# PREFERRED PRACTICE PATTERN® CLINICAL QUESTIONS

















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American Academy of Ophthalmology P.O. Box 7424 San Francisco, California 94120-7424 415.561.8500 Preferred Practice Pattern® (PPP) Clinical Questions are evidence-based statements that guide clinicians in providing optimal patient care. PPP Clinical Questions answer specific questions in the "Patient, Intervention, Comparison, Outcome" (PICO) format.

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Preferred Practice Pattern Clinical Questions should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network (SIGN)<sup>1</sup> and the Grading of Recommendations Assessment, Development and Evaluation (GRADE)<sup>2</sup> group are used. All studies used to form a recommendation for care are graded for strength of evidence individually. To rate individual studies, a scale based on SIGN<sup>1</sup> is used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.<sup>3</sup>

## **SIGN<sup>1</sup> Study Rating Scale**

I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
II++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
III	Nonanalytic studies (e.g., case reports, case series)

## **GRADE<sup>2</sup> Quality Ratings**

Good quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Insufficient quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate  Any estimate of effect is very uncertain

## **GRADE<sup>2</sup> Key Recommendations for Care**

Strong recommendation	Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not
Discretionary recommendation	Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced



#### **TOPIC**

Interventions for involutional entropion in elderly populations

#### **CLINICAL QUESTION**

How effective are the surgical interventions for involutional entropion? Is any one method superior to another?

#### LITERATURE SEARCH

The PubMed literature search for the Cochrane Review was last updated on November 2, 2011. The Cochrane search identified 111 relevant studies; of these, 108 did not meet the inclusion criteria. Of the remaining three reports, one was excluded due to serious methodological flaws, and one represented an in-progress study for which complete data were unavailable. As such, one randomized controlled trial was included. An updated PubMed search was conducted on February 24, 2014, but none of the 125 new citations met the inclusion criteria of the review.

Literature search details

#### SYSTEMATIC REVIEW

Boboridis KG, Bunce C. <u>Interventions for involutional lower lid entropion</u>. Cochrane Database of Systematic Reviews 2011, Issue 12. Art. No.: CD002221. DOI: 10.1002/14651858.CD002221.pub2.



#### SUMMARY

The objective of this review is to examine the effectiveness of medical interventions for involutional lower eyelid entropion, a condition where the eyelid margin and eyelashes turn in toward the eyeball. Involutional entropion is a common disorder in the elderly population. The combination of horizontal and vertical eyelid tightening with everting sutures and lateral tarsal strip, and vertical tightening with everting sutures alone, have been used for treatment. Currently, surgery to advance the lower eyelid retractors (with or without addressing horizontal laxity) is considered the only curative treatment for entropion. To date, the effectiveness of these surgical interventions, alone or in combination, have not been scrutinized. It remains uncertain if one technique is superior to another due to the lack of randomized studies.

The results of a single randomized controlled trial (RCT) suggest that horizontal and vertical eyelid tightening with everting sutures and lateral tarsal strip combined are more effective than

vertical tightening with everting sutures alone. <sup>4</sup> Numerous high-quality retrospective case series also support the practice of combined surgical repair, though these studies were not considered in the Cochrane analysis. Combined horizontal and vertical eyelid tightening with everting sutures and lateral tarsal strip is a highly effective treatment option for involutional lower lid entropion. However, the rates of recurrence of entropion and complications of these procedures can not be ascertained in the absence of well-designed observational studies.

(Study Rating Scale I-, Moderate Quality, Discretionary Recommendation)

#### DISCUSSION

Involutional lower lid entropion is a progressive condition, and there is little consensus on when treatment should be given or what is the best surgical approach. Involutional entropion is characterized by the rubbing of the margin, lashes, and skin against the ocular surface, often leading to conjunctival inflammation and corneal abrasion. Entropion may also cause vascularization, thinning, infection, ulceration, perforation, and/or scarring of the cornea if left untreated. It occurs in 2.1% of the elderly population. Involutional entropion must be distinguished from cicatricial entropion caused by conjunctival scarring and shrinkage because the management is different. It should also be distinguished from trichiasis and distichiasis.

#### **Treatment**

In current clinical practice the only effective treatment for involutional entropion is surgery to repair or advance the lower eyelid retractors (with or without horizontal shortening). Some surgeons have attempted to stabilize the retractors by horizontal tightening of the orbicularis muscle.<sup>6,7</sup> Vertical and horizontal tightening techniques can also be combined, for example, by using a wedge excision or lateral canthal sling.<sup>8,9</sup> Non-surgical treatments, including antibiotic or lubricating ointments, chemodenervation of the orbicularis muscle, or everting the eyelid with adhesive tape, all may help alleviate symptoms of early stage disease but are of temporary benefit.

#### **Inclusion Criteria**

The Cochrane Review authors systematically evaluated the evidence for surgical and non-surgical treatments for involutional entropion. Their review was limited to RCTs; the results of non-randomized studies were discussed in the absence of RCTs, although these were not included in the analysts' formal summary or a meta-analyses. Other review inclusion criteria were as follows:

- 1) Study patients were older than 60 years of age with involutional lower lid entropion;
- 2) Studies compared active interventions for management of involutional lower lid entropion;
- 3) Surgical treatments eligible for consideration: a) directly or indirectly addressed vertical lid laxity, b) directly addressed horizontal lid laxity, or c) combined vertical and horizontal tightening;
- 4) Non-surgical treatments eligible for consideration included taping the eyelid to the cheek, medical symptomatic support, and botulinum toxin injection;
- 5) The primary outcome measure was surgical success (e.g., normal resting eyelid position). Valid secondary outcomes included recurrence, adverse events or complications, health-related quality of life, and socioeconomic variables. Outcomes were evaluated over the short term (within 6 months of the intervention), intermediate term (6 to 18 months following intervention), or long term (more than 18 months after intervention).

#### Combined Vertical and Horizontal Tightening vs. Vertical Tightening Alone

One RCT with 63 total subjects compared combined vertical and horizontal lower eyelid tightening with everting sutures and lateral tarsal strip (36 patients) versus vertical tightening with

everting sutures alone (27 patients).<sup>4</sup> A successful surgical outcome was measured as normal resting eyelid position and an inability to induce entropion via provocation testing at 18 months. Eight patients (7 in the vertical tightening group, 1 in the combined vertical and horizontal tightening group) were lost to follow-up. Of the 55 remaining subjects, all patients in the combined vertical and horizontal tightening group had successful outcomes at 18 months, while six patients in the vertical tightening group were classified as treatment failures. This difference was statistically significant. The study did not examine the differences in treatment based on whether the entropion was constant, intermittent, or occurred only with provocation.

Another RCT, comparing lateral eyelid block excision against lateral tarsal strip, is currently recruiting patients.

#### CONCLUSION

Overall, the authors found evidence suggesting that combined vertical and horizontal eyelid tightening with everting sutures and lateral tarsal strip is superior to everting sutures alone for patients with involutional lower eyelid entropion. This conclusion is based on the results of a single, small RCT and numerous case series. The available published data are not sufficient to determine rates of recurrence of entropion or complications of these procedures. The treatment approach for a particular patient should be individualized. Further research on the efficacy of other surgical procedures and non-surgical treatments is needed.



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