

Perioperative *Arnica montana* for Reduction of Ecchymosis in Rhinoplasty Surgery

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Background: Studies of homeopathic therapies to decrease postrhinoplasty ecchymosis have previously used subjective measurements, limiting their clinical significance. Recently, *Arnica montana* was shown to decrease postoperative ecchymosis after rhytidectomy, using an objective measuring tool. We believe that oral *A. montana*, given perioperatively, can be objectively shown to reduce extent and intensity of postoperative ecchymosis in rhinoplasty surgery.

Methods: Subjects scheduled for rhinoplasty surgery with nasal bone osteotomies by a single surgeon were prospectively randomized to receive either oral perioperative *A. montana* (Alpine Pharmaceuticals, San Rafael, Calif) or placebo in a double-blinded fashion. Ecchymosis was measured in digital “three-quarter”-view photographs at 3 postoperative time points. Each bruise was outlined with Adobe Photoshop (Adobe Systems Incorporated, San Jose, Calif), and the extent was scaled to a standardized reference card. Cyan, magenta, yellow, black, and luminosity were analyzed in the bruised and control areas to calculate change in intensity. P value of <0.1 was set as a meaningful difference with statistical significance.

Results: Compared with 13 subjects receiving placebo, 9 taking *A. montana* had 16.2%, 32.9%, and 20.4% less extent on postoperative days 2/3, 7, and 9/10, a statistically significant difference on day 7 ($P = 0.097$). Color change initially showed 13.1% increase in intensity with *A. montana* but 10.9% and 36.3% decreases on days 7 and 9/10, a statistically significant difference on day 9/10 ($P = 0.074$). One subject experienced mild itching and rash with the study drug that resolved during the study period.

Conclusions: *Arnica montana* seems to accelerate postoperative healing, with quicker resolution of the extent and the intensity of ecchymosis after osteotomies in rhinoplasty surgery, which may dramatically affect patient satisfaction.

Key Words: rhinoplasty, ecchymosis, bruising, *Arnica montana*, homeopathic

(Ann Plast Surg 2015;00: 00–00)

Surgeons and patients involved in rhinoplasty surgery routinely seek methods to decrease ecchymosis after surgery. One challenge for investigating ecchymosis with new or existing interventions is the subjective nature of its assessment. Patient and physician observational scales that measure ecchymosis lack objectivity. An objective measuring tool was recently described by Seeley and colleagues¹ for measuring extent and intensity of ecchymosis using an algorithm in Adobe Photoshop. In that study, investigators examined the effect of *Arnica montana* in rhytidectomy (facelift) surgery.

Received September 12, 2013, and accepted for publication, after revision, June 6, 2014.

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Conflicts of interest and sources of funding: Alpine Pharmacies (San Rafael, California) provided the study drug, *Arnica montana*, at no cost for this research study. None of the authors have a financial interest in any of the products, devices, or drugs mentioned in this article.

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ISSN: 0148-7043/15/0000–0000

DOI: 10.1097/SAP.0000000000000312

Arnica montana is a homeopathic drug used since the 16th century for various aspects of wound healing including ecchymosis and edema.^{1–4} It is extracted from dried flowers that are a member of the Compositae family, mostly found in Siberia and Central Europe.⁵ As a homeopathic medication, *A. montana* does not have a known mechanism of action or defined drug profile. However, the American Society of Plastic Surgeons deems it safe to use, with no reports of homeopathic dosing-related toxicities.⁵ Today, there is widespread use in the United States and worldwide. Many plastic surgery practices incorporate *A. montana* in their perioperative care such as the commercially available oral form named *SinEcch* (Fig. 1), manufactured by Alpine Pharmaceuticals (San Rafael, Calif). According to Alpine Pharmaceuticals, *SinEcch* is prepared “in accord with the FDA’s regulations for homeopathic preparations.”⁶

The randomized controlled trial of Seeley and colleagues that evaluated postoperative ecchymosis after rhytidectomy surgery was the first to use an objective measuring tool (Fig. 2). They showed that the extent of ecchymosis decreased with statistical significance on postoperative days 1 and 7 and decreased on postoperative days 5 and 10 without statistical significance. The change in intensity of bruising in patients using *A. montana* was inconclusive. This study gave a major contribution by the creation of an objective, computer-based algorithm to evaluate bruising.

Our study aims to build on Seeley and colleagues’ objective measurement of ecchymosis and examine the effects of perioperative homeopathic medication *A. montana* in rhinoplasty surgery. We hypothesize that *A. montana* will statistically reduce the extent and intensity of ecchymosis in the early postoperative period.

METHODS

Patient Recruitment

Institutional review board approval was obtained through the University of Wisconsin School of Medicine and Public Health, with enrollment from July 2010 through June 2012.

This trial was registered with clinicaltrials.gov as The Utility of Peri-operative *A. montana* for Reduction of Ecchymosis in Rhinoplasty Surgery, identifier NCT01164644, at <http://www.clinicaltrials.gov/ct2/show/NCT01164644>.

A commercially available oral form of *A. montana* used in multiple recent investigations,^{1,3,4} *SinEcch*, was obtained, which contains 12 capsules—500 mg of *A. montana* 1M is given preoperatively on the morning of surgery and 2 more later that day after surgery, and 500 mg of *A. montana* 12C is given orally 3 times daily for the next 3 days, where “C” indicates a 100-fold serial dilution; and M, a 1000-fold serial dilution.⁴

Study medication and placebo (sugar pill in non-gelatin-containing capsule) were blinded and packaged into blister cards by the Pharmaceutical Research Center at the University of Wisconsin Hospital and Clinics. Randomization was performed in 2 separate groups, prepared for subjects undergoing surgery on 2 possible operative days of the week.

Adult patients scheduled for rhinoplasty surgery with nasal bone osteotomies by the senior author at an outpatient surgery center were recruited as subjects to this study during the routine preoperative history and physical examination visit by the clinic nurse practitioner.



FIGURE 1. Example of a commercially available oral formulation of *A. montana*, SinEcch. Three capsules of 500 mg 1M are taken on the day of surgery, and the remaining 500 mg 12C capsules are taken for the next 3 days.

Preoperative digital photographs in the left and right “three-quarters” views were obtained with the subject holding a measurement marker in front of the ear. The three-quarters view was chosen to show the ecchymosis from osteotomies with the least interference from standard nasal splinting. The subjects and all study personnel were blinded to the delivered drug. Sex, age, and rhinoplasty approach (open or closed) were recorded. Subjective data provided by the subject or the surgeon were not used for the study.

Exclusion criteria included subjects with allergies to the herb and those taking blood-thinning products because of the hypothetical risk for increased bleeding from interaction between *A. montana* and anticoagulant and antiplatelet therapy.^{2,7} (All rhinoplasty patients are



FIGURE 3. Three-quarter view photographs at preoperative visit (A) and postoperative days 3 (B), 7 (C), and 10 (D). The patient is holding the reference card to standardize measuring extent of ecchymosis.



FIGURE 2. Post-rhytidectomy image in Adobe Photoshop showing outlined area of ecchymosis and earlobe control area. The author displays the extensive magenta component on histogram. Permission obtained for reprint from Seeley and colleagues.¹ Adaptations are themselves works protected by copyright. So in order to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.

instructed to hold these and other homeopathic remedies starting on preoperative day 10; those who cannot or others with significant liver or kidney disease did not undergo surgery at this outpatient surgery center and are therefore already ineligible for study participation.) Pregnant and breast-feeding patients are not study or surgical candidates and are screened out through standard questions and pregnancy testing. Lastly, study participation was limited to white participants to reduce variability with underlying skin quality and pigment.

The study participants underwent either open or closed rhinoplasty surgery with nasal bone osteotomies and were given perioperative intravenous decadron and standard postoperative oral methylprednisolone. Left and right three-quarters view photographs were taken of the subjects holding the measurement marker on either postoperative days 2/7/9 or 3/7/10, depending on the day of the surgery. Empty pill blister cards were collected to ensure compliance. Data monitoring and safety reporting for adverse events occurred throughout the study. Blood pressure recordings were made at each follow-up visit per clinic standard of care and for the previously reported potential for *A. montana* to decrease antihypertensive drug efficacy.²

Photographic Analysis

Digital photographs obtained in left and right three-quarters views were analyzed in Adobe Photoshop (Fig. 3). To calculate the extent of ecchymosis, the area of ecchymosis was circumscribed in Photoshop using a tablet-style computer and stylus and standardized to the area of the reference marker held by the subject. Extent from the left and right views was averaged and then compared across the postoperative course.

Next, photographs were converted to the CMYK Color mode, and the mean of each color variable within the area of ecchymosis was recorded—cyan, magenta, yellow, black (K for black), and, luminosity (L). Intensity of each variable is reported on a scale of 0 to 255. To minimize slight differences in lighting and distance from the camera, the same variables were measured on a control area above the brow in the midpupillary line. The difference was calculated as X , where $X = (\Delta C2 + \Delta Y2 + \Delta M2 + \Delta K2 + \Delta L2)/5$ and ΔC is the difference between the mean cyan value for the study region and that of the control region. Seeley and colleagues¹ explain "... if 2 colors were compared and found to have an X of 4.3, they might be nearly indistinguishable to the naked eye. A value of 20.30 might be seen as a mild difference, such as 'rosy cheeks.' If, however, their X value were 114.76, they would be dramatically contrasting colors." Using similarly selected regions on the preoperative photograph, the differences between X in the preoperative photograph and X at each postoperative photograph were determined to be the color change resulting from surgical intervention. Finally, the changes in X for the left and right views were averaged.

Variances were compared between groups using F tests; t tests were used to compare each group for extent and intensity at 3 postoperative time points (Microsoft Excel, Redmond, Wash). Given the variability of skin pigment, extent of osteotomies, and history of nasal bone trauma, we set $P < 0.1$ as a meaningful difference with statistical significance.

RESULTS

After 24 months of enrollment, 74 patients were assessed for eligibility, 28 subjects were recruited as subjects, and 22 completed the study, 13 women and 9 men, aged 18 to 59 years. Postoperative photographs were obtained on all subjects on the first and second time points, and 16 subjects also had photographs on postoperative day 9/10. Of the 6 subjects who did not complete the study, 1 elected to leave the study before surgery, 2 attended only 1 postoperative visit, 2 did not undergo surgery (loss of health insurance [1] and thrombocytopenia [1]), and 1 subject elected to leave the study for laser treatments of ecchymosis on postoperative day 3 (Fig. 4).

Unblinding showed that 13 subjects received placebo and 9 received *A. montana*. In the placebo group, 54% were women and 46% men, mean age, 33 years; in the *A. montana* group, 67% were women and 33% men, mean age, 32 years. Three subjects in each group completed only 2 postoperative photographs. One subject in each group had osteotomies in combination with closed-approach rhinoplasty, and the remainder had an open-approach rhinoplasty. Seven subjects on Wednesday and 6 subjects on Friday received placebo; 4 subjects on Wednesday and 5 subjects on Friday received *A. montana*.

The mean extent and intensity were calculated for each group during the postoperative course (Figs. 5, 6). With the reference card area standardized as 1, the mean extent of ecchymosis with placebo was 0.736, 0.894, and 0.543; the mean extent with *A. montana* was 0.617, 0.600, and 0.432. Compared with the subjects receiving placebo, those taking *A. montana* had 16.2%, 32.9%, and 20.4% less extent of ecchymosis on postoperative days 2/3, 7, and 9/10, respectively, with a statistically significant difference on postoperative day 7 ($P = 0.097$) (Table 1).

The mean intensity changes attributed to surgery was 41.0, 38.2, and 40.0 for those taking placebo and 46.3, 34.0, and 25.5 for those taking *A. montana*. The difference in mean color change

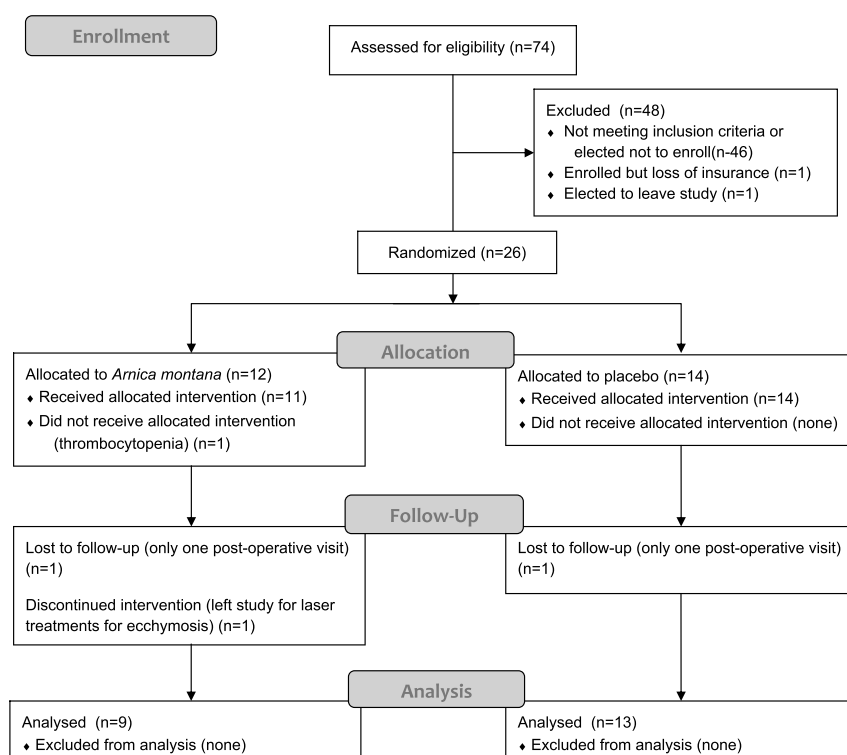


FIGURE 4. Flow diagram of subject progress through the phases of the randomized trial.

between the groups was 13.1% more intensity on the first postoperative visit in the subjects receiving *A. montana* but 10.9% and 36.3% less intensity on day 7 and 9/10. The difference was statistically significant on days 9/10 ($P = 0.074$) (Table 2).

Two minor complications were reported by the subjects. One was found to have septal swelling on postoperative day 3 after early self-discontinuation of nasal packing. Needle aspiration yielded a small volume of blood but no obvious septal hematoma; unblinding showed that the subject was taking placebo. A second subject complained of mild itching and rash that resolved during the study period; unblinding showed that this subject was taking *A. montana*.

DISCUSSION

Although the natural history of healing after rhinoplasty surgery typically involves bruising for 1 to 2 weeks, patients and physicians search for ways to cause less postoperative ecchymosis and accelerate its resolution such as vasoconstrictive-containing local anesthetic or external pressure with a nasal splint.⁸ In this study, we administered oral *A. montana* or placebo to patients undergoing nasal bone osteotomies in rhinoplasty surgery to objectively measure the extent and intensity of postoperative ecchymosis.

In the subjects taking *A. montana*, we found 16.2%, 32.9%, and 20.4% less extent on postoperative days 2/3, 7, and 9/10, with statistically significant difference on day 7 ($P = 0.097$). In addition, our study showed an initial color increase with *A. montana*, followed by 10.9% and 36.3% decreases on days 7 and 9/10, a statistically significant difference on days 9/10 ($P = 0.074$). Oral *A. montana* given perioperatively objectively reduces the extent and intensity of postoperative ecchymosis in rhinoplasty surgery.

Arnica montana is a homeopathic agent and thus does not have a known mechanism of action. Campbell⁷ first endeavored to show its efficacy in 1978 by experimentally inflicting mechanical bruising to 13 healthy volunteers, suggesting some benefit. In a randomized controlled trial, Ramelet et al⁹ suggested but failed to show a statistically significant reduction in the incidence of postoperative hematomas after vein stripping. Many publications have since appeared, subjectively measuring the effect of *A. montana* on ecchymosis as well as muscle soreness, pain after tooth extractions, and pain after carpal tunnel surgery.

More recently, Kulick presented evidence on reducing ecchymosis and edema after liposuction, but these data were not published.^{3,5}

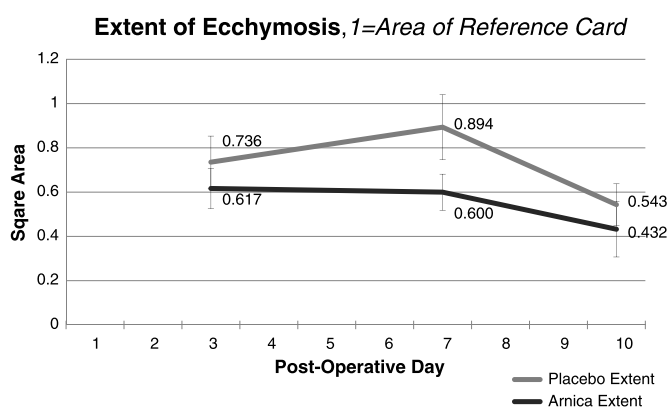


FIGURE 5. Mean extent of ecchymosis for subjects receiving placebo and *A. montana*. Error bars show SEM. The figures' points are displayed only on days 3, 7, and 10 but also represent 2, 7, and 9 data points.

TABLE 1. Reduction in Extent of Ecchymosis of Subjects Taking *A. montana* Compared With Placebo

Postoperative Day	2/3	7	9/10
Placebo (extent)	0.736	0.894*	0.543
<i>A. montana</i> (extent)	0.617	0.600*	0.432
Reduction <i>A. montana</i> /placebo (extent)	-16.2%	-32.9%*	-20.4%
F test (extent)	0.211	0.037†	0.873
P value (extent)	0.468	0.097*	0.486

*Statistical significance, $P < 0.1$.

†Unequal variance.

Arnica montana has been studied in rhinoplasty surgery. Totonchi and Guyuron³ randomized patients to receive SinEcch or corticosteroids or placebo. Panelists subjectively evaluated photographs on postoperative days 2 and 8 for extent and intensity of ecchymosis, as well as the severity of edema. The statistical analysis between all 3 groups failed to show a significant decrease in bruising. However, when comparing the mean rating scores of panelists, they rated less extent of bruising on postoperative day 8 and less intensity of bruising on both postoperative days 2 and 8 in subjects who took *A. montana* compared with those who took placebo or corticosteroids. However, statistical analysis to look for differences between *A. montana* and each group separately was not reported, and these differences may not be significant. In 2006, Seeley and colleagues published their randomized controlled trial showing a decrease in postoperative ecchymosis after rhytidectomy surgery.

Although other formulations exist, we chose SinEcch based on its use in recent publications and oral route. Topical *A. montana* formulations are reported to decrease muscle aches through anti-inflammatory effects and are widely sold. However, studies have not shown efficacy; one examined its effect to prevent ecchymosis in subjects receiving laser therapy for facial telangiectasias, failing to show difference compared with placebo.¹⁰ Furthermore, we chose the oral route because ecchymosis after osteotomies come from deeper facial tissue planes, and the topical route has unknown penetration.

Another homeopathic agent believed to impact postoperative bruising is bromelain, a protease enzyme from pineapple stems thought to accelerate hematoma resorption but without significant evidence of effect in rhinoplasty surgery.^{11,12} Antihistamines have also been investigated.¹²

Seeley and colleagues introduced the objective measurement of ecchymosis in a randomized controlled trial studying *A. montana* in rhytidectomy (facelift) surgery, using Adobe Photoshop. Recently, Strong and Jacono¹³ adopted the objective measurement tool to successfully show less intensity of ecchymosis using hyperbaric oxygen after rhytidectomy, with statistical significance on postoperative days 7 and 10. Kotlus et al⁴ also measured extent of ecchymosis

TABLE 2. Reduction in Intensity of Ecchymosis of Subjects Taking *A. montana* Compared With Placebo

Postoperative Day	2/3	7	9/10
Placebo (intensity)	41.0	38.2	40.0*
<i>A. montana</i> (intensity)	46.3	34.0	25.5*
Reduction <i>A. montana</i> /placebo (intensity)	+13.1%	-10.9%	-36.3%*
F test (intensity)	0.598	0.711	0.328
P value (intensity)	0.567	0.649	0.074

*Statistical significance, $P < 0.1$.

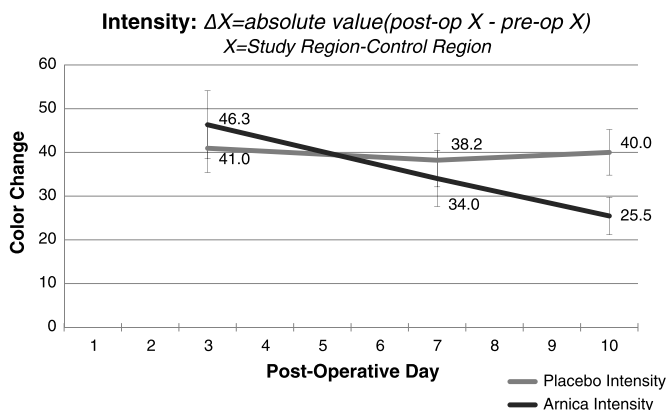


FIGURE 6. Mean intensity of ecchymosis for subjects receiving placebo and *A. montana*. Error bars show SEM. Note suggested more intensity in the subjects taking *A. montana* on the first postoperative visit. The figures' points are displayed only on days 3, 7, and 10 but also represent 2, 7, and 9 data points.

using Adobe Photoshop in blepharoplasty patients receiving SinEcch or placebo, but color intensity was not measured.

In our study, both extent and intensity of bruising were analyzed as primary outcomes during 3 time points. To control the type I error rate and limit a larger number of tests, measurements from the left and right views were averaged. Given the highly variable factors of the patient group that are not easily controlled—underlying skin quality and pigment in white patients, extent of osteotomies, as well as variable presence and extent of prior nasal bone trauma—we believe that differences between the *A. montana* and placebo groups associated with *P* values of less than 0.1 represent clinically meaningful results.

The subjects who underwent surgery on Wednesday were seen on postoperative days 2, 7, and 9; those on Friday were seen on days 3, 7, and 10. Our pharmacy staff created 2 unique randomized sets of drugs for the groups before double blinding. Beyond randomization, we assumed that the subjects from different days would have similar outcomes without variability created by days. Surgically, the placebo and study groups were similar, with only 1 subject from the group undergoing osteotomies in combination with closed-approach

rhinoplasty. Those subjects without postoperative day 10 photographs include 1 subject with lost photographs (study drug group) and 4 subjects who missed appointments (1 in the study drug group and 3 in the placebo group).

Our data suggest a statistical difference in the extent of ecchymosis on postoperative day 7, representing a 32.9% reduction in the area of bruised skin (*P* = 0.097). We attribute the lack of a statistically significant difference on postoperative day 2/3 to sample size and variability because we expected the groups to be distinct. As the extent of ecchymosis resolved, the groups were no longer statistically different on day 9/10. This is shown graphically and numerically where the extent of ecchymosis in subjects taking placebo begins to equalize with those using the study drug as the bruise resolves.

Second, the data show a statistically significant difference in intensity, with a 36.3% reduction in the *A. montana* group on postoperative days 9/10 (*P* = 0.074). Therefore, administration of *A. montana* may give a patient a quicker recovery with smaller extent of bruising earlier and less intensity later in the postoperative period. The increase in intensity of 13.1% on the first postoperative visit in the subjects receiving *A. montana* was not statistically significant. The difference in intensity on day 7 also failed to reach statistical significance.

We noted a challenge to accurately select the entire bruise in the postoperative course with the tablet-style computer and stylus because of diffuse yellow skin coloration accompanying the intense bruise. Some subjects displayed diffuse yellow coloration with or without the typical red and purple, making the complete outline of the bruise difficult (Fig. 7). One reviewer (SRC) made all of the analyses on one computer and selected the area of ecchymosis in a similar fashion throughout, before unblinding occurred. We believe that the objective measurement tool is superior to subjective patient, physician, or panelist assessment when establishing efficacy. However, given Seeley and colleagues' inconclusive change in intensity and our statistically significant difference only on day 9/10, future modifications may be needed in the Photoshop model for measuring color intensity.

We believe that *A. montana* is useful in surgery that involves major soft tissue trauma. Although Kotlus et al failed to show less extent after blepharoplasty, there were no osteotomies, and vigilant hemostasis was ensured intraoperatively with direct visualization of the surgical dissection. Using a similar argument, there may be an increased probability of detecting a difference with more surgical trauma inflicted such as after rhytidectomy surgery, in which there is

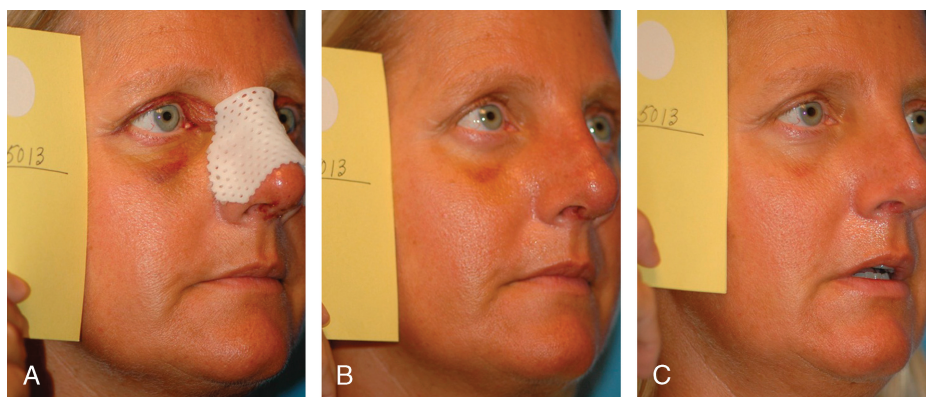


FIGURE 7. Three-quarter view photographs on postoperative days 3 (A), 7 (B), and 10 (C) in a subject taking *A. montana* with diffuse infraorbital yellow postoperative changes.

a higher intensity of ecchymosis at the onset. The subjects of our study who displayed lower intensity of ecchymosis or only a diffuse yellow colored bruise may have contributed to outlying data points.

Further studies would include an increase in the number of patients and increase in compliance to return on the final visit to show statistical significance and better understand the resolution of the ecchymosis. Although we believe that the differences we observed were meaningful, larger studies may be necessary to confirm our findings. Future studies should also incorporate some subjective assessment to correlate clinical impact with the objective findings. Although we found statistically significant changes, an assessment of ecchymosis by blinded evaluators would provide a correlation to the clinical significance of our reductions in extent and intensity, particularly the change in *X* calculated in Photoshop that lacks direct clinical meaning.

Nonetheless, our research shows that oral *A. montana* is safe and suggests efficacy in the perioperative setting. We recommend its use for any nasal surgery associated with potential ecchymosis.

ACKNOWLEDGMENTS

The authors thank Gail Jahnke, RN, APNP, for her role in recruitment, consent, and photography as well as her tireless effort to the study; biostatistician Glen Levenson, PhD, for his advice and guidance in data analysis; and Alpine Pharmacies (San Rafael, Calif) for providing the study drug at no cost for this research study.

Informed consent was received for publication of the figures in this article.

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