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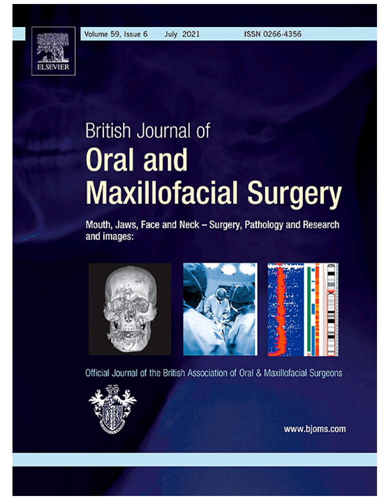

Ageing increases risk of lower eyelid malposition after primary orbital fracture reconstruction

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

Abstract

Background

Lower eyelid malposition (LEM) is a common sequela after orbital fracture reconstruction surgery. This study aimed to analyse the development of LEM, specifically ectropion and entropion, following primary orbital fracture reconstruction surgery, to identify predictive factors for LEM and to assess the effect of the eyelid complication on patients' daily life.

Material and Methods

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.

Results

The overall occurrence of LEM was 7.5%, with ectropion in 5.7% and entropion in 1.7% of patients. Older age, complex fractures, transcutaneous approaches, preoperative traumatic lower lid wound, and implant material were associated with development of LEM. Of all patients, 3.4% needed surgical correction of LEM. Six of the 13 patients (46.2%) who developed LEM, required surgical correction.

Conclusions

The transconjunctival approach and patient-specific implants should be preferred, especially in elderly patients and in 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.

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, entropion (1). Lower eyelid malposition (LEM) is one of the most common sequelae after facial fracture surgery (2, 3). The mechanism for LEM following fracture surgery is considered to be due to scar contracture (5, 7). LEM often resolves spontaneously or with such non-surgical treatment as lubrication, taping, and massage within six months (2, 10). However, severe types of LEM require subsequent surgical correction.

Depending on the severity, ectropion may cause lagophthalmos, impaired corneal lubrication or protection, inflammation, and epiphora (11), whereas entropion may result in pain, irritation, blurry vision, and foreign body sensation as the cilia are in contact with the cornea (10, 12). All symptoms of the eyelid are noticeable and likely to impair patients' quality of life (12).

Among orbital fracture patients, LEM has been studied extensively with regard to the surgical approach (13, 14) but less so regarding other factors. Our hypothesis was that older age, along with other yet undisclosed predisposing factors, would play a role in development of LEM following orbital fracture reconstruction surgery. The primary aim of this study was to analyse the development of LEM, specifically ectropion and entropion, following primary orbital fracture reconstruction surgery. Further aims were to identify new predictive factors for LEM and to assess the effect of the eyelid complication on patients' daily life.

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. Patients 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 eversions or inversions of the lower eyelid, with or without retraction of the lid vertically. Additional outcome variables were type of LEM (i.e. ectropion or entropion), severity of LEM, subsequent surgical correction of LEM (yes/no), total follow-up time, extra visits at the clinic due to LEM, and subjective patient satisfaction, which was assessed at the end of the treatment period. 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, treatments required (no treatment, non-surgical treatment, 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, reconstruction material, screw fixation of orbital implant (yes/no), and orbital lower rim plate fixation (yes/no).

Facial fracture type was classified as 1) isolated orbital fracture, 2) zygomatico-orbital fracture, or 3) midfacial fracture extending to orbit. Orbital fracture site was classified as 1) isolated orbital floor or 2) isolated orbital medial wall 3) orbital floor and associated medial wall fracture. Surgical approach was classified as 1) transconjunctival, 2) subtarsal, or 3) subciliar. Of transconjunctival approaches, those with an associated lateral canthotomy procedure were further identified. Site of reconstruction was classified as 1) orbital floor or 2) orbital floor and medial wall. Reconstruction materials were classified as 1) manually bent titanium mesh, 2) preformed three-dimensional titanium mesh, 3) patient-specific milled titanium implant, or 4) resorbable materials (bioactive glass, polymer of polylactide acid, or polyglycolic acid).

<u>Statistical analyses</u>

STATA (version 15, StataCorp, College Station, TX, USA) 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. The non-parametric test (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 in univariate analysis. Variables with an associated p-value <0.05 in the univariate analysis were included in a multivariable logistic regression analysis to find factors independently associated with LEM. The association between age and risk of LEM was assessed by categorizing age into two groups based on patients' median age and by using age as a continuous variable. The independent association between age and risk of LEM was assessed by using binominal generalized linear and logistic regression models.

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

<u>Ethical approval</u>

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 of patients 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 injuries. The majority (64.9%) of the patients were men. The median age was 46.7 years. Assault (40.2%) and fall on level ground (27.0%) were the most common mechanisms of injury. Isolated orbital fracture was the predominant facial fracture type (70.1%). None of the patients had an isolated orbital medial wall fracture.

In Table 2, the characteristics of reconstructions and LEM are shown. Surgical access to the fracture site was most often gained via transconjunctival approach (61.5%), with additional lateral canthotomy in 19.5%. Materials used in the reconstruction included manually bent titanium mesh (Synthes/DePuySynthes, Stryker), preformed three-dimensional

titanium mesh (Synthes/DePuySynthes, KLS Martin, Stryker), patient-specific milled titanium implant (mtPSI), (Planmeca Ltd.) (15), and resorbable materials that were bioactive glass (BAGS53P4 BonAlive Biomaterials Ltd (16) or a polymer of polyactide acid or polyglycolic acid or both (PLA/PGA/PLGA, Synthes, Stryker). All manually bent titanium meshes were modified to their final shape intraoperatively by the surgeon.

The overall occurrence of LEM was 7.5% (Table 2). Ectropion was observed in 5.7% and entropion in 1.7% of patients. Of the 13 LEM cases, 12 were considered moderate or severe. Subsequent surgical correction of LEM was required in 3.4% of patients.

Table 3 summarizes 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 group. Males predominated in the younger age group. Assaults and sport 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. Mean and median age was higher in patients with LEM than in those without LEM ($p=0.040$). Facial fracture type ($p<0.001$), orbital fracture site ($p=0.009$), presence of traumatic lower eyelid wound ($p=0.003$), surgical approach ($p=0.001$), site of reconstruction ($p<0.001$), reconstruction 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 generalized linear model. The association between age and LEM was significant, when age was a continuous variable. The risk for LEM increases by 4% each year (95% CI 1-8%). The results from the multivariable 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), being 2.3 times longer than in those without LEM (p=0.006). Patients needed a median of four (mean 4.5, range 1−10) extra follow-up visits 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 patients (30.8%) were left with subjectively defined mild disadvantage and one patient (7.7%) with 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 also confirmed that LEM occurrence is associated with complex fractures in particular (5, 7).

Earlier research (7, 11, 12, 17) has reported mechanisms of degenerative processes in the eyelid that cause increased laxity of the lower eyelid. Hakim et al. (12) noted an association between older age and non-traumatic LEM. This study showed that elderly patients have an increased risk of cicatricial LEM postoperatively as well. This is a clinically relevant finding because orbital fractures are known to be more frequent and severe in elderly patients (18), and the proportion of elderly people in the general population is continuously increasing.

The total occurrence of LEM (7.5%) is in concordance with the previous literature (2, 4-9). 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.

Very few studies examined or reported the development of LEM with respect to different fracture types. North et al. (5) showed a significantly higher occurrence of LEM (20%) in patients with complex fractures than in patients with an isolated orbital blowout fracture (4.2%). Our study supports the findings of North and colleagues, as significant associations existed between LEM and all predictors indicating more complex fractures, including associated midfacial fracture, more extensive orbital fractures and reconstructions, and additional orbital lower rim plate fixation.

The transconjunctival approach has the lowest overall LEM rate compared with the transcutaneous (subciliar, subtarsal, and infraorbital) approaches, and the subciliar approach has the highest rate among the transcutaneous approaches (13, 14). However, in all three patients with entropion the transconjunctival approach was used. 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 al. (6), we found that preoperative traumatic wound of the lower eyelid was a significant predisposing factor for developing LEM. Presumably, lacerated skin may suffer from tissue deficiency, lack of soft tissue control, and unfavourable scarring. By contrast, there was no statistical significance between additional lateral canthotomy and LEM. Other studies have shown both positive (20) and negative (6, 21) associations between lateral canthotomy and LEM, and thus, the impact remains unclear.

Very few studies have evaluated implant materials in connection with LEM development. Lee and Nunery (22) described ectropion following the use of titanium implants for orbital fracture repair. Other studies (2, 5, 23) have reported no correlation between LEM development and implant materials. Our study presents a significant association between implant material and LEM development. Preformed three-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 suboptimal individual fit. No lower eyelid complications developed with resorbable material reconstruction. It must be noted, however, that resorbable implants are rarely used in the most challenging fractures, with wide fractures as well as fractures 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 the study of Nikunen et al. (24), mtPSI received a significantly better scoring of implant position than preformed or manually bent titanium implants.

Altogether 3.4% of the patients required subsequent surgical repair for LEM as the sequela persisted despite non-surgical treatments. North et al. (5) reported roughly the similar percentages; surgical repair was needed in 1.1% of the patients with isolated orbital fractures and in 4.2% of patients with complex fractures.

The overall burden to the patient as well as to the health care system due to LEM was substantial, as 46.2% of patients with LEM, required subsequent surgical correction and the treatment period was substantially prolonged with multiple extra visits at the clinic. While most LEM was defined as moderate or severe, it often subsided spontaneously or without surgical treatment. In the long term, the majority of patients were satisfied with 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 fairly common sequela after orbital fracture reconstruction surgery. The transconjunctival approach and patient-specific implants (mtPSI) should be preferred, when possible, especially in elderly patients and in 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

None

Ethics statement/confirmation of patient 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. Patient permission obtained

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Table 1. Demographic data and injuries of 174 patients with orbital fracture reconstruction.

Variable		No. of patients	% of 174
Age (years)			
[illegible]	[illegible]		
mean	47.9		
range	5.4-87.6		
< 47		88	50.6
≥ 47		86	49.4
Sex			
male		113	64.9
female		61	35.1
Aetiology			
assault		70	40.2
fall on ground level		47	27.0
sports		19	10.9
motor vehicle accident		15	8.6
high-energy fall		13	7,5
bicycle		8	4.6
other		2	1.1
Facial fracture type			
isolated orbital		122	70.1
midfacial extending to orbit		34	19.5
zygomatico-orbital		18	10.3
Orbital fracture site			
floor		100	57.5
floor and medial wall		74	42.5
Lower eyelid wound			
yes		5	2.9

Table 2. Data of orbital fracture reconstruction and lower eyelid malposition in 174 patients.

Variable	No. of patients	% of 174
Surgical approach		
[illegible]	[illegible]	[illegible]
subtarsal	56	32.2
subciliar	11	6.3
Transconjunctival and lateral canthotomy		
yes	34	19.5
Site of reconstruction		
floor	152	87.4
floor and medial wall	22	12.6
Reconstruction material		
manually bent titanium mesh	72	41.4
patient specific implant	52	29.9
preformed titanium mesh	37	21.3
resorbable material	13	7.5
Screw fixation of orbital implant		
yes	14	8.0
Orbital lower rim fixation		
yes	40	23.0
LEM		
yes	13	7.5
Ectropion		
yes	10	5.7
Entropion		
yes	3	1.7
Severity of LEM		
mild	1	0.6
moderate	6	3.4
severe	6	3.4
Subsequent surgical correction of LEM		
yes	6	3.4

Abbreviations: LEM=lower eyelid malposition

Table 3. Association between explanatory variables and patients´ age.

	< 47 years (n=88)		≥ 47 years (n=86)		
Variable	**No. of patients**	**% of 88**	**No. of patients**	**% of 86**	**p-value ***
male	70	79.5	43	50.0	<0.001
female	18	20.5	43	50.0	
Aetiology					<0.001
assault	52	59.1	18	20.9	
fall on ground level	8	9.1	39	45.3	
sports	14	15.9	5	5.8	
motor vehicle accident	9	10.2	6	7.0	
high-energy fall	3	3.4	10	11.6	
bicycle	2	2.3	6	7.0	
other	0	0.0	2	2.3	
Facial fracture type					0.06
isolated orbital	68	77.3	54	62.8	
midfacial extending to orbit	15	17.0	19	22.1	
zygomatico-orbital	5	5.7	13	15.1	
Orbital fracture site					0.43
floor	48	54.5	52	60.5	
floor and medial wall	40	45.5	34	39.5	
Lower eyelid wound					1.00
yes	3	3.4	2	2.3	
Surgical approach					0.06
transconjunctival	61	69.3	46	53.5	
subtarsal	21	23.9	35	40.7	
subciliar	6	6.8	5	5.8	
Transconjunctival and lateral canthotomy					0.40
yes	15	17.0	19	22.1	
Site of reconstruction					0.38
floor	75	85.2	78	90.7	
floor and medial wall	13	14.8	9	10.5	
Reconstruction material					0.22
manually bent titanium mesh	32	36.4	40	46.5	
patient-specific implant	31	35.2	21	24.4	
preformed titanium mesh	17	19.3	20	23.3	
resorbable material	8	9.1	5	5.8	
Screw fixation of orbital implant					0.29
yes	9	10.2	5	5.8	
Orbital lower rim fixation					0.13
yes	16	18.2	24	27.9	

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

Table 4. Associations between age and explanatory variables and lower eyelid malposition.

	LEM present		**LEM absent**		
Variable	**n=13**	**% of n**	**n=161**	**% of n**	**p value***
Age					0.04
median	59.1		50.8		
mean	56		47.3		
Sex					0.736
male (n=113)	9	8.0	104	92.0	
female (n=61)	4	6.6	57	93.4	
Facial fracture type					<0.001
isolated orbital (122)	3	2.5	119	97.5	
midfacial extending to orbit (n=34)	8	23.5	26	76.5	
zygomatico-orbital (n=18)	2	11.1	16	88.9	
Orbital fracture site					0.009
floor (n=100)	3	3	97	97.0	
floor and medial wall (n=74)	10	13.5	64	86.5	
Lower eyelid wound					0.003
yes (n=5)	3	60	2	40.0	
Surgical approach					0.001
transconjunctival (n=107)	5	4.7	102	95.3	
subtarsal (n=56)	4	7.1	52	92.9	
subciliar (n=11)	4	36.4	7	63.6	
Transconjunctival and lateral canthotomy (n=34)					0.738
yes	3	8.8	31	91.2	
Site of reconstruction					<0.001
floor (n=152)	6	3.9	146	96.1	
floor and medial wall (n=22)	7	31.8	15	68.2	
Reconstruction material					<0.001
manually bent titanium mesh (n=72)	3	4.2	69	95.8	
preformed titanium mesh (n=37)	9	24.3	28	75.7	
patient specific implant (n=52)	1	1.9	51	98.1	
resorbable material (n=13)	0	0	13	100.0	
Screw fixation of orbital implant					0.002
yes (n=14)	4	28.6	10	71.4	
Orbital lower rim fixation					0.001
yes (n=40)	8	20	32	80.0	

Abbreviations: LEM=lower eyelid malposition
*Wilcoxon rank-sum test, two-sided χ^2 test, and Fisher's exact test

Table 5. Association between lower eyelid malposition types, severity, or surgical treatment and patients´ age.

	< 47 years (n=88)		**≥ 47 years (n=86)**		
Variable	**No. of patients**	**% of 88**	**No. of patients**	**% of 86**	**p-value ***
yes	5	5.7	8	9.3	
Type of LEM					0.40
ectropion	3	3.4	7	8.1	
entropion	2	2.3	1	1.2	
Severity of LEM					1.00
mild	0	0.0	1	1.2	
moderate	2	2.3	4	4.7	
severe	3	3.4	3	3.5	
Subsequent surgical correction of LEM					0.59
yes	3	3.4	3	3.5	

Abbreviations: LEM=lower eyelid malposition
*Two-sided χ^2 test and Fisher's exact test

Table 6. Results from the binominal generalized linear model showing the association between age and lower eyelid malposition.

Variable	Occurrence of lower eyelid malposition	Unadjusted risk ratio (95% CI)	Adjusted risk ratio* (95% CI)
variable			

Abbreviations: 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

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

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