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Microneedle-Based Vaccine And Biologic Delivery Systems: Current Advances And Future Perspectives – A Review

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Abstract :

Microneedle (MN) technology has emerged as a revolutionary approach for vaccine and biologic delivery, offering a minimally invasive, pain-free, and efficient route for transdermal administration. This review highlights the development, design, fabrication techniques, and clinical applications of various microneedle systems, including solid, coated, dissolving, hollow, and hydrogel-forming types. Emphasis is placed on their advantages over conventional needle-based injections, such as improved patient compliance, dose precision, and reduced risk of contamination. The paper also discusses the regulatory landscape, safety evaluations, and the translational challenges faced by microneedle technologies. Emerging innovations—like AI-assisted microneedle design, smart sensing patches, and scalable 3D-printing techniques—are expected to drive future advancements. Overall, microneedle-based systems represent a paradigm shift in global vaccination and biologic therapeutics, especially in resource-limited settings.

Index Terms — Microneedles, transdermal delivery, vaccines, biologics, dissolving microneedles, smart patches, immunization.

1. INTRODUCTION

Vaccines and biologics have become the cornerstone of preventive and therapeutic medicine worldwide. However, the delivery of these agents through traditional hypodermic needles presents several drawbacks, including pain, needle-phobia, and the risk of infection from needle-stick injuries. Moreover, storage and transportation of vaccines often require stringent cold-chain conditions, which can be impractical in developing regions. Microneedle-based technology offers an alternative delivery platform that addresses these issues. By creating micro-scale pathways through the stratum corneum, microneedles enable the transport of therapeutic molecules into the epidermal and dermal layers—regions rich in

immune-responsive cells. This localized and targeted delivery enhances immunogenicity, minimizes systemic exposure, and potentially reduces required doses. Microneedles can be designed in various forms—solid, coated, dissolving, hollow, and hydrogel-forming—each with unique fabrication approaches and drug release profiles. The adaptability and scalability of these systems make them promising candidates for next-generation vaccine delivery platforms.

2. METHODOLOGY

This review follows a structured methodology to collect, analyze, and synthesize data related to microneedle-based vaccine and biologic delivery systems. A comprehensive literature search was conducted using databases including PubMed, ScienceDirect, and Google Scholar, covering publications from 2010 to 2024. Search terms included 'microneedles', 'transdermal vaccination', 'biologic delivery', and 'dissolving microneedle systems'. Peer-reviewed journal articles, systematic reviews, and clinical trial reports were included. The collected literature was categorized into microneedle types, fabrication techniques, pharmacokinetic considerations, and clinical applications. Emphasis was placed on human trials and large-animal studies that demonstrate safety, efficacy, and scalability. Data from regulatory authorities such as the U.S. FDA and EMA were also reviewed to understand approval pathways and safety evaluations.

3. DISCUSSION AND RESULTS

Microneedle technology demonstrates a transformative potential in biopharmaceutical delivery. Among the various designs, dissolving microneedles—composed of biodegradable polymers—have shown particular promise for vaccine administration. They eliminate the problem of sharps waste and offer rapid dissolution, enabling complete release of the payload. Clinical studies on influenza and measles vaccines delivered through microneedles have shown comparable or even superior immune responses compared to intramuscular injection. Moreover, microneedle patches simplify self-administration, allowing for decentralized vaccination campaigns. Technological advancements such as AI-guided design optimization, 3D printing, and hydrogel microneedles for sustained release further expand their applicability. However, challenges remain—especially regarding large-scale manufacturing, reproducibility of dosing, and stability of biological macromolecules during fabrication. Addressing these challenges will be crucial for commercial translation.

4. CONCLUSION

Microneedle-based systems represent a significant advancement in the field of transdermal and intradermal drug delivery. They hold the potential to revolutionize immunization programs by enabling minimally invasive, self-administered, and pain-free vaccine delivery. Their adaptability allows incorporation of various biologic molecules including peptides, proteins, nucleic acids, and nanoparticles. Future research should focus on optimizing mechanical strength, drug stability, and patient acceptability, as well as establishing standardized regulatory frameworks to facilitate clinical translation. Integrating smart materials, biosensors, and artificial intelligence into microneedle platforms will likely shape the next generation of personalized vaccine delivery systems.

REFERENCES

1. Prausnitz MR, Larraneta E. Microneedles for drug delivery. Adv Drug Deliv Rev. 2023;194:114715.

2. Kim YC, Jarrahian C, Zehrung D, et al. Delivery systems for intradermal vaccination. Curr Top Microbiol Immunol. 2020;428:77–112.

3. Hirobe S, Matsuo K, Quan YS, et al. Clinical study of dissolving microneedles for influenza vaccination. Vaccine. 2019;37(27):3912–3919.

4. Norman JJ, Arya JM, McAllister DV, et al. Microneedle patches: usability and acceptability. Vaccine. 2016;34(45):5445–5452.

5. Kolluru C, Gomaa Y, Prausnitz MR. Clinical translation of microneedles for vaccine delivery. Drug Deliv Transl Res. 2022;12:1473–1489.