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ORIGINAL ARTICLE

Comparison between CFR-PEEK and titanium plate for proximal humeral fracture: A meta-analysis

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ABSTRACT

Objectives: The aim of the present meta-analysis was to compare the efficacy and safety of the carbon fiber-reinforced polyetheretherketone (CFR-PEEK) and titanium plate for the treatment of proximal humeral fractures (PHFs) from clinical comparative trials.

Materials and methods: A comprehensive search of English databases was carried out, such as PubMed, Web of Science, ScienceDirect, Springer and Cochrane Library databases. The RevMan version 5.1 software was applied for statistical analysis, and the mean difference (MD) and risk difference (RD) as the combined variables, and "95%" as the confidence interval (CIs).

Results: One randomized-controlled trial and five retrospective controlled studies including 282 PHFs were considered eligible and finally included. Meta-analysis demonstrated that there were significant differences in Constant score (CS) (MD=9.23; 95% CI: 5.02, 13.44; p<0.0001), anterior elevation (MD=18.83; 95% CI: 6.27, 31.38; p=0.003), lateral elevation (MD=18.42; 95% CI: 3.64, 33.19; p=0.01) and adduction (MD=3.53; 95% CI: 0.22, 6.84; p=0.04). No significant differences were observed regarding Constant score compared to the contralateral shoulder, Oxford Shoulder Score, internal rotation, external rotation, screw perforation and cutout, varus/valgus malalignment, humeral head collapse/necrosis, implant removal, and revision surgery between the two groups.

Conclusion: Compared to titanium plate, CFR-PEEK plate showed better Constant score, anterior elevation, lateral elevation and adduction in treating PHFs. The complications are comparable to those achieved with conventional titanium plates.

Keywords: Biomaterial, carbon fiber-reinforced, meta-analysis, plate, polyetheretherketone, proximal humeral fracture, titanium.

Proximal humeral fractures (PHFs) are common injuries and account for about 10% of all fractures in patients older than 65 years.[1] Currently, the most optimal treatment of displaced PHF in adults remains challenging, as PHF has high rates of loss of reduction, nonunion, malunion and humerus head necrosis, which seriously affects the quality of life of patients.[2] Therefore, satisfactory treatment for PHF requires anatomic reduction and rigid fixation.

Open reduction and internal fixation (ORIF) with titanium plate is the most commonly applied procedure and has been considered to be the standard surgical treatment.[3] However, ORIF with conventional titanium plate may lead to postoperative complications, such as screw perforation, extended scar-tissue, cold welding and poor intraoperative imaging of the reduction.[4] The incidence of postoperative complications is relatively high, and the incidence of complications after ORIF with titanium plate ranged from 9.5 to 40%.[5,6]

Recently, a new material of plate for PHF, carbon fiber-reinforced polyetheretherketone (CFR-PEEK) plate has been introduced and applied to overcome the shortcomings of titanium plates.[7] The CFR-PEEK

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material has a similar elastic modulus to the cortical bone.[8] A previous biomechanical study has proved that fixation with CFR-PEEK plates show similar or superior in screws and plate connection stability for PHF.[9] In addition, CRF-PEEK is a radiolucent material that has the advantage of better radiographic assessment and visualization of bone healing. Theivendran et al.[8] performed a systematic review comparing outcomes of fixation using CFR-PEEK and metal implants in orthopedic extremity trauma surgery. However, they did not extract data for further quantitative analysis. Pavone et al.[10] conducted a systematic review to investigate the surgical treatment outcomes of PHFs, focusing on main used devices and surgical approaches and found that the more valid implant is still unclear. Several studies have reported that ORIF with CFR-PEEK plate can lead to satisfactory clinical and radiological outcomes in treating PHF.[11,12] However, whether CFR-PEEK plate is superior to titanium plate still remains controversial.

In the present study, we conducted a meta-analysis with a large sample to compare the efficacy and safety of CFR-PEEK and titanium plate for treatment of PHF.

MATERIALS AND METHODS

Search strategy

This meta-analysis was based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A thorough search of peer-reviewed papers was performed on the PubMed, Web of Science, ScienceDirect, Springer and Cochrane Library databases to identify all studies involving the treatment of PHF with CFR-PEEK and titanium plate from the beginning of the database to November 2023. The following keywords and mesh terms were used: "proximal humeral fracture", "CFR-PEEK", "titanium", and "plate". The references of the identified articles were also examined to identify any additional pertinent studies. There were no language restrictions during the search.

Inclusion criteria

This meta-analysis included the studies meeting following criteria: *(i)* patients treated with PHF undergoing surgery; *(ii)* the intervention group was ORIF with CFR-PEEK plate, the control group was ORIF with titanium plate; *(iii)* included study were conducted as randomized-controlled trials (RCTs) or non-RCTs; and *(iv)* outcome parameter included postoperative function score, postoperative range of motion (ROM), radiological outcomes, and complications. Two independent researchers determined the eligibility of identified articles. Any disagreement between the researchers was resolved by the third senior researcher.

Exclusion criteria

Exclusion criteria were as follows: *(i)* duplicate publications or studies with the same patients, results and content; *(ii)* studies with difficult data extraction or incomplete data; *(iii)* basic research, case reports, letters, economic analyses, systematic reviews, meta-analyses or conference reports; and *(iv)* studies reported nonrelevant outcome.

Data extraction

Two researchers independently extracted relevant data, and all disputes were resolved by the third senior researcher. The general characteristics of the included patients were extracted. The contents were as follows: the first author's name, study design type, sample size, the publication year, the comparable baselines, intervention, the study endpoints and follow-up duration in each included study. Endpoints included postoperative function score, postoperative ROM, radiological outcomes and complications. Whenever the data described in an included study was insufficient or unclear, we contacted corresponding author via e-mail to obtain the additional information.

Quality assessment

The methodological quality assessment of included RCTs were conducted in accordance with recommended standards of the Cochrane Handbook for systematic reviews.[13] The methodological quality assessment of included non-RCTs was performed by the methodological index for nonrandomized studies (MINOR).[14] Two independent researchers individually performed the methodological quality assessment. Any disagreement between the researchers was resolved by the third researcher.

Statistical analysis

Statistical analysis was performed using the RevMan version 5.1 software (The Cochrane Collaboration, Oxford, UK). Risk difference (RD) and 95% confidence intervals (CIs) were calculated for estimated dichotomous outcomes. Mean differences (MDs) and 95% CIs were calculated for estimated continuous outcomes. The p values and I^2 values were used to assess the heterogeneity of pooled results. When $I^2 < 50\%$, $p > 0.1$, the heterogeneity of pooled results was considered to be absent, and the fixed-effect model was applied for statistical analysis. Otherwise, significant heterogeneity was considered, and the random-effects model was applied for statistical analysis. Subgroup analysis was conducted to investigate the sources of significant heterogeneity.

RESULTS

Search results

A total of 92 online studies were identified. By thorough browsing titles and abstracts, 86 studies were excluded. No eligible study was obtained after reference list review. Finally, five non-RCTs[11,12,15-17] and one RCT[18] were included for data extraction and meta-analysis. The flowchart of selection process is shown in Figure 1.

Study characteristics

The investigators extracted the characteristics of the included studies (Table I). In each study, the baseline characteristics of the two groups were similar.

Risk of bias assessment

The methodological quality assessment of RCT is presented in Figure 2. The methodological quality assessment of non-RCTs is presented in Table II. The MINORS scores of non-RCTs range 18 to 22.

Outcomes of meta-analysis

Postoperative function score

Five studies reported postoperative Constant score. Pooled results showed that CFR-PEEK plate increase postoperative Constant score compared to titanium plate (MD=9.23; 95% CI: 5.02, 13.44; $p<0.0001$) without significant heterogeneity (p= 0.45, I^2=0%) (Table III).

Two studies reported postoperative relative Constant score compared to the contralateral shoulder. Pooled results showed that CFR-PEEK plate did not increase postoperative relative Constant score compared to the contralateral shoulder compared to titanium plate (MD=4.75; 95% CI: –3.39, 12.89; p=0.25) without significant heterogeneity (p=0.70, I^2=0%) (Table III).

Three studies reported postoperative Oxford Shoulder Score. Pooled results showed that CFR-PEEK plate did not increase postoperative Oxford Shoulder Score compared titanium plate (MD=2.66; 95% CI: –3.89, 9.21; p=0.43) with significant heterogeneity (p=0.07, I^2=70%) (Table III).

Postoperative ROM of shoulder joint

Two studies reported the postoperative anterior elevation. Pooled results showed that CFR-PEEK plate

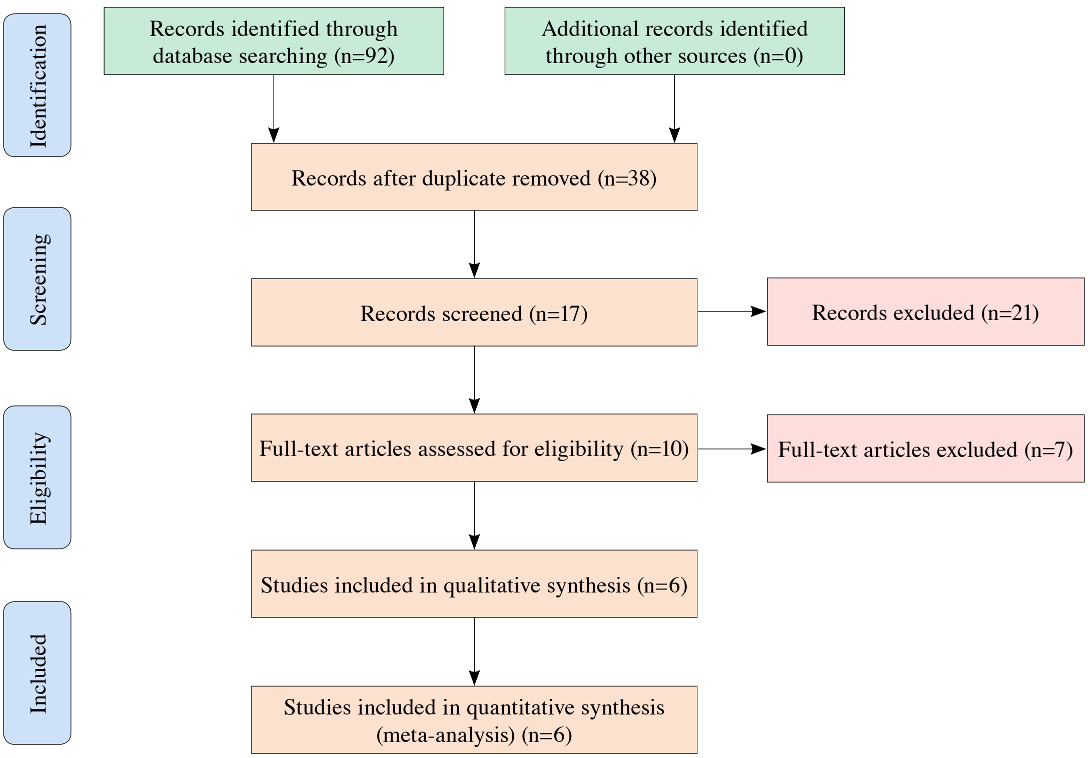

FIGURE 1. Flowchart of the study selection process.

TABLE I
Characteristics of included studies

Study	Year	Design	Intervention	Case	Mean age	Female	Fracture types (Neer 2/3/4)	Follow-up (month)
Fleischhacker et al.[11]	2022	RCS	PEEKPower®	8	55.2	6	NA	12
			Philos®	8	55.2	3	NA	12
Hazra et al.[15]	2023	RCS	PEEKPower®	35	61.2	22	3/21/6	24
			Philos®	35	68.1	26	5/22/8	24
Katthagen et al.[16]	2017	PCT	PEEKPower®	21	66.8	14	2/9/10	12
			Philos®	21	67.4	14	2/12/7	12
Padolino et al.[12]	2018	RCS	Diphos®	21	57.4	12	NA	30.7
			Philos®	21	55.8	14	NA	52.7
Schliemann et al.[17]	2015	RCS	Diphos®	29	66.4	22	Neer 3/4	24
			Philos®	29	66.4	22	Neer 3/4	24
Ziegler et al.[18]	2023	RCT	PEEKPower®	29	62.5	24	6/19/4	12
			Philos®	25	62.8	21	3/13/9	12

RCS: Retrospective controlled trial; PCT: Prospective controlled trial; NA: Not applicable.

increase postoperative anterior elevation compared titanium plate (MD=18.83; 95% CI: 6.27, 31.38; p=0.003) without significant heterogeneity (p=0.68, I^2=0%) (Table III).

Two studies reported the postoperative lateral elevation. Pooled results showed that CFR-PEEK plate increase postoperative lateral elevation compared titanium plate (MD=18.42; 95% CI: 3.64, 33.19; p=0.01) without significant heterogeneity (p=0.84, I^2=0 %) (Table III).

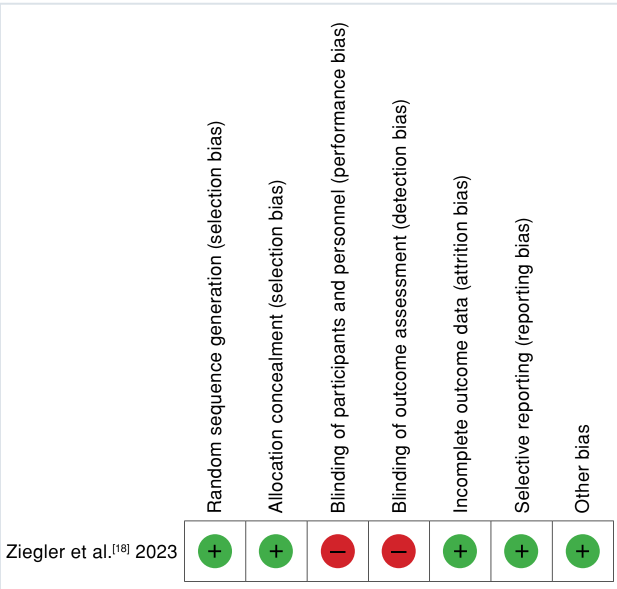

FIGURE 2. The summary of bias risk of randomized controlled trials.

Two studies reported the postoperative adduction. Pooled results showed that CFR-PEEK plate increase postoperative adduction compared titanium plate (MD=3.53; 95% CI: 0.22, 6.84; p=0.04) without significant heterogeneity (p=0.44, I^2=0%) (Table III).

Three studies reported the postoperative internal rotation. Pooled results showed that CFR-PEEK plate increase postoperative internal rotation compared titanium plate (MD=11.60; 95% CI: -12.36, 35.56; p=0.34) with significant heterogeneity (p<0.00001, I^2=94 %) (Table III).

Three studies reported the postoperative external rotation. Pooled results showed that CFR-PEEK plate increase postoperative external rotation compared titanium plate (MD=–0.77; 95% CI: –8.29, 6.76; p=0.84) without significant heterogeneity (p=0.81, I^2=0 %) (Table III).

Postoperative complications

Three studies reported the incidence of screw perforation and cutout. Pooled results showed that CFR-PEEK plate did not improve screw perforation and cutout frequency compared to titanium plate (RD= -0.08; 95% CI: -0.24, 0.08; p=0.32) with significant heterogeneity (p=0.04, I^2 = 70%) (Table III).

Two studies reported the incidence of varus/valgus malalignment. Pooled results showed that CFR-PEEK plate did not improve varus/valgus malalignment frequency compared to titanium plate (RD: –0.06; 95% CI: –0.20, 0.08; p=0.39) without significant heterogeneity (p=0.43, I^2=0%) (Table III).

TABLE II
Quality assessment for non-randomized trials

Quality assessment for non-randomized trials	Fleischhacker et al.[11] 2022	Hazra et al.[15] 2023	Katthagen et al.[16] 2017	Padolino et al.[12] 2018	Schliemann et al.[17] 2015
A clearly stated aim	2	2	2	2	2
Inclusion of consecutive patients	2	2	2	2	2
Prospective data collection	0	2	2	0	0
Endpoints appropriate to the aim of the study	2	2	2	2	2
Unbiased assessment of the study endpoint	2	2	2	2	2
A follow-up period appropriate to the aims of study	2	2	2	2	2
Less than 5% loss to follow-up	2	2	2	2	2
Prospective calculation of the sample size	0	0	0	0	0
An adequate control group	2	2	2	2	2
Contemporary groups	0	0	2	2	0
Baseline equivalence of groups	2	2	2	2	2
Adequate statistical analyses	2	2	2	2	2
Total score	18	20	22	20	18

TABLE III
Meta-analysis results

Outcome	Studies	Groups (PEEK/Ti)	Overall effect			Heterogeneity	
			Effect estimate	95% CI	*p*	I^2 (%)	*p*
Function score							
CS	5	114/114	9.23	5.02,13.44	0.0001	0	0.45
CS%	2	29/29	4.75	–3.39,12.89	0.25	0	0.70
Oxford Shoulder Score	2	58/54	2.66	–3.89/9.21	0.43	70	0.07
Range of motion							
Anterior elevation	2	56/56	18.83	6.27,31.38	0.003	0	0.68
Lateral elevation	2	56/56	18.42	3.64,33.19	0.01	0	0.84
Adduction	2	43/43	3.53	0.22,6.84	0.04	0	0.44
Internal rotation	3	64/64	11.6	–12.36/35.56	0.34	0.0001	94
External rotation	3	64/64	–0.77	–8.29/6.76	0.84	0	0.81
Complications							
Screw perforation and cutout	3	77/77	–0.08	–0.24, 0.08	0.32	70	0.04
Varus/valgus malalignment	3	50/50	–0.06	–0.20, 0.08	0.39	0	0.43
Humeral head collapse/necrosis	3	85/85	–0.06	–0.13, 0.01	0.10	0	0.58
Implant removal	2	64/64	0.06	–0.08, 0.21	0.40	29	0.24
Revision surgery	3	77/77	–0.04	–0.14,0.06	0.43	0	0.81

CI: Confidence interval; CS: Constant score; CS%: Relative CS compared to the contralateral shoulder; PEEK: Poly-etherether-ketone; Ti: Titanium.

Three studies reported the incidence of humeral head collapse/necrosis. Pooled results showed that CFR-PEEK plate did not improve humeral head collapse/necrosis frequency compared to titanium plate (RD= –0.06; 95% CI: –0.13, 0.01; p=0.10) without significant heterogeneity (p=0.58, I^2=0%) (Table III).

Two studies reported the incidence of implant removal. Pooled results showed that CFR-PEEK plate did not improve implant removal frequency compared to titanium plate (RD= 0.06; 95% CI: –0.08, 0.21; p=0.40) without significant heterogeneity (p=0.24, I^2=29%) (Table III).

Three studies reported the incidence of revision surgery. Pooled results showed that CFR-PEEK plate did not improve revision surgery frequency compared to titanium plate (RD= –0.04; 95% CI: –0.14, 0.06; p=0.43) without significant heterogeneity (p=0.81, I^2=0%) (Table III).

DISCUSSION

The main goal of surgical treatment for PHF is to reconstruct anatomical morphology of humerus, restore shoulder function, and prevent traumatic arthritis. The ORIF with titanium plate can well expose the surgical field of view and precise reduction quality with stability, which has become standard surgical treatment in recent years. However, related postoperative complications cannot be always avoided. As a newly introduced material of plate, CFR-PEEK plate not only achieves satisfactory reduction quality, but also overcome the shortcomings of titanium plates. Due to better radiolucency and modulus of elasticity, it has gradually become a new choice for PHF. In the present meta-analysis, we pooled data from recent comparative study and provided the most reliable evidence. Our meta-analysis demonstrated that CFR-PEEK plate could increase Constant score, anterior elevation, lateral elevation, and adduction ROM compared to titanium plate in the treatment of PHFs.[19]

Function score and ROM are the most commonly used tools for the evaluation of treatment results. Rotini et al.[7] performed a multi-center study to evaluate the outcome of PHF after fixation with CFR-PEEK plate for two years or more. They reported that CFR-PEEK plate was as reliable as metallic plates in the treatment of PHFs. The current meta-analysis showed that postoperative Constant score, anterior elevation, lateral elevation and adduction in the CFR-PEEK plate groups were higher than that in the titanium plate groups. Cvetanovich et al.[20] found that the minimal clinically important difference (MCID), substantial clinical benefit (SCB) for Constant after arthroscopic rotator cuff repair were 4.6 and 5.5, respectively. In the current study, the MD values were 9.23. Although Constant scores were higher postoperatively in CFR-PEEK plate group, we found that there was no significant difference between two groups for postoperative relative Constant score compared to the contralateral shoulder. We should consider these while interpreting the present findings. The CFR-PEEK plates have an advantage of similar modulus of elasticity with human cortical bone that reduced stress shielding which potentially leads to better bone quality.[21,22] Previous biomechanical studies[9,23] showed CFR-PEEK plate more elastic properties and increased motion at the bone-implant interface compared to conventional titanium plates. Therefore, elastic fixation of CFR-PEEK plate creates better fracture healing process and may result in better function.

Previous study reported that the incidence of complications after ORIF with titanium plate for PHF ranged from 9.5 to 40%.[5,6] A multi-center retrospective study[24] including 282 PHFs treated with locking plate reported the screw perforation in 23% cases, humeral head necrosis in 10% of cases and secondary fracture displacement in 5% of cases. Compared to conventional titanium plates, the CFR-PEEK plates show radiolucency, which visualize adequate fragment reduction and screw placement intraoperatively and allows for better visualization of bone healing. Rotini et al.[7] analyzed the complications of 160 PHFs treated with ORIF and CFR-PEEK plates. Their study showed nonunions in 1.3% cases, as well as screw perforation in 5% cases and humeral head necrosis in 8.1% of cases. The present meta-analysis showed that postoperative screw perforation/cutout, varus/valgus malalignment, humeral head collapse/necrosis in CFR-PEEK plate group were similar to that in the titanium plate group.

After bony healing of PHF, many of implants are removed for pain, persistent limitation of motion or other indications.[25] For titanium plate and screw, cold welding may occur that increase the difficulty and complication of removing the implant. With CFR-PEEK-metal pairings, the absence of cold welding which facilitates easier removal.[11] Additionally, CFR-PEEK was reported to form fewer adhesions with the surrounding soft tissue. As the hydrophobic surface properties of CFR-PEEK are responsible for the poor cell adhesion properties.[26]

Despite the evident strengths of this meta-analysis, there are several limitations to be noted. First, only six studies were included, and the suboptimal methodological quality weaken evidence level of meta-analysis. Second, included studies had relatively small sample sizes and subgroup analysis was not performed. Third, the CFR-PEEK plate is a new implant for PHF, all included studies had relatively short follow-up period, which may lead to the underestimation of complications.

In conclusion, compared to titanium plate, CFR-PEEK plate showed better Constant score, anterior elevation, lateral elevation and adduction in treating PHF. The complications are comparable to those achieved with conventional titanium plates.

Ethics Committee Approval: No ethical approval was required, as all data in this meta-analysis were derived from previously published research. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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