Early Feasibility Study (EFS) of the POP device that is currently being conducted. DJO Surgical is the device manufacturer of record.

**METHODS:** This study was IRB and FDA approved. Ten TF amputees underwent a two-stage surgery protocol: Stage 1 surgeries to implant an endoprosthetic stem within the residual bone, and Stage 2 to attach a percutaneous post to the stem after a minimum of 5 weeks. Participants completed bone, skin, function and psychological assessments at 5, 12, 24, 36 and 52 weeks after Stage 2 surgery.

**RESULTS:** Ten male amputees, mean age = 48.7 (min 32; max 67) and mean time since amputation of 10.5 years (min 1.5; max 19), received the POP device. Implants were successfully placed with no intraoperative fractures or other surgical complications. All patients were successfully fitted with their prosthetic limb within 24 hours of Stage 2 surgery and were able to immediately load the limb as tolerated under supervision. All progressed to ambulation with an assisted device within 14 days of Stage 2 with no post-operative fractures.

A reduction in the average prosthesis don and doff times of 91.4% and 70.8%, respectively, was observed at 5 weeks. 80% progressed to independent ambulation by the 5-week follow-up. Two device removals occurred: one early loosening at 5 weeks and the other due to a periprosthetic fracture following trauma at 7 months. One perioperative and two superficial infections (9 & 10 months) were resolved with antibiotic treatments. 70% have completed the 12-month follow-up period to date.

Clinical results to-date have demonstrated low preliminary infection rates, maintenance of distal cortical bone, improved functional outcomes, periprosthetic bone density increases, and improved patient reported outcomes following a staged operative approach and accelerated weight-bearing compared to other existing OI techniques. The remaining patient completes 1-year follow-up in April 2018.

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**Portfindr: A Novel and More Accurate Device for Locating Tissue Expander Ports**

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**INTRODUCTION:** Two-stage tissue expander (TE)/implant breast reconstruction is the most common method following mastectomy. TE reconstruction can be associated with complications such as infection, seroma, and rupture. Traditional TE port localization utilizes a small dangle magnet to help determine the needle entry point for expansion. Tissue thickness, fluid accumulation, or displacement of the TE can make precise port localization more difficult. More accurate localization of the magnetic fill port minimizes the risk of inadvertent puncture during access. We have developed a novel device, called PortFindr, to more accurately localize the subcutaneous expander fill port.

**METHODS:** A single-blinded experiment was conducted to determine the accuracy of a traditional dangle magnet in comparison PortFindr. A Sientra single port DermaspanTM tissue expander filled to 300ml was placed beneath three different foam skin equivalents (A 11mm, B 21mm, and C 32mm) by the non-blinded researcher. The blinded researcher then used either the PortFindr or standard dangle magnet to determine the location of the port and insert a needle into the expander port. The distance of the needle to the center of the port was measured (mm) using an electronic caliper and the quadrant the of needle insertion was noted. Thirty trials were completed for each parameter tested. Additionally, the effect of distance on the force of magnetic attraction between the dangle magnet and the TE port was conducted using a tension force gauge.

**RESULTS:** At each tissue thickness, the mean distance from center was significantly less in trials using the Portfindr compared to trials using the magnet (p<0.05). The mean distance from center using the Portfinder at thickness A, B, and C was 1.84mm, 2.39mm, and 5.48mm, respectively. The dangle magnet average distance from center was 3.03mm, 3.71mm, and 6.33mm. Standard deviation values were lower in trials using the Portfindr compared
to the magnet in all tested thicknesses. Examination of the magnet’s mean force of attraction at thickness A, B, and C was 0.55N, 0.16N, and 0.04N, respectively, representing a statistically significant difference between attraction at A versus C (p<0.001).

CONCLUSION: Industry standard magnets lose significant magnetic attraction with increased distance from TE ports. Accurate port localization is important to prevent iatrogenic injury to the tissue expander during the expansion process. This benchtop study demonstrates that the Port-Findr is significantly more accurate at locating the center of the port, than a dangle magnet, through all simulated thicknesses tested. Furthermore, precision, represented by standard deviation, was better in tests using the PortFindr. More accurate and precise localization of subcutaneous ports may help reduce complications.

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A Novel Skin Whole Organ Culture Technique Maintains In Vivo Cellular Characteristics and Population Profiles

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PURPOSE: In reconstructive surgery, large areas of tissue loss represent a major surgical obstacle. Where split-thickness skin grafting and flap transfers fail, cell-based treatments represent a promising therapeutic option. Currently, cell therapies are limited to transplants from non-autologous donors, or expanded isolated skin components (e.g., keratinocytes only). However, literature suggests that keratinocytes and fibroblasts act synergistically to restore functional tissue.1 Typical culture conditions poorly mimic in vivo conditions, and skin cells change dramatically after plating.2 Thus, there is a demand for techniques to expand multiple autologous cell types without fundamentally altering cell behavior. Here, we describe methods for the ex vivo culture of skin cells that allow for efficient expansion while maintaining in vivo cell characteristics.

METHODS: Adult mouse skin was harvested and sterilized using gradient iodine solutions. Tissue was chopped with sterile scissors followed by digestion with 0.5 mg/mL Liberase™ DL (Roche). Cells were grown in DMEM/F12 with 10% fetal bovine serum and 1% penicillin-streptomycin, on polystyrene coated with 0.1% gelatin (EmbryoMax) or in 3D collagen hydrogels of varying stiffness. Morphology was assessed via imaging and analysis using Photoshop CS6 (Adobe). Relative cell populations were quantified using fluorescence-activated cell sorting (FACS). Isolation of Engrailed-positive fibroblasts (EPFs), the dermal fibroblast population responsible for wound healing (collagen deposition), was achieved by FACS of cells from En1Cre;R26mTmG mice.

RESULTS: Skin cells grown via whole organ culture on gelatin-coated polystyrene had no significant change in resident cell population density over multiple passages (2–4% fibroblasts; of non-fibroblasts, 50–60% blood cells; remainder keratinocytes; P>0.05). Upon isolation from whole organ culture, fibroblasts of a single population (EPFs) demonstrated expansion by over 20-fold in two passages. With traditional culture methods, fibroblasts demonstrate increased cell size over repeated passages; in contrast, these phenotypic shifts in EPFs were rescued by culturing in 3D hydrogels or on gelatin-coated polystyrene. Specifically, EPFs grown on gelatin-coated polystyrene demonstrated no significant change in cell size from passage (P)1 to P3 (average fold change=0.879, n=3 biological replicates, all P>0.05).

CONCLUSION: By removing many of the artificial selection pressures that cells experience in culture, we accomplished efficient ex vivo expansion of in vivo-like skin cells. Specifically, by employing whole organ culture rather than culturing cells in isolation, nonselective media, and 3D hydrogels to mimic in vivo mechanical tensions, cells retained their in vivo morphology and population densities. Autologous cell-based therapies hold increasing promise for complex reconstructive surgery, and our results signify a therapeutically relevant advancement that may enable improved cosmesis and functionality of transplanted skin organs. With similar expansion of human skin, a 4mm punch biopsy alone could yield the equivalent of over 250 mm² of skin for transplantation. In the future, we will verify our technique using epigenetic studies and machine learning-based assessment of cell morphology,