TABLE E-1 The Effect of Risedronate on Primary and Secondary End Points*

Outcome	Risedronate	Placebo	Difference (95% CI)	P Value
Primary end point†				
Change in BMD in zone 1 *(%)*				
3 mo	1.2 ± 7.6	–5.9 ± 9.0	7.2 (3.2 to 11.1)	<0.001
6 mo	–0.5 ± 10.8	–9.7 ± 9.9	9.2 (4.2 to 14.1)	<0.001
12 mo	–7.4 ± 14.7	–14.5 ± 11.2	7.2 (1.0 to 13.3)	0.006
24 mo	–13.6 ± 12.3	–17.7 ± 13.1	4.1 (–2.0 to 10.2)	0.066
Change in BMD in zone 7 *(%)*				
3 mo	–3.6 ± 10.2	–10.3 ± 10.9	6.7 (1.6 to 11.7)	0.007
6 mo	–5.1 ± 10.6	–13.1 ± 11.7	8.0 (2.7 to 13.4)	0.003
12 mo	–11.9 ± 12.3	–16.1 ± 12.0	4.3 (–1.5 to 10.1)	0.318
24 mo	–17.2 ± 13.2	–18.1 ± 14.9	0.9 (–5.9 to 7.7)	0.699
Secondary end points				
Change in BMD in zones 1-7† *(%)*				
3 mo	–0.9 ± 3.6	–3.4 ± 4.1	2.5 (0.7 to 4.4)	0.005
6 mo	–0.3 ± 3.7	–4.0 ± 5.0	3.8 (1.6 to 5.9)	<0.001
12 mo	–0.9 ± 4.8	–4.5 ± 4.9	3.6 (1.3 to 5.9)	0.001
24 mo	–2.9 ± 4.9	–5.1 ± 4.9	2.2 (0.2 to 4.6)	0.032
Vertical migration of the stem† *(mm)*				
6 mo	–1.2 ± 1.2	–1.0 ± 0.8	–0.2 (–0.7 to 0.3)	0.520
12 mo	–1.5 ± 1.5	–1.4 ± 1.0	–0.1 (–0.7 to 0.5)	0.809
24 mo	–1.7 ± 1.5	–1.7 ± 1.2	0.1 (–0.6 to 0.8)	0.807
Harris hip score‡				
Preop.	45 (13 to 69)	48 (13 to 69)		0.688
24 mo	100 (81 to 100)	98 (46 to 100)		0.084
EuroQoL‡				
Preop.	0.42 (–0.14 to 0.85)	0.30 (–0.18 to 0.73)		0.081
24 mo	1.0 (0.52 to 1.0)	0.80 (–0.07 to 1.0)		0.134
Pain Numerical Rating Scale‡				
Preop.	7 (4 to 10)	7 (3 to 10)		0.761
24 mo	0 (0 to 3)	0 (0 to 8)		0.183
BMD at L1-L4 at 24 mo† *(g/cm^2)*	1.27 ± 0.24	1.30 ± 0.27	–0.03 (–0.16 to 0.10)	0.631
Fixation and stability score at 24 mo‡	15.5 (7.5 to 23.5)	18.0 (9.5 to 23.5)		0.004
Heterotopic ossification at 24 mo§				0.551
None	25 (69)	28 (76)		
Class I or II	11 (31)	8 (22)		
Class III or IV	0 (0)	1 (2)		

*CI = confidence interval, and BMD = bone mineral density. †The values are given as the mean and standard deviation. The p value was determined with use of the Student t test. ‡The values are given as

the median with the range in parentheses. The p value was determined with use of the Mann-Whitney U test. §The values are given as the number of patients with the percentage in parentheses. The p value was determined with use of the chi-square test.

TABLE E-2 Number of Adverse Events

	Risedronate (N = 36)	Placebo (N = 37)	P Value
Any adverse event	20	24	0.416
Drug-related adverse event*	5	3	0.429
Urticaria	3	1	
Nausea	2	0	
Dyspepsia	0	2	
Surgery-related adverse event*	8	10	0.634
Leg swelling or leg pain on operated side	3	5	
Postoperative anemia requiring transfusion	2	1	
Superficial wound infection	2	1	
Deep venous thrombosis	0	1	
Pulmonary embolism	0	1	
Dislocation	1	1	
Other adverse event†	7	11	0.308
Contusion of lower extremity	4	0	
Upper respiratory tract infection	0	4	
Other minor infection	0	2	
Hypothyroidism	0	1	
Fracture of upper extremity	1	0	
Vertigo	0	3	
Conjunctivitis	1	0	
Hypoglycemia	1	0	
Urinary tract infection	0	1	
Serious adverse event‡	1	2	
Discontinuation of study drug due to adverse event	4	0	0.037

*Adverse events classified as having a certain or probable relationship to the study drug or surgery. †Adverse events classified as having no relationship to the study drug or surgery. ‡Three subjects were hospitalized during the study period, two due to dislocation and one due to pulmonary embolism.