Protocol

Background

Compared to the Caucasian nose, the Asian nose typically has a low, flat nasal dorsum and insufficient nasal tip projection, thick lobular skin, wide lobule, abundant subcutaneous fatty tissue, alar flaring, a retracted columella, and a small osteocartilaginous framework. [1] Consequently, surgeries of nasal tip projection along augmentation of the dorsum are the most Asian patients request. Alloplastic implants are particularly favored in Asian countries for augmentation in rhinoplasty due to the advantages of availability, ease of shape and lack of donor site morbidity. and ePTFE is the most popular alloplast currently. [2] It is generally assumed that alloplast material at the nasal tip can result in plenty of problems such as skin thinning, erythema, transparency, tip deformation, implant extrusion, and compression of the cartilaginous framework [3], which is unaccepted to both patients and doctors. This general view is contrary to our clinical experience so we were urging to confirm the safety and efficacy of the ePTFE using in nasal augmentation of the dorsum and tip. In this study, we intend to present our experience of this technique and provide an alternative for rhinoplasty.

Aim

ePTFE has been used for nasal dorsum augmentation for many years. but until now, there has been no standard assessment for aesthetic outcomes of ePTFE in nasal tip. This comparative, prospective clinical trial evaluated the efficacy and safety of ePTFE used in both nasal dorsum and tip.

Methods

Study design

Study participants were patients with demands for rhinoplasty. Subjects are randomized to two groups. We apply ePTFE at nasal dorsum and tip for both group, but one with conchal cartilage as shield graft, one without.

Study population

Inclusion criteria:
1) Aged 18-65 years; 2) healthy patient; 3) Having not accepted any treatment before; 4) Having not accepted any oral drugs which will affect blood clotting; 5) Ability and willingness to sign an inform consent form after fully understanding the therapeutic and follow-up strategies.

Exclusion criteria:

1) Individuals with diabetes, 2) vascular disorders, 3) autoimmune disorders, 4) persistent chronic infection even in a remote site 5) other systemic disease.

Subjects

Participants conform to the indications can be recruited to the study and randomized to two groups, one receiving rhinoplasty with conchal cartilage as shield grafts above ePTFE at the nasal tip and the other used ePTFE implantation only.

Outcomes Evaluation

Follow-up and Evaluation

All pertinent patient demographics, surgical outcomes, complications, and patient satisfactions need to be investigated. Complications include soft tissue reaction, infection, extrusion, kinking, migration, excessive or inadequate augmentation, and asymmetry that required a revision surgery to improve contouring.

Data Analysis

The descriptive statistics of the study population were analyzed by frequency for categorical variables and mean (SD) for normally distributed continuous variables. Occurrence of complications in different groups was compared using t test or fisher exact test. P<0.05 was considered statistically significant. All the analyses were performed using SPSS.

Sample size

About 100 patients would be enrolled this study.

Funder

None
Start date

April 2006

Expected end date

April 2009

Reference

