

One hundred patients treated with osseointegrated transfemoral amputation prostheses—Rehabilitation perspective

Kerstin Hagberg, RPT, PhD;^{1–2*} Rickard Brånemark, MD, PhD¹

¹Centre of Orthopaedic Osseointegration, Department of Orthopaedics, Sahlgrenska University Hospital, University of Gothenburg, Gothenburg, Sweden; ²Department of Prosthetics and Orthotics, Sahlgrenska University Hospital, University of Gothenburg, Gothenburg, Sweden

Abstract—Treatment with osseointegrated transfemoral prostheses has been shown to improve quality of life. The treatment has been performed in Sweden since 1990 and consists of two surgical procedures followed by rehabilitation. During the first years, the rehabilitation process was not standardized. In 1999, a treatment protocol called OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) was established. This article describes the current rehabilitation protocol and illustrates the overall results. The OPRA rehabilitation protocol is graded to stimulate the process of osseointegration and prepare the patient for unrestricted prosthetic use. It includes initial training with a short training prosthesis followed by gradually increased prosthetic activity. Between May 1990 and June 2008, we treated 100 patients with 106 implants (6 bilaterally; 61% males, 39% females; mean age 43 years; mean time since amputation 11.5 years.) The majority had amputations due to trauma (67%) or tumor (21%) (other = 12%). Currently, 68 patients are using their prostheses (follow-up: 3 months–17.5 years) and 32 are not (4 are deceased, 7 are before second surgery, 6 are in initial training, 4 are not using prosthesis, and 11 had the implant removed). The majority of treatment failures occurred in patients before we established the OPRA protocol. The implementation of graded rehabilitation is considered to be of utmost importance for improved results.

Key words: above-knee amputation, artificial limb, bone anchorage, gait training, implant, OPRA, osseointegration, prosthesis, rehabilitation, transfemoral amputation.

INTRODUCTION

Theoretically, finding a method to attach a prosthetic limb directly to the residual skeleton without requiring a prosthetic socket would be one way to improve the quality of life for patients with amputation. Surgical attempts to create bone-anchored solutions using cemented implants have been previously described but achieved poor results [1–2]. Other treatment solutions have been presented [3–4] or are presently under development [5].

Patient complaints about conventional prostheses include socket-related problems of discomfort, sores, rashes, and pain [6–13]; difficulty donning the prosthesis; unreliability of prosthesis being securely suspended; and mobility difficulties [11–12, 14–15]. Prosthesis users have listed socket comfort as of major importance [11, 15–16]. In a Swedish study of 97 individuals with transfemoral

Abbreviations: CP = commercially pure, HRQOL = health-related quality of life, OI = osseointegration, OPRA = Osseointegrated Prostheses for the Rehabilitation of Amputees, Q-TFA = Questionnaire for Persons with a Transfemoral Amputation, ROM = range of motion, S1 = first surgery, S2 = second surgery, SF-36 = 36-Item Short-Form Health Survey, TFA = transfemoral amputation, VAS = visual analog scale.

* Address all correspondence to Kerstin Hagberg, RPT, PhD; Bruna Stråket 11b, Level 4, Sahlgrenska University Hospital, SE-413 45 Gothenburg, Sweden; +46-(0)31-343-81-33; fax: +46-31-825599. Email: kerstin.hagberg@vgregion.se
DOI:10.1682/JRRD.2008.06.0080

amputation (TFA) for reasons other than dysvascular disease, the majority reported perceived socket-related problems to a degree that affected their quality of life [12]. The results showed that 72 percent of patients reported problems with sweating while wearing the socket, 62 percent reported problems with sores caused by the socket, and 44 percent reported problems with discomfort when sitting while wearing the prostheses.

The method of osseointegration (OI) was first described and named by Swedish professor Per-Ingvar Brånemark. He discovered that implants made of commercially pure (CP) titanium provided stable anchorage for an implant in living bone tissue [17]. OI has been used globally in dental clinical practice for more than 40 years [18]. Today, the method is also used in several other applications, such as bone-anchored hearing aids, bone-anchored prostheses because of defects in the head and neck area, finger joint prostheses, and thumb amputation prostheses [19–22]. The first clinical treatment using OI for amputation prostheses was performed in 1990 in Sweden [23]. Since then, a limited number of new patients with TFA have been treated each year. Today, the Centre of Orthopaedic Osseointegration at the Sahlgrenska University Hospital (Gothenburg, Sweden) has treated 100 individuals with TFA. With support from the Swedish team, this treatment has spread internationally (Australia, Hungary, France, United Kingdom, and Spain), but so far only the United Kingdom team has published reports on their experiences [24].

In this article, we aim to describe the current rehabilitation protocol, briefly overview the results, and illustrate the rehabilitation outcome with case reports of patients treated with TFA OI prostheses.

METHODS

Treatment Protocol

The present surgical treatment protocol has been developed from the vast experiences with OI for dental applications. However, no previous experience exists regarding rehabilitation for patients with amputation beginning to use a bone-anchored prosthesis. During the first years, the rehabilitation was not standardized. Throughout these years, when we only treated a few new patients a year, our experience gradually increased and we developed the present protocol followed today, OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees). We intro-

duced the OPRA protocol in 1999 and it includes surgical and rehabilitation details for patients with TFA.

The OPRA protocol includes two surgical sessions [25]. The OPRA implant system, made of CP titanium, consists of a fixture, an abutment, and an abutment screw (**Figure 1**). At the first surgery (S1), the fixture is carefully inserted intramedullary into the residual femur, and the skin is closed. Once healed, many patients can use a conventional prosthetic socket until the second surgery (S2). S2 is performed 6 months after S1. At S2, the abutment is inserted into the distal end of the fixture and protrudes from the residual-limb skin (**Figure 2**). In addition to abutment insertion, S2 includes major soft-tissue surgery. The patient is immobilized for the first 10 to 12 days to achieve critical healing of the skin penetration area and soft tissues.

OI around the implant can be compared with fracture healing [26]. Although OI starts to establish during the 6 months between S1 and S2, the bone tissue around the implant needs controlled loading regimes to further stimulate bone mineralization and strength after S2. However, on the basis of early clinical experiences, we learned that a rapid increase in implant loading can lead to implant loosening. The rehabilitation protocol aims to gradually increase loading of the bone-implant unit to prepare for unrestricted artificial limb use. We have found that pain during rehabilitation can indicate overload and should be avoided. Registration of pain is performed with the 0–10 visual analog scale (VAS).

Rehabilitation Protocol

Table 1 describes the OPRA rehabilitation protocol, which includes an initial training period using a short training prosthesis and a later training period using the OI prosthesis. It is differentiated into two slightly different protocols: Normal-Speed and Half-Speed. We developed

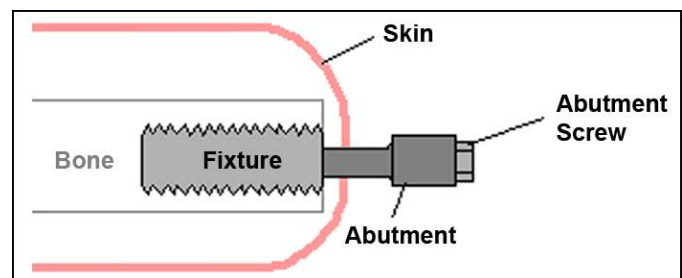


Figure 1.
Schematic view of implant system.



Figure 2. Example of skin penetration area and abutment protruding from residual limb.

the Half-Speed Protocol for patients with poorer skeletal conditions as judged by the surgeons.

All patients begin training about 2 weeks after S2 by performing gentle exercises (i.e., range of motion [ROM] exercises without full voluntary muscle contraction) to prevent development of hip joint contractures. At 4 to 6 weeks after S2, when the skin penetration area and soft tissue are adequately healed, more active training begins. Initial training includes axial weight-bearing and weight-shifting standing on a short training prosthesis. The patient can measure the amount of weight put on the short training prosthesis using a normal bathroom scale (**Figure 3**). In addition, the patient is given a general exercise program emphasizing more active training of hip ROM and muscle strength. The general exercise program's aim is also to stimulate bone mineralization by loading the bone-implant unit in additional directions other than axial (**Figures 4–5**).

In the Normal-Speed Protocol, weight bearing on the short training prosthesis starts at 20 kg and is performed

twice a day for 30 minutes. The patient is instructed to increase weight bearing by 10 kg each week until weight shifting to full body weight is achieved painlessly. Most patients report some pain during weight-bearing training, and pain recorded at VAS level 2 to 3 is considered safe. However, pain reported above VAS 5 should be avoided and weight-bearing exercises should be decreased to a more pain-free level. For all patients, the protocol includes 5 to 6 weeks of training with the short training prosthesis before prosthetic gait training on the definitive prosthesis starts. Thus, prosthetic gait training starts at about 12 weeks after S2 (**Table 1**). Using an Allen key, the patient secures the prosthesis to the abutment with an attachment device (**Figures 6–7**). During the first 2 weeks, we instruct the patient to use the prosthesis a maximum of 2 hours/day, only indoors, and with the support of two crutches for very limited weight-bearing on the prosthetic foot. The prosthesis wearing time, as well as prosthetic activity and weight-bearing, is gradually increased in the following weeks. The patient achieves full-day prosthetic use after 4 to 6 weeks. During the first 3 months of prosthetic use, walking should be done with double support (crutches or sticks). Based on X-rays and the clinical status 6 months after S2, a decision is made by the team on walking without walking aid support both indoors and outdoors. Again, pain reported above VAS 5 should be avoided, and individual protocol progress should be slowed so as not to risk overloading the ongoing integration of bone structure, i.e., the ongoing OI process. To summarize, patients following the Normal-Speed Protocol are treated for about 12 months (from S1 to unrestricted prosthetic use). Patients with poorer skeletal conditions following the Half-Speed Protocol are treated for about 18 months.

Specific Rehabilitation Considerations

Our team assesses all patients before treatment. The team assessment includes X-rays and computed tomography scans of the residual limb, clinical evaluations, thorough information for the patient on risks and possibilities and, when appropriate, patient meetings with a treated patient. Treatment is decided by the team, which includes at least one orthopedic surgeon, physiotherapist, and prosthetist. For treatment acceptance, the patient should report socket-related problems (i.e., discomfort, pain, poor suspension, as described in the "Introduction" section) or an inability to use a conventional prosthesis at all. When the team assesses problems related to socket use, it is

Table 1.

Schematic schedule of OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) rehabilitation protocols (Normal- and Half-Speed) for initial rehabilitation in prosthetic gait training after second surgery (S2).*

Weeks After S2	Normal-Speed	Half-Speed
1–2	Stay immobilized	Stay immobilized
3–4	Start gentle exercises	Start gentle exercises
4–6	Start training with short training prosthesis: Perform axial weight bearing and gentle weight shifting, start at 20 kg, avoid all rotation Perform 2 × 30 min/d Increase 10 kg/wk Follow exercise program with short training prosthesis	Start training with short training prosthesis: Perform axial weight bearing and gentle weight shifting, start at 10 kg, avoid all rotation Perform 2 × 30 min/d Increase 5 kg/wk Follow exercise program without short training prosthesis
7–8	Increase exercise program: Add 1 kg weight on short training prosthesis Crawl with small steps on all fours [†]	Increase exercise program: Add short training prosthesis when performing program
9–10	Increase exercise program: Increase to 2 kg on short training prosthesis if okay Add resistance with light or medium elastic band on short training prosthesis Exercise on all fours [†]	Increase exercise program: Add 0.5 kg weight on short training prosthesis
11–13	Start training with OI prosthesis Start in parallel bars Get used to donning, doffing, and wearing prosthesis Stand with no aid Walk with ~20 kg weight-bearing with support of 2 crutches Sit in chairs with different heights Use prosthesis only twice 1 h each day, only indoors Do not exercise with short training prosthesis	Increase exercise program: Increase to 1 kg on short training prosthesis if okay Crawl with small steps on all fours [†] Add resistance with light elastic band on short training prosthesis
14–16	Gradually increase time of prosthetic use and activity, all walking with 2 crutches: Gradually increase weight bearing on prosthesis when walking Walk on stairs Walk outdoors on level ground Sit in/drive car Continue exercise program with short training prosthesis	Increase exercise program: Exercise on all fours [†] Increase resistance of elastic band if okay
16–24	Gradually increase time of prosthetic use and activity, all walking with 2 crutches: Use prosthesis all day Walk on slopes and uneven ground Ride on exercise bike Start training steps with less support—sideways, walking with stick, etc.	Start training with OI prosthesis: Follow instructions for Normal-Speed Protocol when starting to use OI prosthesis, but with slower progress
At 24 wk	6-month follow-up with X-ray: Follow team's decision regarding when walking without walking aid support can start	6-month follow-up with X-ray: Follow team's decision regarding how to increase prosthetic use and activity

*No increase of training is to be done faster than Normal-Speed Protocol. For Normal-Speed Protocol, no weight-bearing or exercises that cause pain above VAS 5 should be performed; for Half-Speed Protocol, no weight-bearing or exercises that cause pain above VAS 3 to 4 should be performed.

[†]Crawling and exercises on all fours should not be started until loading with half body weight is achieved.

OI = osseointegration, VAS = visual analog scale.

important that they also account for the current level of prosthetic use and activity. Full-day prosthetic use may cause severe sores and discomfort, but a patient reporting limited use and/or activity might report fewer such problems. By asking the patient to complete the Questionnaire

for Persons with a Transfemoral Amputation (Q-TFA) prior to the team assessment, we can create a comprehensive picture of his or her current situation [27]. Furthermore, the dimensions and quality of the residual bone must be appropriate for the treatment. Finally, the patient must



Figure 3.

Axial weight bearing on short training prostheses and controlling weight with bathroom scale. Short training prosthesis connects to abutment with attachment device. "Soft tissue support" is supplied to keep soft tissues stable around skin penetration area.



Figure 5.

Crawling on all fours using short training prosthesis.



Figure 4.

Example of hip-strengthening exercise with short training prosthesis using elastic band resistance.

understand the risk of complications inherent to the treatment and be willing to comply with treatment protocol. Contraindications for treatment are severe vascular disease, ongoing chemotherapy treatment, or other potent immunosuppressive medications. Growing children and patients aged >70 are currently not accepted for treatment.

Most patients referred to us for treatment live far from our location (Gothenburg, Sweden), which can

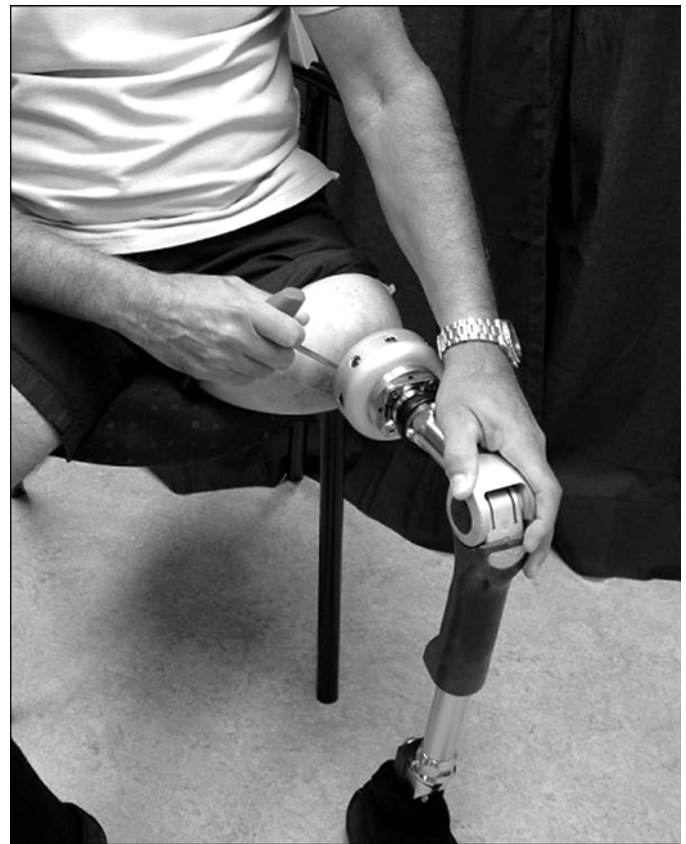


Figure 6.

Donning osseointegrated prosthesis with Allen key.



Figure 7.
Example of osseointegrated prosthesis with soft tissue support and attachment device.

mean extensive travel time and costs. Except for the two surgery sessions, none of the visits lasts for more than a few days. During rehabilitation, all instructions are given at outpatient visits. Daily training is performed at home. Thus, the patient must be able to easily follow the rehabilitation protocol, must clearly understand all instructions, and must be motivated to complete the training. Again, the patient must understand the hazards of OI by not pushing the rehabilitation progression too fast. At OI treatment time, most patients are already established amputees who have accepted their disability. In addition, many patients have prior experience with prosthetic walking and are familiar with various aspects of prosthetic training, making rehabilitation easier. However, we encourage professional support closer to home during rehabilitation. This support is especially helpful with more specific gait-pattern training and OI prosthesis long-term maintenance.

Prosthetic Considerations

Close collaboration between the prosthetist, physical therapist, and surgeon is very important. The prosthetist is responsible for supplying the patient with the short training and full-length OI prostheses. The short training prosthesis is training equipment made in knee-length to reduce the length of the lever arm. The alignment is altered if needed to compensate for a hip-joint contracture. A simple attachment device connects the short training prosthesis to the abutment (**Figure 3**). The attachment device for the full-length OI prosthesis is different and includes a safety function that protects the implant from high torques (**Figure 7**). Initially, the torque release level is low. When the bone is stronger and the prosthetic activity increases, the torque release level is gradually increased. Since the patient is not initially allowed full weight bearing, the prosthetic components must be carefully selected. For this reason, a knee component providing effortless flexion and controlled extension is preferred. Another preferred feature of the patient's first full-length OI prosthesis knee is a high degree of flexion to prevent bending loads to the implant system if the patient falls. Either a soft or firmer foot may be used for the foot component. Moreover, an extra dampener is often needed because each step might be distinctly annoying or painful. Later, when the OI is stronger and walking with full weight bearing has been achieved, changing components is possible. For example, a microprocessor-controlled knee can, in many cases, be supplied 6 to 12 months after S2.

In addition, we produce two more specific components at our workshop for this patient group. The first is a simple silicone device to place on the abutment when the patient is not wearing the prosthesis to protect the patient's partner in bed and prevent tearing the bed linen with the protruding screw. The second is a "soft tissue support" used along with the prosthesis to keep the soft tissues around the skin penetration site stable (**Figures 3 and 7**). It is also made of silicone and produced in different sizes.

Suspension problems no longer exist with OI prostheses, which means we can increase our focus on components. We maintain an ongoing discussion with the patient about prosthetic component choice as his or her functional skills and demands improve.

RESULTS

Summarizing Outcome

As of June 2008, 100 TFA cases with 106 limbs (6 bilaterally) have been treated in Gothenburg, Sweden (Table 2). Of these patients, 61 percent are males and 39 percent females. As illustrated in Table 2, the most common cause of amputation is trauma (67%), followed by tumor (21%). Trauma caused amputation in all patients treated bilaterally. The time from amputation to treatment varies between 0 and 44 years with a mean time of 11.5 years. Three patients scheduled for elective amputation had S1 performed at the time of the surgery. The majority of patients were citizens of Sweden at the time of treatment (64%) and the rest were citizens of Norway (18%), Spain (15%), and other European countries (3%).

Of the 100 patients, 91 had undergone or were undergoing rehabilitation as of June 2008. Three patients died before S2 and six patients have not yet had S2 performed. Thirteen patients have been treated more than once because of failure at the first treatment attempt. We can divide the patients into four different groups based on their stage of treatment development and the rehabilitation protocol they have been following: (1) No Protocol group, consisting of

patients treated before we established any specific protocol; (2) Normal-Speed Protocol group; (3) Half-Speed Protocol group; and (4) Individualized Protocol group, consisting of patients with special requirements (e.g., extraordinary or different skeletal conditions). Table 3 illustrates the distribution of patients in each protocol at the time of the first treatment attempt as well as the patients' current prosthetic status. Table 3 includes 91 patients with 97 implants (6 bilaterally) who have had or are undergoing rehabilitation after S2. Of the 100 patients, 20 have had the implant removed. Thirteen of those have been retreated, nine successfully and four unsuccessfully. Thus, 11 of the 100 patients have no implant system today. We have removed proportionately more implants from patients in the No Protocol and Individualized Protocol groups, and a proportionately higher number of patients in the Normal- and Half-Speed Protocol groups currently use OI prostheses (Table 3). The current prosthetic status illustrates that 68 patients are currently using the OI prostheses, but also that 4 patients are not using their prosthetic limb (Table 3). The reasons for not using the artificial limb include severe phantom limb pain (two patients), osteomyelitis (one patient), and contralateral limb disability (one patient). All

Table 2.

Description of 100 treated patients (May 1990 to June 2008) and subgroup of 51 patients included in OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) study.

Patient Characteristic	Patients N = 100 (106 Implants*)	OPRA Study Group n = 51 (55 Implants*)
Sex, n (%)		
Male	61 (61)	27 (53)
Female	39 (39)	24 (47)
Age (years), Mean ± SD	43 ± 12.9	44 ± 12.1
Min–Max	14–66	19–64
Age at Amputation (years), Mean ± SD	32 ± 13.9	32 ± 13.6
Min–Max	10–63	13–63
Years Since Amputation, Mean ± SD	11.5 ± 11.0	12 ± 10.6
Min–Max	0–44	1–42
Amputation Cause, n (%)		
Trauma	67 (67)	38 (67)
Tumor	21 (21)	12 (23)
Vascular, Including Arterial Embolus	3 (3)	2 (4)
Diabetes	2 (2)	—
Infection	7 (7)	3 (6)
Prosthetic User [†] Before Treatment, n (%)	74 (75) [‡]	41 (80)

*Six patients with bilateral amputations have been treated; four are part of OPRA study group.

[†]Prosthesis is used at least 1 day each week.

[‡]One case unknown; three cases scheduled for elective amputation also had first surgery performed during operation.

max = maximum, min = minimum, SD = standard deviation.

Table 3.Description of transfemoral amputation patients based on rehabilitation protocol ($n = 91$ patients with 97 implants).*

Protocol (Years of Treatment [†])	Patients/ Implants [‡]	Sex (%)		Age at Amputation Mean \pm SD Min–Max	Amputation Years at S1 Mean \pm SD Min–Max		Implant Removed	Treated Again	Current Prosthetic Status for Each Implant <i>n</i> (%)
		Male	Female						
No Protocol (1990–1994)	14/15	50	50	30.0 \pm 15.7 10–56	12.0 \pm 10.3 1–37	10	6	Deceased: 1 patient No implant: 5/14 (36) Use prosthesis: 9/14 (64)	
Normal-Speed Protocol (1995–2007)	54/59	70	30	34.0 \pm 13.9 14–63	11.0 \pm 10.8 1–42	5	4	No implant: 2/59 (3) Not performed S2 second try: 1/59 (2) Short training prosthesis: 6/59 (10) Use prosthesis: 47/59 (80) Not using prosthesis: 3/59 (5)	
Half-Speed Protocol (1998–2007)	15/15	33	67	29.0 \pm 15.1 11–53	16.5.0 \pm 13.4 2–44	1	0	No implant: 1/15 (7) Use prosthesis: 14/15 (93)	
Individualized Protocol (1996–2007)	8/8	63	37	28.0 \pm 7.6 18–42	8.0 \pm 9.4 0–28	4	3	No implant: 3/8 (37.5) Use prosthesis: 4/8 (50) Not using prosthesis: 1/8 (12.5)	

*Patients excluded in table are those not completing S2 (3 died before S2, 6 waiting for S2). One patient (in Normal-Speed Protocol group) also not completing S2 is included since this is second treatment attempt.

[†]Years given are at time of first treatment attempt.

[‡]Patients treated bilaterally (No Protocol group = 1, Normal-Speed Protocol group = 5).

max = maximum, min = minimum, S1 = first surgery, S2 = second surgery, SD = standard deviation.

bilaterally-treated patients are using their OI prostheses. In summary, 68 patients (with 74 implants) are using OI prostheses to date. This group has a mean follow-up time of 5 years (3 months–17.5 years) since S2. Patients not using the OI prosthesis include 4 deceased patients, 7 patients before S2, 6 patients in initial training with the short training prosthesis, 4 patients not using the OI prosthesis, and 11 patients with no implant system today. Further details describing the surgical aspects of this treatment and the complications, failures, and success rates will be published in a separate article.

OPRA Study

We included 51 of the 100 patients (Table 2) in an ongoing prospective clinical investigation, the OPRA study, which started in 1999. The Human Research Ethics Committee at the Sahlgrenska Academy, Gothenburg University, Sweden, approved the study (R 402-98).

Criteria for inclusion in the study are TFA with socket prostheses problems, complete skeletal maturation and normal skeletal anatomy, <70 years old, and suitable for the surgery based on medical and physical examination. Criteria for exclusion are severe peripheral vascular disease with or without diabetes mellitus, specific drug treatments (e.g., chemotherapy, corticosteroids), excessive body weight

(around 100 kg), and pregnancy. We closed inclusion in the OPRA study in 2007, and 51 patients with 55 implants (4 bilaterally) participated (Table 2). All included patients follow the Normal- or Half-Speed Protocols.

The OPRA study includes assessments performed before S1 and until 2 years after S2, such as radiography, registration of complications, hip ROM, walking energy cost, computerized gait analyses, and self-reported health-related quality of life (HRQOL). The general HRQOL is assessed by the 36-Item Short-Form Health Survey (SF-36) [28] and the condition-specific assessment by the Q-TFA [27], both with proven adequate measurement properties. The Q-TFA gives results in four scores (Prosthetic Use, Mobility, Problem, and Global) and is specifically designed for nonelderly patients with TFA. Each score ranges from 0 to 100. A Prosthetic Use score of 100 means the patient normally wears the prosthesis for at least 15 hours every day. The Problem score is reversed, and a lower figure means fewer problems in relation to amputation and the prosthesis. Further details about the Q-TFA can be found elsewhere [27,29].

A preliminary published report from the OPRA study included the first 18 consecutive patients (mean age 45 years [range 22–62 years]; mean time since amputation 15 years [range 10 months–33 years]) who have passed the

2-year follow-up [30]. Of the 18 patients, 17 used the OI prosthesis with unrestricted weight-bearing at follow-up. One patient could not use the prosthesis because of pain and subsequent loosening of the implant. The HRQOL showed improved general and condition-specific results that were statistically significant at the 2-year follow-up compared with preoperation. The Q-TFA Prosthetic Use score improved from a mean of 51 to 83 points ($p = 0.013$), the Mobility score improved from 56 to 74 ($p = 0.001$), the Problem score decreased from 39 to 18 ($p = 0.002$), and the Global score improved from 36 to 72 ($p = 0.002$). According to the SF-36, three of the subscores and one summary score statistically significantly improved (Physical Functioning from 34 to 57, $p = 0.001$; Role Physical Functioning from 38 to 65, $p = 0.004$; Bodily Pain from 57 to 71, $p = 0.046$; and the Physical Component Score from 31 to 42, $p = 0.001$) with no statistically significant difference in the other scores between assessments. We will report the final outcome of the OPRA study when all included patients have passed the 2-year follow-up in 2010.

Case Reports

We illustrate examples of the treatment and outcome with three cases representing different rehabilitation groups, all with at least 7 years of follow-up.

Case 1

The first case is of a female born in 1954. A right TFA was performed in 1977 because of osteogenic sarcoma, resulting in a residual limb classified as short [31]. She used a prosthesis with vacuum suspension for many years and reported prosthetic use to be about three-fourths of each day (Prosthetic Use score ~75). The patient expressed severe socket-related problems when wearing the prosthesis (described as pain, sweating, sitting discomfort, sores and skin irritation, difficulty donning, and not relying on the suspension). S1 was performed in 1992 and S2 performed only 3 months later, which we now regard as too short a time for stability. At that time, rehabilitation did not follow any specific protocol (No Protocol group in **Table 3**) and the OI prosthesis was supplied 4 weeks after S2 with no restriction other than initial use of crutches. For a short period during the following year, the patient experienced excellent prosthetic function. However, she soon began to perceive bothersome pain during prosthetic use. The pain increased, and we removed the implant when we found it to be loose.

After experiencing the short time with excellent function using the bone-anchored prosthesis, the patient stated her willingness to attempt another treatment. We performed the treatment a second time in 1995, now with 12 months between S1 and S2 and with initial weight-bearing on a short training prosthesis before we supplied the OI prosthesis. Six months after S2, she reported full prosthetic use every day and walking with the support of one crutch. At the 2-year follow-up, the patient reported full-day prosthetic use (Prosthetic Use score ~100), no pain in connection with prosthetic use, no problems donning the prosthesis, and no problems relying on the suspension. However, she reported occasional problems with sitting comfort and some sweating problems from the cosmetic covering at the soft tissues of the residual limb. The patient also reported recurrent superficial infections at the skin penetration area to be annoying. At the 3-, 5-, 7-, and 10-year follow-ups, prosthetic use was still all day, every day, with unaided walking at home and the support of one crutch outdoors. The most common complication for this patient has been superficial infections at the skin penetration area, resulting in one to two treatments with oral antibiotics each year. Today, her main problem is osteoarthritis pain in the ipsilateral hip joint. This case illustrates the complications often seen in patients from the early group. In spite of these problems, the patient still uses the prosthesis daily 12 years later, and the complications have been manageable.

Case 2

The second case is of a female born in 1950. A very high left TFA was performed in 1995 because of group A streptococcal necrotizing fasciitis. Prosthetic rehabilitation was initiated 7 months after amputation. Because of the extremely short residual limb, the socket caused the patient major problems. In 1998, the OI procedure started with S1 3 years after amputation and S2 8 months later. The surgeon determined that her rehabilitation should follow the Half-Speed Protocol. We supplied the OI prosthesis 6 months after S2, and rehabilitation continued for another 6 months, resulting in 20 months of treatment.

Before OI treatment, the patient reported daily socket prosthesis use of about half the day (Prosthetic Use score ~50). All outdoor walking with the prosthesis was with two crutches. While wearing the prosthetic socket, the patient reported severe problems such as pain, skin breakdown on the residual limb, not relying on the prosthesis being securely fastened, severe discomfort while sitting,

and heat and sweating from the socket. Measurement of active hip ROM wearing the socket prosthesis showed only 65° of flexion-extension and no rotation in sitting.

At the 2-year follow up, the patient reported OI prosthesis use >15 hours each day (Prosthetic Use score = 100). Further, she reported no problems from pain while wearing the prosthesis, no skin breakdown on the residual limb, and better reliance on the prosthesis being securely fastened. She reported minor problems regarding discomfort when sitting and with heat and sweating while wearing the prosthesis. Walking outdoors was still performed with the support of two crutches. While the patient was wearing the OI prosthesis, active hip ROM was 120° in flexion-extension and 55° in rotation in sitting. At the 7-year follow-up, the results remained stable with a Prosthetic Use score of 100. She now walks at home unaided but still walks outdoors with the support of two crutches. During the 7-year follow-up, the patient reported no superficial infections at the skin penetration area and no mechanical complications with the implant system. We performed the 10-year follow-up in late 2008.

Case 3

The third case is of a male born in 1976. A right-side TFA because of trauma was performed in 1995 and resulted in a short residual limb. Treatment for an OI prosthesis started in 1999 when the patient was 22 years old. Rehabilitation followed the Normal-Speed Protocol with no complications (Table 1). We supplied the OI prosthesis 18 weeks after S2, and the patient performed initial walking with crutches. Three months later, prosthesis walking was done with one stick.

Since this patient is included in the OPRA study, we can present the prospective scores of the Q-TFA. Figure 8 illustrates Q-TFA scores preoperatively and at the 2-, 3-, 5-, and 7-year follow-ups. Preoperatively, the patient reported prosthetic use for 2 days a week for a few hours at a time, resulting in a low Prosthetic Use score of 9. The Mobility score was average since the patient stated an ability to perform different activities while wearing his prosthesis. Because of the very low prosthetic use time, the patient only perceived minor problems with sores, sweating, discomfort, etc., resulting in a very low Problem score. At the 2-year follow-up, the Prosthetic Use score had dramatically improved. The patient reported using the OI prosthesis each day for more than 15 hours (Prosthetic Use score = 100). He also reported using less walking aid support and walking longer distances outdoors, resulting in an improved Mobility score. Although the prosthesis was now used all day,

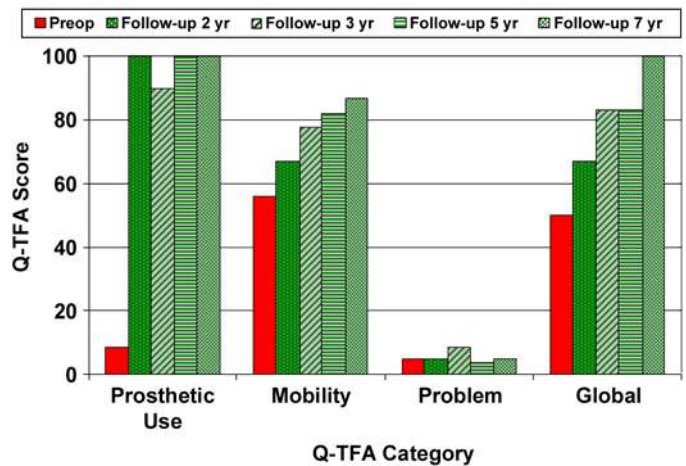


Figure 8.

Case 3 Questionnaire for Persons with Transfemoral Amputation (Q-TFA) scores, preoperatively and at the 2-, 3-, 5-, and 7-year follow-ups after second surgery. Each Q-TFA score ranges from 0 to 100. Problem score is reversed and lower figure means fewer problems in relation to amputation and prosthesis. preop = preoperation. *Source:* Hagberg K, Brånemark R, Hägg O. Questionnaire for Persons with a Transfemoral Amputation (Q-TFA): Initial validity and reliability of a new outcome measure. *J Rehabil Res Dev.* 2004;41(5):695–706.

[\[PMID: 15558399\]](https://pubmed.ncbi.nlm.nih.gov/15558399/)

[DOI:10.1682/JRRD.2003.11.0167](https://doi.org/10.1682/JRRD.2003.11.0167)

every day, the Problem score remained low, with a very limited number of problems reported. Finally, the patient expressed an improved overall situation, resulting in a higher Global score. During the subsequent years, the results have been stable or improved further (Figure 8). Today, the patient reports prosthesis walking without support both indoors and outdoors.

During the 7-year treatment time, this patient has, however, reported some distal mechanical complications with the implant system, resulting in three abutment replacements. The first occurred after 3 years because of a fall, the second after 5 years because of wear, and the third after 7 years because of a broken abutment screw. Each of these occasions caused a few days of prosthetic use restriction, but none caused an inpatient hospital stay. Eight years after S2, the patient had his first and, so far, only superficial infection at the skin penetration area. It was successfully cured with 10 days of oral antibiotic treatment.

DISCUSSION

To date, the Centre of Orthopaedic Osseointegration at the Sahlgrenska University Hospital has, to our knowledge,

the most experience in the world concerning treatment with bone-anchored amputation prostheses. The first treatment was performed 18 years ago. One hundred patients with TFA have been treated in Sweden, and most of them are actively using their OI prostheses. We found only one other publication on Medline about patients with TFA treated with a different bone-anchored solution [3].

For patients successfully provided any bone-anchored prostheses, some immediate and very evident advantages exist over prosthetic suspension with a socket. Advantages include easy and fast donning and doffing of the artificial limb; a proper fit every day that always keeps the same position; no hip ROM restriction because of a socket; and no socket to cause sweating, sores, and/or discomfort [24,29–30,32]. Furthermore, some patients have reported an improved sense of grounding with the prosthetic foot, improved prosthetic limb control, and the perception that the phantom limb is slowly becoming more like the normal limb. These sensations are thought to be from the phenomenon of osseoperception [33].

Nevertheless, complications also exist with OI treatment, such as risk of superficial infections at the skin penetration area, pain, mechanical complications, deep infections, and risk of implant loosening. We described some of the adverse events in the three case reports. Over 18 years of increasing experience, we have learned to handle many complications and gained insight into the great importance of gradually increasing prosthetic use and activity. In many cases, the physiotherapy management is more about adequately instructing activity grading than actually performing hands-on training, at least during the initial training period. We have found pain assessment using the VAS to be a helpful diagnostic and educational instrument not only for registering pain but also for grading training.

Most failures seem to belong to the early group of treated patients (**Table 3**). This finding illustrates the learning curve of treatment development. As illustrated in this article, we have a standardized rehabilitation protocol. The Normal-Speed Protocol has been and is currently followed by close to 60 percent of the patients. However, for patients with poorer primary implant stability, as judged by the S1 surgeon, the slower rehabilitation protocol is used (Half-Speed Protocol). Interestingly, the Half-Speed Protocol has been followed by far more female than male patients and by a larger number of patients with more “amputation years” at OI treatment than those

in the Normal-Speed Protocol (**Table 3**). This finding might reflect poorer skeletal conditions among females and the early onset of osteoporosis due to less load stimulation of the residual bone among patients with a longer time since amputation.

Over the years, we have also learned that this treatment demands a multidisciplinary team in which all members should be familiar with the entire treatment concept. Another important aspect is that the team conducts a thorough preoperative evaluation of all patients. The information given to the patient during the team assessment must include all potential risks as well as advantages. The patient must be given a realistic picture of mobility outcome. For instance, as illustrated in the case reports, the patient must be aware that walking might still require walking aid support and that the gait pattern might not significantly change. As with any conventional prostheses suspension, the ability to perform different activities using OI prostheses also depends on a number of individual conditions, e.g., residual-limb length and strength, prosthetic components, motivation and courage, and the presence or absence of concurrent disabilities.

Research within the field of bone-anchored prostheses is rapidly growing. Further studies are needed to learn how to decrease infections and mechanical complications. Such research is ongoing at the Sahlgrenska University Hospital in collaboration with other centers [34–37], as well as studies that analyze changes of the gait pattern [38], osseoperception [39], and different aspects of mobility, HRQOL, and health economics. We are also implementing a similar graded rehabilitation protocol for patients with upper-limb amputations to be supplied with an OI prosthesis.

CONCLUSIONS

This article presents the development and description of our present rehabilitation protocol and a brief overview of the results. Further details describing the surgical aspects of this treatment and the complications, failures, and success rates will be published in a separate article. We treated several of the 100 patients before we introduced the OPRA protocol. Retrospectively, if the present meticulous rehabilitation program had been followed, we believe that some of these patients might have been successful and that the current rehabilitation protocol might decrease the

frequency of complications. In a few years, the OPRA study will give us prospective data to verify this. The early results of the first 18 patients following the OPRA protocol are very promising, with improved quality of life reported and a 94 percent success rate at the 2-year follow-up [30]. We believe it is reasonable to assume that the present method can make everyday life easier for the increasing number of patients experiencing war casualties, traffic accidents, tumors, and other causes of TFA at younger ages, and we hope this article supports rehabilitation development for patients treated with different bone-anchored prosthetic solutions in the future.

ACKNOWLEDGMENTS

Author Contributions:

Study concept and design: K. Hagberg, R. Brånemark.

Acquisition of data: K. Hagberg.

Analysis and interpretation of data: K. Hagberg, R. Brånemark.

Drafting of manuscript: K. Hagberg.

Critical revision of manuscript for important intellectual content:

K. Hagberg, R. Brånemark.

Statistical analysis: K. Hagberg.

Obtained funding: K. Hagberg, R. Brånemark.

Financial Disclosures: Rickard Brånemark has commercial associations (stock ownership) that might pose a conflict of interest in connection with this article.

Funding/Support: This material was based on work supported in part by an ALF/LUA grant from the Sahlgrenska University Hospital and Sahlgrenska Academy, Gothenburg, Sweden, and the Dr. Felix Neubergh Foundation, Sweden.

Additional Contributions: Eva Häggström, CPO, Department of Prosthetics and Orthotics, Sahlgrenska University Hospital, Gothenburg, Sweden.

REFERENCES

- Hall WC. Permanently attached artificial limbs. *Bull Prosthet Res.* 1977;165–68.
- Mooney V, Schwartz SA, Roth AM, Gorniewsky MJ. Percutaneous implant devices. *Ann Biomed Eng.* 1977;5(1):34–46. [\[PMID: 851262\]](#)
[DOI:10.1007/BF02409337](#)
- Staubach KH, Grundei H. [The first osseointegrated percutaneous prosthesis anchor for above-knee amputees.] *Biomed Tech (Berl).* 2001;46(12):355–61. German. [\[PMID: 11820163\]](#)
- Aschoff H, Grundei H. The endo-exo-femurprosthesis: A new concept of prosthetic rehabilitation engineering following thigh-amputation—Some cases and early results. In: *Proceedings of the 11th World Congress of the International Society for Prosthetics and Orthotics*; 2004 Aug 1–6; Hong Kong, China.
- Pendegrass CJ, Gordon D, Middleton CA, Sun SN, Blunn GW. Sealing the skin barrier around transcutaneous implants: In vitro study of keratinocyte proliferation and adhesion in response to surface modifications of titanium alloy. *J Bone Joint Surg Br.* 2008;90(1):114–21. [\[PMID: 18160512\]](#)
[DOI:10.1302/0301-620X.90B1.19580](#)
- Hoaglund FT, Jergesen HE, Wilson L, Lamoreux LW, Roberts R. Evaluation of problems and needs of veteran lower-limb amputees in the San Francisco Bay Area during the period 1977–1980. *J Rehabil Res Dev.* 1983;20(1):57–71. [\[PMID: 6887067\]](#)
- Walker CR, Ingram RR, Hullin MG, McCreath SW. Lower limb amputation following injury: A survey of long-term functional outcome. *Injury.* 1994;25(6):387–92. [\[PMID: 8045644\]](#)
[DOI:10.1016/0020-1383\(94\)90132-5](#)
- Sherman RA. Utilization of prostheses among US veterans with traumatic amputation: A pilot survey. *J Rehabil Res Dev.* 1999;36(2):100–108. [\[PMID: 10661526\]](#)
- Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: A long-term outcome study. *Am J Phys Med Rehabil.* 2001;80(8):563–71. [\[PMID: 11475475\]](#)
[DOI:10.1097/0002060-200108000-00003](#)
- Gallagher P, Allen D, Maclachlan M. Phantom limb pain and residual limb pain following lower limb amputation: A descriptive analysis. *Disabil Rehabil.* 2001;23(12):522–30. [\[PMID: 11432649\]](#)
[DOI:10.1080/09638280010029859](#)
- Gallagher P, Maclachlan M. Adjustment to an artificial limb: A qualitative perspective. *J Health Psychol.* 2001;6(1):85–100. [DOI:10.1177/135910530100600107](#)
- Hagberg K, Brånemark R. Consequences of non-vascular trans-femoral amputation: A survey of quality of life, prosthetic use and problems. *Prosthet Orthot Int.* 2001;25(3):186–94. [\[PMID: 11860092\]](#)
[DOI:10.1080/03093640108726601](#)
- Dudek NL, Marks MB, Marshall SC, Chardon JP. Dermatologic conditions associated with use of a lower-extremity prosthesis. *Arch Phys Med Rehabil.* 2005;86(4):659–63. [\[PMID: 15827914\]](#)
[DOI:10.1016/j.apmr.2004.09.003](#)
- Nicholas JJ, Robinson LR, Schulz R, Blair C, Aliota R, Hairston G. Problems experienced and perceived by prosthetic patients. *J Prosthet Orthot.* 1993;5(1):36–39. [DOI:10.1097/00008526-199301000-00006](#)

15. Legro MW, Reiber G, Del Aguila M, Ajax MJ, Boone DA, Larsen JA, Smith DG, Sangeorzan B. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev.* 1999;36(3):155–63. [\[PMID: 10659798\]](#)
16. Nielsen CC. A survey of amputees: Functional level and life satisfaction, information needs, and the prosthetist's role. *J Prosthet Orthot.* 1991;3(3):125–29.
17. Dorland WA. *Dorland's illustrated medical dictionary.* 30th ed. Philadelphia (PA): W. B. Saunders; 2003.
18. Brånemark PI, Hansson BO, Adell R, Breine U, Lindström J, Hallén O, Ohman A. Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. *Scand J Plast Reconstr Surg Suppl.* 1977;16:1–132. [\[PMID: 356184\]](#)
19. Tjellström A. Osseointegrated systems and their applications in the head and neck. *Adv Otolaryngol Head Neck Surg.* 1989;3:39–70.
20. Lundborg G, Brånemark PI, Carlsson I. Metacarpophalangeal joint arthroplasty based on the osseointegration concept. *J Hand Surg [Br].* 1993;18(6):693–703. [\[PMID: 8308422\]](#)
[DOI:10.1016/0266-7681\(93\)90224-4](#)
21. Lundborg G, Brånemark PI, Rosén B. Osseointegrated thumb prostheses: A concept for fixation of digit prosthetic devices. *J Hand Surg [Am].* 1996;21(2):216–21. [\[PMID: 8683049\]](#)
[DOI:10.1016/S0363-5023\(96\)80103-1](#)
22. Brånemark PI. *The osseointegration book: From calvarium to calcaneus.* Chicago (IL): Quintessence Publishing; 2006.
23. Brånemark R, Brånemark PI, Rydevik B, Myers RR. Osseointegration in skeletal reconstruction and rehabilitation: A review. *J Rehabil Res Dev.* 2001;38(2):175–81. [\[PMID: 11392650\]](#)
24. Sullivan J, Uden M, Robinson KP, Sooriakumaran S. Rehabilitation of the trans-femoral amputee with an osseointegrated prosthesis: The United Kingdom experience. *Prosthet Orthot Int.* 2003;27(2):114–20. [\[PMID: 14571941\]](#)
[DOI:10.1080/03093640308726667](#)
25. Robinson KP, Brånemark R, Ward DA. Future developments: Osseointegration in transfemoral amputees. In: Smith DG, Michael JW, Bowker JH, editors. *Atlas of amputations and limb deficiencies: Surgical, prosthetic and rehabilitation principles.* 3rd ed. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2004. p. 673–82.
26. Brånemark R. *A biomechanical study of osseointegration. In-vivo measurements in rat, rabbit, dog and man [dissertation].* Gothenburg (Sweden): University of Gothenburg; 1996.
27. Hagberg K, Brånemark R, Hägg O. Questionnaire for Persons with a Transfemoral Amputation (Q-TFA): Initial validity and reliability of a new outcome measure. *J Rehabil Res Dev.* 2004;41(5):695–706. [\[PMID: 15558399\]](#)
[DOI:10.1682/JRRD.2003.11.0167](#)
28. Ware JE Jr, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual framework and item selection. *Med Care.* 1992;30(6):473–83. [\[PMID: 1593914\]](#)
29. Hagberg K. *Transfemoral amputation, quality of life and prosthetic function. Studies focusing on individuals with amputation due to reasons other than peripheral vascular disease, with socket and osseointegrated prostheses [dissertation].* Gothenburg (Sweden): Gothenburg University; 2006. Available from: <http://hdl.handle.net/2077/726/>
30. Hagberg K, Brånemark R, Gunterberg B, Rydevik B. Osseointegrated trans-femoral amputation prostheses: Prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up. *Prosthet Orthot Int.* 2008;32(1):29–41. [\[PMID: 18330803\]](#)
[DOI:10.1080/03093640701553922](#)
31. Persson BM, Liedberg E. A clinical standard of stump measurement and classification in lower limb amputees. *Prosthet Orthot Int.* 1983;7(1):17–24. [\[PMID: 6856447\]](#)
32. Hagberg K, Häggström E, Uden M, Brånemark R. Socket versus bone-anchored trans-femoral prostheses: Hip range of motion and sitting comfort. *Prosthet Orthot Int.* 2005;29(2):153–63. [\[PMID: 16281724\]](#)
[DOI:10.1080/03093640500238014](#)
33. Hagberg K, Häggström E, Jönsson S, Rydevik B, Brånemark R. Osseoperception and osseointegrated prosthetics limbs. In: Gallagher P, Desmond D, MacLachlan M, editors. *Psychoprosthetics.* London (England): Springer; 2008. p. 131–40. [DOI:10.1007/978-1-84628-980-4_10](#)
34. Shubayev VI, Brånemark R, Steinauer J, Myers RR. Titanium implants induce expression of matrix metalloproteinases in bone during osseointegration. *J Rehabil Res Dev.* 2004;41(6A):757–66. [\[PMID: 15685464\]](#)
[DOI:10.1682/JRRD.2003.07.0107](#)
35. Xu W, Xu DH, Crocombe AD. Three-dimensional finite element stress and strain analysis of a transfemoral osseointegration implant. *Proc Inst Mech Eng [H].* 2006;220(6):661–70. [\[PMID: 16961185\]](#)
[DOI:10.1243/09544119JEIM84](#)
36. Lee WC, Frossard LA, Hagberg K, Haggstrom E, Brånemark R, Evans JH, Percy MJ. Kinetics of transfemoral amputees with osseointegrated fixation performing common activities of daily living. *Clin Biomech (Bristol, Avon).* 2007;22(6):665–73. [\[PMID: 17400346\]](#)
[DOI:10.1016/j.clinbiomech.2007.02.005](#)
37. Frossard L, Stevenson N, Smeathers J, Häggström E, Hagberg K, Sullivan J, Ewins D, Gow DL, Gray S, Brånemark R. Monitoring of the load regime applied on the osseointegrated fixation of a trans-femoral amputee: A tool for evidence-based practice. *Prosthet Orthot Int.* 2008;32(1):68–78.

[\[PMID: 18330805\]](#)

[DOI:10.1080/03093640701676319](https://doi.org/10.1080/03093640701676319)

38. Tranberg R, Zügner R, Hagberg K, Brånemark R. Gait analysis of patients with trans-femoral OI-prosthesis—Prospective results at 2 year follow-up. In: Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada. Toronto (Canada): Canadian National Society for Prosthetics and Orthotics; 2007. p. 507.
39. Häggström E, Hagberg K, Rydevik B, Brånemark R. The psychophysical detection level for vibrotactile stimulation

over time in bone-anchored prosthesis: Preliminary prospective results at 2-year follow-up among 20 patients. In: Proceedings of the 12th World Congress of the International Society for Prosthetics and Orthotics; 2007 Jul 29–Aug 3; Vancouver, Canada. Toronto (Canada): Canadian National Society for Prosthetics and Orthotics; 2007. p. 367.

Submitted for publication June 26, 2008. Accepted in revised form December 11, 2008.