# Randomized, proof of concept clinical trials for therapeutic efficacy and safety of the high intensity focused ultrasound stimulators (RHINOS) in patients with severe nasal congestion by hypertrophy


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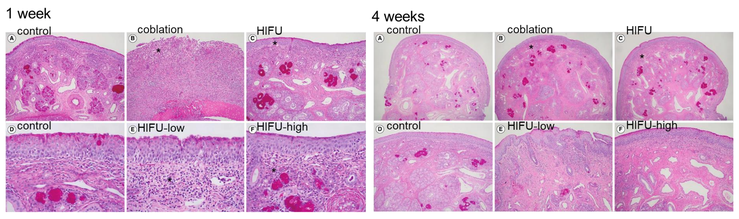
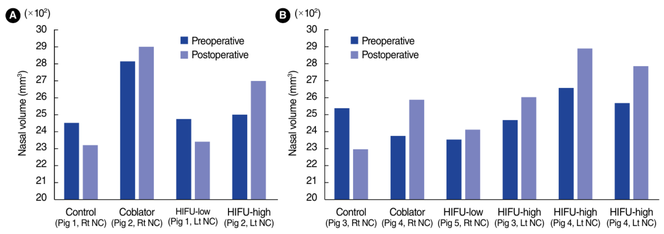
## Introduction

High-intensity focused ultrasound (HIFU) ablation induced histologic change and volume reduction of inferior turbinate in animal study. In previous study, we have proved the efficacy and safety of HIFU turbinoplasty an animal model.




Pathologic evaluation interior turbinate of porcine model treated by control, radiofrequency (coblation), HIFU-high, and HIFU-low groups
(A-C, ×100; D-F, ×400; periodic acid-Schiff staining). This figure demonstrates increased submucosal polymorphonuclear cell count (*) and fibrosis, decreased glandular structure in the HIFU-treated group




Computed tomography evaluation of the control, radiofrequency, and HIFU groups

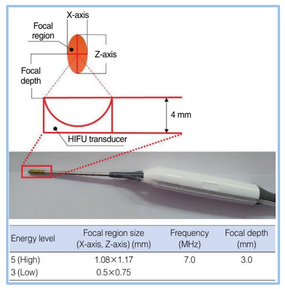
In this study we tried to evaluate weather HIFU could symptomatically improve nasal obstruction in patients with inferior turbinate hypertrophy (ITH).

## Methods and Materials

- A prospective, randomized, single-blinded clinical trial was performed. 16 patients with ITH complaining severe nasal congestion (VAS ≥ 4) were recruited.
- After randomization, 7 patients in test group underwent IT surgery with HIFU system(‘RHINOS’), and 9 in control group underwent conventional high frequency coblator surgery.
- To evaluate subjective and objective improvement, nasal congestion symptom score (10 point VAS scale), NOSE scale, and acoustic rhinometry was evaluated at base line, 1 week, 4 weeks, and 12 weeks. In addition, satisfaction with the procedure (10 point VAS scale) was compared at 12 weeks, respectively.
- Finally, the safety and stability of procedure was compared through evaluation on degree of IT edema, discharge, and crust formation using endoscopic exam during the study period

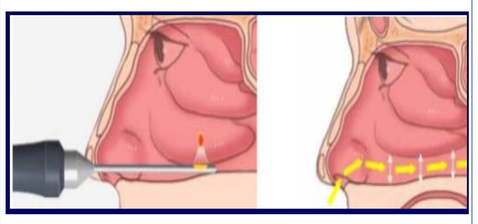
Protocol summary

| Assessment schedule | Screening | Baseline | 1 week | 4 weeks | 12 weeks |
|---|---|---|---|---|---|
| Nasal congestion symptom score (VAS) | • | | • | • | • |
| Nasal obstruction scale evaluation (NOSE) | • | | • | • | • |
| Acoustic rhinometry (MCA) | • | | • | • | • |
| Endoscopic exam | • | | • | • | • |




| Energy level | Focal region size (X-axis, Z-axis) (mm) | Frequency (MHz) | Focal depth (mm) |
|---|---|---|---|
| 5 (High) | 1.08×1.17 | 7.0 | 3.0 |
| 3 (Low) | 0.5×0.75 | | |

Specifications of the high-intensity focused ultrasound (HIFU) prototype design and energy. X, width of the healing region; Z, length of the healing region.



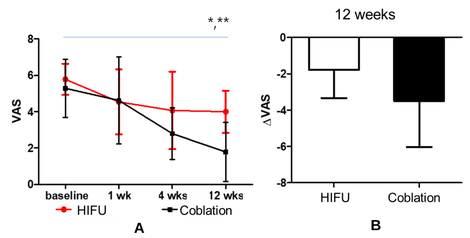
Procedure Illustration: Patients were seated, and topical anesthesia (2% lidocaine) was administered to each nostril just before the procedure. For patients undergoing coblator turbinoplasty, local lidocaine infiltration (2%, 1cc) was performed, followed by a saline injection into the inferior turbinate.

## Results

### Baseline characteristics of randomized patients

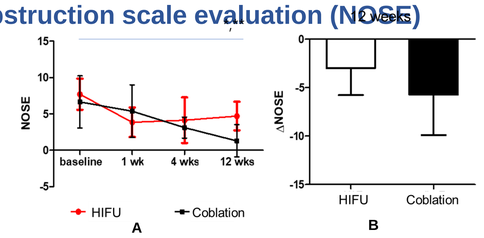
| | | HIFU (N=7) | | Coblation (N=9) | | p-value |
|---|---|---|---|---|---|---|
| | | Mean or N | SD or % | Mean or N | SD or % | |
| Sex | Male | 6 | 85.7 | 8 | 88.9 | 0.849 |
| | Female | 1 | 14.3 | 1 | 11.1 | |
| Age (year) | | 32.29 | 14.75 | 38.33 | 19.16 | 0.502 |
| Weight (kg) | | 70.26 | 12.97 | 65.71 | 9.95 | 0.440 |
| Height (cm) | | 171.01 | 8.24 | 170.9 | 5.99 | 0.975 |
| Medical or surgical history | | | | | | |
| Allergic rhinitis | | 3 | 42.86 | 1 | 11.11 | |
| Allergic conjunctivitis | | 1 | 14.29 | 0 | 0 | |
| None | | 3 | 42.86 | 3 | 33.33 | |
| Medication | | | | | | |
| Allergic rhinitis | | 2 | 28.57 | 1 | 11.11 | |
| Rhinitis | | 1 | 14.29 | 0 | 0 | |
| Allergic conjunctivitis | | 1 | 14.29 | 0 | 0 | |
| None | | 4 | 57.14 | 2 | 22.22 | |

### Nasal congestion symptom score



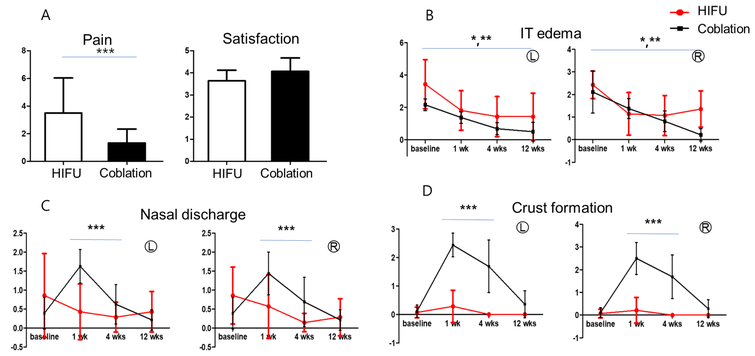

A. Significant improvement visual analogue scale (VAS) in both treatment group compared to baseline after 12 weeks of treatment (*,** : p<0.05) )
B. There was no significant difference in the degree of improvement between the two groups, suggesting the non-inferiority of HIFU treatment compared to coblation turbinoplasty

### Nasal obstruction scale evaluation (NOSE)




A. Significant improvement NOSE scale in both treatment group compared to baseline after 12 weeks of treatment (*,** : p<0.05) )
B. There was no significant difference in the degree of improvement between the two groups, suggesting the non-inferiority of HIFU treatment compared to coblation turbinoplasty

### Safety and tolerability




A. During the procedure, pain was significantly higher in the HIFU treatment group compared to the coblation group. This difference appears to result from the local lidocaine injection (2%, 1cc) administered along the inferior turbinate during coblation turbinoplasty
B. The degree of edema was significantly lower after 12 weeks compared to baseline in both HIFU and coblation treatment group
C and D. Nasal discharge and crust formation were significantly lower among HIFU treatment group compared to coblation treatment group

## Summary and Conclusion

HIFU system seems to have benefits in minimizing procedure related morbidity in office-based procedure for turbinoplasty. This warrants a large prospective clinical trial in the future

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## Suggested readings


- Kim JK, Cho SW, Kim H, Jo SC, Kim HG, Won TB, Kim JW, Lim JH, Rhee CS. Development of High-Intensity Focused Ultrasound Therapy for Inferior Turbinate Hypertrophy. Clin Exp Otorhinolaryngol. 2022 May;15(2):160-167.