



<h1>Punctal Occlusion</h1> <h2>EBMT/CLWP Non-Interventional Prospective Study</h2>	<h1>PATIENT REGISTRATION &amp; TREATMENT FORM</h1> <p>At admission for treatment with punctal occlusion</p>
------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------



Pt study nr  
(provided by data office)

## PATIENT

Centre number (CIC) ..... Unique Identification Code (UIC): .....

The UIC will be allocated by:  The centre  
 The national registry of ..... (name country)  
 The European Data Office in Paris

Hospital Unique Patient Number: .....

Initials: .....(first name(s)-surname(s))

Date of birth: ..... - ..... - ..... Sex  Male  Female  
dd mm yyyy

## EXCLUSION CRITERIA

*If one of these questions is answered with 'yes', this patient can not be included*

Age at transplant under 18 years	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Prior punctal plug insertion	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Dry eyes before SCT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Active ocular infection or other past or present eye disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sjögren's disease before SCT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Use of contact lenses	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## INCLUSION CRITERIA

Diagnosis of dry eyes after alloSCT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Eye symptom score $\geq 2$ for at least 2 months	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## Start of Treatment

Type of punctal plugs inserted  Silicone Punctal Plugs  
 SmartPlugs

Date of allogeneic transplant ..... - ..... - .....  
dd mm yyyy

Date dry eyes were diagnosed ..... - ..... - .....  
dd mm yyyy



CIC:..... Unique Patient Number (UPN): ..... SCT Date ..... dd mm yyyy

Date punctal plugs were installed ..... dd mm yyyy

## Systemic immunosuppressive therapy

### SYSTEMIC IMMUNOSUPPRESSIVE THERAPY USED AT TIME OF INSERTION OF PUNCTAL PLUGS

- Methotrexate
- Cyclosporine a
- Mycophenolate mofetyl
- Myfortic
- Other (specify) .....

Date started: ..... dd mm yyyy

## Condition of the Eyes before treatment with Punctal Plugs

### SYMPTOMS:

#### Distinctive

- Dry eyes
- Gritty eyes
- Painful eyes
- Cicatricial conjunctivitis
- Keratoconjunctivitis sicca or confluent areas of punctuate keratopathy

#### Other features

- Photophobia
- Periorbital hyperpigmentation
- Blepharitis (erythema of the eyelids with erythema)
- Other (specify) .....

### EYE SYMPTOMS SCORE:

- Score 0 no symptoms
- Score 1 mild dry eye symptoms not affecting ADL (requiring eye drops ≤ 3 x per day) **OR** asymptomatic signs of sicca keratitis
- Score 2 Moderate dry eye symptoms partially affecting ADL (requiring drops > 3 x per day or punctal plugs, **WITHOUT** vision impairment
- Score 3 Severe dry eyes symptoms significantly affecting ADL (special eyeware to relieve pain) **OR** unable to work because ocular symptoms **OR** loss of vision caused by pseudomembranes or corneal ulceration



**SUBJECTIVE PARAMETERS**

**Patient reported intensity scale of worst eye symptom** (*visual analogues scale symptoms score or VAS, according to NIH Consensus*)

0-10 patient reported intensity scale (VAS): chief ocular complaint at the time of the visit (10-cm lines are prepared, the patients write down his worst eye symptom and then checks a point on the line corresponding to the degree of this worst symptom)

Chief ocular symptom: .....

Symptom score: 

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

**Use of daily topical lubricant(s) medication** (*diminished use should not have resulted in worsening of symptoms*)

Name of the topical lubricant: .....

- Frequency of use:  Not on a daily basis  
 1-3 times a day  
 4-6 times a day  
 > 6 times a day

**OBJECTIVE TEARDYNAMIC PARAMETERS**

**Schirmer's tear test** (*According to NIH Consensus, done without anesthesia*)

Mean of both eyes  $\leq 5$  mm at 5 minutes, or mean values of 6-10 mm at 5 minutes in patients with sicca symptoms or new keratitis detected by slit lamp examination. y scale (VAS): chief ocular complaint at the time of the visit (10-cm lines are prepared, the patients write down his worst eye symptom and then checks a point on the line corresponding to the degree of this worst symptom)

- Mean score on Schirmer's test:  > 10 mm  
 6 – 10 mm  
  $\leq 5$  mm

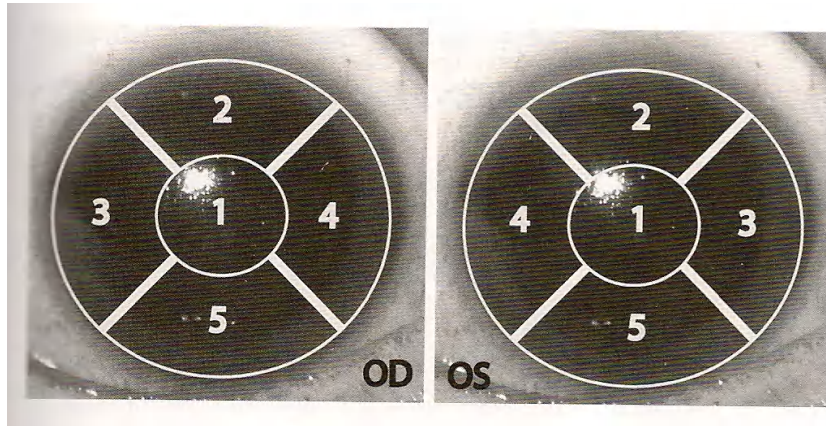
**Tear Film Break-up Time**

- < 5 sec  
 5 – 10 sec  
 10 – 15 sec  
 > 15 sec



**OBJECTIVE CORNEAL DAMAGE PARAMETER**

Standard fluorescent punctate staining, scored according to “The National Eye Institute Corneal Grading System”:



Each cornea is divided in five areas. Each area is scored for fluorescent staining (0 = absent, 1 = present; >3 is abnormal).

**Fluorescent score OD:**

**Fluorescent Score OS:**

Area 1: |\_ |

Area 1: |\_ |

Area 2: |\_ |

Area 2: |\_ |

Area 3: |\_ |

Area 3: |\_ |

Area 4: |\_ |

Area 4: |\_ |

Area 5: |\_ |

Area 5: |\_ |

**Complications of punctal plug insertion**

*Loss will not be judged as complication or failure in case of prompt replacement; need for placement in upper nasolacrimal canaliculi is also not judged as complication or failure.*

**COMPLICATIONS OCCURRING AFTER THE INSERTION OF PUNCTAL PLUGS**

- Ocular discomfort
- Ocular irritation
- Spontaneous loss without prompt replacement
- Granulomas
- Canalicular migration with secondary nasolacrimal obstruction
- Canaliculitis
- Dacryocystitis requiring surgical removal

**IDENTIFICATION & SIGNATURE**

.....  
 .....