

Analysis of contemporary tools for the measurement of enophthalmos: a PRISMA-driven systematic review

C.L. Nightingale^{a,*,1}, K. Shakib^{b,c,2}

^a Plastic Surgery Department, St Thomas's Hospital London

^b Department of Oral and Maxillofacial Surgery, Royal Free Hospital

^c Department of Surgery, UCL

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Abstract

Enophthalmos has many causes, and serious post-traumatic cases indicate the need for operation. Such diagnoses should be made objectively, and a robust method for quantifying the degree to which the globe has been displaced is key. Current methods of measurement, however, have long been considered unreliable and inconsistent, in particular with regard to interobserver variability. The aim of this paper therefore was to review all these methods systematically, to analyse their reliability, and to compare them with others. The paper also includes a proposed protocol for the accurate and reliable measurement of protrusion of an eye, which aims to standardise the assessment of patients and to create a uniform approach that will enable the selection of those who are most likely to benefit from surgical treatment. Analysis of the data showed that computed tomographic (CT) exophthalmometry is the most reliable, followed by the Mourits' exophthalmometer, which performed better than the other clinical methods. In the acute phase of orbital blowout fractures, the measurement of herniated tissue through a fracture defect may give a good prediction of the degree of enophthalmos that is likely to occur without surgical correction. Measurement of the herniated volume and CT exophthalmometry should be the foundation for diagnosis and the planning of treatment. Three-dimensional imaging or Mourits' exophthalmometers (which are reliable non-radiological methods) could be used in a follow-up protocol.

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Introduction

Enophthalmos is generally considered to be the difference of more than 2 mm in the position of two globes along the anteroposterior axis of the orbit.^{1–3}

Orbital blowout fractures are commonly associated with facial trauma. They happen to a wide range of people and are often the result of falls, interpersonal violence (such as

domestic violence), and sporting injuries.⁴ Enophthalmos is the most common sequel of these fractures,^{5,6} and can have a notable influence on facial aesthetics and vision. Functional effects include diplopia, and difficulties with eyelid function and the production of tears.⁷ Acute clinical presentation may include periorbital ecchymosis, diplopia, hypoaesthesia in the maxillary distribution of the trigeminal nerve, intraorbital emphysema, and retrobulbar haemorrhage.⁴

Primary enophthalmos can result from a congenital abnormality. The mean difference between left and right orbital volumes may be no more than 1.4%,^{8,9} so it is reasonable to suggest that both should be similar.

Secondary enophthalmos is caused by a change in the relation between the volume of the rigid bony cavity and

* Corresponding author.

E-mail addresses: Craig.nightingale@doctors.org.uk (C.L. Nightingale), k.shakib@nhs.net (K. Shakib).

¹ Tel.: 07500222313.

² Tel.: 07973600777.

its contents^{7,10} - for example, an enlargement of the cavity without a change in the volume of the contents (an orbital blowout fracture).

Measurements of enophthalmos (or exophthalmos) by exophthalmometry can be further categorised as absolute (in which measurements are made on exact graduations and are often used for anthropomorphic reasoning), relative (in which the degree of globe protrusion is compared to the contralateral side of the same person), or comparative (in which a change in protrusion is compared over a period of time).¹¹

Post-traumatic enophthalmos, which is still not entirely understood, may have several causes that include an increase in the volume of the bony portion of the orbit, or the loss of retrobulbar fat and muscle into the orbital defect.¹² It may not be clinically evident immediately after correction of an orbital blowout fracture because of haematoma or oedema,^{13,14} and may not show until two to three months later.¹⁵

Measurement of enophthalmos

Both radiological and clinical assessments can be used to measure the degree of enophthalmos. Table 1 shows the methods used to diagnose it.

Clinical measurement

Currently, two methods are used to measure the degree of enophthalmos. Hertel's exophthalmometer^{2,16} measures the protrusion of the apex of the globe in relation to the lateral orbital rim. However, potential errors, which include changes in the position of the lateral orbital rim, and a parallax effect when the mirror is not correctly aligned, may occur. Use of a Mourits' exophthalmometer, which is similar to Hertel's but with only one reflective prism instead of two, may reduce the amount of parallax error.^{17,18} The Hertel's exophthalmometer has come under increasing scrutiny in recent years and there is a growing amount of evidence to discredit its reliability.^{19–22}

A similar device, Naugle's exophthalmometer, uses the superior and inferior orbital margin.

Radiographic measurement

To plan for surgical correction, accurate and reliable identification and a quantifiable assessment of the abnormality are required, and the main approach is currently based on computed tomography (CT).

Plain radiographs are inexpensive and easily accessible, and are usually taken as a first-line approach in the diagnosis of orbital blowout fractures, but ophthalmologists often prefer to take a clinical impression to establish the need for

operation. Bhattacharya et al reported the use of preoperative CT in all patients who were thought to need surgical repair, which removed any benefit from the initial radiographs.²³ Plain radiographs therefore are not usually recommended for suspected cases.^{4,23}

Magnetic resonance imaging (MRI) has also been considered useful for the assessment of orbital volumes, and particularly of the soft tissues.⁷ It removes all risk of radiation, but its availability, even in modern hospitals, is limited, and visualisation of bone is poor. Furthermore, metal leaves appreciable artifacts on MRI and, as the repair of fractures of the orbital floor often involve the placement of a metal orbital plate, it is less than ideal for postoperative monitoring.

CT is therefore the current gold standard for assessment. Modern technology has made it possible to create 3-dimensional reconstructions of the skeletal structure from which data on the volume of the orbit can be extrapolated objectively, and the methods used to calculate orbital volumes from these constructs are highly reproducible.^{8,24} CT, however, does have limitations. It typically delivers about 100 times the radiation dose of a plain radiograph, and the involvement of artifacts (such as motion or "streak" artifacts) can have a negative effect on the quality of the image, although these effects can be reduced with multislice CT.²⁵

CT data can also be used to deduce the degree of enophthalmos directly. As with Hertel's exophthalmometer, the techniques used to calculate the position of the globe often depend on the lateral orbital margin as a reference point.^{5,11,18} Fortunately, these data give us the opportunity to try new approaches (which may prove reliable) to measure the degree of proptosis without the need for an intact lateral orbital rim. This can be achieved by the use of a mirror image of the contralateral side with the nasal septum as a midline,^{5,11,26} which ignores a pathological lateral rim altogether²⁶ or the need to measure an absolute distance from a line connecting the styloid processes to the anterior corneal apex.²⁷

Three-dimensional imaging

Three-dimensional imaging can be used to measure facial asymmetry and the degree of enophthalmos. Nkenke et al compared it with traditional methods of measurement,¹¹ but while they reported interesting and comparable results, the resources that are necessary for 3-dimensional imaging in particular, are not widely available, and this renders it less than ideal.

Surgical planning

Patients may require operations at different times after injury (in the acute or late stage, or possibly as a secondary intervention after an initial procedure) and there is much debate about the best time to intervene. Those who require operation acutely after injury are selected on the basis of clinical symptoms such as enophthalmos, diplopia, and limited ocular motility, as well as entrapment of the orbital contents.^{28–30} The most important indication for immediate operation is

Table 1
Methods used to diagnose enophthalmos.

Clinical	Radiographic
Hertel's exophthalmometer	Plain radiographs
Naugle's exophthalmometer	Computed tomography
Leudde's exophthalmometer	Magnetic resonance imaging

retrobulbar haemorrhage followed by persistent vomiting in children (occlusogastric reflex). Operations for diplopia are typically completed two weeks after injury, once the periorbital swelling has subsided.

It has been suggested that of the patients who are treated conservatively, 7%-10% develop enophthalmos³ and require subsequent management. Other indications for late treatment include diplopia or limitation of gaze that does not resolve within two weeks.³¹⁻³³

Method

This systematic review was made according to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. The search of publications included the MEDLINE, EMBASE, clinicaltrials.gov, and WHO International Clinical Trials Registry Platform databases. The terms were “measure enophthalmos” or “enophthalmometer” or “exophthalmometer” or “marginal reflex distance and enophthalmos” or “computed tomography and enophthalmos”. The references of the retrieved full-text articles were then reviewed to find further studies that had not been identified by the primary search. Only studies in the English language were used, and the final search of all databases was completed on 21 May 2018.

Clinical trials were included if they assessed the degree of enophthalmos, compared methods of measurement, showed reliability data for at least one method, included a detailed description of the techniques used, and gave quantitative data that were available for analysis.

Animal studies, those that assessed only individual populations to ascertain normal values, or reported qualitative outcomes, and those that were incomplete, not available, or were reviews, were excluded.

Based on a combination of their title and abstracts, studies were selected from the initial search by a single reviewer (CN). Abstracts were reviewed for the inclusion of more than one method of measurement, or assessment of a method's reliability. If the title or abstract was unclear on this point, the full paper was retrieved, but that was necessary in only a few cases.

Many studies did not include raw data. Those that did were added together and, where possible, Pearson's correlation coefficients and linear regression lines were calculated. Correlation coefficients were defined as very poor (0.00 – 0.30), poor (0.31 – 0.50), moderate (0.51 – 0.70), good (0.71 – 0.90), or very good (more than 0.91).

Results

The initial search yielded a total of 1800 results. After screening, 22 were finally included (Fig. 1).

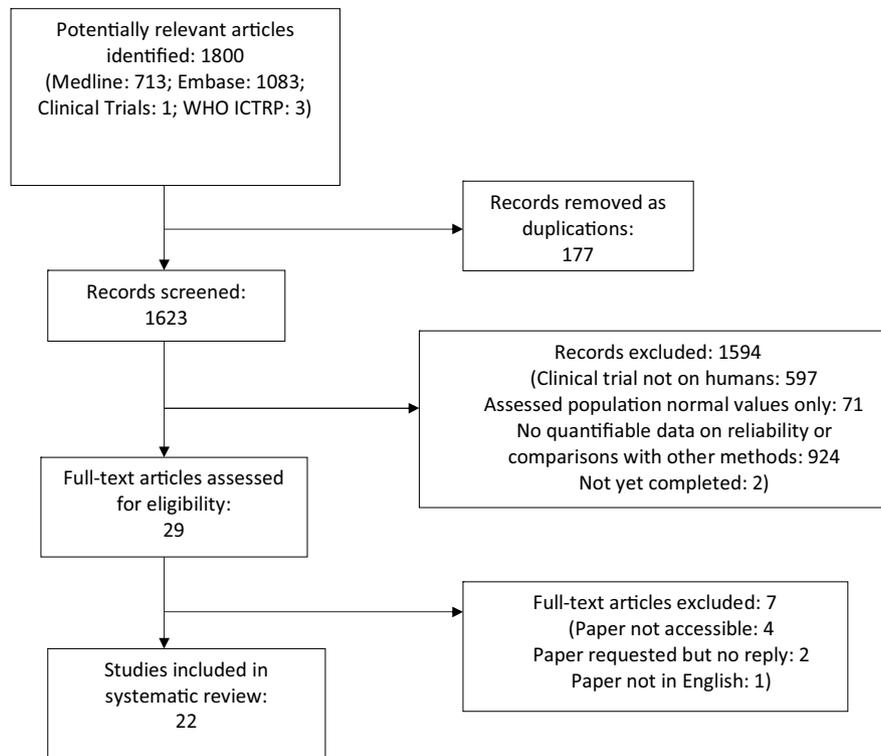


Fig. 1. Flowchart showing the selection of publications.

Reliability data

Few studies had assessed the reliability of the methods used to measure enophthalmos (Table 2).^{18,21,34–40}

Comparison data

The results of the studies that compared methods of measurement were more complicated, as different statistical tests were used, and few included raw data (Table 3).^{7,11,18,26–28,33,36,37,39,41–45}

So many variables have been compared and different interpretations made of the results, that it is difficult to draw any valid conclusions. When considered in detail, however, we can deduce that all the methods probably have a positive correlation, except when 3-dimensional imaging is compared with Hertel's exophthalmometry.

Analysis

There is a wide range of interobserver variation values for Hertel's instrument ($r=0.57$ to 0.89).^{18,34,37} It is important to recognise that the two studies with higher degrees of interobserver variation investigated exophthalmometry in patients with no orbital disease. When abnormal orbits were included, reliability dropped ($r=0.57$).

The only intraobserver quantitative data was from the study by Delmas et al,¹⁸ which suggested a good correlation ($r=0.84$), but again, this was recorded only in healthy people.

Importantly, two studies showed that Hertel's exophthalmometry was associated with a learning curve.^{18,21}

Two papers assessed Leudde's exophthalmometer. Delmas et al suggested that there were good intraobserver, and reasonable interobserver, correlations,¹⁸ and Chang et al suggested that the difference between observers was not significant.³⁶

Delmas et al again contributed to this review in terms of the data gained about the Mourits' instrument. They suggested that it had the best reliability of all three exophthalmometers.¹⁸ In accordance with their findings for the other methods there was clearly the suggestion of a learning curve in terms of their reliability data.

Four studies assessed the reliability of CT data for the measurement of enophthalmos.^{37–40} Vicinanza et al measured the size of the fracture, whilst the others used various (albeit similar) methods to measure the position of the globe directly.³⁸ Only Vicinanza et al recorded poor reliability data, which may suggest that the technique they used was not suitable. The other authors, however, proposed that there was a near perfect correlation coefficient both for intraobserver and interobserver recordings.

Overall, the reliability data suggest that the most consistent method for the measurement of enophthalmos is CT data. The most dependable non-radiological method is measurement by a Mourits' exophthalmometer, which may be important to consider when repeated exposure to radiation is not appropriate.

Table 2
Data from all the studies that assessed the reliability of the methods.

Method and first author	Interobserver variation (r)	Intraobserver variation (r)	Statistical significance between measurements	Extra details
Hertel's exophthalmometry				
Mourits ³⁴ Musch ²¹	0.89		Intraobserver - No Interobserver - Yes	Healthy orbits only Difference partly attributed to experience of observer
Lam ³⁵			Intraobserver - No Interobserver - Yes	
Delmas ¹⁸	0.80 (95% CI 0.68 to 0.88)	0.84 (95% CI 0.75 to 0.90)		Suggestion of experience as important factor
Chang ³⁶ Choi ³⁷	0.57		Interobserver - No	Only mean values appraised Included pathological orbits
Leudde's exophthalmometry				
Delmas ¹⁸	0.72 (95% CI 0.57 to 0.82)	0.86 (95% CI 0.78 to 0.92)		Suggestion of experience as important factor
Chang ³⁶			Interobserver - No	Only mean values appraised
Mourit's exophthalmometry				
Delmas ¹⁸	0.89 (95% CI 0.83 to 0.94)	0.94 (95% CI 0.90 to 0.97)		Suggestion of experience as important factor
CT exophthalmometry				
Vicinanzo ³⁸	0.66 (longitudinal) 0.44 (vertical)			95% CI 0.46 to 0.88 95% CI 0.22 to 0.69
Segni ³⁹ Ramli ⁴⁰ Choi ³⁷	0.98	0.99		

Table 3
Correlations between methods used to measure orbital proptosis.

Method, first author and reference	Correlation (<i>r</i>)	p value	Extra detail
CT cf Hertel			
Afanasyeva ²⁷	0.988		
Ramli ⁴⁰	0.960 & 0.930	0.001	Healthy & proptotic orbits
Choi ³⁷	-0.706	<0.001	Different technique
Segni ³⁹	0.880		Mean p value from two observers
Nkenke ¹¹ 2004	0.033		All patients with zygomatic fractures
Nkenke ⁴¹ 2003	0.232 & -0.795		Healthy & pathological orbits
Delmas ¹⁸	0.670		Mean of values
CT cf Leudde			
Delmas ¹⁸	0.603		Mean of values
Chang ³⁶		<0.05	
CT cf Mourits			
Delmas ¹⁸	0.883		Mean of values
CT cf 3D			
Nkenke ¹¹ 2004	0.963		All patients with zygomatic fractures
Nkenke ⁴¹ 2003	0.237 & 0.958		Healthy & pathological orbits
CT cf CT herniated volume			
Zhang ²⁶		0.005	Suggested location of fracture is important
Whitehouse ⁵	0.870	0.001	
CT cf CT volume change			
Fan ⁴²	0.950	<0.001	
CT volume change cf Hertel			
Schuknecht ⁴³	0.901	0.0002	Results when used as a proportion of overall orbital volume
Choi ³⁷	0.777		
Ploder ²⁸	0.640	0.002	
Jin ³³		<0.05	
CT volume change cf MRI			
volume change cf Hertel			
Kolk ⁷		<0.01	MRI data generally 10.8% higher than CT
CT fracture size cf Hertel			
Sung ⁴⁴	0.812	<0.05	
Choi ³⁷	0.739		
Ploder ²⁸	0.690	<0.001	
Lee ⁴⁵	0.825	<0.0001	
Jin ³³		<0.05	
3D cf Hertel			
Nkenke ¹¹ 2004	0.042		All patients with zygomatic fractures
Nkenke ⁴¹ 2003	0.012 & -0.707		Healthy & pathological orbits

cf: compared with.

Comparability

Table 4 shows the 18 studies that assessed and compared two or more ways of measuring enophthalmos.^{5,7,11,18,26–28,33,36,37,39,40–46}

From all the data collected, we can deduce that the correlation between CT and Hertel's exophthalmometry is highly variable, with coefficients $r=0.033 - 0.988$. This is likely to be because of the nature of the disease being assessed in each study. Both papers by Nkenke et al^{11,41} assessed patients with zygomatic fractures, which will affect the readings from a Hertel's exophthalmometer as the lateral orbital rim is disrupted. When these studies were removed, and only patients with an intact orbital rim were included, the range of correlation improved ($r = 0.670 - 0.988$). This highlights the problems that can arise from use of the Hertel's instrument.

Leudde's and Mourits' exophthalmometers have not been widely researched as yet. Delmas et al¹⁸ suggested that Mourits' was the most closely associated with CT exophthalmometry, and that Leudde's showed the poorest correlation. They found that of all the clinical methods, the Mourits' exophthalmometer had the strongest correlation with CT data, even though $r=0.883$, which was less than some of the r values recorded in studies on Hertel's.

Another method, which is not widely used, is 3-dimensional mapping of the face and correlation with CT data. Nkenke et al seem to be the only group that has published data on this and they showed a strong correlation between CT and 3-dimensional mapping exophthalmometry in patients with orbital blowout fractures. However, there seemed to be poor agreement when the data were used in people with healthy orbits, which may be because most people have a minimal or non-existent relative enophthalmos.

Table 4
Studies that assessed and compared two or more ways of measuring enophthalmos.

Study title	First author and reference	Year of publication	Outcomes
Computed exophthalmometry is an accurate and reproducible method for the measuring of eyeballs' protrusion	Afanasyeva ²⁷	2018	CT cf Hertel
Proptosis–correlation and agreement between Hertel exophthalmometry and computed tomography	Ramli ⁴⁰	2015	CT cf Hertel
Comparison of exophthalmos measurements: Hertel exophthalmometer versus orbital parameters in 2-dimensional computed tomography	Choi ³⁷	2017	CT cf Hertel
Comparability of proptosis measurements by different techniques	Segni ³⁹	2002	CT cf Krahn (Hertel)
Hertel exophthalmometry versus computed tomography and optical 3D imaging for the determination of the globe position in zygomatic fractures	Nkenke ¹¹	2004	CT cf Hertel cf 3D
Relative en- and exophthalmometry in zygomatic fractures comparing optical non-contact, non-ionizing 3D imaging to the Hertel instrument and computed tomography	Nkenke ⁴¹	2003	CT cf Hertel cf 3D
Comparative study of 3 exophthalmometers and computed tomographic biometry	Delmas ¹⁸	2018	CT cf Leudde cf Hertel cf Mourits
Correlation between volume of herniated orbital contents and the amount of enophthalmos in orbital floor and wall fractures	Zhang ²⁶	2012	CT cf CT herniated volume
Prediction of enophthalmos by computed tomography after “blow out” orbital fracture	Whitehouse ⁵	1994	CT cf CT volume
CT assessment of orbital volume in late post-traumatic enophthalmos	Schuknecht ⁴³	1996	CT cf CT volume
The Correlation between the degree of enophthalmos and the extent of fracture in medial orbital wall fracture left untreated for over six months: a retrospective analysis of 81 cases at a single institution	Sung ⁴⁴	2013	CT cf CT volume
Computer-assisted orbital volume measurement in the surgical correction of late enophthalmos caused by blowout fractures	Fan ⁴²	2003	CT volume cf Hertel
Prediction of late enophthalmos using preoperative orbital volume and fracture area measurements in blowout fractures	Choi ⁴⁶	2017	CT volume change cf CT fracture size cf Hertel
Evaluation of computer-based area and volume measurement from coronal computed tomography scans in isolated blowout fractures of the orbital floor	Ploder ²⁸	2002	CT volume change cf CT fracture size cf Hertel
Relationship between small-size medial orbital wall fracture and late enophthalmos	Lee ⁴⁵	2009	CT fracture size cf Hertel
Relationship between the extent of fracture and the degree of enophthalmos in isolated blowout fractures of the medial orbital wall	Jin ³³	2000	CT Fracture size cf CT herniated volume cf Hertel
Clinical exophthalmometry: a comparative study of the Luedde and Hertel exophthalmometers	Chang ³⁶	1995	Hertel cf Leudde
Secondary post-traumatic enophthalmos: high-resolution magnetic resonance imaging compared with multislice computed tomography in postoperative orbital volume measurement	Kolk ⁷	2007	CT volume change cf MRI volume change cf Hertel

cf: compared with.

Errors in measurement will create a considerable disparity in the correlation because of the small values measured, but this is purely hypothetical. When all the data from CT and 3-dimensional exophthalmometry were collated,^{11,41} there was no correlation between Hertel's and CT or 3-dimensional exophthalmometry but, as before, there remained a strong correlation between the latter two methods (Fig. 2).

Changes in volume within the orbit also seem to correlate well with the degree of orbital proptosis, particularly when CT exophthalmometry is compared with changes in orbital volume on CT. The results were more variable when volume data were compared with Hertel's measurements, but they still showed a moderate to good correlation.

Finally, across several studies the size of the fracture, as calculated from CT data, again showed a moderate to good correlation with Hertel's exophthalmometry. When we

put the raw data together and assessed them as one data group,^{33,45} there was a good correlation coefficient ($r=0.836$ (95% CI 0.7186 to 0.9069, $p<0.0001$). We were also able to create a linear regression line between the two methods (Fig. 3).

Discussion

The studies show that CT exophthalmometry seems to be the most reliable method of measuring proptosis of the globe. This is most commonly done by measuring a perpendicular axis to a horizontal line drawn between the two lateral orbital rims.¹⁸ Sometimes when the lateral orbital rim is disrupted (such as in certain orbital fractures), a mirror image of the unaffected side can be a reference, using the nasal septum

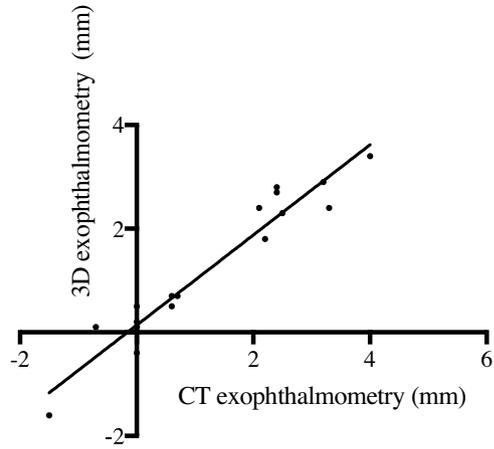


Fig. 2. Correlation between 3-dimensional and computed tomographic exophthalmometry ($3DE = 0.87 CTE + 0.14$, where $3DE = 3$ -dimensional exophthalmometry (mm) and $CTE = CT$ exophthalmometry (mm)).⁴¹

as a midline plane. This depends, however, on there being no appreciable facial asymmetry or disease of the midface, particularly of the nasal septum (Fig. 4). This is a simple and quick measurement that can be done without a specialist radiologist. Most patients who present with a possible orbital fracture will have a diagnostic CT, and this will allow it to be of double benefit as it could help to indicate the most appropriate management.

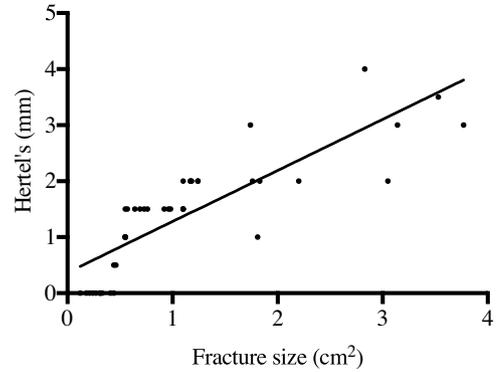


Fig. 3. Collaborated data of fracture size compared with degree of exophthalmos ($E = 0.793A + 0.524$, where $HE =$ Hertel's exophthalmometry (mm) and $A =$ area of fracture (cm^2)).^{33,45}

While methods such as Hertel's and Mourits' exophthalmometers may not be as reliable as CT data, they enable patients to be monitored frequently without the obvious risk of exposure to radiation.

It is important to recognise that accurate use of these clinical exophthalmometers depends on experience.^{18,21} This focuses on the fact that accurate measurement is difficult, and if the results are to be trusted, it is a skill that must be appropriately taught and mastered.

One of the most confounding issues when dealing with orbital blowout fractures, is that in the acute phase there is

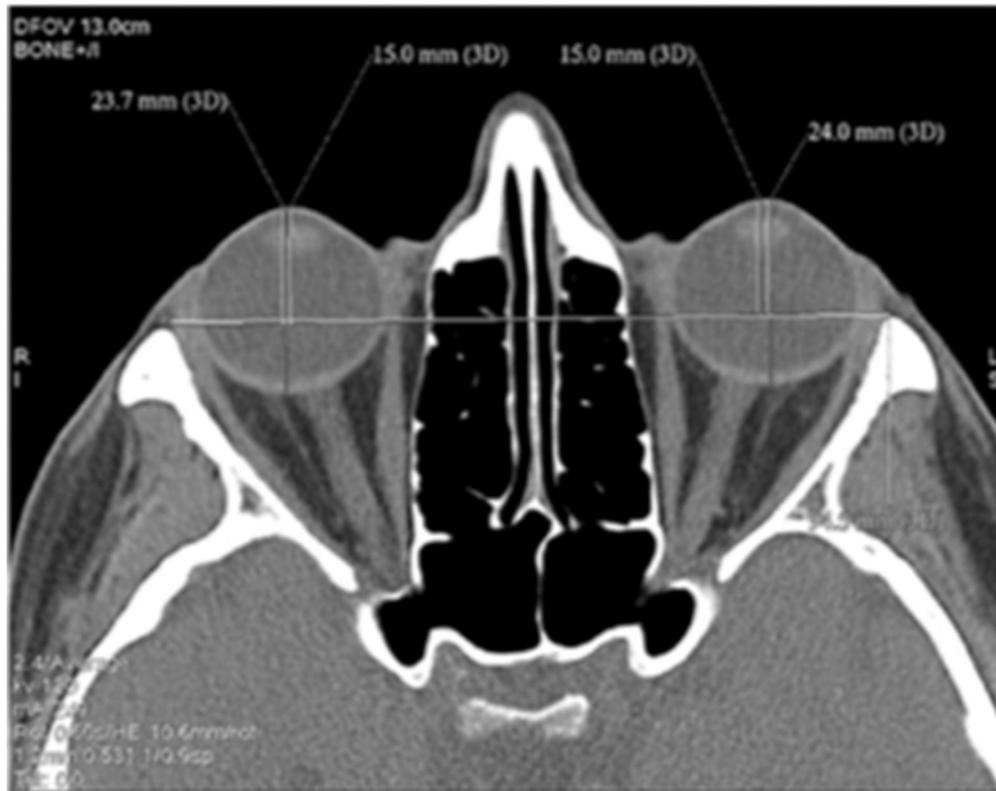


Fig. 4. Measurement of proptosis by computed tomography, showing axial proptosis (in reference to the lateral orbital rims) of 23.7 mm in the right eye, and 24.0 mm in the left.¹⁸

often a considerable amount of intraorbital swelling,^{5,13,14,47} which can result even if there is no relative enophthalmos, regardless of fracture size. This makes assessment difficult in terms of the optimal management plan, and some patients who are treated conservatively will subsequently develop late enophthalmos and others may have operations that were not entirely necessary. Both are detrimental to the patient, and have an impact on hospital resources and finances. Whitehouse et al measured the degree of enophthalmos associated with the volume of herniated contents that resulted from an orbital fracture, as measured on CT.⁵ They compared the CT volumetric data with CT exophthalmometry based on the sagittal distance between a line that connected the lateral orbital rims and the posterior surface of the lens. This could be assumed to be a reliable method in this group as none of the patients had involvement of the zygoma or lateral orbital rim. They showed a stronger correlation between the two methods when the observations were taken at least 20 days after injury. This time delay may allow for a large proportion of the intraorbital swelling to reduce, and therefore gives a more accurate prediction of long-term outcome.

The regression line created by these data could be applied to patients who are assessed at an earlier stage, so that a large herniated orbital volume that is identified in the immediate days after injury can help to estimate the final degree of enophthalmos. This would be a useful tool in the early assessment of orbital blowout fractures, and has been validated as accurate.^{24,48} It does, however, have some disadvantages: the calculations usually require a degree of training in the use of Digital Imaging and Communications in Medicine (DICOM) software, which is usually more complex than standard hospital imaging viewers (that include picture archiving and a communications system (PACS)). It is therefore not a simple calculation that can be done in clinic, but something that must be discussed with a radiologist or an appropriately trained professional who has access to suitable software.

We also know that the size of the fracture and volume of displaced tissue are likely to have a crucial role, but it has been postulated that the site of fracture may also have an important impact on outcome.²⁶ Zhang et al assessed the correlation between the volume of herniated tissue and the degree of enophthalmos when fractures are at different sites in the orbit. They found that the strongest correlation was when the fracture was behind the eyeball equator ($r=0.989$, $p=0.001$) when compared with a fracture that was in front of it ($r=0.324$, $p=0.001$). This may be because the support system for the eyeball is behind the orbit, and damage in this area may disrupt the mechanism.^{26,49}

In conclusion, this review suggests that current best practice is to use CT data to extrapolate the degree of orbital proptosis with the measurement method described above. In acute orbital blowout fractures when long-term sequelae are uncertain, CT data should be used to ascertain the volume of tissue that has herniated through the fracture site, and this

used to predict the degree of enophthalmos with the following equation, as described by Whitehouse et al:⁵

$$E = 0.77 V - 0.68$$

Where, E = enophthalmos (mm) V = herniated volume (cm³)

The site of the fracture should also be considered, and greater importance placed on fractures in the posterior aspect of the orbit, which are less likely to require surgical intervention. Until 3-dimensional imaging becomes more widely available, Mourits' exophthalmometers should be used for ongoing reviews of patients with enophthalmos to limit the exposure to radiation. To ensure that these observations are reliable, clinicians should be trained to use the exophthalmometer appropriately.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

Not applicable.

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