

## **Clinical Research Study of SINECCH™ Compared to Steroids and a Control Group in the Reduction of Edema and Ecchymosis In Rhinoplasty.**

Published as "A Randomized, Controlled Comparison between Arnica and Steroids in the Management of Postrhinoplasty Ecchymosis and Edema," Ali Totonchi, M.D., Bahman Guyuron, Plastic and Reconstructive Surgery, Volume 120, Number 1, July 2007, pgs. 271-274.

This Case Western University, IRB approved, clinical trial compared the Arnica Montana product, SINECCH™, a programmed dosage regimen of high strength Homeopathic Arnica unique to SINECCH™ to Steroids and a Control group. 48 patients who underwent a primary rhinoplasty with osteotomy were randomized into 3 groups:

Group P = 10 mg of dexamethasone (IV intraoperatively). Then changed to a 6 day oral tapering dose of methyl-prednisone

Group A = "arnica (SINECCH, Alpine Pharmaceuticals, San Raphael, Calif.) three times a day for 4 days." p. 272

Group C = Control group received neither Steroids nor SinEcch/Arnica

The goal of this study was to directly compare the efficacy of these two pharmaceutical agents, homeopathic Arnica and Steroids, for their benefit in post-rhinoplasty recovery of edema and ecchymosis.

Digital photos were taken on post-op Day 2 and Day 8. Three panelists were blinded to the nature of the study treatment and were subjectively asked to rate:

1) The extent of ecchymosis (scale of 0-5); 2) the intensity of ecchymosis (scale of 0-4); and 3) the severity of edema (scale of 0-3) on Post-op Days 2 and 8.

### **Results:**

On post-op Day 2: Both SINECCH and the Steroid groups had significantly less edema ( $p < 0.0001$ ) than the Control group.

On post-op day 8, the Steroid group had a significantly larger extent of ecchymosis ( $p < 0.05$ ) and higher intensity of ecchymosis ( $p < 0.01$ ) compared with the SINECCH group and the Control group.

## **Conclusions: SINECCH™ compares favorably to Steroids to reduce post-rhinoplasty edema!**

"Disclosure: The authors have no financial interest or commercial affiliation with any product, device, or drug mentioned in this article." p. 274