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TITLE PAGE

Title: The Success Rate of Glaucoma Drainage Device Revision

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Precis: We report the survival of surgical revision to glaucoma drainage devices for several indications in a large cohort of patients, with an overall success rate of 45% at 36 months.

Abstract

Purpose: To evaluate the outcomes of surgical revision for complications of glaucoma drainage devices.

Methods: 335 eyes of 318 patients who underwent tube revision or removal at UCLA Jules Stein Eye Institute between 1997 and 2019 were included. The pre-defined primary outcome measure was surgical success of the initial revision, defined as resolution of the condition with no additional revisions required, no functionally significant change in vision, and no instances of IOP > 21 mmHg at two consecutive visits postoperatively. Kaplan-Meier survival analysis was applied to evaluate survival at 36 months based on these criteria. The Wilcoxon paired test was used to compare mean pre- and post-operative intraocular pressure, medication usage, and visual acuity.

Results: Overall, survival of revised tubes at 36 months was 45%. The four most common indications for revision were exposure of the implant (42% of all revisions), occlusion (14%), corneal failure or threat of failure (12%), and hypotony (11%). Survival at 36 months for each of these indications was 44%, 45%, 52%, and 37%, respectively.

Conclusions: These results suggest that eyes with glaucomatous damage with long-term GDD complications can still have a reasonably successful outcome when a revision is performed. However, with substantial rates of vision loss and a frequent need for additional revisions to manage complications, managing patient expectations for success and making them aware of the likelihood of additional surgeries or failure is important.

Key words: glaucoma surgery, glaucoma drainage device, surgical revision

Introduction

Glaucoma drainage devices (GDDs) are a mainstay of glaucoma surgical management as an effective option for lowering intraocular pressure.[1] Although initially used in cases of complex or refractory glaucoma where trabeculectomy was not a viable option or in eyes where trabeculectomy had failed, GDDs are increasingly being used as a primary surgical intervention.[2,3] However, GDDs, not unlike trabeculectomy, are subject to considerable rates of post-operative complications; randomized clinical trials have found complication rates of 34% to 69% at 5 years post-implantation.[4-8] The same trials have estimated reoperation rates (including but not limited to revision or removal of the implanted material) of 8.6% to 20.8%.

Although numerous studies have reported on the complications after GDD implantation and the cumulative rates of additional surgery, there is limited data of the outcomes of surgical revisions of GDDs. We present a retrospective case review of tube revisions (including removal) performed by a group of academic glaucoma specialists at a single institution. We examine the success rates of GDD surgical revision over a 22-year period at the UCLA Stein Eye Institute.

Methods

This is a retrospective interventional case series of glaucoma patients who underwent GDD revision from 1997 to 2019 at the Glaucoma Division of the Jules Stein Eye Institute, University of California Los Angeles (UCLA). The study was approved by the Institutional Review Board of UCLA and all study procedures adhered to the recommendations of the Declaration of Helsinki and the Health Insurance Portability and Accountability Act.

Data were obtained from a chart review of 344 eyes of patients who had medically uncontrolled glaucoma and had previously undergone tube shunt implantation at our institution or elsewhere that subsequently required a revision or removal of the device. Patients were identified based on the medical records of the UCLA Jules Stein Eye Institute between 1997 and 2019. All patients' cases coded as revision of aqueous shunt to an extraocular equatorial plate reservoir without graft (CPT 66184) or with graft (CPT 66185), revisions or repair of operative wound of anterior segment (CPT 66250) that included tube revision, and removal procedures from cases coded as removal of tube without graft (CPT 67120) were collected. Revisions for any of the following indications were included in the subsequent analysis: exposure of the tube or plate, obstruction of the tube, hypotony, corneal failure or threat of failure as a result of tube position in the anterior chamber, malpositioned tubes without threat to the cornea, thick encapsulation of the plate, aqueous misdirection, strabismus or other motility disruptions, infection, and pain/dysesthesia. Elevated intraocular pressure (IOP) without a visible tube occlusion was not sufficient for inclusion in the study. These cases were treated with additional medication or glaucoma surgery.

The following demographic data were collected from the medical records of the identified patients: age, gender, ethnicity, history of diabetes or hypertension, glaucoma diagnosis, concurrent ocular conditions, and prior ocular surgery. Data collected from clinical and operative notes included implant type, implant quadrant, date of implantation, location of implantation (UCLA or outside facility), surgeon, graft material, dates and indication(s) for all revisions, and method of surgical revision. Intraocular pressure (IOP), best corrected visual acuity (BCVA), and glaucoma medications were collected from all visits pre- and post- revision surgery.

Visual acuity is reported as the logarithm of the minimal angle of resolution (logMAR). Counting fingers was recorded as 20/2000 (logMAR value 2), and hand movements as 20/20,000 (logMAR value 3). Light perception vision was documented as logMAR vision 4. Visual impairment was classified into four categories: mild (BCVA ≥ 20/60, logMAR value 0.48), moderate (BCVA <20/60 and ≥ 20/200, or logMAR values 0.48 to 1), severe (BCVA <20/200 and ≥ LP, logMAR values 1-4), and total (BCVA NLP, logMAR value 5). Any movement between these categories was considered a functionally significant change in vision.[9] Pre-operative intraocular pressure and visual acuity are reported as the mean of the last two recorded measurements prior to surgery. Post-operative intraocular pressure and visual acuity are reported as the mean of the last two post-operative measurements at the time of data collection.

The primary outcome measure was success of the initial revision; failure was defined as follows:

1. Any additional revisions or tube removals required, OR

2. A functionally significant change in vision, measured at two consecutive visits at least six weeks after the initial revision, and maintained at the last visit, OR

3. IOP measured at > 21 mmHg at two consecutive visits at least six weeks after the initial revision.

Kaplan-Meier survival analysis was applied to evaluate long-term surgical outcomes according to these criteria. The time to failure was defined as the time from initial surgical revision to any of the aforementioned outcomes. For eyes meeting multiple failure criteria, the date of the first event was considered the failure date. Paired t-tests were used to compare mean

pre- and post-operative intraocular pressure, mean pre- and post-operative medication numbers, and mean pre- and post-operative visual acuity. Comparison of survival curves was done with the log-rank test. All statistical analyses were performed with the open-source programming language R, version 3.4.3 (R Project for Statistical Computing).[10] Probability values of <0.05 were considered statistically significant.

Surgical Technique

We will briefly describe here the surgical methods of revision for all analyzed sub-groups. Limited detail is provided as the specifics of each varied according to the complexity of the case, concurrent ocular surgery or pathology, and surgeon preference.

Figure 1 illustrates the surgical method for revision of exposed tubes. Briefly, a T-shaped incision is made along the exposed tube and directed posteriorly to the edge of the plate, and the incision extended along the limbus on both sides of this radial incision. The conjunctiva is dissected under the two triangular flaps formed by the T, and back over the capsule over the plate; care is taken not to perforate the capsule or disturb the plate. The exposed tube is cleaned of any epithelial tissue, and is covered with a split-thickness, half-moon corneal patch graft, secured to the sclera with two 9-0 polyglactin sutures. Several interrupted 9-0 polyglactin sutures are used to close the radial incision toward the limbus and one 10-0 nylon mattress suture is used to anchor the anterior most edge of the conjunctiva to the limbus. In cases where an area of the plate was exposed, a corneal graft was not used to cover the edge of the plate. Healthy adjacent conjunctiva and Tenon's capsule were recruited to cover the exposed area.

In our case series, blocked tubes were revised according to the source of the obstruction. To irrigate occluded tubes, a paracentesis was performed and a 30 gauge cannula was inserted 2-3mm into the tip of the tube. Balanced salt solution (BSS) was used to clear any blockage until the tube was patent. In certain cases of vitreous occlusion, a YAG laser was used to lyse vitreous strands in the anterior chamber. Rarely, anterior vitrectomy was needed.

We defined corneal failure or threat of failure as the tube tip either touching the cornea or deemed to be too close to it, with or without localized corneal edema. Surgical revision for these cases involved externalizing the tube tip, shortening it using scissors, and reinserting it into the same tract; in some cases the tube was re-inserted more posteriorly into the ciliary sulcus.

In hypotonous eyes, two methods of surgical revision were performed. Tube ligation was accomplished by externalizing the tube through a clear corneal incision, placing two prolene sutures around the tube near the opening, and repositing it into the same tract. In some cases, removal from the anterior chamber was required. In these patients, the tube is externalized, tucked posteriorly and sutured to the sclera. A radial 10-0 nylon suture is used to close the track.

Results

Of the 344 eyes that were initially identified as having undergone revision of the GDD, 9 were excluded as a result of missing records. The remaining 335 eyes from 318 patients were included in the analysis. For context, a total of 3492 tubes were implanted in the eyes of 2562 patients over the same time period, 1997-2019. Of the 335 eyes included in our study population, 85 had tube implantation at an outside facility and subsequently underwent revision at the Stein Eye Institute. 84% percent of the GDDs were Ahmed valves and 14% were Baerveldt implants.

The demographic characteristics of the study population are presented in Table 1. Mean (± SD) and median (± IQR) length of time between initial implantation and first revision were 31 (±41) months and 14 (±41) months, respectively (see Figure 2 for frequency distribution). Mean and median duration of follow-up after initial revision were 40 (±42) months and 27 (±54) months (see Figure 3 for frequency distribution). The most common indications for revision were: exposure (136 tubes; 42%), occlusion (46 tubes; 14%), corneal threat (41 tubes; 12%), and hypotony (38 tubes, 11%). A list of all indications for revision is included in Table 2, and the four most common indications are analyzed in further detail here. Success rates are reported in Table 3.

Overall survival at 36 months was 45% (Figure 4). The majority of the failures (62/152, 41%) were a result of a repeat revision; failure to control IOP was also a significant contributor to failure (51/152, 34%). BCVA (reported as logMAR) significantly worsened (1.54 vs 1.84, p=0.02) after revision. IOP decreased from a mean of 17.12 pre-operatively to 13.95 post-operatively (p=0.01) with no corresponding change in the mean number of glaucoma medications (1.82 vs 1.73, p=0.40). See Table 4 for complete tabulation of pre-and post-operative characteristics.

Revisions occurring early in the postoperative period, defined as less than three months from the date of the original tube implantation, had a significantly lower probability of survival than those occurring in the later postoperative period (Figure 5, 38% vs 49%, p = 0.04). However, the majority of revisions (172/242 eyes for which date of original implant was available) occurred during the late postoperative period.

Exposure of the implanted material was the most common indication for surgical revision, accounting for 136 revisions, of which 18 (13%) were removals. Exposure of the tube (120/136, 88%) was more common than exposure of the plate (5/136, 4%). There were 4 instances of exposure of both the tube and the plate (3%) and 2 instances where only suture was exposed (1%). 77% (104/136) of the revised tubes were implanted in the superior-temporal quadrant, 15% (20/136) in the superior-nasal quadrant, 5% (7/136) in the inferior-temporal quadrant, and 4% (5/136) in the inferior-nasal quadrant. The primary method of surgical revision was re-covering the exposed tube (112/118); 61% (72/118) of the grafts were made of donor pericardium and 35% (41/118) were made of donor cornea. We report a 44% chance of survival at 36 months (Figure 6). The need for additional revisions was the most common reason for failure. Pre- and post-operative IOP (13.97 vs 13.39, respectively) did not significantly differ ($p=0.71$), nor did BCVA (1.40 to 1.52, $p=0.09$) or the number of glaucoma medications (1.43 to 1.49, $p = 0.86$).

Occlusion of the tube occurred in 46 cases; the method of surgical revision varied according to the source of the blockage. 35 instances of tube occlusion (75%) were revised by simple tube irrigation, and 11 (25%) were revised by the removal of vitreous either via YAG laser vitreolysis or anterior vitrectomy. By Kaplan-Meier analysis, 36-month survival was 45% (Figure 6). IOP was significantly reduced post-operatively (29.63 to 14.34, $p=0.00$), with no concurrent decrease in the number of glaucoma medications (2.37 vs 1.86, $p=0.06$). BCVA did not change significantly ($p=0.36$).

Corneal threat was identified in 41 cases, and revisions for this indications overall had the highest cumulative probability of survival (52% at 36 months, Figure 6). Surgical revision

involved trimming the tube (29/41, 71%) or removing the tube and re-inserting it along a different tract with or without shortening (17/41, 41%). 5/41 (12%) of these revisions failed to prevent further corneal decompensation and these eyes ultimately required corneal transplantation. IOP, BCVA, and number of glaucoma medications did not significantly change post-operatively (p=0.51, 0.52, 0.93, respectively).

Revisions for cases of hypotony had the lowest survival of all analyzed indications, 37% at 36 months (Figure 6). The method of surgical intervention for hypotonous eyes was more varied than other groups, and included ligating the tube (20/38 revisions, 50%), removing the tube from the anterior chamber and suturing it to the sclera (10/38, 27%), or removing the tube altogether (3/38, 8%). Failures in this group were primarily a result of a repeat revision of the tube. IOP significantly increased post-operatively, rising from 3.77 pre-operatively to 13.82 post-operatively (p=0.00). There was a corresponding increase in the number of medications patients were taking (0.45 pre-operatively to 0.99 post-operatively, p=0.02). BCVA did not significantly change (p=0.24).

Discussion

Although several studies have analyzed risk factors for failure of tube shunt surgery as well as the rates of common post-operative complications, few large studies have analyzed the long-term success of revisions performed to address these complications.[4-8, 11-13] This retrospective case series evaluated the long-term outcomes of surgical revision of glaucoma tube shunts. With criteria for surgical success accounting for repeat revisions, vision loss, and

uncontrolled IOP, we report an overall survival of 45% at 36 months. Revision for corneal threat had the highest success rate at 52%, followed by revisions for occlusion, exposure, and hypotony.

Weinreb et al reported overall survival of revised tubes to be 51% at one year and 41% at 2 years.[14] They estimated that 74% of tube shunt revision surgeries had failed by the fifth postoperative year, defining failure as undergoing an additional glaucoma surgery (not necessarily a revision of an existing tube) or a failure to meet the physician-determined target IOP. To our knowledge, their study is the only one which, like ours, examines the outcomes of revisions for several different indications. The majority of reports have been small case series of patients and surgical management of a single complication, and thus direct comparisons between studies is difficult; it is further confounded by wide variation in criteria for what constitutes failure.

Tube erosion is a well-established complication of GDD implant surgery and is considered a major risk factor for developing endophthalmitis.[13,15,16] Weinreb et al and Kirmaci Kabacki et al both cite exposure as the single most common indication for revision at their institutions (41% and 57.7% of all revisions, respectively), a finding that is consistent with our results.[14,17] In studies of tubes revised for exposure, Weinreb et al, Huddleston et al, and Thompson et al report that 50%, 36%, and 40%, respectively, avoided additional revisions; this is comparable to our reported 44% survival at three years.[14,16,18] Notably, our definition of survival also includes criteria pertaining to vision loss and IOP control – not purely examining rates of re-operation. In our study population, 71% of eyes with a primary tube exposure avoided subsequent re-operation. We found no statistically significant difference in survival for superior

vs. inferior tubes, although the small number of inferiorly placed tubes (12 in total) limits the power of this finding.

A number of studies have cited hypotony as a frequent indication for tube revision, and one with a relatively poor survival prognosis when compared to other post-operative complications.[4,14,19] Weinreb et al report that revisions for hypotony are three times more likely to fail than revisions for exposure and seven times more likely to fail than revisions for malpositioned tubes[14]. Our findings also showed that revisions for hypotony were less likely to succeed than those for exposure, occlusion, corneal threat, or otherwise malpositioned tubes. Stein et al published a success rate (defined as resolution of the hypotony and avoidance of additional surgery) of 57%, higher than our reported 43% although with a smaller sample size.[19] Additionally, 20/21 eyes in their series underwent surgical ligation of the tube, whereas the method of surgical revision varied in our cohort. When examining exclusively the 20 patients who underwent surgical ligation of the GDD in our population, 10/20 (50%) patients avoided additional revisions, compared to their 13/20 (65%). This comparison highlights the need for further study of the success of different surgical techniques in addressing the same complication.

There are few studies that specifically examine the success rate of revisions for corneal threat, although it is an oft-cited risk for corneal decompensation and corneal graft failure and a known complication of glaucoma drainage devices.[20-22] Kirmaci-Kabaki et al observed a small cohort of 11 patients who presented with tube-corneal touch and underwent tube repositioning with or without tube shortening. The authors reported a 100% success rate for this group of patients, defined by no subsequent need for re-operation and no further corneal decompensation.[17] This was substantially higher than our reported 52% success rate, although the

authors acknowledge the effect the small sample size and short follow-up period may have had on their outcomes.

To our knowledge, there are no studies that specifically examine the outcomes of surgical revision of obstructed tubes, although this is another commonly recognized complication of GDDs. Other studies have listed malposition and encapsulation as frequent indications for surgical revision, and, less frequently, diplopia and motility disturbances such as strabismus.[16-17, 23-26] We did not have a sufficient number of patients in these groups to perform a detailed sub-group analysis.

By design, retrospective studies have limitations in the availability of data, which is retrieved rather than recorded as it occurs, missing data, selection bias, and patients lost to follow-up. High rates of patient drop out can affect the accuracy of calculated success rates. Retrospective studies are also subject to investigator biases, although this can be reduced by the use of carefully defined, objective criteria for outcomes and appropriate controls when indicated. Our study was limited to a single institution population of patients and surgeons, and outcomes may not be generalizable to other populations, and may introduce biases such as surgeon specific preferences for revision.

We also recognize the limitations of including a failure to remain below a pre-defined, yet ultimately arbitrary, IOP threshold of 21 mmHg in our definition of tube revision failure. IOP thresholds are imperfect and target values must be individualized to each patient, however we believe that it is important to consider IOP when examining the success rate of surgical revision to glaucoma drainage devices. It also is desirable in order to better compare our results to existing literature, much of which considered the ability of the tube to manage IOP[14,18,21,25]. We

have included a comparison of the survival of the eyes in our case series with and without an IOP criteria in our definition of failure (Figure 7).

Additionally, although we described general surgical methods for revision, these are not applicable to all cases. Surgical technique varies between surgeons and naturally evolves over time. The methods discussed in this paper should not be used to inform surgical decision making but rather to provide additional information with which to contextualize our results. Large, prospective studies, including randomized clinical trials, would be required to provide additional insights into the risk factors for and outcomes of glaucoma tube revisions, as well as to elucidate the potential causes for failure of revision attempts. Further, with increasing use of tubes as a primary surgical intervention, additional study should be done to evaluate revision outcomes in eyes with previously unaltered conjunctiva.[1,2]

A thorough analysis of the risks and benefits of undergoing a surgical revision is important to both surgeon and patient. Surgical outcomes for the various indications should be interpreted critically in the context of the post-operative complication they are attempting to manage. In some cases, with patients at risk of endophthalmitis, hypotony maculopathy, or rapid endothelial cell loss, the surgeon may have no choice but to operate.[13,14,23,24,27] In others, knowing that one surgical revision does not preclude the patient from undergoing several additional re-operations might inform the surgeon to treat more conservatively.

This retrospective case series reports a survival rate of 45% at 36 months for surgically revised GDDs. With substantial rates of vision loss and a frequent need for additional revisions to manage complications, these results suggest that eyes with glaucomatous damage with a failed initial GDD implantation can still have a successful outcome when a revision is performed, but

that managing patient expectations and making them aware of the likelihood of additional surgery is important.

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Figure Legends:

Figure 1: A) The superotemporal tube is noted to be exposed, B) A T-shaped incision is made along the exposed tube superotemporally and directed posteriorly, limbal peritomies are made on both sides of this radial incision, C) The scar tissue is dissected back with sharp dissection, D) The tube is covered with a corneal patch graft, which is then secured onto the sclera using two 9-0 polyglactin sutures, E) Several interrupted 9-0 polyglactin sutures are used to close the radial incision toward the limbus, one 10-0 nylon mattress suture is used to anchor the conjunctiva to the limbal margin.

Figure 2: Distribution of the length of time (in months) between tube implantation and the first revision or removal of that tube

Figure 3: Distribution of the total duration of follow-up (in months) after initial revision of the drainage device

Figure 4: Kaplan-Meier survival curve showing overall survival at 36 months of glaucoma tube shunt revision

Figure 5: Kaplan-Meier survival curve comparing survival at 36 months of early revisions (within 3 months of tube implantation) to late revisions

Figure 6: Kaplan-Meier survival curve showing the survival at 36 months of glaucoma tube shunt revision in the four most common causes for revision: exposure, occlusion, corneal failure or threat of failure, and hypotony.

Figure 7: Kaplan-Meier survival curve showing overall survival at 36 months with and without a failure criteria accounting for elevated intraocular pressure