

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Study Identification

Unique Protocol ID: BezmialemVU-BO-PRT

Brief Title: The Effect of Postrhinoplasty Taping on Postoperative Edema and Nasal Draping (PRT)

Official Title: The Effect of Postrhinoplasty Taping on Postoperative Edema and Nasal Draping

Secondary IDs:

Study Status

Record Verification: December 2015

Overall Status: Completed

Study Start: August 2014

Primary Completion: June 2015 [Actual]

Study Completion: June 2015 [Actual]

Sponsor/Collaborators

Sponsor: Bezmialem Vakif University

Responsible Party: Principal Investigator
Investigator: Berke Özücer [berkeozucer]
Official Title: Otorhinolaryngologist
Affiliation: Bezmialem Vakif University

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved
Approval Number: No. 22/9
Board Name: Local Ethics Committee
Board Affiliation: Bezmialem Vakif University
Phone: 90 212 523 22 88
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Data Monitoring?: No

Plan to Share Data?: No

Oversight Authorities: Turkey: Ethics Committee

Study Description

Brief Summary: The purpose of this study was to investigate the effectiveness of postrhinoplasty taping. The effectiveness was evaluated with Ultrasonography and skin envelope thickness was prospectively measured for analysis.

Detailed Description: All patients were informed individually about the procedures and written informed consent was obtained before the study. Undergoing primary open approach reduction rhinoplasty and receiving osteotomies with lateral guarded osteotomes was an inclusion criteria for the study. Fifty-seven consecutive primary open approach rhinoplasty patients that referred to our tertiary reference center were enrolled in the study. Patients were appointed to either the control, 2-week PRT or 4-week PRT group in a randomized-consecutive fashion. External thermoplastic splint was removed at the end of first postoperative week. Patients in the control group were not subjected to further nasal taping after cast removal. All patients in 2-week (from first to third week) and 4-week (from first to fifth week) PRT groups received taping during their allocated time in addition to one week with external nasal splint. These two groups were provided with 1/2-inch wide tan-colored hypoallergenic 3M™ Micropore™ Surgical Tapes (3M, St Paul, Minnesota). Each volunteer was individually shown how and given instructions regarding PRT.

Nasal swelling of the patients were evaluated individually with a 7.5 mHz linear ultrasound (US) probe: small amount of ultrasonic gel was used to scan the skin in a noncontact mode to prevent distortion of nasal anatomy from transducer pressure. The examiner did not have access to the results of the previously obtained measurements in order to prevent measurements from being contaminated. Measurements were carried out on four different points: nasion, rhinion, supratip and tip and from these four measurements, mean nasal skin thickness (MNST) was calculated.

Subjects in each group were sorted, based on the baseline MNST measurement, consecutively from lowest to highest; half of the patients with higher MNST measurements were categorized as 'thick skinned' and the other half was categorized as 'thin skinned'. The electronic caliper of the machine measured the perpendicular distance from the outer epidermal surface to the underlying cartilage on the 2-dimensional B-mode image (Capasee II Ultrasound, Toshiba Medical Systems, Tustin, California). US measurements were carried out five times for each individual subject: preoperatively; at the end of first, third and fifth postoperative weeks; and sixth postoperative month. Measurements were carried out mainly in the morning to avoid the effect of diurnal variation on the dermal edema.

Surgical Technique All of the patients were operated with open approach rhinoplasty under general anesthesia. All patients underwent rhinoplasty due to cosmetic and functional purposes. All cases were distributed evenly between the surgeons (BO, YSY, BV, ST). Supraperichondrial and subperiosteal dissection plane was the preferred plane of dissection in all the cases. Surgical operation was mainly reduction rhinoplasty and comprised of dorsal reduction and bilateral lateral osteotomies. All lateral osteotomies were carried out intranasally with guarded curved lateral osteotomes. Incision-to-closure operative duration was recorded for each patient. All subjects were routinely administered 0.1mg/kg dexamethasone during the operation. All cases were applied with internal splints, taped with 3M micropores and casted with external thermoplastic splints at the end of the operation. Postoperative suggestions, orders and medications were identical for all groups. Patients were discharged from the hospital on first postoperative day. All subjects were called back on the end of first postoperative week for removal of external nasal packing.

Statistical Analysis Statistical data were analysed using SPSS 20.0 (SPSS, Chicago,IL). All values were calculated and stated in descriptive statistics as mean±Standard deviation unless otherwise stated. ANOVA was used for comparison of means. Repeated ANOVA was used for each patient where the repeated factor was the ultrasonographic measurements (preoperative, first postoperative week, third postoperative week, fifth postoperative week and sixth postoperative month). Significant

results of repeated ANOVA test were further analysed via pairwise comparison with Bonferroni correction. Correlation analysis was carried out with Pearson correlation analysis. Values of $p < 0.05$ were considered statistically significant.

Conditions

Conditions: Nasal Deformity
Edema
Rhinoplasty

Keywords: rhinoplasty
postrhinoplasty taping
edema
draping
postoperative edema
nasal skin thickness
supratip fullness
postoperative swelling

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Intervention Model: Parallel Assignment

Number of Arms: 3

Masking: Open Label

Allocation: Randomized

Endpoint Classification: Efficacy Study

Enrollment: 57 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>No Intervention: Control Control group (n=20): Following removal of nasal cast on postoperative first week, no additional taping was applied to this group.</p>	
<p>Experimental: 2-weeks of PRT 2-weeks of PRT (n=17): Following removal of nasal cast on postoperative first week, 2 weeks of additional postrhinoplasty taping was applied to this group (from 1st to 3rd week).</p>	<p>Procedure/Surgery: Postrhinoplasty taping Postrhinoplasty taping is commonly applied by rhinoplasty surgeons. Following rhinoplasty the nose is generally taped and a (thermoplastic) nasal cast is applied on top of this to make sure the final form of the nose is protected. Postoperatively, this cast is removed at some point. After this, some of the surgeons prefer to tape the nose with nasal tapes such as Micropore (3M) etc. Postrhinoplasty taping is the term used for this. The nose is (generally) taped horizontally with 1/2 inch wide tapes. This is done superiorly from radix to inferiorly to nasal tip. The idea is to compress the nose and to cover it. The duration of postrhinoplasty taping differs according to the preference of the surgeon and the patient</p>

Arms	Assigned Interventions
<p>Experimental: 4-weeks of PRT 4-weeks of PRT (n=20): Following removal of nasal cast on postoperative first week, 4 weeks of additional postrhinoplasty taping was applied to this group (from 1st to 5th week).</p>	<p>Procedure/Surgery: Postrhinoplasty taping Postrhinoplasty taping is commonly applied by rhinoplasty surgeons. Following rhinoplasty the nose is generally taped and a (thermoplastic) nasal cast is applied on top of this to make sure the final form of the nose is protected. Postoperatively, this cast is removed at some point. After this, some of the surgeons prefer to tape the nose with nasal tapes such as Micropore (3M) etc. Postrhinoplasty taping is the term used for this. The nose is (generally) taped horizontally with 1/2 inch wide tapes. This is done superiorly from radix to inferiorly to nasal tip. The idea is to compress the nose and to cover it. The duration of postrhinoplasty taping differs according to the preference of the surgeon and the patient</p>

Outcome Measures

Primary Outcome Measure:

1. Nasal skin thickness (for rhinion, radix, supratip and tip)
 [Time Frame: preoperative, postoperative 1st, 3rd and 5th week, postoperative 6th month] [Safety Issue: No]
 measured with Ultrasonography

Secondary Outcome Measure:

2. Duration of Operation
 [Time Frame: Intraoperative] [Safety Issue: No]
 (minutes)(incision to closure duration)

Eligibility

Minimum Age: 16 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- primary open approach rhinoplasty under general anesthesia
- bilateral lateral osteotomies

Exclusion Criteria:

- revision cases
- abnormal haemostatic parameters
- drug history of decongestant or cortisone

Contacts/Locations

Study Officials: Berke Ozucer, MD
 Study Principal Investigator
 Bezmialem Vakif University

Locations: Turkey
 Bezmialem Vakif University

References

Citations: Hafezi F, Naghibzadeh B, Nouhi A. Management of the thick-skinned nose: A more effective approach. *Ann Otol Rhinol Laryngol.* 2006 Jun;115(6):444-9. PubMed 16805376

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Links:

Study Data/Documents:

Complete statistical Analysis plan

1. All data was collected by (BO) and embedded in Excel.
2. These data were transferred to SPSS V20 by (OU)
3. All statistical analysis was carried out with SPSS v20.0 (OU)
4. All values were calculated as mean±Standard deviation
5. ANOVA was used for comparison of means (mentioned-below)
 - a. Age
 - b. Comparison of operative duration among three groups
6. Correlation was assessed with Pearson correlation analysis (mentioned below)
 - a. Correlation between duration of operation and postoperative skin thickness
7. Repeated ANOVA was used for evaluation of ultrasonographic measurements
8. When the results were significant, pairwise comparison was carried out with Bonferroni correction.
9. Values of $p < 0.05$ were accepted as statistically significant