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Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH-2): The Exploratory Health-Related Quality of Life and Patient-Reported Functional Outcomes of a Multi-Centre 2 × 2 Factorial Randomized Controlled Pilot Trial in Young Femoral Neck Fracture Patients

Gerard P. Slobogean[a,*], Sheila Sprague[b,c], Sofia Bzovsky[b], Taryn Scott[b], Lehana Thabane[c], Diane Heels-Ansdell[c], Robert V. O'Toole[a], Andrea Howe[a], Greg E. Gaski[d], Lauren C. Hill[d], Krista M. Brown[d], Darius Viskontas[e], Mauri Zomar[f], Gregory J. Della Rocca[g], Nathan N. O'Hara[a], Mohit Bhandari[b,c], FAITH-2 Investigators, A. Stephen Malekzadeh, Aaron Nauth, Aaron Perdue, Abdullah Mamun, Abeer Wasim, Adam Klein, Adrienne Brandon, Aimee Theriault, Alisha Garibaldi, Allan Liew, Amit Atrey, Anastasia Lialios-Ramfos, André Spiguel, Andrea Howe, Andrea L. Howe, Andrew Furey, Andrew J. Marcantonio, Andrew N. Pollak, Andrew Schmidt, Ann Dowbenka, Anne Mak, Anthony T. Sorkin, Araby Sivananthan, Ashley Buck, Benita Okocha, Benjamin Frye, Bertrand Perey, Bindu Mohan, Blake Eyberg, Bonnie Sumner, Brenda Chen Fan, Brock Lindsey, Carrie Schoonover, Cary C. Schwartzbach, Charles Lieder, Chris Koenig, Christina Boulton, Christopher LeBrun, Clifford B. Jones, Collin Barber, Craig Donahue, Cyndi Ventry, Cynthia Carter, Dale Williams, Damien Richardson, Daniel Connelly, Daniel Mascarenhas, Daniel Squire, Daniel Whelan, Danyella Dias, Darius Viskontas, Darren M. Roffey, David Hubbard, David J.G. Stephen, David Shearer, David Teague, David Templeman, David Walmsley, Dean Malish, Debra L. Sietsema, Diane Heels-Ansdell, Diane Nam, Dimitrius Marinos, Dory Boyer, E. Barry McDonough, Earl Bogoch, Edward Westrick, Eleanor M. Pullenayegum, Eleni Berhaneselase, Elizabeth Agustin, Emil H. Schemitsch, Eric Meinberg, Erin Baker, Farhad Moola, Fathima Adamsahib, Fiona Howells, Garrett Wells, George K. Bal, George Reahl, Gerard P. Slobogean, Gitana Ramonas, Gordon Guyatt, Greg E. Gaski, Gregory J. Della Rocca, Gudrun Mirick Mueller, H. Michael Lemke, Hans J. Kreder, Heather Grant, Henry Ahn, Henry Broekhuyse, Irene Leung, James Goulet, James Waddell, Jason Lowe, Jason W. Nascone, Jeff E. Schulman, Jeffrey Potter, Jennifer Hagen, Jennifer T. Hidy, Jerald R. Westberg, Jeremy A. Hall, Jessica Burns, Jessica Peattie, Jill Goodwin, Joel J. Gagnier, John France, John Iazzetta, John P. Lubicky, John S. Garfi, Johnathan Kwong, Joseph Walker, Joshua Hustedt, Joshua Rudnicki, Julia Foxall, Julie Robbins, Kalia Sadasivan, Karen Ryan, Karen Walsh, Karyn Moon, Katerina Polihronidis, Katherine Ordonio, Katrina Hatzifilalithis, Katrine Milner, Keegan Au, Kelly Apostle, Kelly Lefaivre, Kim Madden, Krista M. Brown, Krystal Swasey, Kyle Jeray, Lakye Deeter, Landon Fine, Laura Parsons, Lauren C. Hill, Laurence B. Kempton, Lehana Thabane, Lisa Buckingham,

* Corresponding author: Department of Orthopaedics, University of Maryland School of Medicine, R Adams Cowley Shock Trauma Center, 22 South Greene Street, Baltimore, Maryland, USA

E-mail addresses: gslobogean@som.umaryland.edu, gsloboge@gmail.com (G.P. Slobogean).

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Lisa Giblin Sutton, Lolita Ramsey, Marc Swiontkowski, Marcus F. Sciadini, Mark Hake, Mark Richardson, Markku Nousiainen, Martí Bernaus, Martin J. Heetveld, Matthew Dietz, Matthew Menon, Matthew Patrick, Mauri Zomar, Melanie MacNevin, Melissa Johnson, Merryjessica Fuerst, Michael D. McKee, Michael Duran, Michael Holzman, Michael Lucero, Michael S.H. Kain, Michelle A. Bramer, Michelle Vogt, Milena R. Vicente, Mohit Bhandari, Monica Kunz, Murat Pekmezci, Nathan N. O'Hara, Nicole Harris, Nicole Simunovic, Nigar Sultana, Niloofar Dehghan, Nina Clovis, Norman Chutkan, Paril Suthar, Patrick Henry, Paul Knaus, Paul Muccino, Paul Toogood, Peter Berger, Peter O'Brien, Peter Rockwood, Pierce Johnson, Pierre Guy, Piotr Blachut, PJ Devereaux, Raely Pritchard (Moon), Raman Johal, Ravianne Tuazon, Raymond Pensy, Raza Zaidi, Richard J. Jenkinson, Robert A. Hymes, Robert McCormack, RobertV. O'Toole, Robert Walker, Roman Natoli, Russell Meldrum, Ryan Bicknell, Ryan DiGiovanni, Ryan Montalvo, Ryan Shelhamer, Saam Morshed, Sara McFarland, Sarah Anthony, Sarah Ward, Sarim Ahmed, Scott Daffner, Sean Karr, Sean Mitchell, Sharon Haaser, Sheila Rye, Sheila Sprague, Sherri Davis, Sherry Weir, Sofia Bzovsky, Sonya Brisbane, Steven Papp, Susan Beltz, Susan Liew, Susan Mauro, T. Ryan Murphy, Tara Moore, Taryn Scott, Taylor Dykes, Theodore Manson, Thomas DiPasquale, Tigist Belaye, Timothy Daniels, Tina Carter, Todd M. Oliver, Todd O. McKinley, Traci Salopek, Trevor Stone, Troy Caron, Tudor V. Tufescu, Tzivia Leviton, Valisha Keough, Vicki Jones, W. Andrew Eglseder Jr., Wade Gofton, Walter W. Virkus, Wesley Ghent, Yasmin Degani, Zeta Hannaford, Zoe Murdoch

[a] *R Adams Cowley Shock Trauma Center, Department of Orthopaedics, University of Maryland School of Medicine, 22 South Greene Street, Baltimore, Maryland, 21201, USA*
[b] *Division of Orthopaedic Surgery, Department of Surgery, McMaster University, 1280 Main Street West, Hamilton, Ontario, L8S 4L8, Canada*
[c] *Department of Health Research Methods, Evidence, and Impact, McMaster University, 1280 Main Street West, Hamilton, Ontario, L8S 4L8, Canada*
[d] *Department of Orthopaedic Surgery, Indiana University School of Medicine, Indianapolis, Indiana, 46202, USA*
[e] *Department of Orthopaedics, University of British Columbia, New Westminster, British Columbia, V6T 1Z4, Canada*
[f] *Division of Orthopaedics, Fraser Health Authority, New Westminster, British Columbia, V3L 3W2, Canada*
[g] *Department of Orthopaedic Surgery, University of Missouri, Columbia, Missouri, 65212, USA*

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ABSTRACT

Purpose: Femoral neck fractures in young patients are typically managed with internal fixation using either cancellous screws or a sliding hip screw (SHS). Although fixation preserves the hip joint, patients are still at risk of complications and poor clinical outcomes which lead to diminished function and health related quality of life (HRQL). The Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH-2) pilot randomized controlled factorial trial evaluated the effect of surgical fixation (cancellous screws vs. SHS) and vitamin D supplementation vs. placebo on patient-reported function and HRQL.

Methods: Patients between the ages of 18-60 years with a femoral neck fracture requiring surgical fixation were eligible. Eligible patients were randomized to receive either a sliding hip screw or cancellous screws for fracture fixation AND vitamin D_3 4,000 IU or placebo daily for 6 months. Patient-reported function (Hip Outcome Score) and HRQL (Short Form-12) were assessed at standardized time points in the 12 months following their fixation surgery. Patient-reported function and HRQL were summarized using means, SD, and 95% confidence intervals (CIs), or percentages and counts. Longitudinal data analysis with mixed models was used to explore the effect of treatment group and time on the patient-reported function and HRQL.

Results: 86 of the 91 patients randomized into the FAITH-2 pilot study were deemed eligible. There were no significant differences in patient-reported function or HRQL between the treatment groups at 12 months post-fracture. At the 6- and 9-month assessments, a potential benefit in hip function was seen in the cancellous screw group. In all treatment groups, participants reported lower function and HRQL at 12 months post-fracture as compared to their pre-injury assessment.

Conclusions: Few differences were found in function and HRQL among the treatment groups in the FAITH-2 pilot study. Despite modern implants and vitamin D supplementation, neither function nor HRQL returns to baseline in this population. Additional efforts to improve the outcomes of these challenging injuries are still needed.

Level of Evidence: Therapeutic Level II

Introduction

Femoral neck fractures in young patients are typically managed with internal fixation using either cancellous screws or a sliding hip screw (SHS) [1]. Although fixation preserves the hip joint, patients are still at risk of complications and poor clinical outcomes. These poor clinical outcomes lead to diminished function and health related quality of life (HRQL) [2–4]. The recently completed Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH-2) pilot randomized controlled factorial trial, evaluated the effect of surgical fixation (cancellous screws vs. SHS) and vitamin D supplementation (vs. placebo) on clinical outcomes, as well as on patient-reported function and HRQL.

The FAITH-2 trial was designed as a pilot study to determine if proceeding to an 898-patient randomized controlled trial (RCT) would be feasible. Its primary outcome was a composite measure of enrolment, protocol adherence, and data quality [5]. After enrolling 91 participants in the pilot trial, it was determined a definitive trial would not be feasible [6]. A subsequent analysis of the primary clinical outcome, a composite of fracture-related complications, failed to identify any differences in complications between the surgical and vitamin D treatment groups within the limited sample size [7]. Despite being underpowered for the primary clinical outcome comparison at 12-months, we sought to determine if differences in hip function and HRQL would exist between the treatment groups. The importance of this secondary analysis was proposed based on its focus on patient-reported outcomes and its multiple time-point assessment of the longitudinal recovery of young femoral neck fracture patients. We hypothesized that SHS fixation and vitamin D_3 supplementation would independently improve patient-reported outcomes during the 12-month post-fracture follow-up period.

Methods

Trial Design

FAITH-2 was registered with ClinicalTrials.gov (NCT01908751). Ethics approval was obtained from participating clinical sites' research ethics boards/institutional review boards. Fifteen clinical sites participated in FAITH-2 in Canada and the United States. Briefly, patients between the ages of 18 to 60 years with a femoral neck fracture that was amenable to internal fixation with SHS and cancellous screws were eligible. Patients with a known or suspected diagnosis of osteoporosis were excluded. After obtaining consent, patients were randomized into four treatment groups: (1) cancellous screws with vitamin D_3 supplementation (4,000 IU daily for 6 months); (2) cancellous screws with placebo supplementation daily for 6 months, (3) SHS with vitamin D supplementation (4,000 IU daily for 6 months), or (4) SHS with placebo supplementation daily for 6 months. Participants were followed at regular intervals for 12-months following their fracture.

HRQL and Patient-Reported Function Outcomes

Secondary outcomes of FAITH-2 included patient-reported function and HRQL. The Hip Outcome Score was used to measure self-reported functional status through 28 items and two sub-scales that pertain to activities of daily living and activities necessary to participate in sports [8]. HRQL was assessed using the Short Form-12 (SF-12) Physical and Mental Health Composite Scores (PCS and MCS). The SF-12 results were normalized to a score of 50 with a standard deviation (SD) of 10 points.

Statistical Analysis

We initially planned to enroll 60 patients to assess the feasibility of a definitive trial. When it became apparent that a definitive trial would not be feasible, we increased the sample size to 90 patients. This allowed for 15% loss to follow-up and provided 80% power (alpha = 0.05) to detect moderate effect sizes (d= 0.67) within the patient-reported outcomes.

We followed the CONSORT extension to pilot trials when reporting the results of the FAITH-2 pilot trial [9]. For the current analysis, we analyzed the HRQL and patient-reported functional data for the pilot study in the following manner: HRQL and patient-reported function were summarized using means, SD, and 95% confidence intervals (CIs), or percentages and counts. Longitudinal data analysis with mixed models was used to explore the effect of treatment group and time on the Hip Outcome Score and SF-12 patient-reported outcomes. We also descriptively quantified any changes in Hip Outcome Score and SF-12 patient-reported outcomes for the overall cohort over the 12-months following their femoral neck fracture, as well as tested for any statistical differences in Hip Outcome Score and SF-12 scores over time for the overall cohort. All outcome analyses adhered to the intention-to-treat principle. We used SPSS Version 25 to perform all analyses.

Results

Participants & Treatment Details

Of the 86 eligible participants enrolled in the trial, 63 completed at least three hip function and HRQL assessments (73%). 67 participants completed the 12-month follow-up (78%). The mean age of participants was 41 years (SD 12) and 73% were male (Table 1). Falls from height and motor vehicle collisions were the most common mechanisms of injury. 71% of the fractures were displaced (Garden III/IV) and 44% were Pauwels' type III vertical patterns. The mean time to fixation was 27 hours (SD 21), and 56% of fractures were treated with open reduction. Further details on the participant demographics and fracture healing outcomes have been previously reported [6].

Recovery of Patient-Reported Function and HRQL Over Time

Figs. 1 and 2 display the changes in Hip Outcome Score and SF-12 outcomes over 1 year. In all treatment groups, participants reported worse physical function at all time-points compared to pre-injury (Table 2). Even at 12-months post-fracture, the remaining mean difference in physical function exceeded minimum clinically important differences for the Hip Outcome Score Activities of Daily Living scale and Sports scale, and the SF-12 PCS. The Hip Outcome Score Sports scale at 12 months was 31 points lower than pre-injury (95% CI 20.6, 41.3). No significant differences were detected between the pre-fracture and 12-month SF-12 MCS score (95% CI -1.8, 4.2).

Differences in Hip Outcome Score Between Treatment Groups

There was no significant difference in the average 1-year treatment effect on surgical implant on the Hip Outcome Score Activities of Daily Living scale (95% CI -4.8, 17.5) or Sports scale (95% CI -8.0, 24.2). Cancellous screws appeared to have potential improvements in Hip Outcome Score during the mid-study period. At 6-months, patients in the cancellous screws group reported higher Hip Outcome Scores (Activities of Daily Living scale mean difference 10.0; 95% CI: -2.2, 22.2; Sports scale mean difference 12.1; 95% CI: -3.1, 27.3), however, these differences were not statistically significant. A similar magnitude of improvement in Hip Outcome

Table 1
Participant Demographics & Treatment Details.

Characteristic	Cancellous Screw N=43	Sliding Hip Screw N=43	Vitamin D N=45	Placebo N=41	Total N=86
Age in years, mean (SD)	39.2 (13.2)	43.0 (11.4)	40.6 (12.0)	41.6 (13.0)	41.1 (12.4)
Sex, n (%)					
Male	33 (76.7)	30 (69.8)	33 (73.3)	30 (73.2)	63 (73.3)
Female	10 (23.3)	13 (30.2)	12 (26.7)	11 (26.8)	23 (26.7)
Level of the Fracture Line, n (%)					
Subcapital	11 (25.6)	13 (30.2)	11 (24.4)	13 (31.7)	24 (27.9)
Midcervical	13 (30.2)	15 (34.9)	13 (28.9)	15 (36.6)	28 (32.6)
Basal	18 (41.9)	15 (34.9)	21 (46.7)	12 (29.3)	33 (38.4)
Unable to Assess	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.4)	1 (1.2)
Garden Classification, n (%)					
Garden I (undisplaced)	5 (11.6)	9 (20.9)	7 (15.6)	7 (17.1)	14 (16.3)
Garden II (undisplaced)	6 (14.0)	3 (7.0)	5 (11.1)	4 (9.8)	9 (10.5)
Garden III (displaced)	14 (32.6)	13 (30.2)	16 (35.6)	11 (26.8)	27 (31.4)
Garden IV (displaced)	17 (39.5)	17 (39.5)	16 (35.6)	18 (43.9)	34 (39.5)
Unable to Assess	1 (2.3)	1 (2.3)	1 (2.2)	1 (2.4)	2 (2.3)
Pauwels' Classification, n (%)					
Type I	3 (7.0)	9 (20.9)	5 (11.1)	7 (17.1)	12 (14.0)
Type II	16 (37.2)	19 (44.2)	19 (42.2)	16 (39.0)	35 (40.7)
Type III	23 (53.5)	15 (34.9)	21 (46.7)	17 (41.5)	38 (44.2)
Unable to Assess	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.4)	1 (1.2)
Time from Injury to Surgery in hours, mean (SD)	29 (24)	25 (16)	28 (23)	26 (18)	27 (21)
Type of Reduction Used, n (%)					
Closed	16 (37.2)	16 (37.2)	16 (35.6)	16 (39.0)	32 (37.2)
Open	23 (53.5)	25 (58.1)	25 (55.6)	23 (56.1)	48 (55.8)
None	4 (9.3)	2 (4.7)	4 (8.9)	2 (4.9)	6 (7.0)
Procedure Performed, n (%)					
Cancellous Screws	43 (100.0)	1 (2.3)	24 (53.3)	20 (48.8)	44 (51.2)
Sliding Hip Screw	0 (0.0)	41 (95.3)	21 (46.7)	20 (48.8)	41 (47.7)
Cephalomedullary Nail (Protocol Deviation)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.4)	1 (1.2)

Abridged summary: Full details published in JOT 2020.
SD = Standard Deviation

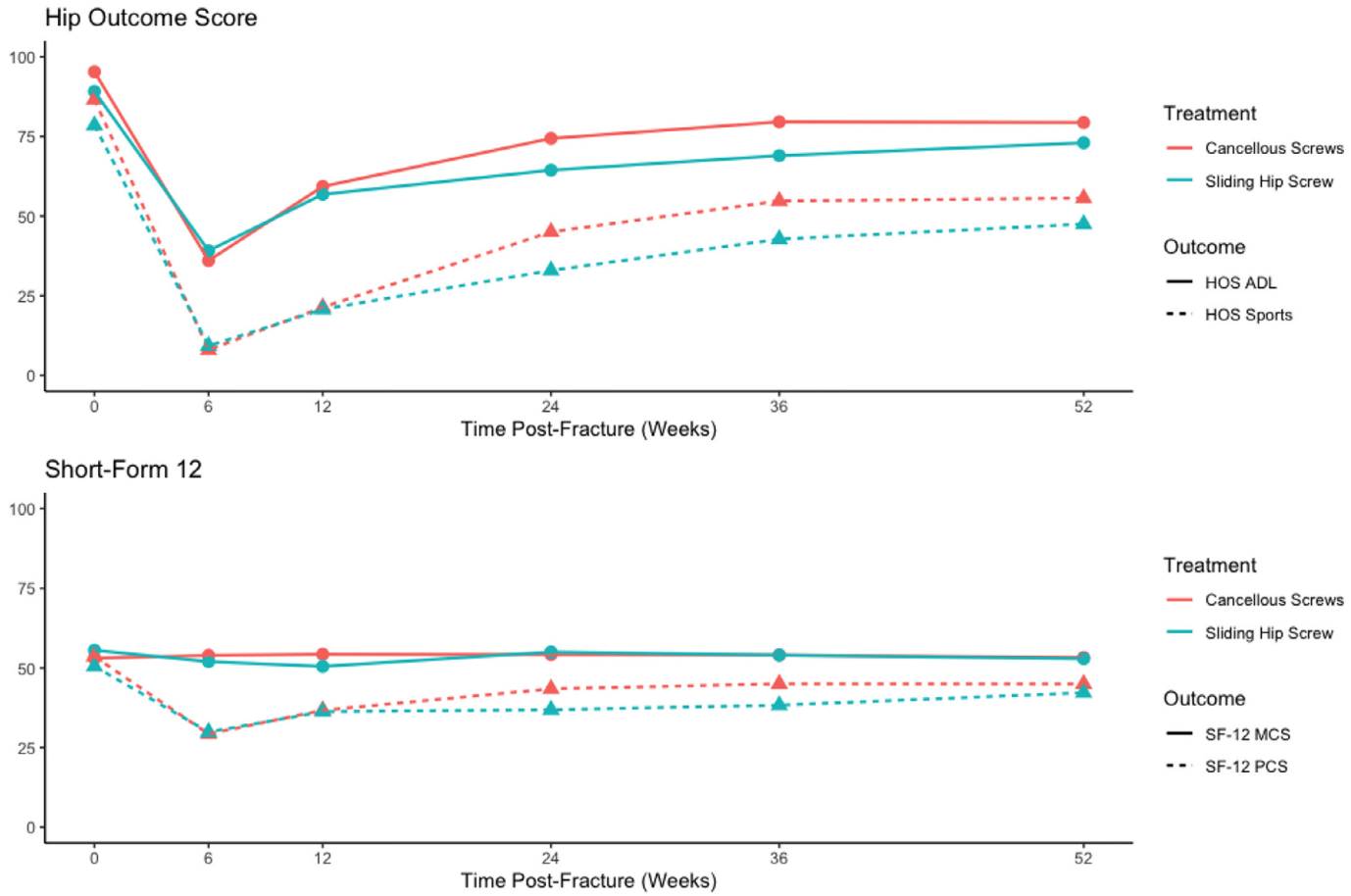

Fig. 1. Patient-Reported Outcomes of SHS vs. Cancellous Screws.
*The day 0 assessment reports pre-injury status
HOS = Hip Outcome Score, ADL = Activities of Daily Living, SF-12 PCS = Short Form-12 Physical Composite Scale, SF-12 MCS = Short Form-12 Mental Health Composite Scale

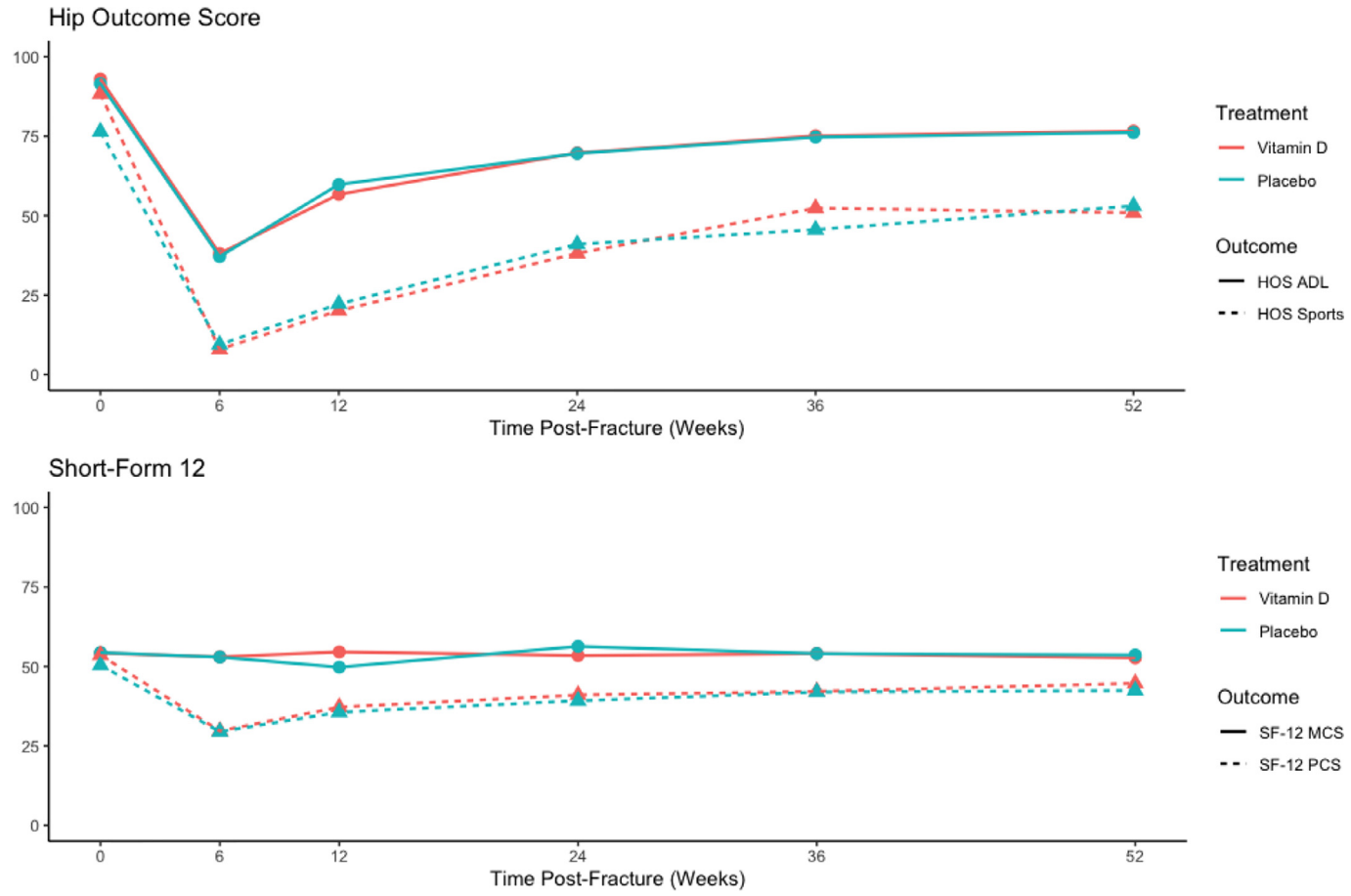

Fig. 2. Patient-Reported Outcomes of Vitamin D_3 vs Placebo.
*The day 0 assessment reports pre-injury status
HOS = Hip Outcome Score, ADL = Activities of Daily Living, SF-12 PCS = Short Form-12 Physical Composite Scale, SF-12 MCS = Short Form-12 Mental Health Composite Scale

Table 2
Differences in Patient-Reported Outcomes Pre-Fracture to 12 Months.

Endpoint	Pre-Fracture Score		12-Month Score		Total
	N=78	Mean (SD)	N=64	Mean (SD)	Mean Difference* (95% CI)
Hip Outcome Score Activities of Daily Living Scale	78	92.4 (17.9)	64	76.4 (22.3)	15.98 (9.32, 22.64)
Hip Outcome Score Sports Scale	78	82.8 (29.9)	63	51.9 (31.8)	30.94 (20.63, 41.25)
SF-12 PCS	77	52.2 (8.9)	63	43.7 (12.0)	8.55 (5.06, 12.04)
SF-12 MCS	77	54.3 (8.2)	63	53.1 (9.4)	1.20 (-1.75, 4.15)

* Mean difference obtained from paired t-testSF-12 PCS = Short Form-12 Physical Composite Scale, SF-12 MCS = Short Form-12 Mental Health Composite Scale, SD = Standard Deviation; 95% CI = 95% Confidence Interval

Scores in the cancellous screws group was seen at 9-months; however, by 1-year the differences no longer approached significance (Table 3). There was no evidence that vitamin D_3 supplementation improved the average 1-year Hip Outcome Scores (Activities of Daily Living: 95% CI -10.8, 11.7; Sports: 95% CI -18.4, 14.0) or Hip Outcome Scores at any other timepoint (Table 4).

Differences in SF-12 Between Treatment Groups

Similar to the Hip Outcome Score, no difference in the average 1-year SF-12 PCS score was detected between the surgical treatment groups (95% CI -3.3, 8.8); however, the mid-study results also suggested potential benefits to cancellous screws. At 6-months, the cancellous screws group reported SF-12 PCS scores 6.6 points higher (95% CI 0.2, 12.9) than the SHS group; at 9-months, the difference was 6.7 points higher (95% CI -0.3, 13.6). These potential differences were no longer present at 1-year post injury (Table 3). Surgical implant choice had no effect on the average 1-year SF-12 MCS score (95% CI -4.4, 5.2), or at any other timepoint (Table 3). Once again, vitamin D_3 supplementation had no effect on the average 1-year SF-12 PCS (95% CI -4.2, 7.8) or MCS (95% CI -6.4, 3.2) scores. Similarly, no trends towards improved SF-12 scores with vitamin D_3 were seen at any other timepoint (Table 4).

Discussion

This study describes the patient-reported hip function and HRQL of 86 young femoral neck fracture patients enrolled in the FAITH-2 multi-center pilot feasibility trial. Participants reported improvements from post-injury to the final 12-month follow-up visit for all three physical function measures (SF-12 PCS, Hip Outcome Score Activities of Daily Living scale, and Hip Outcome Score Sports scale); however, despite modern fracture management, hip function and HRQL did not return to pre-fracture status by 12

Table 3
Differences in Patient-Reported Outcomes by Surgical Treatment.

Endpoint	Cancellous Screws		Sliding Hip Screw		Total	
	N=43	Mean (SD)	N=43	Mean (SD)	N=86	Mean Difference* (95% CI)
Hip Outcome Score Activities of Daily Living Scale						
Pre-fracture	40	95.4 (14.8)	38	89.2 (20.4)	78	6.28 (-1.72, 14.29)
6 weeks	35	36.1 (23.1)	36	39.1 (19.5)	71	-3.09 (-13.14, 6.96)
3 months	36	59.3 (25.5)	34	56.8 (24.1)	70	2.48 (-9.29, 14.25)
6 months	32	74.4 (23.1)	29	64.5 (24.4)	61	9.96 (-2.23, 22.15)
9 months	32	79.6 (22.4)	25	69.0 (21.1)	57	10.60 (-1.09, 22.28)
12 months	34	79.4 (22.7)	30	73.0 (22.7)	64	6.33 (-4.78, 17.49)
Hip Outcome Score Sports Scale						
Pre-fracture	40	86.9 (25.9)	38	78.5 (33.5)	78	8.44 (-5.01, 21.88)
6 weeks	35	8.0 (13.4)	36	9.3 (14.9)	71	-1.26 (-7.97, 5.44)
3 months	36	21.4 (25.1)	34	20.8 (22.9)	70	0.62 (-10.78, 12.02)
6 months	32	45.1 (28.7)	29	33.0 (31.0)	61	12.10 (-3.09, 27.30)
9 months	32	54.8 (28.7)	25	42.8 (33.9)	57	12.00 (-4.62, 28.61)
12 months	34	57.3 (31.4)	29	47.5 (31.0)	64	8.13 (-7.96, 24.21)
SF-12 PCS Scores						
Pre-fracture	40	53.7 (7.1)	37	50.5 (10.4)	77	3.20 (-0.81, 7.21)
6 weeks	35	29.3 (10.2)	34	29.9 (8.5)	69	-0.62 (-5.14, 3.90)
3 months	35	36.7 (10.7)	34	36.2 (11.2)	69	0.48 (-4.77, 5.73)
6 months	32	43.4 (13.0)	29	36.9 (11.5)	61	6.56 (0.24, 12.89)
9 months	32	45.0 (13.2)	25	38.3 (12.8)	57	6.69 (-0.26, 13.63)
12 months	33	45.0 (11.6)	30	42.2 (12.4)	63	2.76 (-3.27, 8.80)
SF-12 MCS Scores						
Pre-fracture	40	53.1 (8.3)	37	55.6 (8.1)	77	-2.54 (-6.26, 1.18)
6 weeks	35	53.9 (9.9)	35	52.0 (11.5)	69	1.95 (-3.20, 7.11)
3 months	35	54.3 (10.1)	34	50.5 (13.2)	69	3.79 (-1.84, 9.43)
6 months	32	54.2 (8.6)	29	55.0 (9.9)	61	-0.84 (-5.60, 3.92)
9 months	32	54.0 (9.9)	25	54.0 (9.7)	57	0.02 (-5.23, 5.26)
12 months	33	53.3 (9.2)	30	52.9 (9.8)	63	0.40 (-4.38, 5.18)

* Mean difference obtained from paired t-testSF-12 PCS = Short Form-12 Physical Composite Scale, SF-12 MCS = Short Form-12 Mental Health Composite Scale, SD = Standard Deviation; 95% CI = 95% Confidence Interval

Table 4
Differences in Patient-Reported Outcomes by Vitamin D_3 Supplementation.

Endpoint	Vitamin D		Placebo		Total	
	N=45	Mean (SD)	N=41	Mean (SD)	N=86	Mean Difference* (95% CI)
Hip Outcome Score Activities of Daily Living Scale						
Pre-fracture	41	93.1 (18.3)	37	91.5 (17.7)	78	1.62 (-6.52, 9.75)
6 weeks	37	38.1 (23.1)	34	37.1 (19.0)	71	0.96 (-9.12, 11.05)
3 months	38	56.7 (25.4)	32	59.8 (23.7)	70	-3.10 (-14.91, 8.70)
6 months	36	69.7 (23.8)	25	69.6 (25.0)	61	0.15 (-12.51, 12.80)
9 months	33	75.1 (23.2)	24	74.7 (21.4)	57	0.44 (-11.65, 12.54)
12 months	35	76.6 (21.5)	29	76.2 (23.5)	64	0.44 (-10.82, 11.70)
Hip Outcome Score Sports Scale						
Pre-fracture	41	88.6 (25.5)	37	76.4 (33.3)	78	12.19 (-1.11, 25.50)
6 weeks	37	8.0 (13.7)	34	9.4 (14.7)	71	-1.46 (-8.17, 5.25)
3 months	38	20.1 (23.8)	32	22.2 (23.9)	70	-2.12 (-13.55, 9.31)
6 months	36	38.1 (30.7)	25	41.0 (29.5)	61	-2.88 (-18.62, 12.86)
9 months	33	52.4 (33.0)	24	45.6 (29.2)	57	6.76 (-10.16, 23.67)
12 months	34	52.4 (33.4)	29	53.1 (29.6)	64	-2.17 (-18.38, 14.04)
SF-12 PCS Scores						
Pre-fracture	40	53.5 (7.1)	37	50.8 (10.5)	77	2.72 (-1.31, 6.75)
6 weeks	36	29.7 (9.6)	33	29.4 (9.2)	69	0.24 (-4.29, 4.76)
3 months	37	37.2 (12.0)	32	35.7 (9.5)	69	1.51 (-3.74, 6.76)
6 months	36	41.4 (12.9)	25	38.8 (12.4)	61	2.59 (-4.03, 9.21)
9 months	33	41.8 (14.0)	24	42.4 (12.5)	57	-0.59 (-7.80, 6.62)
12 months	34	44.5 (10.9)	29	42.6 (13.3)	63	1.92 (-4.15, 7.80)
SF-12 MCS Scores						
Pre-fracture	40	54.3 (7.6)	37	54.2 (9.0)	77	0.09 (-3.68, 3.85)
6 weeks	36	53.0 (9.8)	33	52.9 (11.8)	69	0.07 (-5.11, 5.25)
3 months	38	54.4 (10.3)	32	50.1 (13.2)	69	4.23 (-1.41, 9.86)
6 months	36	52.9 (8.2)	25	57.0 (10.2)	61	-4.08 (-8.80, -9.03)
9 months	33	53.8 (10.0)	24	54.3 (9.5)	57	-0.51 (-5.78, 4.76)
12 months	34	52.4 (9.3)	29	53.9 (9.6)	63	-1.59 (-6.37, 3.18)

* Mean difference obtained from paired t-testSF-12 PCS = Short Form-12 Physical Composite Scale, SF-12 MCS = Short Form-12 Mental Health Composite Scale, SD = Standard Deviation; 95% CI = 95% Confidence Interval

months. The residual functional outcome deficits from baseline to 12-months post-fracture exceed the minimum clinically important difference of 5 points for the SF-12 [10]. This finding is consistent with prior literature [11–13].

In our analyses comparing the treatment groups, we were unable to demonstrate any differences in Hip Outcome Score, SF-12 PCS, or SF-12 MCS at one-year post-fracture or on average over the 12-month follow-up period. At the mid-study period (6-months and 9-months post-fracture), a potential difference in function was observed favouring cancellous screws versus SHS; however, these results should be interpreted with caution given the short duration of benefit and small sample size. Regardless, all treatment groups demonstrated clinically important improvements over the study period in the physical measures (Hip Outcome Score, SF-12 PCS). The MCS remained relatively constant over the follow-up periods across all treatment groups.

Our results are consistent with the limited hip function and HRQL data previously published. In a prospective observational cohort study of 142 young femoral neck fractures in China, similar patterns of SF-36 PCS recovery were seen, while the SF-36 MCS scores also demonstrated minor variation over that time [14]. In the Chinese cohort, 93% of participants were treated with cancellous screws. Our results extend this previous study by comparing patient reported outcomes between two commonly used implants. While we found a potential mid-study benefit to cancellous screws, the study was not powered to detect these differences. It is possible the differences in HRQL at 6-months may be explained by more participants in the SHS group having a re-operation, as compared to the cancellous screws group (nine versus six participants) [6].

When considering the results of our trial in the context of the elderly femoral neck literature, differences in HRQL by implant have not been observed in geriatric populations. Specifically, the predecessor FAITH trial (cancellous screws vs. SHS in fragility hip fracture patients) also found no difference in HRQL and function between cancellous screws and SHS at 12-months post-fracture [15]. Other hip fracture trials comparing cancellous screws to SHS also support this finding [16–19].

We were unable to detect a difference in function or HRQL with vitamin D versus placebo. Although, there has been little research conducted on the impact of vitamin D supplementation in femoral neck fracture patients, our findings are consistent with the available literature. For instance, a randomized controlled trial of 218 adults, aged 65-years or older requiring hip fracture surgery, were assigned to receive a single 250,000 IU loading dose of vitamin D or placebo, as well as daily vitamin D (800 IU) and calcium (500 mg) for 26-weeks [20]. HRQL was measured using the EuroQoL and although higher scores were noted for the 111 participants receiving vitamin D as compared to the 107 adults in the placebo group, overall, there was no statistically significant difference in scores between the two groups. Moreover, recent meta-analyses and large clinical trials in non-fracture patients have suggested no benefits to vitamin D supplementation in multiple clinical populations [21–23]. Despite evidence suggesting vitamin D supplementation may not improve acute fracture healing outcomes, the null effect of supplementation observed in the current trial cannot be confirmed. Due to limited study funding in the pilot trial phase, we were unable to measure participants' serum 25(OH)D levels at enrollment or during the study period. Therefore, without being able to determine if the 4,000 IU supplementation increased serum vitamin D levels, our conclusions are limited to pragmatic effectiveness and not mechanistic efficacy. Our feasibility results reported only 62% of study participants endorsed taking >75% of their daily vitamin D supplement doses [6].

Similarly, the patient-reported function and HRQL comparisons are inherently limited by the nature of a pilot study design. The sample size of the FAITH-2 pilot trial was relatively small because it was selected to test trial feasibility. For this reason, the trial was underpowered to detect smaller treatment effects and is unable to support definitive effectiveness conclusions regarding surgical implant choice or vitamin D supplementation in femoral neck fracture patients. Despite this limitation, this is the first pilot trial to examine the impact of internal fixation methods and vitamin D supplementation on patient-reported outcomes in young femoral neck fracture patients. FAITH-2 suggests that despite modern surgical care, femoral neck fracture patients suffer poor HRQL and function at 12- months post-fracture and do not return to pre-injury levels. The FAITH-2 program will not advance to a definitive trial, due to feasibility challenges, but these pilot trial results continue to inform surgeons, patients, and other stakeholders about the results of current fixation implants and vitamin D supplementation used to treat young femoral neck fracture patients.

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FAITH-2 Investigators

Writing Committee: Gerard P. Slobogean (Co-Chair), Sheila Sprague (Co-Chair), Sofia Bzovsky, Taryn Scott, Lehana Thabane, Diane Heels-Ansdell, Robert V. O'Toole, Andrea Howe, Greg E. Gaski, Lauren C. Hill, Krista M. Brown, Darius Viskontas, Mauri Zomar, Gregory J. Della Rocca, Nathan N. O'Hara, and Mohit Bhandari;

Steering Committee: Gerard P. Slobogean (Co-Chair, University of Maryland), Mohit Bhandari (Co-Chair, McMaster University), Sheila Sprague (McMaster University), Earl Bogoch (St. Michael's Hospital), PJ Devereaux (McMaster University), Gordon Guyatt (McMaster University), Martin J. Heetveld (Spaarne Gasthuis, Haarlem), Kyle Jeray (Greenville Health System), Susan Liew (The Alfred), Robert V. O'Toole (University of Maryland), Andrew N. Pollak (University of Maryland), Emil H. Schemitsch (University of Western Ontario), Marc Swiontkowski (University of Minnesota), Lehana Thabane (McMaster University);

Principal Investigators: Gerard P. Slobogean (Co-Chair, University of Maryland), Mohit Bhandari (Co-Chair, McMaster University),

Methods Centre: Sheila Sprague (Co-Investigator); Dale Williams (Co-Investigator); Sofia Bzovsky, Kim Madden, Alisha Garibaldi, Taryn Scott (Project Managers); Diane Heels-Ansdell (Statistical Analysis); Lisa Buckingham (Data Management); Nicole Simunovic (Grants Management) (McMaster University); Martí Bernaus (Research Fellow, Hospital Universitari Mútua Terrassa);

Data and Safety Monitoring Committee: Eleanor M. Pullenayegum (The Hospital for Sick Children), Matthew Menon (University of Alberta), David Teague (University of Oklahoma Health Sciences Center);

Adjudicator: Gregory J. Della Rocca (University of Missouri);

Clinical Sites

Canada

Richard J. Jenkinson, Hans J. Kreder, David J.G. Stephen, Markku Nousiainen, Diane Nam, Patrick Henry, John Iazzetta, Katrina Hatzifilalithis, Katrine Milner, Monica Kunz, Aimee Theriault, Wesley Ghent, Araby Sivananthan, Fathima Adamsahib, Danyella Dias,

Abeer Wasim, Ravianne Tuazon, Katerina Polihronidis **(Sunnybrook Health Sciences Centre)**;

Emil H. Schemitsch, Aaron Nauth, Michael D. McKee, Jeremy A. Hall, Earl Bogoch, Daniel Whelan, Timothy Daniels, Sarah Ward, Henry Ahn, James Waddell, David Walmsley, Amit Atrey, Laura Parsons, Ann Dowbenka, Gitana Ramonas, Milena R. Vicente, Jennifer T. Hidy, Paril Suthar, Melanie MacNevin **(St. Michael's Hospital)**;

Darius Viskontas, Robert McCormack, Farhad Moola, Bertrand Perey, Trevor Stone, Kelly Apostle, Dory Boyer, H. Michael Lemke, Mauri Zomar, Karyn Moon, Raely Pritchard (Moon), Brenda Chen Fan, Bindu Mohan **(University of British Columbia / Fraser Health Authority – Royal Columbian Hospital);**

Pierre Guy, Kelly Lefaivre, Peter O'Brien, Henry Broekhuyse, Piotr Blachut, Dean Malish, Jeffrey Potter, Raman Johal, Irene Leung, Benita Okocha, Jessica Peattie, Abdullah Mamun **(University of British Columbia/Vancouver General Hospital);**

Steven Papp, Wade Gofton, Allan Liew, Sherry Weir, Darren M. Roffey, Nicole Harris, Julia Foxall **(The Ottawa Hospital – Civic Campus);**

Andrew Furey, Keegan Au, Daniel Squire, Peter Rockwood, Ashley Buck, Karen Ryan, Garrett Wells, Zeta Hannaford, Valisha Keough, Erin Baker, Sarah Anthony **(Memorial University);**

USA

Mark Richardson, Thomas DiPasquale, Paul Muccino, Troy Caron, Adrienne Brandon, Krystal Swasey, Tara Moore **(York Hospital)**;

David Hubbard, John France, Michelle A. Bramer, Brock Lindsey, Benjamin Frye, Matthew Dietz, Adam Klein, George K. Bal, E. Barry McDonough, John P. Lubicky, Scott Daffner, T. Ryan Murphy, Lisa Giblin Sutton, Sheila Rye, Nina Clovis, Sherri Davis **(West Virginia University)**;

Robert A. Hymes, Cary C. Schwartzbach, A. Stephen Malekzadeh, Jeff E. Schulman, Michael Holzman, Anastasia Lialios-Ramfos, Lolita Ramsey, Sharon Haaser **(Inova Fairfax Medical Campus)**;

Gudrun Mirick Mueller, David Templeman, Andrew Schmidt, Tzivia Leviton, Jerald R. Westberg **(Hennepin County Medical Center);**

Saam Morshed, Eric Meinberg, Paul Toogood, David Shearer, Murat Pekmezci, Paul Knaus, Sara McFarland, Tigist Belaye, Eleni Berhaneselase, Johnathan Kwong **(University of California, San Francisco);**

Robert V. O'Toole, Andrew N. Pollak, Gerard P. Slobogean, Christina Boulton, Christopher LeBrun, Jason W. Nascone, Marcus F. Sciadini, Raymond Pensy, Theodore Manson, W. Andrew Eglseder Jr., Andrea L. Howe, Daniel Connelly, Katherine Ordonio, Raza Zaidi, Yasmin Degani, Merryjessica Fuerst, Carrie Schoonover, George Reahl, Katherine Ordonio, Peter Berger, Ryan Montalvo, Dimitrius Marinos, Daniel Mascarenhas, Joshua Rudnicki **(University of Maryland);**

Clifford B. Jones, Sarim Ahmed, Norman Chutkan, Michael Lucero, Jason Lowe, Russell Meldrum, Sarim Ahmed, Niloofar Dehghan, Ryan DiGiovanni, Pierce Johnson, Sean Karr, Sean Mitchell, Robert Walker, Debra L. Sietsema, Cyndi Ventry, Susan Mauro, Karen Walsh, Bonnie Sumner, Taylor Dykes, Michael Duran, Blake Eyberg, Joseph Walker, Collin Barber, Jessica Burns, Jill Goodwin, Ryan Shelhamer, Joshua Hustedt, Damien Richardson, Julie Robbins **(The Center for Orthopedic Research and Education (CORE) Institute);**

Greg E. Gaski, Todd O. McKinley, Walter W. Virkus, Laurence B. Kempton, Anthony T. Sorkin, Roman Natoli, Charles Lieder, Landon Fine, Lauren C. Hill, Krista M. Brown, Lakye Deeter **(Indiana University Health Methodist Hospital)**;

Jennifer Hagen, André Spiguel, Kalia Sadasivan, Matthew Patrick, Melissa Johnson, Susan Beltz, Elizabeth Agustin, Chris Koenig, Sonya Brisbane **(University of Florida);**

Clinical Co-Investigators

Canada

Tudor V. Tufescu and Nigar Sultana (Health Sciences Centre Winnipeg);

Ryan Bicknell, Heather Grant, Fiona Howells **(Queen's University);**

USA

Todd M. Oliver, Michelle Vogt, Vicki Jones, Tina Carter **(Boone Hospital Center – Columbia Orthopaedic Group)**;

Edward Westrick and Traci Salopek (**Allegheny General Hospital**);

Aaron Perdue; Joel J. Gagnier, James Goulet, Mark Hake **(University of Michigan)**;

Andrew J. Marcantonio, Michael S.H. Kain, Craig Donahue, Cynthia Carter, John S. Garfi **(Lahey Hospital & Medical Center);**

Australia

Susan Liew, Anne Mak, Zoe Murdoch **(Alfred Health);**

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