



CASE REPORT

Osseointegration Implant Post Coupling With External Prosthetic Limb

Continuation of Previous Case Reports “Stage III”

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Abstract

An ongoing update of the progress case report for the first patient treated with the Longitude™ osseointegration prosthesis implanted in an amputated residual femur is presented. The patient was given an intensive physical therapy program of strengthening and conditioning in anticipation of coupling to the external prosthesis. A custom prosthesis was fabricated based on the Plie' 2.0 microprocessor knee system. The patient was then successfully trained on use and care of the prosthesis for ambulation without any complications.

Keywords: Amputation, Osseointegration

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Background

As previously reported, the index patient for the Longitude™, Osseointegration implant (OI) is a 65-year-old female. Longitude™ is a prototype custom OI prosthesis system manufactured by Signature Orthopedics USA, Las Vegas, Nevada, USA. The second stage procedure, coupling of the femoral stem implant through the skin with the abutment device was completed on 12/18/2013. The treatment team now presents the patient's progress through coupling with an external limb prosthesis.

An intensive therapy program was initiated in anticipation of progressing to wear and use of the OI implant coupled to an external limb prosthesis. The process of fabrication of a prosthetic limb was started immediately following the completion of the stage II procedure.

there were few pain related issues following the second surgery and subsequent rehabilitation program. All pain medications were discontinued by the 5th week post-surgery. Phantom limb pain had resolved prior to the second stage surgery. Phantom limb sensation has become less symptomatic though it is still present.

The stoma at the terminal aspect of the residual limb, at the implant skin junction, was dressed on a daily basis. The patient was encouraged to take over all dressing and wound care related activities. As anticipated, the stoma initially bled for the first 10 days following surgery. A dressing consisting of a 4 cm x 4cm segment of Silverlon with a central post cut out was applied and changed twice daily. This was backed by absorptive sterile gauze dressing (see figures 1 and 2). Eventually the patient began adapting a commercially manufactured disposable sterile pad mar-

Treatment following stage II

Pain control was easily covered with oral hydrocodone;

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Figure 1: The stoma with silicon basket and dressing in place.



Figure 2: Anteroposterior view of the stoma.

keted for lactating females. The breast pads are circular, conical and fit the silicon basket designed for this function. A simple modification of cutting a hole for the central post is required. As the stoma matured, the drainage diminished to a minimal volume of serous fluid.

On day 32 following the second surgery, increased pain with purulent drainage was noted at the stoma site. The skin did not have any erythema about the stoma or lymphatic streaking present. There was no adenopathy. What had been a serous drainage increased in volume and a foul odor developed. The abutment device was initially covered with a silicon sleeve at the skin implant junction. The sleeve was removed in the outpatient setting without any difficulty under a local anesthetic. Stoma care was altered to include twice-daily cleansing with hydrogen peroxide. The patient was given a 10-day course of oral Cephalexin 500mg every 6 hours. The drainage returned to clear serous material without odor and the pain resolved completely within 4 days of starting oral antibiotics. The patient elected to continue twice-daily hydrogen peroxide cleaning from that day forward.

During the recovery period following the surgery, the patient reported emotional distress and anxiety. Though she had been counseled on the planned outcome extensively, the reality of the metal abutment protruding through the skin of the limb was more psychologically distressing than had been anticipated. Through many counseling sessions with the operative surgeon, the patient adjusted to the implant and she returned to baseline emotional status. A referral to a mental health professional was offered but declined. The patient declined all offered antidepressant medications.

During the period of time following the second surgery, an individual within her community who had undergone an OI implant in another country contacted the patient. The advice and encouragement provided by another OI patient was invaluable. Her emotional well being as well as progress with coupling and weight bearing was improved by the peer-to-peer level communication and support.

Therapy prior to coupling

While awaiting fabrication of the final external prosthesis, the patient initiated a prescribed therapeutic exercise program. The goals of therapy were to maximize the residual limb strength and flexibility at the hip, to maximize the intact limb's strength, flexibility and proprioception and to improve overall balance while also increasing the patient's aerobic capacity.

Strength and conditioning of the residual limb was addressed through a series of prone lying on a padded bolster (see figure 3). Isotonic hip abduction and extension exercises with resistance applied through cuff weights or TheraBand™ in both the laying and standing positions was also used (see figures 4, 5 and 6). Balance was addressed through single limb standing on both stable and



Figure 3: Image of the patient practicing prone extension stretching while laying face down.



Figure 4: Isotonic hip abduction applied via TheraBand™ in standing position.

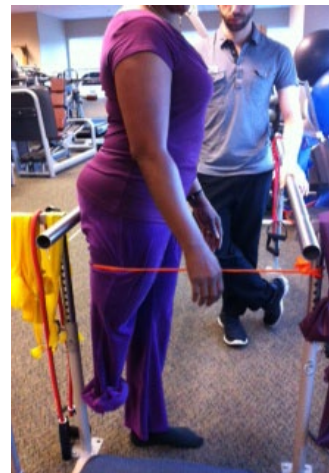


Figure 5: Isotonic hip extension applied via TheraBand™ in standing position.



Figure 6: Isotonic hip abduction applied via TheraBand™ in lying position.



Figure 7: Image of the patient strengthening balance via single limb standing on intact limb.



Figure 8: Image of the patient strengthening the intact limb via leg press exercises.

unstable surfaces without upper extremity support to maximize limb proprioception (see figure 7). The strength of the intact limb was improved with resistance exercises on the leg press (see figure 8). Aerobic fitness was improved through a program of upper body ergometry and recumbent cycling.

Prosthesis design and fabrication

A custom compression garment with a terminal hole for the OI implant was worn most of the time while awaiting fabrication of the external prosthesis.

To aid in the transition to the final prosthesis, a “stubby trainer” prosthetic device was fabricated (see figure 9). This device consisted of a rocker bottom terminal sole with a non-skid rubber surface at the level of the contralateral knee. The stubby trainer was used to begin weight bearing through the OI construct on a hydraulic platform table set at the appropriate height. The patient could bear 50% weight without discomfort immediately on fitting (see figure 10). She rapidly progressed to full weight bearing through the stubby trainer within 2 weeks. The only complaints during this phase were related to hip muscle cramping and fatigue.

During the stubby training phase it was noted that the direct skeletal coupling resulted in a voluntary 90° arc of motion in the internal and external rotation plane. This factor was taken into consideration during the fabrication of the final limb prosthesis.

The final external limb prosthesis was fabricated with the following components. The abutment device was fitted with a terminal adaptor that linked with an offset coupler. The offset coupler was designed to allow for 360° of rotation with up to 15mm of offset (see figures 11, 12 and 13).

The prosthetic knee system selected was the Plie' 2.0, manufactured by Freedom Innovations (See figure 14). The Plie' 2.0 knee is designed for K3 or K4 level performance, with enhanced durability features. One key feature of the Plie' 2.0 is the fact that it is water resistant. Additionally, the Plie' 2.0 knee microprocessor uses an externally exchangeable battery system, allowing the user to have back-up charged batteries while active in the community. Other microprocessor-powered knee systems have an integrated battery system that cannot be changed by the user, requiring the time consuming process of plugging into an external power source for recharging.

The prosthetic ankle was built with a 4R39 torsion adaptor, manufactured by Otto Bock, Duerstadt, Germany. This component was selected to allow for up to 12° of rotation torsion with the foot securely planted to the

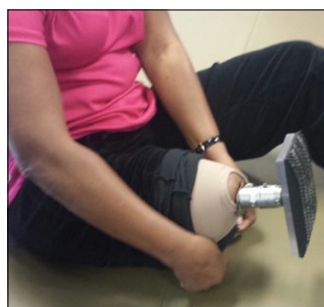


Figure 9: The stubby trainer prosthetic device is attached to the patient in order to begin weight bearing via the osseointegration construct.



Figure 10: The patient bearing weight on a hydraulic platform table set at the appropriate height.



Figure 11: Anteroposterior view of coupler.



Figure 12: Medial view of coupler.



Figure 13: Posterior view of coupler.



Figure 14: Image of the final prosthesis device.

ground. The prosthetic foot selected was the Multiflex Endolite™, manufactured by Blatchford Inc, Basingstoke, UK. The patient had requested the option of an adjustable heel angle to allow for footwear other than flat-soled shoes. The Multiflex Endolite foot is adjustable for up to a 2.5 cm heel lift.

Post coupling therapy program

The patient was fitted with her external limb prosthesis and took her first steps using parallel bars for sup-



Figure 15: The patient training with the coupled final prosthetic device.

port with no problems, roughly 4 months following the second surgery. She initially reported cramping and pain in the hip musculature. Peer to peer advice and encouragement was given, the patient was counseled that this was a normal sensation and had been experienced by others on initial weight bearing. She was able to remain ambulated with upper limb support on parallel bars for a distance of 3 m., turn and then returned 3 m. (see figure 15). She was able to couple and uncouple the prosthesis from the abutment after 10 minutes of instruction without any difficulty.

The goals of physical therapy with the external limb prosthesis were to improve endurance and strength while continuing to work on balance. A prescribed exercise program with the prosthesis was designed to work through gait on level surfaces, uneven surfaces, stairs, and curbs with a long-term goal of ambulation without any assistive device.

The prosthetic offset coupler was initially set at 0/0, no rotational correction, and no offset correction. As the patient ambulated, she reported single limb stance on the prosthetic limb associated with a sensation of medial shifting center of gravity causing her to feel off-balance. An adjustment of 5mm of lateral offset with 0 rotation was then set and the patient reported feeling balanced with gait.

The patient began wearing the prosthesis under supervision of the prosthetist for the first 3 hours of use over 2 therapy sessions. She then advanced to progressive wear as tolerated, increasing duration of wear on a daily basis with a goal of full time wear while ambulatory throughout her activities of daily living. As of this publication she has been routinely using the prosthesis in the home, bracing against furniture or using a walker for support. The gait pattern has progressed to a fluid heel toe motion with the microprocessor deactivated in a passive mode. She has begun training with the microprocessor activated, though not yet fully using the advantage of the computerized knee to its full potential. The patient reports wearing the prosthetic limb OI construct for 4 to 6 hours per day in therapy and during home exercise.

Initially the patient experienced back pain as well as

pain in the hip musculature. With progressive training and exercise the pain has improved. Peer to peer advice has been invaluable and the patient is now training through these pains. The only medications required for pain during this phase have been over the counter NSAIDs. Of note she has not reported thigh pain or pain at the stoma with or without the external prosthesis attached.

As reported in other OI implant systems, the patient reported feeling skeletal vibrations with heel strike of prosthetic foot to floor impact, a sensation that has been termed “osseoperception” in prior reported literature.

Discussion

All aspect of this patient’s care has been designed with the goal of coupling the OI implant to an external prosthesis. Through a collaborative effort between the operative surgeon, the prosthetist, physical therapist and the patient, a coordinated program was developed and implemented. Peer to peer mentoring and advice has been beneficial to the patient’s progress. The patient experienced minor setbacks along the course of treatment. The patient has progressed to using the OI coupled prosthetic limb in activities of daily living. With continued effort, the treatment team is confident the patient will achieve independent functions. Prior to the first surgery the patient expressed a desire to return to occupational function as a health care professional. With continued focus therapy, we are cautiously optimistic that she will attain that status.

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