle.

FIG. 5.—A connective tissue capsule envelops the silicone implant (S) which is adherent to the sclera only anteriorly. M, Muscle. Haematoxylin and eosin. $\times 12$.

Microscopically, the implant was covered by a fibrous capsule adherent to the sclera anteriorly and fused with the body of the muscle posteriorly, as shown in Fig. 5. The fibrous capsule did not adhere to the silicone and was composed of several layers of fibroblasts (Fig. 6). Adherence of the capsule to the sclera was present only anteriorly, near the sutures (Fig. 7). Further back, there were no adhesions (see Fig. 6). Posteriorly, it blended with the muscle (Fig. 8). In the cases where catgut was used instead of silk, the inflammatory reaction around the sutures was greater and giant-cell granulomas were observed. In one case, foreign-body granulomas were seen around small particles of silicone (Fig. 9). These particles were deposited there because trimming of the silicone sheath had been done over the operative field.

FIG. 6.—The capsule which envelops the implant is composed of various layers of connective tissue cells. Sclera below. Haematoxylin and eosin. $\times 60$.

FIG. 7.—Anteriorly the capsule is intimately adherent to the sclera. Haematoxylin and eosin. $\times 48$.

FIG. 8.—Posteriorly the capsule of the implant forms body with the muscle. Arrow shows that the capsule is not adherent to the sclera. Haematoxylin and eosin. $\times 45$.

FIG. 9.—Granulomatous reaction to small particles of silicone (arrows) within the fibrous capsule. Haematoxylin and eosin. $\times 120$.

FIG. 10.—Mild round-cell infiltration in the muscle immediately behind the implant, two months after surgery. Haematoxylin and eosin. $\times 170$.

When silk was used and care was taken not to include hairs or small particles of silicone in the wound, no inflammatory reaction was found. The muscle was incorporated with the fibrous capsule, showing mild and diffuse round-cell infiltration shortly behind the implant (Fig. 10). In two cases, it was found that most of the muscle fibres originally sutured over the implant had shifted backwards on a level with the implant (Fig. 11), but were still firmly adherent to the connective tissue sheet (see Fig. 5). There was no inflammation in the intra-ocular structures in any of the twelve eyes.

FIG. 11.—Some muscle fibres have shifted backwards and under the implant. Same eye as shown in Fig. 5. Haematoxylin and eosin. $\times 45$.

Clinical Observations

In two patients with large-angle esotropia and amblyopia, a silicone implant to the medial rectus was done. The material used was the same as that used in rabbit eyes, silicone rubber sheet 0.010 in. thick.

Case Reports

Case 1. Male, aged 21 years.—Right esotropia since the age of 6 years. Visual acuity: OD : +1.00 Sph. + 0.50 Cyl. $\times 90 = 20/200$; OS: 20/20 s/c. Prism cover: ET 70, ET' 70 $\triangle$. Fig. 12.

Operation: Right lateral rectus 6 mm. resection; Right medial rectus 6 mm. silicone band implant. The surgical technique for the implant was the same as that used experimentally.

Fifteen days after operation: Prism cover ET 16, ET' 18 $\triangle$. Fig. 13.

FIG. 12.—Case 1 before operation.

FIG. 13.—Case 1 fifteen days after operation.

FIG. 14.—Case 2 before operation.

FIG. 15.—Case 2 fifteen days after operation.

Case 2. Female, aged 28 years.—Left esotropia from childhood. Visual acuity: OD: —0.50 Cyl. $\times$ 180 = 20/20; OS: —2.00 Cyl. $\times$ 180 = 20/40. Prism cover: ET 70, ET' 75 Δ . Fig. 14. There was a secondary insufficiency of the left lateral rectus.

Operation: Left medial rectus: 7 mm. silicone implant plus 5 mm. recession. The surgical technique was similar to that previously described except that the implant was attached to the sclera 5 mm. behind the place of the muscle insertion.

Fifteen days after operation: Prism cover: ET 22, ET' 4 Δ . Fig. 15.

These patients have been followed up for over six months (October 1, 1965). They have maintained good motility and good tolerance to the implant.

Comment

Silicone has been widely used clinically and experimentally in almost all parts of the human body (De Nicola, 1950; Melrose, 1953; Carrington, 1959; Kohler and Murphy, 1959; Starr, 1960; Hoopes and Webb, 1964). In the eye it has been used to produce scleral buckles (Schepens, Okamura, Brockhurst, and Regan, 1960; Regan, Schepens, Okamura, Brockhurst, and McMeel, 1962), to reconstruct the orbit (Lipshutz and Ardizzone, 1963), and in solid (Ruedemann, 1962; Ellis, 1960) or liquid form implants (Levine and Ellis, 1963; Cibis, Becker, Okun, and Canaan, 1962; Dufour, 1964). Bowen and Dyer (1962) reported the use of silicone rubber reinforced with Dacron mesh to make a tendon for the extra-ocular muscle in rabbits. Our technique differs from that of these authors in that we have not used the Dacron mesh they found necessary to strengthen the silicone. In our experience, the silastic sheet 0.010 in. thick is resistant enough to withstand the traction of the eye muscles. Even a sheet 0.008 in. thick, which was used in several rabbit eyes not reported here, was found satisfactory. The connective tissue capsule which rapidly develops around the silicone strengthens its attachment to the sclera and to the muscle stump. We have not found the extensive and strong adhesions of the capsule to the sclera described by Bowen and Dyer (1962), except those present at the level of the scleral sutures. A possible explanation for the adhesions found by these authors could be the fact that they used a single U-shaped suture knotted over the implant to attach it to the muscle, and they left a muscle stump in contact with the sclera under the silicone which was probably a source of irritation and fibrosis. We believe that it is important to use a double U-shaped suture knotted over the muscle in order to assure an even spreading of the muscle fibres over the implant, and an even contact of the silicone band to the sclera. The capsule of connective tissue which forms around the implant is similar to that shown by Bowen and Dyer (1962) and to the connective tissue reaction found by Agnew, Todd, Richmond, and Chronister (1962), around silicone implants in the subcutaneous tissue of rats. The fibrous capsule does not adhere to the silicone, and this property has been used by Carroll and Bassett (1963) to induce the formation of a subcutaneous sheath of connective tissue around a silicone implant which is posteriorly removed and replaced by a tendon graft. These experiences suggest the possibility that the silicone tendon of the extra-ocular muscle can eventually be removed from within the capsule or replaced by homologous fascia.

The good experimental results justified its clinical trial, which was the only means of testing the functional results of the technique. This surgical procedure was used in two patients who had a similar type of strabismus: an esotropia of large angle with

amblyopia. In these cases, unilateral surgery is indicated. In Case 1 we did a resection of the lateral rectus plus a moderate elongation of the medial rectus with a 6 mm. silicone implant. In Case 2 we made a large elongation of the medial rectus by a 7 mm. silicone band which was attached to the sclera 5 mm. behind the muscle insertion. Such a large elongation would not have been possible by a recession of the medial rectus alone because the small arc of contact of this muscle with the sclera does not allow a recession of more than 5 mm., as has been stressed by Weekers and Daenen (1955). Fifteen days after surgery in Case 1 versions were good, as shown in Fig. 13.

In Case 2 there was an insufficiency of the adduction due to the recession of the implant which did not keep the arc of contact with the eye. Probably this could have been prevented if a 10 mm. silicone band had been attached to the sclera closer to the muscle insertion, instead of the recession. In both patients, the deviation in the different positions of gaze had greatly improved.

A greater number of cases with a long follow-up is required to evaluate fully the usefulness of this technique. The two cases here reported have now been followed up for over five months, demonstrating that good functional results can be obtained in cases of strabismus of large angle with amblyopia. Several other cases have been recently treated (silicone 0.008 in. thick) with equally good results, except in one case in which the conjunctival wound has opened twice above the scleral insertion of the implant. Therefore it is important to make a thick conjunctival flap, either anterior or posterior to the insertion of the silicone; the edges of this implant should not protrude through the conjunctiva and its corners should be rounded. If the conjunctiva is too thin, or the implant protrudes too much, it is better to attach it 2-3 mm. behind the muscle insertion.

In strabismus of large angle with amblyopia, a recession-resection of the deviated eye is the usual procedure, which frequently is not enough to correct the total deviation. The procedure described would be an additional resource to correct these cases, as, for example, in strabismus fixus. In this condition, some authors have tried, after a resection-recession procedure, to put traction on the globe by placing a suture at the insertion of the medial rectus and attaching it to the temple (Arruga, 1961).

Another possible indication for a silicone implant to the medial rectus would be Duane's syndrome with esotropia and secondary torticollis. In this syndrome several authors have stressed the contra-indications for surgery on the lateral rectus because of the paradoxical innervation which may aggravate the lid retraction (Orlowski and Wójtowicz, 1962; Blodi, Van Allen, and Yarbrough, 1964).

Summary

The experimental and clinical results of the use of silicone rubber implants to extra-ocular muscles are reported.

Experimentally, the implants were used in twelve rabbit eyes, with little post-operative inflammation and good tolerance to the silicone for periods up to five months. These eyes were studied histologically and showed the formation of a connective tissue capsule around the implant, which was firmly adherent to the sclera anteriorly and to the muscle stump posteriorly.

Clinically, a similar procedure was used in two patients with esotropia of over 70 prism dioptres. In both cases, a good cosmetic result was obtained with good motility.

Muscle lengthening by a silicone implant deserves a wider clinical trial in strabismus fixus, in tropias with a large angle, and possibly in Duane's syndrome with esotropia.

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