WOUND HEALING

DISSOLVING TRIAMCINOLONE-LOADED MICRONEEDLES FOR THE TREATMENT OF KELOIDS: A SINGLE-BLINDED INTRA-INDIVIDUAL CONTROLLED CLINICAL TRIAL

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Background: Keloid scars are a prevalent chronic skin disorder with significant psychosocial morbidity. Intralesional corticosteroid injections are the first-line option but are painful, require repeated injections and often recur. Dissolving microneedles are a novel drug delivery device into skin that induces minimal pain. We designed dissolving triamcinolone-loaded microneedles as an alternative treatment for keloids.

Methods: Two keloids per patient were selected for either (a) daily two-minute application with microneedles for four weeks, followed by no treatment for four weeks, or (b) non-intervention as control. In the first phase, 0.025mg of triamcinolone was loaded per patch for a cumulative dose of 0.75mg over 30 days. In the second phase, 0.1mg of triamcinolone was loaded per patch for a cumulative dose of 3mg over 30 days. Primary outcome measure was change in volume measured by a three-dimensional scanner. Secondary outcome measures were pain and itch scores and the Vancouver Scar Scale determined by a blinded investigator.

Results: Twenty-seven patients participated in Phase One while 17 continued participation in Phase Two. There was significant reduction in keloid volume compared to controls after four weeks of treatment in both Phase One (p=0.019) and Two (p=0.035). This reduction was greater with the higher dose of triamcinolone in Phase Two (p=0.029). Pain scores of treated keloids were significantly lower at four and eight weeks compared to baseline in Phase One, but not in Phase Two. Itch scores of treated keloids were significantly lower at four and eight weeks compared to baseline in Phase Two, but not in Phase One. There were no side effects or withdrawals reported and 16/27 (59.3%) subjects preferred the daily micro-needle self-treatment.

Conclusions: Once daily application of dissolving triamcinolone-embedded microneedles significantly reduced the volume of keloids. The treatment was safe and can serve as an alternative for patients unsuitable for conventional treatment.