ABSTRACT INTRODUCTION:
The benefits of homographs for foot and ankle fusion procedures, as compared with allografts, include greater capacity for incorporation, osteoconduction and osteoinduction. Their main disadvantage is the donor site morbidity of up to 30%, particularly postoperative pain. Standard management of postoperative pain is with opioid analgesics, such as morphine sulfate or fentanyl. However, opioid effects, such as respiratory depression, nausea, vomiting, decreased gastrointestinal motility, and peripheral vasodilatation, can potentially worsen the patient’s condition and result in unfavorable outcomes, extended hospital stays, and increased costs.

Xybrex™ Absorbable Hemostatic Bone Putty is a soft, moldable, biocompatible, absorbable material of putty-like consistency intended for use in management of bleeding from the cut surface of bone and has already shown very promising results with reversibly blocking the sciatic nerve over several days in an animal model [1]. The formulation contains 16% (by weight) Lidocaine. The majority of the anesthetic is released over a 3-4 day period. The anesthetic-exhausted hemostatic agent is essentially absorbed in 30-60 days.

METHODS:
A pilot study with 14 subjects was conducted to provide initial evidence of the safety and efficacy of Xybrex for hemostasis and the treatment of postoperative hip pain following Iliac Crest Bone Graft (ICBG) harvest. Subjects were assigned to be treated with either Xybrex or a similar bone putty that did not contain lidocaine (Orthostat). Seven subjects were implanted with Xybrex and seven were implanted with Orthostat. Subjects were provided with Patient Controlled Analgesia (PCA) for management of their postoperative pelvis pain for the first 3 days after surgery. Regional nerve blocks were administered for the control of foot pain. Efficacy (pain evaluation) was monitored every 4 hours post surgery using a 100 mm Visual Analog Scale for the first 72 hours after surgery. Serial blood draws were performed at baseline and at 2, 4, 8, 12, 24, 48, and 72 hours.

RESULTS
The mean size of bone block taken from the iliac crest from the Xybrex subjects was 3.7 ± 2.2 grams vs. 3.4 ± 2.4 grams for the Orthostat subjects (p=NS). The mean amount of Xybrex applied to the resulting bone defect in the Xybrex subjects was 4.3 ± 1.2 grams vs. 4.3 ± 0.8 grams for the Orthostat subjects (p=NS). Subjects treated with Xybrex significantly improved Area Under the Curve of the VAS score (AUC) pain intensity as compared to placebo from 1 to 12 hours (mean AUC, 175 vs. 250; p < 0.05). From 1 to 24 hours the differences between Xybrex and placebo supported the continued positive trend towards lower AUC scores for subjects treated with Xybrex but were not statistically significant. –Fig B

![Figure B](image1)

**Figure B**- Mean VAS Score as AUC after 12 and 24 hours

The serum levels of lidocaine reached a peak at 4-8h after application staying at all times well below the level of cardiotoxicity (6µg/ml).-Fig 2

![Figure C](image2)

**Figure C**- Serum lidocaine levels over a 72h period after application

There were no unanticipated serious adverse effects experienced by subjects in the study. There was one seroma in the graft site that required manual expression of the serous fluid to resolve. This patient was in the Xybrex group.

DISCUSSION:
Xybrex appears to offer significant analgesic effect in the immediate post-operative period. A larger randomized study is being planned in order to verify the results from this pilot study.

REFERENCES: