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Accessibility and Economic Viability of Microneedling Products for Health Care Monitoring

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Abstract:

The global market for microneedling products is experiencing considerable growth due to rising demand for skincare products that address ageing and environmental damage. Extensive research is ongoing for the development of microneedling products that can efficiently deliver therapeutics, as there is a dire need for novel transdermal drug delivery techniques that can augment the transdermal market for hydrophilic molecules, macromolecules, proteins, and traditional medicines for new therapeutic indications. Microneedling products are also being exploited for use in diagnostics, as well as additional medical, cosmetic, and other applications. In this review, we focus on the current state of the art in this field and provide information about safety, economic potential, and market access, to sketch what we consider will be the future of health monitoring.

Keywords: Microneedling products, health care, therapeutics, economic potential, and market access.

INTRODUCTION

Microneedling, a minimally invasive therapeutic intervention, has gained notoriety over the years for boosting skin quality and counteracting the aging process, though scientific data to back its status is limited. This relatively new procedure seeks to improve aesthetics such as wrinkles and scars through the stimulation of the production of essential cutaneous proteins and lipids, utilizing the skin's natural repair mechanisms (Jaiswal and Jawade, 2024; Ramaut *et al.*, 2018). It initiates a sequence of events that ultimately leads to these regenerative processes by causing controlled mechanical micro-injuries. So the secret of the therapy is in the uniformity and reproducibility of the micro-injuries (Alqam *et al.*, 2022). However, variability in application pressure, angle, hole creation, and many other factors may compromise the reproducibility of the lesions and subsequently the outcome of the therapy. Moreover, there can be different individual responses to the injuries due to the genotypic and phenotypic differences between patients, which adds to the complexity of the therapy (Merati *et al.*, 2020; Zoudani *et al.*, 2025). Nevertheless, the addition of drugs for transdermal delivery during and post the microneedling session has shown many potential clinical benefits and could be a good alternative to topical and systemic routes of drug delivery (Ita, 2015; Peng *et al.*, 2025).

Microneedling uses a set of needles to make a large number of very small, shallow punctures in the skin. This process is used in several ways for skin rejuvenation (Nagaraja and Gharsan, 2022). The dermaroller is a tool used in microneedling. The typical medical dermaroller has a handle that is 12 cm long and has a drum-shaped cylinder that is 2 x 2 cm wide at one end. The cylinder is studded with 8 rows and 24 circular arrays of 192 thin microneedles, which are typically 0.5–3 mm long and 0.1–0.25 mm in diameter (Amit, 2013). Collagen is the most abundant of the proteins that make your skin firm and supple. It is important to prevent wrinkles and creases, but it is also important to heal cuts and scars. These single-use microneedles are made on silicon or medical-grade stainless steel by reactive ion etching methods. The device is presterilized by gamma irradiation. Depending on the pressure used, rolling a skin region 15 times with a conventional dermaroller that has 192 needles 2 mm long and 0.07 mm in diameter produces about 250 holes per square centimetre up to the papillary dermis (Bhardwaj, 2013). Each pass creates 16 micropunctures per square centimetre in the stratum corneum without causing much harm to the epidermis (Nair and Arora, 2014).

Microneedling products

Microneedling products use a general anesthetic, and thus, clinic-based microneedling treatments have a good safety profile with a low incidence of significant adverse events. For example, a meta-analysis of the literature found that the most common adverse event noted was skin irritation/erythema, but that this was of 'mild severity' (Gowda *et al.*, 2021). The skin on the face is the most sensitive area due to more nerve endings in this area than in the rest of the body. The treatments can be categorized as topical or intradermal based on the micron forms and diameters of the microneedles. Microneedling treatment is associated with several side effects and complications, especially when not performed by a medical professional (Han *et al.*, 2025). Additionally, prior studies have demonstrated that the risk of possible product variability associated with organically derived or human/animal-based goods, such as those containing growth factors and peptides, may be avoided by using purely synthetic sequences in microneedling technologies (Kulkarni *et al.*, 2022; Younas *et al.*, 2026). Moreover, it has been observed that the use of fully synthetic products may be advantageous in obese patient groups due to improved resonance observed with molecular stiffness; this is important in relation to help ensure a physically constructive energy is efficiently delivered to the surrounding cellular

environment to promote tissue repair and remodelling (Pan *et al.*, 2025).

It is stated that the manufacture of microneedling products should adhere to good manufacturing practice and guidance set out by international and national standards, and that various standardizations are in place to ensure that appropriately high-quality and safe products are produced for public use. These standards specify criteria that must be fulfilled by manufacturers in respect of materials, design, production, packaging, and, importantly, sterility and bio-contamination control (EU., 2017). The product manufacturer also points out that the directions of clinical and laboratory research are focused on proving the long-term reliability, effectiveness, and safety profile of the product (Chu *et al.*, 2021). The potential to deliver a greater clinical efficacy through a minimally invasive and painless route than the traditional hypodermic needle injections would provide new options for healthcare professionals and the lay public's acceptance to get an order (Raslan *et al.*, 2025; Yang *et al.*, 2025).

Cost-effectiveness analysis

Cost-effectiveness analysis of the microneedling product is a critical evaluation that serves to assess the efficiency of the product and whether it offers value for money as a medical and healthcare intervention (Nguyen and Nguyen, 2026). This is achieved by comparing the benefits brought about by using the product against what would be achieved if the money used in acquiring and using the product (the costs) were used in another way. For the cost-effectiveness analysis to be accurate and meaningful, there must be a clear and reasonable comparison between two or more situations or courses of action. The standard microneedling procedures utilize smaller gauge needles, and hence, it involves less discomfort to patients. The standard procedures have therefore been established as cost-effective for the treatment of various disorders in terms of micro-needling techniques. It is usually a requirement that the National Institute for Health and Care Excellence (NICE) guidelines and program studies are well used in performing a cost-effective analysis (Excellence, 2015; Moawad *et al.*, 2026; Nguyen and Nguyen, 2026).

Cost-benefit analysis

A cost-benefit analysis involves an analysis of each of the measurable benefits of a microneedling product and an assessment of each of the costs of that product (Nguyen and Nguyen, 2026). By utilizing cost-benefit analysis data, which includes the determination of quality of life, it is possible to standardize outcomes of several treatment modalities and thus help to determine the best treatment option. CBA has gained the ability to validate the most effective treatments as it is able to demonstrate that the most efficient one provides the most benefit given a certain amount of resources (Brent, 2023). It is also possible to perform sensitivity analysis by utilizing different scenarios in which the costs or the benefits are varied independently of each other. Sensitivity analysis strengthens the knowledge that a particular health outcome is being driven by the relevant and important parameters. By comparing the cost-benefit of treatments that aim to rectify the same ailment, it is possible to determine which treatments are most efficient, and as a result, CBA is often used as a decision aid to inform funding allocation (Ananthapavan *et al.*, 2021; Jiang and Marggraf, 2021). Microneedling products seem to be considered cost-effective in comparison to alternative treatment options (Jaiswal and Jawade, 2024). The comparison with other treatments has shown that the microneedle roller has brought more benefits to the individual’s quality of life than applying steroid ointment, and some reports have criticized that the ointment has only given patients with temporal effect (Pei *et al.*, 2022).

Comparison of substitute treatments

The current worldwide trend in evaluation methods for skin burns focuses widely on the comparison of different treatments. Conventional

methods had their own course of treatment. Conventional methods include creams and collagen-based translational methods (Ivaskiene *et al.*, 2025; Sen *et al.*, 2025). However, treatment strategies should be based on rigorous trials and the newest treatments". Therefore, microneedling will be the primary focus when comparing treatments. Nevertheless, this comparison will be specifically observed for the treatment of hypertrophic, atrophic scars, and keloids. The evaluation of most internal variables for a patient, such as how the scar might feel for them in specific places, may still guide the analysis of the new surface. This methodological approach in practice to see which scar fits the analysis and results might benefit medical professionals and patients' levels for hypertrophic scars and keloids. It is very important to acknowledge the limitations of the evaluation strategy as a whole; however, it is advised that by stating and discussing the main sources of error, a conclusion can be reached. In summary, the current dermatological evaluation guidelines strongly advise a structured, clear comparison of hypertrophic scars and treatment methods that take into account the nature and the features of the scar under evaluation. There is no "best" or "most efficient" treatment, and patients should be advised by experts to understand what is most suitable for their needs (Gianatasio *et al.*, 2021; Meretsky *et al.*, 2024).

Approval of microneedling products

A medical device is defined as "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation replacement, modification, or support of the anatomy or physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body (EU., 2017). The product is filed with the vital information, including the type, executive summary, product description, the company's quality management compliance, the results of risk analysis, and product technical files. A consultant must then be assigned who meets the minimum requirement, and an audit of the quality management system of the company will follow. After conducting the site inspection and ensuring the full compliance of quality management, the expert committee will verify all the documents and statements, the conformity of the device with the filing documentation, the risk analysis and the proper implementation of the quality management systems. Last but not least, the director general of medical devices will issue the final decision regarding the approval of the product for marketing. Different approval processes apply depending on the classification of the medical device (Chu *et al.*, 2021; Natarajan *et al.*, 2025).

Regulatory considerations for labeling and packaging

Another important regulatory consideration for microneedling products involves compliance with labeling and packaging requirements. Labeling requirements include the placement of a label on the immediate container and the outer packaging. The label must contain the name of the product, a batch or lot number, and, importantly, an expiry date. The label must be large enough to accommodate all these pieces of information, and it is important that the information is prominent and readily legible. The expiry date must be followed by the words "use by" or "expire after". The immediate container may contain a leaflet or an outer package insert, which should have all the details specified for the immediate container and at least as it appears on the actual container. This leaflet can justify the therapeutic indication of the product and give instructions as appropriate. All information must be printed within a rectangular area, defined by clear margins. Overall, strict

compliance with the labeling and packaging requirements is crucial for attaining the approval for microneedling products to be marketed (Lutton *et al.*, 2015).

Therefore, the product could finally get the important approval from the relevant authorities and be certified fit to be used by residents. The product can now be produced in large quantities with the requirements of Good Manufacturing Practices being met, and is expected to be launched any time soon after successful clinical trials are done on human subjects. After evaluations, it is concluded that the item complies with the laws. And since the product might be utilized in the middle of a Microneedling remedy, it'll be registered as a medical device. After the marketing approval is given, post-marketing surveillance research must be conducted, and they are to be reported to the Medicines Management Command regularly. Plus, the product shall be tracked for any chance of unwanted results or for any new uses of the medication (Brady and Donnelly, 2016; del Rio *et al.*, 2020; Gattu *et al.*, 2026).

Recommendations for improvement

Last but not least, we recommend better labeling of the product. The companies should state the complete product, including the name, and give more details on the composition of the product on the label. For example, the companies should indicate that the needle size is around 460-520 micrometers and there are 6 needles in the sterile needle head. And the companies should provide a proper name for the product, instead of using "microneedling product" in the documents. Therefore, we recommend that companies provide more details on the labels for the product. This can facilitate the proper use of the product and allow the patient to make a better judgment upon its safe and appropriate use. Second, we recommend lowering the price of the product. From the cost-effectiveness evaluation, we can see that the price is one of the most determining factors for patients to choose the treatment. For new products, the procedure fee and the product fee that is charged by the doctors are different. If the price is not decreasing, then the companies might consider offering the product together with the procedure, so the fee will not be paid by the patient. But at the initial stage, we recommend that companies lower the price so that more patients can afford this treatment (Duncan, 2018; Ramaut *et al.*, 2018; Tucak *et al.*, 2020).

Implications for clinical practice

This exploration has assumed a perspective that, by involving various advanced scientific measurements and theories, it could really push the knowledge of science in the advanced product evaluation and development field in medical and health. This investigation helps not only to understand the importance of drug manufacture and approval, but it may also shed light on the existing knowledge of microneedle technology and the in-depth application of this therapy in different kinds of clinical practices. However, the project included and executed all components required to conduct a successful final product and cover the more passive treatments as well as the advanced medicines. These include product design and development, and evaluation in healthcare and clinical practice. However, further research has to be performed to evaluate the cost-benefit analysis and the long-term efficacy and safety for prolonged usage.

Future research recommendations

The biggest future that the field of microneedling has lies in the research and development of combination therapy with various cosmetic procedures. Combination therapy showed a marked improvement over the use of microneedling as a stand-alone agent. Future directions should then be aimed at investigating the different types of potential combinatorial treatments of microneedling and creating a platform to measure comparative findings in research studies among the combinatorial treatments with cosmetic procedures. The ongoing research on this procedure should focus on future technological advancements in product

development that can provide longer-lasting results and reduce downtime. Current applications of microneedling therapy could be technologically advanced to incorporate cell culture studies. The potential research should look into developing precision-based cosmetic medicine. The ideal is to create a technique that is based on individual genetic makeup and molecular pathways. By visualizing and examining genetic information that is relevant to the type of collagen that the individual can produce, microneedling treatment can be tailored to target and promote the synthesis of the desired type of collagen. Also, the usage of different types of medication for topical use may vary the coverage area and penetration for maximum efficacy. So, the development of dosage and delivery systems that can ensure an even and deep penetration into the skin would be revolutionary. The ideal is that medication can be applied through microneedling and can rejuvenate, but with minimal risk of developing a tumor in the treated area. There is much to be explored by researchers in the field of microneedling, and the advances in both technology and methodology will no doubt lead to even more interesting prospects in the future.

CONFLICT OF INTEREST

The author of this article declares that there is no potential conflict of interest.

GENERATIVE AI STATEMENT

The author(s) declare that no Generative AI was used in the creation of this manuscript.

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