



Ageing increases risk of lower eyelid malposition after primary orbital fracture reconstruction

Hanna Rajantie^{a,*}, Matti Nikunen^a, Rahul Raj^b, Johanna Snäll^a, Hanna Thorén^c

^a Department of Oral and Maxillofacial Diseases, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

^b Department of Neurosurgery, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

^c Department of Oral and Maxillofacial Surgery, University of Turku, Department of Oral and Maxillofacial Diseases, Turku University Hospital, Turku, Finland

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Abstract

Lower eyelid malposition (LEM) is a common sequela after orbital fracture reconstruction. This study aimed to analyse the development of LEM, specifically ectropion and entropion, following primary orbital fracture reconstruction, to identify predictive factors for LEM, and to assess the effect of the eyelid complication on patients' daily lives. The retrospective cohort comprised patients who had undergone orbital floor and/or medial wall fracture reconstruction for recent trauma. Demographics, fracture type and site, surgery and implant-related variables, follow-up time and number of visits, type and severity of LEM, subsequent surgical correction, and patient satisfaction, were analysed. The overall occurrence of LEM was 8%, with ectropion in 6% and entropion in 2% of patients. Older age, complex fractures, transcutaneous approaches, preoperative traumatic lower lid wounds, and implant material were associated with the development of LEM. Of all patients, 3% needed surgical correction of LEM. Six of the 13 patients (46%) who developed LEM required surgical correction. The transconjunctival approach and patient-specific implants should be preferred, especially in elderly patients and those with more complex fractures. LEM often requires subsequent surgical correction, and the treatment period is substantially prolonged, with multiple extra visits to the clinic.

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Keywords: Lower eyelid malposition; Ectropion; Entropion; Orbital fracture reconstruction; Facial fracture

Introduction

Facial injury and fracture reconstruction surgery may cause cosmetic and functional complications to the eyelid such as ectropion or entropion.¹ Lower eyelid malposition (LEM) is one of the most common sequelae after facial fracture surgery,^{2,3} and the mechanism for LEM is considered to be due to contracture of the scar.^{4,5} LEM often resolves spontaneously or with non-surgical treatment such as lubrication, taping, and massage, within six months.^{2,6} However, severe types require subsequent surgical correction.

Depending on severity, ectropion may cause lagophthalmos, impaired corneal lubrication or protection, inflammation, and epiphora,⁷ whereas entropion may result in pain,

irritation, blurred vision, and foreign body sensation, as the cilia are in contact with the cornea.^{6,8} All symptoms of the eyelid are noticeable and likely to impair a patient's quality of life.⁸

Among orbital fracture patients, LEM has been studied extensively with regard to the surgical approach,^{9,10} but less so regarding other factors. Our hypothesis was that older age, along with other yet undisclosed predisposing factors, would play a role in the development of LEM following orbital fracture reconstruction. The primary aim of this study therefore was to analyse the development of LEM, specifically ectropion and entropion, following primary orbital fracture reconstruction. Further aims were to identify new predictive factors for LEM and to assess the effect of the eyelid complication on patients' daily lives.

* Corresponding author at: Department of Oral and Maxillofacial Diseases, PL 447, 00029 Helsinki University Hospital, Finland.

E-mail address: hanna.rajantie@icloud.com (H. Rajantie).

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Material and methods

Study design

Patient data were collected retrospectively from all orbital floor and/or medial wall fracture reconstructions performed at the Department of Oral and Maxillofacial Diseases, Helsinki University Hospital (HUH) from 1 January 2011 to 30 October 2019.

Inclusion and exclusion criteria

All patients who had undergone reconstruction of the orbital floor, medial wall, or both, due to recent fracture (<3 weeks) were included in the study. Those requiring revision surgery and those with fewer than four weeks (28 days) of follow up were excluded.

Study variables

The outcome variable was LEM (yes/no). LEM was established in patients who had either ectropion or entropion, which were visible eversion or inversions of the lower eyelid, with or without vertical retraction of the lid. Additional outcome variables were type of LEM (ectropion or entropion), severity, subsequent surgical correction (yes/no), total follow-up time, extra visits to the clinic due to LEM, and subjective patient satisfaction, which was assessed at the end of the treatment period. The severity of LEM was roughly classified as mild, moderate, or severe. Two authors with vast experience in orbital fracture surgery (JS and HR) reviewed the files of patients with LEM and performed the rough grading based on patient-reported subjective symptoms, treatment required (no treatment, non-surgical or surgical treatment), and duration of LEM.

The primary predictor variable was age. For this purpose patients were classified as <47-year-olds and ≥47-year-olds, based on the median age of the study population.

Explanatory variables were sex, facial fracture type, orbital fracture site, presence of a traumatic wound in the lower lid preoperatively (yes/no), surgical approach, site of reconstruction, reconstructive material, screw fixation of orbital implant (yes/no), and orbital lower rim plate fixation (yes/no).

The type of facial fracture was classified as isolated orbital fracture, zygomatico-orbital fracture, or midfacial fracture extending to the orbit. The site of orbital fracture was classified as isolated orbital floor, isolated orbital medial wall, or orbital floor and associated medial wall fracture. The surgical approach was classified as transconjunctival, subtarsal, or subciliar. Of transconjunctival approaches, those with an associated lateral canthotomy procedure were further identified. The site of reconstruction was classified as orbital floor or orbital floor and medial wall. Reconstruction materials were classified as manually-bent titanium mesh, preformed 3-dimensional titanium mesh, patient-specific milled tita-

nium implant, or resorbable materials (bioactive glass, polymers of polylactic acid, or polyglycolic acid).

Statistical analyses

Stata Statistical Software release 15 (StataCorp) was used for the statistical analyses. Categorical variables are presented as counts with percentages and non-parametric continuous data as medians with interquartile ranges (IQRs), unless otherwise specified. The skewness of continuous variables was assessed using the Shapiro Francia W-test. A non-parametric test (the Wilcoxon rank-sum test) was used to assess differences in distribution between groups. Differences in categorical variables between groups were tested using a two-sided χ^2 test or Fisher's exact test.

To identify independent risk factors for LEM, differences in baseline features and risk factors between patients with and without LEM were analysed by univariate analysis. Variables with an associated p value of <0.05 in the univariate analysis were included in a multivariate logistic regression analysis to find factors independently associated with LEM. The association between age and risk of LEM was assessed by categorising age into two groups based on the patients' median age, and by using age as a continuous variable. The independent association between age and risk of LEM was assessed using binominal generalised linear and logistic regression models.

Results are shown as RRs (risk ratios) and ORs (odds ratios) with 95% confidence intervals (CIs). P-values under 0.05 were considered statistically significant.

Ethics approval

The internal review board of the Head and Neck Centre, Helsinki University Hospital (HUS/356/2017) approved the study protocol. Written informed consent was obtained from all participants.

Results

A total of 265 orbital reconstruction surgeries were identified from a database search. Of these, 10 were excluded for being tumour surgery, 18 for being late or secondary reconstructions (>3 weeks from injury), 15 for being revision surgery, and 48 for lacking the required minimum follow-up time of 28 days (4 weeks). Altogether 174 reconstructions were included in the final analysis. The median follow-up time was 113.0 days (mean 181.2, range 29–862 days). All orbital reconstructions were unilateral.

Table 1 presents the age, sex, and clinical characteristics of the patients. The majority (n = 113, 65%) were men. The median age was 46.7 years. Assault (40%) and a fall on level ground (27%) were the most common mechanisms of injury. Isolated orbital fracture was the predominant facial fracture type (70%). None of the patients had an isolated orbital medial wall fracture.

Table 1
Demographic data and injuries of 174 patients with orbital fracture reconstruction. Data are number (%) unless otherwise stated.

Variable	No. (%) of patients (n = 174)
Age (years):	
Median	46.7
Mean (range)	47.9 (5.4–87.6)
<47	88 (51)
≥47	86 (49)
Sex:	
Male	113 (65)
Female	61 (35)
Aetiology:	
Assault	70 (40)
Fall on ground	47 (27)
Sports	19 (11)
Motor vehicle accident	15 (9)
High-energy fall	13 (8)
Bicycle	8 (5)
Other	2 (1)
Facial fracture type:	
Isolated orbital	122 (70)
Midfacial extending to orbit	34 (20)
Zygomatico-orbital	18 (10)
Orbital fracture site:	
Floor	100 (58)
Floor and medial wall	74 (43)
Lower eyelid wound:	
Yes	5 (3)

In **Table 2** the characteristics of reconstructions and LEM are shown. Surgical access to the fracture site was most often gained via a transconjunctival approach (62%), with additional lateral canthotomy in 20%. Materials used in the reconstruction included manually-bent titanium mesh (Synthes/DePuySynthes, Stryker), preformed 3-dimensional titanium mesh (Synthes/DePuySynthes, KLS Martin, Stryker), milled titanium implant (mtPSI), (Planmeca Ltd),¹¹ and resorbable materials: bioactive glass (BAGS53P4 BonAlive Biomaterials Ltd),¹² or a polymer of polyactic acid or polyglycolic acid (PLA/PGA/PLGA, Synthes, Stryker), or both. All manually-bent titanium meshes were modified to their final shape intraoperatively by the surgeon.

The overall occurrence of LEM was 8% (**Table 2**). Ectropion was observed in 6% and entropion in 2% of patients. Of the 13 LEM cases, 12 were considered moderate or severe. Subsequent surgical correction of LEM was required in 3% of patients.

Table 3 summarises the differences between age groups with respect to other explanatory variables. Sex ($p < 0.001$) and aetiology ($p < 0.001$) were significantly associated with age. Males predominated in the younger age group. Assaults and sports injuries were more common in the younger age group, whereas falls were more common in the older age group.

Table 4 shows the bivariate associations between primary outcome variable, LEM, and age and other explanatory variables. The mean and median age was higher in patients with LEM than in those without LEM ($p = 0.040$). Facial fracture

Table 2
Data on orbital fracture reconstruction and lower eyelid malposition (LEM) in 174 patients.

Variable	No. (%) of patients (n =)
Surgical approach:	
Transconjunctival	107 (62)
Subtarsal	56 (32)
Subciliar	11 (6)
Transconjunctival and lateral canthotomy:	
Yes	34 (20)
Site of reconstruction:	
Floor	152 (87)
Floor and medial wall	22 (13)
Reconstruction material:	
Manually-bent titanium mesh	72 (41)
Patient-specific implant	52 (30)
Preformed titanium mesh	37 (21)
Resorbable material	13 (8)
Screw fixation of orbital implant:	
Yes	14 (8)
Orbital lower rim fixation:	
Yes	40 (23)
LEM:	
Yes	13 (8)
Ectropion:	
Yes	10 (6)
Entropion:	
Yes	3 (2)
Severity of LEM:	
Mild	1 (0.6)
Moderate	6 (3)
Severe	6 (3)
Subsequent surgical correction of LEM:	
Yes	6 (3)

type ($p < 0.001$), orbital fracture site ($p = 0.009$), presence of a traumatic lower eyelid wound ($p = 0.003$), surgical approach ($p = 0.001$), site of reconstruction ($p < 0.001$), reconstructive material ($p < 0.001$), screw fixation of the orbital implant ($p = 0.002$), and orbital lower rim fixation ($p = 0.001$), were significantly associated with the presence or absence of LEM. As shown in **Table 5**, there were no bivariate associations between age groups and LEM, LEM type, severity, or surgical treatment.

Table 6 displays the results of the binominal generalised linear model. The association between age and LEM was significant when age was a continuous variable; the risk for LEM increased by 4% each year (95% CI 1% to 8%). Results from the multivariate logistic regression analysis are shown in the **supplementary material**.

The total follow-up time in patients with LEM was a median of 245 days (mean 316.8, range 31–804 days), 2.3 times longer than in those without LEM ($p = 0.006$). Patients needed a median of four extra follow-up visits (mean 4.5, range 1–10) due to LEM.

Most (61.5%) of the patients who developed LEM were subjectively satisfied at the last follow-up visit, not having a noticeable disadvantage in the lower eyelid after treatment. However, four (31%) had a subjectively defined mild disad-

Table 3
Association between explanatory variables and patients' age.

Variable	No. (%) of patients		p value*
	<47 years (n = 88)	≥ 47 years (n = 86)	
Sex:			<0.001
Male	70 (80)	43 (50)	
Female	18 (21)	43 (50)	
Aetiology:			<0.001
Assault	52 (59)	18 (21)	
Fall on ground	8 (9)	39 (45)	
Sports	14 (16)	5 (6)	
Motor vehicle accident	9 (10)	6 (7)	
High-energy fall	3 (3)	10 (12)	
Bicycle	2 (2)	6 (7)	
Other	0	2 (2)	
Facial fracture type:			0.06
Isolated orbital	68 (77)	54 (63)	
Midfacial extending to orbit	15 (17)	19 (22)	
Zygomatico-orbital	5 (6)	13 (15)	
Orbital fracture site:			0.43
Floor	48 (55)	52 (61)	
Floor and medial wall	40 (46)	34 (40)	
Lower eyelid wound:			1.00
Yes	3 (3)	2 (2)	
Surgical approach:			0.06
Transconjunctival	61 (69)	46 (54)	
Subtarsal	21 (24)	35 (41)	
Subciliar	6 (7)	5 (6)	
Transconjunctival and lateral canthotomy:			0.40
Yes	15 (17)	19 (22)	
Site of reconstruction:			0.38
Floor	75 (85)	78 (91)	
Floor and medial wall	13 (15)	9 (11)	
Reconstruction material:			0.22
Manually bent titanium mesh	32 (36)	40 (47)	
Patient-specific implant	31 (35)	21 (24)	
Preformed titanium mesh	17 (19)	20 (23)	
Resorbable material	8 (9)	5 (6)	
Screw fixation of orbital implant:			0.29
Yes	9 (10)	5 (6)	
Orbital lower rim fixation:			0.13
Yes	16 (18)	24 (28)	

* Two-sided χ^2 test and Fisher's exact test.

Table 4
Associations between age and explanatory variables and lower eyelid malposition (LEM). Data are number (%) unless otherwise stated.

Variable	LEM present (n = 13)	LEM absent (n = 161)	p value*
Age (years):			0.04
Median	59.1	50.8	
Mean	56	47.3	
Sex:			0.736
Male (n = 113)	9 (8)	104 (92)	
Female (n = 61)	4 (7)	57 (93)	
Facial fracture type:			<0.001
Isolated orbital (n = 122)	3 (3)	119 (98)	
Midfacial extending to orbit (n = 34)	8 (24)	26 (77)	
Zygomatico-orbital (n = 18)	2 (11)	16 (89)	
Orbital fracture site:			0.009
Floor (n = 100)	3 (3)	97 (97)	
Floor and medial wall (n = 74)	10 (14)	64 (87)	
Lower eyelid wound:			0.003
Yes (n = 5)	3 (60)	2 (40)	
Surgical approach:			0.001
Transconjunctival (n = 107)	5 (5)	102 (95)	
Subtarsal (n = 56)	4 (7)	52 (93)	
Subciliar (n = 11)	4 (36)	7 (64)	
Transconjunctival and lateral canthotomy (n = 34):			0.738
Yes	3 (9)	31 (91)	
Site of reconstruction:			<0.001
Floor (n = 152)	6 (4)	146 (96)	
Floor and medial wall (n = 22)	7 (32)	15 (68)	
Reconstruction material:			<0.001
Manually-bent titanium mesh (n = 72)	3 (4)	69 (96)	
Preformed titanium mesh (n = 37)	9 (24)	28 (76)	
Patient-specific implant (n = 52)	1 (2)	51 (98)	
Resorbable material (n = 13)	0	13 (100)	
Screw fixation of orbital implant:			0.002
Yes (n = 14)	4 (29)	10 (71)	
Orbital lower rim fixation:			0.001
Yes (n = 40)	8 (20)	32 (80)	

* Wilcoxon rank-sum test, two-sided χ^2 test, and Fisher's exact test.

vantage, and one (8%) had a severe disadvantage despite all treatments for LEM.

Discussion

Our hypothesis was confirmed, as older age was found to be an independent risk factor for LEM, and another previously unreported association between LEM and implant material emerged. This study has also confirmed that LEM is associated with complex fractures in particular.^{4,5}

Earlier research^{5,7,8,13} has reported mechanisms of degenerative processes in the eyelid that cause increased laxity of the lower eyelid. Hakim and Phelps⁸ noted an association between older age and non-traumatic LEM. This study

showed that elderly patients also have an increased risk of cicatricial LEM postoperatively. This is a clinically relevant finding because orbital fractures are known to be more frequent and severe in elderly patients,¹⁴ and the proportion of elderly people in the general population is continually increasing.

The total occurrence of LEM (8%) is in concordance with the previous literature.^{2,4,5,15–18} Occurrence rates vary between 0% and 42% depending on the criteria for LEM. In this study, we included all clinically significant instances of visible ectropion or entropion that were noted in the medical records.

Few studies to our knowledge have examined or reported the development of LEM with respect to different fracture

Table 5
Association between types of lower eyelid malposition (LEM), severity, or surgical treatment and patients' age.

Variable	No. (%) of patients		p value *
	<47 years (n = 88)	≥47 years (n = 86)	
LEM:			0.27
Yes	5 (6)	8 (9)	
Type of LEM:			0.40
Ectropion	3 (3)	7 (8)	
Entropion	2 (2)	1 (1)	
Severity of LEM:			1.00
Mild	0	1 (1)	
Moderate	2 (2)	4 (5)	
Severe	3 (3)	3 (4)	
Subsequent surgical correction of LEM:			0.59
Yes	3 (3)	3 (4)	

* Two-sided χ^2 test and Fisher's exact test.

types. North et al⁴ showed a significantly higher occurrence of LEM (20%) in patients with complex fractures than in those with an isolated orbital blowout fracture (4%). Our study supports their findings, as significant associations existed between LEM and all predictors, indicating more complex fractures including associated midfacial fracture, more extensive orbital fracture and reconstruction, and additional orbital lower rim plate fixation.

The transconjunctival approach has the lowest overall LEM rate compared with transcutaneous (subciliar, sub-tarsal, and infraorbital) approaches, and the subciliar approach has the highest rate among the transcutaneous approaches.^{9,10} However, the transconjunctival approach was used in all three patients with entropion. A probable reason for this is that the transconjunctival incision may cause scarring of the posterior lamella, while transcutaneous approaches cause scarring at the anterior lamella of the eyelid, creating an inward or outward retraction, respectively.¹⁹

Similar to Kesselring et al¹⁶ we found that a preoperative traumatic wound to the lower eyelid was a significant predisposing factor for the development of LEM. Presumably, lacerated skin may suffer from tissue deficiency, lack of soft tissue control, and unfavourable scarring. In contrast, there was no statistical significance between additional lateral canthotomy and LEM. Other studies have shown both positive²⁰ and negative^{16,21} associations between lateral canthotomy and LEM, and thus the impact remains unclear.

Table 6

Results from the binominal generalised linear model showing the association between age and lower eyelid malposition (LEM).

Variable	Occurrence of LEM	Unadjusted risk ratio (95% CI)	Adjusted risk ratio* (95% CI)
Age as continuous variable	13/174 (8%)	1.02 (0.99 to 1.05)	1.04 (1.01 to 1.08)

CI = confidence interval.

* Adjusted for facial fracture type, orbital fracture site, surgical approach, implant material, reconstruction site, screw fixation of implant, orbital lower rim plate fixation, and lower eyelid wound.

Few studies have evaluated implant materials in connection with LEM development. Lee and Nunery²² described ectropion following the use of titanium implants for orbital fracture repair. Other studies^{2,4,23} have reported no correlation between the development of LEM and implant materials. Our study presents a significant association between implant material and development of LEM. Preformed 3-dimensional titanium mesh had the highest occurrence rate of LEM. It is designed to mimic the average anatomy but is poorly malleable and may therefore lead to a suboptimal individual fit. No lower eyelid complications developed with the use of resorbable materials. It must be noted, however, that resorbable implants are rarely used in the most challenging fractures, with wide fractures as well as those extending to both the orbital floor and medial wall. Thus, the most challenging fractures were reconstructed with titanium. Only one patient developed LEM following the use of mtPSI. According to Nikunen et al,²⁴ mtPSI received a significantly better scoring of implant position than preformed or manually-bent titanium implants.

Altogether 3% of the patients required subsequent surgical repair for LEM as the sequela persisted despite non-surgical treatments. North et al⁴ reported roughly similar percentages: surgical repair was needed in 1.1% of the patients with isolated orbital fractures and in 4.2% with complex fractures.

The overall burden to the patient as well as to the health care system due to LEM was substantial, as 46% of patients with LEM required subsequent surgical correction, and the treatment period was substantially prolonged with multiple extra visits at the clinic. While most cases of LEM were defined as moderate or severe, it often subsided spontaneously or without surgical treatment. In the long term, the majority of patients were satisfied with the outcome.

Our study is limited by its retrospective nature, the low number of occurrences of LEM, and multiple surgeons with varying experience and techniques. As the evaluation of the severity of LEM was performed retrospectively, we were unable to use more specific measurements.

Conclusions

LEM is a fairly common sequela after orbital fracture reconstruction. The transconjunctival approach and patient-specific implants should be preferred when possible, especially in elderly patients and those with more complex fractures. LEM often requires subsequent surgical correction and

the treatment period is substantially prolonged, with multiple extra visits to the clinic.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients permission

The internal review board of the Head and Neck Centre, Helsinki University Hospital (HUS/356/2017) approved the study protocol. Written informed consent was obtained from all participants. Patients' permission was obtained

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.bjoms.2022.08.004>.

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