



Intraoperative Image Guidance in Orbital and Lacrimal Surgery

A Report by the American Academy of Ophthalmology

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Purpose: To review the efficacy and safety of the use of intraoperative image guidance (IIG) in orbital and lacrimal surgery.

Methods: A literature search of the PubMed database was last conducted in November 2023 for English-language original research that assessed the use of any image guidance system in orbital and lacrimal surgery that included at least 5 patients. The search identified 524 articles; 94 were selected for full-text analysis by the panel. A total of 32 studies met inclusion criteria. The panel methodologist assigned a level II rating to 2 studies and a level III rating to 30 studies. No study met the criteria for level I evidence.

Results: Procedures reported on were as follows: fracture repair (n = 14), neoplasm and infiltrate biopsy or excision (n = 6), orbital decompression for Graves ophthalmopathy (n = 3), dacryocystorhinostomy (n = 1), and mixed etiology and procedures (n = 8). Four studies used more than one IIG system. One study that met level II evidence criteria compared the outcomes of orbital fracture repair with IIG (n = 29) and without IIG (n = 29). Borderline better outcomes were reported in the IIG group: 2% versus 10% with diplopia (P = 0.039) and 3% versus 10% with enophthalmos (P = 0.065). The other level II study compared the repair of fractures with navigation (n = 20) and without (n = 20). The group in which navigation was used had a measured mean volume reduction of 3.82 cm³ compared with 3.33 cm³ (P = 0.02), and there was a greater measured reduction in enophthalmos in the navigation group of 0.72 mm (P = 0.001). Although the remaining 30 assessed articles failed to meet level II criteria, all alleged a benefit from IIG. No complications were reported.

Conclusions: A small number of comparative studies suggest that there are improved outcomes when IIG is used in orbital fracture repair, but each study suffers from various limitations. No high-quality comparative studies exist for the management of lacrimal surgery, neoplastic disease, or decompression. Complications attributable to the use of IIG have not been identified, and IIG has not been analyzed for cost savings.

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The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an Ophthalmic Technology Assessment is to review systematically the available research for clinical efficacy, effectiveness, and safety. After review by members of the Ophthalmic Technology Assessment Committee, other Academy committees, relevant subspecialty societies, and legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this assessment by the Ophthalmic Technology Assessment Committee Oculoplastics and Orbit

Panel is to review the literature on the efficacy and safety of the use of intraoperative image guidance (IIG) in orbital and lacrimal surgery.

Background

Intraoperative image guidance refers to an ever-evolving imaging tool, most commonly computed tomography (CT) and magnetic resonance imaging (MRI), that is used intraoperatively to identify surgical targets, allowing for better identification of pathology and normal structures. It is used

in a growing number of surgical specialties, including oculoplastic surgery and overlapping specialties, neurosurgery, and otolaryngology. The purported benefits of IIG are precision of surgical dissection; accurate localization of lesions; and avoidance of critical vascular, neurological, and orbital structures.^{1–32} Increased use of IIG has resulted in an increasing number of published reports assessing the benefits of IIG. These assessments are typically based primarily on surgeon impression without more objective, quantitative metrics or comparative control groups.

The evolving acumen of surgeons and the variety of technologies using different IIG systems add complexity to evaluations being made by different studies. For example, both CT and MRI data can be used for IIG. The means of image registration, the process of correlating digital images on a surgical navigation screen with the location on the patient, has varied and evolved substantially over time. Moreover, the variety of diseases and surgical techniques included in published reports makes data collation and comparison challenging. Although the evidence in the literature might seem plentiful and mostly positive, careful and meaningful interpretation of this technology is critical.

Questions for Assessment

This assessment addressed the following questions: (1) Is there high-quality data that focuses on the safety and efficacy of IIG in orbital and lacrimal surgery and what conclusions can be drawn from it? (2) Does the benefit of IIG justify inherent costs?

Description of Evidence

A literature search was last performed in November 2023 in the PubMed database for articles that assessed the use of any image guidance system in orbital and lacrimal surgery. The search terms for this assessment can be found in the [Appendix](#) (available at www.aaojournal.org). Articles were limited to original research published in the English language that included at least 5 patients. The search identified 524 articles, which were reviewed to select those that met the following inclusion criteria: (1) The study evaluated the safety or efficacy of adjunctive image guidance in orbital or lacrimal surgery, and (2) the study included a minimum of 1 month of follow-up. Ninety-four articles were deemed to be of sufficient clinical relevance and were selected for full-text review and abstraction by the panel. Articles were excluded if they included a cadaveric study, had an insufficient number of orbital cases, did not involve IIG, were assessments of technology as opposed to clinical outcomes, and did not contain original data (e.g., meta-analyses and review articles). Many articles were excluded on the basis of more than 1 criterion. A total of 32 studies met the study inclusion criteria.

The panel methodologist (V.K.A.) assessed the quality of the methodologies in each study and assigned each a level of evidence rating based on the scale developed by the 2011 Oxford Centre for Evidence-Based Medicine and adopted by the American Academy of Ophthalmology.³³ A level I

rating was assigned to well-designed and well-conducted randomized clinical trials. A level II rating was assigned to well-designed case-control and cohort studies and lower-quality randomized studies. A level III rating was assigned to case series, case reports, and lower-quality cohort and case-control studies. No study met the criteria for level I evidence. Two studies met the criteria for level II, and 30 studies met the criteria for level III.

Published Results

There was a lack of consistency in IIG application and technology in the studies included in this assessment. The underlying pathologies addressed in the studies included in this assessment were fractures (14 articles), neoplasm and infiltrate biopsy or excision (6 articles), orbital decompression for Graves ophthalmopathy (3 articles), lacrimal surgery (1 article), and mixed etiology (8 articles).³ The IIG manufacturer cited most often in the articles was Brainlab (n = 17), followed by Stryker (n = 5), Medtronic (n = 3), Boston Scientific Polaris (n = 1), Materialise (n = 1), and General Electric Medical Systems InstaTrak (n = 1). Four studies used more than one IIG system.

Orbital fracture repair was the most common IIG-assisted oculoplastic procedure reported in the published literature. In one of the level II studies, Cai et al¹ compared the outcomes of orbital fracture repair between 29 patients who underwent repair with the Kolibri surgical navigation device (Brainlab) and 29 patients who underwent repair without IIG. Better outcomes were reported in the Kolibri group: 2% versus 10% with diplopia ($P = 0.039$) and 3% versus 10% with enophthalmos ($P = 0.065$). The second level II study compared inferomedial fracture repair with navigation (n = 20) and without (n = 20).² Fracture size was inferred from the difference in orbit volume between the involved and uninvolved orbits and was similar between groups preoperatively. Patients were assigned to their group based on the site of surgery, one that was equipped with navigation and one that was not. The group for which navigation was used had a measured mean volume reduction of 3.82 cm³ compared with 3.33 cm³ ($P = 0.02$) for the non-navigation group.² Moreover, there was a greater measured reduction in enophthalmos in the navigation group of 0.72 mm ($P = 0.001$). Although the remaining 30 articles included in this assessment failed to meet level II criteria, all alleged benefit from IIG.^{3,5–32} Apart from financial cost and time demands, no complications or other downsides were described.

In addition to the studies by Cai et al¹ and Parameswaran et al² detailed previously, other notable controlled studies assessed the use of IIG in orbital fracture repair. This includes 1 that compared outcomes of orbital fracture repair with and without the use of IIG and mirror image overlay.⁴ There were 45 patients in both the study and control groups. Better outcomes were described for the patients in whom mirror image overlay was used and who had a more favorable revision rate (4% vs. 20%; $P = 0.03$). He et al⁵ compared outcomes in patients undergoing orbitozygomatic fractures repair using IIG and

custom implants (n = 11) with those not using IIG or custom implants (n = 39). They described outcomes as “perfect” in 100% of the IIG group compared with 74.3% in the traditional group. The groups were not similar with respect to the use of custom implants, nor was a statistical analysis provided.

Zong et al⁶ compared fracture repair surgical duration and outcome with IIG (n = 40) and without (n = 30). By performing volumetric analysis of CT images before and after surgery, they measured better symmetry between the operative and fellow orbits with IIG (mean difference in orbital volume [0.57 ± 0.43 ml vs. 1.60 ± 0.78 ml; *P* = 0.022]). Interestingly, there was no difference in operative time, defined as the mean time from incision to closure (117.41 ± 36.74 minutes vs. 125.28 ± 40.73 minutes; *P* = 0.088). Note that this time did not include time required to set up the navigation system. Zavattero et al⁷ compared patients who underwent fracture repair with IIG (n = 25) and without IIG (n = 30). Without any clearly defined outcome measures or a statistical comparison, they concluded that “significant orbital volume reduction in the reconstructed orbit could be achieved in the navigation group but not in the conventional group compared to the unaffected side.”

In a larger study by Scolozzi⁸ of patients, most of whom underwent surgery with IIG for fractures or other trauma-related abnormality (n = 103), all patients were described as having “good and stable” outcomes.⁸ Notably, the authors specifically stated that there were no complications, supporting the impression that there is limited clinical intraoperative risk to using IIG. Zhang et al⁹ reported good results in 40 patients who underwent fracture repair using IIG. Likewise, Andrews et al¹⁰ reported outcomes of 10 eyes in 8 patients who underwent orbital fracture repair using IIG. No complications were described, and all patients were noted to have normal “ocular function” postoperatively.¹⁰ Baumann et al¹¹ also described 6 patients who achieved “symmetry” after unilateral fracture repair. There are several other largely anecdotal studies judging IIG to be beneficial in fracture repair.^{12–14}

A number of researchers have reported on outcomes in patients undergoing orbital decompression with the assistance of IIG. Prevost et al¹⁵ assessed patients who underwent orbital decompression either with IIG (205 eyes in 106 patients) or without IIG (145 eyes in 85 patients). They reported a statistically significant greater reduction in proptosis on the right (3.8 vs. 3.2 mm; *P* = 0.03) and a greater reduction on the left that was not statistically significant (3.6 vs. 3.4 mm; *P* = 0.54). They also reported a 40-minute increase in operative time when using IIG. Although the numbers are robust, the study lacks strength because it involved multiple surgeons and IIG was used based on the preference of the surgeon. Thus, the difference in outcome or surgical duration may relate to the surgeon and not to the use of IIG.

Dubin et al¹⁶ compared outcomes in patients undergoing orbital decompression with IIG (n = 18) and without IIG (n = 27). Although the IIG group had a greater decrease

in proptosis (6.3 vs. 5.9 mm), this was not statistically significant. Tavassol et al¹⁷ assessed the results of 12 patients (23 orbits) who underwent orbital decompression with IIG. Without precise outcome measures, they concluded that IIG was useful. Although not attributed specifically to IIG, 1 patient developed abducens nerve palsy. In a similar small study, Wu and Kahana¹⁸ described good surgical results, with the desired amount of reduction in proptosis in 7 patients (11 orbits) who underwent decompression with IIG.

One application that is well accepted within the neurosurgical community that overlaps with orbital surgery is the adjunct use of IIG with the excision of skull base meningiomas, including those with extension to the orbit. The study by Maschke et al¹⁹ was the single study identified in the literature search that specifically addressed this, and they described their experience with 30 patients. They assessed more than 1 imaging modality and asserted that bone surface–based registration was significantly more accurate than skin surface–based registration (mean 0.7 ± 0.4 mm and 1.9 ± 0.7 mm; *P* < 0.001). They also concluded that the extent of resection of the intraosseous component was significantly higher using CT plus MRI navigation compared with MRI alone (96% vs. 81%; *P* = 0.044). Others have reported their experiences using IIG for tumor location, excision, and reconstruction in the orbit.^{20–30} Although published opinions in these studies were positive, a well-controlled study with clearly defined outcome measures in orbital neoplastic disease is lacking.

Only 1 study meeting the assessment criteria specifically addressed dacryocystorhinostomy. Reichel and Taxeidis³¹ described using IIG in 17 eyes of 16 patients who underwent endoscopic dacryocystorhinostomy. Based on symptomatic improvement, all but 1 case were deemed successful. No complications attributable to IIG were described.

Study funding and author financial disclosures can be found in [Table S1](#) (available at www.aaojournal.org).

Discussion

The use of IIG is commonplace in many surgical centers and is growing in popularity. In this assessment, the panel found more than 400 published reports that included descriptions of IIG in the orbit. Thirty met level III criteria, and only 2 met level II criteria. Inconsistency in the technology used and variability in surgical applications further dilute the utility of these studies. Moreover, the literature does not address whether anatomic familiarity and training influence clinical IIG outcomes for some surgeons more than others. Experienced surgeons who are more familiar with surgical anatomy and dissection might benefit less from IIG, if at all. One cadaveric study divided participants into novice (postgraduate year 2–4 residents; n = 6) and experienced (postgraduate year 5 residents and fellows; n = 4) cohorts.³² Participants reconstructed iatrogenic cadaveric orbital fractures with or without the use of surgical navigation.

Novice participants had improved outcomes (more symmetric orbital volume) when using navigation without increased operative time, whereas more experienced participants did not have improved outcomes. This single study suggests that with surgeon experience the benefit of IIG diminishes.

Conclusions

There is limited evidence supporting the adjunct use of IIG with various orbital and lacrimal procedures. There are few comparative studies that suggest improved outcomes when IIG is used in orbital fracture repair and decompression, but each study suffers from various limitations. Although the use of IIG is commonly described for the management of neoplastic disease, comparative studies are lacking. The lack of high-quality evidence in part relates to inconsistencies in the evolution of technology, the wide range of surgical applications, and differences in user experience and training. The few studies addressing surgical time indicate that although IIG neither extends nor shortens surgical time, equipment setup and removal extend facility time. Complications attributable to the use of IIG were not identified, and cost analyses are lacking.

Footnotes and Disclosures

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Future Research

There is a need for further research on the use of IIG in orbital and lacrimal surgery. Although the material costs of IIG technology are not defined in the literature, they are significant. Demands on personnel and facility time are impacted by equipment, which also comes with a substantial financial burden. Although the impact on actual operative time may be negligible, retrieval, assembly, and preparation need to be considered. Moreover, training of multiple staff, in addition to the surgeons themselves, is required if IIG is to be dependably available. However, IIG is commonplace in neurosurgery and otolaryngology, and in some institutions no additional equipment may be needed if it is used in orbital surgery. Also, if improved outcomes were to reduce the number of subsequent surgeries, there might be some cost savings. Future research should focus on better assessing clinical benefits and weighing this against the high-resource demand. This will require prospective randomization with quantifiable outcome measures. Specific diseases and procedures as well as surgeon characteristics need to be considered. Further investigation may identify the specific circumstances in which the use of IIG demonstrates improved clinical outcomes to the degree that justifies the substantial allocation of resources.

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No animal subjects were used in this study.

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Abbreviations and Acronyms:

CT = computed tomography; **IIG** = intraoperative image guidance;

MRI = magnetic resonance imaging.

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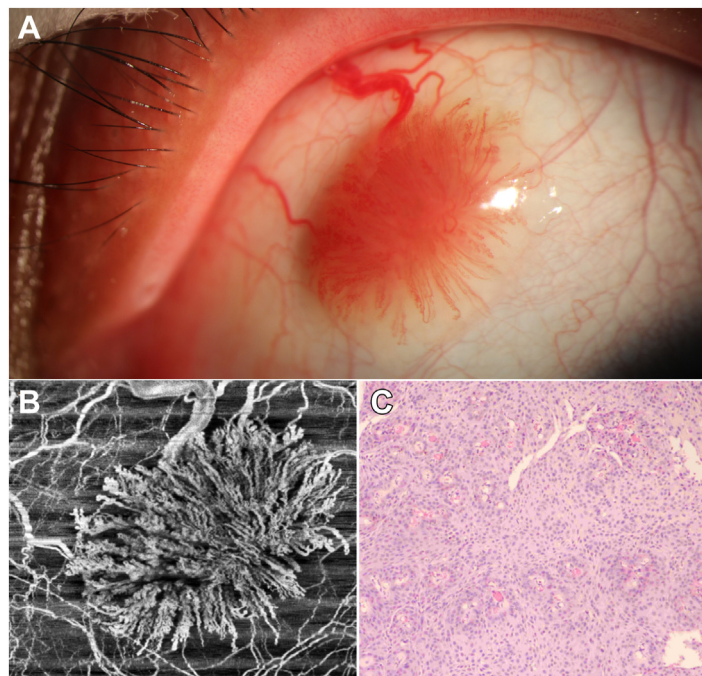
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Pictures & Perspectives



Squamous Cell Papilloma of the Conjunctiva

A 28-year-old woman presented to the ophthalmology department with a 3-year history of a tumor in her left eye. Examination revealed an isolated pink tumor in the conjunctiva with an associated large vessel (A). OCT angiography showed blood vessels in the shape of “coral” (B). After complete resection, pathological examination showed conjunctival papilloma (C). Conjunctival papilloma is an acquired benign tumor that originates from the conjunctival stratified squamous epithelium and usually progresses slowly. Most patients require surgical resection. Lesions may also be treated pharmacologically or via cryotherapy. (Magnified version of Figure A-C is available online at www.aaojournal.org).

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