Universitat de Girona

Facultat de Medicina

ORBIT SIZE IN CT IN PATIENTS WITHOUT PRIMARY INDICATION FOR SURGERY VS DIPLOPIA AND ENOPHTALMOS

FINAL DEGREE PROJECT

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1.- Abbreviations:

QOL: Quality of Life

BOF: Blow out fracture.

EOM: Extraocular muscle

2.- ABSTRACT: ORBIT SIZE IN TC IN PATIENTS WITHOUT INLCUSION CRITERIA VS DIPLOPIA AND ENOPHTALMOS

Background: Diplopia and enophthalmos is a common complication among patients with not surgical criteria. There is still debate regarding which is the best inclusion criteria for this surgery. Studies have shown that anywhere from 0.5 cc to 1 cc of increase in orbital volume will create approximately 1 mm of enophthalmos.

Unfortunately, it was not easy for most clinicians to calculate orbital volumes, because software to automate this process was not readily available.

Nowadays we actually have the software to calculate the orbital volumes.

Objective: The aim of this studio is to compare the increase of the orbit volume with rates of diplopia and enophthalmos in patients which do not have actual inclusion criteria for surgery at the moment of the trauma, with long term objective of reviewing the actual inclusion criteria for surgery.

Design: A prospective cohorts study.

Non probabilistic sampling will be performed in order to obtain our patients. The study is planned to last 10 years; each patient will have a follow up of 6 months. All the patients included must have a CT scan at the moment of the trauma and end the follow up period.

Setting: This cohorts study will take place in the Hospital Josep Trueta.

Participants: Adult patients with an orbit pure fracture without inclusion criteria for surgery that arrive to the emergency room of the Hospital Josep Trueta. The patients will follow up the actual protocol of the hospital, with the difference that

we will look the volume of the orbit at the CT at the moment of the trauma. While the follow up of these patients run as usual, we will look the ratio of diplopia and enophthalmos that appear as the increase of the orbit.

Key words: Orbit fracture. Volume of the orbit in CT. Diplopia and enophthalmos. Size of the orbit. Not surgical patients with Orbit fracture. Blow out fracture.

3.- Introduction:

Orbital fractures are common facial injuries. They deserve special consideration because they are challenging to manage. Orbital trauma is the second leading cause of blindness, so the first priority for these injuries is the health of the globe. Most orbital fractures occur in males in their second decade of life. In adults, motor vehicle accidents and assault are the most common mechanisms of injury.

a) Epidemiology:

Trauma to the eye represents approximately 3% of all emergency department visits in the United States (1). Frequency of orbital fractures in them is however not reported. Maxillofacial fractures are a huge cause of morbidity and they can have aesthetic and functional consequences. The epidemiology of these lesions varies in type, severity and causes depending on the population studied (2,3).

The geographic area and socioeconomic status of the population can affect the results of different studies. However, recent studies show that damage to the skull maxillofacial area are usually caused by trauma, specifically motorcycle accidents, assaults and falls (4-8). Data collection of maxillofacial fractures long term is important because it allows the development and evaluation of preventive measures. Unfortunately, there

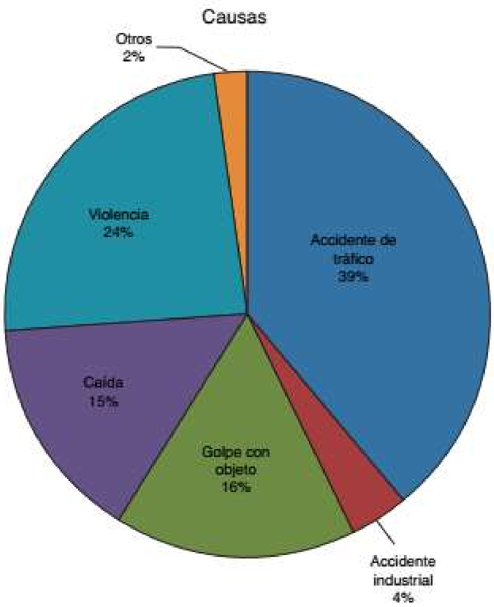

Chart 1: Estudio descriptivo. 1130-0558/© 2013 SECOM

is a lack of descriptive studies of patients with facial trauma and there is little information available on the incidence and causes (9).

A descriptive study of facial fractures in a Chilean trauma center, studied a population consisted of 283 patients, 259 (91.5%) males and 24 (8.5%) females with a mean age of 40.5 (SD: ± 20.5) years. In 499 fracture sites, zygomatic fractures were the most prevalent location of the 499 fracture sites, in both males and females (48%), followed by **orbital fractures (27.2%)**, and jaw fractures (21.2%). The most common type was isolated mid-facial fractures. Traffic-accident-related fractures were the most common cause (39.2%), with the largest proportion of these involving a car accident.

Tabla 1 – Distribución de la edad y el género de las fracturas maxilofaciales

Rango de edad	Violencia	Golpe con objeto	Accidente industrial	Accidente de tránsito	Caídas	Otros	Total
10 a 19	2	1	0	0	1	0	4
20 a 29	10	7	4	29	10	2	62
30 a 39	14	12	2	28	13	2	71
40 a 49	23	12	2	21	11	3	72
50 a 59	13	9	1	22	7	1	53
60 o más	5	3	1	11	1	0	21
Total	67	44	10	111	43	8	283

Chart 2: Edgardo Gonzalez, Christian Pedemonte, Ilich Vargas, Diego lazo, Hernán Pérez. Hospital Clínico Mutual de Seguridad C.Ch.C, Santiago, Chile. Fracturas faciales en un centro de referencia de traumatismos nivel 1, Estudio descriptivo. 1130-0558/© 2013 SECOM. Publicado por Elsevier España,

b) Anatomy:

Most surgeons describe the orbital fractures according to the location within the orbit (floor, medial wall, lateral wall, and roof). Several classification schemes have been proposed to define isolated, multiwalled, and comminuted orbital fractures, as well as, soft tissue displacement (10). Orbits are bone cavities of the facial skeleton with deep quadrangular pyramid shape. The medial walls of the two orbits are split by the two ethmoid sinus and the superior portions of the nasal cavity, while the lateral walls delimit almost in a 90 degrees angle.

Accordingly, the orbital axes diverge about 45 degrees. However, the optical axis of the two eyes are parallel. The orbits contain and protect eyeballs and visual accessory structures, including:

- Eyelids, which limit the orbits ahead and control the previous exposure of the eyeball.
- Extraocular muscles that move the eyes and raise the upper eyelids.
- Nerves and vessels leading to the eyes and muscles
- Orbital fascia surrounding the eyes and muscles.
- Mucous membrane lining the eyelids, the anterior region of the eyeballs and most of the lacrimal system, which lubricates.

All the intraorbital space which is not occupied by the structures just mentioned, is filled with orbited grease, which forms a matrix in which the structures of the orbits are included.

Orbital pyramid has a base four walls and a vertex:

- The base of the orbit is limited by the orbital rim surrounding orbital opening. The bone which forms the orbital rim is reinforced to protect the orbital contents and provides an insert to the orbital septum as a discontinuous fibrous layer that is located inside the eyelids.
- The top wall (roof) is almost horizontal and is mainly formed by the orbital portion of the frontal bone, which separates the orbital cavity of the anterior cranial fossa. Near the apex of the orbit, the top wall is formed by the lesser wing of the sphenoid. In the anterolateral part, a shallow depression of the orbital portion of the frontal, called fossa for the lacrimal gland, accommodates this gland.

- The medial walls of the two orbits are substantially parallel and are formed especially by the ethmoid bone, with contribution from frontal, lacrimal and sphenoid. Anteriorly, the medial wall is indented by the lacrimal groove and the pit for the lacrimal sac. Most of the bone that forms the medial wall is as thin as paper; ethmoid bone is much pneumatized in the ethmoid cells, which are often visible through the skull bone dry.
- The inner wall (floor) is formed mainly by the jaw and partly by the zygomatic and thin bottom wall palatino. The thin bottom wall is shared by the orbit and the maxillary sinus and slopes downward from the apex to the inferior orbital rim. The bottom is separated from the side wall of the orbit by the inferior orbital fissure.
- The lateral wall is formed by the frontal zygomatic's apophysis and the greater wing of the sphenoid. It is the thickest and strongest wall of the orbit, which is important because it is the one most exposed to direct trauma. Its rear portion separates the orbit of temporary graves and middle cranium. The sidewalls of the two orbits are approximately perpendicular to each other.
- The apex of the orbit is located in the optic canal in the lower wing of the sphenoid, medial to the superior orbital fissure.

The wider region of the orbit corresponds to the eyeball ecuador, an imaginary line around the eye, halfway between their anterior and posterior poles.

The bones of the orbit are covered by the periorbita (periosteum of the orbit). Periorbita continues in the optical conduit and the superior orbital fissure by the periosteal layer of the dura. It also continues orbital edges and through the inferior orbital fissure with the periosteum covering the outer surface of the skull (scalp), with orbital partitions in the orbital edges, with the fascia of the extraocular muscles and orbital fascia forms the fascial layer of the eye.

The orbital rim is strong to protect the contents of the orbit. However when blows are strong enough and the impact takes place in the bone edge, the resulting fractures usually occur in the sutures between the bones that form the orbital rim. Because of the thinness of the medial and lower walls of the orbit, a blow to the eye can fracture the orbital walls while the edge remains intact. An indirect traumatic injury displacing the walls of the orbit is called a burst fracture. Fractures of the medial wall may affect ethmoid, and sphenoid sinuses, while the bottom wall fractures can affect the maxillary sinus. Although the top wall is stronger than the middle and the bottom, it is thin enough to be translucent and can be easily penetrated. So a sharp object can pass through and into the frontal lobe of the brain. Orbital fractures often cause intraorbital bleeding, which puts pressure on the eye and cause exophthalmos. Any trauma to the eye can affect adjacent structures; for example, bleeding in the maxillary sinus, displacement of the maxillary teeth and fracture of the nasal bones that produce bleeding, airway obstruction and infection can spread into the cavernous sinus through the ophthalmic vein.

Extraocular muscles (EOM) also are quite important in these types of trauma. Several times they get trap during the trauma turning into criteria for the surgery. These muscles work together to move the globes and the eyelids. Even the action can be described alone, the function of theses muscles usually come in group, moreover no one usually works alone (11).

Muscle	Origen	Insertion	Enervation	Function
Levator palpebrae superioris	Sphenoid bone	Tarsal plate of upper eyelid	Oculomotor nerve	Retracts and elevates eyelid
Superior Oblique	Sphenoid body bone	Eye	Trochlear Nerve (NC IV)	Abduction/ depression/ intorsion
Inferior oblique	Anterior portion of the orbit floor	Eye	Oculomotor Nerve (NC III)	Abduces/ elevation/ extorsion
Superior rectus	Annulus of Zinn	Eye		Elevation / adduction / intorsion
Medial rectus				Adduction
Inferior rectus				Depression/ adduction/ intorsion
Lateral rectus			Abducens nerve	Abduction

Chart 3: EOM. Keith L.Moore, Arthur F. Dalley II, Anatomía con orientación clínica, quinta edición año 2007

c) Mechanism of injuries

There is no direct contact of the bony walls with an external object at the moment of the injuries, so the physical mechanism of the blowout fractures has been debated for years by a lot of specialists. There are 3 main theories: the hydraulic theory, the globe to wall contact theory, and the bone conduction theory. Maybe the oldest one is the bone conduction theory, which suggest that a force, not powerful enough to a fracture the rim, will propagate along the bone to fracture de weaker orbital floor (Le Fort). In 1943, Raymond Pfeiffer proposed the “Globe-to-Wall Theory”, which is when a force pushes the globe into the orbit and causes the globe to contract the orbital floor, resulting in a floor fracture (12). A very much popular theory is the “hydraulic mechanism”, whereby the fracture is the result of increased intra-orbital pressure from the eye entering the orbit and not due to direct contact (13,14). Because of the large variety of blowout fractures that are seen, it is presumptuous to believe that one theory may explain all types of fractures completely, so there should be more than one mechanism occurring simultaneously. The cause is likely a conglomeration or some iteration of all three.

d) Types of injuries

There are many types of orbital fractures, and they can be distinguished into 2 main types: pure and impure. Impure ones are those that involve the orbital rim(s), for examples: zygomatico-orbital, naso-orbito-ethmoid, Le Fort maxillary, and supraorbital rim fractures. Impure orbital fractures are more common that pure, with fractures, o the zygomatic complex being the most common orbital fractures (15,16). The blowout fractures (BOF) refers to a fracture involving only the orbital inferior and/or media wall, where the walls are thinner, with an intact orbital rim. The treatment in case of impure orbital fractures is essentially the same. The main difference is that when treating impure orbital fractures, the orbital rims must first be placed into proper position before internal orbital reconstruction.

The eye is the first priority for any periorbital injury, and it is wise to have ophthalmologic consultation on all internal orbital fractures. Studies have shown that an ophthalmologist can discover injuries that are not recognized by non opthalmologists* (17,18). A thorough periocular and ocular examination should be performed, looking for foreign bodies, laceration/rupture of the globe, retinal detachment, lens dislocation, and other signs. The mobility of the globe is also very important, because there is always the chance that the extraocular muscles and periocular tissues can be incarcerated into the fractures lines or by jagged pieces of bones. Visual acuity, pupillary response, and fundoscopic examinations are mandatory. Once knowing the mechanisms of BOF discussed previously, one would expect that there should be a large association between the blowout fractures and traumatically induced ocular injuries, especially with the hydraulic and the globe-to-wall theories, because in both, the force is delivered directly to the ocular globe. The most common ocular findings, such as commotion retinae, traumatic mydriasis and traumatic iritis, y themselves or in combination, are usually self-limiting and would not usually prohibit the repair of orbital fractures after the injury (17,19,20,21).

e) Diagnosis and clinical Findings

As in other facial injuries, the diagnosis and severity of orbital fractures are based on clinical and imaging findings. Orbital fractures are commonly missed in unconscious, traumatized patients. Most of the clinical findings for patients with blowout fractures are nonspecific and are similar to other fractures involving the orbit (impure fractures). Palpation of the orbital rims can be difficult in patients with marked swelling and tenderness, as the intense edema that can accompany this injury makes the clinical examination extremely difficult.

Subconjunctival ecchymosis is a nonspecific finding that is of limited value. Orbital emphysema is common with internal orbital fractures, especially those involving the medial wall. Infraorbital nerve dysfunction is extremely common with zygomatico-orbital, Le Fort, and pure internal orbital fractures. This can be one of the easiest things for an emergency room physician to check on a patient with a history of being struck in the eye. If their infraorbital nerve is dysfunctional, it is almost certain that there is a fracture of the floor of the orbit (22). The most important portion of the clinical examination is the ocular examination. Limitation in the ability to move the eye can make one suspect that there is an orbital fractures. Whether a muscle is incarcerated is not usually possible to determine by simply asking the patient to move the eye. A forced duction test is the most useful method to make this determination, but it is often not easily performed or diagnostic in the awake patient. Clinical examination cannot thoroughly assess the presence and severity of internal orbital fractures. For this reason, imaging is necessary and mandatory in this kind of fractures. It is mandatory that an eye exam is done promptly to mitigate the risk of vision loss or vision compromise. Blindness associated with orbital fractures has been reported at 0.7%-10%.

f) Imaging

CT imaging remains the gold standard for detecting and defining orbital fractures. Global imaging of the entire face is recommended as concomitant fractures are commonly encountered. Coronal and sagittal reconstructions (axial slice thickness <2mm), and 3D rendering is recommended to optimize maxillofacial assessment. Bone windows can show fractures, but the soft tissue window is best for evaluating the position of the ocular muscles and their relationship to the fractures lines. (see Figure 1: CT). The most common error made when treating orbital fractures is not appreciating the full extent of the injury. Therefore, one should obtain and thoroughly study the CT scans.

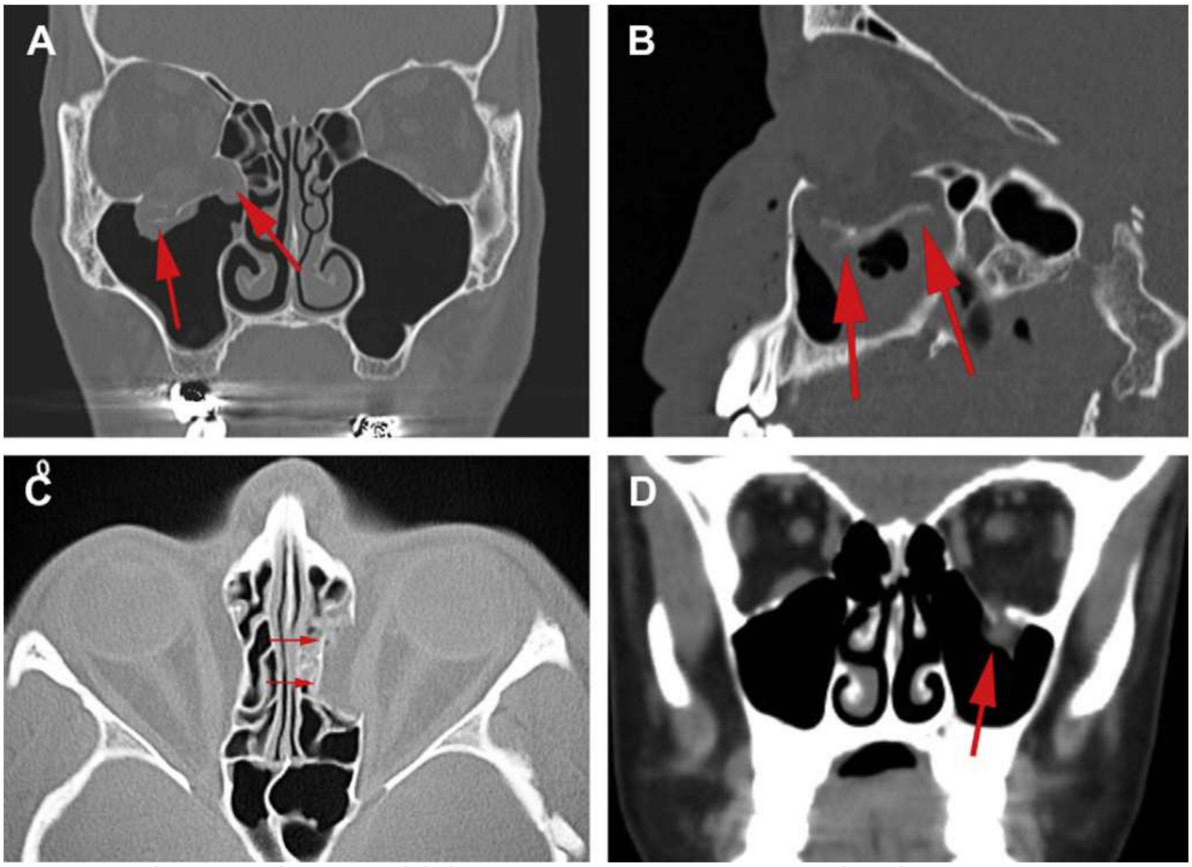

Figure 1: CT scans of the orbit. (A) Coronal cut showing a large orbital floor fracture that is displaced inferiorly (arrows). (B) Sagittal cut showing a large orbital floor fracture that is displaced inferiorly (arrows). (C) Axial cut showing a medial blowout fracture (arrows). (D) Soft tissue window showing the inferior rectus muscle entrapped in an orbital floor fracture. Soft tissue windows show the muscles much better than bony windows. Edward Ellis III, DDS, MS Orbital Trauma Department of oral and Maxillofacial surgery of university of Texas.

g) Surgery Criteria for Orbit fractures

A very common debated topic is which internal orbital fractures require treatment and which not. There are different opinions, but there are 2 major reasons why these fracture are treated: globe malposition and diplopia. Globe malposition from a pure blowout fractures will manifest as enophthalmos and/or hypophthalmos and has been shown to be the result of changes in the volume of the orbit (23,24). Studies have shown that most patients will notice once there is 2 to 4 mm of globe malposition (25,26). Just how much internal orbital disruption is necessary to cause clinically apparent enophthalmos and/or hypophthalmos has been the subject of several studies. The studies have also shown that the amount of internal orbital disruption is related to the amount of globe malposition that may become manifest (23,24,27-34). However, it is clear that it is not just the amount of orbit involved with the fractures or defect but also the location of the defect and the amount of periorbital soft tissue herniation that are important for the development of clinically obvious enophthalmos. In particular, defects that are located at the junction of the floor and medial wall of the orbit are those most prone to cause enophthalmos (15,35). This is the area of convergence of the floor and medial wall and is a convex surface just behind the globe. Anatomically it is the upward bulge of the maxillary sinus and is critical in maintaining the forward position of the globe. When this area is comminuted, the patient will likely have some globe malposition after healing (15,35). Studies have shown that anywhere from 0.5 cc to 1 cc of increase in orbital volume will create approximately 1 mm of enophthalmos (28,31,32,34,36). Unfortunately, it is not easy for most clinicians to calculate orbital volumes, because software to automate this process is not readily available.

Compounding the decision about which orbital fractures require reconstruction is that globe malposition is not common immediately after injury because of associated orbital haemorrhage and swelling that commonly occurs. For acute injuries, imaging findings are a more sensitive method of evaluating the extent of injury that the clinical examination of globe position. For assessment of ocular position before the onset or after the resolution of edema, an exophthalmometer is the best way to clinically measure the relative anteroposterior position of the globes. With Hertel exophthalmometer, the measurement is taken from the lateral orbital rim to the corneal apex. If a patient presents with an orbital fracture or after lateral orbitotomy, the use of Hertel exophthalmometer may be complicated because the lateral orbital rim serves as a reference point for this instrument. Consideration should be given to the use of the Naugle exophthalmometer in these cases.

The second potential reason to reconstruct the internal orbit is to prevent or treat diplopia. However, binocular diplopia is not a sensitive indicator for the need for internal orbital reconstruction early after injury. Most patients will have diplopia immediately after an orbital fracture secondary to intraorbital edema. However, persistent diplopia may be 1 reason for performing reconstruction of the internal orbit, because it may be the result of soft tissue entrapment, displacement of the globe, and displacement of the origin of extraocular muscles. In such cases, surgical dissection and freeing the soft tissues from bone fragments and reconstruction of the bony orbit may improve diplopia. However, one would never operate based solely on the symptom of diplopia. Imaging evidence of a fracture or defect would also be necessary. Choose which orbital fractures require treatment is the main challenge, because the problem associated with not treating some is deformity such as globe malposition, and possibly diplopia, this is why the importance of this study. The potential benefits of internal orbital reconstruction have to be weighed against the possible iatrogenic injuries that attend surgical correction. Asymmetries of the palpebral fissure secondary to surgical intervention have been demonstrated in up to 20% of surgical approaches to the orbit (37). There are factors that are useful in deciding on whether a pure BOF requires internal orbital surgery, and these can be write down in to the following indications:

- Absolute indications such as acute enophthalmos and/or hypoglobus or mechanical restriction of ocular motility. If a patient with a fresh injury presents with acute enophthalmos and/or hypophthalmos, it is almost certain that he or she has a very large internal orbital defect. CT confirmation is necessary, but it will be very unlikely to show anything less than a huge defect with periorbital soft tissue herniation into adjacent sinuses. If a patient has severe restriction of ocular motility, it is likely that he or she has incarceration of periorbital soft tissues into the fracture line. This can sometimes be verified with CT), but a forced duction test is the best method for diagnosis (see Figure 2: duction). In such cases, surgery to free the soft tissue and reconstruct the orbital defect(s) will be necessary.

Figure 2: duction: Photograph showing forced duction test being used to check for incarceration of tissues below the globe. The forceps grasp the insertion of the inferior rectus muscle, and the eyeball is rolled upward. In this case, the test is negative, meaning that the eye moves fine. A positive forced duction test is a test in which the eye does not move properly. The movement of the eye can be checked in all directions by grasping the other rectus muscles and rolling the eye in other directions. Edward Ellis III, DDS, MS Orbital Trauma Department.

- Relative indications such as conditions likely to cause enophthalmos and/or hypoglobus or persistence of diplopia. Conditions likely to cause enophthalmos and/or hypoglobus are a relative indication for surgery.

Conditions likely to cause orbital malposition are large internal orbital defect(s) and can be identified with CT scans. Thus, when a patient is seen with defects of the internal orbit, especially those with fractures in the critical area at the junction of the floor and medial wall (see Figure 3: CT), reconstruction of the internal orbit is often recommended to prevent the development of globe malposition. The other relative indication for surgery is a nonresolving diplopia, especially when the diplopia is in a cardinal field of gaze (forward, downward) and especially when correlated with CT evidence of orbital soft tissues disrupted and extending into the disrupted orbital wall.

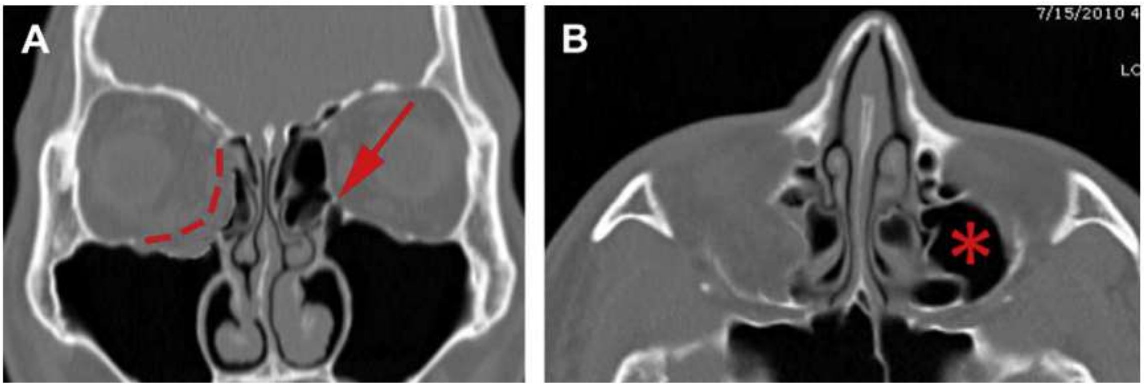

Figure 3: CT. CTs showing the location of the transition zone between the floor and the medial wall. (A) Coronal CT of a combined medial wall/orbital floor fracture of the right orbit demonstrating the great gain in orbital volume by blowout of the transition zone (dashed lines indicate normal anatomy). The arrow on the uninjured (left) orbit demonstrated the location of the transition zone. (B) Axial CT scan showing the location of the upward bulge of the maxillary sinus of the left orbit (asterisk) and its loss on the right orbit, where a fracture of the transition zone has blown out this area. Edward Ellis III, DDS, MS Orbital Trauma Department.

- Relative contraindications such as ocular injuries (eg, hyphema, retinal tears, lens displacement) or the fracture has occurred in the only seeing eye. Vision is much more important to the patient than the position of the globe within the orbit. Therefore, any condition that puts the globe in jeopardy may be a contraindication to internal orbital reconstruction. For instance, a lacerated globe or hyphema may put the globe at further risk by the retraction necessary to perform internal orbital surgery. In such cases, the ophthalmologist will be the individual to make the recommendation about if and when surgery of the internal orbit might be performed. The other thing that must be considered is the status of the noninjured eye. If the patient has no sight in the other eye, one has to be very careful about recommending surgery of the only seeing eye to help prevent globe malposition. Diplopia (binocular) would not be possible in such a patient, so the only reason to perform surgery other than severe restriction of globe motion secondary to incarceration of soft tissues would be to prevent globe malposition. Certainly, in cases when the fracture involves the only seeing eye, the patient must be the one who decides about the worth of internal orbital reconstruction.

h) Timing of treatment

While deciding on which orbits require reconstruction is an important task, deciding on the timing of repair is another. In the 1960s, orbital blowout fractures were considered medical emergencies and so were treated early. A landmark study in 1974 by Putterman and colleagues (38) completely changed the thinking about timing and even the worth of treatment. The results of this study changed the recommendations about treatment of orbital blowout fractures for the next 20 years. The recommendation from Putterman was that orbital blowout fractures should not have any internal orbital reconstruction for 4 to 6 months. One must recall that Putterman's study was in the days before CT scanning, so the amount of internal orbital disruption could not be accurately assessed. Once CT scanning became available and surgeons were able to clearly see the amount of internal orbital disruption, the thinking about which fractures should be treated and their timing changed.

- Immediate Repair: There is one condition that would mandate early repair/entrapped tissues within the fracture line that are causing severe functional limitations/problems especially and predominantly in children.
- Repair within 2 weeks: Most adult orbital blowout fractures that require treatment fall into this category. For instance, those patients with no restriction of ocular motility (or negative forced duction test) but acute enophthalmos and/or hypophthalmos, or those orbits whose CT shows that they will likely develop globe malposition if not treated, fall into this category. There are no urgency patients, and surgery can be deferred until periorbital edema has subsided and/or the patient's medical condition is stable. One should remember that intraorbital edema will limit the amount of surgical exposure that can be obtained, waiting until the edema has subsided in such cases not only may allow the surgeon to attain a better repair, but it may lessen the possibility of globe injury. Another condition that can be treated nonacutely but within the first few weeks is a patient with an adult orbital fracture associated with symptomatic diplopia, some restriction of motion and/or positive forced duction test, and evidence of periorobital soft tissues within the fracture on CT with minimal improvement over time.
- Observation with the Possibility of Later Repair: Patients with orbital fractures associated with minimal diplopia, good ocular motility, no significant enophthalmos and/or hypophthalmos, and a CT scan that shows a defect not likely to result in enophthalmos and/or hypophthalmos can be observed. Should symptoms and/or globe position become problematic, intervention can proceed at that time. Many patients in clinical practice fall into this category.

i) Medical management of internal orbital fractures

Patients who present with internal orbital fractures should be managed medically whether or not they are going to undergo surgical repair. There are several considerations.

- Periorbital Swelling: we should do all measures to help reduce the edema, if the patient is seen before the onset of swelling, steroids can be administered to help reduce the amount that will occur (39). However, a head-up position while in bed will help promote the resolution of edema over the course of days.
- Sinus Precautions: the patient should be told to avoid blowing their nose; not only can this force sinus bacteria into the periorbital tissues, but an immediate air emphysema of the orbital and periorbital soft tissues can occur.
- Antibiotics: there is no convincing evidence that antibiotics are of any value for orbital fractures, and therefore they should be used with discretion.
- Blood pressure: the blood pressure should be managed if it is high, because this can lead to increased bleeding into the orbital and periorbital compartments.
- Anticholinergics: Assuming there are no contraindication to this medication, any patient who has severe bradycardia when attempting to move the eye should have an anticholinergic administered until the trapped periorbita can be freed with surgery.
- Ocular Pressures: An increase in ocular pressure is usually medically managed by the ophthalmologist. If the intraocular pressure is less than 30, medical treatment may be helpful (ie, steroids, acetazolamide,

mannitol, or topical timolol). When the intraocular pressure is higher, immediate surgical decompression is indicated (ie, lateral canthotomy with inferior cantholysis, incision, and drainage).

- Clotting: Patients should not be placed on aspirin or other medications that interfere with clotting. Patients already on anticoagulant/antiplatelet medication must be watched carefully for signs of orbital or periorbital hematoma.

4.- Justification

Over the past decades, the advent of new technology in oculoplastic surgery and comprehensive knowledge of the complex anatomy of the internal orbit have revolutionized the management of orbital trauma. Enophthalmos, a common sequel following orbital trauma, is usually inadequately treated and sometimes is not diagnosed on time. Despite these new advances, it is difficult to identify patients who are at risk of enophthalmos. These challenges are further complicated by the controversial indications, surgery timing and surgical techniques of exposure and reconstruction. We present a prospective study, evaluating the long-term enophthalmos and diplopia that appears in patients who has an increased volume of the orbit at the moment of the trauma; so we can describe the relation between the rise of the orbital volume and the presence of long-term complications.

Studies have shown that anywhere from 0.5 cc to 1 cc of increase in orbital volume will create approximately 1 mm of enophthalmos (6,28,31,32,34). Unfortunately, it was not easy for most clinicians to calculate orbital volumes, because software to automate this process was not readily available. Nowadays with an accurate software we are able to size the orbit volume, making us much easier compare the healthy orbit with the traumatic one.

5.- Hypothesis:

Primary Hypothesis: An increased size of the orbit at the moment of an orbital fracture will increase the rates of diplopia or enophthalmos.

6.- Objectives:

Primary objective: This study aims to get a new inclusion surgical criteria for decrease the secondary effects in not surgical recoveries.

Secondary objective: The use of this software to look for the size of the orbit in the CT scan at the moment of the injury will produce a new protocol with new surgical inclusion criteria, decreasing all the secondary effects in not surgical recoveries.

Moreover, the use of this new protocol, will report a better quality of life to the patients that would have not been treated with surgical treatment by to the old criteria.

Also, we are looking to improve the quality of life of these patients by increasing their vision and the aesthetics aspects of the orbit as well.

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7.- MATERIAL AND METHODS

7.1 Study design

In order to be able to confirm or refuse our hypothesis with the level of evidence expected, we propose a prospective cohorts study.

The patients will be follow by 6 months after the trauma. Will not suppose a problem for them because if the actual protocol of managing this fractures.

7.2 Setting and population of the study

The study will take place in the Hospital dr Josep Trueta.

The study population is based in patients attending the emergency department of the hospital who are diagnosed of orbital pure fractures without surgery inclusion criteria. The diagnosis would be confirmed by orbital CT.

7.2.1 Inclusion criteria

- Patients > 18a.
- Patients diagnosed of orbital pure fractures: only fractures of roof, floor, medial or lateral floor, with no other face bones fractured.
- Patient with no actual inclusion criteria for primary surgery.
- Patients who have read the information sheet for participants and have signed the Informed consent form.

7.2.2 Exclusion criteria

- Patients with life expectancy < 6 months (judged by the investigator).
- Patients with criteria for surgery
- Not availed CT or bad quality scan.

- Patients with history of facial or orbit trauma.
- Patients who already has diplopia or enophthalmos before the trauma.

7.3 Sampling

7.3.1 Patient selection.

The sample recruitment will take place at Hospital dr Josep Trueta during 9 years and a half approximately. A consecutive non-probability sampling will be performed.

Patients with that came to the emergency room with orbital fractures will be potential candidates for our study. If the patients meet all the inclusion criteria, they will receive an information sheet which describes the study. If the patient accepts to participate in our study, we will proceed to give the informed consent form. We will follow up him over 6 months, including the patient data in our study.

7.3.2. Sample Size

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 73 exposed subjects and 73 in the non-exposed are necessary to recognize as statistically significant a relative risk greater than or equal to 1.5. A proportion in the non-exposed group has been estimated to be 0.5. It has been anticipated a drop-out rate of 10%.

We have calculated the necessary sample with the program GRANMO calculator. The Poisson approximation has been used.

We estimate a relative risk of 1.5 according to low data published in previous studies and also according to clinical experience of the surgeons of our hospital.

We calculate that to manage to reach the required number of patients to carry out our study we will need 9 years and a half approximately.

We rely in the information provided by our hospital to state that estimation. According to data accessed by the maxillofacial surgeons, the Hospital Trueta treat about 30 to 40 patients with no surgical criteria per year. We need 73 patients per level of increased volume to be able to compere between then.

Probably, less level 4 and 3 patients will be found, so the time length of the study may be longer than founding 292 inclusion criteria for the study patients.

	Increased in cm3 respect the healthy orbit	Number of sample
Level 1	<0,5 cm3	73
Level 2	0.5 -1 cm 3	73
Level 3	1 -1.5 cm3	73
Level 4	>1,5 cm3	73
Total patients		292

7.7.4 Variables

7.4.1 Independent variables

The independent variable is represented by the increase of the volume of the orbit comparing it to the healthy one at the moment of the trauma. We make this variable qualitative ordinal, dividing the increase of the orbit in four different levels, where level 1 is the lowest one with an increase of less than 0,5 cm^3, level 2 goes from 0.5 to 1cm^3, level 3 goes from 1 to 1.5 cm^3 and level four goes ahead from 1,5 cm^3.

7.4.2 Main dependent variable.

The dependent variable in our study will be whether or not the diplopia and enophthalmos rates are higher in big volume increments. This is a dichotomous qualitative nominal variable and therefore it will be expressed in proportions or percentages.

7.4.3 Secondary dependent variables

Quality of life: QOL will be measured using the SF-36 questionnaire. The questionnaire will be administered to patients from four groups of treatment and we can define it as a quantitative discrete variable.

7.4.3. Covariates

The covariate variables are other factors that can influence our result as they are related with our independent and dependent variables. We will include them in the multivariate analysis in order to assess its impact in the future results.

- Concerning the patients:
    - Gender (male or female) dichotomous variable.
    - Age (measured in years) continuous variable.

- Concerning the medical care:
    - Total follow-up appointments in 6 months: it is a quantitative discrete variable.

7.5 Data collection

For the process of data collection, the communication between the emergency department and the departments of maxillofacial surgery and radiology services will be very important. All the personal will have to work together for data collection; the maxillofacial surgeons will inform the rest of the members of the unit about the study that is being carried out. Also, the patients will play an important role in our study as long as we need them to help us complete the case report form and they must fill in the QOL questionnaires during the follow up. SF-36 which consists of nine scaled scores including: general health, limitation of activities, physical health problems, emotional problems, social activities, pain, energy and emotions, social activities, general health. Assuming that each question carries equal weight, each scale is transformed into a 0-100 scale. The lower score the patients gets, the more disability.

For gathering the information concerned with our study, we will proceed as described below:

Trial entry in the emergency department.

The patients who visit the emergency department with an orbit fracture and meet the inclusion criteria will be asked if they want to participate in our study. An information sheet and the consent form will be given.

If they agree to engage in, we will proceed to collect the data needed for our investigation.

We will use a case report form (annex 1) in which all the variables of our study will be included. The first distinction we will have to do is to indicate in which level of the independent variable is the patient. For this, we will use the same protocol CT scan that is used to check the actual criteria of surgery for size the volume of the orbit, and look for the increase with the Osirix radiology software (all copyrights reserved).

Long term surveillance: after six months

The follow up of the patients will only have a few different of the actual protocol. Our epidemiologist will check after the six months' appointment for check the diplopia (subjective status of the patient) and enophthalmos status on the patients. Also, we will use the QOL questionnaires in this appointment to register the affection to the normal activity life of this patients.

8.- Statistical Analysis.

All statistical analysis will be performed with Statistical Package for the Social Sciences (SPSS) for Windows®.

Univariate analysis

In the univariate analysis, the variables will be defined as categorical or continuous.

On the one hand, for the categorical variables, the results will be expressed in percentages. One the other hand, for quantitative continuous variables, if a normal distribution could be assumed, we will use mean and standard deviation; whereas if a normal distribution cannot be assumed, the median and the quartiles will be estimated.

Bivariate analysis

In our study, both the independent and dependent variables are categorical and for realize the comparison between them, we will use a Chi-square test.

In other words, to prove statistical association between the levels of increased volume and the increasing of diplopia and/or enophthalmos, a $\chi 2$ (Chi Square) test will be required.

While for the comparison between the independent variables with the secondary dependent variables, Student's t-test will be needed as the independent variable is a categorical variable and the secondary dependent variables are quantitative*e.

Multivariate analysis

A multivariate analysis will be accomplished to adjust our variables for co-variables, thus we will try to avoid potential confounders that could modify the results. It will be done using a logistic regression model.

Missing data

During the Follow up, some patients can leave the study. As we only do one valid appointment at the sixth month after the trauma, if the patient don not finish the follow up, the data of these patients will be not carried forward.

9.- Ethical aspects:

We had a good medical practice following the Declaration of Helsinki, of the ethical principles for medical research involving human subjects, according to the 64ª General Assembly, Fortaleza, Brasil, October 2013.

The confidentiality of the data based on the procedures according to the Law on Data Protection have been respected. We guaranteed the anonymity of all patients' data, in order to protect the confidentiality and privacy of patients. We have also requested informed consent of patients and/or relatives prior to the patients' inclusion.

We have respected the confidentiality of data according to the Organic Law 15/1999 of 13 December on Protection of Personal Data (LOPD), the Royal Decree 994/1999 on Security Measures for automated files containing personal data of June 11, 1999 (RMS), and the Royal Decree 1720/2007, of December 21 of the Development of the Organic Law on Data protection.

We will submit the present protocol for an Ethics Review conducted by the Clinical Research Ethics Committee (CEIC) of the J. Trueta Hospital for its approval.

We have not contact with Copyright © 2016 Pixmeo company which owns the Osirix software, we just bought 4 copies of it. We could use other software to measure to size of the orbit, but we have chosen this one.

10.- Study limitations.

There are a few limitations to this study that need to be accepted:

The main limitation in this case will be not to recruit all the patients needed, because not extra procedure will be done in these patients. The main limitation in this case will be the type of sample. For make a viable statistical analysis we should have a sample of 292 patients, 73 in each level of the size volume figure we have developed. The problems may show when we try to complete all of these sample levels, because the incidence of the higher levels may will be low that the lowers ones. We could fix it by making the study a multicentre study in a future.

At this point, is possible that we have more much patients at the lowers level, than the higher, making the study last more for get all the empty vacancies fill. If theses happened, we can randomize inside of each sample group with the finality of take a representative sample of 73 patients of each group.

Another limitation is the extrapolation of our study to other populations. There is very few evidence or previous studies already published, so with the results obtained it is impossible to say that this results may or may not coincide with other centres population.

Also, as we turn our quantitative variable into a qualitative for create the different levels, we may found a huge different between two groups because maybe ahead from a point the ratio increased.

11.- Work Plan

This study is expected to last 10 years. All the activities carried out during this period of time by the researcher team, will be organized in 5 phases which are detailed below:

1- Preparation and coordination phase (4 months).

This first phase of the study will consist in the elaboration of the study from September 2016 to November 2016. A detailed definition of the study variables will be done.

The entire team participating; investigators, collaborators, nursing staff, administrative staff and statisticians, will meet in order to specify which will be the tasks of every member of the team. The chronogram will be arranged in collaboration with the other members of the research team and the methods for data collection will be discussed and set up.

Once the theoretical study is ready, we will present it to the Ethical Committee for its evaluation and approval.

As the study is longitudinal and it will last about 10 years, the researchers decide to organize meetings every three months in order to control the data collected and to assess the progression of the study. The aim of this is to correct the methodological flaws and identify deficiencies of the study design.

2- Field research

- Sample collection (9 years): patients who come to the emergency department and that meet the inclusion criteria for our study will be collected and distributed by the size of the orbit in the CT into different study levels. Inclusion period will last 9 years and it could be prolonged in case of not achieving the predefined sample.

- Follow up: every patient will be followed during six months counting from the day of the inclusion in the study. We are going to follow the actual protocol in front of orbit fractures with not surgical criteria. At the sixth moth appointment, we will check if enophthalmos or diplopia is present in the patient. So, we do the sample collection at the same time we are doing the follow up of the patients that are already selected.

3. Data collection (10 years).

While the trial is taking place, the data collected from each patient will be registered in our database. This collected data, will be periodically evaluated and analysed by our statistician to control if the protocol is being followed.

4. Data analysis and final evaluation (6 months).

After processing the database, all data will be analysed using the appropriate statistical test by a statistician.

5. Results interpretation (6 months).

An interpretation of the results will be performed and of the results found are what we expect, the corresponding articles will be written.

6- Publication and dissemination (1 year).

The researchers will write and edit a scientific paper to publish.

12.- FESIABILITY

The study proposed, will take place in Hospital Universitario Josep Trueta, where all the means necessaries for the study development will be available and provided.

The maxillofacial service and the radiologist unit of the hospital, in coordination with the emergency department, will work together in order to achieve the marked objectives. The emergency department will serve as a gateway to our patients to the study and afterwards.

The hospital also has a service of statistics. We will hire a statistical who will be the responsible of the statistical analysis and processing of the data collection.

For the radiologist service, we will organize a few lessons, were a specialist's team of radiologist and informatics will show how to size volume with the software Osirix (all copyrights reserved).

To carry out the study, the hospital will supply the necessary means. The informatics equipment needed for processing the database for the study development and statistical analysis will be also dispensed by the hospital.

In Hospital dr Josep Trueta, around 35 patients presenting a not inclusion criteria for surgery orbit fracture are admitted per year. According to that, in 9 years, we will have our sample completed.

13.- Impact

The main aim of this project is to achieve more information about the indication of surgery in orbital fractures.

Due to the frequency of the orbital fractures with not surgical criteria that ends with diplopia of enophthalmos, we consider that the necessity of review the actual protocol, proposing the increase of the size of the orbit at the moment of the trauma as new criteria.

If the results obtained are relevant enough and our hypothesis is validated, this will mean that a new protocol for this type of fractures can be done, decreasing diplopia and enophthalmos. This can suppose a change in the routinely treatment. Firstly, because the rates of diplopia and enophthalmos will be lower and secondly because the quality of life of the patient will increase significantly.

As a whole, it will be a positive change in the way we treat these patients.

Although this technique works in our centre, further studies with bigger samples will be needed in order to make a step forward in the establishment of the best treatment.

14.- Budget:

Material resources:

No extra money will be needed for the clinical techniques necessary for the study, since all of them were made in the ordinary way, following the current protocol of the hospital. The required tests will not involve additional expenditure.

Human resources:

It is required a minimum of one technical person who will look at the size of the orbit in the CT and compares with the healthy orbit in the computer using an especial software of the hospital radiology service.

	Budget Proposal	
	Description	Total Cost
STAFF		
Radiologist	50€/h x 300h (1 h/case)	15.000 €
Administrative workers	350€/year x 10 years.	3.500 €
Statistical specialist	50€/h x 120 h.	6.000 €
Material		
Software	750/€ per pc x4 PC	3.000 €
Extra budget	500€ per year	5000€
Publication and dissemination		
Cost of publications		2.000 €
National congress		1.500 €
Total		
		36.000€

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Annex A:

HOJA DE INFORMACIÓN PARA EL PACIENTE

Aumento de tamaño en orbitas fracturadas en pacientes sin criterios quirúrgicos versus diplopía y enoftalmos.

Nos dirigimos a usted para informarle sobre la realización de un estudio en el cual le invitamos a participar de manera voluntaria. Su colaboración en este proyecto sería agradecida ya que podría contribuir de una forma muy importante a mejorar el tratamiento en un futuro de este tipo de lesiones en el Hospital Josep Trueta de Girona. Este proyecto está aprobado por el Comité de Ética e investigación del Hospital, y dispone de todos los permisos del centro y los servicios. Nuestra intención es que reciba toda la información de manera adecuada y suficiente para que pueda decidir si desea participar o no en este estudio. Por eso, le agradecemos el tiempo invertido en leer esta hoja informativa. A continuación, le informamos sobre los aspectos más importantes del estudio.

Este tipo de fracturas llevan bastante tiempo en controversia debido a los diferentes tipos de tratamientos y el momento óptimo para la intervención. Actualmente hay unos criterios establecidos para saber cuándo se ha de operar un paciente y cuando no. Para ello se recurre al TAC, una prueba radiológica que nos es capaz de indicar varios factures útiles para comprobar si hay compromiso de daño de tejidos cercanos, si hay indicación quirúrgica, etc.

La finalidad de este estudio, es fijarnos en un elemento más del TAC que hasta ahora se ha ignorado, proponemos medir el tamaño de la órbita afectada respecto a la sana en el momento del trauma. A usted se le tratará con normalidad, ningún procedimiento extra se le practicará. A los 6 meses, el seguimiento habitual de este tipo de trauma, se le dará un formulario de cualidad de vida y se mirará si tiene afectaciones oculares (diplopía y enoftalmo), comparando estos datos con el tamaño de la órbita en el momento del traumatismo para ver si hay alguna relación. El objetivo a largo plazo sería revisar los criterios se inclusión quirúrgicos para este tipo de traumas.

Ningún riesgo añadido al protocolo actual del tratamiento de este tipo de fracturas será añadido. Para la realización del estudio hemos de conocer algunos datos médicos sobre su enfermedad, así como el acceso al TAC, y a los datos de la historia clínica durante el seguimiento de 6 meses. Le garantizamos que sus datos serán tratados con absoluta confidencialidad según la Ley Orgánica 17/1999 de Protección de datos de Carácter Personal que regula la confidencialidad de datos informatizados.

Annex B

Formulario de Consentimiento Informado

Aumento de tamaño en orbitas fracturadas en pacientes sin criterios quirúrgicos versus diplopía y enoftalmos.

Se trata de un estudio de Cohortes prospectivo que se realizará en el Hospital dr Josep Trueta de Girona.

Nombre y Apellidos del paciente: ____________________________________

Fecha de nacimiento: __/__/____ Teléfono: _____________________

1.- Se me ha informado verbalmente y por escrito (hoja de información para el paciente) sobre las características del estudio, significado, consecuencias y sobre mis derechos y responsabilidades.

2.- Participo en este estudio de forma voluntaria.

3.- Me comprometo a seguir todas las instrucciones que me hagan el personal del estudio.

4.- Confirmo que mis datos son completos y correctos.

5.- Confirmo que no estoy participando en ningún estudio más al mismo tiempo.

6.- He recibido un informe completo y me han aclarado las dudas sobre el estudio.

7.- Confirmo estar de acuerdo sobre el uso de mis datos personales y haber entendido la declaración de protección de datos.

8. En caso de publicación, la confidencialidad de mis datos quedará totalmente protegida y garantizada.

9.- He estado informado sobre el seguro del mi estudio y sobre los requisitos de cobertura (copia de aseguradora adjunta).

10.- Estoy de acuerdo en participar en este estudio de forma voluntaria.

Firma del paciente	**Firma del investigador**
Nombre: ____________	**Nombre: _______________**
Fecha: __/__/_____	**Fecha __/__/_____**

Annex C: SF-36 QUESTIONNAIRE FOR QUALITY OF LIFE

SF-36 QUESTIONNAIRE

Name:____________________ Ref. Dr:___________________ Date: _______ ID#: _______________ Age: _______ Gender: M / F

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

GENERAL HEALTH:

In general, would you say your health is:

☐ Excellent ☐ Very ☐Good ☐ Good Fair ☐ Poor

Compared to one year ago, how would you rate your health in general now?

☐Much better now than one year ago

☐Somewhat better now than one year ago

☐About the same

☐Somewhat worse now than one year ago

☐Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Lifting or carrying groceries

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing several flights of stairs

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing one flight of stairs

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Bending, kneeling, or stooping

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking more than a mile

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking several blocks

☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking one block

 Yes, Limited a lot Yes, Limited a Little No, Not Limited at all

Bathing or dressing yourself

 Yes, Limited a lot Yes, Limited a Little No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities

 Yes No

Accomplished less than you would like

 Yes No

Were limited in the kind of work or other activities

 Yes No

Had difficulty performing the work or other activities (for example, it took extra effort)

 Yes No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities

 Yes No

Accomplished less than you would like

 Yes No

Didn't do work or other activities as carefully as usual

 Yes No

SOCIAL ACTIVITIES:

Emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

 Not at all Slightly Moderately Severe Very Severe

PAIN:

How much bodily pain have you had during the past 4 weeks?

 Not at all Slightly Moderately Severe Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

 Not at all Slightly Moderately Severe Very Severe

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Have you been a very nervous person?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Have you felt so down in the dumps that nothing could cheer you up?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Have you felt calm and peaceful?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Did you have a lot of energy?

□All of the time

□Most of the time

□A good Bit of the Time

□A little bit of the time

□None of the Time

Have you felt downhearted and blue?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Did you feel worn out?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Have you been a happy person?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

Did you feel tired?

□All of the time

□Most of the time

□A good Bit of the Time

□Some of the time

□A little bit of the time

□None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

□All of the time

□Most of the time

□Some of the time

□A little bit of the time

□None of the Time

GENERAL HEALTH:

How true or false is each of the following statements for you? I seem to get sick a little easier than other people

□Definitely true □Mostly true □Don't know □Mostly false □ Definitely false

I am as healthy as anybody I know

□Definitely true □Mostly true □Don't know □Mostly false □ Definitely false

expect my health to get worse

□Definitely true □Mostly true □Don't know □Mostly false □ Definitely false

My health is excellent

□Definitely true □Mostly true □Don't know □Mostly false □ Definitely false

Annex D: Chronogram

TASKS	2016	2017		2018		2019		2020		2021		2022		2023		2024		2025		2026		RESEARCHERS
	Sep - DEC	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	Jan – Jun	Jul - Dec	
Preparation and coordination Phase																						
Protocol Elaboration and evaluation																						Maxillo and radiologist service
Coordination of research team																						All research team
Field research and data collection																						
Recruitment of patients,																						Researchers
Coding and data collection																						Researchers
Data cleansing, quality assurance and control																						
Data Analysis																						
Statistical Analysis																						Statistician
Interpretation and scission of the results																						Statistician
Publication and dissemination																						
Scientific publications and National congress.																						Surgery team.