

**Appendix:** Details of TRUST committees and study investigators; supplementary figure and table [posted as supplied by author]

## **TRUST Committees**

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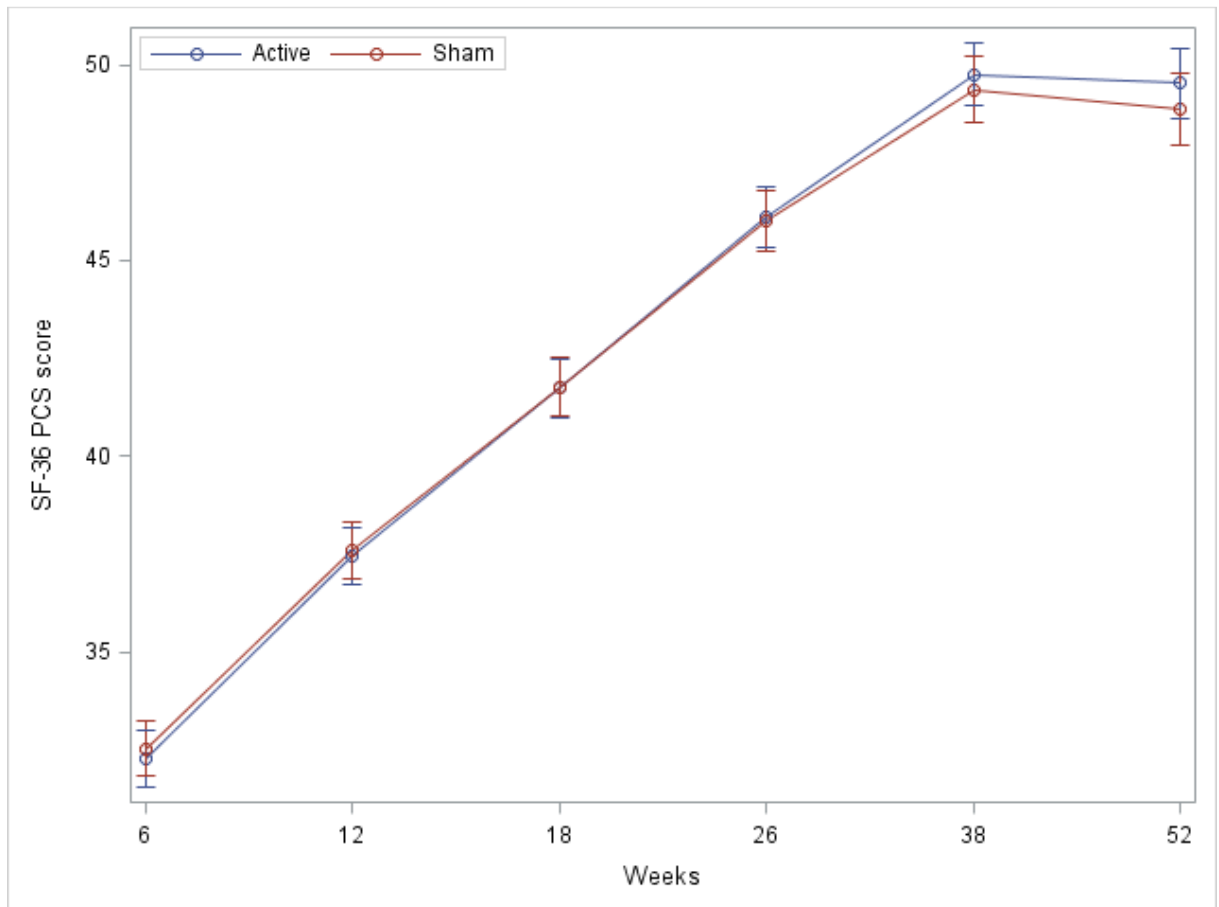
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**Figure A:** Sensitivity analysis of SF-36 PCS scores using a non-linear model to impute missing data



**Table A: Patients affected by early trial stoppage**

<b>Follow-up visit</b>	<b>No. of patients affected by early stoppage at each visit</b>	<b>Cumulative no. of patients affected by early stoppage</b>
6 week visit	3	3
12 week visit	3	6
18 week visit	3	9
26 week visit	32	41
38 week visit	30	71
52 week visit	2	73

**Table B: SF-36 PCS scores for LIPUS and sham therapy**

<b>Follow-up Visit</b>	<b>Active</b>		<b>Sham</b>	
	<b>N</b>	<b>Mean (SD)</b>	<b>N</b>	<b>Mean (SD)</b>
6 weeks	237	31.8 (8.4)	238	32.0 (7.6)
12 weeks	227	39.4 (8.9)	215	38.6 (9.0)
18 weeks	212	43.5 (9.9)	193	43.6 (9.4)
26 weeks	193	46.6 (9.2)	182	46.3 (8.9)
38 weeks	160	48.4 (8.7)	145	48.4 (8.8)
52 weeks	153	51.0 (7.9)	148	49.3 (8.8)



**Table C: HUI-III scores at each follow-up for LIPUS and sham therapy**

Follow-up Visit	Active		Sham	
	N	Mean (SD)	N	Mean (SD)
6 weeks	237	0.515 (0.253)	238	0.509 (0.255)
12 weeks	227	0.667 (0.240)	215	0.659 (0.244)
18 weeks	212	0.761 (0.225)	193	0.756 (0.239)
26 weeks	194	0.812 (0.201)	182	0.812 (0.212)
38 weeks	160	0.838 (0.194)	144	0.834 (0.192)
52 weeks	153	0.853 (0.190)	149	0.846 (0.192)

**Table D: Radiographic healing at each follow-up for LIPUS and sham therapy \***

<b>Follow-up Visit</b>	<b>Active</b>	<b>Sham</b>	<b>Total</b>
6 weeks	1/238 (0.4)	0/240 (0.0)	1/478 (0.2)
12 weeks	54/225 (24.0)	49/218 (22.5)	103/443 (23.3)
18 weeks	142/214 (66.4)	125/201 (62.2)	267/415 (64.3)
26 weeks	189/213 (88.7)	167/197 (84.8)	356/410 (86.8)
38 weeks	200/205 (97.6)	188/194 (96.9)	388/399 (97.2)
52 weeks	206/209 (98.6)	194/195 (99.5)	400/404 (99.0)

\* We included patients affected by early trial stoppage if they achieved radiographic healing before the trial was terminated

**Table E: Return to work at each follow-up for LIPUS and sham therapy (368 patients were employed prior to their injury) \***

	Achieved the Event, n (%)		
	Active	Sham	Total
<b>Follow-up Visit</b>			
6 weeks	7/171 (4.1)	8/170 (4.7)	15/341 (4.4)
12 weeks	31/166 (18.7)	27/153 (17.6)	58/319 (18.2)
18 weeks	60/160 (37.5)	64/147 (43.5)	124/307 (40.4)
26 weeks	90/153 (58.8)	85/146 (58.2)	175/299 (58.5)
38 weeks	114/149 (76.5)	104/134 (77.6)	218/283 (77.0)
52 weeks	126/149 (84.6)	110/138 (79.7)	236/287 (82.2)

\* We included patients affected by early trial stoppage if they reported return to work without limitations before the trial was terminated

**Table F: Return to household activities at each follow-up for LIPUS and sham therapy \***

	Achieved the Event, n (%)		
	Active	Sham	Total
<b>Follow-up Visit</b>			
6 weeks	6/237 (2.5)	3/238 (1.3)	9/475 (1.9)
12 weeks	32/227 (14.1)	28/215 (13.0)	60/442 (13.6)
18 weeks	68/217 (31.3)	69/196 (35.2)	137/413 (33.2)
26 weeks	102/202 (50.5)	102/193 (52.8)	204/395 (51.6)
38 weeks	128/189 (67.7)	130/171 (76.0)	258/360 (71.7)
52 weeks	157/190 (82.6)	147/185 (79.5)	304/375 (81.1)

\* We included patients affected by early trial stoppage if they reported return to household activities without limitations before the trial was terminated

**Table G: Return to full weight-bearing at each follow-up for LIPUS and sham therapy \***

	Achieved the Event, n (%)		
	Active	Sham	Total
<b>Follow-up Visit</b>			
6 weeks	82/238 (34.4)	92/240 (38.3)	174/478 (36.4)
12 weeks	188/234 (80.3)	194/229 (84.7)	382/463 (82.5)
18 weeks	224/232 (96.6)	221/226 (97.8)	445/458 (97.2)
26 weeks	233/234 (99.6)	225/227 (99.1)	458/461 (99.3)
38 weeks	234/235 (99.6)	227/227 (100.0)	461/462 (99.8)
52 weeks	234/235 (99.6)	227/227 (100.0)	461/462 (99.8)

\* We included patients affected by early trial stoppage if they achieved full weight-bearing before the trial was terminated

**Table H: Return to  $\geq 80\%$  pre-injury function at each follow-up for LIPUS and sham therapy \***

	Achieved the Event, n (%)		
	Active	Sham	Total
<b>Follow-up Visit</b>			
6 weeks	40/237 (16.9)	48/238 (20.2)	88/475 (18.5)
12 weeks	100/230 (43.5)	97/221 (43.9)	197/451 (43.7)
18 weeks	156/221 (70.6)	148/208 (71.2)	304/429 (70.9)
26 weeks	181/221 (81.9)	176/209 (84.2)	357/430 (83.0)
38 weeks	197/216 (91.2)	188/204 (92.2)	385/420 (91.7)
52 weeks	206/216 (95.4)	196/209 (93.8)	402/425 (94.6)

\* We included patients affected by early trial stoppage if they reported  $\geq 80\%$  pre-injury function before the trial was terminated

**Table I: Return to leisure activities at each follow-up for LIPUS and sham therapy \***

	Achieved the Event, n (%)		
	Active	Sham	Total
<b>Follow-up Visit</b>			
6 weeks	3/237 (1.3)	1/238 (0.4)	4/475 (0.8)
12 weeks	16/226 (7.1)	6/214 (2.8)	22/440 (5.0)
18 weeks	30/214 (14.0)	26/193 (13.5)	56/407 (13.8)
26 weeks	58/199 (29.1)	51/184 (27.7)	109/383 (28.5)
38 weeks	82/174 (47.1)	72/153 (47.1)	154/327 (47.1)
52 weeks	99/175 (56.6)	95/166 (57.2)	194/341 (56.9)

\* We included patients affected by early trial stoppage if they reported returning to leisure activities without limitations before the trial was terminated