

Background and Importance

Chronic graft versus host disease (cGVHD) associated oral mucositis is a complication after stem-cell transplantation. Corticosteroids are the standard treatment, but there is no consensus in case of refractory lesions. Platelet concentrates may be a safe treatment option.

Aim and Objective

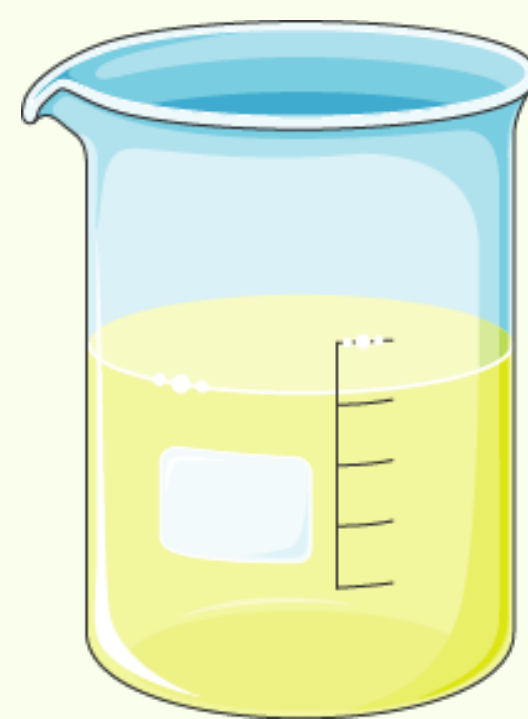
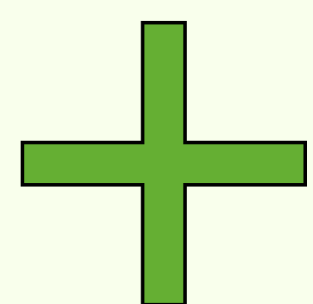
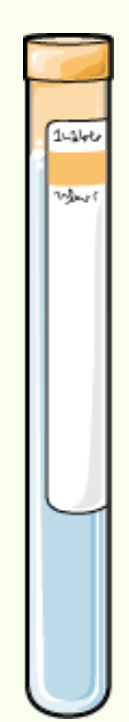
► Design an sterile oral formulation able to release platelet lysate (PL) on oral cavity, and evaluate its effectiveness in a series of cases.

Materials and Methods

ORAL GEL COMPOUNDING

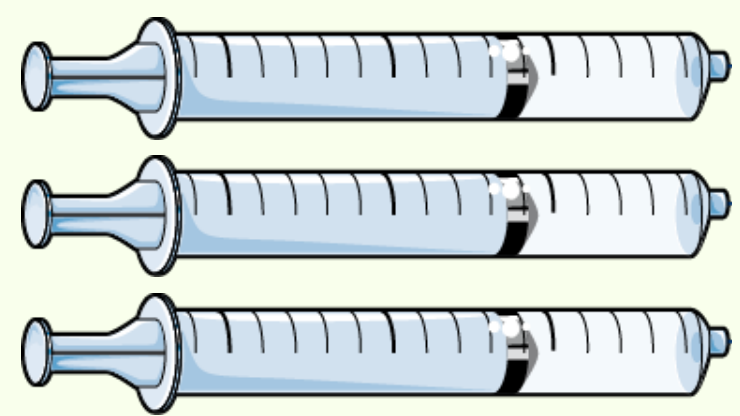
PL diluted 1:1 with sodium chloride 0,9%

Carboxymethylcelulose sodium base 5% gel



Mixed 1:1 in
ASEPTIC CONDITIONS

25% oral Platelet Lysate gel

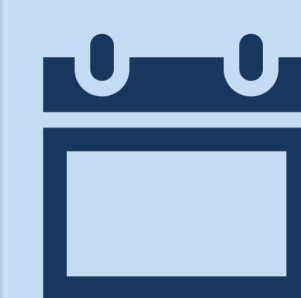


Packaged in 6mL syringes

Stored in freezer



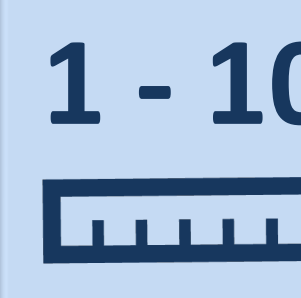
EFFECTIVENESS EVALUATION



Patients with cGVHD associated oral mucositis from November 2021 to August 2022.



Effectiveness was evaluated based on severity of the oral mucositis (NCI-CTCAE Grade 1-4).



1 - 10 Patient satisfaction was self-assessed in a visual scale according to the degree of pain/discomfort.

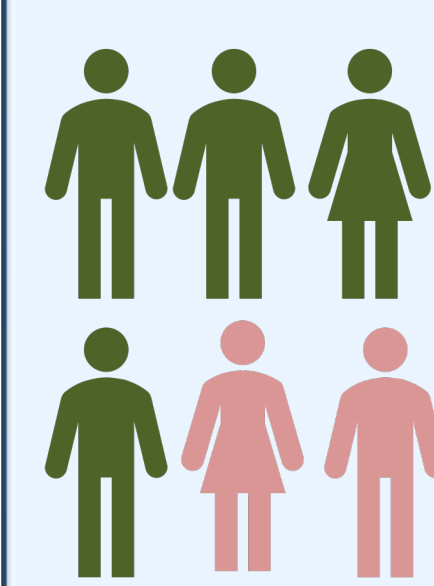


Adherence was assumed based on the number of syringes dispensed.

Results

GEL CHARACTERISTICS

- ✓ Slightly yellow, translucent, pH=6, with medium consistency that leads **adequate bioadhesive characteristics**.
- ✓ No changes of pH, color, weight, or microbial growth were observed during galenic validations.
- ✓ A beyond-use date of 45 days at -20°C was given.
- ✓ **Instructions of use:** apply on the oral lesion 2 mL of the gel every 8 hours.



Six patients with moderate oral mucositis (Grade 2-3) who failed to first line topical steroids therapy started PL gel.

Two patients discontinued treatment after one month because their life-style prevented them from preserving the gel properly.

Four (75% male) went on with the gel with an estimated adherence of 80,8% (95%CI: 56.8-104.9)

Id	Duration (days)	Mucositis grade		Pain Discomfort	
		Before	After	Before	After
1	91	2	1	8	7
2	113	2	1	5	3
3	240	3	1	5	2
4	111	2	2	7	6

Conclusion and Relevance

- The formulation of a gel based on sodium carboxymethylcelulose was adequate to administer PL on the oral cavity.
- Four patients with cGVHD associated oral mucositis refractory to standard treatment were successfully treated.

