***Guidelines to be followed by centres, services and units in order to be designated as Reference Centres, Services and Units of the National Health System as agreed by the Interterritorial Board.***

## 8. ORBITAL DECOMPRESSION IN THYROID OPHTHALMOPATHY[1,2,3].

Thyroid ophthalmopathy is a disease frequently associated to Grave's disease (diffuse hyperplasia of the thyroid gland, thyroid ophthalmopathy and, occasionally, pretibial myxedema).

In thyroid ophthalmopathy, the volume of extraocular muscles and orbital fat increases causing exophthalmos, strabismus and optic nerve compression. Patients may be affected by severe vision loss due to compression of the optic nerve, keratopathy due to exposure and ocular hypertension. Exophthalmos and palpebral changes result in cosmetic disfigurement which, along with the visual loss and, in some cases, diplopia, will entail psychological, professional and social consequences.

Different types of therapeutic measures must be established: immunosuppressive treatment, radiotherapy and, when appropriate, surgery.

Orbital decompression is used in compressive optic neuropathy, severe keratopathy and in patients with significant cosmetic problems. Orbital decompression solves the space problem inside the orbit by increasing the volume of the cavity, bony decompression, and removing fat, lipectomy. Bony decompression, depending on the case, may involve bone removal of one, two or three of the bony walls.

Before orbital surgery units developed, these patients were monitored by ophthalmologists and when orbital decompression was required, decompression of the medial and floor walls were performed by the ENT services, decompression of the lateral wall by maxillofacial or plastic surgery services, and posterior decompression for cases of severe neuropathy by the neurosurgery service using a coronal approach. These specialist do not perform extraconal or intraconal fat removal, nor excision of the periorbita and the cone intermuscular septum, an important step allowing intraconal fat herniation towards the enlarged bony walls and reduction of intraconal pressure, improving optic nerve pressure and, in that way, visual acuity. Nowadays, this is the procedure followed in hospitals without this type of unit. Experience in orbital surgery has developed approaches allowing access to all the walls of the orbital cavity and to the intraconal space, achieving decompression of the three walls at the same time for more severe cases, in addition to fat removal, both extraconal and intraconal, with less morbidity and invisible scars.

Orbital units offer a comprehensive approach, offering ophthalmologic monitoring, medical and surgical treatment, and currently having a significant experience in orbital pathology. Experience in patients with thyroid ophthalmopathy is important when it comes to deciding the treatment to be performed: medical immunosuppressive treatment, radiotherapy, and, when appropriate, surgery.

**A.** ***Rationale for the proposal***

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| ► Epidemiological data on thyroid ophthalmopathy (incidence and prevalence). | Incidence of this pathology in the population is unknown; the number of candidate patients to this surgery might be estimated from the figures of thyroid disease. Most of the patients with thyroid ophthalmopathy have Graves-Basedow disease as cause of their thyroid anomaly. Incidence of Grave's disease is well documented, showing 14 cases per 100,000 people per year. Taking into account that severe ophthalmic conditions occur in 5% of the patients with Grave's disease, in Spain there would be approximately an incidence of 300 severe cases of thyroid ophthalmopathy, out of which 2/3 would require orbital decompression surgery.<br>Incidence in Spain of Grave's disease: 14 cases per 100,000 population per year, 6,000 cases per year.<br>Incidence of severe thyroyd ophthalmopathy: 5% of the patients with Grave's disease, approximately 300 cases per year. |
| ► Data on the use of orbital decompression in thyroid ophthalmopathy. | Necessity for orbital decompression: 2/3 of patients with severe thyroid ophthalmopathy, approximately 200 cases per year. |

**B.** ***Guidelines to be followed by Centres, Services and Units in order to be designated as Reference Centres, Services and Units treating thyroid ophthalmopathy by means of orbital decompression.***

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| ► Experience of the Reference Centres, Services and Units:<br><br>- Activity: | |

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| • Number of orbital decompressions that should be performed in a year to ensure an adequate care. | A minimum of 20 orbital decompressions per year. |
| - Other data: research on the subject, postgraduate teaching, continuing training, etc. | - Accredited postgraduate teaching.<br>- Participation in research projects and publications in the field[a].<br>- Continuing training programs[a]. |
| ► Specific resources of the Reference Centres, Services and Units: | |
| - Human resources required for the adequate implementation of orbital decompression in thyroyd ophthalmopathy. | - Ophthalmologist.<br>- 24 hour continuous ophthalmic care, given the need for postoperative monitoring and the possibility of complications during the first hours.<br>- Nursing staff, surgical auxiliaries and technicians. |
| Professional experience[b]**:** | - Ophthalmologists with experience of at least 5 years in orbital surgery.<br>- Nursing staff with experience of at least 5 years in the care of ophthalmic patients. |
| - Specific equipment required for the adequate implementation of orbital decompression in thyroyd ophthalmopathy. | - Ability to perform pre- and post-operative examinations: exophthalmometry, computerized campimetry, colour test.<br>- Hospitalization unit, since this surgery requires general anaesthesia and hospital admission.<br>- Specific equipment required for orbital surgery:<br>Palpebral surgery standard equipment.<br>Malleable separators (used in neurosurgery).<br>Micromotor system.<br>Oscillating saw, for orbitotomy with osteotomy.<br>Biological glue and bone wax.<br>Frontal lighting source. |
| ► Resources from other units and services | - Neurosurgery services |

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| besides those belonging to the Reference Centres, Services and Units required for the adequate care of thyroyd ophthalmopathy. | - ENT services.<br>- Endocrine services.<br>- Maxillofacial surgery services.<br>- Plastic surgery services.<br>- Medical and radiotherapy oncology services.<br>- Anaesthesia services.<br>- Intensive care unit<br>- Image diagnosis: MRI, CT scan, nuclear medicine.<br>- Neurophysiology.<br>- Haematology services.<br>- Anatomical pathology services |
| ► Procedure and clinical results indicators of the Reference Centres, Services and Units [c]: | **The indicators will be agreed with the Units that will be designated.** |
| ► Existence of an adequate IT system.<br>(Type of data that the IT system must include to allow identification of the activity and evaluation of the quality of the services provided) | - Filling up the complete MBDS of hospital discharge.<br><br>- The unit must have a *registry of patients* with thyroid ophthalmopathy which at least must include:<br>- Medical record number.<br>- Date of birth.<br>- Sex.<br>- Admission date and discharge date.<br>- Diagnosis procedures performed to the patient (ICD-9-CM).<br>- Main diagnosis (ICD-9-CM)<br>• Clinical situation at the time of diagnosis.<br>- Number and type of therapeutic procedures provided to the patient (ICD-9-CM):<br>• Orbital decompression.<br>• Other therapeutic procedures.<br>- Orbital decompression results.<br>• Exophthalmos reduction: |

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| | Exophthalmos <22mm: >2mm.<br>Exophthalmos of 22-25mm: 4-6 mm<br>Exophthalmos >25mm.: 6-8 mm<br>• Visual acuity improvement.<br>- Complications.<br>• Loss of visual acuity, CSF fistula.<br>- Follow-ups.<br><br>- The unit must have the required data which should be sent to the Spanish National Health Service Reference Centres, Services and Units Appointment Commission Secretariat for yearly reference unit monitoring. |

[a] *Criteria to be assessed by the Appointment Commission.*
[b] *Experience will be accredited by certification from the hospital manager.*
[c] *Clinical results standards, agreed to by the experts group, will be assessed, initially by the Appointment Commission, while in the qualification process, as more information from the Reference Centres, Services and Units is being obtained. Once qualified by the Appointment Commission, the Quality Agency will authorize its compliance, as for the rest of guidelines.*

**Bibliography:**

[1] Graded orbital decompresion based on severity of proptosis.
[2] Diseases of the orbit. Jack Rootman. Lippincott Company. 2ª edición. 2003.
[3] Patología orbitaria. Pérez Moreiras JV. Edika Med. 2000.