

Risk Factors for Reoperation after Strabismus Surgery among Patients with Thyroid Eye Disease



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- **PURPOSE:** To examine risk factors for strabismus surgery reoperation in patients with thyroid eye disease (TED).
- **DESIGN:** Retrospective cohort study.
- **METHODS:** An insurance claims database was used to identify patients with TED who underwent at least one strabismus operation between 2003 and 2019. We recorded specific muscles operated on, as well as the timing and frequency of reoperations. Cox regressions were used to estimate associations between time to reoperation and patient and primary surgery characteristics.
- **RESULTS:** Of the 448 patients who met inclusion criteria, 111 (24.8%) underwent a reoperation. Patients were followed for an average of 5.4 ± 3.0 years after their initial strabismus surgery. The rates of reoperation among patients whose initial surgery involved horizontal muscles only, vertical muscles only, and horizontal and vertical muscles were 29 of 120 (24.2%), 33 of 169 (19.5%), and 49 of 159 (30.8%) respectively ($P = .05$). The number of muscles operated on initially was the only independent predictor for undergoing a strabismus surgery reoperation (odds ratio, 1.27; 95% confidence interval, 1.03–1.57; $P = .03$). The number of muscles operated on initially was also associated with shorter time to first reoperation (hazard ratio, 1.22; 95% confidence interval, 1.02–1.46; $P = .03$). Age at first surgery, time between diagnosis of TED and first strabismus surgery, gender, race, and use of adjustable sutures were not associated with time to reoperation.
- **CONCLUSIONS:** Approximately 1 in 4 patients with TED require reoperation after strabismus surgery. The number of muscles operated on was the only independent predictor for both undergoing a reoperation and time to first reoperation. (Am J Ophthalmol 2022;238: 10–15. © 2021 Elsevier Inc. All rights reserved.)

THYROID EYE DISEASE (TED), PREVIOUSLY KNOWN AS thyroid-associated ophthalmopathy and Graves' orbitopathy, is an autoimmune condition that develops in approximately 9% of patients with Graves' disease, with an annual incidence of about 19 per 100,000 people.^{1,2} It is caused by autoantibodies against thyroid receptors that activate orbital fibroblasts, in turn causing enlargement of both extraocular muscles and adipose tissue.³ In some patients with TED, inflammation and swelling of the extraocular muscles leads to restrictive strabismus.⁴ Strabismus surgery may be performed to improve muscle alignment and reduce symptomatic diplopia in these patients.⁵ These operations are technically challenging in patients with TED owing to extensive scarring and have an increased risk of reoperation.⁶

A few previous studies and case reports have examined the rate of strabismus reoperation in patients with TED, with sample sizes ranging from 6 patients to 137 patients, and follow-up periods of approximately 1 year.^{7–16} These studies have shown a range of rates of reoperation from 13.1% to 55.3%. However, the majority of these studies are limited by small sample sizes and single-center design.

We conducted this study to investigate rates of strabismus reoperation in patients with TED using a commercial insurance claims dataset. In addition, we aimed to characterize risk factors associated with undergoing a reoperation and the time to first reoperation. Based on a computerized search for "thyroid eye disease" and "strabismus surgery" in PubMed, this is the largest study to date examining strabismus surgery in patients with TED.

METHODS

- **DATA COLLECTION:** This population-based retrospective cohort study was performed using claims data from the Clinformatics Data Mart Database. This database comprises de-identified commercial claims from a large claims data warehouse from 2003 to 2020, covering a total of approximately 66 million lives from a geographically diverse population spanning all 50 US states. This database provides demographic, socioeconomic, and medical claims data for inpatient and outpatient services, including surgical services. The medical claims data use the *International Clas-*

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sification of Diseases, 9th (ICD-9-CM) and 10th Revisions (ICD-10-CM) diagnosis codes and Current Procedural Terminology (CPT) version 4 procedure codes. This analysis was deemed exempt from Stanford University Institutional Review Board approval. Per PHS Data Core policy to prevent de-identification, all cell sizes less than 11 are reported as <11.

• **DATA EXTRACTION AND ANALYSIS:** All beneficiaries 18 years of age or older with newly diagnosed TED who had undergone strabismus surgery were included if they had continuous enrollment from 1 year before the first diagnosis of TED and 1 year after the initial strabismus surgery. The first diagnosis of TED was defined as the first date of strabismus in a patient with Graves' disease. ICD-9, ICD-10, and CPT codes to define Graves' disease, strabismus, and strabismus surgery are listed in Supplementary Table 1. Patients who had a diagnosis of strabismus before a diagnosis of Graves' disease were excluded to preclude erroneously counting reoperations as initial operations. Data extracted for each patient included age at diagnosis of TED, age at first surgery, gender, period of continuous enrollment, race, CPT codes for initial strabismus operation performed, and dates of strabismus surgery reoperations. Laterality data were also available for a subset of patients.

All CPT codes were determined on the first date of strabismus surgery for each patient. The initial operation for each patient was categorized as horizontal muscles only (CPT codes 67311 or 67312), vertical muscles only (CPT codes 67314, 67316, 67318), or both horizontal and vertical muscles. Unilateral and bilateral surgeries were determined using procedure modifier codes where available, with patients with only a single filed claim on a given procedure date assumed to have unilateral surgery. All other patients were considered to have unknown laterality. The number of muscles operated on was determined by multiplying the number of eyes operated on (1 for unilateral surgery, 2 for bilateral surgery) by the number of muscles operated on (1 for CPT codes 67311, 67314, and 67318, which are used for a single muscle in the same eye, and 2 for CPT codes 67312 and 67316, which are for 2 or more muscles in the same eye), then summing across non-duplicated claims. The number of reoperations was determined by counting the number of unique dates of strabismus surgery claims after the initial operation. The use of adjustable sutures during the initial operation was determined using the add-on CPT code 67335.

Comparisons between patients who did and did not undergo reoperations were made using a χ^2 test for independence for categorical variables, a *t* test for continuous variables with 2 groups, and a 1-way analysis of variance for continuous variables with 3 or more groups. Multiple linear regression with the number of reoperations as the independent variable and age at first surgery, gender, race, time between diagnosis of TED and first strabismus surgery, use of adjustable sutures, and the number of muscles operated

on was performed. Multiple logistic regression with reoperation status as the independent variable and the same dependent variables was also performed. Odds ratios (OR) were summarized with their corresponding 95% confidence intervals (CIs). Univariate Cox regression with time to first reoperation as the independent variable and the same dependent variables with the addition of the type of muscles operated on initially was performed. Cox multiple regression with time to first reoperation as the independent variable and age at first surgery, gender, race, time between TED diagnosis and surgery, use of adjustable sutures, and number of muscles initially operated on as dependent variables was performed. The type of initial surgery was highly correlated with the number of muscles initially operated on and was excluded from the multiple regressions to avoid multicollinearity.¹⁷ Hazard ratios (HR) were summarized along with corresponding confidence intervals. Statistical significance was defined as a 2-tailed *P* value of less than .05. Statistical analyses were conducted using R (version 4.0.2).

RESULTS

• **BASELINE CHARACTERISTICS:** A total of 7,601,339,218 claims for 66,228,965 patients were analyzed in the Optum SES Medical Claims dataset (version 4.0) for the period 2003-2020, from which 48,010 patients underwent at least 1 strabismus operation. Strabismus surgery was performed on 448 patients with TED between 2004 and 2019, and 111 of these patients underwent a reoperation (24.8%). The mean age at first operation was 62.7 ± 11.1 years in patients who underwent reoperation and 63.3 ± 12.0 years for patients that did not. Overall, patients tended to be White (349/448 [77.9%]), with a female predominance (305/448 [68.1%]). The mean number of years patients were followed was 9.6 ± 4.0 years, and the mean follow-up after the initial strabismus surgery was 5.4 ± 3.0 years. The baseline demographics were similar between patients who did and did not receive reoperations (Table 1).

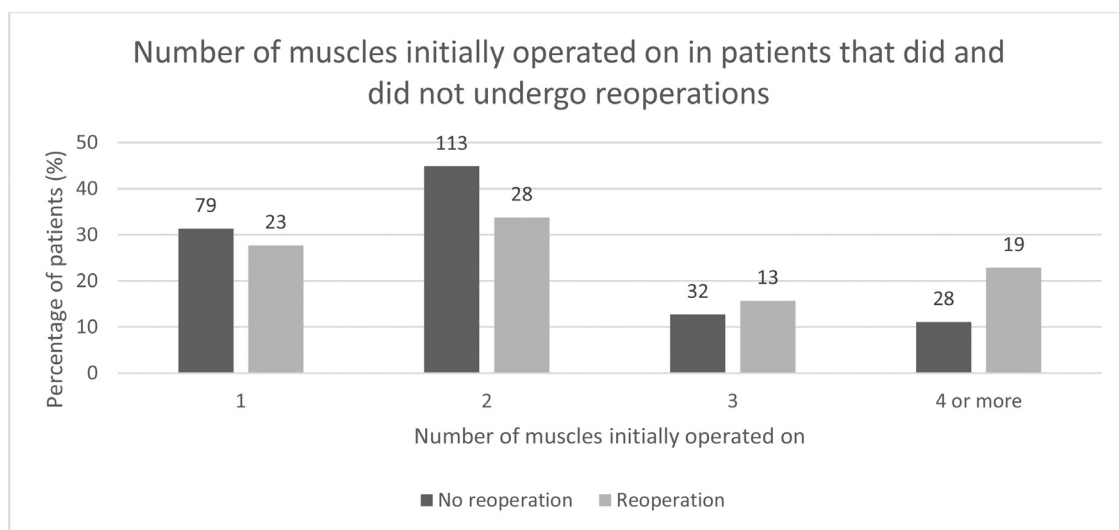
• **CHARACTERISTICS OF INITIAL SURGERIES:** A total of 120 of 448 patients (26.8%) initially underwent surgeries on horizontal muscles only, 169 of 448 patients (37.7%) on vertical muscles only, and 159 of 448 (35.5%) on both horizontal and vertical muscles. The rates of reoperation among patients whose initial surgery involved horizontal muscles only, vertical muscles only, and horizontal and vertical muscles were 29 of 120 (24.2%), 33 of 169 (19.5%), and 49 of 159 (30.8%), respectively (*P* = .06). The mean number of reoperations was 0.30, 0.23, and 0.39 in patients who underwent surgeries on horizontal muscles only, vertical muscles only, and horizontal and vertical muscles, respectively (*P* = .05) (Supplementary Table 2). The mean number of muscles operated on was 1.82, 1.42, and 3.15 in the horizontal muscle only, vertical muscle only, and horizontal

TABLE 1. Baseline Characteristics of 448 Patients with Thyroid Eye Disease Who Underwent a Strabismus Surgery.

	No Reoperation(<i>n</i> = 337)	Reoperation(<i>n</i> = 111)	<i>P</i> Value
Year of first operation			.43
2004–2009	121 (35.9)	38 (34.2)	
2010–2014	96 (28.5)	41 (36.9)	
2015–2019	120 (35.6)	32 (28.8)	
Age	63.3 ± 12.0	62.7 ± 11.1	.46
Sex			.43
Male	119 (35.3)	34 (30.6)	
Female	228 (64.7)	77 (69.4)	
Race			.81
White	262 (77.7)	87 (78.4)	
Non-White	75 (22.3)	24 (21.6)	
Years of continuous enrollment	9.6 ± 4.0	9.7 ± 4.1	.85
Years of follow-up after initial surgery	5.4 ± 3.0	5.4 ± 3.0	.91
Time between TED diagnosis and first strabismus surgery (years)	1.8 ± 1.6	1.5 ± 1.3	.06
Adjustable sutures	139 (41.2)	41 (36.9)	.49

Race was combined for this table to preclude reporting cell sizes of <11. Asian, Black, Hispanic, and unknown/other were grouped as “non-White.” Values are mean ± standard deviation or number (%).

TED = thyroid eye disease.



Note: Percentages were calculated based on the total number of patients in each group. The numbers of patients are shown above each bar.

FIGURE. Percentage of patients by number of muscles initially operated on in those that did and did not undergo reoperation.

and vertical muscles groups, respectively ($P < .001$). The number of muscles operated on in patients that did and did not receive reoperations were 2.07 and 2.42, respectively ($P = .03$) (Figure). Adjustable sutures were used on 139 of 337 patients (41.2%) who did not receive a reoperation and 41 of 111 (36.9%) for patients who did receive a reoperation ($P = .49$). Owing to imperfect coding for laterality, laterality data and the number of muscles operated on for the initial surgery were only available for 336 of the 448 patients.

• **RISK FACTOR FOR UNDERGOING A STRABISMUS SURGERY REOPERATION:** Multiple logistic regression indicated the number of muscles operated on initially was the only independent predictor for undergoing a strabismus reoperation (OR, 1.27; 95% CI, 1.03–1.59; $P = .03$) (Table 2). Furthermore, multiple linear regression demonstrated that the number of muscles operated on initially was the only independent predictor of the number of strabismus surgeries (OR, 1.08; 95% CI, 1.02–1.15; $P = .007$) (Supplementary Table 3). Age at initial surgery, sex, race,

TABLE 2. Odds Ratios for Risk Factors for Strabismus Surgery Reoperation.

	Odds Ratio (95% Confidence Interval)	P Value
Age, years		
18–45	Reference	
45–59	1.79 (0.63–5.94)	.30
60–74	0.97 (0.34–3.23)	.96
≥75	1.10 (0.35–3.89)	.88
Sex		
Male	Reference	
Female	1.40 (0.80–2.50)	.25
Race		
Non-White	1.11 (0.57–2.08)	.74
White	Reference	
Time to first surgery	0.89 (0.72–1.06)	.22
No. of muscles operated on	1.27 (1.03–1.59)	.03
Adjustable sutures	0.86 (0.51–1.45)	.59

TABLE 3. Univariate Hazard Ratios by Prognostic Factor for Time to First Strabismus Surgery Reoperation.

	Hazard Ratio (95% Confidence Interval)	P Value
Age, years		
18–45	Reference	
45–59	1.48 (0.63–3.48)	.37
60–74	1.04 (0.44–2.43)	.94
≥75	1.16 (0.46–2.88)	.76
Sex		
Male	Reference	
Female	1.16 (0.78–1.74)	.46
Race		
Non-White	0.99 (0.63–1.56)	.97
White	Reference	
Time to first surgery	0.89 (0.77–1.03)	.12
No. of muscles operated on	1.25 (1.05–1.48)	.01
Initial surgery type		
Horizontal muscles only	1.29 (0.78–2.13)	.31
Vertical muscles only	Reference	
Horizontal and vertical muscles	1.69 (1.09–2.62)	.02
Adjustable Sutures	0.84 (0.57–1.240)	.38

time to first surgery, and use of adjustable sutures were not independent predictors of either undergoing a reoperation or the number of reoperations.

• **HRS FOR TIME TO FIRST REOPERATION:** The mean time to reoperation among those that received reoperation was 1.04 ± 1.63 years. Univariate Cox analyses indicated the number of muscles operated on (HR, 1.28; 95% CI, 1.05–1.48; $P = .006$) and operating on both horizontal and vertical muscles initially (HR, 1.69; 95% CI, 1.09–2.62; $P = .02$) were predictors of time to first reoperation (Table 3). Multiple Cox regression indicated the number of muscles operated on was an independent predictor of time to reoperation (HR, 1.22; 95% CI, 1.02–1.46; $P = .03$) after controlling for

age at first surgery, race, sex, time between TED diagnosis and surgery, and use of adjustable sutures (Table 4).

• **CHARACTERISTICS OF STRABISMUS SURGERY REOPERATIONS:** Among patients who underwent reoperation and whose initial surgery was on horizontal muscles, 20 of 26 (76.9%) underwent reoperation on horizontal muscles. Similarly, among patients who underwent reoperation and whose initial surgery was on both vertical and horizontal muscles, 24 of 37 (64.8%) underwent a reoperation on vertical and horizontal muscles. However, among patients who underwent reoperation and whose initial surgery was only on vertical muscles, 21 of 48 (43.8%) underwent a reoperation on both vertical and horizontal muscles (Supplementary Table 4).

TABLE 4. Hazard Ratios for Cox Multiple Regression by Prognostic Factor for Time to First Strabismus Surgery Reoperation.

	Hazard ratio (95% CI)	P Value
Age, years		
18–45	Reference	
45–59	1.55 (0.60–4.00)	.37
60–74	0.92 (0.35–2.40)	.86
≥75	1.01 (0.36–2.82)	.99
Sex		
Male	Reference	
Female	1.26 (0.77–2.07)	.35
Race		
Non-White	1.13 (0.66–1.93)	.66
White	Reference	
Time to first surgery	0.91 (0.77–1.07)	.26
No. of muscles operated on	1.22 (1.02–1.46)	.03
Adjustable sutures	0.87 (0.56–1.36)	.54

DISCUSSION

The rate of strabismus surgery for TED, as well as the rate of reoperation, was relatively constant between 2004 and 2019. More females than males underwent strabismus surgery for TED. However, the percentage of females (68.1%) was lower in our study than has been reported in the largest previous study of TED (84% female).¹ The lower percentage of women in our study may be because men generally have more severe disease than women and, as a result, may be more likely to require strabismus surgery.¹⁸ Patients in this study were also older than average patients with TED. This is likely due to the observation that patients older than 60 years of age tend to have more extraocular muscle swelling, as opposed to patients under 40, who tend to have more fat expansion.⁴ Finally, we found that the risk of reoperation increased from about 20% when patients underwent strabismus surgery on 1 or 2 muscles to more than 40% when 4 or muscles were operated on simultaneously.

Previous studies on the rates of strabismus surgery success in patients with TED have reported highly variable results and are limited by smaller sample sizes and shorter follow-up periods. The rate of surgical success has been reported to range from 43% to 82%.^{19–21} In a review in 2004, Mills and associates²² reported a reoperation rate of up to 50% in patients with TED. Nguyen and colleagues⁷ reported reoperations in 44 of 137 (32.1%) patients in a study from 1981 to 1999. More recently, Nicholson and colleagues⁸ reported a 1-year reoperation rate of 22% (13/58) in patients who underwent a variety of strabismus surgeries for TED. Iordanous and colleagues⁹ reported a reoperation rate in 9 of 27 patients (33%), but this study was limited by a short follow-up time (average of 2.4 months). We found a 24.8% overall

strabismus surgery reoperation rate in a large cohort of patients with TED using commercial insurance claims, which is comparable with these previous studies. The advantages of our study over previous reports are a long follow-up time, a larger sample size, and nationally representative data.

We did not find a difference in the reoperation rate among patients with TED who underwent strabismus surgery with or without adjustable sutures. Similarly, Zhang and associates²³ reported no difference in the reoperation rate among patients with TED undergoing strabismus surgery with or without adjustable sutures. The risk of reoperation among patients with TED may not be improved with the use of adjustable sutures because of the difficulty of accurately predicting how their ocular alignment will change after the immediate postoperative period.

We found that the number of muscles operated on was an independent predictor of both risk of reoperation and the time to first reoperation once adjusting for demographics variables. It is likely that the number of muscles operated on initially correlates with disease severity. Unfortunately, disease severity is not a risk factor that either the patient or the surgeon can control.

The time between TED diagnosis and strabismus surgery was not an independent predictor of the time to reoperation or risk of reoperation. This is consistent with Rundle's curve for TED, in which there is an initial inflammatory phase that may last from 6 to 18 months, a subsequent static phase in which inflammation decreases, and a final quiescent phase with gradual improvement. The mean time between diagnosis and first operation was 1.7 years, suggesting that operations were largely taking place in the static phase, during which there would not be a worsening of the patient's TED.²⁴

There are several limitations to our study. First, this study was conducted using claims data, which do not include clinical data, such as angle of deviation, amount of gaze limitation, visual acuity, or stereoacuity. Second, we could not distinguish between operations on the lateral rectus and medial rectus, or between operations on the different vertical muscles. Third, we were unable to investigate patient data outside the enrollment period. Therefore, we may have missed patients who had a remote history of strabismus surgery. However, we excluded patients who underwent previous strabismus surgeries before the diagnosis of TED, with a minimum of a 1-year lookback before diagnosis of TED and an average lookback of 4.3 years before the initial strabismus surgery. Fourth, miscoding may have occurred if a provider submitted the wrong diagnosis or procedure codes. Fifth, it is possible we included patients who underwent strabismus surgery unrelated to TED; however, it is unlikely that an adult with new-onset TED would undergo surgery for unrelated strabismus. Sixth, we were unable to report smoking status, a potential predictor of reoperation, owing to poor sensitivity of insurance claims for determining smoking status.²⁵ Finally, we were only able to ascertain the laterality of surgery for 75% of patients.

In conclusion, our results using claims data reflecting real-world practice in the United States showed a 24.8% reoperation rate in adult patients who underwent strabismus surgery for TED. The number of muscles operated on initially was the strongest independent predictor of

undergoing a reoperation and the time to first reoperation. The mean time to reoperation among those that received reoperation was approximately 1 year. Overall, we believe this work will help with patient education and surgical decision-making.

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