VICRYL® (Polyglactin 910): a new synthetic absorbable suture in ophthalmic surgery

A preliminary study

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The main function of a suture is to hold the wound edges in apposition until healing is sufficiently advanced for the wound to be self-supporting. In practice, as an absorbable material is losing tensile strength, the wound is gaining strength and at a particular time, which varies according to the tissue involved, equilibrium will be reached. Ophthalmic surgery presents the ideal situation where sutures implanted during operative procedures can be readily observed with regard to their tissue reactivity, biological acceptability, and loss of tensile strength. Characteristics of knotting, tissue drag, and knot strength can also be assessed. A clinical trial of VICRYL® Synthetic Absorbable Sutures made by Ethicon was set up in three clinical centres: 27 cataract extractions and thirty squint operations were done to determine the safety and efficacy of this material.

VICRYL®, or Polyglactin 910, is a synthetic absorbable suture which has been synthesized by the co-polymerization of a mixture of purified lactide and glycolide which are cyclic intermediates derived from lactic and glycolic acids. Glycolide and lactide are converted into a polymer in the form of uniform chips which are dyed violet. These chips are melted, and the polymer extruded to form fine filaments. These filaments are strengthened by stretching to allow molecular alignment. The resulting filaments are braided and the braid undergoes a further stretching process to increase further the tensile strength of the resulting suture. Being violet in colour, the suture is easily seen in the wound. The suture material is attached to an eyeless needle, placed dry into a foil package and sterilized by ethylene oxide. The braided VICRYL® is smaller in diameter than the corresponding size of catgut, although its "knot pull strength" is higher (Table I). Knot pull strength is recorded in pounds and is the tension at which a knotted piece of suture material breaks. This strength is always lower than the straight pull value with no knot in the material. In a comparison of VICRYL®, polyglycolic acid, and MERSILENE® it can be shown that VICRYL® has a higher knot pull strength than any of the other materials mentioned (Table II).

Extensive animal work had been performed by Ethicon with VICRYL® to show its safety and efficacy *in vivo* before release for clinical trial. This work included toxicity and carcinogenic studies, in-use animal work, and metabolic studies using radioactive labelled suture

Table I *Relative tensile strengths of 3/0 sutures**

<i>Suture</i>	<i>Knot pull tensile strength (lb.)</i>
Polyglactin 910 (VICRYL®)	4·8
Silk	2·8
Catgut	3·8
Dacron (MERSILENE®)	4·2

® Trademark *Data from Ethicon

Table II *Tensile strength of synthetic absorbable sutures compared with synthetic non absorbable polyester**

<i>Suture</i>	<i>Suture size</i>	<i>Knot pull tensile strength (lb.)</i>
VICRYL®	2/0	7·6
(Polyglactin* 910)	3/0	4·8
Polyglycolic acid†	2/0	6·4
	3/0	3·9
MERSILENE®*	2/0	5·6
	3/0	4·2

® Trademark * Data from Ethicon
† Katz and Turner (1970)

material. VICRYL® was found to be safe, effective, non-toxic, and non-carcinogenic. When implanted in animal tissue, the material evokes a mild tissue response (Figure). Absorption occurs by hydrolysis and is complete by approximately 80 days, while loss of tensile strength is linear in form and tends to be zero by about 30 days.

FIGURE *Transverse section through a braided VICRYL® suture implanted 7 days previously into the lumbar muscle of a rat. Note mild tissue reaction and early invasion of suture by macrophages; a few giant cells are present. Photomicrograph. × 160*

Sutures used in cataract extractions and operations for squints are mainly situated just under conjunctiva, which makes nonabsorbable sutures more likely to ulcerate to the surface even if they are invisible. On the other hand, "natural" absorbable sutures, such as catgut or collagen, may produce a significant inflammatory reaction in addition to the possibility that a wound may gape if the sutures lose strength too soon. VICRYL® (Polyglactin 910), with its features of minimal tissue reaction and linear loss of tensile strength, was therefore, theoretically at least, a good material to use for ophthalmic operations. A suture with similar properties, DEXON (Davis and Geck), *i.e.* polyglycolic acid, has been used in general surgery (Anscombe, Hira, and Hunt, 1970; McCarthy, 1970; Olerud and Ponten, 1970; Miln, O'Connor, and Dalling, 1972); in oral surgery by Wallace, Maxwell, and Cavalari (1970) and Lilly, Cutcher, Jones, and Armstrong (1972); in orthopaedic surgery by Allman (1973) and Scholz, Lewis, and Bateman (1972); experimentally by Herrmann, Kelly, and Higgins (1970), Postlethwait (1970), and Capperault (1971); in gynaecology by Rahman and Way (1972) and Tompkins and Lea (1972). Very recently, Sugar, Lorfel, and Summer (1974) have reported the successful use of 6/0 DEXON in 55 cataract extractions. VICRYL® has also been used extensively in clinical trials in those areas mentioned above and will be the subject of future scientific papers.

Material

SUTURE VICRYL® (Ethicon) was supplied as follows:

Length 18"—45.73 cm.

Diameter 5/0 braided and 8/0 monofilament.

Colour Violet or clear undyed.

NEEDLES 6 mm. curved spatulate, one at each end of the suture. Patients with cataracts and squints were taken without preselection from the waiting lists of the surgeons concerned.

Methods

SQUINT OPERATIONS

Two of the four ophthalmic surgeons contributed to this series. 5/0 VICRYL® suture material was used both in recessions and resections of the horizontal rectus muscles.

CATARACT EXTRACTIONS

Three of the four surgeons contributed to this series. One used a Graefe section and the other two an *ab externo* technique. Two surgeons used interrupted sutures in the limbal section: two or three VICRYL® 8/0 along with three or two (alternating) of their usual suture—one surgeon normally uses Perlon 10/0 on a 4 mm. needle and the other virgin silk 8/0. The third surgeon normally uses a continuous Perlon suture so that all his reported operations used only VICRYL®.

GENERAL HANDLING CHARACTERISTICS OF VICRYL® (Tables III and IV)

(1) *Knot tying*

For the interrupted sutures, VICRYL® required a slightly different technique compared with catgut or nylon, the basis being the classic surgeon's knot. A *double* "throw" makes the first tie, so that the knot holds by itself at the tension judged necessary to appose tissues. (A single initial throw will not hold.) Two further *single* throws are very firmly tied to secure the knot finally, thereby making a slightly more bulky knot than usual. However, that does not seem to be a disadvantage, especially since the material elicited such a mild tissue reaction when *in situ*. It should be noted that when the second (single) throw follows the first (double) throw and is tightened, the underlying double throw rucks up and consequently tightens the loop slightly. This factor should be taken into account when using this material. It is important to realize that, if two single throws are done, the second cannot "run down" the first.

Table III *Characteristics of Monofilament VICRYL® (dyed violet) Polyglactin 910 compared with monofilament nylon and twisted virgin silk in cataract operations*

Characteristics	Monofilament nylon	Virgin silk
Visibility	++	—
Pliability	+	—
Strength	++	+
Passage through tissue	+	++
Ease of tying	+	—
Resistance to fray	+	++
Knotting	+	—
Overall handling	+	—
Tissue reaction	++	++
Preference	VICRYL® preferred	VICRYL® preferred

VICRYL® Superior ++ Similar + Inferior —

Table IV *Characteristics of braided VICRYL® Polyglactin 910 (undyed) compared with plain catgut and braided silk in squint operations*

Characteristics	Plain catgut	Braided silk
Visibility	+	+
Pliability	+	—
Strength	++	+
Passage through tissue	+	+
Ease of tying	+	+
Resistance to fray	++	+
Knotting	+	+
Overall handling	+	+
Tissue reaction	++	+
Preference	VICRYL® preferred	VICRYL® preferred

VICRYL® Superior ++ Similar + Inferior —

(2) Tissue drag

There was no tendency to catch up Tenon's capsule or conjunctiva, and passage through tissues was satisfactory.

(3) Visibility

There was no difficulty, with or without the operation microscope.

(4) Handling in general

This was very good and was rather similar to that of nylon sutures or catgut, *i.e.* the limpness of silk or linen was lacking.

Results

Details of patients are given in Table V with comments. Complications possibly attributable to these new sutures were three small drainage blebs (two patients) in the cataract series; but, after a few months, only one of these possibly remained—no note was made after the 88th postoperative day on the patient who was lost to further follow-up. In one squint, a muscle slipped off.

Table V Results obtained by four surgeons

Surgeon	Operations	Suture	Comments
A	10 squints	5/0 VICRYL® Polyglactin 910 Clear braided—18" Double spatulate needles	Less tissue reaction than with catgut—similar to white silk—some difficulty with knotting
B	14 cataracts	8/0 VICRYL® Polyglactin 910 Violet monofilament—18" Double spatulate needles	Compares well with Perlon. Knotting superior to Perlon. Suture appeared slightly stiff VICRYL® completely absorbed at 88 day follow-up Three cases of iritis (2 trial material—1 control) on 6th postoperative day.
	20 squints	5/0 VICRYL® Polyglactin 910 Clear braided—18" Double spatulate needles	Suture tends to cut forward slightly in rectus muscles in this gauge One muscle slipped off
C	3 cataracts	8/0 VICRYL® Polyglactin 910 Violet monofilament—18" Double spatulate needles	Less reaction than virgin silk—VICRYL® disappeared at 60 days Virgin silk still there with more reaction and in one case, vascularization Careful knotting essential when using VICRYL®
D	10 cataracts	8/0 VICRYL® Polyglactin 910 Violet monofilament—18" Double spatulate needles	Three drainage blebs (2 eyes) at sites of VICRYL® sutures postoperatively; two subsequently disappeared within 3 and 6 months postoperatively One patient failed to attend after 3 months postoperatively In two cases the ends of one suture showed through conjunctiva but disappeared 1 week later Sutures remained visible and apparently intact for an average of 29 days (range 20–43) and completely disappeared after 58 days (range 34 to 111) Small iris prolapse at site of Perlon suture

The overall impression was that the new suture material produced practically no clinically detectable inflammatory reaction, even under observation with the slit-lamp microscope in cases of cataract.

Pre- and postoperative Hb, white blood cells, erythrocyte sedimentation rate, blood sugar and blood urea, S.G.O.T. and S.G.P.T. were done in all cases and did not suggest any systemic toxic effect from the small amount of suture material used.

The use of α -chymotrypsin at operation and cortisone post-operatively in a few cases did not seem to affect the results.

Discussion

A major reason for this study was that synthetic non-absorbable sutures in common use recently for cataract sections, although inert and buried initially under a conjunctival flap, do tend to ulcerate through the flap, especially the ends. However, this seems to produce surprisingly few symptoms, and no untoward complications (although epithelial down-growth is a possibility, as is infection). Various methods of avoiding this are available: *e.g.* pulling the suture through to bury the knot in the track; tying "granny" knots to make the ends of the suture lie parallel with the limbus; cutting off the ends of the suture very close to the knot; leaving the ends very long so that they can be made to lie down more comfortably. No single one of these possibilities seems to be entirely satisfactory.

Absorbable sutures, on the other hand, have the disadvantage of possible insecurity of the wound if premature absorption occurs. In the case of the cataract section, many surgeons will still remember the days of the Graefe section with conjunctival flap without any sutures at all. The iris prolapses and hyphaemata, which were the surprisingly uncommon complications of these operations, very seldom occurred after the sixth postoperative day and our impression is that prolapses were maximal 24 to 48 hrs postoperatively. Accordingly, an absorbable suture which will hold for a week postoperatively should be valuable—but preferably of course longer to prevent the wound "giving" and producing astigmatism. That empirical tentative conclusion is consistent with the experiments on healing of corneal wounds in rabbits by Condon and Hill (1973), who found that in the first 6 days wound strength depended on the presence of a suture, but further support is advisable subsequently, because by the 12th postoperative day unsutured wounds had regained only 8.8 per cent of total intact corneal strength, and by the 56th day 34.9 per cent. The experimental work of Ingram (1966) on monkeys' extraocular muscles, although not specifically directed to quantitative studies of strength of attachment, showed that by the 7th day fibrous healing was established and advancing, so that time-relations of healing are probably of the same order as those of cornea.

The clinical observations on cataract extractions (see Table V) showing (a) the last postoperative day on which the sutures were still visible, and (b) the first day when no trace was visible, should not be misinterpreted, because the tensile strength of the suture might have become negligible in spite of its continued visibility. However, studies by Capperauld (1973) *in vivo* showed that the tensile strength of VICRYL® was retained for 30 days when implanted intramuscularly. Also, patients were examined at the usual times after discharge from hospital, so that the observations are inevitably not a very precise indication of these times.

A trial involving more patients has been started to expand the series, and to introduce simultaneous controls.

Summary

A new synthetic absorbable suture (VICRYL®, made by Ethicon), has been used in 27 cata-

ract extractions (8/0 gauge; interrupted or continuous sutures in section) and thirty squint operations (5/0 gauge). A 6-mm. curved spatulate needle was swaged to each end of 45.7 cm. (18") of suture. The sutures remained visible with the slit-lamp microscope in the cataract patient for an average of 29 days (range 20 to 43), and had disappeared completely by the 58th day (range 34 to 111). VICRYL® is absorbable without undue inflammatory reaction. A surgeon's knot has to be used with this suture, *i.e.* a double throw initially, followed by two separate very firmly tied single throws. A study involving more patients has been started.

The only abnormalities observed which were possibly attributable to the new suture were three drainage blebs in cataract sections (two eyes), two of which disappeared after a few months; and in one case of squint, a muscle "slipped off".

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