SUPPLEMENT

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Table A1. For each group and each time point the mean Qualeffo score (including 95% CI).			
Measure **QUALEFFO★**	**PV group (N=90)** **Mean (95% CI) †**	**Sham group (N=86)** **Mean (95% CI) †**	**Group difference** **Mean (95% CI)§**
At baseline	59.73 (55.96 to 63.51)	60.70 (56.84 to 64.56)	0.96 (−4.43 to 6.36)
At week 1	53.07 (49.29 to 56.85)	51.84 (47.97 to 55.70)	−1.23 (−6.64 to 4.17)
At 1 month	47.77 (43.99 to 51.56)	49.32 (45.45 to 53.19)	1.55 (−3.87 to 6.96)
At 3 months	44.24 (40.44 to 48.04)	44.97 (41.07 to 48.87)	0.73 (−4.72 to 6.17)
At 6 months	43.56 (39.73 to 47.38)	42.90 (38.95 to 46.84)	−0.66 (−6.16 to 4.83)
At 12 months	41.41 (37.54 to 45.28)	42.09 (38.05 to 36.13)	0.68 (−4.91 to 6.27)
Difference between Baseline & 12 months	18.32 (13.03 to 23.61)	18.61 (13.02 to 24.20)	−0.14 (−3.04 to 2.76)

Legends

†   Statistically significant difference between Qualeffo at baseline and at each follow-up.

*   Model estimates were adjusted based on the covariates age, gender, vertebral level, pain

treatment, osteonecrosis, new fractures after baseline and further vertebral height loss.

PV   Percutaneous Vertebroplasty

★   QUALEFFO= Scores on the Quality of Life Questionnaire of the European Foundation of Osteoporosis

range from 0 to 100, higher scores are indicating worse quality of life

§ The between group differences are contrast estimates at each time point based on the custom hypothesis test function in the SPSS Mixed analysis. Positive estimates favor the sham procedure, negative favor the PV procedure.

Table A2. For each group and each time point the mean RMDQ score (inclusing 95% CI)*.			
Measure RMDQ★	PV group (N=90) Mean (95% CI) †	Sham group (N=86) Mean (95% CI) †	Group difference Mean (95% CI)§
At baseline	18.02 (16.75 to 19.29)	17.79 (16.49 to 19.09)	−0.23 (−2.05 to 1.58)
At week 1	14.83 (13.55 to 16.10)	14.01 (12.71 to 15.31)	−0.81 (−2.63 to 1.01)
At 1 month	11.86 (10.56 to 13.14)	12.98 (11.67 to 14.29)	1.12 (−0.71 to 2.95)
At 3 months	10.90 (9.62 to 12.20)	11.51 (10.18 to 12.84)	0.60 (−1.25 to 2.46)
At 6 months	10.09 (8.79 to 11.39)	10.97 (9.62 to 12.33)	0.88 (−1.00 to 2.76)
At 12 months	10.31 (8.98 to 11.63)	10.32 (8.92 to 11.72)	0.01 (−1.92 to 1.94)
Difference between Baseline & 12 months	7.71 (5.87 to 9.55)	7.47 (5.56 to 9.38)	0.12 (−1.11 to 1.35)

Legends

† **Statistically significant difference between RMDQ at baseline and at each follow-up.**

* Model estimates were adjusted based on the covariates age, gender, vertebral level, pain treatment, osteonecrosis, new fractures after baseline and further vertebral height loss.

PV **Percutaneous Vertebroplasty**

★ RMDQ= Scores on the Roland – Morris Disability Questionnaire range from 0 to 24, higher scores indicating worse physical functioning.

§ Contrast estimates represent differences between groups at each time point and are estimated based on the custom hypothesis test function in the SPSS Mixed analysis. Positive estimates favor the sham procedure, negative favor the PV procedure.

Table A3. For both the vertebroplasty and sham groups the number of patients over a one-year time course (x-axis) using no medication, non- opiate medication (aspirin, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs)), weak opiates (codeine, tramadol), and strong opiates (morphine, fentanyl).

Medication	Group	Baseline	1 day	1 week	1 month	3 months	6 months	12 months
No medication	PV	4 (4%) N = 90	19 (21%) N = 89	14 (16%) N = 88	34 (40%) N = 86	34 (40%) N= 85	40 (48%) N = 83	35 (44%) N = 79
	Sham	8 (9%) N = 86	29 (34%) N = 86	21 (25%) N = 85	34 (40%) N = 85	33 (41%) N = 80	33 (42%) N = 78	33 (47%) N = 70
Non-opiate medication	PV	78 (87%) N = 90	60 (67%) N = 89	67 (76%) N = 88	43 (50%) N = 86	45 (53%) N= 85	37 (45%) N = 83	35 (44%) N = 79
	Sham	65 (76%) N = 86	46 (54%) N = 86	60 (71%) N = 85	48 (56%) N = 85	42 (52%) N = 80	40 (51%) N = 78	32 (46%) N = 70
Weak opiates	PV	13 (14%) N = 90	7 (8%) N = 89	6 (7%) N = 88	6 (7%) N = 86	5 (6%) N= 85	4 (5%) N = 83	2 (2%) N = 79
	Sham	17 (20%) N = 86	10 (12%) N = 86	7 (8%) N = 85	4 (5%) N = 85	3 (4%) N = 80	4 (5%) N = 78	0 (0%) N = 70
Strong opiates	PV	42 (47%) N = 90	30 (34%) N = 89	31 (35%) N = 88	18 (21%) N = 86	17 (20%) N= 85	12 (14%) N = 83	13 (16%) N = 79
	Sham	25 (29%) N = 86	24 (28%) N = 86	16 (19%) N = 85	19 (22%) N = 85	13 (16%) N = 80	13 (17%) N = 78	11 (16%) N = 70

Table A4. Computer Tomography (CT) measured cement leakage.		
Measure	**PV group (N-115)** §	
		%
CT leakage★	**No. Vertebra with leakage**	
Type ¶ 1	23	20%
Type 2	17	15%
Type 3	12	10%
Type 4	45	39%
Type 5	8	7%
Type 6	9	8%

Legends

PV   Percutaneous Vertebroplasty

★   The threshold for describing leakage was anything perceptible.

§   Number of vertebral fractures treated in the PV group. The same vertebra could show one or more types of leakage

¶   Type 1 leakage: intervertebral discus above the treated level; Type 2 leakage: intervertebral discus under the treated level; Type 3: perivertebral soft tissue; Type 4: perivertebral veins; Type 5: pulmonary; Type 6: spinal canal.

Figure A1 For both the vertebroplasty and sham groups the number of patients (y-axis) over a one-year time course (x-axis) using no medication, non- opiate medication (aspirin, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs)), weak opiates (codeine, tramadol), and strong opiates (morphine, fentanyl).