



## Supplementary Material

10.1302/0301-620X.103B2.BJJ-2020-1404.R1

### Five-level EuroQol Five-dimensions Health Status and Index descriptive summaries

**Table i.** Participant-level reporting of the five-level EuroQol Five-dimensions Health Status and Index levels for each dimension for retrospective baseline, by randomized treatment arm.

Limitations	Mobility		Self-care		Usual activities		Pain/discomfort		Anxiety/depression	
	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS
No limitations, n (%)	120 (21.35)	113 (20.07)	228 (40.57)	233 (41.39)	177 (31.49)	193 (34.28)	196 (34.88)	199 (35.35)	221 (39.32)	229 (40.67)
Slight limitations, n (%)	99 (17.62)	107 (19.01)	53 (9.43)	59 (10.48)	61 (10.85)	54 (9.59)	79 (14.06)	79 (14.03)	78 13.88)	78 (13.85)
Moderate limitations, n (%)	113 (20.11)	114 (20.25)	58 (10.32)	43 (7.64)	62 (11.03)	68 (12.08)	88 (15.66)	87 (15.45)	72 (12.81)	62 (11.01)
Severe limitations, n (%)	68 (12.10)	62 (11.01)	22 (3.91)	27 (4.80)	44 (7.83)	36 (6.39)	36 (6.41)	31 (5.51)	27 (4.80)	24 (4.26)
Extreme limitations, n (%)	3 (0.53)	7 (1.24)	41 (7.30)	41 (7.28)	58 (10.32)	52 (9.24)	4 (0.71)	6 (1.07)	5 (0.89)	10 (1.78)
Missing, n (%)*	159 (28.29)	160 (28.42)	160 (28.47)	160 (28.42)	160 (28.47)	160 (28.42)	159 (28.29)	161 (28.60)	159 (28.29)	160 (28.42)

\*Includes participants who withdrew or who died before baseline; data not included for three participants who withdrew under "No data, no contact" (XHS = 2, SHS = 1)

SHS, sliding hip screw; XHS, X-Bolt hip system.

**Table ii:** Patient reporting of five-level EuroQol Five-dimensions Health Status and Index levels for each dimension at four months post-intervention, by randomized treatment arm.

\*Includes participants who withdrew or who died before baseline; data not included for three participants who withdrew under "No data, no contact" (XHS = 2, SHS = 1).

SHS, sliding hip screw; XHS, X-Bolt hip system.

Limitations	Mobility		Self-care		Usual activities		Pain/Discomfort		Anxiety/Depression	
	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS
No limitations, n (%)	42 (7.47)	31 (5.51)	123 (21.89)	107 (19.01)	73 (12.99)	77 (13.68)	121 (21.53)	126 (22.38)	189 (33.63)	173 (30.73)
Slight limitations, n (%)	73 (12.99)	84 (14.92)	54 (9.61)	54 (9.59)	58 (10.32)	45 (7.99)	95 (16.90)	82 (14.56)	61 (10.85)	64 (11.37)
Moderate limitations, n (%)	106 (18.86)	84 (14.92)	48 (8.54)	56 (9.95)	78 (13.88)	63 (11.19)	69 12.28)	73 (12.97)	48 (8.54)	48 (8.53)
Severe limitations, n (%)	57 (10.14)	58 (10.30)	23 (4.09)	27 (4.80)	23 (4.09)	37 (6.57)	22 (3.91)	27 (4.80)	16 (2.85)	15 (2.66)
Extreme limitations, n (%)	46 (8.19)	61 (10.83)	75 (13.35)	75 (13.32)	92 (16.37)	97 (17.23)	13 (2.31)	8 (1.42)	5 (0.89)	11 (1.95)
Missing, n (%)*	238 (42.35)	245 (43.52)	239 (42.53)	244 (43.34)	238 (42.35)	244 (43.34)	242 (43.06)	247 (43.87)	243 (43.24)	252 (44.76)

**Table iii.** Patient reporting of five-level EuroQol Five-dimensions Health Status and Index levels for each dimension at 12 months post-intervention, by randomized treatment arm.

Limitations	Mobility		Self-care		Usual activities		Pain/Discomfort		Anxiety/Depression	
	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS	XHS	SHS
No limitations, n (%)	45 (8.01)	37 (6.57)	117 (20.82)	109 (19.36)	88 (15.66)	75 (13.32)	111 (19.75)	106 (18.83)	175 (31.14)	146 (25.93)
Slight limitations, n (%)	62 (11.03)	71 (12.61)	37 (6.58)	34 (6.04)	42 (7.47)	40 (7.10)	85 (15.12)	74 (13.14)	47 (8.36)	60 (10.66)
Moderate limitations, n (%)	88 (15.66)	76 (13.50)	39 (6.94)	51 (9.06)	46 (8.19)	59 (10.48)	55 (9.79)	63 (11.19)	37 (6.58)	35 (6.22)
Severe limitations, n (%)	38 (6.76)	44 (7.82)	18 (3.20)	18 (3.20)	28 (4.98)	25 (4.44)	17 (3.02)	20 (3.55)	15 (2.67)	22 (3.91)
Extreme limitations, n (%)	44 (7.83)	44 (7.82)	66 (11.74)	61 (10.83)	72 (12.81)	72 (12.79)	7 (1.25)	6 (1.07)	1 (0.18)	6 (1.07)
Missing, n (%)*	285 (50.71)	291 (51.69)	285 (50.71)	290 (51.51)	286 (50.89)	292 (51.87)	287 (51.07)	294 (52.22)	287 (51.07)	294 (52.22)

\*Includes participants who withdrew or who died before baseline; data not included for 3 participants who withdrew under "No data, no contact" (XHS = 2, SHS = 1).

SHS, sliding hip screw; XHS, X-Bolt hip system.

## Sensitivity analyses

**Table iv:** Results from the sensitivity analyses for the primary outcome

Sensitivity analysis	X-Bolt XHS		SHS		Treatment effect	
	n	Mean score (SD)	n	Mean score (SD)	Adjusted difference (95% CI)*	p-value
Four-month EQ-5D-5L	437	0.345 (0.355)	443	0.320 (0.359)	0.029 (-0.013, 0.070)	0.175
Additional adjusted†	437	0.345 (0.355)	443	0.320 (0.359)	0.031 (-0.007, 0.069)	0.110
Per-protocol	381	0.350 (0.352)	437	0.324 (0.359)	0.032 (-0.011, 0.075)	0.142
CACE‡	427	N/A	437	N/A	0.032 (-0.014, 0.079)	0.170
Excluding patients who died	324	0.466 (0.337)	318	0.446 (0.351)	0.016 (-0.032, 0.065)	0.503
Bootstrapping#§	437	N/A	443	N/A	0.029 (-0.013, 0.070)	0.175

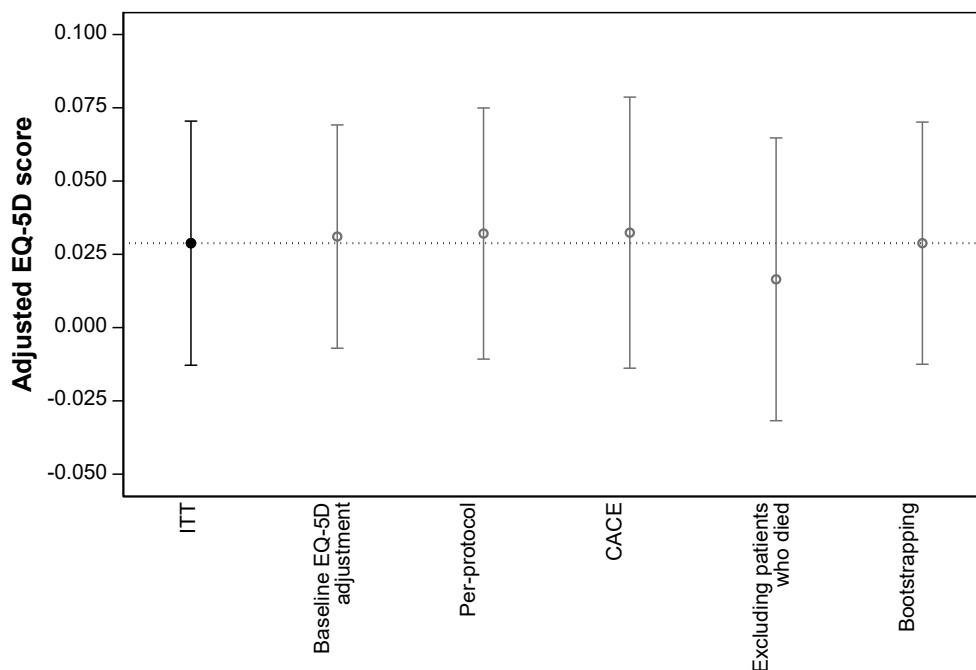
\*Inclusion of EQ-5D-5L score, treatment, centre, age, gender, and cognitive impairment with SHS as the reference treatment group.

†Inclusion of EQ-5D-5L score, treatment, centre, age, gender, cognitive impairment and retrospective baseline EQ-5D-5L score with SHS as the reference treatment group.

‡Estimation of mean score and SD not appropriate.

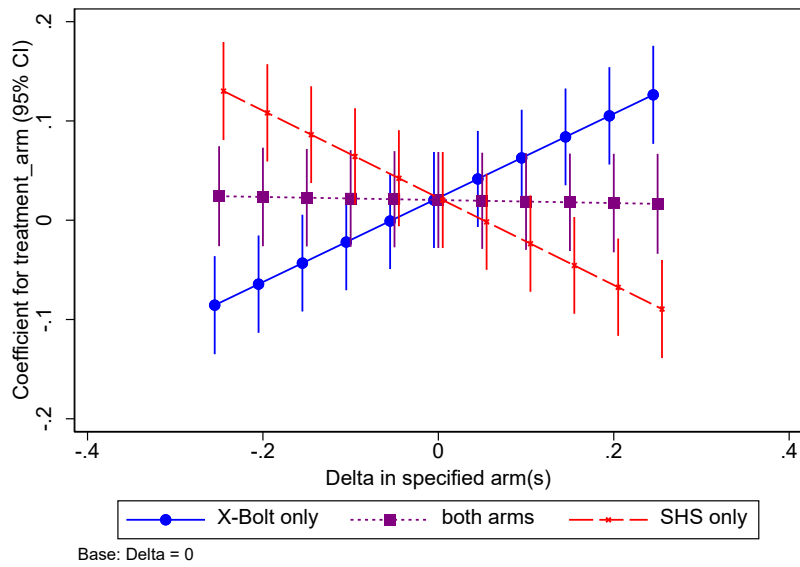
§Using normal-approximation and 10,000 repetitions.

CACE, complier average causal effects; CI, confidence interval; EQ-5D-5L, five-level EuroQol Five-dimensions Health Status and Index; SHS, sliding hip screw; XHS, X-Bolt hip system.

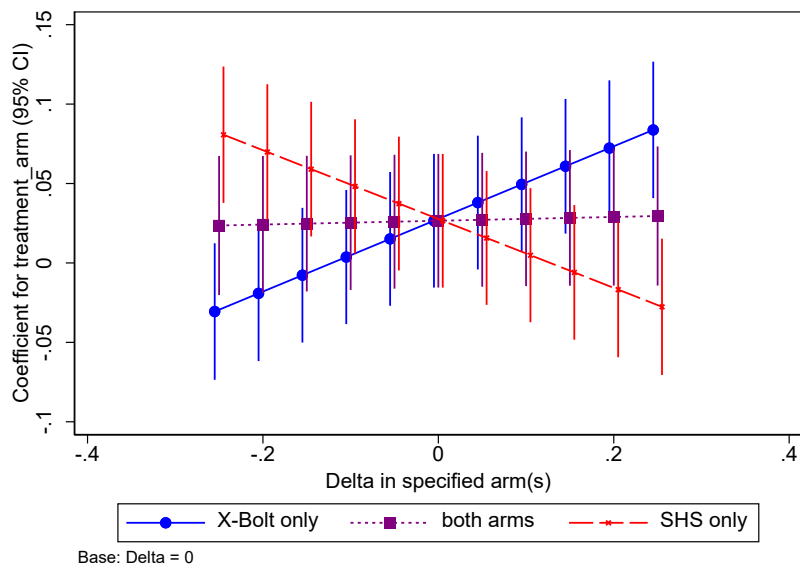


Note: ITT adjusted EQ-5D score indicated by dotted line

**Fig a.** Primary outcome treatment effects from multivariate linear regression and associated sensitivity analyses. ITT, intention to treat; CACE, complier average causal effects; EQ-5D, EuroQol Five-dimensions Health Status and Index.



**Fig b:** Results from the four-month adjusted pattern-mixture modelling. CI, confidence interval, SHS, sliding hip screw.



**Fig c:** Results from the 12-month adjusted pattern-mixture modelling. CI, confidence interval, SHS, sliding hip screw.

## Adverse event reporting

Information on harms, irrespective of their potential relatedness to the participants' hip fracture or treatment, were recorded throughout the trial. Any harms reported as Serious Adverse Events were reviewed by the Chief Investigator and their causality and expectedness confirmed. Serious Adverse Events were classified as untoward medical occurrences which were unexpected and resulted in death, were life-threatening, required hospitalisation or the extension of an existing hospitalisation, resulted in persistent or significant disability or incapacity, or required medical or surgical intervention to prevent one of the outcomes listed. Harms which were expected or were not classified as serious were reported together as complications. The number and proportion of participants reporting Serious Adverse Events and complications, including a breakdown of expected complications, is given in Table v.

**Table v.** Harms reported by participants grouped by treatment received.

Harms	XHS (n = 476)	SHS (n = 582)
Unforeseeable Serious Adverse Events	25 (5.25)	28 (4.81)
Complications*	109 (22.90)	141 (24.23)
Chest infection/pneumonia	28 (5.88)	47 (8.08)
Wound infection	6 (1.26)	6 (1.03)
Venous thromboembolic phenomenon	9 (1.89)	9 (1.55)
Urinary tract infection	34 (7.14)	48 (8.25)
Cerebrovascular accident	6 (1.26)	8 (1.37)
Myocardial infarction/acute coronary syndrome	8 (1.68)	5 (0.86)
Blood transfusion	31 (6.51)	45 (7.73)
Acute kidney injury	5 (1.05)	8 (1.37)
Delirium	4 (0.84)	9 (1.55)
Dislocation	0 (0)	1 (0.17)
Failure of fixation†	12 (2.52)	12 (2.06)
Malreduction	0 (0)	1 (0.17)
Periprosthetic fracture‡	6 (1.26)	2 (0.34)
Other‡	67 (14.07)	73 (12.54)

\*Participants may experience multiple complications so the sum of the individual groupings may not add-up to the overall number of participants reporting complications.

†Irrespective of whether participant underwent revision surgery.

‡Includes damage to a nerve, tendon, or blood vessel, nonunion, and participant-specific complications not captured by predefined groupings.