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Scolozzi, Paolo; Bachelet, Jean-Thomas; Courvoisier, Delphine

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Are Inferior Rectus Muscle Displacement and the Fracture's Size Associated With Surgical Repair Decisions and Clinical Outcomes in Patients With Pure Blowout Orbital Fracture?

*Paolo Scolozzi, MD, DMD,**
Jean-Thomas Bachelet, MD,† and Delphine S. Courvoisier, PhD‡

Purpose: Although orbital blowout fractures are common, there is no consensus with respect to treatment decision making and long-term outcome. The purpose of this study was to evaluate the association between inferior rectus muscle (IRM) displacement and fracture size and the surgical repair decisions and clinical outcomes in patients with blowout fractures (BOFs).

Patients and Methods: We designed a prospective cohort study and enrolled all patients who presented to the University Hospital of Geneva for evaluation of a BOF. The primary predictor variables were the IRM grade, measuring the severity of downward displacement of the IRM relative to the level of the fracture's edge (mild [grade I], moderate [grade II], or severe [grade III]), and fracture size. The primary outcome was surgical repair. The secondary outcomes were post-trauma diplopia (at baseline and at 10 days) and persistent annoying diplopia and/or enophthalmos considered independently or as a composite outcome. Other study variables included demographic and injury-related parameters. Descriptive, bivariate, and multiple logistic regression statistics were computed, and the significance level was set at $P \leq .05$.

Results: The sample was composed of 108 patients with a mean age of 46.8 ± 23 years; 73.1% were men. The IRM grade was associated with surgical repair ($P < .001$), post-trauma diplopia ($P < .001$), and the composite outcome ($P = .003$). Fracture size was associated with enophthalmos ($P = .03$) and the composite outcome ($P = .009$). In the adjusted model, only IRM grades II and III were associated with the decision for surgical repair ($P < .001$).

Conclusions: The results of this study suggest that the IRM grade, unlike fracture size, may be a valid measurement in surgical decision making, as well as in determining BOF severity, as evidenced by the correlation between the IRM grade and surgical repair, as well as clinical outcome.

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Received from Division of Oral and Maxillofacial Surgery, Department of Surgery, University of Geneva & University Hospitals of Geneva, Geneva, Switzerland.

*Head, Faculty of Medicine.

†Chief Resident.

‡Biostatistician, Faculty of Medicine.

Drs Scolozzi and Bachelet contributed equally to this work.

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Address correspondence and reprint requests to Dr Scolozzi: Division of Oral and Maxillofacial Surgery, Department of Surgery, Faculty of Medicine, University of Geneva & University Hospitals of Geneva, Geneva, Switzerland; e-mail: paolo.scolozzi@hcuge.ch

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Despite substantial reports in the literature, the management of blowout fractures (BOFs) of the orbital floor remains a source of heated debate. In recent years, greater comprehension of the pathophysiology of a BOF together with dramatic advances in diagnostic and surgical-technological support have led to remarkable improvements in the management of such fractures.[1-11] However, no international consensus or guidelines exist. The 3 following questions are still awaiting definitive and valid answers: What are the irrefutable criteria for surgical repair decisions for a BOF? What is the ideal timing for surgery? What is the correct material for orbital floor reconstruction?[6-8]

Historically, until the end of the 1960s, the decision to explore a BOF surgically was based entirely on the presence of clinical signs, especially motility disorders such as diplopia.[6,7,12-14] In most cases, BOFs were considered medical emergencies and thus a consensus toward immediate exploratory surgery of all BOFs rapidly emerged.[6,7,12-16] This was dictated by the feeling that if surgery was not performed within the first few weeks, persistent handicapping diplopia and disfiguring enophthalmos would occur. Progressively, from the early 1970s, the tide began to turn because of studies that questioned the previous attitude.[17-19] In fact, some authors reported impressively good long-term results by adopting an observational approach for 4 to 6 months.[17-19] They showed that spontaneous recovery occurs in most cases, thus limiting the need for surgical repair to the very few cases of ocular motility associated with visually handicapping diplopia on downward gaze that interfered with such daily activities as reading and walking.[17-19] Other authors developed additional guidelines proposing a waiting period of 14 days beyond which cases with persistent diplopia in primary gaze with restricted ocular motility should undergo surgery. This modification seemed a wise compromise and is still used in several centers.[6,7,14,16,20-25]

The advent of the computed tomography (CT) scan provided new insights into the structure of the orbits by showing the relationship between the bony and soft tissue components. This rapidly led to a new start in the comprehension of the possible mechanism underlying the occurrence of diplopia and enophthalmos in BOFs.[26,27]

At first, studies focused on the extraocular muscles (EOMs), speculating on the possible Volkmann contracture, by analogy with the peripheral muscles, as the main cause of motility disorders in BOFs.[28,29] Others showed that the position and swelling of the inferior rectus muscle (IRM) in relation to the fracture were associated with persistent diplopia outcomes.[30-40]

To date, only a few retrospective studies have reported specifically on the predictive value of the degree of displacement of the IRM into the maxillary sinus as assessed on CT scans for residual diplopia and/or enophthalmos.[30-40] However, no prospective studies have assessed the predictive value of displacement of the IRM into the maxillary sinus in determining the need for surgical treatment in BOFs and/or preoperative diplopia.

The purpose of this study was to answer the following clinical question: In patients with BOFs, are IRM displacement and fracture size associated with the surgical repair decisions and clinical outcomes? We hypothesized that the severity of IRM displacement and fracture size could be associated with the decision for surgical repair and the clinical outcome (ie, post-trauma and long-term annoying diplopia and/or enophthalmos). The specific aims of the study were to *1)* measure the association between IRM displacement and fracture size and the surgical repair decision, as well as post-trauma and long-term annoying diplopia and enophthalmos, and *2)* identify other variables related to the trauma that contributed to the occurrence of post-trauma and long-term annoying diplopia and enophthalmos.

Patients and Methods

STUDY DESIGN

To address the research purpose, we designed and implemented a prospective cohort study. The study was conducted in accordance with the Declaration of Helsinki and was approved by our local ethical board (study No. 12-255).

STUDY SAMPLE

The study population was composed of all patients presenting for evaluation and management of BOFs at the University Hospital of Geneva, Geneva, Switzerland, between 2012 and 2018. To be included in the study sample, patients had to undergo at least a 1-year period of medical and ophthalmologic follow-up. Patients were excluded from the study if they *1)* were younger than 16 years, *2)* had a history of orbital and/or ophthalmologic surgery, *3)* had a follow-up period of less than 1 year, *4)* had impure orbital fractures, or *5)* had monocular vision or non-stereoscopic vision.

The decision for surgical repair was based on our in-house clinical protocol as follows: *1)* immediate ocular motility restriction on vertical gaze in at least 1 field of the gaze and/or primary gaze diplopia that warranted urgent management or annoying diplopia* not

*Annoying diplopia was defined as double vision interfering with the normal accomplishment of common daily tasks such as reading, walking, and driving.

resolving at the 10-day follow-up examination and *2)* enophthalmos[†] immediately obvious to the naked eye and persisting at the 10-day follow-up examination.

Surgical repair was performed via a transconjunctival approach and the defect was reconstructed using preformed titanium orbital meshes (Matrix MIDFACE; Synthes, Oberdorf, Switzerland) according to a technique previously reported.[5] All patients underwent an immediate (within 6 hours) ophthalmologic assessment (visual acuity, eyelid, conjunctival, corneal and pupil examination; ophthalmoscopy; slit-lamp examination; tonometry; EOM evaluation; and visual-field testing) on the day of trauma.

A comprehensive orthoptic assessment (measurements of binocular misalignment using an alternate prism cover test in all 9 cardinal gaze directions at a distance of 6 m and Hess-Weiss coordimetry, horizontal-vertical and incyclotorsion-excyclotorsion deviation with Harms wall deviometry, torsional deviations of the visual axis with Maddox rod screen testing, the Bielschowsky head-tilt test, and Hertel exophthalmometry) also was performed within 48 hours of the injury and at follow-up intervals of 10 days and 1, 3, 6, and 12 months.

CT SCAN DIAGNOSIS

Diagnosis of the orbital fracture was obtained using one of two 64-slice CT scanning systems (Siemens Sensation 64 [Erlangen, Germany] or GE Healthcare CT750 HD scanning system [Buckinghamshire, United Kingdom]). All CT scan images were simultaneously reviewed in the axial, coronal, and sagittal planes with OsiriX Imaging Software (version 3.0.2, 64 bit; Pixmeo, Geneva, Switzerland; www.osirix-viewer.com) running on MacOSX (version 10.8.5; Apple, Cupertino, CA).

The severity of the fracture was based on the following radiologic parameters: *1)* The degree of downward displacement of the IRM relative to the level of the fracture's edge was classified as either mild (grade I; IRM within the orbit), moderate (grade II; most of the IRM within the orbit), or severe (grade III; most of the IRM within the maxillary sinus) (Fig 1). *2)* The defect size of the fracture was calculated according to the computational method previously described and validated and was classified as either mild (<2 cm^2), moderate (2 to 3 cm^2), or severe (>3 cm^2).[2]

STUDY VARIABLES

The predictor variables were IRM displacement and fracture size. The primary outcome variable was the decision for surgical repair. The secondary outcomes were post-trauma preoperative[‡] and persistent annoying diplopia and/or enophthalmos either independently or included as a composite outcome. Other study variables included age, gender, mechanism of injury, cause of injury, and type of treatment (surgical vs conservative).

STATISTICAL ANALYSIS

Patient characteristics were compared across IRM grades of severity or fracture sizes using the Fisher exact test or Wilcoxon rank sum test. To assess the association of either grade or fracture size greater than 2 cm^2, we used univariate logistic regression adjusting for surgery. Finally, to estimate the strength of these associations, we used the Nagelkerke R^2, which ranges between 0 and 100%, indicating how much the variables in the logistic regression are informative on the outcome, with 0% indicating no information on the outcome and 100% indicating a perfect prediction of the outcome.

The significance level was set at $P \leq .05$. All analyses were performed using R statistical software (version 3.6.3; R Development Core Team, Vienna, Austria).

Results

During the study interval, 108 patients fulfilled the inclusion criteria. The sample's mean age at the time of trauma was 46.8 ± 23 years, with a male predominance (79 patients, 73.1%). Table 1 presents the descriptive statistics. The most common etiology was assault (70.1%). Most fractures (95, 88%) presented with a mild or moderate degree of downward displacement of the IRM (grade I or II) and had a mild to moderate defect of up to 2 cm^2 (93, 86.1%). Of the 108 patients, 34 (31.5%) received surgery. Four patients had annoying diplopia at 1 year, corresponding to a prevalence of 3.7% (95% confidence interval [CI], 1.0 to 9.2%). Six other patients had enophthalmos, corresponding to a prevalence of 5.6% (95% CI, 2.1 to 11.7%).

Table 2 presents bivariate associations between the study variables and the predictor variable IRM grade. Fracture size, decision for surgical repair, diplopia at baseline and at 10 days, enophthalmos at 1 year, and the composite outcome (enophthalmos

[†] Enophthalmos was defined as a difference of at least 2 mm between the 2 eyes as measured by Hertel exophthalmometry.

[‡] Post-trauma preoperative diplopia was defined as double vision at baseline (the day of trauma) and at 10 days after trauma.

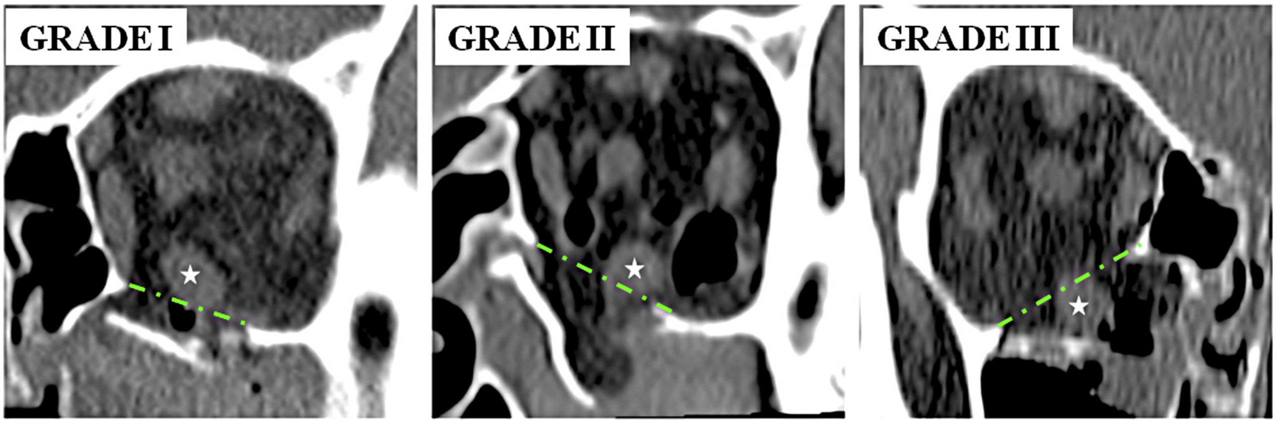

FIGURE 1. Coronal computed tomography scan images showing degree of downward displacement of inferior rectus muscle *(stars)* relative to level of fracture edge. The *green lines* are virtual lines connecting the medial and lateral edges of the orbital floor fracture.

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Table 1. SUMMARY OF STUDY VARIABLES

Study Variable	Data
Demographic variables	
Sample size	108
Age, mean ± SD, yr	46.8 ± 23
Gender, n (%)	
Men	79 (73.1)
Women	29 (27.9)
Fracture variables, n (%)	
Etiology	
Assault	39 (70.1)
Fall	33 (30.6)
Traffic accident	22 (20.4)
Sport accident	14 (13)
IRM grade	
I	64 (59.2)
II	31 (28.7)
III	13 (12)
Fracture size	
<2 cm^2	51 (47.2)
2-3 cm^2	42 (38.9)
>3 cm^2	15 (13.9)
Pretreatment variables, n (%)	
Diplopia at baseline	46 (42.3)
Diplopia at 10 days	34 (31.5)
Treatment variables, n (%)	
Surgical repair	34 (31.5)
Conservative	74 (68.5)
Post-treatment variables (1 yr), n (%)	
Annoying diplopia	4 (3.7)
Enophthalmos > 2 mm	6 (5.6)
Annoying diplopia or enophthalmos	10 (9.2)

Abbreviations: IRM, inferior rectus muscle; SD, standard deviation.

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or annoying diplopia at 1 year) were all significantly associated with IRM grade. Table 3 presents bivariate associations between the study variables and the predictor variable fracture size. Male gender, enophthalmos at 1 year, and the composite outcome were significantly associated with fracture size.

In Table 4, study variables are compared with the primary outcome variable, surgical repair. Age and diplopia at baseline and at 10 days were statistically associated with surgical repair.

Table 5 presents the association between the primary predictors (IRM grade and fracture size) and the primary outcome of surgical repair. Unlike fracture size, the IRM grade was significantly associated with surgical repair.

Table 6 presents the association between the primary predictors (IRM grade and fracture size) and the secondary outcomes. The IRM grade was significantly associated with diplopia at baseline and at 10 days, enophthalmos at 1 year, and the composite outcome (enophthalmos or annoying diplopia at 1 year), whereas fracture size was associated with enophthalmos at 1 year and the composite outcome.

Tables 7 and 8 present the multiple logistic regression model to measure the association between IRM grade and fracture size, respectively, and the primary outcome (surgical repair) adjusted for gender, age, and etiology. IRM grade II (odds ratio [OR], 1.49; 95% CI, 1.28 to 1.75; $P < .001$), IRM grade III (OR, 2.18; 95% CI, 1.75 to 2.71; $P < .001$), and age (OR, 1; 95% CI, 0.99 to 1.00; $P < .001$) were significantly associated with the decision for surgical repair. Conversely, fracture size was not associated with surgical repair.

Discussion

The purpose of this study was to assess the association between IRM displacement and fracture size and

Table 2. SUMMARY OF STUDY VARIABLES VERSUS IRM GRADE

	IRM Grade			
	I	II	III	*P* Value
Demographic variables				
Sample size, n (%)	64 (59.2)	31 (28.7)	13 (12.0)	
Age, mean ± SD, yr	50.2 ± 23.8	43.3 ± 22.9	38.2 ± 15.8	.14
Gender, n (%)				
Men	45 (70.3)	25 (80.6)	9 (69.2)	.517
Women	19 (29.7)	6 (19.4)	4 (30.8)	
Fracture variables, n (%)				
Etiology				.878
Assault	21 (32.8)	13 (41.9)	5 (38.5)	
Fall	23 (35.9)	7 (22.6)	3 (23.1)	
Traffic accident	12 (18.8)	7 (22.6)	3 (23.1)	
Sport accident	8 (12.5)	4 (12.9)	2 (15.4)	
Fracture size				.018*
<2 cm^2	37 (57.8)	12 (38.7)	2 (15.4)	
2-3 cm^2	22 (34.4)	13 (41.9)	7 (53.8)	
>3 cm^2	5 (7.8)	6 (19.4)	4 (30.8)	
Pretreatment variables, n (%)				
Diplopia at baseline	19 (29.7)	15 (48.4)	12 (92.3)	<.001*
Diplopia at 10 days	6 (9.4)	16 (51.6)	12 (92.3)	<.001*
Treatment variables, n (%)				
Surgical repair	6 (9.4)	16 (51.6)	12 (92.3)	<.001*
Conservative	58 (90.6)	15 (48.4)	1 (7.7)	
Post-treatment variables (1 yr), n (%)				
Annoying diplopia	1 (1.6)	1 (3.2)	2 (15.4)	.058
Enophthalmos > 2 mm	2 (3.1)	1 (3.3)	3 (23.1)	.031
Annoying diplopia or enophthalmos	3 (4.7)	2 (6.7)	5 (38.5)	.003*

Abbreviations: IRM, inferior rectus muscle; SD, standard deviation.
* Statistically significant ($P \leq .05$).

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the surgical repair decision, as well as the clinical outcome, in patients with pure BOFs. We hypothesized that the severity of IRM displacement and the defect size could be associated with the need for surgical repair, as well as the post-trauma and long-term annoying diplopia and/or enophthalmos outcomes. The specific aims of the study were to *1)* measure the association between IRM displacement and fracture size and the surgical repair decision, as well as post-trauma and long-term annoying diplopia and enophthalmos, and *2)* identify other variables related to the trauma that contributed to the occurrence of post-trauma and long-term annoying diplopia and enophthalmos.

The results of this study partially supported our hypothesis. We found a significant association between the degree of IRM displacement and the need for surgical repair and post-trauma preoperative and long-term annoying diplopia as well as enophthalmos in patients with BOFs. Although an association between fracture size and the degree of IRM displacement also was found, fracture size alone was predictive only for enophthalmos but not for surgical repair or annoying diplopia. To our knowledge, this relationship has not been shown previously.

Regarding the management of orbital fractures, the only certainty that emerges from the literature is that the decision for surgery relies on empirical in-house algorithms based on clinical and radiologic grounds without consensus. Thus far, studies have been primarily focused on clinical prognostic factors and have reported severe diplopia immediately after trauma and/or persisting at 10 to 14 days and patient age as the most important predictors of the decision for surgical exploration.[1,3,4,9,10,13,14,21,24,25,40] These elements strongly contributed to the generally accepted approach to wait for a 1- to 2-week observation period before deciding on a definitive management strategy, with the exception of pediatric fractures. By contrast, only a few studies have reported on the predictive value of initial diplopia for persistent long-term annoying diplopia.[1,3,9,10,24,25] The

Table 3. SUMMARY OF STUDY VARIABLES VERSUS FRACTURE SIZE

	Fracture Size			
	<2 cm^2	2-3 cm^2	>3 cm^2	*P* Value
Demographic variables				
Sample size	51 (47.2)	42 (38.9)	15 (13.9)	
Age, mean ± SD, yr	47.0 ± 23.1	46.1 ± 23.6	47.8 ± 22.2	.97
Gender, n (%)				
Men	31 (60.8)	34 (81.0)	14 (93.3)	.018*
Women	20 (39.2)	8 (19.0)	1 (6.7)	
Fracture variables, n (%)				
Etiology				.758
Assault	17 (33.3)	15 (35.7)	7 (46.7)	
Fall	17 (33.3)	12 (28.6)	4 (26.7)	
Traffic accident	8 (15.7)	11 (26.2)	3 (20.0)	
Sport accident	9 (17.6)	4 (9.5)	1 (6.7)	
IRM grade				.018*
I	37 (72.5)	22 (52.4)	5 (33.3)	
II	12 (23.5)	13 (31.0)	6 (40.0)	
III	2 (3.9)	7 (16.7)	4 (26.7)	
Pretreatment variables, n (%)				
Diplopia at baseline	20 (39.2)	16 (38.1)	10 (66.7)	.145
Diplopia at 10 days	15 (29.4)	12 (28.6)	7 (46.7)	.398
Treatment variables, n (%)				
Surgical repair	15 (29.4)	12 (28.6)	7 (46.7)	.398
Conservative	36 (71.6)	30 (72.4)	8 (53.3)	
Post-treatment variables (1 yr), n (%)				
Annoying diplopia	0 (0.0)	3 (7.1)	1 (6.7)	.103
Enophthalmos > 2 mm	1 (2.0)	2 (4.8)	3 (4.8)	.033*
Annoying diplopia or enophthalmos	1 (2.0)	5 (11.9)	4 (28.6)	.009*

Abbreviations: IRM, inferior rectus muscle; SD, standard deviation.
* Statistically significant ($P \leq .05$).

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occurrence of the development of enophthalmos has been mainly related to orbital volume increase rather than fracture size.[26,27]

A few studies have reported on fracture size measured on CT scan images and/or IRM changes (morphologic and positional) as radiologic predictors for the decision for surgery and persistence of diplopia and/or enophthalmos in patients with BOFs. Gilbard et al[30] were the first authors to evaluate the possible association between CT scan findings and long-term outcomes in patients with BOFs. They assessed orbital volume expansion, periorbital herniation, and IRM position in 19 patients. They found a proportional correlation between the amount of herniation and orbital expansion and the risk of enophthalmos development. They also determined that IRM position was the most reliable predictor of continued diplopia. No details were given concerning the final management of these patients or the test used for the assessment of diplopia.

Jin et al[31] retrospectively reviewed the records of 63 patients who underwent surgical repair of BOFs to evaluate CT scan risk factors for residual postoperative diplopia. They found a significant association between the presence of IRM or medial rectus muscle swelling, as measured by diameter (increase of 50% compared with that of the intact eye) and residual diplopia (within 30° of the primary position and causing discomfort in daily life). They argued that EOM injury at the time of trauma is a more important factor in the recovery from diplopia than the extent of periorbital herniation. No comprehensive orthoptic assessment was performed to evaluate ocular motility dysfunction.

Higashino et al,[32] in a retrospective study of 106 patients with BOFs, found an association between the degree of protrusion of the IRM into the maxillary sinus (at least half of the muscle's section) and persistent diplopia and/or enophthalmos 6 months after trauma in patients who did not undergo surgery. Their results were similar to our findings. In 2011, Matsunaga et al[33] evaluated the association between preoperative IRM swelling as well as fracture width and long-term

Table 4. BIVARIATE ANALYSIS OF ALL STUDY VARIABLES VERSUS SURGICAL REPAIR

	Surgical Repair		
	Yes	No	*P* Value
Demographic variables			
Sample size, n (%)	34 (31.5)	74 (68.5)	
Age, mean ± SD, yr	37.0 ± 16.4	51.3 ± 24.3	.002*
Gender, n (%)			
Men	53 (71.6)	26 (76.5)	.648
Women	9 (19.4)	29 (29.7)	
Fracture variables, n (%)			
Etiology			.208
Assault	15 (44.1)	24 (32.4)	
Fall	6 (17.6)	27 (36.5)	
Traffic accident	7 (20.6)	15 (20.3)	
Sport accident	6 (17.6)	8 (10.8)	
Pretreatment variables, n (%)			
Diplopia at baseline	23 (67.6)	23 (31.1)	.001*
Diplopia at 10 days	34 (100)	0 (0)	<.001*
Post-treatment variables (1 yr), n (%)			
Annoying diplopia	3 (8.8)	1 (1.4)	.09
Enophthalmos > 2 mm	3 (9.1)	3 (4.1)	.37
Annoying diplopia or enophthalmos	6 (18.2)	4 (5.4)	.07

Abbreviation: SD, standard deviation.
* Statistically significant ($P \leq .05$).

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diplopia outcomes in 18 surgically treated patients by evaluating the IRM area and the maximal width on CT scan coronal images. Their results showed an association between an increase in the rate of IRM swelling and the persistence of diplopia at 1 year. No association between preoperative fracture size and postoperative outcomes was found.

Kang et al[34] evaluated 35 patients by using the method of Matsunaga et al[33] and showed an association between IRM swelling and the occurrence of enophthalmos at 6 months. Kunz et al[35] reported on the possible association between fracture size and long-term diplopia, eye motility, and enophthalmos outcomes. With results similar to our findings, they could correlate fracture size only with enophthalmos and suggested a conservative approach for BOFs with defects of less than 3 cm^2 provided that no enophthalmos or motility disorders, including

Table 5. BIVARIATE ANALYSES OF PRIMARY PREDICTORS (IRM GRADE AND FRACTURE SIZE) VERSUS SURGICAL REPAIR (YES OR NO)

		Surgical Repair, n (%)		
	Sample Size, n (%)	No	Yes	*P* Value
IRM grade				<.001*
I	64 (59.2)	58 (78.4)	6 (17.6)	
II	31 (28.7)	15 (20.3)	16 (47.1)	
III	13 (12.0)	1 (1.4)	12 (35.3)	
Fracture size				.398
<2 cm^2	51 (47.2)	36 (48.6)	15 (44.1)	
2-3 cm^2	42 (38.9)	30 (40.5)	12 (35.3)	
>3 cm^2	15 (13.9)	8. (10.8)	7 (20.6)	

Abbreviation: IRM, inferior rectus muscle.
* Statistically significant ($P \leq .05$).

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Table 6. BIVARIATE ANALYSES OF PRIMARY PREDICTORS (IRM GRADE AND FRACTURE SIZE) VERSUS SECONDARY OUTCOMES

		Diplopia at Baseline		Diplopia at 10 Days		Annoying Diplopia (1 yr)		Enophthalmos (1 yr)		Composite (1 yr)†	
	Sample Size, n (%)	n (%)	*P* Value	n (%)	*P* Value	n (%)	*P* Value	n (%)	*P* Value	n (%)	*P* Value
IRM grade			<.001*		<.001*		.058		.031*		.003*
I	64 (59.2)	19 (29.7)		6 (9.4)		1 (1.6)		2 (3.1)		3 (4.7)	
II	31 (28.7)	15 (48.4)		16 (51.6)		1 (3.2)		1 (3.3)		2 (6.7)	
III	13 (12.0)	12 (92.3)		12 (92.3)		2 (15.4)		3 (23.1)		5 (38.5)	
Fracture size			.145		.398		.103		.033*		.009*
<2 cm^2	51 (47.2)	20 (39.2)		15 (29.4)		0 (0.0)		1 (2.0)		1 (2.0)	
2-3 cm^2	42 (38.9)	16 (38.1)		12 (28.6)		3 (7.1)		2 (4.8)		5 (11.9)	
>3 cm^2	15 (13.9)	10 (66.7)		7 (46.7)		1 (6.7)		3 (4.8)		4 (28.6)	

Abbreviation: IRM, inferior rectus muscle.
* Statistically significant ($P \leq .05$).
† Composite outcome: annoying diplopia or enophthalmos at 1 year.

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diplopia, were present. This was the only study in which diplopia was quantitatively measured using Harms wall deviometry, as in our study. In 2016, we performed a preliminary study on 34 patients to determine the predictive power of fracture size, IRM displacement, and periorbital tissue herniation.[36] We found fracture size and periorbital tissue herniation to be predictors of enophthalmos and persistent annoying diplopia, respectively. No association could be established between IRM displacement and either enophthalmos or diplopia.

Alinasab et al[37] prospectively analyzed the clinical-radiologic data of 79 patients with BOFs indicated for surgical repair to determine the cutoff points of periorbital herniation, fracture size, and the fracture–to–orbital wall area ratio regarding cosmetically visible deformity related to enophthalmos. They included 3 types of BOF (orbital floor, medial wall, and combined) and found an association between visible deformity and the following CT scan criteria: orbital-floor fracture alone (herniation < 1.0 mL and ratio between fracture and orbital wall areas ≥ 42%, or fracture area ≥ 2.3 cm^2); orbital-floor fracture with herniation of 1.0 mL or greater and a distance from the inferior orbital rim to the posterior edge of the fracture of 3.0 cm or greater; or combined fracture of orbital floor and medial wall (≥0.9 mL of herniation). In 2018, the same investigators performed a prospective randomized pilot study to evaluate patients with orbital BOFs and herniation of at least 1.0 mL and determined

Table 7. SUMMARY OF MULTIPLE LOGISTIC REGRESSION ANALYSIS TO MEASURE ASSOCIATION BETWEEN IRM GRADE AND PRIMARY OUTCOME (SURGICAL REPAIR) ADJUSTED FOR GENDER, AGE, AND ETIOLOGY

Model With IRM Grade	OR	95% CI	*P* Value
IRM grade			
I	Ref	Ref	
II	1.49	1.28-1.75	<.001*
III	2.18	1.75-2.71	<.001*
Gender	0.94	0.79-1.12	.498
Age	0.996	0.99-1.00	.029*
Etiology (assault)	0.98	0.82-1.16	.785

Abbreviations: CI, confidence interval; IRM, inferior rectus muscle; OR, odds ratio; Ref, reference category.
* Statistically significant ($P \leq .05$).

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Table 8. SUMMARY OF MULTIPLE LOGISTIC REGRESSION ANALYSIS TO MEASURE ASSOCIATION BETWEEN FRACTURE SIZE AND PRIMARY OUTCOME (SURGICAL REPAIR) ADJUSTED FOR GENDER, AGE, AND ETIOLOGY

Model With Fracture Size	OR	95% CI	*P* Value
Fracture size			
<2 cm^2	Ref	Ref	
2-3 cm^2	1.01	0.84-1.22	.90
>3 cm^2	1.26	0.96-1.65	.10
Gender	0.88	0.70-1.10	.25
Age	0.99	0.99-1.00	.002*
Etiology (assault)	0.93	0.75-1.15	.53

Abbreviations: CI, confidence interval; OR, odds ratio; Ref, reference category.
* Statistically significant ($P \leq .05$).

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an association between enophthalmos and conservative management.[38]

In a retrospective study with 106 patients with orbital-floor BOFs, Frohwitter et al[39] reported on the association between ophthalmologic examination and radiologic findings regarding the treatment decision-making process. They showed the defect size of the fracture and displacement of the IRM to be significantly associated with diplopia and decreased ocular mobility. They suggested considering surgery in patients with diplopia associated with a fracture size larger than 2 cm^2 and/or incarceration of the IRM. Unfortunately, these investigators failed to give details concerning the treatment selected for their study cohort and the test used to evaluate ocular motility disorders. Finally, Jung et al[40] retrospectively reviewed CT scans of patients undergoing surgery after BOFs, and similarly to Matsunaga et al,[33] their results found EOM circling and tenting to be prognostic for long-term residual diplopia (6 months). As in the previous studies, ocular motility was assessed only with a binocular visual-field semi-quantitative test rather than a more comprehensive quantitative orthoptic examination.

Overall, these studies showed that, on the basis of preoperative CT scan images, the persistence of diplopia could be potentially predicted by changes in the shape and/or position of the EOM, especially the IRM, whereas enophthalmos could be predicted by fracture size. Our findings are in agreement with these results. Nevertheless, it should be stressed that none of the previous studies attempted to correlate the preoperative CT scan changes with preoperative diplopia or the management decision (surgery vs conservative), which was done in our study. In fact, in these studies, the need for surgical repair according to specific CT scan parameters was only suggested indirectly from the persistence of diplopia and not related to a direct association with preoperative diplopia.

Our results also confirmed a strong association between the severity of IRM displacement and preoperative diplopia, albeit indirectly. In fact, given that the decision for surgical repair was based on preoperative diplopia, we can assume that severe IRM displacement (grade III) also acts as an independent predictor for surgery. To our knowledge, this association has never been shown in previous studies.

The main strength of this study is that it is the only large case series to date that prospectively assesses the relationship between 2 radiologic parameters (IRM displacement and defect size) and the need for surgical repair, as well as post-trauma preoperative and long-term diplopia and enophthalmos, in BOF patients. Moreover, the orthoptic evaluation was standardized, and the clinical-radiologic follow-up visits were performed in fully compliant patients. Data were collected during well-structured routine clinical examinations, and the physicians, at that time, were blinded to the goal of the study. The main limitation of our study is that the orbital repairs were performed by various surgeons. Moreover, the study sample was too small to draw sound definitive recommendations regarding the long-term clinical outcome. Despite this, diplopia and clinically significant enophthalmos remain rare complications.

The results of this study suggest that the IRM grade and fracture size are valid measurements of BOF severity regarding the clinical outcome. Moreover, the IRM grade, unlike fracture size, was positively correlated with surgical repair and could thus be integrated into evidence-based decision making and patient-oriented clinical research. Nevertheless, further studies including larger samples and, ideally, multicenter cohorts could help determine the value of the IRM grade and fracture size in the management of BOFs.

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