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Facial Paralysis Management: comparison among available surgical procedures for upper lid loading and proposal of customized 3D implant.

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INDEX:

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INTRODUCTION

Face-to-face contact is fundamental to our social life, and any form of facial disfigurement impacts on the way in which we interact. Facial nerve paralysis is a devasting event, even its partial form, resulting in both a very evident deformity, with a significant emotional impact, as well as functional problems of eyelid closure and ocular globe impairment, oral continence, speech, eating and drinking and relative psycho-social consequences.

The restoration of facial symmetry, mostly in a dynamic condition, remains an elusive surgical goal, despite major advances and developments in the treatment, so the patients are often unsatisfied and not pleasant with the outcomes. Moreover this is a challenging condition, both for the physician and the patients, requiring multidisciplinary competences to ensure optimal care and achieve the best outcomes. Infact, multiple anatomic and cosmetic areas and various functional defects complicate the treatment of a paralyzed face and each requires a targeted approach for optimal rehabilitation. Proper management of facial paralysis require a thorough understanding of facial nerve anatomy, physiology, as well as available medical and surgical treatment modalities as well as patient expectations.

STATE OF THE ART

Facial palsy is a condition which affects approximatively 20-30/100.000 individuals/year (1). There are numerous causes (2), the commonest being Bell's Palsy (idiopathic facial paralysis) reported in the 60% of the affected; less common causes of facial paralysis include (3,4):

- infections (27%, Herpes Zoster virus, Ramsay Hunt sindrome, choleostheatoma, Lyme disease, Melkersson-Rosenthal sindrome, etc,);
- neurological disease (8%, Multiple Sclerosis, Millard-Gubler sindrome, Guillaume-Barrè sindrome, etc.);
- traumatic causes (6%, after temporal bone and skull fractures);
- benign or malignant tumours (2-3%, acoustic neuroma, facial nerve and parotid gland tumors, gliomas, meningiomas, etc.);
- iatrogenic injury during neurosurgery, parotid, mastoid o face lift surgery (2%);
- congenital sindrome (<1%, Moebius sindrome, Goldenhar Syndrome, Di George Syndrome, CHARGE Syndrome);
- toxic and metabolic condition (<1%, tetanus, diabetic neuropathy, etc.)

The primary function of the facial nerve (VIIth cranial nerve) is to express voluntary movement of the muscles in the face and expression of involuntary emotions (5). The frequency and intensity of facial expressions may vary, but all of us understand the meaning of these expressions. Such expressions include happiness, joy, fear, anger, scorn, disapproval, and many others, and we use them to communicate our emotional needs.

The cell bodies of the motor fibers of the facial nerve are located in a cluster of cells in the brainstem. On each side of our face, each facial nerve innervates 23 facial muscles. In addition to the muscles of facial expression, the facial nerve innervates the stapedius muscle in the middle ear, the platysma muscle in the neck, the stylohyoid muscle, and the posterior belly of the digastric muscle.

The system responsible for voluntary expressions is the left hemisphere of the brain only. Signals are sent to the right motor nucleus; at the same time, signals cross the corpus callosum to the right hemisphere. Thus symmetric facial expressions can be generated. The muscles of the upper face are innervated by motor neurons that receive bilateral projections from the motor cortex, whereas the motor neurons that innervate the muscles of the lower face receive projections only from the contralateral motor cortex. The strategy of facial reanimation (6) is determined by the extent and level of the injury, the timing of the appearance, the age and condition of the patient, his/her ability to withstand several stages of reconstruction and rehabilitation.

The nerve in its extensive anatomy and physiology spans an array of systems, so the management of its relative disfunctions and disfigurements requires multiple specialistic consultations (7), clinic, diagnostic and instrumental examination and numerous hospital accesses and job absence days.

Successfull outcome for these patients depends on a rational approach and a proper selection of the more appropriate and specialistic rehabilitation technique and possibly a combination of them (8). The critical factor in deciding the surgical approach to facial nerve reconstruction is the status of the musculature (9); after denervation, dissociation of the muscle from the nerve results in muscle atrophy and its replacement by fat and scar tissue (about 24 months). Electromyography can indicate muscle viability and potential for reinnervation that is time dependent (10); successfull muscle unit recovery is beyond 18-24 months after the nerve injury, so we can distinguish:

Reinnervation of the mimic muscles (dynamic techniques - within 24 months) (11)**:**

- neurorrhaphy with or without interpositional nerve grafting (auricular or sural nerve) (12)
- crossover techniques (13, 14)
    - hypoglossal-facial crossover procedure (XII-VII crossover)
    - spinal accessory to facial nerve (XI–VII) crossover technique
    - masseteric-facial nerve anastomosis (15)
- cross-facial grafting

Reconstruction of the facial muscles (dynamic techniques - after 24 months) (16)**:**

<u>Transposition of regional muscular flap</u>

- temporalis muscle / orthodromic temporalis tendon transfer
- masseter muscle
- digastric muscle

<u>Micro-neurovascular free flaps</u>

- gracilis muscle (17, 18)
- latissimus dorsi muscle
- pectoralis minor muscle
- *serratus anterior/rectus abdominis muscle/extensor digitorum brevis/anterolateral thigh* (19,20)

Static techniques to restore static symmetry, eye protection and oral continence (**after 24 months or after failure of the elective procedures)** (21,22)**:**

- hemy-rhytidectomy brow lifts canthopexy
- tarsorrhaphy
- gold/platinum or other alloplastic weight insertion above the tarsal plate of the upper eyelid (23)

- oral commissure suspension using Gore-Tex®, fascia lata or palmaris longus tendon (24)
- Botox®
- chemodenervation (25,26)
- autologous fat transpantation
- hyaluronic acid injection.

Post-operative physiotherapy and speech therapy are essential. Nowadays the patients expectations, mostly in the inveterate paralysis where the muscle degeneration let to a disfigured face, are not exclusively related to functional recovery, but also to the aesthetic one, so obtaining the best quality of life (27).

The different proposed techniques were compared each other regarding the functional outcomes, but to date there has not been any study designed to evaluate the outcomes in terms of aesthetic (anthropometric measurements) and quality of life following these interventions.

	DYNAMIC PROCEDURES		STATIC PROCEDURES		
UPPER THIRD	TRANSPOSITION OF REGIONAL MUSCLE FLAPS o temporal muscle	MICRO-NEUROVASCULAR FREE FLAPS o gracilis muscle o latissimus dorsi muscle o pectoralis minor muscle	BROW-LIFT +/- CANTHOPEXY	UPPER LID ALLOPLASTIC MATERIAL WEIGHT INSERTION o gold o platinum o other alloplastic material	ANCILLARY PROCEDURES o Botox® o autologous fat transfer
LOWER THIRD	TRANSPOSITION OF REGIONAL MUSCULAR FLAPS o temporal muscle o masseter muscle o digastric muscle	MICRO-NEUROVASCULAR FREE FLAPS o gracilis muscle o latissimus dorsi muscle o pectoralis minor muscle	ORAL COMMISSURE SUSPENSION o fascia lata o Gore-Tex ® o palmaris longus tendon	HEMY-RHYTI-DECTOMY o Purse string suture	ANCILLARY PROCEDURES o Botox® o autologous fat transfer

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OVERVIEW

Facial paralysis can result from a wide variety of etiologies including infectious, neurologic, congenital, neoplastic, traumatic, systemic, and iatrogenic causes. Regardless of cause, the management of facial paralysis is complex and often requires multidisciplinary intervention. The evaluation and treatment of facial paralysis is especially intricate because of the wide variation in the potential for regeneration and lack of reliable prognostic indicators for spontaneous recovery. Current management of facial paralysis consists of a combination of medical therapy, physical therapy for facial neuromuscular retraining, and surgical intervention via dynamic and static techniques for facial reanimation.

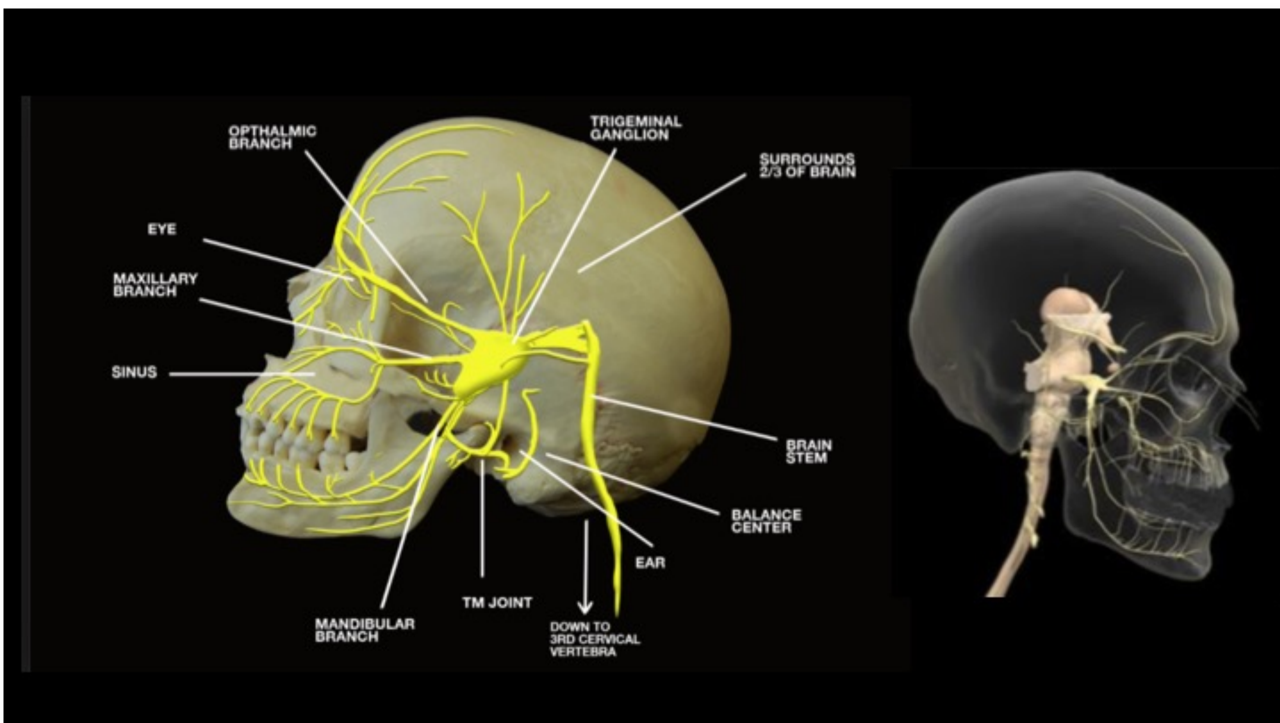
ANATOMY OF THE FACIAL NERVE

The facial nerve (cranial nerve VII) is embryologically derived from, and consequently innervates all structures originating from, the second branchial arch.

It consists of a motor and a sensory part, the latter being frequently described as the nervus intermedius (pars intermedii of Wrisberg). The nerve contains 10.000 fibers out of which 7.000 are myelinated motor fibres. Most of the motor fibers travel to the extratemporal portion of the facial nerve and innervate a total of 23 paired muscles and the orbicular oris, but only 18 of these muscles, working in a delicate balance, produce facial animation and expression.

The remaining 3 000 fibers branch off prior to the stylomastoid foramen and provide autonomic and special sensory innervations to the salivary and lacrimal glands as well as convey taste sensations from the anterior two-thirds of the tongue. They also provide sensory fibers to the posterior aspect of the external auditory canal.

Arbitrarily, the facial nerve can be divided into three segments along its course: *intracranial, intratemporal* and *extratemporal.*



Anatomy of the Facial Nerve

1. Intracranial anatomy

The facial nerve originates from the pontine region of the brain stem.

The cell bodies giving rise to the frontal branch receive bilateral cortical input (all the other facial nuclei cell bodies receive contralateral cortical input). This explains why an ipsilateral supranuclear lesion (upper motor neurone lesion) to the facial nerve results in contralateral facial paralysis but with bilateral sparing of the frontalis muscle. Conversely, a lower motor neurone lesion to the facial nerve results in ipsilateral facial hemiplegia, including the ipsilateral frontalis. The facial nerve enters the temporal bone at the internal auditory meatus with the eighth cranial nerve, the vestibulocochlear nerve.

2. Intratemporal anatomy

The facial nerve enters the internal auditory canal and travels with the acoustic and vestibular nerves for about 8-10mm. It then enters the Fallopian canal, which has 3 segments:

a. Labyrinthine segment: This is 3-5mm long, and courses from the entrance of fallopian canal to the geniculate ganglion. It is the narrowest segment of the fallopian canal, with a mean diameter of 1.42 mm and with the nerve occupying 83% of available space. At the geniculate ganglion the first branch of the facial nerve, the greater petrosal nerve, is given off. The greater petrosal nerve provides parasympathetic innervation to the lacrimal and palatal glands. The junction of labyrinthic and tympanic segments forms an acute angle and traumatic facial nerve shearing often may occur here.

b. Tympanic segment: This is 8-11 mm long, and courses from the geniculate ganglion to a bend at the lateral semicircular canal.

c. Mastoid segment: This is 9-12 mm long, and extends from the angle at the lateral semicircular canal to stylomastoid foramen. This segment has the widest cross-sectional diameter and gives off three branches:

Tympanic nerve. This is a small sensory branch to the external auditory canal. Injury may cause hypo-aesthaesia of part of the external auditory canal, known as *Hitselberger's sign.*

Nerve to stapedius. The stapedius muscle dampens loud noise. Interestingly, the cell bodies of the motor nerve are not located in the facial nucleus and consequently the stapedius muscle is unaffected in Möebius syndrome.

Chorda tympani. This is the last intratemporal branch of the facial nerve; it joins the lingual nerve to provide parasympathetic innervation to submandibular and sublingual glands and taste sensation to anterior two-thirds of the tongue.

3. Extratemporal anatomy

The facial nerve exits the temporal bone at the stylomastoid foramen. Here the mastoid tip, the tympanic ring and mandibular ramus confer protection. However in children under 2 years of age the nerve is superficial and more prone to injury.

The *posterior auricular nerve* is the first branch of the facial nerve following its departure from the stylomastoid foramen and innervates the superior and posterior auricular muscles, the occipital muscles and provides sensory innervation to a small area behind the earlobe.

The next branch is the *motor branch to the posterior belly of digastric and stylohyoid muscles*. Here the facial nerve is located just above the posterior belly of digastric.

The facial nerve then enters the parotid gland and arborises between the deep and superficial lobes of the parotid gland. The nerve first divides into temporozygomatic and cervicofacial divisions. These divisions divide, rejoin and divide again to form the *pes anserinus* (Goose's foot) to ultimately give the terminal branches, namely, temporal (frontal), zygomatic (malar and infraorbital), buccal, mandibular and cervical nerves.

a. Temporal (frontal) branch: This is the terminal branch of the superior division and travels along *Pitanguy' s line* which extends from 0.5 cm below the tragus to 1.5cm above and lateral to the eyebrow. The nerve becomes increasingly superficial as it travels cephalad and lies just deep to the temporo-parietal (superficial temporal) fascia at the temple. At the level of zygomatic arch it arborises into two to four branches to innervate the frontalis muscle from its inferior aspect. Temporal branch injury causes ipsilateral frontalis muscle paralysis.

b. Zygomatic branch. This is arguably the most important branch of the facial nerve as it supplies orbicularis oculi, which enables eye protection. Consequently injury to the zygomatic branch may cause *lagophthalmos* with risks of exposure keratitis, corneal ulceration and scarring. Ultimately, this may lead to blindness.

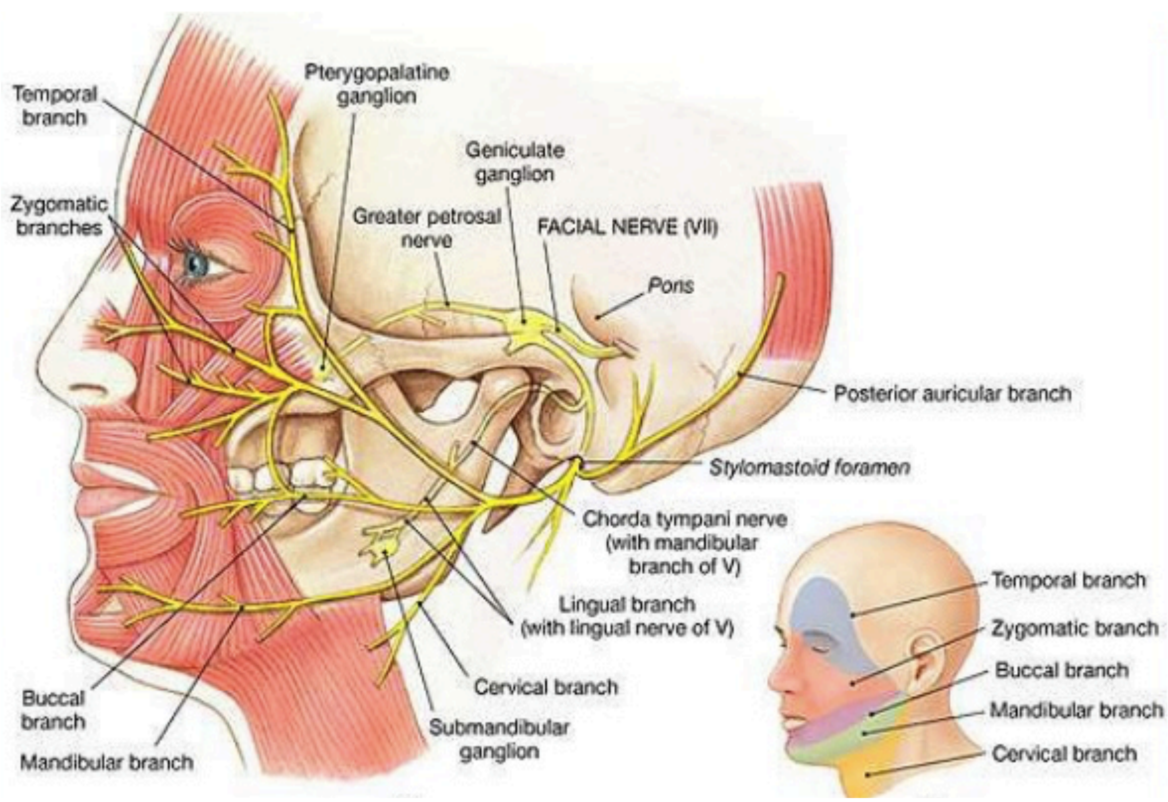
c. Buccal branch: This divides into multiple branches travelling at the level of the parotid duct. The surgical landmark to locate these branches is 1cm or one finger-breadth below the zygomatic arch. The buccal branch innervates the buccinator and upper lip musculature. It is also important for lower eyelid function, as the medial canthal fibres of buccal branch innervate the inferior and medial *orbicularis oculi*. Injury to the buccal branch causes difficulty emptying food from the cheek and an impaired ability to smile. However, due to the high degree of arborisation (buccal branch is always receives input from both the superior and inferior divisions of the facial nerve) damage to this branch is less likely to result in a functional deficit. The zygomatic/buccal motor branch, that innervates the *zygomaticus major* can consistently be found at the midpoint (*Zuker's point)* of a line drawn between the helical root and the lateral oral commissure.

d. Marginal mandibular branch: This is a terminal branch of inferior division and runs just below the border of mandible, deep to platysma and superficial to the facial vein and artery. It supplies the muscles of the lower lip (*depressor anguli oris*). Injury results in ipsilateral lack of depression of the lower lip and asymmetry of open mouth smiling or crying. It is connected to other rami in only 15% of cases; consequently clinical weakness is highly likely following injury.

e. Cervical branch: This is a terminal branch of the inferior division of the facial nerve. It runs down into the neck to supply platysma (from its deep surface).

Interconnections exist between buccal and zygomatic facial nerve branches in 70-90% of patients; hence injury to these branches may be clinically compensated for by these interconnections. This is not true for the frontal and marginal mandibular branches which are terminal branches without significant crossover. Hence injuries to the frontal and marginal mandibular branches are less likely to clinically recover.

Clinically it may be possible to *predict the site of facial nerve injury*. Injuries at or distal to stylomastoid foramen only have paralysis of facial musculature. More proximal injuries may also manifest loss of taste and hyperacusia.



Topography of the Facial Nerve

FUNCTION OF THE FACIAL NERVE

The primary function of the facial nerve is to express voluntary behaviour and spontaneous emotions via innervating twenty-three facial muscles on each side of the face. Facial expressions are ranging from phasic, short-lasting or even flash-like muscle contractions representing momentary emotions or voluntary acts, up to tonic, long-standing muscle activation representing moods or dispositions. Damage to the facial nerve affects all muscles of the facial expression thus facial paralysis is one of the most devastating peripheral nerve injuries. Patients suffer serious functional, cosmetic and psychological problems with impaired ability to communicate both verbally and non-verbally. The loss of oral competence may lead to drooling and difficulty with speech articulation. Loss of eye sphincter function, especially in the absence of tearing, can lead to blurred vision, exposure keratopathy and corneal ulceration. The most dramatic impact of the paralysis is however its psychological effect which may lead to isolation and fear of interaction with others.

AETIOLOGY OF FACIAL NERVE PARALYSIS

Aetiology is the most important factor in determining the timing and choice of reanimation technique. Reconstructive efforts should not commence prior to establishing the aetiology of the paralysis. Besides the aetiology of the denervation dictates the timing of surgical treatment, if any is to be done. In a patient with a paralyzed face secondary to traumatic surgical disruption, the surgeon should initiate reconstruction as soon as possible, generally within the first month. On the other hand, a patient with an intact nerve can be monitored for recovery for up to 12 months. The duration of the facial paralysis is essential.

We can distinguish *congenital* and *acquired* causes of facial nerve palsy.

Congenital causes include obstetric, developmental facial paralysis, Möebius syndrome and idiopathic mandibular division palsy.

Acquired causes include traumatic temporal bone fracture or facial injury, neoplastic, infectious, neuromuscular and iatrogenic (parotidectomy or acoustic neuroma excision).

When the relevant cause of palsy is idiopathic, the condition is known as Bell's palsy.

GRADING OF FACIAL PARALYSIS

There is no single classification system that can describe all the many variations of nerve injuries. Most systems attempt to correlate the degree of injury with symptoms, pathology and prognosis.

To predict the prognosis it is essential to assess the degree of palsy. The classical test for this is the electroneurography. It is non-invasive and relatively easy to use, although it can involve various errors, relating particularly to the use of the surface electrode and to the comparison of the paretic and normal side.

Another feature affecting the clinical appearance, unique to facial nerve injury, is the effect of aberrant facial nerve regeneration. This faulty rerouting results in secondary defects such as synkinesis, hemifacial spasm, contracture, hyperacusia, crocodile tears and dysgeusia. The phenomenons of secondary defects contribute to overall disfigurement and decreased quality of life therefore they are difficult to ignore in an overall assessment of the facial nerve function. Despite of their prominent nature some grading systems do not address these secondary defects.

When assessing the function of the facial nerve, it is important to measure disability from the onset to various stages of recovery and to detect changes over time or after treatment. In the past few decades several, internationally accepted systems have been proposed by different authors, yet most of the existing grading systems are subjective. Due to the lack of objectivity, overall assessment of the facial function in a consistent manner has proven to be difficult.

The subjective scales have two main types. Gross scales with an overall impression of facial nerve function have been proposed by House-Brackmann, May et al and Peitersen. Regional weighted and unweighted scales, like the Yanagihara and the Sunnybrook grading scale, that evaluate different areas of the face, grade each individual facial movement and then summarize the grades.

The main drawback of these scales is that, as with any evaluation involving subjective examination, interobserver variability is particularly difficult to overcome in the assessment of the face: subtle differences in skin wrinkles and surface contour may confound the application of distinct gradations.

In an attempt to address the shortcomings of subjective scales several objective scales (based Grading Scale) evaluate different areas of the face, grade each individual facial exclusively on measurement, were developed like the Stennert and the the Burres-Fisch Nottingham systems. However, they often involve the need for precise measurements and mathematical calculations, are complicated and time-consuming thus impractical to be used in the everyday practice.

The *Glasgow Facial Palsy Scale* is a recently developed, objective and quantitative assessment of facial palsy. It is based on the digital processing of a video recording. Based on the authors' experience this method provides a faster and simpler measurement opportunity compared to earlier objective methods.

Nevertheless the *House-Brackmann* is still the most commonly utilized classification system to describe the severity of any facial palsy.

GRADE	GROSS	AT REST	MOTION
I NORMAL	Normal facial function in all areas	Normal facial function in all areas	Normal facial function in all areas
II SLIGHT DYSFUNCTION	Slight weakness noticeable on close inspection; may have very slight synkinesis	Normal symmetry and tone	• Forehead : moderate to good function • Eye: complete closure with minimum effort • Mouth: slight asymmetry
III MODERATE DYSFUNCTION	Obvious but not disfuring differernce between two sides; noticeable but not severe synkinesis, contracture, and/or hemi-facial spasm	Normal symmetry and tone	• Forehead: slight to moderate movement • Eye: complete closure with effort • Mouth: slightly weak with maximum effort
IV MODERATE SEVERE DYSFUNCTION	Obvious weakness and/or disfuring asymmetry	Normal symmetry and tone	• Forehead: none • Eye: incomplete closure • Mouth: asymmetric wih maximum effort
V SEVERE DYSFUNCTION	Only barely perceptible motion	asymmetry	• Forehead: none • Eye: incomplete closure • Mouth: slight movemet
VI TOTAL PARALYSIS	No movement	No movement	No movement

House-Brackmann Grading Scale (HBGS) represents the standard measure for grading facial nerve function, adopted since 1985 by American Academy of Otolaryngology and the American Neurotology Society.

MANAGEMENT OF FACIAL PALSY

Management can be conservative or surgical. It should be tailored to the individual to restore function, regain resting symmetry and dynamic, spontaneous movement. Determining which strategy to pursue requires a multidisciplinary approach and intimate involvement of the patient and the family. The patient's age, prognosis, and functional, aesthetic and psychological concerns are important considerations.

Conservative management

The first priority is to protect the eye. Infact the most dangerous complication of facial nerve injuries is the paralysis of the orbicularis oculi muscle with implication for the lid closure (lagophtalmos). Normal eyelid closure consists in 85% of the upper lids lowering and in 15% of the lower lid elevation. The lagophtalmos and the consequent corneal exposure with the interruption of the tear film may result already in short term in various ophtalmologic complications from simple ocular discomfort to the loss of vision. Therefore it is of paramount importance in case of facial nerve injury (due to any cause) that the management of the paralysis includes provisions for adequate corneal coverage. In case of temporary palsy the prior ophthalmologic treatment is conservative and symptomatic such as ophthalmic drops and ointment, moisture chambers and taping of the lower lid into proper position. Other conservative interventions include physiotherapy, mime therapy and speech therapy.

Surgical management

The aims of surgical treatment are to protect the eye, restore facial symmetry, facilitate a spontaneous, dynamic smile and improve speech. Any surgical intervention for facial paralysis must carefully take into account the patient's age, medical history, residual hearing, segment of nerve injured, and the patient's expectations and risk tolerance.

Operative procedures may be *static* or *dynamic*.

Static procedures

They can be used at any duration of facial paralysis. There are significant benefits to static techniques of facial reanimation that can provide an alternative to or enhance the results of dynamic facial reanimation.

They are potentially indicated in the elderly, the unfit, those unwilling or unfit to undergo prolonged surgery, those with established paralysis without viable facial musculature, as a temporising measure, with massive facial defects secondary to trauma or cancer extirpation, or after failed microvascular procedures.

a. Brow ptosis correction

Brow ptosis correction is an important part of management of the facial paralysis patient. A variety of treatment approaches have been described: direct brow lift (coronal, mid-forehead, or brow incision), endoscopic brow lift, or minimally invasive temporal brow lift using a biodegradable stabilization device.

b. Management of the lagophtalmos

Oculoplastic management of the paralyzed eye is of paramount importance as exposure keratitis can lead to permanent visual loss. The upper eyelid can be managed with the following procedures as needed:

1) Eyelid weight placement: lid loading via placement of a gold or platinum weight is a very effective technique for correction of lagopthalmos. Thin profile platinum weights are becoming increasingly popular as they offer a better cosmetic outcome and decreased incidence of allergy as compared with gold implants.

2) Palpebral spring procedure: the palpebral spring procedure is a technically difficult procedure that can be employed in lieu of an eyelid weight for lagopthalmos correction. The spring spans between the superior orbital rim periosteum and a pocket at the superior aspect of the tarsus.

3) Upper eyelid blepharoplasty: in patients with significant dermatochalasis, conservative upper lid blepharoplasty can be performed to remove the excess skin.

4) Lateral tarsorrhaphy: a permanent "reversible" lateral tarsorrhaphy can be performed using mattress sutures placed to coapt the lateral aspects of the upper and lower lid tarsal plates. Tarsorrhaphies are typically used in cases of exposure keratitis or in cases where there is loss of the corneal sensation in addition to lagopthalmos.

The lower eyelid is managed with the following procedures as needed.

1) Lateral tarsal strip procedure: the lateral tarsal strip procedure is a powerful technique that can be used to address paralytic lower lid ectropion. In this technique, a lateral canthotomy is performed followed by inferior crus cantholysis. The lower tarsus is trimmed and sutured directly to the lateral orbital rim periosteum.

2) Medial canthopexy: medial paralytic ectropion of the lower eyelid is treated using a precaruncular medial canthopexy technique in which the medial tarsus is sutured to the periosteum of the lamina papyracea.

Other procedures to treat the lagophtalmos are the midface resuspension, the suborbicularis oculi fat (SOOF) lift and/or the transconjuntival injection of Botulinum Toxin A into the palpebral lobe of the lacrimal gland.

c. Nasolabial fold modification

Patients with effacement of the nasolabial fold or patients with overprominent nasolabial folds can be treated with a simple suture technique to create or efface the nasolabial fold crease.

d. Static facial suspension

Static facial slings for facial support are typically placed from the zygomatic arch/temporalis fascia to the oral commissure and nasolabial fold. A number of materials have been described for use as the sling material including fascia lata, Gore-Tex, and AlloDerm. In addition, multivector suture techniques have also been described for facial suspension.

e. External nasal valve repair

An often overlooked aspect of the patient with facial paralysis is external nasal valve collapse. This can be treated with a fascia lata sling from the alar base to the zygoma/temporalis fascia to stent open the external nasal valve.

Static techniques of facial rehabilitation
Brow ptosis correction
Management of the upper eyelid
Eyelid weight placement
Lateral tarsorrhaphy
Palpebral spring procedure
Upper eyelid blepharoplasty
Management of the lower eyelid
Lateral tarsal strip procedure
Medial canthopexy
Nasolabial fold modification
Static facial suspension
External nasal valve repair

Static techniques of Facial Rehabilitation

Dynamic procedures

Dynamic procedures attempt to improve facial symmetry at rest and to provide synchronous facial movement, preferably in a spontaneous manner.

The type of surgical intervention depends on the duration of facial paralysis.

a. Surgical management of acute facial paralysis (<3 weeks)

1. Facial nerve decompression

Transmastoid approach

The transmastoid approach for facial nerve decompression can be utilized when the trauma is clearly localized to the tympanic or mastoid segments of the facial nerve. The nerve should be decompressed for 180 degrees of its circumference. The incus can be removed and then replaced as an interposition graft to achieve decompression of the tympanic segment of the facial nerve all the way to the geniculate ganglion.

Middle fossa approach

The middle fossa approach allows decompression of the facial nerve when the injury extends to the labyrinthine segment. It is sometimes used in combination with the transmastoid approach in cases of temporal bone trauma.

Translabyrinthine approach

The translabyrinthine approach can be utilized for decompression of the entire intratemporal course of the facial nerve in cases where cochlea-vestibular function is absent or has been destroyed by the trauma.

2. Facial nerve repair

Primary nerve repair

Primary neurroraphy provides the best return of facial nerve function. However, the primary repair should be tension free. This sometimes necessitates rerouting or mobilization of the adjacent facial nerve segments in order to provide a tension-free anastomosis. It is important to note that the distal nerve segments can be identified intraoperatively by electrical stimulation for up to 72 hours after nerve transection or injury, making early repair critical. Most authors today recommend epineurial repair of the facial nerve as suture placement with fascicular or perineurial repair is difficult and may injure the axons.

Cable grafting

Cable nerve grafts are utilized when a tension-free primary nerve repair is not possible. Popular choices for donor nerve grafts include: great auricular nerve, sural nerve, and the medial and lateral antebrachial cutaneous nerves. The ansa cervicalis has been used as a donor nerve as well as there may be some evidence that motor nerve grafts are better than sensory nerve grafts. With either primary nerve repair or cable grafting, it is generally accepted that the best possible outcome is House-Brackmann Grade III facial function.

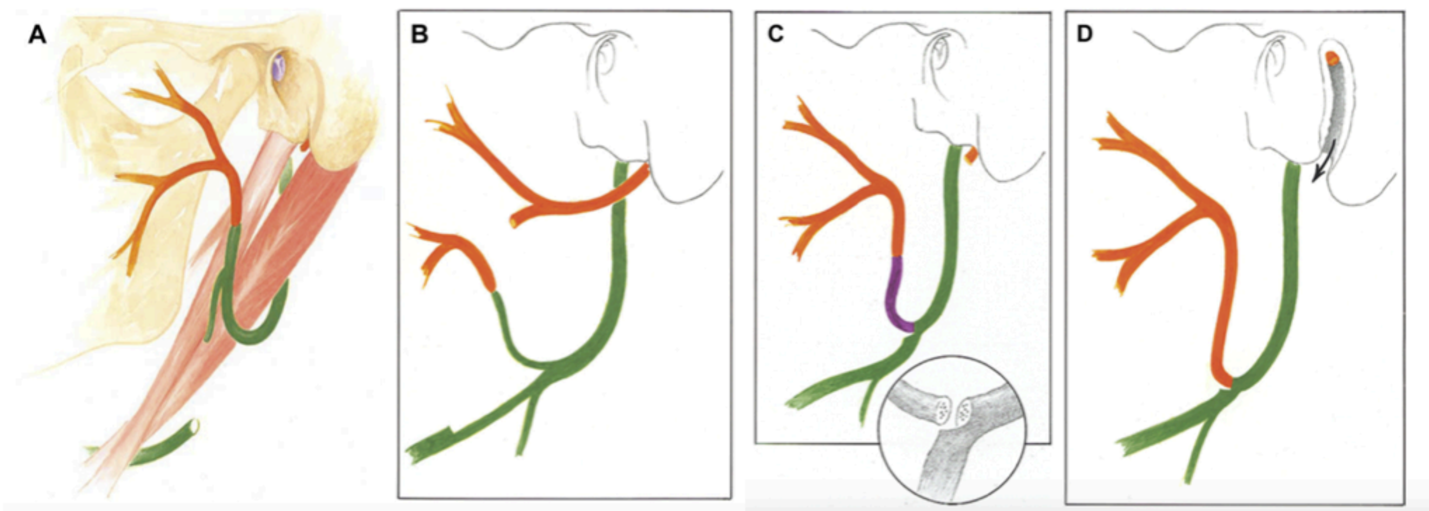
c. *surgical treatment of intermediate duration facial paralysis (3 weeks to 2 years)*

The treatment of intermediate duration facial paralysis typically occurs in the setting of an anatomically intact facial nerve that has not recovered well. Nerve transfers and nerve crossover procedures are typically the treatment of choice in this period as the native facial musculature is still viable.

Nerve transfers and cross-facial nerve grafting

Cross-facial nerve grafting can be utilized if the contralateral facial nerve is intact and functional. Terzis et al. believe that the best outcomes from cross facial nerve grafting are if the period of denervation is less than 6 months. The surgical technique is a 2 stage procedure. In the first stage, a modified preauricular face-lift incision on the normal, functional side of the face. After elevation of a skin flap anteriorly to the level of the lateral canthus, the superficial muscular aponeurotic system layer is penetrated anterior to the parotid gland and the branches of the facial nerve are identified using a nerve stimulator. Nerve branches are carefully selected for sacrifice depending on the desired innervations function and mapping of the innervations targets of each branch. A long sural nerve graft is tunneled to the contralateral face and the donor facial nerve branches are then sacrificed. Under magnification, the proximal end of the sural nerve graft is then coapted to the donor facial nerve branches. After a waiting period of 9 to 12 months, the second stage can be undertaken. In the second stage, secondary neurorraphies are performed between selected facial nerve branches and the cross face nerve grafts. If the period of denervation is longer than 2 years, cross facial nerve grafting can be utilized in conjunction with free muscle transfer for smile reanimation.

Nerve transfer procedures have been described using a variety of donor nerves: hypoglossal, spinal accessory, masseteric branch of the trigeminal nerve and motor branches of the cervical plexus. The most commonly used procedure is the hypoglossal-facial transfer. The classic XII-VII transfer involves transection of the entire hypoglossal nerve distal to the ansa cervicalis and coaptation to the main trunk of the facial nerve.



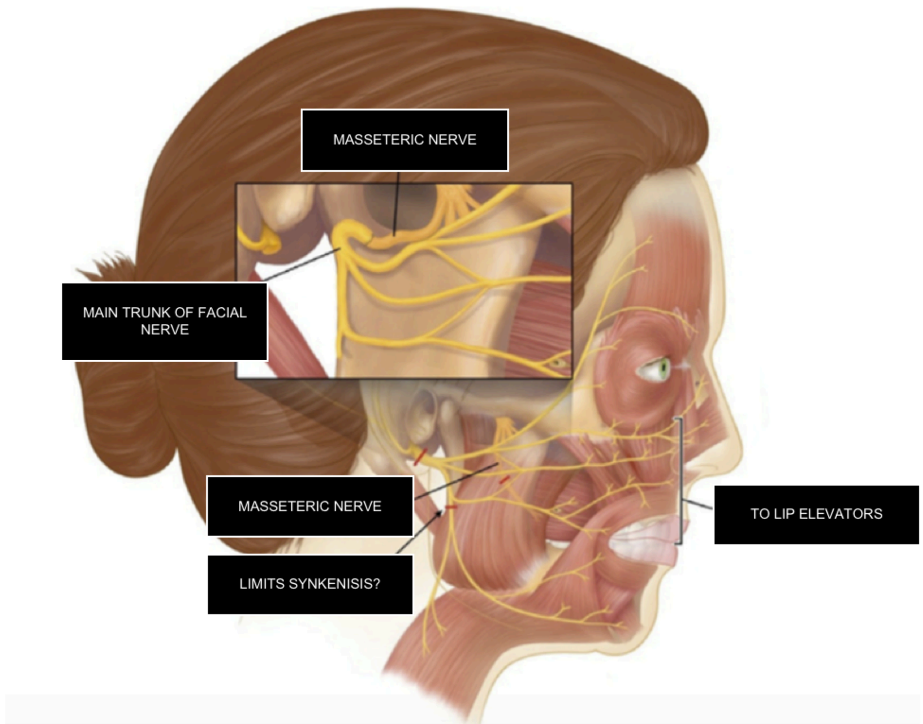
Hypoglossal facial nerve transfer

(A)Classic hypoglossal facial nerve transfer with entire hypoglossal nerve transected.

(B) Hypoglossal facial nerve modification with partial segment of nerve secured to lower division.

(C) Hypoglossal facial nerve jump graft (purple) uses interposition graft harvested from great auricular or sural nerve to connect a partially transected hypoglossal nerve to the facial nerve.

(D) In the facial translocation modification of hypoglossal facial nerve transfer, the facial nerve is identified in the mastoid bone and reflected into the neck and sutured to a partially transected hypoglossal nerve.



Masseteric nerve transfer

d. Surgical treatment of chronic facial paralysis (>2 years)

In most cases of chronic facial paralysis of greater than 2 years duration, the native facial musculature has atrophied and requires the use of alternative muscles for facial reanimation. Muscle transfer techniques, including regional and free muscle transfer, are the mainstay of dynamic facial reanimation for chronic facial paralysis

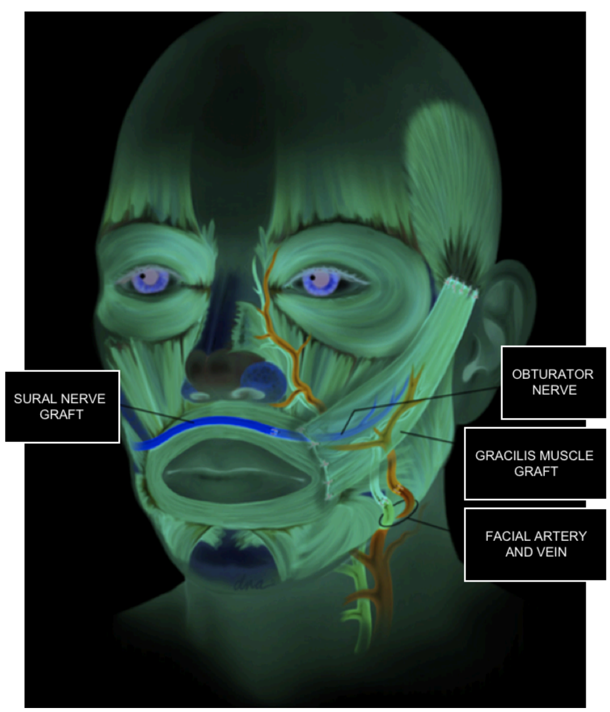
- Regional muscle transfer

The temporalis muscle transfer is the most commonly utilized regional muscle transfer for dynamic facial reanimation. Preoperatively, it is important to ensure that the patient has normal trigeminal nerve function and that the muscle is not atrophic. In the classic temporalis muscle transposition, a 1.5-2.0 cm wide strip of temporalis muscle is elevated from the cranium and rotated inferiorly over the zygoma to reach the oral commissure. The vector of this rotation is favorable because it is typically in the smile vector. A variety of techniques have been described for filling in the depression in the temple created by the muscle transfer including alloplastic implants, fat grafting, and use of the temporo-parietal fascial flap for obliteration of the defect.

Other regional muscle transfers that have been described include the masseter muscle transfer for smile reanimation and the digastric muscle transfer for marginal mandibular nerve injuries. The masseteric muscle transfer is considered inferior to the temporalis muscle transfer because of its more lateral vector of pull.

- Free muscle transfer

The field of facial reanimation has made a dramatic advance with the advent of microvascular free tissue transfer. Free muscle transfer can be utilized if the native facial musculature has been resected, in cases where there is concurrent trigeminal nerve dysfunction precluding use of regional muscle transfer, and as the only way of achieving involuntary, mimetic smile reanimation when used in conjunction with cross-face nerve grafting. A wide variety of muscles have been described for use in the treatment of facial paralysis including the gracilis, pectoralis minor, serratus anterior, latissimus dorsi, and others. The workhorse of free muscle transfer for facial reanimation remains the gracilis muscle. The gracilis muscle is a long, thin muscle located in the medial thigh. It is easily harvested and provides an excellent neurovascular pedicle. Its location in the medial thigh permits the use of a two-team approach with one team for flap harvest and one team for preparation of the recipient site. For unilateral facial paralysis, the gracilis muscle transfer is typically done in two stages. In the first stage, a cross-face nerve graft is performed using a sural nerve graft as described above. After 6-12 months, the second stage is performed wherein the gracilis muscle is harvested and transferred to the paralyzed side of the face. The obturator nerve to the gracilis muscle is coapted to the distal end of the sural nerve graft placed at the first stage. Typically, movement of the muscle is detected by six months but may take up to one year or longer.



Gracilis muscle transfer

In cases of bilateral facial paralysis (Moebius syndrome), the gracilis free muscle transfer can be performed as a single stage. In these cases, where there no cross-facial nerve grafting available, the masseteric branch of the trigeminal nerve is used as the donor nerve to drive the gracilis muscle. For bilateral cases, gracilis muscle transfer can be performed sequentially or simultaneously for both sides.

FACIAL REANIMATION

REINNERVATION OF THE MIMIC MUSCLES	RECONSTRUCTION OF THE FACIAL MUSCLES	STATIC TECHNIQUE
Neurorrhaphy with or without interpositional nerve grafting (auricular or sural nerve)	**Transposition of regional muscular flap** ▪ Temporalis muscle ▪ Masseter muscle ▪ Digastric muscle	**Surgical static technique** ▪ Hemy-rhytidectomy ▪ Brow lift ▪ Canthopexy ▪ Tarsorrhaphy ▪ Upper lid weight insertion (gold,platinum, other alloplastic material) ▪ Oral commissure suspension (Gore Tex, fascia lata, palmaris longus tendon)
Crossover techniques ▪ Hypoglossal-facial crossover procedure (XII-VII) ▪ Spinal accessory to facial nerve crossover technique (XI-VII) ▪ Masseteric-facial nerve anastomosis	**Micro-neurovascular free flap** ▪ Gracilis muscle ▪ Latissimus dorsi muscle ▪ Pectoralis minor muscle ▪ Others (serratus anterior, rectus abdominis muscle/extensor digitorum brevis/ALT flap)	**Non surgical procedures:** ▪ Botox chemodenervation ▪ Autologous fat transplantation ▪ Hyaluronic acid injection
Cross facial grafting		

Most common facial reanimation surgical procedures

Acute facial paralysis (<3 week)	Intermediate-duration facial paralysis (3 week to 2 yr)	Chronic facial paralysis (>2 yr)
Facial nerve	Cross-face nerve grafting	Regional muscle
decompression		transfers
Transmastoid		Temporalis
Middle-fossa	Nerve transfers	Masseter
Translabyrinthine	Hypoglossal	Digastric
	Masseteric	
Facial nerve repair	Spinal accessory	Free muscle transfer
Primary		Gracilis
Cable graft		Serratus anterior
		Latissimus dorsi
		Pectoralis minor

Most common facial reanimation surgical procedures in relation to the timing

PURPOSE OF THE PROJECT AND DATA COLLECTION

The aim of this project was focused principally on the optimization of the treatment of patients affected by inveterate facial paralysis; we have focused our attention on the treatment of the upper third of face and in particular on the treatment of lagophtalmos, the most common pathological condition presents in the upper lid in long standing facial palsy patients.

Till now we have evaluated 81 patients affected by facial palsy who referred to ENT and Plastic Surgery Units. Forty seven of these patients (77%) presented lagopthalmos; 14 patients referred to other centers and so 33 patients were considered for the project.

Five of these patients were eligible for the proposed treatment.

The personal and clinical data of the patients were recorded in a computered EXCEL® database.

Inveterate non complete closure of the upper eyelid was the essential condition to enroll the patients.

CONDITION	PROCEDURE
Non complete closure of the upper lid	Upper lid weight loading

STUDY TYPE: Experimental

STUDY DESIGN: A single center Pilot Perspective non randomized study

PRIMARY OUTCOME MEASURES:

a) Feasibility of a customized upper lid CobaltChrome implant
b) Efficacy of the proposed custom-made lid loading

BENEFITS OF UPPER LID IMPLANT

- Facilitates and improve eyelid closure
- Improves corneal protection
- Assists blinking
- Protects ocular complications
- Eliminates need for disfiguring tarsorrhaphy
- Improves facial appearance
- Reversible procedure

COMPLICATIONS OF UPPER EYELID WEIGHT

Despite several benefits, upper eyelid weight placement includes functional and aesthetic complications.

FUNCTIONAL COMPLICATIONS:

- blepharo-ptosis
- displacement and implant migration

• foreign body reaction

• extrusion of the implant

• infection of the implant

• gold or platinum intollerance/allergy

• vision loss

AESTHETICAL UPPER THIRD COMPLICATIONS

• irregular eyelid contour

• visibility of the implant

• lid bulging

• evident asymmetry with contralateral side

c) Responder lid closure

1c) not possible

2c) partially possible

3c) completely possible

SECONDARY OUTCOME MEASURES:

a) FUNCTIONAL RECOVERY

ocular complications: epiphora, ocular irritation, pain, conjunctivitis, keratytis, corneal exposure, corneal ulceration, blindness

b) AESTHETIC ASPECT AND SYMMETRY OF THE TWO HEMYPARTS OF THE UPPER THIRD OF THE FACE

Post operative 2D anthropometric measurements to evaluate symmetry of the two hemyparts of the upper third of the face in resting and in a dynamic condition and reduction of the ocular surface exposure in vertical and supine position.

Anthropometric parameters:

a) lateral canthus (healthy side/affected side)

b) upper lid lash line at midpupillary line (healthy side/affected side)

c) lower lid lash line at midpupillary line (healthy side/affected side)

d) superior brow at midpupillary line (healthy side/affected side)

UPPER THIRD

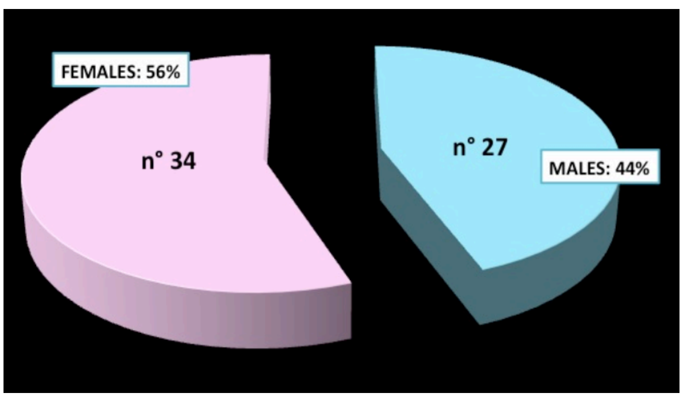
e) nasion (rhinion)

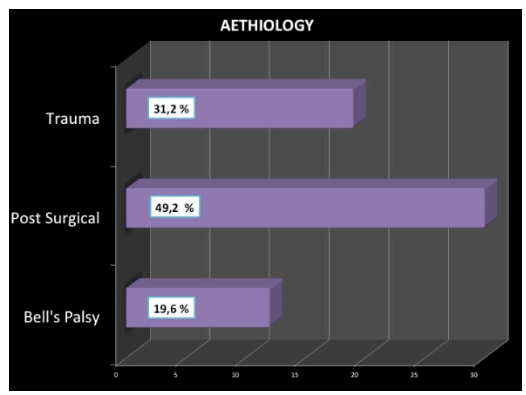
c) QUALITY OF LIFE: QUESTIONNAIRES ABOUT QUALITY OF LIFE (FaCE questionnaire)

DATA COLLECTION

Analizing the patients features collected during the first step, we have found the following data:

- a total of 81 patients, 61 of those affected by inveterate facial palsy and then enrolled in the database
- 56% Females (n° 34)
- 44% Males (n° 27)
- mean age 54 yrs (from 23 yrs to 86 yrs)





AETIOLOGY	*N° patients*	*%*
BELL'S PALSY	12	19,6%
POST TRAUMATIC INJIRIES	19	31,2%
IATROGENIC CAUSES	30	49,2%

GROUPS/COHORTS	ASSIGNED INTERVENTIONS
cohort of consecutively enrolled patients with **lagophthalmos**	individually customized load weight

ELIGIBILITY

- **AGE ELIGIBLE FOR STUDY:** adult > 18yrs
- **GENDER ELIGIBLE FOR STUDY:** M and F

STUDY POPULATION

- Patients with lagophtalmos due to inveterate facial palsy
- Ocular complications due to corneal exposure

CRITERIA

INCLUSION CRITERIA	EXCLUSION CRITERIA
• **Unilateral lagophtalmos due to facial palsy** • **Patients able to understand and sign the informed consent to the procedure**	• Patients < 18 yrs • Known metal allergy • Systemic disease • Potentially aggravating the Peripheral Facial Palsy (neurological, degenerative, endocrinological) • Pregnancy • Abuse of drugs and alchol

The patients who met the inclusion criteria, have been informed on study design and outcomes, and were required to participate in the study. Each patient was assigned an identification code, consisting in the sequential number of the patients and his\her initials (Protocol LIDLOADING01).

PATIENTS ELIGIBLE FOR THE PROJECT: 5

LOCATION: Bologna, Sant'Orsola Malpighi - University Hospital

KEYWORDS: "paralytic lagophthalmos, eyelid OR facial reanimation, tarsorraphy, canthopexy, upper eyelid loading".

PZ ENROLLED	SEX	AGE	DIAGNOSIS
1	M	75	ACOUSTIC NEUROMA
2	M	82	IATROGENIC CAUSES(Parotid Cancer)
3	M	79	IATROGENIC CAUSES (Parotid Cancer)
4	F	61	ACOUSTIC NEUROMA
5	M	72	IATROGENIC CAUSES (Parotid Cancer)

	FUNCTIONAL ASSESMENT	SUBJECTIVE ASSESMENT	
	Facial Palsy Grading	Questionnaire about quality of life	
PZ ENROLLED	**HBGS** House-Brackmann Grading Scale	**FaCE** Facial Clinimetric Evaluation	**FDI score** Facial Disability Index
1	**V°**	**29/100**	0,515
2	**VI°**	**15/100**	0,415
3	**V°**	**21/100**	0,445
4	**IV°**	**38/100**	0,49
5	**VI°**	**16/100**	0,35

	FUNCTIONAL ASSESMENT			
	Residual muscle activity	Ophtalmologic evaluation		
PZ ENROLLED	EMG	LAGOPHTALMOS	KERATITIS/ CORNEAL INJURY	HYPERLACRIMATION
1	-	●	●	●
2	-	●	●	●
3	-	●	●	●
4	-	●	●	●
5	-	●	●	●

FaCE Instrument

The following statements are about how **you** think your face is moving.
You may have answered these or similar questions before.
Please answer **all** questions as best you can.

(CIRCLE only ONE number)

	One side	Both sides	I have no difficulty
When I try to move my face, I find that I have difficulty on:	1	2	0

(NOTE: **If** you have problems on **both** sides, answer the questions in the remainder of the survey with regard to the **more** affected side, or with regard to both sides of they are **equally** affected.)

In the past week: (CIRCLE only ONE number on each line)

On the Affected Side:	Not at all	Only if I concentrate	A little	Almost Normally	Normally
1. When I *smile*, the side of my mouth goes up	1	2	3	4	5
2. I can raise my eyebrow	1	2	3	4	5
3. When I *pucker* my lips, the affected side of my mouth moves	1	2	3	4	5

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4. Parts of my face feel tight, worn out, or uncomfortable	1	2	3	4	5
5. My affected eye feels dry, irritated, or scratchy	1	2	3	4	5
6. When I move my face, I feel tension, pain, or spasm	1	2	3	4	5
7. I use eye drops or ointment in my affected eye	1	2	3	4	5
8. My affected eye is wet or has tears in it	1	2	3	4	5
9. I act differently around people because of my face or facial problem	1	2	3	4	5
10. People treat me differently because of my face or facial problem	1	2	3	4	5
11. I have problems moving food around in my mouth	1	2	3	4	5
12. I have problems with drooling, or keeping food or drink in my mouth or off my chin and clothes	1	2	3	4	5

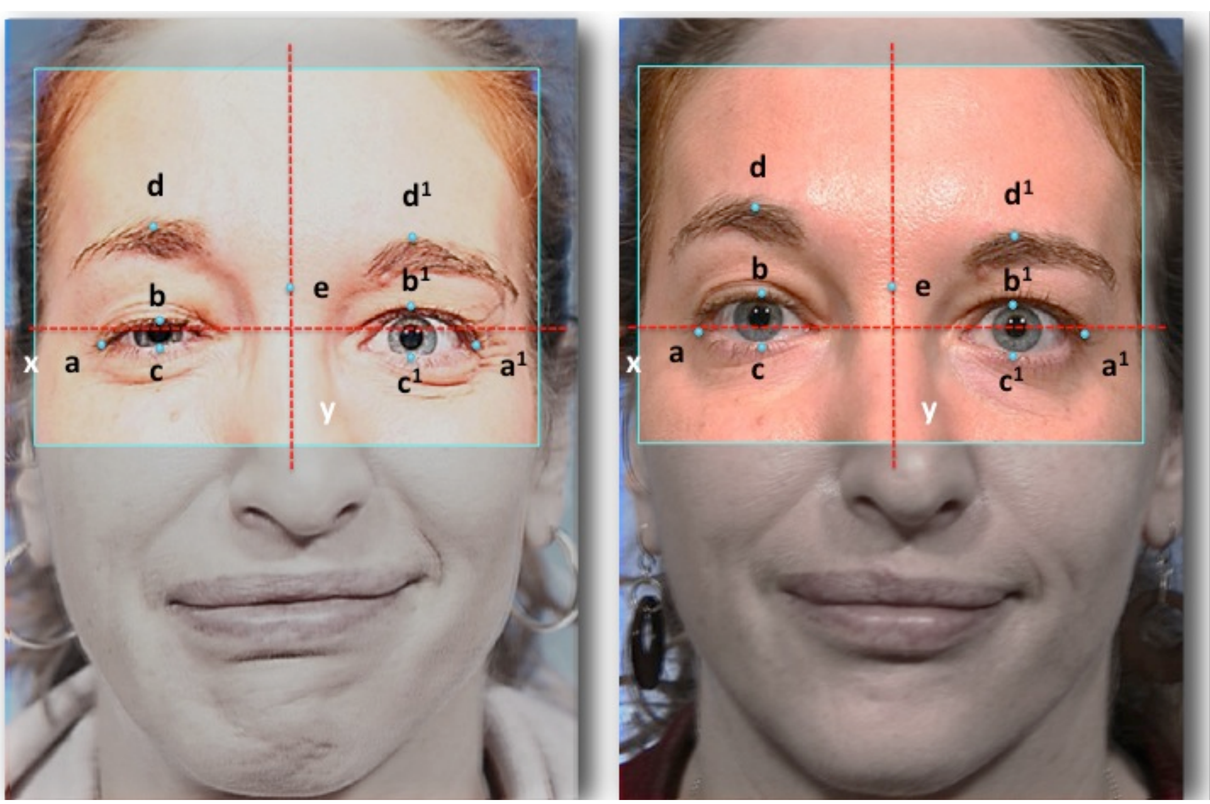
The following are statements about how you might have **felt or been doing** in the **past week** because of your face or facial problem. Please rate how much you agree with each statement:

(CIRCLE only ONE number on each line)	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
13. My face feels tired or when I try to move my face, I feel tension, pain, or spasm	1	2	3	4	5
14. My appeareance has affected my willingness to participate in social activities or to see family or friends	1	2	3	4	5
15. Because of difficulty with the way I eat, I have avoided eating in restaurants or in other people's homes	1	2	3	4	5

The careful physical and clinical examination includes detailed photo documentation, to assess pre-operative 2D anthropometric measurements, to evaluate asymmetry of the halves of the face and to evaluate the rate of reduction of the ocular surface exposure in vertical and supine position.

Anthropometric parameters considered for UPPER THIRD were:

a)	**lateral canthus (healthy side/affected side)**
b)	**upper lid lash line at midpupillary line (healthy side/affected side)**
c)	**lower lid lash line at midpupillary line (healthy side/affected side)**
d)	**superior brow at midpupillary line (healthy side/affected side)**
e)	**nasion (rhinion)**



- a: ***lateral canthus***
  (healthy side / affected side)
- b: ***upper lid lash line at midpupillary line***
  (healthy side / affected side)
- c: ***lower lid lash line at midpupillary line***
  (healthy side / affected side)
- d: ***superiore brow at midpupillary line***
  (healthy side / affected side)
- e: ***nasion (rhinion)***

  - **resting**
  - **tight eye closure**

The measured facial landmarks, will be related to the vertical midline plane (*y*) and orizontal plane (*x*). The anthropometric evaluation will be performed on the basis of the most common facial landmarks proposed by Farkas during resting (stand-up and supine position) and in dynamic selected movements (tight eye closure/blinking and smiling).

2D Image Based Computer Aided Diagnosis

To overcome the shortcomings of subjectivity and disparity in the various manual grading systems, several objective facial asymmetry grading systems have been reported. They are typically based on 2D images focusing on automated analysis of asymmetry of facial features. Apparently, the severity of the patient’s condition is closely relevant to the degree of the asymmetry of the face. Several of pioneering works also involve manually placing markers on the face to trace the facial movements, or label the feature points on the images. For example, Wachtman et al. evaluated the severity of facial paralysis by measuring the facial asymmetry for static 2D images. Facial feature points were labeled manually on the images to define the face midline. Although these methods make the image processing simpler, they have relatively poor maneuverability since they need well-trained technicians to accurately and precisely place the markers on the right positions.

Some other automated methods without the use of markers have also been developed. McGrenary et al. quantified the differences between the images of a video as the measurement of facial paralysis. Wang et al. developed an objective facial paralysis grading method based on P-face and eigenflow on the static pictures of voluntary expressions of a patient. P-face which stems from a human identification index, is a facial asymmetry measurement between two sides of the face. Eigenflow is a measurement of the expression variation between the patient and normal subjects. He et al. presented an approach automatically analyzing patient video data, which would need to manually define the relevant facial regions. However, 2D image and video acquisitions are the projection process from 3D to 2D space, which definitely causes information loss. Compared to traditional 2D images or videos, 3D images retain more information of local contour, and thus should be introduced to the facial contour analysis work. Some of these methods also analyze the difference of radial coordinates between opposite points in cylindrical coordinate system, and thus require an accurately set reference coordinate system.

In summary, although facial paralysis is a 3D problem, most reported works on the development of computer based objective grading system for facial paralysis are based on 2D images or videos. Few studies have applied the 3D technology which provides more local contour information of the face. Moreover, few reported works have examined the sensitivity of the proposed grading system for the evaluation of improvement or deterioration of the proposed objective grading systems.

As a result, lots of practitioners have considered computer-based 3D technologies, which offer surgical professionals with more contour information than mere 2D images. This is in view of the fact that details are lost while projecting a 3D object to 2D, and 3D models are also not susceptible to the lighting condition variation or camera pose. Moreover, advanced 3D scanners are characterized by their convenience, portability, non-invasiveness, precision, and accuracy, and the adoption of 3D technology to aid surgeons will avoid uncertainty and subjectivity which is inherent to current analysis techniques.

All the objective facial paralysis diagnosis studies reviewed above suffered from a serious limitation in that they rely on manually setting the landmarks. Meanwhile, there is still a huge potential of untapped 3D techniques for facial mesh asymmetric analysis.

SYSTEMATIC REVIEW

One of the purposes of the project was to collect the necessary literature to improve and modernize the various therapeutic algorithms described, to define a standardized protocol of treatment. A through literature search was conducted until December 2017 using PubMed/MEDLINE/Scopus to identify and include all citations reporting outcomes of upper eyelid facial palsy treatment.

We have conducted a systematic review following the guidelines of the **P**referred **R**eporting **I**tem for **S**ystematic Reviews and **M**eta-**A**nalysis (**PRISMA** statement), which are a standardized and widely utilized criterion for performing effective systematic reviews.

Using the search terms, paralytic [All Fields] AND lagophthalmos [All Fields] AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) a query of the Pubmed/Medline, Scopus and Web of Science was performed for articles describing the SURGICAL management of the eye in facial palsy.
Eligibility of the papers depended on PICOS criteria:

- *Patients*
- *Intervention*
- *Comparison*
- *Outcomes*
- *Study design*

A total of 21 articles were included in the study after screening 158 publications regarding this topic.

TREATMENT OF LAGOPHTALMOS
Blepharorrhaphy
Upper lid loading (precious metal)
Upper lid loading (allograft)
Upper lid loading (cartilage graft)
Magnetic implantation
Lateral tarsorrhaphy
Palpebral spring
Tarsal string procedure
Canthopexy
Muscle transfer
Cross-facial Nerve grafting – Nerve transfer
Eye weight patch
Ocular drops and medical management (ointments or artificial drops)

The results were collected in the manuscript:

"Surgical treatment for long standing paralytic lagophtalmos: a systematic review"

Pinto V, Camacho M, Marchetti C, Pirodda A, Piccin O

accepted for next publication on Laryngoscope Journal (IF 2,7).

PROJECT DESCRIPTION

Critical point of the traditional “lid loading”

As previously reported we focused our attention on the treatment of the upper third of the face and in particular on the treatment of lagophtalmos.

lag·oph·thal·mos (lag’’of-thalŕm s) [Gr. *lagṓs* hare + *ophthalmos* eye] a condition in which the eye cannot be completely closed

TREATMENT OF LAGOPHTHALMOS
EYE WEIGHT PATCH
BLEPHARORRHAPHY
UPPER LID WEIGHT (PRECIOUS METAL)
UPPER LID WEIGHT (CARTILAGE GRAFT)
UPPER LID WEIGHT (SILICON IMPLANT)
MAGNET IMPLANTATION
METAL SPRING IMPLANTATION
FASCIA GRAFT
MUSCLE TRANSFER
NERVE TRANSFER

Classic treatments of the lagophthalmos

Surgical treatment of upper eyelid retraction in the setting of facial palsy most commonly involves upper eyelid loading by adding weights to the upper eyelid and using gravitational forces to move the eyelid downward. For many years, rigid gold weights were the recommended eyelid loading material. Many studies have reported improvement in lagophthalmos, keratopathy, visual acuity, and cosmesis after the placement of upper eyelid gold weights, with good patient satisfaction. Recently, the use of platinum has been advocated as an alternative to gold.

Platinum has a reduced allergic response and is denser than gold, which allows for the use of smaller implants of the same weight and a lower risk of extrusion. Although low-profile rigid weights are available, a flexible platinum/iridium chain implant is now available, which is thought to adapt better to the shape of the upper eyelid tarsus.

The platinum chain matches much more the anatomic prerequisites of the upper eyelid, but it is much more expensive. By using the platinum chain as an implant, postoperative complications can be decreased and thus the effectiveness of the treatment can be enhanced. Moreover, although is a technically simple procedure feasible in all centers, this technique is not for every patients because of high cost of the implant and especially for the customization of the system failure which often results in high rate of complications and poor tolerability and discomfort by the patient.

Traditional Gold or Platinum Lid loading

For these reasons and to avoid the complications related to the loading material and pertinent surgical techniques, the purpose of this dissertation was to develop a technical refinement both of the shape and material of the implant, and also of the surgical technique.

First, reviewing the literature, we evaluated the presumed reasons of the failure of the described techniques, to carry out the appropriate changes to optimize the implant.

In the upper eyelid weight implant is often inappropriate to promote the closure of the eye after its placement: one of the reasons could be the migration of the implant on the tarsal plate in a high position. The easy displacement can be explained with the different angle between the vertical line and the transversal axis of the prosthesis that does not match with the natural curvature of the eyeball; this condition is more evident when patient changes head position, so the result could be acceptable in stand by position, but the eye closure it is not guaranteed in supine setting. The efficacy of upper eyelid weights, in fact, is dependent on head position as well as the globe size and right placement.

They tend to be most effective when the head is in the upright position and gravitational forces are optimal. As the head reclines, the vector changes and the degree of eyelid closure decreases, with loss of efficacy beginning approximately at a 45-degree incline. So we assert that, according to the principles of the physics and gravity, to plan an anatomical shape implant, fitting the lower lid edge, with a different specific weight, it can maintain its function also during head movements, thanks to the most of its weight centered along the entire eyelid margin.

Another disadvantage is that the traditional upper eyelid implant has the same specific weight along the entire surface of the prosthesis: we think that to permit the correct eye closure during supine position, the most of the weight must be centered at the middle part and lower edge of the upper eyelid combined to an anatomical curvature that follows the upper lid crease. This shrewdness on the shape avoids the backwards slipping of the implant and then the pathological opening of the upper lid and the exposure of the eyeball.

Regarding these practical and physical considerations, we considered the possibility to perform a pre-operative 3D model of the healthy side to have a customized prosthesis as an alternative treatment to the traditional gold weight implant.

Planning of the customized upper lid implant

Design of the 3D upper lid implant (CAD-CAM technology)

As we know, the actual upper lid implants have a non-standard weight and can be made of gold or platinum. About weight, there are seven standard sizes, ranging from 0,6 to 2,0 grams, and, some Companies produce also special sizes, ranging from 2,0 to 2,8 grams, but the actual implants have the same shape for every patient.

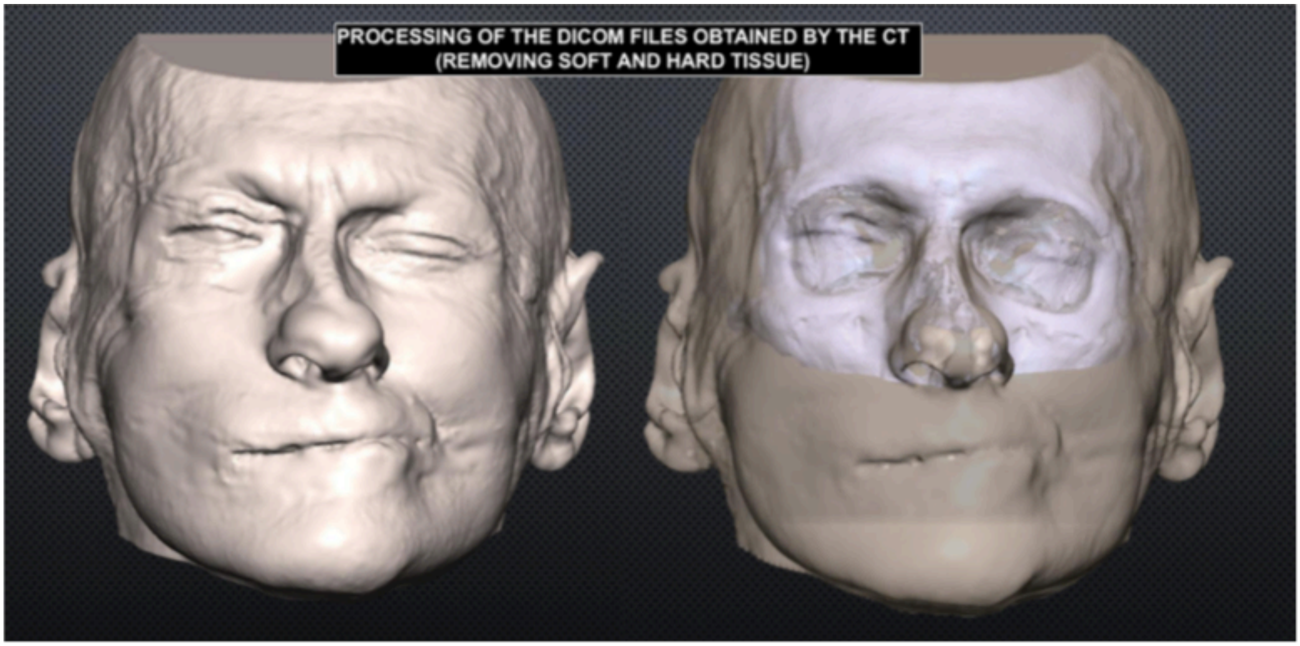
In our opinion it is essential to produce eyelid implants fitting perfectly to the anatomical curvature and to the eyeball size, respecting the patient's proper anatomy. The ideal anatomical eyelid implant must have a curved shape which conforms to the fitting spherical ocular globe. Moreover, it have to respect the longitudinal diameter of the upper lid and it must reach and fit the natural upper lid crease to avoid rotation, migration or inversion of the implant.

We have planned to perform an anatomical specular 3D model based on the contralateral healthy side that can be considered a "Custom-made" Upper Eyelid Implant model.

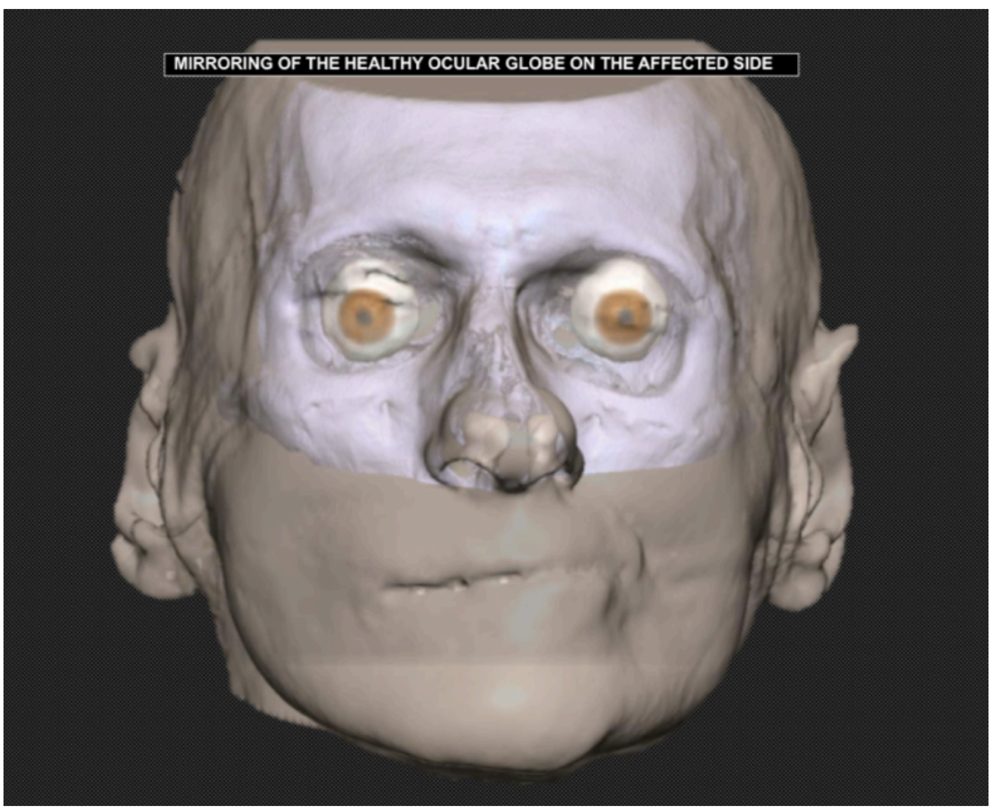
Computer-assisted technology using computerized tomography plays an emerging role in orbital reconstruction during preoperative planning, implant design, intraoperative navigation and postoperative auditing. In preoperative planning, a mirror image overlay is created based on the "uninjured", contralateral eye and is superimposed onto the images of the "injured" side. During computer-aided design and computer-aided modeling (CAD/CAM), the bidimensional CT data is segmented and digitally transformed to create a three-dimensional model via stereolithography. This is then used to manually mould or manufacture a "patient- specific" implant. To address these issues, the use of a direct computer-aided design/computer aided manufacturing procedure (CAD/CAM) with the manufacture of a custom-made implant through direct metal laser sintering has been introduced (DMLS). This technology is able to reproduce carefully the spherical curvature conforms to the shape of the ocular globe fitting on the 3D customized model based on contralateral upper lid CT based anatomy. The eyelid implant was manufactured directly using an EOSINT M270 system (Electro Optical Systems GmbH, Munich, Germany). The working principle was based on DMLS, in which metal powder is fused into a solid part and melted locally using a focused laser beam. As usual for additive manufacturing technologies, the parts were built up additively in layers.

DATA SHEET – EOSINT M270	
PRINTING SPEED	2 – 20 mm^3/sec
THICKNESS OF THE PRINTING LAYERS	20 – 100 micron
LASER TYPE	Yd-fibre laser – 200 W
FOCUS DIAMETER	100 – 500 micron
CAD interface	STL
CERTIFICATE	CE NFPA

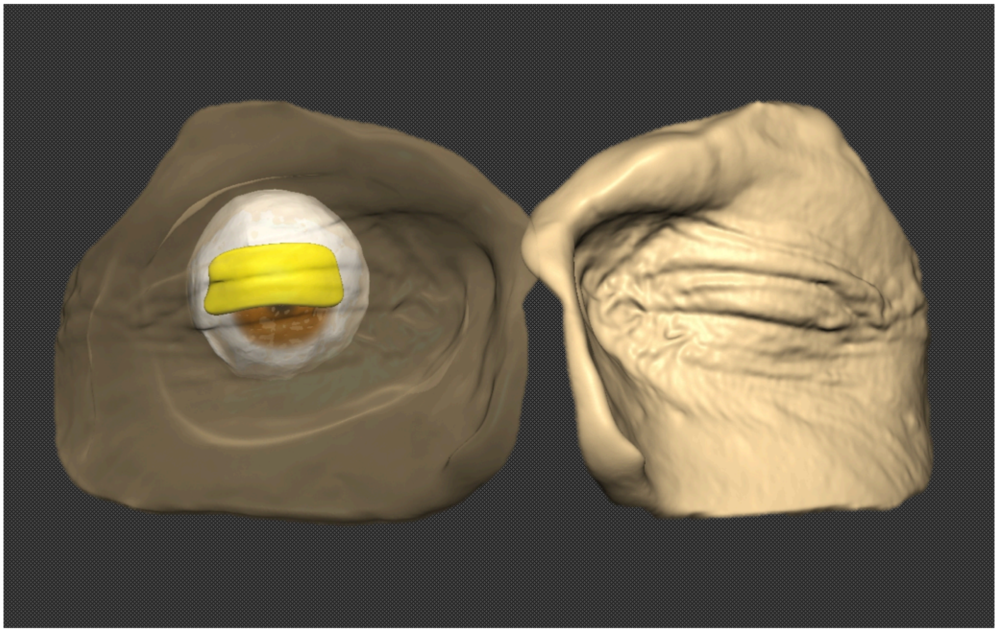
EOSINT M270 system (Electro Optical Systems GmbH, Munich, Germany)



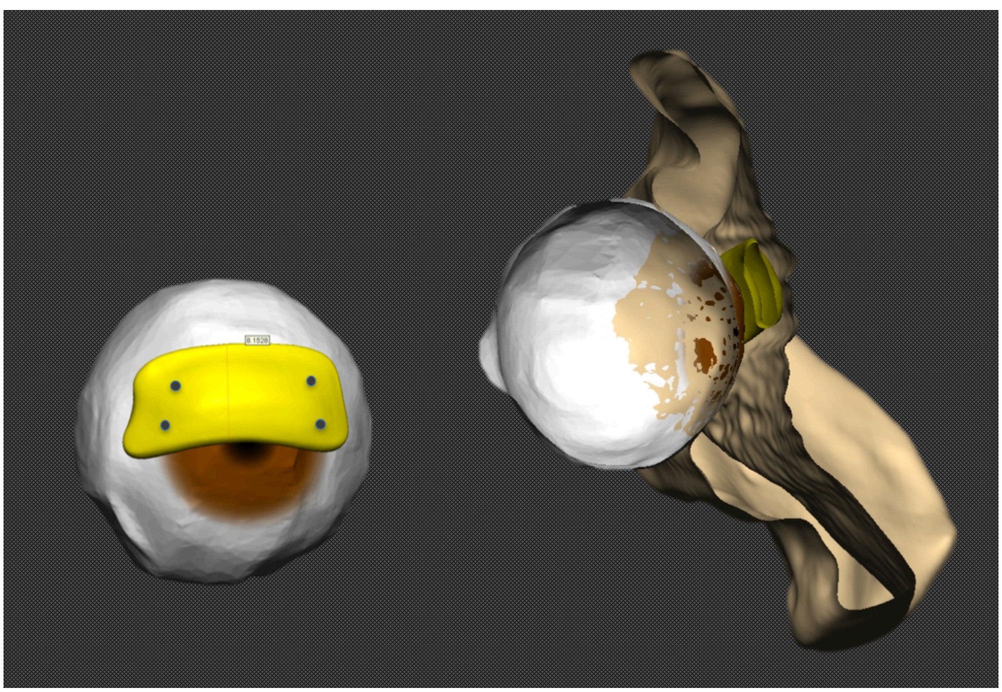
Processing of the DICOM files obtained by the CT scan



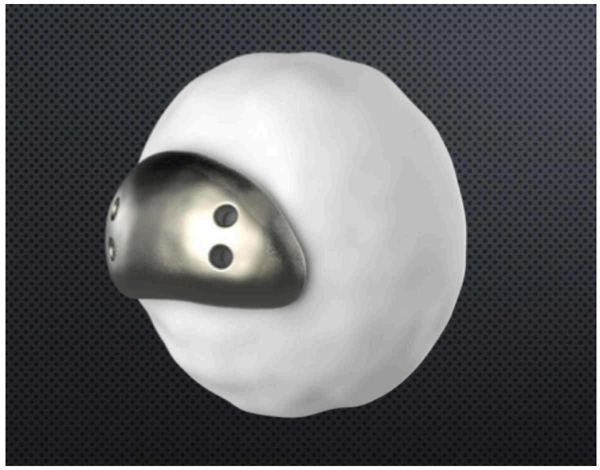
Mirroring of the healthy ocular globe on the affected side



Simulation of the custom made Lid Loading implant



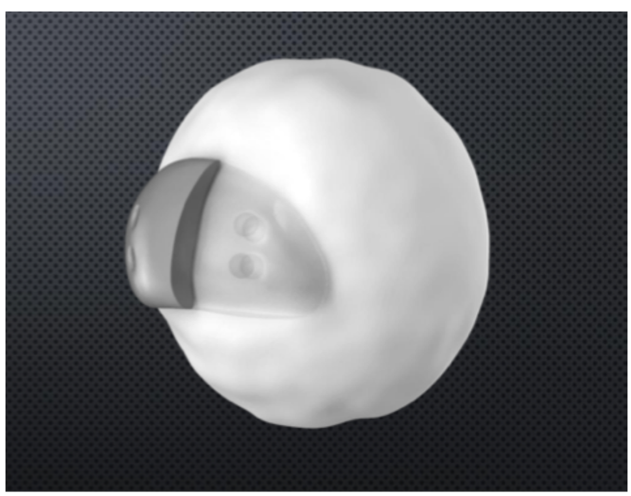
Custom made lid loading implant model



Curvature of the lid loading implant fits natural curvature of the eyeball

The upper part of the implant must fits the natural curvature of the eyeball and must have a thin profile design allowing for superior cosmesis and reduced migration and extrusion.

The upper part is significantly thinner than the thicker lower part of the prosthesis, where is centered the most of the driving weight. This implant design should also improve facial appearance.



Sagittal view of the lid loading implant

As the platinum has a high cost, we have proposed to use an alternative biocompatible material, according to its specific weight, flexibility and strenght).

METAL - ALLOY	SPECIFIC WEIGHT	METAL - ALLOY	SPECIFIC WEIGHT
acciaio comune	7.8 - 7.9	mercurio	13.6
acciaio inox	7.48 - 8	metallo antifrizione	9.3 - 10.6
acciaio laminato	7.85	metallo bianco	7.1
alluminio laminato	2.70 - 2.75	metallo delta	8.6
alluminio fuso	2.56 - 2.64	molibdeno	10.2
alpacca	8.4 - 8.9	monel	8.36 - 8.84
argentana	8.4 - 8.9	nichel	8.8
argento	10.49	oro	19.25
berillio	1.84	ottone in getti	8.4 - 8.7
bronzo (8-14% stagno)	7.4 - 8.9	ottone laminato e trafilato	8.43 - 8.73
bronzo fosforoso	8.78 - 8.92	piombo	11.34
bronzo di alluminio (3-10% Al)	7.7 - 8.7	platino	21.4
bronzo al piombo	8.8 - 9.5	rame	8.93
ferro	7.85	rame al berillio	8.1 - 8.25
ghisa	6.8 - 7.8	stagno	7.28
leghe leggere a base Mg	1.76 - 1.87	tungsteno	19.1
leghe leggere a base Al	2.56 - 2.8	zinco	7.1

With the aid of some chemical engineering of the University of Bologna and of the Sintac srl Company, we have tried to apply others biocompatible material to the implant.

We suggested to produce the device using EOS CobaltChrome SP2, a multi-purpose cobalt–chrome–molybdenum-based super alloy powder that has been optimised for DMLS on EOSINT M270 systems.

The bio-model of the actual upper eyelid was manufactured directly using a 3D soluble support technology rapid-prototyping machine (Stratasys, Eden Prairie, MN, USA).

CobaltChrome SP2	
MATERIAL COMPOSITION	Co: 61,8 – 65, 8 wt % Cr: 23,7 – 25,7 wt % Mo: 4,6 – 5,6 wt % W: 4,9 – 5,9 wt % Si: 0,8 – 1,2 wt % Fe: max. 0,50 wt % Mn: max. 0,10 wt %
RELATIVE DENSITY WITH STANDARD PARAMETERS	Approximatively 100%
ABSOLUTE DENSITY WITH STANDARD PARAMETERS	Min. 8,50 g/cm^3

<u>CobaltChrome SP2 (Super Metal Alloy) has many advantages in comparison to gold and platinum:</u>

CobaltChrome SP2 (Super Metal Alloy)
Biocompatible
Amagnetic
Stainless
White shiny color *(similar to platinum, not visible under the eyelid)*
Without impurities *(Gold, on the contrary, is processed by fusion and laminating, therefore it presents a high risk of impure metal residues, responsible for allergic reactions and foreign body , as demonstrated in dental implantology)*
Cost saving in comparison to gold and even more to platinum

The appropriate weight for the implant is found by adhering different weights from the Weight sizing set to the outside of the upper eyelid, as for the traditional implant. To determine the correct weight for the eyelid implant we have to affix the adhesive strip weight (1.0 gram sizing weight) to the concave side with the patient sitting up-right, approximately 3.0 mm above the lash line (centered at the junction of the medial and central thirds of the eyelid). At this point the action of the levator function is maximal. Then increase or decrease the sizing weight until the best result is achieved. Because the levator seems to strengthen after the weight is added, the optimal weight is usually that which holds the lid about 1.0 mm lower than the normal lid as the patient looks straight ahead.

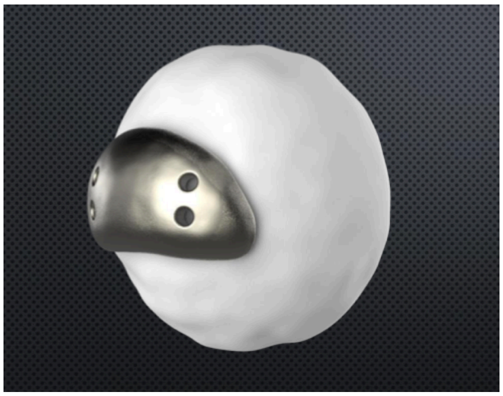
Anyway, according to the literature, a weight implant 0,2 g heavier than expected should be chosen to obtain better eye closure in terms of quantity and time of closure for lagophatlmos in facial paralysis. We believe that a 3D customized modification of the existing eyelid implant and of the surgical procedure, could decrease the complication rate and could increase patient's compliance and tolerability.

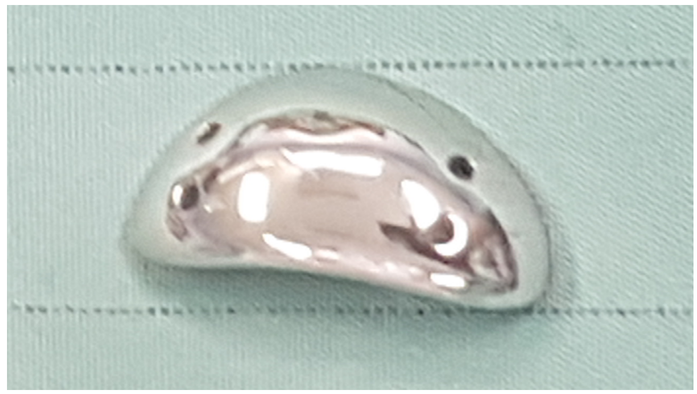
Other implant features

- spherical curvature conforms to the shape of the ocular globe fitting on the 3D customized model based on contralateral upper lid anatomy (concave shape on the inner part to adapt itself to the tarsal plate)
- tapered, smooth edge and rounded corners
- surfaces and edges of the implant are smoothly polished to ensure tissue compatibility

- 1.0 mm suture holes for secure fixation on the tarsal plate

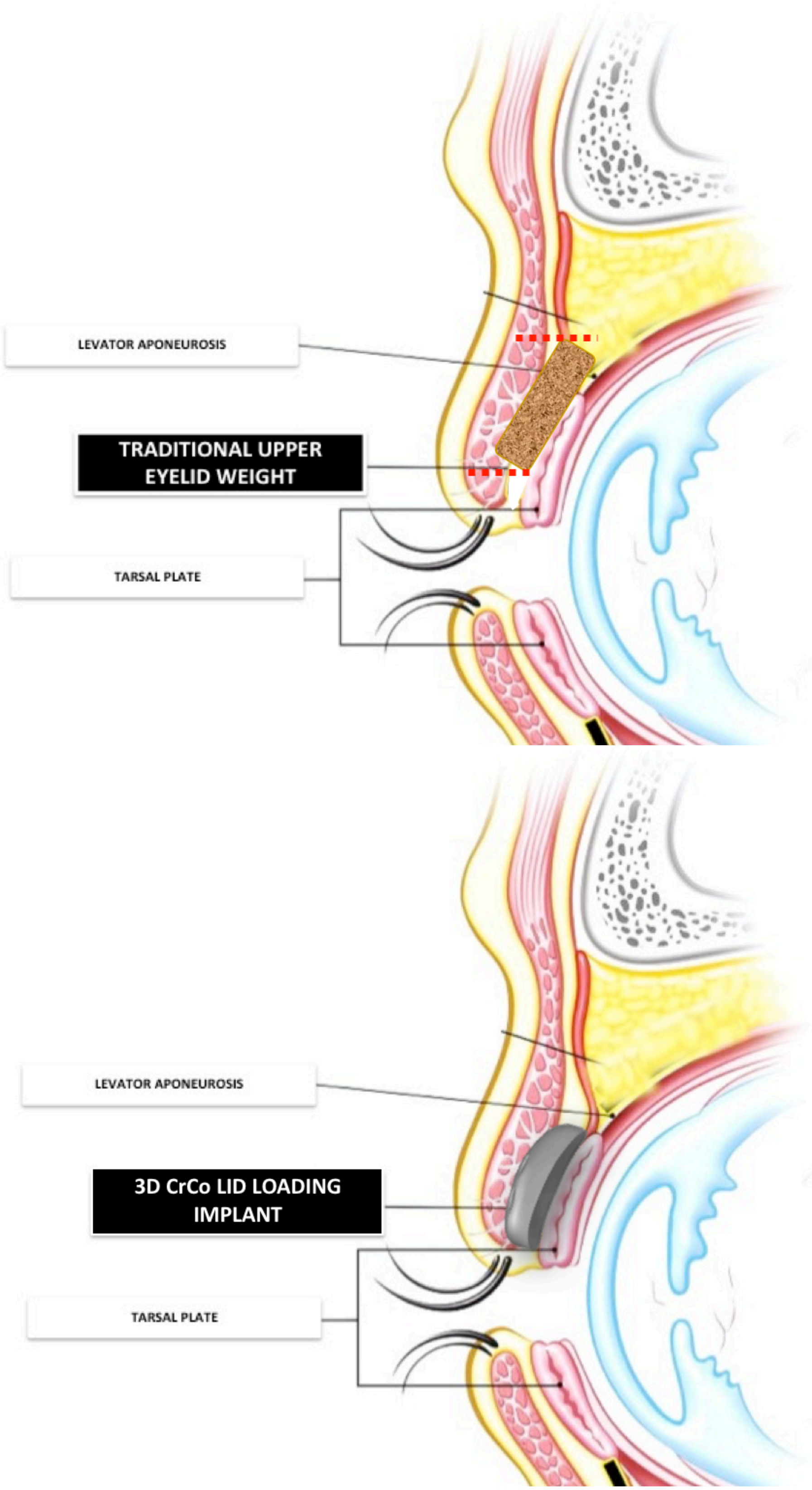
The planned implant must be sterilizable for aseptic surgical utilization.





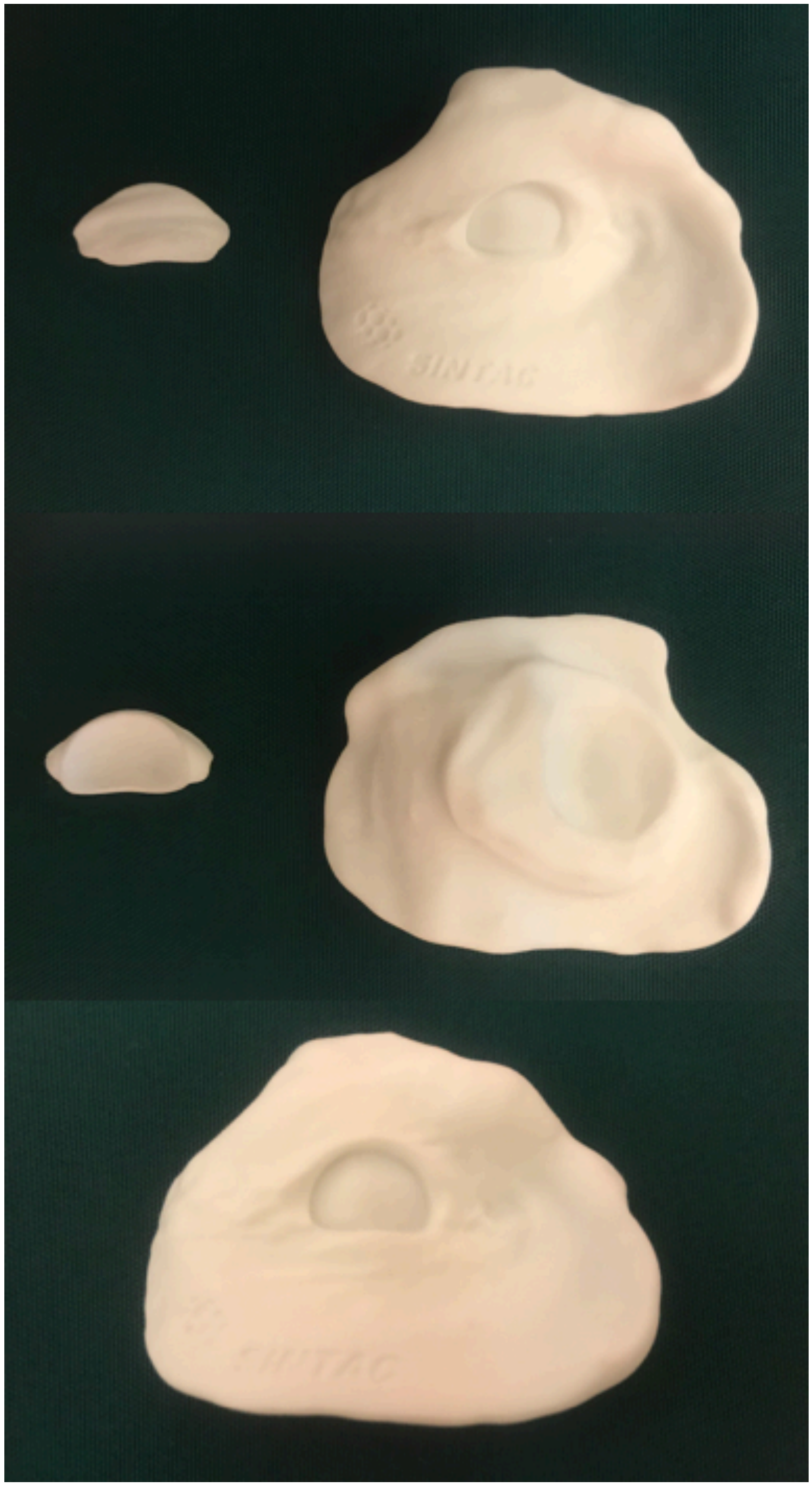
Features of the customized CobaltChrome lid loading

Comparison between traditional gold implant and customized Cobalt Chrome implant



Implant placement

3D simulation



3D simulation

Planning of the surgical procedures

The traditional approach using the pretarsal crease incision leads to interruption of the anterior levator muscle fibers, which attach to the face of the tarsus at its upper two thirds. This disruption can lead to excessive permanent upper eyelid blepharoptosis, leading to obstruction of vision.

The retrograde approach avoids this problem but results in an incision at the lid margin, the dependent aspect of the weight. This theoretically increases the risk of implant extrusion. We propose a surgical technique that uses a supratarsal skin crease incision as during a blepharoplasty procedure, and a supramuscular dissection along the entire anterior levator muscle surface. At this time we separate the fibers in the midline, without interrupting them to access to the tarsal plane. So we can create a submuscolar pocket for implant insertion, and layered closure. We performed this technique on three cadavers (6 lid dissections), and we believe that this approach provides effective surgical treatment for paralytic lagophthalmos while avoiding some of the pitfalls of previously described techniques.

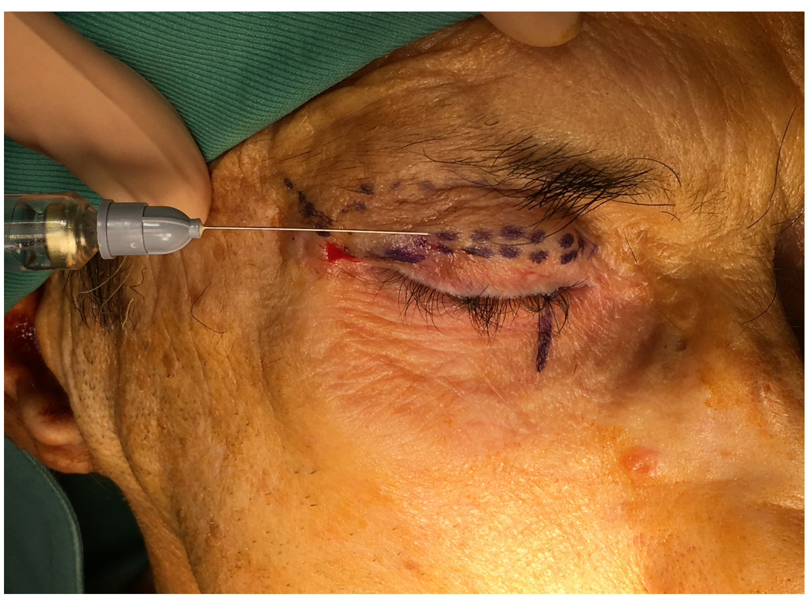
Supratarsal crease incision marking	Sub-muscular pocket over the tarsal plate	Implant *in situ*

Exposure of the tarsus and levator aponeurosis	Lid loading placed in sub muscolar pocket over the tarsal plate	Lid loading in situ sutured to tarsus

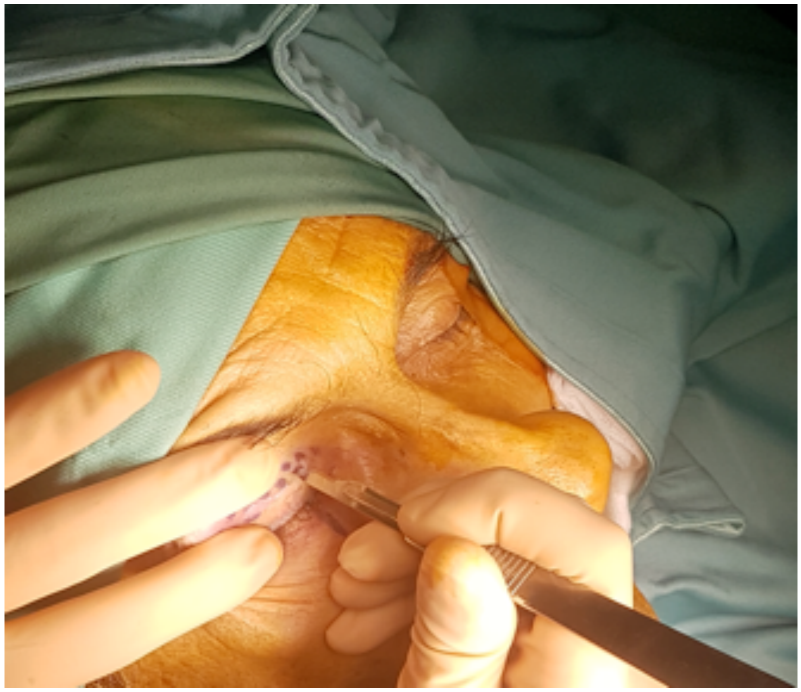
Surgical steps

We plan that implant can be placed under local anesthesia or with sedation;

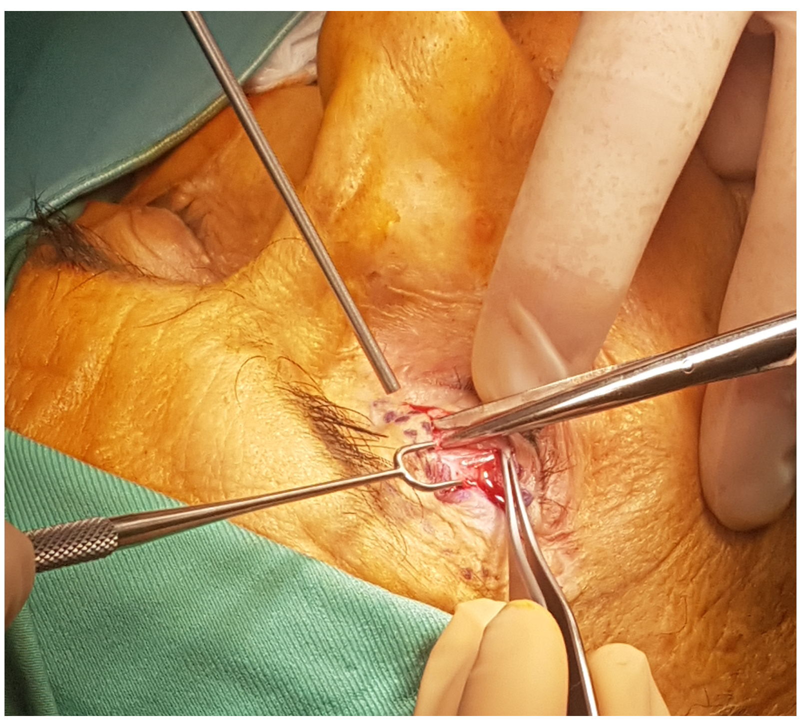
- Injection of local anesthetic solution (a solution of 0.5% bupivacaine hydrochloride with 1:200.000 epinephrine) in the eyelid skin;

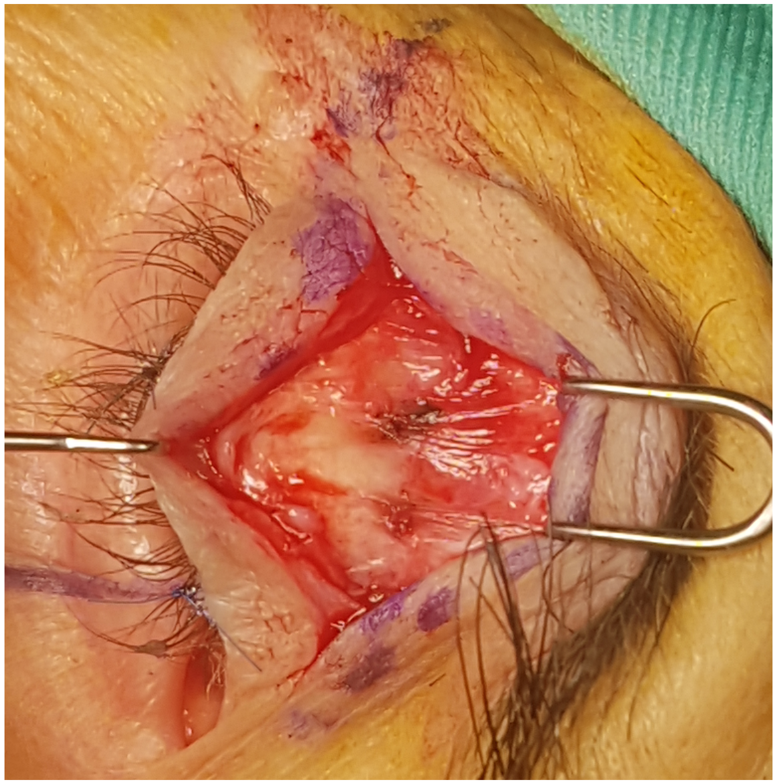


- Skin incision is made along the upper eyelid crease;

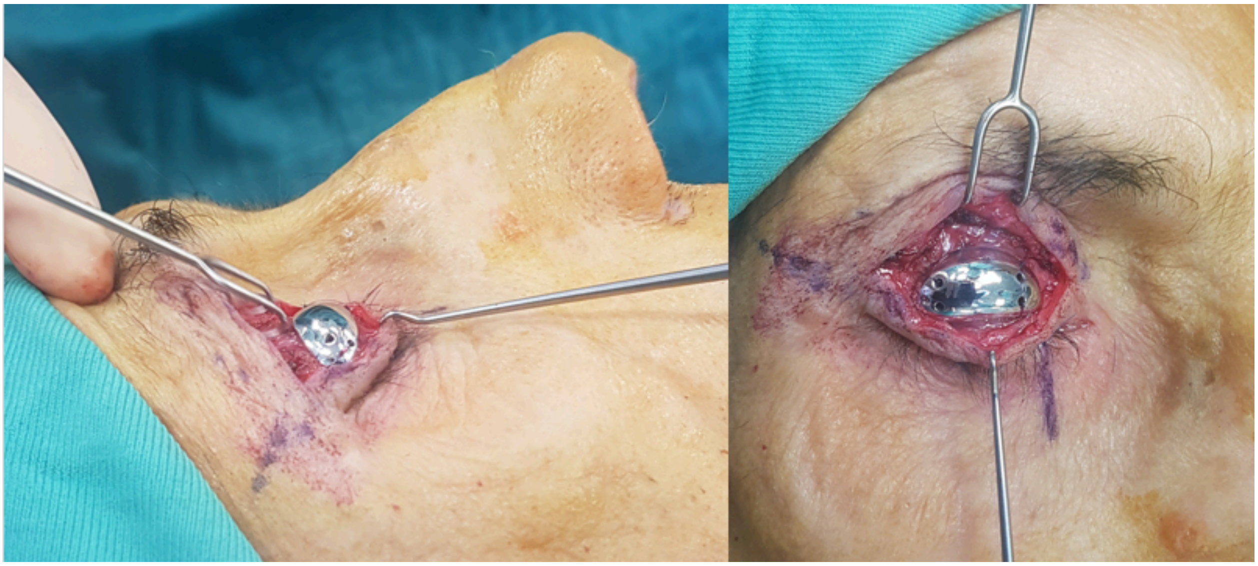


- Blunt dissection to perform an implant pocket, deep to the orbicularis oculi muscle but superficial to the tarsal plate;

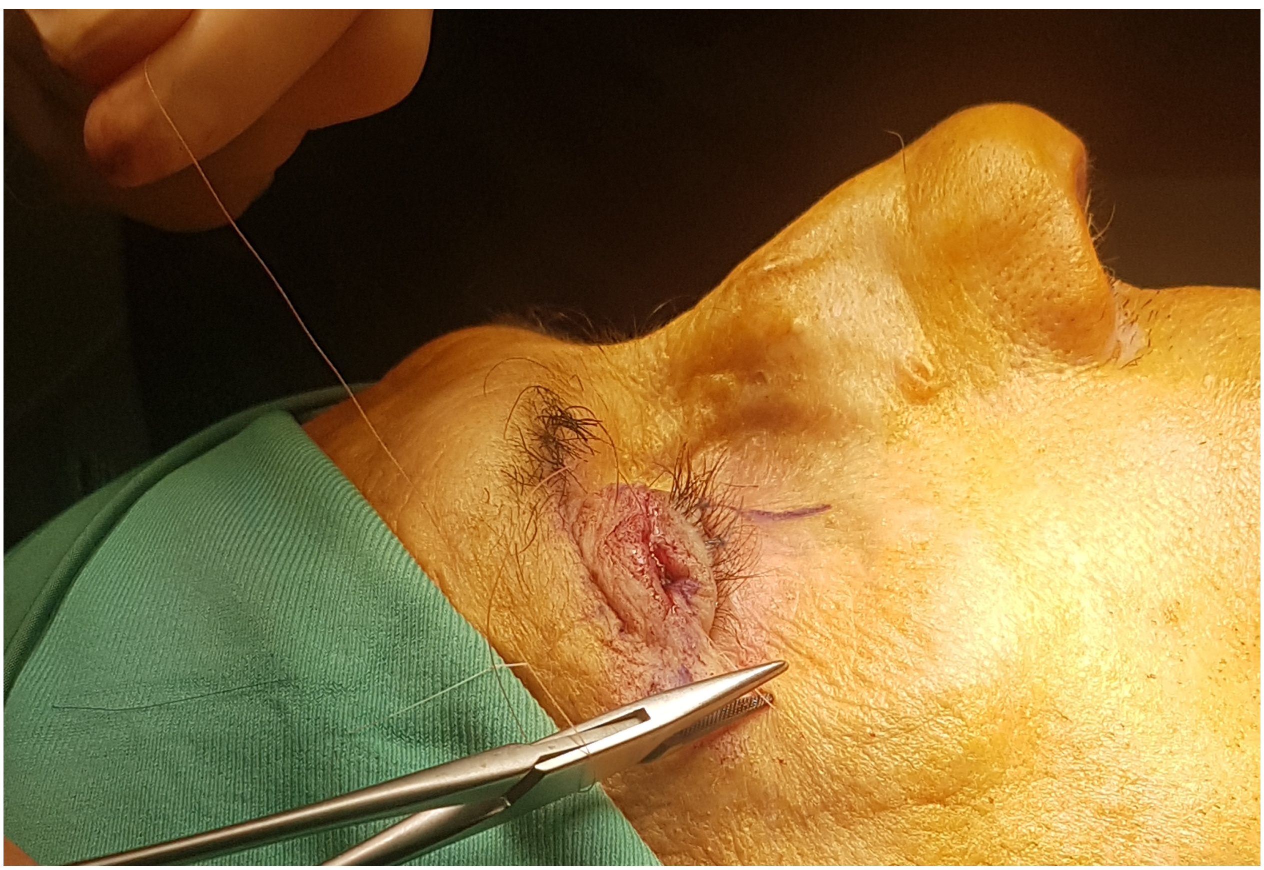




- Placement of the implant fitting anatomical curvature of the ocular globe;



- Anchoring to tarsal plate across the present holes of the implant using 6.0 Nylon;



- Closure of the muscular pocket (Vicryl 6.0) and skin access (Prolene 6.0)

- Antibiotic prophylaxis (2.0 g of intravenous cefazolin) and 7 days post-operative therapy.

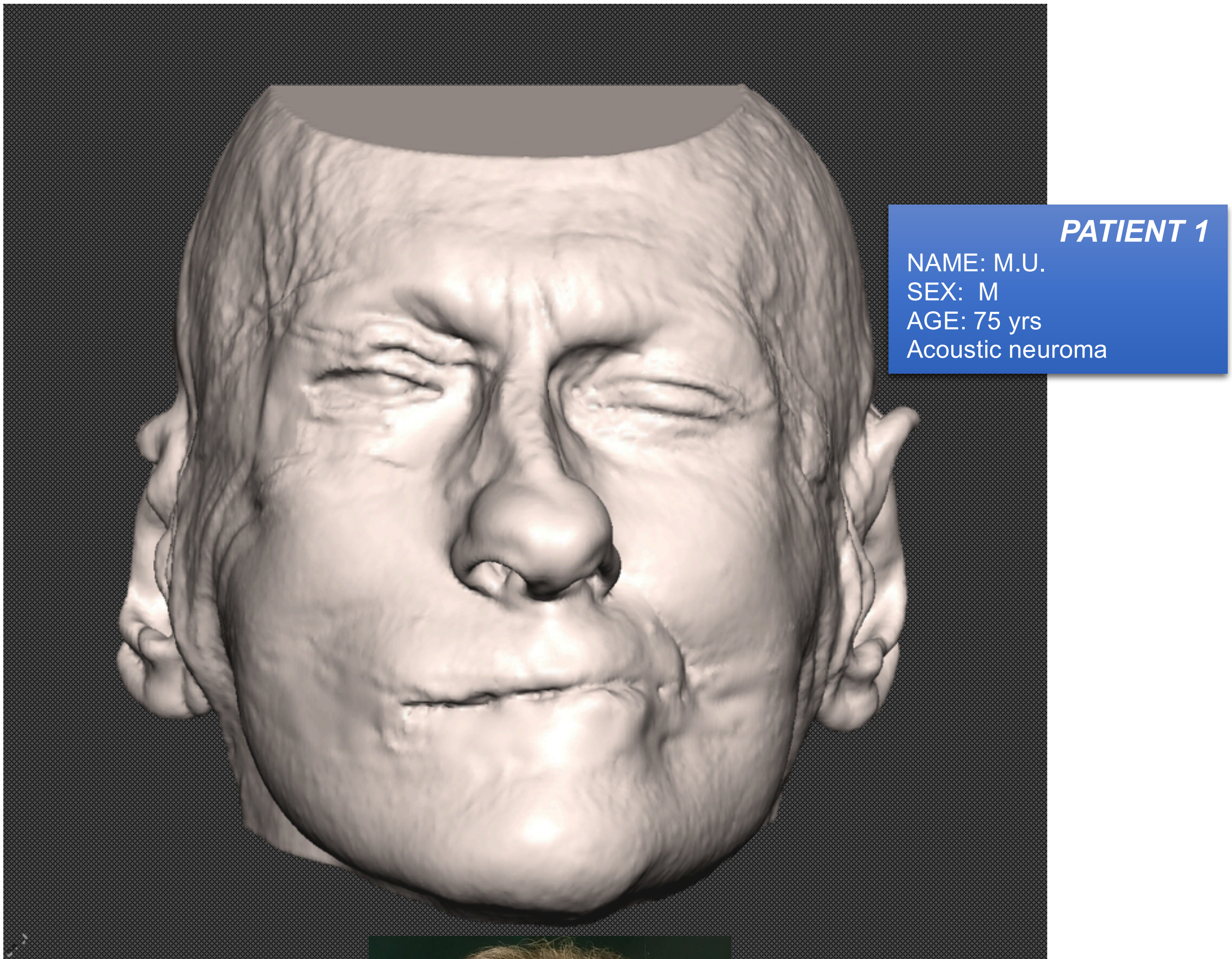
Other ancillary static procedures may be used to complement eyelid implant, as:

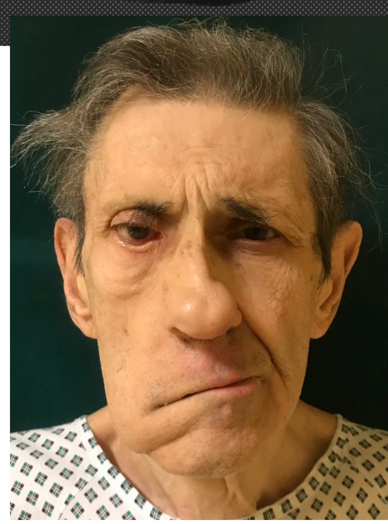
- lower lid suspension and supporting procedures
- lateral tarsal strip
- lateral and/or medial canthoplasty
- brow lift procedures
- lower eyelid shortening for ectropion
- fascial slings.

PATIENTS

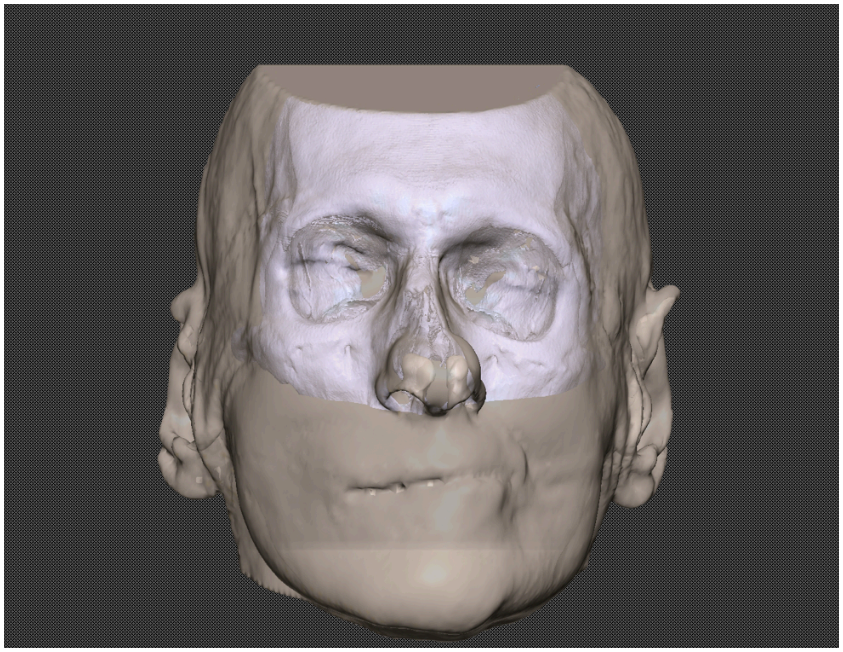
Till now the study included 3 consecutive patients with facial palsy and eye-related symptoms. The cause of the palsy was acoustic neuroma in one patient, and parotid gland malignancy in two cases. In all patients, a customized CobaltChrome implant was planned.

The fourth patient died for other causes (ischemic disease) and the last patients is nowadays under pianification.

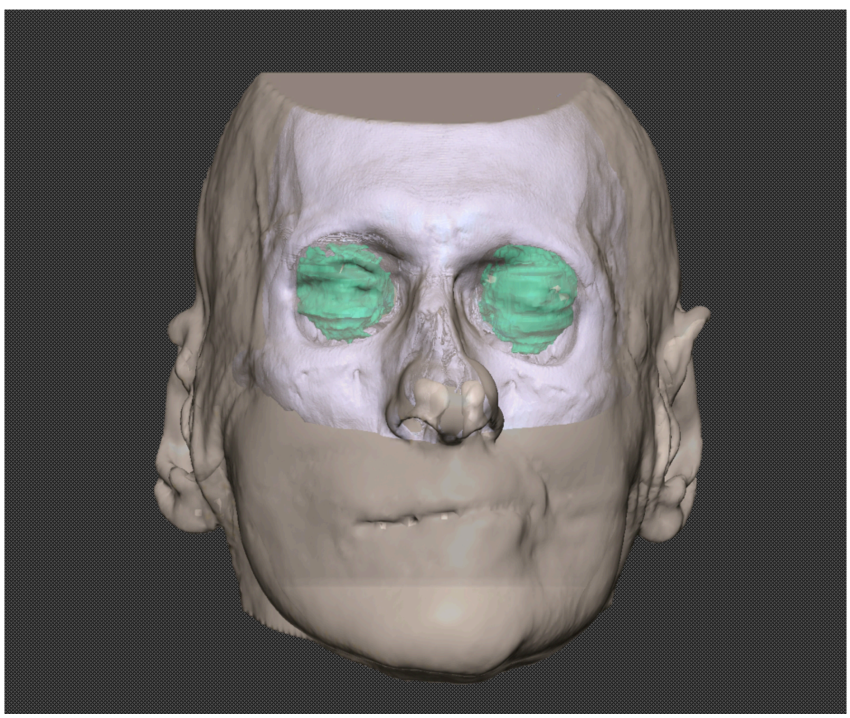




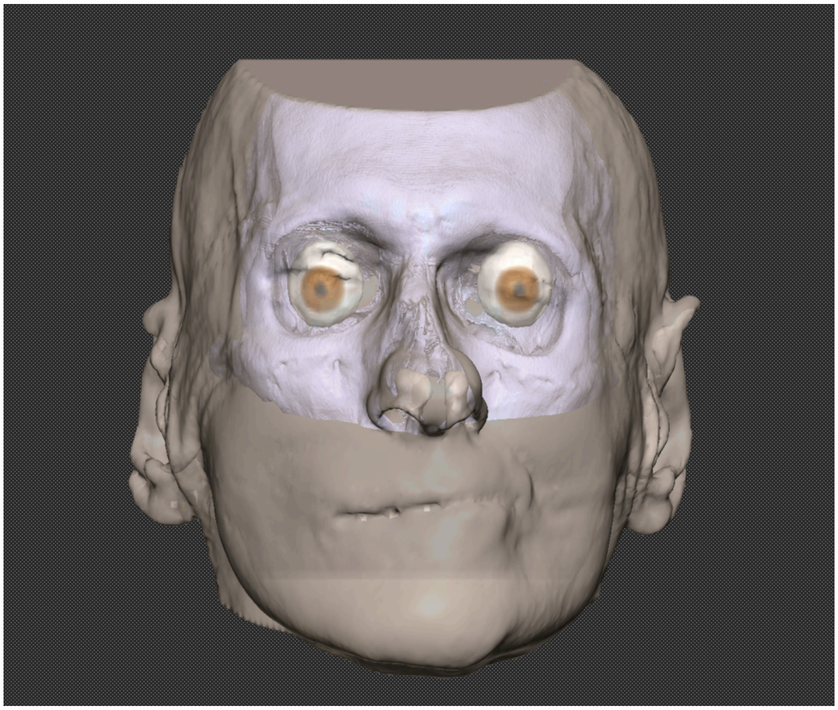
Processing of the DICOM files obtained by the CT scan



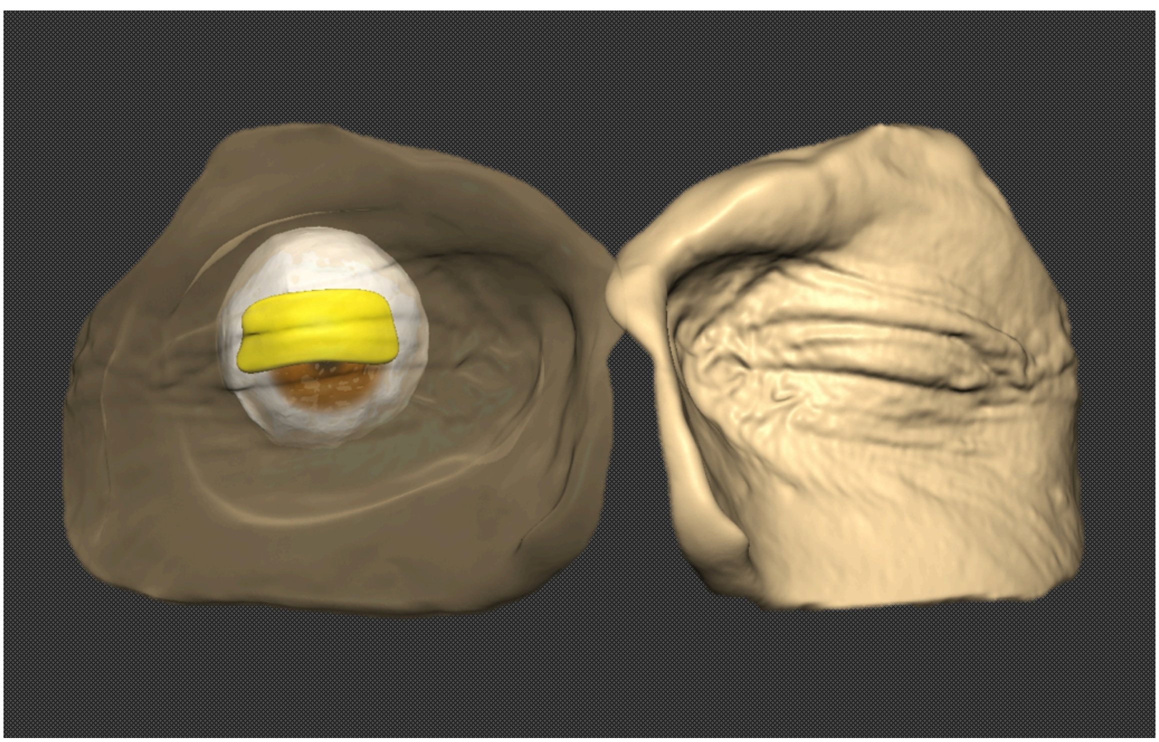
Processing of the DICOM files obtained by the CT scan (removing soft and hard tissue)

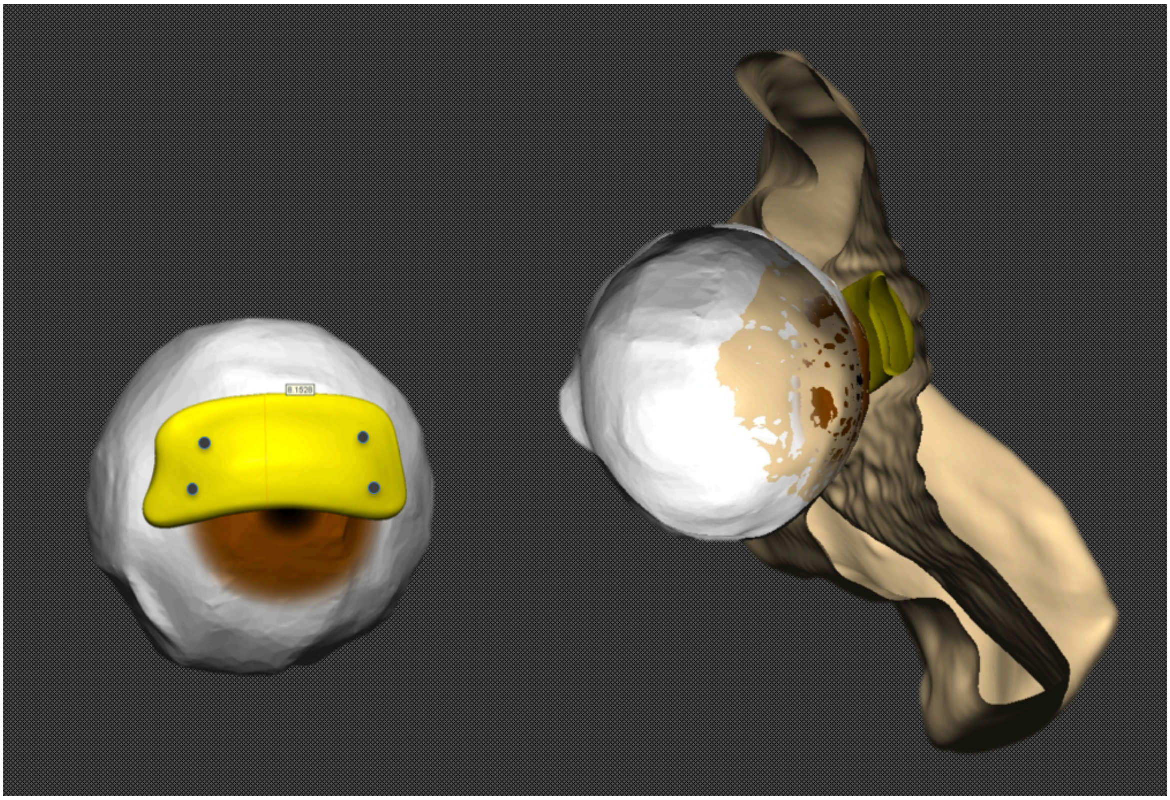


Study of the ocular globes structure

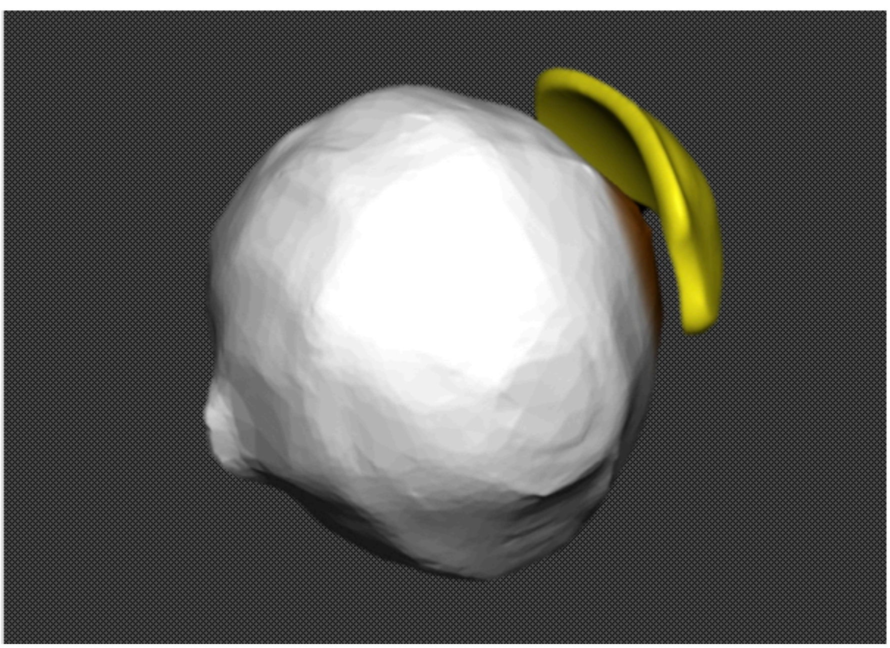


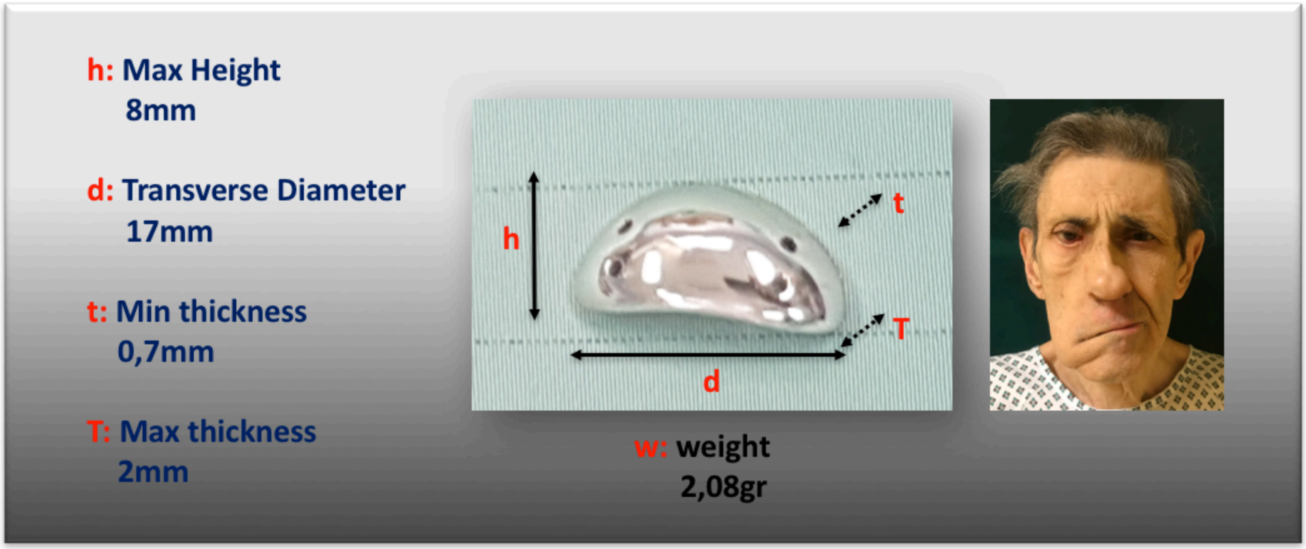
Mirroring of the healthy ocular globe on the affected side and simulation of the custom made Lid Loading implant



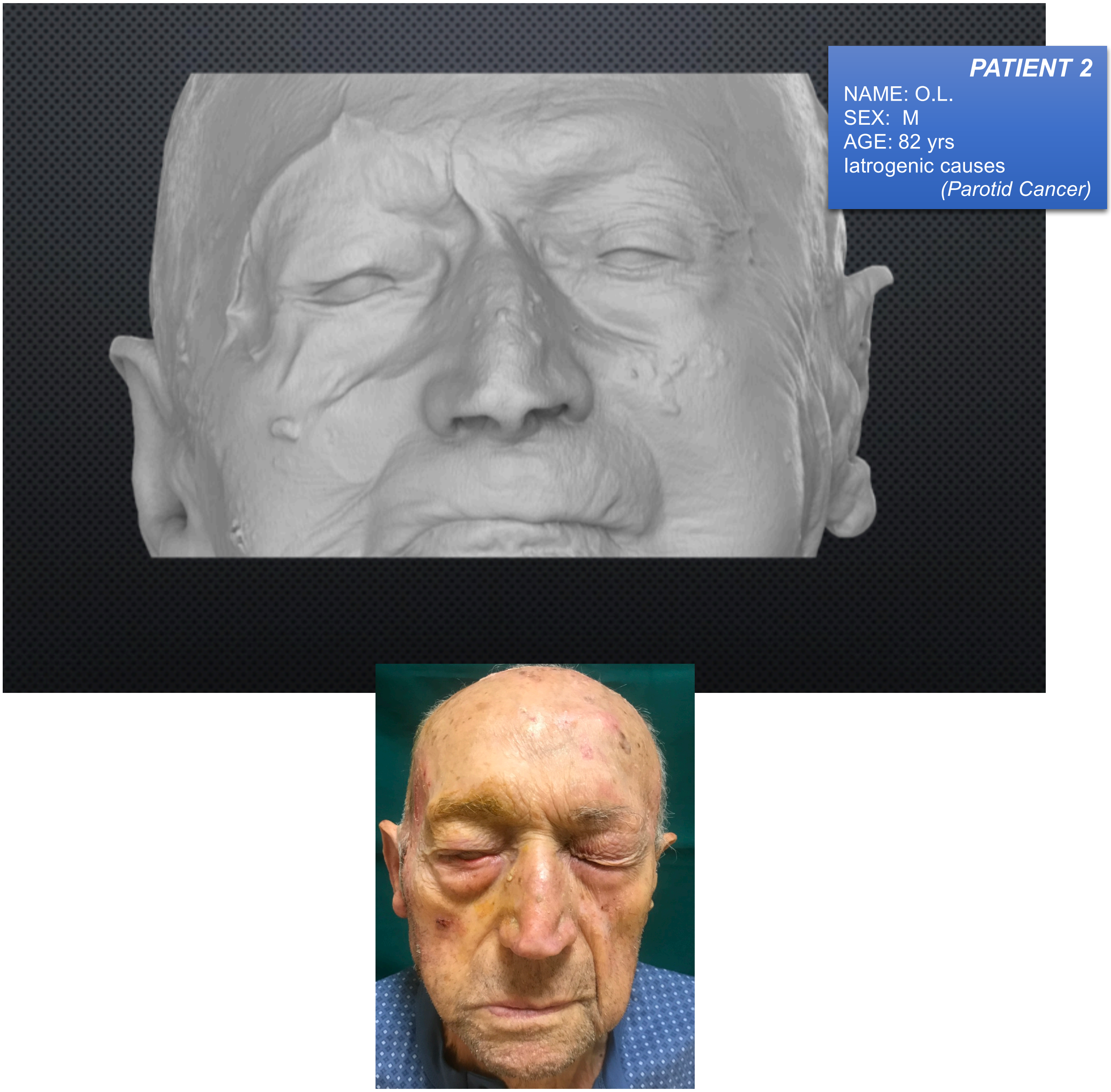


Custom made lid loading implant model

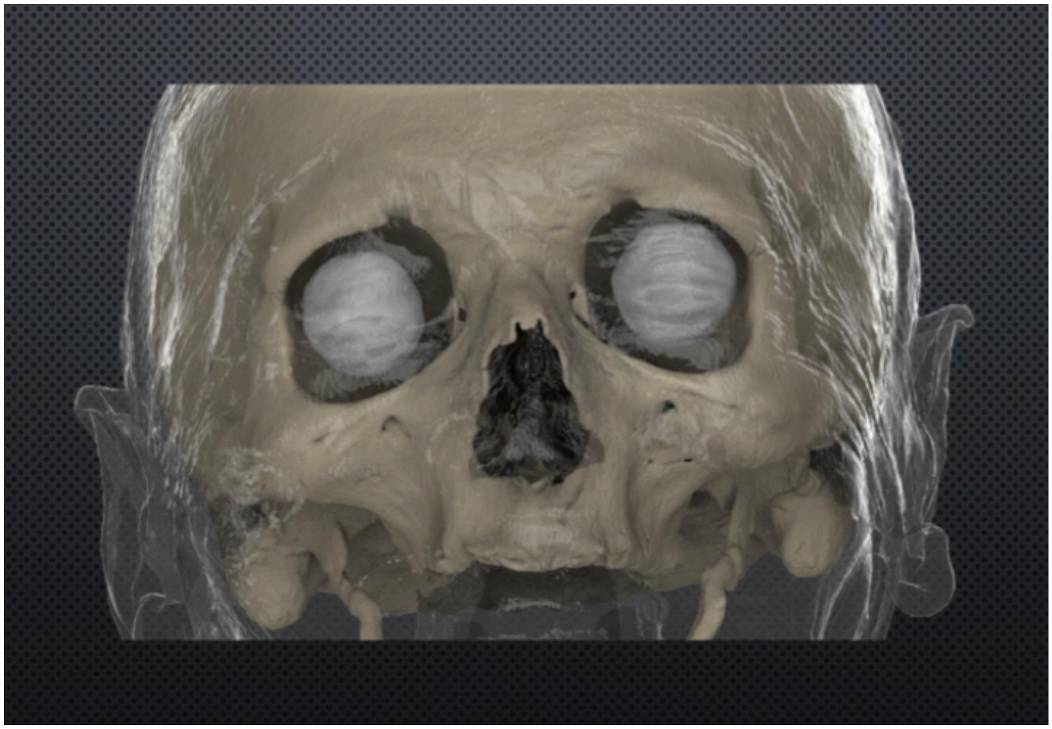




Custom made lid loading implant features (patient 1)

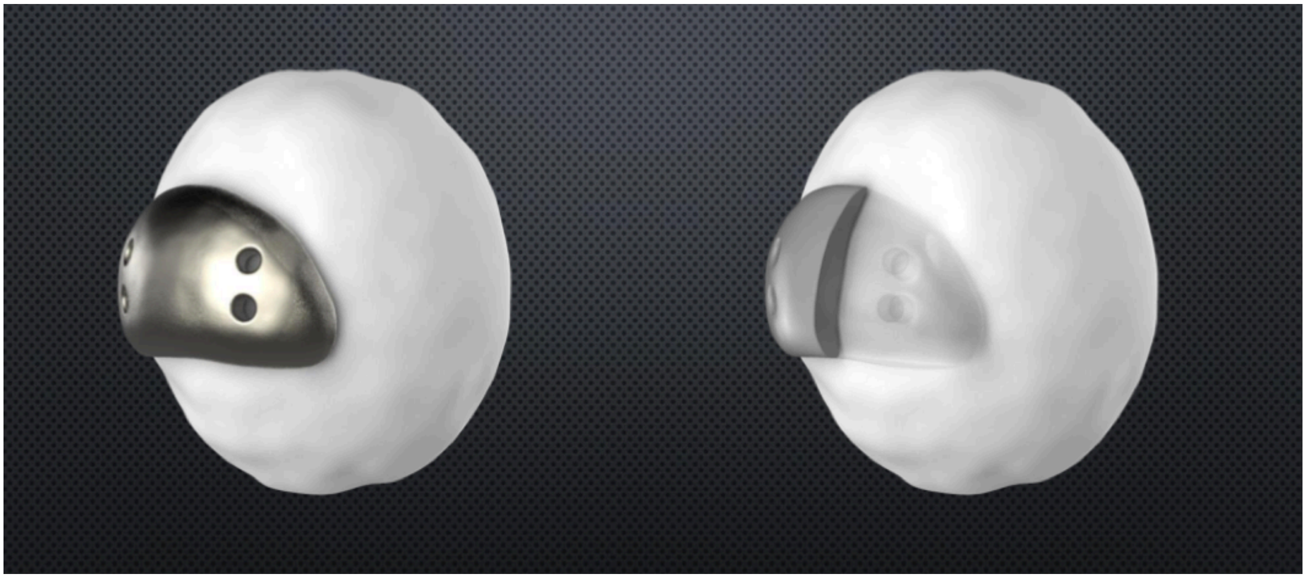


Processing of the DICOM files obtained by the CT scan

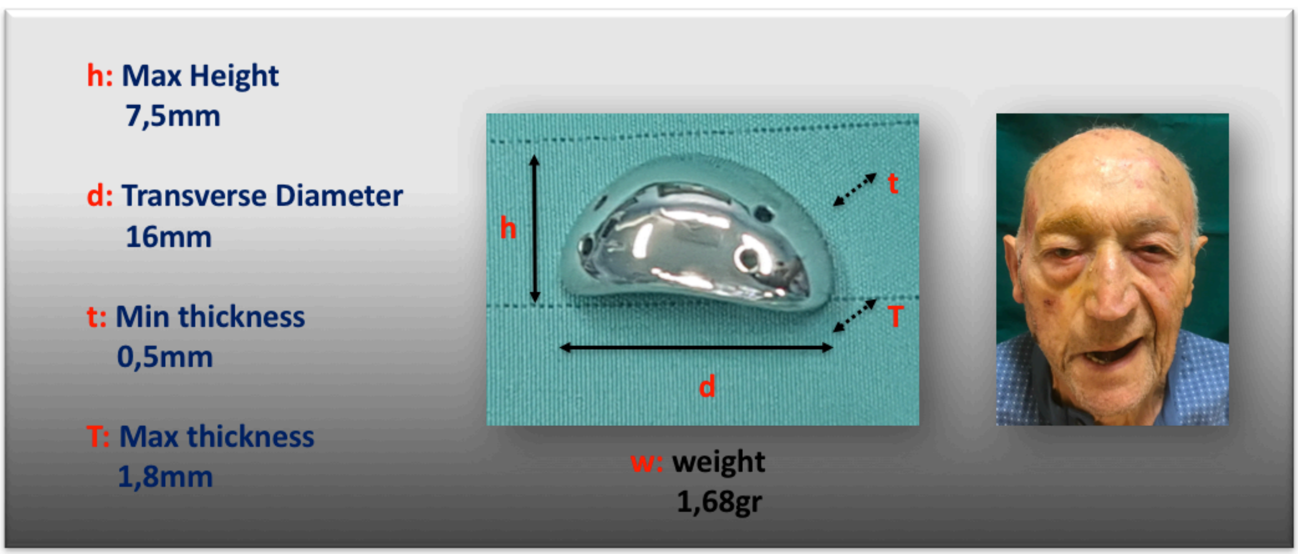


Processing of the DICOM files obtained by the CT scan (removing soft and hard tissue)

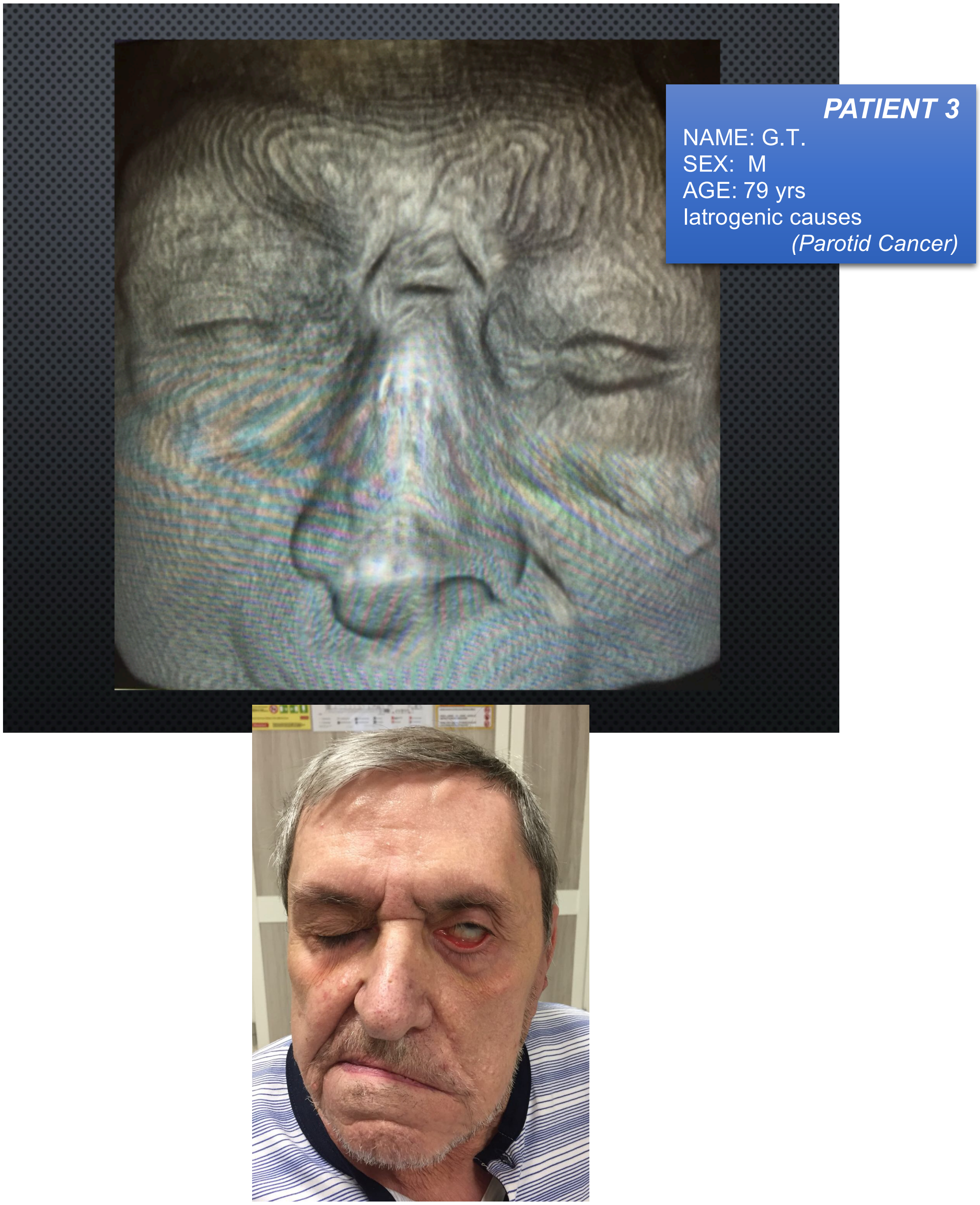
Study of the ocular globes structure



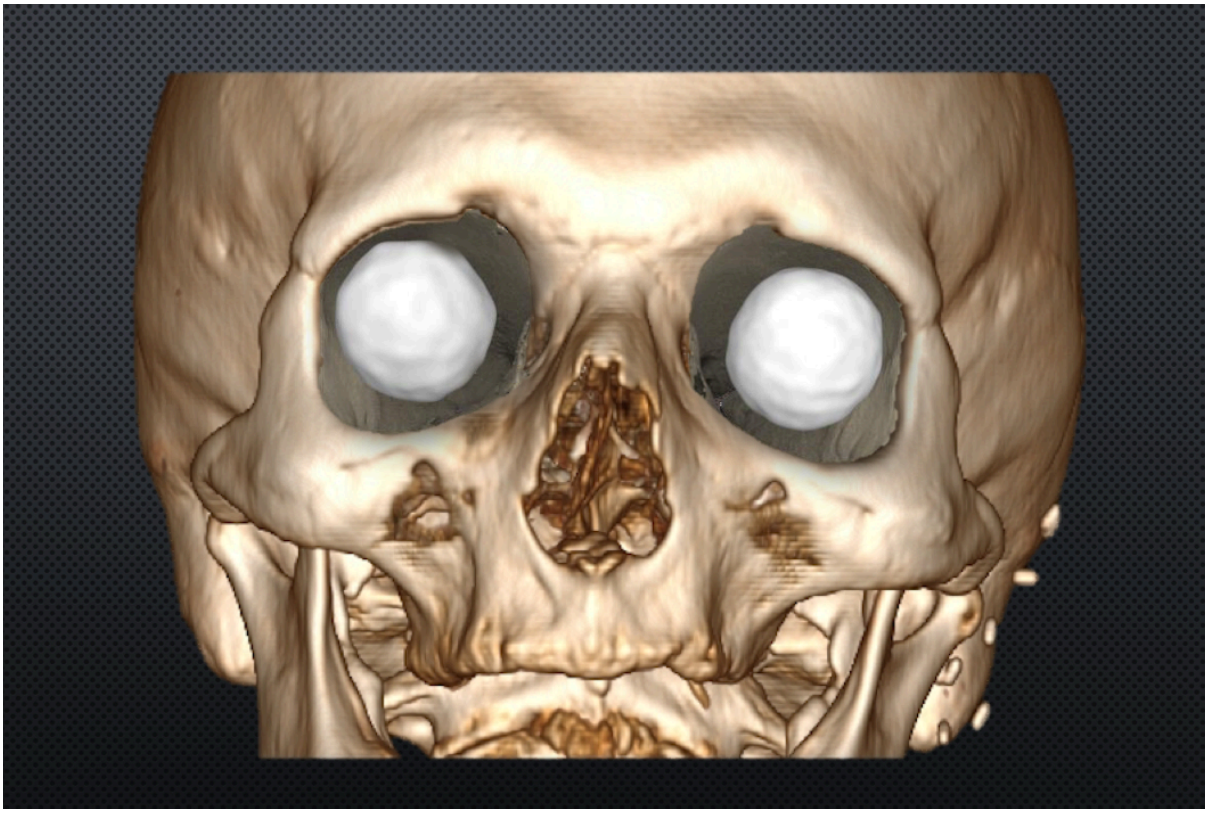
Simulation of the custom made Lid Loading implant



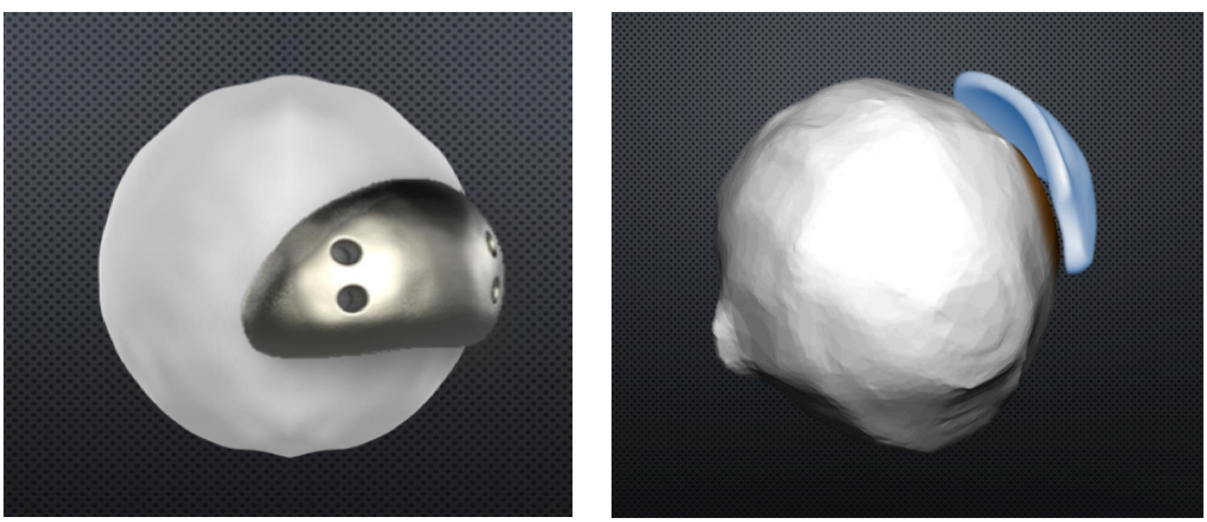
Custom made lid loading implant features (patient 2)



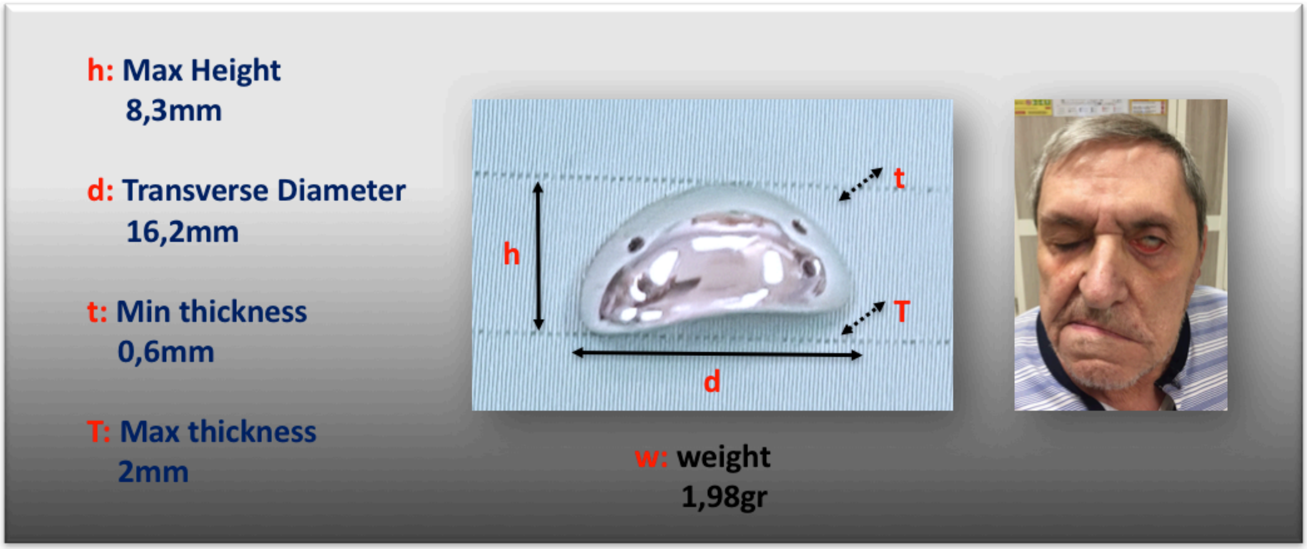
Processing of the DICOM files obtained by the CT scan



Study of the ocular globes structure



Simulation of the custom made Lid Loading implant



Custom made lid loading implant features (patient 3)

	PRE OPERATIVE FUNCTIONAL ASSESSMENT				
	RESIDUAL MUSCLE ACTIVITY	OPHTALMOLOGIC EVALUATION			
PZ ENROLLED	EMG	LAGOPHTALMOS	KERATITIS/ CORNEAL INJURY	TEARING	NOCTURNAL TAPING
1	✗	✓	3 ✓	0 ✓	✓
2	✗	✓	3 ✓	1 ✓	✓
3	✗	✓	3 ✓	0 ✓	✓
4	✗	✓	2 ✓	2 ✓	✓
5	✗	✓	2 ✓	1 ✓	✓

3: severe
2: moderate
1: mild
0: absence of disease

0: excessive tearing
1: frequent
2: moderate
3: absence of tearing

	POST OPERATIVE FUNCTIONAL ASSESSMENT				
PZ ENROLLED	KERATITIS/ CORNEAL INJURY RESOLUTION	TEARING IMPROVEMENT	NOCTURNAL TAPING	PAIN DURING & AFTER SURGERY	PATIENT SATISFACTION FaCE
1	0	3	✗	3	✓
2	0	3	✗	2	✓
3	1	2	✗	3	✓
4					
5					

3: severe
2: moderate
1: mild
0: absence of disease

0: excessive tearing
1: frequent dropping
2: good restoration
3: complete restoration

0: severe pain
1: moderate pain
2: mild pain
3: no pain

FaCE score was 21,6, and the mean postoperative score was 52.7.


PRE-OP
POST-OP
AT REST
BLINKING
CLOSED EYES

All the patients reported an improvement in overall QOL on their FaCE survey.

The mean preoperative FaCE score was 21,6 and the mean postoperative one was 52.7

Postoperative closure of the upper lid was satisfactory in all patients, and the lids covered the cornea almost completely.

The keratopathy index, tested by ophthalmologist, improved on average from 1.3 to 0.3. As for the cornea, visual acuity improved as well.

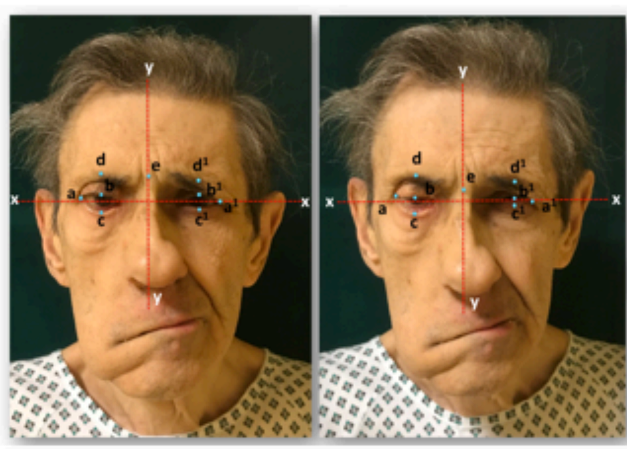
No need of nocturnal tapering in any patients.

All patients felt that restoring lid closure was a visual and aesthetic improvement and graded the postoperative result as good or very good in a questionnaire.

The anthropometric measurements were carried out in a randomized fashion, using a digital caliper.

Lagophthalmos decreased in all the treated patients, with an average of the reduction of the corneal exposure from 4,58 to 0.51 mm.

The data regarding anthropometric parameters used for corneal surface exposure (at resting and tight eye closure) are listed in the following table.



pre-operative

RESTING		TIGHT EYE CLOSURE	
b-c	10,15 mm	b-c	6,1 mm
b^1-c^1	9,11 mm	b^1-c^1	0 mm

post-operative

RESTING		TIGHT EYE CLOSURE	
b-c	9,95 mm	b-c	1,40 mm
b^1-c^1	9,11 mm	b^1-c^1	0 mm

pre-operative

RESTING		TIGHT EYE CLOSURE	
b-c	9,87 mm	b-c	4,3 mm
b^1-c^1	11,21 mm	b^1-c^1	0 mm

post-operative

RESTING		TIGHT EYE CLOSURE	
b-c	8,72 mm	b-c	0,51 mm
b^1-c^1	11,21 mm	b^1-c^1	0 mm

pre-operative

RESTING		TIGHT EYE CLOSURE	
b-c	13,31 mm	b-c	11,03 mm
b^1-c^1	10,53 mm	b^1-c^1	0 mm

post-operative

RESTING		TIGHT EYE CLOSURE	
b-c	11,07 mm	b-c	4,58 mm
b^1-c^1	10,53 mm	b^1-c^1	0 mm

Final objective that the research project should achieve

FINAL REMARKS

Nowadays there are low possibilities to introduce improvements to dynamic techniques, because they are always more refined and sophisticated. In addition their effectiveness depends on the ability and experience of the surgeons and on the ability of the physiotherapist in carrying out postoperative rehabilitation. On the contrary, the static techniques, widely used in long standing paralysis, are susceptible to large improvements because of availability of more refined and biocompatible materials.

The aim of the study was to develop a technical refinement both of the shape and material of the lid implant, as well as of the surgical technique. To address these issues, the use of a direct computer-aided design/computer aided manufacturing procedure (CAD/CAM) with the manufacture of a custom-made implant through direct metal laser sintering has been introduced (DMLS). This technology is able to reproduce carefully the spherical curvature conforms to the shape of the ocular globe fitting on the 3D customized model based on contralateral upper lid CT based anatomy. The eyelid implant was manufactured directly using an EOSINT M270 system (Electro Optical Systems GmbH, Munich, Germany). The working principle was based on DMLS, in which metal powder is fused into a solid part and melted locally using a focused laser beam. As usual for additive manufacturing technologies, the parts were built up additively in layers. The device is produced using EOS CobaltChrome SP2, a multi-purpose cobalt–chrome–molybdenum-based super alloy powder that has been optimised for DMLS on EOSINT M270 systems. The bio-model of the actual upper eyelid was manufactured directly using a 3D soluble support technology rapid-prototyping machine (Stratasys, Eden Prairie, MN, USA).

Regarding innovation in the material, our choice was addressed on CobaltChrome SP2 (Super Metal Alloy); this metal alloy has many advantages in comparison to gold and platinum. It is:

- Biocompatible
- Amagnetic
- Stainless
- White shiny color, similar to platinum, not visible under the eyelid
- Without impurities *(Gold, on the contrary, is processed by fusion and laminating, therefore it presents a high risk of impure metal residues, responsible for allergic reactions and foreign body (as has been demonstrated for implantology)*
- Cost saving in comparison to gold and even more to platinum.

Moreover, to avoid the most common complications of the traditional surgical approach we modified the surgical technique in the respect of anterior levator muscle fibers.

In conclusion, in case of facial palsy with long standing lagophtalmos, upper lid loading represents an effective and helpful procedure.

The results of our study (even if again with a small sample), have shown that the development of new biocompatible materials and a customized planning, led to better results (in term of compliance, tolerability, complications, costs) compared with traditional and standardized devices.

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