

## Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009;361:557-68.

**Web Supplementary Table 1. Baseline characteristics of participants\***

	<b>Vertebroplasty (n=38)</b>	<b>Placebo (n=40)</b>
Age, years, mean (SD)	74.2 (14.0)	78.9 (9.5)
Female, N (%)	31 (82)	31 (78)
Median (IQR) duration back pain, weeks	9 (3.8 – 13)	9.5 (3 – 17)
Duration symptoms <6 weeks, n (%)	12 (32)	13 (32)
Body mass index (BMI), (kg/m <sup>2</sup> ), mean (SD)	25.6 (5.5)	24.6 (5.7)
Smoking status, N (%)		
Never	20 (53)	12 (33)
Former	14 (37)	24 (60)
Current	4 (10)	3 (7)
Alcohol use, N (%)		
Never	8 (21)	12 (30)
Sometimes	17 (45)	18 (45)
Daily	13 (34)	10 (25)
Median duration (IQR) corticosteroids, years	(n = 12) 3 (0.3 - 10.8)	(n = 17) 2 (0.3 – 12 .5)
Overall pain, mean (SD) (0 - 10, 10=worst pain)	7.4 (2.1)	7.1 (2.3)
Pain at rest, mean (SD) (0 - 10, 10=worst pain)	4.5 (2.3)	4.8 (2.8)
Pain in bed at night (0 - 10, 10=worst pain), mean (SD)	4.8 (3.0)	3.6 (3.2)

QUALEFFO total score, mean (SD) (0 – 100, 100=worst quality of life)		56.9 (13.4)	59.6 (17.1)
Pain		72.2 (17.3)	72.1 (16.5)
Physical function		50.2 (17.7)	54.3 (22.9)
Leisure, social activities		66.3 (21.8)	74.3 (23.1)
General health perception		78.9 (17.3)	78.1 (16.7)
Mental function		44.3 (15.9)	44.3 (17.7)
AQoL, mean (SD) (-0.04 – 1.0, 1=perfect health)		0.33 (0.25)	0.27 (0.26)
Roland Morris, mean (SD) (0 - 23, 23=worst function)	(n = 30)^	17.3 (2.8)	(n = 29)^ 17.3 (2.9)
EQ5D (0 – 1, 1 = perfect health), mean (SD)	(n = 30)^	0.30 (0.32)	(n = 29)^ 0.28 (0.33)
Timed up and go test, seconds, mean (SD)	(n = 36)	20.5 (8.8)	(n = 37) 23.9 (13.8)
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Taking any medication for osteoporosis, N (%)		35 (92)	37 (93)
Calcium supplements		27 (71)	25 (63)
Vitamin D		14 (37)	18 (45)
Bisphosphonates		31 (82)	32 (82)
Previous fractures, N (%)		25 (66)	25 (63)
Spine		18 (47)	21 (53)
Hip		5 (13)	3 (8)
Wrist		7 (18)	7 (18)
Ribs		8 (21)	6 (15)

Other†	10 (26)	13 (33)
Taking opioids for pain, N (%)	30 (75)	34 (89)
Lumbar BMD T score < -2.5 SD, N (%)	(n = 34) 21 (62)	(n = 28) 21 (75)
Femoral neck BMD T score < -2.5 SD, N (%)	(n = 34) 13 (38)	(n = 28) 15 (54)
Fracture appearance, N (%)	(N = 45)	(N = 47)
Biconcave	4 (9)	4 (9)
Crush	6 (13)	10 (21)
Wedge	35 (78)	33 (70)
Severity of fracture, N (%) <sup>+</sup>	(N = 45)	(N = 47)
Mild	13 (29)	12 (25)
Moderate	21 (47)	24 (51)
Severe	11 (24)	11 (23)
Number of vertebral bodies treated, N (%)		
1	31 (82)	33 (83)
2	7 (18)	7 (17)

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\*no significant difference between groups for any of the measured variables

^Roland Morris and EQ5D were added to protocol in June 2005 (to be comparable to outcomes used in another trial (36)

†includes arm, leg, pelvis, shoulder, clavicle

+Genant semi quantitative technique (20)

**Web Supplementary Table 2. Further outcomes of the study participants at 1 week, 1, 3 and 6 months by treatment group**

Outcome measure	1 week		1 month				3 months			6 months		
			Adjusted		Adjusted		Adjusted			Adjusted		
	Mean (SD) change		between group		Mean (SD) change		between group		Mean (SD) change			between group
			Mean				Mean			Mean		
			difference‡				difference‡			difference‡		
	Active (n=37)	Placebo (n=37)	(95% CI)	Active (n=35)	Placebo (n=38)	(95% CI)	Active (n=35)	Placebo (n=36)	(95% CI)	Active (n=34)	Placebo (n=35)	(95% CI)
QUALEFFO												
Subscales												
Pain	7.8 (20.5)	16.1 (23.1)	-8.5 (-18.2, 1.1)	14.8 (21.2)	19.3 (27.7)	-4 (-15.1, 7.1)	18.1 (21.1)	21.1 (30.6)	-2.7 (-14.5, 9.1)	20.4 (25)	20.7 (25)	-0.5 (-11.2, 10.2)
Physical function	-1.1 (8.8)	1.8 (10.3)	-2.7 (-7.1, 1.6)	2.6 (10.0)	1.5 (14.8)	1.6 (-4.5, 7.6)	8.2 (12.3)	6.7 (17.4)	2.5 (-3.9, 8.9)	7.6 (17.6)	6.2 (17.6)	2.1 (-4.9, 9.0)
Leisure, social	-3.5 (17.3)	3.3 (15.2)	-4.8 (-11.9, 2.4)	-2.7 (15.7)	0.7 (17.5)	-1.7 (-9.3, 5.8)	0.8 (20.0)	2.7 (16.6)	-0.1 (-8.2, 8)	2.8 (18.8)	8.0 (18.8)	-3.0 (-11.3, 5.3)
General health	2.9 (15.2)	4.1 (15.8)	-2.1 (-8.9, 4.8)	3.6 (18.9)	-2.0 (15.4)	5.4 (-2, 12.7)	7.2 (17.3)	2.3 (17.2)	5.1 (-2.4, 12.6)	5.0 (16.8)	1.9 (16.8)	2.4 (-5.4, 10.1)
Mental function	-3.1 (12.5)	-0.4 (14.2)	-2.6 (-8.7, 3.5)	-0.8 (16.0)	-3.9 (14.4)	3.1 (-3.6, 9.8)	-1.9 (12.9)	-1.1 (17)	-0.6 (-7.2, 6)	-1.3 (15.1)	-3.2 (15.1)	1.5 (-5.7, 8.6)

<b>Perceived change</b>	<b>N (%)</b>	<b>N (%)</b>	<b>Relative risk*</b>	<b>N (%)</b>	<b>N (%)</b>	<b>Relative risk*</b>	<b>N (%)</b>	<b>N (%)</b>	<b>Relative risk*</b>	<b>N (%)</b>	<b>N (%)</b>	<b>Relative risk*</b>
<b>Fatigue</b>												
Better <sup>#</sup>	7 (19)	4 (11)	1.8 (0.6 – 5.5)	7 (20)	7 (18)	1.1 (0.4 – 2.8)	7 (19)	6 (16)	1.2 (0.4 – 3.2)	8 (23)	13 (36)	0.6 (0.3 – 1.3)
No change	25 (68)	28 (76)		24 (69)	23 (61)		23 (64)	22 (60)		21 (60)	15 (42)	
Worse <sup>#</sup>	5 (13)	5 (13)		4 (11)	8 (21)		6 (17)	9 (24)		6 (17)	8 (22)	
<b>Overall health</b>												
Better <sup>#</sup>	4 (11)	8 (22)	0.5 (0.1 – 1.5)	8 (23)	9 (24)	1.0 (0.4 – 2.2)	6 (17)	9 (24)	0.7 (0.3 – 1.7)	11 (32)	15 (42)	0.7 (0.4 – 1.4)
No change	30 (81)	27 (73)		25 (71)	22 (58)		25 (69)	21 (57)		19 (54)	13 (36)	
Worse <sup>#</sup>	3 (8)	2 (5)		2 (6)	7 (18)		6 (17)	7 (19)		5 (14)	8 (22)	
<b>Change in pain</b>												
<b>Overall Pain</b>												
<2.5 units	23 (62)	23 (62)	1.0 (0.6, 1.8)	17 (49)	22 (58)	1.2 (0.7, 2.0)	17 (47)	24 (65)	1.5 (0.9, 2.6)	16 (46)	21 (58)	1.3 (0.8 – 2.1)
≥ 2.5 units	14 (38)	14 (38)		18 (51)	16 (42)		19 (53)	13 (35)		19 (54)	15 (42)	
<b>Pain at rest</b>												
<2.5 units	30 (81)	25 (68)	0.6 (0.3, 1.3)	24 (69)	24 (63)	0.9 (0.4, 1.6)	23 (64)	26 (70)	1.2 (0.7, 2.3)	20 (57)	21 (58)	1.0 (0.6 – 1.8)
≥ 2.5 units	7 (19)	12 (32)		11 (31)	14 (37)		13 (36)	11 (30)		15 (43)	15 (42)	
<b>Pain at night</b>												
<2.5 units	28 (76)	29 (78)	1.1 (0.5, 2.6)	21 (60)	28 (74)	1.5 (0.8, 3.0)	26 (70)	23 (64)	1.2 (0.7, 2.3)	22 (63)	28 (78)	1.7 (0.8 – 3.5)
≥ 2.5 units	9 (24)	8 (22)		14 (40)	10 (26)		11 (30)	13 (36)		13 (37)	8 (22)	

‡ From multiple linear regression analyses adjusted for stratification variables and baseline values. Positive values favor the active group.

\* Relative risk of being better compared with being unchanged or worse.

# Moderately or a great deal better or worse