**Conclusions:** Ex-vivo normothermic limb perfusion preserves limb physiology and function for at least 12 hours. Thermography and ICG angiography are valuable tools in the assessment of limb perfusion quality with the advantage of providing an immediate evaluation which allows for the visual identification of perfusion gradients and regions of mal-perfusion. Muscle contraction upon nerve stimulation, a uniform physiologic temperature and tissue oxygenation, and the distal dye distribution on angiography identify a successful perfusion. These methods may have important future implications on the decision to transplant or replant a perfused limb. Myoglobin and CK concentration increased in all limbs during ex vivo perfusion, but the functional significance of this is still to be determined.

**Topical Application of Nitrosonifedipine, a Novel Free Radical Scavenger, Ameliorate the Ischemic Skin Flap Necrosis**

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**Introduction:** Ischemic flap necrosis is often occurred by insufficient blood supply, which prolongs the treatment period and occasionally requires an additional surgery. Ischemic flaps generate an excess amount of free radicals which is regarded as a major factor of ischemic skin necrosis. Thus free-radical scavengers would be an effective drugs in improvement of flap survival. In our previous studies, we have reported nitrosonifedipine (NO-NIF), which is a photolytic compound of nifedipine, possesses a potent radical scavenging activity, and shows the favorable effects against vascular endothelial dysfunction and type 2 diabetic nephropathy. In this study, we evaluated the ameliorating effect of NO-NIF on the ischemic flap model mice.

**Material and Methods:** 9–10 weeks old Male C57BL/6 mice were divided into 2 groups, NO-NIF or control (n=6 in each group), respectively. A 1.0×3.0 cm cranially based random pattern flap was elevated on the dorsum of mice. NO-NIF 30mg/kg or vehicle was injected subcutaneously immediate after the operation and once a day until evaluation. Seven days after surgery, the survival area was calculated as a percentage of the total flap area. To detect the oxidative stress, malondialdehyde (MDA) in the distal part of the flap at post-operative day 1 and 3 was measured by thiobarbituric acid reactive substances assay. Protein expression of p22phox, an essential component of NADPH-oxidase, in the flap was measured by western blotting.

**Results:** At post-operative day 7, the flap survival area was significantly larger in the NO-NIF-treated mice than controls (78.29±7.04% vs. 51.81±6.85%, p=0.021). The amount of MDA significantly decreased in the NO-NIF-treated mice at post-operative day 3 (2.31±0.28µmol/g protein vs. 4.21±0.32µmol/g protein, p=0.001), whereas MDA was same level in the both groups at the post-operative day 1 (2.77±0.61µmol/g protein vs. 2.96±0.51µmol/g protein). In a manner consistent with MDA levels, protein expression level of p22phox was decreased in the NO-NIF-treated mice at post-operative day 3 (p=0.002).

**Conclusions:** We present the ameliorating effect of NO-NIF on ischemic flap survival. MDA and p22phox protein was decreased by NO-NIF treatment, which suggests the ameliorating effect was exerted via free radical scavenging. This investigation indicates that free-radical scavengers including NO-NIF are effective drugs in improvement of flap survival.

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**Safety and Efficacy of Sufentanil Sublingual 30 mcg Tablets for the Treatment of Acute Pain following Outpatient Abdominoplasty**

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**Introduction:** The sufentanil sublingual tablet system is a non-invasive, patient-controlled analgesia (PCA) drug/device product recently approved by the European Medicines Agency for treatment of acute moderate-to-severe post-operative pain in a hospital setting. A second sufentanil product, a 30 mcg tablet (ST) dispensed sublingually by a healthcare professional via a single-dose applicator, is
in Phase 3 development for treatment of moderate-to-severe pain in medically-supervised settings, such as outpatient or ambulatory surgery. Sublingual sufentanil appears well-suited for short duration acute pain management because it acts rapidly (plasma-CNS equilibration time of 6 minutes), does not require an invasive route of delivery and possess a predictable offset, in part due to lack of active metabolites. The primary objective of this study was to compare the efficacy and safety of the ST to placebo tablet (PT) for the management of moderate-to-severe acute pain following typical outpatient abdominal surgeries.

METHODS: The study was multicenter, randomized and placebo-controlled for up to 48 hours in adult patients undergoing the following outpatient abdominal surgical procedures: abdominoplasty, open tension-free inguinal hernioplasty or laparoscopic abdominal surgery. Following IRB approval and patient informed consent, approximately 180 patients who met all inclusion and none of the exclusion criteria were randomly assigned at a 2:1 ratio to treatment with ST or PT. Efficacy was assessed by patient reports of pain intensity on an 11-point numerical rating scale (0 = no pain, and 10 = worst possible pain) and a five-point pain relief scale (0 = no relief, 4 = complete relief). The primary efficacy variable was the summed pain intensity difference to baseline over the 12-hour study period (SPID12). Safety was assessed via periodic measurement of vital signs, continuous monitoring of oxygen saturation, spontaneously reported adverse events (AEs) and the use of concomitant medications.

RESULTS: A total of 161 (107 ST and 54 PT) patients were randomized and received study drug. Average patient age was 41 years, 68% were female and approximately 50% had undergone abdominoplasty surgery. Statistically significant SPID12 differences were observed in favor of ST over PT (25.8 vs. 13.1; p<0.001) for the entire cohort, demonstrating superiority of sublingual sufentanil 30mcg for management of acute post-operative pain. Subgroup analysis by surgery type, despite much smaller sample sizes, also yielded significantly higher scores for ST over PT for abdominoplasty patients (30.8 vs 17.6; p=0.001). Most AEs were mild to moderate in severity with nausea and headache as the most common across both treatment arms.

DISCUSSION/CONCLUSION: The sufentanil sublingual 30 mcg tablet has shown benefit over placebo across a range of surgical procedures as a non-invasive analgesic modality requiring short-term treatment of acute moderate-to-severe pain.

Racial and Ethnic Variations in Clinical and Patient-Reported Outcomes Following Breast Reconstruction

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INTRODUCTION: Existing studies evaluating disparities in breast reconstruction have assessed variations in types and rates of reconstruction among racial and ethnic minorities.1–3 However, variations in postoperative outcomes for minority populations remain understudied.4 The objectives of this study are to evaluate racial and ethnic variations in complications and patient-reported outcomes (PROs) following breast reconstruction.

MATERIALS AND METHODS: The Mastectomy Reconstruction Outcomes Consortium is an 11 center, prospective cohort study assessing clinical and patient-reported outcomes following autologous and implant-based breast reconstruction. Race and ethnicity data were available by self-report and medical records. Complications (major or any) and reconstructive failures at one-year post-reconstruction were recorded. PRO measures included BREAST-Q subscales for satisfaction with breasts, sexual, psychosocial, and physical well-being, as well as the PROMIS subscale for physical functioning. Mixed-effects logistic regression models were used to assess clinical outcomes and mixed-effects linear models were used to evaluate patient reported outcomes at one-year postoperatively.

RESULTS: A total of 2,476 women with known race and ethnicity information had one-year follow-up data, including 2,058 (83.1%) White, 146 (5.9%) Black, 133 (5.4%) Hispanic or Latino, and 139 (5.6%) patients from other minority groups. Patient age, body mass index, education, household income, laterality, diabetes status, and indication for mastectomy differed by race and ethnicity. Clinical outcomes were available for all women, but PROs at one-year were completed by 1,456 (response rate = 74.1%) White, 65 (47.4%) Black, 74 (56.9%) Hispanic or Latino, and 80 (59.3%) patients from other minority groups. To account for differential non-response rates across race groups, all PRO analyses were weighted by the inverse of the response probability, in addition to adjusting for baseline covariates. At one-year postoperatively, no differences were noted in clinical outcomes by race or ethnicity, but black women experienced higher psychosocial (P=.001) and sexual well-being (P=.004) relative to white women.