

Return to the Operating Room After Repair of Rhegmatogenous Retinal Detachment

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Purpose: To report the rate of all-cause returns to the operating room (OR) after surgery for rhegmatogenous retinal detachment (RRD).

Patients and Methods: This was a retrospective consecutive case series; 1278 eyes underwent RRD repair from 1/1/2014 to 12/31/2016 at a tertiary care center. A total of 507 eyes returned to the OR. Surgical indication, procedure, number of reoperations, and final vision were recorded.

Results: At least one secondary procedure was performed in 24.9% at 6 months, 34.7% at 1 year, and 39.7% as of last follow-up. The most common indications for reoperation were cataract (43.9%) and recurrent RRD (12.8%). Cornea, glaucoma, and oculoplastic issues were rare (each <1.1%). There was no association between final visual outcome and number of reoperations ($p > 0.05$). SB/PPV had the highest rate of return to OR ($p < 0.001$) but lowest rate of recurrent RRD ($p = 0.007$).

Conclusion: To our knowledge, there are no other large studies that examine all-cause returns to the OR after primary RRD repair. This study provides important risk-benefit and prognostic information to patients undergoing RRD repair.

Keywords: reoperation, complication, recurrent RRD, glaucoma, cornea, oculoplastics

Introduction

Rhegmatogenous retinal detachment (RRD) is an emergent condition occurring in approximately 6.3 to 17.9 per 100,000 population.¹ Incidence is higher in patients in their 7th to 8th decade, in young myopes, and in males.¹ Reoperation for recurrent RRD has been extensively studied,^{2–4} including the need for subsequent cataract removal⁵ and macular hole repair.⁶ However, there is little information in the literature regarding return to the operating room for other indications after RRD repair.

This study examines the proportion of eyes requiring reoperation for any reason after primary RRD repair with specific attention to the time course, indications for reoperation, and types of procedures performed.

Patients and Methods

Ethical approval for this retrospective, consecutive case series was obtained by the Institutional Review Board (IRB)/Ethics Committee for the University of Miami/Miller School of Medicine (ID: 20160347). Informed consent was not applicable in the current study. This research was conducted in accordance with the Declaration of Helsinki. The cases included in the study were identified in the electronic medical record by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and ICD, Tenth Revision, Clinical Modification (ICD-10-CM), codes and Current Procedural Terminology (CPT) codes.

All cases of RRD undergoing primary surgical repair between January 1, 2014 and December 31, 2016 at a tertiary care center were reviewed. Cases that returned to the operating room at any time after the initial RRD repair were included in the study. Exclusion criteria included RRDs associated with open globe injury, endophthalmitis, retinitis,

vitreoretinopathy/connective tissue disorders, and follow-up of less than one week. Data points included patient age, gender, date of initial repair, reoperation date, number of reoperations, date of last follow-up, lens status, surgical indication, and surgical procedure.

Statistical analysis was performed using Statistical Package for the Social Sciences software (SPSS V25.0 Inc, Chicago, Illinois, USA). For the results to have clinical applicability, analysis was focused on determining the proportion of eyes (rather than the proportion of total re-operations) with each surgical indication or procedure. Subgroup analysis was performed by grouping procedures by ophthalmic subspecialty (ie, retina, glaucoma, cornea, plastics). Unpaired *t*-test compared means of two unmatched groups (ie, gender and number of reoperations). Chi-square test compared categorical variables (ie, gender in reoperated eyes vs non-reoperated eyes). Pearson correlation coefficient compared quantitative variables (ie, age and number of reoperations). A *p*-value <0.05 was considered significant.

Results

Patient Demographics and Initial Surgery

From January 1, 2014 through December 31, 2016, 1278 eyes underwent surgical RRD repair at a tertiary care center. The average age was 56.4 years old (standard deviation (SD): 15.8, range: 7.75–98.8 years). Sixty-seven percent (853/1278) were male and 33.2% (425/1278) were female. Combined scleral buckle and pars plana vitrectomy (SB/PPV) was the most common procedure performed (61.2%, 783/1278), followed by PPV (20.7%, 264/1278), and SB (17.6%, 225/1278) (Table 1). Most eyes were phakic (64.1%, 819/1278) while 34.7% (443/1278) were pseudophakic and 1.3% (16/1278) were aphakic. Thirteen eyes underwent lens removal at the time of primary RRD repair. A history of trauma was reported in 11.7% (149/1278). Proliferative vitreoretinopathy (PVR) or epiretinal membrane was documented preoperatively in 15.7% (201/1278).

Reoperation was performed in 39.7% (507/1278) of eyes at the time of last follow-up. The average age of those requiring reoperation was 56.6 years old (standard deviation (SD): 13.3, range: 12.5–91.3 years). Sixty-five percent (330/507) of those requiring reoperation were male and 34.9% (177/507) were female. There was no difference in terms of age (diff = 0.21; 95% CI [−1.67, 2.09]; *p* = 0.83) or gender (χ^2 = 0.80, *p* = 0.37) between eyes that had a reoperation and eyes that did not have a reoperation.

Of the 507 cases requiring reoperation, 70.4% (357/507) had initially undergone primary combined SB/PPV, 17.2% (87/507) received PPV, 11.2% (57/507) received SB, and 1.1% (6/507) underwent pneumatic retinopexy (Table 2). When vitrectomy was performed (*n* = 444), octafluoropropane (C3F8) was the most utilized tamponade agent (59.5%, 264/444), followed by silicone oil (21.6%, 96/444), and sulfur hexafluoride (SF6) (17.8%, 79/444).

Reoperation

Of the 1278 eyes that underwent RRD repair, 27.3% (349/1278) required 1 return to the operating room, 7.9% (101/1278) had 2 reoperations, and 4.4% (57/1278) had 3 or more reoperations. At least one secondary procedure was performed in 24.9% (318/1278) by 6 months, 34.7% (444/1278) by 1 year, and 39.7% (507/1278) as of final follow-up.

Mean follow-up time was 1.3 years (median: 1.1 years, SD 1.0 years, range: 7 days – 4.1 years). Seventy-two percent (914/1278) followed up at least 6 months and 53.4% (682/1278) followed up at least 1 year.

Table 3 details indications for reoperation. Recurrent RRD led to reoperation in 12.8% (163/1278) as of last follow-up. PVR led to reoperation in 5.0% (64/1278) of eyes. It should be noted that PVR was listed as a surgical indication for 64 eyes: 57 of them were associated with recurrent RRD and are included in that statistic, while 7 were surgeries for PVR alone (ie, macular membranes, progressive traction, or high risk of detachment). Notably, 0.2% (3/1278) developed choroidal hemorrhage and 0.1% (1/1278) had an exposed scleral buckle. Surgical intervention was needed for 1.1% (14/1278) of eyes due to the development of a cornea issue (the most common being bullous keratopathy [*n* = 5] and corneal graft failure [*n* = 2]), 1.1% (14/1278) of eyes due to glaucoma unable to be controlled with topical medications only, and 0.2% (3/1278) of eyes due to significant ptosis.

Among eyes that remained phakic after the initial RRD surgery (*n* = 806), CEIOL was performed in 15.4% (124/806) within 6 months, 34.1% (275/806) within 1 year, and 43.9% (354/806) at last follow-up. Among eyes that returned to the OR in the current study (*n* = 507), a large proportion (44%, 223/507) were for cataract extraction only.

Table 1 Initial RRD Repair

	SB	PPV	SB/PPV	Pneumatic	Total
Phakic	216 (26)	94 (11)	506 (62)	3 (0)	819
SF6	41 (19)	33 (35)	63 (12)	2 (66)	139 (16.9)
C3F8	34 (16)	50 (53)	352 (70)	–	436 (53.2)
Air	28 (13)	1 (1)	–	–	29 (3.5)
SO	–	9 (10)	87 (17)	–	96 (11.7)
Unspecified Gas	2 (1)	1 (1)	4 (1)	1 (33)	8 (1)
None	111 (51)	–	–	–	111 (13.6)
Pseudophakic	9 (2)	167 (38)	264 (60)	3 (1)	443
SF6	1 (11)	40 (24)	52 (20)	3 (100)	96 (22)
C3F8	1 (11)	108 (65)	171 (65)	–	280 (63)
Air	–	–	–	–	–
SO	–	15 (9)	35 (13)	–	50 (11)
Unspecified Gas	1 (11)	4 (2)	6 (2)	–	11 (2.5)
None	6 (66)	–	–	–	6 (1)
Aphakic	–	3 (19)	13 (81)	–	16
SF6	–	2 (66)	2 (15)	–	4 (25)
C3F8	–	–	6 (46)	–	6 (38)
Air	–	–	–	–	–
SO	–	1 (33)	5 (38)	–	6 (38)
Unspecified Gas	–	–	–	–	–
None	–	–	–	–	–
	225 (17.6)	264 (20.7)	783 (61.2)	6 (0.5)	1278

Notes: Data displayed as n (%) where % = n/total n for each respective column or row. Data listed are from all primary RRD surgeries from January 2014 through December 2016.

Abbreviations: RRD, rhegmatogenous retinal detachment; SF6, sulfur hexafluoride; C3F8, octafluoropropane; SO, silicone oil; SB, scleral buckle; PPV, pars plana vitrectomy.

Table 2 Initial RRD Repair for Eyes That Required Reoperation

	SB	PPV	SB/PPV	Pneumatic
C3F8	13 (23)	38 (44)	226 (63)	–
SF6	9 (16)	33 (38)	46 (13)	3 (50)
Unspecified Gas	1 (2)	1 (1)	4 (1)	3 (50)
SO	–	15 (17)	81 (23)	–
None	34 (60)	–	–	–
Total	57	87	357	6

Note: Data displayed as n (%) where % = n/total n for each column.

Abbreviations: C3F8, octafluoropropane; SF6, sulfur hexafluoride; SO, silicone oil; SB, scleral buckle; PPV, pars plana vitrectomy.

Table 3 Indication for Reoperation

	Within 6mo	Within 1 Year	Total ^a
Retina			
Recurrent RRD	144 (11.3)	156 (12.2)	163 (12.8)
PVR ^b	49 (3.8)	60 (4.7)	64 (5.0)
Retained SO	64 (5.0)	118 (9.2)	136 (10.6)
ERM	31 (2.4)	48 (3.8)	60 (4.7)
MH	12 (0.9)	15 (1.2)	16 (1.3)
NCVH	3 (0.2)	4 (0.3)	4 (0.3)
Choroidal Hemorrhage	3 (0.2)	3 (0.2)	3 (0.2)
Hypotony	–	2 (0.2)	2 (0.2)
Exposed SB	1 (0.1)	1 (0.1)	1 (0.1)
SB-Associated Diplopia	1 (0.1)	1 (0.1)	1 (0.1)
Vitreous opacities	–	2 (0.2)	2 (0.2)
Lens			
Cataract ^c	124 (15.4)	275 (34.1)	354 (43.9)
Dislocated IOL	6 (0.5)	10 (0.8)	15 (1.3)
RLF	3 (0.2)	4 (0.3)	4 (0.3)
Aphakia	7 (0.5)	13 (1.0)	16 (1.3)
PCO	–	–	1 (0.1)
Cornea			
Band Keratopathy	–	1 (0.1)	1 (0.1)
Cornea Graft Failure	–	–	2 (0.2)
Conjunctival cyst	1 (0.1)	1 (0.1)	1 (0.1)
Bullous Keratopathy	–	1 (0.1)	5 (0.4)
Cornea Scar	–	–	1 (0.1)
Anisometropia	–	1 (0.1)	1 (0.1)
Synechiae	1 (0.1)	1 (0.1)	2 (0.2)
Exposure keratopathy	–	1 (0.1)	1 (0.1)
Glaucoma			
Glaucoma	6 (0.5)	7 (0.5)	14 (1.1)
Plastics			
Ptosis	–	1 (0.1)	3 (0.2)

Notes: ^aData displayed as number (%) of eyes (out of a total n=1278) requiring at least one surgery for the listed indication within 6 months, 1 year, and as of last known follow-up ("Total"). Instances of multiple reoperations for the same indication in the same eye were excluded. ^bTable rows are not mutually exclusive. For example, PVR was listed as a surgical indication for 64 eyes: 57 of them were associated with recurrent RRD while 7 were surgeries for PVR. ^cWhere total n = 806 as this was the total number of phakic eyes following initial RD surgery.

Abbreviations: RRD, rhegmatogenous retinal detachment; PVR, proliferative vitreoretinopathy; SO, silicone oil; ERM, epiretinal membrane; MH, macular hole; NCVH, non-clearing vitreous hemorrhage; SB, scleral buckle; IOL, intraocular lens; RLF, retained lens fragments; PCO, posterior capsular opacity.

Stratifying by type of initial surgery, reoperation rate was highest for eyes that underwent primary SB/PPV (45.6%, 357/783), followed by PPV-only (33.0%, 87/264) and SB-only (25.3%, 57/225). SB/PPV returned to the OR more than expected ($\chi^2 = 35.83$, $p < 0.001$) and had a significantly higher rate of cataract extraction (78.2%, 279/357), compared to PPV-only (67.8%, 59/87) or SB-only (28.1%, 16/57) groups ($\chi^2 = 59.9$, $p < 0.001$). When controlling for cataract extraction, there was no difference in return rates (SB/PPV 20.6% [57/277], PPV 22.2% [38/171], SB 22.2% [2/9], $\chi^2 = 0.18$, $p = 0.92$).

In terms of return to the OR for recurrent RRD, the SB group returned in 17.7% (40/225) cases, PPV in 14.4% (38/264), and SB/PPV in 10.3% (81/783). The SB/PPV group returned to the OR for recurrent RRD significantly less than expected ($\chi^2 = 9.92$, $p = 0.007$).

Table 4 outlines types of secondary procedures performed. Three choroidal hemorrhages required drainage. Two scleral buckles required removal: one for diplopia and one for exposure. Partial or full thickness corneal transplantation and ethylenediaminetetraacetic acid (EDTA) chelation were performed rarely (0.5% and 0.1% respectively). Glaucoma

Table 4 Type of Procedures Performed Excluding Repeat RRD Repair

	Within 6 Months	Within 1 Year	Total ^a
Retina			
Choroidal heme drainage	3 (0.2)	3 (0.2)	3 (0.2)
SB Revision/Removal ^b	2 (0.2)	3 (0.3)	3 (0.3)
Membrane peel for ERM	21 (1.6)	36 (2.8)	49 (3.8)
Macular Hole	12 (0.9)	15 (1.2)	16 (1.3)
Lens			
Secondary IOL	8 (0.6)	15 (1.2)	20 (1.6)
Lens Reposition	2 (0.2)	6 (0.5)	8 (0.6)
Capsulotomy	–	–	1 (0.1)
Cornea			
EDTA chelation	–	1 (0.1)	1 (0.1)
Conjunctival Cyst removal	1 (0.1)	1 (0.1)	1 (0.1)
DSAEK	–	–	3 (0.2)
PK	–	–	4 (0.3)
Synechiolysis	1 (0.1)	1 (0.1)	2 (0.2)
Glaucoma			
CPC	1 (0.1)	2 (0.2)	3 (0.2)
GATT	–	–	1 (0.1)
GDI	2 (0.2)	2 (0.2)	5 (0.4)
Plastics			
CMMR/ELA	–	1 (0.1)	3 (0.2)

Notes: ^aData displayed as number (%) of eyes (out of a total n=1278). Instances of multiple reoperations of the same procedure in the same eye were not included. ^bWhere total n=1008 as this was the total number of eyes with a scleral buckle either after the initial RD repair or subsequent reoperation.

Abbreviations: SB, scleral buckle; ERM, epiretinal membrane; IOL, intraocular lens; EDTA, ethylenediaminetetraacetic acid; DSAEK, Descemet stripping automated endothelial keratoplasty; PK, penetrating keratoplasty; CPC, cyclophotocoagulation; GATT, gonioscopy-assisted transluminal trabeculotomy; GDI, glaucoma drainage implant; CMMR, conjunctival Müller's muscle resection; ELA, external levator advancement.

procedures were performed in 9 eyes and included 5 glaucoma drainage implants (GDI), 3 cyclophotocoagulations (CPC), and 1 Gonioscopy-Assisted Transluminal Trabeculotomy (GATT). Ptosis repair was performed in 3 cases: 2 eyes received levator advancements and 1 underwent conjunctival Müller's muscle resection (CMMR).

Table 5 illustrates the specific procedure performed in each case of reoperation for recurrent RRD or PVR ($n = 170$, including 163 recurrent RRDs and 7 cases of PVR-only). Silicone oil was the most frequent choice for tamponade agent in the first (59.4%, 101/170), second (62%, 31/50), and third reoperations (76.5%, 13/17) followed by C3F8 and SF6. Of the 170 eyes that did not receive a scleral buckle during primary repair, 19% (33/170) required a scleral buckle during reoperation.

Among eyes that returned to the OR, there was no association between gender (diff: -0.04 ; 95% CI $[-0.18, 0.10]$; $p = 0.55$) or age ($r = -0.09$) with the number of reoperations. There was no association between final BCVA and reoperation ($p = 0.75$) or number of reoperations (-0.02 ; 95% CI $[-0.19, 0.15]$; $p = 0.85$).

Discussion

The results of this study provide important risk-benefit and prognostic information for patients undergoing RRD surgery. To our knowledge, there are no other large studies in the literature that examine all-cause returns to the OR after primary RRD repair.

The IRIS registry, a nationwide clinical data repository, has been used to study returns to the OR after macular hole, epiretinal membrane, and vitreous floater surgery – but not RRD repair. Parke and Lum⁷ showed a reoperation rate of 18.3% after macular hole repair and 17.0% after epiretinal membrane repair. Rubino et al⁸ found a reoperation rate of 18.7% after vitrectomy for floaters. Registry data are powerful given the quantity of information. However, potential drawbacks may include coding errors which may lead to inaccurate case inclusions or exclusions, lack of follow-up data, inaccessibility to data points easily found via charting, and sampling bias given most registry participants are private practices.⁷ In comparison, the current study has a strong sample size with full access by authors to chart data. Unlike a registry study that compiles CPT codes without context, individual operative notes were reviewed in this study, ensuring accurate case inclusion and precise reporting of reoperation rates.

Many non-registry studies in the literature evaluate the single operation success rate (SOSR) after RRD repair. Heimann et al⁹ demonstrated in the Scleral Buckling versus Primary Vitrectomy Study that recurrent detachment rates were 25.1–26.3% in phakic eyes and 20.4–39.8% in pseudophakic eyes at 1 year. Hajari et al² found a similar rate, while Brazitikos et al¹⁰ reported 17% in a SB-only group and 6% in a PPV group. In comparison, our data showed a recurrent detachment rate of 17.7% in SB, 14.4% in PPV, 10.3% in SB-PPV, and an overall redetachment rate of 12.8%. The SB/PPV group had the lowest rate of recurrent RRD ($p = 0.007$) but did return to the OR more frequently ($p < 0.001$), likely

Table 5 Surgical Procedures for Recurrent Detachment or PVR

	1st Reop	2nd Reop	3rd Reop	4th Reop	5th Reop
PPV/SF6	16 (9)	7 (14)	2 (12)	–	–
PPV/C3F8	46 (27)	12 (24)	2 (12)	2 (67)	–
PPV/SOI	101 (59)	31 (62)	13 (77)	1 (33)	1 (100)
MP	81 (458)	38 (76)	12 (71)	1 (33)	–
SB	27 (16)	5 (10)	–	1 (33)	–
Retinectomy	21 (12)	6 (12)	1 (6)	–	–
Total	170	50	17	3	1

Notes: Data displayed for each reoperation in which recurrent detachment or proliferative vitreoretinopathy (PVR) was listed as the indication. Data displayed as $n(\%)$ where $\% = n/\text{total } n$ for each column.

Abbreviations: SF6, sulfur hexafluoride; C3F8, octafluoropropane; SO, silicone oil; MP, membrane peel; SB, scleral buckle.

due to having the highest rate of cataract extraction ($p < 0.001$). Initial surgical choice did not influence return rates when controlling for cataract extraction ($p = 0.92$).

Macular hole development after RRD repair was previously studied at our institution. Fifteen patients developed a macular hole after RRD repair over 5 years,⁶ while another series showed 12 eyes (0.5%) over 8 years.¹¹ The current study showed a comparable rate of 1.3%.

Cataract extraction rate after RRD repair has varied reports in the literature owing to differences in vitrectomy gauge, tamponade, and follow-up. Feng and Adelman found rates as high as 50% at 1 year after combined PPV-SB.¹² A 23g PPV group had a 16% cataract extraction rate at 6 months,¹³ while a 25g PPV with silicone oil group had a 44% rate at 5 months.¹⁴ In the current study, 15.4% (124/806) underwent CEIOL at 6 months and 34.1% (275/806) at 1 year.

There is relatively little research on corneal complications after vitreoretinal surgery. However, corneal decompensation is common after silicone oil tamponade, with a reported range of 4.5% to 63%.¹⁵ Silicone oil is thought to induce endothelial cell damage, decreasing cell density up to 40% and leading to the development of retrocorneal membranes.¹⁶ Paradoxically, when the oil is removed, the stroma can hydrate, leading to corneal edema. Even without silicone oil, endothelial decompensation has been reported after vitrectomy.^{17,18} In eyes with a history of photorefractive keratectomy (PRK), subepithelial scarring may develop – a phenomenon termed late-onset corneal haze (LOCH).^{19,20} In the current study, only 7 eyes required cornea transplant and all had history predisposing to corneal decompensation: two had a history of PK due to keratoconus and the remaining 5 had silicone oil in the anterior chamber.

Secondary glaucoma occurs in approximately 15–20% after vitreoretinal surgery.^{21,22} This is usually attributed to tamponade overfill, direct tamponade obstruction of aqueous outflow, or pupillary block. In one series of vitrectomized eyes, glaucoma surgery was required in 39% (27/70): 27% (19/70) CPC, 6% (4/70) trabeculectomy, 4% (3/70) GDI, and 1% (1/70) peripheral iridotomy at 4 years.²³ The authors noted these numbers were overestimates due to referral bias, and that secondary glaucoma occurred at an estimated rate of 4.8%. In the current study, glaucoma procedures were even more infrequent (1.1%) with GDI being most common. No eyes received trabeculectomy. Two eyes underwent silicone oil removal due to elevated IOP, which has been shown to improve IOP even without filtering surgery.²⁴

Oculoplastic procedures are also needed after RRD repair.^{25,26} Altieri et al²⁶ reported a ptosis rate of 6.7% and that 5.5% underwent surgical repair. The authors noted the patients were not told during the consent process that ptosis was a possible risk. In the current series, only 0.2% required ptosis repair.

The current study has several inherent limitations. As a tertiary care center, there is an intrinsic sampling bias for eyes with multiple comorbidities and complex retinal detachments. This is reflected in the high rate of preoperative PVR and trauma history in the initial sample set. This could explain the relatively higher proportion of SB/PPV performed compared to SB or PPV alone. Following modern trends in the literature, PPV only was performed more frequently in pseudophakics than phakics (38% vs 11%) and SB only was performed more frequently in phakics than pseudophakics (26% vs 2%). Therefore, this data is generally applicable with the caveat that it may represent reoperation rates of eyes with more complex detachments and comorbidities to begin with, which would be expected from a tertiary care academic center. As a retrospective trial, it was not possible to control for inter-physician variability in surgical decision-making that could have contributed to the need for secondary procedures. While there was a relatively strong rate of follow-up in the current study (71.5% at 6 months), it was not possible to account for reoperations that may have been completed elsewhere. Given this fact, a minimum follow-up of one week was selected to eliminate cases that may have returned to a referring provider immediately after surgery while capturing as many reoperations at our institution as possible. Although an arbitrarily longer follow-up requirement (ie, 1 year) is more ideal, it would have led to identifying less reoperations (particularly early or rare ones), which goes against the principal goal of this study.

While several studies have focused on the rate of specific secondary procedures after RRD repair, the strength of the current study is that it is the first to simultaneously look at all-cause returns to the operating room in a specific cohort of eyes after RRD repair for the complete length of their follow-up. This gives a more realistic comparison of prevalence of different secondary procedures, rather than extrapolating from registry data or studies with disparate clinical settings and follow-up.

Conclusion

After primary RRD repair, 39.7% eyes returned to the operating room for a secondary procedure. The most common indication was cataract followed by recurrent RRD. Cornea, glaucoma, and oculoplastic issues were rare. Most eyes only required one reoperation, and final visual acuity was not associated with number of reoperations. The SB/PPV group had the lowest rate of recurrent RRD but did return to the OR more frequently and had the highest rate of cataract extraction. These results provide valuable prognostic information for counseling patients about RRD repair.

Ethics

Ethical approval for this study was obtained by the Institutional Review Board (IRB)/Ethics Committee for the University of Miami/Miller School of Medicine (ID: 20160347). This research was conducted in accordance with the Declaration of Helsinki. The collection and evaluation of all protect patient health information was performed in a Health Insurance Portability and Accountability Act (HIPAA)-compliant manner.

Disclosure

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