

# A comparison of bone-anchored sutures and radiofrequency energy for treatment of lateral wall collapse causing nasal obstruction.

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<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2015	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lateral nasal wall collapse (collapse of the side of the nose) can cause nasal congestion. The side of the nose (nasal sidewall) collapses due to negative pressure and structural weaknesses of the nose. Bone anchored suture suspension is a technique used by many surgeons to treat it. It involves anchoring the nasal sidewall to the bony rim below the eye. A recently described technique involves treating the soft tissue of the side of the nose with radiofrequency heat to create a scar that makes the tissue firmer. We want to compare the two treatments to each other. We hope to determine how well the new technique performs in managing lateral nasal wall collapse when compared to one of the standard surgical treatments and also non-surgical treatments. This knowledge could change surgical management as radiofrequency thermotherapy is less invasive, could be performed with only local anesthesia, and does not involve implants - in contrast to the more established bone anchored suture suspension.

### Who can participate?

Adults (aged over 18) with nasal obstruction (blockage).

### What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 are treated using radiofrequency thermotherapy. Those in group 2 are treated using the conventional bone anchored suture suspension technique. Those in group 3 are given non-operative treatments. All patients are assessed for lateral wall insufficiency, nasal obstruction and pain caused by the nasal obstruction before and after treatment.

### What are the possible benefits and risks of participating?

Radiofrequency thermotherapy of the lateral nasal wall is a new technique, but radiofrequency treatment itself is well established in the field of otolaryngology (ear, nose and throat specialists) to treat conditions such as sleep apnea and other causes of nasal obstruction. Known risks include excess thermal (heat) damage and pain.

Where is the study run from?  
Stanford University (USA)

When is the study starting and how long is it expected to run for?  
February 2010 to February 2012

Who is funding the study?  
1. Stanford University (USA)  
2. American Academy of Facial Plastic & Reconstructive Surgery (USA)

Who is the main contact?  
Dr Sam Most

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sam Most

**Contact details**  
801 Welch Road  
Stanford  
United States of America  
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## Additional identifiers

**Protocol serial number**  
IRB-18115

## Study information

**Scientific Title**  
Treatment of lateral nasal wall collapse - a comparison of Bone Anchored SuTure suspension versus Radiofrequency Thermotherapy.

**Acronym**  
BAST vs RF

**Study objectives**  
Our hypothesis is that RF will work as well as bone-anchored sutures in treatment of lateral wall insufficiency (LWI).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Stanford Human Subjects, 2/3/2010, ref: IRB-18115

### **Study design**

This is a single-center, randomized, interventional trial comparing two techniques for treatment of lateral wall insufficiency.

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Lateral nasal wall collapse is a source of nasal congestion which plagues many people as the sidewall of the nose collapses due to negative pressure and structural weaknesses of the nose.

### **Interventions**

Bone anchored suture suspension is used by many surgeons to treat lateral wall insufficiency, and involves anchoring the nasal sidewall to the bony rim below the eye. A recently described technique involves treating the sidewall soft tissue with radiofrequency heat to cause scar contraction of the tissue to minimize laxity. We will compare the two treatments to each other, and to non-operative treatment of otherwise surgically-eligible candidates.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

1. Clinician-derived measure of lateral wall insufficiency (LWI score).
2. NOSE (nasal obstruction symptoms evaluation)

Measured at preoperative and postoperative visits.

### **Key secondary outcome(s)**

1. Visual analog scale for nasal obstruction (VAS)

Measured at preoperative and postoperative visits.

### **Completion date**

28/02/2012

## **Eligibility**

### **Key inclusion criteria**

1. Healthy adults with nasal obstruction
2. Over age 18
3. Either gender
4. Any ethnic background

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Children
2. Pregnant women

**Date of first enrolment**

01/02/2010

**Date of final enrolment**

28/02/2012

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

Stanford University

United States of America

**Sponsor information****Organisation**

Stanford University Department of Otolaryngology

**ROR**

<https://ror.org/00f54p054>

**Funder(s)****Funder type**

University/education

**Funder Name**

Stanford University

**Alternative Name(s)**

Stanford, Leland Stanford Junior University, SU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United States of America

**Funder Name**

Educational and Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery

**Alternative Name(s)**

AAFPRS Foundation, Educational & Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery, Educational and Research Foundation for the American Academy of Facial, AAFPRS Foundation; Educational & Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery, AMERICAN ACADEMY OF FACIAL PLASTIC AND RECONSTRUCTIVE SURGERY, INC., AAFPRS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2015		Yes	No