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Risk Ractors for Strabismus Surgery after Pediatric Cataract Surgery in the United States

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Purpose: To determine the cumulative incidence of strabismus surgery after pediatric cataract surgery and identify the associated risk factors.

Design: US population-based insurance claims retrospective cohort study.

Participants: Patients ≤ 18 years old who underwent cataract surgery in 2 large databases: Optum Clinformatics Data Mart (2003–2021) and IBM MarketScan (2007–2016).

Methods: Individuals with at least 6 months of prior enrollment were included, and those with a history of strabismus surgery were excluded. The primary outcome was strabismus surgery within 5 years of cataract surgery. The risk factors investigated included age, sex, persistent fetal vasculature (PFV), intraocular lens (IOL) placement, nystagmus and strabismus diagnoses before cataract surgery, and cataract surgery laterality.

Main Outcome Measures: Kaplan–Meier estimated cumulative incidence of strabismus surgery 5 years after cataract surgery and hazard ratios (HRs) with 95% confidence intervals (CIs) from multivariable Cox proportional hazards regression models.

Results: Strabismus surgery was performed on 271/5822 children included in this study. The cumulative incidence of strabismus surgery within 5 years after cataract surgery was 9.6% (95% CI, 8.3%–10.9%). Children who underwent strabismus surgery were more likely to be of younger age at the time of cataract surgery, of female sex, have a history of PFV or nystagmus, have a pre-existing strabismus diagnosis, and less likely to have an IOL placed (all $P < 0.001$). Factors associated with strabismus surgery in the multivariable analysis included age 1 to 4 years (HR, 0.50; 95% CI, 0.36–0.69; $P < 0.001$) and age > 5 years (HR, 0.13; 95% CI, 0.09–0.18; $P < 0.001$) compared with age < 1 year at time of cataract surgery, male sex (HR, 0.75; 95% CI, 0.59–0.95; $P < 0.001$), IOL placement (HR, 0.71; 95% CI, 0.54–0.94; $P = 0.016$), and strabismus diagnosis before cataract surgery (HR, 4.13; 95% CI, 3.17–5.38; $P < 0.001$). Among patients with strabismus diagnosis before cataract surgery, younger age at cataract surgery was the only factor associated with increased risk of strabismus surgery.

Conclusions: Approximately 10% of patients will undergo strabismus surgery within 5 years after pediatric cataract surgery. Children of younger age, female sex, and with a pre-existing strabismus diagnosis undergoing cataract surgery without IOL placement are at greater risk.

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Strabismus is commonly associated with pediatric cataract surgery and is a major cause of difficulty in achieving binocular vision in children who undergo successful cataract extractions.[1] Many children that develop strabismus after cataract surgery will undergo strabismus surgery. Estimates of the rates of strabismus surgery after pediatric cataract surgery range from 3% to 70% and vary greatly by population, patient age, and follow-up time.[2–13] These rates are much higher than the rates of strabismus surgery among children generally, which range from 0.4% to 1.99%.[14] Previously identified risk factors for strabismus after pediatric cataract surgery include younger age at cataract surgery, pre-existing diagnosis of nystagmus, anisometropia, poor postoperative best-corrected visual acuity, and unilateral cataract surgery.[1,15]

In this study, we leveraged 2 large commercial insurance claims databases to investigate the nationwide incidence of strabismus surgery after pediatric cataract surgery in the United States. We hypothesize that a claims-based approach would provide a large enough cohort to evaluate the magnitude of association between strabismus surgery and various risk factors and outcomes of interest, including age, sex, ocular history, intraocular lens (IOL) use, and the number of muscles operated on for strabismus surgery.

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Based on a computerized search for "strabismus surgery" and "pediatric cataract surgery" in MEDLINE in July 2022, this is the largest study examining strabismus surgery in pediatric patients who have undergone cataract surgery.

Methods

Study design and data source

This population-based retrospective cohort study was performed using administrative claims data from Optum's de-identified Clinformatics Data Mart (CDM) (2003−2021) and IBM MarketScan Research Databases (2007−2016).[16,17] The CDM Database (OptumInsight) is a de-identified commercial and Medicare Advantage claims database. Clinformatics Data Mart includes data on approximately 15 to 18 million annual enrollees, for a total of over 63 million individuals from a geographically diverse population spanning all 50 states of the United States. Clinformatics Data Mart provides demographic and medical claims data for all inpatient and outpatient services, including ambulatory surgery. The IBM MarketScan Research Databases include more than 240 million individuals insured by 350 unique health carriers. IBM MarketScan data include health insurance claims across the continuum of care (e.g., inpatient, outpatient, outpatient pharmacy, and carve-out behavioral healthcare) and enrollment data from large employers and health plans across the United States. Both medical claims datasets include the *International Classification of Diseases, Ninth and Ten Revisions* (ICD-9-CM and ICD-10-CM, respectively) diagnosis codes, and Current Procedural Terminology (CPT) version 4 procedure codes. Data access for this project was provided by the Stanford Center for Population Health Science Data Core, which is supported by the National Institutes of Health National Center for the Advancing Translational Science Clinical and Translational Science Award (UL1TR003142) and internal Stanford funding. The content of this article is solely the responsibility of the authors and does not represent the official views of the National Institutes of Health. The Stanford University School of Medicine Institutional Review Board determined that this study involving the use of de-identified data did not require institutional review board approval.

Study population

Individuals were included in the study if treated with cataract surgery at 18 years of age or younger based on the appropriate CPT codes (Table 1).[18] We included individuals with continuous enrollment before cataract surgery (180 days for children age $\geq$ 1 year old and no requirement for children $<$ 1 year old to capture all newborns undergoing cataract surgery). To avoid capturing strabismus reoperations, patients that underwent strabismus surgery before cataract surgery were excluded. However, patients with strabismus diagnoses before cataract surgery were not excluded, for better comparison with the previous literature, such as the Infant Aphakia Treatment Study (IATS).

Data collection

The variables collected for each individual included age, sex, date of cataract surgery, CPT and procedure modifier codes on the day of and up to 90 days after cataract surgery, date of first strabismus surgery, and CPT and procedure modifier codes from the date of first strabismus surgery. Patient age in these de-identified datasets was available as the nearest integer value and treated as a categorical variable divided into age $<$ 1 year, age 1 to 4, and age $\geq$ 5 years at the time of cataract surgery. Other risk factors of interest were also treated as categorical variables and included sex, persistent fetal vasculature (PFV) diagnosis (ICD Q14.0, 743.51), placement of an IOL (CPT 66982, 66983, 66984), nystagmus diagnosis (ICD 379.5x, H55.x), and pre-existing strabismus diagnosis (ICD 378.x, H49.x, H50.x). The number and type of muscles operated on during strabismus surgery were determined as previously described.[19] Cataract surgery was considered bilateral if there were either a bilateral procedure modifier code (50) or procedure modifier codes for both right and left eyes on the initial date of cataract surgery. Cataract surgery was also considered bilateral if there was a second cataract surgery date within the sooner of 90 days or first strabismus surgery, regardless of the presence of procedure modifier codes, unless the procedure modifier codes indicated surgery on the same eye for all dates. All other cataract surgeries were considered unilateral.

Primary outcome

Our primary outcome was strabismus surgery within 5 years of cataract surgery. For children with bilateral cataracts, we used the date of the first cataract surgery.

Statistical analysis

For the univariable analyses, we directly compared the baseline patient demographics and operative factors between children who did and did not develop strabismus within 5 years of cataract surgery. We reported means and standard deviations for continuous variables and frequency and proportions for categorical variables. We performed t tests and chi-square tests. For the time-to-event analysis, we reported the cumulative incidence of strabismus repair at 5 years after cataract surgery using the Kaplan−Meier estimator. Individuals were censored based on length of continuous enrollment or administratively 5 years after the initial cataract surgery. For the multivariable analysis, we reported adjusted hazard ratios (HRs) for each risk factor estimated using a multivariable Cox proportional hazards regression model adjusting for all other covariates. Age was treated as a categorical variable in the regression model. We performed an additional stratified analysis of the Kaplan−Meier estimated probability of strabismus surgery by previous strabismus diagnosis. We also performed an ordinal logistic regression with the number of muscles operated on during strabismus surgery as the independent variable, reporting odds ratios for each risk factor. Statistical significance was defined as a 2-tailed P value less than 0.05. We reported 95% confidence intervals (CIs). Statistical analyses were conducted using R, version 4.0.2 (R Core Team) with the survival package for time-to-event analysis.

Results

Strabismus surgery was performed in 271 of the 5822 who met the inclusion and exclusion criteria for this study (Fig 1). The cumulative incidence of strabismus surgery within 5 years after cataract surgery was 9.6% (95% CI, 8.3%−10.9%). The median (interquartile range) time between initial cataract surgery and strabismus surgery was 378 days (218−694.5 days) (Fig 2).

Patients who underwent strabismus surgery within 5 years after cataract surgery were more likely to be of younger age (mean 2.9 versus [vs.] 8.4 years, $P < 0.001$), female sex (54% [147/271] vs. 43% [2352/5551], $P <$ 0.001), PFV diagnosis (11% [29/271] vs. 4% [228/5551], P

Table 1. Diagnosis and Procedural Codes Used

Strabismus diagnosis	ICD 9/10	378.x, H49.x, H50.x
Nystagmus diagnosis	ICD 9/10	379.5x, H55.x
PFV diagnosis	ICD 9/10	743.51, Q14.0
Cataract surgery	CPT	66840, 66850, 66852, 66920, 66930, 66940, 66982, 66983, 66984
Strabismus surgery	CPT	67311, 67312, 67314, 67316, 67318
IOL placement	CPT	66982, 66983, 66984

CPT = Current Procedural Terminology; ICD 9/10 = *International Classification of Diseases, Ninth and Tenth Revision*; IOL = intraocular lens; PFV = persistent fetal vasculature.

< 0.001), nystagmus diagnosis (14% [38/271] vs. 5% [270/5551], $P < 0.001$), or strabismus diagnosis (35% [96/271] vs. 13% [732/5551], $P < 0.001$), and were less likely to have an IOL placed during time of cataract surgery (53% [144/271] vs. 75% [4170/5551], $P < 0.001$) (Table 2).

The demographic and operative factors associated with strabismus surgery after pediatric cataract surgery identified using the multivariable Cox regression model included age 1 to 4 years (HR, 0.50; 95% CI, 0.36–0.69; $P < 0.001$) and age > 5 years (HR, 0.13; 95% CI, 0.09–0.18; $P < 0.001$) compared with age < 1 year at time of cataract surgery, male sex (HR, 0.75; 95% CI 0.59–0.95; $P < 0.001$), IOL placement (HR, 0.71; 95% CI, 0.54–0.94; $P = 0.016$), and strabismus diagnosis before cataract surgery (HR, 4.13; 95% CI, 3.17–5.38; $P < 0.001$). PFV diagnosis, nystagmus diagnosis, and cataract surgery laterality were not associated with strabismus surgery after cataract surgery, after adjusting for all other covariates (Table 3). Risk factors among patients without a diagnosis of strabismus before cataract surgery included age 1 to 4 years (HR, 0.52; 95% CI, 0.34–0.79; $P = 0.002$) and age > 5 years (HR, 0.10; 95% CI, 0.06–0.15; $P < 0.001$) compared with age < 1 year at time of cataract surgery, IOL placement (HR, 0.65; 95% CI, 0.46–0.92; $P = 0.014$), and unilateral cataract surgery (HR, 1.45; 95% CI, 1.03–2.04; $P = 0.033$) (Table S1). Younger age at cataract surgery was the only risk factor for subsequent strabismus surgery among patients with a diagnosis of strabismus before cataract surgery (HR, 0.58; 95% CI, 0.33–0.99; $P = 0.048$ and HR, 0.23; 95% CI, 0.13–0.40; $P < 0.001$ for age 1–4 years and ≥ 5 years, respectively, compared with reference < 1 year) (Table S2).

The cumulative incidences of strabismus surgery within 5 years after cataract surgery among patients less than 1 year, between 1 and 4 years, and greater than or equal to 5 years of age at the time of cataract surgery were 27.3% (95% CI, 22.0%–32.1%), 17.5% (95% CI, 13.2%–21.7%), and 3.2% (95% CI, 2.3%–4.1%) respectively, $P < 0.001$. The cumulative incidences of strabismus surgery within 5 years of cataract surgery among patients with and without a prior diagnosis of strabismus were 8.7% (95% CI, 6.4%–9.0%) and 21.8% (95% CI, 16.8%–26.6%), respectively, $P < 0.001$ (Fig 3). The cumulative incidence of strabismus surgery was also higher among patients that underwent cataract surgery at younger ages among both patients with a pre-existing diagnosis of strabismus (50.3%, 37.1%, and 10.3% in ages < 1, 1–4, and ≥ 5 years, respectively, $P < 0.001$) and without a pre-existing diagnosis of strabismus (25.2%, 11.8%, and 2.2% in ages < 1, 1–4, and ≥ 5 years, respectively, $P < 0.001$) (Table S3). The cumulative incidences of strabismus surgery within 5 years after cataract surgery among children with unilateral and bilateral cataracts were 9.8% (95% CI, 8.3%–11.3%) and 9.0% (95% CI, 6.5%–11.4%), respectively, $P = 0.51$. When stratified by age at cataract surgery, the cumulative incidence of strabismus surgery at 5 years was higher among patients with unilateral cataracts at age < 1 year (30.9% vs. 20.9%, $P = 0.024$) and age 1 to 4 years (19.5% vs. 13.0%, $P = 0.023$). There was no difference in children ≥ 5 years (3.2% vs. 3.1%, $P = 0.55$) (Table 4).

Among children < 1 year of age, male sex (HR, 0.66; 95% CI, 0.46–0.95; $P = 0.024$) and unilateral cataract surgery (HR, 1.58; 95% CI, 1.07–2.33; $P = 0.022$) were associated with strabismus surgery in a multivariate Cox regression analysis, whereas PFV, nystagmus diagnosis, and IOL placement were not associated. The rates of strabismus surgery at 5 years did not differ between aphakia and pseudophakia among patients with unilateral cataracts who

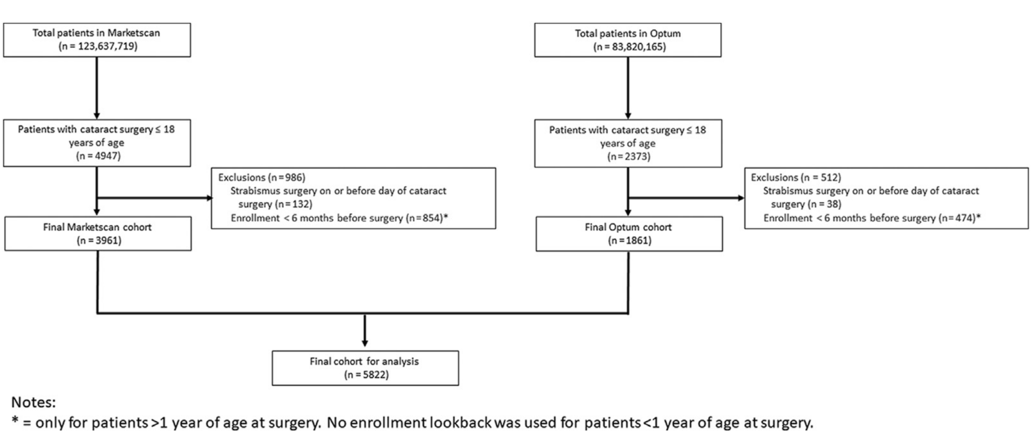

Figure 1. Flowchart illustrating the identification of strabismus surgery in patients who underwent cataract surgery at or before 18 years of age in the Optum and MarketScan datasets.

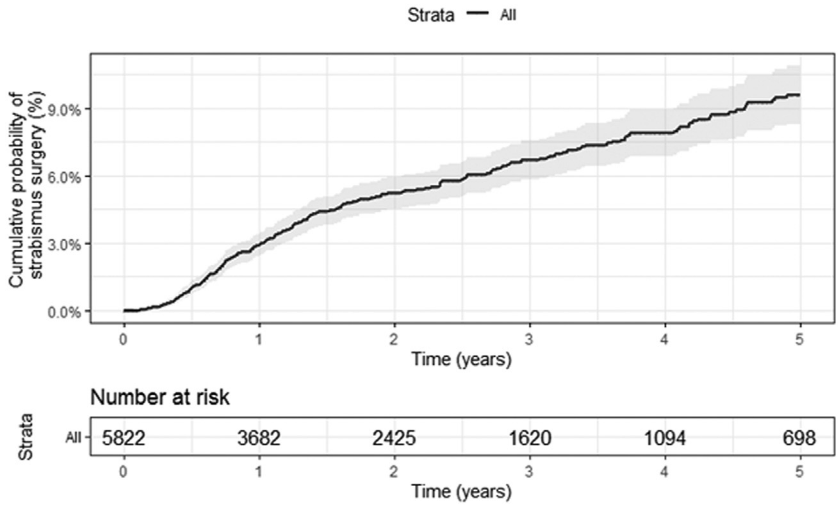

Figure 2. Kaplan-Meier estimate of cumulative incidence of strabismus surgery after pediatric cataract surgery.

underwent cataract surgery at less than 1 year of age (33.9% vs. 29.6%, $P = 0.41$). However, rates of strabismus surgery were lower in patients less than 1 year of age with bilateral cataracts who underwent primary IOL implantation compared with those left aphakic after cataract surgery (12.2% vs. 24.8%, $P = 0.028$).

Among the 271 patients who underwent strabismus surgery, 49 (18.1%) underwent operations on both horizontal and vertical muscles, 222 (68.9%) underwent operations on horizontal muscles only, and 4 (1.5%) underwent operations on vertical muscles only. Laterality data were available for 173 of these patients, of whom 34 (19.7%) underwent an operation on 1 muscle, 112 (64.7%) underwent an operation on 2 muscles, and 27 (15.6%) underwent an operation on 3 or more muscles.

Discussion

Approximately 27%, 18%, and 3% of children who underwent cataract surgery at the age of less than 1 year, between 1 and 4 years, and greater than 5 years, respectively, underwent strabismus surgery within 5 years after cataract surgery. Our study estimates are similar to other nationally representative cohort studies such as IATS and the Toddler Aphakia and Pseudophakia Treatment Study. To our

Table 2. Baseline Demographics and Operative Techniques of Patients Who Underwent Pediatric Cataract Surgery

	Did Not Undergo Strabismus Surgery (n = 5551)	Underwent Strabismus Surgery (n = 271)	P
Dataset, n (%)			0.15
Optum	1763 (31.8%)	98 (36.2%)	
Marketscan	3788 (68.2%)	173 (63.8%)	
Age, n (%)			
Age at surgery, mean (SD)	8.4 (6.2)	2.9 (4.3)	<0.001
Age, median (IQR)	8 (2–14)	1 (0–4)	
Age < 1 yr, n (%)	963 (17.3%)	130 (48.0%)	<0.001
Age 1–4 yrs, n (%)	904 (16.3%)	78 (28.8%)	
Age ≥5 yrs, n (%)	3684 (66.4%)	63 (23.2%)	
Male sex, n (%)	3199 (57.6%)	124 (45.8%)	<0.001
PFV diagnosis, n (%)	228 (4.1%)	29 (10.7%)	<0.001
IOL placement, n (%)	4170 (75.1%)	144 (53.1%)	<0.001
Nystagmus, n (%)	270 (4.9%)	38 (14.0%)	<0.001
Cataract laterality, n (%)			0.5
Unilateral	4044 (72.9%)	203 (74.9%)	
Bilateral	1507 (27.1%)	68 (25.1%)	
Pre-existing strabismus diagnosis, n (%)	732 (13.2%)	96 (35.4%)	<0.001
Time enrolled in days (SD)	1599 (1132)	1908 (1166)	<0.001
Time between initial cataract surgery and strabismus surgery (days), median (IQR)	NA	378 (218–694.5)	NA

IOL = intraocular lens; IQR = interquartile range; NA = not applicable; PFV = persistent fetal vasculature; SD = standard deviation.

Table 3. Factors Associated with Strabismus Surgery after Pediatric Cataract Surgery from a Multivariable Cox Proportional Regression Model Adjusting for All Covariates

	HR (95% CI)	*P*
Age		
< 1 yr	Reference	
1–4 yrs	0.50 (0.36–0.69)	<0.001
≥ 5 yrs	0.13 (0.09–0.18)	<0.001
Male sex	0.75 (0.59–0.95)	0.018
PFV diagnosis	1.00 (0.66–1.49)	0.99
IOL placement	0.71 (0.54–0.94)	0.016
Nystagmus	1.28 (0.90–1.82)	0.18
Unilateral cataract (reference bilateral)	1.32 (0.99–1.75)	0.056
Strabismus diagnosis before cataract surgery	4.13 (3.17–5.38)	<0.001

CI = confidence interval; HR = hazard ratio, IOL = intraocular lens; PFV = persistent fetal vasculature.

knowledge, our claims-based approach has identified the largest cohort of patients that underwent strabismus surgery after pediatric cataract surgery described in the literature to date.

Unsurprisingly, our study found that unilateral cataract surgery was associated with a higher rate of strabismus surgery. This is similar to previous studies in which unilateral cataract surgery was associated with both a higher rate of strabismus and strabismus surgery.[1,2,4,9,15,20] Regardless of aphakia or pseudophakia, unilateral cataracts can often lead to anisometropia predisposing to strabismus.[21]

In both the univariate and multivariate analyses, pseudophakia was associated with a decreased risk of undergoing strabismus surgery. However, when examining unilateral cataracts in children that underwent cataract surgery at younger than 1 year of age, there was no difference in the rates of strabismus surgery between aphakic and pseudophakic patients. Overall, this is consistent with the overall results reported in IATS at both the 5 and 10 year follow-ups, in which there was no difference in strabismus surgery rates between aphakic and pseudophakic patients. The difference in strabismus rates between aphakic and pseudophakic patients in patients who received bilateral cataract surgery at younger than 1 year of age could be because of different patient populations receiving primary IOL placement. Some other studies have also found a lower prevalence of strabismus (although not strabismus surgery) in pseudophakic compared with aphakic patients, especially considering that many more patients with bilateral cataracts are likely to have systemic disorders or neurodevelopmental impairment.[22,23] Additionally, the IoLunder2 study found that IOL implantation was associated with better visual outcomes in bilateral but not unilateral outcomes; this may also explain differences in strabismus surgery rates.[23]

The distribution of muscles operated on was similar to previously reported studies. More patients in IATS 38/45 (84%) underwent operations on horizontal muscles alone compared with only 68% in our cohort. In both studies, few patients underwent operations on vertical muscles alone (1.5% in our cohort vs. 6.6% in IATS).[11]

The strength of our claims-based approach over previous studies is access to a very large sample size from a nationally representative cohort of patients. This study, which includes outcomes outside of academic centers, complements existing studies such as IATS and the Toddler Aphakia and Pseudophakia Treatment Study that have collected more detailed clinical information. The robust sample size provides enough statistical power to identify potential risk factors and their magnitude of association.

There are several limitations to this study. First, the data are based on administrative claims data, which include few clinically relevant data. An investigation of the risk factors for strabismus surgery would benefit from a deeper understanding of the type and etiology of cataracts, visual acuity, the type of strabismus and the angle of deviation in patients with strabismus, specific muscles operated on, stereoacuity,

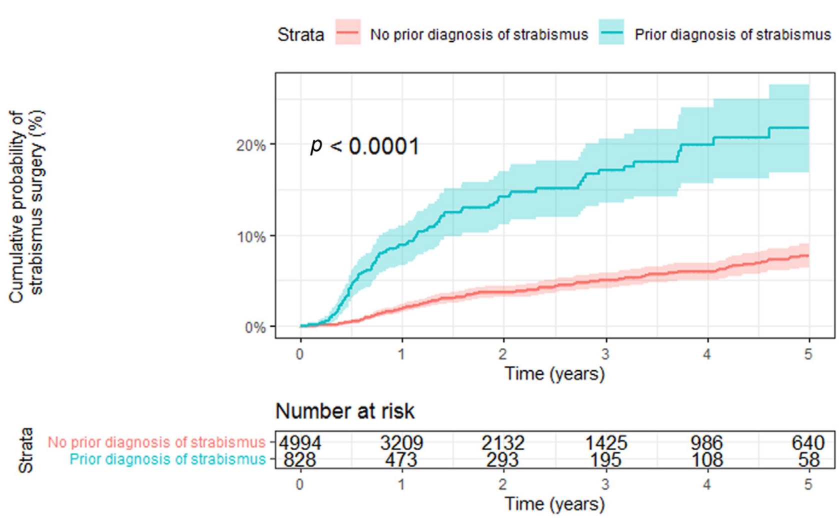

Figure 3. Kaplan–Meier estimate of cumulative incidence of strabismus surgery after pediatric cataract surgery, stratified by strabismus diagnosis before cataract surgery.

Table 4. 5-year Kaplan—Meier Estimates for Rates of Strabismus Surgery by Cataract Laterality and Age at Cataract Surgery

Group	5-yr Estimated Rate of Strabismus Surgery	Lower 95% CI	Upper 95% CI
Unilateral, age at cataract surgery $<$ 1 yr	30.9%	24.1%	37.1%
Bilateral, age at cataract surgery $<$ 1 yr	20.9%	12.8%	28.2%
Unilateral, age at cataract surgery 1—4 yrs	19.5%	14.3%	24.4%
Bilateral, age at cataract surgery 1—4 yrs	13.0%	4.9%	21.5%
Unilateral, age at cataract surgery $\geq$ 5 yrs	3.2%	2.1%	4.3%
Bilateral, age at cataract surgery $\geq$ 5 yrs	3.1%	1.5%	4.6%

CI = confidence interval.

and other aspects of patient history. Second, miscoding of claims data is problematic and is especially prevalent for diagnostic codes. For this reason, we focused on procedural codes, which are tied to physician reimbursement and are more likely to be accurate. We acknowledge this is a more conservative approach, especially given that even many severe cases of strabismus in pediatric patients are not treated surgically. Third, CPT codes often do not contain information on laterality, which may result in a skewed distribution of unilateral and bilateral cataract surgeries, as well as an underestimation of the number of muscles operated on in strabismus surgeries. Fourth, the 6-month lookback period used in this study for children over the age of one may have also been insufficient to capture rates of pre-cataract surgery diagnosis of strabismus. This may lead to overestimation of the rate of strabismus surgeries in patients without a diagnosis of strabismus before cataract surgery. Fifth, the end point used in this study of 5 years after cataract surgery was based on the median length of enrollment in the cohort and may not capture delayed cases of strabismus surgery. The recent 10-year follow-up to the IATS found that approximately 7% of the cohort underwent strabismus surgery between the 5- and 10-year follow-up periods.[12] Sixth, we did not include amblyopia as a risk factor in our analysis because of inconsistent coding of amblyopia diagnosis, lack of visual acuity data, and the fact that essentially all children who undergo cataract surgery have amblyopia to some degree. Seventh, we did not include the type of strabismus in our analysis due to inconsistent coding of strabismus diagnosis. Furthermore, recent evidence shows that infants who undergo unilateral cataract surgery are more likely to be esotropic while younger and exotropic when older, making the type of strabismus a moving target depending on the age of the child.[12] Finally, there is the potential for overlap between the databases used in this study, as employers providing data to IBM MarketScan may also purchase their insurance from the supplier of CDM data. There is also potentially double counting of patients who transfer insurance providers during treatment.

The large nationwide sample provided cumulative incidence estimates for strabismus surgery after cataract surgeries that were lower than previously described cohorts. However, once stratifying by age and pre-existing strabismus diagnoses, the estimates were comparable with previously described studies. Younger age at cataract surgery, female sex, aphakia, and a pre-existing diagnosis of strabismus were predictors of undergoing strabismus surgery after pediatric cataract surgery, and future efforts toward screening would be particularly beneficial in these patients.

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Footnotes and Disclosures

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No animal subjects were included in this study.

Author Contributions:

Conception and design: Hwang, Oke, Lambert

Analysis and interpretation: Hwang, Oke, Lambert

Data collection: Hwang, Oke, Lambert

Obtained funding: Lambert

Overall responsibility: Hwang, Oke, Lambert

Abbreviations and Acronyms:
CPT = Current Procedural Terminology; **CDM** = Optum Clinformatics Data Mart; **CI** = confidence interval; **HR** = hazard ratio; **IATS** = Infant Aphakia Treatment Study; **ICD 9/10** = International Classification of Diseases, Ninth and Tenth Revision; **IOL** = intraocular lens; **PFV** = persistent fetal vasculature; **vs.** = versus.

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