Military Hospital, University of Ulm

Department of Maxillofacial Surgery

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A prospective study of the clinical outcomes of orbital floor and medial wall blowout fractures using preformed 3-D implants

Doctoral thesis

for the attainment

of the medical doctoral degree

at the medical faculty of the University of Ulm

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Investing in your future

To my family for their continual support

Index of abbreviations

°	Degree
♂	Male
♀	Female
#	Fracture
2-D	2-dimensional
3-D	3-dimensional
AO	Arbeitsgemeinschaft für Osteosynthesefragen
ASA	American Association of Anaesthesiologists
Bl	Blood
CAD-CAM	Computer Aided Design-Computer-Aided Manufacturing
Cm	Centimetre
cm^2	Centimetre squared
cc/cm^3	Cubiccentimetre
Co.	Contralateral
CRF	Case report form
CT	Computed tomography
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information
DS	Dual source
ENT	Ear, Nose and Throat
ex.	Example
F	Fracture
FS	Frontal sinus
gr.	Gram

I.C.	Informed consent
ITU	Intensive Therapy Unit
i.v.	intravenous
L	Left
MRI	Magnetic resonance imaging
M.W.	Medial wall
MS	Maxillary sinus
Mm	Millimetre
NGA	No glasses available
NGR	No glasses required
No.	Number
Oper.	Operation
O.F.	Orbital floor
PACS	Picture archiving and communication system
P/Pat.	Patient
Po.	Postoperative
Pr.	Preoperative
prn	pro re nata (as required)
R	Right
S	Surgeon

1 Introduction

1.1 Orbital anatomy

The orbit can be considered as a conical structure with the optic canal located at the apex, the base of the cone is formed by a plane ending from the supraorbital rim to the infraorbital rim in the supero-inferior direction and the fronto-zygomatic suture to the anterior lacrimal crest in the latero-medial direction as according to Deveci et al.(2000). The orbital cavity is built cranially by the frontal bone and the lesser wing of the sphenoid bone, medially by the lacrimal bone, the orbital plate of the ethmoid bone and the body of the sphenoid bone, caudally by the orbital part of the maxilla, the orbital processes of the zygomatic and palatine bones, and laterally by the greater wing of the sphenoid bone and zygomatic bone. The orbital walls vary in thickness and density. The lateral is the thickest, followed by the roof, floor and medial wall as in Read et al.(1998). See Figure 1.

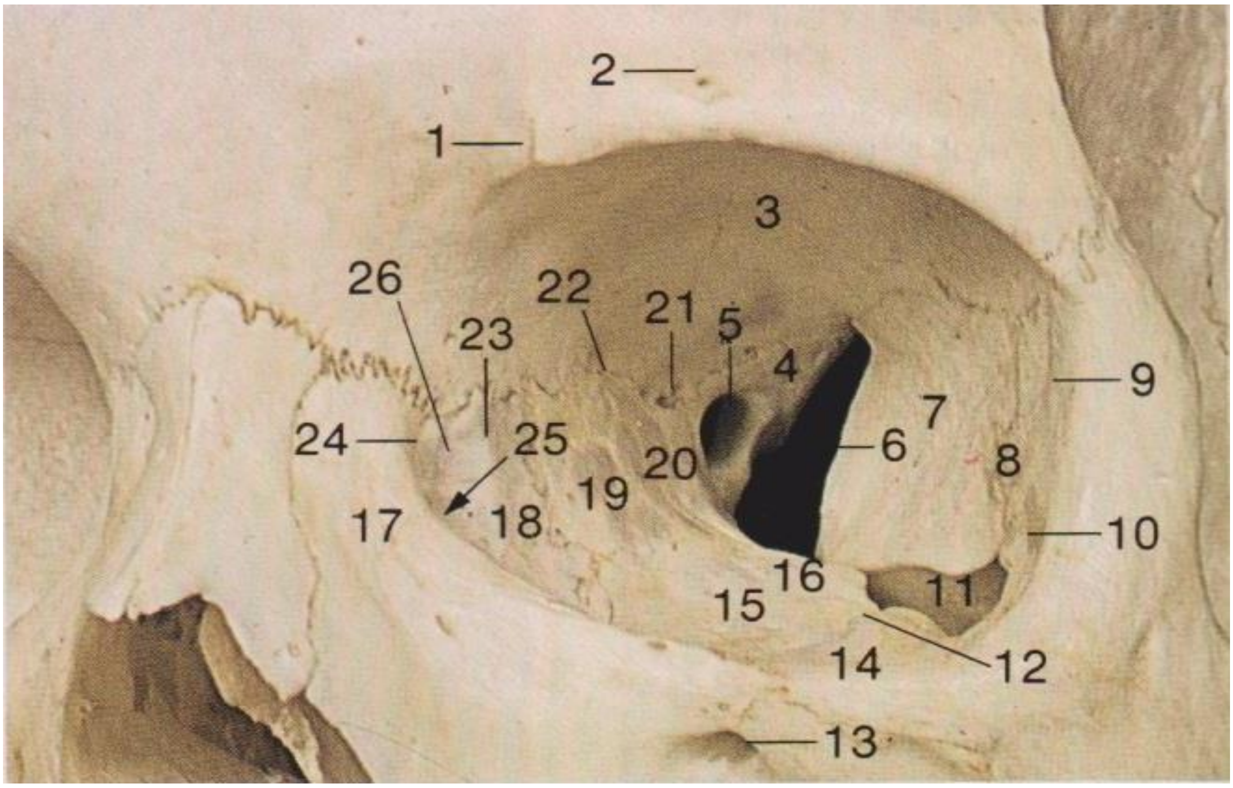


Figure 1: Photo of the bony left orbit (Reproduced from 'A Colour Atlas of Human Anatomy' 3rd Edition by Permission of Wolfe Publishing(1993); Editors: Mc Minn, Hutchings, Pegington, and Abrahams, Page 20 Figure A). For illustration: 1) Frontal notch, 2) Supraorbital foramen, 3) Orbital part of frontal bone, 4) Lesser

wing of sphenoid bone, 5) Optic canal, 6) Superior orbital fissure, 7) Greater wing of sphenoid bone, 8) Zygomatic bone, 9) Marginal tubercle, 10) Zygomatico-orbital foramen, 11) Inferior orbital fissure, 12) Infra-orbital groove, 13) Infra-orbital foramen, 14) Orbital border of zygomatic bone, 15) Maxilla, 16) Orbital process of palatine bone, 17) Frontal process of maxilla, 18) Lacrimal bone, 19) Orbital plate of ethmoid bone, 20) Body of sphenoid bone, 21) Posterior ethmoidal foramen, 22) Anterior ethmoidal foramen, 23) Posterior lacrimal crest, 24) Anterior lacrimal crest, 25) Nasolacrimal canal, 26) Fossa for lacrimal sac.

The anatomical configuration of the junctional area between the medial wall and floor in the posterior third of the orbit is of particular importance; the maxillary sinus produces a bulge in this region, obliterating the angle between the orbital floor and the medial wall. This prominence is crucial in maintaining the forward projection of the globe, and failure to reconstruct this area results in posterior globe displacement and enophthalmos. Most of the openings of the orbit are entry points for the nerves and vessels. Through the optic canal of the sphenoid bone passes the optic nerve and the ophthalamic artery. Caudal and lateral to this lies the superior orbital fissure (between the greater wing, the lesser wing and the body of the sphenoid bone); through this fissure pass the superior ophthalamic vein and all the orbital nerves (frontal, lacrimal, trochlear, oculomotor, nasociliary and the abducent). In between the maxilla and the greater wing of the sphenoid bone lies the inferior orbital fissure, through which passes the inferior ophthalamic vein and the infraorbital nerve, the latter then passing through the infraorbital groove and canal.

The periorbital tissue, mainly the periosteum, covers the bony orbit. The orbital contents include the eyebulb, ocular muscles, vessels, nerves and connective tissue rich with adipose tissue. The connective tissue becomes denser in the area of the ocular muscles and builds a strong capsule around the bulb. Through this capsule pass the 6 extrinsic ocular muscles directly to the bulb; the 4 straight muscles (superior rectus, inferior rectus, medial rectus, and lateral rectus) as well as the superior oblique muscle all of which originate from the optic nerve circularly as a common tendinous ring (also known as the annulus of Zinn); see Figure 2. The inferior oblique muscle arises from the anterior medial orbital wall.

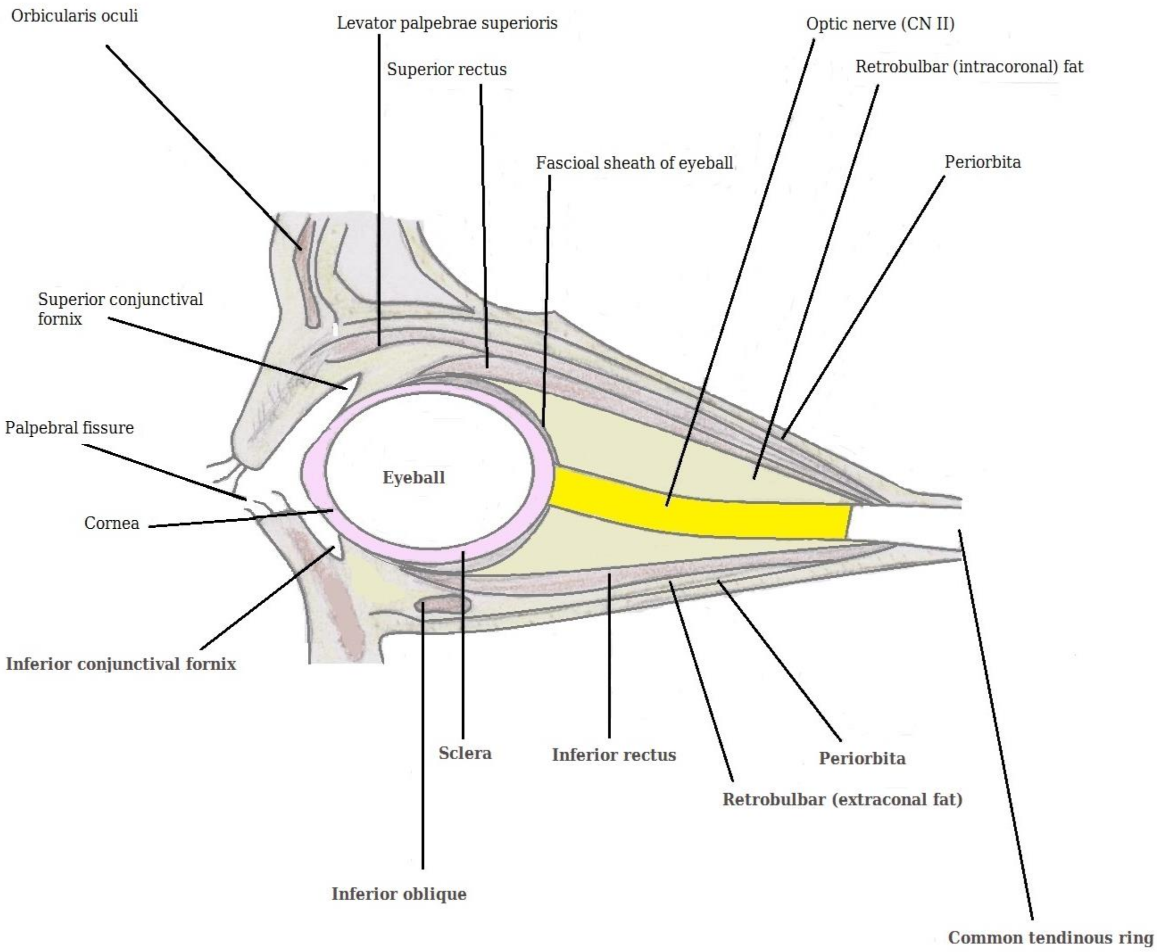


Figure 2: Orbital contents; sagittal section.

The orbital septum forms the anterior border of the orbit; it pulls as a connective tissue plate from the orbital edge to the tarsus of the upper and lower lid. The levator palabrae superioris muscle, also an extraocular muscle, arises from the lesser wing of the sphenoid bone, superior and anterior to the optic canal, and inserts into the superior tarsus and to the skin of the superior eyelid. Figure 3 and 4 show a diagrammatic representation of the extraocular muscles and the movements they produce.

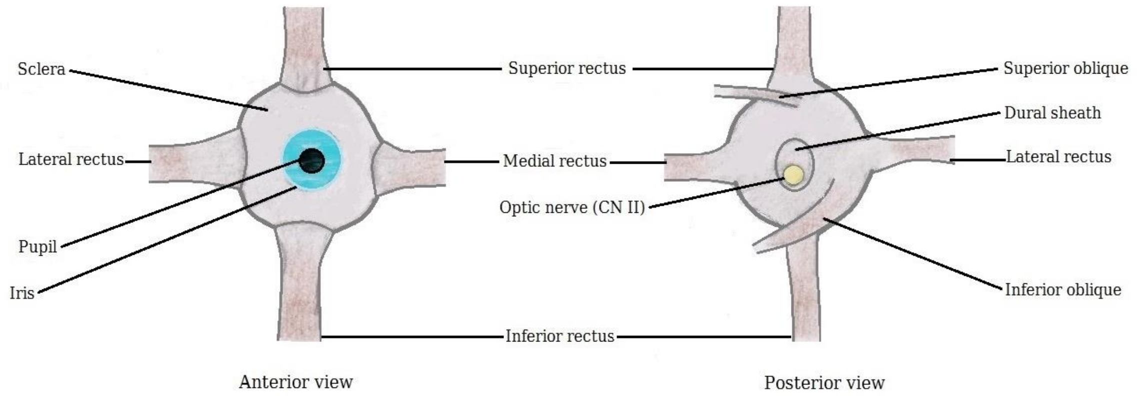


Figure 3: Extraocular muscles.

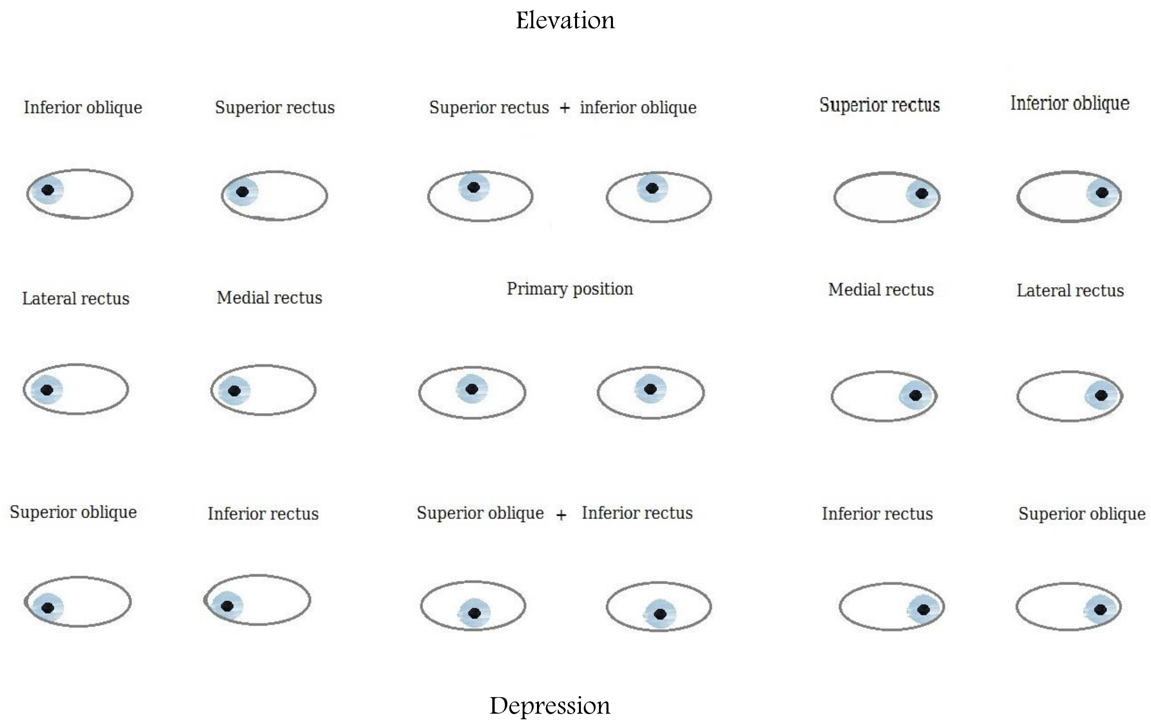


Figure 4: Binocular movements produced by the extraocular muscles of the eyeball from the primary position, together with a representation of the muscles and nerves producing them. While the trochlear nerve (Cranial nerve IV) supplies the superior oblique muscle with motor fibres, and the abducent nerve (Cranial nerve VI) supplies motor fibres to the lateral rectus muscle, the rest of the extraocular muscles are all supplied by the

oculomotor nerve (Cranial nerve III). Movements in the right direction is caused by abduction of the right eye and adduction of the left eye, and in the left direction by abduction of the left eye and adduction of the right eye.

1.2 Fracture introduction

In craniofacial trauma, the involvement of orbital structures is noted in up to 40% of cases as in Ellis E III et al.(1985). They can occur either in isolation or in combination with fractures of the adjacent facial bones such as orbitozygomatic and naso-orbital-ethmoid fractures as in Schramm et al.(2008). The spectrum severity ranges from simple linear fractures which can be treated conservatively, to more complex comminuted fractures whose reconstruction can be demanding and challenging. Generally, orbital blowout fractures are caused by direct trauma to the globe, which produces an overall increase in intraorbital pressure that is dissipated by fragmentation of the orbital floor; it is defined as the disruption of the orbital wall (usually the orbital floor and/or the medial wall) with fracture fragments directed away from the orbit without disruption of the orbital rim; Lee et al.(2004). Approximately half of the cases can develop late enophthalmos depending on the range of orbital tissue expansion into adjacent sinus cavities; approximately one-fourth of the patients develop diplopia due to ischaemic muscle injury or restriction associated with displaced or traumatized muscle. Hinged or trapdoor orbital floor fractures retain a degree of continuity with the intact orbital floor, resulting in a periorbital "hinge", allowing the fractured bony segment to pivot. Infraorbital nerve hypoaesthesia can also occur. Combined medial wall and floor fractures may be associated with ocular trauma in more than half of the cases.

In most cases, diplopia resolves spontaneously so that enophthalmos is the most common late sequela of orbital fractures. Very commonly, patients presenting with ocular fractures, also have other co-existing facial injuries. Of course it cannot be underestimated, how imperative it is for every such fracture to be examined by an ophthalmologist, whether the patient is treated conservatively or surgically. The fractures of the orbital floor, account for the majority of all traumas involving the middle-third of the face (mid-face); sometimes as pure blow-out, themselves accounting for up to 21.4%. Trauma in such an area usually results from assaults, driving accidents, sports trauma, and falls due to any reason including seizures, faintness, or just stumbling. Orbital blow-in fracture occurs when the fragments are displaced into the orbit consequent upon blunt force near the orbit; they may cause impingement on intraorbital soft tissues, especially the extraocular muscles and globe. Globes having a past history of surgery as for example cataract surgery, have a much higher risk of perforation resulting from trauma.

Orbital roof fractures are more common in children younger than 7 years and in more than two-thirds of the cases in boys; Ben Simon et al.(2009). They may be a consequence of the lack of frontal sinus pneumatization and the relatively larger cranium in this age group. In multiple wall fractures, involving the orbital roof, there is an associated increased risk of concurrent intracranial injury. Pure blow-out fractures involve fracturing of the thin inferior, medial, or lateral walls of the orbit, whereas impure blow-out fractures also include disruption of the thick orbital rim and often adjacent facial bones. Impure orbital fractures as reported by He et al.(2007) account for 76% of all orbital fractures, and are characterized by interruption of the orbital rim continuity, large orbital wall defects with multiple-wall involvement, deep defect extension resulting in facial cosmetic disfigurement, enophthalmos with/without diplopia, restricted globe movement, and visual impairment. Orbital floor fractures normally result from nonpenetrating blunt forces to the orbital area by an object that has dimensions greater than the orbit itself as sustained by Jin et al.(2007). There is a controversy as to the mechanism of these fractures. According to the "buckling theory" as described by LaGrange(1918) and Kirby et al.(2011), a sufficient blow to the orbital rim causes a compression fracture to the wall and the energy is transmitted through the thinner orbital floor. In the "hydraulic theory", as postulated by Smith et al.(1957), Waterhouse et al.(1999) and Warwar et al.(2000) states that retropulsion of the globe causes a rise in intraorbital pressure, which is itself transferred to the walls of the orbit, creating a force large enough to cause a fracture. Both mechanisms are plausible depending on the injury (i.e. a large blunt object that hits the rim vs. a smaller object that transmits most of the force to the globe)/ a combination of both as according to He et al.(2007). However, while the hydraulic theory can be adapted to explain both orbital floor and medial wall fractures, it is more difficult to assign the buckling theory to pure medial orbital wall fractures, while providing an acceptable explanation for floor fractures as in Barry et al.(2008). Re-emerging is the "globe to wall" theory, as described by Erling et al.(1999).

A retrospective study by de Silva et al.(2011), including 152 patients, compared the type of orbital blowout fractures and its variation with the Caucasian, Afro-Caribbean, and Asian (Oriental and Indian) races. Caucasians and Asians had most commonly isolated floor fractures, and Afro-Caribbean's isolated medial wall fractures. There was an apparent similarity between the proportion of patients with involvement of the strut fractures in the African and Asian patients, when compared with the Caucasians. The orbital floor is widely regarded as the most liable to blow-out fractures, even though the medial wall, comprising the extremely thin lamina papyracea, would reasonably be regarded as the area most susceptible to injury. Apparently, the ethmoid labyrinth buttresses strengthens the medial wall. After some case reports, it was suggested that black patients have a higher risk of medial wall fracture because of fewer ethmoidal septa, but there are few studies comparing the ethnic variations in orbital osteology. Caucasian and Chinese orbits are similar with regard to the position of foramina and fissures as reported in Cheng et al.(2008), and therefore account for the similar pattern for blowout fractures in the 2 groups. However, compared with autopsy evidence, the small proportion of medial fractures reported suggests that lack of symptoms, or limited imaging may have led to underdiagnoses of this injury as found in Hammerschlag et al.(1982).

Fractures of the orbital cavity occur mainly medial to the infraorbital groove and canal. Floor fractures are regularly combined with fractures of the medial wall, due to the limited thickness of the bone in this area, as noted in Metzger et al.(2007). Unlike classic blowout fractures of the orbital floor, medial orbital wall fractures have not received much clinical attention; Burm et al.(1999). Many patients are asymptomatic, and the signs and symptoms so subtle, that the condition eludes diagnosis; they occur in the most fragile area, the lamina papyracea, and are caused by blunt periorbital trauma. Enophthalmos, one of the most feared complications of blowout fractures of the orbit, has been thought to be less frequently associated with medial wall fractures, but several studies have reported that medial wall fractures play a major role in traumatic enophthalmos, as in Nolasco et al.(1995). Scolozzi(2011) investigated the use of titanium mesh plates in a combined transcaruncular-transconjunctival approach for severe medial orbital wall fractures. Pearl et al.(1978), found out that medial orbital wall fractures exist in as many as 31% of cadavers studied, Burm et al.(1999) reported the incidence of isolated medial wall fractures to be 54.9%, being the highest amongst blowout fractures of the orbit. They can lead to a significant enophthalmos in spite of small volume changes as reported by Raskin et al.(1998). Biesman et al.(1996), reported a significant postoperative diplopia in patients with combined orbital floor-medial wall fractures than those with only floor fractures. Kim et al.(2009) found out that the height-to-width (H-W) ratio of the medial rectus muscle in coronal views of CT scans is a useful parameter to predict enophthalmos in patients with medial orbital wall fractures.

The orbital bones in the paediatric patients are more flexible, and this results in the bones snapping back to cause a "trapdoor fracture", where entrapment of the orbital soft tissue contents occurs. This may of course cause ischaemia to the extraocular muscles with resultant diplopia and a vagal response including nausea and syncope due to the trapped parasympathetic nerve fibres that travel within the muscles. In Parbhu et al.(2008), only 9 out of 24 paediatric patients showed radiological evidence of entrapment, when measured through CT scans, while there was intraoperative evidence of 21 entrapped globes. Surgery should be performed early in patients with "white-eyed" blowout fractures, severe oculocardiac reflex, and entrapped orbital contents as noted in Burnstine et al.(2002). Surgical procedures at a later stage cannot prevent ischaemic damage, and the formation of excess scar tissue causes postoperative complications; Grant et al.(2002). Out of the 88 patients with orbital floor fractures undergoing endoscopic endonasal/transmaxillary repair by Otori et al.(2003), 15.9% of them had a trapdoor fracture which needed a surgical exposure for the diagnosis.

The adult population on the contrary tend to have the "open-door" type of orbital floor fractures, clinically resulting in enophthalmos. Yano et al.(2010) suggest that in patients without a 'missing rectus', surgery for diplopia in linear-type blowout fractures can be postponed for several days until the swelling has subsided. In patients with a 'missing rectus', surgery should be performed immediately to save unstable regions of the orbital muscle because recovery time and sequelae were correlated to both the degree of the damage and to the time of surgery. Yano et al.(2010), published a retrospective study on 22 patients having a linear-type fracture, of whom only 14 were chosen as requiring surgery. The word 'missing rectus', also reported in Wachler et al.(1998) and Anda et al.(1987) was used to denote patients which showed minimal or no inferior rectus muscle density that could be confirmed above the floor on coronal CT scans. Many publications on trapdoor fractures have mentioned the lack of a spontaneous cure which can attribute to mechanical interferences, such as entrapment; Okinaka et al.(1999) and

Koornneef(1979). Entrapment in linear-type blowout fractures may result in changes that are more focally vulnerable than in other types of fractures. These results indicate that the primary pathologic finding of linear-type blowout fractures is dyskinesia resulting from adhesive impingement of the content or impairment of the contracting muscle as discussed in Iliff et al. (1999).

During the early postoperative course of some fractures, a paradoxical eye movement might be observed. After dissolving the impingement in the fracture by surgical intervention, it may result from compensation or disturbance of the afferent nervous signalling by stretch receptors in the orbit, as discussed by Dancause et al.(2007) and Demer et al.(2006). In patients with the missing rectus, early effective rehabilitation is important for fully recovered ductions because infraduction restriction initially remains serious despite the removal of mechanical interference. While binocular vision exercises are difficult for severely injured or juvenile patients, a monoculus on the unaffected eye during the early phase of postoperative recovery may help to rehabilitate the affected eye motion while avoiding amblyopia in children.

In any type of blowout fractures including medial wall, vertical gaze, especially upgaze impairments are more common than lateral gaze restriction. Linear-type or closed trapdoor fractures may be frequent in the floor because of the structural differences in the paranasal sinuses (ethmoid cells vs. maxillary sinus). This specificity may be related to Bell phenomenon at injury, as described by Yano et al.(2009). Almost all patients with blowout fractures have experienced blunt injuries and are therefore forced to close their eyes firmly just before injury. Closing the eyes results in supraduction (Bell phenomenon), which lengthens the inferior rectus and brings the muscle in front of the eye's equatorial plane. If fracture occurs under the muscle leading to herniation through the fracture site, more damage may occur on closing the trapdoor when the eye returns to the primary position. The returning force may assist in closing the door, lodging of the muscle and it being damaged at the fracture edge. Iliff et al.(1999), reported that the inferior rectus muscle near the apex was delicate in comparison to the denser connective tissue around the muscle at its global insertion; they also noted muscle swelling on the floor without the identification of the missing rectus on CT findings. The rectus may be damaged on return to the primary position, similar to degloving injury.

Abed et al.(2011), studied the morphometric and geometric anatomy of 47 exanterated orbits from 24 formalin-fixed Caucasian cadavers to study the orbital floor. When comparing these measurements to similar studies of Chinese, Korean and Thai orbits, the differences were quite similar. In cases where an orbital floor fracture is involving the posterior half, the infraorbital nerve in the infraorbital groove has to be separated from the periorbita to insert the sheet. Unexpected bleeding might be encountered. Coulter et al.(1990) described orbital haemorrhage resulting from "orbital branches of the infraorbital artery", and Rubin et al.(2005) reported about "the orbital perforating branch of the infraorbital artery". Hwang et al.(2009), reported that when the fracture site in orbital floor fractures involves the posterior half, the periorbita does not have to be separated from the infraorbital nerve, thus avoiding injury to the orbital branch of the infraorbital artery.

Ploder et al. (2005), found that the volume of displaced tissue in pure orbital wall fractures, correlated significantly with ophthalmological findings; possibly due to musculofibroelastic structures, which influence the motility path of the rectus muscles. Originally, fat atrophy was thought to be the central problem in the cause of enophthalmos. However Lieger et al.(2010) show no evidence for this assumption; the main reason for enophthalmos is an increase in volume of the posterior segment of the orbit and changes in the deep orbital cone area. Forward movement of the globe is often achieved by volume reduction, and very important is the precise reconstruction of the retrobulbar bulge. Lieger et al.(2010), published a 10-year retrospective study on 29 patients using CAD/CAM implants for reconstruction of posttraumatic enophthalmos. Zhang et al.(2010) performed a study on 21 patients presenting late for treatment of unilateral impure orbital fractures and post-traumatic enophthalmos, using CAD/CAM techniques to fabricate a custom-made titanium plate through mirror-imaging the uninjured side. According to this study, a 1mm of enophthalmos was associated with an orbital volume expansion of 2.24 cm^3, which was much larger than those reported by for example Ploder et al.(2002). Consequently, the authors concluded that severe post-traumatic enophthalmos is associated with a higher degree of volume expansion for each millimeter of degree of enophthalmos and a sharper volume decrease relative to each millimeter of enophthalmos correction. Fan et al.(2007) carried a prospective study of the late reconstruction on 17 patients with unilateral complex orbital fractures using CAD/CAM techniques on patients which had co-existing multiple facial fractures. Bell et al.(2009), published a retrospective review on 15 patients with complex primary/secondary unilateral post-traumatic and postablative orbital deformities receiving computer-assisted treatment.

1.3 The statement of the problem

The orbit and the diseases/injuries which affect it, has been extensively researched in the past century, from all over the continents of the globe. What interests us is the fractures which affect it; that is whether it is a blowout/blowin fracture, pure/impure, the number of walls affected, the eyeball itself, the periorbital tissues in combination with other midfacial/cranial fractures/injuries or a combination of all these. The maxillofacial surgeon, when faced with such a clinical picture, strives to optimally reconstruct the orbit to the pre-injury state, to restitute the integral state. On the other hand, what interests the patient, is how he/she will aesthetically appear, and how he/she will function in the daily activities if there will be any post-traumatic/post-operative deficit.

A vast amount of different implants (autogeneous, allogeneous and alloplastic) have been used on different patients in the last century, and different results were published. Titanium has been very extensively researched as the pure metal or when mixed with other materials ex. porous polyethylene to improve the characteristics, as for example in SynPOR (DePuy Synthes, Germany). However the effectiveness of the preformed titanium implants by Synthes (Germany) has not been widely reported except in a few cases; Scolozzi et al.(2009) and then involving only 10 patients. Our study focusses on a larger amount of patients; 23, reconstructed for existing pure orbital floor and/or medial wall fractures by using the 3D preformed 'Synthes' orbital implants with a 0.4mm profile.

2 The Study: Materials and Methods

2.1 The study

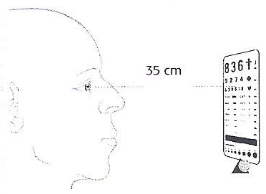
Our research was part of a prospective multicenter trial organized by the AO Foundation; "Orbita 3". The AO (Arbeitsgemeinschaft für Osteosynthesefragen) research involves the preciseness of medial orbital wall and/or floor reconstruction, by comparing preoperatively preformed and non-preformed orbital plates. The multicenter trial involved different centres in Germany including Hannover (university, maxillofacial department), Ulm (the military hospital, maxillofacial department), Freiburg (university, maxillofacial department) and Munich (university, maxillofacial department). Other countries involved included 3 in the U.S.A.; San Antonio (university, maxillofacial department), Sacramento (university, ENT department) and Baltimore (university, Oculoplastic department), 1 place in Singapore (university, plastic surgery department), 1 place in Madrid, Spain (university, maxillofacial department), and 1 centre in Innsbruck, Austria (university, maxillofacial department).

A separate file was provided to us from the AO Foundation for each patient, and every information sheet was followed by a carbon copy. Thus, when any information was entered on the original copy, this was always automatically included in the carbon copy. The original papers had to be all sent back to the AO Foundation (after being filled up), while the carbon copies stayed in our department; see Figure 5.

AO Foundation ORBITA 3 4 WEEKS INVESTIGATOR 2/4

2 Visual acuity

- Perform this test in a well illuminated room
- Ask the patient to cover one eye with his hand
- Hold the visus pocket card at a distance of 35cm (14 in)
- Ask the patient to read progressively smaller letters
- Record the smallest line the patient can read successfully
- Repeat the test for the other eye



2.1 Visus **without** correction glasses

Affected side:
☐ <5%
☐ 5%
☐ 10%
☐ 20%
☐ 50%
☐ 60%
☐ 75%
☐ 85%
☐ 90%
☐ 95%
☐ 100%
☐ Visual acuity could not be assessed

Visus **without** correction glasses

Unaffected side:
☐ <5%
☐ 5%
☐ 10%
☐ 20%
☐ 50%
☐ 60%
☐ 75%
☐ 85%
☐ 90%
☐ 95%
☐ 100%
☐ Visual acuity could not be assessed

2.2 Does the patient usually need vision aid? (contact lenses, correction glasses)

☐ No → Go on to ocular motility
☐ Yes → Please answer the question below

2.3 Visus **with** correction glasses

Affected side:
☐ <5%
☐ 5%
☐ 10%
☐ 20%
☐ 50%
☐ 60%
☐ 75%
☐ 85%
☐ 90%
☐ 95%
☐ 100%
☐ Visual acuity could not be assessed

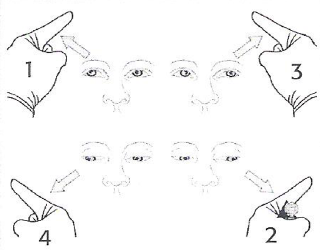
Visus **with** correction glasses

Unaffected side:
☐ <5%
☐ 5%
☐ 10%
☐ 20%
☐ 50%
☐ 60%
☐ 75%
☐ 85%
☐ 90%
☐ 95%
☐ 100%
☐ Visual acuity could not be assessed

3 Ocular motility

- Sit opposite to the patient
- With one hand, fix the patient's head.
- Move the finger of the other hand into the directions shown in the pictures. Follow the numbers!
- Ask the patient to follow your finger with his eyes without moving his head
- Ask the patient to indicate whenever he has double vision.
- Always hold your finger perpendicular to the moving direction (as shown on the pictures)

3.1



1: Motility limited? ☐ Yes ☐ No
Double vision? ☐ Yes ☐ No

2: Motility limited? ☐ Yes ☐ No
Double vision? ☐ Yes ☐ No

3: Motility limited? ☐ Yes ☐ No
Double vision? ☐ Yes ☐ No

4: Motility limited? ☐ Yes ☐ No
Double vision? ☐ Yes ☐ No

Please complete all appropriate items. Missing or inconsistent data will require additional queries.

PATIENT TRIAL NUMBER

4 Weeks Investigator v1.2

Figure 5: A copy of an AO Foundation file sheet; here depicting page 2 of the 4-week investigation visit. Reproduced by permission of the AO Foundation.

Our prospective cohort study, which ran at the maxillofacial department of the military hospital, Ulm focusses on the outcomes collected on our patients. It does not compare the preformed and non-preformed orbital plates as in the multicenter trial. The reason being that in our study, there was only 1 patient which required a non-preformed orbital plate. The time period involved in the collection of our patients included a total of 28 months – to be exact, the first day-related visit for the first patient was on the 22.07.2011 and the last visit for the last patient in the study was documented on the 28.11.2013. To be accepted, patients collected in the study had to fall under inclusion criterias (as according to the AO protocol) and of course the listed exclusion criterias further limited others.

2.2 Inclusion and exclusion criterias

The inclusion criterias for a patient to be accepted in the study included:

1.Patients ≥ 18 years

2.Fracture (not older than 14 days) of the medial orbital wall and/or orbital floor

3.Scheduled for reconstruction surgery with one of the following implants: Matrix MIDFACE preformed orbital plates, custom-made orbital implants, orbital floor mesh plates and SynPOR titanium reinforced fan sheets

4.At least partial sight in both eyes before the accident

5.Written patient informed consent

6.Ability to understand and read local language at elementary level

The exclusion criterias exempting the patient from the study were:

1.Bilateral orbital fractures

2.Fractures of the orbital roof

3.Complex zygoma fracture

4.Previous dislocated orbital fractures on either side

5.Vision or diplopia not assessable

6.Injury to the globe restricting surgical reconstruction, ex. retinal detachment, globe rupture

7.Neurological diseases with influence on eye motility or sight

8.Legal incompetence

9.Active malignancy

10.Life-threatening conditions

11.Alcohol and drug abuse that prevents from a reliable study participation

Every patient had an assigned file (supplied by the AO Foundation) and was given a separate code number (to protect patient's privacy). Every date-associated visit was recorded on the file, and the original copy was sent back to the AO Foundation in Davos Platz, Switzerland (together with a burned CD of the patient's pre- and post-operative scans), while the carbon copy was left for our use.

During this 28-month period, we collected a total of 32 patients which were suitable for the study. However 8 of them resulted in drop-outs due to a number of factors, including;

•decision to treat the patient conservatively without surgery, after initially having been included as a study patient

•an intraoperative decision of not using the orbital implant by the operating surgeon, instead zygomatic plates being used in order to secure the reconstruction

•intraoperatively a more complex fracture was discovered

•the development of a generalized seizure preoperatively, deeming the patient's medical condition as not fit for surgery, while the patient was also symptomless from the fracture

•patient refused to further attend to our follow-up visits

Out of the remaining 24 patients, there was again another drop-out from our study, as the reconstruction was intraoperatively decided for a non-preformed orbital floor mesh, while the other 23 patients had a preformed orbital implant.

2.3 Ethics committee and informed consent

Our investigation was accepted by the Ethics committee of the University of Ulm; see the Appendix.

After the patient was initially clarified about the investigation and what it involved, he/she was then given the patient information sheets to read (in German, the mother language). The last sheet was then signed by both the patient and the consentor, showing that the information was read by the consentor to the patient. The informed consent was then signed in the original and copy form by both patient and consentor. The original was held in the patient's file, and the copy was given to the patient, see the Appendix for a copy of the consent.

2.4 The investigations

4 principal examinations were done on each patient;

1.a baseline investigation (including the preoperative- and intraoperative findings)

2.a 1-week postoperative investigation (± 2 days)

3.a 4-week postoperative investigation (± 1 week)

4.a 12-week postoperative investigation (± 2 weeks)

The examination at each visit was performed independently of the other visits, that is not looking at the previous data. The comparison of the raw data was done only after entry of the values in the AO file.

2.4.1 The baseline investigation

The baseline investigation includes the pre- and intraoperative findings. The preoperative investigations include;

1.the date of injury and injury details

2.the pre-injury status: whether the patient had any pre-existing eyelid disorders on the affected side/any pre-existing ocular motility impairments/any pre-existing globe position problems (ex. enophthalmos, exophthalmos)

3.any pre-injury sensory disturbance to the 2^{nd} branch of the 5^{th} cranial nerve

4.the eyelid examination; any existing eyelid lacerations, palpebral border, entropion, ectropion

5.visual acuity was examined (without and then with glasses on both the affected and the unaffected eyes) through a provided Snellen Chart (see Figure 6) kept at a distance of 35 cm from the patient's respective eye while covering completely the other eye. If the lowest numbers in the chart could be read at the distance of 35 cm, then the patient had a 100% vision, if the read numbers/symbols extended till the third line from the top, then a 10% vision was recorded)

6.ocular motility and double vision recorded in 8 planes (refer to Figure 7)

7.globe position; measured in 3 different planes; vertical, sagittal and coronal (Figures 8-12)

8.any post-traumatic sensory disturbances of the maxillary cranial nerve on the affected side.

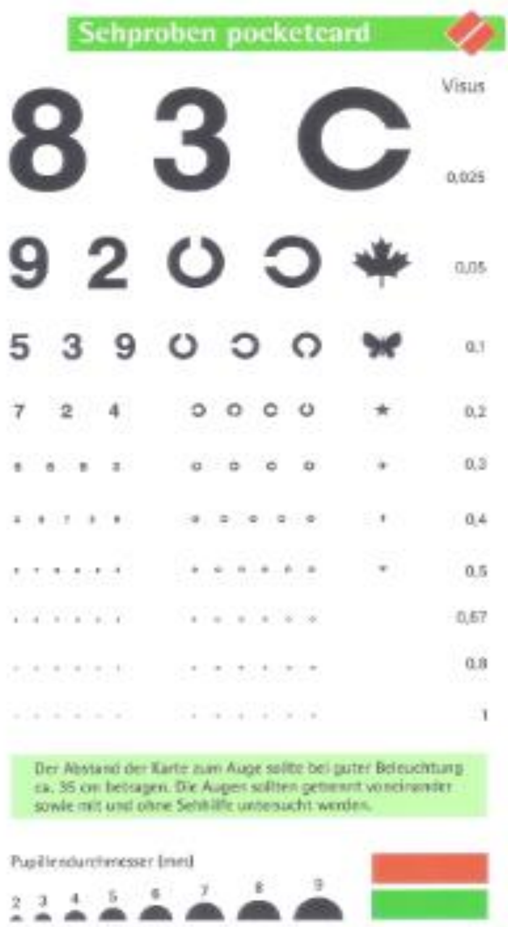
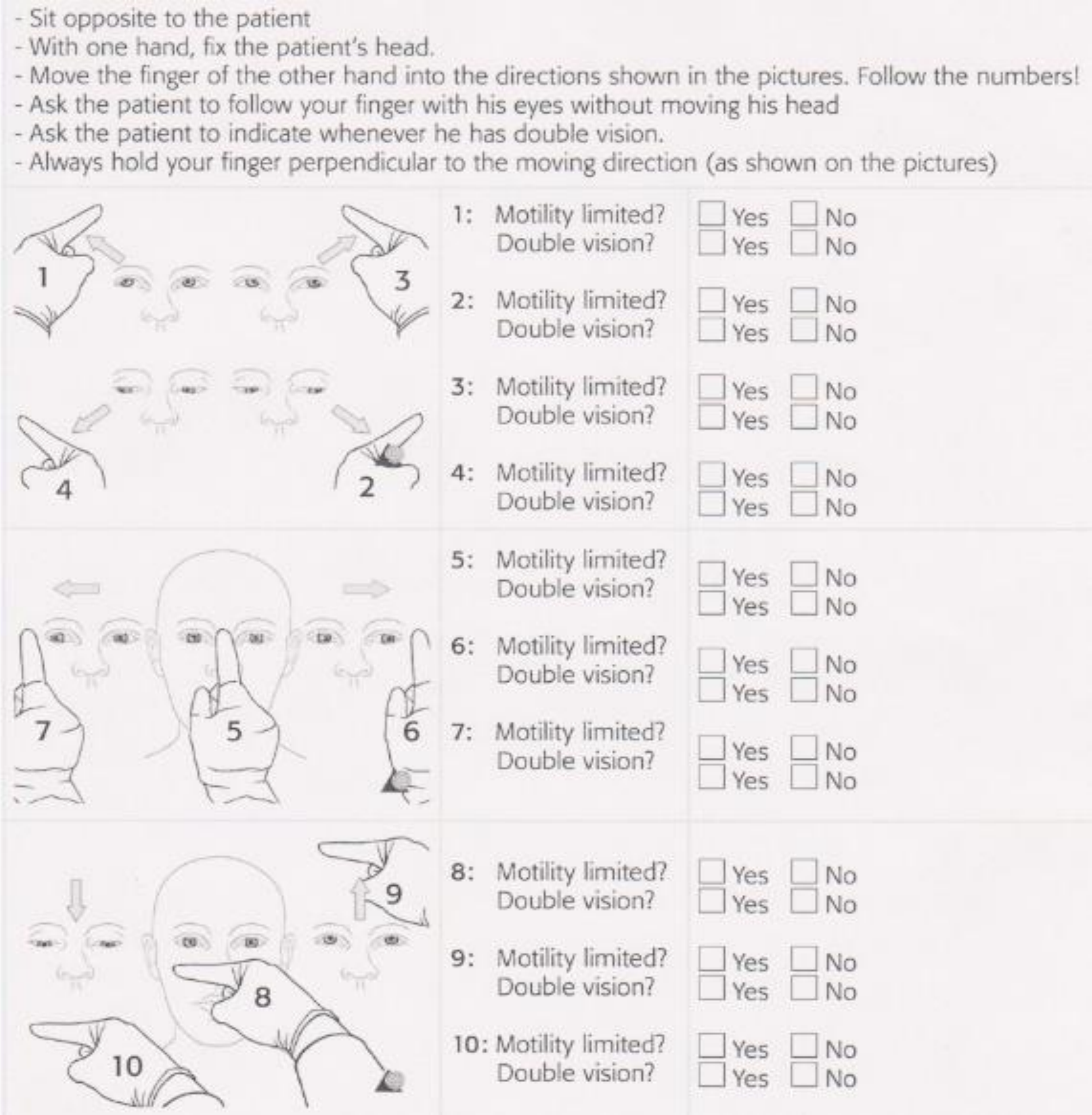


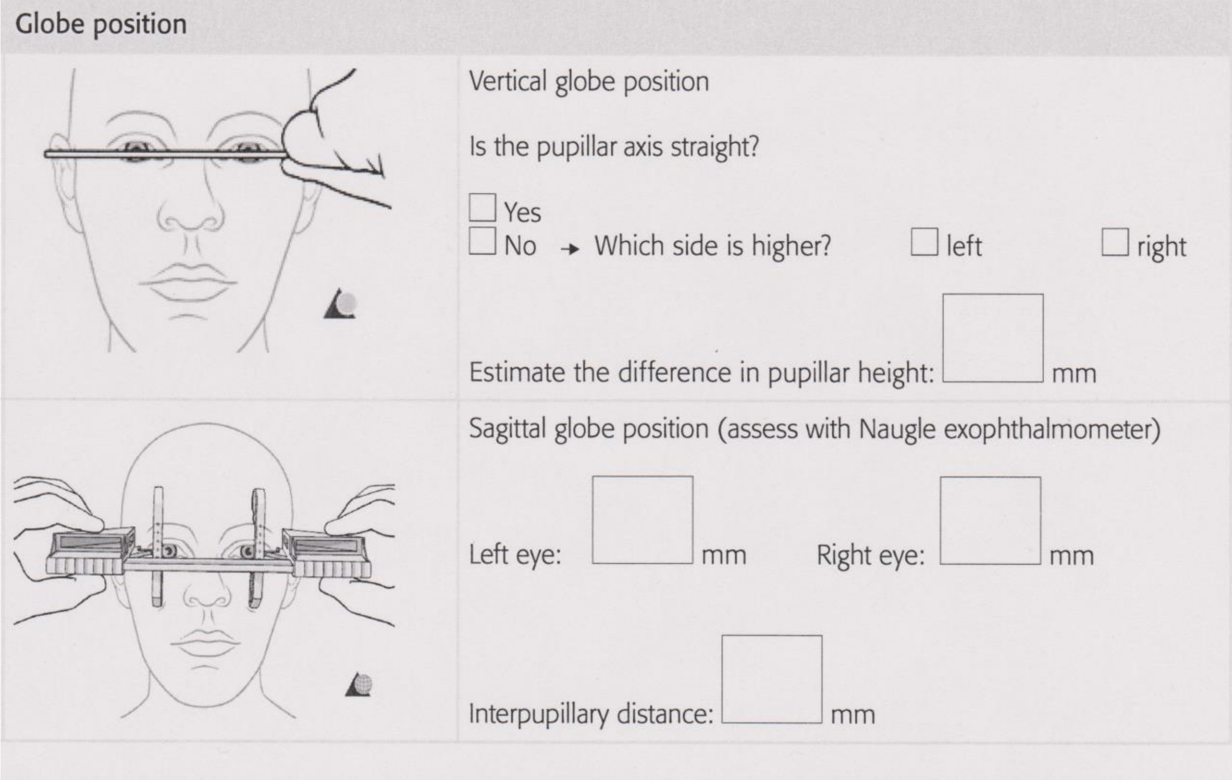
Figure 6: A copy of the Snellen chart supplied by the AO Foundation (reproduced by permission of the AO Foundation).



- Sit opposite to the patient
- With one hand, fix the patient's head.
- Move the finger of the other hand into the directions shown in the pictures. Follow the numbers!
- Ask the patient to follow your finger with his eyes without moving his head
- Ask the patient to indicate whenever he has double vision.
- Always hold your finger perpendicular to the moving direction (as shown on the pictures)

1:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
2:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
3:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
4:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
5:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
6:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
7:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
8:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
9:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No
10:	Motility limited? Double vision?	☐ Yes ☐ No ☐ Yes ☐ No

Figure 7: A copy of the Ocular motility chart; figure reproduced by permission of the AO Foundation. Page taken from the Orbita 3 file used for the study (Orbita 3 CRF BASELINE INVESTIGATOR FORM Page 4).


Globe position

Vertical globe position

Is the pupillar axis straight?

☐ Yes
☐ No → Which side is higher? ☐ left ☐ right

Estimate the difference in pupillar height: ☐ mm

Sagittal globe position (assess with Naugle exophthalmometer)

Left eye: ☐ mm Right eye: ☐ mm

Interpupillary distance: ☐ mm

Figure 8: The globe position measured in 3 planes; figure reproduced by permission of the AO Foundation Orbita 3 file used for the study: CRF(case report form) baseline investigator form Page 5.

Figure 9: Naugle exophthalmometer (supplied from the AO Foundation for the study); view from above. Note the scale (in mm) on the ruler for measuring the interpupillary distance. The plastic mounts centrally (C-shaped) should be placed on the patient's superior and inferior orbital rims respectively on each side.

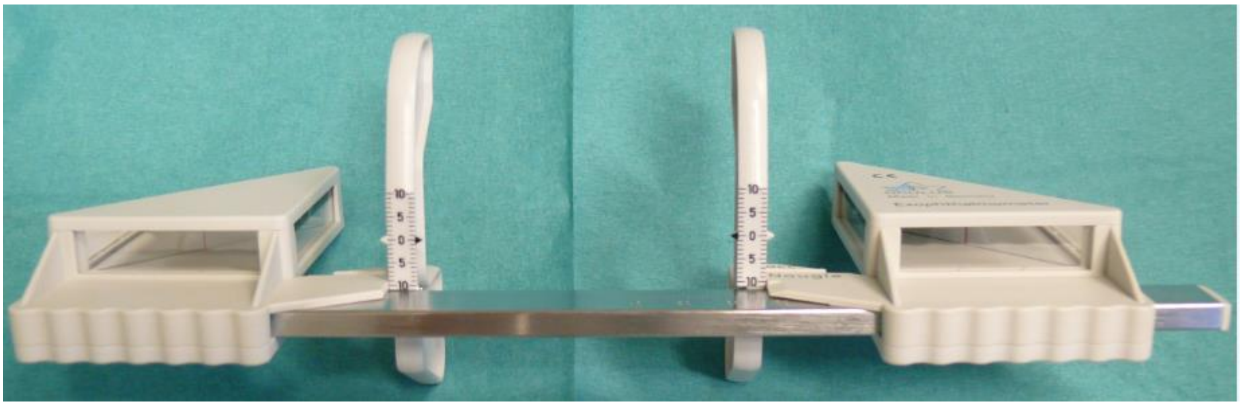


Figure 10: Naugle exophthalmometer; straight-on view. Note the scale in the centre of the picture on each side (in mm) to measure the vertical level of the globes as compared to each other. Laterally, on each side, there is a red vertical line marked on the mirrors to help read the proptosis of each eye (i.e. the sagittal distance). The examiner has to read this measurement with only one eye open (the one facing the patient´s respective examined eye).

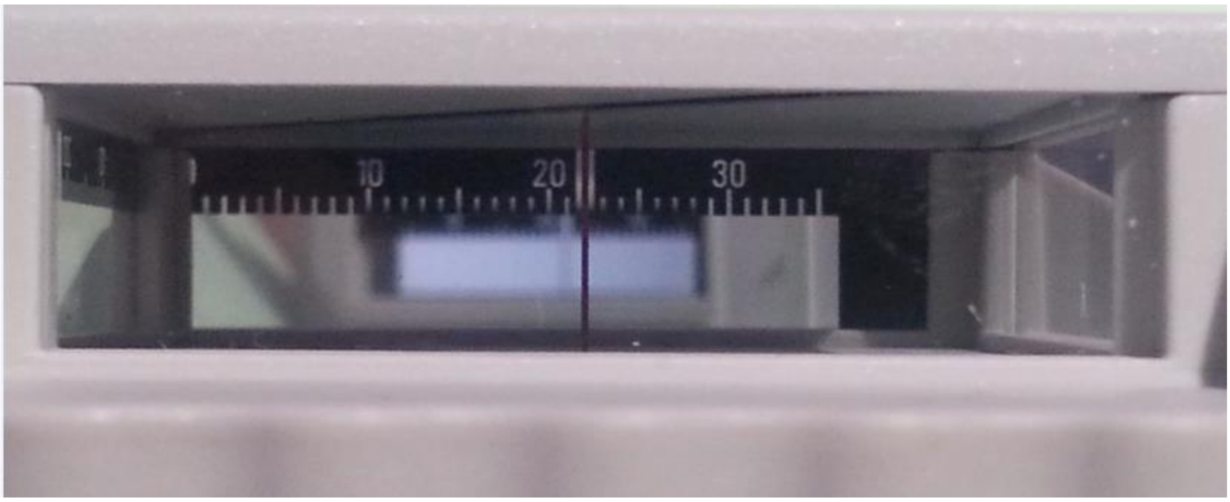


Figure 11: A close-up view of the mirrors on the right side of the exophthalmometer (i.e. the left side of the patient). While the patient should focus on the examiner's bridge of the nose, the examiner moves his/her head so that the red line should be coinciding to the notch on the scale on both sides and then the level of the corneal apex of the patient's eye on each side can be measured.

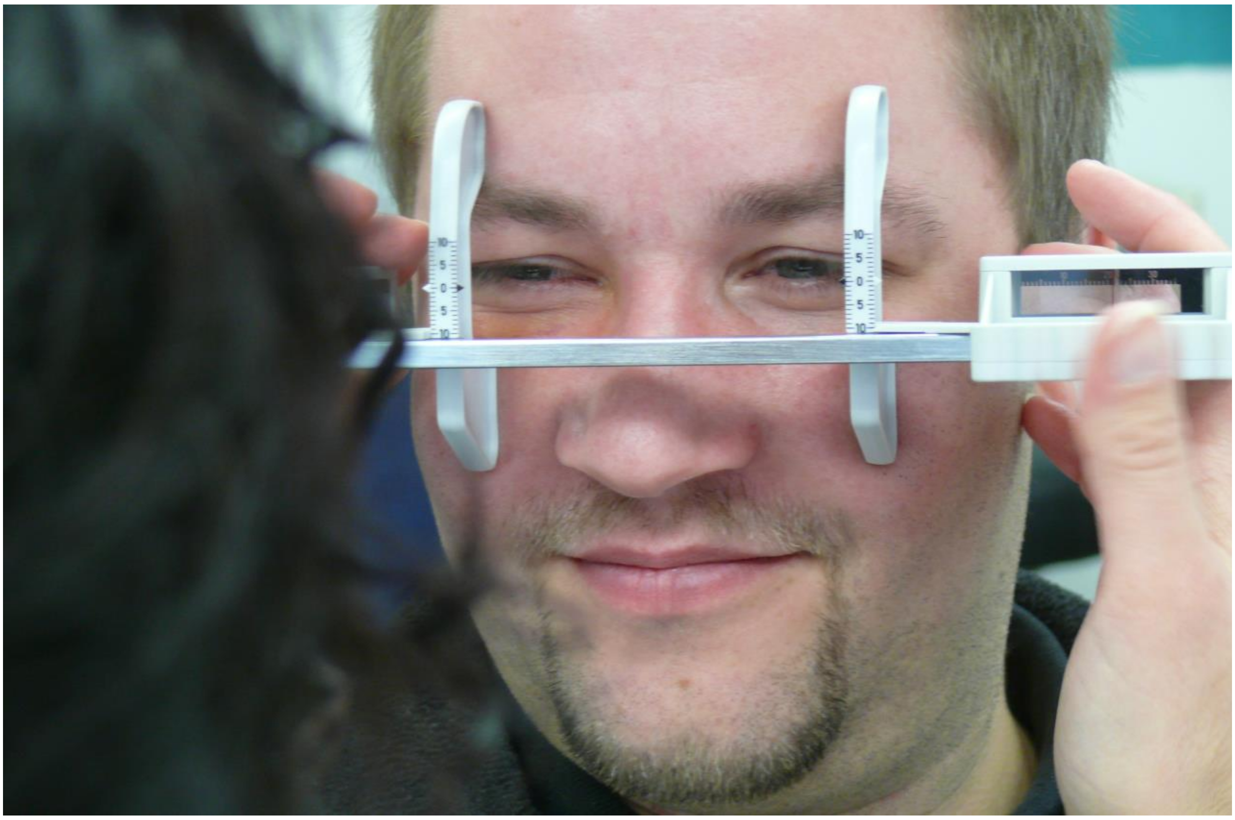


Figure 12: The Naugle exophthalmometer in use on one of our patients.

The intraoperative findings include the recording of;

1.fracture details; side affected and fracture extension (if the zygomatic buttress is complex, the patient is excluded from the study)

2.surgical details; whether the zygomatic buttress is repositioned prior to the orbital reconstruction, date of surgery, surgical approach, whether a lateral canthotomy was performed, type of orbital retractors used, if a retracting foil was used, type of orbital implant used, if bending of the orbital implant occurred, if intra-operative navigation was used, if the implant was cut, the number, diameter and position of the screws used to fix the implant, what kind of intraoperative light source was used, whether intraoperative imaging was used, the timing of the operation, name of the surgeon, and his years of experience, whether postoperative antibiotics, corticosteroids, and anti-inflammatory agents were used, date of admission and discharge of the patient, and any adverse events noted.

2.4.2 The postoperative follow-up visits

The postoperative visits performed were at 1-week, at 4-weeks and at 12-weeks; these included the eyelid examination, the visual acuity, the ocular motility, the globe position, any sensory disturbances of the maxillary nerve on the affected side, any necessary medications (antibiotics, corticosteroids, and non-steroidal anti-inflammatory agents) and if any advent events occurred. Any adverse events and dropouts were recorded and immediately sent to the AO Foundation on the provided sheets.

Even though not requested in the AO protocol, **every patient-related visit in our department was followed by a referral to the ophthalmic department in our hospital** to be professionally examined for any visual and/or globe motility problems. Some patients had their own private ophthalmologist, and the postoperative examinations were followed-up externally.

2.5 Virtual planning

Preoperative planning, intraoperative navigation and imaging are used to treat complex facial trauma as in Schramm et al.(2000, 2006 and 2011), as well in ablative tumor and orbital and midface reconstruction as in Hohlweg-Majert et al.(2005). With preoperative planning, the intended reconstructive results can be precisely foreseen; Schramm et al.(2011), especially when using the mid-facial plane as described by De Momi et al.(2006). By using navigation, the planned reconstruction can be guided intraoperatively, and the final intraoperative validation is obtained through an intraoperative imaging as for example by using the 3D C-arm as in Wilde et al.(2014). In this way, dislocation and malformation of fragments and transplants can be avoided in facial reconstruction and a reliable quality control of surgical outcome and the number of further (secondary) surgeries can be reduced.

The aim of preoperative planning is to produce a virtual model as in Schramm et al.(2006), which strives at producing the optimal result. Besides the basic model movements, including rotation and translation, and the calculation from individual slice cuts, the skin incision and the surgical approach should be defined. Modern preoperative planning offers segmentation, mirroring of the individual parts, free displacement and deformation of the segments, as well as the importing of CAD-CAM (Computer aided design-computer aided manufacturing) implants in order to produce a 3D model of the desired implant as in Wilde et al.(2013). Fusing the pre- and the postoperative data resulted in a mean deviation of 1.74mm in Zizelmann et al.(2005). The simulation produces a template which compares the pre- and intraoperative datasets radiologically after the 3D intraoperative scan, as well as comparing the pre- and intraoperative results when using navigation. When using navigation, an initial referencing is required and this is usually repeated for another 2 times during the whole operation. Referencing is applied either non-invasively by using an upper jaw splint; Schramm et al.(2002), or invasively by using temporal or frontal screws, placed preoperatively transcutaneously under local anaesthesia; Wilde et al.(2011).

Our fracture cases were preoperatively virtually preplanned. After the surgical placement of the preformed implant, its position was intraoperatively controlled by using a cone beam 3D scan and the resultant images fused with the preoperative scan and virtual implant, in order to confirm accuracy, and if necessary intraoperative intervention as in Gellrich et al.(2003).

2.6 Surgical approach and intraoperative tools

Kim et al.(2010) investigated the complication rates of 286 patients treated for unilateral pure blow-out fractures using the subciliary approach. The zygomatic branch of the facial nerve innervates the orbicularis oculi muscle, and damage to this nerve has been associated with lower eyelid surgical approaches when managing trauma patients or when used in aesthethic surgery, causing scleral show, ectropion, and pretarsal flattening cause by loss of muscle tone of the lower eyelid; Rohrich et al.(2003). Ouattara et al.(2004) published anatomical studies which revealed that the zygomatic branches form fascicles by means of positioning underneath the subciliary orbicularis oculi muscle and segmentally innervating nearly vertical to muscle, and no existence of functionally dominant branches. A tranconjunctival approach was thus discovered to avoid the septum injury; Zarem et al.(1993). Ridgway et al.(2009) published a retrospective review of 180 cases treated with a lower eyelid incision for orbital and/or zygomatico-maxillary fractures; the subciliary, the subtarsal, and the transconjunctival incisions were compared. Kim et al.(2005), used the transcaruncular combined with the transconjunctival approach for treating medial wall or combined orbital floor/medial wall fractures.

Hwang(2009), published a retrospective review of 30 patients treated through a subciliary skin-muscle flap incision for medial orbital wall reconstruction. None of the patients reported a visible scar or ectropion postoperatively, the reason being pinpointed to the method of flap elevation; a skin-muscle flap incision being used. De Riu et al.(2008) treated orbital floor exploration through 2 different methods; the subciliary approach and the transconjunctival approach with lateral canthotomy (the swinging eyelid approach). Shi et al.(2012) documented about the effectiveness of the combination of the transorbital and the endoscopic transnasal approach in the repair of orbital medial and floor fractures in Chinese patients; an increased intercanthal distance of the Chinese race in comparison to Indian and white people, produces a problem in locating the fracture edge and defect when involving the medial wall or orbital floor fractures, when using the traditional subciliary or transconjunctival approaches.

The caruncular approach was first reported in Garcia et al.(1998), and since it has been shown to be a versatile alternative approach in the treatment of varied orbital pathologic conditions, including the orbital medial wall. Major complications, such as persistent inferior oblique underaction, inferior canalicular obstruction, and scarring resulting in handicapping diplopia have been the exception, as in Malhotra et al.(2007). This technique allows the 2 fundamental principles of surgical correction of primary or secondary post-traumatic orbital reconstruction that were originally stressed and popularized by Manson since the 1980's to be met; that is, the complete and meticulous subperiosteal dissection of the bony orbital soft tissues, especially in the posteromedial area, and the proper restoration of the bony orbital volume and shape through materials that correct the anteroposterior and vertical position of the ocular globe.

Surgical approach

For the 23 patients involved in the study, the surgical approaches were as follows;

•21 transconjunctival retroseptal; of which 17 were employed for pure orbital floor fractures and 4 for combined orbital floor-medial wall fractures

•1 transconjunctival retroseptal with transcaruncular extension for a pure floor fracture

•1 transconjunctival retroseptal with transcaruncular extension for a combined orbital floor-medial wall fracture

Lateral canthotomy was not used on any of our patients. Figure 13 and 14 show the initial stages of surgery.

Figure 13: Joseph's lid retractor used to have an easier access to the transconjunctival retroseptal incision.

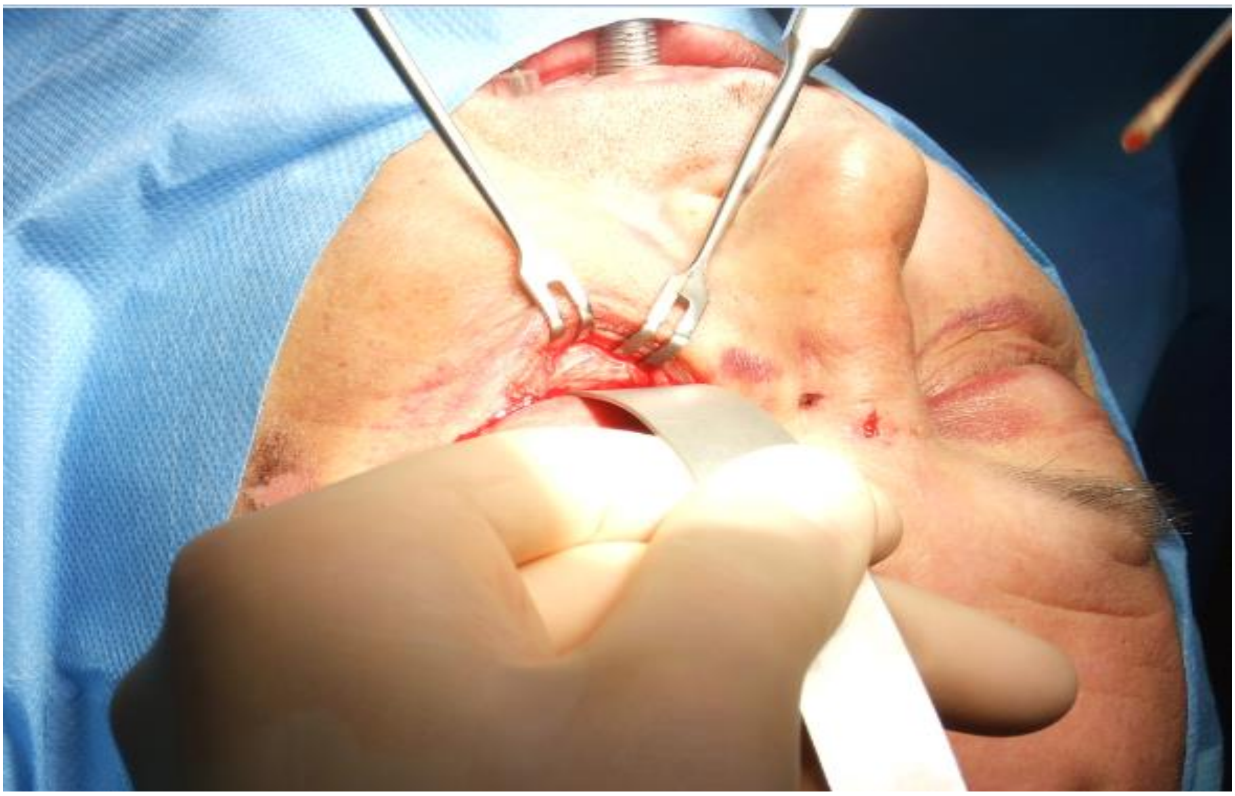


Figure 14: Dissecting the periosteum, holding the lower lid with 2 Volkmann's retractors and the orbital bulb with the brain retractor BT750R.

Intraoperative tools

The brain retractor BT750R, and a retracting foil (only in 9 patients) was used to protect the orbital contents during surgery, while Joseph's and Volkmann's lid retractors were used to protect the lower lid from untowarded postoperative entropion/ectropion. The malleable Synthes orbital retractor, incorporated in each MatrixORBITAL™ Synthes Set was used in only one case. In 22 out of 23 patients, the headlight was used besides the operating theatre light; and in P3, the operating theatre light alone was used as a light source. Due to a surgeon's decision, P22 was reconstructed with the help of intraoperative navigation; see Figure 15, as described in Schmelzeisen et al.(2003), Wada et el.(2004), and Schramm et al.(2007, 2009, 2011, 2012); a preoperative CT scan with a navigation splint wore on the upper jaw as described by Schramm et al.(2007) was required; see Figure 16 and 17.

Figure 15: Intraoperative Navigation with frameless stereotaxy.

Figure 16 (a) and (b): The recording of a set number of points on the navigation splint wore on the upper jaw (photo above) by means of the navigation probe in the surgeon's hand (photo below) as firstly introduced by Schramm et al.(1999). In turn this is being recorded by the navigation´s camera. Note the navigation tripod which is fixed to the patient's scalp until the end of the operation. The intraoperative navigation splint on the upper jaw is the same one as that wore during the preoperative CT scan and is wore throughout the operation.

Figure 17: The navigation camera while in use, together with the accompanying monitor on the right side; in this way the surgeon has feedback on his location and can communicate in 3D with the software.

Intraoperative navigation as in Schramm et al.(2005) has emerged as a viable tool to assist the reconstructive surgeon by allowing real-time visualization of bony landmarks via comparison to preoperative computed tomography images present in the operating room as according to Gellrich et al.(1999), Schramm et al.(2000), Schramm et al.(2004), Wada et al.(2004), Wilde et al.(2014), Markiewicz et al.(2012). Navigation technology is based on the synchronization of the intraoperative position of the instruments with the imaging of the patient's anatomy previously obtained by CT or MRI. The synchronization is realized through image registration, the process of computing and mapping the system coordinates of the preoperative planned CT images and that of the actual patient during the surgical procedure. After the registration is performed, the orientation and position of any tracked instrument can be displayed on-screen, showing its real-time relationship to the preoperative images and actual surgical anatomy. Image-guided navigation has shown great potential for clinical applications, particularly when precise location of any instrument or bony anatomic landmark is required.

In maxillofacial surgery, navigation technology has been extensively used in different fields as for example the reconstruction of medial orbital wall and floor fractures. The technical system accuracy is less than 0.5mm as noted in Marmulla et al.(1997), but the intraoperative precision for the patient using this non-invasive registration technique is 1 mm as described by Schramm et al.(1999). Yu et al.(2010) navigated the surgery of 6 patients sustaining zygomatic-orbital floor reconstruction who presented late due to various reasons. All patients had facial asymmetry with flattened malar eminence, increased facial width and enophthalmos on the affected side. Some had diplopia, ocular motility restriction, infraorbital hypoaesthesia and malunion due to previous improper reduction. With the side-to-side comparison, the position of the displaced segments to be reduced was defined and displayed on a 3D reconstruction image with different colours as firstly described by Gellrich et al.(2002). Virtual osteotomy and reduction was performed on the 3D model.

Once the simulation was completed, the original and simulated virtual data sets were imported into an intraoperative navigation system (TBNavis). Intraoperative navigation using frameless stereotaxy and infrared camera was used to track the navigation pointer and trackers. The patient's position was identified using a digital reference frame, which was rigidly fixed to the patient's forehead. Instrument orientation was determined by reference markers, which are fixed to the surgical probe, the light-reflecting markers of the digital reference frame and those on the instruments reflected the infrared rays emitted by cameras, allowing the system to track their position. The virtual image on the workstation was matched with the patient by individual registration using reference screws which were previously implanted on the maxillary bone and the tracking information was then processed by the system and merged with the 3D craniomaxillofacial model, providing the surgeon with continuous 3D positioning of the instruments as also described by Schramm et al.(2000). Registration accuracy was checked visually for every patient by repeatedly pinpointing the anatomic landmarks.

The maximal deviation between the preoperative design and actual surgical results for each patient was less than 2 mm, as verified through a postoperative CT scan. The surgeons must be aware of the limitations of the system (for example as in image drift) and therefore intraoperatively, a recalibration should be performed regularly using anatomic landmarks. The registration mode used also has a decisive influence on the precision of the system. Registration errors can be caused by shifting, or unfavourable spatial distribution of the markers. Calibration using anatomic landmarks is not precise enough and could lead to 2 to 5mm divergence as in Helm et al.(1998).

2.7 Orbital implants and screws

To reconstruct an orbital wall accurately, the implant must be stable, thin, and easy to handle. Small and medium-sized defects can be managed by using bio-degradable implants, but extensive fractures are ideally treated by calvarian bone or titanium mesh to give sufficient support of the orbital content. Calvarial bone can be difficult to mould and to adapt to the form and size of the orbital lesion, plus the additional donor site morbidity risk. Orbital titanium meshes are on the other hand always available and easy to apply. The presence of an alloplast typically generates a fibrous interface separating it from native tissue - a phenomenon observed by alloplastic materials throughout the body. The thickness and cellular composition of this fibrous capsule correlates with the biocompatibility and surface characteristics.

The criterion standard treatment for a reliable and predictable 3D (horizontal, vertical, and transverse) anatomical, cosmetic, and functional orbital contouring continues to be a source of debate. Many different materials can be used to restore orbital blow-out fractures including autogeneous, allogeneic and alloplastic. The autogenous absorbable graft may be taken for example from the nasal septal cartilage as in Lai et al.(1998), the auricular cartilage as in Constantin(1982), the maxillary bone as in Lee et al.(1998), the mandibular symphysis as in Krishnan et al.(1997), the coronoid process as in Mintz et al.(1998), the external cortical layer of the iliac crest, ribs and calvarial cortical layer as in Johnson et al.(1999), Lee et al.(1999), Tessier(1982), and even the temporal fascia as in Yan et al.(2012). Autogenous bone grafts have however the limitations of donor site morbidity and the difficulty of accurate contouring. The use of allogeneic implants as for example lyophilized dura mater, as in Chen et al.(1992), and Munoz Guerra et al.(2000) have been successfully adopted until transmission of donor site diseases, slow viruses, and cases of Creutzfeldt-Jakob disease consistent with its use were reported from different parts of the world, as reported by Brooke et al.(2004), making such grafts unpopular. Inert alloplastic materials include titanium mesh, silastic silicone membranes, polytetrafluoroetylene, and absorbable alloplastic structures with different percentages of poly-L-glycolic acid and poly-L-lactic acid. The best material remains controversial. Alloplastic implants may be subject to infection, foreign body reaction, migration or extrusion as discussed by Murthy et al.(2005). Another disadvantage of alloplastic titanium materials are that the orbital cavity is transformed into a rigid and unbroken cavity. The orbit should normally break in the presence of huge pressure, in order to preserve the eyeball. When the aim is to adjust the downward movement of the eyeball, the material should be placed inferiorly at the axis of the eyeball, but when the aim is to adjust for enophthalmos, then the material should be implanted posterior to the axis, as discussed in Wang et al.(2008).

Before1950, orbital floor fractures were repaired by packing the maxillary antrum with gauze or balloons through a Caldwell-Luc approach as described in Gear et al.(2002). With the advent of the direct or infraorbital approach to the orbital floor, a multitude of both autogeneous and alloplastic materials have been used for orbital reconstruction, including methylmethacrylate, Teflon, silicone, Supramid, Marlex, Silastic, gelatin film (Gelfilm), bone and cartilage. The use of alloplastic materials was tempered initially by complications such as infection as reported in Browning et al.(1967), Weintraub et al.(1981), Mauriello et al.(1987), Jordan et al.(1992); displacement and extrusion as in Weintraub et al.(1981), Burres et al.(1981), Wolfe(1981); extraocular muscle entrapment as in Mauriello(1990); dacryocystitis as in Mauriello et al.(1987), Kohn et al.(1976); fistula formation as in Goldman et al.(1976), Alpar(1977), Aronowitz et al.(1986); globe elevation as in Browning(1967); proptosis secondary to haemorrhage into the implant's fibrous capsule as in Mauriello et al.(1984); cyst formation as in Loftfield et al.(1988); and vision loss as in Converse et al.(1967), Nicholoson et al.(1971), Lederman(1981). The overall complication rate ranged from 0.4 to 10%; Freeman(1962), Sewall et al.(1986).

The orbital floor has an initial shallow convex section behind the rim, then inclines upward behind the globe, to meet the medial wall, creating a distinct bulge behind the globe. These convex curves of the medial wall and floor create a "postbulbar constriction" of the orbital cavity, which must be reconstructed when the orbit is rebuilt following fractures. Treatment is directed at precise anatomical reconstruction of orbital shape and volume in order to restore the correct position of the eye. The orbital implants used in our study were all MatrixMIDFACE preformed orbital plates from DePuy Synthes, Johnson & Johnson in Germany. The preformed three-dimensional shape of such implants is manufactured for minimal bending time and cutting, in order to reduce the amount of operational time required to contour the plate. The contoured plate edges allow easier plate insertion and less interference between the plate and surrounding soft tissue. They have a segmented design to customize plate size and to address orbital topography in order to maintain contoured plate borders with minimal sharp edges.

The purpose of internal reconstruction materials is to isolate the orbital contents from the antrum or nasal cavity and provide postoperative support sufficient enough to prevent enophthalmos. The minimum requirement for support is to provide enough resistance to the load created by the combined internal orbital contents. This includes the weight of the globe, extraocular musculature, orbital fat, neurovascular structures, lacrimal apparatus and even the musculocutaneous lids. The weight of the globe is reported in the literature by Duke-Elder et al.(1961) as that being of 7.5 gr.(grams), and an estimation of the weight of the orbital contents can be made by multiplying the average density of the internal orbital tissues that is 1.09 g/cc by the average orbital volume 28.5cc(cubiccentimetre) as reported in Jo et al.(1989). The resulting estimate of approximately 30 gr. does not take into consideration the extension of the globe beyond the limits of the orbital rim or the musculocutaneous lids. The total weight of the combined internal orbital contents was first investigated by Haug et al.(1999); a mean ± standard deviation was found to be 42.97 ± 4.05 gr. It has been shown experimentally that if all the orbital structures remain intact in the absence of an orbital floor (as in case of ablative oncologic surgery), the eye would not necessarily droop; Mustarde(1968). In orbital trauma, not only can these soft tissue support mechanisms be interrupted/lacerated, but the origins can be compromised by orbital comminution/avulsion.

Wu et al.(2011) demonstrated, that treating combined orbital floor and medial wall blowout fractures through a combined endoscopic transethmoidal approach combined with a transconjunctival inferior fornix approach is a very good technique for repairing such fractures as compared with a combined medial canthal incision and the transconjunctival inferior fornix approach. Han et al.(2009) compared the endoscopic endonasal reduction and transcaruncular approach to treat medial orbital wall blowout fractures on a total of 48 patients. A retrospective medical record review by Lee et al.(2009), was performed on 23 patients who underwent reduction surgery for isolated large medial orbital wall fractures using silicone elastomer sheeting as a restorative material. According to several studies, each cm^3 increase in volume causes an increase in enophthalmos ranging from 0.47mm as in Raskin et al.(1998), and 0.89mm as in Fan et al.(2003). Possible explanations for the absence of significant enophthalmos despite a 1.48 cm^3 increase in orbital volume is explained by Lee et al.(2009) through the anatomy of the orbit. The inferomedial bulge, the region where the orbital floor meets the medial wall is important in maintaining the forward projection of the globe, and if not adequately reconstructed, posterior globe displacement may develop even from small fractures, as reported in Kolk et al.(2007). This characteristic region lies approximately in the posterior third of the orbit. The far posterior medial orbit past this region, may not significantly contribute to the sinking of the globe.

Kim et al.(2012), performed reduction of the medial orbital blow-out fractures on 20 patients through an endoscopic transnasal approach. Bae et al.(2007), found no difference in the outcome of treating medial orbital wall fractures with porous polyethylene implants or hydroxyapatite implants or by using the transnasal approach. Many different materials are described to cover the orbital floor and walls. Mainly due to the work of Paul Tessier, autogeneous bone grafts (calvarial origin) were the implants of choice at the end of the twentieth century; Tessier(1982), Wolfe(1997). Problems in the use of bone grafts, such as unpredictable resorption (up to ⅓ of graft volume expected to resorb over time, with increased resorption occurring more posteriorly than anteriorly) resulting in delayed enophthalmos, donor site morbidity, scar alopecia and demanding handling have made alloplastic materials increasingly popular, as reported in Kirby et al.(2011), Heung et al.(2001), and Gear et al.(2002). Harvesting the cranial bone graft can lead to dural tears, subarachnoid haemorrhage and subdural haematoma; when using the iliac crest, neuropathy of the lateral cutaneous femoral nerve may result and pneumothorax when using rib cartilage; Chowdhury et al.(1998). Postoperative evaluation of the donor site has revealed diminished strength up to 50% in the area of calvarial bone graft harvest; Goldberg et al.(1993). Sakakibara et al.(2009), published a retrospective study of 101 patients which underwent surgical reconstruction of pure blowout fracture of the orbit with the medulla of the iliac bone. Kosaka et al.(2004) harvested mandibular bone from 3 sites; the mental region, the area posterior to the mental foramen and the ramus area to reconstruct the fractured orbital floor. Mintz et al.(1998), reconstructed 8 orbital floor fractures with a defect size ranging from 2-2.5cm in diameter using the coronoid process of the mandible. Strong et al.(2004), approached the orbital floor to treat the orbital floor fracture through an antrostomy in the maxilla and then working further endoscopically. Gago et al.(2003), reported on the ability of Seprafilm to reduce postoperative adhesions. Taban et al.(2009) treated 4 patients sustaining trap door orbital wall fractures with Seprafilm. Noda et al.(2011) investigated the outcome of a periosteal suturing technique in orbital blowout fractures on 15 patients.

Yavuzer et al.(2004), used solvent-dehydrated calvarial allograft bone for reconstruction of the orbital floor fractures with good results. Lieger et al.(2010), produced satisfactory results for correcting late enophthalmos in 8 patients which had already been primarily reconstructed through different alloplastic materials; an autogeneous calvarial graft together with a lyophilized cartilage rib graft was used. De Souza Kruschewsky et al.(2011) compared treatment of fractured blow-out orbital wall using an auricular cartilage graft with absorbable copolymer poly-L-lactic(82%) and poly-L-glycolic(18%). A retrospective review by Yan et al.(2012), considered 32 patients whose orbital floor was reconstructed using temporalis fascia grafting. In a study by Özyazgan et al.(2006), conchal cartilage was used to restore orbital floor/medial wall fractures when the orbital defect did not exceed 2x2cm and did not include the orbital rim. Kraus et al.(2001), used autogeneous nasal septal cartilage for treating pure and impure orbital blowout fractures in defects greater than 8mm or 50% of the orbital floor and reported good results. Morong et al.(2010) used maxillary bone or titanium grafts to treat orbital floor fractures. According to Kusiak et al.(1985), membranous bone grafts revascularize earlier than endochondral bone grafts, maintaining their volume with minimal resorption.

Of the alloplastic materials, titanium is the most reliable and safe implant for orbital reconstruction; Gear et al.(2002), Mackenzie et al.(1999), Schubert et al.(2002), Sugar et al.(1992). Titanium was first introduced in the mid-1960's. Initially in orbital reconstruction, it was used either as an adjunct to bone grafts to reconstruct large defects; Glassman et al.(1990) or alone in reconstructing smaller defects, initially its use being hampered by concerns over potential complications, particularly infection; as in Jordan et al.(1992). The actual infection rate is however low, even in the mouth; Chowdhury et al.(1998), as also after its use as a percutaneous anchor for facial prostheses; Stringer et al.(1986). Titanium's low infection rate relates in part to its excellent biocompatibility, manifesting itself as osseointegration, during which the bone bonds to titanium (through screws) on a molecular level; Albrektsson et al.(1981, 1983, 1986). Titanium is chemically similar to calcium. Its resistance to corrosion, ease of fashioning, and absence of reported allergy, toxicity, or tumorigenesis have made it very popular in different disciplines of medicine for more than 30 years. The soft-tissue response to titanium is less well understood and appears to involve fibrous integration. Gear et al.(2002) reported the development of only 1 abscess in a patient who received high-dose steroids for 72 hours preoperatively due to optic nerve swelling and vision changes during a 5-year period of using titanium meshes.

Adell et al.(1981), in a 15-year follow-up study of reconstructing the edentulous jaw, found a 90% success rate with titanium versus less than 50% for nonosseointegrated implants such as steel. Titanium when juxtaposed to moving bone, can induce a variable degree of inflammation through the release of particles; Meachim et al.(1973), Moberg et al.(1989). Some authors; Santavirta et al.(1991) claim that titanium deposition is associated with macrophage infiltration, inflammation, and periprosthetic osteolysis, while others; Schliephake et al.(1993) claim no inflammatory reactions.

Preliminary results in the use of the preformed mesh by Synthes have shown good accuracy in reconstruction as recorded in Scolozzi et al.(2009). Also, the use of AO orbital titanium mesh plates (profile of 0.3mm) by Scolozzi et al.(2008) showed that the volume data of the reconstructed orbit fitted that of the contralateral uninjured orbit with an accuracy to within 1.85 cm^3. 4 techniques have been designed to reconstruct orbital defects using titanium mesh plates. The first is using mesh plates, which are trimmed and moulded intraoperatively to contour the conical shape of the orbits. A preliminary comparison between the use of nonpreformed versus preformed titanium mesh (both from Synthes), showed no differences in the accuracy of the reconstruction, when comparing volumetric studies using the OsiriX Medical Image software; Scolozzi et al.(2010). The second technique involves the production of an individually preformed titanium mesh by computer-assisted preoperative planning through stereolithography and placing it by navigation-guided procedures. A third option, involves plates which have been designed from CT scan data of the general population as in Metzger et al.(2007), thus approximating the mean topographical anatomy of the human orbital walls. The 3-D meshes are preformed with the posterior retrobulbar bulge already designed, minimizing intraoperative manoeuvres, such as bending, trimming, and repetitive fittings of the modified plates. The fourth option is the fabrication of computer-designed custom-made alloplastic implants based on individual 3-D computer-based models as recommended by Kozakiewicz et al.(2011) and Fax et al.(2007). It is however difficult to reproduce the precise limits of the orbital wall fractures accurately, because the thinness of the orbital floor and medial wall (<1mm) is beyond the resolution limit of current 3-D CT-scanning techniques; Scolozzi et al.(2008).

Ellis III E et al. (2003) compared the use of autologous cranial bone grafts versus titanium mesh of 0.4mm(millimetre) thickness in reconstructing unilateral pure orbital blowout fractures. Titanium mesh showed better overall reconstruction than bone grafts; the reasons being the better contouring and adaptation of the titanium mesh to the intricate contours of the internal orbit. Cranial bone is very brittle, cannot be easily contoured and sometimes osteotomy of the bone graft itself was necessary to provide the required contour. The most popular titanium meshes feature a profile height between 0.3 and 0.6mm (Orbital floor mesh 0.3mm - KLS Martin, Jacksonville, FL; Matrix ORBITAL 0.4mm – Synthes; MEDPOR TITAN 0.6mm – Stryker Medical , Portage, MI; Medartis 0.2-0.25mm – Modus OPS 1.5).

Becker et al.(2010) compared the use of a collagen membrane (Biogide; Geistlich Pharma AG, Wolhusen, Switzerland) to a PDS foil (0.15mm, perforated; Ethicon, Norderstedt, Germany) in treating orbital floor fractures. Dietz et al.(2001), found that using the 0.15mm PDS foil was effective when repairing orbital floor defects not exceeding 20mm. Gierloff et al.(2012)

evaluated the prevalence of orbital floor fracture-related problems after surgical treatment using resorbable polydioxanone implants (PDS). Büchel et al.(2005) found Ethisorb, a resorbable alloplastic material composed of nondyed Vicryl (polyglactin 910; Ethicon) and nondyed PDS, effective in the repair of small to moderate orbital floor fracture defects up to a maximum size of 2x2cm. Jank et al.(2003) also reported a significantly lower incidence of exophthalmos 3 months after surgery when comparing Ethisorb to PDS, with the maximum size of the fractures of the orbital floor being that of 2x2cm (centimetre). Porous polyethylene improves the advantages of titanium; it has a porous structure, permitting fibrovascular ingrowth of surrounding soft tissue and bone into the implant. Ozturk et al.(2005) used porous polyethylene Medpor implant to reconstruct the orbital floor fractures in their patients; however the implant is not visualized on radiographs, making postoperative imaging unproductive. Porous polyethylene with incorporated titanium such as SynPOR (Synthes, Paoli, PA) and TITAN (Porex Surgical) combine the advantages offered both by titanium and porous polyethylene, but minimizes the disadvantages of each.

Han et al.(2011), compared the clinical outcomes of using 2 types of porous implants; Macropore and Medpore implants to treat orbital fractures. A longitudinal cohort study by Wajih et al.(2011) in reconstructing orbital floor fractures using an autogeneous bone graft in 14 patients, and a Medpor graft in 12 patients, showed comparable results. Bahmani Kashkouli et al.(2011), reported the long-term results of using Medpor enophthalmos wedge implants to correct enophthalmos and hypophthalmos. In a retrospective study by Lieger et al.(2010), 46 patients with orbital blow-out fractures with at least 1.5 cm^2 (centimetre squared) bone defects in 1 or 2 walls were treated within 2 weeks of injury. Kim et al.(2012) compared the surgical outcomes of large orbital fractures reconstructed with either porous polyethylene channel or porous polyethylene titan barrier(PPTB) implants. Al-Sukhun et al.(2012), investigated the usage of an SG (stiffness-graded) biodegradable implant on the biomechanics of bone-fracture repair on a patient who had an orbital blow-out fracture, with a 2.2 cm^2 bony defect in the inferior orbital floor.

The Synthes orbital plates which we have used, have a rigid zone, over which \`L\` or \`R\` (meaning left- or right-sided respectively) is inscribed. This restores the shape to the posterior orbital floor to help maintain the correct position of the globe. The plates are 0.4mm thick, are malleable and composed of pure titanium. There are 4 co-existing preformed orbital plates from Synthes (Figure 18);

1.small-sized left-sided implant (purple colour) for left-sided smaller orbits

2.small-sized right-sided implant (purple colour) for right-sided smaller orbits

3.large-sized left-sided implant (gold colour) for left-sided larger orbits

4.large-sized right-sided implant (gold colour) for right-sided larger orbits

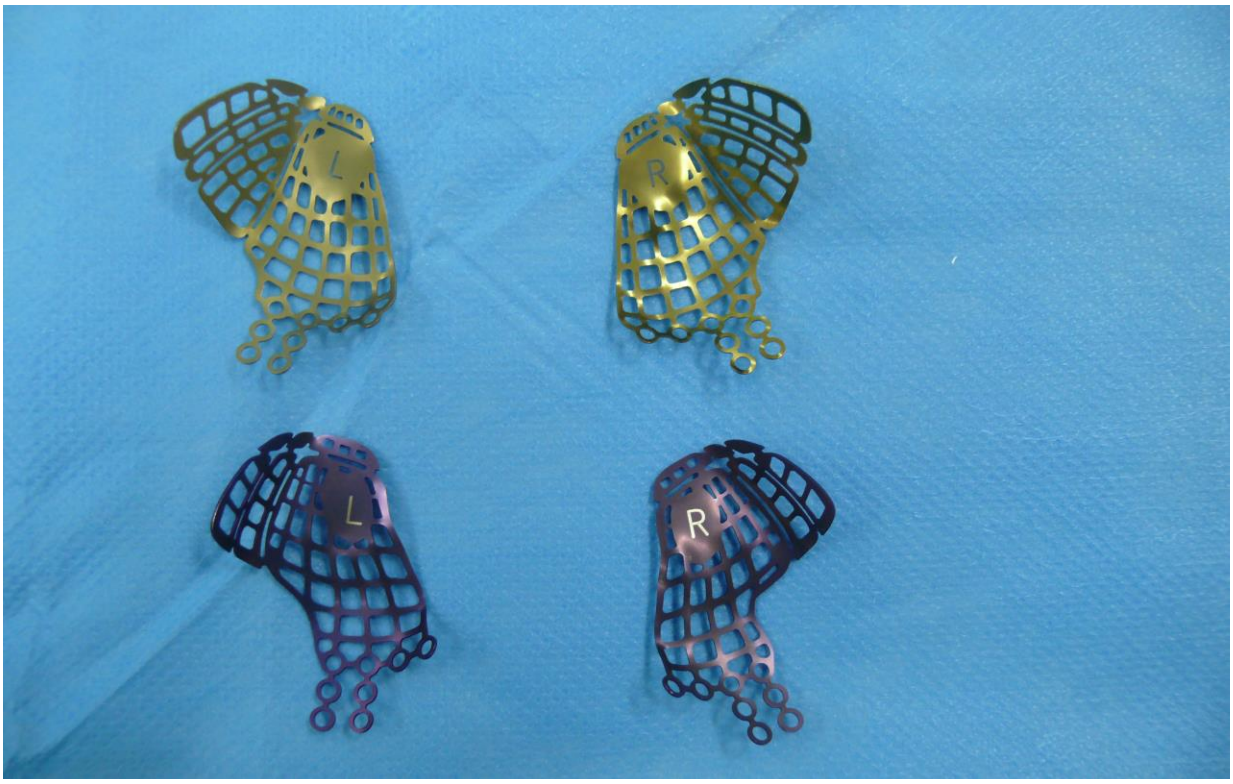


Figure 18: Matrix orbital plates; the S-shape of the plates is made to match precisely the contour of the orbital floor. Abbreviations; (I) L – left-sided, (II) R – right-sided.

The regular screws used to fix these implants were self-tapping with a diameter of 1.5mm and with varying lengths of 4-8mm. The emergency screws which were also available in our set, have a diameter of 1.8mm and are available in lengths of 4-8mm (Figure 19 and 20).

Figure 19: MatrixORBITAL Set with representation of the available screws at the right lower corner, while in use. Note the Synthes left and right orbital retractors as part of the set, situated in the upper compartment.

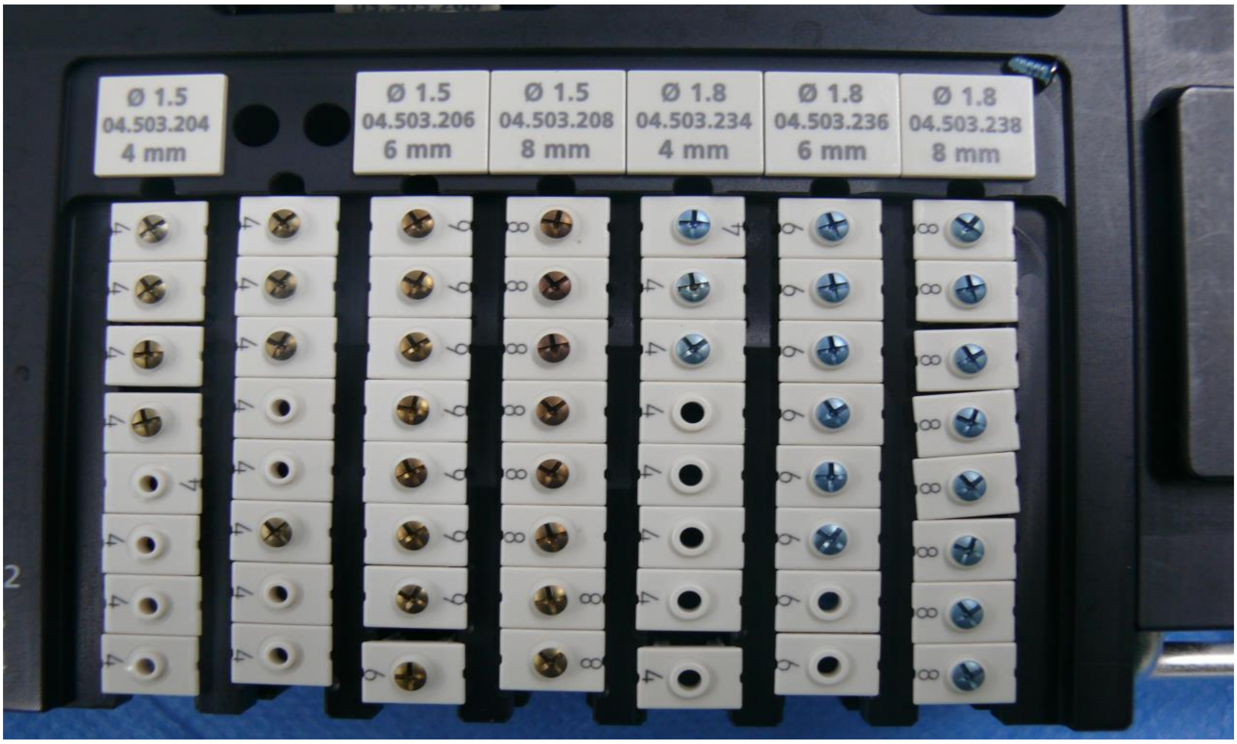


Figure 20: A close-up view of the screws in the MatrixORBITAL set.

2.8 Preoperative and intraoperative imaging

Traditional radiographs can show conspicuous infraorbital border fractures, but the diagnosis can easily be missed, resulting in delayed treatment, because of the overlapping projection of various anatomical structures, and inadequate information being supplied to the radiologist as reported by Kozakiewicz et al.(2011). Radiological investigation with computed tomographic scan in 3 different axis at 90° to each other is the gold-standard. Bony contours, including their fractures and soft tissues for ex.(example) prolapsed orbital fat, extraocular muscles, haematoma or an unrelated antral retention cyst are both very well represented. The 1980's marked the beginning of a new era related to the advent of substantial ameliorations in 3-dimensional (3-D) computed tomography, which has revolutionalized the global approach not only for the correction of orbital defects but also for all craniofacial surgery; Ploder et al.(2002). Coronal CT (computer tomography) sections are most sensitive for evaluating orbital floor involvement, and sagittal sections are most sensitive for demonstrating the anterior and posterior extent of floor fractures. Computer-assisted orbital volume measurement techniques have dramatically improved surgical strategies in orbital reconstruction, especially with respect to the prediction of secondary enophthalmos and the preoperative planning of suitable surgical volume reduction for its correction. In the experimental studies using orbital fractured models on dried skulls, Ploder et al.(2002), demonstrated that both 2D (2-dimensional) and 3D measurement methods are accurate for assessing the fracture area and herniated tissue volume of isolated blowout fractures, but 2D-based calculations offered less processing time and fewer errors.

Preoperative imaging

As a standard, we always had a preoperative CT scan of the midface and skull down to the cervical column for the diagnosis and for the decision-making before any surgery was contemplated on any of our patients. If the CT scan was external and did not include the cervical column, then a plain radiograph of the cervical column in 2 planes was performed preoperatively to exclude concomitant cervical fractures. The patients were referred to us from other nearby hospitals or clinics and sometimes they came directly to us themselves after the trauma. All the patients were seen initially in the emergency department of our hospital, or in our out-patients department and then the decision was taken whether to admit them in-patient. In this context, we had patients referred to us with a copy of the posttraumatic CT scan from the referrer, read on a CD, which we then transferred into our hospital radiological's PACS system (Picture archiving and communication system) for us to have access to. When the patients came directly to us after the trauma, we then organized the CT scan in our own hospital.

We had 15 patients which had a previous CT scan, and 8 patients in which a CT scan was performed in our hospital (see Figure 21). 3 of the patients which presented with a CT scan were soldiers, while 2 patients which had no external CT scan were soldiers; the soldiers were injured during sports or due to altercation; none of them during combat. The CT scans of the paranasal sinuses in our hospital are always done spiral, and reconstructed so that we have access to them in 3-D; that is in the axial, coronal and sagittal plane (see Figures 22-25).

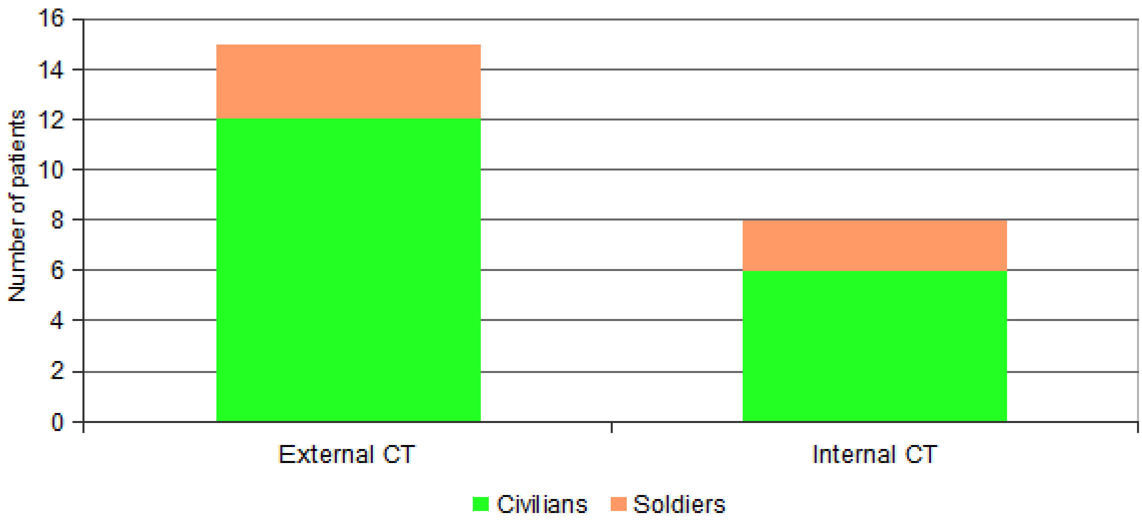


Figure 21: A bar chart showing the number of patients (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013) with the number of external/internal CT's preoperatively.

The CT scans in our hospital were done in either of 2 separate places; in the emergency resuscitation room which has also a CT scan facility, or in the radiological department, depending on to what extent the patient is injured. The radiological department's CT scanner 'Siemens Definition DS (Dual Source) which permits 64 slices has been in use since December 2007. The emergency resuscitation room's CT scanner 'Siemens Definiton AS' which allows 128 slices, is running in the department since December 2010. Moreover, the radiological department's CT scanner, runs the slices in a thickness of 1mm in the axial plane, while the reconstructions in the coronal and sagittal planes are made in 2mm thicknesses. The gantry tilt is always 0°(zero degree), and the pixel size is 0.6 x 0.6mm. The range of interest is first chosen on each patient, before the actual CT scan starts to run. Some of the external CT scans (which formed the majority in our study patients) had increased slice thicknesses than ours, of course making the reading of the CT scan more difficult, especially when coming to calculate the volumetric measurements of the orbits.

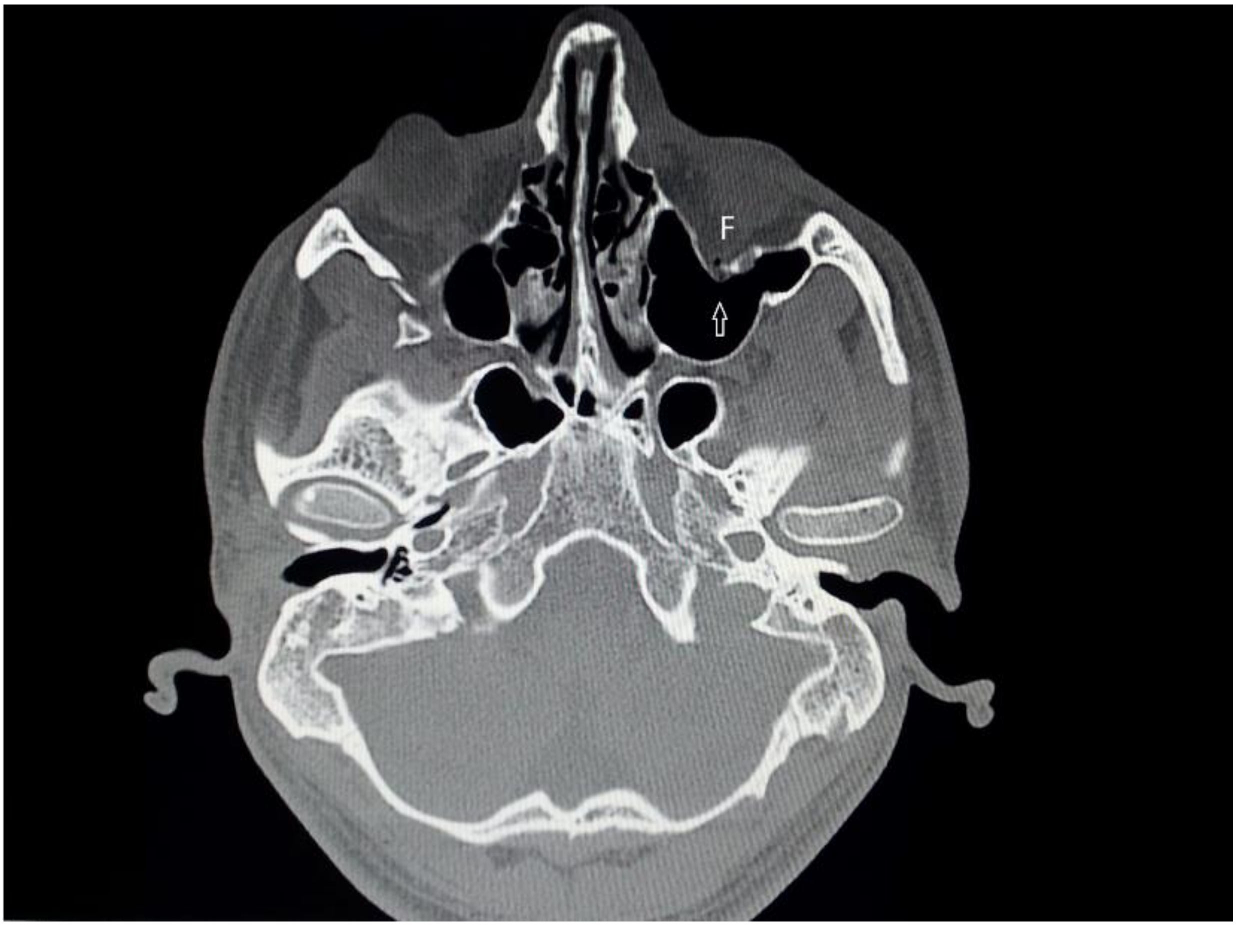


Figure 22: An axial view of a patient sustaining a left-sided pure orbital floor fracture; the arrow demarcates the fracture (F).

Figure 23: Coronal view of the patient in Figure 22 with the tear drop appearance depicted with an arrow.

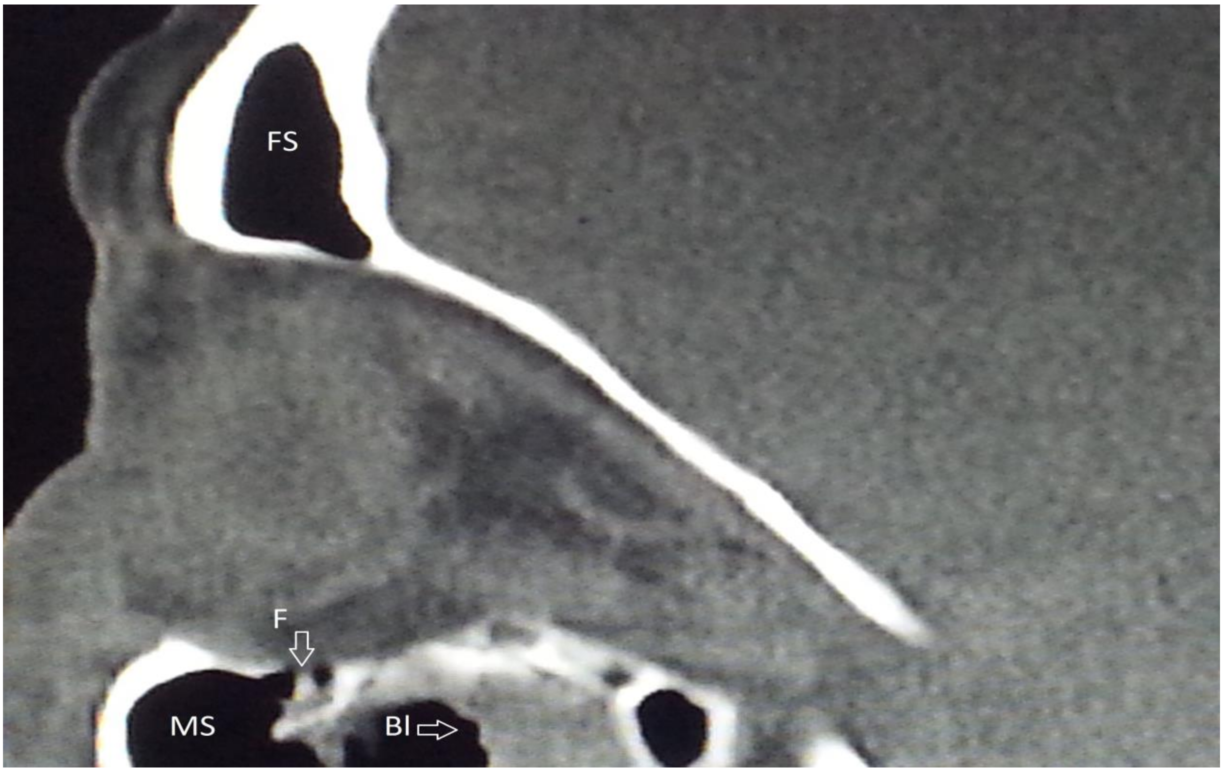


Figure 24: Sagittal view of a left orbital floor fracture in another patient with a haemosinus. Abbreviations; (I) Bl - blood in the maxillary sinus, (II) F - fracture, (III) FS - frontal sinus, (IV) MS – maxillary sinus.

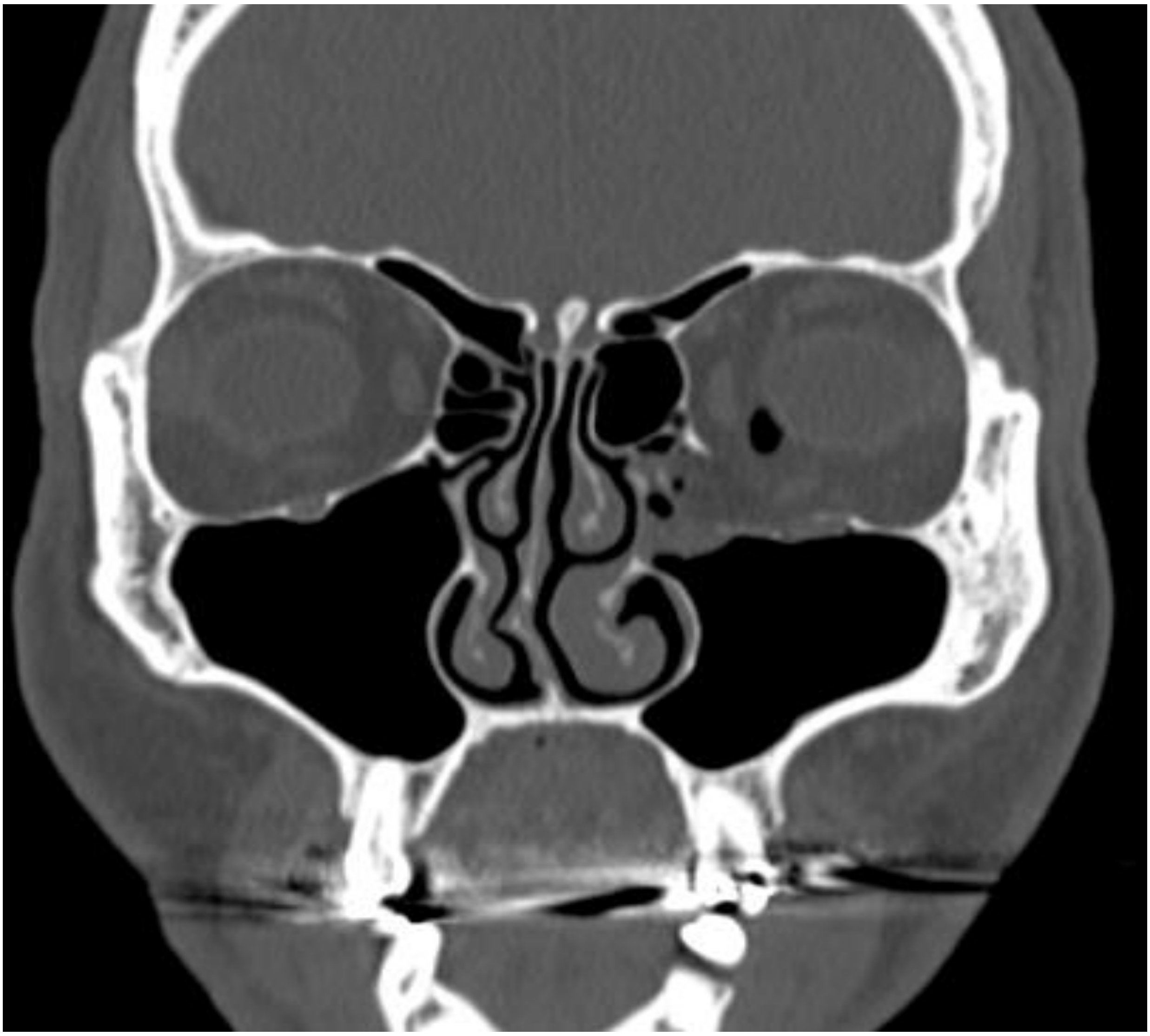


Figure 25: Coronal CT scan of a patient who sustained a left-sided combined orbital floor/medial wall fracture. Note the intra-orbital emphysema on the left side.

Intraoperative imaging

After the placement of the orbital implant satisfactorily into position, intra-operative imaging by using a cone beam computed tomography scan as in Schramm et al.(2005), was employed to check intraoperatively the accuracy of the implant position, as described by Schmelzeisen et al.(2002), Zizelmann et al.(2007), Gebhard et al.(2012), and Wilde et al.(2013). When an adjustment was required, a second intra-operative scan was done. The Ziehm cone beam scan was the 3D intraoperative equipment mostly used on our patients; the cone beam scan belonging to Siemens was also sometimes employed. Refer to Figures 26-28.

Figure 26: The Ziehm C-arm cone beam equipment (left photo) together with its monitor (right photo) used in our department. The produced CT scan can then be viewed.

Figure 27: The C-arm cone beam equipment in use in our department from Siemens.

Figure 28: The monitor from Siemens used in conjunction with the Siemens 3D cone beam equipment.

The surgeon could intraoperatively access the preoperative and intraoperative scans on a digital light box (Figure 29). In one patient (P3) due to technical difficulties on-site this was not possible; a postoperative CT scan was done instead.

Figure 29: The digital light box from Brain LAB is a computer software with a touch screen sensitive monitor, installed in our operating theatre. The scans can be accessed by the operating surgeon in 3D at all time.

2.9 Statistical analysis and literature review

Since the study concerns the clinical outcomes of 2 particular types of fractures and the treatment employs only one type of implant (not a combination/comparison of plates), the statistical representation involved bar-, line- and pie-charts, scatter graphs, their averages and tables. The mean and the median was in a lot of cases given. The *p*-value or statistical significance in this case played no role. To access the past and contemporary literature review on the topic, a search on DIMDI (Deutsches Institut für Medizinische Dokumentation und Information) was made online, and included english- and german-language journals.

3 Results

3.1 Gender distribution and age at injury

From July 2011 till November 2013, 23 patients fullfilled our criteria for the study and attended regularly to our visits: 19 of them were male and 4 were female. For the sake of anonymity, the patients were referred to as numbers; that is the first patient in the study will be referred to as P1 (that is patient number 1), and the last patient as P23 (see Figures 30-33).

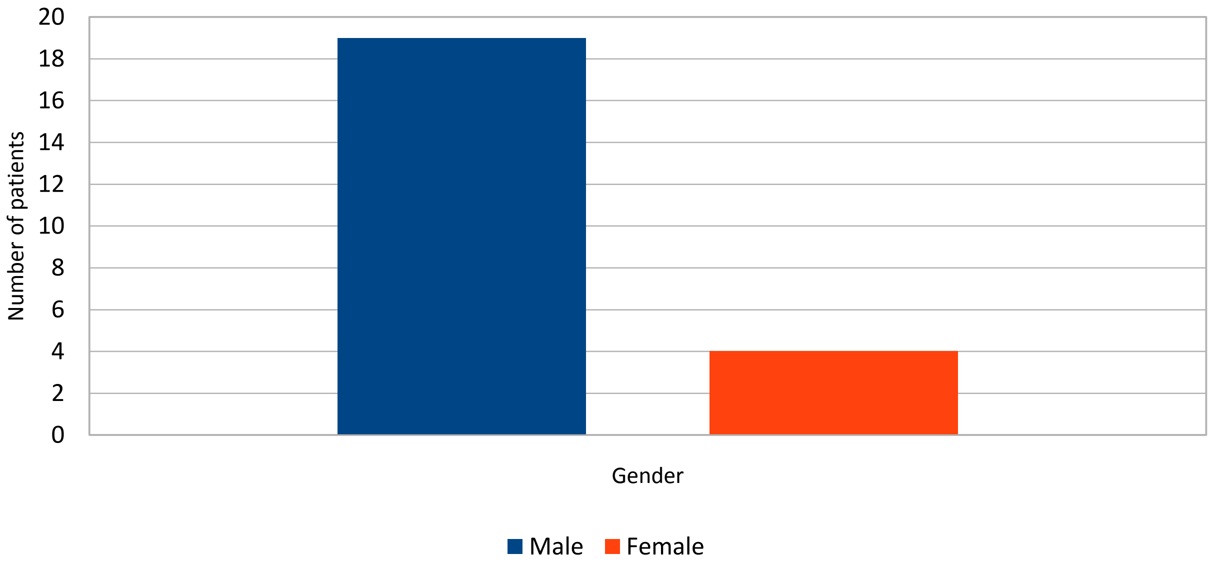


Figure 30: A bar chart showing the patients separated according to gender distribution (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

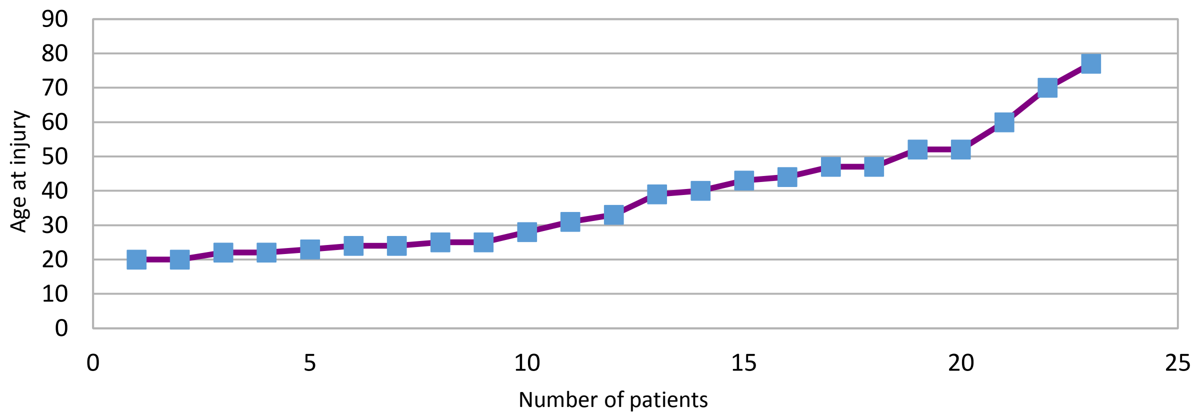


Figure. 31: A line chart showing the age at injury of the patients starting from age 20 as the youngest till age

77 as the oldest. The mean age of injury is 35.38 and the median is 28 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

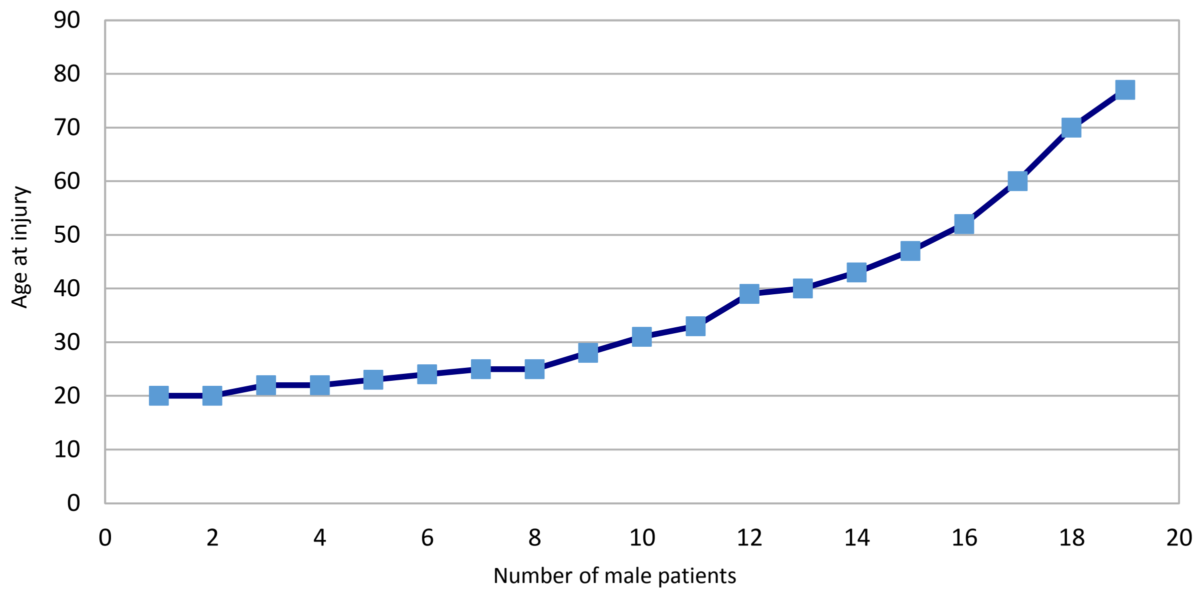


Figure 32: A line chart showing the age at injury of the male patients only (19 in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013) starting from age 20 as the youngest till age 77 as the oldest. The mean age of injury is 36.89 and the median is 31.

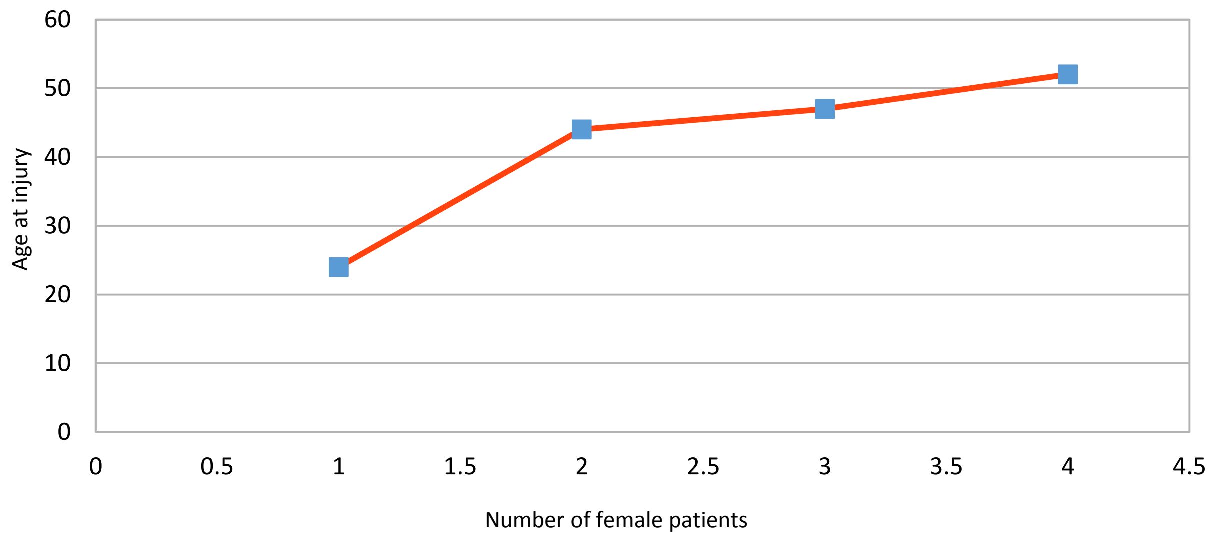


Figure 33: A line chart showing the age at injury of the female patients only (4 in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013) starting from age 24 as the youngest till age 52 as the oldest. The mean age of injury is 41.75 and the median is 45.5.

3.2 Causes of injury

As causes of injury (see Figure 34), there were (♂ refers to males, ♀ refers to females):

•8 sports injuries: 7 ♂ (age 22, 25, 25, 31, 39, 47, 70) and 1 ♀ (age 24): Mean: 35.4, Median: 28

•7 violent assaults: all ♂ (age 20, 22, 23, 24, 28, 43, 52): Mean: 30.3, Median: 24

•4 falls: 3 ♂ (age 40, 60, 77) and 1 ♀ (age 44): Mean: 55.3, Median: 52

•2 road traffic accidents: 1 ♂ (age 20) and 1 ♀ (age 52): Mean and Median: 36

•1 accident at work: ♂ (age 33)

•1 horse kick: ♀ (age 47)

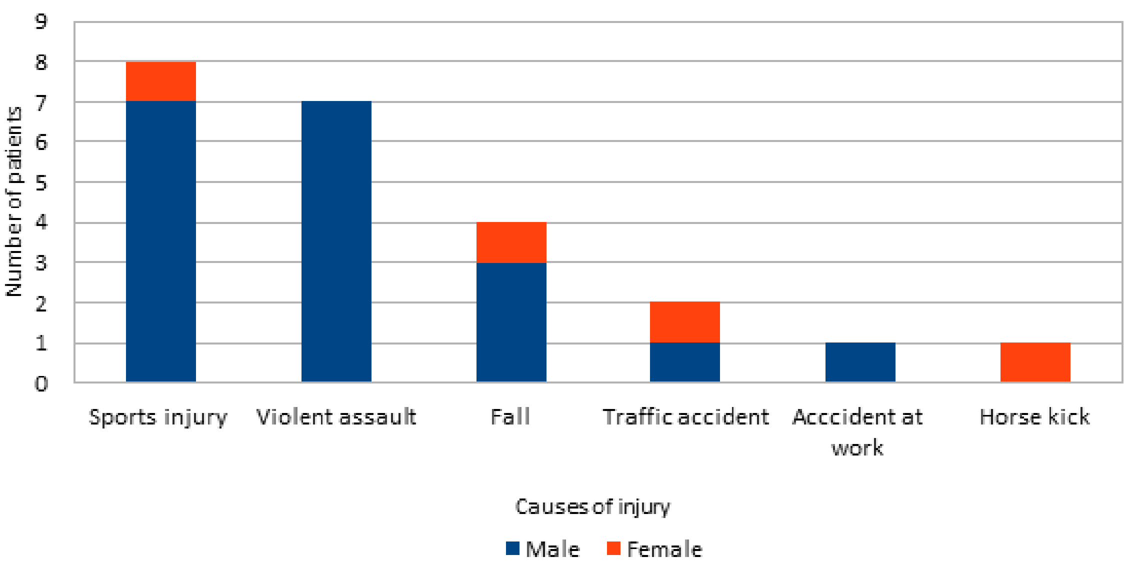


Figure 34: A bar chart showing the various causes of injury in our study group (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

3.3 Pre- and postoperative ocular conditions

Preoperative ocular conditions

Only 1 patient (P7) had a pre-existing ocular disorder before injury; that is squint surgery was required for the uninjured side (left eye) in 2010. Since the squint surgery, the patient had always been complaining of minimal double vision when looking to the right. No patients sustained any eyelid disorders or globe position problems (enophthalmos, exophthalmos) before the injury. Also, there was no disturbance to the maxillary branch of the trigeminal nerve on the affected side before injury reported. 1 out of 23 patients (P10) sustained a preoperative (post-traumatic) eyelid laceration, while the palpebral border was intact in all patients. Entropion was present in one patient (P15), and ectropion was absent.

Postoperative ocular conditions

The palpebral border was intact in all patients postoperatively. Entropion was absent postoperatively, and ectropion developed in 1 patient (P8); of note is that P8 had bilateral laser operation 11 months before the injury to correct myopia.

3.4 Fractures

3.4.1 Gender distribution and location of fractures

The 23 patients were also divided into 9 left-sided and 14 right-sided orbital fractures. The males contributed to a total of 19 patients (8 left-sided and 11 right-sided fractures) and the females to 4 patients (1 left-sided, and 3 right-sided fractures), see Figure 35.

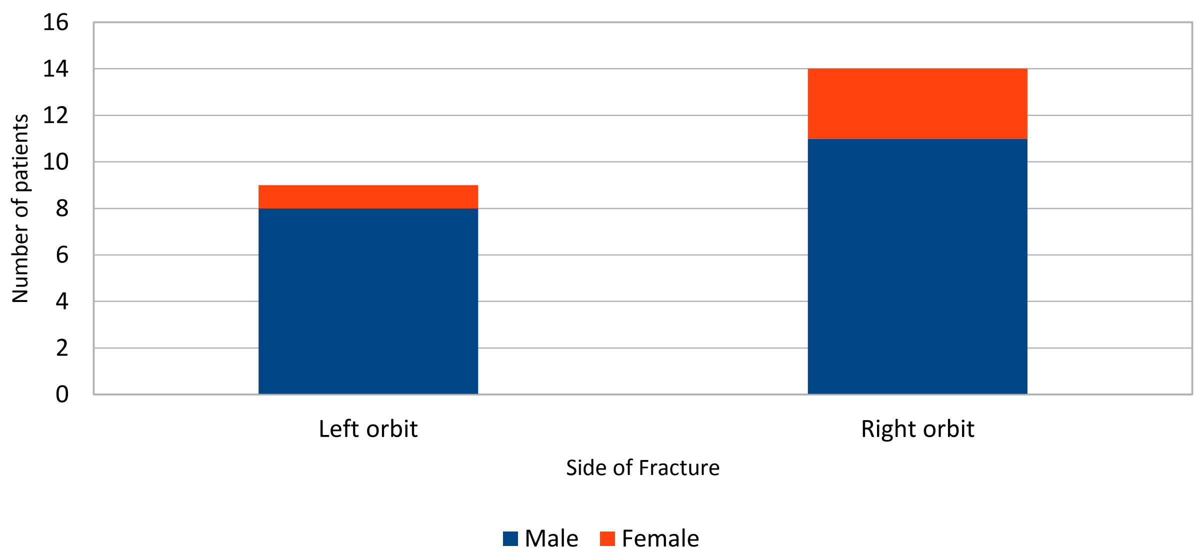


Figure 35: A bar chart showing the distribution of fractures into left- and right-sided with a separation of

the genders (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

The age range of ♂ sustaining left-sided fractures is:

•22, 23, 31, 39, 43, 47, 52, 70; a Mean of 40.9 and Median of 41.

The age range of ♂ sustaining right-sided fractures is:

•20, 20, 22, 24, 25, 25, 28, 33, 40, 60, 77; a Mean of 34 and a Median of 25.

N.B. The right-sided fractures in males represent a younger age population.

Only 1 ♀ sustained a left-sided fracture with an age of 24. The age range of ♀ sustaining a right-sided fracture is:

•44, 47, 52; a Mean of 47.7 and a Median of 47

3.4.2 Extension of fractures

From our 23 study patients, 18 sustained pure orbital floor fractures, and 5 sustained combined orbital floor/medial wall fractures. This study did not have any pure medial wall fractures, because no such fractures presented to us during this period (see Figure 36).

The 18 pure orbital floor fractures (14 ♂ and 4 ♀) are divided into:

•11 entire floor; 3 left-sided (all ♂), 8 right-sided (5 ♂, 3 ♀)

•4 middle and posterior ⅔ of the floor; 2 left-sided (1 ♂, 1 ♀), 2 right-sided (both ♂)

•2 middle ⅓ of the floor; 1 left-sided and 1 right-sided (both ♂)

•1 anterior and middle ⅔ of the floor; left-sided (♂)

The 5 combined orbital floor/medial wall fractures were all ♂ and divided into:

•1 orbital floor fracture (entire floor) combined with a medial wall fracture (involving middle and posterior ⅔); right-sided

•3 orbital floor/medial wall fractures (all involving the middle and posterior ⅔ of the fractured orbital walls); 2 left-sided and 1 right-sided

•1 orbital floor fracture (entire floor) combined with a medial wall extension (middle ⅓); right-sided

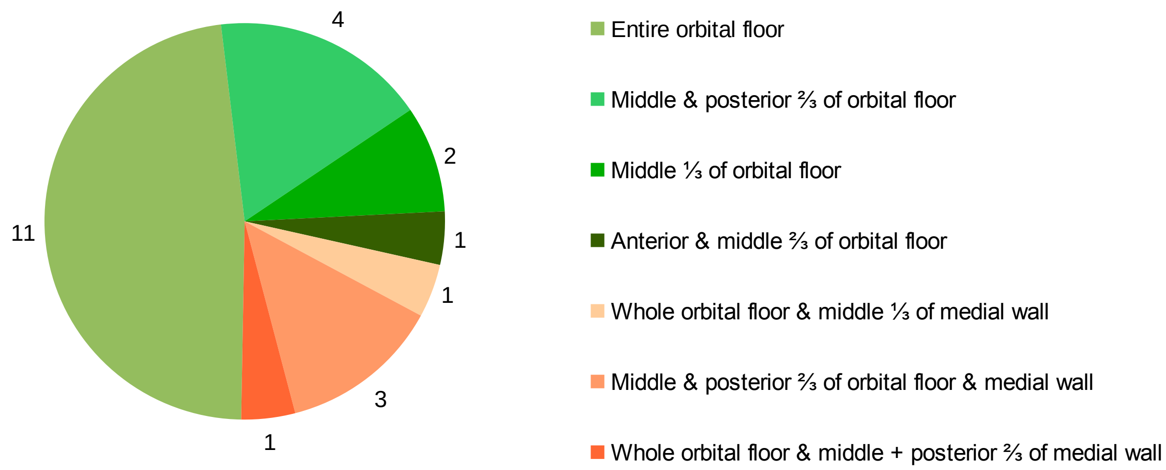


Figure 36: A pie chart showing the extension of fractures. All the green shades represent the pure orbital fractures (14 males, 4 females), while the peach shades represent the combined orbital floor/medial wall fractures (all males). 23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013.

As seen here, the combined orbital floor/medial wall fractures which are more extensive than the pure orbital wall fractures, occurred exclusively in the male population and the causes were sports injury, violent assault and road traffic accidents.

3.4.3 Associated zygomatic and nasal fractures

In 1 patient (P23) there was an accompanying zygomatic fracture on the ipsilateral side. This was a simple fracture and the zygoma was repositioned after the reduction of the orbital fracture. There were also 6 accompanying nasal fractures, 5 of which were reduced together with the orbital fracture; P2, P8, P14, P19 and P23. 1 patient, P18 had an undislocated nasal fracture which required conservative treatment.

3.5 Orbital implants and screws

Out of our 23 patients, 19 required the large size of preformed orbital plates (16 males and 3 females), while the remaining 4 (3 males and 1 female) required the small size. For the pure orbital floor fractures we used 3 small implants and 15 large implants, and for the combined orbital floor-medial wall fractures we used 1 small implant and 4 large implants.

In 22 patients, the implant was cut intraoperatively to be accommodated into the orbital cavity; only in 1 patient (P10) was the implant suitably placed without the need to be shortened. In 22 patients, the implant was cut intraoperatively to be accommodated into the orbital cavity; only in 1 patient (P10) was the implant suitably placed without its need to be shortened. In 3 patients, the preformed orbital plate was additionally bent manually intraoperatively by the surgeon to fit the fractured orbital wall contours, while in 20, no bending was necessary. 3 consultants were responsible in the reduction of the orbital fractures in this study, and for anonymity's sake, numbers were used for the surgeons, according to who operated numerically first our study patients (see Table 1).

All the screws used in our study patients were of the 1.5mm diameter, except in 1 patient (P19), where a 1.8mm (emergency) screw replaced a customary 1.5mm screw. In our study;

•10 patients required only 1 screw for plate fixation

•9 patients required 2 screws for plate fixation

•4 patients required 3 screws for fracture reduction

Table 1: Table showing the surgeons involved, number of patients (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013), gender distribution, implant sizes, and the location of the fractures. Abbreviations; (I) M.W. – medial wall, (II) O.F. – orbital floor, (III) S1, S2, S3 – surgeon number 1, 2, 3 respectively.

Surgeon	Number of patients	Gender	Size of implant	Location of fracture
S1	2	Male	Small	Pure O.F.
S1	3	Male	Large	Pure O.F.
S1	1	Female	Large	Pure O.F.
S1	2	Male	Large	Combined O.F./M.W.
S2	1	Female	Small	Pure O.F.
S2	1	Male	Large	Pure O.F.
S2	1	Male	Small	Combined O.F./M.W.
S3	8	Male	Large	Pure O.F.
S3	2	Female	Large	Pure O.F.
S3	2	Male	Large	Combined O.F./M.W.

As a summary, the screws were inserted in:

•9 patients – inside the orbit

•3 patients – on the orbital rim

•6 patients – over the orbital rim

•2 patients – inside the orbit and on the orbital rim

•3 patients – inside the orbit and bent over the orbital rim (see Table 2 and Figure 37).

Table 2: Table showing the surgeon involved, the number of patients (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013), the number and type of screws inserted, and the location of screws. As seen from this table, no screws were inserted into the medial orbital wall. Abbreviations; S1, S2, S3 – surgeon number 1, 2, 3 respectively.

Surgeon	Number of patients	Number & type of screws	Location of screws
S1	5	1 x 1.5mm	Inside orbit
S1	1	2 x 1.5mm	Inside orbit
S1	2	1 x 1.5mm	On the orbital rim
S2	3	1 x 1.5mm	Inside orbit
S3	1	2 x 1.5mm	On the orbital rim
S3	5	2 x 1.5mm	Over the orbital rim
S3	1	1 x 1.5mm, 1 x 1.8mm	Over the orbital rim
S3	1	2 x 1.5mm	Inside orbit, on the orbital rim
S3	1	3 x 1.5mm	Inside orbit, on the orbital rim
S3	3	3 x 1.5mm	Inside orbit, over the orbital rim

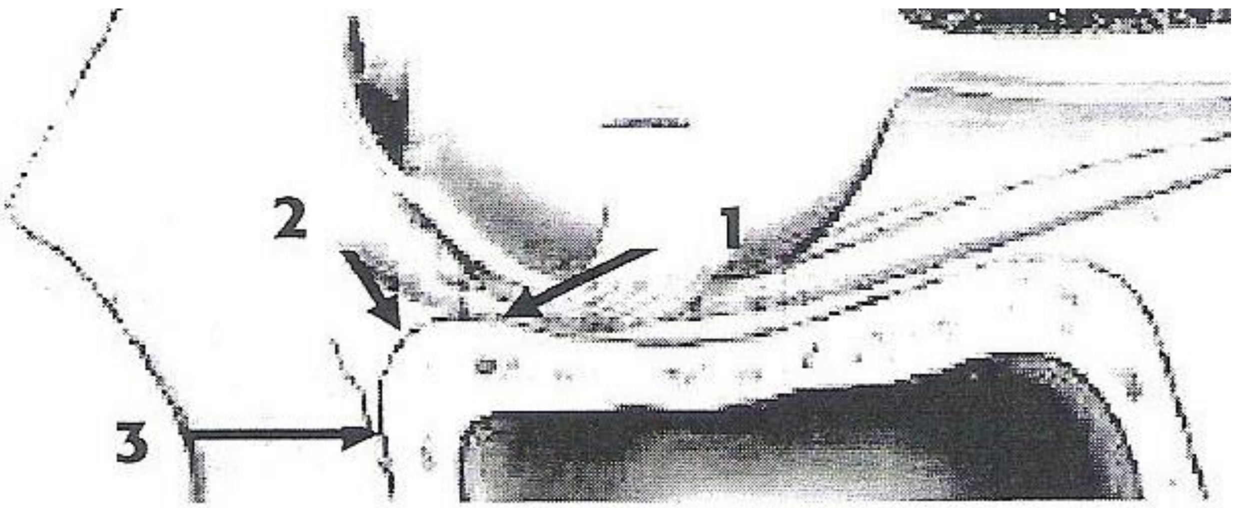


Figure 37: Location of orbital screws in different orbital locations; figure reproduced by permission of the AO Foundation and copied from the Orbita 3 study file: 1; inside the orbit, 2; on the orbital rim, 3; over the orbital rim.

3.6 Days passed/days awaited for surgery

The time lapse (in days) before surgery is for clarity separated into 2 types (refer to Figure 38 and Table 10 in the Appendix):

1.the days passed from injury to operation; that is the actual days awaited by the patient (represented in green colour)

2.the days awaited from admission to surgery (that is the days passed from presentation to us till the date of operation (represented in peach colour).

The former was affected partly from the duration of the referrer to send the patient, or to the patient himself to present to us, and partly from our decision to operate. The latter is affected wholly from our decision to surgery, which is in itself due to a number of different reasons; primarily waiting for the patient's swelling to subside, and waiting until we manage to get a slot within our hospital's main operating theatre.

Date of admission refers to the date that the patients presented to us or were referred to us. After the clinical and radiological diagnosis, each patient was immediately admitted as an in-patient on the same day/night that he/she was seen. The patients were also all clarified and had to sign preoperatively in order to consent to participate in our study, besides of course the usual preoperative clarification of the operation involved, with its particular risks.

As seen in Figure 38, all our patients were operated between 1 and 15 days of injury (Mean; 5.09, and Median; 4), and between 1 and 7 days of presentation to us (Mean; 2.91, and Median; 3).

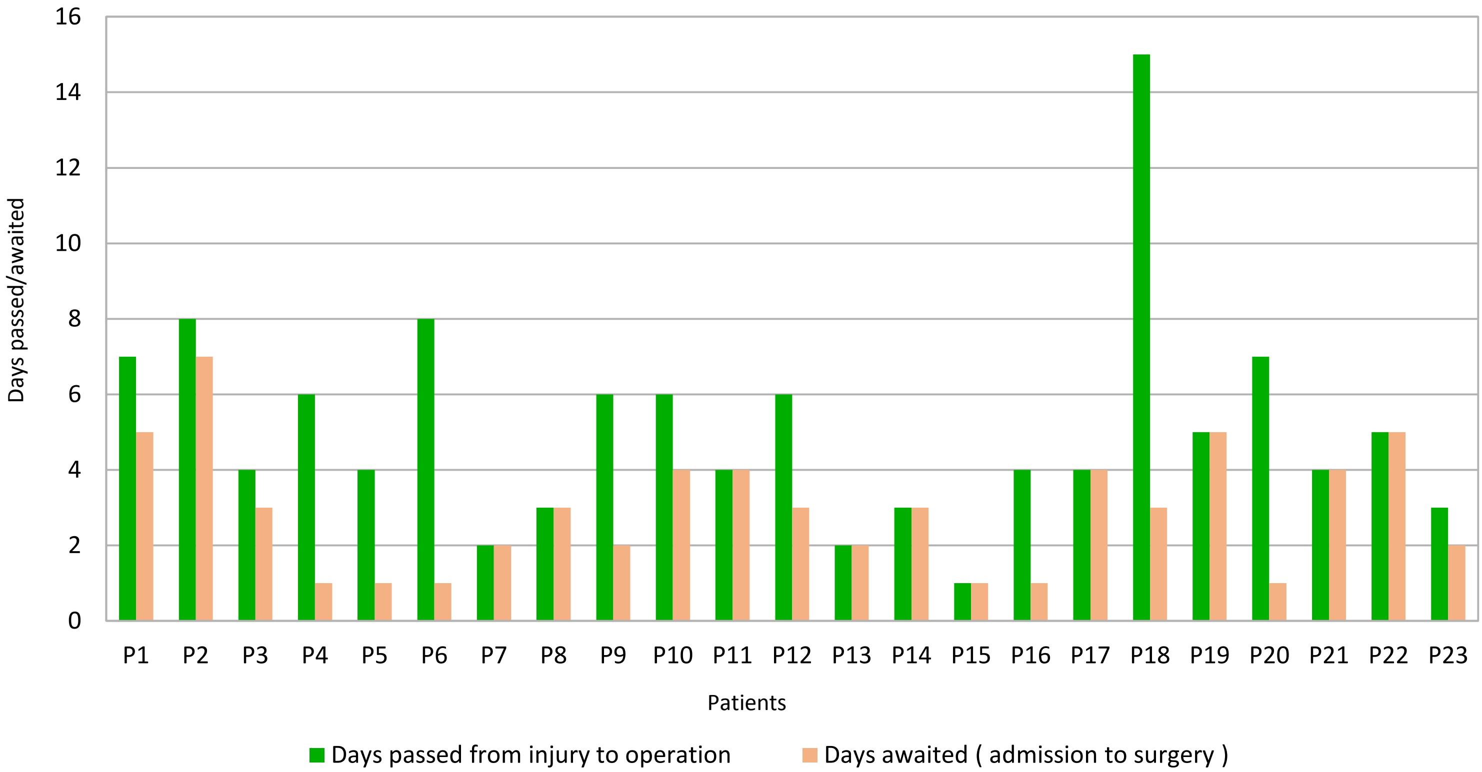


Figure 38: A bar chart showing the actual number of days passed from injury to operation and the days awaited from admission to surgery for each patient (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Abbreviation; P – Patient as for example P1 = patient number 1).

3.7 In-hospital stay (in days)

As seen in bar chart Figure 39, when excluding P2, the in-patient period is between 2 to 9 days; a total average of 6.52 days when including P2.

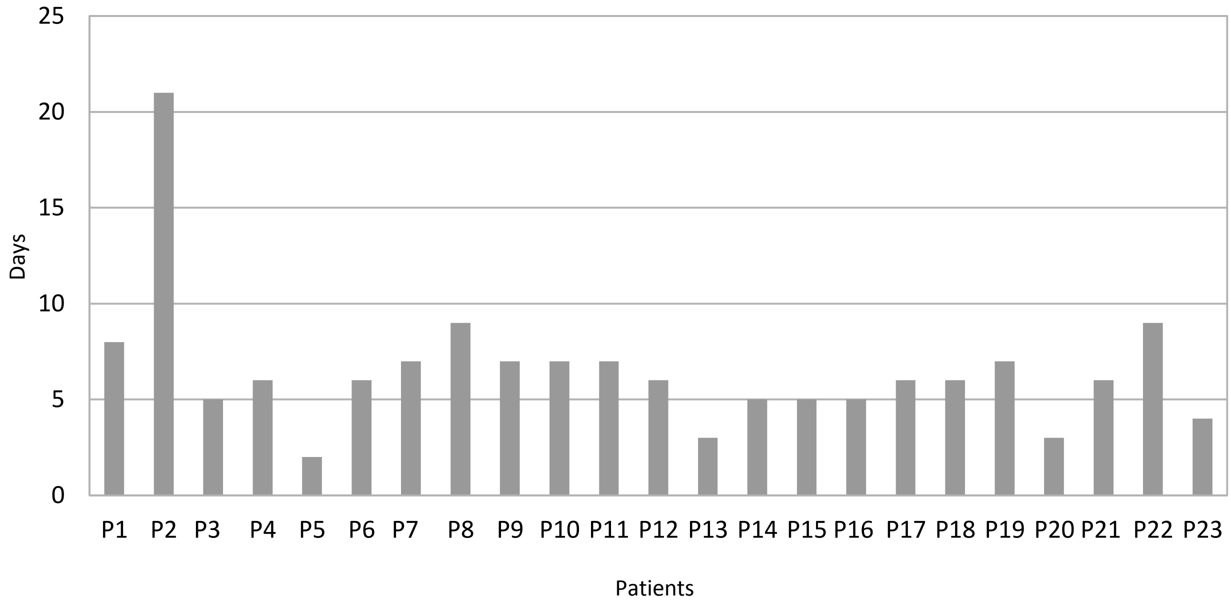


Figure 39: A bar chart showing the in-patient period for each patient; that is from the date of admission till the date of discharge (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). When including all the patients, the median is 6 days. Abbreviation; P – patient.

3.8 Operation time (in minutes)

The operation time required for the 23 patients from the start of incision to the end of the last suture including the intraoperative cone bean scan (except for P3 as previously mentioned), varied from 30 minutes to 115 minutes; an average of 66.3 minutes for the pure orbital floor fractures, and an average of 71.6 minutes for the complex orbital floor/medial wall fractures. This is represented in Figure 40. As mentioned before, all the operations were performed by 3 different consultants in our department, with a variety of experience between less than 5 years to more than 10 years in the reconstruction of orbital fractures. The operating time was recorded in minutes.

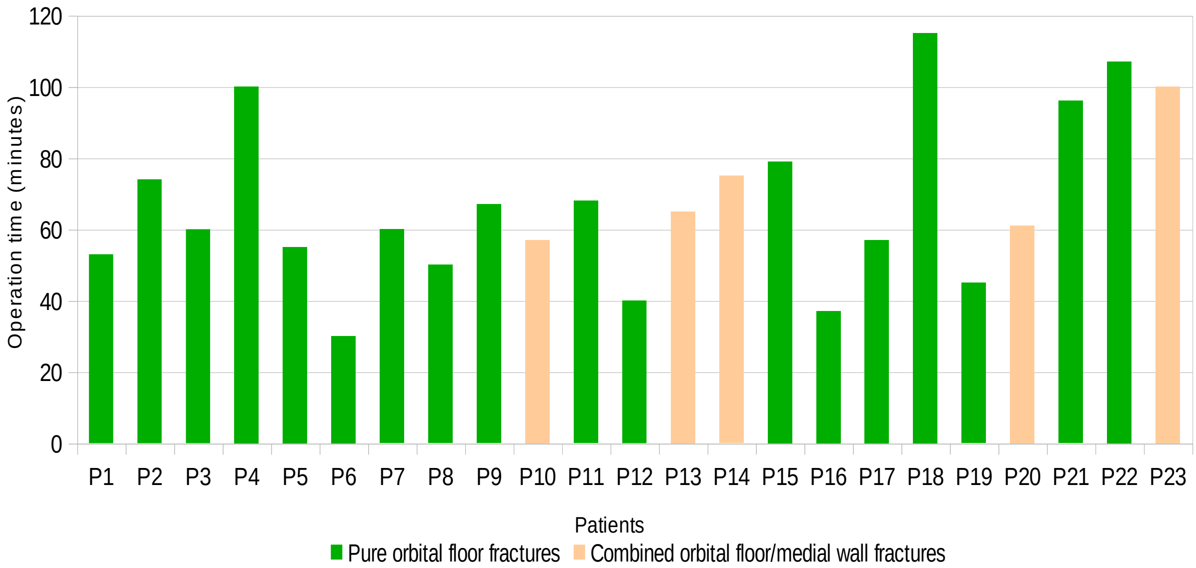


Figure 40: A bar chart showing operation time (in minutes) required for the patients for both pure orbital floor fractures and combined orbital floor/medial wall fractures (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Abbreviation; P – patient.

3.9 Visual Acuity

The preoperative result for the visual acuity, as well as the 1-week, 4-weeks' and 12-weeks' follow-up visits was recorded for each patient (see Table 3) through the Snellen Chart, which was supplied to us by the AO Foundation (see Figure 6). As already mentioned, all of our patients in the study on admission were referred to the ophthalmic department in our hospital, for an orthoptic and ophthalmological examination, both preoperatively. Postoperatively, the patients were again referred for a follow-up examination, before discharge, and this repeated itself at the 1-, 4- and 12-weeks' visit. Sometimes the patients preferred their follow-up visits at their private ophthalmologist. For this reason, we have used our results for the visual acuity, and not of the hospital ophthalmological department.

The visual acuity of both eyes was assessed separately (the affected first followed by the unaffected eye) using the Snellen chart kept at a distance of 35 cm, covering each time the contralateral eye. This test was done without correction glasses first, and then with the glasses (when available). The initial baseline investigation was compared to the final (12-week) examination and the results entered in Table 3 (see the Appendix, Table 12 for more detail).

Table 3: Table depicting the number of patients sustaining a change of visual acuity on the injured and uninjured sides and the effect of correction glasses on it (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Visual acuity	Fractured side without glasses	Fractured side with glasses	Uninjured side without glasses	Uninjured side with glasses
Improvement	12	1	9	3
Same	8	4	13	2
Worsening	3	3	1	3
		13 patients; no glasses required, 2 patients; no glasses available		12 patients; no glasses required, 3 patients; no glasses available
Total patients	23	23	23	23

In the column depicting 'fractured side with glasses', 13 patients did not require correction glasses and 2 patients had no glasses available on examination. In the column showing 'uninjured side with glasses', 12 patients required no correction glasses and 3 patients had no glasses available on examination. The discrepancy between the 2 columns is because one patient (P1) did not require any correction glasses for the eye on the fractured side, but required correction to the eye on the uninjured side; usually he wears a contact lens, which on hospital admission he had removed.

3.10 Ocular Motility and Double Vision

The objective ocular motilities and the subjective double visions, were recorded for the preoperative, 1-week, 4- weeks' and 12-weeks' visits through the 8 fields of gaze (see Figure 7) together with the additional convergence/divergence field by the ophthalmic department (see Tables 4 and 5).

Table 4: Table demonstrating the ocular motility limitations in our patients at the various examinations (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Ocular motility limitation	Preoperative	After 1 week	After 4 weeks	After 12 weeks
Yes (number of patients)	10	14	14	8
No (number of patients)	13	9	9	15
Total number of patients	23	23	23	23

Table 5: Table demonstrating the recorded double visions at the various examinations (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Double vision	Preoperative	After 1 week	After 4 weeks	After 12 weeks
Yes (number of patients)	16	17	15	8
No (number of patients)	7	6	8	15
Total number of patients	23	23	23	23

3.11 Globe position (measured in mm)

The globe position was measured from 3 positions; the vertical, sagittal and horizontal as shown in Figure 8.

3.11.1 Vertical globe position

The preoperative vertical globe position was straight in 15 out of 23 patients; that is the left and the right pupils were on the same vertical level as measured by means of the Naugle exophthalmometer (Figures 9-12). The remaining 8, had a difference in the globe position of a range between 2-5mm; whatever the side of the fracture, the right globe was always in a more cranial position/ in hyperglobus when compared to the left side (or the left globe was always in a hypoglobus position). As a reference point, the left pupil was always taken to be at level 0 and then the level of the right pupil compared, so as to avoid negative values. As one can notice from the graph in Figure 41, in the 1-week postoperative period, the number of patients which had a difference in the pupillary level across both sides increased; and this was true for both genders. At the 12-week examination, we had 13 patients with a globe position on the same vertical level, and the remaining 10 had a difference in globe positions ranging between 1-6mm. Figure 41 depicts the preoperative results compared with the results at 1 week, 4 weeks and 12-weeks in our 23 patients.

In Figure 42, the average vertical globe levels for each examination date were calculated and the results plotted. On average, the globe position at the 12-week examination was approximately on the same level as the preoperative value; in the area of '1'; thus, on average the right globe is 1mm higher in the vertical level than the left globe (in hyperglobus) or the left globe 1mm lower than the right (in hypoglobus) in our patients.

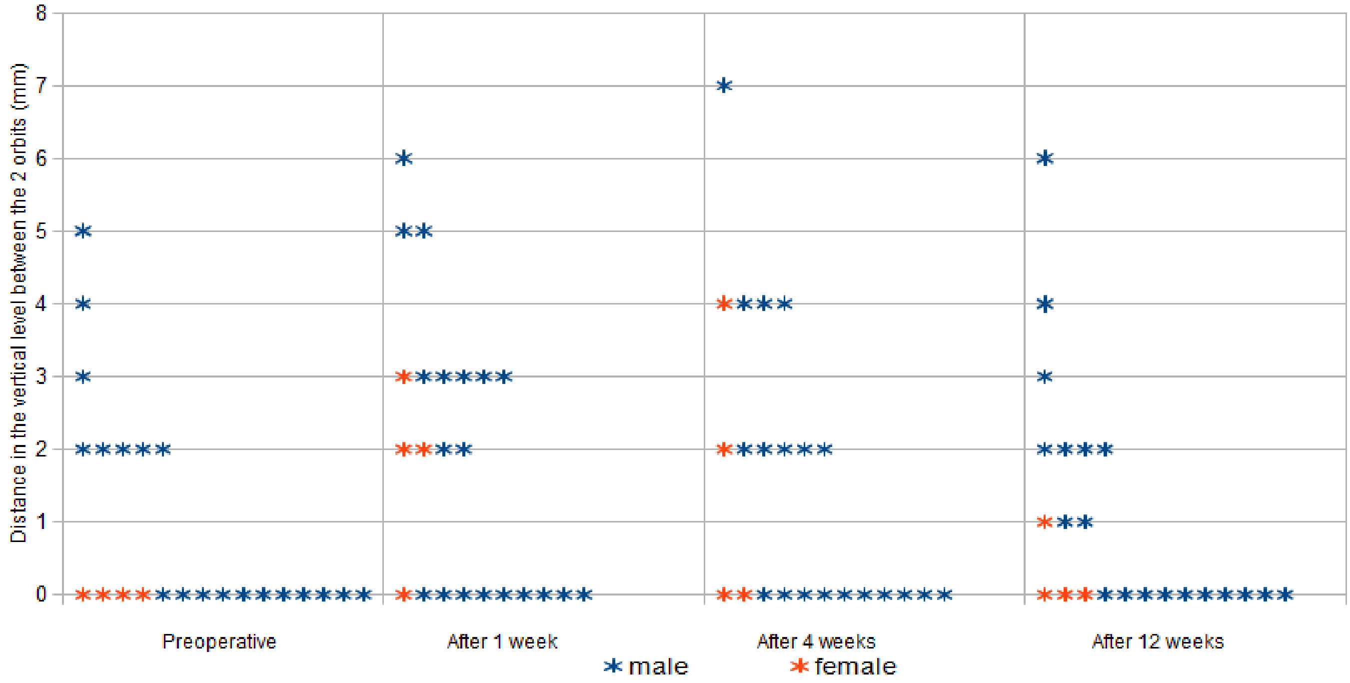


Figure 41: A scatter graph showing the difference in the vertical level between the 2 orbits at the four various investigation periods (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Also refer to the Appendix, Table 15 for more detailed information.

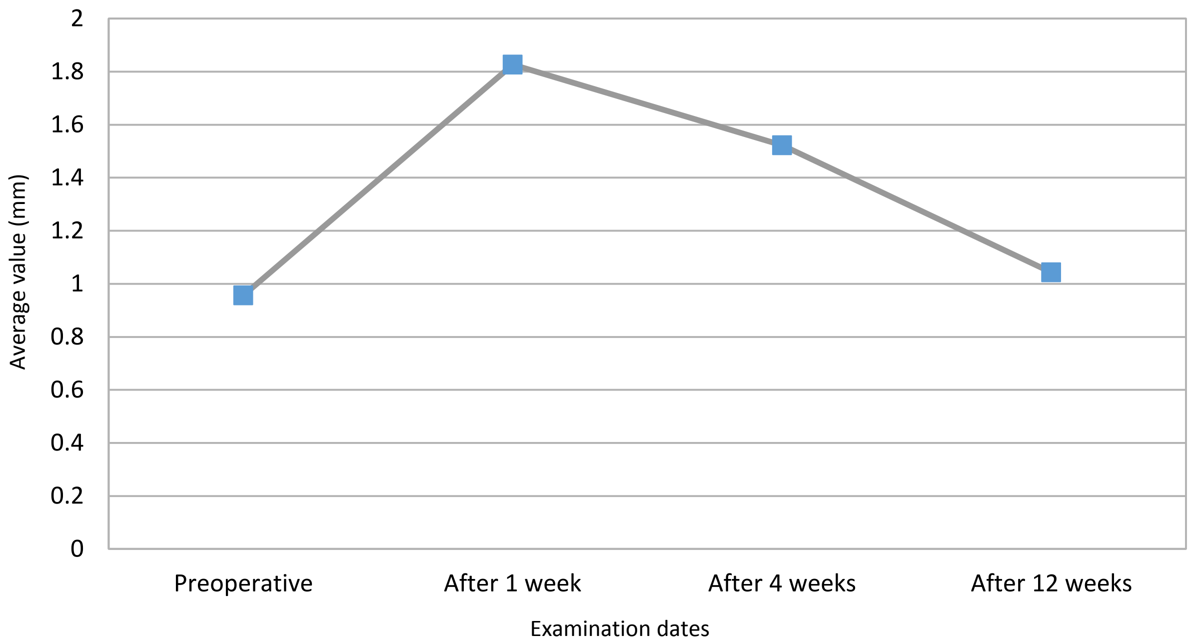


Figure 42: The average values of the vertical globe position at various visits (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

3.11.2 Sagittal globe position (exophthalmometer readings)

The sagittal values for both orbits were measured through the Naugle exophthalmometer (Figures 9-12), and the results for the preoperative, 1-week's, 4-weeks', and 12-weeks' visits compared. Measurements were always recorded in millimetres (mm): see Figure 43. The non-injured orbit was taken as the 'normal-sized' orbit; a negative exophthalmometer measurement means that the fractured orbit is shrunken in the sagittal plane by that value, a plus measurement means that the fractured orbit is increased in the sagittal plane by that value (both in mm). A zero value between the 2 orbits indicates no resultant enophthalmos/exophthalmos between the 2 orbits. The average of all the readings for all the separate visits are portrayed in Figure 44. While in the preoperative examination, the average value was of -0.174mm, in the 12-week follow-up visit it was -0.652mm.

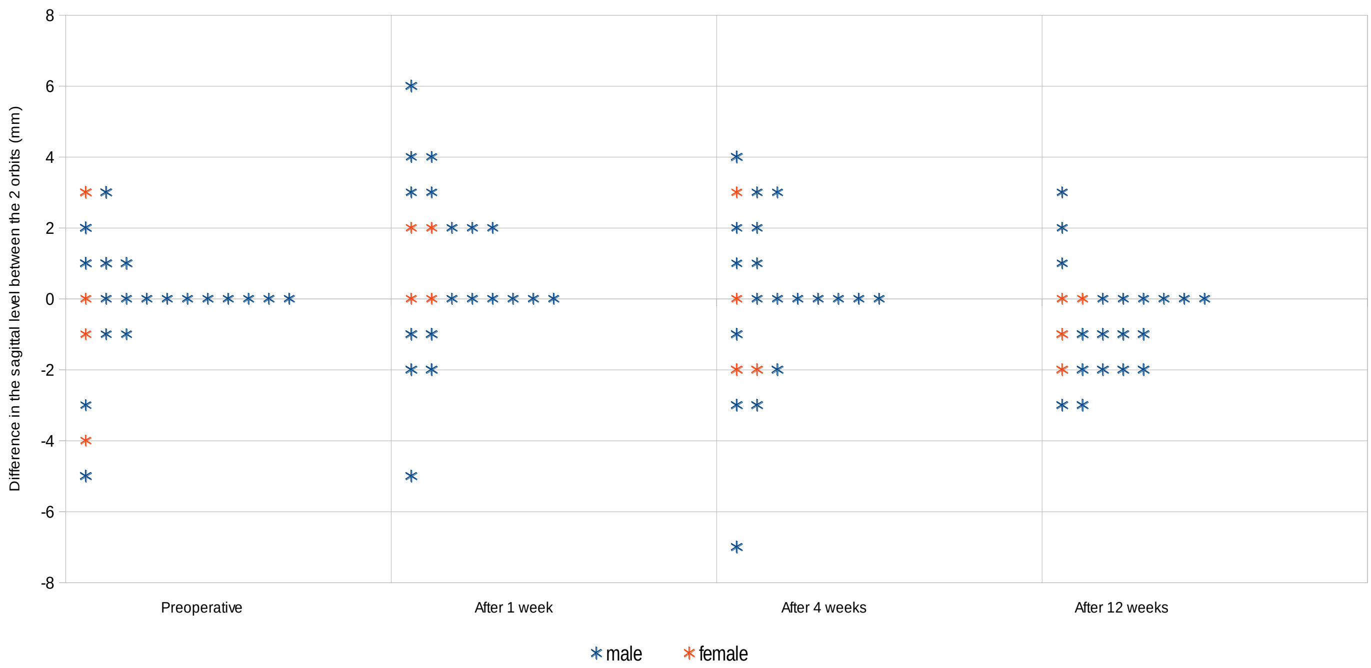


Figure 43: A scatter graph showing the difference in the sagittal level between the two orbits for each patient at each separate visit (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Also refer to Appendix Table 16 for more detailed information.

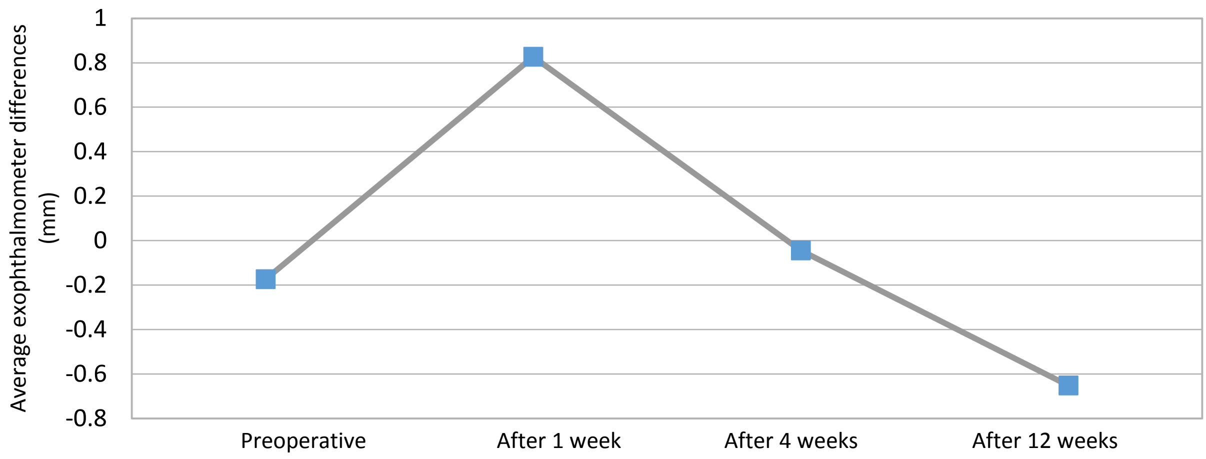


Figure 44: The average exophthalmometric differences (in mm) for each separate examination (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

3.11.3 Horizontal globe position (the interpupillary distance)

The interpupillary distance (in mm) was measured preoperatively, and at 1 week-, 4 weeks-, and 12 weeks- postoperatively; this is specifically the distance measured between the centre of the left and right pupils, by means of the exophthalmometer (see Figure 45).

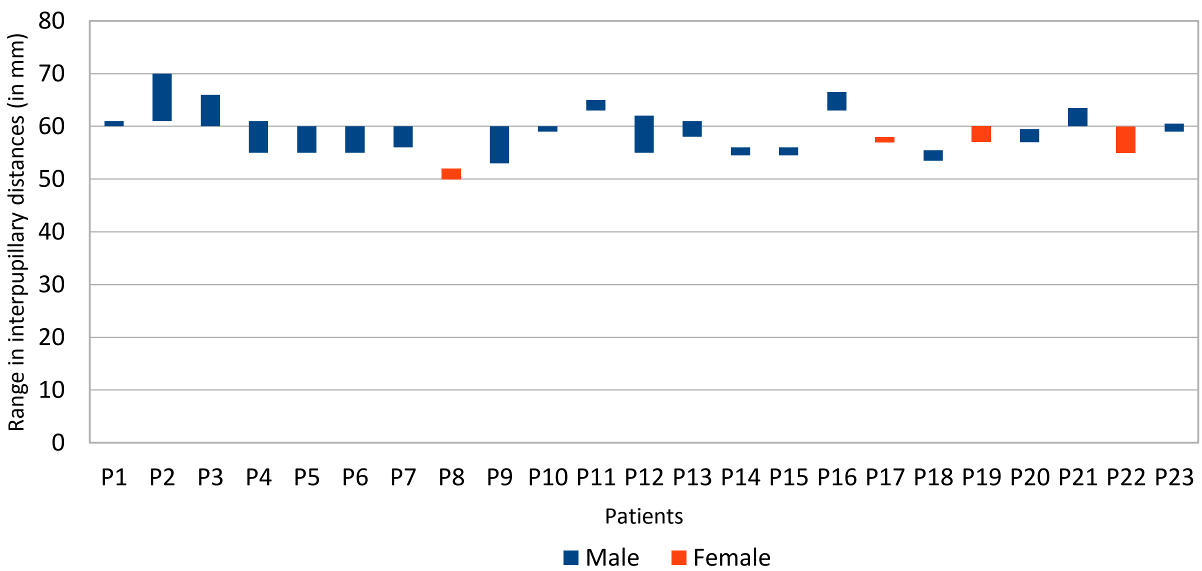


Figure 45: A bar chart showing the ranges of interpupillary distances for the four separate examinations on

each patient; the mean interpupillary distance is 59 mm (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Also refer to the Appendix Table 17 for more detailed information.

3.12 Sensory disturbance to the maxillary nerve

The sensory disturbance to the maxillary division of the trigeminal nerve on the affected side, was compared pre- to postoperatively. Hypoaesthesia was noted when the patient recorded a reduced sensation in the area, paraesthesia with a tingling sensation, hyperaesthesia with an increased sensation and anaesthesia when a complete loss of sensation in the territory of the nerve. A normal sensation was of course recorded when the patient had a full sensation (see Table 6).

Table 6: Table recording the degree of the maxillary nerve disturbance/its normality on the affected fractured side at various visits (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Sensation/its loss	Preoperative	After 1 week	After 4 weeks	After 12 weeks
Normal sensation	13	1	3	6
Hypoaesthesia	9	20	18	10
Paraesthesia	0	1	2	7
Hyperaesthesia	1	0	0	0
Anaesthesia	0	1	0	0
Total patient number	23	23	23	23

3.13 Medications required

As a protocol and unless otherwise required, we gave our patients only a single shot of intravenous(i.v.) antibiotic - Unacid® 3gr. (or Clindamycin 600mg in case of allergy to penicillin), as well as a single shot intravenous corticosteroid - SDH® 250mg, both intraoperatively. The night before surgery, all our patients were given 0.4ml Clexane® (Enoxaparine Sodium) through a subcutaneous route as a thrombosis prophylaxis (except P2, who was already on Marcumar (Phenprocoumon). In addition, we gave non-steroidal anti-inflammatory drugs, namely Ibuprofen 600 mg three times daily orally as our standard analgesia and as an anti-inflammatory means (unless contraindicated), during the hospital stay and then we prescribed them post-operatively for the first 2 postoperative weeks. Consecutively, they were just used on `as required basis`. The following table compares the medications our patients needed from admission till 12 weeks postoperative (see Table 7).

Table 7: The medications required at different time spans, excluding the pre- and intraoperative medications which have been already mentioned above (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Medication	Inpatient	At discharge	After 1 week	After 4 weeks	After 12 weeks
Antibiotics	P2, P8, P11, P13, P15, P21	P8	P8	No	No
Corticosteroids	No	No	No	No	No
Non-Steroidal anti-inflammatory drugs	All patients	All patients except P10 & P20	P2, P4-8, P12, P17, P18, P22	P22	P19, P22 on a pro re nata basis

The patients were strongly recommended against blowing their nose, and as a decongestive means, Nasic® (Xylomethazoline) nasal drops were prescribed three times daily for 2 weeks. If the patient was not previously covered against tetanus, then he/she was immunized during the hospital in-stay period, usually before admission, at the emergency department.

3.14 Associated orbital and periorbital injuries

The associated orbital and periorbital injuries (not including ocular motility disturbances and their resulting double vision which have been already described in Section 3.10) have been recorded from both our findings and those of the ophthalmic department in our hospital (see Figure 46). For details see the Appendix Table 19.

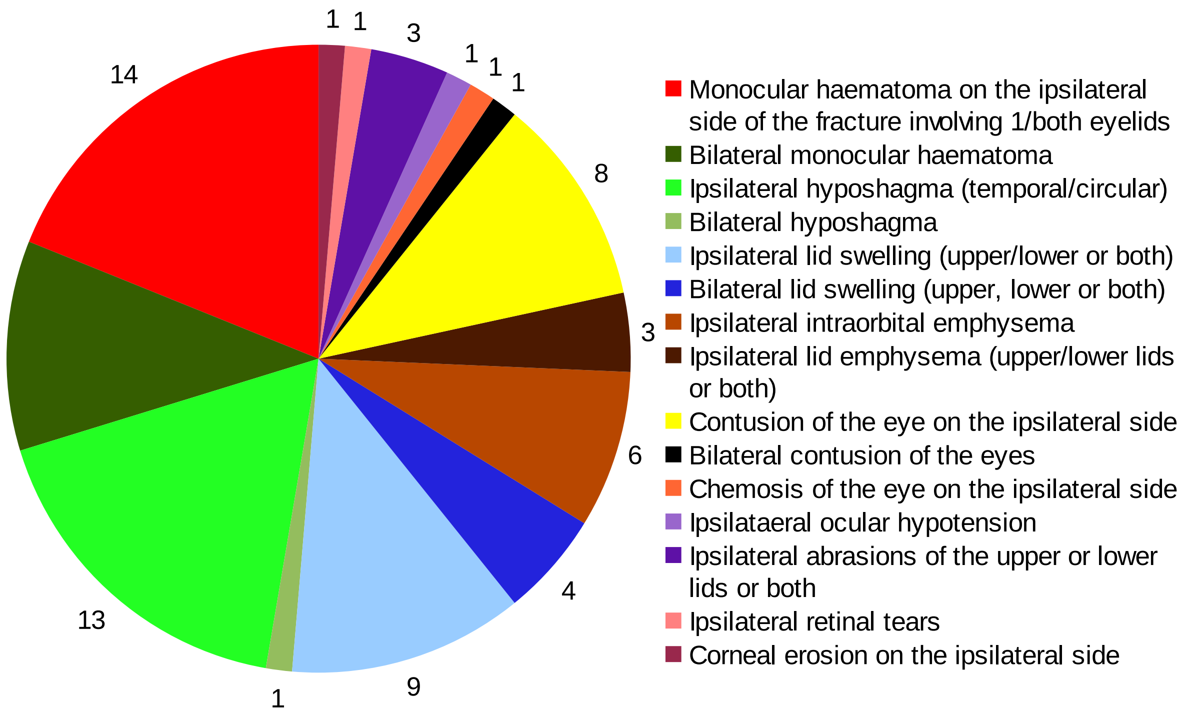


Figure 46: A pie chart representing the associated orbital and periorbital injuries. When bilateral injuries were involved, the ipsilateral side of the fracture had much more pronounciated features than the contralateral side (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

3.15 Accompanying injuries (excluding orbital and periorbital injuries)

The accompanying bodily injuries (excluding the orbital and periorbital areas) are shown in

Figure 47. For details see the Appendix Table 20.

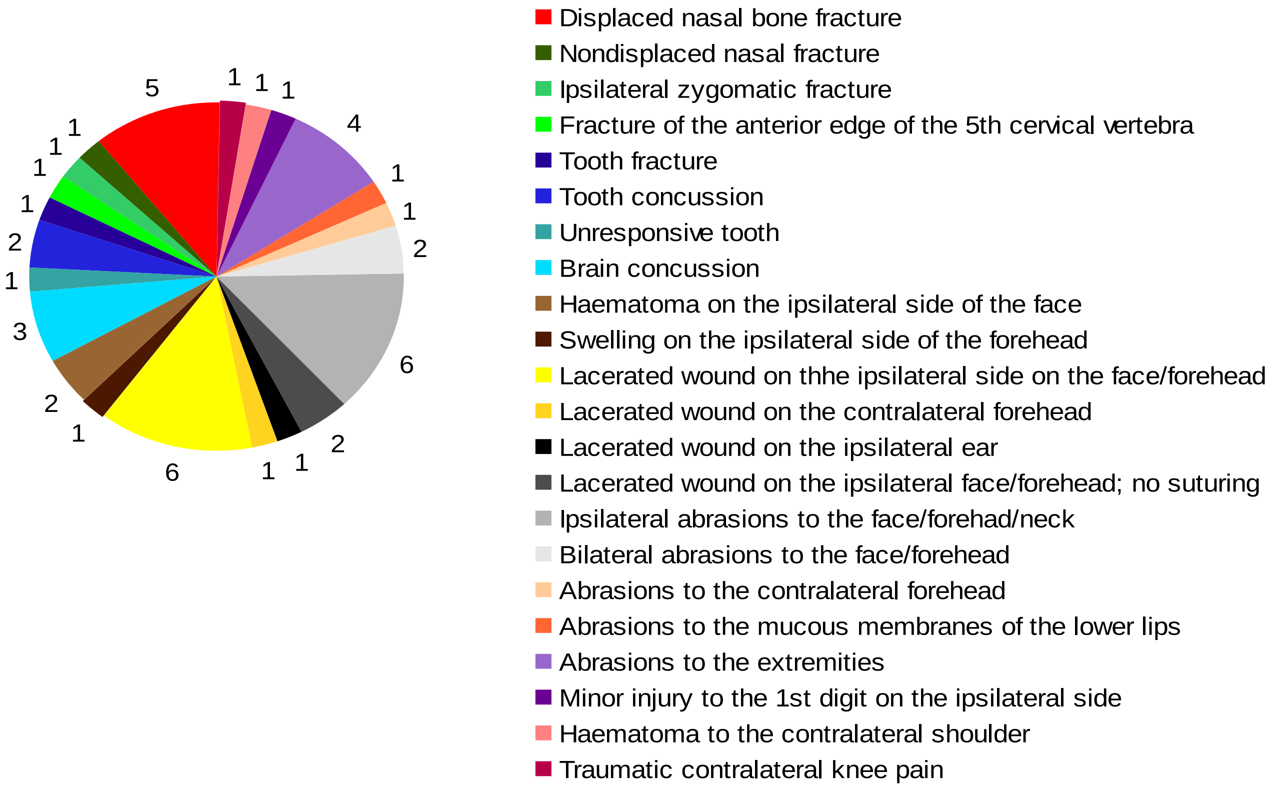


Figure 47: A pie chart representing the accompanying injuries excluding the orbital and periorbital tissues (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

3.16 Postoperative complications/posttraumatic sequelae and their treatment

16 patients (P1, P3, P6, P7, P9-P18, P20, and P21) had no postoperative complications. The remaining 7 patients sustained different events, which are represented in Table 8.

Table 8: Postoperative complications/posttraumatic sequelae in our study group and their treatment (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

P2	Repeated epistaxis following septorhinoplasty (to treat a concomitant nasal fracture) Postoperative chemosis in the ipsilateral eye of the fracture Postoperative night spent at ITU (intensive care unit) due to ASA III and co-existing sleep apnoea syndrome
P4	Dry eye symptoms on the fracture side reported at the 4-weeks' postoperative visit
P5	29 days postoperatively, the patient collapsed
P8	Postoperative conjunctivitis on the affected side Removal of the orbital titanium mesh 5 months postoperative Postoperative ectropion of the lower lid on the injured side
P19	Persisting 'post-traumatic headaches'
P22	'Chronic pain syndrome'
P23	'Recurring hemicrania of unknown origin' at the 12-week examination

3.17 Volumetric measurements of the orbits (in cm^3)

For an analysis of our operative results in respect to the achieved orbital volume changes, three orbital volumes were calculated; the preoperative and postoperative fractured sides, and the contralateral uninjured side. A CD was burned of every patient's pre- and postoperative CT/ cone beam CT scans, and then analysed through our available computer software; **iPlan Cranial 3.0** from **BRAINLAB AG.** The necessary information from each patient's CD was imported onto the BRAINLAB computer software, the points of interest marked, the best pre- and postoperative scan views (that is the ones giving most information) chosen and superimposed on each other (that is fused). The scans were then aligned in the Frankfurt's plane, each orbit segmented and the bony orbital volumes (that is not including the periorbital soft tissues) could then be measured (see Figures 48-51).

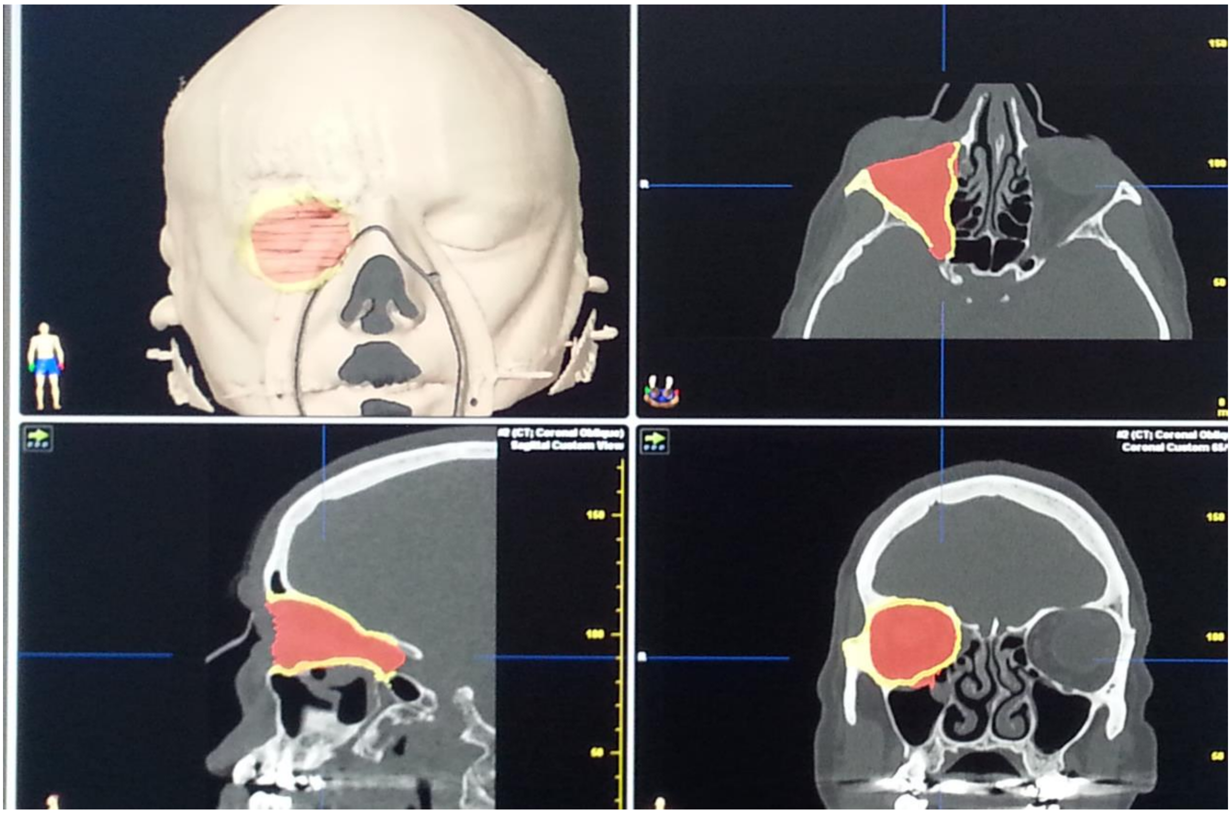


Figure 48: Figure showing the measured preoperative volume of the fractured orbit (right side in this case) in a study patient in 3D; demarcated in red, while the segmentation is depicted by the yellow outline.

From the preoperative scan, the fractured orbit was segmented, the volume measured and noted. The obtained 3-D orbit was then mirror-imaged to the contralateral (uninjured) orbit, and then again re-mirror imaged to the fractured side for calculating now the postoperative 3-D measurement of the reconstructed orbit using the postoperative scan. The 3 different orbital measurements were assigned different colours for contrast's sake; the preoperative fractured side being red, the contralateral side green, and the postoperative reconstructed orbit blue, while orbital segmentation was always shown by a yellow outline.

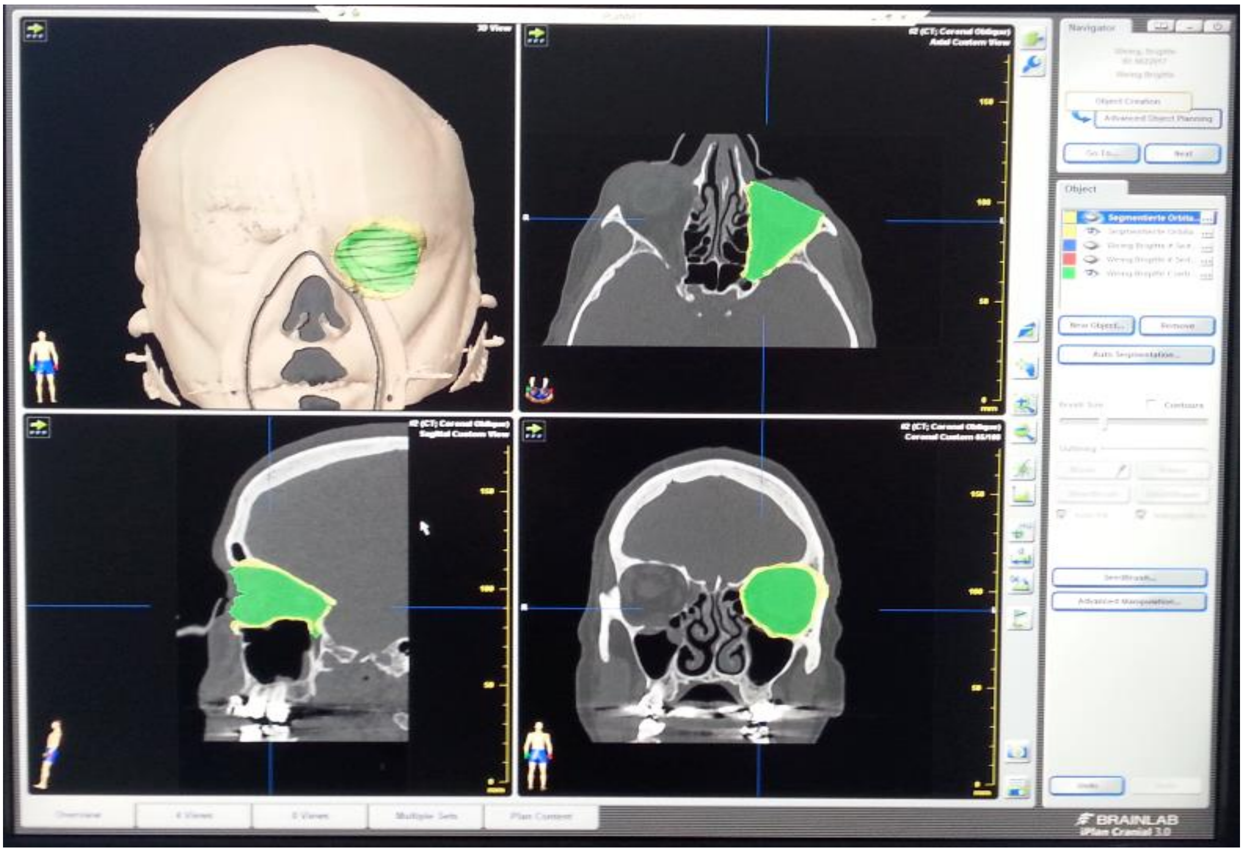


Figure 49: A photo of the segmented contralateral orbit (left side in this case and marked in green); segmentation is also shown here in yellow.

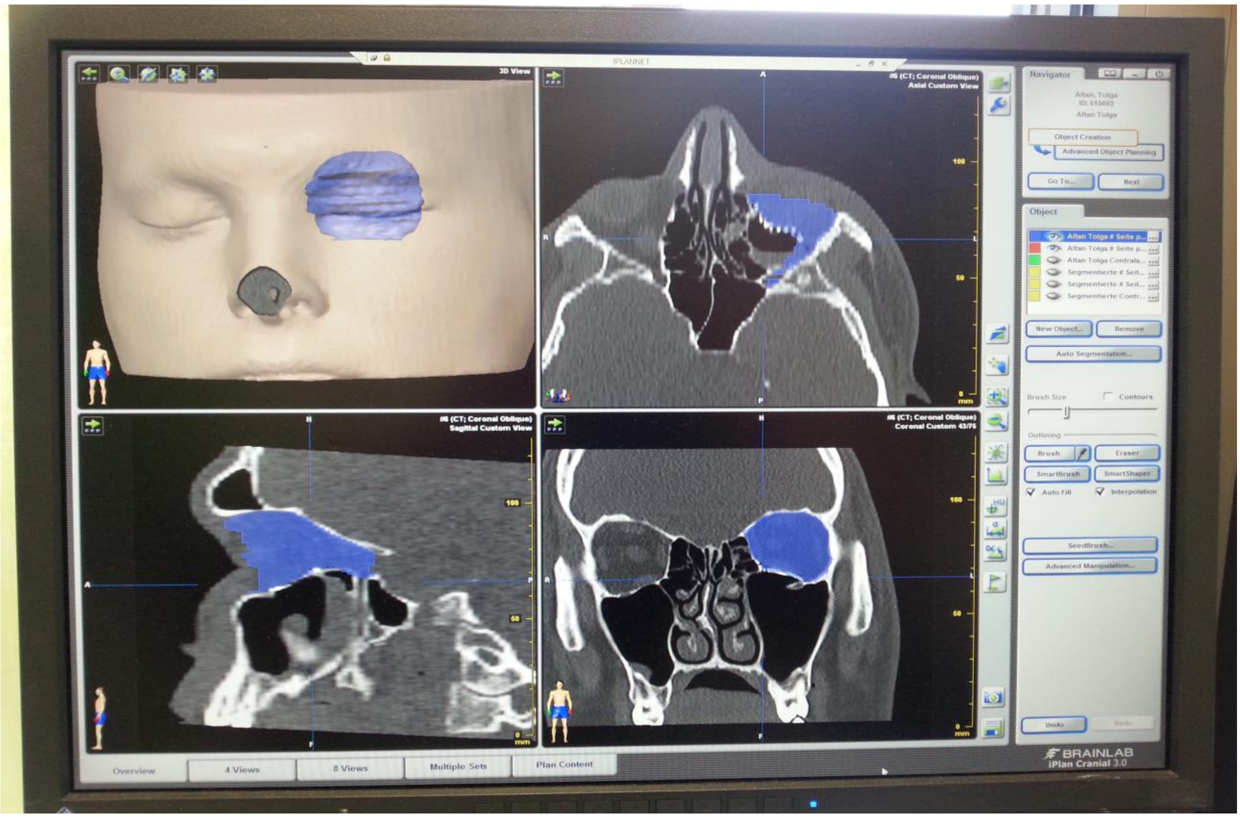


Figure 50: A photo of the measured postoperative fractured orbit on the left side (marked in blue); the orbital

implant is here better demarcated on the axial and coronal cuts. The segmentation is in these views not depicted.

For accuracy, the outlining of the orbital borders was performed with the help of an ergonomic pen on a drawing tablet for freehand drawing (instead of the very inaccurate computer mouse).

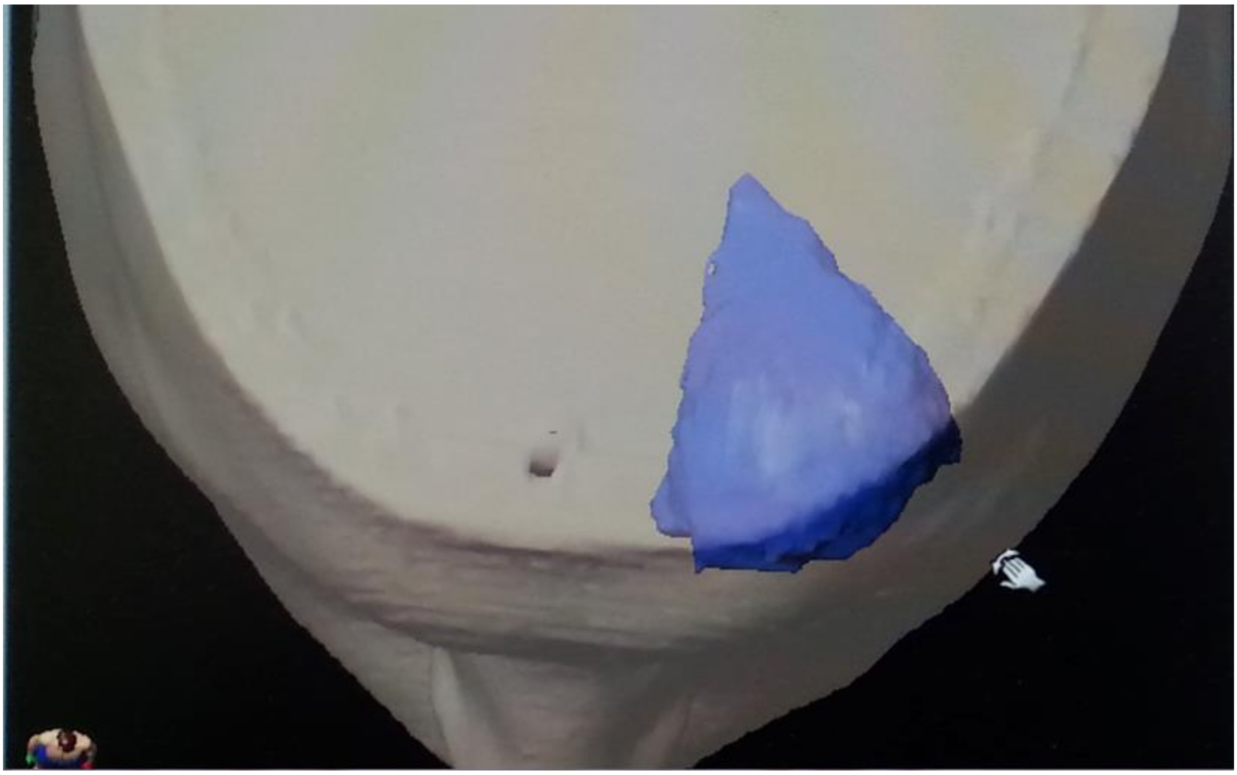


Figure 51: The completed left-sided orbit (same patient as in Figure 50) as seen on the 3D computer model; in this case the view is from above.

The preoperative (Pr.) volumetric measurement on the injured side was compared with the ipsilateral postoperative (Po.) measurement for each patient, and the difference noted. After measuring the contralateral uninjured orbit, the difference in volume from the postoperative fractured orbit to the contralateral (Co.) orbit was also measured. The measurements were then recorded to the 3rd decimal point and the graphs plotted as seen in Figures 52-55; Appendix Table 21 provides more detail. Figures 56 and 57 show postoperative scan views of the implant on a patient in place.

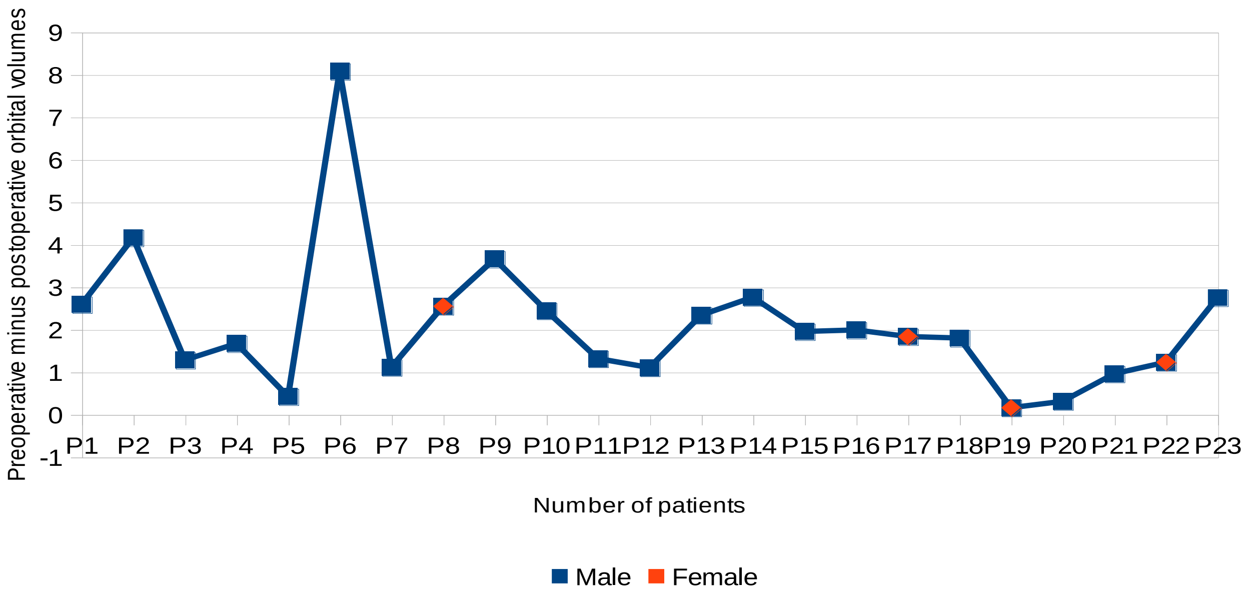


Figure 52: A line chart showing the difference in the preoperative and postoperative volumetric measurements for every patient (in cm³); the values are all positive. The male and female values lie within the same ranges (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

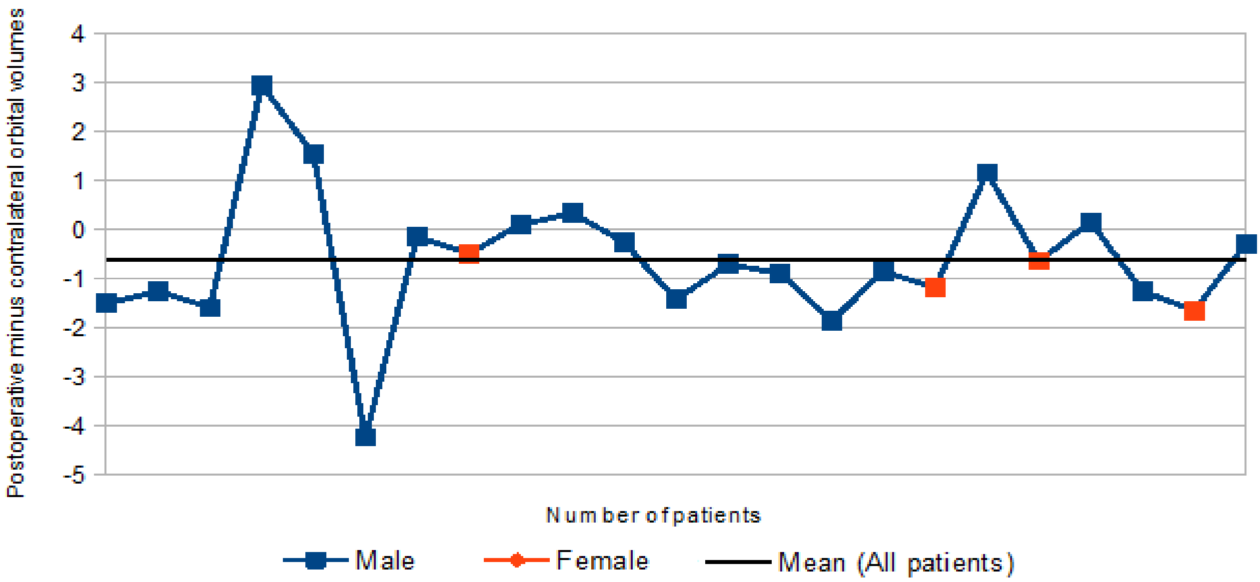


Figure 53: A line chart showing the difference in the postoperative and contralateral volumetric measurements for each patient (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

The average orbital volumes of the preoperative injured sides measured was **31.497cm³**.

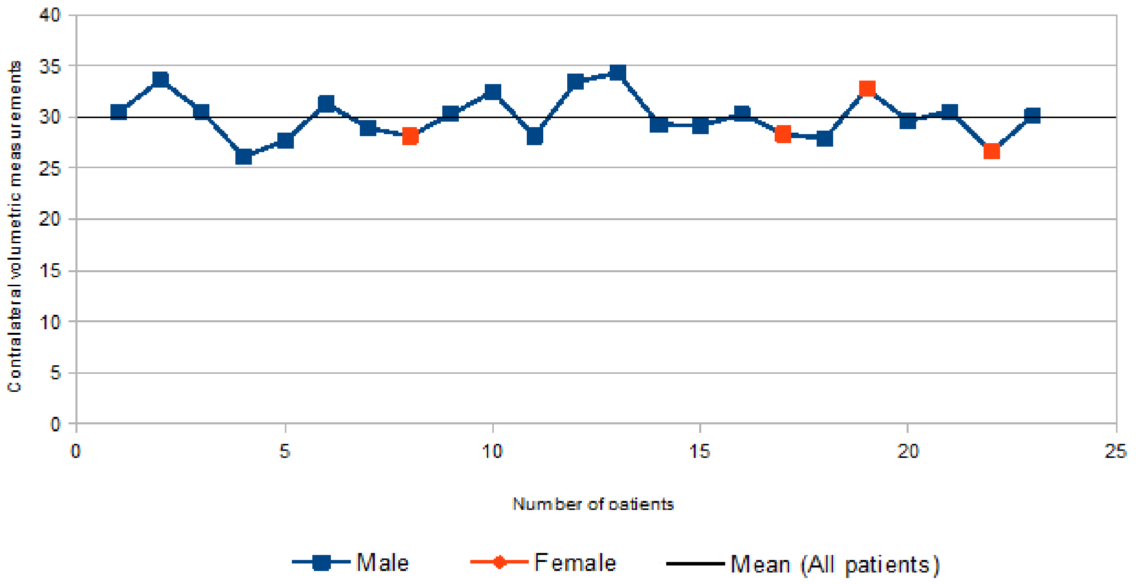


Figure 54: A line chart to show the contralateral volumetric measurements. The average value is **30.002 cm³** and there is no difference between the ♂ and ♀ population (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

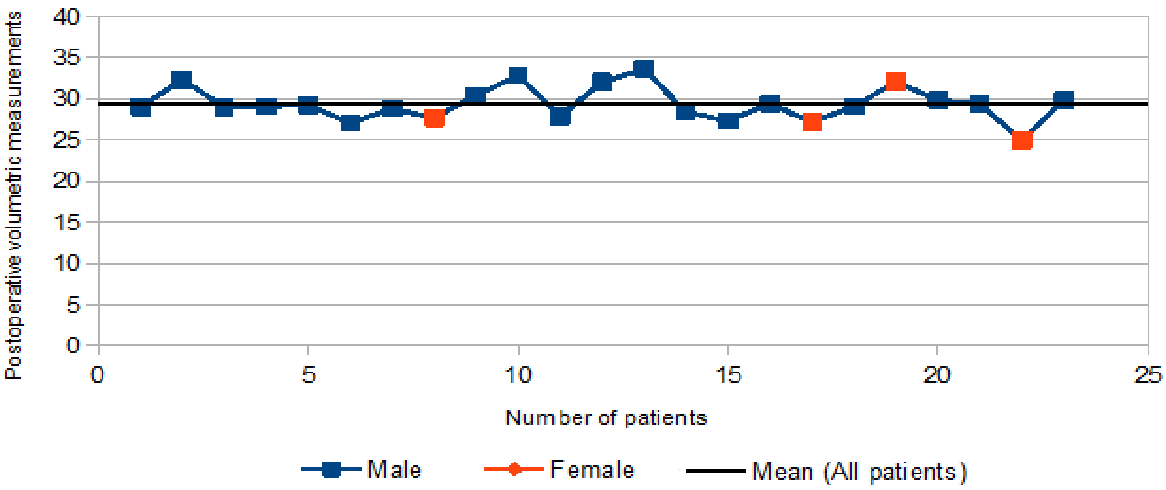


Figure 55: A line chart to show the postoperative volumetric measurements. The average value is **29.389 cm³** (smaller than the contralateral side) and again no difference between the ♂ and ♀ group (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

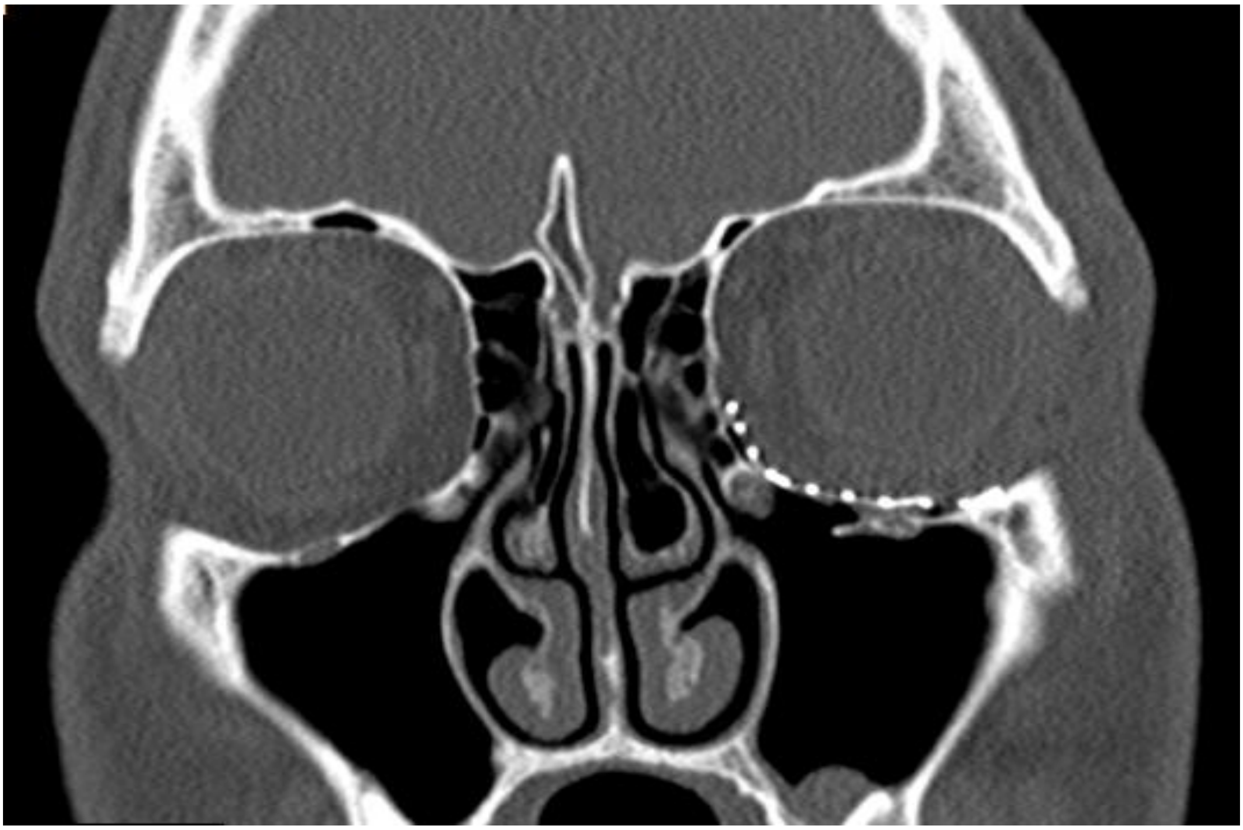


Figure 56: A postoperative coronal CT scan view of P3 (in a pure orbital floor fracture patient) with the orbital implant contour matching that of the orbital floor.

Figure 57: A posterior view of the postoperative CT scan view of P3 showing the orbital implant in position.

3.18 Surface areas of the defects (in cm²)

The surface areas of the orbital floor and medial wall fracture defects were also recorded and corrected to the 2nd decimal point. For the orbital floor fractures, the biggest diameters of the fracture in the coronal and sagittal planes were recorded and multiplied. For the medial wall fractures (existing only in the context of combined orbital floor/medial wall fractures), the biggest diameters of the fracture in the axial and sagittal planes were recorded and multiplied. The measurements were also here obtained by using the **iPlan Cranial 3.0** computer software programme from **BRAINLAB AG** for better accuracy; see Figures 58 and 59 and refer to Appendix Table 22 for a detailed explanation.

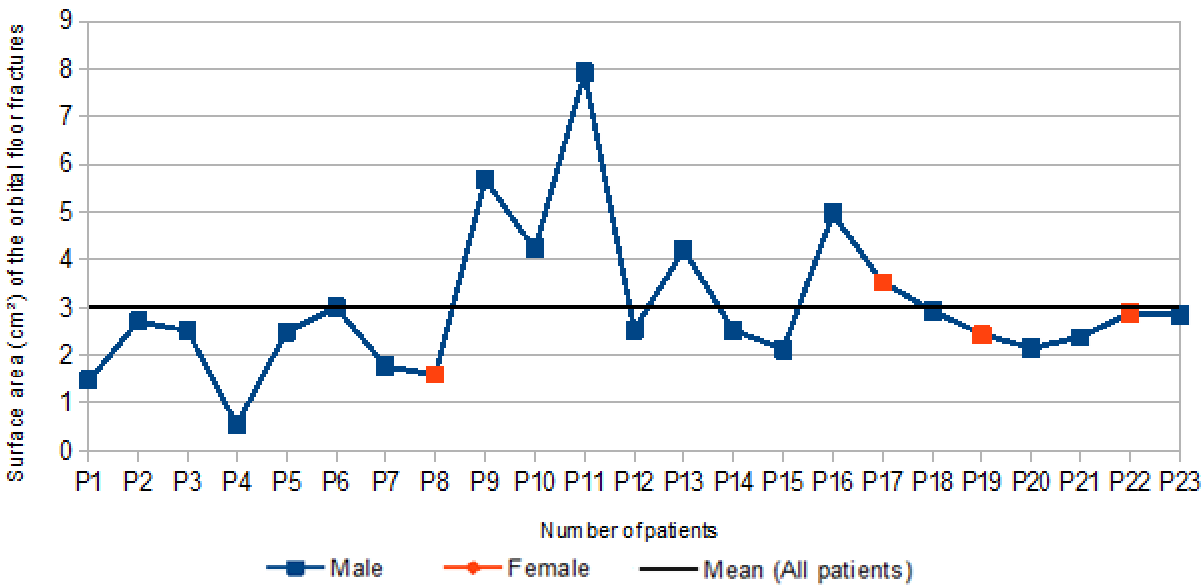


Figure 58: Line chart showing the surface areas (in cm²) of the orbital floor fractures in the 23 study patients, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013. Note that there is no difference between the male and the female populations. The grey line demarcates the average value (3.01cm²).

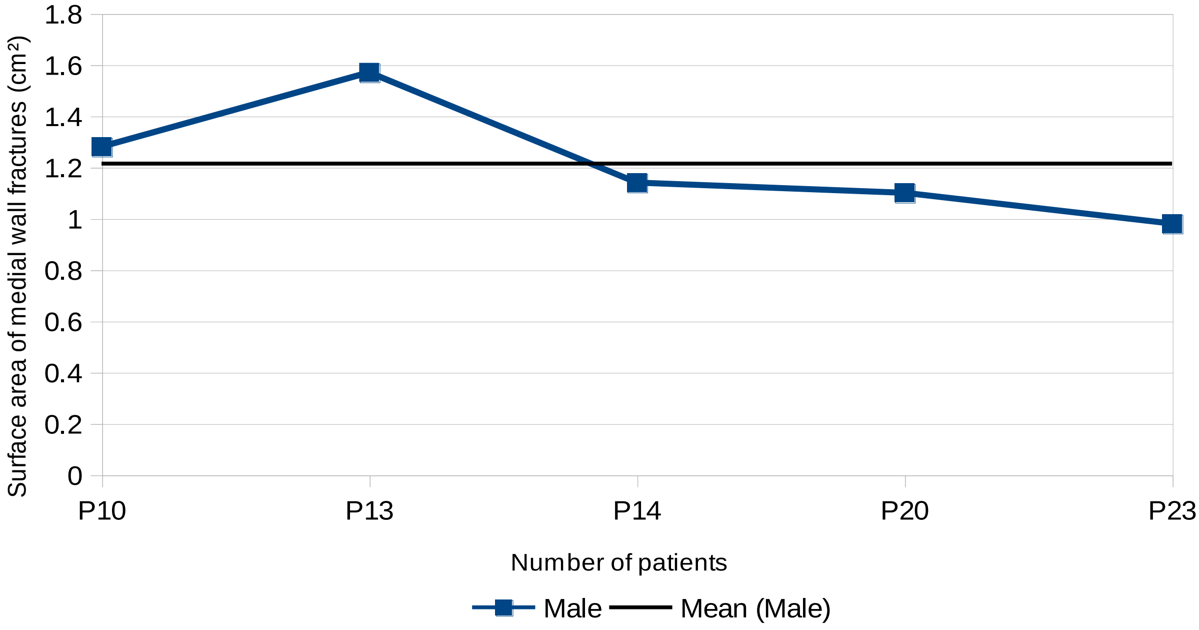


Figure 59: Line chart showing the surface areas (in cm²) of the medial orbital wall fractures in the only 5 patients sustaining these fractures in the Maxillofacial Department, Military hospital Ulm from July 2011 till November 2013; grey line demarcates the average value (1.21cm²).

4 Discussion

The subject 'orbital floor and medial wall blowout fractures' has been in our study group of 23 patients, although in a small group, vastly investigated.

Gender distribution and age at injury

When referring to section 3.1; 'Gender distribution and age at injury', one can see the strong male predominance; a ratio of 19:4 males:females in our study, nearly 5:1, as is also noted in other studies; Jin et al.(2007), Ozturk et al.(2005), Kosaka et al.(2004). While children were in this study excluded, since by the AO criteria the patient should be 18 years or over to be included, really we had no children presenting during this period to our department with the suspicion or confirmation of orbital fractures. The youngest patient in our study was 20 years old and male, while the oldest 77, was also male. If one looks at Figure 31 (mixed sexes), the median of age at injury is 28; while in Figure 32 (males graph only) one notices that the median is 31, only a mild increase from 28. However the median of the female group (although only 4 patients) as seen in Figure 33, is 45.5, that is a significantly older age group.

Causes of injury

When referring to Figure 34, the highest column is that referring to 'sports' injury; 8 patients in all - most of which are males (7) with a median of 28 years. This is followed by the column indicating 'violent assault' which is exclusively dominated by males, and then from the late 2nd till the early 6th decades of life; a median of 24 years. Traffic accidents contributed to an equal ratio of males and females (1:1), with the only male being in his late 2nd decade, and the only female being in her late 6th decade of life. Falls have again a male predominance, tending then to an older age group, and accident at work/horse kick responsible by 1 male/1 female respectively. One can thus conclude from this study, that males tend to indulge more than females in sports activities, and are the ones involved in altercation accidents. This was also noted in Kontio et al.(2006).

Fractures

Orbital facial fracture management is germane to maxillofacial surgeons, oculoplastics, and facial plastic surgeons. There is a general consensus on orbital fracture treatment, that a primary reconstruction should be performed to re-establish the normal anatomy as precisely as possible; that is to try and restore the preoperative bony orbital volume and shape. Incorrectly restored orbital fractures can result in unpleasant and handicapping functional and cosmetic impairments, such as visual alteration, diplopia, and enophthalmos. The posterior orbital floor and medial wall are critical areas for fracture-induced globe displacement, where dislocation of relatively small bone fragments leads to significant globe retrusion, and where standard fracture repair remains a surgical challenge even for experienced surgeons, as reported in Hammer et al.(1999).

As already mentioned before, we had 23 patients in our study with a ratio of 19 males to 4 females. In the male population, there were 8:11 left-sided:right-sided orbital fractures, that is nearly 1.5 times more fractures on the right side (see Figure 35). The females show a 3:1 ratio of right-sided to left-sided fractures, although our female group is too small to comment about. Also, as seen in the pie chart in Figure 36, nearly half of our patients; 11, had a pure orbital floor fracture extending the entire orbital floor. Another 2 patients sustained fracture of the entire orbital floor when combined with different variations of medial wall fracture. We had mostly pure orbital floor fractures in our study group; 18 out of 23, with the remaining 5 being the extensive combined orbital floor/medial wall fractures and then only in the male gender. We had no pure medial wall fractures during this period. 1 patient had an accompanying simple zygomatic fracture and 6 patients had an accompanying displaced nasal fracture, 5 of which were reduced with the same anaesthesia as the orbital reconstruction, and one patient was treated conservatively for an undisplaced nasal fracture.

Orbital implants and screws

Considering the complex anatomic structure of the bony orbit and the limited surgical visualization of the defect, one would aim for a preformed implant which does not need any further modification. In an extensive analysis of the orbital form, Kamer et al.(2010) demonstrated significant interindividual size variability. In a CT-data analysis of the human floor of 279 uninjured Caucasian patients without traumatic deformation of the midface in Metzger et al.(2007), a computer software (VoXIM) was used to process the information. 12 variations of the orbital floor anatomy were found; 6 for the male and 6 for the female gender, each being divided into 3 left-sided and 3 right-sided variations and then subgrouped into small, medium and large. The variation in the depth of the orbital floor was small among the patients. Age has no influence on the shape of the orbital wall once the bony skeleton has matured. The volume and morphology of the orbital cavity are constant and steady after the age of 17 years. Regarding the shape of the orbit, there are sex variations as confirmed with this study using cephalometric measurements; for example males demonstrate a larger and higher posteromedial bulge than females do. Also, the medial anterior part of the inferior orbital rim and the width of the orbital cavity were smaller in females.

In a subsequent study by Metzger et al.(2006), unilateral orbital floor and medial wall fractures were artificially produced in 8 human cadaveric heads, some on the left-side and some on the right-side. Pre-bent titanium mesh fan plates from Synthes (0.4mm) moulded from aluminium templates (obtained from the previous study) were produced, and placed in both the injured orbit and in the uninjured contralateral orbit. CT scan evaluation post-surgery, showed that implants placed into uninjured orbits, approximated the native bony contour to within 1mm (0.68±0.63mm), and implants placed into injured orbits also showed symmetry to within 1 mm (0.93±0.82mm), even though the latter has innate limitations since the fractured orbit could be compared only with mirrored datasets from the contralateral uninjured orbit. In another study by Metzger et al.(2006), virtual reconstructions of the uninjured orbits were mirror-imaged to the defective side, and a subvolume file could be read by a CAD/CAM program. A stereolithographic machine polymerized a resin template, which was then adjusted to the correct side and a titanium mesh then adapted to the template by hand. After sterilization of the mesh, it was navigated into the patient, with an accuracy of reconstruction of approximately 1mm.

The preformed orbital implants used in our study patients were from Synthes, with a thickness of 0.4mm. There are 4 varieties in all; small- and large-sized, left- and right-sided (see Figure 18). All the screws used (with the exception of 1) were the customary 1.5mm diameter ones; only one patient required an emergency 1.8mm diameter screw to secure the fracture. Most of our implants needed to be cut intraoperatively and some (in 3 patients) also bent manually by the surgeon intraoperatively for an optimal fit. We required 19 large orbital plates and 4 small ones for our patients. 3 out of our 4 females required a large-sized plate, and this was for pure orbital floor fractures, as none of the females sustained the extensive combined orbital floor/medial wall fractures. Therefore the size of the implants used in our study were irrelevant of the gender involved or of the extension of the fracture in itself; in fact one patient (P20) with a combined extensive fracture, involving an entire orbital floor fracture and a medial wall fracture involving the middle and posterior two-thirds, required a small implant.

To keep the names of the surgeons treating the patients anonymous, they were given the initials

S1, S2 and S3 to denote the first, second and third surgeons respectively who operated our patients first in the list. The experience of our surgeons in treating the orbital fractures varied from 5 to 10 years, to more than 10 years, and the information is inputted in Table 1. As seen in Table 1, surgeon number 1 (S1) used both small and large prosthesis for the pure orbital floor fractures, irrelevant of the gender concerned, but always large ones for the combined orbital floor-medial wall fractures. S2 used a small implant for a female, and for a male sustaining a combined orbital floor/medial wall fracture, and a large implant for a male patient sustaining fracture to the orbital floor. S3 used only large implants, whatever the extension of the fracture and the gender involved.

Nearly half of our patients (10 patients) required 1 screw for the orbital reduction, while the rest of the patients required 2 or 3 screws. The locations varied from within the orbit, on the orbital rim and over the orbital rim, or a combination of all three. As seen in Table 2, S1 used screws inside the orbit or on the orbital rim, and all patients except one required only 1 screw in each fractured orbit. The only one requiring 2 screws, was the navigated patient. S2 used screws solely inside the orbit and then only 1 screw on each fractured orbit. S3 always used 2 or 3 screws per fractured orbit with a combination of screw locations varying from within the orbit, on the orbital rim and over the orbital rim. A forced duction test was always completed at the end of each operation by all consultants, to ensure unrestricted lateral, medial, upward and downward movements of the globe.

Days passed/days awaited for surgery

Not every blow-out fracture requires surgical management; defects more than ½ of the area of the orbital wall, restrictions in eyeball movement with definite evidence of orbital tissue entrapment on CT scan, persistent diplopia within 30° of primary gaze, and enophthalmos of ≥

2mm involving the injured eye are some indications; Jin et al.(2007). It is generally agreed that patients, generally children, with "white-eyed" blowout fractures, should be operated on immediately, within 24 to 48 hours. Older patients having restriction of ocular motility during forced duction test, suggesting entrapment of the extraocular muscles, require also an urgent reduction of the periorbital soft tissues and orbital floor reconstruction; Egbert et al.(2000), Burnstine(2002), Ben Simon et al.(2009).

Patients with persistent diplopia or with large fractures at risk for enophthalmos, should be operated on within 2 weeks as according to Hawes et al.(1983), Meyer et al.(1998), Burstine(2002, 2003), Ben Simon et al.(2009), Yano et al.(2009), Shin et al.(2011) while a minority of authors assume that better results can be achieved by a delayed strategy, which may prevent a useless surgical intervention especially in patients with minimal diplopia and good ocular motility restriction with intact periorbita; Putterman et al.(1974). In a series of 597 orbital floor fractures, Koutroupas et al.(1982), showed that in orbital floor fractures, the group treated conservatively had long-term sequelae in 34% of cases while the group which underwent surgery demonstrated sequelae in only 10% of cases. Late repair of orbital fractures results in less satisfactory enophthalmos correction because of fat atrophy and fibrosis in the orbit that begins soon after the trauma and progresses over several months.

If muscle entrapment is observed, it involves only limited portions of the muscle, leaving more than half of the muscle belly still intact as noted in Yano et al.(2009). It should be also said, that since muscle ischaemia becomes irreversible within hours, it may be nearly impossible to perform the operation after awaiting for definitive diagnosis as discussed in Grant et al.(2002), and Manson et al.(2002). Yano et al.(2010), believe that blood flow may not be completely absent in muscles entrapped in blowout fractures. Regions of ischaemic necrosis and unstable regions such as the zone of stasis in thermal trauma, as reported by Jackson(1953), may coexist around the fracture site; Smith et al.(1984). Since missing rectus recovery is time-consuming, early surgery and rehabilitation are indispensable for such fractures. Dal Canto et al.(2008), found no difference in the diplopia outcome when treating orbital blowout fractures within 2 weeks or between 3-4 weeks.

As seen in the bar chart in Figure 38, all our patients were operated between 1 and 15 days of injury (Mean; 5.09, and Median; 4), and within 1 to 7 days of presentation to us (Mean; 2.91, and Median; 3). P18 was the only patient who had the longest period of injury to operation (15 days); this was due to the fact that he was a soldier on a mission, and needed to be transferred to our department from another continent. The range of days awaited from admission to surgery was between 1 and 7 days, the latter being long due to the time required to stabilize the medical condition of P2 before surgery plus the need to concurrently stop Marcumar and heparinize the patient.

In-hospital stay

Figure 39 depicts the in-hospital stay for each of our patients. P2 has the longest in-hospital stay recorded and this is due to the critical pre-operative condition of the patient and the repeated episodes of epistaxis after the septorhinoplasty (as a correction for the nasal fracture) and not due to the orbital fracture. The median is 6 days and this includes the time awaited preoperatively for the swelling of the periorbital tissues to subside, and thus our decision to wait, and the availability of an emergency theatre plus the post-operative recovery period, until the patient was fit enough to be discharged home.

Operation time

Figure 40 represents the amount of time required to reduce the different fractures; the combined orbital floor-medial wall fractures did not take much longer to reduce when compared to the pure orbital floor fractures. The pure orbital floor fractures (represented in green) showed on average of 66.3 minutes to be reduced, while the complex orbital floor/medial wall fractures (represented in peach) required an average of 71.6 minutes, not a significant difference. Of course the time includes the intraoperative cone beam scan (except in P3 as already mentioned). In P22, intraoperative navigation was used besides an intra-operative cone beam scan. P2, P8, P14, and P19 had a co-existing nasal bone fracture which was reduced together with the orbital fracture. P23 had a co-existing ipsilateral zygomatic fracture and a nasal bone fracture, which were both reduced together within the same operation as the orbital fracture; a total of 100 minutes in all.

Visual acuity

Trauma resulting in orbital fractures, as well their accompanying treatment is often associated with ocular and periocular injuries as reported in Gellrich et al.(2008). These injuries and their accompanying functional sequelae, range from eyelid abrasions and lacerations to traumatic optic neuropathy and globe rupture causing blindness; Green et al.(1990). Several studies report widely varying results concerning the frequency and severity of ocular injury in cases of orbital fractures. Correlations between fracture type, visual acuity, mechanism of injury, and even intraocular pressure have been made to help predict orbital injuries. The most important question is the timing of an ophthalmological referral. There is an argument that early treatment of fractures results in improved cosmesis, however if there is a significant ocular injury, the eye must take precedence over the orbit. Al-Qurainy et al.(1991), propose a scoring sheet to help maxillofacial surgeons in the initial evaluation of a patient, and to assist with determining when a referral to an ophthalmologist should be made. The scoring is based on 4 factors: visual acuity, fracture type, ocular motility dysfunction, and amnesia. They found out that visual acuity was the best outcome predictor. Many patients do not have 20/20 vision to begin with and are being evaluated at the bedside with a near card. Presbyopic patients and patients with media opacities will have lower visual acuities that cannot be changed from baseline.

As for the visual acuity in our patients (refer to Table 3), we had an improvement in 12 (52%) on the injured side when recorded without glasses, 9 of which required no correction glasses. 8 (35%) of which 3 required no correction glasses, stayed the same. From the 3 remaining patients (13%) which had a worsening eyesight on the fractured side when assessed without glasses (P2, P4, P17), 2 reported the same vision as the preoperative examination on wearing the glasses, and one did not require any glasses, but also did not subjectively complain of any vision loss. Out of the 3 (13%) patients which had a worsening of the eyesight on the affected side with glasses (P6, P7, P8), one had a better vision without glasses when comparing the preoperative and 12-week follow-up visits (P6), and the other 2 (P7, P8) sustained the same vision when not wearing glasses. All 3 (P6, P7, P8) did not subjectively record any vision loss at the 3 months' follow-up visit. Out of our 23 patients, we had no severe vision loss or blindness, as otherwise reported in Villarreal et al.(2002). Of course, the pre-injury visual status of the patients was not known, but when referring to the Appendix, Table 12, the patients who had preoperatively a good vision, improved, while patients who had a poor vision, sustained a constant vision.

Even though we did not perform any surgical measures on the uninjured side, the follow-up visits showed that 9 patients (39%) improved their vision on the unoperated side, mostly by 1 or 2 levels up the Snellen chart; 2 of which (P5, P6) showed a worsening of the vision on wearing the glasses by a maximum of three levels down the Snellen chart, one patient (P4) had an improvement of the vision on wearing the glasses by three levels up the Snellen chart, and the remaining 6 did not require any glasses. P1 (4%), had a worsening of the vision on the uninjured side when not wearing glasses by one level down the Snellen chart, which could not be assessed with glasses as the patient never wore the contact lens on the unaffected side. P8 had a constant vision on the unaffected side without glasses, but a reduction of vision with the glasses at the 12 weeks' follow-up visit.

Ocular motility and double vision

The main causes of ocular motility disturbance and diplopia are extrusion or incarceration of intraorbital contents through the fracture site, resulting in oedema, haemorrhage, or even necrosis, and deviation of the eyeball especially vertical, by the fractured walls of the orbit. However even after proper surgical treatment, ocular motility disturbance and diplopia may persist in 10-30% of patients; Jin et al.(2007). The authors found that in pure blowout fractures of the orbit, patients who showed a swelling of the extraocular muscles on CT scan are more likely to develop residual diplopia (that is disturbing diplopia in the daily activities) after surgery.

Diplopia may result from deformity of the orbit; Converse et al.(1967), Iliff et al.(1999) causing positional changes of the muscles, adhesive impingement of the contents; Koornneef(1982) disturbing ocular excursion, and impairment of the contracting muscle; Iliff(1999) resulting from neurogenic or myogenic palsy, which is in itself caused by contusion and intramuscular haematoma. Since living organisms have the adaptability to compensate for functional defects, such problems especially diplopia may be ameliorated with time. The potential causes of persistent diplopia after surgery is well documented in the literature; Lyon et al.(1989). Timing of the surgical repair and orbital enlargement has been one of the advocated issues. The disruption and entrapment of the orbital connective tissue system in orbital blow-out fractures has been investigated by Koornreef(1982), and explained through a system of fine connective tissue ligaments that connect all the orbital soft tissue structures. Therefore an incarceration of any part of the system may produce tethering by restricting the range of excursion of an extraocular muscle; Harris et al.(2000), by reasoning that injuries to the fibrofatty-muscular complex may subsequently cause intrinsic fibrosis and contraction, and tethering globe movement despite complete surgical reduction of the herniated tissue.

There are other possible mechanisms for the development of persistent diplopia, such as damage to the extraocular muscles, to a motor nerve, both, or a combination of all the afore-mentioned processes. Lieger et al.(2010) conclude that even in patients with persistent postoperative restriction of the eye motility, in whom strabismus surgery becomes necessary, the correction of the orbital volume and globe position remains a basic prerequisite. The reported incidence of ocular injuries in patients with orbital fractures varies widely, ranging from 2.7 to 90%; al-Qurainy et al.(1991), Barry et al.(2008). In a retrospective study, Barry et al.(2008) found out that diplopia, and enophthalmos, occur more commonly in the orbital blowout fracture group than in the comminuted/simple orbitozygomatic complex fractures.

As one can notice in Chapter 3, Table 4, and Appendix Table 13, the ocular motility limitation was involving initially nearly half of our patients at the baseline investigation (43%), and then increased more at the 1-week examination (61%). This remained steady at the 4-weeks examination, and then decreased at the 12-week follow-up visit to 35%. Accordingly, the amount of patients recording double vision preoperatively (70%) counted for more than double the amount of patients who were symptomless. Postoperatively, after 1 week, this number had increased by a minimal amount (total of 74%), and at the last follow-up visit, the number halved from the initial level (35%); see Chapter 3, Table 5.

Even though various degrees of ocular motility disturbances or double visions were recorded in our patients, none of them required an emergency surgery to release any entrapment of the extraocular muscles. As mentioned before in Section 3.3, patient P7 had a surgical correction for squint concerning the uninjured (left) side in 2010; that is before the trauma. Since, the patient had always been complaining of minimal double vision when looking to the right. When referring to the Appendix Table 14, P7 has still double vision on abduction gaze at the 12-week follow-up visit; in this case abduction gaze meant when looking to the right as it was his right orbit that he had fractured. So, since this patient had also pre-traumatic double vision, it could be considered that we have really 16 patients who are free of double vision at the 12-weeks follow-up appointment, and therefore 7 (30%) of our patients having still double vision at the 3 months' follow-up visit, 5 (22%); P8, P9, P14, P15, P16, of which were disturbing in the daily activities. By definition this means 20° upgaze, 30° abduction and adduction gaze and 40° downgaze. In the routine ophthalmological follow-up visits, the patients were always recommended to perform ocular motility exercises, which resulted in significant improvement with time. Our study then concords to the double vision reported in other studies; Jin et al.(2007).

Globe position; in the vertical dimension

Figure 41 depicts the preoperative results compared with the results at 1 week, 4 weeks and 12-weeks in our 23 patients. Of course, at the 1-week follow-up investigation, one would expect more accompanying oedema and swelling of the operated orbit, resulting in the displacement of the globe on the fractured side. Besides there is also the human error involved in comparing the vertical levels of the two pupils in space, even when with the help of an exophthalmometer.

There were 6 patients (P1, P4, P16, P17, P20, and P21) which showed a straight vertical globe position throughout the examinations. 2 patients (P3 and P5) with a left-sided fracture had the right pupil 5 and 3mm respectively higher than the left side preoperatively and then reached both a straight level after the surgery; this could be explained with the sinking of the orbit on the fracture side; that is the left orbit was in hypoglobus. 3 patients (P11, 13 and P23) who sustained a left-sided orbital fracture, with a satisfactory fracture reduction, still had a higher right-sided orbit after surgery. 8 patients (P2, P7, P8, P10, P14, P15, P18, P19) which all sustained a right-sided fracture, had a higher right orbit at the 1-week visit, most probably due to the postoperative oedema, with eventual improvement of the differences by time. Some resulted in a straight pupillary level between the 2 orbits. P9's continuously more cranially-positioned orbit (also being the fractured side) is explained by the postoperative oedema and the volume reduction in the orbit (see the Appendix, Table 15), leaving the orbit in a relatively higher position. P6, with a fractured right orbit, has a persisting higher right orbit, due to the extensive volume reduction on the right side. The difference in the measurements noted in P12 is due to the fact that different examiners were involved in the recording of the readings.

As seen in Figure 41, there were no gender difference in the vertical globe positional changes. On average (see Figure 42), the preoperative and the 12-week follow-up vertical globe positions were both of 1 mm difference. Or to be more exact, a difference of 0.96 mm preoperatively and 1.04mm at 12 weeks, with an increase in the difference at the 1-week follow-up (due to the postoperative oedema) and a gradual descent at the 4-weeks' visit.

Globe position; in the sagittal dimension

Primary restorations of preinjury normal 3-dimensional bone contouring is the fundamental prerequisite for complete orbital cosmetic and functional recovery and integrity. Studies have demonstrated that the increase in orbital volume rather than changes in the periorbital fat seems to be linearly correlated with the development and the degree of late enophthalmos, as in Ramieri et al.(2000) and Lai et al.(1998). Between 1889 and 1943, Lang(1987), LaGrange(1918), and Pfeiffer(1943) established that enophthalmos could result after orbital blowout fractures secondary to increased orbital volume. Smith et al.(1984), explained the delayed enophthalmos with Volkmann's contracture, and Manson et al.(1986) suggested that enophthalmos after traumas follows a breakdown of the supporting mechanism of soft tissues surrounding eyeballs and orbits (intramuscular cone fat) and reported a correlation between various connecting tissues, intraorbital adipose tissues and enophthalmos through cadaver dissection. Millman et al.(1987), suggested a clinical algorithm related to CT classification to prevent enophthalmos, and Raskin et al.(1998), supplemented this and helped in predicting delayed enophthalmos by measuring changes of orbital volume with CT. Dolynchuck et al.(1996), showed that enophthalmos began with a volumetric orbital augmentation of 5% to 10%. Dislocation of the orbital wall fragments leads to orbital widening, resulting in an enlarged orbital volume. This also induces displacement and dysfunction of orbital soft tissue structures. Levine et al.(1998) pointed out the rounding of the inferior rectus muscle section on coronal CT scans of patients with orbital fracture, and Matic et al.(2007) found that the rounding of the inferior rectus muscle section on coronal CT scans could be a predictive factor of delayed enophthalmos in orbital floor fractures.

Kolk et al.(2007) found no significant changes in other parameters such as reduced orbital fat or eyeball volume in traumatized enophthalmic orbits, when compared with the controls;

measurement of total fat volume revealed no significant differences between normal and enophthalmic orbits. A coronal plane through the equator of the ocular globe divides the orbital cavity into anterior and posterior segments; defects anterior to this axis do not cause significant volume changes in the orbital volume, and are seen in minor to moderate trauma and can be easily repaired. The volume increase occurs medially at the posterior part of the orbital floor or at the transition to the medial wall and/or on the medial wall itself; improper reconstruction of this results in postoperative enophthalmos due to an increase in the posterior orbital height and width and thus change in the orbital shape from convex to concave.

Forbes et al.(1985) in their study of 42 orbits, noted that the mean difference in orbital volumes in the same person was 0.42 cm^3. Enophthalmos, as defined by Scolozzi et al.(2008), is a difference of greater than 2mm between the 2 corresponding eyes along an anteroposterior axis when measured with an exophthalmometer. Due to some authors, it is believed to be due to the extrusion of orbital contents into extra-anatomic sites, and not to fat necrosis or loss of orbital contents as reported in Wolfe(1997); the extraconic fat and the cicatrical fibrosis seem to have a lesser role as mentioned by Manson et al.(1986), and Whitehouse et al.(1994). On the other hand, atrophy of the intra-conic fat, destruction of the restraining ligaments, increase of orbital volume and remodelling of the soft tissues from a conical shape into a more round shape due to the enlargements is described by other authors in the literature as in Rinna et al.(2005). Recession of the eyeball is a rather frequent consequence, particularly when fractures of the medial wall occur. Several studies based on CT-2D and 3-D scans showed that the average orbital volume is about 28.7 ml in males and 21.6 ml in females as in Schucknecht et al.(1996), and that in post-traumatic enophthalmos its size increases by an average 12% compared to the contralateral. In fact, a recession of 1mm of the eyeball corresponds to a volume increase ranging in vitro, between 2.8% and 5.2% according to different authors as in Parsons et al.(1998), while a volume increase of 1cm^3 causes, in vivo, an enophthalmos of 0.4-0.8mm as discussed by Whitehouse et al.(1994), and Ramieri et al.(2000). Also one should not forget the intraindividual volume difference of 7 to 8% in normal subjects.

In a study by Migliori et al.(1984), 681 adults with an age range from 18 to 91 years, 327 of which were white and 354 black subjects who had uninjured/undiseased orbits or myopia not more than -7 diopters, Hertel exophthalmometer was used to measure the degree of protrusion. It was found that the mean normal protrusion for a white/black male was 16.5mm/18.5mm respectively, and for a white/black female was 15.4mm/17.8mm. No individual had more than 2mm of asymmetry between the eyes. Post-traumatic enophthalmos is a complex orbital deformity resulting from an injury disrupting orbital bone and ligament support, allowing displacement and a change in shape of the orbital soft-tissue contents; Manson et al. (1987). In our study patients, the sagittal globe position was measured with the Naugle exophthalmometer; according to Gellrich et al.(2002), and Schmitz et al.(1999), preoperative clinical assessment of posttraumatic enophthalmos might be misleading when referring to the Hertel scale because it does not address possibly dislocated periorbital bony structures.

As one can see in Figure 43, the sagittal level of both orbits was on the same level (that is a zero exophthalmometric difference) in 11 patients preoperatively with the rest having a range varying from +5 to -5 difference in measurements. 8 patients had a zero exophthalmometric difference at the 1-week, 4-weeks and 12-weeks follow-up postoperative visits with the rest ranging from +6 to -5 in the 1-week visit, +4 to -7 in the 4-week visit, and +3 to -3 in the 12-week visit. In the last visit, where the posttraumatic/postoperative oedema should be the least, there were the least differences in the sagittal levels across the 2 orbits within the 23 patients, when compared to the other visits. Of course, one has to bear in mind, that the preoperative exophthalmometric findings are to a more or less extent fraud by the post-traumatic swelling preoperatively, and at the 1-week postoperative findings they are affected by the post-operative oedema, since one is here dealing also with the soft-tissue component.

When analyzing the raw data in Table 16, and comparing the preoperative to the 12 week visit;

•3 patients (P1, P17, P19) who had an initial enophthalmos, had a zero difference between the 2 orbits at the 12-week follow-up visit (therefore no enophthalmos)

•3 patients (P3, P11, P14) were initially enophthalmic and remained so

•1 patient (P20) was exophthalmic and stayed so

•3 patients (P2, P15, P18) with an initial exophthalmos, had a resultant zero difference

•7 patients (P7, P8, P10, P13, P16, P21, P23) who had initially no difference, resulted in enophthalmos

•2 patients (P4, P12) who had initially no difference, resulted in exophthalmos

•2 patients (P5, P22) with exophthalmos resulted in enophthalmos

•2 patients (P6, P9) who had initially no difference, sustained the same level

However, considering that enophthalmos is defined as the difference between the 2 orbits along an anteroposterior axis of more than 2mm when measured with an exophthalmometer, our 12-week follow-up visit show that only 3 patients show a difference of more than 2mm; +3 in P4 (that is the fractured orbit is presumably overcorrected by 3mm as compared to the uninjured orbit), -3 in P11 and -3 in P13; that is both P11 and P13 are enophthalmic. Thus in all we have 1 overcorrection and 2 enophthalmic patients. On looking at Table 14, P4 and P13 have no double vision recorded in the 12-week follow-up visit, P11 has still double vision, but not disturbing in the daily activities.

When looking at Figure 44, where the average exophthalmometric differences are represented, the preoperative examinations show an average value of -0.174mm, and the 12-week follow-up examination of -0.652mm. That is on average the fractured orbits became slightly more enophthalmic by that value at the 3 months' visit. Of noteworthy, is that at the 1-week examination, the average value of +0.826 shows that the operated-on orbits and therefore manipulated globes showed a normal reaction of postoperative oedema and thus temporarily an exophthalmos in comparison to the uninjured orbit. But since values of 2mm difference as already discussed are 'normal', we can conclude this subject by stating that on average we had no enophthalmos recorded in our patients.

Globe position; in the horizontal dimension

Figure 45 shows the ranges of interpupillary distances recorded in each patient at separate occasions. The higher range of interpupillary measurements as for example in P2 and P12 comes from the fact that the patient had different examiners on different visits. Of course, the post-traumatic as well as the post-operative oedema may cause some shifts in the distances recorded. But in general, the ranges did not vary a lot.

Sensory disturbances to the maxillary nerve on the injured side

As one can see in Table 6, and in more detail in the Appendix, Table 18;

•6 patients (P7, 10, 13, 14, 20, 21) reported normal sensation preoperatively and at 12 weeks postoperatively

•5 patients (P3, P5, P12, P15, and P19) had a preoperative normal sensation and developed hypoaesthesia postoperatively, still present at 12-weeks. The disparity of P12, being recorded as hypoaesthesia only in the 12-week examination, is due to different examiners involved in the case; one for the first 3 examinations, and another for the last examination; a 'nearly normal sensation' being recorded as 'normal sensation' in the first 3 examinations

•2 patients (P2 and P16) had a normal sensation preoperatively, and resulted in paraesthesia at 12-weeks

•4 patients (P1, P6, P8 and P23) had a preoperative hypoaesthesia which stayed at 12 weeks

•5 patients (P9, P11, P17, P18, P22) had a preoperative hypoaesthesia, and paraesthesia at 12 weeks

•1 patient (P4) recorded preoperatively hyperaesthesia and at 12-weeks a hypoaesthesia.

As noted in Table 6, 13 patients (more than half) had a normal sensation preoperatively, but only 6 (26%) still reported normal sensation at the 12 weeks' visit. While 10 (44%) recorded hypoaesthesia postoperatively when compared to the preoperative values 9 (39%), a significant increasing number of patients; 7 (30%) recorded paraesthesia at the 12 weeks' follow-up appointment when compared to the preoperative state. This accounts for a total of 74% sensory loss in all; however one must also say that these patients continually reported improvements in their sensations at every visit. Also to report is that the last visit was only 3 months postoperative. To compare is the study by Gierloff et al.(2012), where 18% of patients still had hypoaesthesia of the infraorbital nerve 6 months after surgery, and in Wu et al.(2011) where 3 out of 59 patients still suffered from sensory disturbances more than 1 year after treatment.

Medications required

The following list gives details for the requirements of patients in Table 7 for extra medications:

•P2 was on i.v. Augmentin® 2.2 gr. three times daily during the in-hospital stay as a prophylaxis against sinus infection

•P8 was started on i.v. Augmentin® 2.2 gr. three times daily as ordered from the ENT department due to a concurrent laceration of the nose including exposure of the nasal cartilage.

The patient was also having Gentamycin & Vigamox eye drops in the operated right eye during the hospital in-stay period, as ordered by the ophthalamic department due to the development of conjunctivitis postoperatively. On discharge, she was still on the antibiotics and since the 1-week examination postoperatively happened to be on the discharge date, then it was also included in the 1-week examination

•P11 was given additionally a 5 day course of i.v. Unacid® 1.5 gr. three times daily due to periorbital emphysema on the ipsilateral side of the fracture

•P13 was given i.v. Unacid® 3 gr. three times daily on admission due to intraorbital emphysema

•P15 was prescribed Floxal® antibiotic eyedrops (besides Corneregel® eyedrops) on admission to the eye on the unfractured side due to contusion

•P21 was prescribed i.v. Unacid® 3gr. three times daily during the in-hospital stay due to concurrent intraorbital emphysema and corneal erosion on the fracture side.

The eventual reduced requirements of the Ibuprofen throughout the consequent visits in our patients, is positive. The only 2 patients which still required this medication for longer use were P19 and P22. The strange requirement of Ibuprofen in P19 only after 12 weeks, is explained by the fact that the patient was suffering from post-traumatic headaches, which still persisted weeks after discharge. At the 4-week postoperative examination, she reported that Metamizole po had been prescribed for her. We had instructed her at this visit to change to the Ibuprofen medication together with the proton-pump inhibitor Nexium as we believe that this has a better effect. Thus in the 3-monthly visit, she was still on Ibuprofen. P22 was also complaining of headaches in addition to facial pain in the region of the maxillary nerve on the operated side and therefore the use of Ibuprofen. After 12 weeks, the medication was taken on a prn (as required) basis.

As a summary, besides the usual intraoperative intravenous single-shot antibiotic, which is a regularity in our department, 6 patients required an additional course of i.v. antibiotics, one of which, P8, required additionally antibiotic eye drops. 2 patients required Ibuprofen for a longer period of time than usual.

Associated ocular/periorbital injuries

Mellema et al.(2009) published a retrospective study of 126 cases of radiographically proven orbital fractures in association with their ocular injuries. Ocular injuries were categorized into inconsequential, moderate and severe. Patients were separated into symptomatic and asymptomatic groups, as based on questioning about specific ophthalmic symptoms. In contrast to visual acuity, it was the ophthalmic symptoms obtained at the initial presentation which were a very sensitive predictor of severe ocular injury. It has been long maintained that the orbit is designed such that the walls will absorb energy and fracture to protect the globe in cases of trauma. Recent studies have concluded that the orbital floor, in particular requires significant less energy to fracture than does the globe to rupture; Green et al.(1990). However the forces are still great enough to cause significant ocular injuries directly or indirectly (as for example resulting from bony fragments). Visual acuity is not perfectly sensitive for picking up severe injuries as in al-Qurainy et al.'s(1991) data set, since many patients in a trauma setting have lost or broken their glasses, limiting the accuracy of visual acuity testing. Patients with co-existing low vision will do poorly on visual acuity testing, presbyopic patients evaluated at the bedside may do poorly on evaluation with a near card, and given the extent of their trauma, some patients may be intubated or sedated, rendering them incapable of providing a visual acuity. Also, severe injuries may coincide with good visual acuity but have other symptoms such as pain, photopsias, floaters, diplopia, or scotomata.

In Read et al.(1998), 87 patients sustaining different orbital fractures were found to have various associated ocular/perioribital injuries. Traumatic optic neuropathy is a documented diagnosis occurring in 39% of orbital wall fractures in the United Kingdom according to Lee et al.(2010). It is a rare cause of severe permanent visual impairment following injury. It can be caused by sharp trauma (direct injury) damaging the optic nerve directly, but classically results from damage from transmitted forces following a concussive blow to the head or orbit (indirect injury). It is important to evaluate each patient separately as double vision in upgaze will be more bothering to athletes for instance than to other patients who have more of a sedentary life. Also, Ben Simon et al.(2005), reported 4 cases (3 males and 1 female) of orbital cellulitis developing as a complication of an orbital blowout fracture and the consequent development of sinusitis.

All the patients in our study had some accompanying orbital/periorbital injuries, most of which were multiple (see Figure 46 and Appendix Table19). In patients which suffered from bilateral injuries, the ipsilateral side was mostly more severely damaged than the contralateral side. The worst injuries sustained by our patients, are as follows:

•Serious; P18, which sustained traumatic retinal tears at peripheral position 2 ò clock and middle peripheral position 2:30 ò clock on the traumatized side. Laser treatment was performed the day following admission under local analgesia by the ophthalmic department, while the reposition of the orbital fracture was done by our department later on under general anaesthesia

•Moderate; P10 with ipsilateral ocular hypotension, whereby the ocular tension was regularly controlled by the ophthalamic department in our hospital

All the rest were mild; including

•P12, with bilateral contusion of the eyeballs

•8 patients (P7, P11, P13, P14, P15, P20, P22, P23) with contusion of the eye on the injured side, with P15 required a topical antibiotic eye drop (see 'medications required')

•P21, due to massive orbital emphysema and corneal erosion on the ipsilateral side of the fracture, where i.v. Unacid® was administered (see 'medications required')

•6 patients (P5, P13, P14, P17, P20, P21) with ipsilateral intraorbital emphysema, with P13 and P21 both being prescribed i.v. antibiotics (see 'medications required')

•3 patients (P5, P7, P11) with ipsilateral lid emphysema; P11 was prescribed i.v. antibiotics (see 'medications required')

We had in all 1 (4.35%) patient (P18) who sustained a serious event in a pure orbital floor fracture, and 1 (4.35%) patient (P10) sustaining a moderate event in a combined orbital floor-medial wall fracture. The rest were all mild injuries as according to Read et al.(1998). To note is that our patients all had an uneventful recovery.

<u>Accompanying injuries (except orbital and periorbital)</u>

Hwang et al.(2009), published a retrospective study of 391 patients with orbital fractures and their co-existing injuries. Head and neck injuries were the most common isolated injuries associated with orbital bone fractures, and these included brain injuries with cranial blood vessel disruption and altered levels of consciousness, cervical spine injuries, and optic nerve injuries. The most common soft-tissue injury associated with orbital bone fractures was injury of the head and neck (87.4%). This finding highlights the frequency with which the head and neck are involved in orbital bone fractures. Skull fractures were the most common fractures associated with orbital bone fractures, in addition to facial bone fractures. The high incidence of associated injuries (30.4%) emphasizes the importance of a complete and thorough assessment in patients who sustain facial trauma.

As seen in Figure 47, Appendix Table 20, only 6 patients (P4, P5, P7, P9, P16, P17) out of the 23 did not sustain any such accompanying injuries. The rest - 17 in all, sustained single/multiple injuries, the most common being ipsilateral lacerations to the face/forehead area (6 patients) which needed suturing, ipsilateral abrasions to the face/forehead/neck area (6 patients) and nasal fractures which needed reduction (5 patients); the latter being performed with the main surgery for orbital reduction. In 1 patient, the nasal fracture was not displaced and therefore treated conservatively. The 5th cervical vertebral fracture in one patient (P22), did not require any treatment - and this was decided after an MRI (magnetic resonance imaging) together with a neurosurgical consultation. The only concomitant ipsilateral zygomatic fracture was treated surgically together with the orbital reduction. Out of the 3 patients sustaining brain concussion, one developed post-traumatic headaches (P22) and later on was diagnosed with chronic pain syndrome, requiring an in-hospital stay for a month in a pain clinic.

Out of 2 patients with an ipsilateral haematoma on the face, one required an incision and drainage at the 1-week follow-up examination which was performed on an out-patient basis. The other patient was treated conservatively. While there was an enamel-dentine crown fracture to the left upper central incisor on one patient, another 2 patients sustained a single tooth concussion each on the upper incisors, with a resulting tooth mobility of Grade 1. A separate patient developed an unresponsive central upper incisor on the ipsilateral side of the orbital fracture, which was subjectively related to the trauma. A preoperative orthopaedic consultation on a patient (P2) with trauma-induced contralateral knee pain diagnosed knee joint arthrosis secondary to trauma, on the background of previous joint infection on the same knee 20 years before; symptomatic pain relief and physiotherapy were recommended.

So, in all we had 17 (73.9%) patients who sustained other concurrent injuries, mostly multiple, due to different reasons, besides the orbital fractures.

Postoperative complications/posttraumatic sequelae and their treatment

P2 required a postoperative night spent at ITU (Intensive Therapy Unit) for monitoring due to an ASA (American Association of Anaesthesiologists) Class III and a concomitant sleep apnoea syndrome. The patient also suffered from repeated episodes of epistaxis postoperatively following septorhinoplasty (performed by the ENT surgeons) for treating a concomitant nasal fracture. The patient was on anticoagulants due to a medical history of atrial fibrillation and pulmonary embolism, requiring a longer in-hospital stay. A postoperative chemosis on the ipsilateral eye of the fracture, required repeated ophthalmic consultations for pressure control.

P4 complained of dry eye symptoms on the fractured side at the 4-weeks follow-up appointment. He was prescribed lubricating eye drops from the ophthalmic department, with improvement.

P5 collapsed on the 29th postoperative day, from which he developed a parieto-occipital lacerated wound and a brain concussion. The patient presented to another hospital, where the wound was surgically closed, and a CT brain organized to investigate anisocoria. The patient was observed as an in-patient for 2 days, during which the anisocoria spontaneously resolved.

P8 developed a postoperative conjunctivitis in the eye of the traumatized side of the fracture, and required antibiotics (see above). 5 months postoperatively the orbital titanium mesh was removed, due to persisting motility disturbances and diplopia; a postoperative examination 2 weeks after, however showed an even more deterioration in the double vision. The patient developed a postoperative ectropion of the lower lid on the operated side, a correction of which was being contemplated by the ophthalmic surgeons in our hospital. Aitasalo et al.(2001), used the bioactive glass S53P4 to treat patients with orbital floor blowout fractures without using any screw fixations; only 1 patient required implant removal 3 months after operation due to diplopia; and this is explained by the fact that the implant was not of the correct size. In the study of Scolozzi et al.(2009) the same 3D preformed implants were used as ours, and one patient out of 10 required removal of the implant due to disturbing double vision (same as in our case, but we had a total of 23 patients).

P19 developed persistent post-traumatic headaches, and an MRI brain organized by the neurologists was reported as normal. 8 months posttrauma, the headaches improved.

P22 developed 'chronic pain syndrome'. During the in-hospital stay, the patient was on full doses of Ibuprofen and the prn medication. Besides, sleeping medication and additional ones were requested for persisting headaches. Due to increasing pain and paraesthesia in the region of the maxillary division of the trigeminal nerve on the ipsilateral side, together with persisting headaches still in the 4th postoperative week, a neurological consultation was organized which led to an MRI brain (reported as normal). The patient was started on Carbamezapine titrated to higher dosages, and with Citalopram, but due to a deterioration in the pain, she was referred to the pain clinic in our hospital. This led to a further referral of the patient to an in-patient rehabilitation clinic, where she was kept for a month in-patient for treatment. Although an improvement was noted, she still remained symptomatic.

P23 was diagnosed with 'recurring hemicrania of unknown origin'; at the 12-week examination, the patient complained of post-traumatic headaches especially on weather changes. A neurological consultation resulted in an EEG (electroencephalogram) which was reported as normal. The recommendation was to avoid triggering factors and to be started on Carbamezapine if the symptoms persist (the patient had a history of sensory loss in both thighs and feet on wearing some new combat shoes approximately 1 year before the injury; the neurological findings at that time ruled out any polyneuropathy).

The most important of all the above-mentioned complications for us as the maxillofacial surgeons, is the complication of P8; that is our decision to remove the orbital implant, 5 months after the initial surgery. Interesting to note too, is that this patient was the only one to have a postoperative conjunctivitis out of all the 23 patients in our study. She was also the one which developed ectropion; a total complication rate of 4.35% from our patients, as compared to for example Ozturk et al.(2005) which had ectropion developing in 3 out of 38 patients (7.9%). Overall, we had 7 patients (30.4%) which sustained postoperative complications, but only 1 of them, in P8, related to the orbital implant. The rest were mostly posttraumatic sequelae.

Volumetric measurements of the orbits

Orbital development is very rapid soon after birth. From the first few months of life to the early teens, there is an orbital volume increase almost linearly from 13-15 cm^3 to 24-26 cm^3 according to Acer et al.(2009). It remains fairly constant beyond approximately 15 to 17 years of age; Bentley et al.(2002). Not only changes in the limited volume of tissue in the orbit but also changes in the shape and size of the orbit cause exophthalmos and enophthalmos; Bite et al.(1984). The water filling method for assessment of the orbital volume is a highly accurate, and highly specialized method for determining volume, but it is not applied in routine practice.

This relies upon the Archimedean principle of fluid displacement, which states that an object displaces its own volume when immersed in water. There are a lot of studies using the water filling method and stereological measurement for volume estimation in different organs. They use both water displacement and magnetic resonance imaging (MRI) or computed tomographic slices (CT). A good correlation exists, and there was no statistically significant difference between the techniques; Akbas et al.(2004). Acer et al.(2009), performed a study on 9 adult dry skulls, where the orbital volume of the skull was determined by filling the orbits with water using ordinary balloons, and subsequently measuring the quantity of water using a cylindrical measuring glass. There was also no statistically significant difference between the right and left sides of the orbital volume. The mean orbital volume measured here is smaller than those reported in other studies, and according to the authors this is due to major differences in the measuring techniques used, that is by using CT scans rather than MRI's. There have been a lot of debates about the laterality of orbital volume. Some investigators argue that there is no real difference in orbital volume between the right and the left orbits in individuals; Futura(2001), and Mc Gurk et al.(1993). However then, other authors argue that the volume between the right and left orbits may differ by approximately 7% to 8%; Ploder et al.(2002).

Kwon et al.(2009), measured the preoperative and postoperative orbital volumes of 24 cases of unilateral pure blowout fractures by reading scans from two different 3D software programs (Vitrea, Minnesota; and Dextroscope, NJ). Difficulties in measuring the exact orbital volumes, include the bony orbital cavities having the shape of a quadrilateral pyramid as according to Cooper et al.(1985), the bony defects, which can introduce measurement errors (ex. orbital apex, inferior- and superior orbital fissures, lacrimal sac, orbital base, and missing the anterior wall), interoperator/intraoperator variability, and usage of different measurement techniques/ software programs.

An observational study by Lieger et al.(2012) was carried out on 27 patients treated by using a low-profile titanium mesh. Selective criteria for this prospective study included age greater than 18 presenting with a unilateral orbital blow-out or blow-in fracture of $\geq 2.0\ cm^2$. Surgery was performed within 2 weeks of trauma and using intraoperatively a Medartis (Basel, Switzerland) titanium mesh with a profile height of 0.25mm along the border and 0.2mm in the mesh area. In the CT volume analysis, the orbit was in the range of $\pm\ 2cm^3$. In 2 patients however the plate was buckled in the posterior edge region and was then replaced through a second procedure.

As already mentioned, the computer software program which we have used to measure our pre-, post- and contralateral orbital volumes, is iPlan Cranial 3.0 from BRAINLAB. As noted from Figure 52, the results of the preoperative minus the postoperative orbital volumes was plotted for each patient (for raw data refer to Appendix Table 21). A positive result of the preoperative (Pr.) minus the postoperative (Po.) volumetric measurements, indicates that the postoperative reconstructed orbit is smaller, while a negative value would show otherwise. The values of Pr. minus Po. in our 23 patients were positive as shown in Figure 52, and this indicates a successful reconstruction of the orbital volume for every patient.

In Figure 53, the differences between the postoperative and the contralateral volumes for each patient were plotted. A negative result indicates that the reconstructed orbit is smaller than the uninjured contralateral side, and a positive value the opposite. By looking at the graph, one notes that there are 17 negative values and 6 positive ones. Also, the black line depicts the average value; $-0.614cm^3$; showing that on average the 23 patients have a reconstructed postoperative orbit which has a smaller volume than the contralateral uninjured side. There is again no difference between males and females. The average orbital volume of the preoperative fractured orbits is 31.497cm^3. In Figure 54, the line chart showing the contralateral volume measurements for each patient has been plotted, and in Figure 55, the postoperative volume measurements for each patient was plotted. The average value for the contralateral volumes is of 30.002cm^3 as opposed to the postoperative volumes which have an average of 29.389cm^3. Therefore the average volume reduction on the fractured side is 2.108cm^3, and the reconstructed orbits are on average 0.613 cm^3 smaller than the uninjured orbits. Now, according to the literature, an average orbital volume difference of up to 1.95cm^3 is normal in healthy, uninjured individuals; Lieger et al.(2012).

Ploder et al.(2002) argue that measurement from 3D CT scanning (rather than in 2D) for evaluation of orbital fractures has 2 major limitations; volume averaging and threshold artefacts reduce the ability of 3D images to show small bony structures, and the contralateral orbit when used as a control is not ideal since the volume difference between the 2 orbits is normally between 7 and 8%. Thus the validity of this method is questionable. However the 2D measurement of the 38 patients treated with isolated orbital floor blowout fractures in Ploder et al.'s study, had CT scans performed with slice thicknesses varying from 2 to 3mm. Also, in the paper published by Schmelzeisen et al.(2004), the average preoperative volumes reported were 30.68 ± 3.39 cm^3, the average reconstructed postoperative orbits 26.72 ± 3.22 cm^3, and the contralateral uninjured orbits had an average volume of 26.13cm^3 ± 2.7 cm; all three values being slightly smaller than in our patients, but with the same goal being achieved.

Surface areas of the defects

Usually the operative indications of an orbital floor fracture results from a personal in-house algorithm, which includes a wise mix of nonstandardized clinical/radiological findings, including diplopia, enophthalmos, and type (linear or comminuted) and size of the fracture.

The defect area often is the main independent criterium influencing the choice of treatment for surgery and even the choice of the specific implant material used. According to Cole et al.(2007), lesions larger than 1 cm^2 of the orbital floor, and according to Burnstine(2002), lesions more than 50% of the entire orbital floor area are critical factors leading to the decision for surgery. However the distinction between nonsignificant and significant radiologic displacement of the fracture is still blurry as no real clear cutoff measurements have yet been defined in the literature. In Kolk et al.(2007), the surface defect of the orbital floor/medial wall fractures as measured by a preoperative MRI scan, showed a minimum preoperative defect length or width of 2.5cm; range 2.5 to 4.7 cm; mean 3.8cm, and a corresponding defect area of at least 3.5cm^2; range 3.5 to 6.4cm^2; mean 4.5cm^2.

Schouman et al.(2012) tested the reliability and accuracy of computed CT Scan in predicting treatment decisions for pure orbital floor blowout fractures. The retrospective study showed that displacement of the inferior rectus muscle strongly affects the treatment decision in pure blowout fractures of the orbital floor for grades 1, 3 and 4 MSS, where MSS stands for muscular subscore. The relatively larger fracture areas of the orbital floor (1.8 cm^2 in the conservative group versus 2.5 cm^2 in the surgical group) corresponded to quite small percentages of the fractured orbital floor (28.1% vs. 37.6% respectively), with the highest ratio being 56%, as compared to the study in Cole et al.(2007), and Burnstine(2002). This compared good to the results of Ploder et al.(2002) who reported that fracture areas were 0.44 to 5.77 cm^2, corresponding to a range of 27.7% to 62.9% of the orbital floor. Therefore the previously-mentioned cutoffs in the literature of 1cm^2/50% of the orbital floor is according to these studies not equivalent.

The surface area of the defects in our patients was also calculated by means of the iPlan Cranial

3.0 computer software and the line charts represented in Figure 58 and 59. The area of the orbital floor fracture was obtained by multiplying the largest coronal diameter by the largest sagittal diameter on CT scan, while the area of the medial wall fracture was obtained by multiplying the largest axial diameter by the largest sagittal diameter on CT scan. Thus;

1. Maximum orbital floor fracture area = Largest coronal diameter x largest sagittal diameter
2. Maximum medial wall fracture area = Largest axial diameter x largest sagittal diameter

Note that there are only 5 patients with combined orbital floor/medial wall fractures and all are male. The maximum surface areas of the pure orbital floor fractures range from 0.54cm^2 in P4 to 7.92 cm^2 in P11 with an average of 3.01 cm^2. The values for the maximum surface areas of the mesial wall fractures(in the context of combined orbital floor/medial wall fractures) range from 0.98 cm^2 to 1.57 cm^2 with an average of 1.21 cm^2; a smaller value than that for the orbital floor fractures. The maximum surface areas of our orbital floor/combined orbital floor-medial wall fractures are smaller than that quoted in Kolk et al.(2007), but the maximum surface areas of our pure orbital floor fractures are bigger than that in Ploder et al.(2002).

5 Summary

As a conclusion, we had a strong male predominance of injured patients of 19 males: 4 females, nearly 5:1 as noted in other studies. The median age of injury of our patients, both genders together is 28, just males is 31, while that for females is 45.5 years. The main causes of injuries were sports (almost exclusive in males), and altercation accidents (only males), from which one can conclude that males tend to indulge more than females in sports activities and in assaults. There were 1.5 times more orbital fractures on the right side in males than the left side and in females a ratio of 3 right-sided: 1 left-sided fractures, although the female numbers is relatively small to comment. Nearly half of our patients had a pure orbital floor fracture extending the whole floor. The rest were a mixture of orbital floor +/- medial wall fractures, but 5 out of the 23 patients (21.7%), had extensive orbital floor-medial wall fractures and were exclusively male. We had no pure medial wall fractures. 1 patient had an accompanying simple zygomatic fracture and 6 patients an accompanying nasal fracture, 5 of which required surgical reduction and 1 was treated conservatively.

The 3D preformed orbital plates from Synthes with a profile of 0.4mm were used in our study, and the screws were almost exclusively (except 1) of the 1.5mm diameter. 3 different surgeons were involved and the screws were placed either within the orbit, on the rim, over the rim or a combination of these 3. The screw numbers varied between 1 and 3 in each orbit. The range of days from injury to operation was between 1 and 15 with a median of 4 days, and the range of days from admission to surgery was 1 to 7 with a median of 3 days. The median in-hospital stay was of 6 days, with an average operation time for the pure orbital floor fractures of 66.3 minutes and for the combined orbital floor-medial wall fractures of 71.6 minutes; not a significant difference. Of course in this time frame, a cone beam CT scan was performed, with 5 patients requiring the reduction of a nasal fracture, one of which an additional zygomatic fracture. In our 23 patients, we had no resulting severe vision loss; on the whole, the patients who had preoperatively a good vision, improved, while patients who had a poor vision, stayed the same. The ocular motility limitation decreased from 43% of the patients in the preoperative level to 35% at the 12-week follow-up visit. Accordingly, we had 70% of our patients preoperatively suffering from double vision, and at the last follow-up visit, the number halved to 35%. Actually we have 7 patients (30%) suffering from double vision when correcting for P7, 5 (21.7%) of which are disturbing in their daily activities. On average the preoperative and the 12-week follow-up vertical globe positions were both of 1 mm difference, and the exophthalmometer readings show on average no enophthalmos recorded in our patients.

13 patients had a normal sensation preoperatively, and 6 (26%) reported normal sensation at the last visit, 10 (44%) recorded hypoaesthesia and 7 (30%) paraesthesia; thus a sensory loss of 74% in our patients. Some patients required a course of antibiotics i.v./ eye drops due to emphysema/conjunctivitis. A patient had an associated severe ipsilateral ocular injury; traumatic retinal tears at peripheral position 2 ò clock and middle peripheral position 2:30 ò clock. We had 17 (73.9%) patients who sustained other concurrent injuries, mostly multiple. 7 patients (30.4%) sustained postoperative complications, 1 of them, P8 (4.35%) being related to the orbital implant, requiring its removal. The same patient also developed ectropion. The average volume reductions on the fractured sides are 2.108 cm^3, and the reconstructed orbits are on average 0.613 cm^3 smaller than the uninjured orbits. The maximum surface areas of the pure floor fractures range from 0.54 cm^2 to 7.92 cm^2, an average of 3.01 cm^2. The values for the maximum surface areas of the medial wall fractures in the combined fracture patients, range from 0.98 cm^2 to 1.57 cm^2; an average of 1.21 cm^2, which is a smaller value than that for the orbital floor fractures. Thus we can conclude from this study that the preformed titanium implants from Synthes has produced a very optimum reconstruction of the traumatic orbital floor/orbital floor-medial wall fractures with relatively very small complication rates.

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Appendix

ulm university universität
uulm Ethikkommission

Universität Ulm • Ethikkommission • 89069 Ulm

Herrn
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14. JAN. 2011

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Unser Zeichen	Durchwahl	Datum
359/10 – UBB/bal	22050	12.01.2011

n/an AO Clinical Investigation and Documentation, CH-7270 Davos, per Telefax: 0041-44-200-2445

Antrag Nr. 359/10 — Eine prospektive Multizenterstudie zur Untersuchung der Genauigkeit der Rekonstruktion von Frakturen der medialen Orbitawand und / oder der Orbitabodens. Vergleich zwischen präoperativ vorgeformten und nicht vorgeformten Orbita-Implantaten
Studien-Nummer: Orbita 3

Sehr geehrter Herr Kollege Schramm,

der o.g. Antrag liegt uns mit der zustimmenden Bewertung der Ethikkommission der Medizinischen Hochschule Hannover vom 17.08.2010 vor. Die Ethikkommission der Universität Ulm anerkennt grundsätzlich Voten anderer öffentlich-rechtlicher Ethikkommissionen.

Auf der Grundlage folgender Dokumente

- Begleitschreiben der AO Foundation vom 05.12.2010
- Ethikantrag (ohne Datum)
- Studienprotokoll, CIP Orbita 3, Version 1.0 vom 30.04.2010
- Patienteninformation "Investigator", v1.0, Version vom 10.11.2010
- Patienteninformation "Patient", v1.0, Version vom 10.11.2010
- Konformitätserklärung der Synthes GmbH vom 19.03.2010
- Technique Guide MatrixORBITAL
- Technique Guide SynPOR Porous Polyethylene Implants
- Technique Guide Titanium Orbital Plates
- CRF-Bögen: Orbita 3 CRF Baseline Investigator, v1.2 vom 11.10.2010
- Orbita 3 CRF 1 Week Investigator, v1.2 vom 14.10.2010
- Orbita 3 CRF 4 Weeks Investigator, v1.2 vom 14.10.2010
- Orbita 3 CRF 12 Weeks Investigator v1.2 vom 14.10.2010
- Zustimmende Bewertung der Ethikkommission der Medizinischen Hochschule Hannover vom 17.08.2010

haben wir den lokalen Aspekt der beantragten Studie in der Sitzung am 10.01.2011 überprüft.

Es bestehen keine begründbaren Bedenken gegen die Durchführung der Studie.

Die Ethikkommission der Universität Ulm schließt sich der zustimmenden Bewertung der Ethikkommission der Medizinischen Hochschule Hannover vom 17.08.2010 an.

Diese Bewertung ergeht nach § 15 der gültigen Berufsordnung der Landesärztekammer Baden-Württemberg.

2

Die ärztliche und juristische Verantwortung verbleibt uneingeschränkt beim Projektleiter und seinen Mitarbeitern.

Wir bitten um eine zeitnahe Nachricht über den Abschluss der Studie und einen Bericht mit der Mitteilung der bei der Studie gewonnenen Erkenntnisse.

Für die Ethikkommission der Universität Ulm

[redacted]

Prof. Dr. med. U.B. Brückner
Vorsitzender

Copy of the Ethics Committee from the University of Ulm showing the acceptance of the multicentre study to be carried out in Ulm too.

Bundeswehrkrankenhaus Ulm

Kopie Prüfarzt

Einwilligungserklärung

Name der Studie:

Eine prospektive[11] Multizenter[12] Studie zur Untersuchung der Genauigkeit der Rekonstruktion[13] von Frakturen der medialen Orbitawand[14] und / oder des Orbitabodens[15]. Vergleich zwischen prä-operativ[16] vorgeformten und nicht vorgeformten Orbita-Implantaten[17].

Inhalt, Vorgehensweise, Risiken und Ziel des obengenannten Forschungsprojektes sowie die Befugnis zur Einsichtnahme in die erhobenen Daten hat mir

Dr. .... ausreichend erklärt.

Ich hatte Gelegenheit Fragen zu stellen und habe hierauf Antwort erhalten.

Ich hatte ausreichend Zeit, mich für oder gegen die Teilnahme am Projekt zu entscheiden. Eine Kopie der Patienteninformation und Einwilligungserklärung habe ich erhalten.

Ich willige in die Teilnahme am Forschungsprojekt ein.

....
(Name des Patienten)

....
Ort, Datum

....
(Unterschrift des Patienten)

[11] Prospektiv: Die Studie wird im Voraus geplant, bevor der erste Patient daran teilnimmt
[12] Multizenter: Die Studie wird in mehreren Kliniken durchgeführt
[13] Rekonstruktion: Wiederherstellung
[14] Mediale Orbitawand: Dünne Knochenplatte, welche die Augenhöhle zur Nase hin begrenzt
[15] Orbitaboden: Dünne Knochenplatte, welche die Augenhöhle nach unten begrenzt
[16] Präoperativ: Vor der Operation
[17] Orbita-Implantat: Metallgitter, welches in der verletzten Augenhöhle befestigt wird um die gebrochenen Knochenplatten zu fixieren

Bundeswehrkrankenhaus Ulm

Kopie Prüfarzt

Information und Einwilligungserklärung zum Datenschutz

Bei wissenschaftlichen Studien werden persönliche Daten und medizinische Befunde über Sie erhoben. Die Speicherung, Auswertung und Weitergabe dieser studienbezogenen Daten erfolgt nach gesetzlichen Bestimmungen und setzt vor Teilnahme an der Studie folgende freiwillige Einwilligung voraus:

1) Ich erkläre mich damit einverstanden, dass im Rahmen dieser Studie erhobene Daten/Krankheitsdaten auf Fragebögen und elektronischen Datenträgern aufgezeichnet und ohne Namensnennung weitergegeben werden an
   a) AO Clinical Investiagation and Documentation, Clavadelerstr. 8, CH-7270 Davos Platz, den Auftraggeber der Studie zur wissenschaftlichen Auswertung;
   b) die zuständige Überwachungsbehörde *(Landesamt oder Bezirksregierung)* oder Bundesoberbehörde *(Bundesinstitut für Arzneimittel und Medizinprodukte, Bonn)* zur Überprüfung der ordnungsgemäßen Durchführung der Studie.
2) Außerdem erkläre ich mich damit einverstanden, dass ein autorisierter und zur Verschwiegenheit verpflichteter Beauftragter des Auftraggebers, der Universität, der zuständigen deutschen und ausländischen Überwachungsbehörde oder der zuständigen Bundesoberbehörde in meine beim Prüfarzt vorhandenen personenbezogenen Daten Einsicht nimmt, soweit dies für die Überprüfung der Studie notwendig ist. Für diese Maßnahme entbinde ich den Prüfarzt von der ärztlichen Schweigepflicht.

....

Ort, Datum (Name Unterschrift des Patienten/der Patientin)

Ich versichere hiermit, die/den o.g. Patientin/Patienten über Wesen, Zweck sowie vorhersehbare Auswirkungen der Studie aufgeklärt zu haben. Sie/Er hat durch Unterschrift einer freiwilligen Teilnahme an der Studie zugestimmt.

....

Ort, Datum (Name Unterschrift des/der aufklärenden Arztes/Ärztin)

A copy of the consent form in the mother language; German.

The following tables show the raw data: for anonymity's sake, the first patient is labelled as P1 and the last as P23.

Table 9: A table showing the patients in the study according to the gender distribution, age at injury, side of fracture, fracture extension, size of implant, no. & type of screws, location of screws and operating surgeon. For anonymity's sake, the surgeons were labelled with numbers (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to Figures 30-33, 35, and 36, Table 1 and 2. Abbreviations; (I) M.W. - medial wall, (II) No. - number, (III) O.F. - orbital floor, (IV) Pat. - patient, (V) S - surgeon.

Pat.	Gender	Age at injury	Fracture side	Fracture extension	Size of implant	No. and type of screws	Location of screws	S
P1	Male	39	Left	Pure O.F.	Small	1x 1.5mm	On the orbital rim	S1
P2	Male	77	Right	Pure O.F.	Large	1x 1.5mm	Inside orbit	S2
P3	Male	22	Left	Pure O.F.	Large	2x 1.5mm	Over the orbital rim	S3
P4	Male	33	Right	Pure O.F.	Large	1x 1.5mm	Inside orbit	S1
P5	Male	70	Left	Pure O.F.	Large	2x 1.5mm	Over the orbital rim	S3
P6	Male	60	Right	Pure O.F.	Large	3x 1.5mm	Inside orbit & over the orbital rim	S3
P7	Male	25	Right	Pure O.F.	Large	3x 1.5mm	Inside orbit & over the orbital rim	S3
P8	Female	47	Right	Pure O.F.	Large	2x 1.5mm	Over the orbital rim	S3

P9	Male	40	Right	Pure O.F.	Large	2x 1.5mm	Over the orbital rim	S3
P10	Male	20	Right	O.F. & M.W.	Large	3x 1.5mm	Inside orbit, on the orbital rim	S3
P11	Male	52	Left	Pure O.F.	Small	1x 1.5mm	Inside orbit	S1
P12	Male	23	Left	Pure O.F.	Large	2x 1.5mm	Over the orbital rim	S3
P13	Male	47	Left	O.F. & M.W.	Large	1x 1.5mm	Inside orbit	S1
P14	Male	24	Right	O.F. & M.W.	Large	1x 1.5mm	On the orbital rim	S1
P15	Male	20	Right	Pure O.F.	Large	2x 1.5mm	On the orbital rim	S3
P16	Male	43	Left	Pure O.F.	Large	3x 1.5mm	1x inside orbit, 2x bent over the orbital rim	S3
P17	Female	24	Left	Pure O.F.	Small	1x 1.5mm	Inside orbit	S2
P18	Male	25	Right	Pure O.F.	Large	1x 1.5mm	Inside orbit	S1
P19	Female	44	Right	Pure O.F.	Large	1x 1.5mm, 1x 1.8mm	Over the orbital rim	S3
P20	Male	28	Right	O.F. & M.W.	Small	1x 1.5mm	Inside orbit	S2
P21	Male	22	Right	Pure O.F.	Large	1x 1.5mm	Inside orbit	S1

P22	Female	52	Right	Pure O.F.	Large	2x 1.5mm	Inside orbit	S1
P23	Male	31	Left	O.F. & M.W.	Large	2x 1.5mm	Inside orbit, on the orbital rim	S3

Table 10: Table showing the relationship of patients, injury-, admission-, informed consent (I.C.) and operation (Oper.) dates, days passed from injury to operation, and days awaited from admission to surgery (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to the bar chart in Figure 38.

Pat.	Injury date	Admission date	Date of I.C.	Oper. date	Days passed	Days awaited
P1	18.07.2011	20.07.2011	22.07.2011	25.07.2011	7	5
P2	18.09.2011	19.09.2011	21.09.2011	26.09.2011	8	7
P3	29.10.2011	30.10.2011	31.10.2011	02.11.2011	4	3
P4	03.11.2011	08.11.2011	09.11.2011	09.11.2011	6	1
P5	19.12.2011	22.12.2011	23.12.2011	23.12.2011	4	1
P6	20.02.2012	27.02.2012	28.02.2012	28.02.2012	8	1
P7	05.03.2012	05.03.2012	06.03.2012	07.03.2012	2	2
P8	11.03.2012	11.03.2012	13.03.2012	14.03.2012	3	3
P9	15.03.2012	19.03.2012	20.03.2012	21.03.2012	6	2
P10	28.04.2012	30.04.2012	02.05.2012	04.05.2012	6	4
P11	07.06.2012	07.06.2012	11.06.2012	11.06.2012	4	4
P12	11.08.2012	14.08.2012	17.08.2012	17.08.2012	6	3
P13	25.12.2012	25.12.2012	27.12.2012	27.12.2012	2	2
P14	26.12.2012	26.12.2012	27.12.2012	29.12.2012	3	3
P15	20.01.2013	20.01.2013	20.01.2013	21.01.2013	1	1
P16	18.02.2013	21.02.2013	22.02.2013	22.02.2013	4	1
P17	23.02.2013	23.02.2013	25.02.2013	27.02.2013	4	4

P18	10.02.2013	22.02.2013	25.02.2013	25.02.2013	15	3
P19	03.04.2013	03.04.2013	05.04.2013	08.04.2013	5	5
P20	06.06.2013	12.06.2013	12.06.2013	13.06.2013	7	1
P21	29.06.2013	29.06.2013	01.07.2013	03.07.2013	4	4
P22	10.07.2013	10.07.2013	12.07.2013	15.07.2013	5	5
P23	01.09.2013	02.09.2013	03.09.2013	04.09.2013	3	2

Table 11: Table showing patients, extension of fractures, in-hospital stay in days, and the operation time required in minutes (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to the information in the bar charts Figures 39 and 40.

Patient	Fracture extension	In-hospital stay (days)	Operating time (mins.)
P1	Pure O.F.	8	53
P2	Pure O.F.	21	74
P3	Pure O.F.	5	60
P4	Pure O.F.	6	100
P5	Pure O.F.	2	55
P6	Pure O.F.	6	30
P7	Pure O.F.	7	60
P8	Pure O.F.	9	50
P9	Pure O.F.	7	67
P10	O.F. & M.W.	7	57
P11	Pure O.F.	7	68
P12	Pure O.F.	6	40
P13	O.F. & M.W.	3	65
P14	O.F. & M.W.	5	75
P15	Pure O.F.	5	79
P16	Pure O.F.	5	37
P17	Pure O.F.	6	57
P18	Pure O.F.	6	115
P19	Pure O.F.	7	45
P20	O.F. & M.W.	3	61
P21	Pure O.F.	6	96
P22	Pure O.F.	9	107
P23	O.F. & M.W.	4	100

Table 12: Visual Acuity assessment using a Snellen chart; this table corresponds to the results in Chapter 3, Table 3. The values show consecutive results at the preoperative, 1-, 4- and 12-week visits (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Abbreviations; (I) * - the values shown are the numerator, the denominator being always 100; optimum vision being 100/100. (II) NGA - no glasses available, (III) NGR - no glasses required,

Patient	Affected side without glasses*	Affected side with glasses*	Unaffected side without glasses*	Unaffected side with glasses*
P1	90, 100, 100, 100	NGR	10, 5, 5, 5	NGA
P2	10, 10, 10, 5	50, 20, 50, 50	20, 10, 20, 20	60, 50, 50, 85
P3	100, 100, 100, 100	NGR	100, 100, 100, 100	NGR
P4	50, 50, 20, 20	50, 85, 50, 50	75, 85, 100, 100	60, 100, 100, 100
P5	10, 10, 20, 20	20, 20, 50, 20	10, 20, 20, 20	50, 20, 50, 20
P6	<5, 10, 20, 10	85, 50, 100, 75	<5, 10, 10, 10	85, 60, 100, 75
P7	50, 50, 50, 50	100, 85, 60, 60	50, 60, 50, 50	100, 100, 100,
P8	20, 20, 20, 20	50, 50, 100, 20	20, 20, 20, 20	60, 50, 100, 50
P9	60, 85,100,100	NGR	100, 100, 100, 100	NGR
P10	85, 85, 100, 100	NGR	100, 100, 100, 100	NGR
P11	20, 20, 20, 20	20, 50, 50, 60	20, 5, 10, 20	20, 20, 20, 60
P12	100, 100, 100, 100	NGR	100, 100, 100, 100	NGR
P13	5, 5, 10, 10	50, 60, 100, 50	20, 5, 10, 20	100, 60, 100, 100
P14	50, 100, 60, 60	NGR	50, 100, 60, 60	NGR
P15	50, 60, 100, 100	NGR	75, 100, 100, 100	NGR
P16	50, 60, 60, 60	NGR	50, 60, 60, 85	NGR
P17	100, 100, 100, 85	NGR	60, 60, 100, 100	NGR
P18	10, 20, 10, 10	3x NGA, 20	10, 50, 10, 10	3x NGA, 20
P19	50, 60, 75, 60	NGR	60, 100, 100, 100	NGR
P20	100, 100, 100, 100	NGR	100, 100, 100, 100	NGR
P21	95, 100, 100, 100	NGR	95,100, 100, 100	NGR
P22	20, 20, 20, 20	50, 3x NGA	20, 20, 20, 20	20, 3 x NGA
P23	75, 100, 100, 100	NGR	100, 100, 100, 100	NGR

Table 13: Ocular motility limitation at the preoperative, 1-week, 4-weeks and 12-weeks examinations for all the patients (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to Chapter 3 Table 4. Abbreviations; Pat. – Patients.

Pat.	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	Mild upgaze deficit	No	No	No
P2	Upgaze deficit	To all directions	Upgaze deficit	No
P3	No	No	No	No
P4	No	Upgaze deficit	Mild upgaze deficit	No
P5	Upgaze deficit	No	No	No
P6	Upgaze & adduction deficit	No	No	No
P7	Downgaze deficit	No	No	No
P8	No	Downgaze deficit	Downgaze deficit	Downgaze deficit
P9	Mild upgaze deficit	Upgaze & adduction deficits	Mild upgaze & minimal downgaze deficits	Mild upgaze deficit
P10	No	No	No	No
P11	No	Upgaze deficit, mild downgaze deficit	Upgaze deficit, mild downgaze deficit	Upgaze deficit
P12	Upgaze & abduction deficits	Upgaze & abduction deficits	Upgaze & abduction deficits	Upgaze-abduction deficit
P13	Upgaze deficit	Deficit in all directions & in primary gaze	Downgaze & abduction deficits	No
P14	No	Mild upgaze deficit	Abduction and primary deficits	Adduction & downgaze deficits
P15	No	Upgaze deficit	Upgaze deficit	Upgaze deficit
P16	No	Upward & adduction deficits	Adduction & upgaze deficits	No

P17	Upgaze & mild downgaze deficits	Upgaze deficit	Downgaze & adduction deficits	No
P18	No	Mild upgaze deficit	All abduction deficits	Downward deficit
P19	No	No	No	No
P20	No	No	No	No
P21	No	Upgaze deficit	Upgaze deficit	No
P22	Upgaze deficit	Upgaze-abduction deficit	Mild upgaze & downgaze deficit	Minimal upgaze deficit
P23	No	No	No	No

Table 14: Double vision recorded for the preoperative, 1-week, 4-weeks and 12-weeks follow-up for the study patients (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to Chapter 3 Table 5. Abbreviations; Pat. - Patients.

Pat.	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	No	No	No	No
P2	On 10° upgaze	No	No	No
P3	No	On central upward-abduction gazes & downward gaze	No	No
P4	On straight abduction	On upgaze	On 40° upgaze	No
P5	No	No	No	No
P6	On central upward gaze	No	No	No
P7	On 15° abduction	Abduction gaze	Abduction gaze	Abduction gaze
P8	On primary gaze	On downgaze	On downgaze & primary gaze	On downgaze
P9	On 40° upgaze	On up- & adduction gazes	On downgaze & abduction-adduction gazes	Upward-adduction & downward gazes, starting from 30°
P10	No	No	No	No
P11	Upper & abduction gazes	Abduction-adduction gazes	On 15° all gazes	On 30° upgaze, 45° adduction gaze, 40° downgaze
P12	On 25° upper & abduction gazes	Abduction & upward gazes	Upward gazes	No
P13	On primary, upper, abduction and adduction gazes	All directions including primary gaze	Downgaze & abduction gazes	No
P14	No	On 30° upgaze & downgaze	Abduction & primary gazes	Adduction & downward gazes

P15	On up- & adduction gazes	On 25° adduction, 20° abduction, 10° upgaze, 35° downgaze	On 18° adduction gaze & 20° upgaze	On upgaze & adduction gaze
P16	On central upgaze & downgaze	All adduction-upward gazes & central downward gaze	All adduction gazes, downward gaze & in primary position	Upward-abduction & -adduction gazes
P17	On 20° upgaze & 40° downgaze	On upgaze	Down- & adduction gazes	No
P18	On all gazes	On 20° all gazes	All abduction gazes & on primary gaze	On 40° downward gaze
P19	No	On abduction gazes	On abduction gazes	No
P20	On central upward gaze	No	No	No
P21	Upward gazes	On 20° upgaze	Upward-abduction gaze	No
P22	Upward gazes	On downgaze	On downward-abduction gazes	No
P23	No	On upgaze	No	No

Table 15: Table depicting the vertical globe position at every examination for each patient. This table corresponds to the information in Figure 41 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Abbreviations; 'R cran. by' means the ´right side is more cranial in the vertical dimension by´.

Patient	Fracture side	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	Left	Straight	Straight	Straight	Straight
P2	Right	Straight	R cran. by 5 mm	R cran. by 2mm	Straight
P3	Left	R cran. by 5	Straight	Straight	Straight
P4	Right	Straight	Straight	Straight	Straight
P5	Left	R cran. by 3mm	Straight	Straight	Straight
P6	Right	Straight	R cran. by 6mm	R cran. by 7mm	R cran. by 6mm
P7	Right	Straight	R cran. by 2mm	R cran. by 4mm	R cran. by 1mm
P8	Right	Straight	R cran. by 3mm	R cran. by 4mm	R cran. by 1mm
P9	Right	Straight	R cran. by 3mm	R cran. by 4mm	R cran. by 4mm
P10	Right	R cran. by 2mm	R cran. by 5 mm	R cran. by 4mm	R cran. by 2mm
P11	Left	R cran. by 2mm	R cran. by 3mm	R cran. by 2mm	R cran. by 3mm
P12	Left	Straight	Straight	Straight	R cran. by 2mm
P13	Left	R cran. by 4mm	R cran. by 3mm	Straight	R cran. by 2mm
P14	Right	R cran. by 2mm	R cran. by 3mm	Straight	R cran. by 1mm
P15	Right	R cran. by 2mm	R cran. by 3mm	R cran. by 2mm	Straight
P16	Left	Straight	Straight	Straight	Straight
P17	Left	Straight	Straight	Straight	Straight
P18	Right	R cran. by 2mm	R cran. by 2mm	R cran. by 2mm	Straight
P19	Right	Straight	R cran. by 2mm	R cran. by 2mm	Straight
P20	Right	Straight	Straight	Straight	Straight
P21	Right	Straight	Straight	Straight	Straight
P22	Right	Straight	R cran. by 2mm	Straight	Straight
P23	Left	Straight	Straight	R cran. by 2mm	R cran. by 2mm

Table 16: Table representing the sagittal globe positions in mm at each examination for every patient; the numbers in brackets show the differences between the 2 related measurements. This table corresponds to the information in Figure 43 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Patient	Fracture side	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	Left	12 L, 15 R (-3)	15 L, 15 R (0)	17 L, 17 R (0)	13 L, 13 R (0)
P2	Right	19 L, 20 R (+1)	19 L, 21 R (+2)	19 L, 19 R (0)	16 L, 16 R (0)
P3	Left	15 L, 16 R (-1)	16 L, 16 R (0)	16 L, 13 R (+3)	11 L, 12 R (-1)
P4	Right	15 L, 15 R (0)	16 L, 16 R (0)	15 L, 14 R (-1)	15 L, 18 R (+3)
P5	Left	17 L, 16 R (+1)	16 L, 16 R (0)	15 L, 15 R (0)	15 L, 16 R (-1)
P6	Right	11 L, 11 R (0)	15 L, 10 R (-5)	15 L, 8 R (-7)	12 L, 12 R (0)
P7	Right	15 L, 15 R (0)	12 L, 12 R (0)	10 L, 10 R (0)	12 L, 10 R (-2)
P8	Right	8 L, 8 R (0)	8 L, 10 R (+2)	14 L, 12 R (-2)	15 L, 13 R (-2)
P9	Right	12 L, 12 R (0)	11 L, 13 R (+2)	14 L, 16 R (+2)	15 L, 15 R (0)
P10	Right	13 L, 13 R (0)	10 L, 16 R (+6)	12 L, 12 R (0)	12 L, 11 R (-1)
P11	Left	12 L, 17 R (-5)	16 L, 17 R (-1)	15 L, 17 R (-2)	14 L, 17 R (-3)
P12	Left	16 L, 16 R (0)	14 L, 16 R (-2)	16 L, 16 R (0)	13 L, 12 R (+1)
P13	Left	15 L, 15 R (0)	15 L, 15 R (0)	16 L, 13 R (+3)	12 L, 15 R (-3)
P14	Right	14 L, 13 R (-1)	12 L, 15 R (+3)	14 L, 14 R (0)	16 L, 14 R (-2)
P15	Right	11 L, 14 R (+3)	10 L, 14 R (+4)	12 L, 9 R (-3)	12 L, 12 R (0)
P16	Left	13 L, 13 R (0)	15 L, 13 R (+2)	15 L, 14 R (+1)	12 L, 14 R (-2)
P17	Left	13 L, 17 R (-4)	17 L, 17 R (0)	16 L, 16 R (0)	16 L, 16 R (0)
P18	Right	13 L, 14 R (+1)	12 L, 16 R (+4)	10 L, 14 R (+4)	14 L, 14 R (0)
P19	Right	12 L, 11 R (-1)	15 L, 15 R (0)	12 L, 15 R (+3)	15 L, 15 R (0)
P20	Right	14 L, 16 R (+2)	16 L, 14 R (-2)	14 L, 16 R (+2)	14 L, 16 R (+2)
P21	Right	13 L, 13 R (0)	12 L, 15 R (+3)	12 L, 13 R (+1)	11 L, 10 R (-1)
P22	Right	15 L, 18 R (+3)	15 L, 17 R (+2)	16 L, 14 R (-2)	16 L, 15 R (-1)
P23	Left	12 L, 12 R (0)	11 L, 12 R (-1)	10 L, 13 R (-3)	11 L, 13 R (-2)

Table 17: Table depicting the interpupillary distance (horizontal globe position in mm) recorded at each examination for all patients. This table corresponds to the information in Figure 45 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

Patient	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	61	61	60	61
P2	61	70	67	66
P3	63	64	66	60
P4	59	61	61	55
P5	56	60	55	59
P6	55	60	60	57
P7	60	56	56	56
P8	50	50	51	52
P9	53	60	60	60
P10	60	59	59.5	59.5
P11	63	64	65	64.5
P12	55	62	61	60
P13	58	61	60	59
P14	56	54.5	55	56
P15	55	56	54.5	56
P16	63	65	66.5	63
P17	57	57	58	57.5
P18	55	55.5	53.5	55
P19	59.5	59.5	57	60
P20	57.5	58	59.5	57
P21	60	63	63.5	60
P22	60	58	56	55
P23	60	59	60.5	60

Table 18: Table depicting the different sensory recordings of the maxillary nerve on the fractured side, throughout the various visits (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). This table corresponds to the information in Chapter 3 Table 6.

Patient	Preoperative	After 1 week	After 4 weeks	After 12 weeks
P1	Hypoaesthesia	Hypoaesthesia	Paraesthesia	Hypoaesthesia
P2	Normal	Anaesthesia	Hypoaesthesia	Paraesthesia
P3	Normal	Paraesthesia	Hypoaesthesia	Hypoaesthesia
P4	Hyperaesthesia	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P5	Normal	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P6	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P7	Normal	Hypoaesthesia	Hypoaesthesia	Normal
P8	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P9	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Paraesthesia
P10	Normal	Hypoaesthesia	Normal	Normal
P11	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Paraesthesia
P12	Normal	Normal	Normal	Hypoaesthesia
P13	Normal	Hypoaesthesia	Hypoaesthesia	Normal
P14	Normal	Hypoaesthesia	Hypoaesthesia	Normal
P15	Normal	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P16	Normal	Hypoaesthesia	Hypoaesthesia	Paraesthesia
P17	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Paraesthesia
P18	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Paraesthesia
P19	Normal	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia
P20	Normal	Hypoaesthesia	Hypoaesthesia	Normal
P21	Normal	Hypoaesthesia	Normal	Normal
P22	Hypoaesthesia	Hypoaesthesia	Paraesthesia	Paraesthesia
P23	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia	Hypoaesthesia

Table 19: Associated orbital and periorbital injuries; the information corresponds to Figure 46 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

P1	Monocular haematoma on the ipsilateral side of the fracture Hyposphagma to the ipsilateral eye
P2	Bilateral periorbital haematomas; ipsilateral side greater than the contralateral
P3	Haematoma, swelling and temporal hyposphagma on the ipsilateral side
P4	Monocular haematoma to the lower lid on the ipsilateral side of the fracture
P5	Monocular haematoma to the upper and lower lid on the ipsilateral fractured side Upper and lower lid swelling on the ipsilateral side causing difficult eye opening Intra-orbital and lid emphysema on the ipsilateral side of the fracture
P6	Monocular haematoma to the upper and lower lids on the ipsilateral fracture side Hyposphagma on the ipsilateral side of the fracture Upper and lower lid swelling on the ipsilateral side of the fracture
P7	Bilateral monocular haematoma; ipsilateral side more than the contralateral side Bilateral lower lid swelling; ipsilateral side more than the contralateral side Lower lid emphysema on the ipsilateral side of the fracture Contusion of the eye on the ipsilateral side of the fracture
P8	Bilateral monocular haematoma; ipsilateral side greater than the contralateral side Bilateral upper and lower lid swelling; ipsilateral side greater than the contralateral Chemosis of the eye on the ipsilateral side of the fracture
P9	Lower lid haematoma on the ipsilateral side of the fracture Temporal hyposphagma, on the ipsilateral side of the fracture

P10	Bilateral monocular haematoma; ipsilateral side much more than the contralateral Lower lid oedema on the ipsilateral side of the fracture Temporal hyposphagma of the eye on the ipsilateral side of the fracture Ocular hypotension on the ipsilateral side of the fracture
P11	Monocular haematoma on the ipsilateral side of the fracture Periorbital emphysema on the ipsilateral side of the fracture Circular hyposphagma on the ipsilateral side of the fracture Contusion of the eye on the ipsilateral side of the fracture
P12	Bilateral contusion of the eyeballs Bilateral temporal hyposphagma to the eyeballs
P13	Abrasions to the ipsilateral lower eyelid Monocular haematoma to the ipsilateral side Ipsilateral intraorbital emphysema requiring the administration of i.v. Unacid® during the in-hospital stay Circular hyposphagma to the ipsilateral side Contusion of the ipsilateral eyeball causing preoperative pupillary difference; the ipsilateral pupil diameter being greater than the contralateral pupil diameter
P14	Bilateral monocular haematoma; ipsilateral side more extensive than contralateral side, causing difficulty in eye opening Swelling of the upper and lower eyelids on the ipsilateral side of the fracture Abrasions to the lower lid on the ipsilateral side of the fracture Intraorbital emphysema on the ipsilateral side of the fracture Circular hyposphagma to the eyeball on the ipsilateral side of the fracture Contusion of the eyeball on the ipsilateral side of the fracture

P15	Monocular haematoma on the ipsilateral side of the fracture Swelling of the upper and lower lid on the ipsilateral side of the fracture Circular hyposphagma to the ipsilateral eyeball Contusion of the eyeball on the ipsilateral side of the fracture; topical antibiotics were prescribed
P16	Monocular haematoma to the ipsilateral side of the fracture Circular hyposphagma to the ipsilateral side of the fracture
P17	Monocular haematoma on the ipsilateral side of the fracture Lower lid swelling on the ipsilateral side of the fracture Orbital emphysema on the ipsilateral side of the fracture
P18	Monocular haematoma to the lower lid on the ipsilateral side of the fracture Retinal foramens at peripheral position 2 ò clock and middle peripheral position 2:30 ò clock on the ipsilateral fracture side; laser treatment was done the day following admission under local analgesia; the orbital reposition was done later
P19	Abrasions to the ipsilateral side of the upper eyelid Bilateral monocular haematoma; ipsilateral side much more than the contralateral Swelling of the upper and lower eyelid on the ipsilateral side of the fracture causing inability to eye opening
P20	Monocular haematoma on the ipsilateral side of the fracture Lower lid swelling on the ipsilateral side of the fracture Circular hyposphagma on the ipsilateral side of the fracture Orbital emphysema on the ipsilateral side of the fracture Contusion of the eyeball on the ipsilateral side of the fracture

P21 Monocular haematoma on the ipsilateral side of the fracture Orbital emphysema and corneal erosion on the ipsilateral side of the fracture; i.v. Unacid® 3 gr. three times daily was administered during the hospital stay Temporal hyposphagma to the ipsilateral side of the fracture
P22 Contusion of the eyeball on the ipsilateral side of the fracture Bilateral monocular haematoma; ipsilateral side more than the contralateral side Bilateral lid swelling; ipsilateral side more than the contralateral side
P23 Bilateral monocular haematoma; ipsilateral side more than the contralateral side Bilateral upper and lower lid swelling; ipsilateral side more than the contralateral Temporal hyposphagma on the ipsilateral side of the fracture Contusion of the eyeball on the ipsilateral side of the fracture

Table 20: Accompanying injuries (excluding orbital and periorbital injuries). This information corresponds to the pie chart in Figure 47 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013).

P1	Haematoma of cheek on the ipsilateral fracture side; at the 1-week postoperative visit, this was incised from intraorally, without requiring any in-hospital stay Lacerated wound in the ipsilateral eyebrow which needed surgical suturing Abrasions to the ipsilateral side of the chin, ala of the nose, bridge of the nose, and cheek and the contralateral cheek Swelling on the ipsilateral forehead Minor injury to the ipsilateral first digit
P2	Nasal bone fracture; reduction of the fracture and septorhinoplasty by the ENT colleagues during the same operation Trauma-induced contralateral knee pain; a preoperative orthopaedic consultation diagnosed a knee joint arthrosis, secondary to trauma, with a past history of a joint infection on the same knee 20 years before. Symptomatic pain relief and physiotherapy were recommended
P3	Lacerated wound at the ipsilateral supraorbital ridge, which was surgically closed
P4, P5	No accompanying injuries
P6	Lacerated wounds in the ipsilateral forehead and ipsilateral side of the bridge of the nose which were both surgically sutured Abrasions on both knees
P7	No accompanying injuries
P8	Nasal bone fracture; reduced with the orbital fracture Lacerated wound at the ipsilateral nasolabial border with extension to the right ala of

	the nose and columella, resulting in exposure of the nasal cartilage; wound was primarily sutured by the ENT department; on the recommendation from the ENT department, the patient was started on i.v. Augmentin 1.2 gr. three times daily Tooth 11 had a mobility grade 1
P9	No accompanying injuries
P10	Abrasions at the contralateral side of the forehead and ipsilateral side of the cheek Multiple abrasions at the extremities especially the right arm to the right shoulder Lacerated wound at the ipsilateral lower lid which was treated conservatively
P11	The left upper central incisor had a negative response to the cold test; subjectively the tooth being injured with the orbital trauma
P12	Brain concussion Lacerated wound at the contralateral supraorbital margin being surgically sutured Abrasions on both elbows and knees Enamel-dentine crown fracture to tooth 21 which was covered with a Calcium Hydroxide dental material Concussion injury to tooth 22 with a resulting motility grade 1 3 abrasions to the mucous membrane of the lower lip
P13	Brain concussion Abrasions to the ipsilateral forehead, cheek, and to the tip of the nose
P14	Nasal bone fracture (reduced together with the orbital fracture) Abrasions to the neck on the ipsilateral side of the orbital fracture Abrasions to the bridge of the nose

P15	Abrasions to the ipsilateral cheek Lacerated wound to the ipsilateral supraorbital ridge treated conservatively
P16, P17	No accompanying injuries
P18	Undislocated fracture of the nasal bone; no therapy was required
P19	Fracture of the nasal bone requiring reposition Abrasions to the ipsilateral side of the forehead, to the ipsilateral side of the ala of the nose and to the ipsilateral cheek
P20	Lacerated wound to the ipsilateral ear lobe, which was surgically sutured
P21	Abrasions to the ipsilateral side of the cheek
P22	Brain concussion Fracture of the anterior edge of the 5th cervical vertebra Haematoma of the chin Lacerated wounds to the ipsilateral eyebrow and upper lip which were sutured Abrasions to the chin, ipsilateral cheek and forehead, ipsilateral knee and foot Bruise to the contralateral shoulder
P23	Lacerated wound to the ipsilateral forehead which was surgically closed Fracture of the nasal bone which was surgically reduced with the orbital fracture Ipsilateral zygomatic fracture which was surgically reduced with the orbital fracture

Table 21: Volumetric measurements (in cm³). This table corresponds to the information in Figures 52-55 (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). Abbreviations; (I) Co. - contralateral, (II) Pat. - patients (III) Po. - postoperative, (IV) Pr. - preoperative.

Pat.	Preoperative	Postoperative	Difference (Pr.-Po.)	Co.	Difference (Po.-Co.)
P1	31.554	28.962	2.592	30.475	-1.513
P2	36.498	32.336	4.162	33.597	-1.261
P3	30.231	28.950	1.281	30.550	-1.600
P4	30.747	29.077	1.670	26.134	2.943
P5	29.651	29.228	0.423	27.697	1.531
P6	35.120	27.032	8.080	31.281	-4.249
P7	29.903	28.791	1.112	28.938	-0.147
P8	30.196	27.645	2.551	28.136	-0.491
P9	34.048	30.388	3.660	30.288	0.100
P10	35.263	32.818	2.445	32.484	0.334
P11	29.186	27.870	1.316	28.137	-0.267
P12	33.100	31.996	1.104	33.434	-1.438
P13	35.955	33.615	2.340	34.327	-0.712
P14	31.120	28.360	2.760	29.253	-0.893
P15	29.251	27.298	1.953	29.164	-1.866
P16	31.383	29.393	1.990	30.255	-0.862
P17	28.964	27.129	1.835	28.319	-1.190
P18	30.878	29.078	1.800	27.917	1.161
P19	32.235	32.075	0.160	32.721	-0.646
P20	30.112	29.801	0.311	29.648	0.153
P21	30.275	29.315	0.960	30.573	-1.258
P22	26.200	24.968	1.232	26.626	-1.658
P23	32.568	29.816	2.752	30.111	-0.295

Table 22: Table demonstrating the largest diameters (in cm) and areas (in cm^2) for each fracture (23 study patients in all, data collected from the Maxillofacial Department, Military hospital, Ulm from July 2011 till November 2013). The table corresponds to the information in Figures 58-59. Abbreviations; (I) # - Fracture, (II) M.W. – medial wall, (III) O.F. – orbital floor (IV) Pat. - patient.

Pat.	O.F. # coronal cut	O.F. # sagittal cut	**Area O.F. #**	**M.W. # axial cut**	**M.W. # sagittal cut**	**Area M.W. #**
P1	1.63	0.90	**1.47**			
P2	1.21	2.23	**2.70**			
P3	1.45	1.73	**2.51**			
P4	1.35	0.40	**0.54**			
P5	1.22	2.04	**2.49**			
P6	1.28	2.34	**3.00**			
P7	1.26	1.40	**1.76**			
P8	1.09	1.46	**1.59**			
P9	2.18	2.60	**5.67**			
P10	1.71	2.47	**4.22**	0.69	1.85	**1.28**
P11	2.53	3.13	**7.92**			
P12	1.36	1.86	**2.53**			
P13	1.94	2.17	**4.21**	0.89	1.76	**1.57**
P14	1.78	1.41	**2.51**	0.66	1.72	**1.14**
P15	1.22	1.74	**2.12**			
P16	1.90	2.61	**4.96**			
P17	1.43	2.46	**3.52**			
P18	1.51	1.94	**2.93**			
P19	1.71	1.42	**2.43**			
P20	1.18	1.81	**2.14**	0.71	1.55	**1.10**
P21	1.34	1.77	**2.37**			
P22	1.33	2.17	**2.89**			
P23	1.96	1.45	**2.84**	0.64	1.53	**0.98**

Figure index:

Table index:

Table index (raw data):

Acknowledgements

I wish to thank Professor Dr. Dr. Schramm, Chairman of the Maxillofacial Surgery at the academic University hospital of Ulm, and also Chairman of the Maxillofacial Surgery at the Military University hospital of Ulm, for allowing me to perform this research in his department, and for his correction of the thesis in order to make the project publishable.

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I wish to thank the librarians at the Military hospital in Ulm, for supplying me with the extensive scientific literature to develop my project, and I would like to thank the innumerable authors of such literature, that have made this field so fascinating and special.

I would like to thank Mrs. Silvia Sandler and Mrs. Beate Einsiedler from the Institute of Epidemiology and Medical Biometrics at the University of Ulm who have directed me to develop the statistics of this study.

I wish to thank Prof. Dr. Dr. Gellrich and the AO Foundation, who developed and directed the multicenter trial on orbital fractures, and from which our study originated.

Curriculum Vitae

Name and Surname: Joanna Bašić (née Pace)
Bachelor of Dental Surgery (University of Malta),
Doctor of Medicine and Surgery (University of Malta),
Specialist in Oral and Maxillofacial Surgery (Germany)

Education

- October 1977 – June 1988: Primary School und Secondary School at "St. Joseph's School, Blata-l-Bajda" (Malta)
- October 1988- June 1989: 1 year at the "Higher Secondary School" (Malta)
- October 1989- June 1991: 2 years college (preparation for A-Levels) at the "Sixth Form College, G.F. Abela College" (Malta)
- October 1991 – June 1992: 1 year doing "Foundation Course" at the "University of Malta"
- October 1992 - February 1997: Read degree in Dental Surgery at the "University of Malta". Graduated in 1997.
- November 1997: promoted with the B.Ch.D. title in Malta
- October 1998 - June 2003: Read degree in Medicine and Surgery at the "University of Malta". Graduated in 2003
- November 2003: promoted with the M.D. title in Malta
- October 2009 till October 2014 – residency at the Maxillofacial Surgery department at the Military hospital, Ulm
- December 2014: promoted with the specialist degree in Maxillofacial Surgery (Germany)
- October 1979 – March 1989: Completed till Advanced level study in Music (Piano)

Teaching Experience

- December 2001: Lecture at Accident and Emergency department in `Dental Emergencies`

Extra-curricular Experience

- October 1995- June 1996. Participated actively in the Maltese Association of Dental Students, serving as a Secretary

- July 2000 – August 2000 – Visited the Maxillofacial Surgery Department in Bratislava, Slovakia as an Exchange student

- June 2001 – July 2001 – Visited the Maxillofacial Surgery Department at AKH Vienna as an exchange student

- October 1998- June 2003. Participated in the Malta Medical Students Association serving in the Exchange students committee

Continuing Education

- September 2004 – Attended the International Conference for Cranio-Maxillofacial Surgery in Tours, France

- June 2004 – Basic Surgical Skills Course (University of Malta on behalf of the Royal College of Physicians and Surgeons of Glasgow)

- December 2004 – Visited Cranio-Maxillofacial Surgery Department in Zurich, Switzerland for 10 days as a guest

- April 2005 – Visited the Cranio-Maxillofacial Department in Graz, Austria for some weeks as a guest

- April 2005 – Anastomoses Course (University of Malta on behalf of the Royal College of Physicians and Surgeons of Glasgow)

- August 2005 – Advanced Life Support (2 day Course organized by the Department of Anaesthesia, and Admitting and Emergency Department)

- July 2006 – Visited the Maxillofacial Surgery Department in Feldkirch, Austria for a month as a guest

- March 2007 – Visited the Maxillofacial Surgery Department in Hannover, Germany for some days as a guest

- March 2007 – Visited the Maxillofacial Surgery Department in Frankfurt, Germany for some days as a guest

- February 2009 – Visited the Maxillofacial Surgery Department in Ulm, Germany for a week as a guest

- June 2009 – Attended the First Mediterranean FESS Course, held in Valletta, Malta

- June 2009 – Participated at the European Trauma Course held in St. Julian`s, Malta

- December 2009: Basic course (1st part) in Ultrasound of the Head and Neck Region organized by the ENT department of the military hospital, Ulm, Germany

- June 2010: Continuation course (2nd part)in Ultrasound of the Head and Neck Region organized by the ENT department of the military hospital, Ulm, Germany

- Sep.-Oct. 2010: Participated in the "2nd OP-Course of the Head and Neck Surgery" organized by the ENT department of the Military hospital in Ulm, Germany

- November 2010: "Prosthetic possibilities with the Straumann system" - a lecture organized by the Maxillofacial department in the military hospital, Ulm through the ITI Study Club

- Nov. 2011 till April 2012: Participated in 20 hours organized by the psychiatric department, military hospital, Ulm (case discussions)

- December 2011: "Maxillofacial basic course" organized by the company Brainlab, in Munich, Germany

- June 2012: "Preprosthetic surgery - Augmentation techniques and their indications in the oral implantology" - a lecture organized by the Maxillofacial department in the military hospital, Ulm through the ITI Study Club

- October 2012: "The current treatment options in patients having biphosphonate treatment" - a lecture organized by the Maxillofacial department in the military hospital, Ulm through the ITI Study Club

- January 2013: "The allogeneous bone transplant in the oral implantology" - a lecture organized by the Maxillofacial department in the military hospital, Ulm through the ITI Study Club

- June 2013: "First Dillingen International Forum on Military Medicine; Update on ballistic injuries to the head and neck" in Dillingen, Germany

- October 2013: "Emergency vascular surgery for non-vascular surgeons"; a course organized by the vascular department of the military hospital in Ulm, Germany

- March till April 2014: Participant in the "6th OP-Course of the Head and Neck Surgery" organized by the ENT department, Military hospital, Ulm, Germany

- October 2014: End course (3rd part) in Ultrasound of the Head and Neck Region organized by the ENT department of the military hospital, Ulm, Germany

- September 2015: Participant in the AOCMF-Basic Course for Doctors with practical exercises in Tübingen, Germany

Language knowledge

- Maltese Mother language
- English Formal Language
- Italian Average knowledge
- French Average knowledge
- German Good knowledge

Work experience

- April 1997 – September 1998. Resident House Dental Surgeon at the University Hospital of Malta (Dental Department, University of Malta)

- October 1998 – September 2009: Practicing Dentistry in a private Clinic (this includes my continuous practicing in Dentistry during my 5 year course leading to Doctor in Medicine and Surgery

- July 2003 – December 2005 – Medical Officer (Houseman) at the University Hospital of Malta during which I did:

- 3 months Orthopaedics and Traumatology (July `03 – September `03) – Consultant: Dr. Esposito

- 3 months Obstetrics and Gynaecology (October `03 – December `03) – Consultant: Dr. Formosa

- 6 months Medicine with a special interest in Rheumatology (January '04 – June `04) – Consultant: Profs. Mallia

- 6 months in General Surgery (July `04 – December `04) – Consultant: Dr. G. Felice

- 3 months in Psychiatry (January `05 – April `05) – Consultant and Director: Dr. Saliba

- 1 week in Plastic and Reconstructive Surgery (26th February '05 – 4th March `05) – Consultants: Dr. Briffa and Dr. Darmanin

- 3 months in ENT (April `05 – July `05) – Consultants – Dr. Said, Dr. Farrugia, Dr. Griscti Soler and Dr. Borg

- 3 months in Admitting and Emergency Department (July `05 – October `05) - Consultants: Dr. Camilleri and Dr. Shah

- 3 months in ENT (October `05 – December `05) with the above-mentioned surgeons

- January 2006 - June 2006 - Senior House Officer at the Admitting and Emergency

Department

- July 2006 – September 2006 – Senior House Officer in ENT
- October 2006 – December 2006 – Senior House Officer in Neurosurgery
- January 2007 – March 2007 – Senior House Officer in ENT
- April 2007 – June 2007 – Senior House Officer in Paediatric Surgery
- July 2007 – December 2007 – Senior House Officer in General Surgery
- January 2008 – June 2008 – Senior House Officer in Orthopaedics and Traumatology
- July 2008 – September 2008 – Senior House Officer in ENT
- October 2008 – January 2009 – Maternity Leave
- January 2009 – September 2009 – Senior House Officer in ENT
- October 2009 till December 2014 – training residency at the Maxillofacial department, Military hospital, Ulm, Germany
- January 2015-April 2015 – finished writing the doctoral thesis, which was then handed over to the University of Ulm, Germany in December 2015
- May 2015 - Positon as a Specialist in the Maxillofacial department of the University hospital in Ulm, Germany

Publications

- Physiology Project: "The Cognitive Neurochemistry of Fear": Doctoral thesis handed to the Physiology department at the "University of Malta": June 2000
- Anatomy Projects:
  1. "The Inferior Alveolar Nerve" - presented in February 1994: Project at the Anatomy Department during the Course leading to Bachelor in Dental Surgery: "University of Malta"

2. Multiple practical patient presentations in different subspecialities as preparation for the final exam leading to the Bachelor of Dental Surgery

3. "The Muscles of Facial Expression" - presented in June 2000: Project at the Anatomy Department during the Course leading to Doctor in Medicine and Surgery: "University of Malta"

- Co-author of the mother multicenter trial which was organized by the AO Foundation: "A prospective multicenter study to compare the precision of posttraumatic internal orbital reconstruction with standard preformed and individualized orbital implants" which will be published next year

- Main author of "A prospective study of the clinical outcomes of orbital floor and medial wall blowout fractures using preformed 3-D implants" which will be published from the results of this thesis, and therefore the study results obtained from the Military hospital Ulm

Presentations

- "Treatment of Lymphangioma in children: our experience of 128 cases" – (Journal of Paediatric Surgery `07) Case Presentation May 2007 during the Journal Club Meeting organized by the Surgical Department

- "A 3-year survey of assault-related Maxillofacial fractures in central Switzerland" - (Journal of Cranio-Maxillofacial Surgery 2007) Case Presentation Oct. `07 during the Journal Club Meeting organized by the Surgical Department

- "Are Outcomes of Bimalleolar Fractures poorer than those of Lateral Malleolar Fractures with Medial Ligamentous Injury?" - (The Journal of Bone and Joint Surgery) Case presentation Mar. 2008 during the monthly meetings organized by the Orthopaedics and Traumatology Department

- "Solid ulcerative lesions of the Oral Cavity": presentation at the ENT Department Feb. 2009