

## **Plastic surgery clinical research project**

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# Summary project

## 一、 Research Program

Project name	Comparison of clinical efficacy of golden microneedles and 1565nm non-ablative dot matrix laser in the treatment of eyelid pouches
Purpose of the Study	The purpose of this test is to compare the efficacy of golden microneedles and 1565nm non-ablative dot matrix laser in the treatment of eyelid pouches.
Type of study	Randomized, double-blind, self-controlled study
Number of cases	16
Inclusion and Exclusion Criteria	Inclusion Criteria: <ol style="list-style-type: none"><li>1. Patients with blepharoplasty;</li><li>2. Fitzpatrick III-V;</li><li>3. Males and females between 18-60 years old.</li></ol>
	Exclusion criteria: <ol style="list-style-type: none"><li>1. Other diseases that can cause pathological changes in periorbital soft tissue, such as collagen disease, kidney disease, liver cirrhosis, Graves disease, diabetes, scleroderma, hyperlipidemia, myasthenia gravis, Horner syndrome, myosermatitis etc;</li><li>2. Other diseases affecting wound healing, such as systemic diseases such as diabetes, heart disease, hypertension, infectious diseases such as tuberculosis, hepatitis, skin diseases, tumors, etc.; such as dry eye syndrome, cataract, glaucoma ophthalmic diseases.</li><li>3. Take steroids, vasodilators, anticoagulants (warfarin, non-steroidal anti-inflammatory drugs, aspirin, heparin, etc.) and retinoids 2 weeks before surgery. Local infections on the skin.</li></ol>

	<p>4. Patients with blepharoplasty, periorbital laser, botulinum toxin type A treatment history, and herpes simplex virus (HSV) infection history 6 months before surgery. History of exposure 2 months before surgery.</p> <p>5. Scar physical, pregnancy, bilateral asymmetrical eye bags. Before entering the group, they were informed of their risks, benefits, and possible complications after the operation, and signed an informed consent.</p> <p>6. Can not guarantee treatment on time, those who fail to cooperate.</p>
Treatment options	<p>16 patients with blepharoplasty bags, and two bilateral blepharoplasty bags were treated with laser respectively, and subjective adverse reactions (pain, burning, and burnout) were recorded before treatment, 4 weeks after each treatment, and 12 and 24 weeks after the third treatment. Itching, dryness), objective adverse reactions (erythema, pimples, edema, exudation, bleeding, scabbing, infection), patient satisfaction VAS score, visa skin tester, 3D skin test, ultrasound measurement of lower eyelid fat volume every 4 weeks Treat once and treat three times per person.</p>
Efficacy evaluation	<p>Effectiveness evaluation indicators:</p> <ol style="list-style-type: none"> <li>1. Patient satisfaction</li> <li>2. Wrinkles, texture and pores by VISIA</li> <li>3. 3D data changes</li> <li>4. Ultrasound measurement of BLEs volume.</li> </ol> <p>Safety evaluation indicators:</p> <ol style="list-style-type: none"> <li>1. Subjective adverse reactions-pain, burning, itching, dryness</li> <li>2. Objective adverse reactions-erythema, pimples, edema, exudation, bleeding, crusting, infection.</li> </ol>
Statistical	<p>The pain of the left and right lower eyelids was tested by paired t</p>

methods	test, the changes of various indexes of visia, 3D, and ultrasound were compared with the Wilcoxon symbol rank test of paired samples, and the subjective and objective adverse reactions were tested by $\chi^2$ test.
Study period	2 years

## 二、 Research process

