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# Robot-assisted cement-augmented percutaneous pedicle screw fixation is associated with greater screw accuracy and fewer mechanical complications in osteoporotic thoracolumbar spine fractures: a retrospective comparative cohort study

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# Abstract

**Purpose** To compare screw placement accuracy and mechanical complications between robot-assisted and conventional fluoroscopy-assisted cement-augmented percutaneous fixation for osteoporotic thoracolumbar spine fractures.

**Methods** This retrospective cohort included 128 patients (64 per group) and 658 screws. Modified Gertzbein–Robbins grade A placement was the primary outcome, analysed with patient-clustered generalised estimating equations. Mechanical complications were assessed with logistic models and longitudinal outcomes with linear mixed-effects models. Independent rereading after database lock assessed grade and breach-distance reliability without replacing the primary grades.

**Results** Grade A placement occurred in 285/326 conventional screws (87.4%) and 314/332 robot-assisted screws (94.6%; clustered odds ratio 2.49, 95% confidence interval (CI) 1.43–4.35; P = 0.001). Among 118 patients with evaluable 12-month status, mechanical complications occurred in 17/60 (28.3%) and 5/58 (8.6%), respectively (risk ratio 0.30, 0.12–0.77; P = 0.008); the adjusted odds ratio was 0.21 (0.07–0.64; P = 0.007). At 12 months, Cobb angle was 2.1° lower and anterior vertebral height ratio was 5.3 percentage points higher with robot assistance, whereas pain was similar. Exact grade agreement was 91.8%; quadratic-weighted κ was 0.86 (95% CI 0.79–0.91), and the breach-distance intraclass correlation coefficient was 0.97 (0.94–0.98).

**Conclusion** Robot assistance was associated with more grade A screws, fewer mechanical complications and better maintenance of fracture correction. These associations require confirmation in adequately controlled prospective studies of longer-term safety and cost-effectiveness.


# Introduction

Fixation of an osteoporotic thoracolumbar spine fracture must restore anterior-column alignment while securing pedicle screws in bone with limited purchase. Loosening, loss of correction, construct failure and adjacent fracture are therefore persistent concerns. A meta-analysis found more screw loosening after non-augmented than cement-augmented instrumentation [1], and computed tomography studies have linked low vertebral bone density with subsequent loosening [2].

Cement augmentation improves the bone–implant interface [3–5], although leakage, embolic events, thermal injury and revision difficulty remain relevant hazards [6–8]. Whether robotic trajectory guidance provides an additional benefit when every screw is augmented is less certain. Reviews generally report more accurate placement with robotic systems, but the magnitude of benefit depends on the platform, comparator and grading threshold [9–11]. Studies confined to spinal fractures have described differences in accuracy, radiation exposure or screw selection [12–15]; many, however, analyse individual screws as independent observations and do not relate placement accuracy to patient-level mechanical failure.

This study compared ZH500 robot-assisted and conventional fluoroscopy-assisted cement-augmented percutaneous pedicle screw fixation in patients aged more than 60 years. Modified Gertzbein–Robbins grade A placement was the primary outcome. Mechanical complications, peri-operative measures, cement-related events, radiographic maintenance, pain and disability were secondary outcomes. We hypothesised that robot assistance would be associated with more grade A screws and fewer mechanical complications.

## Materials and methods

# Study design and participants

This single-centre retrospective comparative cohort followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [16]. The screening log contained 342 potentially eligible cases treated between 1 March 2023 and 30 June 2025; 214 were excluded and 128 treated at Chengdu 363 Hospital were included. Outcomes were ascertained through 30 June 2026, giving the last surgical case at least 12 months of follow-up opportunity. The dataset was locked on 31 July 2026.

Eligibility required age above 60 years, a clinically adjudicated osteoporotic or fragility fracture from T11 to L5, minimally invasive percutaneous fixation with augmentation of every screw, and post-operative computed tomography (CT) for grading. Index-fracture adjudication established eligibility [17]; the dual-energy X-ray absorptiometry (DXA) result and prior fragility-fracture history were baseline descriptors, not alternative eligibility routes. Sixty-four patients underwent conventional fluoroscopy-assisted fixation and 64 underwent ZH500 robot-assisted fixation. Allocation was not randomised and reflected the surgeon's judgement and the patient's preference after discussion.

## Procedures

All patients underwent minimally invasive posterior percutaneous pedicle screw fixation with cement augmentation. Conventional guidewires and cannulated screws were inserted under fluoroscopy. Robot-assisted trajectories were planned and aligned with the ZH500 orthopaedic robotic system (ZOEZEN, Beijing, China) before guidewire and screw insertion; final positions were verified fluoroscopically. All 658 screws were augmented. Cement was polymethylmethacrylate (PMMA) in 96 patients, calcium phosphate cement in 26 and Other/unspecified in six. Osteoporosis treatment was insufficiently documented for comparison, and no standardised regimen was assumed.

## Outcomes

The primary outcome was the proportion of screws assigned modified Gertzbein–Robbins grade A on post-operative CT. Grades were coded as A, no cortical breach; B, > 0 to < 2 mm; C, ≥ 2 to < 4 mm; D, ≥ 4 to

≤ 6 mm; and E, > 6 mm [18]. Grade A–B placement and the presence of at least one breached screw per patient were secondary accuracy outcomes. The principal patient-level secondary outcome was any mechanical complication within 12 months, defined as screw loosening, screw pull-out or breakage, rod breakage, proximal junctional failure or adjacent vertebral fracture. Reoperation was analysed separately. All comparative analyses used the source-reconciled CT grades locked on 31 July 2026.

After database lock, two spine surgeons independently reread all 658 screws without access to treatment allocation, operative records or clinical outcomes. Each reader independently recorded the modified Gertzbein–Robbins grade and breach distance; both rating sets were retained, and a senior spine surgeon adjudicated grade disagreements. The reliability assessment neither replaced the locked grades nor altered the primary Grade A counts.

Other outcomes were operating time, estimated blood loss, fluoroscopy time, recorded radiation dose, total cement volume, hospital stay, patient-level cement leakage, symptomatic leakage and non-cement peri-operative complications. Cement leakage was kept separate from the peri-operative composite. Cobb angle, anterior vertebral height ratio, visual analogue scale (VAS) pain and Oswestry Disability Index (ODI) were recorded pre-operatively, immediately post-operatively, and at three, six and 12 months.

# Statistical analysis

Continuous data are presented as mean ± standard deviation or median (interquartile range), and categorical data as n (%). Standardised mean differences described baseline balance. Comparisons used Welch's t test, the Mann–Whitney U test, Pearson's chi-square test or Fisher's exact test, as appropriate. Effects are reported as mean or median differences, risk ratios, risk differences or odds ratios (ORs) with 95% confidence intervals (CIs).

Screw-level accuracy was analysed with logistic generalised estimating equations (GEE), an exchangeable within-patient correlation structure and robust standard errors. The adjusted model included age, sex, body mass index, bone mineral density (BMD) T-score, AO Spine A4 subtype and multilevel fracture. Mechanical outcomes at 12 months were compared among complete cases with Fisher's exact test and logistic regression using heteroscedasticity-robust standard errors. Adjustment was restricted to age and BMD because only 22 events occurred. Extreme-case analyses examined the possible influence of the ten patients without an evaluable 12-month status.

Longitudinal outcomes were analysed with linear mixed-effects models containing fixed effects for group, categorical time and the group-by-time interaction. Models included a patient random intercept and random time slope. Estimated marginal means, interaction P values and 12-month contrasts are reported; a baseline-adjusted 12-month analysis of covariance was used for sensitivity. All available observations entered the mixed models without imputation. Propensity-score matching was not performed because it would reduce the sample available for the 22-event mechanical analysis. Secondary analyses were exploratory without multiplicity adjustment. Tests were two-sided with $\alpha = 0.05$. Analyses used Python 3.12, SciPy 1.18.0 and statsmodels 0.14.6; the seed was 20260808.

Inter-reader reliability was estimated from the two original ratings, before adjudication. Exact grade agreement and Cohen's weighted κ were calculated, with quadratic weights for the primary ordinal estimate and linear weights for sensitivity. Breach-distance reliability was quantified with a two-way random-effects, absolute-agreement, single-measure intraclass correlation coefficient [ICC(A,1)]. Confidence intervals were derived from 20,000 patient-cluster bootstrap samples, retaining all screws from each resampled patient; the seed was 20260816.

## Results

# Cohort and baseline characteristics

The screening log contained 342 records, of which 214 were excluded. The remaining 128 patients comprised 64 patients in each group and 658 screws (326 conventional and 332 robot-assisted; Fig. 1). Mean ages were 73.0 ± 6.6 and 71.7 ± 7.4 years, and mean BMD T-scores were − 2.7 ± 0.6 and − 2.8 ± 0.6, respectively. Several standardised mean differences exceeded 0.10; the maximum absolute value was 0.28. Complete 12-month VAS, ODI and radiographic outcomes were available for 60 conventional and 58 robot-assisted patients (118/128). Seven patients were lost to follow-up and three died. These ten patients had no evaluable fixed 12-month outcome (Table 1).

Table 1
Baseline characteristics

| Variable | FH-CA (n = 64) | RA-CA (n = 64) | Effect (RA-CA vs FH-CA), 95% CI | P value | SMD |
|---|---|---|---|---|---|
| Participants, n | 64 | 64 | — | — | — |
| Age, years | 73.0 ± 6.6 | 71.7 ± 7.4 | -1.3 (-3.8 to 1.1) mean difference | 0.281 | -0.19 |
| Male sex, n (%) | 22 (34.4%) | 21 (32.8%) | RR 0.95 (0.59–1.55) | 1.000 | -0.03 |
| Body mass index, kg/m² | 23.1 ± 3.7 | 23.2 ± 3.4 | 0.1 (-1.2 to 1.3) mean difference | 0.899 | 0.02 |
| ASA class III–IV, n (%) | 36 (56.2%) | 37 (57.8%) | RR 1.03 (0.76–1.39) | 1.000 | 0.03 |
| Charlson Comorbidity Index | 2.0 (1.0–3.0) | 2.0 (1.0–3.0) | 0.0 (-1.0 to 0.0) median difference | 0.233 | -0.17 |
| Current smoking, n (%) | 11 (17.2%) | 14 (21.9%) | RR 1.27 (0.63–2.59) | 0.656 | 0.12 |
| Diabetes mellitus, n (%) | 15 (23.4%) | 8 (12.5%) | RR 0.53 (0.24–1.17) | 0.166 | -0.28 |
| Hypertension, n (%) | 30 (46.9%) | 22 (34.4%) | RR 0.73 (0.48–1.12) | 0.208 | -0.25 |
| Chronic steroid use, n (%) | 4 (6.2%) | 1 (1.6%) | RR 0.25 (0.03–2.18) | 0.365 | -0.24 |
| Prior fragility fracture, n (%) | 14 (21.9%) | 17 (26.6%) | RR 1.21 (0.66–2.25) | 0.680 | 0.11 |
| BMD T-score | -2.7 ± 0.6 | -2.8 ± 0.6 | -0.1 (-0.3 to 0.1) mean difference | 0.259 | -0.20 |
| Fracture level: L1 | 22 (34.4%) | 18 (28.1%) | Fisher–Freeman–Halton exact test (Monte Carlo) | 0.676 | — |
| L2 | 9 (14.1%) | 7 (10.9%) | — | — | — |
| L3 | 7 (10.9%) | 6 (9.4%) | — | — | — |
| L4 | 5 (7.8%) | 4 (6.2%) | — | — | — |
| L5 | 1 (1.6%) | 3 (4.7%) | — | — | — |
| T11 | 8 (12.5%) | 6 (9.4%) | — | — | — |
| T12 | 12 (18.8%) | 20 (31.2%) | — | — | — |
| AO Spine subtype: A1 | 3 (4.7%) | 4 (6.2%) | Fisher–Freeman–Halton exact test (Monte Carlo) | 0.928 | — |

| Variable | FH-CA (n = 64) | RA-CA (n = 64) | Effect (RA-CA vs FH-CA), 95% CI | P value | SMD |
|---|---|---|---|---|---|
| A2 | 7 (10.9%) | 4 (6.2%) | — | — | — |
| A3 | 35 (54.7%) | 33 (51.6%) | — | — | — |
| A4 | 15 (23.4%) | 18 (28.1%) | — | — | — |
| B1 | 3 (4.7%) | 4 (6.2%) | — | — | — |
| B2 | 1 (1.6%) | 1 (1.6%) | — | — | — |
| Multilevel fracture, n (%) | 13 (20.3%) | 14 (21.9%) | RR 1.08 (0.55–2.11) | 1.000 | 0.04 |
| Injury-to-surgery interval, days | 5.0 (3.8–6.0) | 4.0 (3.0–5.0) | -1.0 (-1.0 to 1.0) median difference | 0.322 | -0.18 |
| Pre-operative Cobb angle, degrees | 21.7 ± 4.9 | 21.9 ± 4.2 | 0.2 (-1.4 to 1.8) mean difference | 0.845 | 0.03 |
| Pre-operative anterior vertebral height ratio, % | 57.4 ± 10.2 | 54.5 ± 10.7 | -2.9 (-6.5 to 0.8) mean difference | 0.120 | -0.28 |
| Pre-operative VAS score | 7.1 ± 1.0 | 7.2 ± 0.9 | 0.1 (-0.2 to 0.4) mean difference | 0.539 | 0.11 |
| Pre-operative ODI score | 63.7 ± 7.9 | 61.8 ± 7.8 | -1.9 (-4.7 to 0.9) mean difference | 0.178 | -0.24 |

Values are mean ± SD, median (IQR), or n (%). Effects compare RA-CA with FH-CA. Baseline P values are descriptive. SMD values >|0.10| indicate potential imbalance. ASA, American Society of Anesthesiologists; BMD, bone mineral density; CI, confidence interval; FH-CA, conventional fluoroscopy-assisted cement-augmented group; IQR, interquartile range; ODI, Oswestry Disability Index; RA-CA, robot-assisted cement-augmented group; RR, risk ratio; SD, standard deviation; SMD, standardised mean difference; VAS, visual analogue scale.

## Primary accuracy outcome

Grade A placement was recorded for 285/326 conventional screws (87.4%) and 314/332 robot-assisted screws (94.6%). The patient-clustered GEE gave an OR of 2.49 (95% CI 1.43–4.35; P = 0.001; Fig. 2). The absolute difference was 7.2 percentage points (patient-cluster bootstrap 95% CI 3.0–11.5), and the adjusted OR was 2.35 (95% CI 1.33–4.15; P = 0.003). Grade A–B placement was 94.8% and 97.3%, respectively (GEE OR 1.91, 95% CI 0.89–4.10; P = 0.095). At least one breached screw was present in 30/64 conventional patients (46.9%) and 16/64 robot-assisted patients (25.0%; risk ratio 0.53, 95% CI 0.32–0.88; P = 0.016). In the independent reliability assessment, the two readers assigned the same grade to 604/658 screws (91.8%); a senior surgeon adjudicated all 54 disagreements. Quadratic-

weighted κ was 0.859 (patient-cluster bootstrap 95% CI 0.790–0.906), the linear-weighted estimate was 0.730 (0.648–0.797), and breach-distance ICC(A,1) was 0.969 (0.945–0.983). Rereading did not change the locked Grade A counts used in the primary comparison.

## Mechanical and peri-operative outcomes

Mechanical complications were recorded in 17/60 conventional patients (28.3%) and 5/58 robot-assisted patients (8.6%). The risk difference was − 19.7 percentage points (95% CI − 33.2 to − 6.2), the risk ratio was 0.30 (95% CI 0.12–0.77; P = 0.008; Fig. 4), and the adjusted OR was 0.21 (95% CI 0.07–0.64; P = 0.007). Cement-formulation sensitivity analyses were similar, including after exclusion of the six Other/unspecified records (adjusted OR 0.22, 95% CI 0.07–0.71; P = 0.012; Supplementary Table S4). Screw loosening occurred in 11/60 conventional patients (18.3%) and 2/58 robot-assisted patients (3.4%; OR 0.16, 95% CI 0.03–0.75; P = 0.020). Four and two complete cases, respectively, underwent reoperation (P = 0.680). Assigning an event to every robot-assisted patient with missing 12-month status attenuated the risk ratio for mechanical complications to 0.65 (P = 0.285).

Compared with conventional fixation, robot-assisted procedures had a shorter operating time (mean difference − 15.3 minutes, 95% CI − 20.2 to − 10.4), less blood loss (median difference − 28.5 mL, 95% CI − 41.0 to − 14.5), a shorter fluoroscopy time (− 65.0 seconds, 95% CI − 79.0 to − 55.0), and a lower recorded radiation dose (− 16.5 mGy, 95% CI − 22.3 to − 12.9); all four comparisons had P < 0.001 (Table 2). Total cement volume was similar. Patient-level cement leakage occurred in 24/64 conventional patients (37.5%) and 13/64 robot-assisted patients (20.3%; risk ratio 0.54, 95% CI 0.30–0.97; P = 0.050). Symptomatic leakage occurred in two conventional patients and no robot-assisted patients (P = 0.496). No pulmonary embolism was recorded.

Table 2
Accuracy, peri-operative, and 12-month mechanical outcomes

| Variable | FH-CA (n = 64) | RA-CA (n = 64) | Effect (RA-CA vs FH-CA), 95% CI | P value | SMD |
|---|---|---|---|---|---|
| Operation time, minutes | 109.9 ± 15.7 | 94.6 ± 12.0 | -15.3 (-20.2 to -10.4) mean difference | < 0.001 | -1.09 |
| Estimated blood loss, mL | 73.5 (45.8–87.8) | 45.0 (22.8–63.8) | -28.5 (-41.0 to -14.5) median difference | < 0.001 | -0.89 |
| Fluoroscopy time, seconds | 146.5 (123.5–176.0) | 81.5 (68.5–95.0) | -65.0 (-79.0 to -55.0) median difference | < 0.001 | -2.31 |
| Radiation dose, mGy | 34.8 (28.5–45.2) | 18.2 (12.7–22.5) | -16.5 (-22.3 to -12.9) median difference | < 0.001 | -1.98 |
| Total cement volume, mL | 5.2 ± 1.6 | 5.2 ± 1.6 | 0.1 (-0.5 to 0.6) mean difference | 0.832 | 0.04 |
| Hospital stay, days | 7.0 (5.0–9.0) | 7.0 (5.0–9.0) | 0.0 (-1.0 to 1.0) median difference | 0.764 | 0.09 |
| Patient-level cement leakage, n (%) | 24 (37.5%) | 13 (20.3%) | RR 0.54 (0.30–0.97) | 0.050 | -0.38 |
| Symptomatic cement leakage, n (%) | 2 (3.1%) | 0 (0.0%) | RR 0.20 (0.01–4.09) | 0.496 | -0.25 |
| Any reported non-cement peri-operative complication, n (%) | 5 (7.8%) | 4 (6.2%) | RR 0.80 (0.23–2.84) | 1.000 | -0.06 |
| Modified Gertzbein–Robbins grade A screws, n/N (%) | 285/326 (87.4%) | 314/332 (94.6%) | GEE OR 2.49 (1.43–4.35) | 0.001 | — |
| Clinically acceptable grade A–B screws, n/N (%) | 309/326 (94.8%) | 323/332 (97.3%) | GEE OR 1.91 (0.89–4.10) | 0.095 | — |
| At least one breached screw, patients, n (%) | 30 (46.9%) | 16 (25.0%) | RR 0.53 (0.32–0.88) | 0.016 | -0.46 |
| Screw loosening at 12 months, n (%) | 11/60 (18.3%) | 2/58 (3.4%) | RR 0.19 (0.04–0.81) | 0.016 | -0.48 |
| Any mechanical complication, n (%) | 17/60 (28.3%) | 5/58 (8.6%) | RR 0.30 (0.12–0.77) | 0.008 | -0.51 |
| Reoperation, n (%) | 4/60 (6.7%) | 2/58 (3.4%) | RR 0.52 (0.10–2.72) | 0.680 | -0.15 |

Values are mean ± SD, median (IQR), n (%) or n/available n (%). Accuracy analyses used the source-reconciled CT grades locked on 31 July 2026. In an independent reliability assessment after database

lock, the readers agreed on 604/658 grades (91.8%); quadratic-weighted κ was 0.859 (95% CI 0.790–0.906), breach-distance ICC(A,1) was 0.969 (0.945–0.983), 54 disagreements underwent adjudication, and the Grade A counts were unchanged. Screw-level odds ratios and P values are from logistic GEE with patient clustering; other binary outcomes are patient-level. Twelve-month mechanical outcomes were available for 60 FH-CA and 58 RA-CA patients. Patient total cement volume equalled the sum of screw-level volumes, and patient leakage equalled any screw-level leakage. CI, confidence interval; CT, computed tomography; FH-CA, conventional group; GEE, generalised estimating equation; ICC, intraclass correlation coefficient; IQR, interquartile range; OR, odds ratio; RA-CA, robot-assisted group; RR, risk ratio; SD, standard deviation; SMD, standardised mean difference.

# Longitudinal outcomes

Cobb-angle trajectories differed between groups (interaction P = 0.019). At 12 months, the estimated mean was 2.1° lower in the robot-assisted group (95% CI − 3.3 to − 0.8; P = 0.001). Anterior vertebral height ratio also differed over time (interaction P < 0.001), with a 5.3-percentage-point advantage for robot assistance at 12 months (95% CI 1.7–8.9; P = 0.004). Baseline-adjusted complete-case analyses gave similar results. VAS trajectories differed (interaction P < 0.001), but the 12-month difference was 0.0 (95% CI − 0.2 to 0.2; P = 0.902). The ODI interaction was not significant (P = 0.146); the exploratory 12-month contrast was − 3.3 points (95% CI − 5.2 to − 1.5; P < 0.001; Table 3 and Fig. 3).

Table 3
Longitudinal radiographic and patient-reported outcomes

| Outcome / timepoint | FH-CA estimated mean (95% CI) | RA-CA estimated mean (95% CI) | Difference, RA-CA − FH-CA (95% CI) | P value | Group × time P value | Random-effects structure |
|---|---|---|---|---|---|---|
| Cobb angle (degrees): Pre-operative | 21.7 (20.9–22.5) | 21.9 (21.1–22.6) | 0.2 (-0.9 to 1.2) | 0.776 | 0.019 | random intercept and random time slope |
| Post-operative | 8.5 (7.8–9.2) | 7.2 (6.5–7.9) | -1.3 (-2.3 to -0.3) | 0.013 | — | — |
| 3 months | 9.4 (8.7–10.1) | 7.7 (7.0–8.4) | -1.6 (-2.6 to -0.6) | 0.001 | — | — |
| 6 months | 9.9 (9.1–10.6) | 8.1 (7.3–8.8) | -1.8 (-2.9 to -0.8) | < 0.001 | — | — |
| 12 months | 10.5 (9.6–11.4) | 8.4 (7.5–9.3) | -2.1 (-3.3 to -0.8) | 0.001 | — | — |
| Anterior vertebral height ratio (%): Pre-operative | 57.4 (55.6–59.3) | 54.5 (52.7–56.4) | -2.9 (-5.5 to -0.3) | 0.031 | < 0.001 | random intercept and random time slope |
| Post-operative | 78.8 (77.0–80.6) | 82.8 (81.0–84.6) | 4.0 (1.5 to 6.5) | 0.002 | — | — |
| 3 months | 77.3 (75.4–79.2) | 81.9 (80.0–83.8) | 4.6 (1.9 to 7.2) | < 0.001 | — | — |
| 6 months | 76.3 (74.2–78.5) | 81.1 (79.0–83.2) | 4.8 (1.7 to 7.8) | 0.002 | — | — |
| 12 months | 75.3 (72.8–77.8) | 80.6 (78.1–83.2) | 5.3 (1.7 to 8.9) | 0.004 | — | — |
| VAS score (0–10): Pre-operative | 7.1 (6.9–7.2) | 7.2 (7.0–7.4) | 0.1 (-0.2 to 0.4) | 0.439 | < 0.001 | random intercept and random time slope |
| Post-operative | 3.1 (2.9–3.3) | 2.8 (2.7–3.0) | -0.3 (-0.5 to 0.0) | 0.021 | — | — |
| 3 months | 2.5 (2.3–2.6) | 1.7 (1.5–1.8) | -0.8 (-1.0 to -0.6) | < 0.001 | — | — |
| 6 months | 1.6 (1.4–1.7) | 1.4 (1.3–1.6) | -0.1 (-0.4 to 0.1) | 0.185 | — | — |
| 12 months | 1.2 (1.0–1.3) | 1.2 (1.0–1.3) | 0.0 (-0.2 to 0.2) | 0.902 | — | — |

| Outcome / timepoint | FH-CA estimated mean (95% CI) | RA-CA estimated mean (95% CI) | Difference, RA-CA − FH-CA (95% CI) | P value | Group × time P value | Random-effects structure |
|---|---|---|---|---|---|---|
| ODI score (0–100): Pre-operative | 63.7 (62.1–65.3) | 61.8 (60.2–63.4) | -1.9 (-4.1 to 0.3) | 0.098 | 0.146 | random intercept and random time slope |
| Post-operative | 30.7 (29.4–32.1) | 29.5 (28.1–30.8) | -1.3 (-3.2 to 0.7) | 0.204 | — | — |
| 3 months | 24.0 (22.7–25.2) | 19.8 (18.6–21.0) | -4.1 (-5.9 to -2.4) | < 0.001 | — | — |
| 6 months | 18.7 (17.5–19.9) | 14.7 (13.6–15.9) | -4.0 (-5.6 to -2.3) | < 0.001 | — | — |
| 12 months | 14.4 (13.2–15.7) | 11.1 (9.8–12.4) | -3.3 (-5.2 to -1.5) | < 0.001 | — | — |

Values are estimated marginal means (95% CI) from linear mixed-effects models with group, categorical time and group-by-time interaction. Models used patient random intercepts and random time slopes. All 64 patients per group contributed through six months; 12-month outcomes were available for 60 FH-CA and 58 RA-CA patients. CI, confidence interval; FH-CA, conventional group; ODI, Oswestry Disability Index; RA-CA, robot-assisted group; VAS, visual analogue scale.

# Discussion

ZH500 assistance was associated with 7.2 percentage points more grade A screws and fewer mechanical complications and loosened screws. Operating and fluoroscopy times, recorded radiation dose and radiographic maintenance also favoured robot assistance. Pain did not differ at 12 months, and the disability difference was small.

The grade A result is consistent with reviews that favour robotic placement accuracy [9, 19–25], although randomised evidence remains dependent on the platform and comparator [10, 11, 26–28]. The broader grade A–B threshold did not differ conclusively, so the result should not be extended to every definition of acceptable placement.

Mechanical failure is more relevant to patients than CT grade. With all screws augmented, the association may reflect trajectory consistency, pedicle-wall preservation, screw selection or load distribution [15]. Interpretation remains tentative: only 22 events occurred, and the risk ratio attenuated to 0.65 under the adverse missing-outcome assumption. Similar formulation-adjusted and restricted estimates cannot exclude residual confounding by fracture morphology, construct choice, surgeon experience or treatment era.

CT grade is a technical outcome, not a clinical surrogate. Its interpretation depends on reproducible multiplanar assessment [29] and prespecified breach thresholds [18]. Independent rereading supported measurement consistency, yet 54 screws required adjudication. The inconclusive Grade A–B analysis cautions against treating every non-A screw as unsafe or assuming that accuracy mediated the mechanical association.

At 12 months, the robot-assisted group had a 2.1° lower Cobb angle and a 5.3-percentage-point higher anterior vertebral height ratio [30–32], without lower pain scores. The exploratory 3.3-point ODI difference was well below the 12.8-point benchmark reported for lumbar operations [33], making a comparable patient-perceived benefit unlikely.

Cement augmentation improves fixation but carries leakage and embolic risks [3, 6–8]. The lower leakage rate with robot assistance was exploratory and does not show that guidance prevents extravasation. Injection safety still depends on viscosity, volume, imaging and pedicle integrity, and clinical benefit is not uniform across outcomes [34].

Robot guidance and cement augmentation act through distinct mechanisms. Guidance can standardise trajectory and pedicle containment, whereas construct stability also depends on bone quality, screw design, and cement volume and distribution; a small cadaveric study suggested that cement distribution may affect cyclic stability [35]. The sensitivity analyses reduce concern about measured cement heterogeneity but neither establish mediation nor remove residual confounding.

Shorter operating and fluoroscopy times contrast with reports of longer robotic procedures [10, 22], perhaps because of local workflow or learning-curve position [36–38]. Recorded dose was lower, but operator exposure was unmeasured. Costs were unavailable; economic value depends on case volume and revisions avoided [39, 40] and cannot be inferred.

If replicated, the findings may be most applicable when poor bone quality, narrow or deformed pedicles, multilevel fixation or repeated fluoroscopy make trajectory consistency important. Robot assistance does not replace osteoporosis treatment, leakage surveillance or surgical judgement. Results from one platform should not be assumed for other systems.

Non-random allocation and the single-centre retrospective design leave confounding by indication. The mechanical model contained 22 events. Osteoporosis was clinically adjudicated, but the analytic export did not retain each source-record pointer or a defined severity code. Reliability was assessed after database lock; imaging features may have suggested the technique despite masking, and rereading cannot correct selection bias. Ten patients lacked 12-month outcomes, and 12 months may miss late failures. Cement formulation varied, six products were unspecified, and occupational radiation, costs, bone-health treatment and learning-curve stage were unrecorded. No prospective sample-size calculation was performed.

# Conclusion

Among patients aged more than 60 years who underwent cement-augmented percutaneous fixation for osteoporotic thoracolumbar spine fractures, ZH500 assistance was associated with more grade A screws and fewer mechanical complications and loosened screws. The retrospective design, 22 mechanical events and missing 12-month outcomes in ten patients preclude causal inference. Adequately powered prospective studies with longer follow-up should assess effectiveness, safety and cost-effectiveness.

## Abbreviations

ASA
American Society of Anesthesiologists
BMD
bone mineral density
CI
confidence interval
CPC
calcium phosphate cement
CT
computed tomography
DXA
dual-energy X-ray absorptiometry
FH-CA
conventional fluoroscopy-assisted cement-augmented fixation
GEE
generalised estimating equations
ICC
intraclass correlation coefficient
IQR
interquartile range
ODI
Oswestry Disability Index
OR
odds ratio
PMMA
polymethylmethacrylate
PPSF
percutaneous pedicle screw fixation
RA-CA
robot-assisted cement-augmented fixation
RR

risk ratio
SD
standard deviation
SMD
standardised mean difference
STROBE
Strengthening the Reporting of Observational Studies in Epidemiology
VAS
visual analogue scale.

## Declarations

# Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of 363 Hospital (no. 363-IRB-2022-008; 14 November 2022). The Ethics Committee of 363 Hospital waived the requirement for individual informed consent because de-identified routinely collected clinical data were analysed.

# Consent for publication

Not applicable.

# Competing interests

The authors have no relevant financial or non-financial interests to disclose.

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# Author Contribution

HZ and XL conceived and designed the study. HZ and QZ developed the methodology. HZ performed the formal analysis and investigation and wrote the original draft. QZ and XL reviewed and edited the manuscript. XL supervised the study. All authors read and approved the final manuscript.

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# Data Availability

The de-identified participant-level data are not publicly available because of privacy and ethics restrictions. An analysis specification, variable dictionary and aggregated results are provided as supplementary material; additional de-identified data may be available from the corresponding author subject to ethics and institutional approval.

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# Figures

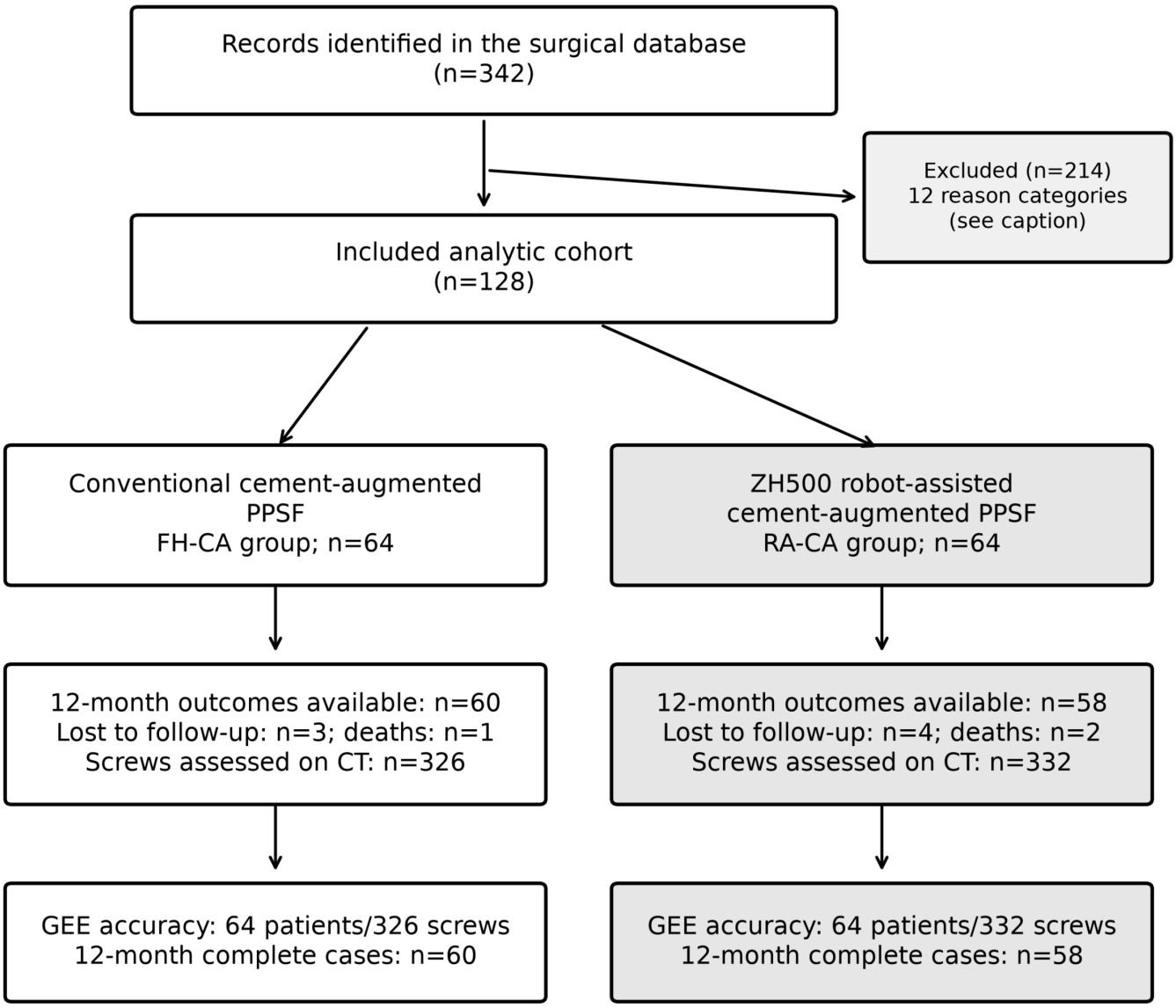
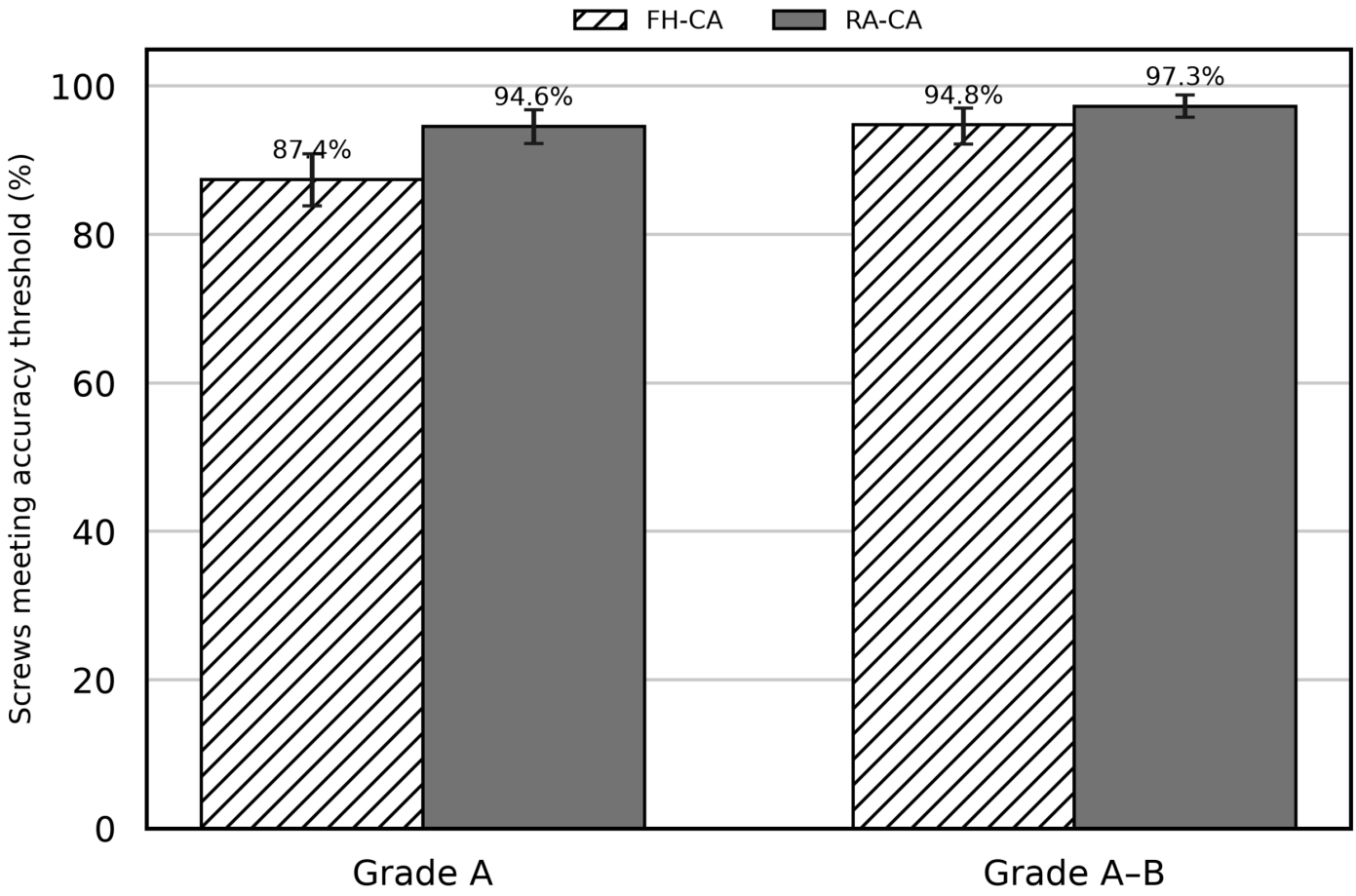



**Figure 1**

Participant flow and analysis populations. The institutional screening log identified 342 records; 214 were excluded according to documented age or eligibility criteria, fracture or bone-health criteria, surgical approach or cement-augmentation criteria, neurological or pathological exclusions, prior instrumentation, device or treatment criteria, incomplete records, insufficient evaluable follow-up, or other documented reasons. The analytic cohort comprised 128 patients. All contributed to clustered accuracy analysis; fixed 12-month outcomes were evaluable for 60 FH-CA and 58 RA-CA patients. FH-CA, conventional fluoroscopy-assisted cement-augmented fixation; RA-CA, robot-assisted cement-augmented fixation




Grade A: GEE OR 2.49 (95% CI 1.43–4.35), P=0.001;  Grade A–B: GEE OR 1.91 (95% CI 0.89–4.10), P=0.095

**Figure 2**

Pedicle screw placement accuracy. Bars show screw-level proportions; error bars are 95% confidence intervals from patient-cluster bootstrap resampling. Odds ratios and P values are from logistic generalised estimating equations with exchangeable within-patient correlation. CI, confidence interval; FH-CA, conventional group; GEE, generalised estimating equation; OR, odds ratio; RA-CA, robot-assisted group

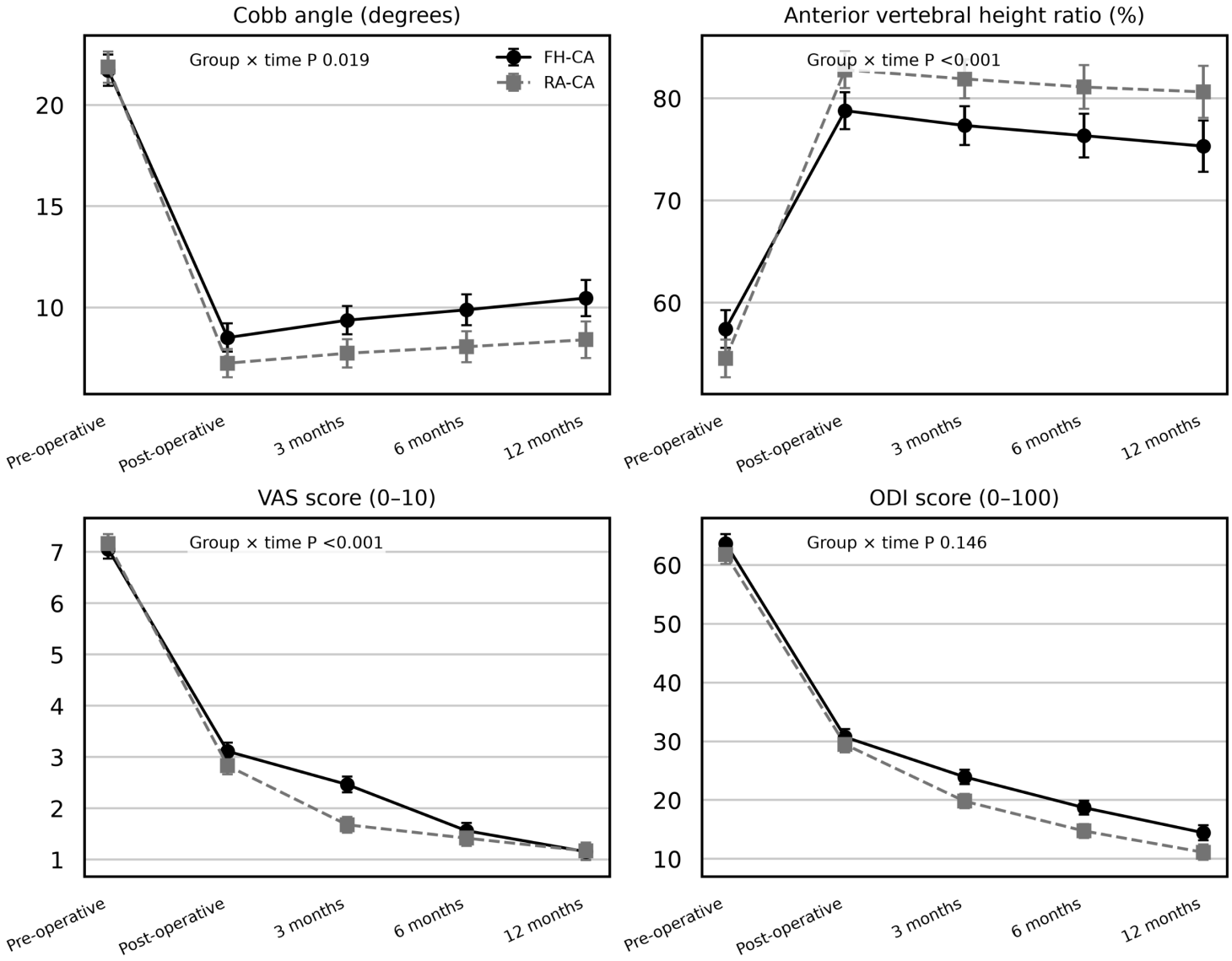



**Figure 3**

Longitudinal radiographic and patient-reported outcomes. Points are model-estimated marginal means and error bars are 95% confidence intervals from linear mixed-effects models containing group, categorical time and group-by-time interaction. FH-CA, conventional group; ODI, Oswestry Disability Index; RA-CA, robot-assisted group; VAS, visual analogue scale

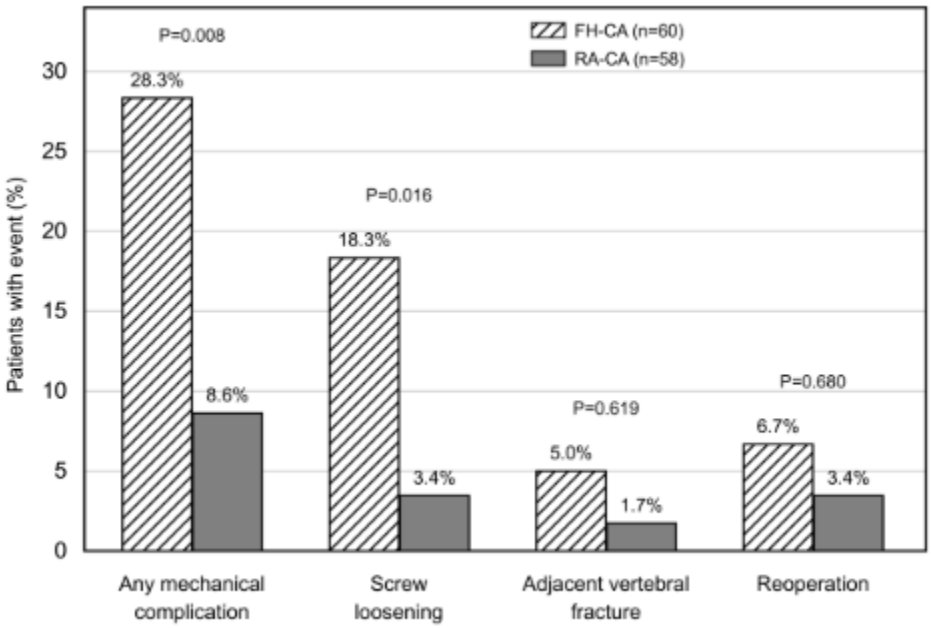



**Figure 4**

Patient-level mechanical outcomes through 12 months. Bars show complete-case event proportions (FH-CA, n=60; RA-CA, n=58), and P values are from Fisher's exact tests. Components may overlap within a patient; the composite counts each patient once. FH-CA, conventional group; RA-CA, robot-assisted group

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryStatisticalAnalysis.docx