Long-term Results of Primary Trabeculectomies and Molteno Implants for Primary Open-Angle Glaucoma

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Objective: To describe the long-term outcomes of primary trabeculectomies and primary Molteno implants performed in cases of primary open-angle glaucoma at Dunedin Hospital.

Methods: Prospective comparative case series of 718 eyes (500 patients) and 260 eyes (195 patients) that had trabeculectomy and Molteno implants, respectively, at Dunedin Hospital as the first drainage operation for primary open-angle glaucoma between 1976 and 2007, and followed up for a mean of 7.7 (range, 0.0-28.0) and 5.0 (range, 0.0-27.4) years, respectively.

Results: The probability of intraocular pressure (IOP) control at 21 mm Hg or less following trabeculectomy at 1, 2, 5, 10, 15, and 20 years was 0.95 (95% confidence interval [CI], 0.94-0.97), 0.93 (95% CI, 0.91-0.96), 0.89 (95% CI, 0.86-0.92), 0.82 (95% CI, 0.78-0.86), 0.74 (95% CI, 0.68-0.80), and 0.68 (95% CI, 0.59-0.77), respectively. There were 96 (13%) failures (using the >21–mm Hg definition of failure) in the trabeculectomy group by the final follow-up. The probability of IOP control at 21 mm Hg or less following Molteno implant insertion at 1, 2, 5, 10, 15, and 20 years was 0.98 (95% CI, 0.97-1.0), 0.97 (95% CI, 0.96-1.0), 0.96 (95% CI, 0.92-0.99), 0.96 (95% CI, 0.92-0.99), 0.91 (95% CI, 0.81-1.00), and 0.91 (95% CI, 0.81-1.00), respectively. In the Molteno implant group, there were 8 (3%) failures (using the >21–mm Hg definition of failure) by the final follow-up.

Conclusion: Insertion of a Molteno implant provided superior IOP control to trabeculectomy when carried out as a first operation in cases of primary glaucoma.

Criteria for selecting trabeculectomy included field loss that did not extend to or split fixation, a successful trabeculectomy in the fellow eye, and reasonable general health and compliance. Criteria for choosing drainage by an implant included field loss threatening fixation, pseudophakia, complications from trabeculectomy in a fellow eye, and frail general health and/or poor compliance owing to the patient's mental state. These criteria were weighed on an individual case basis, and the relative risk of trabeculectomy and implants, with or without cataract extraction, was discussed with patients and/or family prior to operation.

DATA COLLECTION

Full clinical information was prospectively collected and entered into both the patients’ clinical records and study ledgers from 1976 to 1993 and, subsequently, a computerized database. Data from 1976 until 1993 was later entered into the computerized database. The data collected included preoperative clinical findings, surgical procedure, postoperative behavior, and all subsequent outpatient visits. Ethics approval for this study was granted by the Lower South Regional Ethics Committee. The study adhered to the tenets of the Declaration of Helsinki.

DATA RECORDED PREOPERATIVELY

The results of the preoperative medical history and clinical examination were recorded in a standardized format including visual acuity, IOP, medications, findings of slitlamp examination and ophthalmoscopy, and determination of visual fields. Visual acuity was measured on a standard illuminated Snellen-type logarithm of the minimum angle of resolution chart incorporating 12 lines from 20/15 to 20/200. The IOP was measured using a slitlamp-mounted Haag-Streit Goldmann applanation tonometer (Haag-Streit AG, Konizz, Switzerland). Until 1988, all visual fields were manually plotted on a Goldmann perimeter. From 1988 to 1992, an automated Humphrey static perimeter (Humphrey Instruments, Dublin, California) was used for new cases. Previous old cases were transferred to Humphrey perimeter by plotting Goldmann and Humphrey fields within a short time of each other. This process was repeated after 1992 when the Medmont automated static perimeter (Medmont Pty Ltd, Victoria, Australia) replaced the Humphrey perimeter in the department. All current topical and systemic ocular medications, including hypotensive and anti-inflammatory agents, were recorded. Details of the patient’s clinical diagnosis, major general medical conditions, surgical technique, and any intraoperative complications were recorded.

POSTOPERATIVE FOLLOW-UP

Slitlamp, tonometry, and funduscopy examinations were undertaken at each postoperative visit. All cases were reviewed on the first postoperative day. In the absence of complications, follow-up visits were scheduled 1, 3, 7, and 9 weeks after surgery. Thereafter visits were scheduled every 3 months for the first year, then every 6 months for the next 2 years, and at least annually thereafter. Patients who failed to present for follow-up were traced through their general medical practitioner, the electoral roll, and cemetery records to determine their current location or status.

SURGICAL TECHNIQUE

Most cases were operated on using local anesthesia with regional block, while general anesthesia was reserved for cases considered unsuitable for local anesthesia. All operations were concluded by subconjunctival injection of cephalosporin, gentamycin, and methyl prednisolone acetate. All operations were performed by specialist ophthalmologists or by supervised residents in training.

The surgical technique for trabeculectomy closely followed that described by Cairns in 1966. A posterior incision through the conjunctiva and Tenon tissue was made, and a rectangular half-thickness, limbal-based scleral flap 3 to 4 mm along each side was raised. A small block of tissue was excised from the chamber angle using either the Cairns technique or the Watson modification according to the needs of the individual case, and a peripheral iridectomy was performed. The scleral flap was replaced and sutured, after which the flap of Tenon tissue and conjunctiva was replaced and each layer successively closed using 8-0 silk or 10-0 nylon. Mitomycin C and 5-fluorouracil were used in selected cases of trabeculectomy during the operation (15 [2%]) or after (12 [2%]), to modulate wound healing. These cases had no separate analyses owing to small numbers.

The surgical technique for Molteno implant insertion has been described previously. Before 2004, single plate implants (Molteno Ophthalmic Limited, Dunedin, New Zealand) were used in less severe cases and in older and more frail patients expected to produce less fibrosed blebs; double plate implants were used in cases of more severe glaucoma, defined as cases that required 2 or more hypotensive medications or having an untreated IOP greater than 30 mm Hg or treated IOP greater than 25 mm Hg. Molteno3 implants were used in most cases from 2004 onwards, the 175 mm² (small) implant being used in 255 (98%) cases and the 230 mm² (large) implant being used in 5 (2%) cases in which a stronger fibrotic reaction was expected.

POSTOPERATIVE MANAGEMENT

Routine postoperative management consisted of topical steroids and cycloplegic agents that were administered 2 to 4 times daily for several weeks until the eyes were white and quiet. Patients who showed signs of excessive bleb inflammation or fibrosis during the first 4 weeks after surgery were treated with the oral anti-inflammatory fibrosis suppression regimen of 5 mg of prednisone, a nonsteroidal anti-inflammatory agent such as 30 mg of diclofenac, and 0.3 mg of colchicine, all administered 3 times a daily for 5 to 6 weeks to suppress bleb inflammation and fibrosis and allow aqueous to spread widely beneath the conjunctiva. This regimen was used in 119 of cases of trabeculectomy (17%) and 6 of Molteno implant (2%), but these cases had no separate analysis, the trabeculectomy experience having been reported and the Molteno implant cases being too few to analyze.

DEFINITION OF END POINTS

Intraocular Pressure

The preoperative IOP for each eye was taken as the mean IOP in the month prior to surgery. After surgery, the IOP was taken as the mean of all IOP readings of all cases for each postoperative year. Early postoperative hypotony was defined as 1 or more record of an IOP of 5 mm Hg or less within the first 6 weeks after surgery.

In this study, control was defined as an IOP of 14, 17, or 21 mm Hg or less with or without hypotensive medication. Failure was defined as IOP greater than 14, 17, or 21 mm Hg, phthisis, repeated surgery, or total loss of vision due to early or late complications of trabeculectomy. The time of failure was taken as the first date at which any of these events was recorded.
Visual Fields

Progressive visual field loss was defined as any definite reduction in field area or extension of a paracentral scotoma toward fixation due to glaucoma. The degree of loss was determined by comparing scores from visual fields plotted near the time of operation with those plotted at or shortly before the last postoperative visit. Moderate field loss was defined as either a reduction of the total area of field remaining by 1 step of 20% or progression of the central scotoma toward fixation by 1 step of 5°. Marked field loss was defined as a total of 2 or more steps of deterioration made up of any combination of reduction in area and progression of scotoma.

Visual Acuity

Preoperative visual acuity for each patient was taken as the best-corrected visual acuity recorded in the month prior to surgery. Postoperative visual acuity was taken as the best visual acuity for each postoperative year. Blindness was defined as irreversible reduction of the central visual acuity to 20/400 or less or reduction of central visual field to 5° radius or less. This level of vision in the better eye is the level that defines legal blindness in New Zealand. The date of blindness was taken as the time when these parameters were first recorded.

ANALYSIS METHODS

Survival methods were used to analyze both the probability of retaining vision and the probability of trabeculectomy or implant failure. Patients who had not experienced an adverse event were censored at the last follow-up visit. Survival curves were calculated using all 718 trabeculectomy eyes and 260 implant eyes and therefore estimate the survival probabilities of a randomly selected eye from a patient population in which half received bilateral trabeculectomy or bilateral implant. We note that survival curves based only on the first eye treated did not differ from those shown by more than 4% at any time point. Confidence intervals were based on data for the first eye treated in each patient, to eliminate the effects of any correlation introduced by patients who underwent bilateral trabeculectomy or bilateral implant.

Trabeculectomies were performed on 718 eyes of 500 patients, of whom 394 (55%; 273 patients) have died. Molteno implant insertion was performed on 260 eyes of 195 patients, of whom 153 (59%; 111 patients) have died. Demographic details and details of preoperative status are described in Table 1. Details of operative technique are given in Table 2.

INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS

There were no intraoperative complications in either group apart from 1 case of trabeculectomy that had a perioperative myocardial infarction with good short-term recovery. Early postoperative complications and the numbers of cataract extractions at any time postoperatively are described in Table 3, with the only significant difference being that of more subtotal hyphema in the trabeculectomy group (P = .006).

THREATENED PRIMARY BLEB FAILURE

Systemic anti-inflammatory fibrosis suppression was used in 119 cases of trabeculectomy (17%) and 6 of implant (2%) for mean durations of 5.7 (range, 1-21) and 5.2 (range, 4-6) weeks, respectively.

Mitomycin C and 5-fluorouracil were used intraoperatively with trabeculectomies in 13 and 2 cases, respectively. Twelve cases had 5-fluorouracil injected subconjunctivally after surgery, 8 within 4 weeks after surgery, and the rest between 2 months and 1.1 years. No cases of implant insertion had antimetabolite administered intraoperatively or postoperatively.

LATER SURGICAL INTERVENTION

In the trabeculectomy group, 1 or more postoperative intraocular procedures were undertaken in 219 eyes (31%),
with cataract extraction being the most common in 169 cases (24%). A repeated drainage procedure was required in 62 cases (9%) (54 had Molteno implant insertion and 2 had repeat trabeculectomies).

In the Molteno implant group, 1 or more postoperative intraocular procedures were undertaken in 66 eyes (25%), with cataract extraction being the most common in 56 (22%). In 1 case, 1 plate of the double-plate implant was removed and 1 other case had the implant tube repositioned. A repeated drainage procedure was required in 6 cases. In 3 cases, the implant was removed and converted to a trabeculectomy, all of which had good IOP control at final follow-up 2.2, 7.8, and 8.1 years later. In the remaining case, an implant was piggybacked to the original implant and good IOP control was achieved at the final follow-up 2.5 years later.

**INTRAOCULAR PRESSURE**

Preoperative and postoperative IOP and medication use in cases of trabeculectomy are described in Table 4. The probability of IOP control at 14, 17, and 21 mm Hg or less following trabeculectomy at 1, 2, 5, 10, 15, and 20 years is shown in Table 5 (Figure 1, Figure 2, and Figure 3). The mean number of hypotensive medications used declined from 1.12 at 1 year after surgery to 0.96 at 10 years and 0.80 at 20 years (Table 4).

Using the definition of failure as an IOP of greater than 21 mm Hg, phthisis, reoperation, or total loss of vision due to early or late complications of trabeculectomy, there were 96 failures (13%) in the trabeculectomy group; 70 (16%)...
and 26 (16%) were in the open-angle glaucoma and pseudoexfoliative glaucoma subgroups, respectively. Of the failures, 56 had a Molteno implant inserted, 8 had a further trabeculectomy, 2 were enucleated, 6 became phthisical, and 26 had high IOP but did not receive repeated surgery. The 56 implants then had 5.4 years of follow-up (range, 0.0-17.1); 48 (89%) controlled their IOP at 21 mm Hg or less at the final follow-up and 6 failed (of which 1 became phthisical and 1 was enucleated). Of the 8 that had subsequent trabeculectomies, 2 required further trabeculectomies at 2.1 and 11.0 years and 1 required insertion of a Molteno implant at 5 weeks following the second trabeculectomy. The remaining 5 repeated trabeculectomies controlled the IOP at 21 mm Hg or less following trabeculectomy and Molteno implant insertion.

Preoperative and postoperative IOP and medication use in cases of Molteno implant are described in Table 6. The probability of IOP control of 14, 17, and 21 mm Hg or less following Molteno implant insertion at 1, 2, 5, 10, 15, and 20 years is shown in Table 5 (Figures 1, 2, and 3). The mean number of hypotensive medications used declined from 1.13 at 1 year after surgery to 0.85 at 10 years and 0.81 at 15 years (Table 6).

Using the definition of failure of an IOP of greater than 21 mm Hg, phthisis, reoperation, or total loss of vision due to early or late complications of Molteno implant insertion, in the Molteno implant group, there were 8 failures (3%); 6 (2%) and 2 (1%) were in the open-angle glaucoma and pseudoexfoliative glaucoma subgroups, respectively. Three implants were removed and converted to trabeculectomy; 2 implants were removed and replaced with another Molteno implant; one 175-mm² Molteno3 implant had another 175 mm² Molteno3 implant piggybacked onto it, 1 eye became phthisical, and the final case had a high IOP but did not receive repeated surgery.
VISUAL ACUITY

In the trabeculectomy group, 43 eyes (6%) were blind preoperatively, of which 36 had a visual acuity of 20/1200 or less and 7 had advanced field loss. The mean preoperative visual acuity was 20/40; this improved to 20/32 at the first postoperative year before declining to 20/42 at 10 years and 20/60 at 20 years (Table 4). The probability of not being blind following trabeculectomy at 1, 2, 5, 10, 15, and 20 years was 0.96 (95% confidence interval [CI], 0.95-0.98), 0.94 (95% CI, 0.92-0.96), 0.86 (95% CI, 0.83-0.89), 0.76 (95% CI, 0.71-0.81), 0.67 (95% CI, 0.61-0.74), and 0.62 (95% CI, 0.53-0.70), respectively.

In the Molteno implant group, 96 eyes (37%) were blind preoperatively, of which 23 had a visual acuity of 20/1200 or less and 73 had advanced field loss. The mean preoperative visual acuity was 20/50; this improved to 20/42 at the first postoperative year before declining to 20/90 at 10 years and 20/125 at 15 years (Table 6). The probability of not being blind following implant at 1, 2, 5, 10, and 15 years was 0.95 (95% CI, 0.91-0.98), 0.89 (95% CI, 0.83-0.95), 0.77 (95% CI, 0.68-0.86), 0.62 (95% CI, 0.50-0.74), and 0.60 (95% CI, 0.46-0.74), respectively.

VISUAL FIELDS

Visual fields from both the preoperative and final assessments were available for only 561 (78%) and 183 (70%) cases of trabeculectomy and Molteno implant respectively, primarily owing to poor preoperative or postoperative visual acuity, advanced age, and reduced cognitive ability. Visual field loss is described in Table 7 and Table 8.

COMMENT

In this long-term study, cases chosen for Molteno implants were, on average, 6 years older at the time of surgery; a higher proportion had pseudoexfoliation and previous or coexisting cataract requiring operation or were legally blind preoperatively. The surgical complication rates were similar in both groups, with more hyphema in the trabeculectomy group. The rate of field loss during follow-up was similar in the 2 groups. The IOP control and hypotensive medication use was similar in both groups throughout follow-up; however, the salient difference between the 2 groups was that the probability of IOP control after 10 years was 0.82 and 0.96 in cases of trabeculectomy and Molteno implant, respectively.

It is useful to compare these results with the Tube vs Trabeculectomy Study\textsuperscript{25} (TVT), as our population and selection criteria were similar; however, there are some differences. More TVT patients had had previous cataract extraction (80% vs 2% of the trabeculectomy groups and 79% vs 11% in the implant groups), 18% of our patients who received trabeculectomies and 24% who received implants had cataract extraction at the time of the glaucoma surgery, and a higher percentage of our patients had pseudoexfoliative glaucoma (23% vs 1% in the trabeculectomy groups and 38% vs 7% in the implant groups). The
operative technique also differed in that, in our study, mitomycin C or 5-fluorouracil was used in only 2% of trabeculectomies and none of the implants, and threatened bleb fibrosis was treated with oral anti-inflammatory fibrosis suppression; whereas in the TVT, all trabeculectomies included application of mitomycin C. Overall, our results with respect to IOP control were similar to the first 3 years of follow-up in the TVT in that the implant groups had higher success rates compared with trabeculectomy. However, our study had larger numbers and significantly longer follow-up, and Molteno implants were used in our study while Baerveldt implants were used in the TVT.

In summary, induction of a Molteno implant provided superior long-term IOP control to trabeculectomy when carried out as a first operation in cases of primary glaucoma.

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