Percutaneous Osseointegration Prostheses:
A New Solution for Transfemoral Amputees

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Abstract

Background/Purpose: the aim of this paper is to explore percutaneous osseointegrated prostheses as a viable option to compete with the standard of care socket prosthesis as it relates to pain, comfort, and function. A case study is presented to show the effectiveness of the procedure as well a review of ten articles from the literature.

Case Description: a 47 year old male who sustained a right above the knee amputation in addition to several other injuries from a motor vehicle accident in 1985. He had great difficulty and pain associated with a socket prosthesis, so in April 2013 he underwent an osseointegration surgery in Sydney, Australia and reports increased levels of function with the new system.

Outcomes: four databases (PubMed, Cinahl, Cochrane, and PEDro) were searched, and ten articles were selected for analysis based on the patient population and demographics. Most of the literature reports for patients experiencing pain and discomfort with a socket prosthesis, they can benefit with increased endurance, range of motion, aerobic efficiency, and agility when using osseointegration. However, others experienced failure with infections or implant loosening being the most common reasons to remove the implant.

Discussion: osseointegration is a surgical procedure that began in 1990 in Sweden. Now it is being practiced all around the world. The United States is currently in the process of performing clinical trials to move towards approving the procedure. Until then, American citizens must travel out of the country and pay for the procedure out of pocket with little to no help from insurance companies. Research is ongoing, but the current research is very promising for the population that does not benefit from the conventional standard of practice care.
SECTION 1: Background and Purpose

Traditionally, amputees have been fitted with prostheses via a socket attachment system. The socket is customized to fit around the amputee’s residual limb and is designed to promote weight bearing through specific regions. This socket is usually secured to the residual limb and suspended with silicone sleeves utilizing direct suction or a pin (Tranberg, et.al.). For most amputees, this system works fairly well and allows for adequate suspension of the prosthesis. However, this system may fail amputees who fall within specific populations. Following are the three main circumstances where a standard prosthesis may not function optimally. First, patients with short residual femur length have difficulty with the socket due to insufficient skin being available to anchor the prosthesis with the silicone sleeve (Shelton, et.al.). Also, the socket causes discomfort and restricts range of motion since it is close to the pelvic area (Tranberg, et.al.). Second, amputees with heterotopic ossification also experience severe pain while weight bearing in the socket (Webster, et.al.). Heterotopic ossification usually results from trauma where a piece of new bone grows near the periosteum of the femur. When the amputee weight bears, the bone tissue compresses muscle and skin against the hard socket causing pain. Third, weight bearing in a socket causes several issues due to heat and skin wearing (Lee, et.al.). Heat causes the residual limb to fluctuate in size due to swelling that is typically controlled with socks of differing thickness. However, this often results in sweating of the residual limb which can lead to skin breakdown and infection as well as pain with weight bearing. While this is certainly not an exhaustive list, these are some of the more typical populations where the traditional socket-based prostheses do not work, and another treatment option is indicated to address their decreased function and medical concerns.

In 1990, a group of physicians in Sweden performed the first osseointegrated treatment to address this population where the standard of care (socket based prosthesis) does not work (Branemark, R., et.al.). Osseointegration (OI) utilizes commercially pure titanium that is textured to allow bony growth to cement it further in the intramedullary space of the femur. The process requires two surgeries. The first is to place the
fixture into the femoral intramedullary space of the residual limb. Once the soft tissue is healed then the amputee can continue to utilize the traditional socket until the second surgery. The second surgery installs the abutment as well as soft tissue surgery to create the stoma. The prosthesis is then attached to the abutment using a common Allen wrench. Currently, this surgery is only offered in Europe, Australia, and Africa, requiring patients not in these countries to pay out-of-pocket and travel fare for this treatment. However, the George E. Wahlen Department of Veterans Affairs Hospital in Salt Lake City, Utah was granted one million dollars to perform clinical trials on ten above the knee amputees (AKA) in an attempt to provide this procedure within the United States (Webster, et.al.).

Several different styles of surgical and rehabilitation protocols have been developed. Sweden has developed the Osseointegrated Prostheses for the Rehabilitation of Amputees or OPRA (Hagberg, K., et.al., Branemark, R., et.al.). Surgeries are six months apart with rehabilitation lasting twelve to eighteen months after the second surgery, depending on bone integrity. In May 2009, the Netherlands developed the Integrated Leg Prosthesis, also known as osseointegration prosthesis or OIP (Van de Meent, et.al.). The rehabilitation program for OIP is six to eight weeks. The United States of America is currently attempting to develop its own protocol to be used with the VA research study (Webster, et.al., Shelton, et.al.). A key difference is that instead of having threads on the implant to screw into the intramedullary space, each implant will be custom made to fit inside the intramedullary space of each unique residual femur. This allows for greater surface area to hold the implant in place and lessen the risk of loosening. This also allows for weight bearing to be performed hours after surgery to stimulate bone growth instead of two weeks of bed rest which is the norm for the European procedures. The intervention currently used by the Osseointegration Group of Australia will be described in greater detail later in the paper.

There are several advantages associated with osseointegration. First, is increased range of motion due to a lack of impediment from a socket (Tranberg, et.al.). Second, there is a lack of skin or residual limb problems from sweating, sores, and discomfort. Third, donning and doffing utilizes an Allen wrench and can
be done in seconds as opposed to minutes. Fourth, because it is attached via an Allen wrench, the same fit and orientation is assured every time (Lee, et.al.). When donning a socket, it is significantly more difficult to ensure that the socket is not rotated which causes inappropriate pressures that can result in skin breakdown. Fifth, a phenomenon known as “osseoperception” has been noted with these implants (Shelton, et.al.). Because the implant is directly mounted into the bone then the vibrations of the prosthesis hitting the ground is transmitted into the femur much like how a healthy leg operates. This allows the amputee to differentiate different surfaces as well as increase proprioception. Research also indicates that due to the central sensory feedback, osseoperception can also assist with phantom pain and sensation (Lundberg, et.al.).

Like all surgeries, there are risks associated with this procedure. First, the most problematic issue is the high infection rates at the skin-implant interface where the abutment protrudes through the stoma. Infection rates have been reported to be between 18-50% depending on which source is examined. Typically, most infections are minor and can be treated with a ten day course of antibiotics. However, if there is a deep infection that reaches the bone, then the entire implant must be removed and a heavy course of powerful antibiotics must be utilized (Webster, et.al.). Second, there is some risk of the implant loosening from the femoral intramedullary space causing severe pain and a decrease in prosthetic function (Winson, et.al.). If this happens, the entire implant must be removed. Implant loosening has decreased in incidence as the rehabilitation program and implant design continues to be developed. Contraindications for osseointegration include severe vascular diseases, ongoing chemotherapy treatment, taking potent immunosuppressants, growing children, and patients over 70 years of age (Hagberg, et.al.).

No statistical data is available on how many transfemoral amputees experience pain or discomfort with their prostheses. Osseointegration is a viable option for this population. While there are risks associated with this procedure, there are benefits as well. The PICO question presented in this paper is as follows: For patients with above the knee amputations, does percutaneous osseointegrated prosthesis
improve ambulatory independence and efficiency as compared to traditional socket-based prostheses?

Due to the rarity of this procedure so far, the PICO question was formulated and research was performed before a case study was found via a osseointegration support website. The subject in the case study has already had the procedure performed, so the PICO question is now considering whether this was an appropriate move for him. This paper is also meant to be educational for both patients and healthcare providers.
SECTION 2: Case Description

As stated above, the case study portion of this paper was provided by a man who will be known as F.H. He was contacted through an osseointegration support group found online. As such, most of the information is retrospective and based off of his experiences as well as information found from the facility where he had the surgery.

F.H. was involved in a motor vehicle accident in May 1985 when he was 17 years old. He sustained injuries in both legs and pelvic fractures. One week after the accident, he had an above the knee amputation due to a gangrene infection of his knee. He was fitted and utilized a conventional socket based prosthetic until 2013 when he travelled to Sydney, Australia and underwent the osseointegrated procedure. Now, he reports that the operation was an enormous success and fulfilled his goal to live his life without discomfort and pain from his amputated side. A condensed timeline is shown below of major events.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>May 1985</td>
<td>Motor vehicle accident</td>
</tr>
<tr>
<td>One week after MVA</td>
<td>Above knee amputation due to gangrene infection</td>
</tr>
<tr>
<td>1986</td>
<td>Rehabilitation complete, patient ambulating with socket prosthesis</td>
</tr>
<tr>
<td>April 2013</td>
<td>First Surgery performed in Sydney, Australia</td>
</tr>
<tr>
<td>May 2013</td>
<td>Second Surgery</td>
</tr>
<tr>
<td>3 days after 2nd Surgery</td>
<td>Rehabilitation program begins</td>
</tr>
<tr>
<td>10 days after 2nd Surgery</td>
<td>Ambulating on implant using forearm crutches and lightweight training knee</td>
</tr>
<tr>
<td>24 days after 2nd Surgery</td>
<td>Microprocessor knee prosthetic and using single forearm crutch</td>
</tr>
<tr>
<td>July 2013</td>
<td>Utilizing a cane to ambulate</td>
</tr>
<tr>
<td>August 2013</td>
<td>No assistive device necessary for ambulation and wears prosthesis for full day without complications</td>
</tr>
<tr>
<td>March 2014</td>
<td>10 months post-surgery at the time he was contacted and interviewed for this paper</td>
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EXAMINATION: History, Systems Review, and Tests & Measurements

All information was provided from questions and answers with the patient via e-mail and his blog from when he was undergoing surgery and rehabilitation. Please note that the surgical procedures, the
implant design, and the rehabilitation protocol are the intellectual property of the Osseointegration Group of Australia.

**Initial Communication:** March 26, 2014 via an email response from an osseointegration support group website.

**General Demographics:** 46 year old male of Hispanic ethnicity.

**History:**

As explained above, F.H. was involved in a motor vehicle accident in May 1985. His initial rehabilitation took one year before he was able to walk with a prosthesis. His rehabilitation was complicated by injuries incurred at the accident including removal of dorsiflexors resulting in dropfoot on the left lower extremity that is currently being corrected using an ankle foot orthosis.

The first socket he used utilized direct suction. The prosthesis was constructed of wood with the knee being a Mauch Unit. The foot was a simple single axis comprised of rubber and wood. After his osseointegration surgery, he now uses the Integral Leg Prosthesis (ILP) and uses a microprocessor for the knee portion.

**Surgeries:** Besides the amputational surgeries, patient has required two residual limb revisions.

**Social and Family History:**

F.H. lives in a two story house which requires utilizing a step-to pattern to ascend and descend the stairs. He lives with family members. He currently is employed as a consultant who requires little physical activity. He also states that he doesn’t participate in sports, so most of his physical activity comes from activities of daily living and participation in community ambulation.

**Patient Values, Goals, and Expectations:**

F.H. stated the following when asked what his goals are today and he replied, “My goal today is to raise awareness with OI technology, letting amputees know that it is a viable option for a number of them without vascular issues.”
F.H. described that initially following his amputation, he thought that the socket system was primitive and didn’t work, and had a concept for osseointegration. When he heard about the technology, he researched the different protocols and chose the Osseointegration Group of Australia. He is very vocal that all the different procedures are valid, but he went to Australia based on the shorter rehabilitation time of three months and the team approach that this group is known for.

EVALUATION

Diagnosis

Guide to Physical Therapy Practice:

- Pattern 4J: Impaired Motor Function, Muscle Performance, Range of Motion, Gait, Locomotion, and Balance Associated With Amputation

ICD-9 Codes:

- Phantom Limb (syndrome) 353.6
- Other acquired deformities of limbs 736
- Abnormality of gait 781.2
- Other symptoms involving nervous and musculoskeletal systems 781.9

Narrative Assessment

Patient is a 46 year old male who suffered a motor vehicle accident 29 years ago which resulted in trauma to bilateral lower extremities and pelvic fractures. Patient has damage to the dorsiflexor muscles on the left lower extremity which is corrected with an ankle foot orthosis as well as an above the knee amputation on his right lower extremity from a gangrene infection of the knee. Patient experienced multiple problems with the direct suction socket that included skin problems, gait abnormality, impaired balance, and particularly pain with ambulation as well as sitting. In 2013, he sought a new treatment in
osseointegration and now lives without pain and is able to wear his prosthesis all day without any complaints.

Clinical Judgments and Problem List

Impairments, activity limitations, and participation restrictions before OI surgery:

1. Unable to wear prosthesis long-term without pain. Pain averaged 8/10, but “most times 10 when in socket.”
2. Skin infections, rashes, and abrasions from socket.
3. Unable to perform single leg balance for more than 3 seconds on R LE.
4. Difficulty with heat rash and keeping prosthesis on when residual limb sweats.
5. Unable to sit comfortably with prosthesis applied.
6. Unable to ambulate long distances due to pain and skin issues.
7. Phantom pains with significant intensity occurring since amputation that starts in low back and ending in the foot area of his missing limb.

Prognosis and Goals

The goals and prognosis presented here are from the author of this paper and are based off of information gathered from the patient and his blog. The following is what the author would have written if she had assessed the patient immediately after the second surgery and his initial evaluation.

Goals:

1. Patient will weight bear 50% body weight within 1-2 weeks using a short prosthetic limb in standing.
2. Patient will ambulate with light weight training leg and utilizing forearm crutches for 500 feet with no LOB in 2-4 weeks.
3. Patient will progress to one forearm crutch utilizing a leg of his choice for 1000 feet with no LOB in 4-8 weeks.
4. Patient will ambulate with no assistive device and preferred prosthesis for 1000 feet with no LOB in 3-6 months.

5. Patient will demonstrate independently residual limb wound care within 2 weeks to decrease risk of infection.

6. Patient will demonstrate independently donning/doffing and operation of prosthetic limb in one month.

Prognosis was good based on the following factors:

1. Patient had high motivation/compliance for the rehabilitation process.

2. He had an excellent support group with family and friends.

3. During the first surgery, patient was found to have an exceptionally strong bone for a residual limb which bodes well for implantation.

4. Patient’s age was favorable for rehabilitation.

5. Patient was overweight for the surgeries, but was in the process of weight loss before and after the surgeries.

The typical rehabilitation for this implant is 3-6 months to be able to ambulate without an assistive device.

**INTERVENTIONS**

All interventions listed are the intellectual property of the Osseointegration Group of Australia where the patient was treated.

Interventions Based on Setting:

**Medical/Surgical:**

- April 17, 2013: first surgery with the OI implant secured into intramedullary space of the femur. Bone was assessed to be strong which increases probability of a good prognosis. Surgery was followed by three days in hospital to treat with intravenous antibiotics and stabilization.
significant effort was devoted to pain management after surgery and as an attempt to “rewire” the brain to diminish phantom pain.

- May 15, 2013: second surgery with abutment attached to the implant of the first surgery. No complications arose. Patient again spent three days in the hospital for medical stabilization, pain management, and antibiotics.

**Gym/Overall Fitness:**

- For the one week prior to second surgery, patient attended a local gym owned by an OI patient who is a member of the team approach. Fitness routine emphasized weight loss and core strength.
- For the two weeks after second surgery, gym workouts were contraindicated in order to reduce risk of infection. After two weeks, patient began attending workout routines again.

**Rehabilitation:**

- May 20, 2013: first day of physical therapy. Patient stood on implant for first time utilizing a short prosthesis. A bathroom scale was placed on several boxes to measure force on prosthesis. Patient was allowed to load 40 pounds on the first day for 5 minutes with 4 repetitions. He was given the home exercise program to repeat this process nightly at home.
- May 21, 2013: second day of physical therapy. Weight bearing increased by 11 pounds. Patient also utilized a lateral rocking motion to stimulate the piezoelectric effect to stimulate bone growth into the implant.
  - Every day, weight bearing increased by 11 pounds until patient reached 50% of his body weight.
  - Physical therapist also utilized a sonogram for biofeedback in stimulating select muscles.
- May 27, 2013: patient walked for first time in parallel bars using a lightweight leg. This prosthesis reduces downward pressure and pain.
Patient experienced no pain with weight bearing. However, he did experience muscle pain when ambulating. Patient educated that certain muscles are not used within a socket. However, now that his gait is more natural with the force being directed through the femur, those atrophied muscles are experiencing hypertrophy and need to build up strength. This is normal for OI patients, and F.H. struggled with this issue until it resolved two months later.

Home Exercise Program: walk several times per day in 5 minute intervals at home.

- May 29, 2013: 12 days post operation and ambulating with two forearm crutches. Patient was able to demonstrate increased hip range of motion as compared to baseline utilizing a socket prosthesis.
- June 5, 2013: ambulating with one forearm crutch.
- June 19, 2013: patient returned to United States and continued rehabilitation on his own. At one point, he was ambulating excessively at a conference and experienced hip pain. He asked his physical therapist in Australia about it and she speculated that he had anterior hip joint impingement. He stopped physical activity for a few days until pain diminished. Patient did not report any other complications following this event.
- August 2013: patient was able to ambulate without an assistive device. He reported that he was able to keep prosthesis on all day without any pain or discomfort. He still has difficulty ambulating due to his injuries on his left lower extremity, but feels that his quality of life has significantly improved since surgery.
- Several months after the surgery, patient experienced osseoperception for the first time when walking across gravel and realized that he could differentiate between gravel and concrete without visual confirmation.
Wound Care:

- 1-2 Weeks after second surgery, dressing changes performed by medical staff after physical therapy sessions. Patient trained in wound care utilizing normal saline to clean the area before bandaging. Patient was able to independently care for his wound after this time period.
- May 20, 2013: stoma is clean and shows signs of healing. No pain or discharge noted from wound, but itching commenced that day.
- May 27, 2013: stoma secreting a clear liquid which is normal for post-OL surgery. The clear fluid is the body’s natural defense around the stoma and acts much like saliva of the mouth to stave off infections to the open site. The implant is also designed to prevent major bone infections based on shape at the stoma. Patient assured that secretions will decrease with healing.
- June 23, 2013: patient reports that residual limb continues to vary in size due to swelling and differing amounts of discharge from the stoma.
- January 2014: discharge from stoma presents as dry mucus in the morning. Patient treats stoma with washing the area with soap and water during his daily shower. He did not report any problems with infections.

Outcomes

By August 2013, patient was able to ambulate without an assistive device. He also was able to keep prosthesis applied all day without pain or discomfort. He no longer has the skin breakdown and infections that he experienced with the socket. He is independent with his stoma care, and has not experienced any major infections. He shows increased range of motion now as compared to before the surgery. Patient still ambulates up and down stairs with a step-to gait pattern due to injury of his other leg and use of AFO. He also still experiences phantom pain. However, he also has experienced
osseoperception and can differentiate walking surfaces of carpet, gravel, and concrete with gravel providing the most biofeedback.

F.H. reports a definite increase in quality of life after the surgery. He experiences less pain and more mobility. He also stated that before his OI surgery, his contact with the amputee community was limited. However, now he is a major advocate for OI technology and wishes that other amputees know that it's a viable option. He said, “I am more than satisfied with living life with an OI implant. Life doesn't surround whether or not I am in socket pain or if it is too hot outside. Osseointegration is like having my leg back again and I don’t have to take the leg off until I go to bed at night ever. Osseointegration is not without complications, but the technology is safe and a viable option for amputees who experience socket related problems. Stoma infections do occur from time to time, but I never had one myself. Stoma infections are treated the same as infections of other body stomas (eye, nose or mouth), with oral antibiotics and are not serious in nature. An implant patient can always go back to a socket system without the loss of bone and can also utilize a socket with an OI implant for sporting activities if they wanted to.”
SECTION 3: Evidence Based Analysis

Methodologies of Search:

Databases Used:

1. PubMed
2. Cinahl
3. Cochrane
4. PEDro

Key Words

1. PubMed: osseointegration and prosthesis and (transfemoral or above knee amputate) yielded 29 results.
2. Cinahl: osseointegration and prosthesis yielded 220 results.
3. Cochrane: osseointegration yielded 1 result.
4. PEDro: osseointegration yielded 0 results.

Of the 250 results, 220 were excluded upon title review due to being a different medical procedure (dental implants and arthroplasty).

30 articles remained and were subjected to an abstract review.

10 articles were selected for article review.

20 articles were excluded for not involving humans or large mammals and for not having functional outcomes.
Level of Evidence: 3b

Purpose:
The aim of the study was to determine perceptions and acceptance of osseointegration as a means of prosthetic suspension among individuals with lower limb amputations. With osseointegration drawing closer to completing clinical trials in the United States, it seemed prudent to determine if there was a willing population and to find correlation to seek to improve the procedure to allow it to be more available.

Methods:
A survey with four sections was created. Section I gathered demographic data. Section II gathered amputation-related circumstances (e.g. pain, skin breakdown, technical problems with prosthesis, etc.). Section III evaluated current activity level. Section IV gave the overview, risks, and benefits of osseointegration along with asking if they would consider using this method of treatment. The survey was given to 15 individuals to validate and to correct grammatical errors and minor format changes. The survey was given in person or mailed to amputees associated with the University of Utah or the George E. Wahlen Department of Veterans Affairs in Salt Lake City, UT. 73 surveys were completed and sent back to researchers.

Results:
33% of participants replied that they would consider osseointegration. Some of the perceived benefits included advanced prosthetic function, improved activity level, security of suspension system, improved walking ability and ease of prosthetic attachment. 42% of participants replied that they would not consider having the procedure due to infection, potential activity limitations due to implant failure, long rehabilitation course, and risk of a broken bone in the residual limb. A significant correlation was found between 1. Webster, J.B., Chou, T., Kenly, M., English, M., Roberts, T.L., Bloebaum, R.D. (2009). Perceptions and Acceptance of Osseointegration Among Individuals With Lower Limb Amputations: A Prospective Survey Study. Journal of Prosthetics and Orthotics, 21(4), 215-222.
participants considering osseointegration and the following characteristics: living in a rural area, pain interfering with daily activity, and problems with prosthetic detachment during activities.

Critique/Bottom Line:

This was a survey study that was sent via mail or in person to the VA in Salt Lake City, UT as well as the University of Utah. This is most likely not indicative of the general population due to a high amount of veterans (the study never specified how many of the subjects were veterans). The study was written by the authors and validated by 15 people for grammatical errors, but it cannot be compared to another survey already in existence. Characteristics like living in a rural location, pain interfering with activity level, and difficulties with prosthesis falling off were correlated to subjects being more likely to consider OI as a means of suspension. Perceived advantages to consider osseointegration included improved prosthetic function, improved walking ability, easy and quick attachment, improved activity level and lifestyle, secure attachment and suspension, comfort and decrease pain, improved feeling of the prosthesis, and less skin breakdown. Perceived disadvantages included infection risk, potential for limited activity due to failure, long rehabilitation period, bone fracture risk, multiple surgeries, potential to lose more of residual limb, presence of percutaneous rod, bent/broke implant, long-term antibiotic use, and need to avoid running. These are all correlations and while useful to speculate, they are not cause and effect and care must be taken not to confuse the two. For all of its flaws, it is interesting to see how different subjects responded and could be useful to show to patients considering OI so they could see what a sample of their peers chose.

**Level of Evidence:** 4

**Purpose:**
The aim of the current study was to increase the researchers’ knowledge about the living with an osseointegrated prosthetic limb experience and to compare that with a socket suspended prosthesis through the use of a qualitative phenomenological research method.

**Methods:**
13 subjects were recruited via purposive sampling. Three were upper extremity amputees and ten were single limb amputees. The subjects came from Sweden and spoke Swedish fluently. The inclusion criteria included having an OI prosthesis for at least three years and they are currently using the prosthesis. All subjects were audio-taped in a setting of their choice for 1-2 hours for the entire interview. The interviewer was the first author who had no prior relationship with participants and no clinical experience of working with amputee rehabilitation. Data analysis was performed using the empirical phenomenological psychological method which is a descriptive idiographic qualitative methodology that aims to describe the meaning structure of a lived phenomenon. In this case, the lived phenomenon is living with osseointegrated prosthesis. This analysis uses a five step process to create the final result which is the general structure typology or basic type of attitude based on the context of interview.

**Results:**
All participants in this study reported improvement in quality of life and some described the surgery as a “revolutionary change.” Some changes included that they didn’t have to worry with skin chafing, aches, and pinches. Therefore, they could be more engaged in day-to-day activities and experience less frustration on a daily basis. Three typologies were identified in this study: practical prosthesis, pretend limb, and a part of
me. In the first typology, practical prosthesis, the individuals identified with the prosthesis as a tool, but not integrated into their body image. They still experienced technical limitations with the osseointegrated prosthesis, but reported that osseointegration was still superior to the socket. They still felt that the artificial limb was not perfect and not at the level of their original leg before amputation. The second typology, pretend limb, felt that the prosthesis was almost a part of their body, but not quite. These subjects described a conflict of their own body image with and without the prosthesis as compared to their body image before amputation. The final typology described the prosthesis as “a part of me.” They felt the prosthesis was an incorporated part of the body and had complete acceptance and trust in the functioning of the prosthesis. Some patients described that they forget they have had an amputation. They also reported that they feel more like healthy people than they do as disabled and they are generally treated as healthy by their peers. All of the subjects experienced increased function and increased quality of life after surgery, but showed the different levels of acceptance of the artificial limb.

Critique/Bottom Line:
This study is a qualitative study in which thirteen subjects were chosen in Sweden by the researchers who performed the operation. This makes it more difficult to compare to an American population as well as the general amputee population. All thirteen subjects reported increased functioning as compared to the socket-based prosthesis. However, one of the inclusion criteria included current prosthesis use. There have been other studies of patients who were unhappy with the osseointegrated prosthesis who ceased to wear the prosthesis who would have been excluded from this study. The study also does not identify how many subjects identified with the different typologies. Therefore, it is unsure of which typology was the dominant one based on this small study size. This study shows some interesting data with the hope and possibility of complete functioning of the prosthetic limb that is integrated into a patient’s body image. However, it is a qualitative study, so the sample size is non-randomized and small, and it is reflective of a Swedish population.

**Level of Evidence:** 3b

**Purpose:**

The aim of this study was to investigate whether walking ability and quality of life of subjects with osseointegrated prostheses (OIP) are superior to walking ability and quality of life of the same persons with conventional socket prostheses.

**Methods:**

22 subjects with transfemoral amputations were referred from the University Medical Center in the Netherlands. All of them were screened for appropriateness for osseointegration based on socket-related skin and residual problems that contributed to limited prosthesis use. All subjects received the same two surgeries with residual femur shortened to 20 cm and the same rehabilitation program that is completed in 6-8 weeks according to OIP protocol. Subjects were tested before surgery with socket prostheses with the Timed Up and Go (TUG), 6-minute walk test (6MWT), and oxygen consumption test at preferred walking speed. Quality of life was measured with the Questionnaire of Persons With a Transfemoral Amputation (Q-TFA) and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). Subjects were retested 12 months after second surgery.

**Results:**

All participants significantly improved prosthesis use and prosthesis-related quality of life. The Q-TFA global score was 68% higher than when the participants used a socket prosthesis. Prosthesis use increased by 45% in hours being worn per week. In addition, subjects were able to walk 27% further. Decreased time was seen with TUG test with OI as well as less oxygen was consumed at preferred walking speed on the treadmill.
Critique/Bottom Line:

This is a well done quasi-experimental study. The authors used validated and reliable testing measures to use with the socket and with the new osseointegrated prosthesis. It could have had another follow-up at two years or more since the first year is typically filled with adverse events like infection and residual limb pain. The subjects were recruited for this study which means they most likely do not represent the general population. Also, these are subjects who were having difficulty with the standard of care which is socket-based prostheses. It shows that if someone is having difficulty with using the socket prostheses then osseointegration may be more indicated since it does improve quality of life, decrease oxygen consumption, increase walking distance, and prolongs prosthetic wear. However, balanced against the benefits are the risks of infection or failure of the implant resulting in loosening or femoral bone damage.

**Level of Evidence:** 2b

**Purpose:**
The purpose was stated clearly at end of the introduction: “This study aimed to present: A) The measurement of the load applied on the osseointegrated implant system of transfemoral amputees during normal walking in a straight line. B) The step-to-step and subject-to-subject variability of the load for a group of 12 transfemoral amputees.”

**Methods:**
Twelve subjects who were over one year post-implant of osseointegrated prostheses were selected to ambulate a total of 120 meters with a device to wirelessly record force data at the abutment to a computer for analysis. The subject was also recorded using data force plates and gait analysis. All subjects were able to ambulate 200 meters without an assistive device. All instruments were calibrated and were analyzed by acceptable programs. Force was measured in three planes and subjects’ steps were averaged to allow different subjects to be compared to each other and all subjects’ forces were displayed on the same graph.

**Results:**
Forces recorded directly from the abutment are similar to the ground reaction force plates used in gait analysis labs and both show accurate data collection. The variability from step-to-step is minimal in a single subject, but the subject-to-subject variability is quite large. The authors suggest that rehabilitation protocol must either be individually customized or be designed for the largest force recorded to prevent mechanical failure.

**Critique/Bottom Line:**
This wasn’t really an intervention study, but rather a data collection of twelve amputees measuring the force exerted on the abutment which could lead to mechanical failure. Data is always important to collect and is useful when considering a rehabilitation program and different prostheses. However, a problematic issue is that the authors doesn’t specify where the subjects came from and how they were recruited which makes it more difficult to compare to the general population. The amputees are also higher functioning and are most likely finished with rehabilitation since they are able to ambulate 200 meters without an assistive device.

The basic results of the study suggests that rehabilitation programs should either be individually customized or should be based on the highest force exerted by an individual since the average steps of a single subject were similar, but between subjects there was a large range of forces exerted on the abutment. This conclusion seems reasonable, but a study with a larger, randomized population would be beneficial.
Level of Evidence: 2b

Purpose:
The purpose of this study was to assess the first nineteen patients using the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) rehabilitation program in their gait patterns pre-operatively with socket prostheses and two years after the surgery with osseointegrated prosthesis. Main focus was on hip and pelvic motion in the sagittal plane.

Methods:
The first 19 subjects who were tested using the OPRA program were analyzed for sagittal hip and pelvic range of motion and position using a gait analysis lab two days before their osseointegration surgery using their socket prosthesis. Then they were tested again two years following the surgery. 57 healthy subjects who were age-, side-, and gender-matched were used in the control group.

Results:
On average, hip extension improved by seven degrees and anterior pelvic tilt was reduced by four degrees when wearing the osseointegrated prosthesis as compared to the socket prostheses which indicates better range of motion. However, these subjects lack another 4.6 degrees of hip extension and 10.3 degrees of pelvic tilt to reach the level of the healthy and non-amputated controls. Almost no changes of the hip extension were found on the contralateral side.

Critique/Bottom Line:
This article shows improvements in the hip and pelvic range of motion for patients who changed from the traditional socket intervention to osseointegration. However, the subjects were not randomly selected, but were from the first 19 subjects under the OPRA program which may not be comparable to the general population. Also, there was a control group who were matched based off of gender and age, but they were
not amputees. While it is interesting to know the general population’s hip and pelvic range of motion, it seems unreasonable to compare the control group to subjects who may be lacking musculature and are on highly variable prostheses. The difference in range of motion is present, but it is a small amount.
Level of Evidence: 3b

Purpose:
The main purpose of the study is to estimate the risk of failure during gait for an amputee with OI fixation since the implants are designed to withstand an axial load, but less equipped to withstand torsional loading. However, data was derived from subject-specific data and implant stability secured by a porous implant surface instead of a thread. This study uses a finite element model that needs to be optimized before the study can estimate the risk of failure during gait.

Methods:
Several steps were taken to optimize the finite element analysis method. First, since CT scans are generally not available for patients fitted with OI after their surgeries, the necessary CT scans from an intact femur came from subject 1. This data was then used to construct a finite element model for an amputated femur of subject 2. The density and alignment of the various tissues and the hardware were entered into the computer as mathematical formulas and data using prior studies and proven equations. These computerized limbs were then tested for torsional and axial loading and compared to each other. Loads for subject 2 were measured directly using a load cell on the distal end of the residual limb. 20 simulations were performed for the amputated and intact femurs.

Results:
The highest risk of failure in bone was always present at the bone implant interface in the amputated femur. However, the maximum risk of failure in an intact femur was found to be on the outer surface of the bone in the proximal part of the area 10 mm below lesser trochanter to the distal end of the bone. The maximum risk of failure in the implant/abutment was always present in the abutment. The authors’
final conclusion is that it is likely that a porous-coated implant could be beneficial for osseointegrated fixation, with similar limitations as patients fitted with threaded implants.

**Critique/BOTTOM LINE:**

This was a very technical study that utilized equations and mathematical terms to describe the study which makes the study more challenging to understand for someone without a comprehensive mathematical background. However, the purpose was to create a simulation of both an intact and amputated femur. These simulations were based off of two patients and are a very poor sample of the transfemoral amputee population. There were also some assumptions that were used to be able to transfer imaging into an interactive three dimensional map. Assumptions and error is to be expected when the full experiment is almost solely in the computer. On the other hand, the simulations are the only way to get this information since it would be unethical to apply force until there is a failure of either the hardware or the bone. This information was also used to experiment with lowering the 12 month rehabilitation program while lowering incidences of implant loosening. This article has valuable information, but also the potential for bias.
Level of Evidence: 3b

Purpose:
This study aims to investigate muscle activity in the residuum of the amputees’ muscles with osseointegration. Many amputees have muscle atrophy after surgery due to cut muscles, so this study aims to see if there is retention of more muscle using osseointegration as compared to a socket where it can pinch the muscles together and lessen forces and moment arms. Also, there is a pattern that type II fast twitch fibers are more likely to atrophy than the slow twitch fibers which could also be different between socket and osseointegrated prostheses.

Methods:
Five male unilateral above the knee amputees were selected after surgery using the OPRA protocol. The OPRA protocol involves soft tissue reform of anchoring residual muscles to the residual femur to allow continued contraction and utilization of these muscles. A control group of ten subjects was also assembled and was made up of individuals without an amputation. Surface EMG were applied to gluteus maximus, gluteus medius, adductor magnus, rectus femoris, and biceps femoris. Maximum isometric contractions were obtained with subjects resisting against manual resistance applied by experimenter for five seconds. Subjects were allowed a practice round then data was collected on two contractions with the higher ones being selected for analysis. Subjects from the controlled group were tested on their left side with the same muscles being analyzed.

Results:
First, the amputee group fluctuated in their outcomes due to difficulty maintaining a steady contraction and constant amplitude that is seen in the control group. Second, the percentage of power was shown to be
significantly less for contracting muscles as compared to relaxed muscles in the 20 Hz-150 Hz, but wasn’t significantly different in the 45 Hz-55 Hz. Third, all muscles, except gluteus medius, showed a lower increase in sEMG amplitudes in the amputee group when compared to the control group. Fourth, the mean median frequency is during the maximum isometric contraction. The largest difference is the activity of adductor magnus between the two groups.

Critique/Bottom Line:

is understandable that the subject pool is small, but a large oversight of the study is that they failed to identify where and how the intervention subjects were recruited. It is unknown if the five were statistical outliers and thereby skew the data. Due to the small size, they are not specific for the amputee population who are experiencing problems with conventional prostheses. Maximal contraction was achieved with subjects pushing against manual resistance from a researcher’s hand. Manual force can vary and cannot be calibrated or consistent with all subjects, so it is unclear if patients did reach and maintain maximal force. The unsteadiness of manual resistance could have also attributed to the difficulty with maintaining steady amplitude in the amputees. Overall, this study has some interesting data, but there are some errors that introduce bias into the study.

**Level of Evidence**: 3b

**Purpose:**

The purpose is stated clearly at the end of introduction: “The specific aim of this study was to establish a load-bearing amputation animal model that could be used to evaluate percutaneous osseointegrated implant technology and to monitor the animal’s changes in gait patterns over time.” Two hypotheses were stated. First, the animals would return to pre-amputation limb loads within 12 months. Second, the animals would return to a symmetrical gait pattern within 12 months.

**Methods:**

9 sheep were selected out of 20 crossbred and mature female sheep. Their right forelimbs were scanned for a custom-made porous titanium implant to fit exactly inside the intramedullary space. The sheep’s right forelimbs were amputated and the implant was inserted. Subject’s gait was analyzed by using a commercial force detecting surface covered by carpet to protect the sheet and to gain more natural surface for sheep to walk comfortably past the measuring device. Subjects were analyzed pre-operation and at months 1, 2, 3, 6, 9, and 12 after surgery.

**Results:**

Step length and step time as compared between right and left forelimbs were symmetrical and had no difference statistically in both pre-operation and post-operation stages. However, the loading capacity did change. For the first two months, the right forelimbs were loaded on average with 80.4 +/-2.5% of pre-operative load. In months 3-6, this force dropped considerably to 78.6 +/-4.8% of pre-operative loading capacity. At 12 months, the peak vertical force was 74.4 +/-4.0%. Authors suggested another study to extend past 12 months to see if the PVF continues to decrease.
Critique/Bottom Line:

This study was created for the purpose to test the new implant for the United States protocol. This implant is custom made for the individual's intra-medullary space so that when it is inserted, pressure from the surface area will hold the implant in and grow into the implant which will allow for faster healing and quicker weight bearing. It should also decrease risk for implant loosening which is another huge problem with this type of surgery. Even though load decreased by 25%, several explanations are proposed. Also, the step length and time remained symmetrical which was advantageous. This study continues to advocate for the new surgical procedure for osseointegration in the United States to approve it for other hospitals to practice nationwide.
Level of Evidence: 3b

Purpose:
The Centre of Orthopaedic Osseointegration located in Gothenburg Sweden has performed 106 implants on 100 patients from 1990 to 2008. The aim of this study was to describe the current rehabilitation protocol, briefly overview the results, and illustrate the rehabilitation outcome with case reports of patients treated with OI prostheses.

Methods:
The Centre of Orthopaedic Osseointegration surveyed about basic demographics, prosthesis use, health issues, and activity levels to its first 100 patients with 106 implants. They also described in detail the Osseointegrated Prostheses for Rehabilitation of Amputees (OPRA) protocol for both surgery and rehabilitation. The two surgeries are separated by six months with the first surgery inserting the implant into the intramedullary space and the second surgery attaching the abutment and doing soft tissue work. After the second surgery is a 12 or 18 month rehabilitation program which is decided on the integrity of the skeletal attachment. Typically, patients are immobilized for initial two weeks to allow for tissue healing, and then the next two weeks are gentle range of motion exercises. One month after the surgery is when axial weight bearing is allowed on a short prosthetic until 3 months when the subject is transitioned into an OI prosthesis. Over the next nine months, the subject increases weight bearing gradually to avoid implant loosening. At six months after surgery, the subjects are evaluated to see if they could walk without walking aids. The majority of the paper focuses on the OPRA protocol and the general background of osseointegration. They also describe three different case studies of those they treated. Follow up ranged from 3 months to 17.5 years.
Results:

Basic demographics include the following: 61% male and 39% female, mean age of subjects were 43 years, and mean time since amputation was 11.5 years. Also, 67% of amputations were due to trauma with 21% being due to tumors. Currently, 68 patients are still using their prostheses. 32 subjects are not using their prostheses with 4 deceased, 7 are in between surgeries, 6 are in initial training, 4 are not using prosthesis (but with implant intact), and 11 had the implant removed. The OPRA was implemented in 1999, and the majority of those who had adverse effects and chose to remove the implant or not use their prosthesis were treated before the rehabilitation protocol was established.

Critique/Bottom Line:

This study is more of a review of the OPRA protocol and general information about osseointegration rather than an experimental study. It is retrospective with a range of 18 years and gives good information of who is still using their prosthesis and who is not, but the results are generalized. The authors believe that most of the people who failed to benefit from the implant were part of the initial group before a rehabilitation program could be implemented. The authors allude to another study which utilizes more objective measures like questionnaires and testing of the people who followed the OPRA technique that was published after this study which may have more concrete results on walking, quality of life, and so on. This study gives a good overview of the background, pros and cons, as well as the OPRA protocol, but very little objective data
Level of Evidence: 3b

Purpose:
The medical group in Sweden has developed osseointegrated prosthesis for transfemoral amputees based on the titanium implants used in other specialties. This study is the result of 51 consecutive patients with a two year follow-up after their second surgery.

Methods:
This was a prospective, single-center, non-randomized study with 51 patients from 1999 to 2007 who were followed for two years following their second surgery. In 1999, this hospital developed the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) protocol that was not in place during an earlier study with 100 patients. This study follows patients using this specific protocol. Patients were reviewed before surgery and at three, six, 12, and 24 months following second surgery. They used the Questionnaire for Persons with Transfemoral Amputations (Q-TFA) and the Short-Form 36 Health Survey (SF-36) to assess functional outcome and health-related quality of life. The questionnaires were completed before first surgery and at 12 and 24 months after second surgery. Descriptive statistics were used for patients detailing the mean, standard deviation, median, minimum and maximum values, and frequencies and percentages.

Results:
Of the 51 patients, three were withdrawn for reasons unrelated to the implant. Another three patients chose to remove implants during the study and another one removed his after the study. The authors included the failures in their statistical analysis. 101 complications were reported, and of these 49 were considered
serious. Superficial infections were the most common complication with 41 instances. Superficial infections were resolved with oral antibiotics. Four patients had a deep infection of which one had to remove implant and another was successfully treated with antibiotics. Three patients had pain with weight bearing and eventually had implants removed due to loosening. Four patients suffered five fractures (3 ipsilateral hip, 1 below-elbow, 1 vertebral compression). Nine mechanical complications regarding the abutment and/or abutment screw were reported (one patient had 6 incidences with this mechanical problem) with a return to normal function in all cases after damaged components were repaired. At the two year mark, 89% of subjects reported daily prosthesis use which improved from 57% from before surgery. Q-TFA scores showed improved prosthetic mobility, fewer problems and improved global situation. 69% of patients reported that they felt they have improved at the two year mark as compared to pre-surgery.

Critique/Bottom Line:

This is a study that is focused on descriptive data of 51 patients who were treated at a single center in Sweden. They did use questionnaires that were valid and reliable and followed the subjects for an appropriate timeline of two years. They reported both positive and adverse events, and described the adverse events in great detail. However, since this is a study based off of descriptive data, there is very little control over the environment. This means that the only data that can be compared are the objective results from the questionnaires. All of the other adverse events were listed, but cause and effect cannot be determined in this study since there is very little control of the independent variables. This gives useful information, but since the study was non-randomized, it is more difficult to determine if the sample is an honest representation of the transfemoral amputee population.
Discussion

The available evidence supports the PICO question and supports that percutaneous osseointegrated prosthesis improves ambulatory independence and efficiency in select populations when compared to socket-based prostheses. The research also indicates several other benefits of osseointegration besides ambulatory ability such as increased acceptance of prosthesis, increased proprioception, and reduction of pain and discomfort.

The quality of evidence is low across the board for this topic. However, with this population that is to be expected. The gold standard for research is a randomized controlled study. It is quite difficult to randomize subjects into control and intervention groups. Therefore, most of these studies utilize quasi-experimental studies where they compare the subjects before and after surgery (Van de Meent, et al., Tranberg, et al.). For the studies where a control group of healthy individuals was utilized then blinding the researchers and the subjects is difficult since an amputation is an obvious factor in what separates the two groups (Tranberg, et al., Pantell, et al.) Other studies used a one-time visit to analyze and gain certain information in a snap-shot format (Lee, et al., Branemark, et al., Hagberg, et al.).

Many of these studies were chosen to not only answer the PICO question, but to also gain a more global look at the amputee. For example, the psychological effects of a prosthesis is an important factor for an amputee (Lundberg, et al., Webster, et al.). Other articles related to the American protocol that is in the process of being developed and will impact American amputees (Shelton, et al., Webster, et al.). Many studies were devoted to overall function of the prosthesis. Many of these studies assisted in answering the PICO question, but not quite. For example, Pantell, et al. describes surface electromyography in key muscles of the residual limb which is gives objective data on muscle strength. However, manual muscle strength and activity in an open kinetic chain is not the best predictor for the closed kinetic chain and functional strength seen in ambulation. Also, Tranberg, et al. reported a study on increased hip and pelvic range of motion in amputees which does improve ambulation quality. All of the intervention group’s range of
motion increased when compared to those wearing the hard sockets. Even though they did not reach the same range of motion as the non-amputees in the control group, they were able to make significant increases in range which would result in a more natural and efficient gait pattern.

The study that most effectively answered the PICO question was the article by Van de Meent, et al. This was a quasi-experimental study that studied patients immediately prior to operation and one year after osseointegration. The authors looked at a large variety of results that contribute to gait quality with testing for endurance, oxygen consumption, efficiency, agility, and a questionnaire that deals specifically with quality of life for transfemoral amputees. This study answers the PICO question quite well that amputees with osseointegration on average experience a better gait pattern compared to when they were using the conventional socket prosthesis. The research also supports that the osseointegration prosthesis made a powerful and significant change in the amputee’s ability to utilize a prosthesis which increases quality of life. This study compliments the experience of the case study described in this paper, where the subject was able to wear his prosthesis longer with a more equal weight bearing pattern due to decrease in pain and skin breakdown.

The main focus of this paper was to research osseointegration for an amputee which is a largely obscure field in mainstream medicine, particularly in the United States. This is a viable option for the select population that cannot utilize the conventional prosthetic method. More research is required as with any new approach. The clinical trials in Salt Lake City, UT will be a major step to opening up a new country for osseointegration which will help American citizens seeking this treatment. While there are plenty of excellent doctors overseas that can provide this service, American patients must pay for the surgery with their own money and no help from their insurance companies. If the Americans are able to approve the osseointegration protocol then this would open the option to more American citizens who cannot pay for the surgery out of pocket.
In conclusion, the answer to the PICO question is that osseointegration has been proven to increase ambulatory independence and quality over a socket-based prosthesis in a transfemoral amputee. This was also an appropriate and successful surgery for F.H. The evidence shows that for those individuals who experience pain or dysfunction with a socket-based prosthesis tend to perform better with osseointegration. However, there are always risks associated with the surgery. More research needs to be published regarding the risks and complications as well as the effects on rehabilitation and quality of life. While osseointegration may not be appropriate for all amputees who do not tolerate the traditional prosthesis, based on the research, it should be an option for them to consider.
References


