Appendix 1: Template of clinical research plan
Project source and number: Self-selected topic

Plastic surgery clinical research project

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Participating Unit: Xijing Hospital
Study Period: Jan 01, 2018-Jan 01, 2020

Version Number: V 2.0
Version date: Dec 08, 2017
## Summary project

### 一、Research Program

<table>
<thead>
<tr>
<th>Project name</th>
<th>Comparison of clinical efficacy of golden microneedles and 1565nm non-ablative dot matrix laser in the treatment of eyelid pouches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of the Study</td>
<td>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.</td>
</tr>
<tr>
<td>Type of study</td>
<td>Randomized, double-blind, self-controlled study</td>
</tr>
<tr>
<td>Number of cases</td>
<td>16</td>
</tr>
</tbody>
</table>

### Inclusion and Exclusion Criteria

**Inclusion Criteria:**
1. Patients with blepharoplasty;
2. Fitzpatrick III-V;
3. Males and females between 18-60 years old.

**Exclusion criteria:**
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, myoscreratitis etc;
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.
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.
### Treatment options

| 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. |

### Efficacy evaluation

| Effectiveness evaluation indicators:  
1. Patient satisfaction  
2. Wrinkles, texture and pores by VISIA  
3. 3D data changes  
4. Ultrasound measurement of BLEs volume. |

| Safety evaluation indicators:  
1. Subjective adverse reactions - pain, burning, itching, dryness  
2. Objective adverse reactions - erythema, pimples, edema, exudation, bleeding, crusting, infection. |

| Statistical | The pain of the left and right lower eyelids was tested by paired t |
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

16 BLEs patients (Baggy Lower Eyelids)

FMR side (Fractional Microneedle Radiofrequency)

NAFL side (Non-ablative Fractional Laser)

Every 4 Weeks $\times$ 3 Times

Efficacy evaluation 1

Efficacy evaluation 2