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SYSTEMATIC REVIEW

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Uncementing the status quo: systematic review of a loose-fit, polished stem radial head prosthesis shows stable clinical results in complex elbow injuries with a concomitant radial head fracture

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Abstract

Introduction Selecting the optimal radial head prosthesis to treat radial head fractures, especially in the context of complex elbow injuries like terrible triad, Monteggia, and Essex Lopresti, can be challenging, as there is currently no consensus in the field that favors a particular design. This study investigated the safety and performance of a Polished Stem Radial Head Prosthesis (PS RHP) compared to other modern RHP designs.

Materials and methods A systematic review was conducted according to PRISMA guidelines to capture data on a Polished Stem Radial Head Prosthesis (PS RHP) and other Radial Head Prostheses (RHPs). Functional scores, range of motion, complications, and revisions were extracted from published literature and analyzed in parallel with the percentage of complex injuries. Comparison of functional outcomes between groups were based on minimum clinically important differences (MCIDs).

Results There were 16 articles reporting on 711 cases of the PS RHP and 23 articles reporting on 605 cases of other RHPs included in the systematic literature review. Functional scores and range of motion were similar amongst the groups. The PS RHP design achieved a comparable revision rate as other RHPs despite a higher number of terrible triad injuries. Notably, the PS RHP group showed a significantly lower rate of instability (1.0%) than other RHPs (3.4%) ($p < 0.05$). Other complication rates were similar amongst the two groups.

Conclusions The PS RHP group had higher rates of terrible triads at baseline compared to the other RHPs group. Regardless of greater injury complexity, the clinical outcomes of the PS RHP group were favorable and resulted in a significantly lower rate of postoperative instability as compared to other RHPs.

Keywords Radial head arthroplasty, Radial head prosthesis, Terrible triad, Systematic literature review, Radial head fracture, Elbow

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Introduction

Over the past decade, radial head arthroplasty (RHA) procedures have more than doubled, yet complications are still observed in 25% of patients [1, 2]. Damage to stabilizing tissues such as the medial collateral ligament, lateral collateral ligament complex, or interosseous membrane in concomitance with radial head fracture are classified as complex injuries, which can include Monteggia, terrible triad, and Essex Lopresti [3, 4]. Such complex injury patterns pose significant challenges in orthopedic management due to the intricate biomechanics of the elbow joint. Missed diagnosis or inappropriate treatment can result in long-term disability. Thus, it is of paramount importance to carefully consider the interplay of stability and mobility when selecting a radial head prosthesis (RHP) [3].

Technologies have advanced over the years resulting in a plethora of RHPs, which vary in design elements such as polarity, modularity, fixation, materials, stem length, among others. In theory, certain designs confer advantages such as enhanced stability, lower risk of dissociation, greater adaptability to the patient's anatomy, or decreased stress on articular cartilage and the stem-bone interface [5–7]. Conversely, various clinical studies have shown that different designs result in similar patient outcomes and it is inconclusive which features are inherently critical for RHA success [8–15].

Another approach to create adaptability to the complex biomechanics of the radiocapitellar and proximal radioulnar joint is the use of a loose-fit, polished, uncemented stem. Our systematic review sheds light on a key gap in the field surrounding RHP design and optimization of the surgical algorithm for elbow injuries. To this end, we comprehensively evaluated the functional and safety outcomes of a PS RHP compared to other contemporary radial head prostheses.

Materials and methods

Study population

The systematic literature review was intended to include data on patients undergoing RHA with a Polished Stem Radial Head Prosthesis (PS RHP, Evolve© Proline, Wright Medical Technology Inc., which is a full subsidiary of Stryker, Memphis, TN, USA) and other contemporary RHPs (Other RHPs).

Systematic search methodology

A systematic review was performed using PubMed and EMBASE. The PRISMA guidance for transparent reporting of systematic reviews and meta-analyses was followed (Fig. 1)[16]. Search terms were designed to capture articles that mention brand names of the PS RHP and other RHPs. The following search terms were used to capture articles on the PS RHP: "Evolve Proline," "Evolve prosthesis," "Evolve implant," "radial head" combined with Boolean operators AND/OR. The following search terms were used to capture articles on Other RHPs: "Ascension Modular Radial Head," "ExploR," "Biomet," "CRFII," "Judet Prosthesis," "Radial Head," "RHS," "Radial Head System," "Tornier" combined with Boolean operators AND/OR. The search included all available literature up to July 2023.

Three authors evaluated full-text articles for inclusion/exclusion. Only Level IV or higher clinical studies that used one of the RHPs mentioned in the search terms above and reported on at least one performance or safety outcome of interest were included. For inclusion, the articles had to stratify outcomes by the prosthesis design or brand. Reasons for exclusion were the following: E1) Animal, Cadaveric, Biomechanical, or Diagnostic Study, E2) Surgical Technique Methods, E3) Unable to extract safety and performance data, E4) Not relevant to PS RHP or Other RHPs, E5) Higher level of evidence available.

Data extraction and outcome analysis

Two authors independently reviewed each study and extracted the following information: year of publication, Level of Evidence, number of cases, type of RHP used, mean follow-up period, mean age, and gender distribution. Discrepancies were discussed to reach a consensus. The following performance outcomes were extracted: Mayo Elbow Performance Score (MEPS), Disabilities of the Arm Shoulder Hand Questionnaire (DASH), Visual Analog Score (VAS) Pain, flexion and extension deficit. Minimal clinical important differences (MCIDs), which is a well-accepted method to determine the minimal amount of change that a patient can perceive, were leveraged to establish a clinically meaningful margin for evaluation of differences between the device groups. [17]. MCIDs established by Sun et al. (2021) were used to evaluate MEPS (MCID = 12 points), flexion (MCID = 14.5°), and extension deficit (MCID = 10.8°) [18]. MCIDs established by Challoumas et al. (2023) were used to evaluate VAS-pain (MCID = 1 point) and DASH (MCID = 8.9 points) [19].

Reported complications were extracted to determine the incidence of implant loosening, stiffness, mechanical failure of the implant, instability, and implant revision. Events were scored as "implant loosening" if the event was described as symptomatic or leading to revision. Solely radiographic loosening that was not described as symptomatic in the primary article was not scored as a complication. Events such as limited range of motion, contracture, arthrofibrosis, synostosis, or ankylosis were scored as "stiffness." Postoperative events where the elbow joint was described as unstable, dislocated, or

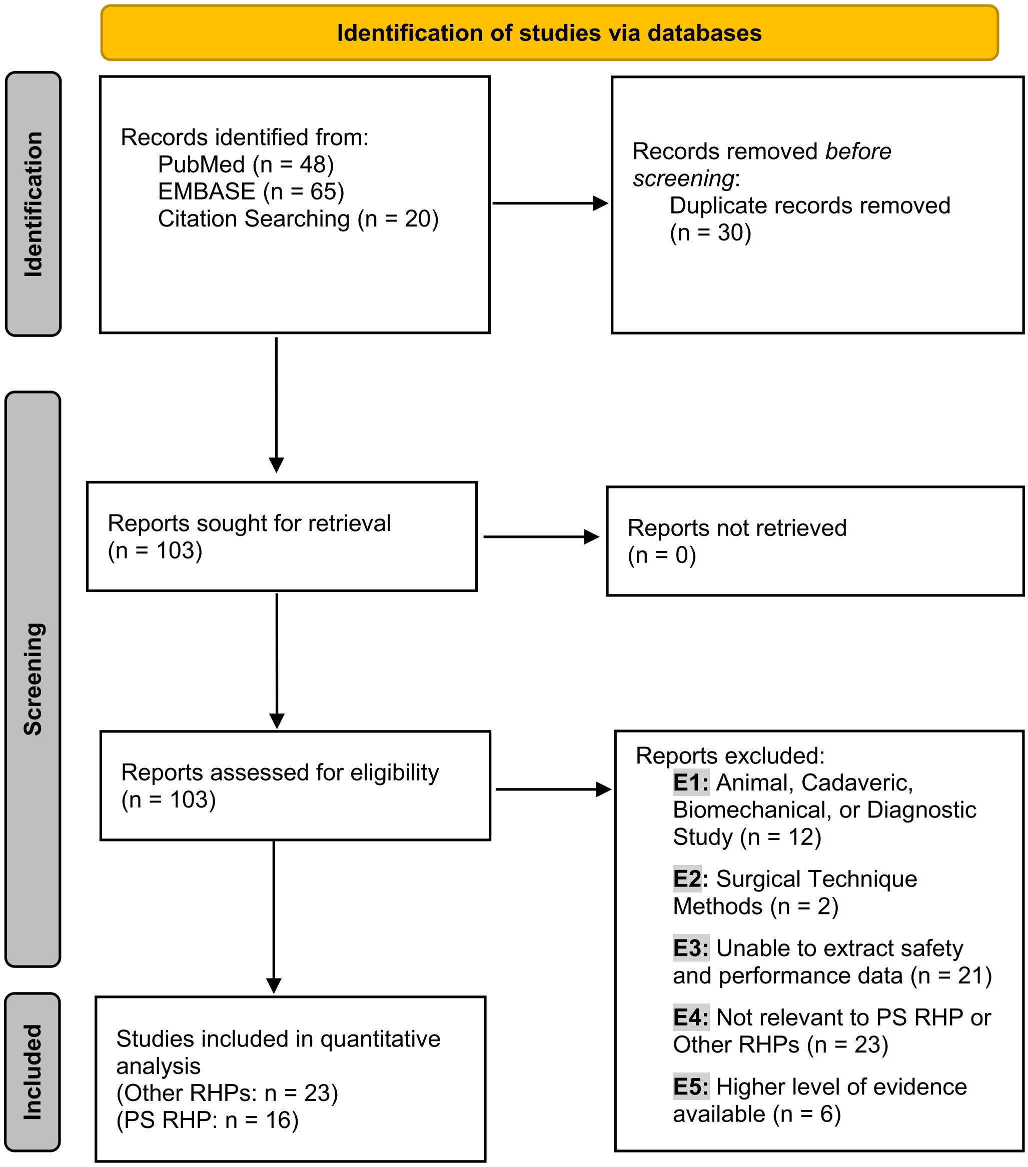

Fig. 1 PRISMA diagram illustrating flow of information during the systematic review process

subluxated were scored as "instability." "Mechanical failure of the implant" was defined as component breakage, wear, dissociation, or failure of any RHP components. Revision was defined as removal or exchange of the implant or any of its components.

Statistical analysis—systematic literature review

Continuous or quantitative variables (age, follow-up time, DASH, MEPS, VAS-pain, flexion, and extension deficit) were summarized by device group calculating the overall valid total and overall weighted average with 95% confidence interval (CI), using the arithmetic means, the standard deviations (if available), and the total number of subjects/devices given in the individual sources by variable in scope. For statistical comparison of age and follow-up time, either the 2-independent samples t-test was used (for equal variances assumed) or the 2-independent samples Welch-test (modified t-test) was used in case that unequal variances were detected. For assessment of differences between the device group's variances, the F-test was used. For comparisons of DASH, MEPS, VAS, flexion, and extension deficit differences between the device groups against the applicable MCIDs, the one-sample t-test was used. As the weighted results are based on summarized parametric statistics, normality must be assumed and cannot be tested upfront. Nominal or qualitative variables (injury subgroups, and complications) were summarized using the simple proportion meta-analysis method by Stuart-Ord and DerSimonian-Liard (random effects model). The random effects model was chosen to adjust for potential effects caused by bias between the populations in the sources. For the individual sources, exact 95% confidence intervals (CI) using the Clopper-Pearson exact method were calculated together with standard effects and random weights. The overall pooled proportion was calculated per device group with 95% CI. For statistical comparison of injury subgroups, and complications (AE breakdown) between the device groups, the Fisher's exact test was used. The significance level (α) for all statistical hypothesis tests was set to 5% (0.05). The post-hoc power (1-β) was set to 80% (0.80). For analysis, the software packages StatsDirect version 3.3.4 (StatsDirect Ltd., Manchester, UK) and IBM SPSS version 27 (IBM Corporation, Armonk, New York, US) were used.

Results

Systematic review

The systematic literature searches returned 133 articles. After removal of duplicates, 103 articles underwent inclusion/exclusion screening. This resulted in the inclusion of 23 studies on Other RHPs (N = 605 cases) and 16 studies (N = 711 cases) on the PS RHP for quantitative analysis (Tables 1 and 2).

Population characteristics in published literature

The published literature on the PS RHP was pooled and compared to Other RHPs to determine if there were differences population characteristics. There was no statistically significant difference in the overall weighted mean ages of the PS RHP group (51.0 years) and Other RHPs group (50.7 years) ($p > 0.05$). The PS RHP group had a shorter overall weighted mean follow-up (4.3 years) than the Other RHPs group (4.6 years), which was found to be statistically significant ($p < 0.05$). There was a similar proportion of males in the PS RHP group (42.8%) as compared to the Other RHPs group (46.9%) ($p > 0.05$). There was a higher pooled proportion of terrible triad injuries in the PS RHP group (30.5%) than the Other RHPs group (25.6%) ($p < 0.05$). No difference was found for Monteggia lesions and Essex Lopresti injuries when comparing the overall pooled proportions of all included studies ($p > 0.05$) (Table 3).

Functional outcomes

There were 400 implanted with PS RHPs and 376 patients implanted with Other RHPs that were evaluated for MEPS in the published literature. The PS RHP subgroup had a larger proportion of Terrible Triad injuries (21.8%) compared to the Other RHPs subgroup (16.5%), which was found to be statistically significant ($p < 0.05$). The PS RHP subgroup had an overall weighted mean MEPS of 84.3 points, which falls within the "good" range (75–89 points). The Other RHPs group had a slightly higher overall weighted mean MEPS (87.6 points), which also fell within the "good" range. The overall weighted mean difference (3.4 points) between the two groups was significantly lower than the clinically meaningful difference (MCID ≥ 12 points) ($p < 0.0001$). The PS RHP subgroup showed clinically similar MEPS scores as the Other RHPs subgroup (Table 4).

There were 421 patients implanted with PS RHPs and 204 implanted with Other RHPs that were evaluated for DASH in the published literature. The PS RHP subgroup had a greater pooled proportion of Terrible Triad injuries (34.0%) than the Other RHPs subgroup (6.9%), which was found to be statistically significant ($p < 0.05$). The PS RHPs and the Other RHPs subgroups had overall weighted mean DASH scores of 21.8 points and 16.4 points, respectively. The weighted mean difference (5.4 points) between the two groups was significantly lower than the clinically meaningful difference (MCID ≥ 8.9) ($p < 0.0001$). The PS RHP subgroup was found to exhibit clinically similar DASH scores as the Other RHPs subgroup (Table 5).

There were 153 patients implanted with PS RHPs and 206 implanted with Other RHPs that were evaluated for VAS-pain in the published literature. The PS RHP subgroup had a greater pooled proportion of Terrible Triad injuries (39.9%) than the Other RHPs subgroup (5.3%), which was found to be statistically significant ($p < 0.05$). Additionally, the PS RHP subgroup had a higher pooled proportion of Monteggia injuries and Essex Lopresti injuries than the Other RHPs subgroup, but these differences were not found to be statistically significant ($p > 0.05$). The PS RHP and the Other RHPs subgroups had overall weighted mean VAS-pain scores of 1.7 points and 1.3 points, respectively. The weighted mean difference (0.4) between the two groups was significantly lower than the clinically meaningful difference (MCID ≥ 1.0) ($p < 0.0001$). The PS RHP subgroup was found to exhibit clinically similar VAS-pain scores as the Other RHPs subgroup (Table 6).

To further investigate elbow function, published literature reporting range of motion, specifically flexion and extension deficit, was compared between patients implanted with PS RHPs and Other RHPs. The weighted mean differences in flexion (0.8°) and extension deficit (1.9°) between the groups were negligible and were significantly less than the MCIDs ($p < 0.0001$). The PS RHP showed a similar range of motion as Other RHPs (Table 7).

Table 1 Individual study characteristics of articles included in the systematic literature review and quantitative analysis on PS RHP

Author	Year	Polarity, fixation	Study design	Level of evidence	N of cases	Gender (M:F)	Mean age at time of surgery	Follow-up (yrs.)	Complex Injuries (N, %)	Outcomes collected
Grewal [20]	2006	Monopolar, uncemented	Prospective	Level IV	26	9:17	54	2	Terrible Triad: 13, 50% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, MEPS, flexion, extension deficit, complications
Doornberg [21]	2007	Monopolar, uncemented	Retrospective	Level IV	27	13:14	52	3.3	Terrible Triad: 10, 37% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, MEPS, flexion, extension deficit, complications
Muhm [22]	2016	Monopolar, uncemented	Retrospective	Level III	25	12:13	58.9	3.7	Terrible Triad: 14, 56% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, flexion, extension deficit, complications
Marsh [23]	2016	Monopolar, uncemented	Retrospective	Level IV	55	21:34	53	8.2	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Moghaddam [24]	2016	Monopolar, uncemented	Retrospective	Level IV	75	35:40	55.9	3.5	Terrible Triad: 0, 0% Monteggia: 2, 3% Essex Lopresti: 1, 1%	DASH, MEPS, flexion, extension deficit, complications
Laflamme [25]	2017	Monopolar, uncemented	Retrospective	Level III	21	11:10	45.6	10.4	Terrible Triad: 6, 29% Monteggia: 0, 0% Essex Lopresti: 1, 5%	DASH, MEPS, VAS
Strelzow [26]	2017	Monopolar, uncemented	Retrospective	Level II	148	43:105	55	4.7	Terrible Triad: 59, 40% Monteggia: 2, 1% Essex Lopresti: 1, 0.7%	DASH, flexion, extension deficit, complications
Jung [27]	2019	Monopolar, uncemented	Retrospective	Level III	57	31:26	49	8.4	Terrible triad: 26, 46% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, MEPS, VAS, flexion, extension deficit, complications
Jung [28]	2020	Monopolar, uncemented	Retrospective	Level IV	27	20:13	44.8	5.8	Terrible Triad: 0, 0% Monteggia: 27, 100% Essex Lopresti: 0, 0%	DASH, MEPS, VAS, flexion, extension deficit, complications
Chen [12]	2018	Monopolar, uncemented	Retrospective	Level IV	33	11:16	56	9	Terrible Triad: 14, 42% Monteggia: 3. 9.1% Essex Lopresti: 0, 0%	Flexion, extension deficit
Chen [29]*	2020	Monopolar, uncemented	Retrospective	Level IV	–	–	–	–	–	MEPS, DASH, VAS, complications
Mazhar [30]	2018	Monopolar, uncemented	Retrospective	Level III	15	9:6	36	3.8	Terrible Triad: 15, 100% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, MEPS, VAS, flexion, extension deficit, complications
Chien [31]	2010	Monopolar, uncemented	Retrospective	Level IV	13	–	–	3.2	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications

Table 1 (continued)

Author	Year	Polarity, fixation	Study design	Level of evidence	N of cases	Gender (M:F)	Mean age at time of surgery	Follow-up (yrs.)	Complex Injuries (N, %)	Outcomes collected
Sims [32]	2021	Monopolar, uncemented	Retrospective	Level IV	26	11:15	24	2	Terrible Triad: 3, 12% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Ajrawat [33]	2023	Monopolar, uncemented	Prospective	Level III	25	14:11	41.2	0.5	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, complications
Mirzayan [34]	2023	Monopolar, uncemented	Retrospective	Level IV	138	–	–	0.9	Terrible Triad: 57, 41% Monteggia: 0, 0% Essex Lopresti: 0, 0%	Flexion, extension deficit

*Chen et al. (2020) reports on the same study population as Chen et al. (2018)

Table 2 Individual study characteristics of articles included in the systematic literature review and quantitative analysis on Other RHPs

Author	Year	Polarity, Fixation	Study Design	Level of Evidence	N of cases	Gender (M:F)	Mean Age at time of surgery	Follow-up (yrs.)	Complex Injuries (N, %)	Outcomes Collected
Martin-Fuentes [35]	2013	Monopolar, press-fit	Retrospective	Level IV	44	17:27	51	1.8	Terrible Triad: 35, 79.5% Monteggia: 2, 4.5% Essex Lopresti: 4, 9.1%	Flexion, extension deficit, complications
Bustamante-Recueco [36]	2019	Monopolar, press-fit	Retrospective	Level IV	48	20:27	NR	3.6	Terrible Triad: 39, 81.3% Monteggia: 2, 4.2% Essex Lopresti: 1, 2.1%	MEPS, complications
Martin-Fuentes [37]	2020	Monopolar, press-fit	Retrospective	Level IV	26	11:15	52	1.7	Terrible Triad: 19, 73.1% Monteggia: 4, 15.4% Essex Lopresti: 1, 3.8%	Complications
Laflamme [25]	2017	Monopolar, press-fit	Retrospective cohort	Level III	36	17:19	52.8	4.0	Terrible Triad: 11, 30.6% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, complications
Sullivan [38]	2017	Monopolar, press-fit	Retrospective cohort	Level III	63	NR	NR	1.6	Terrible Triad: 35, 55.6% Monteggia: 25, 39.7% Essex Lopresti: 0, 0%	Complications
Mukka [39]	2020	Monopolar, press-fit	Retrospective cohort	Level III	14	7:7	52	6.0	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 1, 7.1%	VAS, flexion, extension deficit, complications
Popovic [40]	2000	Bipolar, cemented	Prospective	Level II	11	6:5	52.7	2.7	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	Flexion, extension deficit, complications
Dotzis [41]	2006	Bipolar, cemented	Prospective	Level II	14	10:4	44.8	5.3	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	DASH, flexion, complications

Table 2 (continued)

Author	Year	Polarity, Fixation	Study Design	Level of Evidence	N of cases	Gender (M:F)	Mean Age at time of surgery	Follow-up (yrs.)	Complex Injuries (N, %)	Outcomes Collected
Popovic [42]	2007	Bipolar, cemented	Retrospective case Series	Level IV	51	32:19	51	8.4	Terrible Triad: 0, 0% Monteggia: 6, 11.8% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Ruan [43]	2007	Bipolar, cemented	Comparative	Level III	14	8:6	37.4	1.3	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	Complications
Burkhart [44]	2010	Bipolar, cemented	Retrospective case Series	Level IV	17	14:3	44.1	8.8	Terrible Triad: 3, 17.6% Monteggia: 6, 35.3% Essex Lopresti: 1, 5.9%	MEPS, DASH, flexion, extension deficit, complications
Celli [45]	2010	Bipolar, cemented	Retrospective case Series	Level IV	16	11:5	46.1	3.5	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, flexion, extension deficit, complications
Laun [46]	2015a	Bipolar, cemented	Retrospective case Series	Level IV	10	4:6	52.4	1.0	Terrible Triad: 0, 0% Monteggia: 10, 100% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, flexion, complications
Laun [47]	2015b	Bipolar, cemented	Retrospective case Series	Level IV	12	5:7	48.6	1.1	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, flexion, complications
Brinkman [48]	2005	Bipolar, cemented	Case series	Level IV	11	8:3	43	2.0	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	VAS, complications
Van Hoecke [49]	2016	Bipolar, cemented	Case series	Level IV	21	N/R	N/R	9.4	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, flexion, extension deficit, complications
Laun [50]	2019	Bipolar, cemented	Retrospective case series	Level IV	37	12:16	49.9	5.6	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, complications

Table 2 (continued)

Author	Year	Polarity, Fixation	Study Design	Level of Evidence	N of cases	Gender (M:F)	Mean Age at time of surgery	Follow-up (yrs.)	Complex Injuries (N, %)	Outcomes Collected
Marcheix [51]	2021	Bipolar, cemented	Retrospective case series	Level IV	41	15:13	59	6.8	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, DASH, VAS, flexion, extension deficit, complications
Montbarbon [52]	2020	Bipolar, cemented	Retrospective case series	Level IV	16	9:7	52.50	12.0	Terrible Triad: 4, 25.0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Kodde [53]	2016	Bipolar, press-fit	Retrospective case series	Level IV	30	9:21	48	4.0	Terrible Triad: 5, 16.7% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Viveen [54]	2017	Bipolar, press-fit or cemented	Retrospective case series	Level IV	16	2:14	49	6.3	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, VAS, complications
Heijink [55]	2016	Bipolar, cemented	Retrospective case series	Level IV	25	7:18	55	4.2	Terrible Triad: 0, 0% Monteggia: 0, 0% Essex Lopresti: 0, 0%	MEPS, flexion, extension deficit, complications
Mukka [39]	2020	Bipolar, cemented	Retrospective cohort	Level III	13	3:10	52	6.0	Terrible Triad: 0, 0% Monteggia: 2, 15.4% Essex Lopresti: 0, 0%	VAS, flexion, extension deficit, complications
Lee [56]	2022	Bipolar, cemented	Retrospective cohort	Level III	16	NR	NR	3.6	Terrible Triad: NR Monteggia: NR Essex Lopresti: NR	MEPS, VAS

Table 3 Overall pooled population characteristics

	PS RHP	Other RHPs	p-value
Valid N Weighted Mean Age (yrs) (95% CI)	560 51.0 (52.1–49.8)	457 50.7 (49.5–51.9)	p > 0.05 Power = 7.2%
Valid N Male, % Valid N Female, %	240, 42.8% 320, 57.1%	235, 46.9% 266, 53.1%	p > 0.05 Power = 12.9%
Valid N Weighted Mean Follow-up (yrs) (95% CI)	711 4.3 (4.2–4.5)	605 4.6 (4.4–4.8)	p < 0.05*
Valid N Terrible Triad, % Pooled Estimate (95% CI)	217 of 711, 30.5% 27.4% (10.0–49.3%)	151 of 586, 25.6% 11.7% (3.1–24.6%)	p < 0.05*
Valid N Monteggia Lesions, % Pooled Estimate (95% CI)	34 of 711, 4.8% 3.9% (0.4–11.1%)	57 of 586, 9.5% 6.8% (2.4–13.1%)	p > 0.05 Power = 57.1%
Valid N Essex Lopresti, % Pooled Estimate (95% CI)	3 of 711, 0.4% 0.9% (0.3–1.7%)	8 of 586, 1.3% 1.8% (0.9–3.1%)	p > 0.05 Power = 22.9%

CI Confidence Interval, *Statistically significant

Table 4 MEPS subgroup analysis (points)

	PS RHP	Other RHPs	Difference	MCID	p-value
Valid N Weighted Mean MEPS (95% CI)	400 84.3 (83.0–85.5)	376 87.6 (86.2–89.1)	3.4	≥ 12.0 points [18]	p < 0.0001***
Valid N Terrible Triad, % Pooled Estimate (95% CI)	87 of 400, 21.8% 20.9% (6.4–41%)	62 of 376, 16.5% 8.5% (1.1–22.1%)	–	–	p < 0.05*
Valid N Monteggia, % Pooled Estimate (95% CI)	32 of 400, 8.0% 5.6% (0.1–18.8%)	24 of 376, 6.4% 6.1% (1.3–14.2%)	–	–	p > 0.05 Power = 5%
Valid N Essex Lopresti, % Pooled Estimate (95% CI)	2 of 400, 0.5% 1.1% (0.3–2.4%)	2 of 376, 0.5% 1.3% (0.4–2.6%)	–	–	p > 0.05 Power = 5%

CI Confidence Interval, *Statistically significant, ***Highly significant

Table 5 DASH Subgroup Analysis (points)

	PS RHP	Other RHPs	Difference	MCID	P-value
Valid N Weighted Mean DASH (95% CI)	421 21.8 (19.8–23.9)	204 16.4 (14.9–17.9)	5.4	≥ 8.9 points [19]	p < 0.0001***
Valid N Terrible Triad, % Pooled Estimate (95% CI)	143 of 421, 34.0% 36.4% (15.8–59.9%)	14 of 204, 6.9% 4% (0.5–11.9%)	–	–	p < 0.05*
Valid N Monteggia, % Pooled Estimate (95% CI)	31 of 421, 7.4% 6.8% (0.03–23.7%)	16 of 204, 7.8% 8.6% (0.5–25.0%)	–	–	p > 0.05 Power = 5%
Valid N Essex Lopresti, % Pooled Estimate (95% CI)	4 of 421, 1.0% 1.2% (0.4–2.5%)	3 of 204, 1.5% 1.3% (0.2–3.3%)	–	–	p > 0.05 Power = 13%

CI Confidence Interval, *Statistically significant, ***Highly significant

Safety in published literature

Upon analysis of implant loosening, mechanical failure, stiffness, and revision, there were no statistically significant differences between the PS RHP and Other RHPs (Table 8). For both groups, 7% of revisions were due to implant loosening. In the Other RHPs group, subluxation/dislocation accounted for 13% of revisions, and instability accounted for 7%. In comparison, in the PS RHP group, subluxation/dislocation caused 0% of revisions, while instability accounted for 2% (Table S1).

Table 6 VAS-Pain Subgroup Analysis (points)

	PS RHP	Other RHPs	Difference	MCID	*p* value
Valid N Weighted Mean VAS (95% CI)	153 1.7 (1.4–2.0)	206 1.3 (1.0–1.5)	0.4	≥ 1.0 points [19]	$p < 0.0001$***
Valid N Terrible Triad, % Pooled Estimate (95% CI)	61 of 153, 39.9% 42.3% (12.1–76.2%)	11 of 206, 5.3% 3.1% (0.3–8.9%)	–	–	$p < 0.05$*
Valid N Monteggia, % Pooled Estimate (95% CI)	30 of 153, 19.6% 16.7% (1.0–65.4%)	12 of 206, 5.8% 6.7% (0.4–19.8%)	–	–	$p > 0.05$ Power = 79.7%
Valid N Essex Lopresti, % Pooled Estimate (95% CI)	1 of 153, 0.65% 1.2% (0.1–3.5%)	1 of 206, 0.49%1.4% (0.3–3.4%)	–	–	$p > 0.05$ Power = 6%

CI Confidence Interval, *Statistically significant, ***Highly significant

Table 7 Range of Motion Subgroup Analysis (degrees)

	PS RHP	Other RHPs	Difference	MCID	p-value
Valid N Weighted Mean flexion (95% CI)	664 130.1° (129.2°–131.1°)	335 130.9° (130.1°–131.8°)	0.8°	≥ 14.5° [18]	$p < 0.0001$***
Valid N Weighted Mean extension deficit (95% CI)	664 12.7° (11.6°–13.9°)	299 14.6° (13.9°–15.3°)	1.9°	≥ 10.8° [18]	$p < 0.0001$***

CI Confidence Interval, ***Highly significant

Table 8 Analysis of complication rates

	PS RHP	Other RHPs	p-value
Valid N Implant Loosening, % Pooled Estimate (95% CI)	10 of 711, 1.4% 1.6% (0.5–3.3%)	6 of 589, 1.0% 1.6% (0.7–2.7%)	$p > 0.05$ Power = 5.3%
Valid N Instability, % Pooled Estimate (95% CI)	4 of 711, 0.6% 1.0% (0.4–2.0%)	18 of 589, 3.1% 3.4% (2.0–5.2%)	$p < 0.05$*
Valid N Mechanical Failure, % Pooled Estimate (95% CI)	1 of 711, 0.1% 0.7% (0.2–1.5%)	4 of 589, 0.7% 1.4% (0.6–2.5%)	$p > 0.05$ Power = 14.8%
Valid N Stiffness, % Pooled Estimate (95% CI)	27 of 711, 3.8% 5.6% (3.2–8.6%)	21 of 589, 3.6% 3.8% (1.9–6.2%)	$p > 0.05$ Power = 59%
Valid N Revision, % Pooled Estimate (95% CI)	38 of 711, 5.3% 4.7% (2.3–8.0%)	34 of 589, 5.8% 5.8% (3.6–8.5%)	$p > 0.05$ Power = 25.9%

CI Confidence Interval

*Statistically significant

Notably, the PS RHP group had a significantly lower rate of instability ($p < 0.05$) than the Other RHPs group (Table 8). Plots for instability are presented in Fig. 2.

Discussion

Taken together, this study shows that treatment of radial head fractures with PS RHPs results in comparable functional outcomes, a significantly lower instability rate, and similar revision rate as compared to Other RHPs, albeit in the context of more cases with terrible triads (Fig. 3). Importantly, our systematic review revealed key differences in the indications for the PS RHP and Other RHP groups; however, the mean age and gender distribution were statistically similar. To this point, older age and female gender are associated with poorer bone quality and worse healing potential [57], but RHA in younger patients remains a current concern in the field. Multiple studies identified younger patient age is associated with higher rates of radial head implant revision [58, 59]. However, a recent systematic review found that there was no significant difference in postoperative MEPS, DASH, flexion–extension arc, and implant revision when comparing patients < 50 years and patients > 50 years old [60]. Nonetheless, a similar mean age and gender ratio amongst the PS RHP and Other RHP groups strengthens the comparison, as it decreases variables that could influence clinical outcomes.

In contrast to the age debate, a topic that is widely agreed upon is the notorious challenge in managing patients with terrible triads. "Terrible triad" earned its name, as it is a complex injury to treat and historically linked to poor outcomes due to concomitant soft tissue damage, elbow dislocation, and fracture of both the radial head and coronoid process [61]. Approximately one third of terrible triads require reoperation due to high rates of postoperative complications such as heterotopic ossification, arthrosis, stiffness, and ulnar neuropathy [62]. Terrible triad is associated with increased risk of RHP revision and instability as compared to isolated radial head fractures [63]. This imbalance underscores the importance of fully dissecting baseline injuries and exercising caution when comparing studies that have diverging patient characteristics [29, 63, 64]. Furthermore, clinical studies on RHA are often heterogeneous and include a wide spectrum of elbow injuries, which can hinder the interpretation of outcomes; therefore, it is critical for investigators to provide a detailed stratification and classification of injuries observed to draw meaningful conclusions.

Interestingly, our analysis found that PS RHPs resulted in clinically comparable measures of elbow functionality as Other RHPs, despite having a significantly higher number of terrible triads. We propose that employing MCIDs as a threshold allows a more clinically meaningful quantitative analysis, as recent publications have pointed to differences between statistical significance and clinical relevance [65, 66]. Data from clinical trials on different joint arthroplasties identified a mismatch, where nearly half of the statistically significant results were deemed not clinically relevant [67]. Moreover, when analyzing occurrence rates of complications, it may be useful to interpret functional parameters or revision outcomes in tandem. For example, interpreting the rate of postoperative stiffness should be accompanied by an analysis of range of motion or MEPS to ascertain clinical relevance.

Our findings highlight that a polished, smooth-stemmed, uncemented monopolar RHP implant design can achieve favorable outcomes amidst challenging injury patterns. Additionally, our study indicates that the PS RHP may be associated with greater stability compared to Other RHPs, aligning with biomechanical studies showing that monopolar designs may confer enhanced radiocapitellar stability in terrible triad injuries [68]. This potential advantage of the PS RHP could contribute to a reduced risk of instability in terrible triad patients. Notably, the PS RHP group had a statistically significant lower pooled estimate of instability (1.0%) as compared to Other RHPs (3.4%). Additional cases and a higher-powered analysis are needed to further support that the PS RHP confers more elbow stability than other designs. The stem of the PS RHP fits loosely into the medullary canal and allows for slight movements to maintain congruency at the joint surfaces, which could enhance stability [69]. This mechanism is different from the tight-fitting stems of other RHPs, which are fixed in place by cement or have a rough grit-blasted or plasma-sprayed surface that promotes osseointegration.

Additionally, monopolar RHPs have a fixed head-neck angle and are thought to offer more stability than bipolar RHPs that have a mobile articulation at the neck separated by a polyethylene insert [6, 70]. In traumatology, a fixed head is the preferred design to treat terrible triad, as bipolar implants rely on soft tissue integrity to accomplish radiocapitellar stability [71]. The PS RHP is distinct in that it possesses the stability of a monopolar construction yet is adaptable to the patient's forearm movement due to the loose-fit stem. Other monopolar RHPs are fixated into the proximal radial intramedullary canal, thus having a fixed center of rotation that may be less compatible with the posttraumatic biomechanics of the elbow joint. To date, there is no field consensus on the ideal design features to treat varying injury patterns and future research in this area is warranted [12, 72].

Our study also demonstrated that the PS RHP group had a similar revision rate as compared to the Other RHP group, despite a higher proportion of terrible triad cases. Previous studies have reported loose-fit stems

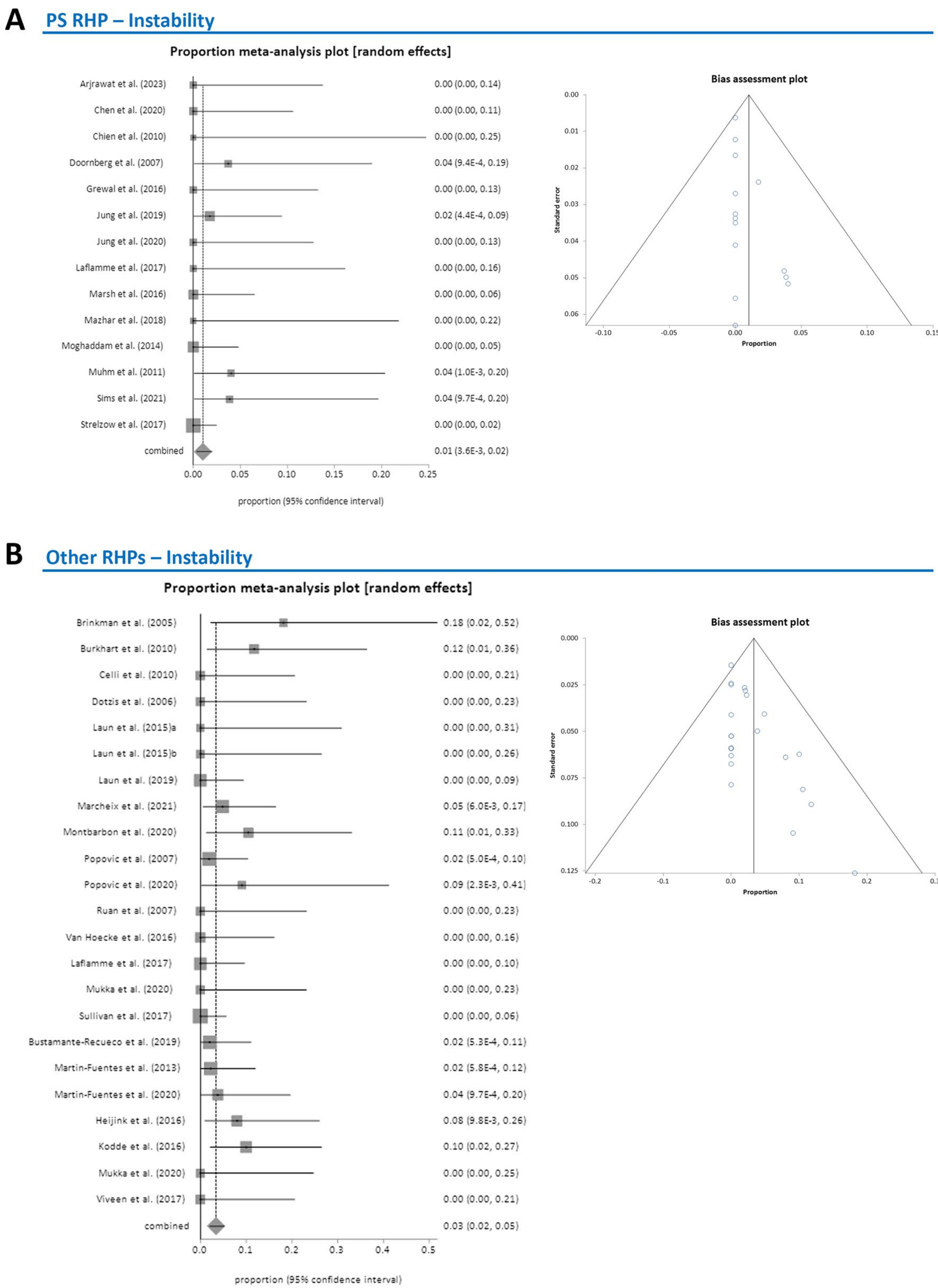

Fig. 2 Forest plot (left) and Funnel bias assessment plot (right) for instability. Proportion meta-analysis was based on a random effects model (DerSimonian-Liard). **A** PS RHP group **B** Other RHP group

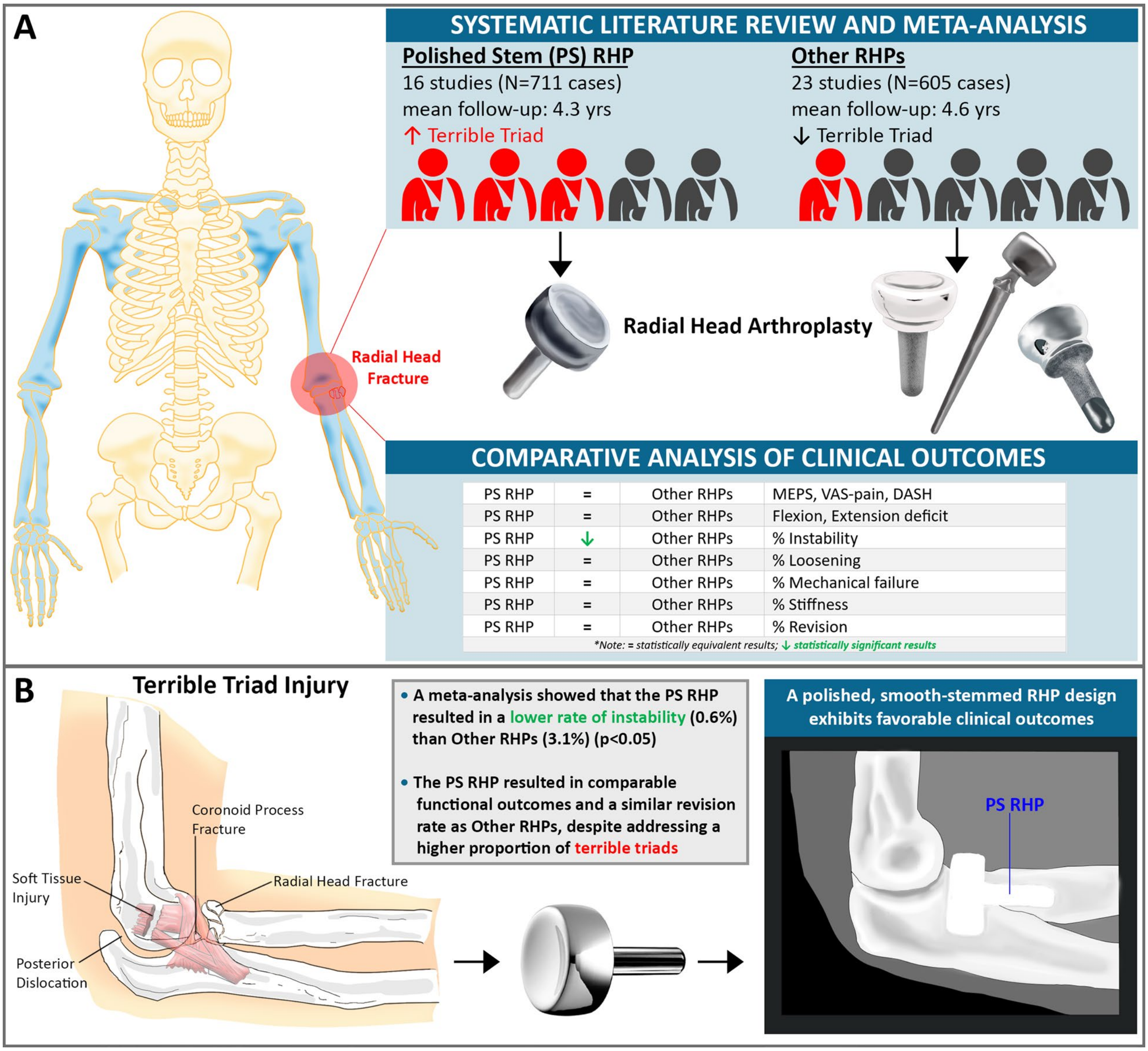

Fig. 3 Graphical summary of key findings. **A** Illustrates results of a comparative analysis between a PS RHP and Other RHPs based on a systematic review of published literature. **B** Treatment of complex elbow injuries with soft tissue involvement, like terrible triad, with a PS RHP results in favorable clinical outcomes

have a lower rate of revision as compared to press-fit or cemented stems; however, both designs produce similar functional outcomes [8, 73, 74]. Of note, there are mixed reports on whether RHP design and materials impact revision rate. Systematic reviews by Heijink et al. (2016) and Kachooei et al. (2018) found that type of fixation, material, stem length, and polarity had similar incidence of implant revision, but the majority of studies included were limited to short- and mid-term follow-up [11, 14]. Additional studies are needed to determine the impact of RHP design on long-term implant survival and design-specific reasons for failure. Some press-fit RHPs exhibit high rates of aseptic loosening and more frequently fail due to this reason than intentionally loose-fit RHPs [10, 75, 76]. It is possible that press-fit stems are more susceptible to aseptic loosening due to poor bone ingrowth and micromotion causing osteolysis [77]. Additionally, oversizing a tight-fitting stem may increase stress at the bone-implant interface, resulting in micro-fractures, stress shielding, and subsequent symptomatic loosening [9]. Alternatively, Viveen et al. (2019) reported that loose-fit RHPs failed more often due to stiffness than press-fit RHPs; however, this data could have been influenced by the complexity of injuries at baseline, which were unable to be assessed [10]. Taken together, it is feasible that treatment with a PS RHP may decrease the risk of revision for terrible triad patients, as compared to other RHP designs, but future research is warranted.

Systematic reviews can provide valuable insights, but have inherent limitations, especially when conducting comparative analyses. Differences in patient populations can introduce additional variables that are difficult to account for or require sub-analyses. In the PS RHP group in our systematic review, we found an over-representation of certain characteristics that could impact clinical outcomes, such as terrible triad injuries. Moreover, heterogeneous reporting impacts the quality and quantity of the data, which creates challenges in conducting a meaningful meta-analysis. Random models were therefore used to adjust for potential heterogeneity and bias. Greater uniformity in the reporting of outcome parameters, baseline injury patterns, and standard deviation per outcome assessed would improve the quality of future RHA studies. Furthermore, there is a disparity in the published literature regarding long-term clinical studies.

The current literature lacks specific guidelines regarding the optimal RHP design or treatment strategy for complex elbow injuries like terrible triad, Monteggia, and Essex Lopresti fractures. Consequently, our research provides valuable insights that may help inform decision-making when treating extensive elbow injuries. Taken together, our study demonstrates the performance of a PS RHP design in treating complex elbow injuries and achievement of favorable functional and safety outcomes. Our data suggests there are advantages to the PS RHP design that were previously unrecognized, such as its reliable performance in treating terrible triad injuries and a lower risk of instability. By accommodating the pathomechanics of the injured elbow, the loose-fit stem aims to optimize both stability and mobility, thereby mitigating the risk of postoperative complications and facilitating a more seamless return to function for patients. Future investigations will aid in tailoring RHP solutions per patient based on their biomechanical needs and further refine the algorithm of individualized surgical management for the myriad of complex elbow injuries.

Supplementary Information

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Supplementary file 1.

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Availability of data and materials
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