METHODS

The guideline was developed according to the ASPS Guideline Methodology, available here.

Work Group Selection Process

The guideline was led by the American Society of Plastic Surgeons (ASPS) with stakeholder input and representation from the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), the American Society for Aesthetic Plastic Surgery (ASAPS), and the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS).

All stakeholders were invited to nominate members from their respective organizations to serve on the Work Group, following their own policies and procedures for addressing content expertise, guideline experience, and potential conflicts of interest. Initially, one patient representative was also included on the panel to provide insight related to patient values and preferences but was removed due to apparent conflicts of interest, which had not previously been disclosed but later developed, and did not participate in recommendation statement formation. A replacement patient representative was sought but a suitable candidate could not be found prior to the recommendation statement development meeting. An ASPS quality department staff member was assigned to manage the project and provide expertise in clinical practice guideline development methodology.

All applicants were required to submit an online conflict of interest disclosure form for membership consideration. The co-chairs were free of all conflicts of interest for the duration of the project, as required by ASPS policy.

Clinical Question Development

Work Group members used a consensus-based approach to select the clinical questions to be addressed in this evidence-based guideline. Clinical questions were submitted via a blinded process to the ASPS project manager, who compiled and dispersed the clinical questions for consideration and discussion at the introductory meeting. The clinical question topics were then discussed in detail at the in-person introductory meeting with diverse representation from plastic surgery, otolaryngology, ophthalmology, and patients.

A total of 16 clinical questions were reviewed by the Work Group. Clinical questions were developed and selected based on the scope and importance to patient outcomes, as determined by the Work Group. The patient population for the guideline is adult patients with visual field impairment due to dermatochalasis, blepharoptosis, or a combination of both. Patient-related outcomes of interest were determined to be cosmetic appearance (including symmetry), rate of revision, surgical complications, visual field improvement (marginal reflex distance-1 improvement), quality of life (including patient satisfaction), and patient safety. The final 7 clinical questions below were chosen based on clinical relevance to the outcome of the surgery and patient satisfaction.

1) In adult patients with visual field impairment, how does physical examination alone (e.g.

measurement of marginal reflex distance-1 (MRD-1) and levator function) compared to additional laboratory and/or other studies (e.g. peripheral visual field exam) help the surgeon correctly determine underlying etiology of the impairment and indications for specific surgical techniques/approaches?

2) In adult patients with visual field impairment, how does physical examination alone (e.g. measurement of marginal reflex distance-1 (MRD-1) and levator function) compared to additional laboratory and/or other studies (e.g. peripheral visual field exam) help the surgeon correctly determine underlying etiology of the impairment and indications for specific surgical techniques/approaches?

3) In adult patients with visual field impairment undergoing ptosis repair (with or without blepharoplasty), how does anterior ptosis repair compared to posterior ptosis repair differ in lid margin correction, symmetry, cosmetic appearance, longevity of results, change in vision, complications, rate of revision, and quality of life?

4) In adult patients with unilateral visual field impairment, how does blepharoplasty compared to ptosis correction differ in lid margin correction, symmetry, cosmetic appearance, longevity of results, change in visual field, complications, rate of revision, and quality of life?

5) In adult patients with unilateral visual field impairment, how does unilateral compared to bilateral surgical intervention differ in lid margin correction, symmetry, cosmetic appearance, longevity of results, change in visual field, complications, rate of revision, and quality of life?

6) In adult patients with visual field impairment undergoing upper eyelid blepharoplasty and/or ptosis correction (without concomitant procedures), how does general anesthesia compared to local anesthesia differ in patient satisfaction, complications, cost, and visual field improvement?

7) In adult patients with visual field impairment undergoing eyelid surgery, how does upper eyelid blepharoplasty and ptosis correction with brow surgery versus without brow surgery differ in patient satisfaction, complications, rate of revision, cost, visual field improvement, and quality of life?

8) In adult patients with visual field impairment undergoing blepharoptosis surgery, how does levator plication compared to levator advancement differ in lid margin correction, symmetry, longevity of results, change in visual field, complications, rate of revision, and quality of life?

Literature Search

Multiple literature searches were performed during 2018 to identify relevant studies published from 1990 to 2018. The initial search dates were January 1, 1980 through April 16, 2018, with a subsequent updated and final search on November 2, 2018. Electronic searches of PubMed, Embase, and Cochrane Central Register of Controlled Trials (CENTRAL) were performed using appropriate combinations of the following MEDLINE Medical Subject Headings (MeSH) terms and keywords, as permitted by the search functionalities of each database/journal:

- MeSH terms (used in PubMed only): "Visual Fields"[MeSH], "Blepharoptosis"[MeSH], "Blepharoplasty"[MesH], "Eyelids/surgery"[MeSH]
- Keywords: Visual field(s), field of vision, visual hemifield(s), impairment(s), drooping, weakness, ptosis, ptoses, prolapse, blepharoptosis, blepharoptoses, palpebra, eyelid, brow, upper lid, levator, reconstruction, correction, repair, tarsoplasty, eyelid reconstruction, eyelid surgery

Initial study selection for each clinical question was performed by two reviewers with a multi-level screening process. Level I screening involved title and abstract review to identify potentially relevant studies for inclusion in level II screening. Level II screening was full-text review of articles to confirm relevance given the inclusion/exclusion criteria below:

Inclusion Criteria:

- Published since 1980 (01/01/1980 – 11/02/2018)
- English language
- Reported a meta-analysis/systematic review, RCT, prospective or retrospective cohort/comparative, case-control, or case series
- Reported outcomes of interest for clinical questions
- Included at least 20 patients per study and/or per arm of study
- Human subjects

Relevant clinical practice guidelines and systematic reviews underwent a separate bibliographic screening, as a cross-reference to ensure no relevant literature was excluded during the search process. These articles were screened as described above. Duplicate articles were eliminated. Studies meeting inclusion criteria were assessed for methodologic quality, as described below. Excluded studies and their reasons for exclusion were documented for review by the Work Group to confirm the final rejection or reconsider the study for inclusion. See Appendix for details.

Additional references were included in this review if considered necessary for background or discussion; however, these references were not critically appraised or used in the development of recommendation statements.

Critical Appraisal of Evidence

A modified version of the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) process was used to evaluate the methodologic quality of clinical studies and the strength of clinical evidence for the purposes of developing clinical practice guidelines and performance measures. GRADE determines the quality of evidence across outcomes rather than assessing each study individually. The quality of evidence for each outcome is initially determined by study design. The evidence from randomized controlled trials (RCTs) is assigned as high-quality evidence, while evidence from observational studies begin as low quality. From there, high quality evidence can be downgraded, and low-quality evidence can be graded up or down based on the following: risk of bias; publication bias; imprecision related to the estimate of effect; inconsistency across studies; and indirectness related to the clinical questions. Studies with <10% of the population between the ages of 16 and 18 were included but downgraded as indirect evidence. The full Quality Appraisal and Evidence Tables can be found here.

Grading of Recommendations

Clinical practice recommendations were developed using BRIDGE-wiz (Building Recommendations in a Developers' Guideline Editor) software[1] with consideration of the following 4 factors: 1) level of evidence (study quality); 2) assessment of benefits versus harms; and 3) patient preferences; 4) feasibility. Work Group members participated in several rounds of revisions until unanimous consensus was achieved for each recommendation statement. Each recommendation in this guideline is accompanied by a grade indicating the strength of the recommendation, which was determined by considering the overall

level of evidence supporting the recommendation and the judgment of the guideline developers. See Figure 1 and Table 1 in the manuscript for explanations.

Peer Review and Public Comment Process

The draft guideline was peer reviewed by the American Society of Plastic Surgeons, the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), the American Society for Aesthetic Plastic Surgery (ASAPS), and the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS). Peer Reviewers were invited to review and provide feedback on the validity, generalizability, and clarity of the draft guideline using the Appraisal of Guidelines for Research & Evaluation Global Rating Scale (AGREE-GRS) instrument, as well as asked to review the clinical content and attest to either support, support with modifications, or do not support the individual recommendations. The draft guideline was posted on the ASPS website for a 30-day public comment period from 10/05/2019 until 11/04/2019, as well as distributed through the Council of Medical Specialty Societies (CMSS) Clinical Practice Guidelines email distribution list. Comments were reviewed by the full Workgroup and assessed for relevance. Revisions were made when the workgroup agreed that the modifications would add clarity or value to the document. Reviewer recommendations without evidentiary support are not able to be considered.

Guideline Approval Process

After the peer review and public comment process, the guideline draft was reviewed and modified by the Work Group after consideration of peer review and public comments. The final guideline was approved by the Executive Committee of the American Society of Plastic Surgeons during their March 2020 meeting.

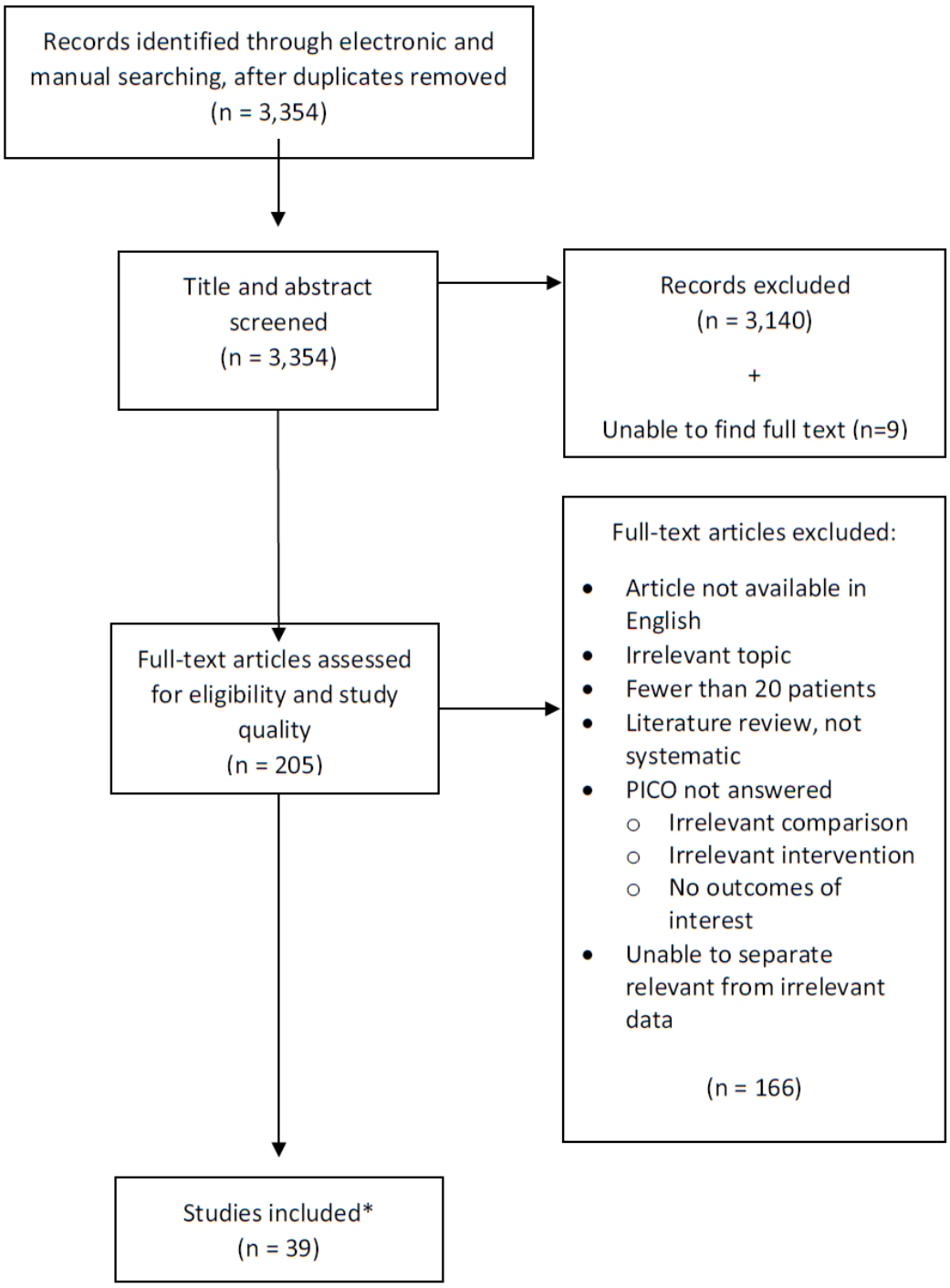
Plan for Updating Guideline

In accordance with the inclusion criteria of the ECRI Guidelines Trust, this guideline will be updated within 5 years or in the event when newly published evidence may result in a change to current recommendations. ASPS uses a digital platform (P.E.E.R.) to store literature and data, thereby facilitating an efficient updating process.

References

[1] Shiffman RN, Michel G, Rosenfeld RM, Davidson C. Building better guidelines with BRIDGE-Wiz: development and evaluation of a software assistant to promote clarity, transparency, and implementability. J Am Med Inform Assoc. 2012;19(1):94-101.

Appendix Figure 1. Literature Search Attrition Diagram



* While 39 studies fit the inclusion criteria, were critically appraised, and had data extracted, only 23 studies were included in the manuscript as supporting evidence for the recommendations developed. For example, several studies compared diagnostic tools for quantifying visual field impairments but the work group focused Recommendation 1 on assessments of the underlying etiology for the deficit.