A prospective controlled study of a 10/0 absorbable polyglactin suture for corneal incision phacoemulsification

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CLINICAL STUDY

Abstract

Purpose **To evaluate the performance of a 10/0 monofilament absorbable polyglactin suture for temporal 5.2 mm corneal incision phacoemulsification.**

Methods **A prospective randomised controlled study of 49 patients undergoing phacoemulsification with a sutured temporal 5.2 mm corneal section was conducted to compare the refractive results and complications of a 10/0 monofilament absorbable polyglactin suture with 10/0 nylon.**

Results **Thirty-eight patients completed the study. There was no significant difference in induced astigmatism between the two groups. All absorbable sutures were intact at 1 week. Six weeks post-operatively the absorbable suture was still intact in 1 (6%) patient, present but broken in 4 (24%) and completely absent in 12 (70%) patients. All polyglactin sutures had been completely absorbed by 12 weeks. Absorption of the polyglactin sutures was associated with mild localised corneal haze in 3 (18%) cases ($p = 0.055$). One of the 18 patients (6%) in the polyglactin suture group presented with iris prolapse associated with knot failure 1 week post-operatively. There was no significant difference in foreign body symptoms between the two groups.**

Conclusions **10/0 polyglactin sutures maintain adequate tensile strength during the immediate post-operative period for small incision surgery and are associated with minimal induction of astigmatism. Their subsequent absorption obviates the need for routine suture removal. Suture absorption is well tolerated although in some cases a mild degree of local tissue reaction raises concern about possible mechanisms of absorption. The risk of knot failure may be reduced by an alternative suture tying technique. 10/0 monofilament polyglactin is an attractive option when a suture is required during small incision cataract surgery.**

Key words Absorbable, Astigmatism, Cataract surgery, Polyglactin suture, Vector analysis

Phacoemulsification by means of a sutureless corneal incision is an established technique that offers rapid rehabilitation and minimal induction of astigmatism. Although self-sealing sections have important advantages, there remain indications for the use of sutures in corneal section phacoemulsification. Although foldable and injectable intraocular lenses (IOLs) are popular, rigid IOLs continue to enjoy widespread use in phacoemulsification surgery. A suture may be used routinely in self-sealing sections for added security. Alternatively it may be held in reserve, for use if the section fails to seal or has been extended, for example, to accommodate a large optic. The availability of this option is of particular importance for the purposes of surgical training, where wound construction may be suboptimal and intraoperative complications requiring wound extension more likely.

The low toxicity, high elasticity and prolonged tensile strength of monofilament nylon have led to its widespread use in modern cataract surgery.[1,2] Although nylon sutures are often left *in situ* indefinitely, the incidence of suture-related complications is high[3–7] and in many cases the sutures are ultimately removed at unplanned visits to the eye casualty. Elective suture removal reduces suture-associated complications and related casualty attendances but is demanding of resources in the clinic and may delay spectacle prescription. An alternative solution would be an absorbable suture that maintains its tensile strength during the immediate post-operative period to prevent wound leakage and infection and subsequently undergoes absorption without local tissue reaction or induction of corneal astigmatism. A 10/0 monofilament polyglactin 910 suture has been proposed as such a solution.

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The authors have no proprietary interest in the products investigated in this study

Table 1. *Absorption of polyglactin sutures*

State of suture	Post-operative time		
	1 week	6 weeks	12 weeks
Intact	17 (100%)	1 (6%)	0
Present but broken	0	4 (24%)	0
Absent	0	12 (70%)	17 (100%)

Values are the number of patients (% of total).

We present the results of a prospective randomised controlled study to compare refractive results and complications of a 10/0 monofilament absorbable polyglactin suture with 10/0 nylon in patients undergoing phacoemulsification with a sutured temporal 5.2 mm corneal section.

Patients and methods

Forty-nine consecutive patients undergoing routine phacoemulsification were recruited to participate in the study. Patients listed for conventional extracapsular surgery and those with any coexisting ocular abnormality were excluded. Informed consent was obtained from each patient recruited. The surgery was performed by the senior surgeon or by a junior under his supervision. All patients underwent phacoemulsification via a 3.2 mm temporal corneal stab incision with side port. Capsulorhexis and hydrodissection were followed by phacoemulsification of the nucleus by the divide-and-conquer technique and aspiration of the cortex. The incision was extended with a diamond blade to 5.2 mm, using calipers to measure wound width, for implantation of a one-piece polymethylmethacrylate (PMMA) IOL (Iolab MC550) into the capsular bag. Patients were randomised to receive either a 10/0 monofilament absorbable polyglactin suture ('Vicryl' polyglactin 910 W1702, Ethicon) or a 10/0 nylon suture (monofilament nylon 198001, Alcon), the surgeon knowing the type of suture only at the time of wound closure. A single X stitch was tied using a three-and-one knot configuration, the knots being tied in a buried position. At the end of the procedure a subconjunctival injection of betamethasone and gentamicin was given and the eye covered with a plastic eye shield. Dexamethasone/neomycin/polymixin B (Maxitrol; Alcon) eye drops were prescribed, initially four times daily. These were gradually reduced in frequency and discontinued by 6 weeks post-operatively.

Patients were reviewed at 1 week, 6 weeks and 12 weeks post-operatively. At each visit patients were asked whether they had experienced any foreign body sensation in the operated eye. Slit lamp biomicroscopy was performed and the integrity of the suture, the presence of corneal haze at the suture site, and the presence of wound leakage were recorded. Keratometry was performed pre-operatively and at each post-operative visit. Surgically induced astigmatism was calculated by vector analysis.[8] All nylon sutures were removed after 6 weeks. Statistical analysis was performed using a chi-squared test.

Results

Eleven of the 49 patients recruited failed to complete the study due to non-attendance at their scheduled times. Of the 38 patients who completed the study, 18 patients were recruited to the polyglactin suture group and 20 patients to the nylon suture group. One (6%) of the 18 patients in the polyglactin suture group presented 7 days post-operatively with iris prolapse associated with knot failure; the knot had slipped and the suture, although unabsorbed, was loose. With this exception all polyglactin sutures were intact at 1 week (Table 1). By 6 weeks post-operatively the polyglactin sutures had been completely absorbed in 12 (70%) patients; in 4 (24%) patients the suture was present but broken and in 1 (6%) patient the suture was still intact. At 12 weeks post-operatively all polyglactin sutures had been fully absorbed. Mild localised corneal haze was associated with absorption of the polyglactin suture in 3 (18%) cases (1 case at 1 week, and 2 cases at 6 weeks) but was not seen in association with the nylon sutures. This difference approached statistical significance ($p = 0.055$). There were no wound leaks. All the nylon sutures were intact until they were removed at the sixth week and none was associated with corneal haze or wound leak. Foreign body symptoms were reported by 2 (11%) of the polyglactin group compared with 1 (5%) of the nylon group. The difference was not significant.

Table 2. *Surgically induced corneal astigmatism*

	Post-operative time		
	1 week	6 weeks	12 weeks
Nylon suture			
Total vector	0.42 ± 0.70	0.28 ± 0.32	0.10 ± 0.13
WTR Component	0.03 (7%) ± 0.11	0.08 (29%) ± 0.12	0.05 (50%) ± 0.07
ATR Component	0.39 (93%) ± 0.70	0.20 (71%) ± 0.35	0.05 (50%) ± 0.13
Polyglactin suture			
Total vector	0.21 ± 0.25	0.24 ± 0.31	0.19 ± 0.15
WTR Component	0.11 (52%) ± 0.14	0.12 (50%) ± 0.12	0.14 (74%) ± 0.14
ATR Component	0.10 (48%) ± 0.26	0.12 (50%) ± 0.38	0.05 (26%) ± 0.11

Values are the mean dioptres ± standard deviation. Figures in parentheses are the percentage value of the total vector.
WTR, with-the-rule; ATR, against-the-rule.

Table 2 shows the post-operative surgically induced astigmatism calculated by vector analysis, including the percentage with-the-rule and against-the-rule components. There was a trend towards less astigmatism in the polyglactin group compared with the nylon group at 1 week but the difference in surgically induced astigmatism between the two groups was not statistically significant at any point during the study. In the nylon group there was a progressive reduction in the total vector and in the against-the-rule component over time. This reduction was particularly marked after removal of the sutures between the sixth and twelfth weeks post-operatively. In the polyglactin group where was relatively little change in the total vector but a relative increase in the with-the-rule component was apparent at 12 weeks.

Discussion

Nylon sutures are removed in some patients to correct induced post-operative astigmatism. In the remainder of patients, however, opinion remains divided as to whether sutures should be left *in situ* or removed routinely. Nylon sutures undergo extensive enzymatic biodegradation *in situ*[9–11] by the second week after surgery. Monofilament nylon is formed of long molecular chains joined by amide linkages between carboxyl and amide monomers. The amide linkages are subject to *in vivo* hydrolysis,[9] mediated by lysosomal enzymes, leading to biodegradation and loss of tensile strength. After 3 years 90% of nylon sutures left *in situ* have undergone degradation and 50% of patients have symptoms related to broken sutures.[4] Complications associated with nylon corneal sutures left *in situ* are mainly caused by protruding broken suture ends and include conjunctival inflammation, corneal vascularisation and pannus, giant papillary conjunctivitis, bacterial keratitis and acute bacterial endophthalmitis.[3–6,12] Up to 14.4% of visits to eye casualty departments are due to suture-related problems.[3] Hydrolysis of nylon sutures is also associated with a late astigmatism shift that continues for at least 2 years post-operatively.[13] Routine removal of sutures, advocated at between 3 and 12 months post-operatively,[3–5] reduces suture-associated complications and related casualty attendances but is demanding of resources in clinic and delays spectacle prescription.

Polypropylene (Prolene) is non-hydrolysable but its elasticity has been associated with poor wound security in the early post-operative period[14] as well as prolonged post-operative astigmatic drift.[14,15] Polyester suture (Mersilene) material undergoes no clinically detectable, and minimal microscopic, biodegradation when left *in situ* following cataract surgery, but in one study 12.6% of patients still required suture removal for suture-related problems.[16]

Monofilament absorbable polyglactin 910 (Vicryl) is promoted as a suture that offers secure wound closure during the critical post-operative healing period but absorbs with minimal tissue reaction and no induced astigmatism. Suture absorption is said to occur by hydrolysis to glycolic acid and lactic acid.

In this study the iris prolapse in one patient of the polyglactin group resulted from failure of the knot, probably in association with abnormal wound stresses induced by eye rubbing, the suture material itself being apparently intact. The manufacturer's recommended knot technique is a double throw followed by two reverse single throws. In a pilot study we found that a triple throw was necessary initially in order to maintain adequate suture tension before the two reverse single throws are tied. Following our report of knot failure using this technique the manufacturer has suggested that doubling the second reverse throw ensures knot security (personal communication), but further studies are required to confirm this.

In this study 30% of the polyglactin sutures were incompletely absorbed at 6 weeks post-operatively and in 80% of these cases the sutures were present but broken. This suggests that absorption does not occur uniformly along the length of the suture. It was noted in these cases that the exposed parts of the suture were broken while the intrastromal parts remained intact. Foreign body symptoms reported by 2 (11%) patients in the polyglactin group are consistent with the observation of exposed broken ends of partially absorbed sutures, but foreign body symptoms were also reported in the nylon group. Although we noted no suture-related complications in this study, it is possible that exposed polyglactin suture ends predispose to complications similar to those associated with broken nylon sutures. As its duration, however, is likely to be of shorter with polyglactin than with nylon, such exposure may be of less consequence. Excluding the one case of knot failure, the polyglactin suture provided adequate wound security with no wound leak in all patients for the 5.2 mm section studied.

Absorption of the polyglactin suture was associated with mild corneal haze at the suture site in 3 (18%) cases whereas no reaction was observed around the nylon sutures. Absorption of polyglactin is reported to occur by hydrolysis alone, yielding glycolic acid and lactic acid. In view of the local tissue reaction noted in this study, however, there may be other, possibly inflammatory, mechanisms involved. We are currently performing histological studies to investigate this observation further.

In conclusion, this study suggests that following phacoemulsification and IOL insertion via a 5.2 mm corneal stab incision 10/0 monofilament absorbable polyglactin 910 sutures offer adequate wound security in the early post-operative period, do not require routine suture removal and are not associated with significant induced astigmatism. Although partial absorption can result in protruding broken suture ends and in some cases is associated with mild local tissue reaction, 10/0 monofilament polyglactin is an attractive option when a suture is required during small incision cataract surgery.

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