Joint Implant Surgery & Research Foundation
Chagrin Falls, Ohio, USA

Stage II Osteointegration Implant (OI) Skin Coupling Procedure

(Continuation from Case Report September 2013)

(First Reported Case in U.S.)

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Background

Patient's over health was unchanged following stage I procedure, 8/17/2013, 123 days post surgery.

The patient had been followed closely since the time of the stage I procedure. The patient was 65 years of age at the time of the Stage II procedure, 12/18/2013. Her wounds at the residual limb had completely healed without any problems by 14 days after the Stage I surgery. Her pain medication requirement was completely resolved by day 21 after the Stage I surgery. She had worn a stump shrinking compressive stalking for the majority of the time leading up to the Stage II procedure; the patient reported that the pressure on the residual limb was comforting. The scar was tender over the lateral aspect of the residual limb with a positive Tinel's Sign [1] and no palpable mass or swelling.

A planning full length standing radiograph of both limbs on a long image cassette was obtained (see figure 1). All imaging studies showed the femoral implant positioned as it had been on the day of the Stage I procedure with progressive evidence of boney ingrowth as demonstrated by the plain film images.

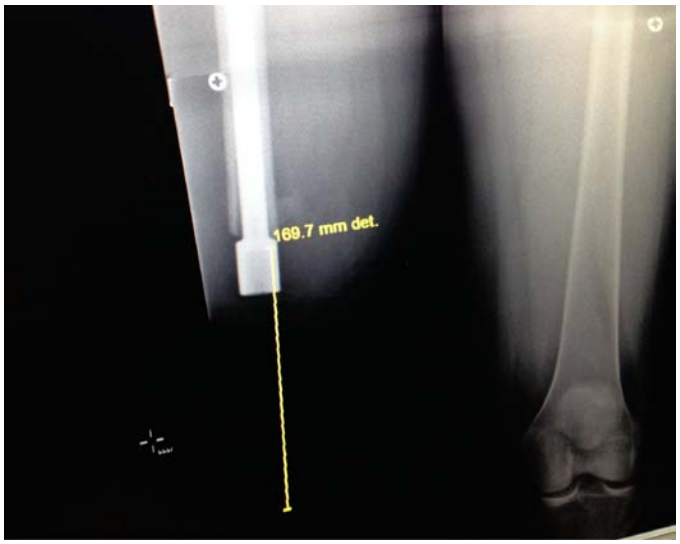

Figure 1. Preoperative radiograph used to plan stage II surgery. Demonstrates more than 10 cm space from the end of the femoral stem to the joint line of the contralateral knee.

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Day of surgery

The patient was prepared for surgery following standard protocols. She was NPO for 8 hours prior to anesthesia. Preoperative laboratory testing showed no abnormalities.

Please review Dr. Andrew Zak's article on the anesthetic method employed in this patient's surgery.

Standard prophylactic intravenous antibiotic was given, Cefazolin [2] 1gm, was administered on entering the operating room.

Positioning

The patient was positioned supine on a standard radiolucent operating table. The right lower limb was then prepped with ChloraPrep® [3] circumferentially from the inguinal fold to the terminal aspect of the stump. Impervious split drapes and paper split drapes were then applied.

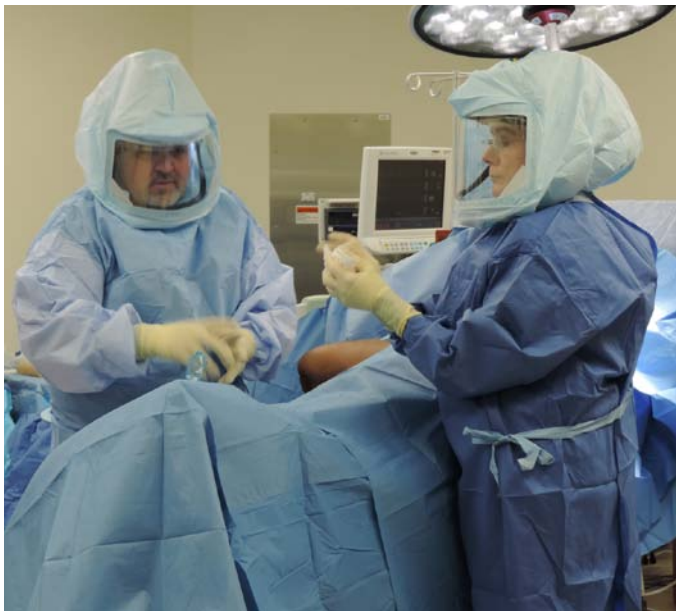


Figure 2. Draping and positioning of patient.

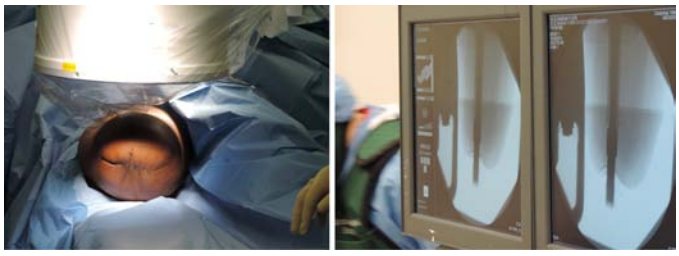


Figure 3. Fluoroscopic imaging was used during the procedure.

Fluoroscopic imaging figure 2 &3 was used throughout the procedures, total image time was 25 seconds, divided over 6 static images.

Procedure

After standard surgical skin preparation and draping the terminal stump was palpated to confirm the position of the previously implanted stem. Fluoroscopic images were used to confirm the orientation of the female coupling mechanism of the stem.

The soft tissue about the distal stem was then infiltrated by the surgeon with a 18 gauge 6 cm needle. A cocktail of Duramorph [4] 10 mg, Ketorolac Tromethamine [5] 30 mg, and Ropivicaine [6] with epinephrine in a total volume of 60 ml was injected/infiltrated into the tissues about the stem to supplement the anesthesia field block.

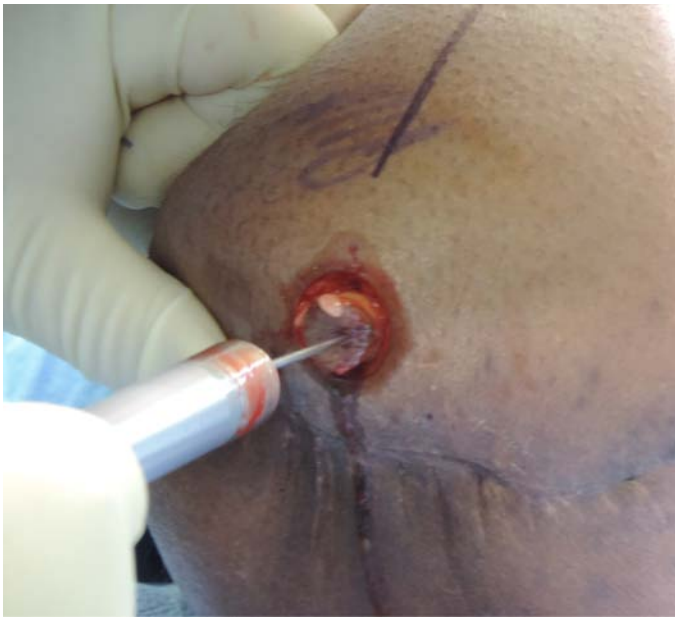


Figure 4. A 18 gauge 6 cm needle was then used to administer a cocktail of Duramorph [7] 10 mg, Ketorolac Tromethamine [8] 30 mg, and Ropivicaine [9] with epinephrine in a total volume of 60 ml.

A sterile spear tipped 2 mm k-wire was then advanced through the skin into the distal aspect of the stem by hand, metal on metal contact was palpable through the wire. The wire was manipulated to engage the internal threads of the femoral stem, engagement was confirmed with fluoroscopic images as well.

A 18 mm cannulated circular cutting instrument was then advanced over the 2 mm wire until metallic contact was palpated.

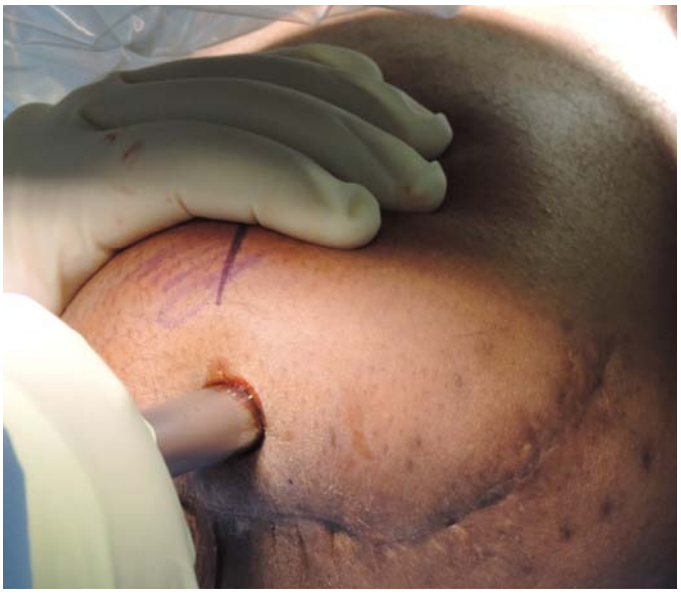


Figure 5. A 18mm circular hand cutting trephine was used to expose implant.

The device was advanced with hand pressure along the axis of the wire through a steady twisting motion. The path from the skin to the stem was then cleared of remaining soft tissue with a #10 scalpel. Electrocautery was used to obtain homeostasis. Total blood loss during this procedure was less than 25 ml.

A depth gauge was then passed down the path and engaged into the female coupling. The thickness of soft tissue from the end of the stem to the skin surface was measured and found to be 2 cm.

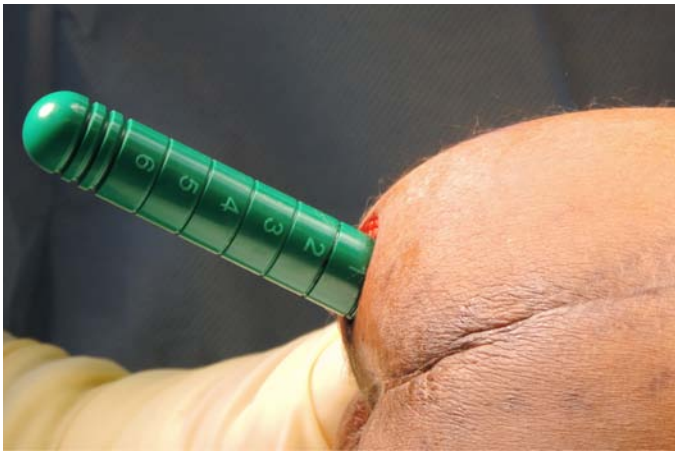


Figure 6. A depth gauge was then passed down the path and engaged into the female coupling.

The 2 cm coupling device was then selected and advanced into the female coupling.

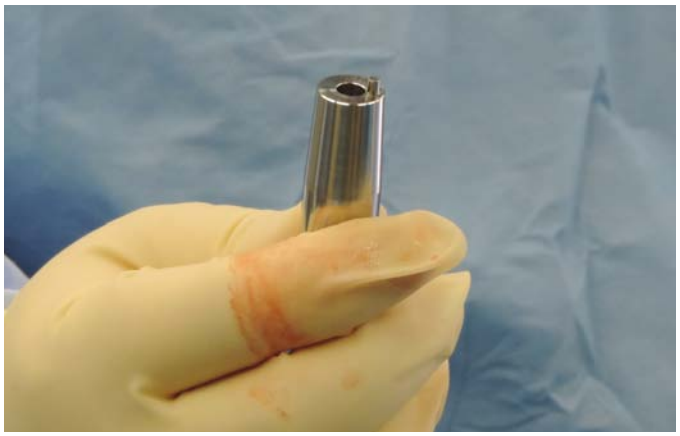


Figure 7. The 2 cm coupling device was then selected and advanced into the female coupling.

The tapered portion was gently manipulated to engage the stem female opening. The shear pin was oriented at the 6 o'clock position to align with the stem's matching receptacle. The device engaged with minimal effort. A locking screw was then advanced into through the coupling device into the threads of the femoral stem. The screw engaged without incident and was advanced until it was felt to be tight enough. Fluoroscopic imaging confirmed the implant position and alignment was consistent with visual inspection of the device.

Figure 8. Implant positioning was checked with Fluoroscopic imaging.

A silicon sleeve was then passed over the coupling device to create a barrier between the soft tissues and the implant to prevent the formation of a tight seal.

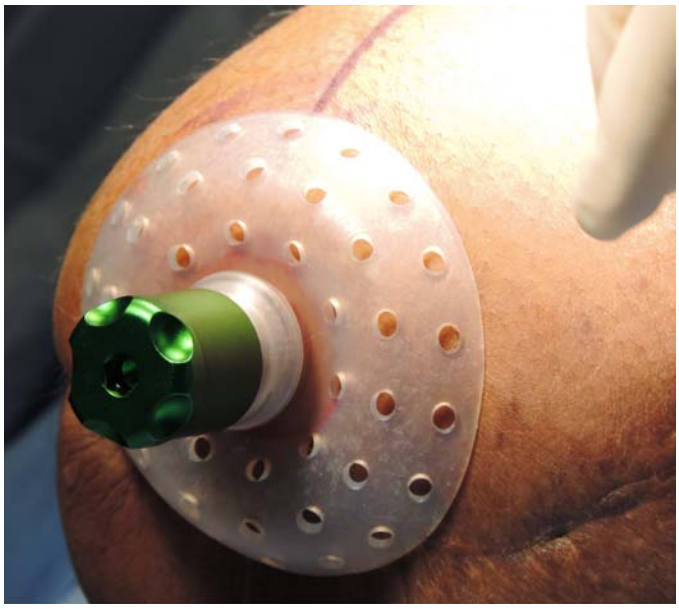


Figure 9. Silicon sleeve in place.

The intended goal was to create a stoma through which the coupling device passes from the skin to the stem. A series of end protectors were then attached to the coupling device to prevent damage to the implant during the rehabilitation therapy to follow.

Dressing

A dressing was then built in multiple layers. The skin implant level was dressed with a piece of Sliverlon® [10] dressing material cut to slide over the coupling device, measuring roughly 4 cm x 4 cm.

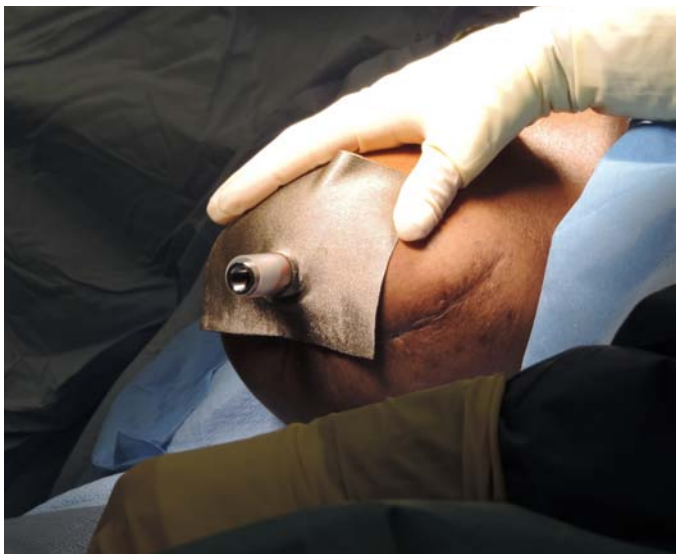


Figure 10. Silverlon dressing applied.

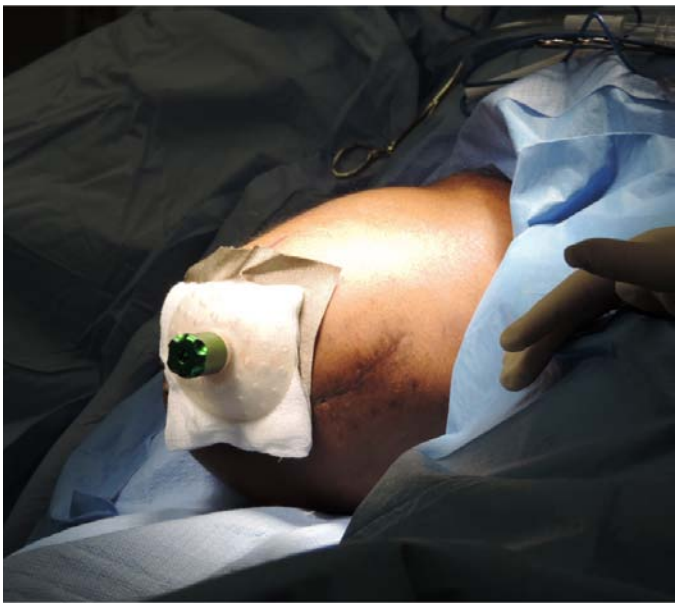


Figure 11. 4x4 dressing applied.

This was then reinforced with sterile 4 cm x 4 cm gauze sponges, 6 layers thick. A silicon basket was then placed over the stem to compress the sponges and firmly secure their position.

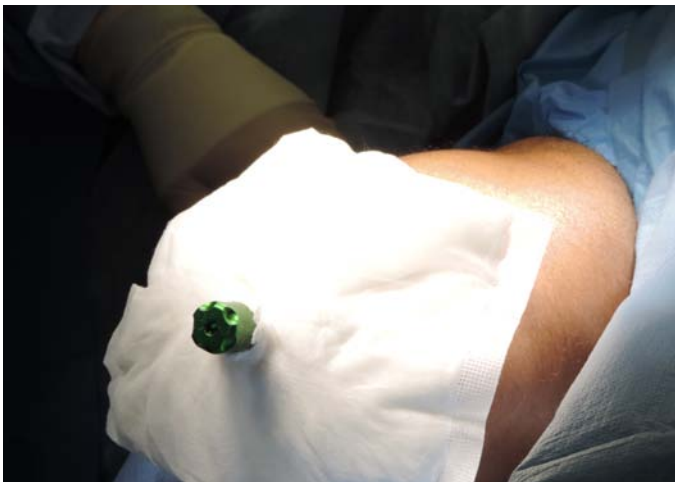
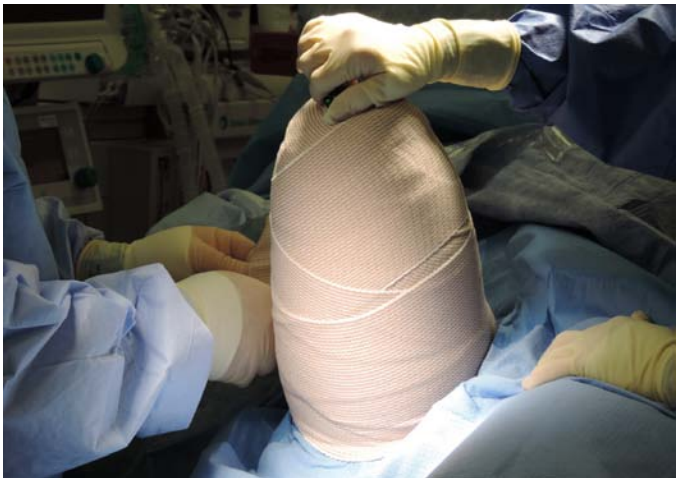


Figure 12. An ABD dressing in place.



The entire dressing mass was then over warped with a sterile 10 cm compressive ace wrap, applied in a figure of 8 amputation compression technique.

Postoperative Care

The patient was then held on a post surgical care ward for 23 hours after surgery. She received 2 additional doses of cefazolin per standard surgical protocol for all orthopedic procedures. Her pain was controlled, a personal controlled anesthesia unit had been made available and was used for a total of 3 self administered doses of 0.2 mg hydromorphone2 over the 8 hours following surgery. Ketorolac3 injection was available as a back up medication for break through pain but was not needed. She stated that she had no pain at 20 hours post surgery, the next morning.

The dressing was changed at the bedside the next morning and there was minimal staining (see figure). The patient was counseled on wound care and dressing methods. She was advised that she could shower and allow soapy water to flow over the wound/prosthesis area but not to submerge the area under water for an additional 2 weeks. The patient was advised that the Silverlon® dressing could be recycled by cleaning in water, being applied in a moist yet not wet state. The Silverlon® dressing can be used and recycled with simple water baths for up to 30 days per the manufacturer's recommendations.

Physical therapy ambulated the patient to confirm safety and stability with a walker. The patient was discharged to home for further out patient care. Physical Therapy was started 2 weeks after surgery, please refer to separate report for the rehabilitation protocol to follow.

A final report will be presented in approximately three months as follow up demonstrating the patient fitted with final leg prosthesis and her progress.

Both patient and development team remain very optimistic that this alternative treatment will provide an improved functional outcome as compared to traditional socket prosthesis.

References

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