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Longitudinal Rates of Postoperative Adverse Outcomes after Glaucoma Surgery Among Medicare Beneficiaries:

1994 to 2005

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Abstract

Purpose—To determine longitudinal rates of postoperative adverse outcomes after incisional glaucoma surgery in a nationally representative longitudinal sample.

Design—Retrospective, longitudinal cohort analysis.

Participants—Medicare beneficiaries 68 years who underwent a primary trabeculectomy (PT), trabeculectomy with scarring (TS), or glaucoma drainage device (GDD) implantation from 1994 to 2003 with follow-up through 2005.

Intervention—Primary trabeculectomy, TS, and GDD were identified from International Classification of Diseases (ICD-9-CM) and Current Procedural Terminology (CPT) procedure codes. Change in rates of postoperative adverse outcomes associated with these 3 surgical interventions was analyzed by cumulative incidence rates and Cox proportional hazards model regression; regression analysis controlled for prior adverse outcome measures (3-year run-up) and demographic variables.

Main Outcome Measures—First-, second-, and sixth-year cumulative rates and probability of experiencing serious adverse outcomes (retinal detachment, endophthalmitis, suprachoroidal hemorrhage), less serious adverse outcomes (choroidal detachment, corneal edema, hypotony), and receipt of additional glaucoma surgery were identified through Medicare claims for each treatment group.

Results—At the 1-year follow-up, rates of severe adverse outcomes were higher among beneficiaries in the GDD group (2.0%) relative to the PT (0.6%) and TS groups (1.3%). Controlling for prior adverse outcomes to the surgery and demographic factors in Cox proportional analysis, differences were often reduced, but generally remained statistically and clinically significant. Rates of severe outcomes, less severe outcomes, corneal edema, and low vision/blindness were higher for persons undergoing GDD than PT or TS. However, rates of reoperation were higher for TS than GDD.

Conclusions—The risk for adverse outcomes was higher in GDD than in PT surgery or TS, controlling for a number of important case mix and demographic factors.

Glaucoma surgery can effectively reduce intraocular pressure and delay disease progression.¹⁻⁴ Conventional glaucoma filtration surgery (trabeculectomy) has been the mainstay of therapy for patients with elevated intraocular pressure despite maximum tolerated medical therapy and laser trabeculoplasty. Traditional indications for implanting a glaucoma drainage device (GDD) include patients who fail conventional filtering surgery, have significant conjunctival scarring, which can make filtration surgery technically challenging to perform, or in those with uveitic, neovascular, or other forms of glaucoma with an increased propensity for filtration surgery failure.⁵⁻⁷ Recent findings from the first year of follow-up of the Tube vs. Trabeculectomy (TVT) study, a multicenter prospective randomized clinical trial of 212 patients,⁸ demonstrated comparable intraocular pressure reduction among patients undergoing trabeculectomy and GDD surgery with fewer adverse outcomes among persons receiving the GDDs. Thus, some authorities contend that performing GDD surgery may be appropriate earlier in the course of the disease.⁹

To provide additional insight into the choice of surgeries, information about the complications and problems associated with the major glaucoma surgeries would be helpful. In addition, data derived from the use of therapies in the community setting outside of randomized controlled trials is vital to understanding the actual risk and effectiveness profile of medical and surgical treatments. Updating observational analysis using more recent data,¹⁰ this study's main purpose is to ascertain whether postoperative adverse outcome rates for the major incisional glaucoma surgeries (primary trabeculectomy [PT], trabeculectomy with scarring [TS], and GDD implantation), obtained from a large nationally representative longitudinal database spanning 15 years, yields findings similar to rates previously reported in smaller observational series and clinical trials. The advantage of this and similar analyses are that the results complement those of randomized controlled trials or single site observational studies, where surgeon- and patient-specific factors, among others, may have a larger impact on results.

Methods

Data

Medicare 5% inpatient, outpatient, Part B, and durable medical equipment claims files were used to identify a nationally representative sample of Medicare beneficiaries aged 65 who underwent incisional glaucoma surgery and related adverse outcomes from 1991 to 2005. The data contained information on demographic characteristics as well as diagnosis (International Classification of Diseases, 9th Revision [ICD-9], Clinical Modification) and procedure codes (Current Procedural Terminology [CPT-4]) submitted with each claim. Durable medical equipment claims files, which contained Healthcare Common Procedure Coding System codes, were used to identify beneficiaries requiring low vision aids. Data were linked by a unique identifier, permitting construction of longitudinal, person-specific data from January 1, 1991, through December 31, 2005. The 1994 to 2003 Medicare 5% claims database contained claims data on 3.3 million beneficiaries, 15.5% of whom were diagnosed with glaucoma (ICD-9 code 365.xx) during this period.

Sample Selection

We selected beneficiaries who underwent 1 of 3 procedures: implantation of a GDD (CPT code 66180); trabeculectomy ab externo in absence of previous surgery (PT, 66170); or trabeculectomy ab externo with scarring from previous ocular surgery or trauma (TS, 66172). Receipt of these procedures established the 3 treatment groups. A given individual could appear in our analysis sample only once, and the procedure we selected for analysis was the first study procedure we found after a 3-year look-back period.

Beneficiaries with claims indicating receipt of any of these procedures together with a glaucoma diagnosis code from January 1, 1991, through December 31, 2005, were identified. We used 2003 as the termination point for entry into the surgery groups to allow for 2 years of follow-up after surgery. The GDD group consisted of all beneficiaries who received the procedure during 1994–2003. The TS group included beneficiaries who first obtained a TS during 1994–2003, and for whom no GDD was reported during 1991–2003. The selection procedure for the PT group included those who first had the surgical procedure during 1994–2003, had no prior TS claim, and for whom no GDD was reported during 1991–2003.

We did not include surgeries from 1991 to 1993 because we used claims data for 1991 to 1993 as a 3-year look-back period. To maintain a 3-year look-back period for all sample persons, those who received the marker surgery before age 68 were also excluded from the analysis sample. Treatment groups only included persons aged 68 but <96 as of December 31 of the year during which the procedure was performed and did not have a study procedure during the look-back period. Some Medicare beneficiaries joined Medicare risk plans, and claims data were not available for such persons for the times they were enrolled in such plans. We excluded all persons who were enrolled in a Medicare risk plan or resided outside the United States for >12 months during the 3-year look-back period. We also excluded all individuals who had a prior to baseline report of the outcome being analyzed.

Once in the sample, an observation was censored when the person (1) died, (2) left Medicare fee-for-service for a Medicare risk plan >6 months, (3) moved outside the United States in a calendar year, or (4) received a GDD, PT, or TS procedure. Censoring observations after another study procedure was received assured that outcomes could be attributed to a specific procedure and not to procedures received subsequently. In addition, we also censored on *any* subsequent intraocular procedure (not just a glaucoma procedure) so as to minimize the risk of misattribution to a subsequent procedure. Enrollment data only indicated whether or not the person was in the United States during the calendar year. Thus, persons who were recorded as not being in the United States for the year were censored at beginning of that year. After these exclusions, the samples were 1398, 9719, and 3374, for the GDD, PT, and TS groups, respectively.

Baseline was defined as the date on which the beneficiary underwent a study procedure. Beneficiaries in the 3 treatment groups were followed for 6 years from baseline or until censored.

Outcomes Classification

Adverse outcomes were identified in the database using ICD-9-CM and CPT codes. Adverse outcomes were grouped into (1) severe adverse outcomes, endophthalmitis, rhegmatogenous retinal detachment, tractional retinal detachment, or suprachoroidal hemorrhage; (2) less severe adverse outcomes, choroidal detachment, corneal edema, and hypotony; (3) use of subsequent glaucoma surgical procedures, wound revision, glaucoma drainage implant revision, or cyclodestructive procedures; and (4) development of blindness or low vision defined by use of low-vision aids (Table 1; available online at <http://aaojournal.org>).

Analysis

National longitudinal analysis of outcomes of ophthalmologic procedures was introduced by Javitt et al.^{10,11} More recently, computer software, which more accurately accounts for censoring, has become available. We computed the 1-, 2-, and 6-year cumulative incidence probabilities of adverse outcomes from baseline¹² (SAS 9.0; SAS Inc., Cary, NC). Cumulative incidence reflected time to an adverse outcome and the length of the follow-up

period for an individual. Sample sizes did not change by year; we used survival analysis to calculate cumulative incidence.

To assess the role of adverse outcomes before the date of the study procedure and demographic characteristics of the individual, we used a Cox proportional hazards model. Dependent indicator variables were set to 1 if there was a report of a particular adverse outcome among all persons in the sample up to 2190 days after study treatment procedure was performed. The dependent variables were onset of severe adverse outcomes, less severe adverse outcomes, subsequent operations, endophthalmitis, corneal edema, and blindness or low vision.

In the Cox proportional hazards analysis we included covariates for persons who received PT or TS, with GDD the omitted reference group. In addition, we controlled for case mix by including binary explanatory variables for related diagnoses and procedures occurring before date of receipt of the study procedure: severe adverse outcome, less severe adverse outcome, intraocular surgical procedure, age-related macular degeneration, neovascular glaucoma, uveitic glaucoma, narrow angle glaucoma, suspect glaucoma, other glaucoma, diabetic retinopathy, and same-day cataract surgery. The binary variables for prior diagnoses were coded 1 if these codes were recorded for care rendered within 1095 days before baseline. The variables for intraocular surgical procedures were defined from CPT codes listed in Table 2 (available online at <http://aaojournal.org>). Demographic characteristics were age (at the date of receipt of the study procedure), male gender, black, and other race, with white race as the omitted reference group.

Results

Beneficiaries in the PT and TS were about the same age on average as those in the GDD group (Table 3). There were higher proportions of females ($P<0.05$) and whites ($P<0.01$) in the 2 trabeculectomy groups than in the GDD group. Before treatment, beneficiaries in the GDD group were much more likely to be diagnosed with age-related macular degeneration and neovascular and uveitic glaucoma than were those in the other groups ($P<0.001$), but less likely to have been diagnosed with primary open-angle glaucoma. Persons in the PT group were more likely to have had a prior claim with a suspect glaucoma diagnosis code than were persons in the GDD group ($P<0.001$), whereas persons in the TS group were less likely to have been diagnosed with other glaucoma than were persons in the GDD group ($P<0.05$). Beneficiaries in the GDD group were more likely to have had a prior claim for a severe ($P<0.001$) and a less severe adverse outcome ($P<0.001$) during the 3 years before baseline than were those in the PT and TS groups.

Unadjusted rates of adverse consequences were consistently higher for beneficiaries who underwent GDD surgery than PT and TS groups (Fig 1; Table 4 available online at <http://aaojournal.org>). The share of beneficiaries at risk of experiencing 1 severe, potentially sight-threatening adverse outcome in the first postoperative year in the GDD group (2.0%) was > 3 times higher than the rate for the PT (0.6%), and more than twice as high as for the TS (0.8%) groups. The rate of less severe adverse outcomes was also higher among the GDD (3.3%) as compared to the PT (1.0%) and TS (1.6%) groups. First-year cumulative incidence risk of endophthalmitis in the GDD (0.4%) was 4 times higher than in the PT (0.1%) and twice that of the TS (0.2%) group. Similarly, 6-year cumulative incidences of serious and less serious adverse outcomes were much higher in the GDD group, 24.4% and 43.0% compared to 8.2% and 13.6% for the PT group, and 11.1% and 23.0% for the TS group. Rates of blindness/low vision were substantially higher for the GDD group than for PT and TS groups in all follow-up years. In the GDD group, 1.1% were identified as being

blind or having low vision at year 1. By year 6, 21.2% were identified as being blind or having low vision.

Rates of subsequent operations for glaucoma were similar for the GDD group and the PT group at 1 and 2 years but higher for the GDD group at 6 years. Additional surgery was more likely in the TS than in the GDD group at all time intervals. As defined, rates of wound revision and revision of a GDD are not comparable between the groups.

In the Cox proportional hazards analysis, without and with controlling for other factors, rates of adverse outcomes were lower in the PT and TS groups (Fig 2; Table 5 available at online <http://aaojournal.org>). With 2 dependent variables, less severe outcomes and corneal edema, controlling for other factors had little effect on the size of the hazard ratios for PT and TS. With the other dependent variables, controlling for other factors appreciably reduced the difference in adverse outcomes for PT and TS. Without controlling for other factors, except for subsequent operations, all hazard ratios on the PT and TS binary variables were statistically significant at the 5% level or better.

Controlling for other factors, the hazards ratios (HR) for severe adverse outcomes among persons in the PT group were lower than for those in the GDD group (HR, 0.49; 95% confidence interval [CI], 0.38–0.62) as were the hazard ratios for persons in the TS group (HR, 0.54; 95% CI, 0.42–0.69). The probability of experiencing less severe outcomes was also lower for the PT than the GDD groups (HR, 0.33; 95% CI, 0.27–0.39) and for the TS than the GDD groups (HR, 0.49; 95% CI, 0.41–0.59). Persons in the TS group were more likely to have subsequent operations (HR, 1.23; 95% CI, 1.01–1.50) than were those who received a GDD implant. Among the remaining outcomes, particularly noteworthy is the difference in probabilities of having corneal edema by glaucoma surgery groups (PT: HR, 0.20 and 95% CI, 0.16–0.26; TS: HR, 0.34, and 95% CI, 0.27–0.44).

Among the other clinical explanatory variables, the most consistent statistically significant findings were for cataract on the same day as the GDD, PT, and TS surgeries. The hazard ratios for having cataract surgery on the same day ranged from 0.43 (95% CI, 0.29–0.65) to 0.64 (95% CI, 0.57–0.72). Hazard ratios for the other clinical variables were statistically significant at the 0.05 level in not more than 3 of the 6 regressions.

Among the results for the demographic variables, the most notable differences in adverse outcomes were for blindness/low vision. Blacks were much more likely to experience this adverse outcome than were whites (HR, 1.73; 95% CI, 1.43–2.09).

Finally, we also performed 2 additional analyses to address concerns specific to use of claims data. First, we assessed the rate at which beneficiaries did not receive any additional eye care visits outside of the 90 days postoperative period. In all 3 groups, this was less than 4% of all participants. Most importantly, there was no difference among the groups, minimizing the risk that differences in outcome could be due to (differential) ascertainment bias. Second, in sensitivity analysis, we extended the look-back period to 6 years to reduce the risk that an adverse outcome from 1 surgery (TS or GDD) was due to a misattribution of risk to a PT (and PT in the case of GDD) surgery in the fellow eye. The results of this analysis showed that the patterns in relative rates and proportions among the 3 surgery types did not change, but the reduced sample size made some of the differences nonsignificant statistically.

Discussion

This study documented adverse outcomes after GDD implantation, PT, and TS, using data from a nationally representative, longitudinal sample of US elderly persons. As such, results

from the analysis are generalizable to the underlying population of such persons in the Medicare program in the United States. Rates of adverse outcomes after incisional surgery for glaucoma tended to be substantially more common among those who received GDD implants than those who underwent primary trabeculectomies or trabeculectomies with previous scarring. By 6 years after undergoing a GDD procedure among those who remained in the sample for this long, more than two fifths had experienced a less severe adverse outcome. Nearly 30% received a code indicating blindness and/or a low vision aid. Nearly a quarter share had experienced a severe adverse outcome. Even after controlling for the influence of other factors in multivariate analyses, substantial differences in rates of adverse outcomes between GDD, PT, and TS remained.

These results likely reflect the influence of ocular case mix not captured in the variables included in our analyses, information not reported in administrative databases in general. During the time period of analysis, patients would have PT, followed by trabeculectomy with antimetabolites (with scarring), and then potentially undergo GDD. Thus, patients undergoing TS and GDD would be expected to have higher risks for complications owing to their prior surgeries as well as underlying disease(s) status, which is consistent with our results. In addition, we cannot eliminate the risk of misattribution of adverse events in the case of GDD (and even TS) arising from an adverse event in the fellow eye with a prior TS, although we reduced this risk by the 3-year look-back in the study and in the additional sensitivity analysis using a 6-year look-back described above.

External validation of the findings in this study can be seen in the results of clinical trials and limited site observational series in the literature (Table 6 and Table 7 [available online at <http://aaojournal.org>]).^{13–32} Earlier studies of outcomes after trabeculectomy procedures reported rates of endophthalmitis ranging from 0.2% in 1240 patients followed for 1 year³³ to 1.2% in 26 551 eyes undergoing full thickness filtering surgery within a 6-year period.¹⁰ Retinal detachment rates ranged from 0.2% in 435 eyes with trabeculectomies followed up for 7 years¹ to 2.4%,¹⁰ whereas cyclodestructive procedures were between 1.9% and 2.6%.¹⁰ Ruderman et al³⁴ reported a 2% rate of suprachoroidal hemorrhage in 500 trabeculectomies. Our findings are similar to the 1-year rates reported in the other studies. However, the rates we report for a 6-year period sometimes exceed those reported by others. This difference most likely reflects a difference in study methodology. Using a measure of adverse outcomes observed over a 6-year period divided by the number of persons undergoing the study procedure at baseline resulted in much lower rates of adverse outcomes than reported in this article.

Three other studies have compared GDDs with trabeculectomies.^{8,14,18} All were based on small samples (ranging from 112 to 223 eyes), and conducted at a few sites. In 2, which were conducted in Saudi Arabia and Sri Lanka, no statistically significant differences were observed in rates of complications associated with the 2 treatments.^{14,18} In recent results from the TVT study in the United States, endophthalmitis and suprachoroidal hemorrhage were more common at 1 year among patients undergoing trabeculectomies relative to persons undergoing GDDs.⁸ Case mix variation was reduced in the TVT study by using screening criteria and in the other 2 studies by randomizing treatment among consecutive cases. The TVT study reported associations between both the occurrence and number of postoperative complications and vision loss at 1 year ($P<0.001$).⁸ Our study results thus supplement the data from the TVT study in reporting actual community use of the 3 glaucoma surgery techniques. The relative rate of endophthalmitis among GDD and TS patients after the first year are of note. Our results demonstrate much lower rates of endophthalmitis among TS patients than those with GDD. Even with adjustment for type of diagnosis and prior surgeries and with censoring of cases after *any* subsequent intra-ocular procedure (which could occur after an unrelated surgery in the fellow eye, resulting in a

conservative bias to the resulting rates), rates of endophthalmitis remained higher in the GDD group. In trying to understand this result, we note that surgeries analyzed in this study were performed in the 1990s during the early dissemination of such GDD surgeries as well as when they were reserved for patients in extremis after having had multiple other glaucoma surgeries. Such factors are likely to be incompletely accommodated in our analyses. There is also the risk that a “sterile” endophthalmitis arising from an inflammatory reaction arising from the surgery or use of specific materials in a “ripcord” (if used) would be coded presumptively as an infectious endophthalmitis. Alternatively, these results may indicate an under-appreciated concern with the use of tube surgeries that bears additional analyses.

Only 1 previous study²¹ used Medicare claims data and then only for 1 year. Procedure rather than diagnosis codes were used to identify adverse outcomes, which makes a comparison with our study findings difficult. Rates of retinal detachment, endophthalmitis, cyclodestruction, and tube revision were lower in our study than in theirs. However, our methodology of calculating cumulative incidence differed from theirs, and our 1-year follow-up period was longer, making the 2 studies even more difficult to compare. Another study reported associations between both conjunctival erosion ($P<0.01$) and age <18 years ($P<0.05$), and endophthalmitis at 1 year after GDD surgery.¹³

Ophthalmologists are increasingly opting for GDD surgery in complicated cases of glaucoma.^{5,6,35,36} As we move forward, we might expect to see a decrease in the complications rates if, as we surmise, most of the differences in rates with GDD and TS compared with PT are due to case severity differences as opposed to the use of the devices themselves.

There are a number of advantages to using a large administrative database to study rates of surgical adverse outcomes. Unlike the clinical studies that collect data from 1 or a few specific sites, the Medicare 5% claims database provides a nationally representative sample of elderly Americans with glaucoma. Second, although it is often challenging to recruit large numbers of patients for clinical trials and observational series, using administrative databases, researchers can study adverse outcome rates on large numbers of persons. The larger sample size enables easier study of rates of infrequent adverse outcomes such as endophthalmitis. Third, the longitudinal nature of these data allows for much longer and more uniform follow-up of individual cases than do most clinical or observational studies. Fourth, we can capture the care provided by all practitioners and not just that of the primary surgeon and his or her referrals, including those “lost to follow-up” in clinical observational series. Finally, although many of the smaller clinical series report the outcomes of 1 or a few participating surgeons, this analysis contains the collective outcomes of many surgeons, and is thus not biased by factors such as surgical technique, surgeon experience, or patient case mix.

We acknowledge several limitations, many of which are noted earlier. First, claims are filed with the purpose of obtaining payment rather than to document details of the clinical encounter. For claims data to be useful, clinicians must not only accurately identify the adverse event of interest, they must also use the proper code(s) to bill for it. Second, there is no attribution as to the cause of a given adverse outcome. As the rates of a variety of other intraocular procedures are high among Medicare beneficiaries, particularly cataract surgery,³⁷ some of the adverse outcomes we document may have occurred as a result of other diseases or procedures used to treat them.

Studies have compared medical records with claims data, but not for the procedures included in our study. Javitt et al¹¹ have previously demonstrated the utility of claims data in

assessing associations between rare adverse outcomes and surgical procedures in the case of cataract surgery. Studies of other diseases have reported lower sensitivity (range, 70%–77%) than specificity for claims data (specificity, ~90%).^{38–40} We would not expect there to be a difference in coding levels for the 3 kinds of surgery compared here. Third, GDD surgery has historically been restricted to patients who have already failed or are more prone to failing traditional filtering surgery.³⁵ As noted, differences in unmeasured case severity may explain the differences we observe in rates of adverse outcomes. Although we controlled for many important case mix factors using logistic regression, data limitations may have prevented us from being able to fully account for differences noted preoperatively.

Fourth, even by pooling data across 10 years, the GDD sample was rather small. Finally, because this analysis was generated using Medicare claims data, it may not adequately generalize to other populations, such as persons <68 and elderly persons in the Veterans Administration system. Fifth, our data were censored owing to entry into a Medicare risk plan or moving outside the United States.

In sum, although severe adverse outcomes are uncommon after filtering surgery for glaucoma, risk of adverse outcomes is higher after GDD as compared with PT surgery and TS surgery. Importantly, rates reported in this study are generally comparable with those reported in clinical trials and observational studies; the TVT study, for example, shows evidence that GDDs and trabeculectomies are about equally effective for medically uncontrollable glaucoma over a 1-year follow-up.⁴¹ Use of administrative databases, as suggested by other authors,^{11,42,43} are likely to provide an important tool for monitoring the long-term complications of glaucoma and eye surgery. Most important, this study does not assess the benefits of glaucoma surgery in the preservation of useful eyesight. Analyses of blindness and significant visual impairment have been performed with administrative databases such as Medicare^{44–46}; however, such codes represent only the most severely affected individuals. We cannot determine how many patients had useful eyesight that was saved by the surgery. From a clinical perspective, the decision to undergo surgery is based on an assessment of both the likely benefits of surgery and the possible adverse consequences of such surgery. The use of GDDs and TS are innovations in the last 30 years that have allowed many patients to undergo sight-saving surgery that they would not have had before their use. As such, the rates of adverse consequences seen in the literature should be reviewed with this in mind.

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References

1. Mills KB. Trabeculectomy: a retrospective long-term follow-up of 444 cases. *Br J Ophthalmol*. 1981; 65:790–795. [PubMed: 7326225]
2. Lichter PR, Musch DC, Gillespie BW, et al. CIGTS Study Group. Interim clinical outcomes in the Collaborative Initial Glaucoma Treatment Study comparing initial treatment randomized to medications or surgery. *Ophthalmology*. 2001; 108:1943–1953. [PubMed: 11713061]
3. Melamed S, Cahane M, Gutman I, Blumenthal M. Postoperative complications after Molteno implant surgery. *Am J Ophthalmol*. 1991; 111:319–322. [PubMed: 2000901]
4. Ramulu PY, Corcoran KJ, Corcoran SL, Robin AL. Utilization of various glaucoma surgeries and procedures in Medicare beneficiaries from 1995 to 2004. *Ophthalmology*. 2007; 114:2265–2270. [PubMed: 17466376]

5. Chen PP, Yamamoto Y, Sawada A, et al. Use of antifibrosis agents and glaucoma drainage devices in the American and Japanese Glaucoma Societies. *J Glaucoma*. 1997; 6:192–196. [PubMed: 9211144]
6. Joshi AB, Parrish RK II, Feuer WF. 2002 survey of the American Glaucoma Society: practice preferences for glaucoma surgery and antifibrotic use. *J Glaucoma*. 2005; 14:172–174. [PubMed: 15741822]
7. Melamed S, Fiore PM. Molteno implant surgery in refractory glaucoma. *Surv Ophthalmol*. 1990; 34:441–448. [PubMed: 2194308]
8. Gedde SJ, Herndon LW, Brandt JD, et al. Tube Versus Trabeculectomy Study Group. Surgical complications in the Tube Versus Trabeculectomy Study during the first year of follow-up. *Am J Ophthalmol*. 2007; 143:23–31. [PubMed: 17054896]
9. Jamil AL, Mills RP. Glaucoma tube or trabeculectomy? That is the question. *Am J Ophthalmol*. 2007; 143:141–142. [PubMed: 17188048]
10. Sastry SM, Street DA, Javitt JC. National outcomes of glaucoma surgery: complications following partial and full-thickness filtering procedures. *J Glaucoma*. 1992; 1:137–140.
11. Javitt JC, Vitale S, Canner JK, et al. National outcomes of cataract extraction: endophthalmitis following inpatient surgery. *Arch Ophthalmol*. 1991; 109:1085–1089. [PubMed: 1867549]
12. Penman AD, Johnson WD. A SAS program for calculating cumulative incidence of events (with confidence limits) and number at risk at specified time intervals with partially censored data. *Comput Meth Programs Biomed*. 2008; 89:50–55.
13. Al-Torbak AA, Al-Shahwan S, Al-Jadaan I, et al. Endophthalmitis associated with the Ahmed glaucoma valve implant. *Br J Ophthalmol*. 2005; 89:454–458. [PubMed: 15774923]
14. Wilson MR, Mendis U, Paliwal A, Haynatzka V. Long-term follow-up of primary glaucoma surgery with Ahmed glaucoma valve implant versus trabeculectomy. *Am J Ophthalmol*. 2003; 136:464–470. [PubMed: 12967799]
15. Tong L, Frazao K, LaBree L, Varma R. Intraocular pressure control and complications with two-stage insertion of the Baerveldt implant. *Ophthalmology*. 2003; 110:353–358. [PubMed: 12578780]
16. Roy S, Ravinet E, Mermoud A. Baerveldt implant in refractory glaucoma: long-term results and factors influencing outcome. *Int Ophthalmol*. 2001; 24:93–100. [PubMed: 12201350]
17. Krishna R, Godfrey DG, Budenz DL, et al. Intermediate-term outcomes of 350-mm(2) Baerveldt glaucoma implants. *Ophthalmology*. 2001; 108:621–626. [PubMed: 11237919]
18. Wilson MR, Mendis U, Smith SD, Paliwal A. Ahmed glaucoma valve implant vs trabeculectomy in the surgical treatment of glaucoma: a randomized clinical trial. *Am J Ophthalmol*. 2000; 130:267–273. [PubMed: 11020403]
19. Britt MT, LaBree LD, Lloyd MA, et al. Randomized clinical trial of the 350-mm² versus the 500-mm² Baerveldt implant: longer term results: is bigger better? *Ophthalmology*. 1999; 106:2312–2318. [PubMed: 10599663]
20. Huang MC, Netland PA, Coleman AL, et al. Intermediate-term clinical experience with the Ahmed glaucoma valve implant. *Am J Ophthalmol*. 1999; 127:27–33. [PubMed: 9932995]
21. Topouzis F, Yu F, Coleman AL. Factors associated with elevated rates of adverse outcomes after cyclodestructive procedures versus drainage device procedures. *Ophthalmology*. 1998; 105:2276–2281. [PubMed: 9855160]
22. Nguyen QH, Budenz DL, Parrish RK II. Complications of Baerveldt glaucoma drainage implants. *Arch Ophthalmol*. 1998; 116:571–575. [PubMed: 9596491]
23. Law SK, Kalenak JW, Connor TB Jr, et al. Retinal complications after aqueous shunt surgical procedures for glaucoma. *Arch Ophthalmol*. 1996; 114:1473–1480. [PubMed: 8953978]
24. Sidoti PA, Dunphy TR, Baerveldt G, et al. Experience with the Baerveldt glaucoma implant in treating neovascular glaucoma. *Ophthalmology*. 1995; 102:1107–1118. [PubMed: 9121760]
25. Coleman AL, Hill R, Wilson MR, et al. Initial clinical experience with the Ahmed glaucoma valve implant. *Am J Ophthalmol*. 1995; 120:23–31. [PubMed: 7611326]
26. Higginbotham EJ, Stevens RK, Musch DC, et al. Bleb-related endophthalmitis after trabeculectomy with mitomycin C. *Ophthalmology*. 1996; 103:650–656. [PubMed: 8618766]

27. Greenfield DS, Suner IJ, Miller MP, et al. Endophthalmitis after filtering surgery with mitomycin. *Arch Ophthalmol*. 1996; 114:943–949. [PubMed: 8694729]
28. Fluorouracil Filtering Surgery Study Group. Five-year follow-up of the Fluorouracil Filtering Surgery Study. *Am J Ophthalmol*. 1996; 121:349–366. [PubMed: 8604728]
29. Three-year follow-up of the Fluorouracil Filtering Surgery Study. *Am J Ophthalmol*. 1993; 115:82–92. [PubMed: 8420383]
30. Ticho U, Ophir A. Late complications after glaucoma filtering surgery with adjunctive 5-fluorouracil. *Am J Ophthalmol*. 1993; 115:506–510. [PubMed: 8470724]
31. Wolner B, Liebmman JM, Sassani JW, et al. Late bleb-related endophthalmitis after trabeculectomy with adjunctive 5-fluorouracil. *Ophthalmology*. 1991; 98:1053–1060. [PubMed: 1891213]
32. Rockwood EJ, Parrish RK II, Heuer DK, et al. Glaucoma filtering surgery with 5-fluorouracil. *Ophthalmology*. 1987; 94:1071–1078. [PubMed: 3684224]
33. Edmunds B, Thompson JR, Salmon JF, Wormald RP. The National Study of Trabeculectomy. III. Early and late complications. *Eye*. 2002; 16:297–303. [PubMed: 12032721]
34. Ruderman JM, Harbin TS Jr, Campbell DG. Postoperative suprachoroidal hemorrhage following filtration procedures. *Arch Ophthalmol*. 1986; 104:201–205. [PubMed: 3947293]
35. Hong CH, Arosemena A, Zurakowski D, Ayyala RS. Glaucoma drainage devices: a systematic review and current controversies. *Surv Ophthalmol*. 2005; 50:48–60. [PubMed: 15621077]
36. Minckler DS, Vedula SS, Li TJ, et al. Aqueous shunts for glaucoma. *Cochrane Database Syst Rev*. 2006; 2 CD004918.
37. Williams A, Sloan FA, Lee PP. Longitudinal rates of cataract surgery. *Arch Ophthalmol*. 2006; 124:1308–1314. [PubMed: 16966626]
38. Lawthers AG, McCarthy EP, Davis RB, et al. Identification of in-hospital complications from claims data: is it valid? *Med Care*. 2000; 38:785–795. [PubMed: 10929991]
39. Fisher ES, Whaley FS, Krushat WM, et al. The accuracy of Medicare's hospital claims data: progress has been made, but problems remain. *Am J Public Health*. 1992; 82:243–248. [PubMed: 1739155]
40. Jollis JG, Ancukiewicz M, DeLong ER, et al. Discordance of databases designed for claims payment versus clinical information systems: implications for outcomes research. *Ann Intern Med*. 1993; 119:844–850. [PubMed: 8018127]
41. Gedde SJ, Schiffman JC, Feuer WJ, et al. Tube Versus Trabeculectomy Study Group. Treatment outcomes in the Tube Versus Trabeculectomy Study after one year of follow-up. *Am J Ophthalmol*. 2007; 143:9–22. [PubMed: 17083910]
42. Coleman AL, Morgenstern H. Use of insurance claims databases to evaluate the outcomes of ophthalmic surgery. *Surv Ophthalmol*. 1997; 42:271–278. [PubMed: 9406373]
43. Javitt JC. Outcomes of eye care from Medicare data. *Arch Ophthalmol*. 1991; 109:1079–1080. [PubMed: 1867547]
44. Javitt JC, Zhou Z, Willke RJ. Association between vision loss and higher medical care costs in Medicare beneficiaries costs are greater for those with progressive vision loss. *Ophthalmology*. 2007; 114:238–245. [PubMed: 17270673]
45. Salm M, Belsky D, Sloan FA. Trends in cost of major eye diseases to Medicare, 1991 to 2000. *Am J Ophthalmol*. 2006; 142:976–982. [PubMed: 17157582]
46. Sloan FA, Picone G, Brown DS, Lee PP. Longitudinal analysis of the relationship between regular eye examinations and changes in visual and functional status. *J Am Geriatr Soc*. 2005; 53:1867–1874. [PubMed: 16274366]

Figure 1. Cumulative incidence (Table 4). (◆) GDD = glaucoma drainage device; (■) PT = primary trabeculectomy; (▲) TS = trabeculectomy with scarring.

Figure 2.

Hazard ratios (HR), 95% confidence intervals (CI) from Cox proportional hazards models of adverse outcomes. GDD = glaucoma drainage device is the omitted reference group; PT = primary trabeculectomy; TS = trabeculectomy with scarring.

Table 1**Codes Used to Identify Treatment Groups and Adverse Outcomes**

Treatment group classification	
Glaucoma drainage device (GDD) group—implantation of a GDD	66180
Primary trabeculectomy (PT) group—ab externo in absence of previous surgery	66170
Trabeculectomy with scarring (TS) group—trabeculectomy ab externo with preexisting scarring	66172
Diagnostic category	
Age-related macular degeneration	362.51, 362.52, 362.53, 362.5, 362.50, 362.57
Primary open-angle glaucoma	365.1x
Neovascular glaucoma	365.63
Uveitic glaucoma	363.21, 364.00–364.02, 364.10, 364.11, 364.2, 364.22, 364.3, 364.21, 365.62, 053.22, 054.44
Other glaucoma	364.73, 365.0, 365.00, 365.01–365.04, 365.13, 365.14, 365.2x, 365.3x–365.5x, 365.6, 365.60, 365.61, 365.64, 365.65, 365.8x, 365.9
Severe adverse outcomes	
Endophthalmitis	360.0x
Rhegmatogenous retinal detachment	361.0, 361.0x
Tractional retinal detachment	361.8
Suprachoroidal hemorrhage	363.6x, 363.72
Less severe adverse outcomes	
Choroidal detachment	363.7, 363.70, 363.71
Corneal edema	371.20, 371.21, 371.22, 371.23
Hypotony	360.3, 360.30, 363.31, 363.32, 360.34
Subsequent operations	
Revision of aqueous shunt	66185
Wound revision, major and minor	66250
Cyclodestruction therapy	66710, 66711, 66720
Blindness/low vision	360.41, 360.42, 369.xx, 92392, V26.00, V26.10, V26.15

Table 2**Intraocular Surgical Procedures and Current Procedural Terminology (CPT) Codes**

Procedure	CPT Code
Keratoplasty	65710–65755
Keratoprosthesis	65770
Corneal surgery to correct surgically induced astigmatism	65772–65775
Paracentesis of anterior chamber with removal vitreous, blood, etc.	65800–65805, 65810, 65815
Synechialysis (not including goniosynechialysis)	65870, 65875, 65880
Removal of epithelial downgrowth, implanted material, blood clot	65900, 65920, 65930
Injection of air, liquid, or meds into anterior chamber	66020, 66030
Trabeculectomy	66150, 66155, 66160, 66165
Wound revision major/minor	66250
Surgical peripheral iridotomy (PI)	66500–66505
Repair iris	66680, 66682
Intraocular lens (IOL) repositioning	66825
Cataract extraction	66830–66984
Insertion of IOL (not assoc with cataract surgery)	66985
IOL exchange	66986
Partial anterior vitrectomy	67005, 67010
Posterior sclerostomy	67015
Injection medication into vitreous	67025, 67027
Dissection of vitreous	67030, 67031
Pars plana vitrectomy	67036, 67038, 67039, 67040
Repair retinal detachment	67101, 67105, 67107, 67108, 67110, 67112, 67115, 67120, 67121

Table 3

Characteristics of Treatment Groups

	GDD (CPT 66180)	PT (CPT 66170)	TS (CPT 66172)
Demographic characteristics			
Mean age	77.9	78.1	78.1
Male (%)	39.8	36.9 [*]	36.4 [*]
White (%)	74.3	80.1 [†]	78.7 ^{**}
Black (%)	20.6	15.5 [†]	17.2 ^{**}
Other (%)	4.9	3.9	3.9
Unknown/race missing (%)	0.2	0.5	0.3
Diagnosis before treatment			
Age-related macular degeneration	25.5	16.9 [†]	20.6 [†]
Primary open angle glaucoma	62.9	68.9 [†]	73.7 [†]
Neovascular glaucoma	6.2	0.4 [†]	0.7 [†]
Uveitic glaucoma	5.1	1.2 [†]	2.2 [†]
Narrow angle glaucoma	5.7	6.0	4.8
Suspect glaucoma	8.1	13.1 [†]	9.0
Other glaucoma	11.2	10.0	9.3 [*]
Adverse outcomes before treatment			
Severe complications	9.0	1.6 [†]	4.0 [†]
Endophthalmitis	2.0	0.3 [†]	0.7 [†]
Retinal detachment: rhegmatogenous	5.3	1.1 [†]	2.8 [†]
Retinal detachment: tractional	1.4	0.2 [†]	0.4 [†]
Suprachoroidal hemorrhage	1.3	0.1 [†]	0.5 ^{**}
Less severe complications	25.0	1.8 [†]	6.9 [†]
Choroidal detachment	1.9	0.1 [†]	0.8 ^{**}
Corneal edema	23.0	1.6 [†]	5.2 [†]
Hypotony	1.9	0.1 [†]	1.3
Reoperation	3.4	0.9 [†]	4.2
Cyclodestruction TDC	2.9	0.4 [†]	0.9 [†]
Cyclodestruction therapy	0.4	0.2	0.2
Wound revision	0.0	0.4 [*]	3.1 [†]
Tube revision	0.1	0.0 [†]	0.0 [*]
Blindness/low vision	8.6	2.0 [†]	3.5 [†]
Sample	1,398	9,719	3,374

CPT = Current Procedural Terminology; PT = primary trabeculectomy; TDC = transscleral diode laser cycloablation; TS = trabeculectomy with previous scarring.

^{*} $P < 0.05$ for values compared against glaucoma drainage device (GDD) group.

^{**} $P < 0.01$ for values compared against glaucoma drainage device (GDD) group.

[†] $P < 0.001$ for values compared against glaucoma drainage device (GDD) group.

Table 4

Cumulative Incidence Probability of New Adverse Outcomes

Adverse Outcome	GDD Group (CPT 66180)			PT Group (CPT 66170)			TS Group (CPT 66172)		
	Year 1	Year 2	Year 6	Year 1	Year 2	Year 6	Year 1	Year 2	Year 6
Severe Adverse Outcome	2.0	4.3	24.4	0.6	1.3	8.2	0.8	1.8	11.1
Endophthalmitis	0.4	1.0	6.4	0.1	0.3	1.8	0.2	0.4	2.7
Rhegmatogenous retinal detachment	0.8	1.8	10.7	0.2	0.6	3.8	0.3	0.7	4.6
Tractional retinal detachment	0.2	0.5	2.6	0.0	0.1	0.7	0.1	0.2	0.9
Suprachoroidal hemorrhage	0.8	1.7	9.1	0.2	0.5	3.0	0.4	0.9	4.9
Less Severe Adverse Outcome	3.3	7.6	43.0	1.0	2.2	13.6	1.6	3.7	23.0
Choroidal detachment	1.3	2.7	14.5	0.5	1.1	6.3	0.7	1.6	9.0
Corneal edema	1.6	4.0	27.8	0.3	0.6	4.8	0.5	1.2	9.8
Hypotony	1.3	2.9	15.4	0.4	0.8	4.9	0.7	1.5	9.2
Subsequent Operation	1.8	4.2	25.8	1.6	3.6	19.6	2.5	5.4	29.1
Cyclodestruction TDC	0.4	1.0	8.1	0.1	0.3	1.9	0.4	0.8	5.2
Cyclodestruction therapy	0.1	0.3	1.9	0.0	0.1	0.5	0.1	0.2	1.3
Wound revision	n/a	n/a	n/a	1.5	3.3	17.7	2.1	4.6	25.0
Tube revision	1.6	3.5	20.4	n/a	n/a	n/a	n/a	n/a	n/a
Blindness/Low Vision	1.1	2.9	21.2	0.4	0.9	7.7	0.6	1.4	12.9
Sample	1,398	1,398	1,398	9,719	9,719	9,719	3,374	3,374	3,374

GDD = Glaucoma Drainage Device; PT = Primary Trabeculectomy; TS = Trabeculectomy with Previous Scarring; CPT = Current Procedural Terminology; TDC = Transscleral Diode Laser Cycloablation.

Table 5
Hazard Ratios (%95 Confidence Intervals) from Cox Proportional Hazards Analysis of Adverse Outcomes

	Severe adverse outcomes		Less severe adverse outcomes		Subsequent operations		Endophthalmitis		Corneal edema		Blindness/low vision	
	1	2	1	2	1	2	1	2	1	2	1	2
Primary Trabeculectomy	0.31 (0.26–0.38)	0.49 (0.38–0.62)	0.26 (0.22–0.31)	0.33 (0.27–0.39)	0.70 (0.59–0.83)	0.90 (0.74–1.10)	0.28 (0.24–0.48)	0.53 (0.33–0.86)	0.15 (0.12–0.19)	0.20 (0.16–0.26)	0.33 (0.27–0.41)	0.61 (0.47–0.78)
Trabeculectomy with scarring	0.46 (0.34–0.54)	0.54 (0.42–0.69)	0.46 (0.39–0.55)	0.49 (0.41–0.59)	1.10 (0.91–1.32)	1.23 (1.01–1.50)	0.41 (0.26–0.65)	0.56 (0.35–0.91)	0.31 (0.25–0.40)	0.34 (0.27–0.44)	0.57 (0.45–0.72)	0.81 (0.63–1.03)
Prior diagnosis/procedure												
Severe adverse Outcome				1.18 (0.85–1.63)		0.95 (0.68–1.31)		1.11 (0.48–2.57)		1.05 (0.67–1.66)		1.23 (0.85–1.79)
Less severe Outcome		1.53 (1.15–2.02)				1.27 (1.01–1.59)		1.66 (0.98–2.80)		1.54 (0.81–2.93)		1.54 (1.18–2.00)
Age-related macular degeneration		0.99 (0.80–1.21)		0.99 (0.85–1.16)		0.99 (0.86–1.15)		1.05 (0.70–1.57)		0.99 (0.79–1.25)		1.50 (1.25–1.80)
Intra-ocular surgical procedure		1.07 (0.89–1.29)		1.00 (0.87–1.15)		0.87 (0.76–0.99)		1.07 (0.75–1.54)		1.16 (0.95–1.41)		1.03 (0.86–1.23)
Neovascular glaucoma		1.29 (0.72–2.29)		0.44 (0.23–0.87)		0.69 (0.37–1.27)		1.25 (0.43–3.67)		0.51 (0.22–1.17)		2.11 (1.29–3.45)
Uveitic glaucoma		1.26 (0.76–2.08)		1.28 (0.87–1.87)		1.07 (0.73–1.55)		0.53 (0.13–2.16)		1.55 (0.95–2.55)		1.51 (0.98–2.34)
Narrow angle glaucoma		1.17 (0.83–1.64)		1.42 (1.12–1.80)		1.24 (1.00–1.54)		0.99 (0.48–2.04)		1.23 (0.85–1.80)		1.48 (1.09–2.03)
Suspect glaucoma		1.09 (0.84–1.42)		0.90 (0.73–1.11)		0.84 (0.70–1.02)		1.50 (0.95–2.36)		0.91 (0.65–1.26)		0.98 (0.74–1.29)
Other glaucoma		1.06 (0.81–1.38)		1.21 (1.00–1.47)		0.95 (0.79–1.14)		0.44 (0.20–0.95)		1.30 (0.98–1.73)		1.45 (1.15–1.84)
Diabetic retinopathy		1.33 (0.87–2.04)		0.69 (0.46–1.03)		0.95 (0.67–1.35)		1.28 (0.56–2.92)		0.74 (0.43–1.26)		1.41 (0.97–2.06)
Same day cataract surgery		0.64 (0.52–0.77)		0.63 (0.55–0.73)		0.64 (0.57–0.72)		0.43 (0.29–0.65)		0.61 (0.49–0.77)		0.58 (0.48–0.71)
Demographic Characteristics												
Age		1.02 (1.00–1.03)		1.01 (1.00–1.02)		0.99 (0.98–1.00)		1.02 (0.99–1.05)		1.02 (1.00–1.04)		1.04 (1.02–1.05)
Male		1.15 (0.97–1.35)		1.08 (0.95–1.22)		1.00 (0.90–1.12)		1.04 (0.74–1.46)		0.91 (0.75–1.10)		1.11 (0.94–1.31)
Black		0.79 (0.63–1.00)		0.88 (0.74–1.04)		1.05 (0.91–1.21)		1.01 (0.65–1.56)		0.80 (0.61–1.04)		1.73 (1.43–2.09)
Other		0.77 (0.48–1.21)		1.17 (0.88–1.56)		0.88 (0.65–1.18)		0.52 (0.17–1.65)		1.68 (1.15–2.45)		1.44 (0.99–2.09)

Notes: 1 = Not including prior diagnosis/procedure or demographic characteristics; 2 = includes all covariates.

Table 6
Published Rates of Adverse Outcomes Following Glaucoma Drainage Device and Trabeculectomy Surgery (%)

Study	Device/Adjunctive Drug	n (eyes)	Endophthalmitis	Retinal detachment	SCH	Choroidal detachment	Corneal edema	Hypotony	Revision of tube/ Trabeculectomy	Cyclodestruction	Follow-up (fixed period range or mean)
Panel A. Glaucoma Drainage Devices (GDDs)											
Current Study	Any GDD	1,398	0.4	1.0	0.8	1.3	1.6	1.3	1.6	0.5	1 year
Gedde et al. 2007 ⁸	B350mm	107	0.9		1.9		6.5	2.9	1.9	0.9	54/60 mos
Al-Torbak et al. 2005 ¹³	Ahmed S1/S2	542	1.5								8.9 mos
Wilson et al. 2003 ¹⁴	Ahmed S2	59	0.0		0.0				5.1		31 mos
Tong et al. 2003 ¹⁵	B 350mm	19			10.5		10.5	5.3			17 months
Roy et al. 2002 ¹⁶	B250/350/425mm	51	2.1		2.1				11.8		37.6 mos
Krishna et al. 2001 ¹⁷	B350mm	65	3.1	3.1	0.0						2 years
Wilson et al. 2000 ^{7,18}	Ahmed	55	0.0		0.0				1.8		9.7 mos
	B350mm	53		1.9							
Britt et al. 1999 ¹⁹	B500mm	50		8.0							37/34 mos
Huang et al. 1999 ²⁰	Ahmed S2	159		1.9	3.1		20.8	8.2			13.4 mos
Topouzis et al. 1998 ²¹	Any GDD	1,563	1.7	1.7					12.4	2.2	5 mos
Nguyen et al. 1998 ²²	B350mm	107	0.9	1.9	3.7						7.3 mos
Law et al. 1996 ²³	B350mm	38	2.6	2.6	7.9						11.4 mos
Sidoti et al. 1995 ²⁴	B350/500mm	36		8.3	2.8	11.1		8.3			15.7 mos
Coleman et al. 1995 ²⁵	Ahmed	60			1.7	21.7		3.3	16.7		9.3 mos
Panel B. Trabeculectomy w/ Mitomycin C (MMC) or 5-Fluorouracil (5FU)											
Current Study	5FU/MMC	9,719	0.1	0.3	0.2	0.5	0.3	0.4	1.5	0.1	1 year
Gedde et al. 2007 ⁸	MMC	105	2.9	0.0	2.9		2.9	0.0			54/60 mos
Wilson et al. 2003 ¹⁴	MMC	64	0.0		0.0			3.1	6.3		31 mos
Wilson et al. 2000 ¹⁸	MMC	62	0.0		0.0			1.6	4.8		9.7 mos

Study	Device/Adjunctive Drug	n (eyes)	Endophthalmitis	Retinal detachment	SCH	Choroidal detachment	Corneal edema	Hypotony	Revision of tube/ Trabeculectomy	Cyclodestruction	Follow-up (fixed period range or mean)
Higginbotham et al. 1996 ²⁶	MMC	229	2.6								18.5 mos
Greenfield et al. 1996 ²⁷	MMC	609	2.1								16.0 mos
FFSSG 1996 ²⁸	5FU	108	1.9		4.6				1.9	5.6	5 years
	w/o 5FU	105	1.0		4.8				5.7	5.7	
FFSG 1993 ²⁹	5FU	108	0.9		4.6		12.0				3 years
	w/o 5FU	105			4.8		20.0				
Ticho & Ophir 1993 ³⁰	5FU	105	3.8				2.9				32.3 mos
Wolner et al. 1990 ³¹	5FU	229	5.7								23.7 mos
Rockwood et al. 1987 ³²	5FU	155	2.5	2.6	5.8						4 years

SCH = Suprachoroidal hemorrhage. Additional details on these studies are shown in Appendix B.

*Topouzis et al. analyzed claims data from the complete Medicare database, the only study reported here to use claims data.

[†]Model of Ahmed not specified in Wilson et al. 2000 and Coleman et al. 1995.

Table 7

Synopsis of Prior Studies

Study	Synopsis
Gedde et al 2007 ^a	Seventeen clinical centers studied 212 patients aged 18–85 with previous trabeculectomy and/or cataract surgery, and persistently high intraocular pressure despite maximum medical therapy were randomized to either trabeculectomy or implantation of a 350 mm ² Baerveldt GDD. Glaucoma studied: POAG, CACG, PXFG, PG, other. Mean follow-up: 54–60 months.
Al-Torbak et al 2007 ¹³	All patients implanted with Ahmed Valve GDDs between January 1994 and November 2003 were screened for endophthalmitis in a relational database of all surgeries performed at King Khaled Eye Specialist Hospital in Riyadh, Saudi Arabia. Age ranged from 0.8–78 years. Glaucoma studied: congenital, secondary, primary. Median follow-up: 8.9 months.
Wilson et al 2003 ¹⁴	One hundred twenty-three consecutive patients needing surgical treatment for POAG or CACG, with no previous intraocular surgery or conditions requiring combined surgeries at Columbo Eye Hospital in Sri Lanka were randomized to receive either trabeculectomy or an Ahmed implant. Glaucoma studied: POAG, CACG. Mean follow-up: 31 months.
Tong et al 2003 ¹⁵	Researchers reviewed medical records of all (19) patients undergoing 2-stage implantation of Baerveldt GDD for advanced glaucoma between January 1995 and November 1998 at Doheny Eye Institute who had a minimum of 6 months follow up or whose surgery failed within 6 months. Patients were aged 30–88 years. Glaucoma studied: angle closure glaucoma, combined mechanism, open angle glaucoma, uveitic. Median follow-up: 17 months.
Roy et al 2002 ¹⁶	Medical records were reviewed for 48 patients with medically uncontrolled refractory glaucoma, no longer eligible for filtering surgery, who underwent Baerveldt implant surgery between June 1994 and December 1998, and were followed up for a minimum of 12 months at Jules Gonin Hospital, Lausanne, Switzerland. Mean (SD) age of patients was 58.4 (21.6) years. Glaucoma studied: traumatic, aphakic, neovascular, uveitic, congenital. Mean follow-up: 37.6 months.
Krishna et al 2001 ¹⁷	Data on all patients at Bascom Palmer Eye Institute from January 1989 to August 1998 receiving Baerveldt 350-mm ² implants and no concurrent trabeculectomy or revision of trabeculectomy or implant, who had a minimum of 2 years of follow-up or implant failure within 2 years (n = 4) were extracted from medical records. Glaucoma studied: POAG, neovascular, uveitic, other. Follow-up: 24 months.
Wilson et al 2000 ¹⁸	One hundred seventeen patients aged >4 years from 1 hospital in Saudi Arabia and 1 in Sri Lanka were randomized to trabeculectomy or implantation of an Ahmed GDD for glaucoma. Mean (SD) age for the GDD group was 52.63 (2.51), and for the trabeculectomy group, 51.76 (2.18). Glaucoma studied: POAG, CACG, secondary. Mean follow-up: 9.7 months.
Britt et al 1999 ¹⁹	Medical records of 107 patients randomly assigned to 350/500-mm Baerveldt devices at Doheny Eye Institute between March 1999 and April 1993 were reviewed. Results presented are for those participants available for follow-up at 2–5 years, aged >12 years, with no diagnosis of neovascular glaucoma or uveitis, no record of previous cyclodestructive procedures, and who met additional restrictions. Glaucoma studied: aphakic, anterior chamber of intraocular lens, posterior chamber intraocular lens. Mean follow-up: 37 and 34 months.

CACG = chronic angle closure glaucoma; GDD = glaucoma drainage device; PG = primary glaucoma; POAG = primary open-angle glaucoma; PXFG = Pseudoexfoliation glaucoma; SD = standard deviation.