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ANALYSIS OF THE CURRENT STATE OF DEVELOPMENT OF MICRO-NEEDLE SYSTEMS FOR TRANSDERMAL DRUG DELIVERY (A SCOPING REVIEW)

Liubov Bodnar, Tetiana Kovalova, Natalia Sydora, Oleksandr Shmalko, Ihor Berdey, Liliia Vyshnevska

The aim *is to examine the current state of development of microneedle systems for transdermal drug delivery.*
Materials and methods. *Analysis, systematization, and generalization of data from scientific literature sources on the development of microneedle systems, research on their effectiveness, and prospects for use in pharmacy. A modified Arskey O'Malley methodology was used, refined by a research group led by H.M. Daudt. A total of 480 publications from the last ten years were analysed.*
Results*. The results of the analysis show that most of the experimental studies focus on the development of microneedle systems for transdermal delivery of vaccines, insulin, and analgesics. In contrast, studies devoted to the creation of drugs with a different direction of action or drugs for the gradual release of active substances using microneedles occupy a smaller segment of the total number.*
Conclusions*. It has been established that most scientists choose to develop microneedle-based drugs for systemic use. The main areas of publication are reviews of literature sources, the development of new microneedle systems, etc. The results obtained indicate the potential and relevance of conducting research on the development of microneedle systems*
Keywords*: microneedle system, transdermal delivery, improved penetration of active substances, bibliosemantic analysis*

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1. Introduction

Analysis of the current state of scientific research is a key stage in the formation of a sound strategy for further experimental developments. A review of the scientific literature allows us to identify the most promising areas for future research. In modern pharmaceutical science, microneedle drug delivery systems are considered a promising alternative to traditional injection and transdermal methods. Their relevance is due to the need for safe, effective and patient-friendly methods of drug administration that avoid pain, improve compliance and ensure high bioavailability of active pharmaceutical ingredients. Dissolvable and coated microneedles deserve special attention, which could control the release of drugs into the skin layers without damaging blood vessels or nerve endings, which minimizes the risk of side effects and complications.

Over the past decade, there has been an active increase in the number of studies devoted to improving microneedle manufacturing technologies, researching biocompatible materials, studying the mechanisms of penetration through the skin, and developing new drugs based on them.

The use of microneedles is being studied in a wide range of medical areas – from vaccination, insulin delivery, hormonal and antitumor drugs to the treatment of dermatological and neurological diseases. In addition, microneedle platforms are being actively investigated for use in personalized medicine and nanotechnology.

The aim of the research. Study of the current state of development of microneedle systems for transdermal drug delivery by analyzing, systematizing and summarizing data from scientific literature sources.

2. Research planning (methodology)

A retrospective analysis of publications on a given topic was conducted, as well as a detailed overview of the current state of research. The analysis of the current state of scientific research on the development of microneedle systems was conducted using a methodological approach developed by the research group led by H. M. Daudt, which is based on an adapted structure proposed by [1]. The methodology includes six consecutive stages aimed at a systematic study of scientific publications in the selected field (Fig. 1).

To obtain the most relevant information, a number of electronic scientometric databases were selected that met predefined criteria (Fig. 2).

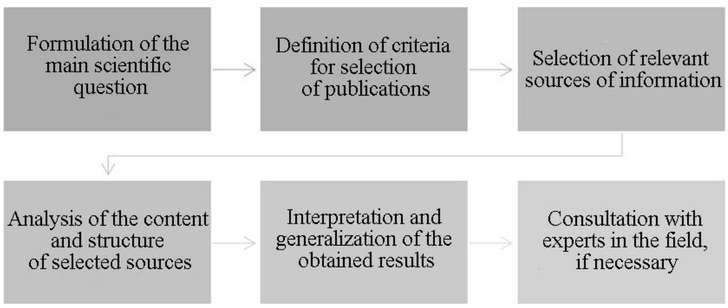

Fig. 1. Methodology of the study

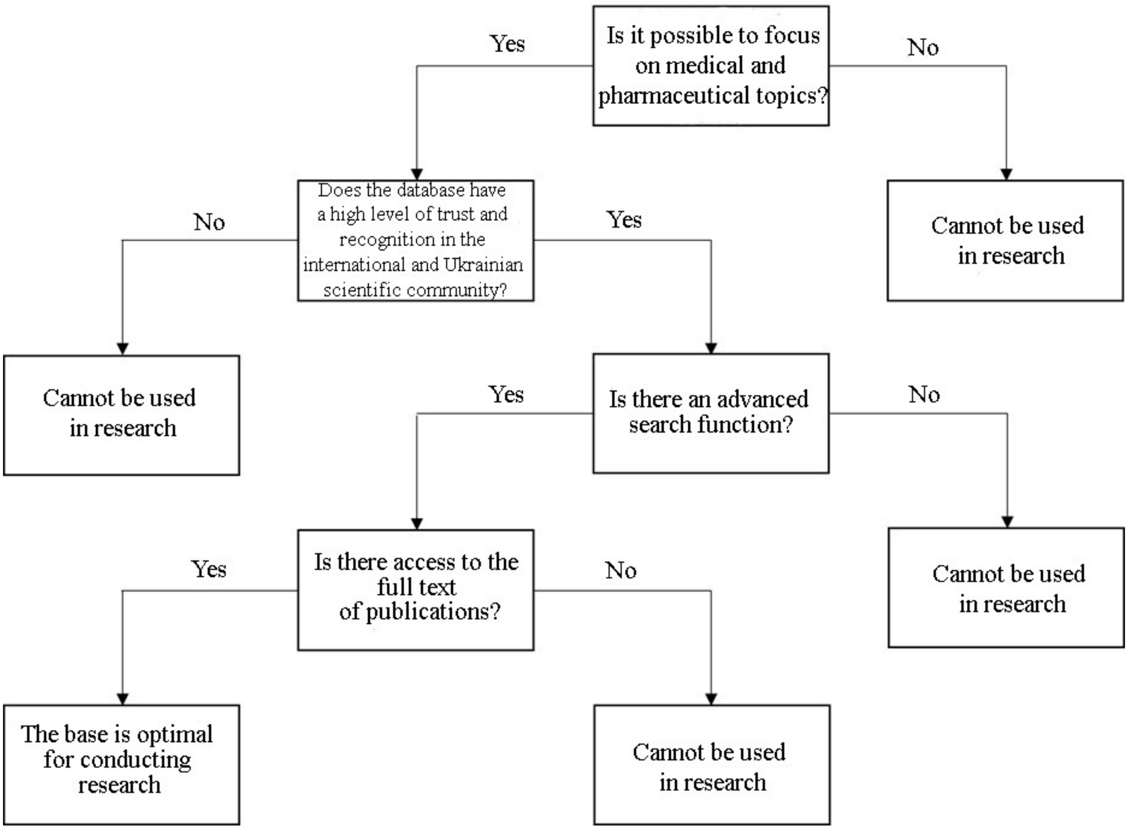

Fig. 2. Decision tree for selecting databases for research

3. Materials and methods

The following databases were used in the research process: Google Scholar, Wiley Online Library and PubMed, which satisfy all the specified requirements.

Keywords used to form the sample of scientific publications: microneedle transdermal patch, microneedle drug administration, microneedle patch pharmacology (Fig. 3).

Wiley Online Library and PubMed demonstrate high quality of publications based on evidence-based approaches. Although the number of publications found was limited, their scientific level and depth allowed to ensure high quality of input data for analysis.

Google Scholar, in turn, provides a wider range of results, but often includes sources that do not fully correspond to the research topic. Therefore, we defined filters for selecting publications for the study (Fig. 4).

In total, 480 scientific publications that meet all the established criteria were included in the analysis and constitute a representative sample for studying the current state of development of microneedle systems.

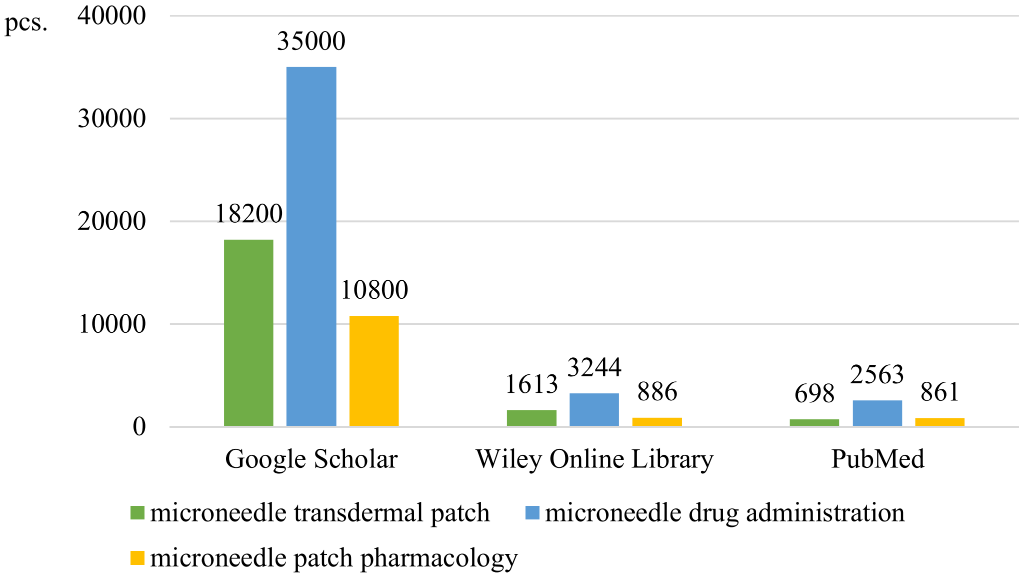

Fig. 3. Distribution of search results by keywords in the studied electronic databases, pcs.

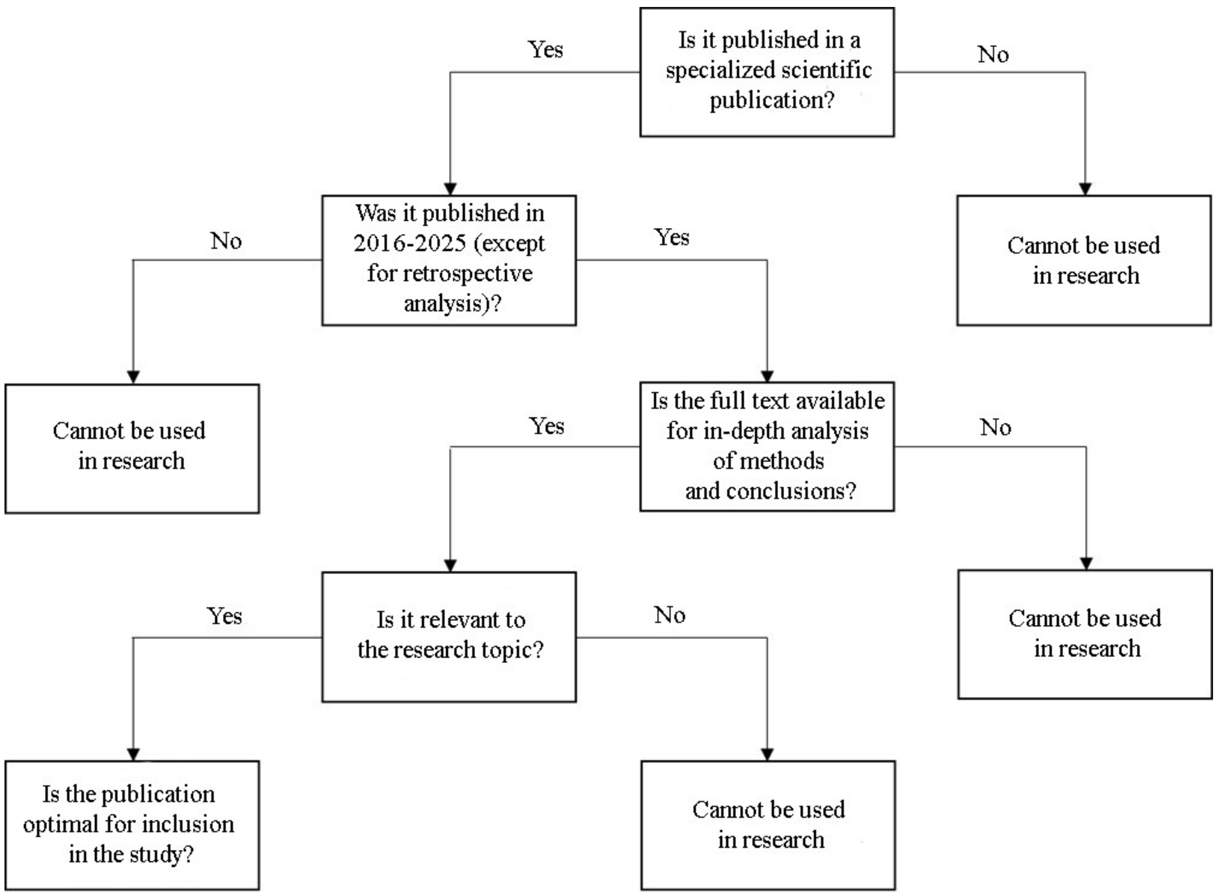

Fig. 4. Decision tree for selecting publications for inclusion in the study

4. Research results

The idea of microneedles as a tool for microinvasive delivery of substances through the skin began to take shape even before the 1990s, when scientists investigated the possibilities of penetration of active pharmaceutical ingredients through the upper layer of the skin with minimal damage. At that time, experiments with the use of simple materials such as glass, silicone and metal prevailed, which did not allow achieving high manufacturing accuracy. The total volume of publications during this period was small, and most of them concerned patent ideas and basic research [2].

In the 1990s, there was a transition from ideas to practical demonstrations of the effectiveness of microneedles. It was proven that microneedles can effectively penetrate the stratum corneum of the skin and improve transdermal delivery of substances. The first experimental samples of solid microneedles made of metal and with the addition of silicone appeared, which had satisfactory quality indicators. During this period, the number of publications began to increase, in particular due to interest in comparing microneedles with traditional delivery methods such as oral administration or injections [3].

The 2000s were marked by the active development of various types of microneedles, including coated, hollow and soluble forms. The first clinical trials began, and research became more in-depth and diverse: from in vitro experiments to animal studies. Much attention was paid to biosafety, material selection and control of the release of active substances. Manufacturing technologies were improved, in particular, photolithography and microfabrication became the basis for the creation of high-precision microneedles. The volume of scientific publications during this period increased significantly, and clinical research received greater development [4–7].

The 2010s saw the active introduction of combined technologies: hydrogel microneedles, core-shell structures, nanoparticle carriers, and devices combining microneedles with microfluidic systems appeared. At the same time, attention was increasing to painlessness, ease of use, drug stability, and the possibility of large-scale production. The topics of publications expanded significantly, from the delivery of vaccines and protein drugs to applications in cosmetology and regenerative medicine. During this period, the number of scientific papers and patents increased significantly [8–10].

Since the early 2020s, the development of microneedle technologies has been characterized by the introduction of advanced manufacturing methods, such as 3D printing and two-photon polymerization, as well as the creation of biocompatible and fully soluble materials. The emergence of technologies that respond to external stimuli and can control the release of drugs opens up new opportunities for personalized therapy. Integration with nanotechnology and biotechnology allows for the combination of diagnostic and therapeutic functions in a single device. The volume of publications during this period is increasing due to efforts in the field of clinical trials of vaccines and therapeutic drugs [11–15].

Thus, the field of microneedle research has progressed from simple ideas and experiments to complex multifunctional systems that are actively tested in the clinic. Innovations in materials, manufacturing methods, and drug delivery approaches have played a significant role in this process. Current trends indicate that the coming years will be devoted to the development of microneedle systems with increased biocompatibility, integration of diagnostic capabilities, and optimization of production for commercial use (Fig. 5).

Based on the analysis of selected literature of the last 10 years, two main categories were identified, which cover the majority of current studies on microneedle systems. Systemic application of microneedle patches – 71% of publications. This category includes studies aimed at the use of microneedles for drug delivery in diseases such as diabetes, cancer, infectious diseases, Parkinson's disease, hypertension, etc. [16–18]. Local application of microneedle systems – 29% of publications. This category includes works related to the local delivery of analgesics, anti-inflammatory drugs, cosmetics or bioactive substances of natural origin [19–24].

Each of these categories can be detailed by subcategories (Fig. 6).

Review articles:

– systematic reviews and meta-analyses of current microneedle delivery technologies;

– comparison of microneedles with traditional delivery methods (oral, injectable, transdermal without microneedles) [25–27].

Development of new drugs with microneedles: creation of biodegradable, soluble, hydrogel, hollow, polymer microneedles. Use of 3D printing, photopolymerization, microlithography in the manufacture of microneedles. Use of nanoparticles, liposomes, hydrogel matrices as carriers. Combined delivery systems: microneedles with electrophoresis, microneedles with microfluidic systems [28–35].

Conducting preclinical and clinical trials:

– study of release kinetics, bioavailability, penetration depth and therapeutic effect;

– study of safety, tolerability and efficacy of microneedle patches on volunteers;

– analysis of patient compliance, pain reduction and adverse reactions compared to traditional forms [36, 37].

Applications in dermatology and cosmetology: the use of microneedles for the delivery of anti-aging agents, vitamins, acids, anti-acne agents, hyperpigmentation [38–43].

Transcutaneous immunization:

– research on the development of vaccines against COVID-19, influenza, human papillomavirus and other diseases using microneedles [44–52].

The vast majority of the analyzed experimental publications are focused on the creation, improvement and evaluation of new types of microneedle systems with specified physicochemical properties. However, the largest segment is review articles – 35%.

There is a tendency to increase the number of publications that highlight innovative solutions in this area. For example, the combination of microneedles with nano- and biotechnology, which opens up prospects for individualized pharmacotherapy and delivery of biomolecules with minimal side effects [53–55].

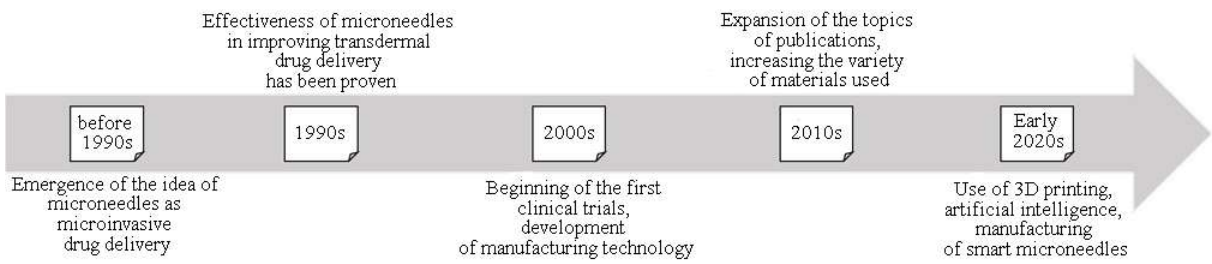

Fig. 5. Generalized chronology of the development of microneedle systems

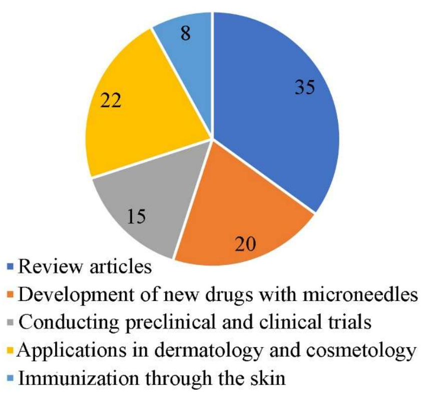

Fig. 6. Distribution of scientific publications by established subcategories, %

5. Discussion of research results

5. 1. Review articles

The current state of development of microneedle patches for long-term contraception was presented. The authors analyzed the types of materials, the principles of controlled release of contraceptives and biocompatibility. They considered the possibilities of using biodegradable polymer systems and the prospects for their clinical implementation [56].

The use of soluble microneedle patches as alternative platforms for vaccine delivery was summarized. The results of three case studies in this area were reviewed – studying the immunogenic activity of vaccines loaded into microneedles based on different polymers. They concluded that microneedles could be used for transcutaneous vaccine delivery [57].

We reviewed the latest technologies for manufacturing microneedle scaffolds, such as micromolding, 3D printing, electroforming, bioprinting, etc. We paid attention to the problems of scaling up production, choosing materials, and ensuring the stability of drugs manufactured by one or another method [58].

We reviewed microneedle patches as an innovative painless transdermal drug delivery system. We emphasized the possibility of increasing the bioavailability of drugs in the treatment of diseases, in particular in newborns, and the use of microneedles for vaccination [59].

We reviewed the current state of research in the field of microneedle patches for drug and vaccine delivery. We summarized the types of microneedles, mechanisms of penetration through the skin, advantages over traditional injection methods, and prospects for practical implementation [60].

We proposed a review of microneedle systems as a promising form for the delivery of drugs, proteins, and vaccines. In addition to systematizing data on manufacturing methods and release mechanisms, we outlined directions for further optimization of materials used for the manufacture of microneedle scaffolds [61].

We considered the prospects for the use of microneedle patches based on plant extracts and bioactive compounds for the destruction of microbial biofilms, as well as the potential of phytonanotechnologies in the creation of biocompatible antimicrobial delivery systems [62].

Bioadhesive microneedle patches for tissue sealing were described. The main advantages of such patches were the ability to provide a strong connection without sutures and to stimulate healing. Thus, they can become an alternative to traditional surgical methods of wound closure [63].

Several innovations in the development of long-term microneedle patches for the function of a biosensor were considered. The microneedle patch is a minimally invasive and convenient way to monitor health, in particular by collecting biomarkers from interstitial fluid and sweat, such as glucose, lactate and electrolytes. It was noted that new possibilities for integrating microneedles with microfluidic and porous structures, as well as the use of wireless data transmission and autonomous sensing are being studied. The problems of biocompatibility, stability of sensors and the scale of implementation of such technologies in personalized medicine are discussed, emphasizing the role of artificial intelligence in their development [64].

The potential of microneedle patches in cardiology was reviewed. The possibility of delivering antihypertensive and antiplatelet agents through the skin was described, which ensures uniform drug delivery and reduces the risk of side effects typical of oral therapy [65].

The current knowledge about microneedle patches as a platform for transdermal drug delivery was systematized. The types of microneedles, their mechanism of action, materials used in their manufacture, advantages, limitations, and directions for further research were described [66].

5. 2. Development of new drugs with microneedles

A soluble microneedle patch capable of simultaneously delivering hydrophilic and hydrophobic active pharmaceutical ingredients for acne therapy was developed. It was found that such a system provides better skin permeability, increased drug bioavailability, and improved combined therapeutic effect [67].

A nanoparticulate delivery system for curcumin based on sodium caseinate integrated into microneedle patches was developed. The increase in the solubility and bioavailability of curcumin was proven, and the high potential of the developed drug for the treatment of obesity was concluded [68].

Inkjet printing was proposed for precise, individualized manufacturing of microneedle scaffolds. Technical reproducibility, geometric accuracy, and in the future, uniformity of drug distribution was demonstrated [69].

We proposed a 3D printing technology to produce microneedle systems with wound healing activity. The possibility of creating structures with controlled mechanical and resorbable properties, which would ensure effective local drug delivery and accelerate tissue healing was described [70].

We proposed polymer microneedle patches for the treatment of wounds in patients with diabetes. The system combines mechanical strength, controlled drug delivery, biocompatibility and demonstrates acceleration of tissue regeneration in a model of chronic inflammation [71].

A study of microneedles with different geometries manufactured using digital light printing was conducted. We found that conical microneedles are the most optimal in terms of strength and penetration depth. Also conducted cytotoxicity studies and found that the photopolymers used are biocompatible [72].

Flexible and elastic microneedle patches with embedded rigid metal microneedles have been developed that can be used as biomedical sensors [73].

Microneedle patches have been proposed that provide simultaneous delivery of monoclonal antibodies and antimicrobial peptides for effective elimination of microbial loads. The results obtained confirm the increase in antimicrobial activity and acceleration of tissue healing [74].

Microneedle patches have been developed that generate weak electrical signals to stimulate collagen synthesis and reduce the depth of wrinkles. The technology combines physiological stimulation with the delivery of active cosmetic substances [75].

Microneedle patches with integrated MXene material (a two-dimensional inorganic material) were proposed, which simultaneously provides high conductivity and the ability to encapsulate molecules. It was found that the system can promote wound healing by controlled drug delivery and stimulation of cell proliferation [76].

Polymer microneedle patches with glucose-sensitive components were created for personalized diabetes therapy. The system provides automatic insulin dosing in response to blood glucose levels, which demonstrates the potential to replace injection treatments [77].

Engineering approaches to the creation of polymer microneedle patches loaded with tetanus toxoid were described. The stability of the antigen after encapsulation, the efficiency of inducing an immune response, and the prospects for using the technology for vaccination purposes were demonstrated [78].

Microfluidic microneedle systems with microchannels for controlled drug delivery are being developed. Previous studies have demonstrated the potential of such systems for personalized drug delivery [79].

Photothermal microneedle patches based on gelatine and graphene (a two-dimensional material) have been developed for the treatment of wounds with prolonged healing periods. The system combines antimicrobial activity, thermal stimulation of regeneration, and controlled drug release [80].

Microneedle patches with a multilayer structure have been proposed for the treatment of diabetic wounds. Due to optimal air permeability and moisture control, the patch promotes faster healing and reduces the risk of secondary infection [81].

The use of plasma-polymer barrier layers to regulate the release rate of active pharmaceutical ingredients from soluble microneedle patches was investigated. It was found that changing the thickness and composition of the plasma coating allows for precise control of the release kinetics, which is important for dosed transdermal drug delivery [82].

An electrically conductive hydrogel based on polyvinylpyrrolidone and graphene oxide cross-linked by radiation was developed. Such hydrogels can be used to fabricate microneedle patches capable of transmitting electrical signals, which can be used for effective drug delivery using electrical stimulation [83].

Cryomicroneedle patches were created that deliver capsaicin embedded in mesoporous dopamine. This technology promotes local fat burning and weight loss, demonstrating the potential for non-invasive treatment of obesity [84].

Dissolvable microneedle patches were developed for the administration of the antidiabetic drug lobeglitazone. In vivo studies showed increased bioavailability of the drug compared to oral administration, indicating the effectiveness of transdermal delivery [85].

Liposomal microneedle patches containing bosentan monohydrate (a drug for the treatment of pulmonary hypertension) were developed. The authors managed to obtain a stable formulation with a high degree of penetration and controlled release, which may improve therapeutic efficacy and reduce side effects [86].

A microneedle patch containing sodium heparin was proposed. Their mechanical strength, dissolution rate, and release profile were studied. The results of the release profile study confirm the feasibility of using the development for thrombosis prevention [87].

Microneedle wound healing patches made of silk and gelatine were proposed. The development combines biocompatibility, mechanical stability, and the ability to control the release of growth factors, accelerating tissue regeneration [88].

Microneedle patches with controlled release of antimicrobial peptides have been proposed for the elimination of biofilms on wounds. The system responds to environmental changes, in particular, light exposure, and locally activates the release of the active substance, which effectively eliminates pathogenic microorganisms [89].

Nanoparticle-loaded soluble microneedle systems have been developed for the delivery of the antihypertensive drug labetalol. It was found that in this form the rate of skin penetration and bioavailability are significantly increased compared to traditional forms [90].

Microneedle systems for monitoring and treating wounds are proposed for development. It is assumed that they are able to combine sensory elements, controlled drug delivery, and the ability to respond to physiological changes in tissues [91].

Microneedle patches made of recombinant human collagen loaded with platelet plasma have been developed for the treatment of diabetic wounds. The patches have been shown to promote angiogenesis, reduce inflammation, and accelerate epithelialization [92].

5. 3. Conducting preclinical and clinical trials

We highlighted recent progress in the development of integrated transdermal bioelectronics based on microneedle patches. We reviewed devices with various functions, including health monitoring, drug delivery, and therapeutic treatment. We outlined directions for future research, including implementation in clinical practice [55].

A clinical trial was conducted to evaluate the efficacy of soluble microneedle patches with active ingredients for the treatment of acne. The results showed a reduction in inflammation, the number of comedones, an improvement in the overall condition of the skin, and no adverse effects from the drug [93].

A randomized clinical trial was conducted to show that the additional use of soluble microneedle patches based on hyaluronic acid effectively reduces inflammation, hyperkeratosis, and plaques in psoriasis and increases the effectiveness of standard therapy [94].

A clinical trial was conducted to evaluate the combination of a cream with a local anesthetic with microneedle patches for anesthesia of the palate in children.

The use of microneedles significantly enhanced the local anesthetic effect and shortened the time to onset of anesthesia without adverse reactions [95].

Microneedle patches with detachable needles that deliver exosomes derived from adipogenic stem cells modified with the protein thymosin β-4 have been developed. The developers believe that the system can restore cellular youth and accelerate the healing of wounds that are characterized by a long regeneration period [96].

5. 4. Application in dermatology and cosmetology

A microneedle system for transdermal therapy with a collagen-based coating has been developed. This system increases biocompatibility, reduces immune reactivity, and ensures effective collagen penetration into the dermal layers, which promotes tissue repair [97].

5. 5. Immunization through the skin

The potential of microneedle systems for intradermal delivery of molecularly defined cancer vaccines is being evaluated. Studies have been conducted on the effect of different microneedle designs on skin penetration and drug delivery efficiency [98].

A microneedle vaccine has been developed that delivers inactivated *Mycobacterium paragordonae* as a booster for anti-tuberculosis immunity. Preclinical studies of the developed microneedles have shown a pronounced immune response in experimental animals to the administration of test vaccine samples [99].

Practical significance. The conducted study allows us to systematize current knowledge about microneedle systems and their role in transdermal drug delivery. It helps to identify potential directions for future experimental research.

Study limitations. The study was conducted using previously published sources and does not include our own experimental data.

Prospects for further research. The next stage of work is to develop a methodology for developing microneedle systems and conducting experimental research.

6. Conclusions

It was found that most scientists choose the direction of developing drugs with microneedles for systemic use. The main directions of publications are a review of literary sources (35%), the development of new microneedle systems (20%), their preclinical or clinical trials (15%), their use in dermatology and cosmetology (22%), as well as for transdermal immunization (8%). The data obtained by us from the analysis of literary sources confirm the progress in the development of microneedle systems as a promising form for transdermal drug delivery and indicate the potential and relevance of conducting research on the development of microneedle systems, in particular in Ukraine.

Conflict of interest

The authors declare that they have no conflict of interest regarding this study, including financial, personal, authorship or other, that could influence the study and its results presented in this article.

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The study was conducted without financial support.

Data availability

The manuscript contains data included as additional electronic material.

Use of artificial intelligence tools

The authors confirm that they did not use artificial intelligence technologies in the creation of the presented work.

Authors' contributions

Liubov Bodnar: Conceptualization, Methodology, Investigation, Formal analysis, Writing; **Tetiana Kovalova:** Visualization, Verification; **Natalia Sydora:** Verification; **Oleksandr Shmalko:** Visualization; **Ihor Berdey:** Conceptualization; **Liliia Vyshnevska:** Conceptualization, Supervision, Project administration.

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Liubov Bodnar*, Assistant, Department of Drug Technology, National University of Pharmacy, Hryhoriia Skovorody str., 53, Kharkiv, Ukraine, 61002
ORCID: https://orcid.org/0000-0002-3268-0683

Tetiana Kovalova, PhD, Associate Professor, Department of Drug Technology, National University of Pharmacy, Hryhoriia Skovorody str., 53, Kharkiv, Ukraine, 61002
ORCID: https://orcid.org/0000-0002-5984-6196

Natalia Sydora, Doctor of Pharmaceutical Sciences, Professor, Department of Pharmaceutical and Biological Chemistry, Pharmacognosy, Private Higher Educational Establishment «Kyiv Medical University», Boryspilska str., 2, Kyiv, Ukraine, 02099
ORCID: https://orcid.org/0000-0002-3333-2250

Oleksandr Shmalko, Doctor of Pharmaceutical Science, Associate Professor, Department of Pharmacy, Pharmacology, Medical, Bioorganic and Biological Chemistry, Medical Institute, Petro Mohyla Black Sea National University, 68 Desantnykiv str., 10, Mykolaiv, Ukraine, 54000
ORCID: https://orcid.org/0000-0002-5777-0896

Ihor Berdey, PhD, Associate Professor, Department of Pharmacy Management, Economics and Technology, I. Horbachevsky Ternopil National Medical University, Voli sq., 1,, Ternopil, Ukraine, 46001
ORCID: https://orcid.org/0000-0002-8344-1033

Liliia Vyshnevska, Doctor of Pharmaceutical Science, Professor, Head of Department, Department of Drug Technology, National University of Pharmacy, Hryhoriia Skovorody str., 53, Kharkiv, Ukraine, 61002
ORCID: https://orcid.org/0000-0002-6887-3591

***Corresponding author:** *Liubov Bodnar, e-mail: bodnar_la@ukr.net*