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Structural Optimization, Design, and Fabrication of Dissolvable Microneedle Arrays

Authors : Choupani Andisheh, Temucin Elif Sevval, Bediz Bekir

Abstract : Due to their various advantages compared to many other drug delivery systems such as hypodermic injections and oral medications, microneedle arrays (MNAs) are a promising drug delivery system. To achieve enhanced performance of the MN, it is crucial to develop numerical models, optimization methods, and simulations. Accordingly, in this work, the optimized design of dissolvable MNAs, as well as their manufacturing, is investigated. For this purpose, a mechanical model of a single MN, having the geometry of an obelisk, is developed using commercial finite element software. The model considers the condition in which the MN is under pressure at the tip caused by the reaction force when penetrating the skin. Then, a multi-objective optimization based on non-dominated sorting genetic algorithm II (NSGA-II) is performed to obtain geometrical properties such as needle width, tip (apex) angle, and base fillet radius. The objective of the optimization study is to reach a painless and effortless penetration into the skin along with minimizing its mechanical failures caused by the maximum stress occurring throughout the structure. Based on the obtained optimal design parameters, master (male) molds are then fabricated from PMMA using a mechanical micromachining process. This fabrication method is selected mainly due to the geometry capability, production speed, production cost, and the variety of materials that can be used. Then to remove any chip residues, the master molds are cleaned using ultrasonic cleaning. These fabricated master molds can then be used repeatedly to fabricate Polydimethylsiloxane (PDMS) production (female) molds through a micro-molding approach. Finally, Polyvinylpyrrolidone (PVP) as a dissolvable polymer is cast into the production molds under vacuum to produce the dissolvable MNAs. This fabrication methodology can also be used to fabricate MNAs that include bioactive cargo. To characterize and demonstrate the performance of the fabricated needles, (i) scanning electron microscope images are taken to show the accuracy of the fabricated geometries, and (ii) in-vitro piercing tests are performed on artificial skin. It is shown that optimized MN geometries can be precisely fabricated using the presented fabrication methodology and the fabricated MNAs effectively pierce the skin without failure.

Keywords : microneedle, microneedle array fabrication, micro-manufacturing structural optimization, finite element analysis
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