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Alternate Drug Delivery Systems in the Management of Oral Submucous Fibrosis: A Narrative Review with Emphasis on Oral Mucosal Iontophoresis

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Abstract
Oral submucous fibrosis (OSMF) is an areca nut–driven, potentially malignant disorder in which a stiffening lamina propria progressively limits mouth opening. Corticosteroids remain the pharmacological backbone of treatment, yet the two routes most often used to deliver them each carry a familiar penalty: topical agents are washed away by saliva, while submucosal injections are painful and demand repeated needle punctures into fibrotic tissue. This has prompted interest in alternate drug delivery systems that can place an adequate concentration of drug in the lamina propria without a needle. The present narrative review discusses these systems in turn, namely medicated oral rinses, mucoadhesive gels, buccal films and patches, microneedle patches, nanocarrier and biomaterial platforms, and iontophoresis, drawing on literature indexed in PubMed,scopus and web of science. Mucoadhesive systems have reached small clinical trials with encouraging symptomatic results, whereas microneedles and nanocarriers remain largely preclinical. Iontophoresis receives particular attention: laboratory studies on oral mucosa show several-fold increases in drug delivery within 5 to 10 minutes of low-intensity current, with tissue concentrations well above antifibrotic thresholds, although controlled clinical trials in OSMF are still lacking. Drug ionisation, electrode polarity and current dosing emerge as the key variables that future trials must standardise.

Keywords: oral submucous fibrosis; alternate drug delivery system; iontophoresis; mucoadhesive drug delivery; microneedles; triamcinolone acetonide

I. Introduction

Few oral diseases combine functional disability and cancer risk as bluntly as oral submucous fibrosis. The condition affects millions of people across South and Southeast Asia, chewing of areca nut is its dominant risk factor, and despite decades of therapeutic effort its prognosis has barely shifted.[1] Patients typically present with a burning sensation on eating spicy food, blanched and leathery mucosa, palpable fibrous bands and a mouth opening that shrinks year by year. At the tissue level, areca alkaloids push buccal fibroblasts towards excess collagen synthesis while collagen breakdown is suppressed, and the resulting fibrosis settles in the lamina propria and, in advanced cases, the underlying muscle.[2]

The cancer risk is not trivial. A 2022 meta-analysis pooling studies from 1956 onwards estimated an overall malignant transformation rate of about 6%, rising to 8% in Indian cohorts, although heterogeneity between studies was wide.[3] An earlier meta-analysis arrived at a somewhat lower pooled figure of 4.2%.[4] Either way, OSMF sits among the more consequential oral potentially malignant disorders.

Treatment options have multiplied without converging. When Cochrane reviewers updated their analysis in 2024, they identified 30 randomised trials but could state with moderate confidence only that antioxidants help; for everything else, trial design limitations kept certainty low.[5] A separate update of drug trials published between 2011 and 2022 catalogued steroids, hyaluronidase, pentoxifylline, lycopene, curcumin, aloe vera and several other agents, which says as much about the absence of a gold standard as about therapeutic creativity.[6] A network meta-analysis has since tried to rank these competing interventions against one another.[7]

A less discussed question runs underneath this debate. Even a well-chosen drug is only useful if it reaches the fibrotic lamina propria in adequate concentration, and the oral cavity is a difficult place to deliver anything. Saliva dilutes and clears topical agents within minutes, the epithelium resists penetration, and injections into stiff fibrous tissue hurt. This review examines the alternate drug

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delivery systems proposed to solve that problem, beginning with the limitations of conventional routes and moving from the simplest vehicles to the most technology-dependent, with particular attention to iontophoresis, the application of a small electric current to drive drug molecules across the mucosa.

II. Conventional Drug Delivery in OSMF and Its Limitations

2.1 The therapeutic target

The therapeutic target in OSMF is not the epithelium but the connective tissue beneath it, where inflammatory cells, activated fibroblasts and densely packed collagen accumulate.[2] A drug applied to the surface must therefore cross an epithelium that, in OSMF, is often atrophic in places and hyperkeratotic in others, and then persist long enough in the lamina propria to influence collagen turnover. Salivary flow works against both steps.

2.2 Systemic (oral) drug delivery

Systemic drugs avoid the salivary barrier but distribute throughout the body. Oral pentoxifylline, which improves microcirculation, has been compared directly with dexamethasone in OSMF; a small randomised study of 30 patients that tracked submucosal thickness on ultrasound found the pentoxifylline group improving marginally more than the steroid group.[8] Systemic corticosteroids for a chronic, localised disease are harder to justify, and most clinicians reserve steroids for local use.

2.3 Intralesional (submucosal) injection

Submucosal injection remains the most widely used local route. Its appeal is obvious: the drug is placed directly into the fibrotic zone. In a double-blind, three-arm trial of 45 patients receiving biweekly injections for five weeks, hyaluronidase alone produced quicker and larger gains than dexamethasone alone or the combination.[9] A larger trial in 160 patients who received weekly injections for 12 weeks and were followed for a year reported the best gain in mouth opening, about 7.3 mm, when placental extract, hyaluronidase and dexamethasone were combined, compared with under half a millimetre in patients who received only supplements and exercises.[10] Adding systemic curcumin to intralesional dexamethasone with hyaluronidase raised the mean 12-week gain from roughly 5.4 mm to 8.7 mm in a Nepalese randomised trial.[11] Retrospective data from grade III disease have likewise been used to argue for injected hyaluronidase and dexamethasone in advanced stages.[12]

These numbers look encouraging, but the pooled evidence is more cautious. A meta-analysis of six trials involving 244 patients found no clear added benefit of hyaluronidase combined with corticosteroids over comparator drugs for maximum mouth opening at one, two or three months.[13] The procedure also asks a lot of patients: repeated punctures into rigid tissue, weekly or biweekly visits for weeks on end, and a real chance that some drop out before the course is complete. Needle trauma in already fibrotic mucosa is a further theoretical concern. It is this combination of modest average benefit and high procedural burden that has pushed researchers towards needle-free alternatives.

2.4 Conventional topical application

Topical corticosteroid gels and pastes are painless and cheap, and they can be applied at home. Their limitation is residence time. A gel smeared on the buccal mucosa is diluted and swallowed long before a meaningful fraction reaches the lamina propria, and the tissue concentration achieved is uncertain. Most of the newer systems described below are, in essence, attempts to keep a topical drug in place for longer or to push it deeper.

III. Alternate Drug Delivery Systems in OSMF

Alternate drug delivery systems for OSMF can be grouped by how they overcome the salivary and epithelial barriers: by prolonging contact with the mucosa, by physically breaching the epithelium, by packaging the drug in carriers, or by applying an external driving force. Figure 1 outlines this classification, and Table 1 summarises the principal advantages and limitations of each system. The sections that follow take them in the same order.

International Journal Dental and Medical Sciences Research
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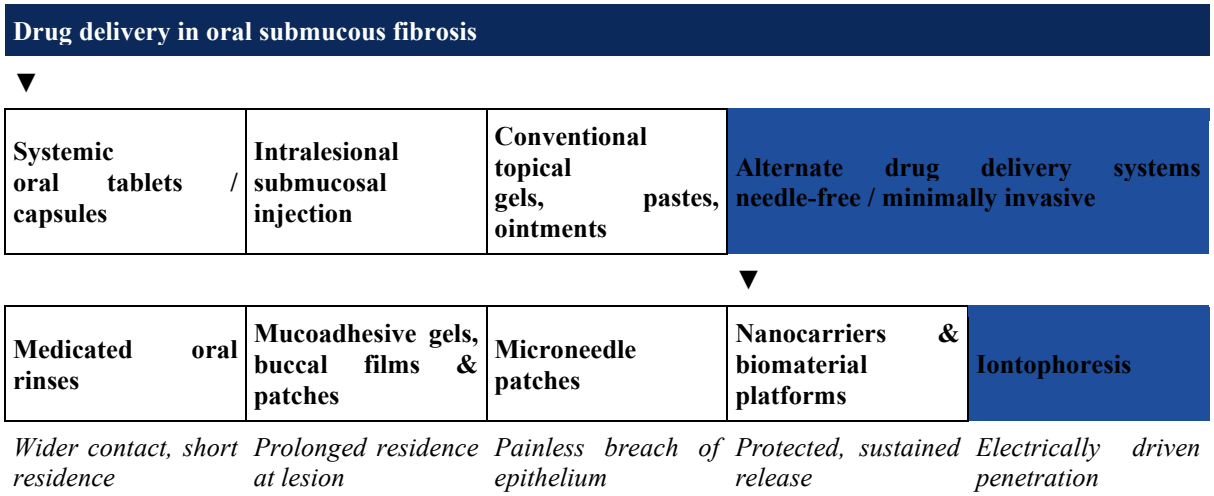

Figure 1. Classification of drug delivery approaches in oral submucous fibrosis, with the alternate drug delivery systems discussed in this review.

Table 1. Alternate drug delivery systems for OSMF: mechanism, advantages and limitations.

Delivery system	How it works	Advantages	Limitations	Current stage in OSMF
Medicated oral rinse	Drug in solution swished over mucosa	Simple, self-administered, covers all affected sites	Very short contact time; dose to lamina propria uncertain	Clinical trial[14]
Mucoadhesive gels, films & patches	Bioadhesive polymers hold drug on mucosa for hours	Painless, sustained local release, low systemic exposure	Patch retention during speech and eating; passive diffusion only	Small clinical trials[15,16]
Microneedle patches	Micro-projections pierce epithelium and release drug into connective tissue	Reaches lamina propria without injection pain; release over days	Manufacturing complexity; no human OSMF data	Preclinical[17]
Nanocarriers & biomaterials	Drug packaged in nanoparticles, hydrogels or vesicles	Protects drug, improves retention and penetration, allows targeting	Cost, regulatory pathway, safety data sparse	Preclinical[18]
Iontophoresis	Low electric current drives ionised drug into mucosa	Needle-free, rapid (minutes), controllable dose, inexpensive devices	Needs ionisable drug; polarity and current must be standardised	Ex vivo evidence; clinical trials lacking[19,20]

3.1 Medicated oral rinses

The simplest variation on topical therapy is to change the vehicle. A randomised trial from Nagpur tested a prednisolone mouthwash, given with antioxidant capsules, against antioxidants alone in 64 patients with grade III disease, measuring interincisal opening, burning sensation and recurrent ulceration.[14] Rinses reach a wider mucosal surface than a gel applied with a fingertip, though contact time is short and the dose delivered to the lamina propria remains hard to estimate.

3.2 Mucoadhesive drug delivery systems: gels, buccal films and patches

Mucoadhesive polymers such as chitosan, hydroxypropyl methylcellulose and carbopol cling to wet mucosa and release drug over hours instead of minutes. Early formulation work on a chitosan–HPMC buccal film loaded with valdecoxib showed that roughly 69% of the drug was released over six hours in vitro and a little over half permeated pig buccal mucosa; pharmacokinetic sampling in healthy

International Journal Dental and Medical Sciences Research
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volunteers suggested the drug stayed largely at the application site, with minimal systemic absorption.[16]

Clinical data are still thin but point in a consistent direction. In a trial of 40 OSMF patients using curcumin either as a gel or as a buccal mucoadhesive patch twice daily for eight weeks, burning sensation had resolved in every patient by week four, and mouth opening improved by 5.5 mm with the gel and 5.9 mm with the patch.[15] The difference between the two vehicles was small, which is itself informative: in that trial, the drug seemed to matter more than the carrier. Patches do have a practical drawback. They must stay attached through speech and swallowing, and patient-reported comfort with prolonged patch wear in a stiff, restricted mouth has not been studied systematically.

3.3 Microneedle-based drug delivery

Microneedles bridge the gap between a patch and an injection. Arrays of sub-millimetre projections pierce the epithelium painlessly and release drug directly into the connective tissue. A Chinese group designed a two-layer patch for OSMF, pairing a silk fibroin microneedle layer with a silk fibroin–tannic acid adhesive backing modelled on a bandage. The patch released triamcinolone for at least seven days, adhered to wet tissue more strongly than commercial buccal patches (about 38 kPa), and in ex vivo mucosa reached the lamina propria.[17] A similar strategy has been used for oral mucositis, where dissolving microneedles carrying triamcinolone acetonide in polydopamine nanoparticles were developed precisely because the drug's hydrophobicity limits its bioavailability on the oral surface.[21] No human OSMF trial of a microneedle device appears in PubMed yet.

3.4 Nanocarrier and biomaterial-based drug delivery

Nanoparticles, hydrogels, electrospun fibres and exosome-based carriers have all been proposed for OSMF. A 2026 review of biomaterial-based strategies concluded that these systems address three recurring problems of oral delivery, namely poor mucosal retention, limited epithelial penetration and fast salivary clearance, but noted that the supporting evidence is almost entirely preclinical.[18] One line of work is worth highlighting because it links nanocarriers with electrical enhancement: chitosan nanoparticles loaded with oxaliplatin and applied as a mucoadhesive topical treatment for oral tumours showed further gains in ex vivo mucosal delivery when iontophoresis was added.[22] The two technologies need not compete.

3.5 Iontophoresis

3.5.1 Principle of iontophoresis

Iontophoresis uses a low-intensity electric field to increase the movement of drug molecules into or across a membrane. Two mechanisms dominate. Electromigration moves charged molecules away from the electrode of the same charge, so an anionic drug is placed under the cathode and a cationic drug under the anode. Electroosmosis is a bulk flow of solvent generated because biological membranes carry a net negative charge at physiological pH; it runs from anode to cathode and can carry neutral molecules with it.[23] The distinction matters for drug selection, and we return to it in Section 5.

The oral cavity offers some advantages over skin. The mucosa is well vascularised and generally more permeable, and drug absorbed across it bypasses first-pass hepatic metabolism. A 2018 review of iontophoresis in the mouth described significant enhancement of transbuccal delivery over passive diffusion for a range of drugs, and local applications in enamel, dentine and soft tissue. The same review observed that dental use had so far concentrated on fluoride and lidocaine, that the mechanisms in oral tissues are incompletely understood, and that animal and human studies had found the technique safe under the conditions tested.[24] A dental review from 2022 cited enhancement ranging from 10 to 2,000 times conventional delivery, noted that alternating current has outperformed conventional direct current in some settings, and emphasised that suitable drugs should be water-soluble and ionisable, with smaller molecules moving more readily.[25]

3.5.2 Laboratory evidence specific to OSMF

The most rigorous OSMF-directed iontophoresis work comes from the Kalia laboratory in Geneva. In the first study, buflomedil hydrochloride, a vasoactive drug that inhibits collagen production, was applied to buccal mucosa from solution, hydrogel or thin film. Ten minutes of current at 1 mA/cm² delivered roughly 13 times more drug from a thin film than passive application (323 versus 25 µg/cm²), and the concentration measured in the lamina propria, the real therapeutic target, was about 700 times the level needed to block collagen synthesis in vitro.[19]

The follow-up study is directly relevant to steroid therapy. Using a concentric electrode arrangement on porcine mucosa, the group delivered cationic buflomedil and anionic dexamethasone sodium phosphate simultaneously. Just five minutes of current raised dexamethasone phosphate delivery from about 29 to 193 nmol/cm² compared with

International Journal Dental and Medical Sciences Research
Volume 8, Issue 5, Sep.-Oct 2026 pp: 126-133 www.ijdmsrjournal.com ISSN: 2582-6018

passive controls, with a similar rise for buflomedil. Dexamethasone phosphate did not spread laterally without current, but with it, delivery increased more than fivefold under its own electrode and more than eightfold in the tissue between electrodes. The authors concluded that therapeutically relevant concentrations were reached within five minutes.[20] Short sessions of this kind would fit comfortably into an outpatient visit.

3.5.3 Clinical experience in and around the mouth

Iontophoresis has a longer clinical history in the perioral region than in OSMF itself. A mucoadhesive formulation combined with iontophoresis has been developed with the explicit aim of needle-free buccal anaesthesia.[26] The most useful clinical analogue for a disease of restricted mouth opening, though, comes from paediatric rheumatology. In children with juvenile idiopathic arthritis affecting the temporomandibular joint, dexamethasone iontophoresis was delivered through an electrode over the joint with a return electrode on the upper arm. In the 28 children with before-and-after measurements, median maximal interincisal opening rose from 35 mm to 39.5 mm, and the authors assessed safety alongside effectiveness.[27] That was a retrospective record review, not a trial, and the target tissue was a joint rather than fibrotic mucosa, but it shows that corticosteroid iontophoresis can translate into measurable gains in jaw opening.

3.5.4 The clinical gap in OSMF

Here the evidence thins sharply. Searching PubMed for controlled trials of mucosal iontophoresis in OSMF patients returns very little. The 2024 Cochrane review considered physical and alternative interventions as well as drugs, yet the only therapy it could support with moderate certainty was antioxidant supplementation; nothing in it establishes an iontophoretic protocol.[5] The recent update on OSMF drug trials is organised around systemic, topical and injected agents.[6] Some clinical studies of steroid iontophoresis in OSMF have been published in regional journals, but those we traced did not carry PubMed listings and were therefore outside the scope of this review. The practical consequence is that iontophoresis in OSMF currently rests on laboratory pharmacokinetics and on analogy with other conditions, not on controlled clinical outcomes.

IV. Key Clinical and Laboratory Studies

Table 2 brings together the principal studies discussed above, grouped by route of delivery. Figures are those reported by the original authors; they come from different populations, disease stages and follow-up periods and are not directly comparable.

Table 2. Key studies on conventional and alternate drug delivery in OSMF.

Route / system	Study (design)	Key reported finding	Ref.
Intralesional injection	Hyaluronidase vs dexamethasone vs combination (double-blind RCT, n=45)	Hyaluronidase alone gave quicker, greater improvement	[9]
Intralesional injection	Placentrex, hyaluronidase, dexamethasone and combination (RCT, n=160, 12-month follow-up)	Combination group gained 7.30 ± 0.80 mm; control 0.37 mm	[10]
Intralesional + systemic	Curcumin added to dexamethasone/hyaluronidase injection (RCT)	12-week gain 8.71 vs 5.35 mm	[11]
Intralesional (pooled)	Hyaluronidase + corticosteroid (meta-analysis, 6 RCTs, 244 patients)	No significant added benefit over comparators at 1–3 months	[13]
Mucoadhesive gel vs patch	Curcumin gel vs buccal patch (clinical trial, n=40)	Burning resolved in all by week 4; opening +5.45 mm (gel), +5.9 mm (patch)	[15]
Mucoadhesive film	Valdecoxib chitosan–HPMC film (formulation + volunteer PK)	~69% released in 6 h; mainly local action	[16]

International Journal Dental and Medical Sciences Research
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Route / system	Study (design)	Key reported finding	Ref.
Microneedle patch	Triamcinolone silk fibroin patch (in vitro / ex vivo)	Release ≥7 days; reached lamina propria	[17]
Iontophoresis	Buflomedil, buccal mucosa (ex vivo)	Film delivery 323 vs 25 µg/cm²; lamina propria level ~700× antifibrotic IC50	[19]
Iontophoresis	Buflomedil + dexamethasone phosphate co-iontophoresis (ex vivo)	5 min current: dexamethasone 29 → 193 nmol/cm²	[20]
Iontophoresis (analogue)	Dexamethasone iontophoresis, TMJ arthritis in JIA (retrospective, n=28)	Median opening 35 → 39.5 mm	[27]

Note: no randomised controlled trial of oral mucosal iontophoresis in OSMF patients with a PubMed listing was identified during this review.

V. Clinical Implications and Challenges

Three conclusions stand out from this literature. The first is that the delivery problem in OSMF is real and has been underweighted. Much of the trial literature compares drugs while holding the route constant, usually injection, so differences in outcome are attributed to pharmacology when some of the variation may reflect how much drug actually reached the lamina propria. The laboratory work on iontophoresis makes this point quantitatively: the same drug, applied to the same tissue, can reach concentrations an order of magnitude higher depending on whether current is applied.[19,20]

The second is that the needle-free systems sit at very different stages of maturity. Mucoadhesive gels and patches are already in clinical use and have produced trial data, however small.[15] Microneedles and nanocarriers are elegant but remain almost entirely preclinical.[17,18] Iontophoresis falls in between. The physics is well understood, the devices are inexpensive and widely available in physiotherapy and dermatology, and safety in the oral cavity has been reasonably established,[24] yet its clinical efficacy in OSMF has not been demonstrated in a trial that a systematic reviewer could include.

The third conclusion concerns drug selection, and it has direct implications for anyone designing an iontophoresis trial. Electromigration only helps a molecule that carries a charge. Dexamethasone sodium phosphate is anionic and is delivered from the cathode, which is how it was used in both the Geneva work and the arthritis study.[20,27] Triamcinolone acetonide, by contrast, is essentially un-ionised at physiological pH. Any enhancement of its transport would have to come from electroosmotic flow, which runs from anode to cathode, so a neutral drug placed under the cathode would be moving against that flow rather than with it.[23] Trials using triamcinolone acetonide gel should therefore justify their electrode polarity explicitly, consider anodal placement, or use a charged steroid salt. Protocols that treat all corticosteroids as interchangeable for iontophoresis risk producing null results for avoidable reasons.

Several other design questions follow. Current density, not just total current, governs both delivery and tolerability, and should be reported in mA/cm² along with electrode area. Session length can probably be short, since ex vivo delivery was substantial within five to ten minutes.[20] Outcome measures should match those used elsewhere in the OSMF literature, typically interincisal opening, burning sensation on a visual analogue scale and cheek flexibility, so that results can later be pooled.[5] Follow-up needs to extend well beyond the treatment period, because relapse after intralesional therapy varies considerably between regimens.[10] Finally, comparator choice matters. A trial of iontophoretic steroid against the same steroid applied passively answers a clean pharmacokinetic question, whereas a trial against intralesional injection answers the question patients and clinicians actually care about: can a painless technique match the established one?

The available evidence has clear limitations. Much of it comes from single-centre studies with small samples, short follow-up and inconsistent staging systems, a problem the Cochrane authors flagged repeatedly.[5] Laboratory studies used porcine tissue, which approximates but does not replicate fibrotic human mucosa, where increased collagen density and altered epithelium may change permeability in either direction. Adverse effects of alternate delivery systems are also sparsely reported.

VI. Future Directions

A few priorities seem reasonable. Adequately powered, randomised trials of mucosal iontophoresis in OSMF are the obvious first need, ideally comparing a charged corticosteroid delivered iontophoretically with both passive topical application and intralesional injection. Combination approaches deserve attention too: pairing iontophoresis with mucoadhesive or nanoparticulate vehicles has already improved delivery in other oral applications,[22,26] and co-iontophoresis of an antifibrotic with a steroid has been shown to be feasible.[20] Measuring drug concentration in biopsy tissue, even in a small subset of patients, would help link clinical response to actual delivery. Given the malignant potential of the disease, trials should also report long-term surveillance outcomes rather than stopping at symptom relief.[3]

VII. Conclusion

Drug delivery is one of the quieter reasons why OSMF treatment has disappointed for so long. Injections reach the target but at a cost to comfort and compliance; topical agents are comfortable but largely wash away. Mucoadhesive systems have begun to close that gap in small clinical studies, and microneedles and nanocarriers may follow. Iontophoresis offers a needle-free way to push charged drugs into the lamina propria within minutes, and laboratory data on oral mucosa support that claim convincingly. What is missing is clinical proof. Until well-designed trials with appropriate drug selection and standardised current dosing are published, iontophoresis in OSMF should be regarded as a promising adjunct under investigation rather than an established therapy.

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