Improvement in Bone Mineral Density after a Distal Weight-Bearing Implant in a Series of 13 Cases

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ABSTRACT

Introduction: The amputation of lower limbs and the subsequent use of a prosthesis require the adoption of new biomechanical patterns of load and gait by the patient, which may favor the onset of local or generalized bone mineral density loss. Osseo-anchored implants that allow distal weight bearing of the residuum may be able to mitigate bone mineral density loss related to amputation. The objective of this study is to determine the effect of the use of a distal weight-bearing implant on the bone mineral density of the amputated limb in relation to the nonamputated limb.

Materials and Methods: An interrupted time series clinical trial carried out in the Outpatient Department of Rehabilitation of the five participant hospitals. Thirteen patients with previous transfemoral amputations of traumatic, oncologic, and vascular etiology were enrolled. These patients underwent surgical implantation of an osseo-anchored implant with a distal spacer that allows a direct load on the residuum over the distal surface of the socket. Patients were followed for a 14-month period and assessed presurgically and postsurgically using dual-energy x-ray absorptiometry of the femur neck.

Results: The mean increase in bone mineral density for the amputated limb was 0.020 g/cm^2, which represented a mean percentage increase of 3.0%. For the nonamputated limb, the mean increase in bone mineral density was 0.005 g/cm^2 and the mean percentage increase was 0.5%, with eight patients showing improvements in bone mineral density. The mean percentage of bone mineral density of the amputated limb in comparison with the nonamputated limb was 70.6% preimplantation and 73.2% postimplantation, with an average increase of 2.6%.

Conclusions: The results of this study show an improvement in bone mineral density in individuals with transfemoral amputation 14 months after having received a distal weight-bearing implant. (*J Prosthet Orthot*. 2020;32:116–120)

KEY INDEXING TERMS: bone mineral density, distal weight bearing implant, case series

The amputation of lower limbs and the subsequent use of a prosthesis require the adoption of new biomechanical patterns of load and gait by the patient,[1] which may predispose to injuries due to either overload or disuse.[2] Alterations in the gait pattern and a poor fit of the socket on the residual limb may favor the onset of local or generalized bone mineral density loss.[3] This prosthesis-related bone mineral density loss is primarily a result of the phenomenon of stress shielding, although immobilization and operative trauma also have an impact on bone mineral density loss.[2–5]

The mechanical stress over a bone stimulates the action of the osteoblasts and generates an increase in local bone mineral

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Device status statement: The device that is the subject of this article is not Food and Drug Administration approved and is not commercially available in the United States.

The device is Agencia Española de Medicamentos y Productos Sanitarios approved (no. 358/10/EC) for the indicated usage in Spain.

Trial registration: This clinical trial has been approved by Agencia Española de Medicamentos y Productos Sanitarios with the following registration number: 358/10/EC.

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density (ossification).[5] However, the use of a prosthesis modifies the stress distribution in the surrounding tissue. The prosthesis now shares the load and the carrying capacity with bone, and as a result, the bone is subjected to reduced stresses and hence stress shielded.[6–8] Normally, the femur carries its external load by itself where the load is transmitted from the femoral head through the femoral neck to the cortical bone of the proximal femur. However, in individuals with amputation, the prosthesis absorbs most of the mechanical stress and reduces its presence over the bone. This produces a stress-shielding phenomenon on the bone that has been previously studied.[5] Based on Wolff's law, bones develop a structure most suited to resist the force acting upon them. Areas of bone experiencing high load or stress will respond by increasing bone mass and areas under lower load or stress will respond by decreasing bone mass.[9] Therefore, the lack of support or load on the residual limb could cause the loss of bone mineral density, giving way to complications that may affect the rehabilitation of these patients.[10]

In individuals with transfemoral amputations, there is a greater risk of developing osteopenia and osteoporosis when the amputated limb is compared with the nonamputated limb.[10,11] A previous study has shown that bone mineral density of the femoral neck decreases by 12% to 28% in individuals with transfemoral amputation when compared with the nonamputated limb.[12]

The objective of this study is to determine the effect of the use of a distal weight-bearing implant on the bone mineral density of the amputated limb in relation to the nonamputated limb. The hypothesis derived from this intervention is that there will be an improvement in the bone mineral density of the residual limb after the intervention.

METHODS

Participants were recruited using a single standardized protocol from March 1, 2011, through November 1, 2014, in the outpatient Department of Rehabilitation of the five participant hospitals (Hospital de Mataro, Hospital Universitario y Politecnico La Fe, Hospital Universitario Virgen del Rocio, Hospital Universitario Virgen Macarena, and Hospital Universitario Nuestra Señora de Candelaria). This interrupted time series clinical trial has been approved by Agencia Española de Medicamentos y Productos Sanitarios and the Ethical Committee of the participating hospitals with the following registration number: 358/10/EC. The trial meets the standards of the Helsinki Declaration. All participants gave their informed consent.

The inclusion criteria for intervention were as follows: unilateral femoral amputation, femur length of the amputated limb of at least 15 cm measured from the greater trochanter, use of the prosthesis for at least 12 months and for more than 6 hours per day before enrollment, and ability to walk indoors with or without supervision and with or without ambulation aids. The exclusion criteria were as follows: hip flexion deformity greater than 30°, body weight greater than 100 kg, active oncological pathologies, active infection, previous residuum infection, psychological disorders, cognitive impairment hindering the ability to follow instructions or perform the tests, and/or pregnancy. The patients who met the inclusion criteria were interviewed individually and the intervention carefully explained before they were asked to participate in the study.

A total of 29 patients were invited to participate and all accepted and were included in the study. Each patient acted as his/her own reference. All patients were amputated before the surgical intervention discussed here. Each patient underwent both a postamputation, preintervention dual-energy x-ray absorptiometry and a postimplantation surgery dual-energy x-ray absorptiometry of the femur neck to evaluate bone mineral density on both the amputated and nonamputated limbs. No concerns are present due to issues regarding different equipment at different data collection sites, calibration procedures, or positioning of limb during the dual-energy x-ray absorptiometry. Personnel involved in the testing belong to the same research group and were properly instructed on the testing procedure. The presurgical controls were performed during preoperative testing and the postsurgical controls at 14 months postintervention once the patients had been rehabilitation-free for 4 months.

The distal weight-bearing implant designed for this study is composed of four pieces. The femoral stem consisted of a titanium alloy (Ti-6Al-4 V) and a spacer made of high-density polyethylene, which was distally connected to the stem by a titanium screw and a polyethylene plug. The spacer allowed distal support of the residuum within the socket. The implant is designed for optimal long-term osseointegration. It is expected that the bone-implant bond will progressively get stronger and therefore reduce the risk of loosening.

The distal part of the residual femur was smoothed, and the medullary canal reamed to the appropriate diameter to create space for the implant stem. Specialized tools were used to determine the appropriate size of the stem, both in length and diameter, whereas the size of the spacer was determined with trial implants. The length of the stem ranged from 120 to 180 mm, and the diameter, from 12 to 17 mm. The spacer size used was the largest size available (54, 58, or 62 mm) that permitted closure without soft tissue tension. The definitive implant was assembled and placed into the femur with the press fit method. Soft tissue closure was performed with a myoplasty procedure that completely covered the spacer.

All patients were fitted a contoured adducted trochanteric-controlled alignment method socket with distal support such as those used for knee disarticulation amputation. All patients maintained the same prosthetic knees and feet used previously.

To evaluate the effect of the intervention on bone mineral density, the results obtained from the dual-energy x-ray absorptiometries preintervention and postintervention were compared. The absolute differences and the percentage increase in bone mineral density within each limb across time were calculated. Each value of bone mineral density of the amputated limb was also calculated as a percentage of the bone mineral density of the nonamputated limb. The change in this value was also calculated. Finally, the effect size was determined following the formula shown: effect size = [(mean postintervention) – (mean preintervention)]/pooled standard deviation. For the analysis of the absolute differences and the percentage increase, the bone mineral density preintervention was considered as the control

value, and the bone mineral density postintervention, as the study variable. In the analysis of the relative bone mineral density values of the amputated limb to the nonamputated limb, the bone mineral density of the nonamputated limb was considered as the control value, and the bone mineral density of the amputated limb, as the study variable.

RESULTS

The initial sample of the study was 29 patients. One patient was excluded for not completing the established schedule and five patients required the removal of the implant.

Complete bone mineral density information (preimplantation and postimplantation values for both limbs) was available for 13 patients. Cases were lost mainly because of the lack of preoperative bone mineral density values of the nonamputated limb. Thirteen participants with a mean age of 46.92 years and a range between 18 and 67 years old were included in the study. Patients had been amputated for a mean of 6.31 years before the intervention, with a range between 1 and 32 years. Ten of the 13 (76.9%) patients were men. The average body mass index was 24.48. The etiology of amputation was traumatic in 10 patients (76.9%) and vascular in 3 patients (23.1%), with no oncologic patients. Individualized demographic data can be found in Table 1.

Table 2 shows the results for bone mineral density of the amputated and residual limbs preintervention and postintervention. Seven patients showed an improvement in bone mineral density of the amputated limb. The mean increase in bone mineral density for the amputated limb was 0.020 g/cm^2, which represented a mean percentage increase of 3.0%. The range in increase in mineral density was −0.093 to 0.318 and for the percentage increase was −12.1% to 120.0%. For the nonamputated limb, the mean increase in bone mineral density was 0.005 g/cm^2 and the mean percentage increase was 0.5%, with eight patients showing improvements in bone mineral density. The range in increase in mineral density was −0.086 to 0.138 and for the percentage increase was −10.4% to 14.3%. The mean percentage of bone mineral density of the amputated limb in comparison to the nonamputated limb was 70.6% preimplantation and 73.2% postimplantation, with an average increase of 2.6%. Preimplantation, the patient with the worst results had 32.0% bone mineral density in the amputated limb as in the nonamputated limb, whereas postimplantation, the worst result was 63.0%. The effect size is 0.2, meaning that the average person in the postimplantation group would score higher than 58% of a preimplantation group that was initially equivalent. Bone mineral density values are presented as percentages of the nonamputated limb and not absolute values to avoid bias due to the heterogeneity of the group. Sex, age, etiology of amputation, years amputated, and others, can all influence overall bone mineral density. However, using the nonamputated limb for comparison minimizes the effect of possible confounders.

DISCUSSION

Osteopenia is a condition in which bone mineral density is lower than normal, whereas osteoporosis is defined as a bone mineral density of 2.5 standard deviations below that of a young adult.[13–15] Decreased bone density leads to bone fragility and an increased risk of bone fracture, which in turn may lead to chronic pain and reduced mobility.[16] Severe bone mineral density loss can lead to loss of height, stooped posture, humpback, and severe pain.[16] Etiologically, osteoporosis can be distinguished into primary forms and secondary ones, which comprise an underlying clinical cause. The bone mineral density loss related to amputation and use of prosthesis would be a secondary form of osteoporosis. Bone mineral density loss related to amputation has been corroborated in several previous studies.[3,4,17,18]

Table 1. Individualized demographic data

	Sex	Age, years	Etiology	Years Amputated	Weight, kg	Height, m	BMI
1	F	44	Trauma	2	55	1.65	20.20
2	M	67	Vascular	3	64	1.62	24.39
3	M	62	Vascular	3	73	1.75	23.84
4	M	39	Trauma	8	70	1.76	22.60
5	F	57	Trauma	2	67	1.6	26.17
6	M	63	Trauma	1	83	1.7	28.72
7	M	37	Trauma	11	69	1.69	24.16
8	F	43	Vascular	2	54	1.55	22.48
9	M	35	Trauma	2	75	1.75	24.49
10	M	52	Trauma	32	70	1.7	24.22
11	M	18	Trauma	2	60	1.67	21.51
12	M	48	Trauma	1	80	1.7	27.68
13	M	45	Trauma	13	98	1.88	27.73
Mean		46.92		6.31	70.62	1.69	24.48

BMI, body mass index.

Table 2. Individualized BMD values

	Femur Neck Pre-BMD, g/cm^2			Femur Neck Post-BMD, g/cm^2			Amputated		Nonamputated		
	Amputated	Nonamputated	%[a]	Amputated	Nonamputated	%[a]	Δ BMD, g/cm^2[b]	Percentage Increase	Δ BMD, g/cm^2[b]	Percentage Increase	Δ%[b]
1	0.506	0.791	63.97	0.512	0.734	69.75	0.006	1.19	−0.057	−7.21	5.79
2	0.265	0.828	32.00	0.583	0.742	78.57	0.318	120.00	−0.086	−10.39	46.57
3	0.654	0.963	67.91	0.741	1.101	67.30	0.087	13.30	0.138	14.33	−0.61
4	0.737	1.120	65.80	0.718	1.139	63.04	−0.019	−2.58	0.019	1.70	−2.77
5	0.691	0.860	80.35	0.648	0.825	78.55	−0.043	−6.22	−0.035	−4.07	−1.80
6	0.911	0.936	97.33	0.868	1.002	86.63	−0.043	−4.72	0.066	7.05	−10.70
7	0.499	0.712	70.08	0.553	0.730	75.75	0.054	10.82	0.018	2.53	5.67
8	0.480	0.865	55.49	0.536	0.789	67.93	0.056	11.67	−0.076	−8.79	12.44
9	0.831	0.994	83.60	0.854	1.007	84.81	0.023	2.77	0.013	1.31	1.20
10	0.777	0.988	78.64	0.684	1.007	67.92	−0.093	−12.08	0.019	1.92	−10.72
11	0.666	0.950	70.11	0.618	0.978	63.19	−0.048	−7.21	0.028	2.95	−6.92
12	0.828	1.063	77.89	0.784	1.097	71.47	−0.044	−5.31	0.034	3.20	−6.43
13	0.747	1.009	74.03	0.760	0.995	76.38	0.013	1.74	−0.014	−1.39	2.35
Mean	0.661	0.929	70.56	0.681	0.934	73.18	0.020	3.03	0.005	0.54	2.62

BMD, bone mineral density.
[a](Amputated/nonamputated) × 100.
[b]Femur neck post – femur neck pre.

In this study, all patients presented with osteopenia in the amputated limb when compared with the nonamputated limb both preimplantation and postimplantation. Only one patient met the criteria for relative osteoporosis in the amputated limb preimplantation, whereas none did so postimplantation. An overall improvement in bone mineral density values was observed. When considering the amputated limb, 53.8% (7/13) of patients showed improvement in bone mineral density. For the nonamputated limb, improvement was present in 61.5% (8/13) of patients. The range of change in bone mineral density was much greater for the amputated limb than for the nonamputated limb. When considering the relative bone mineral density values of the amputated limb to the nonamputated limb, an improvement was observed in 46.2% (6/13) of patients. This value should be considered with caution because the ideal effect would be the overall improvement in bone mineral density in both limbs if possible, not just making them more symmetrical.

The improvements in bone mineral density found in this study occurred after only a 14-month period, which included major surgical trauma and a rehabilitation period, and therefore further improvement in bone mineral density can be expected after a longer follow-up period. This study demonstrates the short-term benefit on bone mineral density of using a distal weight-bearing implant for patients with transfemoral amputations in a clinical trial of patients. Other previous studies involving the distal weight-bearing implant here studied have shown improvements on other outcome measures such as the 2-minute walk test.[19]

LIMITATIONS AND STRENGTHS

This study has several important limitations. First is the total number of patients; this study included a sample size of 23 patients, for which complete bone mineral density information was only available for 13. However, given the design of the clinical trial where each patient acted as his/her own reference, the internal validity of the trial is very high. The complication rate of 17% and missing data reduced our already small starting sample size. Complications were a result of uncontrollable circumstances and could continue to present a problem. The second limitation is the heterogeneity of the sample, given mainly by the causes of amputation and patient profile. The different etiologies of amputation are linked with different comorbidities and patient characteristics.

CONCLUSION

The results of this study show an improvement in bone mineral density in individuals with transfemoral amputation 14 months after having received a distal weight-bearing implant. Further studies in larger clinical trials of patients over longer follow-up periods while using a wider range of relevant outcome measures, such as visual analog scale scores, are needed to confirm the improvements observed.

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