CLINICAL BRIEFING · ORAL SUBMUCOUS FIBROSIS

MARCEL OMR Therapy™

What it is, how it works, and what the interim evidence shows

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Confidential briefing for professional and scientific discussion · Interim data

A structured, stage-based supportive-care approach

MARCEL OMR Therapy™ (Oral Mucosa Restoration Therapy) is a structured, stage-based supportive-care approach being developed for people living with Oral Submucous Fibrosis (OSMF)..

It integrates oral-care support, functional guidance, symptom assessment and professional follow-up.

It is intended to complement appropriate clinical management, not replace specialist assessment or established medical and surgical care.

CORE COMPONENT

MARCEL OraShield™

MARCEL OraShield™ is the principal product component of MARCEL OMR Therapy™. The programme's clinical rationale and the supplied interim scientific evidence relate primarily to MARCEL OraShield™.

MARCEL Smile™ Toothpaste, prescribed exercises and the optional MARCEL® MOFlex Device are supplementary adjuncts. They should not be represented as equivalent in evidentiary status, or as independently proven to produce the reported outcomes.

02 HOW IT WORKS

A five-step, clinician-guided pathway

Delivered as a 12-week care journey and matched to the stage of OSMF.

1	2	3	4	5
ASSESS	**PLAN**	**CARE**	**MONITOR**	**REVIEW**
Record symptoms, mouth opening and clinical findings.	Select the care programme with a qualified clinician.	OraShield™ is the core product; supplementary measures are used as indicated.	Track symptoms, IID and mucosal findings.	Review response; refer or escalate when indicated.

WHY A PATHWAY?

OSMF is a chronic, potentially malignant oral disorder associated with mucosal fibrosis and functional restriction. Patients may experience burning, intolerance to spicy food, pain, altered taste and reduced mouth opening. Care therefore requires risk-factor counselling, clinical assessment, symptom management, functional support and continuing surveillance for mucosal changes.

Two programmes, matched to OSMF stage

FOUNDATION PROGRAMME

OSMF Stages 1–2

Designed for early-stage OSMF. MARCEL Oracare™ is the core product component, supported by appropriate oral-care guidance and follow-up.

ADVANCE PROGRAMME

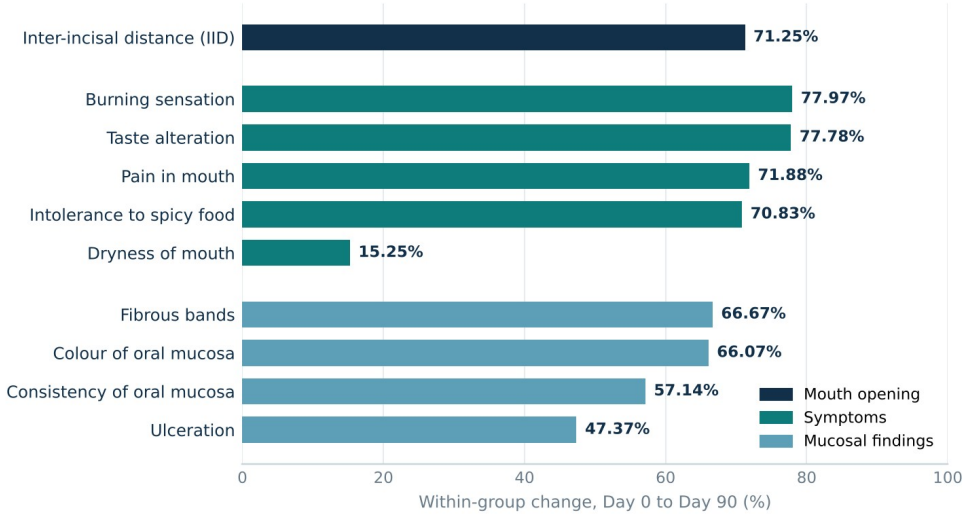
OSMF Stages 3–4

Designed for more advanced OSMF. MARCEL OraShield™ is the core product component, with supplementary functional support and clinical monitoring as appropriate.

CLINICAL SAFEGUARDS

The programme does not replace habit-cessation counselling, specialist diagnosis, biopsy or histopathological assessment when indicated, surveillance for potentially malignant changes, or established medical and surgical treatment. Persistent ulcers, suspicious lesions or clinical deterioration require prompt professional evaluation. The 12-week care journey is a care-organisation framework, not itself proof of tissue restoration.

Day 0 to Day 90: within-group change in all ten parameters



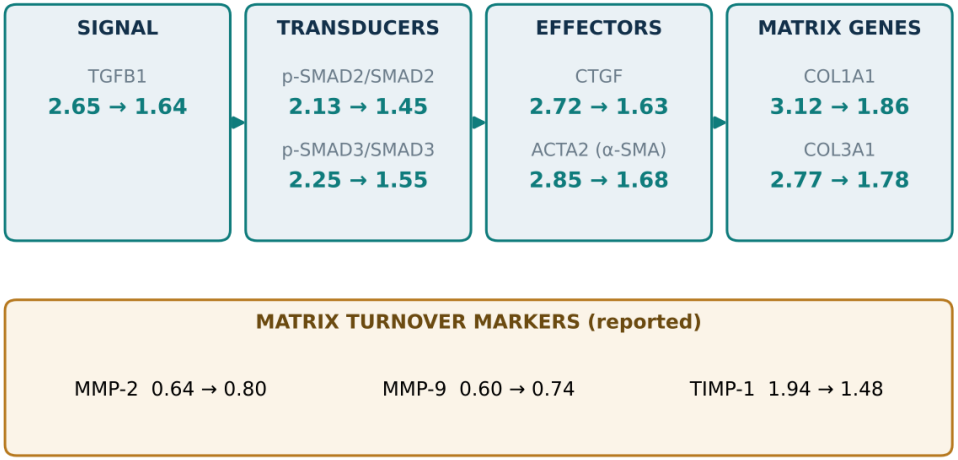
Source: Podar clinical summary (interim). Within-group changes only; no between-group comparison is reported.

WHAT THE DATA SHOW

- Largest changes: burning sensation (77.97%) and taste alteration (77.78%).
- Inter-incisal distance (mouth opening): 71.25%.
- Smallest change: dryness of mouth (15.25%).
- Reported for MARCEL® Poly Herbal Oral Rinse, IEC ref. RAPMC/IEC/PROJECT/04/2026.

Markers along the profibrotic pathway

Profibrotic signalling → myofibroblast activity → collagen deposition



Molecular markers, reported before → after.

HOW TO READ THIS

- Separate biological findings report lower values for markers of myofibroblast activity, profibrotic signalling and collagen genes.
- MMP-2, MMP-9 and TIMP-1 are shown separately as matrix-turnover markers.
- The layout is conceptual; it does not itself demonstrate mechanism.

Cellular and tissue-level findings

IN-VITRO CELLULAR MARKERS (BEFORE → AFTER)

MARKER	REPORTED	MARKER	REPORTED
α-SMA	2.44 → 1.31	Collagen III	2.28 → 1.69
TGF-β1	2.16 → 1.38	MMP-2	0.65 → 0.86
CTGF	2.32 → 1.54	TIMP-1	1.94 → 1.50
Collagen I	2.54 → 1.69		

TISSUE-LEVEL FINDINGS

ENDPOINT	REPORTED VALUE
Fibrosis score	3.24 → 2.15
Collagen-positive area	61.25% → 40.00%
Masson's Trichrome	59.38% → 38.88%
Picrosirius Red	60.25% → 40.75%
α-SMA	*Reported as reduced; numerical values not supplied in summary table*

Three layers, three different questions

CLINICAL	The Podar summary reports within-group changes in symptoms, oral mucosal findings and IID over 90 days.
CELLULAR & MOLECULAR	Changes in markers associated with myofibroblast activity, profibrotic signalling and matrix biology.
TISSUE	The interim brief reports reductions in fibrosis score and collagen-associated measures.

These layers address different questions and are not interchangeable. Mouth-opening improvement alone does not prove fibrosis regression; biomarker changes alone do not prove tissue remodelling.

STATUS OF THE EVIDENCE

The clinical summary and the separate biological findings are interim and require review against full reports and source data. The biological report is under final review for statistical analysis. Histopathology and collagen-associated measurements may provide structural evidence, but interpretation depends on study design, validated methods, controls and reproducibility.

We welcome independent perspectives

We welcome independent clinical perspectives and constructive discussion on patient selection, outcome measures, evidence interpretation and future research priorities.

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DOCUMENT STATUS

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