

Vibrotactile evaluation: Osseointegrated versus socket-suspended transfemoral prostheses

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Abstract—This study investigated detection thresholds of vibrometric stimuli in patients with transfemoral amputation supplied with osseointegrated (OI) and socket-suspended prostheses. It included 17 patients tested preoperatively with socket-suspended prostheses and after 2 yr with OI prostheses and a control group ($n = 17$) using socket-suspended prostheses, evaluated once. Assessments on the prosthetic and intact feet were conducted at six frequencies (8, 16, 32, 64, 125, and 250 Hz). Furthermore, measurements were conducted to investigate how vibrometric signals are transmitted through a test prosthesis. The results showed that the OI group had improved ability to detect vibrations through the prosthesis at 125 Hz ($p = 0.01$) at follow-up compared with the preoperative measurement. Compared with the control group, the OI group at follow-up had better ability to detect high frequency vibrations through the prosthesis (125 Hz, $p = 0.02$; 250 Hz, $p = 0.03$). The vibrometric signal transmitted through the test prosthesis was reduced at 8, 125, and 250 Hz but was amplified at 16, 32, and 64 Hz. Differences between the OI and the control groups were found in the highest frequencies in which the test prosthesis showed reduction of the vibrometric signal. The study provides insight into the mechanisms of vibration transmission between the exterior and bone-anchored as well as socket-suspended amputation prostheses.

Key words: artificial limb, osseointegration, osseoperception, prosthesis, prosthetic foot, prosthetic knee, sensibility test, transfemoral amputation, vibrometric measurement, vibrotactile sensibility.

INTRODUCTION

Osseointegration for bone-anchorage of prostheses has been used in various prosthetic applications [1–3]. The most common is in dental care [4–5], and other attachments are in facial reconstructions [6–7] and hearing aids [8]. Today, osseointegration is also used in bone-anchorage of external prostheses as an alternative to conventional socket-suspended prostheses for patients with limb amputations [1,9–11].

Patients using such osseointegrated (OI) prostheses have reported an improved ability to identify various sensations through their artificial limb [12–15], a phenomenon called osseoperception. Osseoperception has also been identified regarding the benefit of improved sensory feedback for bite force and oral function in patients with OI implants in the edentulous jaw [13,16]. Later work has further established the importance of osseoperception

Abbreviations: CGRP = calcitonin gene-related peptide, ICC = intraclass correlation coefficient, OI = osseointegrated, QST = quantitative sensory testing, TFA = transfemoral amputation.

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in patients with dental implants [17–18]. The term osseoperception has been stated to imply “the mechanosensibility associated with osseointegrated implant rehabilitation,” further defined as “(i) the sensation arising from mechanical stimulation of a bone-anchored prosthesis, transduced by mechanoreceptors that may include those located in muscle, joint, mucosal, cutaneous and periosteal tissues, together with (ii) a change in central neural processing in maintaining sensorimotor function” [13].

Clinical observations have shown that patients can experience and identify various types of mechanical loading through OI implants. This suggests that a neurophysiological peripheral feedback pathway can be partly restored [16,19–20]. Such an assumption is supported by findings showing that two types of stimulation (pressure and strokes by a toothbrush) of an OI thumb prosthesis resulted in cortical activation on both sides of the somatosensory cortex, using functional magnetic resonance imaging of the brain [21]. Ysander et al. found an increase of calcitonin gene-related peptide (CGRP), a neuropeptide, around OI implants in an animal experimental study [22]. The increase of CGRP indicates that there might be an enhanced innervation of bone tissue around OI implants. However, the underlying mechanisms of the phenomenon of osseoperception are incompletely understood and the clinical effect of improved osseoperception in patients with limb amputations has not been fully explored.

Through different kinds of stimuli, e.g., light touch, thermal, vibration, or pain, sensibility can be measured. To evaluate sensibility, quantitative sensory testing (QST) has frequently been used in different clinical, epidemiologic, and research studies [23]. There are various QST methods, such as a simple patient answer of yes or no whether stimuli could be identified [24], choice between one out of two time periods that include stimuli [25], or when the patient is asked to press a button when a vibration stimuli is perceived and to press again when the stimulus disappears (the method of limits) [26]. Sensibility studies using vibration as stimuli have shown that mechanoreceptors in the skin can detect vibration frequencies between 0.4 and 800 Hz [27]. However, most published clinical data are from studies on patients with various type of neuropathic conditions [28–29], and in those studies, vibration frequencies between 20 and 250 Hz have been used as stimuli [28–30]. In patients with transfemoral amputation (TFA), testing sensation in

terms of vibration seems to be one natural choice since vibration is one type of stimuli the patient hypothetically can experience when the prosthetic foot strikes the ground. At heel strike, the prosthetic knee joint should be in an extended position to make it safe to move the non-disabled limb forward [31–33]. Improved ability to detect vibration at heel strike could therefore mean safer walking for this group of patients.

The first study attempting to learn more about osseoperception and vibrations transmitted through the OI fixation in persons with amputation was initiated by Rydevik et al. [12]. A type of Békésy instrument for measuring vibrometric tactile thresholds was refined by Stenfeldt et al. [34]. Using this instrument, Jacobs et al. tested the vibrometric tactile thresholds in a group of patients with upper- or lower-limb OI prostheses and a control group with socket-suspended prostheses [35]. The study used frequencies of 8, 16, 32, 64, 125, and 250 Hz. These researchers found that the detection thresholds for vibratory stimulation of socket-suspended prosthetic limbs generally were higher than for nondisabled limbs, while OI prostheses yielded better perception than the socket-suspended prostheses. The authors suggested that the artificial limbs probably reduced the vibrometric signal [35]. There are, to our knowledge, no data available on how prosthetic components reduce vibrometric signals. Furthermore, there are no data available concerning the time course of the development of osseoperception in relation to implant insertion in patients with OI prostheses.

The aims of the present study were (1) to increase our knowledge regarding the detection level of vibrotactile stimulation in patients with transfemoral prostheses, (2) to report prospective data for the prosthetic and non-disabled limb in patients treated with unilateral transfemoral OI prostheses, (3) to compare the data with a group of controls using socket-suspended prostheses, and (4) to start to explore how vibrometric signals are absorbed/reduced through a test prosthesis.

The overall hypothesis was that patients with OI prostheses should have improved ability to detect vibrations compared with their own preoperative situation with socket-suspended prostheses and also compared with other patients with socket-suspended prostheses. The hypothesis concerning the test prosthesis was that the prosthesis would influence the transmission of the vibrometric signal.

METHODS

Participants

Two groups of patients were included in the current study: a group of patients having the osseointegration treatment and a group of controls. For both groups, the inclusion criteria were having a unilateral TFA for at least 2 yr from causes other than diabetes or arteriosclerosis, being between 20 and 65 yr old, and being a prosthetic user. Patients with bone-anchored prostheses (OI group) should have been treated in Sweden and had their surgery performed between the years 1998 and 2007. In addition, patients in the OI group should have undergone the vibrometric measurements preoperatively with their socket-suspended prosthesis and at 2 yr follow-up with their OI prosthesis. The control group was selected from the group of patients from an earlier study [36], and participants were excluded if the reason for amputation was diabetes or arteriosclerosis.

The OI group included 17 patients (8 males and 9 females; mean age 44.6 yr [range: 23–63 yr]; mean time since amputation 14.5 yr [range: 2–42 yr]; cause of amputation: 11 trauma, 6 tumor). The control group included 17 patients (11 males and 6 females; mean age 43.2 yr [range: 29–63 yr]; mean time since amputation 18 yr [range: 2–34 yr]; cause of amputation: 11 trauma, 6 tumor). All patients in the control group had a prosthetic

socket suspended by vacuum without any liner. Details of all prosthetic components are presented in **Table 1**. The classification of the type of prosthetic knee and foot components included in the prostheses at each assessment for all participants was done according to the classification proposed by REHAB Tech, Biomedical Engineering, Department of Electrical and Computer System Engineering, Monash University in Australia. A large number of patients in the OI group underwent changes of various prosthetic components between the two assessments. At follow-up, five patients had exactly the same type of prosthetic components as preoperatively and 12 had changed at least some of the components (**Table 1**) (5 changed foot, 5 changed to a more massive knee joint, 2 changed to a less massive knee joint, 5 added a shock absorber/torsion adapter). Most of the patients had a cosmetic cover (**Table 1**).

Apparatus

The test setup for the vibrometric evaluation is similar to a hearing test and replicates the one described by Stenfeldt et al. [34] and Jacobs et al. [35]. The hardware consists of a box, which contains a vibrating device, a response button, and a computer with the custom-designed Vibra98 software (Integrum AB; Gothenburg, Sweden). The command signal for the start of the assessment came

Table 1.

Prosthetic components. Prosthetic knee joints, foot component, shock absorber/torsion adapter, and cosmetic cover in osteointegrated (OI) group preoperatively and at 2 yr follow-up and control group. Classification of prosthetic knee joint and prosthetic feet was made using system proposed by REHAB Tech, Biomedical Engineering, Department of Electrical and Computer System Engineering, Monash University in Australia.

Component	OI Group (<i>n</i> = 17)		Control Group (<i>n</i> = 17)
	Preoperative	2 Yr Follow-Up	
Prosthetic Knee Joint			
Polycentric Cadence Responsive	4	6	9
Polycentric	0	0	1
Single-Axis Cadence Responsive	9	9	4
Single-Axis Friction	0	2	1
Single-Axis Stance Locking	4	0	2
Prosthetic Foot			
Dynamic	11	8	7
Multiaxis	3	6	4
Solid Ankle Cushion Heel	0	0	2
Single-Axis	3	3	3
Syme	0	0	1
Shock Absorber/Torsion Adapter	0	4/1	1/1
Cosmetic Cover	16	15	16

from the computer and was fed through a power amplifier located in the box connected to the device with a vibrator. The patient received stimulation under the intact and prosthetic foot through a pin extension (area 7 mm^2) of a vibrator (model V4, Gearing and Watson Electronics Ltd; Hailsham, England), which produced a variable force to the vibrating pin. A force transducer (Dytran model 1051V1, Dynamic transducer and Systems; Chatsworth, California) was used to measure the force level delivered by the vibration unit.

Measurement Procedure

The measurement procedure was based on the experience from earlier tests [34–35]. The participant was seated comfortably in a chair in a quiet room. One foot at a time was placed on a box. Through a 50 mm^2 hole in the box, a vibrating pin hit the foot at the location of the first metatarsal head (**Figure 1**). The skin (or cosmetic

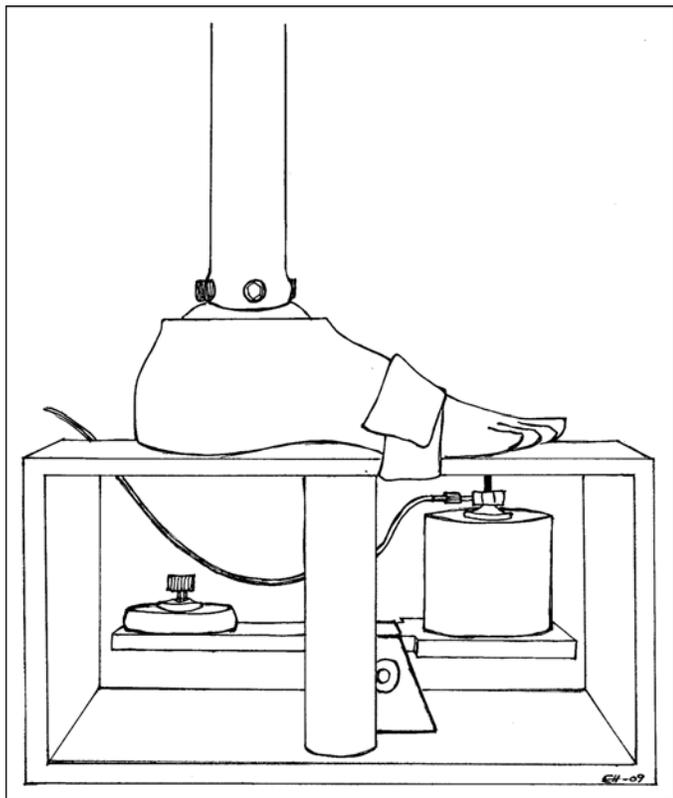


Figure 1.

Test setup for measurement of vibrometric signals through participants' intact and prosthetic feet. Extension pin from vibrator is hitting feet at location of first metatarsal head.

cover of the prosthetic foot) touched the surrounding surface of the box, and the depth from the pin at the forefoot was 1 mm. The participant operated the response button, and a software program controlled the order of the frequencies and the increase and decrease of the signal. When the measurement started, the amplitude from the vibrating pin started low and continuously increased. As soon as the participant could detect the vibration, he or she pressed the remote button. When the participant pressed the button, the amplitude began decreasing and the participant was asked to stop pressing the button as soon as the vibration was no longer noticed. Then the amplitude rose again when the patient let go of the response button and the procedure started all over again. The order of frequencies investigated was 32, 64, 125, 250, 8, 16, and 32 Hz, and each frequency was rerun 16 times before the next was investigated. The order of the different frequencies was unknown by the participant but known by the examiner. The apparatus showed the amplitude in decibel/second. The step-size was set to 0.2 dB/s and the range was 0 to 130 dB. If no vibration was detected at 130 dB, the system went into overload and the cycle was recorded as 130 dB. A familiarizing trial was conducted before each assessment. The full assessment (both prosthetic and intact foot) lasted approximately 45 min and could be stopped at any time if the patient so required. Participants in the OI group were measured at two occasions: first preoperatively using their socket-suspended prosthesis and second at 2 yr after osseointegration treatment using their OI prosthesis. Participants in the control group, with socket-suspended prostheses, were measured once.

Test Prosthesis

To get an idea of the amount of absorption of vibrometric signals through a prosthesis, a copy of the prosthesis with the most numerous and massive components in the study group was built. This prosthesis was chosen since we hypothesized that a prosthesis including the largest number of interacting components most likely would reduce more of the vibrometric transmissions than a less massive prosthesis.

This experimental, or test, prosthesis was placed on the same box (**Figure 2**) and all test frequencies were measured at two locations: (1) at the prosthetic foot blade at the position of the first metatarsal head and (2) at the proximal medial socket edge. The points of measurement were chosen because a horizontal position of the sensor

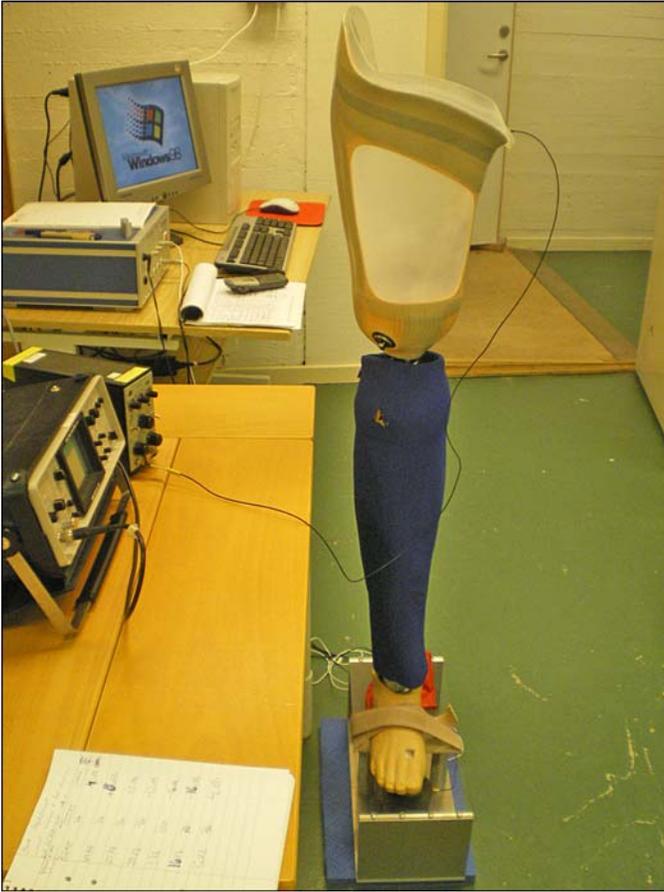


Figure 2.

Test of vibrometric signals through test prosthesis. Most massive socket-suspended prosthesis (4.9 kg) included in study was duplicated for test. It included ischial containment vacuum socket with thermoflex inside and laminated carbonfiber frame with built-in pyramid adapter, transversal adapter 4R57, Mauch knee joint, 30 mm tube, Ceterus standard prosthetic foot (category 7 with shock absorption combined with torsion adapter), and cosmetic cover distal part up to knee joint. Height from tuber ischii to heel was 100.5 cm, height from medial socket edge to heel was 98 cm, and height from center of knee to heel was 58 cm. Foot size was 29 cm.

was needed. The difference between the two values gave a value of the absorption of the vibrometric signal through the test prosthesis. The outcome was read when the signal from the power amplifier showed 115 dB. The measurement equipment used was a sensor (4393, Brüel & Kjær; Nærum, Denmark) and an amplifier accelerometer (Charge amplifier: Brüel & Kjær, type 2635; Spectrum Analyzer: RION SA-24, Real Time Analyzer from RION

Co Ltd; Tokyo, Japan). To compare the results of absorption in the test prosthesis, an attenuation factor was calculated. This factor is used when comparing gradual loss of intensity or some kind of flux through a medium, for example, light or sound through water. An example of attenuating of vibrations is when different seat designs in cars are compared [37].

Analysis and Statistical Methods

The amplitude of the detection threshold for all tests was calculated after 16 cycles at each frequency (mean value in micronewtons). Since the apparatus showed the amplitude in decibels per second, the vibrotactile threshold was measured as a force level expressed in decibels (F_{dB}) relative to micronewtons ($F_{\mu N}$) using the formula $F_{\mu N} = 10^{(F_{dB}/20)} \times 10^{-6}$ N.

The results are presented as mean and standard deviation for each frequency. The repeated measurements at 32 Hz are presented as a mean of the two cycles for each participant. For analyses of differences within groups, the Wilcoxon signed rank test was used. For analyses of differences between groups, the Mann-Whitney U-test was used. All tests were two-tailed and conducted at 5 percent significance level.

The accuracy of the assessment was determined by comparing the data obtained at the repeated measurements at 32 Hz (the first and last measurement within each assessment) using the intraclass coefficient (ICC) [38]. The ICC was calculated for all measurements, irrespective of group, on the prosthetic limb and the intact limb separately.

The results of the measurements conducted on the test prosthesis are presented as the difference between the two signals read at the proximal and distal part of the prosthesis. The difference is expressed in decibels. A negative and a positive numeral mean a reduction and a strengthening of the transmitted vibration, respectively. The attenuation factor "A" ("absorbing factor") is expressed with the formula: $A = (dB) 10^{(a/20)}$, where "a" corresponds to the attenuation in decibels.

RESULTS

Results of the detection level of vibration signals for each frequency measured on the prosthetic and intact limbs for the OI and control groups are presented in **Table 2**. **Table 3** presents all differences between measurements.

Table 2.

Detection threshold of vibrotactile stimulation in prosthetic and intact limbs in frequencies between 8 and 250 Hz. Sensitivity in prosthetic and intact limbs (in μN) for 17 patients before osseointegrated (OI) treatment with socket-suspended prostheses and at 2 yr follow-up with OI prostheses and for 17 patients with socket-suspended prostheses (control group). Values are mean \pm standard deviation.

Frequency (Hz)	OI Group				Control Group	
	Preoperative		2 Yr Follow-Up		Prosthetic Limb	Intact Limb
	Prosthetic Limb	Intact Limb	Prosthetic Limb	Intact Limb		
8	121.4 \pm 17.7	102.4 \pm 14.8	120.4 \pm 14.1	98.9 \pm 11.2	120.5 \pm 16.8	105.4 \pm 17.2
16	115.4 \pm 13.0	103.9 \pm 13.9	114.6 \pm 16.9	99.2 \pm 12.0	123.0 \pm 10.6	106.1 \pm 14.1
32 (Mean)	108.4 \pm 13.8	100.8 \pm 14.7	108.5 \pm 10.9	96.7 \pm 10.7	112.8 \pm 11.0	101.4 \pm 14.9
64	107.5 \pm 9.6	95.1 \pm 12.7	103.6 \pm 7.7	91.5 \pm 10.3	109.2 \pm 10.5	97.8 \pm 14.2
125	110.0 \pm 13.4	98.6 \pm 17.0	100.7 \pm 13.8	95.8 \pm 12.6	113.7 \pm 15.8	97.1 \pm 18.1
250	121.6 \pm 15.7	111.6 \pm 16.3	110.9 \pm 17.2	104.8 \pm 13.1	122.9 \pm 15.7	109.0 \pm 16.9

The OI group showed a statistically significantly improved ability to detect the vibration at a frequency of 125 Hz on the prosthetic limb at 2 yr follow-up (mean difference 9.4 μN , $p = 0.02$) (**Table 3**). Furthermore, the results showed that the OI group had better ability to detect high frequency vibrations (125 and 250 Hz) in the prosthetic limb at follow-up than the control group ($p = 0.01$ and 0.03 , respectively) (**Table 3**). For most frequencies, in both groups, statistically significantly lower detection thresholds were found for the intact limb.

The ICC of the first and last frequency at 32 Hz was 0.83 for the prosthetic limb and 0.79 for the intact limb.

Results illustrating the transmission of vibrometric signals through the test prosthesis (**Figure 2**) are pre-

sented in **Table 4**. The differences in transmitted vibrations were between -16 dB and $+12$ dB depending on the frequency measured. The signal was reduced in the frequencies 8, 125, and 250 Hz and amplified in the frequencies 16, 32, and 64 Hz.

DISCUSSION

This is the first study evaluating osseoperception before and after osseointegration treatment in patients with a TFA. The main findings are that the OI prosthetic connection seems to improve the patients' ability to detect vibrotactile stimuli of higher frequencies applied

Table 3.

Differences of detection threshold of vibrotactile stimulation.

Frequency (Hz)	OI Preop vs 2 Yr Follow-Up						OI Group Preop Prosthetic vs Intact Limb		
	Prosthetic Limb			Intact Limb			Mean \pm SD (μN)	Det/Imp/Tie (n)	p-Value
	Mean \pm SD (μN)	Det/Imp/Tie (n)	p-Value	Mean \pm SD (μN)	Det/Imp/Tie (n)	p-Value			
8	1.0 \pm 11.6	3/3/11	0.92	-0.6 \pm 8.72	8/8/1	0.68	-22.0 \pm 18.8	1/12/4	0.002
16	1.6 \pm 17.9	6/7/4	0.92	2.6 \pm 9.4	5/11/1	0.16	-13.6 \pm 18.0	1/12/4	0.01
32 (Mean)	-0.1 \pm 9.51	5/11/1	0.64	3.4 \pm 15.6	7/10/0	0.19	-8.3 \pm 18.8	4/13/0	0.07
64	-3.9 \pm 13.5	10/7/0	0.59	1.0 \pm 12.3	7/10/0	0.59	-15.1 \pm 12.9	2/15/0	0.001
125	9.4 \pm 15.5	3/13/1	0.02	4.2 \pm 16.0	7/10/0	0.36	-10.0 \pm 17.5	2/12/3	0.003
250	10.7 \pm 20.3	3/8/6	0.08	9.5 \pm 16.3	3/11/3	0.07	-7.4 \pm 21.3	3/6/8	0.21

Note: Results of comparisons within groups are noted as "Det," "Imp," or "Tie," meaning how many results were lower, higher, or same when comparing OI Det = deteriorated, Imp = improved, OI = osseointegrated, Preop = preoperative, SD = standard deviation.

under the prosthetic foot. At 2 yr follow-up, the OI group showed a lower detection threshold at 125 Hz than in the preoperative measurement. Moreover, at follow-up the OI group had a lower detection threshold than the group of controls at both 125 and 250 Hz (**Table 3**). The improved osseoperception might help to explain why patients with OI prostheses have reported their prosthesis to become “as a part of me” [15], and the result adds to the published benefits of OI prosthesis [10,39–41]. Another main finding was that vibrometric signals tested through a test prosthesis not only reduced the vibrometric signals at 8, 125, and 250 Hz but also amplified the vibration at 16, 32, and 64 Hz (**Table 4**).

Although patient groups were not matched, most aspects of patient demographics were similar in the two groups. However, it should be noted that there was a difference in sex distribution, with more females in the OI group than the control group. The results showed no statistically significant differences of detection level of signals when the prosthetic limb was compared between the preoperative measurement in the OI group and the control group (both with socket-suspended prostheses) (**Table 3**). Furthermore, no differences were found when comparing the intact limb between groups (**Table 3**). Altogether, these findings show the groups to be comparable.

The study included some limitations. One is the relatively low number of patients included. However, the 17 patients in the OI group represented more than 10 percent

of the existing population of patients treated with TFA OI prostheses worldwide at the time of the study [9–10]. Moreover, the number of participants is comparable to other studies in the prosthetic and orthotic field [35,39–40,42–43]. Because of practical considerations, the test was performed in a sitting position. We found it difficult for this group of patients to accomplish the test while standing (>30 min) and having to concentrate on the vibrometric sensations and press a response button. It is not known if the sitting posture in contrast to a standing posture might have influenced the results. The single occasion measurement in the control group was a limitation; this prevented analyses of changes of the ability to detect vibration over time in patients using socket-suspended prostheses. Another limitation was the large variation of prosthetic components and the fact that many patients in the OI group had changed components between measurements (**Table 1**), which probably affected the results. In a few cases, a shock absorber or a torsion adapter had been added to the OI prosthesis at follow-up (**Table 1**). Those components are designed to reduce forces at heel strike and to reduce rotational forces, respectively, and hypothetically would reduce vibrations. However, 10 patients in the OI group had the same knee components at both assessments (**Table 1**). Change of components in OI prostheses is usually done between 6 and 12 mo after the OI treatment when the patients can put full weight-bearing on the prosthesis [9].

Table 3. (Continued from across left page)

Differences of detection threshold of vibrotactile stimulation.

OI Group 2 Yr Follow-Up Prosthetic vs Intact Limb			Control Group Prosthetic vs Intact Limb			Control vs OI Preop <i>p</i> -Value		Control vs OI 2 Yr Follow-Up <i>p</i> -Value	
Mean ± SD (μN)	Det/Imp/Tie (<i>n</i>)	<i>p</i> -Value	Mean ± SD (μN)	Det/Imp/Tie (<i>n</i>)	<i>p</i> -Value	Prosthetic Limb	Intact Limb	Prosthetic Limb	Intact Limb
	0/14/3	0.001	−15.2 ± 18.9	2/10/5	0.01	0.74	0.38	0.79	0.23
−15.4 ± 13.7	1/14/2	0.001	−17.0 ± 15.6	1/13/3	0.002	0.08	0.39	0.10	0.15
	4/13/0	0.004	−11.4 ± 12.0	1/14/2	0.01	0.65	0.88	0.28	0.50
−12.1 ± 9.2	2/15/0	0.001	−11.4 ± 10.2	1/14/2	0.001	0.74	0.40	0.44	0.26
−4.9 ± 9.6	6/9/2	0.047	−16.5 ± 21.9	2/12/3	0.01	0.49	0.52	0.01	0.99
−6.2 ± 12.5	4/8/5	0.10	−13.9 ± 20.3	2/11/4	0.04	0.85	0.54	0.03	0.32

preoperatively with OI 2 yr follow-up.

Table 4.

Result of absorption of the vibrometric signal through transfemoral test prosthesis.

Frequency (Hz)	Socket Edge (dB)	Footblade (dB)	Difference (dB)	Result, Attenuation Factor/ Absorption Factor
8	-26	-22	-4	0.6 (Reduction)
16	-16	-20	+4	1.6 (Strengthening)
32	-4	-16	+12	4.0 (Strengthening)
64	8	2	+6	2.0 (Strengthening)
125	2	8	-6	0.5 (Reduction)
250	-12	4	-16	0.2 (Reduction)

Note: Readings at medial edge of prosthetic socket and at prosthetic foot blade at 115 dB/ μ N out-signal from amplifier accelerometer. Result shows difference between two readings, and attenuation factor ("absorbing factor") is reported as reduction/dampening or strengthening/amplifying of vibration signal through test-prosthesis. Attenuation factor A is expressed as: $A = (\text{dB}) 10^{(a/20)}$; "a" corresponds to attenuation in dB.

The scope of the current study was not to conduct vibrometric measurement on all prosthetic components or all combinations of components, and we encourage future studies in this area.

Finally, there was no randomization of the order of the frequencies tested between trials. However, since the frequencies were not in a numerical order of size, there is no reason to believe the OI patients would remember the order of frequencies 2 yr later at the second test.

The method of evaluation used was similar to the QST method of limits Claus et al. used [26], with the patient answering with a response button when vibrometric stimuli could be detected or not detected anymore. The method was chosen because it provides some comparable measurements to previous work [35]. The objectivity of the method of measuring sensitivity has been questioned by Freeman et al., who proposed that subjects can deceive the examiner [44]. On the other hand, Chong and Cros concluded that the reliability is highly dependent on accurate use of methodology [23]. In the current study, the first and last measurement of each trial was made at the same frequency (32 Hz) to test the accuracy. The results showed the reliability to be satisfactory since the ICC of the repeated measurement was above the adequate level of 0.70 for group comparisons [38], both when analyzed for the prosthetic limb (ICC = 0.83) and the intact limb (ICC = 0.79).

Most research on perception has used different evaluation methods and equipment and has been performed on different groups of patients, making comparisons to the current results difficult. Lundborg et al. used equipment comparable to the apparatus in the present study and used similar frequencies to assess the vibrotactile thresholds in the pulp of the index and little fingers in subjects with diverse diagnoses in the upper limb compared to an age-

matched reference population [29]. The mean values among the reference population were in the range between 100 and 120 μ N in the frequencies 32.5, 65, 125, and 250 Hz. Our values in the same frequencies were between 104 and 111 μ N for OI prostheses, 108 and 123 μ N for socket-suspended prostheses, and 95 and 112 μ N for the intact limb (**Table 2**). Aaserud et al. showed higher vibrometric thresholds on the upper than the lower limb in a study assessing 12 nondisabled subjects [30]. The results from Aaserud et al. could explain why our values for the intact limb were somewhat lower than those reported by Lundborg et al. [29].

The only study in which results more directly can be compared with the results of the present study was conducted by Jacobs et al. [35]. In that study, patients with socket-suspended upper- and lower-limb prostheses showed an average of 20 percent higher detection levels on the prosthetic side than on the intact side. The results are comparable to our control group, which showed 11 to 17 percent higher thresholds in the prosthetic limb than in the intact limb (**Tables 2 and 3**). The same authors also proposed that the most important factor decreasing the signal would be the prosthetic components [35]. Participants in the current study had a large variation of prosthetic components (**Table 1**), and within the OI group many had changed some part of their prostheses between the assessments. We agree that the prosthetic components can have important implications on the results. This was one of the reasons why we conducted measurements on a test prosthesis. The results from the test prosthesis showed that the vibration signal was dampened in some frequencies (8, 125, and 250 Hz) but, surprisingly, amplified at others (16, 32, and 64 Hz) (**Table 4**). This varying result could be due to the different parts of the prosthesis, which might give rise to self-oscillation or resonance

amplification. An amplification of the vibrometric signals occurred at the middle frequencies (16, 32, 64 Hz) and a dampening of the vibrometric signal at the highest (125 and 250 Hz) and the lowest (8 Hz) frequency. There is no simple explanation for this behavior and it is important to emphasize that the results presented for the test prosthesis should only be considered as a result of how a single representative prosthesis attenuates the tested vibrations. The transmission of vibration through the different components will depend on, for instance, stiffness and dampening factors in the components as well as in the boundaries between the components. Why the highest and the lowest frequency resulted in absorption of vibration instead of resonance and whether the choice of prosthesis tested influenced the result cannot be answered in the current study, and further studies are needed to resolve this issue. It should also be noted that the test prosthesis was not attached at the proximal end. If the prosthesis had been fitted to a patient and a residual limb had been placed into the socket, the prosthesis would probably have been less inclined to resonance behavior. Therefore, the result of the test prosthesis should be read with the consideration that the lack of proximal attachment might have affected the self-oscillation. Moreover, it is unknown how an individual residual limb and socket fit might influence the outcome in the vibrometric measurements.

In the current study, the statistically significantly lower detection levels were all shown in the higher frequencies (**Table 3**) and were shown in the same frequencies in which signals transmitted through the test prosthesis were reduced (at 125 Hz with -6 dB and at 250 Hz with -16 dB, **Table 4**). If the results of the test prosthesis, with dampened signals in higher frequencies, correspond to the behavior of the prostheses in the study groups, it means the OI group could detect the dampened vibrations better at 2 yr follow-up.

The statistically significant improvements were found in the higher frequencies. There is, however, no information available on which frequencies are more important to detect, nor do we know which detection level is of clinical importance. We can only conclude that the OI group at 2 yr follow-up could detect a few more frequencies better through their prostheses than before OI treatment and than the control group. Safe walking and fear of falling are important issues for a majority of patients with lower-limb amputations [45–46]. Because of the loss of the knee joint, patients with TFA need strat-

egies to maintain balance and to overcome limitations in function of the prosthesis [31–32]. A safe and secure gait and confidence in walking can partly be achieved by training and adequate prosthetic fit and suspension. The decreased sensory feedback through the prosthesis as compared with the intact limb can be a limiting factor in this regard. We suggest that a better ability to detect vibration through the prosthesis at heel strike can give the patient additional feedback of the position of the prosthetic foot and knee. Whether increased sensibility from under the prosthetic foot can prevent falling is not a question the current study can answer, but we believe the more feedback a patient can get for safety, the better. The literature so far presents no evidence of the relationship between less incidence of fall and improved osseoperception. Hypothetically, it can be expected that the firm connection with OI prostheses is advantageous compared with conventional socket-suspended prostheses, resulting in improved stumbling control and less falling.

CONCLUSIONS

The results of this study showed that patients with TFA using OI prostheses have an improved detection threshold for high-frequency vibratory stimulations applied under the prosthetic foot. Furthermore, vibrations transferred through a test prosthesis were found to be decreased or amplified depending on the frequency of the vibration. Feedback of high frequency vibrations from the surroundings through the prosthetic components have in this study been shown to be more easily recognized by patients treated with OI amputation prostheses as compared with conventional socket prostheses, potentially leading to advantages in gait control for patients with an OI prosthesis.

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