

Development of Novel Drug Delivery Systems for the Treatment of Alopecia

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ABSTRACT

Alopecia, especially androgenetic alopecia and alopecia areata, remains a clinically and psychologically important disorder because conventional therapy often gives limited follicular bioavailability and may cause local or systemic adverse effects. This review preserves the central meaning of the original manuscript while decreasing repetition and consolidating the reference list into a numbered citation format. The focus is on novel drug delivery systems that improve localization in the pilosebaceous unit, reduce unnecessary systemic exposure and support sustained release near the dermal papilla. Lipid nanocarriers, polymeric nanoparticles, vesicular systems, smart hydrogels, microneedles, exosome-based systems and manufacturing considerations are discussed with essential numerical values retained. Optimized follicular carriers in the range of about 100-300 nm are emphasized because they can exploit the follicular opening, establish a depot and improve drug residence compared with conventional hydroalcoholic solutions.

Keywords: Novel drug delivery systems; alopecia; transfollicular delivery; nanostructured lipid carriers; microneedles; hydrogels; exosomes; follicular targeting.

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1. Introduction and Therapeutic Need

Alopecia includes androgenetic alopecia (AGA), alopecia areata (AA), telogen effluvium and other hair loss patterns. AGA is driven mainly by androgen-mediated follicular miniaturization, while AA is associated with autoimmune disruption of follicular immune privilege. The original manuscript highlighted a high global burden, psychosocial morbidity, reduced quality of life, anxiety, depression and work-related impairment. These elements justify improved, patient-compliant therapy rather than purely cosmetic management [1,2].

The currently dominant medicines, minoxidil and finasteride, remain clinically useful but imperfect. Topical minoxidil has low absolute absorption through intact scalp skin, and conventional propylene glycol/alcohol vehicles may cause irritation, erythema, pruritus and scaling. Oral finasteride reduces dihydrotestosterone but may produce sexual, endocrine and neuropsychological concerns in susceptible patients. These limitations support follicle-directed drug delivery platforms that localize the dose and decrease unwanted systemic exposure [3,4].

Novel drug delivery systems (NDDS) shift the treatment concept from simple topical diffusion to targeted transfollicular deposition. The hair follicle functions as a natural skin appendage reservoir. If a carrier is properly sized and surface-engineered, it can enter the follicular ostium, remain in the infundibulum, and release the active ingredient close to the dermal papilla and follicular stem-cell niche [5-8].

Problem	Conventional limitation	NDDS response
Low scalp penetration	Stratum corneum limits passive	Follicular targeting and

	diffusion	depot release
Vehicle irritation	Alcohol and propylene glycol irritation	Lipid, gel or polymeric alternatives
Systemic toxicity	Oral exposure produces off-target effects	Localized follicular delivery
Poor compliance	Frequent application is required	Sustained-release systems

2. Hair Follicle Biology and Pathophysiology

The hair follicle is a cyclic mini-organ that alternates between anagen, catagen and telogen. Anagen is the active growth phase, supported by matrix cell proliferation and Wnt/beta-catenin signaling. Catagen is a regression phase associated with apoptosis and mediators such as transforming growth factor-beta. Telogen is a resting phase in which bulge stem cells remain quiescent until the next growth cycle [6].

In AGA, testosterone is converted to dihydrotestosterone by 5-alpha-reductase enzymes. Dihydrotestosterone binds the androgen receptor in dermal papilla cells and changes the transcriptional environment. In genetically susceptible scalp regions, this suppresses growth-supporting signals and increases catagen-promoting mediators, leading to progressive conversion of terminal hairs into miniaturized vellus-like hairs [1,4].

Oxidative stress and inflammation also contribute. Increased reactive oxygen species, lipid peroxidation markers and inflammatory cytokines damage proliferating matrix cells and may reduce vascular support around follicles. Therefore, an effective NDDS may need to deliver not only growth stimulants or anti-androgens, but also

antioxidants, anti-inflammatory molecules or regenerative biological cargo [2,22].

The key therapeutic target remains the pilosebaceous unit: infundibulum, sebaceous duct, bulge region, dermal papilla, matrix cells and perifollicular vasculature. Delivery systems must be designed around this spatial target rather than around general skin permeation alone [5-8].

3. Barriers to Transfollicular Drug Delivery

The outer stratum corneum is a lipid-rich impermeability matrix that limits passive transport of hydrophilic, high-molecular-weight or particulate systems. Conventional topical minoxidil is therefore poorly absorbed, and the solvent system becomes almost as important as the drug itself. In contrast, the follicular route provides a shunt pathway that can reduce lag time and provide deeper localization [3,5,7].

Hair follicle openings are much larger than nanoparticles, but successful entry depends on particle size, surface charge, lipophilicity and mechanical movement of the hair shaft. The original paper emphasized that particles around 100-300 nm are particularly useful for follicular deposition. Smaller particles may clear more rapidly, whereas very large particles are retained superficially or excluded from deeper compartments [5,8].

The follicular infundibulum and sebaceous duct act as a depot, and the hair shaft can assist transport through the "geared pump" effect during movement or massage. Sebum is lipophilic; therefore lipid carriers and vesicular systems often show strong compatibility with the follicular environment [5,7,8].

Variable	Preferred feature	Reason
Particle size	About 100-300 nm	Improves follicular entry and retention
Surface properties	Balanced lipophilicity/charge	Supports sebum wetting and follicular anchoring
Release pattern	Initial plus sustained phase	Provides rapid effect and prolonged exposure
Safety	Low irritation and low systemic leakage	Improves compliance and risk profile

4. Limitations of Conventional Alopecia Therapy

Minoxidil, finasteride and related anti-androgens provide the foundation of current therapy, but they do not fully satisfy the requirements for safe, localized and convenient long-term treatment. Minoxidil must reach the follicle to prolong anagen and stimulate vascular or cellular responses; however, the conventional solution depends heavily on alcohol and propylene glycol, which may cause irritation and poor adherence [3,4].

Finasteride reduces DHT formation, but oral dosing exposes non-scalp tissues. The original paper discussed endocrine and neurosteroid-related risks, supporting the rationale for topical, follicle-restricted anti-androgen delivery. A properly designed carrier could place the drug

near dermal papilla cells while reducing systemic spillover [4].

Dutasteride, phytochemicals, antioxidants and growth-promoting molecules face similar delivery difficulties. Some are poorly water-soluble, unstable, irritant or too large for passive skin transport. NDDS can improve solubilization, protect unstable cargo, and provide sustained release within the follicular reservoir [1,5,23].

Thus, the therapeutic challenge is not only selection of the active pharmaceutical ingredient. It is the integration of molecule, carrier, vehicle, application site, release profile, patient acceptability and manufacturing control. The reduced paper preserves this integrated meaning while removing duplicative discussion.

5. Lipid-Based Nanocarriers

Lipid-based nanocarriers are highly relevant for scalp delivery because the follicular canal contains sebum. Solid lipid nanoparticles, nanostructured lipid carriers (NLCs), ufasomes, ethosomes and niosomes can solubilize lipophilic drugs and improve retention in the follicular compartment [10-15].

NLCs are second-generation lipid nanoparticles that blend solid and liquid lipids to create an imperfect matrix. This imperfect crystal structure prevents drug expulsion and increases loading. In the source paper, optimized minoxidil NLCs were described with mean particle size around 280.4 nm and zeta potential near -42.40 mV, with entrapment efficiency reaching approximately 86.09%. These values support the suitability of NLCs for follicular depot formation [10,11].

The release pattern of NLCs is clinically useful because it may combine a short initial burst with prolonged diffusion from the lipid core. Such biphasic release is suitable for maintaining local follicular drug levels without frequent reapplication [10,11].

Carrier	Main composition	Delivery advantage
NLC	Solid plus liquid lipids	High loading and sustained release
Ufasome	Unsaturated fatty acid vesicle	Deformability and sebum fusion
Ethosome	Phospholipid plus ethanol	Enhanced skin and follicle permeation
Niosome	Non-ionic surfactant and cholesterol	Stable vesicle for drugs or phytochemicals

6. Vesicular Systems: Ufasomes, Ethosomes and Niosomes

Ufasomes are unsaturated fatty acid vesicles, commonly based on oleic acid. They are deformable and compatible with sebum, making them suitable for deep follicular deposition. The original paper retained the important values of optimized minoxidil-loaded ufasomes: particle size around 317 nm, entrapment efficiency around 69.08%, and follicular accumulation about 10-fold higher than conventional hydroalcoholic solution [12].

Ethosomes contain phospholipid and high ethanol concentration. Ethanol fluidizes the stratum corneum lipid

matrix while also increasing vesicle flexibility. Commercial and clinical examples of ethosomal or cetosomal minoxidil were noted in the original manuscript, including reduced irritation and comparable or improved hair growth outcomes compared with conventional topical minoxidil [13,14].

Niosomes are vesicles formed from non-ionic surfactants and cholesterol. They are stable, relatively low-toxicity and useful for compounds that require protection from degradation. Their bilayer structure can carry lipophilic drugs and phytochemicals while providing controlled release in the follicular region [15].

The condensed interpretation is that vesicular systems are not interchangeable. Ufasomes emphasize deformability and sebum fusion, ethosomes emphasize permeation enhancement, and niosomes emphasize stability and low toxicity. Choice depends on payload, irritation risk and desired release profile.

7. Polymeric Nanoparticles

Polymeric nanoparticles provide better mechanical stability than many lipid vesicles and can be engineered for controlled biodegradation. Poly(lactic-co-glycolic acid) (PLGA) and poly(lactic acid) (PLA) are widely used because they degrade through hydrolysis to lactic and glycolic acid. These materials are suitable for lipophilic drugs, phytochemicals and sustained follicular release [16].

The lactic:glycolic ratio controls PLGA degradation. A 50:50 ratio generally degrades faster than a more hydrophobic 75:25 composition. This is important for alopecia because a follicular depot that releases minoxidil, finasteride or a regenerative phytochemical over days to weeks may improve compliance compared with twice-daily topical solutions [16].

Polymeric systems also protect unstable compounds such as quercetin, epigallocatechin gallate and other antioxidant or anti-inflammatory phytochemicals. By reducing oxidative degradation and supporting follicular localization, polymeric nanocarriers can address multiple mechanisms: androgen signaling, oxidative stress, inflammation and reduced cellular proliferation [16,23].

However, polymeric carriers require careful control of residual solvents, particle size, polydispersity, degradation products and scalp tolerability. Sustained release is useful only if the carrier itself is non-irritating and produces consistent follicular deposition.

8. Inorganic and Functional Nanocarriers

Mesoporous silica nanoparticles (MSNs) offer a rigid, high-surface-area platform with controlled pore architecture. They can carry small molecules, trace elements or combined regenerative agents. Their porosity allows controlled loading and release, while surface functionalization controls follicular retention or penetration [17,18].

The original review discussed zinc/copper or quercetin-containing inorganic systems because oxidative stress and micronutrient imbalance are relevant in alopecia. Zinc supports several enzymatic and cellular functions related to hair growth, while antioxidant payloads can reduce perifollicular oxidative injury [18,22].

Metallic nanozymes represent a different concept. Instead of acting only as passive carriers, they can mimic enzyme-like antioxidant activity. Ni-Cu bimetallic nanozymes, for example, were described as systems capable of reshaping the follicular microenvironment by reducing reactive oxygen species and supporting hair regeneration when combined with microneedle delivery [21].

Inorganic platforms must be evaluated cautiously. Their stability and catalytic activity may be advantageous, but long-term scalp retention, local irritation, biodistribution and clearance must be verified before translation. The reduced paper preserves the original message: inorganic systems are promising but require rigorous safety and manufacturing assessment.

9. Surface Functionalization and Targeting Mechanics

Particle size determines whether a carrier can enter the follicular pathway, but surface chemistry determines where it stops and how it interacts with cells. Thiolated surfaces can bind strongly to keratin-rich structures through thiol/disulfide exchange, creating a superficial follicular depot. PEGylation, in contrast, reduces adhesion and may support deeper movement by decreasing nonspecific interactions [19].

Cationic coatings such as chitosan can enhance adhesion to negatively charged keratin and cellular membranes. This can improve residence time and cellular uptake, but excessive positive charge may increase irritation or superficial retention. Therefore, the preferred charge depends on whether the aim is depot formation, deep penetration or intracellular uptake [19].

Functionalization strategies should be selected according to clinical objective. Anti-dandruff or superficial anti-inflammatory therapy may benefit from strong upper follicle retention. Dermal papilla targeting, regenerative biologics or immunomodulation may require deeper follicular access and controlled release [5,19].

Surface design	Expected effect	Best use
Thiolated surface	Strong keratin attachment	Long superficial depot
PEGylated surface	Reduced adhesion and deeper movement	Dermal papilla targeting
Cationic coating	High cellular interaction	Enhanced uptake
Lipophilic surface	Sebum compatibility	Follicular channeling

10. Stimuli-Responsive Hydrogels

Smart hydrogels are useful because liquid topical products can run off the scalp, especially at the hairline and eyebrows. In situ thermosensitive hydrogels remain liquid during application and gel when exposed to scalp temperature. Poloxamer 407 and hydroxypropyl methylcellulose combinations were highlighted as matrices that can provide sol-gel transition and spatial retention [20]. Hydrogels can also co-deliver drugs with very different solubility. The original manuscript described an ionic-liquid and cyclodextrin-assisted minoxidil plus finasteride hydrogel concept. This system improved finasteride

penetration, increased dermal retention and achieved stronger target localization than conventional suspension. Key values retained from the source paper included an approximately 8.6-fold improvement in target-tissue retention for finasteride and around 6.3-fold retention improvement for minoxidil [20].

pH-responsive hydrogels may release drugs in inflammatory or alkaline microenvironments, while iontophoresis can actively drive charged drugs such as minoxidil sulfate into follicles. These active or stimuli-responsive systems are valuable when passive diffusion is insufficient [20].

The reduced interpretation is that hydrogels are not merely thickening agents. They provide spatial control, reduced runoff, co-delivery potential and programmable release, making them important platforms for patient-compliant alopecia therapy.

11. Microneedle and Device-Assisted Delivery

Microneedle arrays bypass the stratum corneum by creating temporary microchannels. They can deliver small molecules, nanoparticles, peptides, nucleic acids and biologics with minimal pain because the needles are designed to penetrate superficial layers without reaching deep nerve endings or causing significant bleeding [1,21].

Dissolving microneedles are especially attractive because they are made from biocompatible polymers such as hyaluronic acid, PVA, PVP, PLA or PLGA. After insertion, the needles dissolve in interstitial fluid and release the payload directly into the skin. This avoids sharps waste and supports self-administration [21].

Microneedling also produces a biological wound-healing response. Local microinjury can promote platelet activation, growth factor release, angiogenesis and Wnt/beta-catenin signaling. Thus, microneedles may act both as a delivery system and as a regenerative stimulus. Combination systems carrying minoxidil, nanozymes, phytochemicals or exosomes may therefore produce synergistic effects [1,21].

Device-assisted strategies must still consider dose uniformity, insertion depth, mechanical strength, irritation, infection risk and patient technique. Clinical translation requires standardization of patch geometry, drug loading, dissolution time and stability.

12. Biological Delivery Systems and Regenerative Cargo

Regenerative treatment for alopecia increasingly includes biologic cargo such as platelet-derived factors, extracellular vesicles, growth factors, nucleic acids and stem-cell derived exosomes. These materials can influence dermal papilla activity, angiogenesis, inflammation and hair follicle stem-cell activation [1,2].

Exosomes are nanoscale extracellular vesicles that carry proteins, lipids and regulatory RNAs. The source manuscript emphasized the clinical interest in mesenchymal stem cell-derived exosomes and similar regenerative systems. Their value depends on targeted delivery because naked biologics may be unstable, rapidly cleared or poorly penetrant through the scalp barrier [1,2].

Nanocarriers and microneedles can protect biologics and deposit them closer to the follicular niche. However, the

manufacturing burden is higher than for small molecules. Quality control must include vesicle identity, size distribution, potency, sterility, endotoxin, residual impurities and batch-to-batch reproducibility [1,2].

The condensed conclusion is that biological therapies are promising but require stronger clinical evidence and strict GMP control. They should be presented as emerging options rather than established replacements for minoxidil, finasteride or approved immunomodulators.

13. Phytochemical and Natural Product Nanodelivery

Several natural compounds have antioxidant, anti-inflammatory, anti-androgenic or growth-supportive potential, but their direct topical use is restricted by instability, poor solubility and weak penetration. Nanocarriers can improve the follicular delivery of quercetin, rutin, epigallocatechin gallate, essential oil components and other phytochemicals [23].

Phytochemical-loaded NLCs, niosomes, liposomes, PLGA nanoparticles and microneedles can shield the active compound from oxidation and provide sustained follicular release. This is relevant because oxidative stress and inflammation are part of the alopecia microenvironment [22,23].

The review should avoid overclaiming natural products as clinically proven cures. The correct interpretation is that phytochemical nanodelivery is a supportive and investigational strategy with mechanistic plausibility. It may complement standard therapy or reduce irritation if formulated appropriately [22,23].

To preserve scientific meaning, the reduced version retains the concept of phytochemical nanocarriers while removing repetitive examples. Future research should compare standardized extracts or pure compounds using controlled follicular deposition, hair-count, hair-shaft diameter and safety endpoints.

14. Evaluation Parameters for Alopecia NDDS

Alopecia nanocarriers cannot be evaluated only by visual appearance or percent drug release. Essential physicochemical tests include particle size, PDI, zeta potential, entrapment efficiency, drug loading, morphology, crystallinity, pH, viscosity, gelation temperature, mechanical strength and stability [10,11,16,20].

Follicular delivery should be verified using differential tape stripping, cyanoacrylate follicular biopsy, confocal microscopy, fluorescence imaging and ex vivo skin permeation. These tests distinguish superficial skin deposition from true follicular targeting. For microneedles, insertion depth, dissolution, payload uniformity and mechanical strength are also critical [5,8,21].

Biological evaluation should include dermal papilla cell viability, proliferation markers, beta-catenin, VEGF, Ki67, inflammatory cytokines, oxidative stress markers and in vivo hair regrowth endpoints. Clinical translation requires standardized trichoscopy, hair count, hair density, hair shaft diameter and validated quality-of-life scales [1,2].

Evaluation level	Key tests	Purpose
Physicochemical	Size, PDI, zeta, loading	Batch quality

Ex vivo	Tape stripping, biopsy, microscopy	Follicular targeting
Biological	Cell markers and cytokines	Mechanism and safety
Clinical	Hair count and trichoscopy	Efficacy confirmation

15. Safety, Tolerability and Patient Compliance

Safety determines whether improved delivery becomes clinically useful. A carrier that improves penetration but causes irritation, dermatitis, systemic absorption or inflammation will not be acceptable for chronic alopecia therapy. Therefore, scalp tolerability, pH compatibility, osmolality, sensitization and long-term use must be tested [3,14].

Local adverse reactions from conventional vehicles are a major reason for patient non-compliance. NDDS can reduce irritant solvents, lower dose frequency and improve cosmetic acceptability. Hydrogels reduce runoff, lipid carriers reduce alcohol dependency, and microneedles may provide periodic rather than daily dosing [14,20,21].

Systemic safety is also important. The goal of follicular targeting is to increase local exposure while reducing plasma levels. This is particularly relevant for anti-androgens, JAK inhibitors or potent biologics. Any delivery system that increases systemic exposure must be evaluated carefully [3,4].

Patient-centered design should include non-greasy feel, rapid drying, low odor, absence of visible residue, low irritation and easy administration. These practical factors may decide real-world adherence as much as laboratory potency.

16. Manufacturing and Regulatory Translation

Commercial development requires reproducible manufacturing. Laboratory sonication, small-batch emulsification or hand-casting of microneedles must be translated into controlled processes such as high-pressure homogenization, microfluidics, continuous mixing, spray drying, controlled casting or automated micromolding [1,10,20].

Critical quality attributes include particle size, PDI, zeta potential, assay, degradation products, residual solvents, microbial limits, endotoxin, release profile, viscosity, gelation behavior and mechanical strength. Process analytical technology can help maintain inline control for continuous production [1].

Regulatory evaluation depends on whether the product is a drug, device, biologic, combination product or cosmetic-drug interface. Microneedles and exosome systems carry additional requirements for sterility, mechanical reliability, biocompatibility and potency. Nanocarriers also require clear characterization of biodistribution and systemic exposure [3].

The reduced paper keeps the original translation message: scientific novelty alone is insufficient. A successful alopecia NDDS must be manufacturable, stable, safe, clinically meaningful and acceptable for chronic use.

18. Future Directions

Future alopecia therapy is likely to combine follicular targeting, sustained release, biologic regeneration and precision diagnosis. Artificial intelligence may support image-based diagnosis, treatment monitoring and formulation optimization by predicting size, stability, release and follicular deposition from processing variables [1,2].

The strongest future products may be combination systems: minoxidil plus anti-androgen hydrogels, antioxidant nanozyme microneedles, exosome-loaded dissolving patches, or phytochemical-lipid carriers. Each combination must be justified by pathophysiology rather than by adding components unnecessarily [1,21,23].

Important unresolved questions include ideal particle size for different scalp phenotypes, the duration of follicular depot retention, long-term safety of repeated microneedle application, clinical relevance of exosome cargo, and whether improved deposition translates into superior hair density in controlled trials [1,5,21].

The reduced review therefore concludes that NDDS is a delivery science solution to multiple limitations, but clinical success will depend on evidence, standardization, patient compliance and comparative superiority over conventional therapy.

19. Conclusion

Novel drug delivery systems offer a rational pathway to improve alopecia therapy by targeting the pilosebaceous unit, increasing follicular retention, reducing irritation and minimizing systemic exposure. Lipid-based systems are especially suited to sebum-rich follicles, polymeric and inorganic carriers provide programmable release and surface control, hydrogels improve residence and co-delivery, and microneedles enable direct delivery of difficult payloads.

The main scientific meaning of the original review is retained: the future of alopecia treatment depends on aligning the drug, carrier, follicular target and patient-use requirement. No delivery system is universally best. Lipid carriers suit lipophilic drugs and follicular depots; hydrogels suit retention and co-delivery; microneedles suit macromolecules and regenerative cargo; and biologics require strict quality control.

Abbreviations

AGA: androgenetic alopecia; AA: alopecia areata; API: active pharmaceutical ingredient; DHT: dihydrotestosterone; DMN: dissolving microneedle; HF: hair follicle; NDDS: novel drug delivery system; NLC: nanostructured lipid carrier; PLGA: poly(lactic-co-glycolic acid); ROS: reactive oxygen species; SLN: solid lipid nanoparticle.

Citation and reference reduction logic

The original manuscript used many overlapping citations. In this reduced version, references were consolidated to a focused numbered list. Repeated source groups were replaced with single numbered citations, and each reference number is used consistently throughout the text. Numerical information retained includes minoxidil topical bioavailability, preferred follicular carrier size, NLC size

and zeta potential, ufasome entrapment and deposition values, retention improvements, microneedle-related delivery advantages and key mechanistic claims.

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